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Circular Economy Package

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009

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Introduction

The market of fertilising products covers different categories namely fertilisers, soil improvers, liming materials, growing media, plant biostimulants, fertiliser additives and mixtures thereof. *For an explanation see also glossary of technical terms in Section 10.* Each product category has different characteristics and safety profiles depending on the nature of the feedstock used in manufacturing them (mined feedstock, domestic organic and secondary raw materials from waste streams or industrial by-products) as well as different market dynamics.

Fertilisers provide 'food for plants'. They replenish soils with nutrients and help professionals and private consumers to maintain or increase crop yields to produce food and non-food products (e.g. energy commodity crops) for the world's growing population. They accounted for approximately 60% of the registered yield increase in the last 50 years. Consequently, the access to efficient fertilisers to feed an additional 2 billion people by 2050 is a relevant issue.

Fertilisers can be divided into three sub-categories:

1. inorganic fertilisers composed of synthetic chemicals and/or minerals such as various nitrogen, phosphate, and potassium substances;
2. organic fertilisers mainly made of organic matter from various sources such as processed manure and compost;
3. organo-mineral fertilisers which result from the chemical reaction between organic and inorganic fertilisers with the objective to delay the release of nutrients.

Alongside fertilisers, other product categories such as soil improvers, liming materials and growing media are also used in agriculture to improve crop yield.

Soil improvers include products added to soil *in situ* to maintain or improve its physical, chemical or biological properties (e.g. increasing organic matter/carbon content through adding compost, limiting soil dewatering and erosion…).

Liming materials are inorganic products whose main function is to correct soil acidity.

Growing media are products used in horticulture to offer a growing substrate for root development, e.g. off-soil greenhouse production systems, potted plants in nurseries.

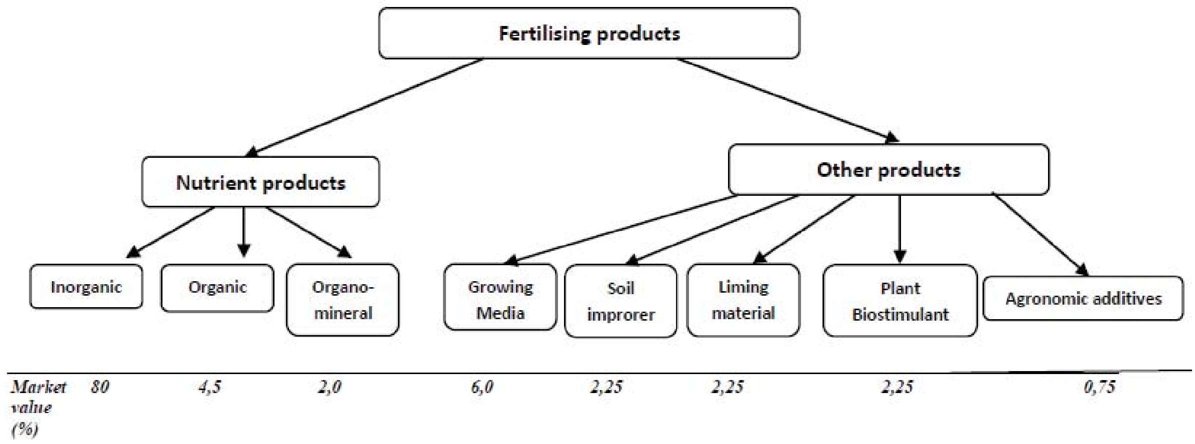
Plant biostimulants are products that, when applied to a crop or to its rhizosphere (on the soil close to the roots), will influence its nutrition pathways and hence will either enhance its nutrition efficiency or its resistance to abiotic stress, or modify the quality traits of the plant, mainly by improving the crop's capacity for nutrient uptake or by improving its nutrient use efficiency.

Agronomic fertiliser additives are products which influence the release patterns of nutrients present in fertilising products to modify their availability for feeding crops more efficiently.

As illustrated in Figure 1 below, the inorganic fertiliser business represents 80% of the estimated total value of the EU fertilising product market. Not all inorganic fertilisers are marketed as EC fertilisers (*See* Section 2). The organic fertiliser market represents around 4.5% of the market. This figure however excludes raw manure which is an important source of nutrients for crops but is mainly used by farmers directly on their own or neighbouring fields generally without commercial transactions. Commercial transaction of raw manure between Member States is subject to mutual agreement under Regulation (EC) No 1069/2009[1] laying down health rules as regards animal by-products and derived products not intended for human consumption (hereinafter the Animal By-Products Regulation - ABPR). By convention raw manure is therefore not considered as a fertilising product in the sense of the future regulation on fertilising products and should not be included in its scope.

Organo-mineral fertilisers, soil improvers, liming materials and growing media represent about 12.5 % of the current value of the EU fertiliser market. Plant biostimulants represent only 2.25% but with a strong market development potential. Lastly agronomic fertiliser additives represent less than 1% of the current market value but again with a strong market development potential. *See* Annex I for more details on the current size and future market trends for each sub-category.

Figure 1: Market value distribution per category of fertilising products. *(Source: the Fertilisers Study)*



Note: 'Other products' can be defined as products the primary objective is not to bring nutrients to the plants.

According to Eurostat and the Fertilisers Study[2], the EU fertilising product market as presented above, is an economic sector that has between EUR 20 billion and EUR 25 billion in annual turnover. Around 95 000 to 100 000 jobs (expressed as Full Time Equivalent) are involved: i.e. approximately 1% of European Gross Value Added for the whole manufacturing sector and 0.2-0.3% of the workforce in manufacturing.

Due to the lack of available statistics in Eurostat (except for inorganic fertilisers), the number of SMEs active in the sector was estimated on the basis of information collected from various industry federations. In the inorganic fertilisers (which are international trade commodities), large companies represent 75% of the total market value whereas for the other groups of products, SMEs represent approximately 98%. In total, 90% of the number of enterprises active in the production, sales and imports of fertilising products are estimated to be SMEs.

As fertilising products are key ingredients for crop production, a competitive European fertilising product industry is essential to ensure a reliable access of European agriculture to fertilising products at competitive prices.

[1] OJ L 300, 14.11.2009, p 1

[2] http://ec.europa.eu/enterprise/sectors/chemicals/files/fertilizers/final_report__23jan2012_en.pdf.

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Identification

Lead Directorate General: Internal Market, Industry, Entrepreneurship and SMEs (DG GROW).

Other Directorates-General involved in the ISSG: Environment, Health, Agriculture, Trade, Secretariat General and Legal Service.

Agenda Planning/WP Reference: 2012/ENTR/001.

1.2. Organisation and timing

DG Growth set up an Inter-service Steering Group (ISSG) on the revision of Regulation (EC) No 2003/2003 (hereinafter the 'Fertilisers Regulation') to which the above-mentioned Services were invited. The ISSG met in July 2012, February 2013, May 2013, September 2013, March 2014, May, July and October 2015 in order to discuss the preparation of the impact assessment and the legal proposal. The members of the ISSG were also invited to participate in meetings with industry and Member States representatives held during the preparation of this report.

1.3. Consultation and expertise

In September 2009, the French Ministry for Food, Agriculture, Fisheries and Rural Affairs and the French Ministry for Economy, Financial Affairs and Industry organised a workshop[3] to identify the main regulatory failures that hamper the functioning of the EU fertilising product market. It concluded that the intra-EU trade of fertilising products not covered by the Fertilisers Regulation is hindered by diverging national requirements. The entry into force of Regulation (EC) No 764/2008[4] of the European Parliament and of the Council of 9 July 2008 (hereafter the 'Mutual Recognition Regulation') that applies to non-harmonised products has not entirely met the expectations of the economic operators in terms of reducing the administrative burden. Many Member States hold negative opinions towards applying mutual recognition to fertilising products covered by national rules as described in Section 3.2.

In December 2010, the Commission published the results of an ex-post evaluation[5] of the Fertilisers Regulation and the implications of the entry into force of the Mutual Recognition Regulation for the fertilising products sector (hereinafter 'the ex-post evaluation'). The evaluation covered 10 Member States representing around 75% of the total EU fertilising products consumption in 2008, 28 companies and 4 European Trade associations. The evaluation concluded that the Fertilisers Regulation had been effective in simplifying and harmonising the regulatory framework for the inorganic fertiliser market. However, the limited scope of the current Fertilisers Regulation was seen as the most important deficiency to be addressed in order to ensure a functioning internal market. The findings of the ex-post evaluation are further detailed in the problem definition and are all addressed by this impact assessment.

In January 2011, the Commission mandated an external study for the collection of data on the EU fertilising product market and the assessment of different policy options in view of the potential extension of the scope of the Fertilisers Regulation. During the preparation of this

[3] 300 Participants from 20 Member States represented the EU fertiliser industry, public administration, farmer organisations and NGOs.

[4] OJ L 218, 13.8.2008, p. 21-29.

[5] Available at: http://ec.europa.eu/growth/sectors/chemicals/specific-chemicals/index_en.htmas

study (hereinafter the ‘Fertiliser Study’[6]), a broad range of businesses and competent authorities[7] were invited to share their expertise on the current legal framework for the placing on the market of fertilising products through several questionnaires and interviews.

The consultation confirmed that the intra-EU trade of fertilising products other than those covered by the Fertilisers Regulation is hindered by major differences between national legislation covering the placing on the market of national fertilising products (i.e. fertilising products not covered by the Fertilisers Regulation). More details are available in Section 3 and Annex II.

These differences lead to considerable additional costs of product registration for producers (according to the analysis described in Table 23 of Annex III this could amount up to EUR 25.2 million annually for the whole industry).

In December 2011, the results of the study and a set of policy options for the revision of the Fertilisers Regulation were presented to the Working Group of the Competent Authorities responsible for the implementation of the Fertilisers Regulation (hereinafter referred to as the ‘Fertilisers WG’), which is composed of representatives of the Member States and open to observers from EU fertilising products manufacturers, non-EU producing countries, environmental NGOs, Trade Unions, Farmers and Consumer associations[8]. The options examined in this impact assessment were presented in detail and stakeholders were requested to provide their initial views on the options either orally in the meeting or by sending written comments to the Commission in the subsequent weeks. Since 2011, the members of the Fertilisers WG were regularly consulted on the developments of a future proposal for a revised Regulation and at the beginning of 2014 bilateral meetings took place in several European capitals to discuss the possible consequences of the revision of the Fertilisers Regulation for the competent authorities and local stakeholders. The outcomes of the Member States consultation are detailed in Section 6 for each examined option.

In the framework of the implementation of the Small Business Act, requests for inputs on the various options examined in this impact assessment report were submitted to Small and Medium Size Enterprises (SMEs) during the last quarter of 2012 via the Enterprise Europe Network[9]. The aim of this consultation was to ensure that the specific concerns of SMEs involved in the production and/or marketing of fertilising products could be considered. 61 companies in 10 Member States participated in the consultation. In summary, the replies show that SMEs are in favour of a flexible regulatory approach to allow an easy access to the market of safe products.

In line with the Commission Communication on Industrial Policy[10] "*to ensure that all policy proposals with a significant effect on industry undergo a thorough analysis for their impacts on competitiveness*", a consultant team was mandated to further deepen the economic analysis

6 http://ec.europa.eu/smart-regulation/evaluation/search/download.do?documentId=4416

7 23 Member States plus Norway and 38 companies replied to the fertiliser survey

8 COPA COGECA, CEN (European Committee for Standardisation), EEB (European Environmental Bureau), IMPHOS (World Phosphate Institute), Fertilisers Europe (European Fertilisers Association), EFBA (European Fertilisers Blenders Association), EFIA (European Fertilisers Imports Association), EBIC (European Biostimulant Industry Council), EPAGMA (European Peat and Growing Media Association), ECN (European Compost Network), EBA (European Biogas Association)…

9 See the annex of the European Commission guidelines on Impact Assessment concerning the “SME test” at: http://ec.europa.eu/enterprise/policies/sme/files/docs/sba/iag_2009_annex_en.pdf.

10 COM(2010) 614 "An Integrated Industrial Policy for the Globalisation Era: Putting Competitiveness and Sustainability at Centre Stage".

of the effects of the various options on business competitiveness – hereinafter referred to as 'the Competitiveness Proofing'[11] – in several key sectors. Annex IV (SME test and competitiveness proofing) summarises the results of the SMEs survey as well as the analysis of impacts on competitiveness.

In the course of 2012, the Commission organised 13 meetings of four ad-hoc technical working groups composed of representatives of competent authorities, the fertilising products industry and NGOs to discuss a broad range of technical issues related to the implementation of the different options identified in the Fertiliser Study. The overall structure of a possible proposal, definitions of the various categories of products, agronomic and safety criteria as well as labelling and enforcement issues were addressed. A summary of the main outcomes of the stakeholders consultations carried out since 2012 is available in Annex XII.

In 2013, the Commission mandated an external consultant to carry out an analysis of existing regulatory approaches in the Member States and third countries for plant biostimulants and agronomic fertiliser additives. Although there are grounds and support from the technical working groups to cover these product categories in a future proposal, some details about information on safety and quality requirements needed to be further worked out[12] in cooperation with representatives of the industry and Member States.

The various consultations conducted as part of the preparation of this impact assessment report have been carried out in compliance with the Commission's minimum standards on consultation[13]. Since mid-2010, all the relevant target groups have been consulted. In each consultation, the Commission has allowed sufficient time for participation. All the opinions expressed in writing and/or orally during the consultation procedure have been considered by the Commission. During the consultation period, DG GROW made an extensive use of the Fertilisers Working Group as an open platform for Member States, industry and NGOs to collect feedback on various issues relating to the revision and in particular on the content of the various options (see Annex XII). An open public consultation to help the Commission to better identify and define the main barriers to the development of a more circular economy was organised mid 2015. The outcomes of that consultation regarding the market of secondary raw materials for fertiliser use are reported in Annex XII.

1.4. Scrutiny by the Commission Impact Assessment Board

The Impact Assessment Board of the European Commission assessed a draft version of the present impact assessment and issued its first opinion on 22 January 2014. The Impact Assessment Board made several recommendations to improve the quality of the report Therefore a revised draft impact assessment report:

– Better showed the magnitude of the problems related to the fragmentation of the internal market, mutual recognition of fertilisers and weaknesses of the Fertilisers Regulation (amendments to section 3, Annex II, Annex XI);

[11] http://bookshop.europa.eu/en/competitiveness-proofing-fertilising-materials-pbNB0413158/

[12] Plant biostimulants and agronomic fertiliser additives include a huge variety of different products. The level of details in data to be required for the assessment of such products will depend on the potential risks that they can cause to the environment and human health. The study has been used as input to determine an adequate approach as regard the level of information that operators will have to submit http://ec.europa.eu/growth/sectors/chemicals/specific-chemicals/index_en.htm

[13] Available at: http://www.cc.cec/home/dgserv/sg/stakeholder/index.cfm?lang=en&page=guidance .

- Better demonstrated that diverging national rules create adverse consequences in terms of trade within the EU and competition distortions in different segments of fertilisers' market (amendments to sections 2, 3.1, Annex II);
- Better presented the operational set-up of the various options and clarified the content of their safety and quality requirements (amendments to section 5 and Annex VII);
- Clarified how the proposed maximum limit values for contaminants were selected and how they relate to the current values in commercialised products and limit values in national legislation (amendments to section 3.3, Annexes VI and XI;
- Improved the assessment of the economic, environmental and social impacts of the proposed limit values for contaminants and clarified any significant international impacts (amendments to sections 3.5, 3.6 and 5, Annexes VI);
- Explained how stakeholders' concerns as regards the preferred option have been addressed and described the results of the consultations carried out in view of the preparation of the revision.

The Impact Assesment Board issued its second opinion on the revised report on 16th July 2014.

In light of the recommendations in the second opinion, this final report:

- Provides more evidence regarding the extent of the market fragmentation, the role of the diverging national rules as a driver and the size of environmental and public health concerns (amendments to Sections 3.1, 3.2.1, 3.3.1, 6.3.3);
- Better defines the content of each option, the need for harmonised standards, transitional provisions and the intervention logic (amendments to Section 5 and Annex VII);
- Explains the reasons for setting the proposed limit values for contaminants, how a consensus was achieved and under which conditions Member States can deviate from them under Article 114 TFEU (Amendments to Sections 3.3.1, 6.3.3 and 3.7.2);
- Explains in deeper details the order of magnitude of key impacts (Amendments to Section 6 and Annex XIII);
- Better justifies the assumptions underpinning the calculations of the development costs of harmonised standards (Annex III);
- Better presents stakeholders views throughout the report

2. REGULATORY CONTEXT

Regulation (EC) No 2003/2003[14] of the European Parliament and of the Council of 13 October 2003 relating to fertilisers only covers inorganic fertilisers listed in its Annex I. Other fertilising products are – if at all – currently governed by national legislation in the Member States.

The Fertilisers Regulation replaced Council Directive 76/116/EEC which covered inorganic fertilisers and had been amended several times. The Fertilisers Regulation intended to

[14] OJ L 304, 21.11.2003, p. 1-194

harmonise the inorganic fertiliser market and to reduce the complexity of the regulatory environment in the pre-2003 period in line with the SLIM initiative ('Simpler Legislation for the Internal Market'). According to the ex-post evaluation, the Fertilisers Regulation has effectively contributed to this objective by removing the various procedures required by national legislation, thus eliminating the former trade barriers for 60 to 70% of inorganic fertilisers although the marketing of national inorganic fertilisers is still permitted[15]. It has also facilitated the import of inorganic fertilisers from third countries as reported by the European Fertilisers Importers Association (EFIA).

Still, such a benefit from the Regulation is not able to counterbalance the generally negative trend in the EU exports of fertilisers (*See* Annex I, Section 2) during the last decade that reflects, primarily, the lower production costs in certain non-EU countries (e.g. Russia, North African countries) due to the availability of cheaper raw materials (gas, phosphate rocks) in those regions.

The Fertilisers Regulation (*See* Annex X) lays down rules for 'EC Fertilisers' with regard to their agronomic efficacy and information about their nutrient content to farmers. However the result of the consultations described under section 1.3 indicates that there is a need to strengthen the environmental and human health protection aspects in the Fertilisers Regulation, in particular through setting limit values for potential contaminants in inorganic fertilisers (for more details see section 3.3 below).

The Fertilisers Regulation does not affect fertilising products placed on the market in Member States in accordance with national rules which consist of a basic law supplemented by technical annexes that are subject to regular updates as confirmed by notifications under Directive 98/34. Around 50% of the fertilising product market value is out of the scope of the Fertilisers Regulation.

In general, Member States' fertilising product laws are not limited to inorganic fertilisers but cover a broader range of fertilising products. As confirmed in the ex-post evaluation, national rules diverge with regard to; *inter alia,* definitions and scope, forms of national registration and authorisation procedures, environmental or safety requirements, labelling, national standards for control and market surveillance. National regulatory approaches for domestic organic and secondary raw materials differ also as regards the origin of the authorised waste materials used for their production as well as regards the limit values for contaminants and product standards applying to them. Lastly, some rules can be contained not only in fertilising product law but also in legislation pertaining to waste, water protection or chemical legislation. (*See* Annex XI for more details on the scope of national laws and evidence showing their divergences and Annex II for examples of additional compliance costs due to the current regulatory framework).

Fertilising products legally placed on the market according to national rules should circulate freely within the internal market according to the mutual recognition principle. This concept is based on the assumption that Member States are applying equivalent criteria for the protection of the environment and human health so that a product lawfully produced and marketed in one Member State enjoys a basic right to free movement in another Member State. However, as described in Section 3.2 and in Annex II, there are indications that mutual recognition is not functioning well for fertilising products covered by national rules.

[15] Manufacturers can also market inorganic fertilisers according to national rules to satisfy demand for products with different compositions from those defined in the Fertilisers Regulation. On average, 30 to 40% of the volume of inorganic fertilisers marketed in Europe is still covered by national legislation.

Several Member States are already engaged in the development of a local market for fertilising products in line with the objectives of the circular economy action plan on the use of recycled nutrients. However, the current regulatory context, i.e. the non-functioning mutual recognition of national authorisations makes the access to the entire EU market for the producers of such products often prohibitively expensive. The resulting lack of critical mass for such fertilising products limits their visibility for end users and hampers investment in the sector. The problem is of particular importance for producers established in Member States with a small domestic market compared to the surplus of organic, secondary raw materials (typically manure) of which they dispose.

3. PROBLEM DEFINITION

3.1. Lack of awareness about nutrient recycling

Further efforts to manage the nutrient cycle in a more resource-efficient, sustainable and cost-effective way are required under the General Union Environment Action Programme to 2020 'Living well, within the limits of our planet'.

Global competition for resources is increasing worldwide. Concentration of phosphorus mines and gas fields outside the EU makes the EU fertilising product industry and the European society dependent and vulnerable on imports, high prices of raw materials as well as the political situation in supplying countries. The transition to nutrient recycling would therefore be a key element to increase the European food security.

The production of inorganic fertiliser is high energy intensive. It has been estimated that 2% of the world's energy production is devoted to the production of inorganic nitrogen fertilisers (*Source*: International Fertilisers Industry Association - IFA). In 2007, the global inorganic fertiliser industry (including nitrogen and phosphorus fertilisers) generated 465 million tons of CO_2 (*Source*: IFA). Nutrient recycling would contribute to mitigation of climate change via less energy demanding technologies which can combine sometimes the production of alternative energy sources (e.g. digestion of bio-wastes generating bio-gas and heat) thereby contributing to a transition towards a low-carbon and more sustainable economy.

Disrupted nutrient recycling is a problem for Europe and all over the world. Phosphorus and nitrogen are lost across environmental media during food production or are wasted instead of being used for plant nutrition. The leaks of nitrogen and phosphorus from human activities have led to ecological deterioration of surface water via eutrophication and "dead-sea" bottoms in coastal oceans along the EU coastlines close to mined phosphorus factories. The total losses to water and landfill are substantial and would account for 30% to 35% of the annual usage of phosphorus fertilisers (*Source*: The European Sustainable Phosphorus Platform).

By maintaining the value of the raw materials and energy used in products from extraction to recycling, the transition towards a more circular economy[16] can promote innovation, increased competitiveness in the sector and lead to job creation (See also annex VIII Section 3.1.1 for more details).

Possibilities to stimulate further substitution of inorganic phosphate fertilisers by alternatives have been examined in the Commission Communication on future steps in bio-waste management in the EU[17] as well as in the Consultative Communication on sustainable use of

[16] http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2015_env_065_env+_032_circular_economy_en.pdf
[17] COM (2010) 235 final

phosphorus[18]. Priority actions include rigorous enforcement of the targets on diverting bio-waste away from landfills[19] as well as proper application of the waste hierarchy and other provisions of the Waste Framework Directive to introduce separate collection systems as a matter of priority. Progress in this regards can be accelerated with initiatives such as the technical report supporting the End of Waste criteria for biodegradable waste (e.g. compost and digestate) finalised by the Joint Research Centre in January 2014[20] (hereinafter 'the JRC EoW report').

Several other EU legislations are also regulating the safe use of fertilising products to ensure the protection of water resources and air quality. Annex V contains a list of relevant existing EU legislations with information on their relation to fertilising products.

3.2. Lack of internal market

The internal market only exists for a majority of inorganic fertilisers and several types of liming materials. Fertilising products derived from the recycling of bio-wastes and biomass do not have access to the internal market due to the existence of diverging national rules and standards.

Inclusion in the current Fertiliser Regulation of such products is challenging. This Regulation as it stands is clearly tailored for well characterised, inorganic fertilisers from primary raw materials. The current Regulation lacks robust control mechanisms and safeguards necessary for creating trust in products from inherently variable composition.

As illustrated in Annex II and in Table 22 of Annex III, the multiplicity of diverging national rules leads to additional compliance costs for non-harmonised products[21] which discourage economic operators to find new markets. For example, a company active in the production of organic fertilisers mentioned that total compliance costs to five national legislation can amount up to EUR 90 000. Given the low profit margin of the sector (around 10%), the investment would be only paid off after 10 years.

The lack of an internal market can also be illustrated by the costs of marketing fertilising products in various Member States. According to an EU fertiliser association, prices of similar organic fertilisers can vary by a factor of two between Member States. A maximum price difference of 60% for organo-mineral fertilisers between Member States was also reported.

Table 52 of Annex IV shows that the costs of registration, compliance check and labelling are the top three identified costs for SMEs. A range of estimated compliance costs per type of requirements is also described in table 52.

This situation hampers intra–EU trade of organic fertilisers although there is a growing interest from industry to find new markets as mentioned in Section 3.2 and Figure 16 of Annex IV which shows that around 80% of SMEs supports the harmonisation process. It is

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18 COM (2013) 517 final

19 The Landfill Directive requires that waste is treated before being landfilled. Member States shall progressively reduce landfilling of municipal biodegradable waste by 35% in 2016 compared to 1995. A landfilling ban by 2025 is foreseen under the renewed Circular Economy Package

20 http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=6869

21 In this regard, the costs of registration of new products in the EU (estimated to be around EUR 25 million annually – see annex III) does not take into account direct compliance costs (e.g. fees) and indirect compliance costs (e.g. searching information on how to register products, costs of translation) that are illustrated with few examples in Annex II. Identical products are sometimes treated differently between Member States as there is no common definition for organic based materials.

however difficult to assess the impacts of the lack of harmonisation as there is no information about the number of companies that were discouraged to trade because of the complex legal environment.

The lack of an internal market concerns products derived from various types of organic materials such as some organic fertilisers or organic soil improvers for which, according to some national legislation, users need an environmental permit from waste management authorities to dispatch the material[22]. However, compost or digestate for example that do not require a permit or an exemption under waste law but are recognised as organic fertiliser or organic soil improver can be used at lower costs. The UK's Quality Protocol for compost, for example, allows the use of compliant compost in England and Wales without having to pay an exemption fee related to waste status. The avoided costs were estimated at more than GBP 2/tonne of compost (The Composting Association, 2006).

It has also been reported that farmers are hesitant to use materials classified as waste as it may be perceived as causing adverse impacts to the environment and agricultural produce. In that case, compost price for example is often very low compared to its actual agricultural benefits. In fact, it is likely that the agronomic value of compost is higher than the price paid for it when it is considered as a waste[23].

The recycling of organic materials (organic waste, animal by-products, sewage sludge, by-products from the agro-food industry…) generates market development opportunities for European manufacturers by using domestic feedstock to produce either organic or inorganic fertilisers[24]. Such products could make the EU less dependent on inorganic fertilisers produced in non-EU countries with finite resources (e.g. phosphorus) or intensive energy consumption (e.g. nitrogen fertilisers).

For example, some initiatives to recover nutrients from animal manure have emerged in Member States where the high amount of animal manure produced each year becomes an environmental problem. As animal manure has a low market value, it should be processed into a tradable good before being exported to other Member States. However, the complex regulatory framework (multiplicity of national rules regarding the treatment of animal by-products, difficulty to apply for mutual recognition of fertiliser, varying implementation of the Waste Framework Directive) prevents economic operators to develop further the market of secondary raw materials and the trade of fertilisers stemming from them across the EU.

National authorities still use national or even regional analytical test methods. The diversity of such national testing standards hampers the recognition of fertilising products sourced from domestic resources or lead to additional compliance costs notably as regards labelling[25]. The issue of the existence of diverging national standards could be addressed by developing harmonised EN standards.

Moreover, as reported in the ex-post evaluation, national producers often lack knowledge on the legal situation in other Member States and are unsure whether they should adapt their products to the requirements of the Member State of destination by modifying the product (which means additional costs) or if they can rely on Mutual Recognition procedures (which

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22 See for example Section 2 of Annex XI

23 For instance, it was a reason for including end-of-waste criteria in the Austrian Compost Ordinance to avoid that the value of compost is unduly underestimated because of waste status.

24 Ashes from the incineration of biomass contains exclusively nutrients in the inorganic form

25 See examples of diverging national provisions for the growing media sector in Section 3 of Annex XI

may cause delay for access to the market and costs of prior authorisation procedure in some Member States).

According to the ex-post evaluation, although trade barriers have been removed for about 60 to 70% of the inorganic fertiliser sector, economic operators still have to comply with diverging national rules for the remaining part of the inorganic fertilisers sector in particular with respect to limit values for contaminants.

3.3. The impacts of mutual recognition of fertilisers covered by national laws

The free movement of goods is one of the fundamental pillars of the EU, and is being upheld by the principle of mutual recognition deriving from the case law of the Court of Justice of the EU. According to that principle, Member States may not prohibit the making available on their market of any product (including fertilisers) that is lawfully placed on the market of another Member State, unless they can demonstrate that there are specific legitimate reasons (i.e., in the case of fertilisers, mainly protection of the environment and of human health) against accepting the product. Regulation (EC) No 764/2008 on Mutual Recognition (hereinafter 'MRR') regulates the application of that principle. According to the MRR, a Member State intending to impose such a prohibition on a product based on a technical rule shall notify the economic operator wishing to market the product. After the expiry of the time limit for the receipt of comments from the economic operator, the Member State shall take a decision and notify the economic operator thereof. The MRR also obliges Member States to designate Product Contact Points ('PCPs'), whose task is, *i.a.* to provide information to operators upon request.

The ex-post evaluation found that in 2009, the year of entry into force of MRR, an annual average of no more than 5 to 10 fertilising products had been placed on the market under the application of the procedures for mutual recognition in most Member States. Since then, the yearly reports of the Member States on the implementation of the MRR show that 20 Member States out of 27 specifically mentioned issues relating to fertilising products. They are reported as one of the product categories for which economic operators submit many information requests to PCPs, which means that there is a significant interest in intra-EU trade, but that economic operators are uncertain about the requirements applicable in different Member States (*See* Annex II for more details).

In February 2010, DG ENTR published a guidance document on the application of the MRR to prior authorisation procedures[26]. The yearly reports on the implementation of MRR do not show that this guidance document has eased the difficulties of economic operators in this regard. Some Member States have continuously indicated encountering particular difficulties with the implementation of the MRR for products subject to prior authorisation procedure in general, and fertilising products in particular.

The ex-post evaluation has identified three main areas of concern for Member States and industry:

3.3.1. Lack of trust in MRR by economic operators

For a few operators, the use of the Mutual Recognition Regulation provides a suitable alternative as a way to overcome the lengthy registration procedures of the Fertilisers Regulation or the various registration procedures and tests required in the different Member States. However, the ex-post evaluation (See a summary of the report in annex XII) shows

[26] http://ec.europa.eu/enterprise/policies/single-market-goods/free-movement-non-harmonised-sectors/mutual-recognition/index_en.htm

that a large majority of operators doubt the effectiveness of the MRR in the area of fertilising products. During the survey organised for the ex-post evaluation industry complained about the lack of clarity of the European legislation on mutual recognition, and argued that this tool is not suitable for creating uniform market conditions for fertilising products in the EU.

The high technical complexity and diversity of national rules applying to a large range of products/ingredients (sometimes captured in positive lists) and the uncertain outcome of procedures invoked by Member States on the grounds of human health or environment protection deter economic operators from applying for mutual recognition.

In addition, several Member States apply prior authorisation procedures[27] which the MRR has explicitly left out of its scope. Such procedures discourage economic operators from marketing their products in Member States where the procedures are in place. This conclusion is not altered by the fact that the Court of Justice of the European Union has defined certain conditions to be fulfilled for such procedures to be justified with regard to the free movement of goods.

3.3.2. Divergences in environmental and human health safety standards

Member States are concerned that the MRR may jeopardise their national requirements to protect the environment (in particular their national soil and water standards) and/or human health. For example, one Member State reported 4 cases of requests for mutual recognition in 2010, where all four products exceeded the limit on heavy metals that it had imposed nationally.

There are also concerns that inappropriate or low quality products will enter the market. For example, one Member State stated that some recycling companies, which are not fertilising products producers, may try to put low quality products (in terms of agronomic efficacy and contaminants levels) on the market to get rid of potentially dangerous waste or ineffective by-products as fertilising products. This would be achieved by lawfully placing them on the market in a Member State where no environmental or quality criteria for such products apply, and benefit from the mutual recognition procedure to make them available in other, more stringent, Member States.

3.3.3. Additional costs for Member States

The view that the MRR does not have the potential to create a functioning internal market for fertilising products was repeatedly expressed by almost all Member States during the various consultations[28].

The burden of proof in justifying the measures adopted according to the MRR lies entirely with the Member States, and not with the economic operators. Member States need to comply with strict rules regarding the production of evidence that national technical rules are required to ensure that overriding public interest for health and environment are respected. The application of the MRR therefore imposes administrative costs on Member States.

In particular, Member States mentioned that many enquiries for mutual recognition were outside the scope of the MRR[29] (sometimes more than 50% of questions) which in their view

[27] A measure by which, before a product may be placed on a given Member State's market, the competent authority of that Member State should give its formal approval following an application.

[28] With the exception of one Member State who sees the Mutual Recognition Regulation as a means to allow an internal market for non-harmonised fertilisers if producers are able to demonstrate that the product complies with the national legislation of the country of origin. Since 2010, this Member State has already recognised 133 fertilising products under the Mutual Recognition Regulation.

creates useless administrative costs on national competent authorities. This is seen as resulting mainly from the complexity of the legislations in place and the confusion of economic operators with regard to the concept of 'legally placed on the market in another Member States. According to the Fertilisers Study, the annual costs for competent authorities to analyse requests for mutual recognition is around EUR 420.000 (*See* Annex III p 46).

Member States' authorities have also expressed strong concerns to the Commission that their administrations might be overwhelmed if many fertilising products lawfully placed on the market in other Member States with different technical requirements were to be placed on their markets over a short period of time. National authorities would not be able to react within the short period of time provided for by the MRR (maximum 40 calendar days). This could lead to a situation where products lawfully marketed in another Member State would be marketed in their territories as well, without giving the receiving Member State any possibility to challenge the assessment of their potential risks for health and the environment.

In addition, Member States do not necessarily use the same analytical methods for control purposes. This can lead to administrative costs for authorities who verify with their own methods that the fertilising product complies with the requirements for human health and the environment applicable in another Member State.

In addition to the direct costs, reliance on mutual recognition is likely to have significant opportunity costs. The large number of information requests to PCPs indicates that there is willingness to trade within the EU across national borders. Regulatory uncertainty and hurdles, in particular in the form of national pre-marketing authorisation schemes, have been reported in the ex-post evaluation. The current regulatory framework discourages fertiliser producers using domestic resources from expanding their markets beyond national borders. This limits competition, which in turn implies that farmers may be paying higher prices for fertilising products. The potential costs hereof have not been included in the quantitative impact assessment, due to the difficulty to estimate its magnitude, but must not be disregarded.

3.4. Weaknesses of the current EU Fertilisers Regulation

3.4.1. Lack of consideration for environmental and public health concerns

In recent decades, interests have moved from solely providing extensive information about the nutrient content of fertilisers to also addressing environmental concerns. The current provisions are however lagging behind in this respect as no limits for contaminants are specified. The Fertilisers Regulation is therefore perceived as providing a lower level of protection of the environment and public safety than national legislation and, from the information collected from Member States, can even be used as a means to circumvent some national safety provisions by selling inorganic fertilisers containing harmful substances as EC Fertilisers[30].

In fact, Article 14 (c) of the Fertilisers Regulation requires that *"a fertiliser type may only be included in Annex I if under normal conditions of use it does not adversely affect human, animal or plant health or the environment"*. It is therefore the responsibility of the

[29] Products for which the MRR does not apply (e.g. products for which there is partly or full harmonisation at EU level) or products for which the query did not concern a technical rule within the meaning of MRR

[30] The specific case of **cadmium in phosphate fertilisers** has been subject to a separate impact assessment. The two impact assessments are fully consistent with each other and complementary. One Member State reported also that some phosphorus derivate products (e.g. phosphonates) authorised under the plant protection product regulation are added to EC fertilisers for plant nutrition purposes.

Commission and the Fertilisers Committee to check that a fertiliser type is not harmful before it is included in Annex I of the Fertilisers Regulation. However, several Member State authorities argued that the information required in the technical files for the registration of new fertilisers as EC Fertilisers is not clearly stipulated[31]. According to these Member States, the nature of the information to be provided and how this information should be presented should be specified more precisely. Moreover, the evaluation of these technical files should be given to a scientific committee of technical experts covering the whole range of relevant disciplines, which are not necessarily represented in the Fertilisers Working Group/Fertilisers Committee.

In addition, the Inter Service Steering Group has highlighted that the absence of contaminants limits for EC fertilisers is an issue for other pieces of EU legislation and policy:

- As regards the protection of **surface water**, EU Environmental Quality Standards (EQS) for several contaminants[32] in rivers, lakes and other surface waters have been adopted under the Water Framework Directive 2000/60/EC and there is an obligation for Member States to progressively reduce and in some cases completely phase out emissions, discharges and losses of those substances to the aquatic environment. Recent research suggests that the EQS for cadmium may not be sufficiently strict to properly protect the aquatic ecosystem[33]. Mined inorganic phosphate fertilisers are identified as the main contributor to soil cadmium inputs and surface water inputs through runoffs.

- As regards **groundwater,** specific measures also have to be taken under the Water Framework Directive to prevent and control groundwater pollution and achieve good groundwater chemical status. Directive 2006/118/EC on the protection of groundwater against pollution and deterioration includes criteria for assessing the chemical status of groundwater and for identifying trends in pollution of groundwater bodies. Under this Directive the Member States are required to establish threshold values for a so-called minimum list of pollutants in case they identify risks of pollution. This list includes arsenic, cadmium, lead, and mercury which are found in mined phosphate fertilisers. The Groundwater Directive also includes a European quality standard for nitrates based on the Nitrate Directive. The presence of nitrates in groundwater is mainly due to an excessive use of inorganic nitrogen fertiliser and manure.

- Contaminants in **food** are regulated by Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs. The Regulation provides an increased level of protection of consumers from listed pollutants (nitrate, lead, cadmium, mercury, PCBs and PAHs[34]). Several recent scientific opinions[35] and

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[31] The current technical requirements (e.g. information on effects on health, environment and safety, agronomic data) are described in a non-binding guidance document produced by the Commission in cooperation with Member States, industry and CEN experts. http://ec.europa.eu/enterprise/sectors/chemicals/files/fertilizers/2009_02_03_new_guidance_final_en.pdf.

[32] For example, cadmium, mercury, PAHs are listed as priority hazardous substances; lead and nickel as priority substances in Directive 2008/105/EC and the recently adopted Directive 2013/39/EC.

[33] E. Van Ael et al., Environnemental Pollution 186 (2014) 165-171.

[34] PolyChlorinated Biphenyls and Polycyclic Aromatic Hydrocarbons

[35] Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on cadmium in food. The EFSA Journal (2009) 980, 1-139
Scientific Opinion on tolerable weekly intake for cadmium. EFSA Journal 2011;9(2):1975. [19 pp.]
Scientific Opinion on Lead in Food. EFSA Journal 2010; 8(4):1570. [151 pp.].

exposure reports[36] demonstrated the need to further reduce dietary exposure to heavy metals such as cadmium and lead. Food is the major source of human exposure to lead and it accumulates in the body and most seriously affects the developing central nervous system in young children. EFSA has recommended reducing the dietary exposure to lead in food by lowering existing maximum levels and setting additional maximum levels for lead in relevant commodities. On cadmium, EFSA concluded that the current exposure to Cd at the population level should be reduced as well. (*See* Section 6.3.3 and Annex VI for more details).

- Except for the use of sewage sludge in agriculture, which is regulated by Directive 86/278/EEC, there are no standards for soil contaminants at EU level. Nevertheless, the **Soil** Thematic Strategy[37] advocates for action at source to prevent diffuse soil contamination. There is evidence that contaminants inputs from anthropogenic sources (including fertilising products) affect the natural background concentration of such contaminants in arable soils. For example, the French Environment and Energy Management Agency (ADEME 2007) estimated that approximately 4,500 tons/year of copper and zinc are added to agricultural soils in France mainly due to animal manure spreading on farm fields. Chromium, nickel and lead have inputs ranking between 500 to 1,000 tons/year and approximately 150 tons of arsenic, 50 tons of cadmium and 12 tons of mercury are added each year to French soils from 7 different sources[38]. Fertilising products (inorganic fertilisers, soil improvers, liming materials, animal manure) contribute to more than 50% of the inputs mentioned above and their intensive use leads to difficulties for Member States to correctly enforce the Directives on water protection and the Regulation on the maximum values for contaminants in foodstuffs.

  Plastic mulch films offer a wide range of advantages for farmers. For example, it reduces the amount of water, energy and chemicals used for crop production[39]. However, 68% of the plastic mulch films used in EU agriculture (Annex I contains some information on the size of this market) are not recycled and end up in landfills, incinerators or are left on soils which lead to reduced crop yields[40] .

- Finally, urea-based fertilisers are an important source of ammonia emissions, an important **air pollutant**, and the review of the Fertilisers Regulation should also include appropriate solutions to minimise such emissions. Urea-based fertilisers represent about 20% of total inorganic fertiliser use in the EU but due to higher volatility compared to other sources of nitrogen, they are responsible for about 50% of the ammonia emissions deriving from fertiliser use. Compared to the total

[36] Cadmium dietary exposure in the European population. EFSA Journal 2012;10(1):2551. [37 pp.]
Lead dietary exposure in the European population. EFSA Journal 2012; 10(7):2831. [59 pp.]

[37] COM (2006) 231

[38] http://partage.ademe.fr/data/public/6c32bb3647341cab67e6572af4dd921d.php?lang=fr
http://partage.ademe.fr/data/public/128cc3ee8770a890156fbea88a92292b.php?lang=fr
(in particular spatial representation of soil contamination on pages 149 to 168)

[39] It has been demonstrated that the amount of drinking water that could be saved with the use of plastic mulch is equivalent to the annual water demand of over 8 million people. Similarly, 6% fossil fuels could be saved annually which corresponds to the residential energy use of 24.8 million people in Chine (Source: BASF)

[40] In China, an average decrease over 15 years of 8.5% per year in cotton field has been correlated to the use of 10µm polyethylene mulch film (Source: BASF)

ammonia emissions from agriculture overall, urea-based fertilisers represent approximately 10% of these emissions[41].

In conclusion, the compliance with the very stringent limits for contaminants in water and food becomes more and more difficult because of the presence of contaminants in the environment brought by anthropogenic interventions such as farming activities. This confirms the need for an overall action to limit further contaminants inputs to arable soils through the use of fertilising products which remain important contributors to soil contamination.

3.4.2. Market access problems for new products

The inorganic fertiliser industry is a mature industry. Novelty is limited compared to the chemicals industry, and even more so compared to the plant protection product industry. It is mainly concentrated on the development of agronomic fertiliser additives that modify the nutrient release pattern.

The impact of the Fertilisers Regulation on innovation in inorganic fertiliser is nevertheless an important source of concern for industry[42].The key problem is the lengthy procedure for the listing of a new product type in Annex I to the Fertilisers Regulation. It takes on average 4-5 years to get a new type included in Annex I during which time the related products cannot be marketed as an EC Fertiliser. Most companies believe that this duration is not in pace with the innovation cycle in the inorganic fertiliser industry[43], which is of the order of 1-2 years.

The main reasons for this unduly long approval period are the time required for the development of European Standards[44] for test methods to ensure market surveillance for the new EC Fertiliser type and the lengthy discussion in the Fertilisers Working Group/Fertilisers Committee where decisions on the relevant technical files are taken.

The provisions of the current Fertilisers Regulation are tailored for conventional fertilisers, typically inorganic or chemically produced, from well characterised primary raw materials. These provisions are not adapted to new fertilising products produced from organic or otherwise unknown materials, such as animal by-products or recycled waste. In particular the robust control mechanisms and safeguards necessary for creating trust in such products are missing, and the links with existing legislation on animal by-products and waste are not clear. This distortion of competition turns in favour of conventional inorganic fertilisers and hampers the investment in new fertilising products from domestic organic or secondary raw material, in particular in Member States with a small domestic fertiliser market compared to their organic matter surplus.

Moreover market dynamics have evolved since the entry into force of the Fertilisers Regulation which covered only inorganic fertilisers. EU farmers are increasingly demanding more products allowing for new combinations of fertilising products not in the scope of the current Fertilisers Regulation and tailored to the needs of their crops.

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41 The other main agricultural source of ammonia emission is manure. Options to regulate manure management are addressed separately in the review of the EU air policy http://ec.europa.eu/environment/air/pdf/clean_air/Final%20Report.pdf

42 During the SMEs consultation (Annex IV), more than 83% of the responding companies estimated that the harmonisation would improve the access to the EU market for more sustainable products. The industry associations consulted during the ex-post evaluation expressed the same concerns

43 From the time of invention to the development of a final product with all the necessary internal tests

44 This time is needed to ensure examination of stakeholder comments. Although CEN is required to develop standards in 36 months, this deadline is not always met for technical reasons.

3.5. Drivers of the problem

- The market for fertilising products is evolving. More focus on the recovery of nutrients is already well recognised in some Member States but not yet at EU level.
- The regulatory framework for the EU fertilising product market becomes increasingly complex. Member States have adopted national measures with different scopes, authorisation procedures, limits for contaminants, labelling requirements, and control measures that entail extra compliance costs for industry and for authorities themselves. Moreover, there is a general lack of confidence among the Member States in the mutual recognition of fertilising products because of diverging levels of stringency in national legislation. This complex regulatory framework is not conducive to innovation in the whole sector and emerging products are thus not available throughout the Union market (See Annex XI) in particular for domestic organic and secondary raw materials.
- Member States and industry suffer from that complexity. There are growing expectations and demands from various industry segments for a better integrated EU regulatory framework with faster procedures to favour the emergence of more fertilising products sourced from domestic resources (See the summary of the SMEs consultation in Annex IV).
- Member States do not have the necessary human resources to ensure sufficient market surveillance activities for products placed on their market in accordance with the MRR. For example, the Italian authorities reported during the ex-post evaluation that Mutual Recognition of national fertilisers harms the process of market surveillance as the Italian system is based on a system of registration of companies.
- Expectations from farmers and society in general in terms of protection of the environment, human health and better use of natural resources (including lands) are also expanding. The absence of maximum limits for contaminants at EU level is perceived to be a clear limitation of the Fertilisers Regulation and an area where Member States would like to see specific harmonised provisions put in place. Limited awareness among farmers and a general lack of information about the potential release of ammonia from urea-based fertilisers contributes to negative health impacts through increased concentrations of secondary particulate matter and increased nitrogen deposition and acidification (See Annex VI and Annex VIII Section 3.3 for more details).

3.6. Who is affected, in what ways and to what extent?

In the current situation, the stakeholders listed below are affected by the identified weaknesses of the Fertilisers Regulation, the shortcomings of the application of the Mutual Recognition Regulation, and trade barriers caused by the diverging requirements of the Member States' national laws:

European fertilising products manufacturers (in particular SMEs), importers, distributors, traders and retailers who, without a harmonised market for new products sourced from local raw materials have to comply with different rules throughout the Union and thereby continue to face extra compliance costs. This hampers the recycling of nutrients from bio-wastes, hence the development of the circular economy and makes the EU more vulnerable to imports from non-EU countries. Inorganic fertiliser producers have difficulties to market new products due to the lengthy procedures for inclusion of new fertiliser types in Annex I to the Fertilisers Regulation.

Private and public recovery operators (such as operators of waste water treatment plants or of waste management plants producing compost or digestates) want to valorise their outputs and at the same time will face, due to the revised waste legislation under preparation in the framework of the Circular Economy Package, increasingly difficult disposal regulations and recycling targets (landfill ban of organic wastes by 2025 and 70% recycling of municipal solid waste by 2030).

National competent authorities have difficulties enforcing their national limit values for contaminants due to their obligations to accept the free circulation of EC Fertilisers which do not specify any limit value for contaminants and the mutual recognition of fertilising products. This situation undermines the efforts made by some Member States to impose stringent rules to protect their environment and/or human health.

Food safety authorities face difficulties in the implementation of safe maximum levels of contaminants in foodstuffs without unduly restricting the supply of food commodities that are beneficial and essential to human health (fruits, vegetables, cereal…). These limits are set taking into account the recommended daily intake but also considering the current load of contaminants in the environment.

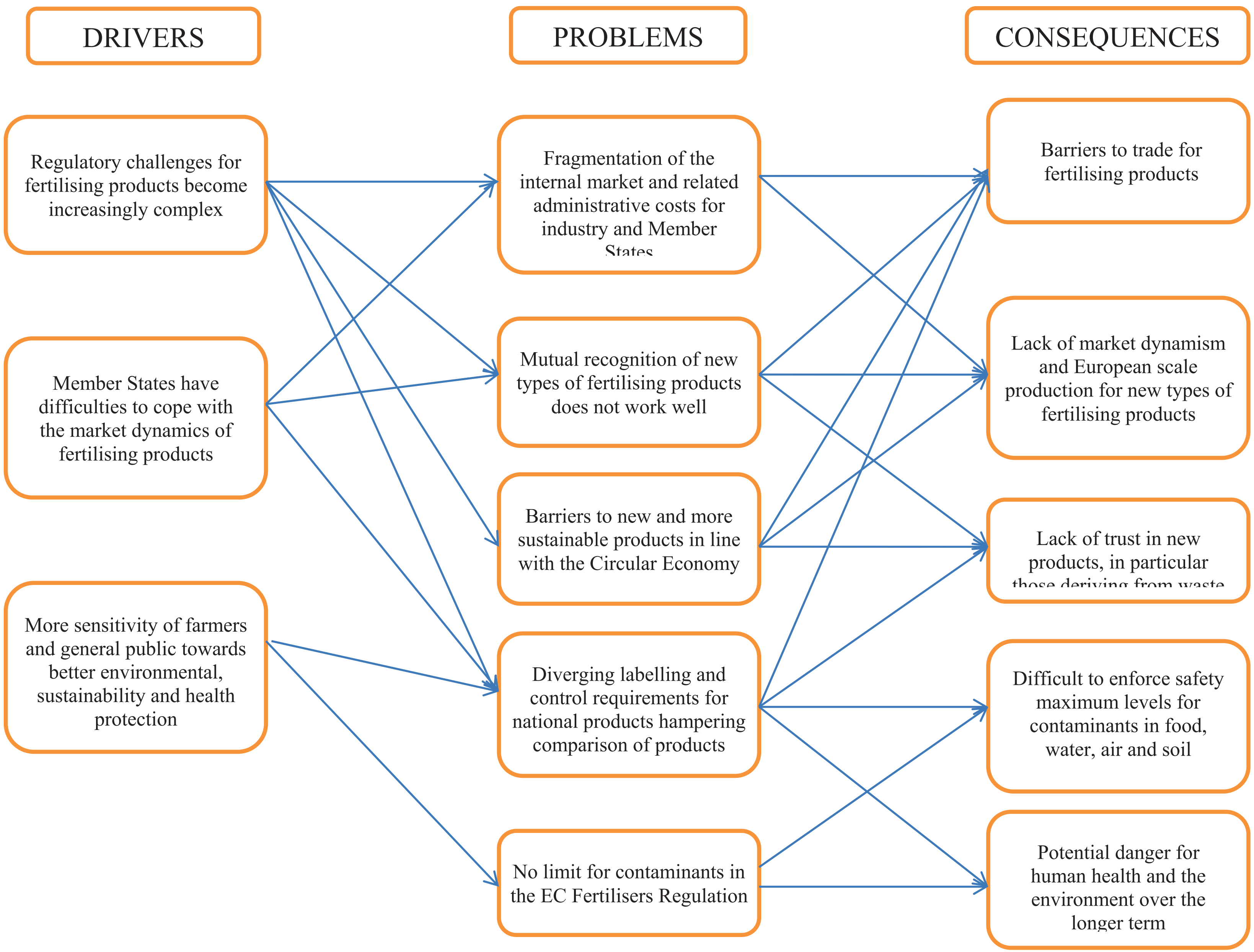
The general population has no access to a wide variety of new fertilising products sourced from domestic resources. Some parts of the population are affected by the presence of contaminants in fertilising products. According to EFSA, exposure of the general population to cadmium and lead needs to be reduced (See Section 3.3.1 and Annex VI Section 5 for more details). Such safety concerns are not equally addressed by the Member States.

EU farmers, professional gardeners and the general public currently do not benefit from an internal market for fertilising products because of existing trade barriers between Member States, which limits competition. Access to a broad range of valuable domestic raw materials (e.g. compost) is currently hampered by their classification as waste or variations in the implementation of waste legislation in Member States. New agri-environmental climate measures are in place under the Rural Development Programs to promote the use of organic fertilisers with the aim to increase the organic matter content of arable soils.

Phosphate producing companies in non-EU countries and **the European inorganic fertiliser industry** currently have no incentives to develop and implement technologies that are able to remove cadmium during the production of inorganic phosphate fertilisers.

The underlying drivers of the problem and the direct and indirect consequences are summarised in Figure 2.

Figure 2: Drivers, problems and consequence of the lack of internal market for fertilising products



3.7. Expected evolution of the problem

If no action is taken, legal and administrative divergences between Member States will increase leading to a more fragmented internal market for fertilising products. Consequently, operators proposing alternatives to conventional inorganic fertilisers to support the circular economy would remain confined to their national markets which will not help to reduce the dependance of the Union on critical raw material such as phosphorus or on imports of important volumes of natural gas for the production of inorganic nitrogen fertilisers. The Bio Based Industries Joint Undertaking[45] has identified phosphorus recycling for fertiliser production as an emerging and economically promising new value chain from organic waste. Easy access to the internal marketfor such fertiliser would be a pre-conditon for achieveing this goal and bringing results from research to the market.

Member States will continue to take national legislative action to reduce the potential negative impacts of the presence of contaminants in fertilising products which will further increase the fragmentation of the market. As there would be less market opportunities to export organic fertilisers made of processed animal manure, Member States would continue to request derogations under the EU Nitrate Directive to allow farmers to apply raw manure in vulnerable zones leading to increase risk of eutrophication of water bodies. Municipalities would have increasing difficulties to valorize the outputs of waste treatment plants as market opportunities would remain limited in particular in densely populated areas.

If the number of requests for mutual recognition increases with the increasing fragmentation of the market, national competent authorities wishing to enforce stringent limit values to avoid soil contamination, and thereby food and water contamination, will have increasing difficulties to review such requests in accordance with the requirements of the MRR.

In the absence of limits for contaminants in EC Fertilisers, accumulation of contaminants (particularly heavy metals) in the soil will continue, contrary to the objectives of the Soil Thematic Strategy, and Member States wishing to enforce national limit values for EC Fertilisers would have to request derogations based on Article 114(5) TFEU. This would create administrative burdens for Member States – examples from the past have shown that gathering the necessary data requires significant resources for the requesting Members States as well as for the Commission in order to evaluate and decide on the requests.

The objectives of a Commission communication on a new Clean Air Programme for Europe[46] will be more difficult to achieve unless ammonia emission from urea-based fertilisers is specifically addressed in EU legislation. EU consumers would not be equally protected against exposure to heavy metals such as cadmium and lead through the food chain as some Member States may not wish to enforce limit values for contaminants in fertilising products.

EU farmers, professionals and citizens would have limited access to efficient and innovative products at competitive prices because of extra compliance costs that fertilising products producers currently face due to the complex regulatory framework.

[45] http://bbi-europe.eu/

[46] COM (2013) 0918 final
http://eur-lex.europa.eu/resource.html?uri=cellar:bbdc17de-76dd-11e3-b889-01aa75ed71a1.0001.01/DOC_1&format=PDF

3.8. EU right to act

3.8.1. Legal basis

The legal basis for action is Article 114 of the Treaty on the Functioning of the European Union (TFEU), which is also the legal basis of the current regulation. The objective of Article 114 is to establish an internal market while ensuring a high level of protection of human health and the environment.

3.8.2. Subsidiarity and Proportionality

From the point of view of the operators diverging national measures have led to an incoherent regulatory framework that does not provide a level playing field for all manufacturers and leads to increased compliance costs. These existing market barriers in the form of diverging national regulatory frameworks can only be removed though EU action.

Pursuant to Article 31(2) of the Fertilisers Regulation, requests have been submitted to include fertilising products made of secondary raw materials in its Annex I. Such requests have been so far rejected on the grounds that the current Fertilisers Regulation does not provide the necessary regulatory procedures to ensure the safety of such products. Consequently, the competition between more sustainable fertilising products in line with the circular economy and inorganic fertiliser produced in line with a linear economy model is currently tilted in favour of the latter.

The weaknesses of the current Fertilisers Regulation and the problems that they cause cannot be resolved by Member States alone, as a revision of the regulation requires EU action.

As the amount of fertilising products applied on arable soils depends on the crop grown and soil and climatic conditions in each Member State, this impact assessment report will only concern *the placing on the market* of fertilising products, while it will continue to be left to Member States to regulate *the use* of such products (e.g. amounts that can be applied per hectare). In addition, a future framework would have to provide flexible tools to address emerging concerns from Member States relating to safety by providing an appropriate procedure for managing fertilising products presenting a risk.

According to Article 114 (4) and (5) TFEU, Member States may maintain or introduce national limits for contaminants based on the evaluation of risks for the environment and human health under certain strict conditions and after authorisation by the Commission.

As one of the general policy objective of the initiative aims at reaching a critical mass for fertilising products made of domestic secondary raw materials through the development of an internal market for such products, product harmonisation should not go beyond what is necessary for providing the regulatory certainty required to incentivise large scale investment in the circular economy while imposing a high level of protection of health and the environment.

The proportionality of possible options will be discussed in more details in later sections of this report.

4. OBJECTIVES

4.1. General policy objective

The general objective is to incentivise large scale fertilising products production in the EU from domestic organic or secondary raw materials by creating a regulatory framework granting such fertilisers access to the internal market and to address the well-recognised issue of soil contamination by contaminants present in fertilisers.

4.2. Specific policy objectives

In order to achieve the general objectives and address the identified problems, the following specific objectives have been identified:

– To ensure an improved functioning internal market and a level playing field for manufacturers and importers of fertilising products in particular for those made of domestic and secondary raw materials in line with the Circular Economy model;

– To reduce the administrative burden resulting from diverging national rules and incomplete application of the mutual recognition of fertilising products;

– To improve the safety of fertilising products as regards the protection of the environment and human health (in particular soil, water, air and food quality);

– To ensure coherence with other existing EU legislation to support investments into new economic opportunities for public and private operators.

4.3. Operational objectives

– To remove trade barriers for the intra-EU trade of fertilising products;

– To limit pollutants levels in fertilising products;

– To reduce administrative burdens for economic operators, Member States authorities and the Commission, improve the overall cost efficiency and simplify the regulatory framework;

– To facilitate innovation and allow a quicker access to the market for more sustainable products, in particular for organic products issued from the recycling of nutrients from biomass, in accordance with the objectives of a European Circular economy.

– To streamline the information obligations requirements as regards quality parameters for all product categories in order to allow farmers and consumers to easily compare products and address the information gaps for users concerning urea-based fertilisers as regards their impact on the environment.

4.4. Consistency with other policies and objectives

Consistency with other EU policies and stated priorities has been sought in the development of the policy options. Policies particularly considered include:

– 'Europe 2020'[47], notably in relation to its smart, sustainable and inclusive growth priorities and associated flagship initiative on 'Resource Efficient Europe'. An internal market for organic fertilising products would help to support a partial substitution of inorganic fertilisers for which the EU is highly dependent on imports thereby contributing to the circular economy. The main ideas on how to do more with less are being taken further in the EU's Environment Action Programme to 2020[48].

[47] COM (2010)2020. More information on: http://ec.europa.eu/europe2020/index_en.htm.
[48] http://ec.europa.eu/environment/newprg/index.htm

– "Closing the loop – An EU action plan for the circular economy" recently adopted by the Commission[49] has identified the Fertilisers Regulation revision as a key legislative proposal to boost the market for secondary raw materials. The Commission Communication calls for new measures to facilitate the EU wide recognition of organic and waste-based fertilisers, thus stimulating the development of an EU-wide market.

– The EU raw material strategy[50] includes phosphorus in the critical raw materials list. Since its publication in 2010 the list of critical raw materials has proven to be an important tool for the Commission to raise awareness, determine priority actions and open up funding opportunities under the Horizon 2020[51] (e.g. the research activities launched under the Societal challenges 2 - "food security, sustainable agriculture and forestry, marine and maritime and inland water research and the bio-economy" and 5 – "climate action, environment, resource efficiency and raw materials) which aim at providing technological solutions for recycling more efficiently and safely bio-wastes and encouraging researchers to deliver innovative products in compliance with the market and societal needs.

– The Small Business Act[52] as the proposal accompanied by the impact assessment report addresses issues (e.g. barriers to trade, compliance costs and innovation) faced by numerous SMEs that are involved in the manufacture of fertilising products.

– EU policies related to the protection of the environment, in particular soil (as defined in the Soil Thematic Strategy), water (as set out in the Water Framework Directive and in particular the Nitrate Directive), air (the new Clean Air Policy Package tabled in December 2013[53]) and to the protection of human health, in particular with regard to contaminants in foodstuff.

This initiative is undertaken with the objectives of the Commission's Communication on Smart Regulation in the European Union[54] in mind. The problems to be addressed by the initiative are based on the ex-post evaluation of the existing legislative framework for fertilisers.

5. POLICY OPTIONS

Based on the weaknesses identified during the evaluation of the current Fertilisers Regulation, the Commission developed eight possible policy options which could address the identified problems.

5.1. Possible options which have been discarded at an early stage

5.1.1. Improvement of the Mutual Recognition without harmonisation

The Commission concludes from the explanation given in Section 3.2 and further detailed in Section 2 of Annex II that the internal market for non-EC Fertilisers has not substantially progressed since the existence of the MRR despite a comprehensive body of case law and

[49] More information on: HTTP://EC.EUROPA.EU/ENVIRONMENT/CIRCULAR-ECONOMY/INDEX_EN.HTM
[50] http://ec.europa.eu/enterprise/policies/raw-materials/index_en.htm
[51] http://ec.europa.eu/programmes/horizon2020/
[52] More information on: http://ec.europa.eu/enterprise/policies/sme/small-business-act/index_en.htm.
[53] More information on: http://ec.europa.eu/environment/air/clean_air_policy.htm
[54] Available at: http://eur-lex.europa.eu/lexuriserv/lexuriserv.do?uri=com:2010:0543:fin:en:pdf.

guidance and that further progress cannot be expected. Increased enforcement activities of the MRR by Member States are also not a promising alternative in view of the distrust of most EU companies for the mutual recognition of fertilisers.

The ex-post evaluation showed that neither economic operators nor national authorities were of the opinion that mutual recognition could be an effective tool for ensuring free movement of fertilisers, a product category for which legitimate product quality, environmental, and public safety concerns warrant stringent rules.

Moreover, the problems stemming from the Fertilisers Regulation itself would not be addressed by this option. This option has therefore been discarded.

5.1.2. Voluntary agreement by industry

On top of the existing Fertilisers Regulation and other applicable EU legislation, fertilising products manufacturers and importers would need to agree to voluntarily establish quality procedures and standards for all the categories of fertilising products to ensure a certain level of harmonisation of the market. This would include safety and quality elements (limits on contaminants and agronomic efficacy criteria), good manufacturing practices based on best available techniques, self-control activities, and certification schemes.

Although self-regulation by industry to improve the quality and safety standards of its products generally leads to a market with fewer barriers to trade, it is unlikely that the Member States would repeal their existing national legislation. Also, while such voluntary commitments have already been adopted in some Member States and for specific product types (for instance, the "Quality Assurance Scheme for Compost" adopted by the members of the European Compost Network – ECN), a meaningful EU-wide commitment would be difficult to achieve as partners would not necessarily have the same economic interests. As a result, several private commitments could be generated and create a multitude of monitoring systems and enforcement problems. Representation of SMEs in the preparation of such voluntary scheme could also be an issue. Finally, this option is clearly rejected by all stakeholders as this would not bring the same level of legal certainty compared to regulatory harmonisation, especially in the long run.

5.1.3. Withdrawal of the EU legislation on fertilisers and reliance on other relevant existing EU legislations to ensure the safety of fertilising products

The Fertilisers Regulation would be repealed and only the requirements of other existing EU legislation (i.e. REACH, CLP[55], Animal By-Products Regulation…) would apply to ensure the safety of the products placed on the market[56]. There would be no harmonised limit values for heavy metals or organic pollutants at EU level.

Member States would, in line with the provisions of the Treaty, be free to maintain or introduce national legislation. Manufacturers would have to comply with national provisions or apply the provisions of the Mutual Recognition Regulation to market their products. This would increase the fragmentation of the internal market for fertilising products and uncertainty for producers and market surveillance authorities.

The costs of managing national legislation would increase as Member States would have to convert existing EC Fertilisers into 'national' fertilisers which would further increase the

[55] EU OJ L 396, 30.12.2006 and OJ L 353, 31.12.2008

[56] Note that this would imply that there is no regulation at EU level regarding cadmium in phosphate fertilisers (except for organic farming).

compliance costs for operators. REACH and CLP do not properly cover the issues at stake concerning the presence of contaminants in fertilising products and their scope is currently not adapted for the categories of fertilising products outside inorganic fertilisers and liming materials deriving from industrial by-products. The Animal By-Products Regulation is addressing hygienic safety issues relating to the use of such materials in the composition of organic fertilisers or soil improvers but not environmental issues such as the presence of heavy metals except for each consignment of raw manure which is subject to prior acceptance by the Member State of destination.

This option is not considered as a viable option by Member States and industry as they favour a dedicated instrument to ensure a level playing field for economic operators and the safety of fertilising products placed on the market.

5.2. Description of the examined options

For *each option* (except option 1), two possible variants would be examined for implementation:

1) *Full harmonisation*: if this variant were to be applied to the options 2 to 5 described below, the scope of harmonisation would be extended to all fertilising products (including the EC fertilisers) placed on the market in the EU. All existing national legislation would have to be repealed.

2) *Optional harmonisation*: under that variant, which could be applied to either of the options 2 to 5, the scope of harmonisation would be extended to all fertilising products (including EC fertilisers) on an optional basis. Operators interested to get products CE-marked for easy access to the EU-wide internal market would have the option of ensuring that their products comply with the harmonised requirements. However, non-harmonised products could still remain on the national markets, subject to any applicable national requirements and mutual recognition. This variant would also be more flexible in defining the scope and the level of the legal requirements of a future regulation depending on the level of political ambition of the circular economy.

5.2.1. Option 1: the current EU legislation governing the placing on the market of fertilisers remains unchanged (baseline scenario)

In this baseline option, the existing EU legislation framework would be maintained. The Fertilisers Regulation would continue to apply to inorganic fertilisers. There would be no specific EU legislation for other fertilising products – instead national fertiliser laws and mutual recognition would continue to apply albeit with a number of problems as identified above.

As regards safety, no maximum limits for heavy metals in inorganic fertilisers would be adopted at EU level. Member States having established limit values for heavy metals for national or EC Fertilisers (where authorised – see 3.7.2) will maintain them, whilst others might introduce them in the future.

*5.2.2. Option 2: creation of an internal market for fertilising products in the format of the current Regulation, i.e. **listing individual product types***

The option (as the options 3 to 5) would imply the extension of the current scope to organic fertilisers, organo-mineral fertilisers, soil improvers, growing media and plant biostimulants as defined in the introduction. All technical details such as minimum nutrient content and quality criteria, description of manufacturing procedures, specific labelling obligations would be fully described in fertilising product types.

Maximum limit values for contaminants for each product category would be defined. **Specific quality criteria** would apply to each product category. **Labelling requirements** would apply to each product category in accordance with its specific characteristics.

In order to list a new fertilising product type, producer would have to follow a procedure including the submission of an application dossier containing safety and agronomic data and an evaluation of such data involving all Member States (Variant 2A) or an EU Agency[57] i.e. ECHA –Variant 2B or EFSA – Variant 2C before a decision for inclusion by the Member States and the Commission would be taken (See Annex III for details).

As regards the safety criteria limit values for contaminants will be proposed. The values are selected on the basis of an extensive stakeholder consultation after peer-review of available studies (soil contamination and human health studies) with the aim to limit as far as possible further accumulation of contaminants in EU soils from the use of fertilising products. More detailed justification for the proposed limit values can be found in Annex VI. Information on how these limits relates to the current values in national legislation can be found in Annex XI.

European standards relating to test methods (nutrient content, organic matter content, quantity, density…) would be developed and referenced in an annex to the legislation to facilitate the control of all products. The verification of the compliance of the products to the requirements of a future regulation would continue to be carried out by manufacturers during production and by market surveillance authorities during controls.

Apart from informing users about the characteristics of the product, labelling provisions will also have the objective of increasing awareness about environmental aspects, such as cadmium levels (particularly relevant for phosphate fertilisers – See IAR on cadmium for further details).

In case of full harmonisation, sufficiently long transitional provisions (e.g. 10 - 15 years – See examples from the Biocidal product regulation) would be required to allow fertiliser producers and importers to register their established products in the EU authorised list of fertilising product types.

5.2.3. *Option 3: creation of an internal market for fertilising products by **listing authorised ingredients***

Permitted ingredients allowed in the manufacture of fertilising products would be listed in the annexes of a new regulation repealing the current Fertilisers Regulation. A detailed description of fertilising product types would no longer be needed and the central rule to place a product on the market would be that it results from combination of authorised ingredients only.

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[57] ECHA can be financed by fees paid by applicant companies while EFSA only relies on Commission subsidies. The peer-review processes carried out by EFSA or ECHA would be very similar. Their respective average administration costs were estimated taking into account the fees applying to REACH and biocides authorisation processes and the budget allocated by the Commission to EFSA for the authorisation of active substances in accordance with the plant protection products Regulation. ECHA has already the necessary IT infrastructure and staff to perform the foreseen tasks (registration of products) whereas EFSA is more specialised in the delivery of opinions relating to the ‘end of pipe’ risks in the food chain based on Commission mandates.

Maximum limit values for contaminants (the same as under option 2) for each product category would be defined in a future proposal. **Minimum quality criteria** would apply to each product category. **Labelling requirements** would apply to each product category in accordance with its specific characteristics.

To be listed in an annex, new ingredients would have to follow the same procedure as described under option 2 i.e. submission by the producer of the ingredient of an application dossier containing safety and agronomic data and evaluation of such data involving all Member States (Variant 3A) or an EU Agency i.e. ECHA – Varian 3B or EFSA – Variant 3C. European Standards relating to test methods and labelling requirements would apply to final products.

A shorter transitional period could be envisaged as the number of ingredients for fertilising product production would be less than the number of product types.

5.2.4. Option 4: creation of an internal market for fertilising products using the 'New Legislative Framework[58] *- NLF*

This framework aimed to be less prescriptive and restrict the content of legislation to 'essential requirements' leaving technical details to European Harmonised Standards. The objective of the NLF is to facilitate the functioning of the internal market for goods and to strengthen and modernise the conditions for placing a wide range of products on the EU market. It builds upon existing systems to introduce clear EU policies which will strengthen the application, monitoring and enforcement of single market legislation. The NLF objectives are to ensure that products available in Europe meet a high level of protection to public interests like health and safety, consumer protection or environmental protection and to ensure the free movement of products.

Legal requirements with regard to safety (including the same limit values for contaminants that would be proposed under options 2 and 3), product quality and other specific rules appropriate for the placing on the market of safe and efficient fertilising products would be specified **for each product category**. There would be no listing of ingredients or types and hence no need for frequent adaptations to technical progress.

Maximum limit values for contaminants (the same as under option 2) for each product category would be defined in a future proposal. **Minimum quality criteria** would apply to each product category. **Labelling requirements** would apply to each product category in accordance with its specific characteristics.

Harmonised EN Standards would be developed and published in the Official Journal to allow demonstrating conformity of the products to the legal requirements of the legislation.

Producers would have to declare conformity with the legal requirements, or, alternatively, notified bodies designated by Member States would have to confirm compliance with the legal requirements. This would range from self-certification (Variant 4A) to various levels of third party certification (Variant 4B: verification of the compliance of products to the legal requirements by notified bodies - Variant 4C: verification of the compliance of products to the

[58] For more details, please visit http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/new-legislative-framework-and-emas/index_en.htm

legal requirements by notified bodies plus regular tests on specific aspects –Variant 4D: verification of the compliance of products to the legal requirements by notified bodies plus random testing on specific aspects). More detail on the content of the various variants of option 4 is available in section 3.4 of Annex III.

Shorter transitional provisions (e.g. 3 years) could be envisaged provided that the necessary harmonised standards are available in particular under variant 4A. Under the other variants of option 4, a reasonable delay (e.g. 3+1 years) could be foreseen to allow Member States to notify the bodies that will be tasked to certify the compliance of products.

5.2.5. Option 5: creation of an internal market for fertilising products and additives by adopting different variants of option 4 for different types of fertilising products

As under option 4, harmonisation of the EU market for fertilising products is achieved through the 'New Legislative Framework'. However, third party involvement in the assessment of conformity with the legal requirements *varies* between product categories, and is highest for fertilising products sourced from waste and other secondary materials with potentially variable composition.

The regulatory regime for the different categories of fertilising products would look as follows:

Inorganic fertilisers as well as liming materials would be mostly regulated by variant 4A (self-certification) as these products have constant composition and are deriving from well-known chemical processes[59]. A limited number of inorganic fertilisers and liming materials (those derived from industrial by-products) would be regulated under Variant 4B (third party certification regarding the composition of the final product and its fulfilment of legal requirements) as they could contain some contaminants such as heavy metals. Ammonium nitrate fertilisers would need to be more strictly regulated under Variant 4C (third party certification regarding the composition of the final product and its fulfilment of legal requirements plus detonation tests) for security reasons[60]. However it has to be noted that these stringent requirements for ammonium nitrate are already described in the current Fertilisers Regulation and would be also covered by the other options envisaged in this impact assessment. A future regulation would ensure that such products are periodically and evenly controlled by authorised laboratories across Europe.

The coexistence of three different certification procedures for inorganic fertiliser is feasible as the different product types are easily identifiable by market surveillance authorities.

Growing media would also be regulated under variant 4A (self-certification) as the stakeholders consulted in 2012 agreed that most of the ingredients used in growing media present limited risks to the environment or human health that could be easily addressed with generic safety criteria.

The organic matter used in the production of organo-mineral fertilisers will have to be of high quality[61] to ensure the effectiveness of the end-product. As only source segregated materials could be used to achieve this high quality target, it is proposed to regulate those products under variant 4B.

[59] Inorganic nitrogen fertilisers for example do not contain contaminants.
[60] In certain specific conditions they are able to detonate.
[61] The efficacy of the organo-mineral fertiliser is directly dependent on the content in humic acid.

Many organic fertilisers and organic soil improvers derive from bio-wastes. As opposed to mined fertilisers, the nature of potential contaminants in fertilisers from waste cannot be easily predicted, which creates problems of market acceptance. For fertilising products sourced from waste, it is therefore necessary to lay down essential legal requirements not only for the composition (including contaminants) of the end-product, but also – as a means of excluding potential contaminants – for the origin and treatment of the input-materials. For the purpose of establishing the necessary trust and confidence in waste-based fertilising products, it is therefore also necessary to establish harmonised rules for processing and traceability, and to include third-party-certification in the conformity assessment procedure. Although the Commission can take inspiration of the JRC report on biodegradable waste subject to biodegradation of January 2014 to establish such criteria for compost and digestate, similar EU criteria should be developed in the future for other fertilising products deriving from waste.

In order to address their wide variety in composition and use patterns, plant biostimulants – unless they are currently exempted - such as microorganisms and certain plant extracts – and agronomic fertiliser additives would be subject to REACH registration. Microbial plant biostimulant will have to be recognised as safe and be listed in a table annexed to the proposal to be modified by a Commission delegated acts taking into account available scientific assessment such as the Qualified Presumption of Safety developed for clearing the safety of biological agents which are intentionally added at different stages into the food or the feed chain. No functionality or biostimulant effect may be claimed on the label without having been proven by the producers. Application of a plant biostimulant on a crop may not lead to residue exceeding the limit of quantification, in order to limit the risk of contamination of the food chain. If the actual level found on a given crop would be higher than this limit of quantification, maximum residue level shall be set at a level ensuring the appropriate protection of human health resulting from the consumption of the treated crops.

Table 47 in Annex III summarizes the type of regulatory option that is proposed for each category of products.

Maximum limit values for contaminants (the same as under option 2) for each product category would be defined in a future proposal. **Minimum quality criteria** would apply to each product category. **Labelling requirements** would apply to each product category in accordance with their specific characteristics.

Under a full harmonisation scenario, all national rules on fertilisers would need to be repealed and there would be no more need for recourse to mutual recognition as the new Regulation would apply to all kinds of fertilising products currently governed by national rules.

The safety criteria relating to fertilising products would be more easily adaptable to new scientific evidence or any modification to the list of priority substances in relevant environmental legislation.

A transitional period of maximum 3 years is envisaged. Products considered as safe will get a quick access to the market as they will follow the self-certification procedure. More risky products (i.e. products deriving from animal by-products or waste) will have to wait the designation of notified bodies by the competent authority.

More information on the content of the options is available in Annex VII.

6. ANALYSIS OF IMPACTS

6.1. Descriptions of impacts and their corresponding assessment criteria

Based on the main drivers and causal links identified in Section 3.4 and the EU over-arching policies on promoting the safety of products and the sustainable development of SMEs, the impacts of the possible options have been analysed. The merits of each option have been assessed with the help of assessment criteria. Annex VIII explains the methodology to set up these criteria and where relevant how they are linked to the policy objectives of this initiative.

Economic impacts

Criterion 1: do the policy options achieve a better level playing field for products? (Qualitative)

Criterion 2: do the policy options lead to administrative simplification? (Qualitative)

Criterion 3: do the policy options minimise administrative and compliance costs? (Quantitative)

Criterion 4: do the policy options support innovation by facilitating access to the market and by minimising the time to market new products? Could the option lead to significant trade impacts? Is the option compatible with WTO obligations? (Qualitative)

Social impacts

Criterion 5: can the options effectively contribute to the reduction of contaminant inputs to agricultural soil at EU level and hence decrease contaminant exposure of human beings via the food chain and drinking water? (Qualitative)

Criterion 6: can the options lead to the creation of jobs and economic growth? (Qualitative)

Environmental impacts

Criterion 7: can the various options foster significantly the recycling of nutrients and contribute to the circular economy? (Qualitative)

Criterion 8: can the options effectively contribute to the reduction of contaminant inputs to agricultural soil at EU level and hence improve soil function? (Qualitative)

Criterion 9: will the options ensure that farmers are correctly informed about the potential release of ammonia from different inorganic fertilisers in order to choose the optimal type of fertiliser and/or implement remediation measures? (Qualitative)

6.2. Option 1: no action

For the baseline scenario, the problems identified in Section 3 would persist and the objectives of this initiative would not be achieved. An internal market would only exist for part of the inorganic fertiliser market, which would not favour the emergence of alternatives to inorganic fertilisers deriving from waste. There would be no improvement in the safety of EC Fertilisers, and therefore no expected benefits for the environment and human health. Farmers would not be informed about the possible release of ammonia from urea-based fertilisers.

Producers of non-harmonised products would continue to suffer from the absence of a level playing field with the related compliance costs. Total annual costs for all stakeholders together are estimated at EUR 43-44 million. Of this amount, EUR 26 million are representing annual compliance costs for businesses (mainly stemming from the inclusion of new products in Member States positive lists) and more than EUR 17 million are linked to annual costs for EU and national authorities (mainly for managing the current regulatory system) (*see* comparison table in chapter 7 for an overview and explanations in Annex III for more details). The problems linked to the mutual recognition would continue, and increase over time as new types of products enter national markets. The fragmentation of the internal market, and the complexity of the regulatory environment, would not be conducive to innovation.

Stakeholders' opinion

The current situation is clearly no longer supported by Member States and industry except for two national inorganic fertiliser associations which fear a loss in market share if more domestic secondary raw materials are allowed in the production of CE-marked fertilising products. Producers of soil improvers, plant biostimulants, organic and organo-mineral fertilisers are requesting urgent harmonisation of the rules at EU level (*see* also results of SME test in Annex IV).

6.3. Option 2: creation of an internal market for fertilising products by listing individual product types

6.3.1. Economic impacts

6.3.1.1. Impact on the functioning of the EU fertiliser market and simplification potential

Criterion 1: contribution to the creation of a level playing field for products.

In case of full harmonisation, Option 2 would clearly improve the functioning of the internal market for all fertilising products not yet harmonised but only after a long transitional period due to the huge number of product types that would need to be listed in the Annex(es) of a future Regulation. There would be a transition cost for the products currently put on the market as national fertiliser that would need to be registered at EU level.

In the longer term, there would be no national rules on fertilisers anymore and the uncertainty concerning the procedures of mutual recognition would disappear. This would significantly reduce compliance costs for companies (*See* criterion 3 (e)).

If optional harmonisation is envisaged, option 2 would improve the functioning of the internal market for a broad range of fertilising products while allowing other products to remain on national markets. The uncertainty concerning the procedures of mutual recognition would not disappear as national rules would remain. However, compared to the current situation, the number of requests for mutual recognition would be expected to seriously decrease as harmonised legislation would be available to market products across the EU.

Criterion 2: does the policy option lead to administrative simplification?

The full harmonisation under Option 2 for a wide range of product categories would require constant efforts to adapt the annexes of a regulation to technical progress, which would put significant demand on resources in the Member States, the Commission (possibly also ECHA or EFSA) and industry itself. The current regulation contains around 100 product types. This could be easily tripled if the new regulation is extended to organic based fertilising products.

The lengthy adoption process of a new product type is due to the detailed nature of technical dossier required to demonstrate that the product type is safe and effective. This, combined with the decision making process including a qualified majority voting in the Regulatory Committee on fertilisers, rendered in many cases the current Annexes of the EU legislation difficult to implement. Option 2 would generalise those difficulties to all fertilising products including those which are currently present on national markets. This will create severe market disruption for these national fertilisers if no sufficiently long transition period is foreseen. This would also lead to administrative complication with regard to the mutual recognition of products in particular during this necessary long transition period where a co-existence of a European list of types with national products is unavoidable.

Optional harmonisation would reduce the number of requests to include new fertiliser types in the Annex(es) of a future Regulation. Small companies would still be allowed to market products for local needs without trade disruption. Optional harmonisation could therefore be considered as better achieving the objective of administrative simplification for industry in the short term. However, it would fail to achieve this objective for national public administration which will have to maintain national provisions in place.

6.3.1.2. Administrative costs

Compared to the baseline, many more type designations for fertilising products (*see* Annex III) would have to be listed in several annexes to a regulation, in particular for the categories of products falling outside the scope of the current Fertilisers Regulation. Several variants of this option have been analysed with different roles allocated to the public 'bodies' (e.g. public administration and EU agencies – ECHA or EFSA) involved in the risk assessment of newly harmonised fertilising products.

Variant 2A: only Member States and the Commission would review applications for listing types in the Annexes of a new regulation.

Variant 2B: the peer-review process for applications would be managed by the European Chemicals Agency (ECHA). An opinion would have to be delivered for each entry proposed.

Variant 2C: the peer-review process for applications would be managed by the European Food Safety Agency (EFSA). As for variant 2B, an opinion for each entry proposed would be required.

Criterion 3: contribution to the minimisation of administrative and compliance costs.

The list below shows the impacts on different types of costs:

(a) <u>Costs related to the governance of EU and national legislations</u>

In case of full harmonisation, the costs for the management of the Fertilisers Regulation would increase compared to Option 1**.** The members of the Fertilisers Committee would have to meet more frequently to adopt opinions based on the assessment of ECHA or EFSA. The selected agency would have to hire new staff to assess the requests for inclusion of types not yet covered by the Fertilisers Regulation. Under variant 2B, companies would be required to pay fees for the services delivered by ECHA (*see* Annex III for more information). Under variant 2C, EFSA would receive a payment from the Commission through an EU budget contribution.

The SMEs consultation reported that more than 80% of the responding SMEs are in favour of harmonisation. Although it is not possible to establish with any accuracy the precise part of the market for which producers would opt for EU rules and the part that would stay under national rules under optional harmonisation, it is assumed, for the purpose of this IAR, that the respondents are broadly representative and that they would use the same strategy for their entire range of products. With this in mind, it is assumed that 20% of the products would remain under national rules and that 80% would fall under EU rules.

If 20% of the current products remain on national markets under the optional harmonisation option, the costs of governance of national legislation would have to be increased accordingly whereas the costs of EU governance would have to be reduced proportionally compared to the full harmonisation scenario (See Annex III Section 3.6 for more details)

(b) Costs related to the placing on the market of new products and mutual recognition

Under the full harmonisation option, **industry** would have to resubmit applications for the registration of products that have been authorised for years under national laws. The costs for industry to prepare application dossier for types would be higher than the average today, as data requirements would result from the addition of national requirements in order to satisfy expectations of all Member States. More types to assess would also mean increased workload for **Member States** to conduct a first evaluation of dossiers submitted and then participate in the peer-review process organised by ECHA or EFSA. More explanations and assessment of the possible costs are available under Section 3 of Annex III.

As regards the costs of standardisation, the compliance of most existing products with regard to the safety and agronomic parameters of the future legislation could be controlled by means of existing EN Standards (conclusions of the stakeholders working groups established in 2012). For organic fertilisers, plant biostimulants and agronomic fertiliser additives, additional standardisation work is expected either to check the reliability of some existing test methods (in the case of organic fertilisers) or to develop new methods for the detection of active substances in plant biostimulants or agronomic fertiliser additives (*see* details in Annex III). The costs of mutual recognition would disappear.

Under optional harmonisation, products that have been registered under national laws would remain on the market without being obliged to comply with EU requirements. Less product types to assess at EU level would mean fewer registrations and standardisation costs for industry and Member States compared for full harmonisation (See Annex III Section 3.6). National fertilisers would be still subject to mutual recognition. However, it is assumed that, in the presence of harmonised legislation, the costs of mutual recognition would go down as producers interested in marketing their products across several Member States would more likely opt for getting EU approval.

(c) Market surveillance costs

Member States do not differentiate between EC and 'national' fertilisers during their market surveillance activities. Consequently, compared to option 1, the costs of market surveillance would not change under all variants of Option 2 (including the variants on full or optional harmonisation) as it is unlikely that activities of the Member State authorities would vary.

(d) Compliance costs

Compared to Option 1, full harmonisation of the safety, quality and labelling requirements would overall lead to a considerable reduction of the current compliance costs borne by industry[62]. Harmonisation would lead to a level playing field for all producers as they would no longer have to fulfil diverging legal requirements and criteria in different Member States. In 2012, Member State experts and industry representatives, as well as one NGO, agreed in the context of an expert group that limits on contaminants in fertilising products should be set for a range of contaminants already addressed by national fertiliser legislation. The contaminant contents should be set at a level that would both help Member States to meet

[62] Except for the current EC fertilisers which will have to comply with the costs of heavy metal determination. Cadmium is the most pertinent issue in this regard (See IAR on cadmium)

their environmental targets and reduce as much as possible the risks of non compliance for existing products. The limits proposed in Annex VI meet these conditions.

Each variant of options 2 to 5 would, however, introduce mechanisms for the reduction of compliance cost over time. For example, the costs reduction potential for monitoring the content of contaminants in compost compared to the first reference year could be estimated at up to EUR 1 650 per company and per year. The conditions that would justify a reduction of the frequency of controls have been described in the JRC EoW report and would consider:

1. The nature of the input materials preventing the presence of contaminants (or at least at a low acceptable level): *A priori* excluding sewage sludge and municipal waste from the input materials might reduce the likelihood of high levels of contaminants;
2. The volume of production: smaller capacity installations shall not be submitted to the same frequency of analytical testing compared to larger installations;
3. The fact that the producer can prove that during the recognition year the level of contaminants in the end-products was well below the regulatory limits (at 95% confidence level).

See Annex IV, Section 4 for information about other mitigation measures.

As regards urea based nitrogen fertilisers, producers would be required to inform farmers about the potential release of ammonia via labelling information. It is not expected that this information would lead to important additional compliance costs for producers.

Uniform labelling requirements for quality parameters under options 2 to 5 would help farmers and other users to choose the most effective and cost-efficient fertilising product for their crops. However it has not been possible to estimate what would be the costs savings for farmers of the improved transparency of the market.

Under optional harmonisation, companies wishing to access the entire EU market would benefit from the harmonisation while others would be able to continue to market products that could satisfy local demand. Optional harmonisation would have less disruptive effects on trade of existing products and therefore less compliance costs would be expected overall.

(e) <u>Summary of costs assessment under criterion 3</u>

For the full harmonisation, the total costs for authorities would be approximately EUR 21.5 million per year, i.e. which represents an increase by EUR 4.5 million per year compared to the baseline. *See* Table 1in Section 7.

The significant costs for managing national legislation and requests for mutual recognition of products would disappear. This would mean overall a considerable reduction in annual total compliance costs for businesses which would be reduced to approximately EUR 3-6 million, compared to EUR 26 million under the baseline, i.e. saving of about 75-90% of current costs.

Option 2 would lead to total costs for businesses and administration of EUR 25-28 million per year compared to approximately EUR 43 million under the baseline, i.e. a saving of roughly one third of current costs. More details are available under Section 3 of Annex III.

Option 2 would positively contribute to the reduction of administrative costs resulting from the diverging regulatory framework among the Member States. However the burden of listing all available fertilising product types in an annex would be considerable in particular for SMEs as explained below and would lead to an overly long transitional period.

In case of optional harmonisation, it was assumed that approximately 20% of the current fertilising products would remain on national markets (result of the SMEs consultation in Annex IV).

The total costs for authorities would be approximately EUR 20 million per year, i.e. which represents a cost reduction of about 1.5 million per year compared to the full harmonisation option (See Table 1). The costs associated with keeping national rules would be compensated by the reduction of costs related to the assessment of applications for the registration of all existing fertilising products in the Annex(es) of a future EU regulation and the costs related to the involvement of Member States in the CEN standardisation activities.

Optional harmonisation would also mean a reduction in annual total compliance costs for businesses which would be reduced to approximately EUR 0.5-1 million, compared to the full harmonisation option. This cost reduction accounts for the possibility to keep 20% of the existing products on national markets but does not address future requests for registration of products under national rules.

Option 2 would lead to total costs for businesses and administration of EUR 23-25 million per year compared to approximately EUR 25-28 million under the full harmonisation, i.e. a saving of roughly 10%. More details are available under Section 3 of Annex III.

6.3.1.3. Impact on competitiveness, innovation and international trade

All options in this IA would apply to products being put on the EU market, regardless whether they were manufactured in the EU or abroad.

Criterion 4: does the policy option support innovation by facilitating the access to the market and by minimising the time to market new products? Could the option lead to significant trade impact? Is the option compatible with WTO obligations? (Qualitative)

Under Option 2 and full harmonisation, producers and importers would face significant delays to get all types that they want to keep on the market included in the annex(es) to a new regulation. This would lead to market disruption for several products currently present on national markets as producers would have to get their products listed in the annex(es) to the Regulation in order to stay on the market. These efforts could also reduce their capacity to innovate at least in the short-term, as their efforts would concentrate on the authorisation of products already on the market. A similar reaction from industry has been observed under the Plant Protection Products[63] and Biocidal Products[64] Regulation where the resources needed to keep existing substances on the market via the respective review programmes took up resources which could otherwise have been spent on the development of more sustainable substances.

The lengthy procedure for the inclusion of fertiliser types in the Annex(es) of a future regulation could negatively discriminate against small inorganic fertiliser producers operating on the local market, but also against the organic fertilisers and soil improver producers. In particular the costs of registration of types for compost and digestate as organic or soil

[63] See impact assessment report supporting the proposal for a revision of the Plant Protection Products Directive 91/414/EEC HTTP://EC.EUROPA.EU/FOOD/PLANT/PLANT_PROTECTION_PRODUCTS/LEGISLATION/DOCS/REPORT_IMPACT_ASSESSMENT_2006_EN.PDF

[64] See impact assessment report supporting the proposal for a revision of the Biocidal Products Directive 98/8/EC at: HTTP://EUR-LEX.EUROPA.EU/LEGAL-CONTENT/EN/TXT/PDF/?URI=CELEX:52009SC0773&FROM=EN

improvers could be considerable, as the nutrient composition of such products is quite variable compared to inorganic fertiliser and depends on many parameters (such as the animal species, feed…). A change in the composition of a fertilising product type would trigger the need to revise the wording of the current type if the new product can no longer satisfy the existing requirements. Consequently, for certain products currently marketed under national legislation, companies would not be willing to apply for type listing in a future regulation, leading ultimately to reduced product choice for the users.

Furthermore, as the listing of types would not be linked to the specific companies having submitted an application dossier, those having borne the costs for compiling a dossier would later have to compete with other companies placing products on the market that fit within a listed type description without having themselves submitted a dossier (free riding), which could discourage innovation.

The lengthy procedure for the evaluation of applications for listing a new type could considerably slow down the innovation cycle of the industry, as noticed in recent requests introduced by companies under the current Fertilisers Regulation. Consequently, industry would be more reluctant to innovate as they would not be able to quickly obtain the required return on investment.

In addition, stringent limits on contaminants might disqualify certain raw materials that are currently used in the production of inorganic fertilisers, i.e. certain phosphate rocks or phosphate fertilisers might no longer be eligible for the EU market. A summary of the impact assessment regarding cadmium[65] in inorganic fertilisers is available in Section 5 of Annex VI. The limit values for the other contaminants are not expected to lead to any significant effect on trade as they are the results of in-depth consultations with Member States and are deemed to represent current best available practices.

Relative to the baseline, Option 2 would lead to transitional costs for manufacturers to get their products listed in the annexes of a future regulation. In particular small producers would have difficulties to prepare applications and get their product types included in an EU regulation in the short term. This would lead to a reduction of the availability of products if the transition to the new system is too short and therefore higher prices with negative consequences for the competitiveness of European farmers and less innovation in particular from small companies.

On the other hand, in the longer term harmonisation of the requirements for all products will facilitate trade (as no producer would face the uncertainties and costs related to mutual recognition and diverging national rules) and increase competition among producers in all Member States. In particular, trade in product categories that are not yet harmonised might increase considerably, e.g. compost producers exporting compost would no longer need to take part in different quality assurance schemes[66]. This would lead to increased recycling of nutrients from waste and hence lower demand for 'new nutrients' from chemical sources, thus putting downward pressure on inorganic fertiliser prices and allowing for mixing ‘new’ sources of nutrients with inorganic phosphate fertilisers, which can serve as an alternative or a complement to decadmiation technologies for the purpose of reducing the cadmium content in such products.

[65] The contaminant that could lead to disruptive effect on trade

[66] For example, Dutch compost producers are currently being asked to comply with the Dutch compost quality label (Keurcompost) and with the quality label in Germany (RAL-GZ 251) if they want to export to Germany.

Additionally, depending on the Member States or regions, the use of compost is regulated either by product, soil protection or waste legislation. Setting clear product criteria at EU level, which would qualify compost as product rather than waste, may avoid uncertainty with regard to investment decisions. The suppression of compliance costs due to waste legislation (Articles 12, 13 and 35 of the Waste Framework Directive) for the use[67] of compost and digestate would also be a factor to increase the farmer's demand for compost and digestate, leading to prices better reflecting their usefulness over the long term. In addition, small producers might be able to develop new products that fit into the type descriptions listed in annex(es) to a future Regulation, without themselves having to go through the costly listing process. The initially negative consequences for small producers described above could be further mitigated by sufficiently long transition periods, that would allow small producers to continue marketing their established products while they adapt product characteristics to new types being included in the annex(es) of a regulation.

Therefore, the initial drawbacks of Option 2 will turn into advantages in the long term, with more products of more diversified nature being traded throughout more Member States than today. This would lead to increased competition and pressure to innovate for producers, resulting in lower prices and wider choices of products which would increase competitiveness of the producers and of European farmers.

Optional harmonisation would have less negative impacts on the competitiveness and innovation of companies as less disruptive effects on trade can be expected compared to full harmonisation. National markets can also be considered by small producers as a place for testing new products before being introduced at EU level thereby allowing companies to progressively invest in more important installations.

6.3.2. Social impacts

Criterion 5: can the option effectively contribute to the reduction of contaminant inputs to agricultural soil at EU level and hence decrease contaminant exposure of human beings via the food chain and drinking water?

Full harmonisation under option 2 promotes harmonised limit values for contaminants in all fertilising products, and would thus lead to a reduction of the input of contaminants to agricultural soil, and ultimately to lower contaminant levels in food, with expected benefits for human health protection.

However, as explained in more detail in Annex VI, it is not possible with the current scientific knowledge, to derive risk-based limit values for contaminants in fertilising products that would ensure that the exposure of the general population via the food chain remains under a safe limit value.

In order to reduce dietary exposure of the population via the food chain, the largest beneficial effect is achieved by reducing the contribution of staple food (i.e. cereals, potatoes, vegetables), meaning by lowering the existing maximum levels for heavy metals in such commodities, which is directly influenced by the presence of such contaminants in agricultural inputs.

As these crops are largely consumed, a mere decrease of 10% of the tolerable limit for cadmium in staple food would help to reduce significantly the exposure of the population to

[67] Most of the costs due to the waste regime are due to environmental permitting and costs for e.g. land spreading or record keeping of the actual use on land.

cadmium. However, in 2011, a blocking minority of Member States opposed such reduction on the grounds that such a decrease would have excluded a large part of the annual production of cereals in some regions which would have led to important economic losses for farmers. Similar situations exist for lead.

In view of achieving the necessary reduction of consumer dietary exposure, legislation leading to a reduction of the heavy metals in fertilising products is therefore an effective step to achieve this goal.

In accordance with Article 114 TFEU, Member States enforcing tighter limit values than the values proposed in a future revised Fertilisers Regulation would be allowed to submit requests for maintaining them based on scientific justification. Given the potential health and environmental benefits, further harmonisation as recommended under Option 2 would promote market integration better than mutual recognition could.

Under variants 2B and 2C, ECHA or EFSA would assess the risks of new products types and the safety of products should therefore increase under these variants even though the time required to achieve these assessments for all product types would delay the expected safety improvements.

Farmers and other users would be more confident in products that are placed on the market, in particular those of waste origin, if harmonised limits for contaminants were put in place. Increased competition among a wider range of products will lead to lower prices in the long run and more possibilities to choose the most adequate product for a given user's need.

Compared to full harmonisation, optional harmonisation would not fully achieve the objective of increasing the safety of fertilising products in particular if national legislation imposes less stringent limit values for contaminants than a future revised Fertilisers Regulation (See Table 66 in Annex XI as example of divergence between the proposed EU limits and the existing national limits)

Criterion 6: can the option lead to the creation of jobs and economic growth?

Under the full harmonisation option, employment in the fertilising product sector might initially be negatively affected – in particular if small, locally operating producers do not manage to put dossiers together to list types in the annexes of a future regulation which correspond to their commercial products. However, over time they might adapt their production strategies to place on the market products that would fall under an existing type listing obtained by other (bigger) producers, which would then boost employment, as the free movement of fertilising products offers additional growth possibilities for small producers, thus boosting employment in the sector. Lastly, the need to prepare and evaluate a high number of dossiers for type listing could create some limited employment opportunities in companies applying for registration of new products as well as in the Member States authorities (for evaluating dossiers), and in the Commission or ECHA/EFSA, respectively.

If effective, optional harmonisation would allow a smoother transition to the new system than the full harmonisation option. As discussed above, compliance costs would be minimized and disruptive effects on innovation and production are less likely to occur under optional harmonisation hence leading to more opportunities for local development and job creation.

6.3.3. Environmental impacts

Criterion 7: can the option foster significantly the recycling of nutrients and contribute to the circular economy?

Option 2 would help to reach a more resource-efficient economy through the promotion of nutrient recycling from waste materials. A shift towards fertilising products production from domestic secondary raw materials would also reduce CO_2 emissions, hence contributing to the objective of the low carbon economy (See Annex VIII Section 3.1). Some Member States are already actively involved in the development of this sector, but due the current diverging national rules, such products are often locked into national markets.

Improved recycling of phosphorus would also reduce the reliance on imports of inorganic phosphate fertilisers. Today 92% of the EU consumption in phosphate originates from non-EU countries (Morocco, Russia, Tunisia). Plant nutrients contained in compost and/or digestate as well as in other secondary raw materials sourced from biomass can to some extent substitute inorganic fertilisers. In Germany, the substitution potential for phosphate is estimated at 28 000 tonnes[68] which corresponds to 10% of the phosphate imported as inorganic fertilisers. Currently only 4% of the nitrogen fertiliser placed on the market is deriving from domestic secondary raw materials. This amounts up to around 10% for phosphate and potash. In the mid term, the volume of recyclable nutrients could increase up to 7% for nitrogen and to around 30% for phosphate and potash (based on current data on available biomass excluding raw manure – COM estimation[69])

Although environment and health risks are associated with the production and use of compost and digestate[70], overall those industrial processes have environmental advantages over landfilling or incineration. The identified risks of production and use of compost are covered by the recommendations of the EoW JRC report on biodegradable waste. If compliance with those EoW criteria were required in a revised Fertilisers Regulation, only safe fertilising products derived from waste-streams would be placed on the market, which would increase consumer confidence and support the objective of nutrient recycling.

Optional harmonisation would not affect the objective of the circular economy. On the contrary, the existence of national markets could be seen as an opportunity for newcomers in the fertilising product market to test new nutrient recovery technologies at smaller scale.

Criterion 8: can the options effectively contribute to the reduction of contaminant inputs to agricultural soil and hence improve soil function at EU level?

Full harmonisation under option 2 would bring environmental benefits through a reduction of contaminant inputs into the environment. It would contribute positively to achieving the objectives of the Water Framework Directive and the EU legislation on contaminants in food.

The need for limit values on contaminants has to be considered in a wider context. If very stringent limit values are adopted, a great deal of compost and digestate that could be applied to the soil to improve its organic matter content would not reach the product status and would have to be discarded as waste in landfills or incinerators with the related environmental

68 43 000 tonnes of inorganic potassium fertiliser (9% of the German potash market) could also be theoretically replaced through the extensive reuse of source separated biodegradable materials. This is less clear for nitrogen as the nitrogen contained in organic matter is more mobile and can escape more easily to various environmental compartment (notably air) than phosphate and potash.

69 Consolidated data will be available in a near future via the DONUTSS project of the European Sustainable Platform for Phosphorus

70 Air and greenhouse emissions (CO_2, ammonia, N_2O, volatile organic compounds, bioaerosols), soil related effects (pollutants content). Plant permits address these issues for composting plants above a production capacity of 75 tonnes per day.

consequences. Therefore a trade-off has to be sought between long term protection of soils and the limit values that can be reasonably achieved by the sector.

As mentioned in section 1.3 and 6.3.1.3, the COM services consulted a broad range of experts in order to prepare this report. A Technical Working Group was responsible for the determination of appropriate contaminant limits in fertilising products with the objectives of helping Member States to meet their environmental targets. The sustainability of the EU industry was also ensured by taking into account the availability of existing mining resources and constraints with regard to trade obligations and external relations (See the IAR on cadmium). The findings of the draft JRC technical report[71] for EU End of Waste (EU EoW) criteria on biodegradable waste subject to biological treatment were also considered in the setting of agreed limits for contaminants in organic fertilisers and soil improvers.

All stakeholders have however called on the Commission to establish a mechanism in the legislative proposal under which the list and the maximum limit values could be revisited based on new scientific evidence or modifications to the list of priority substances in relevant EU environmental legislations. All stakeholders also agreed that risk-based limits are preferable in the longer term and encouraged the Commission to support an EU research programme for that purpose.

Optional harmonisation would not fully achieve this objective in particular if Member States enforce less stringent limit values for contaminants than a future EU Regulation.

Criterion 9: will the options ensure that farmers are correctly informed about the potential release of ammonia from different inorganic fertilisers in order to choose the optimal type of fertiliser and/or implement remediation measures?

Full harmonisation under option 2 could also contribute to improved air quality by providing the necessary information to farmers about the potential release of ammonia from the fertilisers they use so that they can take appropriate remediation measures. (*see* Annex VI for more details).

Compared to full harmonisation, optional harmonisation would only help to inform farmers of the potential release of ammonia from urea-based CE-marked fertilisers, while it would remain up to the Member States to decide whether similar requirements are included in national legislation on fertilisers.

6.3.4. Stakeholders' opinion

From the various consultations it emerges that some Member States could support either Options 2 or 3. They argue that listing of types or ingredients is an efficient way to ensure the safety of products, in particular for those derived from waste. All those Member States are well aware, that these options could be costly for them and would be time-consuming for reviewing and listing the product types or ingredients not yet harmonised. One Member State proposed a generic type designation similar to the registry of feed raw materials. This registry could be maintained by industry, which would allow flexibility and easy access to the market. This option was, however, not supported by other Member States supporting options 2 and 3, who want to continue to be informed about the origin of the products placed on the market via prescriptive measures.

[71] http://susproc.jrc.ec.europa.eu/activities/waste/

Other Member States noticed that broad types or ingredients have no benefit in terms of market surveillance, and the level of safety would not be improved compared to essential safety requirements to be fulfilled by commercial products.

From the industry point of view, supported by the SMEs survey (*see* Annex IV), it appears that a majority of companies would favour a more flexible approach as regard the marketing of fertilising products. However, some national inorganic fertiliser federations expressed their interest in maintaining the lists of authorised types at least for inorganic fertilisers currently covered by the Fertilisers Regulation. However they may not have fully considered the fact that these EC types are not covering national fertilising product types which would require a specific review and adaptation before they can be maintained on the market.

Optional harmonisation would satisfy part of the SMEs active in the sector and that are concerned by the introduction of EU rules on fertilising products while they are perfectly satisfied to serve only their local market.

6.4. Option 3: creation of an internal market for fertilising products by listing authorised ingredients

6.4.1. Economic impacts

6.4.1.1. Impact on the functioning of the EU fertilising product market and potential for simplification

Criterion 1: contribution to the creation of a level playing field for products?

If full harmonisation is envisaged, option 3 would clearly improve the functioning of the internal market for all fertilising products but the significant delay to get all the existing ingredients listed in the Annexe(es) of a future Regulation would be a serious limitation. Long transitional period would be required to ensure that all existing ingredients can be listed in the Annex(es) of a future revised regulation. There would be no national rules anymore and the uncertainty concerning the procedures of mutual recognition would disappear.

In a optional harmonisation scenario, option 3 would improve the functioning of the internal market for a broad range of fertilising products. Companies interested in the internal market would have a quicker access to it. Other manufactures would be allowed to keep their product on national markets without trade disruption. The uncertainty concerning the procedures of mutual recognition would not completely disappear as some products would remain on national markets. However, compared to option 1, requests for mutual recognition would considerably decrease as producers wishing to market their product across the EU would opt for the EU Regulation.

Criterion 2: does the policy option lead to administrative simplification?

In the full harmonisation option, the listing of authorised ingredients in the annexes of a future proposal would still require constant adaptation to technical progress, albeit less frequently than the updating of product types under Option 2. Once an ingredient is included in the list, it could be used in combinations with other authorised ingredients to produce fertilising products that would meet user needs. The regulatory framework would thus be simplified compared to Option 2 and the marketing of new formulations would be facilitated but only in the longer term.

Under optional harmonisation, Member States would maintain national rules for ingredients not receiving a broad support for intra EU trade (e.g. processed manure placed on the market under national rules). Compared to the full harmonisation, the availability of national rules would avoid the risks of market disruption and would therefore lead to administrative simplification for small producers active on local markets in the short term. For public administration, optional harmonisation would be less conducive to simplification as national rules would have to be maintained.

6.4.1.2. Administrative costs

As for Option 2, several variants have been analysed to describe the roles of public administration and different EU scientific agencies in the implementation of Option 3.

Variant 3A: only Member States administrations and the Commission review applications for listing types in the annexes of the revised Fertilisers Regulation.

Variant 3B: the peer-review process for applications will be managed by the European Chemicals Agency (ECHA). An opinion will have to be delivered for each new entry proposed.

Variant 3C: the peer-review process for applications will be managed by the European Food Safety Authority (EFSA). An opinion will have to be delivered for each new entry proposed.

Criterion 3: contribution to the minimisation of administrative and compliance costs

(a) Costs related to the governance of EU and national legislation

Under full harmonisation and for all variants of option 3, a certain level of simplification would occur as the same ingredients could be mixed to produce several product types which would normally require separate listing under Option 2. This means less staff required in the Commission and its agencies and fewer meetings of the Fertilisers Committee to review the candidate ingredients for inclusion in the annex(es) of the regulation. Section 3 of Annex III explains in detail how this would work for the different variants of the option.

Under the optional harmonisation scenario and similarly to option 2, the costs of management of national legislation would be maintained at 20% of the costs described under option 1.The costs of intervention of EU agencies would decrease by 20%.

(b) Costs related to the placing on the market of new ingredients and mutual recognition

As regards the costs relating to the placing of products containing ingredients not yet harmonised on the market, the reasoning developed under Option 2 would remain valid although fewer requests for inclusion would be expected. Under Option 3 only allowed ingredients would be listed (*see* Section 3 of Annex III for more explanations about the calculation).

The costs of standardisation would be similar to option 2. Costs for managing national legislation and requests for mutual recognition of products and their related costs would disappear. This consequently would lead to significant cost reductions for businesses. Annual compliance costs for businesses under Option 3 are estimated at EUR 1-2 million per annum compared to EUR 26 million per annum under the baseline. This is a saving of more than 90% of current compliance costs (*see* Annex III for more details).

Under optional harmonisation, less product types to assess at EU level would mean fewer registrations and standardisation costs for industry and Member States in particular for the ingredients already present on local markets. Costs of mutual recognition would remain void as it was assumed that in the presence of harmonised rules, products complying with national requirements would remain on national markets.

(c) Market surveillance costs

For both the optional and full harmonisation scenarios, it is assumed that the costs of market surveillance would not change under Option 3 compared to Option 1, as most Member States explained that they would not change their level of enforcement activities.

(d) Compliance costs

For Option 3, the same considerations as described under Option 2 would apply. The mitigation measures described under Option 2 regarding information obligations would also apply.

Under optional harmonisation, only companies wishing to access the entire EU market will benefit the reduction of compliance costs from the harmonisation while others may be satisfied with national markets. Optional harmonisation would have less disruptive effects on trade of existing ingredients and therefore, compared to the full harmonisation option, less compliance costs would be expected.

(e) Summary of cost assessment under criterion 3

Under full harmonisation, the total costs for administration would be considerably reduced to approximately EUR 13 million per year (i.e. a saving of more than EUR 4 million per annum compared to the baseline).

Option 3 would lead to total costs for businesses and administrations of EUR 15-16 million per year compared to approximately EUR 43 million under the baseline, i.e. a saving of more than half of current costs (*see* Annex III for more details and Section 7).

If optional harmonisation applies under option 3, the total costs for administration would slightly increase (i.e. around EUR 0.5 million) compared to the full harmonisation option. This means that the costs of keeping national legislation would not be compensated by the cost reduction of less involvement of Member States in the evaluation of application for the registration of new ingredients and the development of standards at EU level.

Optional harmonisation would slightly reduce the compliance costs for businesses (i.e. around EUR 0.2 to 0.3 million) in the short term as it was assumed that 20% of the existing products already registered at national level would remain covered by national rules.

Option 3 and optional harmonisation would lead to total costs for businesses and administrations of EUR 15-15.5 million per year compared to approximately EUR 15-16 million under full harmonisation, which is considered as insignificant change (*see* Annex III for more details and Section 7).

6.4.1.3. Impact on competitiveness, innovation and international trade

Criterion 4: does the policy option support innovation by facilitating the access to the market and by minimising the time to market new products? Could the option lead to significant trade impact? Is the option compatible with WTO obligations? (Qualitative)

Under Option 3 and full harmonisation, producers and importers would face significant delays to get all necessary ingredients included in annex(es) to a regulation, which could initially reduce their capacity to innovate. However, compared to Option 2 these delays would overall be shorter, as fewer ingredients would have to be listed compared to types, and a list of authorised ingredients would later help companies to manufacture tailor-made products that would best suit the needs of local agricultural production, without the need to request another listing in an annex to a regulation. This acceleration of the procedure would be beneficial for profitability and innovation in the longer term.

Any delay in the listing of these ingredients will constitute a loss in profit for both the producer of the ingredient and the producer of the fertilising products using it. This profit will vary and be dependent on the potential use of this particular ingredient but would initially be more detrimental for SMEs than for big companies as it is assumed that SMEs would have less time and resources to prepare registration dossiers. However, later on, SMEs would benefit from the listing of ingredients submitted by bigger companies unless the listed ingredients are protected through patents or trade secrets[72] .

Analysis of impacts on international trade of inorganic fertilisers is similar to Option 2 as option 3 would specify the same maximum limit values for contaminants.

As less disruptive effects on trade would occur under optional harmonisation, less negative impacts on competitiveness and innovation would be expected in the short term. National market could be considered by small producers or newcomers as a place to test new ingredients before envisaging an EU-wide marketing thereby allowing companies to progressively invest in new production facilities.

6.4.2. Social impacts

Criterion 5: can the option effectively contribute to the reduction of contaminant inputs to agricultural soil at EU level and hence decrease contaminant exposure of human beings via the food chain and drinking water?

Under the full harmonisation scenario, the same positive impacts on human health could be expected as for Option 2.

Under variants 3B and 3C, ECHA or EFSA would assess the risks of new ingredients. The safety of products should therefore increase under these variants even though the time required to achieve these assessments for all product types would delay the expected safety improvements.

Compared to full harmonisation, optional harmonisation would not fully achieve the objective of reducing the exposure of the general population to contaminants from fertilising products in particular if national legislation imposes less stringent limit values for contaminants than those at EU level.

Criterion 6: can the option lead to the creation of jobs and economic growth?

The same considerations as for Option 2 apply to expected impacts on employment. Optional harmonisation would have no disruptive effects compared to full harmonisation and therefore, no negative impacts on employment would be expected. Less demand for inclusion of ingredients in the Annex(es) a future regulation would also mean a quicker access to the EU market for producers of fertilising products sourced from domestic secondary raw materials who have genuine interest to access the entire EU market.

[72] Plant biostimulants are typically based on extracts of natural products so are generally not eligible for product patents although the manufacturing process may be patentable. However, in order to avoid the listing of commercial products, the description of approved ingredients will not contain any detail on the method of production so that the entry can be used to produce the same ingredient in a different manner.

6.4.3. *Environmental impacts*

Criterion 7: can the option foster significantly the recycling of nutrients and contribute to the circular economy? Criterion 8: can the options effectively contribute to the reduction of contaminant inputs to agricultural soil and hence improve soil function at EU level? Criterion 9: will the options ensure that farmers are correctly informed about the potential release of ammonia from different inorganic fertilisers in order to choose the optimal type of fertiliser and/or implement remediation measures?

The environmental impacts of the harmonisation via listing of ingredients would be similar to those described under Option 2.

Stakeholders' opinion

As under Option 2, a few Member States are supportive of this approach. They remain concerned by the fact that, without a positive list of authorised ingredients (or types under Option 2), dangerous chemical contaminants could be incorporated into fertilising products through dilution. Other Member States have however expressed concerns about the time needed to list authorised ingredients, especially if each ingredient has to be defined with a significant level of relevant details to allow its clear identification and a common Union-wide understanding.

Some parts of the industry (mainly inorganic fertiliser producers) remain attached to current national regulatory systems, which are often based on a list of ingredients or types, whereas a majority of SMEs active in the recycling of domestic sources of nutrients seek a flexible regulatory framework for the placing on the market of fertilising products, in line with the agricultural needs in various regions of Europe.

6.5. Option 4: creation of an internal market for fertilising products by using the New Legislative Framework

6.5.1. *Economic impacts*

6.5.1.1. Impact on the functioning of the EU market and potential for simplification

Criterion 1: contribution to the creation of a level playing field for products?

Both under the full or optional harmonisation option, option 4 would clearly improve the functioning of the internal market for all fertilising products by imposing generic legal requirements and not prescriptive information to reach the market. A shorter transitional period could be granted.

Under full harmonisation, national rules would no longer exist and the uncertainty concerning the procedures of mutual recognition would disappear.

Criterion 2: do the policy options lead to administrative simplification?

Full harmonisation under option 4 would be feasible and would constitute a significant simplification by allowing producers to demonstrate that their products comply with safety and quality criteria (e.g. the legal requirements) without being obliged to go through the process of listing new types/ingredients in annexes to a new regulation.

Under Option 4 producers would also be allowed to market a given material under different product categories without having to request the inclusion of this material into various type or ingredient lists. For example, compost could be used in the manufacture of organic fertiliser, soil improver or growing media provided that the end product fulfils the quality and safety requirements for these respective categories.

Compared to options 2 and 3, the Commission and the Member States would not need to meet frequently to discuss and adopt opinions on ECHA or EFSA assessments regarding the requests for the registration of new types or ingredients.

Under optional harmonisation, the maintenance of national rules would help small companies to continue to market products corresponding to local needs. Optional harmonisation would therefore lead to less administrative burden for industry whereas public administration would have to continue to manage both EU and national legislation.

6.5.1.2. Administrative costs

Criterion 3: contribution to the minimisation of administrative and compliance costs;

(a) Costs related to the governance of EU and national legislation

Under Option 4 and full harmonisation, there would be no more need for listing types or ingredients for fertilising products in annex(es) to a regulation, which would greatly reduce the need for meetings of competent authorities to agree on the peer-review of applications and to consider adaptations to technical progress of the annex(es) as proposed under Options 2 or 3.

As for options 2 and 3, optional harmonisation would not help to reduce the costs of management of the EU Regulation and organisation of meetings. Costs of maintaining national rules would be reintroduced at the level of 20% of the costs foreseen under option 1.

(b) Costs related to the placing on the market of new products and mutual recognition

For the full harmonisation, the costs for the preparation and assessment of new applications for listing types or ingredients in annex(es) to a future regulation would be replaced by the costs of product conformity assessment performed by companies themselves or by 'notified bodies' designated by Member States prior to the placing on the market[73] of products. The costs for industry to get their products certified and be allowed to affix the CE marking will strongly depend on the choice of the required conformity assessment module.

This would range from:

- Self-certification – Variant 4A – to various levels of third party certification:
- Verification by third party certification that the products comply with the essential safety criteria – Variant 4B;
- Verification by third party certification that the products comply with the essential safety criteria plus regular tests on specific aspects (e.g. contaminant content) – Variant 4C;
- Verification by third party certification that the products comply with the essential safety criteria plus product checks conducted at random intervals – Variant 4 D.

A clarification of the procedures related to each module is given in Section 3 of Annex III which contains detailed information on the approach followed to assess their respective costs.

[73] Guide to the implementation of directives based on the NLF and the Global Approach http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf.

In order to facilitate the comparison with other options, one-off costs (fees to be paid for compliance check of all products under variants 4B, 4C and 4D) and recurrent costs (costs for additional tests under variants 4C and 4D) have been distributed over the whole commercial life of products which, according to industry, has been assumed to be 20 years.

Compared to Options 2 or 3, the costs for standardisation under Option 4 would increase as new harmonised EN standards would be required to facilitate examination of commercialised products and to turn existing EN Standards into harmonised EN standards[74]. Compared to Option 2, an additional annual budget for standardisation of EUR 200 000 during 20 years was assumed to be necessary to support the development of these new standards.

Costs for managing requests for mutual recognition of products would disappear.

Under optional harmonisation, less product types to be assessed by notified bodies at EU level would mean fewer costs of product conformity assessment and standardisation for industry. The costs of mutual recognition would remain void as, in the presence of harmonised rules, this regulatory approach would not be used to market fertilising products in other Member States.

(c) Market surveillance costs

It is assumed that the costs of market surveillance would be slightly reduced[75] under variants 4B to 4D as products would have to be controlled by notified bodies before they are first placed on the market. This means that for Option 4A no change is expected, whilst for the other options, competent authorities could decide to reduce their market surveillance activities. For example, a 10% reduction is foreseen compared to Option 1 for variant 4B. For variants 4C and 4D a further decrease of 10% and 20% compared to option 1 is assumed as supervised controls would be performed by third parties at regular intervals under these options.

(d) Compliance costs

The overall cumulative impact on compliance costs for the industry is expected to be chiefly driven by the costs of quality assurance and regular testing under variant 4C or 4D. Examples of such cost are provided in Table 44 of Annex III and Table 56 of Anne IV respectively and would range between EUR 6 and 0.12/ ton of product[76]. These costs would create additional costs for SMEs. For example, annex IV Section 4.1 shows that these costs might not be very significant in relative terms for large scale compost and digestate production (lowest end of the cost range mentioned before), but may represent more than 15 % of total costs in the case of very small-scale production plants (top end of the costs range mentioned above).

These costs may be compensated, at least partly, by increased revenues through higher prices in fertilising products sourced from domestic materials if users accept that there is a

74 Harmonised standards are European Standards to which Regulation (EU) No 1025/2012 and sectorial Union harmonisation give a special meaning. The differences between European Standards (EN) and harmonised EN Standards essentially relate to the degree of obligation on the part of national standardisation bodies. Harmonised EN Standards must be implemented at national level and conflicting national standards must be withdrawn.

75 During a survey carried out in April-May 2013 on fertiliser market surveillance costs in the Member States, the Commission asked whether national authorities would agree to reduce their market surveillance costs if a pre-market control is performed by notified bodies. 10% supported this idea whereas 30% responded negatively. 60% did not answer the questionnaire.

76 From the figures mentioned in annex I, between 80 Mio and 100 Mio tons of fertilising products are marketed in the EU each year.

sufficiently high benefit to them in terms of avoided compliance costs (which otherwise occur when for example compost is considered as waste) and better and more reliable product quality.

Optional harmonisation would have less disruptive effects on trade of existing products and therefore less compliance costs would generally be expected for the benefits of small companies mainly active on local markets. For example, under optional harmonisation, compost or digestate falling in the scope of the EU EoW criteria but not meeting all its provisions would be allowed to stay on the market under national rules.

(e) Summary of cost assessment under criterion 3

In the full harmonisation scenario, total costs for administration would be reduced to EUR 8-11 million per year, which is a cost saving of EUR 6-9 million p.a. compared to the baseline. The annual compliance costs for companies vary from EUR 0.6 million (if self-certification of all products is possible) up to EUR 54-310 million per year (if certification is required for all products placed on the market). Product certification for each fertilising product would thus lead to significantly higher compliance costs than the baseline (*see* Table 1 in Section 7 and Section 3 of Annex III for more details).

From the above, it can be concluded that Option 4A has the highest potential to lead to significant administrative costs reduction. Under variants 4B, 4C or 4D, certification by third parties could be very burdensome for individual companies currently benefitting from a type approval or operating in a country without any authorisation or registration scheme

Under optional harmonisation, total costs for administration would slightly increase by around EUR 0.5 million compared to full harmonisation which is insignificant. The annual compliance costs for companies would decrease by 20% compared to the full harmonisation option. Optional harmonisation would have the advantage of leaving operators a maximum of flexibility to put new products on the market.

6.5.1.3. Impacts on competitiveness, innovation and international trade

Criterion 4: do the policy options support innovation by facilitating the access to the market and by minimising the time to market new products? Could the option lead to significant trade impact? Is the option compatible with WTO obligations? (Qualitative)

Under Option 4 and full harmonisation, delays related to the listing of types or ingredients in annex(es) to the regulation would disappear, but the administrative burden would significantly increase for manufacturers if every single product were to be certified by a notified body. In comparison, variant 4A would be less burdensome for industry than variants 4B, 4C and 4D. However, the figures have to be considered with care, as they are biased by the huge number of commercial growing media present on the market, which significantly affects the costs for industry. Variants 4B, 4C or 4D could however be made mandatory for products potentially presenting increased level of risks, e.g. those derived from waste streams.

The flexibility for marketing products introduced by the NLF under variant 4A would greatly benefit industry, as the 'time to market' would be much shorter. The profitability of producers would increase, allowing more investments in innovation and an increase in competitiveness. Farmers and end-users would benefit more rapidly than under Options 2 or 3 from a larger choice of products at competitive prices.

However, self-certification is not considered sufficient to guarantee the safety of products derived from waste. As a matter of fact, compliance with the criteria suggested in the JRC

EoW report would require third party certification at regular interval (equivalent to variant 4C) in order to ensure the safety of products.

The broader offer of products from the reuse of organic materials could help EU farmers to slightly decrease their reliance on inorganic fertilisers. According to Rosemarin et al.[77], more than 35% of the phosphate fertiliser imports could theoretically be replaced by recycled phosphate from EU urban waste water treatment only. Today, this volume ends up in landfills, cement, ashes of power plants and waste incinerators.

Overall, if certification were needed at each product level, compliance costs would considerably increase compared to the baseline, harming the competitiveness of businesses and farmers.

The analysis of impacts on international trade of inorganic fertilisers is similar to Option 2, as option 4 would specify the same maximum limit values for contaminants.

Under optional harmonisation, existing fertilising products sourced from domestic raw materials would be allowed to stay on national markets. Optional harmonisation would again have less disruptive effects on trade than full harmonisation.

6.5.2. Social impacts

Criterion 5: can the options effectively contribute to the reduction of contaminant inputs to agricultural soil at EU level and hence decrease contaminant exposure of human beings via the food chain and drinking water?

As harmonised limit values for contaminants would apply for all products, variants 4A to 4C would effectively achieve this objective. Variant 4D would foresee regular controls of products and would therefore ensure an even higher degree of safety of products compared to options 4A to 4C.

Optional harmonisation would not be fully effective in reducing the exposure of the general population to contaminants in fertilising products. This could only be achieved if Member States adopt the limit values laid down in a revised Fertilisers Regulation.

Criterion 6: can the option lead to the creation of jobs and economic growth?

Under variant 4A and full harmonisation, the removal of unnecessary regulatory obstacles would benefit industry's competitiveness and innovation capacity. Companies would be able to speed up the return on their investments for new products as the time to market new products would disappear for all variants of option 4. The flexibility of the regulatory framework could also facilitate access to the market for SMEs, in particular for new products such as plant biostimulants, and hence increase growth and job creation.

The transition to the NLF could lead to some job creation in notified bodies where third party certification is required.

A optional harmonisation approach would benefit small operators who could avoid the costs of third party certification if the marketing conditions for their products are more favourable in their country.

[77] Future supply of phosphorus in agriculture and the need to maximise efficiency of use and reuse. International Fertiliser Society, 2011

6.5.3. *Environmental impacts*

Criterion 7: can the option foster significantly the recycling of nutrients and contribute to the circular economy?
Criterion 8: can the options effectively contribute to the reduction of contaminant inputs to agricultural soil and hence improve soil function at EU level?
Criterion 9: will the options ensure that farmers are correctly informed about the potential release of ammonia from different inorganic fertilisers in order to choose the optimal type of fertiliser and/or implement remediation measures?

The application of EU EoW criteria for input materials would offer some benefits in terms of inorganic fertiliser substitution (e.g. making the EU less dependent on imported resources), improved carbon balance and soil improvement. These benefits are not easily quantifiable, and only a few MSs have tried to assess them. For example in the UK it has been estimated that around EUR 10 million have been saved by adopting a quality assurance scheme similar to the JRC EoW over a period of 10 years (*Source*: the JRC EoW report).

Many organic fertilisers and organic soil improvers derive from bio-wastes. As opposed to mined fertilisers, the nature of potential contaminants in products sourced from waste cannot be easily predicted, which creates problems of market acceptance. It is therefore necessary to lay down essential legal requirements not only for the composition (including contaminants) of the end-product, but also – as a means of excluding potential contaminants – for the origin and treatment of the input-materials. For the purpose of establishing the necessary trust and confidence in such products, it is therefore also necessary to establish harmonised rules for processing and traceability, and to include third-party-certification in the conformity assessment procedure. Although the Commission can take inspiration of the JRC report on biodegradable waste subject to biodegradation of January 2014 to establish such criteria for compost and digestate, similar EU criteria should be developed in the future for other products deriving from waste. In the meantime national measures establishing end of waste criteria could continue to apply until similar EU conditions are defined in an annex of a future proposal.

Optional harmonisation would not fully meet the objectives of reducing soil inputs of contaminants from fertilising products and informing farmers about the potential emissions of ammonia from urea-based fertilisers if equivalent limit values or information are not included in national legislation – which is rarely the case today for contaminants limit values (See Table 67 in Annex XI).

6.5.4. *Stakeholders' opinion*

Several concerns were expressed by seven Member States on the applicability of the New Approach legislative format to fertilising products. In this regard, the role of CEN in the development of standards was seen as a major issue, and a few Member States considered that CEN mainly defends the interests of industry and that the work of CEN would be biased on issues regarding the protection of human health and the environment. Furthermore, it was argued that SMEs could be disadvantaged as participation in standard development was a very time-intensive activity for small businesses.

However, it is noted that European standardisation is organised by and for the stakeholders concerned based on national representation, and is founded on the principles recognised by the World Trade Organisation (WTO) in the field of standardisation, namely coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency. In accordance with the founding principles, it is important that all relevant interested parties, including public authorities and small and medium-sized enterprises (SMEs), are appropriately involved in the national and European standardisation process. National standardisation bodies and CEN encourage and facilitate the participation of stakeholders via the new Regulation (EC) No 1025/2012 on standardisation.

Moreover, three Member States and CEN expressed concerns about the availability of human resources for the development of harmonised standards regardless of the commitment of the Commission to support financially the development of any standardisation work necessary to verify the compliance of products. Several stakeholders also voiced concern that the development of such standards would take the same amount of time as listing ingredients or types in annex(es) to a regulation.

In response to this concern, it is noted that a lot of EN and international test methods applicable to products covered by the future legislation have already been developed on a voluntary basis by industry, but are unfortunately enforced by a few Member States only. The future standardisation work would mainly consist in transforming these available EN standards into harmonised EN standards, and in removing any conflicting national standards. Contractually CEN is required to develop harmonised standards within 36 months.

Harmonised EN standards are helpful for facilitating the process for demonstrating compliance, so the costs for developing them might be offset by faster and less costly certification procedures, such as in variant 4C. Issues regarding safety of products would be set out in essential safety requirements, and not in standards. Essential safety and quality requirements would be kept to a minimum in order to reduce as far as possible the costs for companies of purchasing new harmonised standards (around EUR 100/ standard).

6.6. Option 5: creation of an internal market for fertilising products by adopting different variants of options 4

6.6.1. Economic data

6.6.1.1. Impacts on the functioning of the EU market and potential for simplification

Criterion 1: contribution to the creation of a level playing field for products?

The conclusions under Option 4 would apply, i.e. clear improvement of the functioning of the market and simplification for the products categories following the self-certification procedure. Products subject to third party certification would be disadvantaged as compliance costs would be higher than under self-certification. Optional harmonisation would help to reduce such costs when similar but less costly procedures are already enforced at national level.

Criterion 2: do the policy options lead to administrative simplification?

The implementation of conformity assessment procedures proportionate to the safety profiles of products would simplify the regulatory framework.

The development of legal requirements for plant biostimulants and agronomic fertiliser additives would be challenging but not impossible according to industry.

Developing harmonised standards to provide presumption of conformity with the legal requirements would take time even if most of technical methods are already available. In order to reduce as much as possible the transition to the new system, coordination groups among the Member States representatives would be mandated to issue guidance on how to interpret the legal requirements and demonstrate conformity.

6.6.1.2. Administrative costs

Criterion 3: contribution to the minimisation of administrative and compliance costs.

(a) Costs related to the governance of EU and national legislations

Under Option 5, all product categories would follow the NLF. This would mean less Commission staff time to manage the legislation, and less meetings of the Regulatory Committee. Agencies would not be consulted for peer-review.

(b) Costs related to the placing on the market of new products and mutual recognition

Different policy regimes would be combined to ensure that the products with the highest potential for adverse effects would be subject to the most stringent regulatory oversight. In the light of the assessment of the various options – and the higher number of ingredients or types of fertilising products, various variants of Option 4 would be selected. In fact, consultations with Member States have shown that systematic third party verification would be considered excessive and disproportionate and should, therefore, be limited to fertilising products with higher risk profiles, in particular materials containing ingredients deriving from waste recycling activities, which may therefore contain dangerous contaminants.

While industry already developed voluntarily EN test methods for fertilising products, most of the Member States still use national or even regional analytical methods. Under its standardisation action grant commitment, the Commission could foresee a budget to ensure that existing validated EN test methods are turned into equivalent harmonised EN standards, which could be used to verify the compliance of products to the legal requirements of a future regulation. For plant biostimulants and agronomic additives, as no voluntarily EN test methods have been developed so far for such products, the development of harmonised standards would be required (*See* details in Section 3 of Annex III)

Costs for managing national legislations and requests for mutual recognition of products would disappear under the full harmonisation option.

The variant of optional harmonisation would have the advantage of affecting only economic operators with a genuine interest in getting access to the market in several Member States, in line with the principles of subsidiarity and better regulation.

(c) Costs for market surveillance

Similarly to Option 4, the costs of market surveillance would be slightly reduced by 10% compared to the baseline, as the most sensitive products in terms of variable composition would have be controlled by notified bodies before they are placed on the market.

(d) Compliance costs

Third party involvement in the assessment of conformity with the legal requirements would vary between fertilising product categories, and would be highest for waste and other secondary materials with potentially variable composition. Therefore the costs of third party certification would overall decrease compared to a full application of options 4C and 4D across the board.

According to the competitiveness proofing study, between 39% and 52% of the European compost and digestate producers already operate under an external certification scheme[78]. Nonetheless, under full harmonisation, the costs of third party certification could be significant, in particular where the existing national quality certification would have to be upgraded to comply with the new EU rules (mainly costs of complying with harmonised EN Standards).In such case, optional harmonisation would benefit economic operators who would be allowed to continue to market products responding to local market needs in accordance with national requirements.

Other compliance costs and their reduction potential would be equivalent to Options 2 to 4.

(e) Summary of costs assessment under criterion 3

This option would allow reducing costs for administrations considerably, namely to approximately EUR 10 million per year compared to EUR 17 million in the baseline, i.e. savings of more than EUR 7 million per year.

The costs for industry to place new products on the market tailored to their expected risks to the environment are estimated to be around EUR 9 million per year, which is a considerable reduction compared to the baseline (more than 65% savings) (*see* Section 3 of Annex III for details).

Option 5 would improve the business environment by simplifying and harmonising the procedures for placing products on the market and reducing administrative burden and costs, while adapting the procedures and/or constraints to the level of risks or uncertainties from materials either due to potential safety concerns due their variable composition or proximity with plant protection products (e.g. plant biostimulants) or due to the origin of their components (e.g. waste-derived fertilising products).

Under optional harmonisation, total costs for administration would slightly increase by around EUR 0.5 million compared to full harmonisation which is insignificant. The annual compliance costs for companies would decrease by 20% compared to the full harmonisation option.

6.6.1.3. Impacts on competitiveness, innovation and international trade

Criterion 4: do the policy options support innovation by facilitating the access to the market and by minimising the time to market new products? Could the option lead to significant trade impact? Is the option compatible with WTO obligations? (Qualitative)

For all product categories falling under variant 4A (most of the inorganic fertilisers, liming materials and growing media), the same considerations apply as described in the analysis of Option 4A, i.e. competitiveness and innovation capacity of the producers of the materials concerned should improve in the short term, favouring the entry of new actors, wider choices and consequently lower prices, which in turn should be beneficial for the competitiveness of European farmers.

For organic fertilisers and soil improvers deriving from waste, third party certification (costs of quality assurance and regular testing) under variant 4C may create additional costs for SMEs as described in Section 7.5.1.2.d. Mitigations measures are proposed in Annex IV to reduce such compliance costs. For example the minimum frequency of controls should be 4 in the first year (one sample every season) unless the plant treats less than 3 000 tonnes of input

78 http://ec.europa.eu/enterprise/sectors/chemicals/files/fertilizers/fx98655-final-report_en.pdf.

material. In that case, one sample every 1 000 tonnes of input material rounded to the next integer would be required.

According to the JRC EoW report, where quality certified compost or digestate is used today under waste regulatory controls, future end-of-waste criteria are likely to lead to a net cost reduction. The cost reductions accrue in the use sector, and may possibly be transferred back to some extent, through the acceptance of increased compost and digestate prices, to compost and digestate producers, and through reduced gate fees to municipalities or other relevant waste generators.

Analysis of impacts on international trade of inorganic fertilisers is similar to Option 2, as option 5 will specify the same maximum limit values for contaminants.

As for options 2 to 4, optional harmonisation would have the advantage of keeping more technologically advanced products on the market in particular plant biostimulants and products deriving from waste that meet national EoW criteria.

6.6.2. Social impacts

Criterion 5: can the options effectively contribute to the reduction of contaminant inputs to agricultural soil at EU level and hence decrease contaminant exposure of human beings via the food chain and drinking water?

Criterion 6: can the option lead to the creation of jobs and economic growth?

The social impacts would be similar to those described under Option 4 for the product categories that would be regulated under the various variants of Option 4.

According to the Baltic Sea Action Group, provided that all nitrogen (N) and phosphorus (P) contained in biomass and waste streams are recycled into valuable fertilising products, the annual economic value[79] of P would be 4.2 billion EUR and that of N around 11 billion EUR. Thus, nutrient contained in domestic waste and biomass should not be considered as 'waste' but also as commercially valuable plant nutrient sources. Similarly, the European Sustainable Phosphorus Platform (ESPP) estimates that full implementation of the current technologies to recover phosphorus from biomass and improvements in the coherence and implementation of union environmental legislation could create 66 000 non de-localisable jobs.

Option 5 would support such investment by providing a flexible and coherent approach to access the market without compromising on safety of products.

Compared to full harmonisation, optional harmonisation would offer a more flexible environment for the development of emerging fertilising products sourced from domestic secondary raw materials. Producers of such products would be allowed to gradually invest in new production techniques to produce CE marked fertilisers.

6.6.3. Environmental impacts

Criterion 7: can the option foster significantly the recycling of nutrients and contribute to the circular economy?

Criterion 8: can the options effectively contribute to the reduction of contaminant inputs to agricultural soil and hence improve soil function at EU level?

[79] Based on Finnish fertiliser prices

Criterion 9: will the options ensure that farmers are correctly informed about the potential release of ammonia from different inorganic fertilisers in order to choose the optimal type of fertiliser and/or implement remediation measures?

The Communication "Towards the Circular Economy" and the related legislative proposal on the revision to the waste directive establish very **ambitious targets for recycling**[80]. This means that more domestic secondary raw materials are likely to be available in a near future which calls for the use of a flexible regulatory framework that could be operational when these targets enter into force.

As mentioned under 7.3.3, a first estimation of the replacement potential of inorganic fertiliser shows that around 30% of the mined inorganic fertiliser could be substituted by organic fertilisers deriving from domestic secondary raw materials. However a transition to a more circular economy for fertilising products would only be possible if key regulatory elements are not obstructing more sustainable solutions and market creation for nutrient recycling. Interdisciplinary cooperation and efficient communication between stakeholders (fertiliser industry, waste holders, public administration, farmers, agronomists, and economists) would also be key to get a holistic picture of the complicated area of plant nutrition. Tackling all these challenges would create new businesses opportunities for competitive clean technologies.

More fertilising products deriving from recycling of biomass would also mean less GHG emissions generated during production. According to the European Compost Network, emissions generated during composting contribute for 0.01 to 0.06% to the total national GHG inventories for the EU. The inorganic fertiliser industry counts for 0.5% of such emissions. Diverting more bio-waste from landfills would have also the advantage of reducing the amount of GHG emitted during landfilling.

The use of conventional plastic mulch films creates after 15 years of use, severe environmental and economic risks due to the release of micro plastic particles in the environment. The open burning of such films is also a source of toxic substances released in the environment. The CE mark should therefore be limited to fully biodegradable plastic mulch films.

The combination of limit values for contaminants (as for options 2 and 4) and third party certification before products are placed on the market would reinforce the safety of products in particular for those deriving from waste.

Option 5 could also contribute to improved air quality by providing the necessary information to farmers about the potential release of ammonia from the fertilisers they use.

6.6.4. Stakeholders' opinion

The comments made under Option 4 remain valid as Option 5 would follow this regulatory Approach in particular as regards the role of CEN and the costs of standardisation (See stakeholders' opinion on option 4).

[80] Increase recycling/re-use of municipal waste to 70% in 2030 and phase out landfilling by 2025 for recyclable waste (including plastics, paper, metals, glass, wood and bio-waste) in non-hazardous waste landfills – corresponding to a maximum landfilling rate of 25%.

Some industry representatives expressed concerns that under the NLF, the information included in the authorised type of ingredients or products would be lost. The NLF defines generic criteria applying across the board whereas lists provide technical details on ingredients or products such as the method of production and specific quality criteria. The inorganic fertiliser industry is particularly interested in keeping this information available to farmers. According to the industry, this is the only way to keep efficient products on the market. This could be solved by a guidance document to be developed by industry listing ingredients or products that meet the legal requirements of a future legislation. A statement on the label could refer to this voluntary standard.

Some Member States expressed concerns about the costs of regular testing in particular for SMEs active in the production of compost and digestate. Those costs could be mitigated by the reduction of the frequency of controls according to the volume of production and the reduction of the number of external samplings after the recognition year (see Annex IV Section 4 for more details).

Some Member States also explained that the system of certification by third parties could be expensive for micro entities applying national end of waste criteria for which such requirement does not exist. A substantial transitional period could be granted to allow producers to adapt to the new rules. If optional harmonisation is effective, national End of Waste criteria would continue to apply.

Although a full harmonisation via the NLF has been found unrealistic (i.e. the costs of third party certification would be disproportionately high if applied without distinction to all fertilising products), there is much broader consensus on option 5 to address safety and quality issues without entailing disproportionate costs for industry or unduly delay the placing on the market of new products.

7. COMPARING THE OPTIONS

The comparison of the various policy options has been conducted taking into account the criteria of:

- Effectiveness:

  Each option has been given a score relating to its ability to achieve the operational objectives (removal of trade barriers, improvement of safety, simplification potential, support to innovation and harmonised labelling);

- Efficiency:

  The costs for the implementation of the policy options have been compared with their effectiveness in reaching the policy objectives;

- Coherence:

  Each option has been given a score relating to its complementarity and compatibility with other EU objectives (Air policy review, Resource Efficient Europe initiative, the Nitrate Directive…).

Table 1 compiles the information for each option and variant.

Qualitative assessment

The columns on effectiveness and coherence in Table 1 provide a qualitative analysis of the arguments developed in Section 6 in order to facilitate comparison and to identify trade-offs.

The options have been assessed as being 'strongly negative (--)', 'negative (-)', 'neutral (=), positive (+) and strongly positive (++) compared to the baseline scenario (**Option 1**).

Under the full harmonisation scenario, options 2 to 5 would reach the same level of effectiveness (**albeit not at the same pace**) in achieving the objectives of removing trade barriers and harmonised labelling as they would complete the harmonisation of the EU market for fertilising products.

The various options differ in their capacity to meet the objectives of safety improvement, simplification potential and support to innovation in the circular economy.

Under optional harmonisation, options 2 to 5 would equally fail to fully achieve the objectives of removing trade barriers and harmonised labelling. According to the outcomes of the SMEs consultation, 20% of the current market would remain national. Over the longer term, national markets would shrink if more and more products/ingredients are covered by the EU scheme.

Under full harmonisation**, the different variants of Option 2** (list of authorised types) have the potential to be effective in improving the safety of products compared to the baseline. In particular variants 2B and 2C (examination by European agencies of application dossiers for the listing of new fertiliser types) would be highly effective. However, producers – other than the first applicant for the inclusion of a new fertiliser type – could self-declare that their product complies with an existing entry of the tables listing the authorised fertiliser type without having to demonstrate compliance with the data submitted to register the original product. The compliance of their product could only be checked by post-market controls after the product is already on the market.

Option 2 would not be conducive to innovation. Companies applying for the registration of a new type would face a first mover disadvantage trying to get existing product types registered as other companies would have the possibility to use these new product types afterwards to place their own products on the market without bearing the same costs. Pioneering products based on extracts or recovery of natural products are generally not eligible for product patents. Companies would be therefore reluctant to request the inclusion of such product types in an Annex of a future Regulation.

Option 2 would not lead to administrative simplification as in light of the experience with the current Regulation, it would be extremely time consuming for industry to have all existing national product types included on a case-by-case basis in the annexes of a future regulation. In addition, the burden of such type listing upon SMEs only manufacturing specialities for the local market would be disproportionate. Consequently, some existing products could be removed from the market (market disruption) due to the burden generated by the obligation for type listing. Companies would mainly spend time and money getting their products on the EU list, although these would have already been recognised at national level. Simplification effects would only be observed once all existing national types had been listed. Option 2 is therefore considered as meeting the objective of simplification in the long term only.

Optional harmonisation would be less effective in reaching the objectives of safety of products but would better support innovation and administrative simplification as the risks of market disruption would be minimised in the short term.

Under full harmonisation, **the different variants of Option 3** (lists of authorised ingredients) would also improve the situation as regards the safety of products, in particular under variants

3B and 3C for which opinions of EU agencies on applications of registration of new ingredients would be required. However, as for Option 2, producers – other than the first applicant for the inclusion of a new ingredient – using approved ingredient(s) listed in the annexes of a future regulation would not be obliged to demonstrate the conformity of their own ingredients with the requirements of the registered ingredient(s). Compliance of their products could be checked by post-market controls only.

Support to innovation is stronger than under Option 2. Ingredient manufacturers would have an incentive to register at EU level to make their ingredients more widely available to manufacturers of fertilising products across the EU.

Compared to Option 2, Option 3 would be more conducive to simplification for public administration and industry, as there are obviously less ingredients than possible product types. Listing authorised ingredients compared to listing product types in the annexes of a future regulation would require less work, and as a result the time to market new commercial products would be reduced. However, listing all authorised ingredients present on the EU market would still take a considerable effort. The regulatory Committee would still have to discuss and agree on common definitions for each ingredient, which would be consuming time and resources. Therefore the variants of Option 3 would not lead to simplification at least in the mid-term and could also lead to market disruption for fertilising products present on the national markets.

Optional harmonisation would better support innovation (less investment risks at the early stage of the marketing of the fertilising ingredients) and would lead to administrative simplification at least for industry. However, optional harmonisation would not fully achieve the objectives of safety of products.

Under full harmonisation, **variant 4A** (New Approach – self certification) would be very effective in achieving most of the operational objectives in particular regarding simplification and innovation potential. The safety of products would be significantly improved compared to the baseline, as conformity would be required with the Regulation's essential safety requirements, which would include limits for hazardous contaminants such as cadmium. However, there would be no pre-marketing compliance control by third parties. In particular products derived from waste streams may need to be controlled more intensively, as regards their conformity to the safety legal requirements, before they are placed on the market.

The other variants of Option 4 (different modules for third party certification for all fertilising products) would not lead to simplification, in particular if each product had to be certified individually. The associated costs would be likely to undermine innovation. This issue could be addressed through the certification of product families rather than of individual products (See point 3.4 of Annex IV).

The safety of products would increase progressively from variants 4B to 4D as products would be certified and increasingly controlled by third parties before being placed on the market.

Although option 4 would bring the most radical change to the fertiliser legislation, and hence to the existing national procedures, some of the critical statements expressed by some Member States' experts in preliminary consultations are based on misunderstandings. For example, it was not clear to all that Member States can participate directly in the development of the harmonised EN standards, and retain ultimate control with regard to the acceptability of harmonised standards drawn up by CEN: they can also reject them if they consider that the standards do not adequately ensure compliance with the legal requirements laid down in the

Regulation. In addition, the New Approach legislative format has been used successfully for other very sensitive sectors such as toys, pyrotechnic articles and civil explosives, where it now ensures the safety of products placed on the EU market.

Compared to full harmonisation, optional harmonisation would be less effective in reaching a level playing field as regards limit values for contaminants in fertilising products. National limit values would have to be maintained to avoid water and food contamination from the use of national fertiliser. The objectives of administrative simplification and innovation support would be better achieved under optional harmonisation.

Option 5 (New Approach – with various levels of third party certification depending on the expected level of risks potentially caused by the fertilising products) would have the advantage of improving the current situation as regards all operational objectives in the short and/or longer term.

Option 5 would lessen the burden on products that are deemed less risky by allowing self-certification, and therefore lead to simplification compared to options 2 and 3 and variants 4B, 4C and 4D.

As regards safety, fertilising products would have to comply with generic essential safety requirements (i.e. limit values for contaminants) and agronomic requirements specific to each product category. The conformity of products with these requirements would have to be checked either by the producers themselves or by a third party, depending on the nature of the raw material used. These pre-market conformity assessments and – as the case may be – recurrent controls would reassure farmers and public authorities about the safety of products derived from waste streams.

As regards SMEs and competitiveness, limiting third party certification to some product categories which deserve more attention, such as materials deriving from waste because of their higher variability in composition, would provide greater flexibility and impose less red tape. This should create an environment of improved business opportunity and facilitate innovation and greater competition in particular for alternatives to inorganic fertilising products. The greater flexibility would be reinforced by the optional harmonisation variant.

Farmers and consumers would benefit from more choice in line with the agricultural needs[81] in various regions of Europe therefore contributing to better match supply and demand and from competitive prices, while products will satisfy adequate safety standards.

The new instrument would be also adaptable to new scientific evidence relating to the safety of fertilising products and/or modifications to the list of contaminants in relevant environmental legislation. A safety net of prohibited ingredients will be implemented to address recurring problematic feedstock which triggers non-compliance with the essential safety requirements

Quantitative Assessment

When comparing the costs against the expected effectiveness, all variants under Options 2 and variant 4D could be discarded, as they would trigger a significant increase in costs either for authorities or industry. Variants 4B and 4C would also lead to very significant costs for producers if certification is required at product level, whereas a certification limited to certain groups of products such as those sourced from waste could significantly reduce the costs of

[81] There are a general trend towards fertilising products customisation to respond to specific farmer needs

certification. The variants under option 3 would be cost-effective both for industry and public administration.

Option 5 would be more costly than Options 2 and 3 and variant 4A for the part of industry that does not benefit from the self-certification of products (mainly products deriving from waste and animal by-products but also plant bisotimulants and agronomic fertiliser additives).

Optional harmonisation would facilitate the smooth transition to the new regulatory framework leaving producers the choice to market product either for the local or for the EU markets.

Table 1: Comparison table of options

Option	Scope of harmonisation	Effectiveness							Total annual costs for companies (EUR)	Total annual costs for MS authorities (EUR)	Total annual costs for the Commission (EUR)	Total annual costs (EUR)	Coherence
		Removal trade barriers	Improvement of safety of products	Simplification potential		Support innovation in the circular economy		Harmonised labelling					
				Short term	Long term	Short term	Long term						
1		=	=	=	=	=	=	=	26 062 500	17 165 150	328 000	43 555 650	=
2A	Full	++	+	--	+	--	+	+	3 184 750	21 617 330	631 050	25 433 130	+
2A	*Optional*	+	=	-	+	-	+	=	*2 585 260*	*20 060 610*	*611 950*	*23 257 820*	=
2B	Full	++	+	--	+	--	+	+	6 065 015	21 617 330	406 050	28 088 395	+
2B	*Optional*	+	=	-	+	-	+	=	*4 889 470*	*20 060 610*	*386 950*	*25 337 030*	=
2C	Full	++	+	--	+	--	+	+	3 184 750	21 617 330	1 421 050	26 223 130	+
2C	*Optional*	+	=	-	+	-	+	=	*2 585 260*	*20 060 610*	*1 198 950*	*23 844 820*	=
3A	Full	++	+	-	+	-	+	+	1 278 335	13 411 995	441 080	15 131 410	+
3A	*Optional*	+	=	=	+	=	+	=	*1 078 765*	*13 454 955*	*421 980*	*14 955 700*	=
3B	Full	++	+	-	+	-	+	+	2 085 660	13 411 995	366 080	15 863 735	+
3B	*Optional*	+	=	=	+	=	+	=	*1 724 625*	*13 454 955*	*346 980*	*15 526 560*	=
3C	Full	++	+	-	+	-	+	+	1 278 335	13 411 995	650 580	15 340 910	+
3C	*Optional*	+	=	=	+	=	+	=	*1 078 765*	*13 454 955*	*574 580*	*15 108 300*	=
4A	Full	++	=	++	+	+	+	+	621 890	11 268 855	219 365	12 110 110	+
4A	*Optional*	+	=	++	+	+	+	=	*502 800*	*11 734 335*	*194 665*	*12 431 800*	=
4B	Full	++	+	=	+	-	+	+	54 256 390	10 161 245	219 365	64 637 000	+
4B	*Optional*	+	=	+	+	=	+	=	*43 410 400*	*10 626 725*	*194 665*	*54 231 790*	=
4C	Full	++	+	-	+	--	+	+	156 161 940	9 053 635	219 365	165 434 940	+
4C	*Optional*	+	=	=	+	-	+	=	*124 934 840*	*9 519 115*	*194 665*	*134 648 620*	=
4D	Full	++	+	--	+	--	+	+	309 020 265	7 946 025	219 365	317 185 655	+
4D	*Optional*	+	=	-	+	-	+	=	*247 221 500*	*8 411 505*	*194 665*	*255 827 670*	=
5	Full	++	+	+	+	+	+	+	8 781 180	10 161 240	219 365	19 161 785	+
5	*Optional*	+	=	++	+	++	+	=	*7 030 235*	*10 626 720*	*194 665*	*17 851 620*	=

8. MONITORING AND EVALUATION

8.1. Supporting the implementation of the new legislative proposal

The Commission will develop together with Member States' experts and interested stakeholders, a number of accompanying activities to facilitate the implementation of the measures such as an implementing act outlining data requirements on EU EoW criteria, an FAQ document, CEN standards, guidance documents for the implementation and enforcement of the selected option.

8.2. Measuring the fulfilment of the objectives

The evaluation of the effectiveness of the legislation will be based on the feedback received through various cooperation mechanisms already established under the current Fertilisers Regulation (expert groups).

8.2.1. Removal of trade barriers and simplification (operational objectives 1 and 3)

Progress in removing trade barriers will be measured by an ex-post evaluation of the future legislation and a new SME consultation 5 years after its implementation. This includes verifying to which extent national measures on fertilisers have been effectively removed. An SME survey could measure whether the expectations of the sector in terms of administrative burden reduction and simplification have been met. The evolution of municipal waste treatment technologies and in particular the emergence of a higher number of recovery installations would be an indicator of the reduction of trade barriers for organic fertilisers and soil improvers. Data are available in Eurostat (*See* Annex 1).

8.2.2. Better market access for more sustainable products deriving from domestic resources (operational objective 4)

Other initiative than the revision of the Fertilisers Regulation could support the development of the market of fertilising products sourced from domestic secondary raw materials. A detailed analysis of the framework conditions supporting further investments in such products could intensify the role of nutrient recovery. It would be particularly important to identify which type and which amount of biomass is available for valorisation into fertiliser production.

Progress in allowing better access to the market for more sustainable products will be measured by an ex-post evaluation. The analysis of the number of patent registrations for new products or industrial processes before and after the enforcement of the future Regulation could be used as monitoring indicator of the achievement of this objective.

8.2.3. Better safety of products (operational objective 2)

The monitoring of compliance will be possible on the basis of a number of enforcement indicators (e.g. number of products checked, number of non-compliant products among those checked, type of non-compliance found, number of non-compliant products whose manufacturer/importer was identified, number of products refused at the border). These enforcement indicators will be based on information provided via:

– Use of RAPEX, the EU rapid alert system that facilitates the rapid exchange of information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers with the exception of food, feed, pharmaceutical and medical devices, which are covered by other mechanisms. Since 1 January 2010, RAPEX also facilitates the rapid exchange of information on products posing a serious risk to the health and safety of professional users and on those posing a serious risk to other public interests protected via the relevant EU legislation (e.g. environment, workplace, energy consumption, incorrect measurement, security). Both measures ordered by national authorities and measures taken voluntarily by producers and distributors are reported in RAPEX.

GRAS-RAPEX is the General Rapid Alert IT tool used for the RAPEX notifications. Since May 2012, Member States can notify in the GRAS-RAPEX system all products falling under the scope of the proposal;

– the safeguard clause procedures established under the future proposal according to which Member States notify restrictive measures adopted against products that although complying with the provisions of the current legislation, present serious risks or shortcomings (e.g. as regards quality);

– a general database established under Article 23 of Regulation (EC) No 765/2008 for the exchange of information among Member States on market surveillance activities and non-compliant products (ICSMS database). This database allows Member States to exchange information about non-compliant products found in the market (market surveillance, authorities, customs etc.);

– the data provided by customs authorities. The latter have a duty to cooperate with market surveillance authorities according to the relevant provisions of Regulation (EC) No 765/2008;

– the National Market Surveillance Programmes established by Member States on the basis of Regulation (EC) No 765/2008 and their report on the state of the implementation of the programmed activities.

In 2012 the Joint Research Centre in Sevilla carried out a broad survey on the content of contaminants in compost and digestate. A similar study shall be performed 5 years after the implementation of a future regulation to verify whether the setting of harmonised rules has effectively reduced the contaminants content of such products.

Over the longer term (i.e. 10 years or more as it could take more time to observe the effects of a reduction of contaminants in fertilising products on the environment and transitional periods depend on the choice of the regulatory approach), progress on the reduction of certain soil contaminant inputs via fertilising products could be gauged from monitoring and assessment carried out in accordance with Article 3(6) of Directive 2013/39/EU and with Articles 4 and 5 of Directive 2006/118/EC, which oblige Member States to determine trends in the levels of pollutants in surface and groundwater bodies. The findings have to be reported under Article 15 of Directive 2000/60/EC. Analysis of the inventories of emissions, discharges and losses of priority pollutants required from Member States under Article 5 of Directive 2013/39/EU could also provide information on progress.

Following the results of constant monitoring and market surveillance, the lists of contaminants and their corresponding limit values could be adjusted via delegated act.

The quality of services provided by notified bodies should also be verified in line with the provisions contained in Decision (EC) No 768/2008 and regular round robin testing to which all Notified Bodies will have to participate.

8.2.4. Better information of farmers and consumers (operational objective 5)

A revised Fertilisers Regulation will propose a harmonised labelling information system that will allow end-users (farmers, growers and the general public) to make conscious choices based on the intrinsic product quality declared on the labels. Where necessary, CEN will be required to develop appropriate European harmonised standards to complement the labelling requirements set out by the future legislation.

In accordance with Articles 7 and 8 of Council Directive 2001/81/EEC on national emission ceilings for certain atmospheric pollutants, Member States shall prepare and annually update and report to the European Environment Agency national emission inventories for the air pollutants covered by the Directive, including ammonia emissions. This information, as broken down by emission source category can be used to assess whether the improved information for farmers on high-emitting fertilising products and urease inhibitors will lead to lower overall emissions of ammonia. Relevant additional information, including on the sales of urea-based inorganic fertilisers vs. nitrate-based inorganic fertilisers Member State by Member State may be obtained from Eurostat.

In accordance with Article 10 of Council Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources, Member States shall submit a report to the Commission containing the information outlined in Annex V of that Directive. The report should include information about the measures in place to avoid fertilisation resulting in nitrogen leaching into waters.

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10. GLOSSARY OF TECHNICAL TERMS AND ABBREVIATIONS

- **Bio-waste** is defined in the Waste Framework Directive as 'biodegradable garden and park waste, food and kitchen waste from households, restaurants, caterers and retails premises, and comparable waste from food processing plants'.
- **Biodegradable waste** is a broader concept and is defined in the Landfill Directive as 'any waste that is capable of undergoing anaerobic or aerobic decomposition such as food and garden waste, paper and paperboard'.
- **Agronomic fertiliser additives** means any substance added to a fertiliser, soil improver, liming materials or growing medium which act on the fertilising products to which it is added in order either, to modify the release of nutrient(s) in the environment, or to improve the agronomic efficacy of the final product.
- **Compost** means solid particulate matter resulting from controlled decomposition, by thermophilic and mesophilic microorganisms under predominantly aerobic conditions, of biodegradable waste other than those classified as animal by-products Category 1 under Regulation (EC) No 1069/2009:
  - **Green compost** means compost exclusively made of untreated, source separated (or separately collected) plant material derived from solid material from the production or processing of agricultural or horticultural produce, timber and natural textiles;
  - **Bio-waste compost** means compost produced from biodegradable garden and park waste, food and kitchen waste from households, restaurants, caterers and retail premises and comparable waste from food and fodder processing;
  - **Bark compost** means a compost produced from bark; usually not mixed with other organic residues but with additives as a nitrogen source;
  - **Sewage sludge compost** means compost of precipitated semi-solid residues from the treatment of waste water;
  - **Mixed waste compost** means any of the materials listed as compost, green compost or bio-waste compost but with the inclusion of any of the following:
    (a) animal-derived material which is classified as animal by-products Category 2 or 3 under Regulation (EC) No 1069/2009, which may be composted (under controlled conditions) and can include catering and food waste, some slaughterhouse waste (such as blood and feathers), manure and gut;
    (b) material that has previously been anaerobically digested.
- **Digestate** means the residual semisolid or liquid material of anaerobic digestion of biodegradable materials.
- **Fertilising products**: any substance or mixture which delivers nutrients to crops or improve the physico-chemical properties (pH, organic matter…) of soils. In the context of this impact assessment, it means inorganic, organo-mineral and organic fertilisers, soil improvers, growing media and plant biostimulants and their combinations.

- **Fertiliser** is a material, the main function of which is to provide nutrients for plants, of which we can identify:
  - *Inorganic fertiliser*, i.e. fertiliser in which the declared nutrients are in the form of minerals obtained by extraction (e.g. potash and phosphate rocks) or by physical and/or chemical industrial processes (e.g. urea);
  - *Organic fertiliser* means a fertiliser which consists of organic materials of plant and/or animal origin. Compost and digestate described above can be recognised as organic fertilisers or soil improvers depending on their nutrient content;
  - *Organo-mineral* fertiliser means a fertiliser obtained by chemical reaction of inorganic and organic fertilisers in order to delay the nutrient release to the plants.
- **Growing media** are materials, other than soils *in situ*, in which plants are grown and which is used independently from soil *in situ*.
- **Heavy metal** means any compound of arsenic, cadmium, chromium (VI) and chromium total, copper, lead, mercury, nickel and zinc as well as these materials in metallic form, as far as these are classified as hazardous substances. Copper and zinc are also valuable nutrients for plants.
- **Ingredient** means a substance that forms part of a mixture.
- **Liming materials** are inorganic substances and mixtures whose main function is to correct soil acidity containing either calcium and/or magnesium under the forms of oxides, hydroxides, carbonates or silicates.
- **Nutrients** are the elements that are essential for plant growth and ensure a good yield of harvested crops. They are often classified as macronutrients (nitrogen, phosphorous and potassium, calcium, magnesium, sodium and sulphur) and micronutrient fertilisers (boron, cobalt, copper, iron, manganese, molybdenum and zinc) in accordance with their application patterns and concentration in plan tissues. Other elements such as oxygen, carbon dioxide and water are also crucial for plants but are however not considered as nutrients as they are found in abundance in the environment or are not considered to pose any environmental problems.
- **Organic pollutants (OPs)** are organic substances that are resistant to environmental degradation through chemical, biological and photolytic processes.
- **Plant biostimulant** means a material which contains substance(s) and/or micro-organisms aimed at stimulating plant nutrition processes independently of the product's nutrient content, with the exclusive aim of improving one or more of the following characteristics of the plant:
  - The plant's nutrient use efficiency,
  - The plant's tolerance to abiotic stress, or
  - The plant's crop quality traits.
- **Soil improvers** are any material which improves the physical, chemical and/or biological properties of soil. However, the more usual interpretation relates to materials which are added to soils to enhance their physical properties. Such materials include manure, and

various types of composted materials which may or may not also provide some useful quantities of plant nutrients, planting materials or mulches, acidifying products, perlite, clay, stone meal, biochar…

- **Type of fertiliser** means fertilisers with common characteristics as indicated in Annex I to Regulation (EC) No 2003/2003.
- **Urea-based fertiliser** is an inexpensive form of nitrogen fertiliser. Although urea is naturally produced in humans and animals, synthetic urea is manufactured with anhydrous ammonia. Special steps must be taken when applying urea to the soil to prevent the volatilisation of ammonia.

ANNEX I

The global and EU supply and demand of fertilising products and additives

A fertiliser is any material, inorganic or organic, natural or synthetic, that supplies plants with the nutrients necessary for plant growth and acts to increase yield in optimum conditions. Plants live, grow and reproduce by taking up water and mineral substances from the soil, absorbing carbon dioxide from the air and energy from the sun. Plants contain practically all (92) natural chemical elements but need about 14 of them for their optimal growth. Nitrogen and phosphorus for example are essential to build plant proteins. Every plant nutrient whether required in large or small amounts has a specific role in plant nutrition and growth. One nutrient cannot be substituted for another.

1. Global inorganic fertiliser supply

The majority of the world's intensive agricultural systems depend on synthetic fertilisers to provide three key nutrients: nitrogen (N), phosphate (P_2O_5) and potash (K_2O) to crops. The commodities market at the origin of these inputs has experienced substantial changes in recent years. Since 2005, emerging economies (China, India) have massively invested in the production of fertilisers mainly to ensure that the food needs of their growing populations are met. In 2008, prices of agricultural products (including fertilisers) soared as shown in figure 5. This episode highlighted the increasing importance of accessibility to these essential resources, especially considering that mines and production capacities are situated in third countries.

After a 7.6% contraction in 2009, 2010 marked a strong rebound of global nutrient production due to slight recovery in traditional markets and a sustained level of consumption in emerging markets.

Inorganic fertilisers containing nitrogen (N) represent the bulk of the global fertiliser consumption (60%) followed by phosphorus (P) (25%) and potassium (K) (15%). Figure 3 illustrates the relative importance of the various nitrogen sources in European agriculture. Figure 4 provides more information on the EU and global inorganic nitrogen fertilisers market.

Figure 3: Sources of nitrogen inputs in European agriculture. *(Source: Eurostat)*

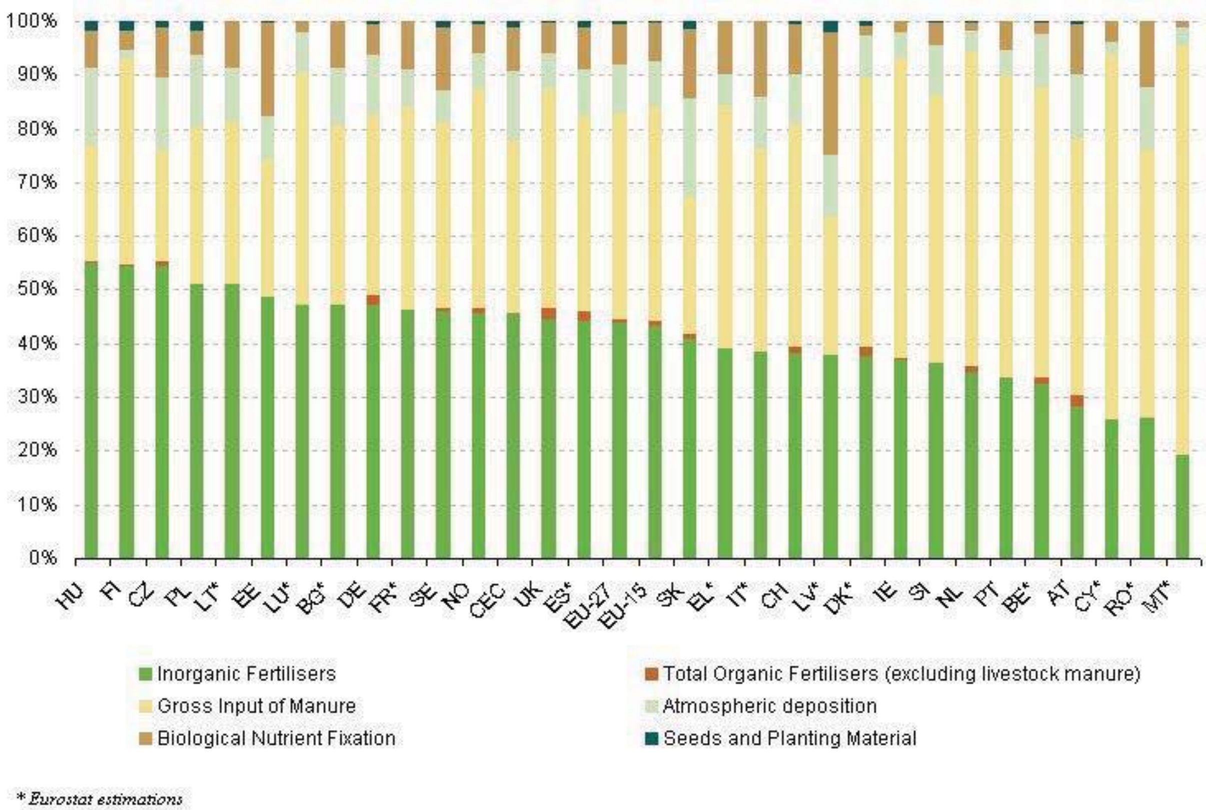
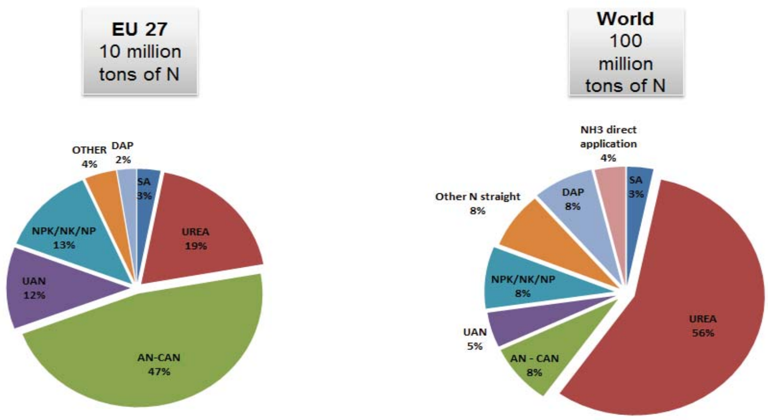


Figure 4: Sources of inorganic nitrogen inputs in EU agriculture and worldwide. *(Source: Fertilisers Europe 2012)*



Over the next five years, world global capacity will further increase with the realisation of about 250 new industrial projects. The International Fertilisers Association (IFA) estimates that about USD 88 billion will be invested by the fertilisers industry between 2010 and 2015.

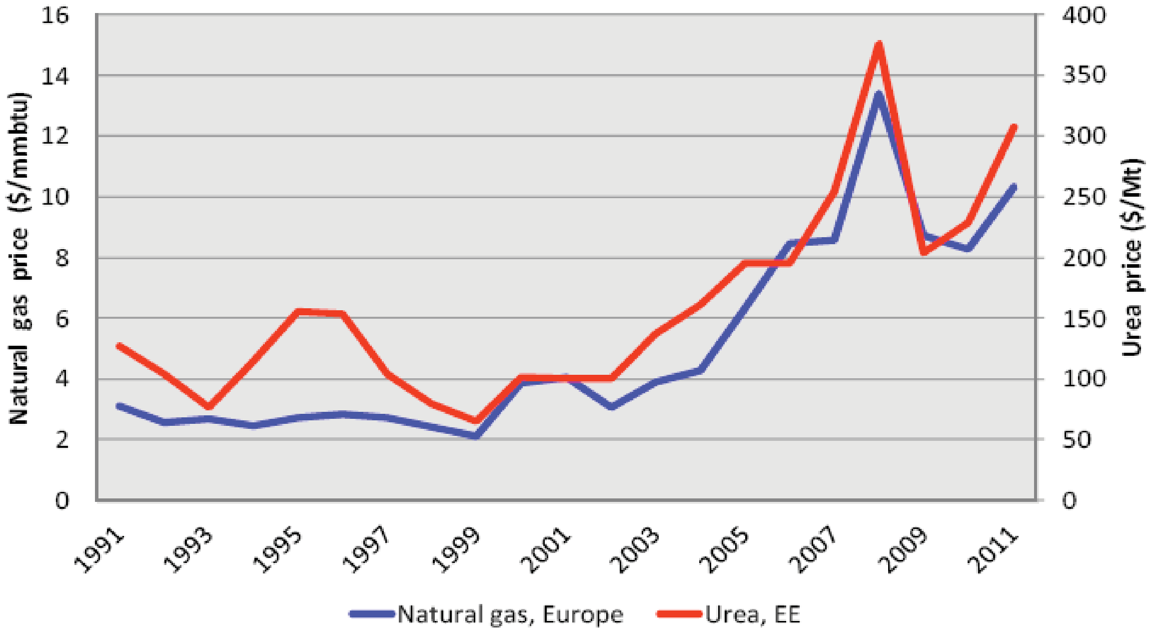
1.1. Inorganic nitrogen fertilisers

The production of inorganic nitrogen fertilisers depends largely on the availability of gas at competitive prices[82] (*see* figure 5) and ammonia is the main intermediate during the production of all nitrogen fertilisers. In a volatile energy market with fluctuating natural gas availability, the industrial dimension of nitrogen production has a strategic element. Natural gas contributes to 70% of total production costs of inorganic nitrogen fertilisers. Europe is amongst the regions with the highest gas prices in the world with a 230% increase in the last decade. Measures to secure gas supply would therefore also stabilise the price of inorganic nitrogen fertilisers in Europe.

The world inorganic nitrogen fertiliser production is currently concentrated in Russia (20%), the United States (19%) and Canada (6%). For developing countries, the main driver for investment in nitrogen fertiliser production is the strong desire to optimise the use of local resources and to reduce their reliance on imports (mainly urea[83]).

No increase in ammonia capacity is expected in Western Europe. Central Europe will more or less maintain its existing capacity.

Figure 5: Price of urea and natural gas in Europe *(Source: Blanco, 2011 derived from World Bank database; price normalised to 2000; accessed in 2011)*



[mmbtu = Million Metric British Thermal Units]

The production technology for commodity inorganic nitrogen fertilisers is readily available but the production process is highly capital intensive. Member States are no longer financially supporting the production of fertilisers and consequently, industry has been more market driven than in the past. Economies of scale are important to reduce fixed costs per tonne and achieve good competitiveness.

1.2. Inorganic phosphate fertilisers

[82] As part of its recent accession to WTO, Russia has made commitments concerning the gas double pricing system which could reduce the negative impacts on EU fertiliser manufacturers.

[83] Urea accounts for 90% of nitrogen-based products growth since 1999.

Despite relative abundance, resources of phosphate rocks are unevenly distributed around the world. Morocco, China and the US hold two-thirds of the world phosphate rocks reserves and it might therefore be considered a strategic resource. Some national companies intend to benefit from the increase in fertiliser demand by investing in new mining projects (e.g. Ma'aden in Saudi Arabia). In 2008, prices of phosphorus rock went up by 700% in little over a year.

In Europe, some companies[84] have invested in the production of NP and NPK fertilisers via the nitrophosphate route to reduce the generation of gypsum waste produced in the conventional phosphoric acid route. The availability of phosphate rocks might be a source of concern for those companies as many producing countries strongly encourage the local production of more valuable finished products. The only source of phosphate rock in Europe is located in Finland which cannot satisfy the needs of the European fertiliser industry.

Some countries including the EU are encouraging the use of recycled phosphorus which would help diversify the supply of this fundamental raw material and strive for a more even distribution of phosphorus resource at regional and global level.

1.3. Inorganic potassium fertilisers

Canada, Russia, Belarus and Israel represent more than two-thirds of the world production, while eight companies control 80% of the production. No scarcity of potassium is foreseen over the long term in Europe but reserves are in the hands of a few countries and companies. The most important producing Member States are Germany, Spain and the UK.

It is now generally accepted that, whatever the existing proven resources, the complete dependence of the EU fertiliser market on non-renewable resources such as N and P must be addressed over the longer term by a food security strategy.

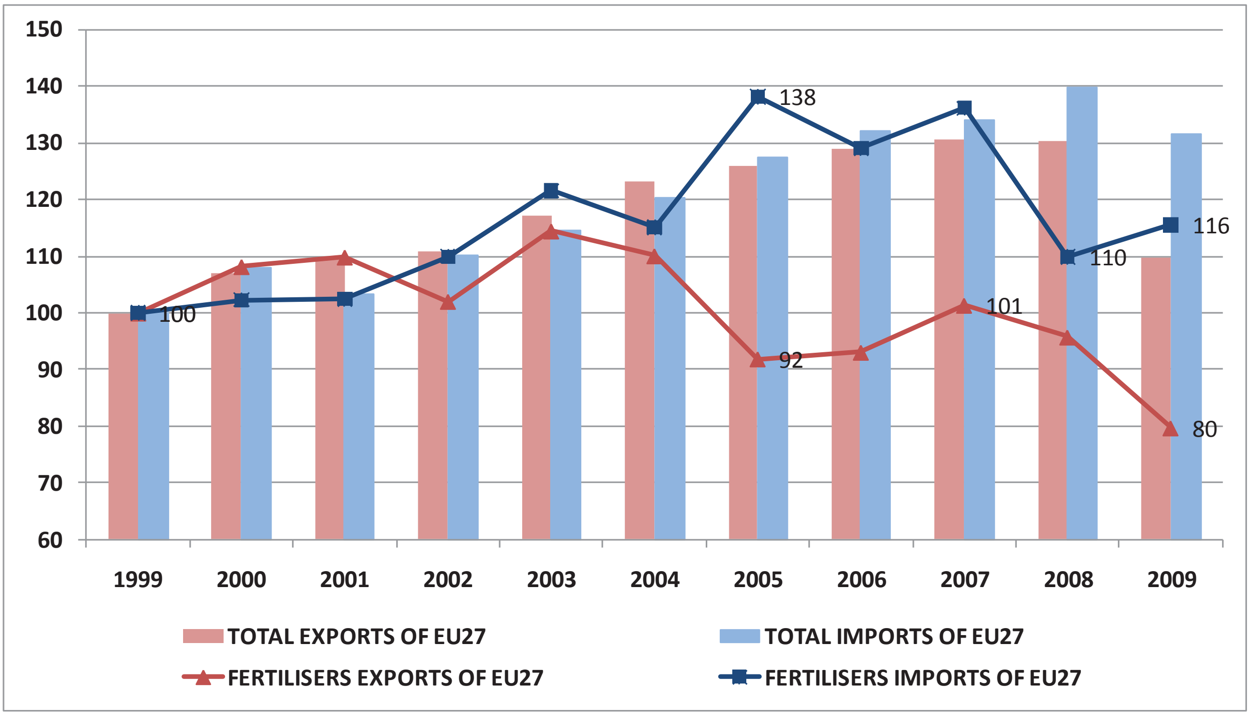
2. Development of the internal market for inorganic fertilisers since 2003

The current fragmentation of the market for inorganic fertilisers does not indicate particular problems in the overall development of the Internal Market for inorganic fertilisers. As far as the main part of the inorganic fertiliser sector is concerned, most of the multinational firms and the other smaller exporting firms have shifted their production towards EC fertilisers. For the existing categories of fertiliser covered by the Regulation, this facilitates the smooth operation of the Internal Market with limited problems reported as regards their trade. It has also facilitated the import of fertilisers from outside the EU as reported by the importers association (EFIA). In addition, according to a couple of manufacturers, it supports the export of EC-labelled inorganic fertilisers that are accepted without additional tests or documentation requirements by a number of third countries (inside and outside Europe). Still, such a benefit from the Regulation is not able to counterbalance the generally negative trend in the EU exports of fertilisers during the last decade that reflects, primarily, the lower production costs in certain non-EU countries due to cheaper access to raw materials in those regions.

The choice of the national label in some countries appears to reflect the presence of an existing market for lower nutrient content in inorganic fertilisers that the Fertilisers Regulation does not cover. It also arises because various new products with additional ingredients (additives, coating agents) are only partially or not yet covered by the Fertilisers Regulation.

[84] BASF, Belgium; YARA, Norway; AMI, Austria; Azomures, Romania; Lovochemie, Czech Republic.

Figure 6: Evolution of extra-EU trade in fertilisers (all categories) in EU27 (1999=100). Comparison with evolution of total imports and exports[85] *(Source: Eurostat, External trade statistics, 2010)*



Thus, from the point of view of national authorities and most parts of the industry, the problems for the development of the Internal Market stem from the fact that the Regulation does not cover all segments of the fertiliser market. It is the "non-coverage" of the remaining segments of the market and the important problems in trading them cross-border that is considered to be the main weakness of the existing regulatory framework.

The table below shows the production and trade of inorganic fertilisers in the EU. It shows that intra EU trade (the difference between trade of individual Member States and EU-27 trade) is approximately three times as high as the EU trade with third countries.

Table 2: Production and trade of inorganic fertilisers in the EU27, top-6 in (€m) producing, exporting and/or importing member states in 2011 *(Source: Based on Eurostat PRODCOM ANNUAL SOLD [DS-043408])*

Category	Export		Import		Production	
	1,000 tonnes*	€m	1,000 tonnes*	€m	1,000 tonnes*	€m
EU27	3,525	2,291	5,131	4,306	32,015	14,836
France	341	276	3,410	2,222	2,139	1,168
Poland	661	502	771	447	1,782	1,126
Germany	932	804	1,629	1,349	1,853	955
Netherlands	2,813	1,770	1,399	653	:	:
Belgium	2,591	1,388	2,335	1,625	364	84

85 The general trend may hide specific areas where exports have increased (e.g. CAN, diammonium phosphate or potassium magnesium sulphate).

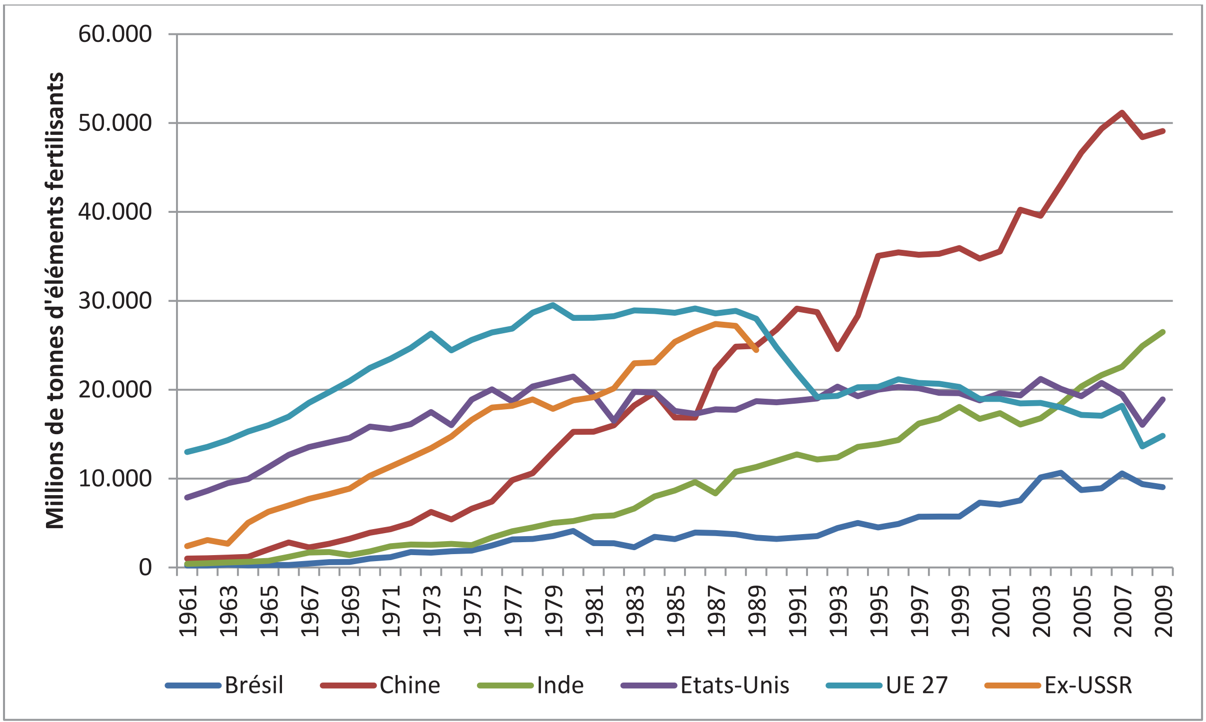
Category	Export		Import		Production	
Lithuania	1,595	925	116	153	1,649	942
Others	5,204	3,452	6,308	4,717	8,709	3,703
Total individual Member States	14,137	9,917	15,968	11,166		

* Nutrient volume, n.a. = not available

3. Increasing demand for inorganic fertilisers to feed the world

The global consumption of inorganic fertilisers has increased by 40% between 1980 and 2006. Over the past decade, consumption of inorganic fertilisers has moved from industrial countries to developing countries. China and India now account for respectively 31% and 16% of the world fertiliser consumption. Inorganic fertiliser demand in Western and Central Europe has only partly recovered from its sharp contraction in 2009.

Figure 7: Evolution of the worldwide inorganic fertiliser consumption over the last 50 years *(Source: Fertilisers Europe)*

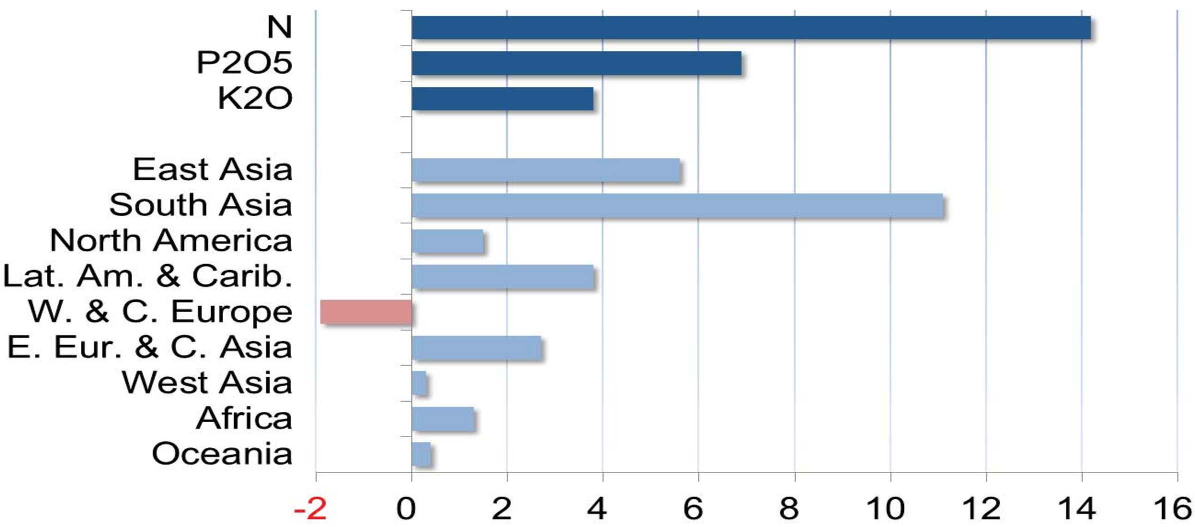


Total inorganic fertiliser nutrients (N + P_2O_5 + K_2O) consumption estimated at 168.3 million tonnes in 2010 reached 172.4 million tonnes in 2012. With an annual growth of more than 2.0%, it is expected to reach 183.4 million tonnes by the end of 2015 as indicated in the table below.

Table 3: World demand for inorganic fertiliser nutrients, 2011-2015 (million metric tonnes) *(Source: FAO and IFA)*

Year	2011	2012	2013	2014	2015
Nitrogen (N)	105.3	107.3	109.3	111.1	112.9
Phosphate (P_2O_5)	34.3	35.4	36.3	37.2	38.0
Potash (K_2O)	28.7	29.7	30.7	31.7	32.5
Total (N+ P_2O_5+K_2O)	**168.3**	**172.4**	**176.3**	**180.0**	**183.4**

Figure 8: Foreseen evolution of inorganic fertilisers demand for 2016/17 compared to 2007/08 (Mtonnes of nutrients) (*Source: the International Fertiliser Industry Association – IFA)*



The global fertiliser market value increased by 12.9% in 2010 compared to 2007 and reached a total value of EUR 91.1 billion. In 2015, the global fertiliser market is forecast to have a value of EUR 121.1 billion, an increase of 31.9% compared to 2010.

These forecasts are however subject to a number of uncertainties. Apart from weather conditions, the main issues that could influence the forecast are 1) the world economic context; 2) demography; 3) the evolution of the biofuel policy and energy policies in developed countries; 4) fertiliser prices relative to agricultural commodity prices; 5) natural gas and other energy prices; 6) policies aiming at increasing nutrient efficiency; and 7) recycling of nutrients from organic sources. The Food and Agriculture Organisation of the United Nations (FAO) has however recently predicted an increase of 69% in fertiliser demand in developing countries to meet the expected 60% increase in food production by 2050.

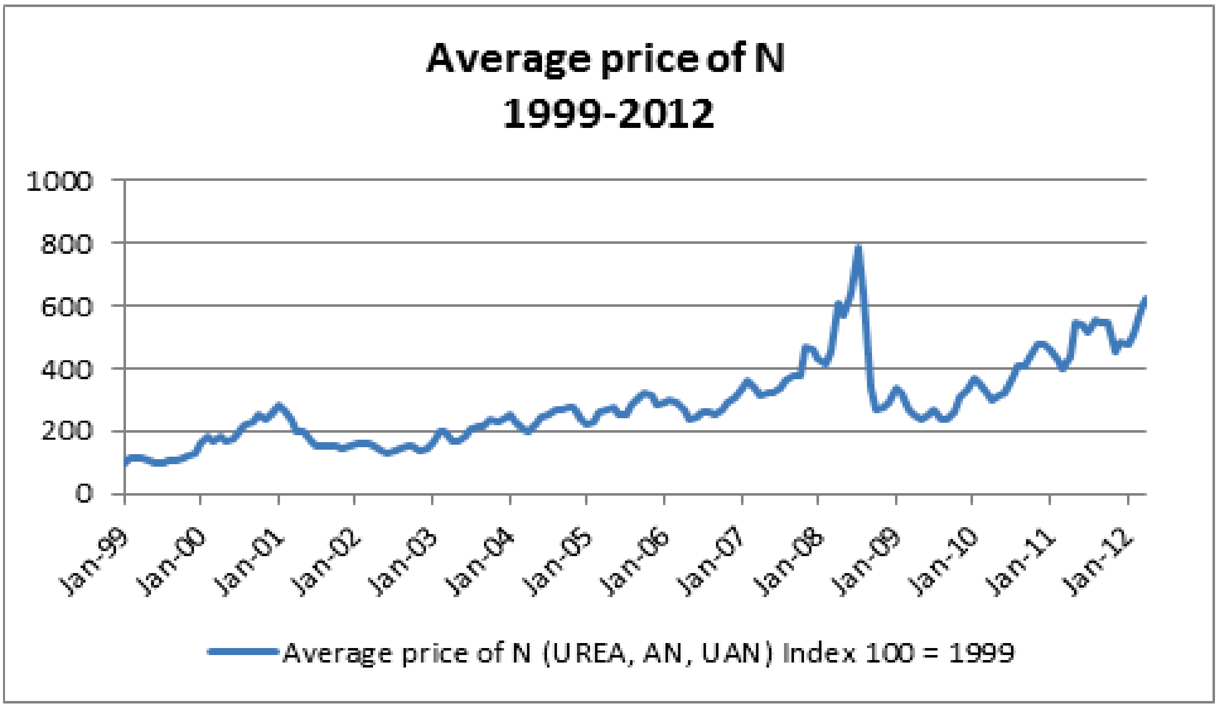
In Western Europe, there will be a decline in nitrogen and phosphate consumption, of respectively minus 0.2 and minus 0.7% during the 2010-2015 period and a slight increase (of 1%) for potash driven by more sustainable farming practices concerning the use of fertilisers. However an increase in fertiliser consumption is expected for all these nutrients in Central Europe (+ 2.3, + 4.5 + 3.2%, respectively) where the levels of P_2O_5 and K_2O in soils seem to be insufficient.

4. Inorganic fertiliser prices

The global inorganic fertiliser market experienced a decline in prices until the late 90s. The beginning of the 2000s showed a moderate increase in inorganic fertiliser prices followed in 2008 by a sharp increase. After a major contraction in 2009, commodity prices for inorganic fertilisers have strongly rebounded since mid-2010.

The magnitude of these recent fluctuations is due to the convergence of several factors. From 2006, the lack of investment in the previous years and increasing inorganic fertilisers demand in Brazil, China and India contributed to soaring prices and volatility. Increase of energy prices and speculation in the raw materials market played an important role in amplifying this trend in particular for nitrogen and phosphate.

Figure 9: Evolution of inorganic nitrogen fertiliser prices over the last decade
(Source: Fertilisers Europe)



Over the period 2009-11, the prices of inorganic fertilisers went up. For instance, the index of FOB[86] price of diammonium phosphate (DAP) (reference year 2002 = USD100) increased from USD 176 in 2009 to USD 263 in 2010 and moved further up at USD 323 in the first half of 2011 as a result of the soaring of energy and food prices. The financial crisis in Europe led to a disruption of credit lines granted by banks to farmers to buy fertilisers and the postponement of a number of investment projects. Consequently, the EU fertiliser market shrunk which led to an overall decrease in consumption of inorganic fertilisers in Europe[87].

[86] Free on Board Price. A product is sold or bought at FOB price when transport, insurance and other fees costs are not included.

[87] The consumption of nitrogenous fertilisers in the EU decreased by 13.5% while that of phosphorus and potassic fertilisers fell approximately by 40%

Table 4: Prices variation of three common fertilisers: urea, diammonium phosphate and muriate of potash *(Source: FAO and IFA)*

Fertiliser input price index (2002 = 100)[88] - USD					
	2007	**2008**	**2009**	**2010**	**2011**
Urea	222	362	184	206	269
DAP	228	515	176	263	323
MOP	182	573	541	293	363

It is expected that inorganic nitrogen fertiliser prices will stay firm in the mid-term and will fluctuate with the gradual implementation of new production units. Inorganic phosphate and potash fertilisers are expected to remain firm as their supply is dominated and controlled by a limited number of existing players.

5. Impacts of inorganic fertiliser price volatility on EU farmers incomes

The Food price Index of the FAO shows that inorganic fertiliser prices have been increasing since mid-2010 in response to a tight market environment caused by factors such as bad weather conditions in major producing countries resulting in harvests smaller than expected, a low level in cereal stock worldwide and the high crude oil price which provides strong incentive for biofuel production leading to increased competition among the food, feed and fuel sectors.

According to the Organisation for Economic Co-operation and Development (OECD), FAO and Food and Agricultural Policy Research Institute, the world stock of main agricultural commodities is not predicted to evolve much over the next five years and prices of all agricultural commodities should remain firm well above pre-crisis level.

Table 5: Prices variation of some agricultural commodities *(Source: FAO)*

	2007	**2008**	**2009**	**2010**	**2011**
Cereals	167	238	174	183	257
Dairy	212	220	142	200	230
Meat	125	153	133	152	175
Oils & Fats	169	225	150	193	265
Sugar	143	182	257	302	371
Food	**159**	**200**	**157**	**185**	**233**

(Source: World Food Situation: Food Prices Index[89], FAO, Rome)

Under such a scenario, the high agricultural commodity prices provide incentives for farmers in market-oriented economies to invest in fertilisers for higher productivity. However during the episode of soaring prices of agricultural products of 2008, the prices of agricultural commodities (e.g. crops) grew much less than the price of fertiliser which reduced farmers' revenues. This illustrates the potential danger that farmers face from volatile fertiliser prices.

[88] Calculated from average FOB prices quoted in various Fertiliser Trade Journals
[89] Http://www.fao.org/worldfoodsituation/foodpricesindex/en/

Depending on their activities, EU farmers are affected differently by the current volatility in inorganic fertiliser prices as illustrated in the figure below. According to COPA-COGECA, inorganic fertilisers currently represent on average 20 to 30% of the production costs of agricultural produce. Dairy farmers are the most affected as they also face difficulties to obtain credits and do not have the possibility to pass on extra costs to customers.

Table 6: Average increase of fertilisers in farmers input costs during the period 2007-2010 *(Source: Finnish farmer organisation)*

Cereal farmers	+ 42%
Dairy farmers	+ 20%
Beef farmers	+ 20%

6. General description of the EU inorganic fertiliser industry

The EU inorganic fertiliser market is composed of:

– Fertiliser producers,
– Traders,
– Distributors/retailers.

Inorganic fertiliser manufacturing plants are distributed throughout the EU. Major producing Member States are France, the Netherlands, Germany, Poland and Spain. Together with energy costs, the other main factor affecting the competitive position of inorganic fertiliser manufacturers and importers is the price and the availability of the raw materials and intermediate products[90].

Traders import inorganic fertilisers from third countries and purchase mainly urea, DAP and nitrogen fertiliser solutions for selling them to producers and distributors.

In some Member States (e.g. France), some distributors sell fertilisers directly to farmers. They are mainly agricultural cooperatives. Over the past 20 years, a large number of mergers and acquisitions have increased the degree of concentration on the agricultural distribution market.

The overall EU inorganic fertiliser market volume can be estimated at about 16 million tons of nutrients per year i.e. 45 million tonnes of products per year (around 9% of the world consumption, according to IFA).

According to Fertilisers Europe, the market size (annual average nutrients consumption from 2007 to 2010) of the European inorganic fertiliser can be estimated as follows:

– Nitrogen (N) consumption/year: 10 368 000 tonnes;

– Phosphorus (P_2O_5) consumption/year: 2 408 000 tonnes;

– Potassium (K_2O) consumption/year: 2 704 000 tonnes.

[90] E.g. ammonia average production cost structure: energy and raw materials (80%), the rest is capital expenditure, labour costs, utilities, sales, R&D, maintenance costs, transport costs, costs of environmental legislation... The production costs vary according to the region, technology, production capacity and the age of industrial installation.

The EU inorganic fertiliser market at farmer retail prices represent around EUR 17 billion in 2010 with a compound annual growth rate (CAGR)[91] of 12.6% for the period 2004-2010. The performance of the market is forecast to decelerate, with an anticipated CAGR of 5.7% for the five-year period 2010-2015, which is expected to drive the market to a value of EUR 21.4 billion by the end of 2015.

The information collected during the ex-post evaluation of the current Fertilisers Regulation indicates that 5 EU companies represent more than 80% of the total production while there are still independent players in Poland, Romania and Greece. All in all, the EU inorganic fertiliser market share of large companies is estimated at about 90%. They transform basic elements (nitrogen from air, phosphorous and potassium from mines) into a small range of inorganic fertilisers that are mainly marketed for cereal production or sold to small and medium enterprises.

Between 10 and 15 medium-sized companies per Member State produce compound inorganic fertilisers or organic and organo-mineral fertilisers for specific local market needs (vineyards, fruits, vegetables…). They cover both the professional market and the hobby sector. Thirty percent of those companies exports to other European and Third countries.

Finally, a large number of small producing firms – estimated at 800 – focus exclusively on blending fertilisers bought from multinational companies to cover specific needs in the local market.

The inorganic fertiliser industry relies on a large European distribution network including two different types of structures:

– Private sector (represented at EU level by COCERAL);

– Agricultural cooperatives (represented at EU level by COPA-COGECA).

Spain, Italy and France have the largest number of enterprises (228, 187 and 175 respectively) most of them being SMEs. Eastern Member States (i.e. Poland, Romania, Lithuania and Romania) and Germany have the largest companies employing more than 2 000 FTEs (Full Time Equivalent) each. According to NACE data, the gross operating surplus of inorganic fertiliser producers can be estimated at 9% for the whole EU. However, the profitability of fertiliser producers varies largely between Member States despite the existing harmonisation of the inorganic fertiliser market.

Table 7: Profitability of inorganic fertiliser producers corresponding to NACE 2415 in 2007*(Source: Eurostat)*

	Number of enterprises	Turnover = gross premiums written	Value added at factor cost	Persons employed	Persons employed per enterprise	Gross operating surplus/ turnover
	Number	€m	€m	Number	Number	%
EU27	1,058	19,583	3,672	564,000	53	9.0
Belgium	33	509	87	771	23	7.1
Bulgaria	15	236	39	2,445	163	10.2
Czech Republic	:	:	:	:	:	:

[91] The year-over-year growth rate of an investment over a specified period of time representing the smoothed annualised gain earned over the investment time horizon.

	Number of enterprises	Turnover = gross premiums written	Value added at factor cost	Persons employed	Persons employed per enterprise	Gross operating surplus/ turnover
Denmark	8	17	3	29	4	6.0
Germany	54	3,397	951	10,512	195	11.3
Estonia	8	:	:	:	:	:
Ireland	12	295	46	375	31	9.2
Greece	10	212	53	837	84	8.0
Spain	228	1,309	277	3,607	16	11.0
France	175	3,295	328	5,350	31	2.8
Italy	187	1,541	199	2,855	15	5.6
Cyprus	0	0	0	0	:	:
Latvia	5	:	:	75	15	:
Lithuania	7	784	180	3,067	438	16.6
Luxembourg	0	0	0	0	:	:
Hungary	12	220	50	712	59	16.4
Malta	0	0	0	0	:	:
Netherlands	30	1,947	363	1,631	54	11.9
Austria	7	403	107	941	134	11.8
Poland	83	1,406	396	9,473	114	18.8
Portugal	22	:	:	:	:	:
Romania	22	491	61	5,589	254	3.5
Slovenia	6	:	:	:	:	:
Slovakia	:	:	:	:	:	:
Finland	14	489	74	730	52	4.1
Sweden	17	:	:	:	:	:
United Kingdom	74	1,904	257	2,622	35	4.7

7. Information about other fertilising products

The consultant mandated to support the Commission in the preparation of this impact assessment (the Fertiliser Study) was not able to provide a detailed overview of the economic importance and structure of the whole EU fertiliser market as data available in Eurostat, Datamonitor or Kompass is limited to inorganic nitrogen, phosphorus and potassium fertilisers. Data on other fertilising products are scarce and not always consistent and comparable.

In order to estimate the production, trade, employment and size of companies for other fertilising products, the consultants and the Commission have collected information directly from industry associations and reviewed economic literature. The information thus collected could not be verified by comparison to official statistics.

7.1. The organic fertiliser sector

The organic fertiliser sector has traditionally been organised at the regional level, but trends towards more sustainable farming make organic fertilisers increasingly attractive to intensive farming systems.

Organic fertilisers (mainly livestock manure) contain the necessary content and forms of nutrients (essentially nitrogen) to grow crops but they need to be applied in higher volumes compared to inorganic fertilisers. For the whole EU, livestock manure and inorganic fertilisers are the main sources of nitrogen. More than 1 500 million tonnes of pig and cattle manure are produced each year as illustrated in the following figure.

Table 8: Estimated amount of cattle and pig manure in the EU 27 Member States (*Source: FAOSTAT 2005*)

MS	Cattle	Pigs	Cattle	Pigs	Cattle manure	Pig manure	Total manure
	(in 1,000 Heads)		*(in 1,000 livestock units)**		*(in million tonnes)*		
AT	2,051.0	3,125.0	1,310.0	261.0	29.0	6.0	35.0
BE	2,695.0	6,332.0	1,721.0	529.0	38.0	12.0	49.0
BU	672.0	931.0	429.0	78.0	9.0	2.0	11.0
CY	57.0	498.0	36.0	42.0	1.0	1.0	2.0
CZ	1,397.0	2,877.0	892.0	240.0	20.0	5.0	25.0
DE	13,035.0	26,858.0	8,324.0	2,242.0	183.0	49.0	232.0
DK	1,544.0	13,466.0	986.0	1,124.0	22.0	25.0	46.0
EE	250.0	340.0	160.0	28.0	4.0	1.0	4.0
EL	600.0	1,000.0	383.0	83.0	8.0	2.0	10.0
ES	6,700.0	25,250.0	4,279.0	2,107.0	94.0	46.0	140.0
FI	950.0	1,365.0	607.0	114.0	13.0	3.0	16.0
FR	19,383.0	15,020.0	12,379.0	1,254.0	272.0	28.0	300.0
HU	723.0	4,059.0	462.0	339.0	10.0	7.0	18.0
IE	7,000.0	1,758.0	4,470.0	147.0	98.0	3.0	102.0
IT	6,314.0	9,272.0	4,032.0	774.0	89.0	17.0	106.0
LT	792.0	1,073.0	506.0	90.0	11.0	2.0	13.0
LU	184.0	85.0	118.0	7.0	3.0	-	3.0
LV	371.0	436.0	237.0	36.0	5.0	1.0	6.0
MT	18.0	73.0	11.0	6.0	-	-	-
NL	3,862.0	11,153.0	2,466.0	931.0	54.0	20.0	75.0
PL	5,483.0	18,112.0	3,502.0	1,512.0	77.0	33.0	110.0
PT	1,443.0	2,348.0	922.0	196.0	20.0	4.0	25.0
RO	2,812.0	6,589.0	1,796.0	550.0	40.0	12.0	52.0
SE	1,619.0	1,823.0	1,034.0	152.0	23.0	3.0	26.0
SK	580.0	1,300.0	370.0	109.0	8.0	2.0	11.0
SL	451.0	534.0	288.0	45.0	6.0	1.0	7.0
UK	10,378.0	4,851.0	6,628.0	405.0	146.0	9.0	155.0
Total	***91,364.0***	***160,528.0***	***58,348.0***	***13,401.0***	***1,283.0***	***294.0***	***1,579.0***

Volumes of nutrients based on organic industrial by-products and waste[92] (***excluding nutrients from manure)*** are much less important compared to those brought by inorganic fertilisers and raw manure. This organic 'resource' can be estimated as follows[93]:

– 332 800 tonnes of N (2.9% of the total yearly N inputs);

– 540 800 tonnes of P_2O_5 (15.2% of the total yearly P_2O_5 inputs).

On this basis, the Fertilisers Study has estimated that the market value of organic fertilisers (excluding manure) represents around 6% of the total inorganic fertiliser market value but with the potential to replace partly inorganic fertilisers if all valuable waste streams are used to recycle nutrients.

Most companies involved in this business are small or medium-sized companies (about 10 000 employees in total according to the Fertilisers Study), but are generally very well organised and have very effective marketing. In some Member States they have developed private quality schemes for mixtures of inorganic and organic fertilisers. The agronomic needs and use of organic fertilisers vary significantly from North to South. Mediterranean countries generally use these products more than the Nordic countries as climate and soil conditions favour the mineralisation[94] of the organic forms of nutrients.

92 Meat and bone meal, extracts (vinasse) from molasses and grapes, etc

93 Statistics for potassium are not available. Data on organic fertilisers (excluding manure) is only available in a limited number of Member States (AT, BE, DE, ES, FI, IE, NL, SE, UK, CZ, HU, SK, DK).

94 A natural process through which organic nutrients are converted into minerals that are available for plants.

The following figure shows the import, exports and production of organic fertilisers of animal and plant origin in 2011.

Table 9: Organic fertilisers (Prodcom code24156000) *(Source: Eurostat, PRODCOM ANNUAL SOLD [DS-043408])*

	Export		**Import**		**Production**	
	1,000 tonnes	**€m**	**1000 tonnes**	**€m**	**1,000 tonnes**	**€m**
EU27	518	157	46	20	4,813	678
France	28	15	613	38	525	175
Netherlands	791	80	474	25	n.a.	n.a.
Germany	117	22	76	15	n.a.	49
Italy	394	129	134	42	736	210
United Kingdom	16	6	262	38	228	31
Ireland	46	9	48	6	480	40
Denmark	19	4	3	2	19	3
Greece	0	0	4	3	19	3
Portugal	4	1	31	15	195	19
Spain	41	21	44	19	488	62
Belgium	815	52	363	16	189	38
Luxemburg	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sweden	6	2	18	3	n.a.	n.a.
Finland	2	0	0	0	5	3
Austria	59	15	84	17	73	10
Malta	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Estonia	n.a.	n.a.	3	1	n.a.	n.a.
Latvia	0	0	0	0	n.a.	n.a.
Lithuania	n.a.	n.a.	12	3	n.a.	n.a.
Poland	0	0	9	3	237	5
Czech Republic	10	2	6	2	n.a.	13
Slovakia	3	0	1	1	n.a.	n.a.
Hungary	23	4	14	4	n.a.	n.a.
Romania	0	0	8	5	n.a.	n.a.
Bulgaria	1	0	10	6	n.a.	n.a.
Slovenia	3	1	8	1	n.a.	n.a.
Cyprus	n.a.	n.a.	1	0	n.a.	n.a.

7.2. The organo-mineral fertiliser sectors

Organo-mineral fertilisers consist of organic matter with mineral compounds bound to it either chemically or by adsorption. Organo-mineral fertilisers are produced by treating humic acids or materials containing them (peat, lignite, silts) with ammonia, ammoniacal solutions of phosphates or phosphoric acid, and potassium salts.

The agronomic efficacy of an organo-mineral fertiliser is based on the interaction between the organic and inorganic components of the fertiliser which results in a dual mode of action:

- The gradual release of nutrients as a result of the mineralisation of the organic component;
- The general increase of the efficacy of the fertilisers through the presence of humified components that prevent the release or the immobilisation of nutrients from the soil.

The Italian market is the biggest market in Europe for the production and consumption of organo-mineral fertilisers and represents more than 360 000 tonnes of products per year. An European Association estimated the annual EU market of organo-mineral fertilisers at around 1.2 Mio tonnes. Other markets can be found in Spain, France, Germany, Belgium and the Netherlands.

7.3. The liming material sector

Lime is an essential raw material used in many applications (cement production, construction…) including agriculture. For instance, lime can be used for soil remediation (i.e. treatment of soils that have been polluted with hydrocarbons and heavy metals) and to correct soil acidity. However, agriculture uses less than 20% of the lime produced in Europe; the rest being used mainly in construction.

The European lime business is composed of around 100 companies employing 11 000 FTEs in 23 Member States[95] and producing an annual volume of 28.4 million tonnes of lime and dolomite with a market value representing approximately EUR 2.5 billion[96] (i.e. 500 million for the agricultural market).

As far as the agricultural sector is concerned, 4 or 5 companies are distributing liming materials across Europe. About 30 companies are active at national or regional levels. Most of them, especially SMEs, are connected with the traditional agricultural distribution network but they are generally managing a specific distribution network to better support farmers in their choice. Logistics are a specific and important aspect of this business which concerns large volume of products to be applied per hectare, which must therefore be produced as closely as possible to where they are used in order to reduce transport costs.

Commission Regulation (EC) No 463/2013 adapting Regulation (EC) No 2003/2003 to technical progress has harmonised 90% of the liming fertiliser market.

7.4. The soil improver sector

Soil improvers will be divided into two sub-categories: the organic soil improver category and the 'others' soil improver category.

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95 Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, Switzerland, Turkey, United Kingdom.

96 2009 statistics from liming industry

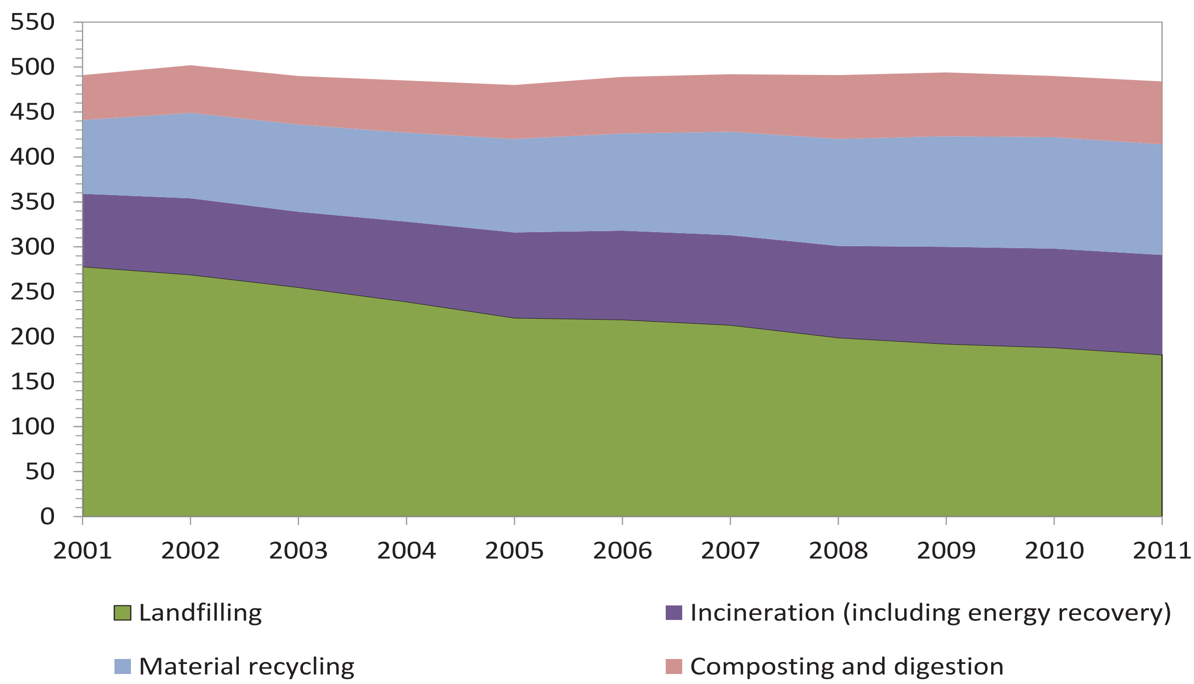
The organic soil improvers sector depends primarily on recycling activities related to biodegradable waste (to produce compost or digestate). In practice, organic soil improvers are primarily applied to improve the physical structure by adding stable organic matter to the soil. In some Member States compost and digestate can be labelled as organic fertilisers if they exceed a defined minimum nutrient content level. In this case, it is the nutrient content of the product which is valued by the company and the organic matter becomes secondary.

Eurostat data for 2011 showed that on average 15% of the municipal waste in the EU-27 was treated by composting or digestion. Belgium, Luxemburg, the Netherlands and Austria composted/digested at least 20% of their municipal waste. The Eurostat dataset also suggested that composting/digestion of municipal waste is still relatively limited in Ireland, Greece and Portugal, as well as in most of the EU-12 countries, with less than 10% of the municipal waste being composted/digested. Nonetheless, composting/digestion figures of 17% for Poland and 10% for Estonia were recorded.

However, not all Member States report similar amounts of municipal waste production per capita. Hence, the largest *per capita* municipal waste composting/digestion figures were encountered in Austria (179 kg/person), the Netherlands (142 kg/person), Luxemburg (135 kg/person) and Germany (103 kg/person).

The figure below shows the evolution of municipal waste treatment options in the EU-27 until 2011, indicating that composting/digestion grew steadily during the last decade, from about 50 kg/capita in 2001 to 70 kg/capita in 2011.

Figure 10: Treatment of municipal waste in EU-27 from 2001 to 2011 (in kg/capita). (*Source Eurostat)*



7.4.1. The EU compost market

According to ORBIT/ECN (2008), the main compost exporting countries in the EU are Belgium and the Netherlands. On average, they exported 4.5 % of their annual production in 2005 and 2006. The main reason for exports in these cases was a low national demand because of strong competition with other cheap organic material (mainly manure).

According to the European Compost Network (ECN), the potential collectable annual amount of compostable bio-waste and green waste in the EU 27 is estimated at 81 million tonnes (more than 150 kg/inhabitant/year) of which only 29.5% (or 23.6 million tonnes) are currently collected separately and treated biologically. It should be noted however that compost producers usually supply markets within a distance of 50 km[97] around the producing plant or less. This corresponds to the distance that a lorry of 25 tonnes capacity can make within an hour for an average cost of EUR 50 to EUR 60. The transport costs and other marketing expenses are then covered by a compost price of EUR 5/tonne. All plants close to borders (less than 50 km distance) contacted by ECN underlined the importance of this local market and expressed their appreciation of the end-of-waste provisions which could potentially help them to overcome the constraints of selling their compost over the border. Nonetheless, ECN also mentioned cases in Germany where compost is being transported over a distance of 200 km.

Green waste and bio-waste represent around 80% of the composted biodegradable waste in Europe. European Compost Network estimated the European compost market size at up to 10.5 million tonnes (based on the ORBIT report – 2008).

- Compost for agricultural use;
- Compost for landscaping and gardening purposes;
- Compost for professional horticultural use;
- Compost for hobby gardening.

Table 9: market volume for compost products in the EU (*Source ORBIT 2008*)

Compost product	Market share	Amount of compost in tonnes	Medium price (EUR/tonne)	Market price (EUR)
Compost for agriculture use	48%	5 016 718	4.00	20 066 872
Compost for lansdscaping and gardening use	20%	2 090 299	10.00	20 902 992
Compost for the hobby market	12%	1 254 179	12.00	15 050 154
Compost for horticulture	20%	2 090 299	12.00	25 083 590
Total	**100%**	**10 451 496**		**81 103 608**

Taking the potential of 40 million tons of compost products into the calculation, compost products with a market value of EUR 310 400 000 could be produced.

The main markets for EU compost are illustrated in the table below with the corresponding market price

Table 10: Main market for EU compost (*Source: ECN 2012 – information from 12 Member States*)

Market type	Market ranges (%)	Market value (consumer price in EUR/ton)

97 The JRC report on EU EoW criteria on biodegradable shows in its annex 21 that **37% of the EU population** is actually living within an area of maximum 100 km from intra-EU borders: http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=6869

Agriculture	45-78	0-28
Horticulture	3-15	1-29
Landscaping	6-20	5-30
Blends/soil mix	10-15	5-15
Land reclamation	2-10	1-2
Hobby gardening	12-20	5-320
Export	6-7	Not available

The demand for compost varies in Europe depending mostly on soil improvements needs and consumer confidence. The EU initiative on a proposal for End of Waste criteria for biodegradable waste could significantly enhance demand in particular in areas where there is a high demand such as in the Mediterranean countries. However, the use of compost and digestate from biodegradable waste has limited capacity to solve the soil quality problems and/or plant nutrition needs. With a typical application rate of 10 tonnes/hectare/year, only 3.2% of agricultural land could be covered if all bio-waste were collected in the EU[98]. Whilst the need for inorganic phosphate fertilisers is declining in Europe, the complete recycling of phosphorus from all available phosphate organic sources will not be able to replace them completely. However, the promotion of bio-waste reuse would still manage to reduce the reliance of the EU agriculture on imports of inorganic phosphate fertilisers.

Without the gate fee (a charge levied upon a given quantity of waste received at a waste processing facility) paid by waste collection companies, the price of bulk compost for use as an organic fertiliser or as an organic soil improver would not cover the production costs, i.e. the costs of treating biological wastes in a composting plant. The prices achieved for compost for agricultural use in Central Europe are rarely higher than EUR 5/tonne of compost and, in most cases, lower. Often, the compost is actually given to farmers free of charge. A typical scenario in Germany is that the compost producer offers the compost material, the transport and the spreading of the compost on the field as a service to farmers, usually through subcontractors, and charges about EUR 1-2/tonne for the whole service.

Compost sales to agriculture become very difficult when there is a fierce competition with manure. This is the case in Flanders and the Netherlands, where, on account of the huge animal husbandry, a surplus in manure arises and up to EUR 30/tonne of manure is paid to the users. This and a restrictive application regulation make it difficult to sell compost for agricultural uses in those countries (ORBIT/ECN, 2008).

An interesting approach to generate higher revenues from compost is applied in certain compost plants in Germany. An external company provides the marketing tools, such as billboards, information folders etc. The local plant operator prepares the mixtures according to prescriptions and pays the marketing company based on the amount of compost products sold in bulk or bagged. In order to encourage citizens to respect source separation guidelines for biowaste collection and to create trust in the manufactured compost products that they purchase, references are made to regional affiliations on the compost bags. In this way, the consumers understand that the compost bought is the output of their proper collection and sorting efforts.

98 Source: Green paper on the management of bio-waste in the European Union – COM(2008)811final.

By using this marketing approach, plants do not only guarantee good compost quality, but they are also able to combine high turnover to private customers with high revenues. In this way, they can sell around 30% of the compost production to private end-users and generate prices of up to EUR 40/ton for compost and even higher prices for compost blends. A requirement for such a strategy is that the compost plant is situated in areas with a considerable number of garden owners.

The German Quality Assurance Organisation of Compost (BGK) calculated a theoretical price for compost based on its nutrient content. The fertiliser value for compost with 8.3 kg N/tonne, 3.8 kg P_2O_5/tonne, 6.8 kg K_2O/ tonne and 25.1 kg CaO/tonne was considered to be EUR 11.3/tonne in April 2011. When the organic matter was taken into account, the monetary value of compost was calculated at EUR 22.8/tonne fresh matter.

The JRC-IPTS[99] 2008 report evaluated the theoretical recycling potential of biowaste and green waste in EU 27 at around 124 million tonnes per year. An objective of 80 million tonnes per year (150 kg/inhabitant/year) is more realistic according to ECN which means that between 30 and 40 million tonnes of bio and green compost could be produced.

Furthermore, the potential production of compost from sewage sludge was estimated between 5 and 10 Mio tonnes/year. The potential for the production of compost from other organic materials cannot reasonably be quantified, because of the very heterogeneous properties even within one sub-waste stream. The suitability of treating those materials in an aerobic composting process depends on the composition, degradability, water or nutrient content (C/N ratio). Composting is not always the first choice. Most of the food and vegetable residues, for instance, are very wet which makes them more suitable for anaerobic digestion. For bark and wood, energy generation might sometimes be the preferred option.

Composting of collected organic waste from kitchens, households, gardens, parks and industries is currently happening at about 6 000 sites in the EU of which 40% treat only green waste. The number of composting sites is increasing regularly as composting is considered as a solution for providing a renewable source of organic matter for agriculture.

According to the European Federation of Waste Management and Environmental Services (FEAD), at least 1 100 companies (public or private, national or local) are involved in the manufacturing and trading of organic soil improvers. The business model includes two different sources of revenues: the input revenue for the waste collection and disposal, and the selling of compost after composting.

7.4.2. The ‘digestate’ market

The total amount of digestate produced in Europe is estimated at 56 million tonnes fresh matter/year. However, it should be noted that not all of the digestate produced is derived from biodegradable waste only. In view of the high prices paid for electricity produced from biogas (up to EUR 0.3/kWh), digestion plants frequently rely on energy crops as input material for biogas production.

Further data on digestion facilities for biowaste (source separated organics) and municipal solid waste is provided in a study by De Baere and Mattheeuws (2010). They made an inventory of the existing plants, contracted installations and plants under construction in several EU Member States.

[99] Joint Research Centre – Institute for Prospective Technological Studies.

Table 11: Installed capacity of anaerobic digestion plants for biowaste and municipal solid waste. *(Source: De Baere and Mattheeuws, 2010)*

Member States	Total capacity (tonnes/year)	Average capacity (tonnes/year)	Number of plants
AT	84 500	12 071	7
BE	173 700	34 740	5
DE	1 732 805	23 104	75
DK	31 000	40 500	1
SP	1 495 000	59 536	25
FI	15 000	15 000	1
FR	862 000	66 308	13
IT	397 500	36 136	11
LU	23 000	11 500	2
MT	45 000	45 000	1
NL	476 500	59 563	8
PL	52 000	13 000	4
PT	85 000	21 250	4
SE	40 000	10 000	4
UK	202 500	40 500	5
Total	**5 175 505**		**166**

According to this study, the capacity of EU anaerobic digestion plants doubles every 5 years. Additionally, around 800 small agricultural co-digestion plants are located mainly in Germany, France and Austria.

The vast majority of the digestate is recycled in agriculture (80-97%). The application of digestate requires special equipment and therefore does not really fit the hobby market. It is estimated that the overall ratio of digestate to compost use on farmland is about 1/10 in countries with a well-developed compost market.

According to the European Biogas Association, several thousand tonnes of dried digestate produced from energy crops and manure are already available in the market and sold to fertiliser factories as well as transported across borders. Prices range from EUR 5 to EUR 30 per tonne dried digestate (production costs range from EUR 10 to EUR 30 per tonne excluding investment costs whereas revenues are generated by the sale of biogas), depending on the feedstock, content of nutrients and quality. Wet digestate are sold at prices of EUR 0 to 8/tonne, whereas composted digestate generally generate prices of EUR 0 to 50 per tonne; a price that competes with inorganic fertilisers and constitutes a new source of revenues for biogas plants. The wide price span is explained by different levels of demand across the EU regions, whereby regions with a high manure supply are characterised by lower digestate prices.

Very few Member States mentioned current exports or imports of digestate. Sweden and the Czech Republic explicitly mentioned not importing or exporting digestate.

Import or export of digestate is more likely to happen in smaller countries with a large digestate production and reduced uptake possibilities in the own market. As such, digestate is exported from the Flemish Region towards France, after it is treated in permitted manure treatment plants under Regulation (EC) No 1069/2009, or sanitised in the digestion plant.

This concerns mainly the solid fraction of digestate (20-25% dry matter), digestate after biothermal drying (40-45% dry matter) or thermally dried digestate (65-85% dry matter). No liquid digestate is exported, except as incubation material to set up new anaerobic digestion plants abroad.

According to the *German* Quality Assurance Organisation of Compost (BGK), the fertiliser value for digestate (with 5.2 kg N/m^3 fresh matter, 1.6 kg P_2O_5/m^3 fresh matter, 2.3 kg K_2O/m^3 fresh matter and 2.2 kg CaO/m^3 fresh matter) was EUR 6.4/m^3 fresh matter in April 2011. When the organic matter is taken into account, the monetary value of digestate is calculated at EUR 7.2/m^3 fresh matter.

Recycling rates of bio-waste, such as food, remains low. Only 7 Member States increased by 5 percentage points or more the rate of biowaste recycled between 2001 and 2010. As biowaste is estimated to constitute up to 37% of municipal solid waste in Europe, increased focus on this type of waste would be valuable. The target set out in the Waste Framework Directive that 50% of all household waste should be prepared for reuse or recycled by 2020 should be a strong incentive to value segregated sources of municipal waste.

Some materials of organic origin that do not undergo a composting or digestion process can be considered as organic soil improver for which the primary objective is not to improve the soil organic matter content but to improve other physical soil parameters such as for examples water retention or water drainage. This category of products would cover inorganic substances such as perlite, schist, sand… but also organic materials such as mulches. A description of the EU market for such products is not possible due to the lack of data. In France, the market sales of organic soil improvers other than compost and digestate is close to EUR 58 million and represent more than 600 000 m^3 of products. This category of products would cover inorganic substances such as perlite, schist, sand… but also organic materials like mulches. A description of the EU market for mulch is difficult due to the lack of data. In France, the market sale for mulches is close to EUR 58 million and represents more than 600 000 m^3 of products. The general public and municipalities are the dominant markets with respectively 70% and 30% of the market shares expressed in volume.

The EU market plastic mulch film is rather specific and does not appear in national statistic on soil improvers. However, according to industry experts, this market has a size of around 100.000 tons a year. Only 32% of the plastic mulch films are currently collected after use. The rest is burnt, landfilled or left on soils. Member States such as Spain, UK or Germany have not yet standards for biodegradability of plastic much in arable soils whereas France and Italy have already national standards in place.

It is estimated that no more than 3000 tons/year of plastic mulch films currently on the EU market are biodegradable. Only 2000 tons/year of such biodegradable plastic are able to meet the highest biodegradability requirements. The price of such films is three times higher than conventional polyethylene films. However, this would be to a large extent compensated by lower operational costs as the films would not have to be collected and recycled after each growing season.

7.5. The growing media sector

According to a socio-economic study of September 2008 conducted by the relevant industry association EPAGMA[100], the peat and growing media industry in the EU has a strong influence on three levels: 1) extraction of the raw material, 2) production of growing media, and 3) usage of growing media in the horticulture and in the hobby market.

Most of the horticultural peat producers in the EU are small- to medium-sized companies but with strong presence in rural areas where peat reserves are located. Growing media are produced also in Member States that do not dispose of peat resources. About 500 companies are involved in the production of growing media in the following countries: EE, FI, DE, IE, LV, LT, NL, PL, SE and the UK. Most of these companies are SMEs while only 14 large companies have been found[101].

The estimated number of full-time employees involved in the production, processing, development, marketing and sales of peat and peat-based horticultural products in the eleven 'producer countries' and five 'consumer countries' surveyed by EPAGMA is around 13 000.

In another survey conducted in spring 2007, EPAGMA indicated that over 37 million m^3 of growing media were produced in the EU Member States surveyed; over 22 million m^3 of this was for the professional market and about 15 million m^3 for the hobby sector (representing a market value of about EUR 1.3 million in 2005[102]). Peat was by far the main growing medium constituent representing about 29 million m^3 of the growing media produced in Europe in 2007.

The largest overall peat producing countries in the EU are Finland, Ireland and Germany, harvesting 74% of the total EU production. Most of the peat produced in Finland and Ireland is used for energy purposes.

71% of the total amount of growing media produced in the EU (over 37 million m^3) remain in the producing Member States, 25% is traded within the EU and 4% exported. However there are some deviations to this general trend: Germany is strongly export-oriented: 47% of the growing media produced in Germany remain in the domestic market, 46% go to the EU market and 7% outside the EU.

For performance, quality and availability reasons peat is the dominant constituent in the market. R&D focuses mainly on quality improvement, including peat substitution.

7.6. The plant biostimulant sector

Collecting economic data on the biostimulant sector is more challenging than for other fertilising products. The lack of a regulatory framework makes the collection of reliable statistics difficult as definitions for plant biostimulant products vary between Member States, even if there is official recognition of the product category.

According to a limited number of industry representatives and the European Biostimulants Industry Council (EBIC)[103], the European bio-stimulants market value can be estimated at

[100] http://www.epagma.com/_sitenote/www/getfile.aspx?uri=%2fdefault%2fhome%2fnews-publications%2fpublications%2ffiles.off%2fmainbloc%2fsocio_economic_study1_9864371f-20be-4d6b-9182-7e6a84816468.pdf.

[101] EPAGMA presentation 2009. (*see* http://www.rittmo.com/img/pdf/microsoft_powerpoint_-_06_-_paris_epagma_gm_harmonization_09-09-09-ppt.pdf).

[102] More recent figures are not available.

[103] EBIC is a newly created consortium composed of industries involved in R&D and marketing of biostimulants. More info on: http://www.biostimulants.eu/2011/12/economic-overview-of-the-european-biostimulants-sector/.

about EUR 400 million in 2010. It is mainly a national trade business and very few products are imported. 200 EU companies (90% SMEs) working on plant biostimulants have been reported so far accounting for 3 300 FTEs. 75% of those companies are located outside of dominant economic centres, thus providing a welcome source of skilled jobs in rural areas and small cities.

The plant biostimulant market is mainly developed in Spain, Italy, France, Portugal, the Netherlands and Germany and is growing fast, driven by economic and socio-political factors. Information provided by EBIC indicates that more than 6.2 million hectares of agricultural land are treated with plant biostimulants in Europe. The market is supposed to grow steadily at 10% or more per year (market forecast EUR 800 million in 2018 for EUR 500 million in 2013) for the foreseeable future. In 2012 R&D investments represented between 3% and 10% of annual turnover. Companies also form partnerships with universities and research organisations.

Although most important EU players are already exporting to 40 third countries i.e. South America, North Africa, Middle East and Asia. A CE mark for plant biostimulants is considered by industry as a positive marketing argument that would greatly facilitate further exports.

A recent study by PiperJaffray[104] estimates the global plant biostimulants market at approximately $ 1 billion with annual growth of about 20%. The same study indicates that the largest regional market for bio-based products (including plant biostimulants and biopesticides) is North America, currently accounting for around 40% of sales. Europe, Asia and Latin America, represent 25%, 20% and 10%, respectively. PiperJaffray indicates that there are a couple of significant explanations for these trends. First, growers in North-America and Western Europe are generally about 5-10 years ahead of developing new products. Second, most biological developers and distribution networks are situated in developed countries. Finally, middle-class demand for organic foods, residue-free produce and overall wellness has been much stronger in developed countries.

Plant biostimulants are generally sold in mixture with liquid fertilisers for high value crops. Very few of them are sold as solid products as they are typically applied in foliar treatments. An exception to this is the development of plant biostimulants applied on high value seed crops (e.g. coatings of vegetables seeds).

Factors of growth can be summarised as follows:

– Plant biostimulants use is spreading from some pioneer countries to a wider number, both within Europe and the rest of the world;

– The plant biostimulants sector has developed new innovative products targeting specific agronomic needs, thus attracting new customers;

– Biostimulant products were initially primarily used in organic production, based on organic raw materials, and on high-value fruit and vegetable crops. They are increasingly being introduced in conventional crops to respond to economic and sustainability imperatives;

– Recent high and volatile prices for agricultural inputs such as fertilisers have created incentives for farmers to optimise the efficiency of input use;

[104] PiperJaffray, Industry note, "Agriculture: Biological crop chemistry primer: green shoots through green products; August 27, 2013.

– In response to consumer demands for healthy food crops with minimal environmental impacts, farmers are looking for ways to use synthetic chemicals and inorganic fertilisers more efficiently and effectively. Plant biostimulants are therefore increasingly seen by farmers as a way to improve return on their investment in other inputs and as way to respond to consumer demands for a 'greener' or more sustainable agriculture.

7.7. Market overview of the agronomic fertiliser additives (fertilising additive)

According to a report discussed at an International Conference on slow and controlled release (CRFs) and stabilised fertilisers (SNFs) in 2013, the key characteristics of the market for such products[105] are:

- Markets for CRFs and SRNFs are globalised for already several years:
- The United States, Western Europe and Japan have historically been the 3 largest world regional markets for CRFs. The US CRFs market (700,000 tons) is almost 5 times larger than the Western European market (150,000 tons), based on product volume, and nearly 13 times larger than the Japanese market (about 50,000 tons);
- In the EU, the CRFs market distribution reads as follows (2009 data):
  - 61% of the total volumes go to professional markets;
  - 29% to consumers; and
  - 10% directly to agricultural crops
- The projected average annual growth rate to 2015 is about 1.5%-2.5% in Western Europe, slightly lower than growth rate in the US (2.0%-3.5%) and in Japan (3.0%-4.5%);
- The global market for stabilised N fertilisers (SNFs) is developing rapidly:
  - US and Western Europe consumptions of SNFs amounted to an estimated 3,381,000 and 129,000 metric tons of nitrogen in 2010 respectively;
  - Nitrification inhibitor-stabilised fertilisers are widely used in Japan; however consumption data are not available.

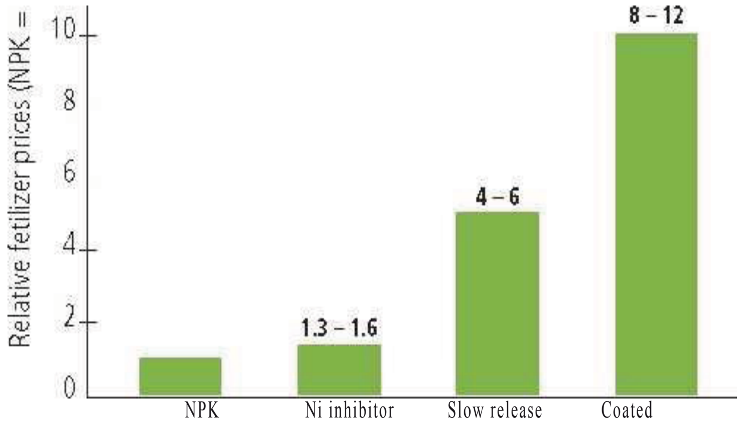
It can be observed that business is dominated by a small number of large chemical international companies which have developed new innovative products that are added to commodity fertiliser formulations. The exact number of such companies and the related number of employees active in the Union is unknown.

The main obstacle to the wider use of slow- and controlled-release fertilisers, particularly in agriculture, is their cost compared to conventional fertilisers. Farmers who grow high value crops can more easily afford to pay for slow- and controlled-release fertilisers.

Prices for controlled-release and stabilized fertilisers vary locally and seasonally. In general, the prices for slow- and controlled-release fertilisers are substantially greater than those for standard fertilisers but as raw material prices rise, the cost gap becomes smaller while the benefits from efficiency increase. Lammel (2005), at the IFA International Workshop on Enhanced-Efficiency Fertilisers presented the following figure on the price relationship of the different product groups.

[105] The products covered by this category are detailed in Annex IX

Figure 11: Price comparison of slow and controlled-release fertilisers with standard fertilisers (Adapted from Lammel 2005).



8. Summary of economic data

The following table summarises the above-mentioned data:

Table 12: Data summary per fertilising products and additives

Sub-sector	Market value (sales)	Market volume	Employment (FTE)	Companies	SME representation	R&D investment on turnover	Additional information
Inorganic fertilisers	**EUR 17 billion** **Mature market**	- WORLWIDE 170 Mio tonnes (2008-2009) (of which 60% nitrogen) - EU MARKET 16 Mio tonnes nutrients (consumption/year) (9% of world volumes	**56 400**	**1 056** companies (Source: ESTAT)	- Nitrogen production: Low - Potassium production: Low - Phosphate production: Low - Blends: High	0.05%	Market with different actors for each nutrient Developed distribution networks Low risk of substitution through organic fertilisers
Organic fertilisers (excluding manure, compost and digestate)	**EUR 1 billion** **Moderate market value increase potential**	- EU MARKET - 332 800 tonnes of organic N (2.9% of total N inputs) - 540 000 tonnes of P2O5 (15.2% of total P2O5 inputs) - On average this means about 6% of total inorganic fertiliser market	**2 600**	**95** companies	Very high (98%)	3%	Some producers also active in bio-stimulant and soil improver sectors Market developed mainly in Mediterranean countries
Organo-mineral fertilisers	**EUR 475 million** **High market value increase potential**	Producing Member States: IT, FR, ES, DE, BE, NL	**1 650**	**75** companies	Very high	1%	Main markets in IT, ES, FR, DE, NL, BE, HR + Serbia. High exports to non-EU MS. Market potential in other MS
Liming materials industry	**EUR 500 million** **Mature market**	- EU MARKET - 5.6 million tonnes	**2 200**	**30** companies active in the agricultural sector	Very low for producers Very high for distributors	0.5%	Part of a larger business sector where the agriculture market represents only 20%
Soil improvers	**EUR 500 million** **High market**	- EU MARKET 23.6 Mio tonnes of bio-	**20 000** for the whole sector	Around **8 000** companies, including	Very high	3%	The turnover of EUR 1 045 billion

Sub-sector	Market value (sales)	Market volume	Employment (FTE)	Companies	SME representation	R&D investment on turnover	Additional information
sector (mainly products from waste) recycling activities, compost and digestate)	**value increase potential**	waste collected separately out of 80 Mio tonnes collectable: 23.6 Mio tonnes 13.3 Mio tons compost produced from the 23.6 Mio tonnes collected: Green waste compost: 5.6 Mio tonnes Bio-waste compost: 4.8 Mio tonnes Sewage compost: 1.5 Mio tonnes; Mixed waste compost: 1.4 Mio tonnes Agricultural use + growing media products = 70% of consumption.	including the treatment of non-sorted waste (municipal waste and sewage sludge), the production of compost and digestate from energy crops, and source segregated raw materials and the production of mixed waste	very large waste processors and a majority of SMEs active in the production of compost and digestate from source segregated waste			results from 2 sources: First and for the largest part, the price paid by waste producers to deliver waste to the compost producing plants Second and for a minor part, the price paid by the users of compost It is this second part which might be considered as being part of the fertilising products market. We estimate it at EUR 500 Mio maximum
Growing media sector (mainly peat)	**EUR 1.3 billion** **Mature market**	- EU MARKET - 74% of EU production located in FI, IE and DE - Intense intra-EU trade (25% of global EU market) compared to other organic product markets - 37 Mio m^3 equivalent to circa 11 Mio tonnes according to EPAGMA	**13 000**	**500** companies including 14 large companies	Very high	1%	
Fertilising additives	**EUR 640 million** **High market value increase**	- EU MARKET Markets in ES, FR, IT,	**3 300**	**200** (Source: industry)	Very high	3%	

Sub-sector	Market value (sales)	Market volume	Employment (FTE)	Companies	SME representation	R&D investment on turnover	Additional information
	potential	DE, BE, DK, HU, PL, UK, NL,PT,CZ					

Source: The Fertilisers Study and industry communication

ANNEX II

Additional evidence illustrating the problems with the current regulatory framework

Fragmentation of the internal market

During the ex-post evaluation, the European growing media manufacturers association reported that they face diverging quality requirements. Growing media marketed in several Member States have to bear different labelling information and comply with divergent product standards in accordance with national rules. The compliance with those diverging rules entails additional costs for industry. They have also to be constantly aware of the new provisions introduced by the Member States in national legislation.

The following examples show that any change in national legislation has financial consequences on businesses. Many departments within one single company may be affected by a change in legislation (IT/Quality/production/Sales/Administration).

Example 1:

The first case study relates to the costs of introducing an existing substrate into a new EU Member State. These mainly concern labeling and packaging costs as the national labeling system on growing media shall apply.

Table 13: estimation of the costs of adapting the labeling and packaging of one GM to the national rules of one Member State

	Unit price	Amount of units	Price per day	Amount of days	Total costs
CASE STUDY: marketing of existing growing media according to the national rules of another Member State					**Euro**
Packaging:					6300
changing lay out - labels - legal descriptions	500	1			500
new cliché	2800	1			2800
value of old stock (1 ton à 3 euro/kg)	3000	1			3000
Marketing:					**2200**
modifications on website	200				200
modification and printing of brochures	2000	1			2000
Labour					**6730**
IT					
change description on invoices, commands,...			500	0,1	50
change standards and norms in software program			500	0,1	50
Sales/strategy/marketing					
sales meetings with customers			600	3	1800
travel costs, phone calls,...					3000
communication: new brochures, changes on website,..			300	3	900
Quality/R&D					
developing new compositions of the substrates			500	0	0
changing printing texts on the bag			500	0,1	50
defining standards and norms			600	0,2	120
price per extra analysis on product	80	2			160
hours spent on extra analysis			300	2	600
TOTAl COSTS					**15230**

Example 2:

The second case study is linked to the diverging requirements for growing media among the Member States. For example, in one Member State, specific phytosanitary products can be mixed with growing media whereas in other Member States phytosanitary products in growing media are simply not allowed. In this latter case, an application file has to be compiled and submitted to the ministry for registration of the growing media as 'mixed product'. The file must contain many analyses proving the efficacy of the mixed product as well as its effect potential negative effects on the environment. Every time, the composition of the mixed product is changed, a new file has to be submitted.

Table 14: estimation of the costs of compliance to diverging requirements among two Member States

	Unit price	Amount of units	Price per day	Amount of days	Total costs
CASE STUDY: request to market phyto product in growing media					Euro
Packaging:					6300
changing lay out - labels - legal descriptions	500	1			500
new cliché	2800	1			2800
value of old stock (1 ton à 3 euro/kg)	3000	1			3000
Marketing:					**2200**
modifications on website	200				200
modification and printing of brochures	2000	1			2000
Compiling a file to sumit at the ministry					**27000**
submission of file "produit mixte"		1			2000
external analysis on substrate (chemical, physical, biological, plant experiments..)		1			25000
Labour					**11800**
IT					
change description on invoices, commands,...			500	0,1	50
change standards and norms in software program			500	0,1	50
Sales/strategy/marketing					
sales meetings with customers			600	2	1200
travel costs, phone calls,...					3000
communication: new brochures, changes on website,..			300	1	300
Quality/R&D					
writing/ compiling the file			**500**	**10**	5000
defining standards and norms			600	0,5	300
price per extra analysis on product	80	5			400
hours spent on extra analysis			300	5	1500
TOTAl COSTS					**47300**

Mutual recognition applied to national fertilisers

The ex-post evaluation concluded that, despite the provision of a legal framework for the application of mutual recognition under the MRR, economic operators have made very little use of this mechanism for fertilising products and additives placed on the market according to national laws. Data collected for the evaluation indicated that in most countries no more than 5-10 products per year had been sold on that basis. Companies interviewed for the evaluation showed limited familiarity with MRR, and expressed fear that Member States may still block entry of their products into national markets.

The Commission has already taken steps to improve the practical implementation of the MRR for such products. For example, the Commission verifies the presence of an adequate mutual recognition clause in draft national technical rules communicated under Directive 98/34. In this regard, the Commission interpretative communication on the practical application of mutual recognition (2003/C 265/02) proposes four model clauses to Member States. Moreover, in 2011, in addition to other guidance documents clarifying the concept of mutual recognition, the Commission issued a specific guidance document[106] for fertilisers which unfortunately have not helped to remove the lack of confidence from stakeholders [107].

106 http://ec.europa.eu/enterprise/policies/single-market-goods/files/mutual-recognition/fertilisers/guidance-document-fertilisers_en.pdf.

107 According to industry associations, producers are still required to repeat tests or pay fees to have access to the market of other Member States

Businesses often allege that national authorities of Member States of destination do not accept certifications already provided by the Member State of origin. Businesses are often required to pay fees, repeat tests and prepare requests for the mutual recognition[108] that are specific to each Member State. Some producers have challenged decisions of competent authorities by filing a complaint or lodging a complaint to a national Court with the related costs (between EUR 5000 and 10.000 – Source industry federations).

Companies often do not have any information on the best tool available for trading their products to another Member State. They thus cannot choose in full knowledge of the legal situation and consequences between conforming their products to the importing Member State's rules – and possibly having to modify the product – and relying on the Mutual Recognition procedure.

This lack of knowledge on the costs and timeframe of each option is coupled with unawareness of SMEs on the applicability of the Mutual Recognition Regulation.

The views of Member States on the mutual recognition of national fertilisers are illustrated in the yearly reports on the implementation of the Mutual Recognition Regulation.

Under Article 12(1) of Regulation 7642008 (EC) laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State of 9 July 2008 (hereinafter, 'the Mutual Recognition Regulation' or 'MRR'), "*each Member State shall send the Commission on a yearly basis a report on the application of this Regulation*."

In these reports, national authorities shall state the following:

- the number of decisions taken by the competent authorities in the period, negatively affecting the marketing of products imported from other Member States, the authorities involved and the legal basis on which the decisions were taken;
- an analysis of types of products and/or sectors in which the Regulation was applied most often;
- information on the structure and functioning of the Product Contact Points (PCPs);
- an assessment of any difficulties experienced applying the Regulation and proposals for possible improvements;
- an assessment of the impact of the Regulation on the practical functioning of the MRR.

The yearly reports currently available cover the period from May 2009 (since the application of Regulation 764/2008) to December 2012.

The following main conclusions can be drawn from these reports:
(1) The opinions of the Member States have been almost unanimously positive as regards the effectiveness of the Regulation in raising the awareness of the principle of mutual recognition among those businesses involved in intra-EU trade;
(2) The majority of decisions, requests for information and complaints received by the national administrations concern specific categories of goods: articles of precious metals,

[108] These costs could range between EUR 5000 and 25 000 (Source industry federations).

foodstuffs, food additives and food supplements, construction products, **fertilisers**, automobile spare parts, electrical products, and spring water.

(3) As regards the application of mutual recognition where prior authorisation is applied, some Member States highlighted the confusion which exists for these products. Prior authorisation procedures are, as such, excluded from the scope of MRR, as explained in its Recitals 11 and 12. However, it follows from the case law of the Court of Justice that these procedures restrict the free movement goods[109].

Prior authorisation procedures imply that a company needs to formally apply to the competent authorities of the Member State where it wishes to benefit from mutual recognition before the product may be placed on the market. The MRR has left such requirements out of its scope, while recalling that they restrict the free movement of goods, and therefore are permitted only in so far as they are justified by a public-interest objective and comply with the principle of proportionality.

The Court of Justice has judged that prior authorisation procedures had gone beyond what was accepted under free movement rules.[110] It follows that this possibility left to Member States opens the door to some difficulty in its application.

For fertilising products, it has been seen as an obstacle by competent authorities as well as companies. For example, in its 2011 yearly report, CZ highlighted the difficulty it experiences with its own preauthorisation procedure: "*since [the testing bodies carrying out the 'authorization processes'] are not administrative bodies capable of taking administrative decisions, national authorities find it uncertain in what way these bodies should apply the mutual recognition principle. Moreover, it is unclear if the types of authorisation schemes, which they are in charge of, are obligatory and could be regarded as prior authorisation procedures within the meaning of Court of Justice case law and paragraphs (11) and (12) of the Recitals of MRR*."

Below are the main points highlighted in the yearly reports sent by the Member States to the European Commission on the specific issue of the application of the principle of mutual recognition to fertilising products.

2010

These first reports after the application of the Mutual Recognition Regulation from 13 May 2009 do not bring much information as many Member States underlined it was too early to draw effective conclusion on the implementation of the MRR.

However, these reports do show that some Member States had already identified fertilising products as a particular obstacle for the smooth implementation of mutual recognition.

For the period May 2009 to May 2010, the yearly reports show that 20 Member States mentioned fertilising products as one product for which they had the most queries: Belgium (21%); Germany (28%); Luxembourg (30%); Slovakia (13%); Spain (43% for the chemical sector); Portugal (21%); France (14%)…

[109] Case C-390/99, Canal Satélite Digital SL, 22 January 2002, §43 ; Case C-443/02, Nicolas Schreiber, 15 July 2004, §49-50; Recital 11 of Regulation (EC) 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State.

[110] Case C-432/03, Commission v. Portuguese Republic, 10 November 2005, §52.

Further, Austria, Hungary and Slovakia highlighted specific difficulties in dealing with requests of mutual recognition for fertilising products.

In its yearly report 2010, Austria reported fertilising products as the only goods posing particular difficulties for the implementation of the Mutual Recognition Regulation. According to Austria, fertilising products were difficult to accommodate with the Mutual Recognition Regulation in particular as regards market surveillance and controls, product checks, non-compliant products, and uncertainty for consumers because of diverging national rules.

In its yearly report 2010, Hungary indicated to have issued a written notice under Article 6 (1) of the Mutual Recognition Regulation, as well as a decision on the basis of Article 6 (2)[111] of the Regulation. Both decisions concerned "products increasing yield".

Hungary underlined that it had put in place prior authorisation procedures for fertilising products which economic operators had difficulties understanding and implementing within the framework of mutual recognition.

In its yearly report 2010, Slovakia underlined that even though there had been no decision affecting negatively the marketing of imported products, the authorities had taken "preventive measures to reclaim the principle of mutual recognition". According to Slovakia, "*these cases were not linked with unwillingness of the competent authorities. They occurred due to complicated legislation in several product categories belonging mostly to partially harmonised area such as textiles and fertilisers*".

2011

For the period May 2010 to December 2011, the Member States' yearly reports on the implementation of mutual recognition show that 12 Member States out of 27 listed fertilising products as one of the products for which they received the most queries. Further, 7 Member States mentioned having issues with products subject to prior authorisation procedures, which is often the case of fertilising products.

Apart from general issues with the implementation of the mutual recognition principle, in particular language and access to information as well as scope issues, Member States highlighted that they face particular problems when it comes to the mutual recognition of some products.

The Belgian and Austrian yearly reports for 2011 highlight the particular obstacles faced for a smooth application of mutual recognition to fertilising products.

In 2011, Belgium reported that 9% of all enquiries made to the Belgian Product contact Point related to fertilising products. The problems related to the placing on the market of fertilising products as well as with designation and labelling of the products.

The Belgian report for 2011 highlighted that in addition to the queries directly received by the Product Contact Point, the Pesticides and Fertilisers authority regularly receives enquires

[111] Article 6 of the Mutual Recognition Regulation provides for decisions taken by national competent authorities against economic operators and with the effect of prohibiting the placing on the market of a product; modifying and requesting additional testing of a product before it can be placed on the market; or withdrawing a product from the market.

about the marketing in Belgium of fertilisers and soils improvers which are already on the market in another Member States and to which the Mutual Recognition Regulation applies.

Mainly, the Belgian report highlights that differences between national rules on product designation and product categories lead to different designations being given to the same product; the differences in methods of analysis in various Member states makes it difficult for national authorities to verify the composition of products as well as to monitor them.

Finally, Belgian authorities shared their views that the application of the mutual recognition principle has lowered the safety of products, as certain products placed on the market in other Member States had to be admitted on the Belgian market even though the authorities felt there was insufficient proof that these products were safe.

The Belgian authorities concluded the 2011 report in highlighting that "*in* [their] *experience, Regulation 764/2008 is not the best way to facilitate the trade in fertilisers, soil improvers and cultivations substrates in the EU. In Belgium, the Regulation has lowered the level of protection, made monitoring more difficult and led to less transparency for consumers*."

The 2011 Hungarian report emphasises the issues of mutual recognition of fertilising products, products for which prior authorisation procedures have been put in place in Hungary:

"*The Agricultural Administration Office has already pointed out the problem regarding the implementation of the Regulation where there is no prior authorisation procedure in most EU Member States for products considered as 'yield-enhancing products' in Hungary. Clients from these Member States do not wish to accept that Hungary has a different procedure for these products. Each year some 90 to 100 clients contact the Office (in person or by e-mail, sometimes via the contact point) in connection with the mutual recognition of products, and it is difficult to make them accept that they have to request authorisation from the competent authority before placing the product on the market. It would be much simpler if, similarly to EC fertilisers, there were EU-level harmonisation in respect of the other yield-enhancing products.*

There were no cases during the implementation of mutual recognition where an authorisation for a product lawfully marketed in another Member State could be accepted without further tests being carried out. The authorisation procedure in Hungary for yield-enhancing products is stringent when it comes to the tests required to protect human, animal and plant health, consumers and the environment and in terms of the limit values applied." (emphasis added)

In its yearly report for 2011, CZ highlights the fact the difficulty in applying mutual recognition to goods subject to prior authorisation procedures: "f*or the time being there is an immense legal uncertainty involved as to how to apply the mutual recognition principle in practice*."

2012

For the period January to December 2012, the Member States yearly reports on the implementation of mutual recognition show that 20 countries out of 27 listed fertilising products as one of the products for which they received queries through their PCPs. Seven Member States specifically listed fertilising products as being a difficulty for the smooth application of the MRR. Further, 10 Member States mentioned having issues with products subject to prior authorisation procedures.

These latest reports show that over the period January to December 2012, the three Member States to mention specific issues with mutual recognition of fertilising products in 2012 had already raised the subject in 2009.

A decrease in queries received by PCP on fertilising products could be noticed in the period 2009 to 2012, which could mean either that economic operators know the rules to be applied, are unaware of the rights conferred to them by the MRR or that they do not wish to place their products on other markets[112].

Despite the general acknowledgment that the rules and principle of mutual recognition are well-known by national authorities as well as by economic operators, the issues reported in 2009 for fertilising products do not seem to have reduced in the Member States concerned.

Hungary, Austria and Slovakia raised once again the same issues they had in their previous yearly reports.

As in its 2009 yearly report, AT indicated persistent issues with the application of the Mutual Recognition Regulation to fertilising products, in particular in relation with product designation, labelling, market surveillance and the uncertainty it creates for consumers.

HU reported a total of 21 decisions taken on 'yield-enhancing products' in 2012, with three decisions resulting in products being withdrawn from the market and three other decisions to redress labelling issues of products placed on the market.

It justified the number of decisions taken in indicating that economic operators did not understand the regulatory framework for these products where prior authorisation applies.

HU called for harmonisation of the whole fertilising products market: "*the regulatory environment would be clearer if, as with fertilisers, the on-going EU level harmonisation was achieved in respect of other yield-enhancing products*".

In its 2012 yearly report, SK indicated that "*the persisting problem of application of the Regulation remains demonstrating that the product has been already lawfully marketed in another Member State. Placing on the market does not instantly mean that the product meets all the legal requirements. Verification of compliance with all requirements by the network of contact points is time, but also administratively burdensome. Problems remain also in the product groups where some prior authorization procedures exist.*"(emphasis added)

2013

The yearly reports confirmed the continuous decrease in enquiries received by PCPs on

[112] As remarked by Portugal in its yearly report 2012 on the number of enquiries to the PCP: "*economic operators either have reasonable knowledge of the Portuguese technical rules or are still unaware of the rights conferred on them by the MRR*"; and on prior authorisation: "*We would first point out that there was a substantial drop (around 36.7%) in the total number of prior authorisation requests in the period under analysis in relation to previous periods measured in years. This may be explained by a reduction in imports of products from the European Economic Area due to the economic and financial crisis. Furthermore, there was a fall in the number of prior authorisation requests subject to the MRR which may partly be the result of a reduction in imports and the tighter control brought about by the existence of technical rules*".

fertilisers. In 2013, fertilisers represented around 5% of the requests received by the PCPs while they represented more than 20% in 2009 and 2010 in some Member States. This means either that economic operators are still unaware of the rights conferred to them by the MRR or more likely that they abandoned the idea of marketing national fertiliser in accordance with the MRR.

Around 10 Member States still reported problems with the mutual recognition of fertilisers and in particular for organic-based fertilisers.

The Belgian PCP reported that an administrative decision on the basis of a technical rule was taken against a particular fertiliser for which the competent authority had some concerns.

AT confirmed high costs of checking all products against the Austrian requirements and the national requirements of the Member State of origin. The discrepancies between national rules create uncertainty for consumers.

PT clarified that during the period under analysis, economic operators lodged three appeals against the confiscation of products labelled as 'fertilisers'. The Courts decided in these three cases to maintain the decision as there were indications that the products did not comply with the applicable legislation.

Hungary, Austria and Slovakia called again for a rapid harmonisation of the rules for organic based fertilisers.

Weaknesses of the current Fertilisers Regulation

On top of the most critical deficiencies described in Section 3.3, the results of the interview programme of the ex-post evaluation have identified the following issues:

– Several Member States have reported cases of inorganic fertilisers being put on the market as EC Fertilisers to avoid the limit values for contaminants (e.g. heavy metals) that had been established in national legislation.
– The labelling requirements for EC fertilisers are not very clear and scattered in at least 5 different Articles of the Regulation
– Some safety provisions should be included for coating agents which are used in combination with fertilisers to delay the release of nutrient in the environment
– Some stakeholders considered the definition of the term ’manufacturers’ in the Regulation as not appropriate and would like different definitions for importers, distributors and producers.

ANNEX III

Evaluation of administrative burden costs

1. ASSUMPTIONS

The administrative costs have been estimated based on the following main assumptions:

– Clustering of Member States according to blocks for extrapolation to EU level

In order to estimate the workload (and thus the cost) for the placing on the market of new fertilising products, information was collected from relevant stakeholders (the Commission, four national administrations and the European Committee for standardisation - CEN) via specific questionnaires. Direct payments (e.g. fees) incurred by industry were directly collected from four national administrations. The elements obtained were extrapolated to all Member States in order to estimate the overall costs related to the management of the current EU and national legislation and the costs of marketing either EC or national fertilisers. Information about the costs of market surveillance was also gathered.

The table below summarises the main characteristics of the Member States' national policies selected for the case studies. It is assumed that all current national legislations would be more or less covered by the representative type of legislations mentioned below. However, it has not been found possible to specify the degree by which national legislations are covered by each type as they are often composed of different requirements that could fit several different types. The analysed national regulatory approaches have been ranked from the most expensive to the least expensive.

Table 15: Characteristics of the four regulatory approaches analysed in the case studies

Member State	**Main characteristics of the regulatory approach concerning the registration of new products** (classified from the most demanding to the less demanding legislation)
France	*New fertilising products not covered by existing national standards* **Full authorisation** procedure requiring from the applicant a technical file on the risks and effectiveness of its product. Data are evaluated by the French Agency for Food, Environmental and Occupational Health and Safety. If approved, the applicant receives an authorisation number to market the product. The authorisation is valid for 10 years. *Listing of national standards describing well-known products* An important number of **standards** for the well-known products have been developed. They contain lists of authorised type designations (products and ingredients), information about the methods of production and agronomic parameters (e.g. minimum nutrient content). The specific labelling information that need to be declared for each type is also described as well as the corresponding methods of analysis. These standards have reduced the costs of registration for non-innovative products which represent 95% of products placed on the market in France. A previously authorised material can be inserted in a standard only after a long period of historical use. In this case, other manufacturers can use the newly created type to market a similar product. Frequency: 9 full registration per year on average (12 in 2012, 5 in 2011).
Czech Republic	System based on notifications (free of charge) for specific product types (i.e. inorganic fertilisers, liming materials and several organic fertilisers). For other materials, an individual registration procedure including safety assessment and agronomic testing is requested. A broad set of technical specifications on labelling, production method, storage and usage need to be respected.

	Frequency: 147[113] individual registrations and 83[114] notifications in 2012.
UK	*New fertilising products* The procedure is comparable to the system as laid down in the Regulation (EC) 2003/2003 and involves the participation and consultation of a large number of actors. *Previously authorised fertilising material* A list of authorised fertiliser types exists[115], for which a number of requirements are defined. The products conforming to these requirements can be placed on the market. Frequency: 4 to 6 requests for registrations.
Netherlands	Authorisation procedure is based on a **set of generic criteria** that applies to all fertilising products (except for waste and industrial by-products for which specific criteria apply). Each producer is responsible for compliance with these criteria and might be subject to market surveillance control. Registration of national producers and traders is mandatory. Frequency: No registration dossiers for new products.

– Labour costs

Estimates of labour costs are expressed in terms of a number of Full Time Equivalents (FTE) necessary to perform the required tasks each year. As detailed information on the salary costs of administrative staff employed in the fertiliser sector are missing in the EU Administrative Cost model, information about the category 'Professional' for the targeted Member States was collected as part of the 'Action Programme Reducing Administrative Burdens in Europe'. These costs have been further increased by 25% to take into account overhead costs. This leads to an average yearly gross salary cost per FTE of kEUR 75 for industry. For the tasks performed by the European Commission, a yearly gross salary of kEUR 60 has been assumed, to which also 25% of overhead was added. Member States specific salary costs have been assessed for the 4 case studies mentioned above and are further detailed in Table 14. Finally, it was assumed that one FTE corresponds to approximately 220 effective working days.

– Number of enterprises

The number and size of enterprises affected varies largely under the different categories of products. Although good statistical data are available for the inorganic fertiliser market, there is less information about the numbers and sizes of companies producing other fertilising products. Therefore it has not been found possible to differentiate the costs for the different types of companies. Some measures to reduce administrative burden for SMEs are discussed under Section 4 of the present annex.

– Calculated costs are maximum costs

Member States have adopted different regulatory procedures for fertilising products. It is thus very difficult to give a detailed estimation of the costs of each approach. Therefore the costs calculated are expected to be maximum costs. In those Member States where one of the proposed options is already (partly) applied, the costs for both operators and Member States for enacting the option in question would be lower than calculated here.

– Calculated costs are recurring and one-off costs

[113] 32 Inorganic fertilisers, 20 organic fertilisers, 19 organo-mineral fertilisers, 45 growing media, 21 plant biostimulants, 10 soil improvers.

[114] 63 Inorganic fertilisers and 20 organic fertilisers.

[115] Cf. Schedule I of the 1991 UK Fertilisers Regulation which includes both mineral and organic fertilisers.

The costs presented for the different options are both recurring costs (e.g. costs of Fertilisers Working Group meeting, costs of labelling obligations…) that would occur once the respective options would be fully operational and one-off costs (e.g. costs of registration of new products) as they are likely to be significant costs.

– Costs related to information obligations

As one important objective of the future proposal is to correctly inform professionals and consumers about the composition of the final products, the report has tried to evaluate the costs for industry to analyse and label their products in accordance with the criteria set out for the different categories.

2. LIMITATIONS

On the basis of interviews with industry representatives, it appears that the costs related to respecting the imposed obligations can vary greatly within the same fertilising material category depending for example on the complexity of data requirements for registration dossiers. Therefore, it has not been found necessary to try to differentiate costs between subsectors (except for the one-off costs under Options 4) since variability of costs within the same subsector can already be very high.

3. DETAILED ASSESSMENT OF THE ADMINISTRATIVE COSTS

This paragraph clarifies the method followed to estimate the administrative costs of each option. Sections 3.1 to 3.5 contain information on the estimation of the costs under the scenario of full harmonisation. Section 3.6 explains how the costs under the partial harmonisation scenario have been determined.

3.1. Option 1

Costs of governance of EU and national legislation

These costs include:

- Costs of management of the Fertilisers Regulation by the Commission (A.10);
- Costs related to the organisation of Fertilisers Working Groups meetings (A.20);
- Costs of governance of national legislation (A.30).

A.10 Costs of management of the Fertilisers Regulation by the Commission

Currently, 2 FTEs are allocated by the Commission for the management of the Fertilisers Regulation. The total yearly costs are estimated at **EUR 150 000 (A.10)**.

A.20 Costs related to Fertilisers Working Group meetings

The Commission is assisted by the Fertiliser Working Group, which is composed of experts from the Member States, in the presence of observers from industry to ensure the correct implementation of the Fertilisers Regulation. Such meetings are currently organised *twice a year*. The annual costs of the meetings are described in Table 17.

Table 16: Analysis of the costs for the management of meetings of the Fertilisers Working Groups

A.20	***Travelling costs reimbursed to each national expert (EUR)***	***Number of meetings***	***Number of expert (BE is not reimbursed)***	***Annual salary costs[116] (EUR)***	***Time spent (fraction of FTE/year)***	***Annual Administrative costs (EUR)***
Commission	*750[117]*	*2*	*27[118]*	*n/a*	*n/a*	*40 500*
Member States	*Travelling costs for additional national experts*					
	750	*2*	*8[119]*	*n/a*	*n/a*	*12 000*
	Salary costs for preparing and attending the meetings					
			34	*72 250[120]*	*0.018*	*44 220*
Industry	*Travelling costs for industry experts*					
	750	*2*	*20*	*n/a*	*n/a*	*30 000*
	Salary costs for preparing and attending the meetings					
			20	*75 000*	*0.018*	*27 000*
Total						***153 720***

A.30 Costs of governance of national legislation

The costs related to the management of national legislations have been estimated based on information collected from four Member States representing the most important regulatory approaches for fertilising products. The figures obtained are then extrapolated to the EU 28 Member States to determine the overall costs relating to the management of national legislations in the EU. These costs cover the management of national legislation and the preparation of technical files supporting requests for derogation made in accordance with Article 114 TFEU.

Table 17: Analysis of the costs for managing national legislations

116 For the Commission, the costs are included in the management of the Fertilisers Regulation.
117 Average reimbursement of travelling costs per Member State expert except Belgium.
118 Croatia joined the EU on 1st July 2013 but has not yet attended the meeting of the FWG as Member State.
119 On average, 34 Member States representatives are attending FWG meetings. As 26 are reimbursed, 8 have to be reimbursed by their competent authorities for their travel expenses.
120 Based on averaged labour costs for the category 'professionals' (overhead included) in each Member State as determined by the external consultant as part of the Fertilisers Study. See table14

A30	*Country specific annual salary costs*[121] *(EUR)*	*Time spent (number of FTE/year)*	*Annual Administrative costs (AAC) (EUR)*
France	*100 000*	*2.5*	*250 000*
Czech Republic	*40 000*	*0.2*	*8 000*
United Kingdom	*76 000*	*0.3*	*22 800*
Netherlands	*75 000*	*1*	*75 000*
Average for 1 MS	*72 250*	*1*	*88 950*
Total for 28 MS			*2 490 600*

As it is assumed that those 4 MS are representative for the EU average (in terms of e.g. wages, size of the country, etc.), the figure above represents only a rough estimation of the costs of managing national legislation.

Table 18: Summary of the costs incurred by all stakeholders for the management of the EU and national legislation under Option 1 as identified under A.10, A.20 and A.30 above

Stakeholder groups	***A.10** (EUR)*	***A.20** (EUR)*	***A.30** (EUR)*	***Total annual costs** (EUR)*
Commission	*150 000*	*40 500*	*–*	***190 500***
Member States	*–*	*56 220*	*2 490 600*	***2 546 820***
Industry	*–*	*57 000*	*–*	***57 000***
Total	***150 000***	***153 720***	***2 490 600***	***2 794 320***

Costs of registration and standardisation

The assessment of these costs has been divided into four categories:

- The costs related to the preparation and assessment of applications for the registration of fertilisers under EC law (B.10);
- The costs related to CEN standardisation activities (B.20) which cover:
  - The annual costs to prepare draft standards and maintain published EN standards for the product categories covered by the current CEN mandate on EC Fertilisers (B.21),
  - The costs of participation in CEN meetings (B.22),
  - The EU budget allocated to the CEN CENELEC Management Center (CCMC) to manage the current mandate (B.23);

[121] Overhead costs included. Source: the Fertilisers Study.

- The costs related to the registration of fertilisers as national fertilisers (B.30) per year for the whole sector;
- The costs related to the Mutual Recognition Regulation of national fertilisers (B.40).

Costs related to the preparation and assessment of applications for the inclusion of fertilisers as 'EC Fertiliser'(B.10)

Since the entry into force of the current Fertilisers Regulation, 18 technical dossiers for the inclusion of new types in its Annex I were submitted to the Commission and then examined in the Fertiliser Working Group. This corresponds to an average of 3 dossiers per year. The **costs for the Commission** for dealing with these dossiers is included in the cost calculated before under A.10.

The cost for Member States is composed of the costs for the Member State supporting the dossier and the costs for the other Member States to review the application for listing the new type.

In general, new entries in the Fertilisers Regulation are subsequent to its approval for national fertiliser. Therefore, the costs for the supporting Member States are covered by the costs for registration of national fertilisers calculated under B.30.

The costs for industry relate to the submission of a technical dossier for analysis by the Fertiliser Working Group. The most sophisticated and costly national registration procedure (i.e. France) was taken as the basis for this calculation given that companies often use the same information that was previously submitted for obtaining a national authorisation/-registration. It is therefore assumed that the cost related to the preparation of a technical dossier at EU level amounts to approximately EUR 50 000[122]. Multiplied by the average number of 3 dossiers per year, this translates into a total annual cost of **EUR 150 000** (B.10).

Only the costs to evaluate the substance in the framework of the Fertilisers Regulation have been evaluated (i.e. agronomic efficacy, safety of products, availability of test method). The REACH registration costs have not been taken into account as they do no result from the requirements of the current Fertilisers Regulation – even though according to the technical guidance, dossiers submitted under REACH could be used to assess the safety of a substance used as the main component of a new fertiliser type.

Costs related to CEN standardisation activities (B.20)

In order to fully understand the cost related to the development of standards by the European Committee for Standardisation (CEN), a description of the standardisation work is available in Section 4 of this annex.

The standardisation work related to the Fertilisers Regulation is currently performed by CEN/TC 260 'Fertilisers and liming materials'[123]. The total cost related to this work can be divided into the costs of drafting standards (Table 20), the costs of TCs meetings to discuss and approve the EN standards (Table 21) and the EU budget to support CEN

[122] The highest costs reported in the Fertilisers Study.
[123] The estimates presented in this section are based on information provided by CEN/TC 260 'Fertilisers and liming materials' (cf. Mandates M 335, M 418 and M 454).

activities in relation with the Mandate M 335 on fertilisers and liming materials (Table 22):

Table 19: Analysis of the annual costs to support the drafting of EN standards

B.21 – Annual costs to prepare 10 draft standards for inorganic fertilisers and liming materials[124]	*Number of Working Groups*	*Annual salary costs (EUR)*	*Number of participants*	*Time spent (fraction of FTE equivalent)*	*Annual Administrative costs (CA) (EUR)*
Member States (National Standardisation Bodies) supervision work only	*n/a*	*72 250*	*27*[125]	*0.045*[126]	*87 780*
Industry	*6*	*75 000*	*10*	*0.015*[127]	*67 500*
Others (universities…)	*6*	*75 000*	*7*	*0.020*[47]	*63 000*

Table 20: Analysis of the costs for technical committees to discuss and approve the content of the draft EN standards

B.22 – Participation in CEN/TC 260 meetings	*Number of annual meetings of the Working Groups*	*Travelling costs (EUR)*	*Annual salary costs (EUR)*	*Number of participants*	*Time spent (fraction of FTE equivalent)*	*Annual Administrative costs (CA) (EUR)*
Member States	*6*	*750*	*n/a*	*5*	*n/a*	*26 250*
	6	*n/a*	*72 250*	*5*	*0.03*[128]	*67 500*
Industry	*6*	*750*	*n/a*	*12*	*n/a*	*63 000*
	6	*n/a*	*75 000*	*12*	*0.03*	*189 000*

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124 Continuous work outside the Technical Committee meetings. CEN TC 260 has developed around 100 EN standards in 10 years i.e. on average 10 standards annually.

125 Croatia as newly Member States has not been taken into account in the calculation of the costs for drafting EN standards or participating in CEN meetings.

126 It is assumed that one representative per Member State is involved in the follow-up of the work done by CEN/TC 260. Based on the fact that around 100 standards have been developed since 2003 for inorganic fertilisers (on average 10 per year) and 1 day per Member State expert is accounted for per standard, the time spent per expert amounts 1day x 10 standards per year/-220 working days = 0.045.

127 The average size of a working group is 10 people. Assuming that 20 days of work are needed per standard, this leads to 2 days of work per person for 1 standard. Since more than 1 standard is developed per WG annually per TC (on average 10 standards/6 Technical Committees = 1.6), the average number of days per person to develop 10 standards for industry is 3.2. Expressed in FTE (3.2/220 = 0.015). For other stakeholder, the same reasoning would apply with a final result of FTE = 0.02.

128 7 days divided by 220 working days. Source: the Fertilisers Study.

Others (universities…)	*6*	*750*	*n/a*	*13*	*n/a*	*68 250*
	6	*n/a*	*75 000*	*13*	*0.03*	*204 750*

For each category of participants, the first line presents the travelling costs and the second line the salary costs of the persons attending the meetings.

Table 21: Description of the costs relating to the current CEN mandate on fertilisers and liming materials

B.23 – CEN Management Centre[129] – EU budget allocated to CEN/TC 260	*Since 2003, an overall EU budget of EUR 1 375 000[130] (corresponding to the development of around 100 standards) has been allocated to the CEN Management Centre by **the Commission**. This corresponds to an average annual budget of **EUR 137 500** for developing 10 standards.* *The EU budget covers the costs of the CEN/TC Secretariat for organising the meetings of the CEN/TC and its related working groups, drafting the documents and the minutes of the meetings, the sampling and distribution of samples, travelling costs of CEN/TC Secretariat, service contract for experimental work etc.*

Costs related to the registration of fertilisers as national fertilisers (B.30)

Data from four Member States representing the most common procedures for the placing on the market of national fertilisers were collected through the Fertilisers Study in order to estimate the costs of registration for the Member State authorities and industry (including the costs of the development of national standard where relevant).

The Fertilisers Study has found that the costs incurred by the **competent authorities** relate to the analysis and management of the risks, liaison with industry, accredited laboratories and enforcement activities and drafting legislation. The costs borne by **industry** vary largely depending on the regulatory system in place. It ranges from the costs relating to the demonstration of compliance to general safety and agronomic criteria to the costs of preparation and submitting application files (sometimes fees and additional testing might need to be paid) and the development of national standards.

Table 22: Description of the costs to include new fertilising products in national legislation

B.30 – Annual costs for inclusion of national fertilises under various regulatory scenarios[131]	***Registration fees and costs of additional testing/per request and per company(EUR)***	***Preparation of the technical dossier for application/per request and per company****(EUR)*	***Average number of products registered annually***	***Country specific annual salary costs****(EUR)*	***Time spent (fraction of FTE/year)***	***Administrative costs (AC) to include new national fertiliser*** *(EUR)*

129 Cf. CEN Annual Report 2010, page 147. The CEN Management Centre is financed for 54% by the EU and EFTA members, for 46% by Membership i.e. National Standardisation bodies and for 2% by other sources.

130 EU contributions for mandates M335 (Parts I , II and III), M418 and M454.

131 Depending on the national regulatory framework, this includes registration fees and/or additional testing and/or development of standards and/or compliance check to generic safety criteria.

France – Competent authorities	–	–		*100 000*	*3.0*[132]	*300 000*
France – Industry	*50 000*[133]	*8 000*	*30*	–	–	*1 740 000*
The Czech Republic – Competent authorities	–	–		*40 000*	*1.5*	*60 000*
The Czech Republic – Industry	*6 000*	*5 000*	*160*	–	–	*1 760 000*
The United Kingdom[134] – Competent authorities	– –	– –	– –	– –	– –	– –
The United Kingdom – Industry	– –	– –	– –	– –	– –	– –
The Netherlands – Competent authorities	–	–	–	*75 000*	*0*	*0*
The Netherlands – Industry	–	*5 000*	*20*	–	–	*100 000*
Average costs for Competent authorities to manage all requests	–	–		–	–	*105 025*

[132] For example in France, the competent authority takes a decision on prior authorisation for products not covered by existing standards on the basis of assessment of the risks and effectiveness of the product carried out by ANSES: the French Agency for Food, Environment, Occupational Health and Safety. 3 FTEs are dedicated to this task.

[133] Tasks related to the full registration procedure. In France, the registration of new products based on existing standards represents 90% of the requests and only 10% of all applications follow the full registration procedure

[134] In the UK there is no requirement for manufacturers to register products, nor are there any government programs in place to evaluate products. It is up to manufacturers in this country to ensure that they comply with the relevant legislation when marketing fertilisers. The UK authorities rely on their self-compliance in doing so, and also on checks of compliance being made by trading standards officers and other enforcing agencies, to ensure that the public is not being conned or sold sub-standard goods.

***Average costs for industry to include a new type or ingredient in a positive list or get a market authorisation*[135]**	–	–		–	–	*900 000*
Annual total costs for EU-28 – Comp. auth. – Industry	– –	– –		– –	– –	***2 940 700*** ***25 200 000***

As mentioned under Table 17, the figure above can only be considered as a rough estimation of the costs of registration of new fertilising products as the four Member States may not be representative as regards the size of the fertiliser markets in the 28 MS.

Costs related to the Mutual Recognition Regulation (B.40)

According to the survey on administrative costs carried out in the Fertilisers Study, the costs for competent authorities to analyse requests for mutual recognition of national fertilising products have been estimated to be 0.2 FTEs x 28 x EUR 75 000 = **EUR 420 000 (B.40)** for the whole EU.

The costs of market surveillance of products placed on the market under the Mutual Recognition principle is covered by the costs detailed in Section C.10.

Table 23: Summary of the total annual costs incurred by different stakeholders for the placing on the market of new products (EC and national brands) under Option 1

Stakeholder groups	*B.10 (EUR)*	*B.21 (EUR)*	*B.22 (EUR)*	*B.23 (EUR)*	*B.30 (EUR)*	*B.40 (EUR)*	*Total annual costs (EUR)*
Commission	–	–	–	*137 500*	–	–	***137 500***
Member States	–	*87 780*	*93 750*	–	*2 940 700*	*420 000*	***3 542 230***
Industry	*150 000*	*67 500*	*252 000*	–	*25 200 000*	–	***25 669 500***
Others	–	*63 000*	*273 000*	–	–	–	***336 000***
Total	***150 000***	***218 280***	***618 750***	***137 500***	***28 140 700***	***420 000***	***29 685 230***

Costs of market surveillance

Costs related to the market surveillance of fertilising products (C.10)

The Member States competent authorities consulted during the collection of data for the four case studies were unable to differentiate the costs of market surveillance of

[135] Total costs for industry divided by 4 Member States.

EC Fertilisers and national fertilisers (inorganic national fertiliser, liming materials, organic fertiliser, soil improver, growing media, plant biostimulants). Market surveillance authorities carry out controls at the premises of producers, retailers, farmers and at the external borders of the EU for products imported from Third Countries.

The frequency of controls depends very much on the priorities of the authorities. Some Member States ensure that every national producer is controlled every 1 to 5 years depending on risk assessment and previous controls. Other Member States clearly mentioned that the control of fertilisers is not a high political priority and that controls depend on the availability of the necessary budget.

Table 24: Costs of market surveillance for all fertilising products currently on the market *(Source: the Fertilisers Study)*

C.10. Total annual costs for market surveillance	***Annual budget for analysis*** *(EUR)*	***Country specific annual salary costs of inspectors*** *(EUR)*	***Time spent by inspectors (fraction of FTE/year)***	***Annual administrative costs (AAC)*** *(EUR)*
France	*200 000*	*100 000*	*11.5*	*1 150 000* *200 000*
The Czech Republic	*26 000*	*16 000*	*3*	*48 000* *26 000*
The United Kingdom		*76 000*	*0.8*	*60 800*
The Netherlands		*75 000*	*1.3*	*97 500*
Average costs				*395 575*
Total for 28 MS				***11 076 100***

3.2. Option 2

The description of several variants is required to describe the different roles of public administration and EU scientific agencies in the implementation of Option 2.

Variant 2A: only Member States administrations and the Commission review applications for listing types in the annexes of the revised Fertilisers Regulation.

The Scientific Committee for Health and Environmental Risk – SCHER - has been used in the past to evaluate the potential negative impacts to the environment or human health of the presence of contaminant in inorganic phosphate fertilisers or for its opinion on the risks for the environment and human health of an existing type of the Fertilisers Regulation.

The possibility to have recourse to SCHER has been discarded because it has been considered that it would not have enough staff[136] to assess the potential huge number of applications for registration of new types (up to 1000 – *see* pg 51) in the annex(es) of the regulation.

Variant 2B: the peer-review process for applications will be managed by the European Chemicals Agency (ECHA). An opinion will have to be delivered for each new entry proposed.

Variant 2C: the peer-review process for applications will be managed by the European Food Safety Authority (EFSA). An opinion will have to be delivered for each new entry proposed.

<u>Costs of governance</u>

Under variant **2A** (assessment by the Fertilisers Working Group), it is assumed that in the Commission Services about 5 FTEs[137] (**A.10: EUR 75 000 x 5 = EUR 375 000**) would be required to manage the different requests for inclusion of new fertiliser type in the annex(es) to the future regulation.

Under variant **2B** (assessment by ECHA) and **2C** (assessment by EFSA), the figure for FTEs in the Commission mentioned for variant 2A will be lower, as some of the tasks for the peer-review process will be managed by such agencies[138]. Compared to variant 2A, it is likely that only 2 FTEs would be required (**A.10: EUR 150.000**).

For **all variants**, members of the Fertilisers Working Group would have to meet more frequently to discuss mainly about applications for the registration of new fertiliser types. Practically, it has been assumed that there would be at least 2 meeting per year for each category of products covered by the proposal[139]. The costs related to Fertilisers Working Group meetings will thus be multiplied by 4 compared to Option 1 (current situation) where the costs for two annual meetings were calculated[140] (**Total costs A.20: EUR 614 880**).

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[136] The SCHER is composed of 6 members whereas one Commission official ensures the secretariat of the Committee. In comparison the number of experts dealing with the assessments of biocides in ECHA or plant protection products in EFSA is respectively 65 and 25.

[137] 10 FTEs for the first five years to deal with requests to examine the current products on the market by Competent authorities. The number of FTEs could be reduced over the years as more and more products are listed in positive lists and the number of new applications would go down. 5 FTEs after 5 years, 3 FTEs after 10 years and 2 FTEs after 15 years. Over the presumed commercial life span of a product of 20 years, 5 FTEs would be required.

[138] The peer-review work of the Agencies will consist in organising the review of the conclusions raised by the applicant supporting the inclusion of a specific type in the list(s) of type specifications annexed to the Regulation. Meetings of experts will be organised and at the end of the review an opinion will have to be issued whether the new type can be listed and under which conditions/specifications. The opinion will then be taken by the Commission in order to draft the implementing act amending the list of types.

[139] WG 1: inorganic fertilisers and liming materials including agronomic additives; WG 2: organic and organo-mineral fertilisers. WG 3: soil improvers and growing media; WG4: plant biostimulants.

[140] It is assumed that the composition of the different working groups will be similar to the composition of the current Working Group on inorganic fertilisers.

Under **all variants of Option 3**, there would be no more cost of governance of national legislation as the placing on the market of fertilising products would be fully harmonised (**A.30: EUR 0**).

Finally, **EFSA or ECHA** will need new staff to perform the assessment of the newly harmonised products. These additional costs are reported in a new column on costs for ECHA/EFSA as **'A.40'**. **Costs borne by ECHA/EFSA are allocated respectively to 'industry' under Option 2B (fees)** and **to the Commission under Option 2C (EU Budget contribution)**.

In order to estimate the additional costs of assessments of newly harmonised products, it is important to estimate the number of products not yet harmonised and the number of corresponding types. In the current Regulation, one hundred types are listed in Annex I, and about 2 400 EC Fertilisers products are placed on the market. On average, 1 type allows the placing on the market of 24 EC Fertilisers. No equivalent information is available for national fertilisers but it would be assumed that based on current market shares of EC Fertilisers and national fertilisers, the number of new types of inorganic fertilisers to be examined for inclusion into the new Fertilisers Regulation could amount to 30-40.

For the other categories of products, the number of new products and the number of new types that would have to be listed in annex(es) to the new regulation have been estimated with industry representatives as explained in the table below[141]:

Table 25: Number of non-harmonised products and corresponding types that would have to be listed in the future proposal

	Range of non-harmonised products in the EU market	***Range of types covering the non-harmonised market***
Inorganic fertilisers[142]	*840-960*	*30-40*
Organic fertilisers	*1 000-1 100*[143]	*200-220*

141 This information was received from various industry associations on their review of several national legislations following this regulatory approach. Only ranges of products and type designations could be estimated by industry.

142 The cost estimates presented above for inorganic fertilisers are based on the assumptions that Member States agreed to maintain all types already included in Annex I to Regulation (EC) No 2003/2003. As a consequence, only those types that are currently authorised under national legislation but not covered by an existing type in Annex I would have to be included (plus further new types that are not yet in Annex I nor authorised under any existing national legislation). In practice, however, Member States will probably want to see evidence for some of the existing types in Regulation (EC) No 2003/2003 that would actually comply with the newly introduced limits for contaminants, so that the reduction in costs would be small.

143 Industry reviewed 10 national legislations to determine the number of types to be included in the Annexes of the revised Regulation.

Organo-mineral fertilisers	*600-700*	*25-30*[144]
Liming materials[145]	*150-200*	*10-15*
Soil improvers	*24 000-32 000*[146]	*30-40*[147]
Growing media	*450 000-550 000*	*40-60*
Plant biostimulants and agronomic additives[148]	*625-665*	*625-665*[149]
Range of new types under Option 2		*960-1 070*

Under **variant 2B,** it has been assumed that the tasks allocated to **ECHA** would include an evaluation of the registration and preparation of an authorisation dossier. The REACH Regulation requires that **companies pay a fee** for certain services delivered by ECHA. These fees[150] are intended to cover the cost of the service provided in accordance with the volume of the product placed on the EU market per manufacturer. For the sake of clarity, the costs for the tonnage band of 10-100 tonnes/year under REACH have been taken as a reference for further calculation. The standard fees would then be respectively equivalent to EUR 3 454 plus EUR 53 300 for one type. Taking these costs into account for about 960 and 1 070 new types, the costs for industry would range between EUR 54 483 840 and EUR 60 726 780 for the registration of all existing products. If we assume a 20 year period by which all product types should be listed and a medium cost of EUR 57 605 310, the annual costs for ECHA registration and analysis of requests for authorisation would amount to about EUR 2 880 265 **(A.40 for variant 2B)**.

Under **variant 2C, EFSA** would receive **a payment from the Commission** to carry out the peer-review process of the not yet harmonised products. Based on the

144 A survey was organised by industry in 6 Member States to collect information on the number of organo-mineral fertilisers placed on the market and the number of corresponding types.

145 90% of the liming materials market has been harmonised by Commission Regulation (EU) No 463/2013. Hence only requests for a limited number of additional types are expected.

146 On average 8 000 installations in Europe are producing 3 to 4 soil improvers. It was not possible to differentiate installations treating source-separated input materials from the installations treating also industrial waste such as sewage sludge.

147 The Commission has identified 20 organic soil improver types in 6 national legislations (ES/BE/CZ/DE/FI/IT). It has been assumed that the examination of other national legislation would at least double the number of types. The CEN report CR 13456:1999 listed 31 type descriptions for soil improver and soil improver constituents.

148 Some agronomic additives are already harmonised in the Fertilisers Regulation.

149 In this case the number of product is similar to the number of type designations as each plant biostimulant and agronomic additive is registered individually.

150 The details on the fees and charges payable to ECHA can be found in the Commission Regulation (EC) No 340/2008 of 16 April 2008, as amended by the Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013.

experience of the EFSA Panel on the review of plant protection products, the costs of peer-review of one plant protection product has been estimated at EUR 20 000. Taking into account the number of types that would need to be included in the new legislation (between 960 and 1 070 types), the costs for the Commission could be evaluated between EUR 19 200 000 and 21 400 000 for all products. Again if a period of 20 years is assumed by which all the products would have been assessed, an annual cost of **EUR 1 015 000 (A.40 for variant 2C)** could be estimated.

The following tables summarises the governance costs under the various variants of Option 2.

Table 26: Summary of governance costs under variant 2A

Total annual costs (EUR)	*A.10*	*A.20*	*A.30*	*Total*
Commission	*375 000*	*159 870*	–	***534 870***
Member States	–	*229 530*	–	***229 530***
Industry	–	*225 660*	–	***225 660***
Total	***375 000***	***614 880***	–	***989 880***

Table 27: Summary of governance costs under variant 2B

Total annual costs (EUR)	*A.10*	*A.20*	*A.30*	*A.40*	*Total*
Commission	*150 000*	*159 870*	–	**–**	***309 870***
Member States	–	*229 350*	–	**–**	***229 350***
Industry	–	*225 660*	–	***2 880 265***	***3 105 925***
Total	***150 000***	***614 880***	–	***2 880 265***	***3 645 145***

Table 28: Summary of governance costs under variant 2C

Total annual costs (EUR)	*A10*	*A20*	*A30*	*A40*	*Total*
Commission	*150 000*	*159 870*	–	*1 015 000*	***1 324 870***
Member States	–	*229 350*	–	**–**	***229 350***
Industry	–	*225 660*	–	**–**	***225 660***
Total	***150 000***	***614 880***	–	***1 015 000***	***1 779 880***

Costs of registration and standardisation

It can be assumed that the **costs for industry** to prepare application dossiers for types will be higher than the average today as the data requirements will probably be higher. Since several years the Commission has observed that listing a new type or revising an existing type is generating much more questions from the Member States than in the past, especially as regards the safety aspects. This general trend is parallel to the overall strengthening of the regulations of farm commodities (e.g. plant protection products, feed additives…) which are destined to be transformed in food commodities. This would justify an increase in dossier preparation costs. It has been assumed that dossier preparation costs would approximately amount to EUR 50 000.

Member States would have to conduct the first evaluation of dossiers submitted and then participate in the peer-review process. Compared to Option 1 (in particular costs under B.10), Member States would need more FTEs per dossier as the dossiers would be more comprehensive and their number would increase. According to the figures mentioned above between 960-1 070 new types would have to be evaluated and peer-reviewed. Consequently, the number of FTEs would increase to 5 FTEs as for the Commission. Considering that a time span of 20 years would be needed to register all the types identified, each national expert would have to deal with approximately 10 peer-review processes annually. The costs for **the Commission** would be covered by the costs of governance reported under A.10.

The costs for participation at the Fertilisers Working Groups meetings are covered under A.20. Given that the costs for ECHA or EFSA are already included under the governance costs (A.40), there is no need to make a distinction between the variants here. Therefore B.10 covers the costs of preparation of application by **industry** and the costs of peer-review by the experts of **the Member States** before a final decision on the application is taken during a meeting of the Fertilisers Working Group.

Table 29: Costs related to the preparation and assessment of applications for the registration of products not yet harmonised under variants 2A, B and C

B.10 (EUR)	Number of national experts	Number of Member States	Annual salary costs (EUR)	Time spent (fraction of FTE equivalent)	Costs of preparation of application (EUR)	Number of types examined per year during 20 years	Annual costs
Member States	5	28	72 750[151]	1	–	–	10 185 000
Industry	–	–	–	–	50 000	50	2 500 000
Total							**12 685 000**

Costs of standardisation work will mainly concern fertilising products for which European analytical methods (EN Standards) have not been developed so far i.e. mainly organic fertilisers, plant biostimulants and agronomic additives.

For plant biostimulant, the objective is not to check the content of defined forms of plant nutrients in the final product but to verify that the ‘active’ substance is present in the amounts claimed/guaranteed by the manufacturer. The number of EN standards for plant biostimulants would in principle be considerable as every active substance, where relevant, as claimed by the manufacturer (e.g. marker substances in case of complex mixture, such as plant/algae) would have to be identified through an appropriate analytical method to be part of an individual CEN standard. The European Biostimulant Industry Council has identified 100 active substances for which CEN would be required to develop specific analytical methods.

In addition, some analytical methods for agronomic additives that are not yet harmonised would have to be developed albeit in lesser amounts than for plant

[151] Average of the salary costs (including overhead) for the four case studies described under Option 1.

biostimulants as the number of new additives will likely be lower than for plant biostimulants. For organic fertilisers, some existing EN standards for soil improvers or growing media would have to be checked for their reliability.

The costs of developing and maintaining one standard could be derived from the costs of standardisation calculated under Option 1[152] (EUR 97 450).

Table 30: Summary of the costs for developing standards (B.20) under all variants for Option 2 (in EUR)

Organic fertilisers	97450 x 20 =	1 949 000
Agronomic additives	97450 x 20 =	1 949 000
Plant biostimulants	97 450 x 100 =	9 745 000
Total costs under B.20 (standardisation activities)		13 643 000
Annual costs assuming that 20 years will be needed to harmonise the whole market		**682 150**

The allocation of costs between the Commission, Member States, industry and other stakeholders involved in the preparation and development of the standardisation work (B.20) would be similar to the distribution of costs calculated under Option 1.

Costs for managing national legislations and requests for mutual recognition of products would disappear (B.30 and B.40).

Table 31: Summary of the costs for the placing on the market of new products under variants 2A, 2B or 2C

	B.10	***B.20***	***B.30***	***B.40***	***Total annual costs** (EUR)*
Commission	*–*	*96 180*	*–*	**–**	***96 180***
Member States	*10 185 000*	*126 880*	*0*	*0*	***10 311 880***
Industry	*2 500 000*	*223 745*	*0*	*0*	***2 723 745***
Others	*–*	*235 345*	*0*	*0*	***235 345***
Total	***12 685 000***	***682 150***	***0***	***0***	***13 367 150***

3.3. Option 3

As for Option 2, several variants will be analysed to describe the roles of public administration and different EU scientific agencies in the implementation of Option 3.

Costs of governance

[152] The sum of the annual costs mentioned under B.21, B.22 and B.23 for Option 1 divided by 10 as on average, CEN TC/260 develops 10 standards annually.

Under variant **3A** (assessment by the **Commission expert group**), it is assumed that 3 FTEs[153] at Commission level (**A.10: EUR 75 000 x 3 = EUR 225 000**) would still be required to manage the different requests for inclusions of ingredients in the legislation. Although most of the ingredients for the manufacture of inorganic fertilisers are known, the level of knowledge is different for other product categories[154] and might require a longer 'phase-in' period to reach fully harmonised lists of well-described ingredients – especially if each ingredient is defined with a significant level of relevant details to allow their clear identification and a common Union-wide understanding. Even after a reasonable implementation period, frequent adaptations to technical progress of the annexes will be necessary.

Under variant **3B** (assessment by **ECHA**) and **3C** (assessment by **EFSA**), the number of Commission staff involved in the peer-review process could be slightly reduced and therefore fewer FTEs would be required to ensure the tasks of peer-reviewing existing ingredients, reviewing new ones and adapt the annexed lists, where necessary. Compared to variant 3A, it is likely that only 2 FTEs would be required over the longer term (**A.10: EUR 150 000**).

As mentioned in all variants of Option 2, Members of the Fertilisers Working Group would have to meet regularly to discuss the applications for the registration of new ingredients. Practically, it is assumed that the costs related to Fertilisers Working Group meetings would be less than the costs indicated for the variants under Option 2 as there would be a lower number of requests for registration of new ingredients compared to 'types' (i.e. several types – each requiring separate listing under Option 2 – could be composed of different mixtures of the same ingredients – requiring only 1 listing). Compared to Option 1, the costs have been assumed to be multiplied by 3 (**total costs A.20: EUR 461 160 for all variants of option 3)**.

Under all variants of options 3, there would be no more cost of governance of national legislation as the placing on the market of fertilising products would be fully harmonised (**A.30: EUR 0**).

On the other hand, as for variants 2B and C, the agencies will need staff to assess the request for inclusions. Based on the information from the Biocides Directive, the Plant Protection Product Regulation and REACH, these costs might be substantial and would have the form of fees that industry would have to pay to ECHA or budget subsidies from the Commission allocated to EFSA.

In order to estimate the additional costs of assessments of newly harmonised products, it is important to estimate the number of products not yet harmonised and the number of new ingredients that would be required to manufacture those products.

Based on the information received from the various industry associations and review of several national legislations following this legislative approach, the number of products

[153] 5 FTEs for the first five years to deal with requests to examine requests for listing ingredients contained in the products currently on the market. The number of FTEs could be reduced over the years as more and more ingredients are already listed in positive lists. 3 FTEs after 5 years, 2 FTEs after 10 years and 2 FTEs after 15 years. Over the presumed commercial life span of a product of 20 years, 3 FTEs would be required.

[154] The growing media industry has prepared a list of possible ingredients for the manufacture of growing media. The EU EoW criteria will provide a list of authorised biodegradable waste for the production of compost and digestate.

on the market per product categories and the number of different ingredients that would have to be listed in annex(es) to the new Regulation could be estimated as follows[155]:

Table 32: number of new ingredients that would have to be listed under Option 3

	Range of non-harmonised products placed on the EU market	***Range of ingredients not yet harmonised***
Inorganic fertilisers	*840-960*	*5-10*
Organic fertilisers	*1 000-1 100*	*30-40*[156]
Organo-mineral fertilisers	*600-700*	*20-30*
Liming materials[157]	*150-200*	*3-6*[158]
Soil improvers	*24 000-32 000*	*30-40*
Growing media	*450 000-550 000*	*50-60*[159]
Plant biostimulants and agronomic additives	*625-665*	*120-125*[160]
Range of ingredients under option 3		*258-311*

Similar to variant 2B, **ECHA** would be required to check the registration and prepare authorisation dossier for each ingredient registered. The standard fees would be respectively equivalent to EUR 3 454 plus EUR 53 300 for one ingredient. Taking into account that between 258 and 311 new ingredients will have to be included in the annexes of the future proposal, the costs for industry would range between EUR 14 642 532 and EUR 17 650 494 for all the ingredients not yet harmonised. If we assume a 20 year period by which all product types should be listed and a medium cost of EUR 16 146 513, the annual costs for ECHA registration and analysis of requests for authorisation of ingredients would amount to around **EUR 807 325 (A.40 for variant 3B).**

155 Only ranges of products and type designations could be estimated by industry.

156 Based on the review of several national legislations and information from industry

157 90% of the liming materials market has been harmonised by including specific type designations in Annex I of the current Fertilisers Regulation. Commission Regulation (EU) No 463/2013

158 The LT legislation lists for example 5 liming materials of industrial origin which are not covered by Section G of Annex I to the Fertilisers Regulation.

159 From the analysis of 6 national legislations (ES/BE/CZ/DE/IT/FI), the Commission identified approximately 50 different ingredients for the manufacture of growing media. It has been assumed that all national legislations would further increase the list up to 60 ingredients.

160 According to the European Biostimulant Consortium

As for variant 2C, the costs for the Commission to support the work of EFSA under variant 3C will depend on the costs to peer-review the safety and agronomic data of each new ingredient and the estimation of the number of ingredients not yet harmonised. From the experience of the EFSA panel on the review of plant protection products (costs of evaluation EUR 20 000 per dossier) and the number of ingredients not yet harmonised (between 258 and 311), the costs for the Commission could be evaluated between EUR 5 160 000 and 6 220 000 for all ingredients. Again assuming a period of 20 years by which all the ingredients would have been assessed and a medium costs of EUR 5 690 000, an annual costs of **EUR 284 500** could be estimated (**A.40 for variant 4C).**

Table 33: Summary of total governance costs for each variant of Option 3

Governance costs	***A.10***	***A.20***	***A.30***	***A.40***	***Total annual costs*** *(EUR)*
Variant 3A – no EU agency	*225 000*	*461 160*	*–*	*–*	*686 160*
Variant 3B – ECHA	*150 000*	*461 160*	*–*	*807 325*	*1 418 485*
Variant 3C – EFSA	*150 000*	*461 160*	*–*	*284 500*	*895 660*

Costs of registration and standardisation

Similar to Option 2, it can be assumed that the costs for **industry** to prepare application dossiers for ingredients will be higher than the average for type registration today, as the data requirements will probably be higher. It has been assumed that dossier preparation costs would be comparable to Option 2 (i.e. EUR 50 000[161]).

Member States would have to conduct the first evaluation of dossiers submitted and then participate in the peer-review process. Compared to Option 1, (in particular the costs B.10), Member States would need more FTEs per dossier on average (as the dossier would be more comprehensive) and many more dossiers would have to be evaluated and peer-reviewed, albeit fewer than in Option 2. According to the figures mentioned in Table 29 between 258 and 311 new ingredients would have to be evaluated and peer-reviewed. Consequently, the number of national FTEs would increase by 1 FTE compared to Option 1. Considering that a time span of 20 years would be needed to register the ingredients identified in Table 29, each national expert would have to deal annually with approximately 13 requests for inclusion. The costs for **the Commission** would be covered by the costs of governance reported under A.10.

The costs for **Member States** for participation at Fertilisers Working Groups meetings where the application would be discussed are covered under A.20. The costs for **the Commission** would be covered by the costs of governance reported under A.10. The costs for the involvement of ECHA or EFSA under variants 3B and 3C are covered under A.40.

Table 34: Costs related to the preparation and assessment of applications for the registration of ingredients not yet harmonised under variants 3A, B and C

B.10	Number of national expert	Annual salary costs	Number of Member States	Time spent (fraction of FTE equivalent)	Costs of preparation of application	Number of ingredients examined per year	Annual costs
Member States	1	72 750	28	1			2 037 000
Industry					50 000	13	650 000
Total							2 687 000

The costs of standardisation activities for analytical methods would be similar to option 2 as the test methods are not specific to each fertiliser type or ingredient but could apply across a broad range of products. Organic fertilisers, plant biostimulants and agronomic additives would still require substantial standardisation work compared to the other product categories as no CEN Technical Committees have been really involved in these product categories so far.

Table 35: Costs of standardisation under Option 3

Organic fertilisers	97 450 x 20 = 1 949 000

[161] That would cover scientific data collection.

Agronomic additives	97 450 x 20 =	1 949 000
Plant biostimulants	97 450 x 100 =	9 745 000
Total costs under B.20 (standardisation activities)		13 643 000
Annual costs assuming that 20 years will be needed to harmonise the whole market		**682 150**

The costs allocation between the Commission, the Member States, industry and other stakeholders involved in the preparation and assessment of applications for registration and the related standardisation work would be similar to the distribution of costs calculated under Option 1.

Table 36: Summary of the costs for the placing on the market of new products under Option 3

	B.10	***B.20***	***B.30***	***B.40***	***Total annual costs*** *(EUR)*
Commission	*–*	*96 180*	*0*	***0***	***96 180***
Member States	*2 037 000*	*126 880*	*0*	*0*	***2 163 880***
Industry	*650 000*	*223 745*	*0*	*0*	***873 745***
Others	*–*	*235 345*	*0*	*0*	***235 345***
Total	***2 687 000***	***682 150***	***0***	***0***	***3 369 150***

3.4. Option 4

Costs of governance

Under all variants of Option 4, it is considered that only **1.0 FTE** (i.e. **A.10: 75 000 x 1.0 = EUR 75 000**) would be sufficient for managing the system in the Commission. As no more evaluation procedure for individual applications would be required at EU level, the Fertilisers Working Group would have to meet less frequently, and it is assumed that one meeting a year would be enough to ensure the correct implementation of the future legislation (Total costs **A.20: EUR 76 860**).

Further, there would be no more costs of governance of national legislation as the placing on the market of fertilising products would be fully harmonised (**A.30: EUR 0**).

Finally, there would be no need to involve ECHA or EFSA in a possible peer-review process **(A.40: EUR 0).**

Table 37: Summary of governance costs under Option 4

Total annual costs	***A.10***	***A.20***	***A.30***	***Total*** *(EUR)*
Commission	*75 000*	*19 980*	*0*	***94 980***

Member States	-	*28 675*	*0*	***28 675***
Industry	-	*28 205*	*0*	***28 205***
Total	***75 000***	***76 860***	***0***	***151 860***

Costs of registration and standardisation

The costs of preparation and assessment of new applications for listing types or ingredients in the annex(es) to a future regulation would be replaced by the costs of product certification. Several scenarios have been envisaged.

Variant 4A – Module A (Producer Self-Certification[162])

The manufacturer establishes the technical documentation which makes it possible for him to assess the products conformity to the essential requirements defined in a new regulation (nutrient content or other quality criteria, information on contaminants, etc.). The documentation also includes a general description of the method of production. The manufacturer keeps technical documentation at the disposal of national authorities. The manufacturer ensures that the manufacturing process and its monitoring are such that the products comply with the technical documentation; the manufacturer then affixes the CE marking to his products. The manufacturer provides a written declaration of conformity for each compliant product and keeps it together with technical documentation.

By allowing self-certification, the costs for administration and testing would be relatively limited. The costs for the manufacturer would be limited to the collection and preparation of technical documentation demonstrating the compliance of the final product with the essential requirements in the legislation. According to the SME survey (*see* Annex IV), producers spend on average EUR 30 000 each year for their quality assurance scheme. However, these costs might be considered as *business-as-usual costs,* i.e. costs resulting from collecting and processing information which would be carried out even in the absence of the legislation and therefore should not be taken into account in the current evaluation of administrative burden costs, i.e. **B.10 for variant 4A: EUR 0.**

Variant 4B – Modules B+C combined: third party certification regarding the composition of the final product and its fulfilment of essential requirements

Under module B, the manufacturer has to prepare the technical documentation to demonstrate that the product complies with the essential requirements set out in the legislation and submit a representative specimen of the envisaged product to a notified body. The notified body examines the technical documentation as well as the actual product, performs appropriate examinations and tests if necessary and issues an EC type examination certificate declaring that the type meets the essential requirements of the legislation. The certification would be valid for the commercial life of the product unless new raw materials and/or new production process are introduced by the manufacturer.

[162] As described in Annex II of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC. OJ L 218, 13.8.2008, p. 82

The costs of product conformity assessment by notified bodies are typically one-off costs that would be required before the first placing on the market of a product.

Under module C, the manufacturer takes the necessary measures so that the manufacturing process is in compliance with the approved type described in the EC-type examination certificate delivered by the notified body under module B. The manufacturer affixes the required conformity marking to each product and draws up a written declaration of conformity. This module does not require the further involvement of a notified body.

Variant 4C – Modules B+C1 combined: third party certification regarding the composition of the final product and its fulfilment of essential requirements plus tests on additional aspects of the product

Under variant 4C, on top of the requirements and costs identified under variant 4B, **notified bodies would carry out regular tests on specific aspects** (e.g. verification of the contaminant content, detonation test for ammonium nitrate fertilisers, etc.). The costs for additional testing would mainly depend on the characteristics of the products that need to be verified. For clarity reasons, it is assumed that the presence of contaminants[163] and occasional verification of the quality parameters through testing would take place and that **all products placed on the market** would follow the same examination at regular interval (i.e. every five years).

Variant 4D – Modules B+C2 combined: third party certification regarding the composition of the final product and its fulfilment of essential requirements plus product checks at random interval

Module C.2 (conformity to type based on internal production control plus supervised product checks at random interval conducted by a notified body) is used where additional assurance is required due to certain risks. A notified body or an accredited in-house body will carry out one or more tests on each product. The conformity assessment procedure ensures that the final product is in conformity with the type described in the EC-examination certificate issued by the notified body. The manufacturer affixes the CE mark on his product together with the identification number of the notified body indicating that the test results were positive.

Under variants 4B, 4C and 4D, the costs of certification by notified bodies will be covered by fees paid by industry.

(2) Estimation of products to be certified and possible mitigation measure

The costs for industry under options 4B, 4C and 4D will depend on the number of products placed on the market. Assuming that each manufacturer would continue his current practices, the number of products could correspond to the number of products currently placed on the market in the EU[164] (sum of EC Fertilisers and national fertilisers). Based on the information received from the various industry associations, the number of products placed on the market can be estimated as indicated in the second column of the following table.

[163] As explained in Annex IV section 3, analytical costs for heavy metals and organic pollutants: EUR 950.

[164] It has been assumed that changes in the production process and/or the composition of the end product would lead to re-certification.

Table 38: Number of products currently present on the market according to industry federations

	Estimation of all existing products placed on the EU market per various categories	***Estimation of families of products***
Inorganic fertilisers	*3 500-4 000*[165]	*5-25*[166]
Organic fertilisers	*1 000-1 100*[167]	*16*[168]
Organo-mineral fertilisers	*600-700*[169]	*13*[170]
Liming materials	*2 000-2 500*[171]	*4*[172]
Soil improvers	*24 000-32 000*	*5*[173]
Growing media	*450 000-550 000*	*4*[174]
Plant biostimulants and agronomic additives	*625-665*	*8*[175]

[165] Each inorganic fertiliser (EC or national) will have to be certified. Industry communication

[166] According to the types described in Annex I to the Fertilisers Regulation. The number of types will depend on the number of details required. For example micronutrient fertilisers could be defined by one family or by 7 families if each micronutrient is contained in one family.

[167] Source: Italian experts but it was not possible to assess exactly the number of organic fertilisers.

[168] Skin and leather materials, feathers and plumes, hair, wool and silk materials, horn and hoofs materials, meat and fish products, bone products, blood products, processed manure, aquatic plant materials, fungal and yeast biomass, bacterial biomass, vinasse, molasses, potato soap, seed cakes.

[169] Industry communication. Only 300 for Italy which is the dominant market

[170] Granulated N, NP and NPK fertilisers, pelletized organo-mineral N, NP, NK and NPK fertilisers, liquid organo-mineral N, NP, NK, NPK fertilisers and K, NPK organo-mineral fertiliser crumbs

[171] Each liming material will have to be certified. Industry communication

[172] Natural limes, oxide and hydroxide limes of natural origin, limes from industrial processes and mixed limes.

[173] Green compost, bark compost, biodegradable compost, liquid and solid digestate

[174] As proposed by the growing media industry: Organic GM (organic matter content > 30% (m/m))/ Organo-mineral GM (organic matter content: 5 to 30% (m/m)/ Mineral GM (organic matter content < 5% (m/m)) and synthetic GM.

[175] The study carried out by Prof.du Jardin could identify 8 groups of plant biostimulants:
- Humic substances,
- Complex Organic materials,
- Beneficial chemical elements,
- Inorganic salts, including phosphite,
- Seaweed extracts,
- Chitin and chitosan derivatives,
- Antitranspirants,
- Free Amino acids and other N-containing substances.

Total number of products or families	*481 725-590 965*	55-75

As shown in Table 38, the number of individual products to be certified could be huge in particular for growing media. Therefore, similar to the Biocide Regulation, products presenting the same level of safety and efficacy could be grouped into one family of products.

Notified bodies would verify that the whole product family complies with the relevant safety and agronomic requirements by verifying the compliance of test materials. If during the examination of samples, a product fails to meet the essential safety or agronomic requirements, the whole family would be deemed to fail. This would allow a reduction of the costs of certification for SMEs without reducing the level of protection of human health or the environment (*see* column 3 of Table 38).

As a notified body could only assess product families which are manufactured by the same manufacturer, it has been estimated that each EU manufacturer and importer (around 10 000 according to Annex I) would on average register 5 families of products i.e. **50 000 families of products** would have to be evaluated and certified.

(3) Evaluation of the costs of third party certification and additional testing

A study on the impacts of the revision of Council Directive 88/378/EEC on the safety of toys (RPA, October 2004) showed that SMEs were predicted to face costs of EUR 1 000 on average for Third Party verification/certification. However, those costs are likely to vary between notified bodies and therefore a maximum costs of EUR 2 000 has been assumed as worst case scenario. The costs for verification of product conformity under variant 4B could therefore be assessed as follows:

Table 39: Evaluation of the costs for Third Party certification under variant 4B

B.10 **Variant 4B: Modules B+C**	Third party certification for **all** products	Third Party certification of **families** of products
Number	Range: *481 725-590 965*	Assumption: 50 000
Cost of notified bodies	EUR 2 000 (fees under module B)	EUR 2 000 (fees under module B)
Total costs	EUR 963 450 000-1 181 930 000 for all products on the market over their whole commercial life	EUR 100 000 000 for all families of products on the market over their whole commercial life
Annual costs assuming a commercial life of 20 years	EUR 53 634 500 average costs distributed over the whole commercial life	EUR 5 000 000 average costs distributed over the whole commercial life

Under variant 4C, some recurring costs would be charged to industry to regularly test (every 5 years) the compliance of the products with the essential safety criteria. It has been assumed that notified bodies would charge maximum EUR 950 for regular verification of the compliance of products with safety limits on contaminants (*see* Annex IV Section 3 – impacts on SMEs for more details).

Table 40: Evaluation of the costs for Third Party certification under variant 4C

B.10 **Variant 4C: Modules B+C1**	Third party certification of all products	Third party certification of groups of products
Number	Range : *481 725-590 965*	Assumption: 50 000
Average costs of notified bodies plus specific tests	EUR 2 000 (fees under module B+C) + EUR 950 (recurring costs every 5 years[176] for testing under module C1)	EUR 2 000 (fees under module B+C) + EUR 950 (recurring costs every 5 years for testing under module C1)
Total costs (number of products multiplied by the average costs of notified bodies and specific tests)	Module B+C: EUR 963 450 000-1 181 930 000 (one-off costs) Module C1[177]: EUR 1 830 555 000-2 245 667 000	Module B+C: EUR 100 000 000 (one-off costs) Module C1: EUR 190 000 000
Annual costs assuming an average commercial life of 20 years	Module B+C: EUR 53 634 500 average costs distributed over the whole commercial life Module C1: average annual additional costs during the commercial life assuming a re-testing of all products every 5 years: EUR 101 905 550	Module B: EUR 5 000 000 average costs distributed over the whole commercial life Module C1: annual additional costs during the commercial life assuming a re-testing of all families every 5 years: EUR 9 500 000

Under Option 4D, the frequency of additional checks would increase to every 2 years. Consequently the costs under module C2 would increase proportionally.

Table 41: Evaluation of the costs for Third Party certification under variant 4D

B.10 **Variant 4D: Modules**	Third party certification for all products	Third Party certification of groups of products

[176] Frequency recommended by JRC for small plants (< 10000 tons/year)

[177] 4 tests will be carried out during the 20 years of the commercial life of the product. Therefore the costs during this period are estimated as follows: 4 x EUR 950 x the number of products

B+C2		
Number	Range: *481 725-590 965*	Assumption: 50 000
Average costs of notified bodies plus specific tests	EUR 2 000 (fees under module B) + EUR 950[178] (recurring costs for testing at random interval under module C2)	EUR 2 000 (fees under module B) + EUR 950 (recurring costs for testing at random interval under module C2)
Total costs (number of products multiplied by the average costs of notified bodies and specific tests)	Module B+C: EUR 963 450 000- 1 181 930 000 (one-off costs) Module C2[179]: EUR 4 576 387 500- 5 614 167 500	Module B+C: EUR 100 000 000 (one-off costs) Module C2: EUR 475 000 000
Annual costs assuming an averaged commercial life of 20 years	Module B+C: EUR 53 634 500 average costs distributed over the whole commercial life of all products Module C2: Average annual additional costs during the commercial life assuming that a re-testing of all products is carried out every 2 years: EUR 254 763 875	Module B+C: EUR 5 000 000 average costs distributed over the whole commercial life of all products Module C2: Additional costs during the commercial life assuming that a re-testing of all families is carried out every 2 years: EUR 23 750 000

Table 42: Average annual costs for third party certification under each variant

B.10. Average <u>annual</u> costs for each variant (EUR)	Type of certification	Variant 4A – self certification	Variant 4B – third party certification	Variant 4C – third party certification plus tests on additional aspects	Variant 4D – third party certification plus checks at random intervals
Fees to be paid to notified bodies for certification of products (Module B)	Individual products	0	53 634 500	53 634 500	53 634 500
	Family of products	0	5 000 000	5 000 000	5 000 000

[178] Same costs as for variant 4C but tests would be carried out every 2 years

[179] 10 tests will be carried out during the 20 years of the commercial life of the product. Therefore the costs during this period are estimated as follows: 10 x 950 x the number of products

Annual recurring costs for testing carried out by notified bodies (Modules C1 or C2)	Individual products	0	0	101 905 550	254 763 875
	Family of products	0	0	9 500 000	23 750 000
Total annual costs	Individual products	0	53 634 500	155 540 050	308 398 375
	Family of products	0	5 000 000	14 500 000	28 750 000

The costs for standardisation under Option 4 would increase as new EN standards could be required to facilitate examination of commercialised fertilising products and additives and to turn existing EN Standards into EN harmonised standards. Compared to Option 2 and based on experience from other sectors, an additional annual budget for standardisation of EUR 200 000 during 20 years was assumed to be necessary to support the development of these new standards (EUR 882 150). The costs of governance of national legislation and mutual recognition would disappear.

Table 43: Summary of the costs for industry to place new products on the market under all variants of Option 4 (in EUR)

B.10	*Type of certification*	*B.10*	*B.20*	*B.30*	*B.40*	*Total annual costs*
Variant 4A	*Not applicable*	*0*	*882 150*	*0*	*0*	***882 150***
Variant 4B	*Per product*	*53 634 500*	*882 150*	*0*	*0*	***54 516 650***
	Per family	*5 000 000*	*882 150*	*0*	*0*	***5 882 150***
Variant 4C	*Per product*	*155 540 050*	*882 150*	*0*	*0*	***156 422 500***
	Per family	*14 500 000*	*882 150*	*0*	*0*	***15 382 150***
Variant 4D	*Per product*	*308 398 375*	*882 150*	*0*	*0*	***309 280 525***
	Per family	*28 750 000*	*882 150*	*0*	*0*	***29 632 150***

The costs of market surveillance would be reduced according to the level of control by notified bodies (See justification in the main text under 6.5.1.1.c

Costs of quality assurance

These costs would include the costs of accreditation and the costs of implementing new harmonised EN Standards.

Accreditation is the attestation by a national accreditation body based on harmonised standards that a notified body has the technical competence to perform specific conformity assessment activity. Accreditation is used in the regulated sector to meet the requirements of certain legislation and the voluntary area where there is no specific legislation. It is based on a peer evaluation system that ensures the proper functioning of accreditation across the EU.

Regulation (EC) No 765/2008 provides a legislative framework for accreditation at the national and EU levels and puts into place an overall policy with its rules, procedures and infrastructures. In order to ensure a level playing field for fertilising products deriving from waste and in accordance with the EU EoW criteria developed by JRC, it is proposed that accreditation of notified bodies will be made mandatory in a future Regulation.

This is very difficult to provide an accurate estimate of the likely accreditation fees for notified bodies as this depend on the complexity of scope of accreditation being sought. These fees include not just the time the assessment team spend at the premises of the notified bodies (audits) but also office time and travelling expenses. In the frame of the future regulation it is foreseen to keep the number of essential requirements as low as possible in order to avoid unnecessary costs for notified bodies who will charge eventually companies.

ORBIT/ECN (2008) produced an overview of quality assurance costs for compost according to the main schemes currently in place in various countries. Table 44 shows that the quality assurance costs (fees to be paid to notified bodies) are mainly determined by the size of the composting plant and range from below EUR 0.08/tonne of input to more than EUR 3/tonne of input. The quality assurance costs in Table 44 covers the external expenses in the renewal procedure of accreditation certificates or quality labels during the continuous operation of the plants. In the first application and validation period (first one to two 'recognition' years) costs are considerably higher on account of a first evaluation of the plants and the higher frequency of tests.

The total compost production costs in a best practice composting plant with 20 000 tonnes capacity were estimated at 45 Euro/tonne of input (Eunomia, 2002). A comparison with the typical quality assurance costs for a plant of this size according to Table 44 shows that the external quality assurance costs represent less than 1 % of total production costs but for smaller plants, quality assurance can make up more than 15 % of total costs.

However, several composting and digestion plants have already suitable quality assurance systems in place (at least one fifth of all composting plants in the EU), and most others regularly carry out some form of compliance testing, so that not all of the quality assurance costs associated with the EU end-of-waste system would be additive.

Table 44: Cost of compost quality assurance in selected European countries *Source: ORBIT/ECN (2008).*

Quality assurance costs/tonne input and year (EURO excluding VAT)										
Throughput/year (tonnes)	**AT (1) (ARGE) Agriculture plants**	**AT (2) (KGVÖ) Industrial plants**	**DE (3) (BGK)**	**IT (4) (CIC)**	**NL (5) (BVOR) (Green C. plants)**	**NL (6) (VA) (VFG plants)**	**SE (7) (SP)**	**UK (8) (TCA) Use in agriculture/ horticulture**	**UK (9) (TCA) Other uses**	**EU Mean value**
500	2.15	3.36	—	—	—	—	—	—	—	—
1 000	0.94	1.80	—	—	—	—	—	—	—	—
2 000	0.97	1.32	0.82	—	1.62	1.99	1.21	1.13	1.10	1.26

5 000	0.63	0.67	0.52	0.48	0.76	0.80	0.48	0.45	0.44	0.59
10 000	0.44	0.58	0.34	0.46	0.53	0.40	0.29	0.28	0.27	0.42
20 000	0.26	0.44	0.31	0.45	0.39	0.20	0.15	0.23	0.22	0.32
50 000	0.17	0.36	0.19	0.43	0.21	0.08	0.06	0.20	0.19	0.23

Sources: Personal information from:

(1) KGVÖ Compost Quality Society of Austria — operates mainly bio-waste treatment plants. Costs include membership fees, laboratory costs and external sampling.

(2) ARGE Compost & Biogas Association Austria — decentralised composting of separately collected bio-waste in cooperation with agriculture. Costs include membership fees, laboratory costs, external sampling and external audits of composting/digestion sites

(3) BGK German Compost Quality Assurance Organisation. Costs include membership fees, laboratory costs and external sampling.

(4) CIC Italian Compost Association CIC — including company fee according to turnover plus external sampling and laboratory costs

(5) BVOR Dutch Association of Compost Plants — costs at green waste plants which include membership fees, laboratory costs and the costs for yearly audits by external organisations — no external sampling.

(6) VA Dutch Waste Management Association — costs at bio-waste (VFG) plants including membership fees, laboratory and external sampling costs, and the costs for yearly audits by external organisations. The expenses are slightly higher compared to BVOR because of additional analysis of sanitisation parameter and the external sampling.

(7) SP Swedish Standardisation Institute execute the QAS scheme — costs include membership fees, laboratory costs, and costs for yearly audits by SP — sampling is done by the plants besides the yearly audit.

(8) TCA the UK Compost Association certification for compost in agriculture and horticulture — total costs associated with certification scheme fees for all parameter and lab testing. Costs associated with testing the compost are higher compared to other application areas, as the compost producer is required to test parameters like total nutrients, water soluble nutrients and pH in addition sampling is done by the plants. For compost used in agriculture and field horticulture, the UK Quality Compost Protocol has introduced for the land manager/farmer the requirement to test the soil to which compost is applied. The costs associated with soil testing are not incorporated here because it is mostly not the compost producer, but the farmer or land manager who pays for.

(9) TCA the UK Compost Association certification for compost used outside agriculture and horticulture — total costs associated with certification scheme fees and lab testing. Sampling is done by the plants.

It can be expected that the **major changes in QA costs** by the possible introduction of EU end-of-waste criteria, compared to existing systems, will be **related to product testing**. These changes originate from likely modifications to the requirements for independent sampling, measurement of organic pollutants and the use of harmonised EN standards instead of national standards.

Several Member States already require external sampling, whereas others allow the plant operators to perform the sampling themselves (e.g. in the UK). The estimated costs for external sampling, based on information from experts, vary widely and are estimated around EUR 200 per sample. In Member States where independent external sampling is already considered an established practice, reported prices for independent sampling generally tend to be the lowest. Nonetheless, the current proposal includes the possibility of reducing external sampling after the recognition year, requiring only one yearly independently collected sample for plants up to 10000 tonne annual input and 3 for plants up to 50000 tonne annual input, effectively reducing the cost for external sampling to less than a few cents per tonne.

The costs of purchasing harmonised EN Standards to verify the compliance of products to the requirements of the future legislation is another issue. Harmonised standards will be available in national linguistic version(s) from national standardisation bodies. The costs ranked from around EUR 10 to around 100 per standard. In the future Commission proposal, it is foreseen to keep the number of essential and labelling requirements as low as possible in order to avoid unnecessary costs for industry and competent authorities of buying harmonized standards.

3.5. Option 5

<u>Costs of governance</u>

Compared to Option 4, the Commission services would face similar workload, but less than in Options 2 or 3, as all product categories would be regulated following the New Approach. At Commission level, 1 **FTE** (i.e. **A.10: 75 000 x 1.0 = EUR 75 000**) would be required to manage the system. The Fertilisers Working Group would have to meet less regularly than under Options 2 and 3 and similarly to option 4, it was considered that one meeting a year would ensure the correct implementation of the future legislation (Total costs **A.20: EUR 76 860**).

Finally, under Option 5, there would be no more cost of governance of national legislation as the placing on the market of fertilising products would be fully harmonised (**A.30: EUR 0**) and no more costs of agencies (**A.40: EUR 0**) for the products covered by the New Legislative Framework approach. The following table summarises the governance costs for Option 5.

Table 45: summary of governance costs for Option 5

Total annual costs	***A.10***	***A.20***	***A.30***	***Total***
Commission	*75 000*	*19 980*	–	***94 980***
Member States	–	*28 675*	–	***28 675***
Industry	–	*28 205*	–	***28 205***
Total	***75 000***	***76 860***	–	***151 860***

Costs of registration and standardisation

All product categories would follow the New Approach legislative format. Third party involvement in the assessment of conformity with the essential requirements *varies* between material categories, and is highest for waste and other secondary materials with potentially variable composition and for plant biostimulants and agronomic additives for which of a verification of the claims by a third party would be required (See Annex IX for justification). The costs of self- or third-party certification identified under variants of Option 4 would apply.

The essential safety requirements for plant biostimulants and agronomic additives would require the registration of such products into REACH. Under that scenario, the following costs could be identified.

Producers would be required to register plant biostimulant not yet covered by REACH prior to the placing on the market of products containing them. Fees would be charged to manufacturers for registration of plant biostimulants. The Commission implementing Regulation (EU) No 254/2013 on the fees and charges payable to ECHA defines such costs depending on tonnage.

The volume of plant biostimulants placed on the market is likely to be less than 10 tonnes per year and per product which corresponds to a fee of EUR 1714 for individual submission. The European Biostimulant Industry Council (EBIC) has identified 100 active substances, 50% of which are currently exempted from REACH registration (Annex V of REACH). Therefore the fees would amount up to EUR 1714 X 50 = EUR 85700. Assuming a commercial life of 20 years, this would result in an annual cost of around EUR 4285.

The costs of compiling a dossier would increase compared to options 2 and 3 as additional studies could be required to assess the potential toxicity of the substances. The study on legal framework for plant bio-stimulants and agronomic additives of 2013 estimated such costs at around EUR 130.000. Therefore the costs of compiling data for 50 substances not yet registered within REACH would be estimated at 130.000 X 50 = 6 500 000 EURO namely EUR 325 000 per year assuming an average commercial life of 20 years for each substance

Agronomic additives are already registered within REACH and are therefore not covered by the evaluation of the costs of registration

The table below summarizes the costs for industry.

Table 46: Assessment of the costs of registration under REACH and conformity assessment for plant biostimulant

B.10 Annual registration costs for industry	Number of substances	Costs for compiling data for one dossier + Fees to be paid for one registration (EUR)	Total one-off costs supported by the sector for the registration (EUR)	**Annual costs** for the sector assuming a commercial life of 20 years (EUR)
Plant biostimulants	50	130 000 + 1 714	6 585 700	329 285

The following table summarizes the proposed regulatory system

Table 47: Estimation of the costs for industry for placing on the market new products (B.10) tailored to their expected risks to the environment and human health of each product category

Type of products	Regulatory option	Highest estimation of the number of products marketed in EU	Annual certification costs for one product assuming a commercial life of 20 years (EUR)	Total annual B.10 costs for each specific category under each proposed option (EUR)
Inorganic fertilisers	Variant 4A Variant 4B	3 550 100[180]	0 100[181]	0 10 000
Inorganic fertilisers: Ammonium nitrate based products manufactured for use as fertilisers and containing more than 28% by mass of nitrogen in relation to ammonium nitrate[182]	Variant 4C[183]	100	2 600	260 000
Organo-mineral fertilisers [184]	Variant 4B	1050	100	105 000
Organic fertilisers	Variant 4C	650	290	188 500
Liming materials	Variant 4A Variant 4B	2 150	0 100	0 10 000

[180] Some phosphate fertilisers derived from by-products of the steel industry.
[181] See Annex VI. One-off costs paid by industry (EUR 2 000) to the notified body to check the conformity of the product to the legal requirements divided by the number of commercial life of the product (20 years).
[182] In accordance with Regulation (EU) No 98/2013 on the marketing and use of explosives precursors, this includes potassium nitrate and calcium ammonium nitrate as well.
[183] Given the security issue of these products, it is proposed that every two years a test of detonation (EUR 5 000) is conducted by an accredited laboratory. In addition to the test of detonation, the provisions of Regulation (EU) No 98/2013 on the marketing and use of precursors to explosives will apply. This additional testing will be carried out under Option 3 or 4. 2000 + (5000*10) = 52000. EUR 52000/20=EUR 2600
[184] Source segregated materials are needed to achieve good quality products

		100		
Soil improvers (SI)	Variant 4A (inert materials used as soil improvers)[185]Variant 4C (organic soil improvers derived from waste)	3000 25 000	0 290[186]	0 7 250 000
Growing media	Variant 4A	500 000	0	0
Plant biostimulants and agronomic additives	Variant 4A[187] Variant 4B Variant 4A	560 65 40	0 100 0	0 6500 0
Plant biostimulant (costs of registration under REACH)				329285
Total annual costs for industry				8 159 285

[185] Classified as 'other soil improvers' in Annex I. They cover products such as perlites, schist, sand,…which do not considered as dangerous, hence the proposal to address them via self-certification (Option 5A)

[186] Costs of module B+C: EUR 2000 (one-off cost) Costs of module C1: EUR 950 (recurring costs – every 5 years). Total costs assuming a commercial life of 20 years: 2000 + (950 X 4) = 5800. Annual costs: 5800 /20 = EUR 290

[187] Self certification would apply to all plant biostimulants except microorganisms for which a conformity assessment by a third party would be required. According to EBIC, microorganisms represent about 10% of the current plant biostimulant market (625 commercialised plant biostimulant X 0.1=65).

As described under Option 4, the possibility to group products presenting the same level of efficacy and safety could be granted to producers. As shown in column 3 of Table 46, only 27 000 fertilising products and additives would have to be examined by certified bodies. This represents only 5% of the products quantified under Option 4 (Table 38) and therefore it is assumed that the number of groups could be reduced accordingly[188]. As a majority of products would follow variant 4C, the evaluation and certification costs by group of products under option 5 have been based on the assumptions described in Table 40. It results that the costs of certification by groups of products would amount to EUR 14 500 000 x 0.05 = 725 000 EUR.

Similarly to option 4, new standards would be required to facilitate examination and declaration of conformity with essential requirements and existing standards would have to be transformed in harmonised EN Standards. (B.20: EUR 882 150)

For plant biostimulants and additives, producers would be required to provide analytical methods for the determination of the pure active substance and the verification of the claims that would be described in the essential quality requirements. Since standard development can be lengthy, coordination group should be mandated to issue guidance for how to interpret essential legal requirements in the meantime.

The situation is described in the following table.

Table 48: Summary of the costs for industry and Member States to place new products on the market under Option 5 (in EUR)

	B.10	**B.20**	**B.30**	**B.40**	**Total annual costs**
COM	–	*124 385*	–	–	**124 385**
Member State	–	*164 080*	–	–	**164 080**
Industry	*8 159 285*	*289 345*	–	–	**8 448 630**
Others	–	*304 340*	–	–	**304 340**
Total	**8 159 285**	**882 150**	–	–	**9 041 435**

The costs of market surveillance would be equal to similar costs under option 4A.

3.6. Partial harmonisation scenario

Under this scenario, Member States would have to maintain at least partly their legislation on fertilisers. Following the results of the SMEs consultation (Figure 16 of Annex IV), it was assumed that around 20% of the existing products would remain on national markets. The costs of governance of national legislation (A.30: EUR 498 120)) have been reintroduced accordingly for each of the examined option above. The costs of governance of EU legislation and meetings at EU level would remain unchanged (A.10 and A.20) under each option.

[188] 5% of 50000 families assumed in Option 4

If 20% of the existing products would remain on national markets, the costs of intervention of EU agencies (A.40), the costs of registration under a revised EU fertiliser law (B.10) as well as the costs of standardisation activities (B.20) would be reduced proportionally

As the objective was to estimate the costs of partial harmonisation for existing products, it has been assumed that the costs of registration of new products as national fertilisers (B.30) would remain void. The costs of mutual recognition (B.40) would similarly remain void as in the presence of EU legislation, it was considered that requests for mutual recognition of national fertilisers would remain exceptional. The costs of market surveillance (C.40) would remain unchanged under each option.

Table 49 summarizes the costs of all examined options under the scenarios of partial and full harmonisation

Table 49: Summarising the annual administrative **costs** (EUR) of the different options (full and partial harmonisation scenarios)

	A.10	A.20	A.30	A.40	B.10	B.20	B.30	B.40	C.10	Total **(full)**	Total **(partial)**
Option 1	150 000	153 720	2 490 600	-	150 000	974 530	28 140 700	420 000	11 076 100	43 555 650	43 555 650
Option 2A	375 000	614 880	-	-	12 685 000	682 150	-	-	11 076 100	25 433 130	25 257 820
Option 2B	150 000	614 880	-	2 880 265	12 685 000	682 150	-	-	11 076 100	28 088 395	25 337 030
Option 2C	150 000	614 880	-	1 015 000	12 685 000	682 150	-	-	11 076 100	26 223 130	23 844 820
Option 3A	225 000	461 160	-	-	2 687 000	682 150	-	-	11 076 100	15 131 410	14 955 700
Option 3B	150 000	461 160	-	807 325	2 687 000	682 150	-	-	11 076 100	15 863 735	15 526 560
Option 3C	150 000	461 160	-	284 500	2 687 000	682 150	-	-	11 076 100	15 340 910	15 108 300
Option 4A	75 000	76 860	-	-	0	882 150	-	-	11 076 100	12 110 110	12 431 800
Option 4B Per product Per group	75 000 75 000	76 860 76 860	-	-	53 634 500 5 000 000	882 150 882 150	-	-	9 968 490 9 968 490	64 637 000 16 002 500	54 231 790 15 324 190
Option 4C Per product Per group	75 000 75 000	76 860 76 860	-	-	155 540 050 14 500 000	882 150 882 150	-	-	8 860 880 8 860 880	165 434 940 24 394 890	134 648 620 21 816 580
Option 4D Per product Per group	75 000 75 000	76 860 76 860	-	-	308 398 375 28 750 000	882 150 882 150	-	-	7 753 270 7 753 270	317 185 655 37 537 280	255 827 670 32 108 970
Option 5 Per product Per group	75 000 75 000	76 860 76 860	-	-	8 159 285 725 000	882 150 882 150	-	-	9 968 490 9 968 490	19 161 785 11 727 500	17 851 620 11 904 190

4. DESCRIPTION OF THE STANDARDISATION WORK

Within CEN, the development of European Standards is carried out by CEN Technical Committees (CEN/TC). A CEN/TC is composed of representatives of national standardisation bodies (NSB). NSB delegations can also contain a representative of the competent national authorities. Each of the 33 NSB members of CEN can send a delegation of up to three people to the Technical Committee. These delegations relay the position of their national stakeholders to the CEN/TC. Participation in a CEN/TC is not limited to national delegations. Representatives from CEN Associates or Affiliates, the European Commission and relevant European Industry Federations can participate as observers in the TC's activities without voting rights.

The secretariat of the CEN/TC is held by one NSB. A chairperson is appointed by the CEN/TC to manage its plenary meetings. The chair conducts meetings impartially and ensures that balanced, transparent and prompt decisions are taken. The chair has no voting rights. Typically, TCs meet once or twice a year in plenary sessions but much work is carried out by correspondence.

The CEN/TC is a technical decision making body with precise scope and work programme established by the CEN Technical Board to mainly manage the preparation of the CEN deliverables. The technical work of drafting European Standards is conducted in the Working groups (CEN/WG) established by the CEN/TC, with a secretariat and a convenor. The standards are drafted by experts who are appointed by the NSB.

The experts of a specific Working Group develop draft standards within a given time-frame. When a first draft is ready, it is submitted by the secretariat of the CEN/TC, after consultation of the chair, to a public enquiry open to all European stakeholders. The purpose of the enquiry is to further refine the draft standard by gathering broad comments on its content. Following this enquiry, the comments received are examined and commented by the experts of the CEN/WG. The documents are transmitted to the members of the CEN/TC which decide whether the draft standard can be submitted to the final vote.

The CEN Management Centre in Brussels launches formal voting processes. The standard must receive at least 71% positive votes (weighted votes) to be adopted. Following its approval, CEN members are obliged to accept the new European standard as national standard without modification and to withdraw any conflicting national standard.

On the basis of a legal act, the Commission can issue a mandate to CEN for the development of technical standards or reports. If the mandate is accepted by CEN, a financial proposal is submitted to the Commission which can then co-finance the work programme. Any financial support by the European Commission for European Standardisation Bodies is covered by the requirements of the 'Framework Partnership Agreement – 2009'.

ANNEX IV

SMEs Test and competitiveness proofing

1. RESULTS OF CONSULTATION OF SMES

In the context of the implementation of the Small Business Act, Small and Medium-sized Enterprises (SMEs) were asked for input on the various options being developed in the impact assessment report. They were supplied with a specific questionnaire supported by a background note clarifying the technical and economic aspects of the proposal.

The purpose of this consultation was to receive information from industry on their estimated compliance costs and effects in the supply chain from the different policy options.

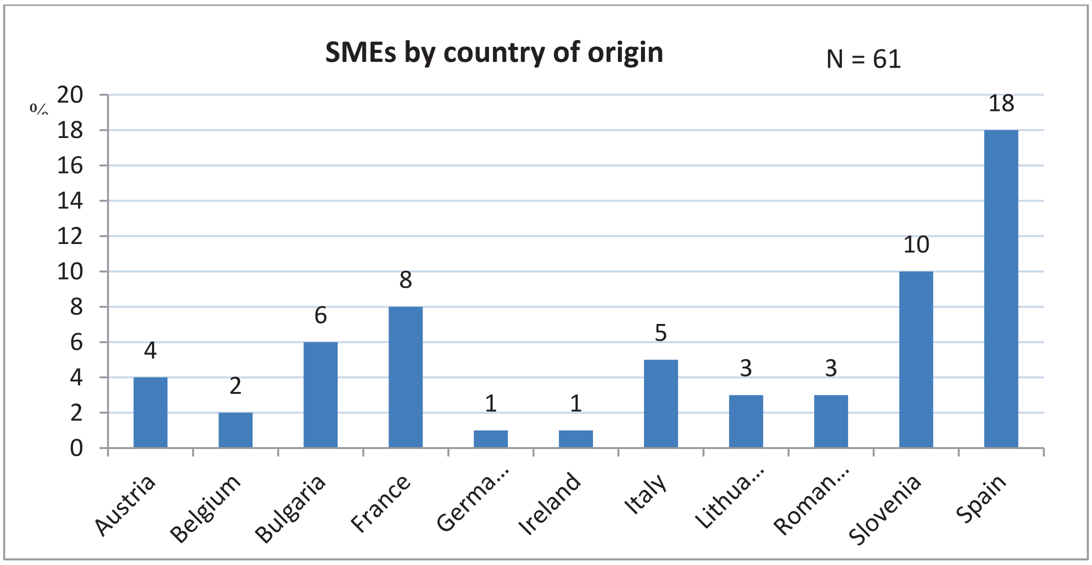
The questionnaire was divided into five sections and SMEs were asked to provide: 1) information on the company; 2) their general attitude as regards the harmonisation of the fertiliser market; 3) the costs for marketing EC Fertilisers under the current Fertilisers Regulation; 4) the costs factors for marketing national fertilisers in compliance with national legislation; and 5) possible impacts on business of the options for harmonisation of the European fertilisers market.

Section 1: SMEs details

Q1: in which country is your business located?

61 replies from SMEs located in 10 EU Member States were collected. No contributions from the other 17 EU Member States were received. The number of replies would represent approximately 2% of the SMEs active in the different sectors covered by the proposal.

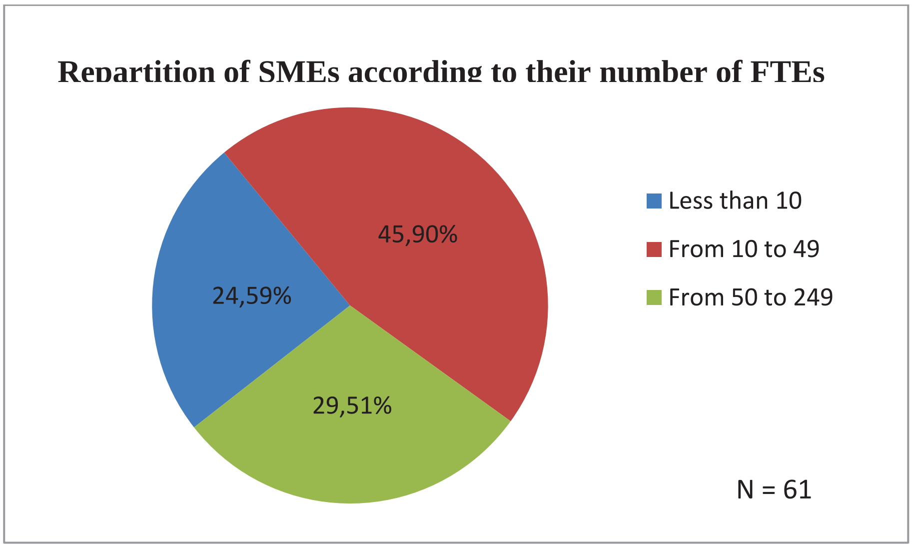
Figure 12: Respondents representation per Member States



Q2: How many persons do you employ (expressed in full time equivalents – FTEs)?

The following figure shows that about half of the respondents were medium holdings employing between 10 and 49 FTEs.

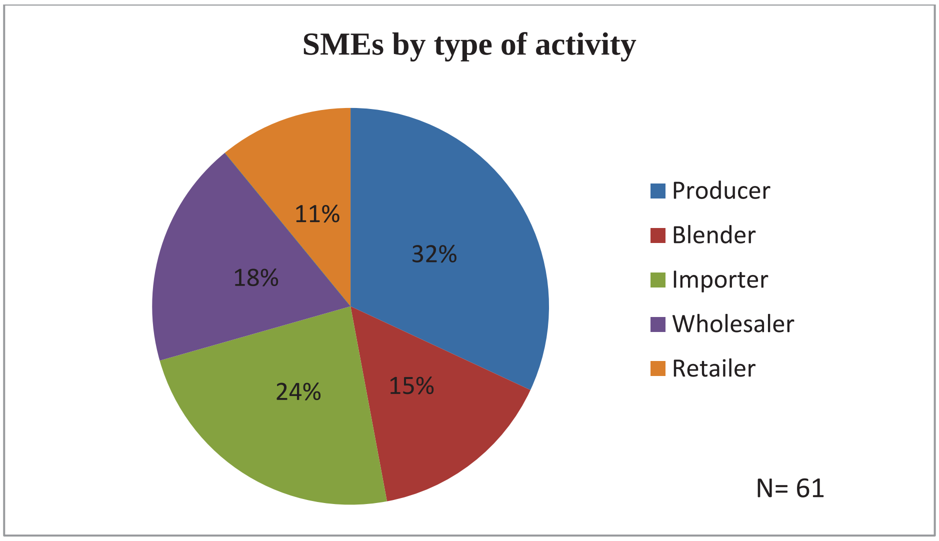
Figure 13: Respondents according to the number of FTEs employed



Q3: In which type of activity are you engaged?

The following figure shows that most respondents were producers, importers or wholesalers. Some SMEs are involved in more than one activity. No agricultural cooperative responded to the survey.

Figure 14: Respondents according to type of activity



Q4: Where do you sell your products?

The table below illustrates the most important markets for the respondants. Several choices were possible.

Table 50: Representation of the dominant markets for the respondents:

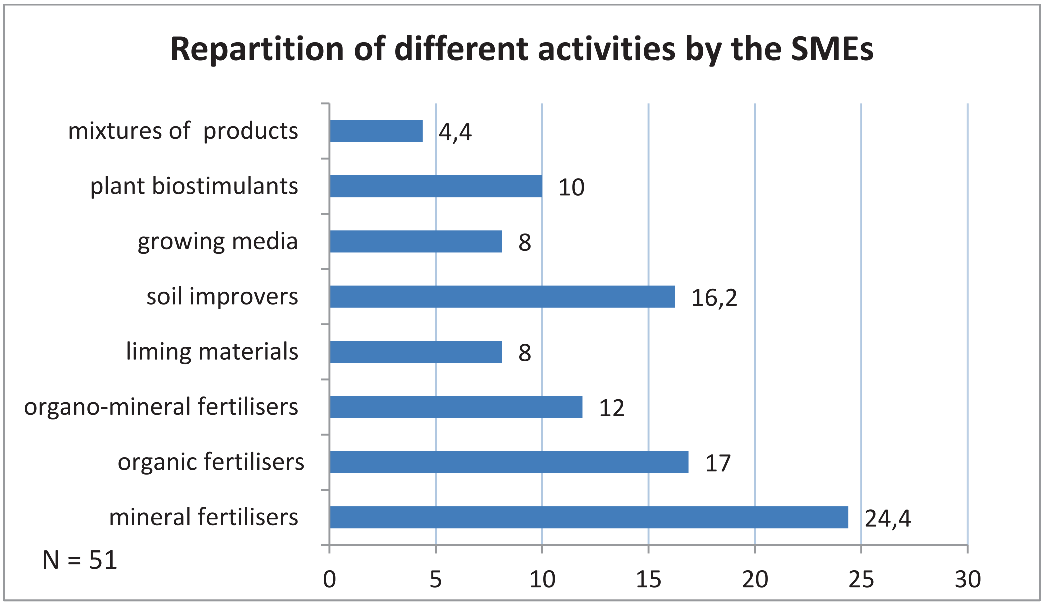
N=61	**Mostly** (%)	**To a minor extent** (%)	**Not at all** (%)
National	88.5	6.6	0.0
Neighbouring countries	13.1	57.4	8.2
All EU countries	16.4	13.1	26.2
Third countries	23.0	27.9	16.4

SMEs are mostly present on national markets (88.5%) while 23% of them have also indicated that they are present on third countries markets. Overall, when SMEs are present on foreign markets, they are mainly present on neighbouring countries markets (70.5%). About 30% of responding companies are present on the whole EU market.

Q5: What is your product portfolio? (expressed in approximate share of turnover in 2011)

Figure 12 shows that responding SMEs are mainly active in the inorganic fertilisers market followed by the organic and soil improvers markets. SMEs are often involved in several sectors. Only 51 respondents answered this question.

Figure 15: Respondents by product category

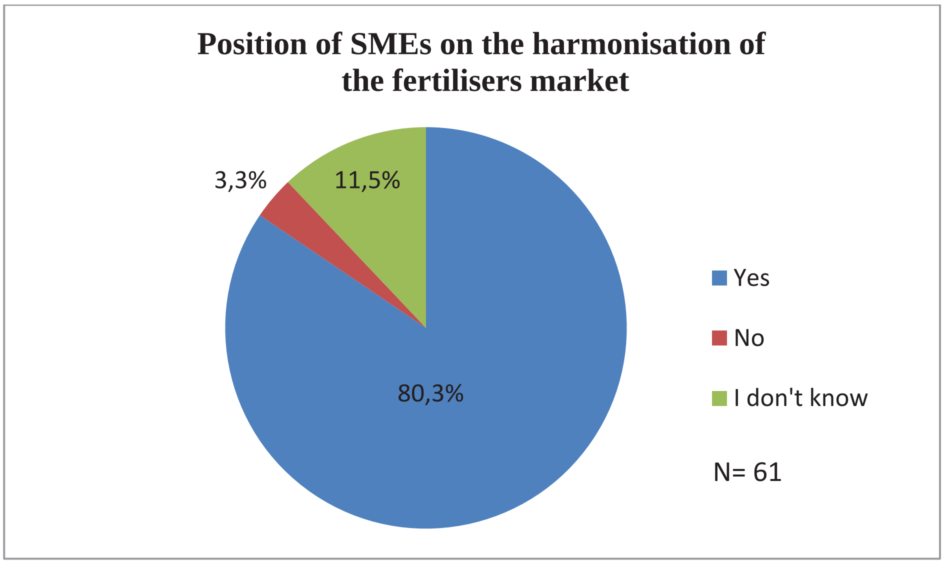


Section 2: SMEs position about the harmonisation of the fertiliser market

Q6: Do you believe that the harmonisation of the fertilisers market is the best way to address its current problems?

Most of the respondents (80.3%) are positive that the harmonisation of the fertiliser market will address the problems identified with the current situation (diverging legal requirements for fertilising products, mutual recognition of national fertilisers, promotion of innovation, etc.). However, around 12% of the SME do not have any clear views on the benefits of the harmonisation of the fertiliser market and 3.3% answered negatively.

Figure 16: SMEs opinions on the harmonisation of the fertilisers market on EU level



Q7: Can you estimate the consequences of the full harmonisation of the fertiliser market for your business regarding the criteria mentioned below?

The answers collected via the survey are presented in Figure 14. It shows that SMEs are generally quite positive towards the full harmonisation of the EU fertiliser market. However there are concerns that harmonisation would lead to more competition with neighbouring or third countries. The criterion on economy of scale was considered as only neutral. This might be explained by the fact that most EU SMEs are mainly active in their national fertilisers market.

The criteria rated as very and slightly positive by the companies responding to this questionnaire were as follows:

– improved access to the European market for innovative products (81.3%),

– improved level playing field between EU fertilisers manufacturers (79.7%),

– better product safety (72.9%) and quality (74.6%),

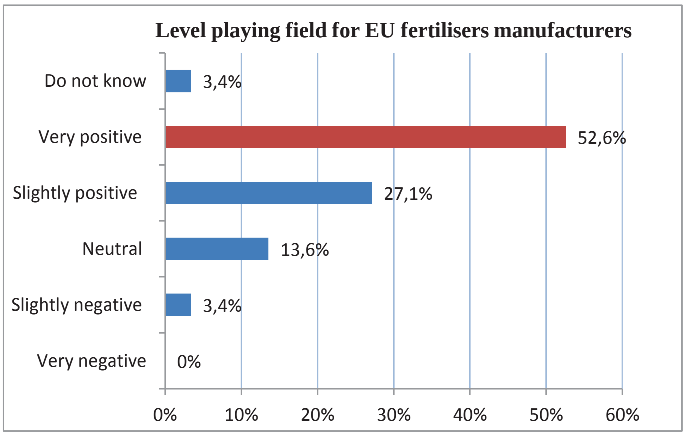
– turn-over development (65.5%),

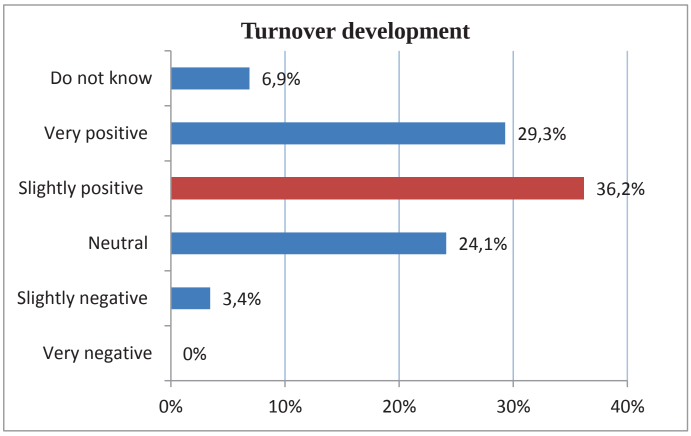
– better access to third country markets (58.6%) and economy of scale (46.5%),

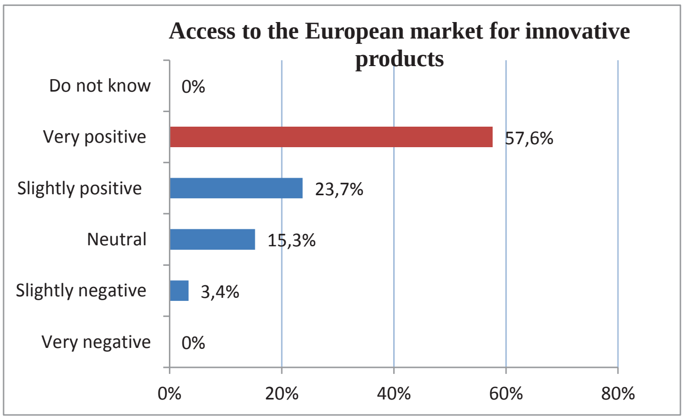
– less administrative burdens (44.8%).

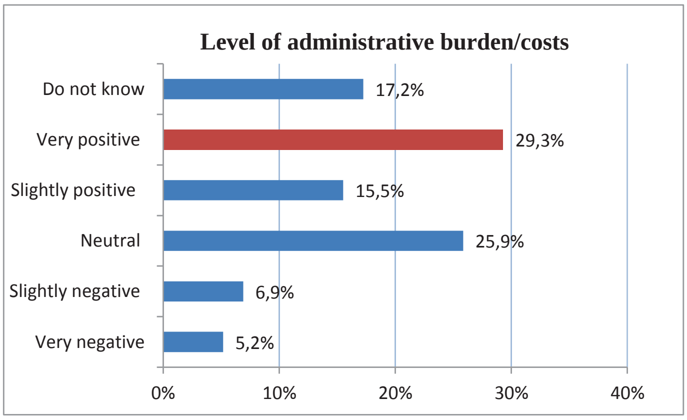
The questionnaire also proposed participants to identify specific criteria that would be relevant for them. One SME mentioned that the harmonisation could bring an increase in fertiliser prices. Another reported that harmonisation could allow producers to have access to a broader selection of raw materials.

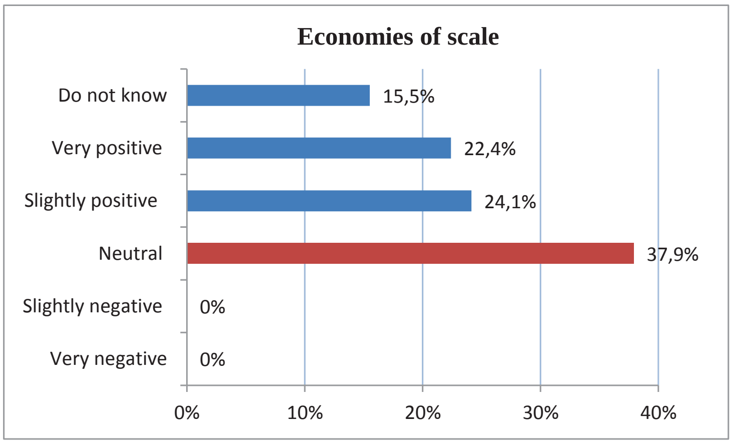
Figure 17: SMEs expectations as regards the harmonisation of the EU fertilisers market according to different criteria

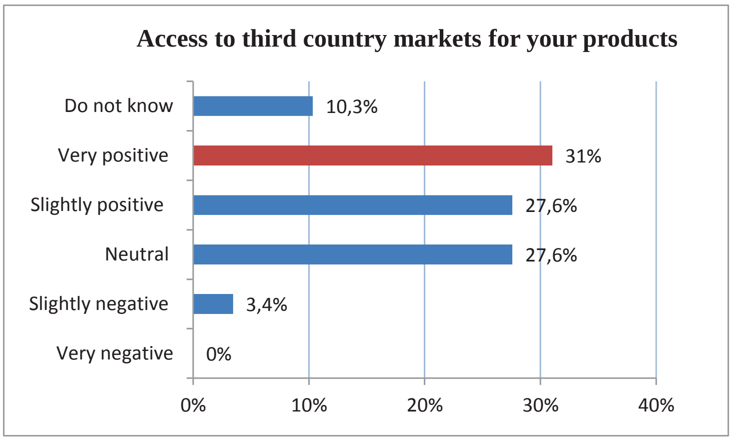

Level playing field for EU fertilisers manufacturers
Do not know
Very positive
Slightly positive
Neutral
Slightly negative
Very negative
3,4%
52,6%
27,1%
13,6%
3,4%
0%
0%
10%
20%
30%
40%
50%
60%

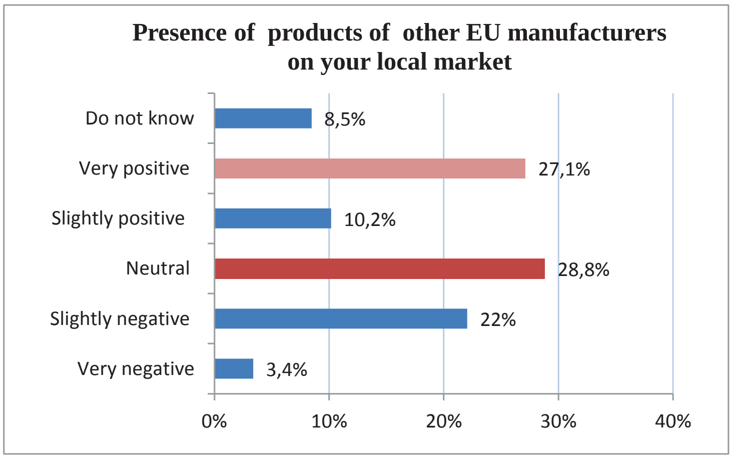

Turnover development
Do not know
Very positive
Slightly positive
Neutral
Slightly negative
Very negative
6,9%
29,3%
36,2%
24,1%
3,4%
0%
0%
10%
20%
30%
40%

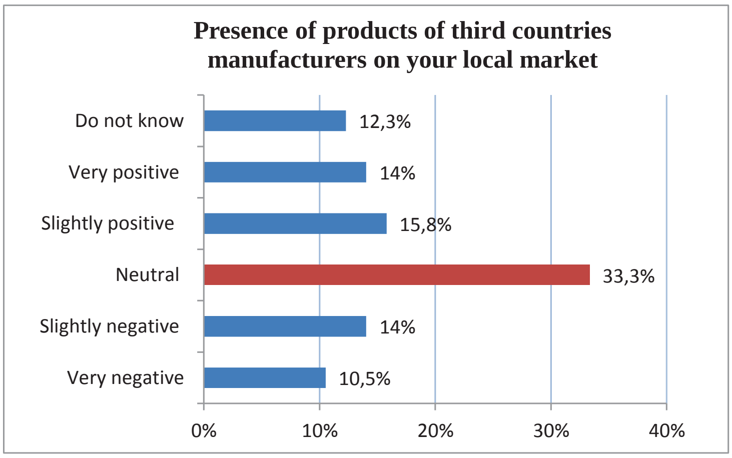

Access to the European market for innovative products
Do not know
Very positive
Slightly positive
Neutral
Slightly negative
Very negative
0%
57,6%
23,7%
15,3%
3,4%
0%
0%
20%
40%
60%
80%

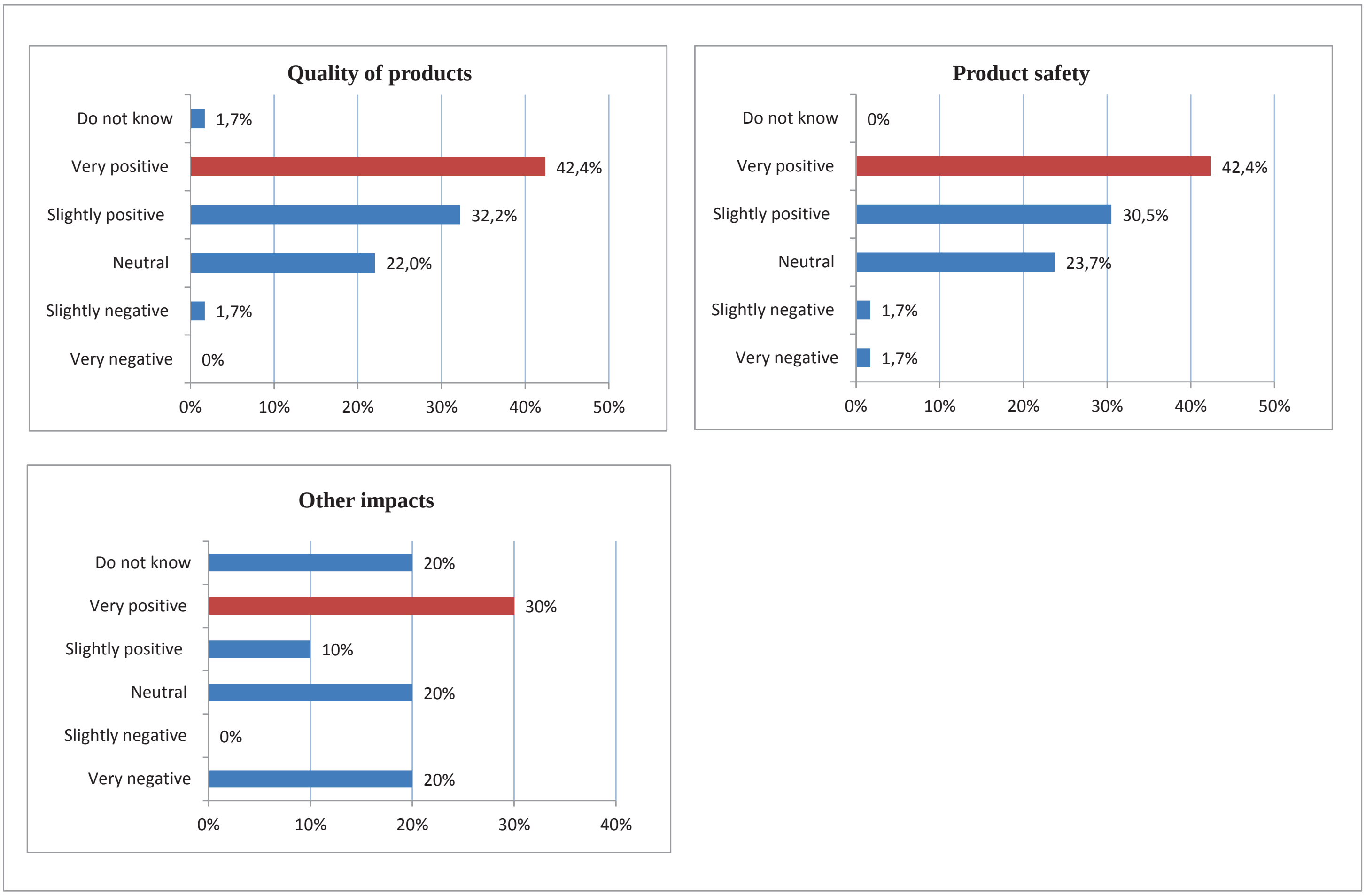

Level of administrative burden/costs
Do not know
Very positive
Slightly positive
Neutral
Slightly negative
Very negative
17,2%
29,3%
15,5%
25,9%
6,9%
5,2%
0%
10%
20%
30%
40%


Economies of scale
Do not know
Very positive
Slightly positive
Neutral
Slightly negative
Very negative
15,5%
22,4%
24,1%
37,9%
0%
0%
0%
10%
20%
30%
40%


Access to third country markets for your products
Do not know
Very positive
Slightly positive
Neutral
Slightly negative
Very negative
10,3%
31%
27,6%
27,6%
3,4%
0%
0%
10%
20%
30%
40%


Presence of products of other EU manufacturers on your local market
Do not know
Very positive
Slightly positive
Neutral
Slightly negative
Very negative
8,5%
27,1%
10,2%
28,8%
22%
3,4%
0%
10%
20%
30%
40%


Presence of products of third countries manufacturers on your local market
Do not know
Very positive
Slightly positive
Neutral
Slightly negative
Very negative
12,3%
14%
15,8%
33,3%
14%
10,5%
0%
10%
20%
30%
40%

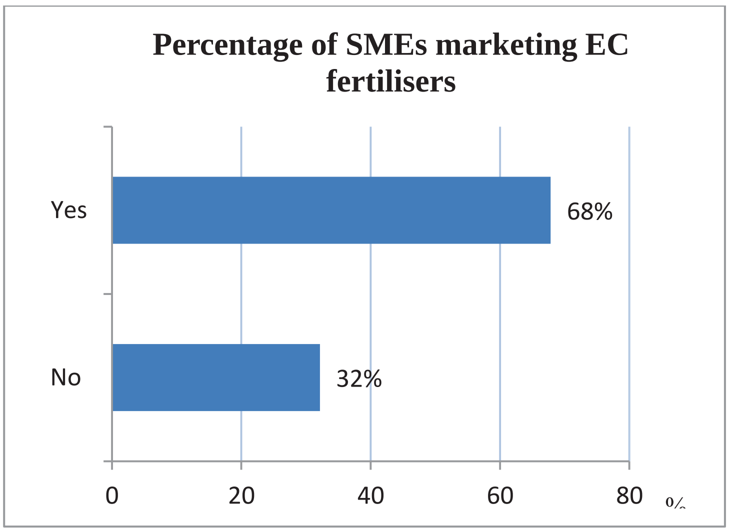


Section 3: Evaluation of the current costs for the marketing of EC Fertilisers

Q8: Are you marketing EC Fertilisers?

68% of the responding SMEs are marketing both EC Fertilisers and national fertilisers. 32% are marketing exclusively national fertilisers.

Figure 18: Percentage of SMEs currently marketing EC Fertilisers



Q9: What are the costs for compliance with the current Fertilisers Regulation? Please estimate the costs on a yearly basis (unless otherwise specified) and where relevant.

The costs for compliance with the current Fertilisers Regulation for the SMEs active on the internal market are shown in next table.

Table 51: The current costs for marketing EC Fertilisers according to responding SMEs

Evaluation of the current costs for marketing EC Fertilisers	**Min.** (EUR/yr)	**Max.** (EUR/yr)	**Percentage of respondents in respect to all participants**
Registration of a new EC Fertiliser type (one-off costs)	30	10 000	15
Costs to adapt your production process (including raw materials) to an existing fertiliser type designation of the Fertilisers Regulation (one-off costs)	250	30 000	10
Costs for compliance check and monitoring of your production	250	100 000	18
If your monitoring authority charges fees for control measures, please provide information on the costs	1 500	5 000	10
Costs to develop and get a European standard approved – only for companies which requested the introduction of a new fertiliser type in the Fertilisers Regulation (One off-costs)	50	50	2
Costs of keeping records of the traceability of ammonium nitrate EC Fertilises of high nitrogen content	250	10 000	10
Costs of labelling obligations	200	80 000	20

Section 4: Evaluation of the costs for marketing national fertilisers

Q10: what are the costs for compliance with your national legislation(s) on fertilisers and related materials (soil improvers, liming materials, growing media and plant biostimulants). Please estimate the costs on a yearly basis (unless otherwise specified) and where relevant?

Similarly as for the previous section, table 49 displays the costs the SMEs have to pay in order to comply with their national legislation(s) on fertilisers and related materials.

Table 52: Current costs for marketing national fertilisers according to responding SMEs

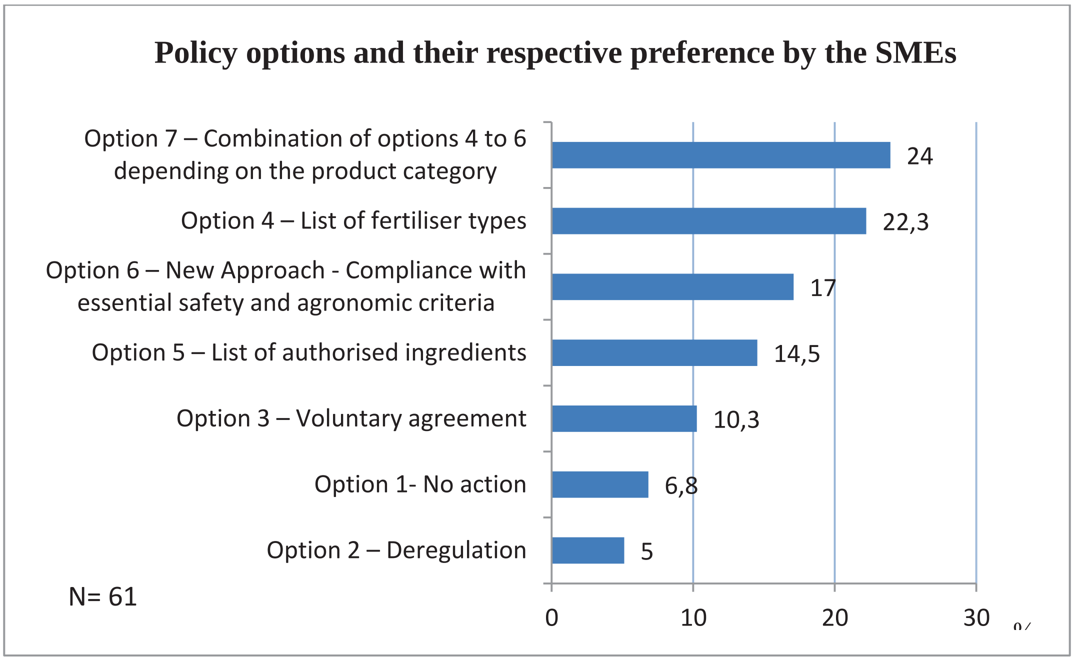
Evaluation of the current costs for marketing national fertilisers	**Min.** (EUR/yr)	**Max.** (EUR/yr)	**Percentage of respondents in respect to all participants**
Registration of a new national fertiliser type – if applicable (one-off costs)	250	75 000	31
Costs to adapt your production process (including raw materials) to an existing fertiliser type designation of your national law – if applicable (one off-costs)	1 000	400 000	15
Costs for compliance check and monitoring of your production	75	100 000	33
If your competent authority charges fees for control measures, please provide information on the costs	500	50 000	15
Costs to develop and get a national standard related to a new product approved – if applicable (one-off costs)	200	200 000	13
Cost of prior authorisation procedure for the marketing of a new product – if applicable (one off-costs)	50	160 000	16
Costs of reporting and keeping records required by your national legislation on fertilisers – if applicable	60	250 000	23
Costs of labelling obligations	400	100 000	36

Section 5: Impact on your business of possible options for the harmonisation of the European fertiliser market

Q11: Following the description of the possible options given in the background document, could you indicate what would be your preferred option(s)?

At the time of the consultations 7 policy options were described. They have been ranked in decreasing order of performance in the following figure.

Figure 19: Legislative options shown as preferred by the SMEs (multiple choices were allowed: the number of votes for each option was recalculated to fit to 100%)



Companies expressed a preference for Option 7, followed by Options 4 and 6.

The least favoured legal approaches were Options 3, 1 and 2.

Q11 bis: Could you estimate the advantages and drawbacks for your business of the selected options? Open question

The information collected during the survey is presented below and has been classified according to different criteria.

Table 53: The advantages and drawbacks of the selected policy options according to responding SMEs

Legal options		Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7
Level playing field	Pro:							
	Con:	1) Unfair situation for products out of its scope. Companies in countries with more flexible requirements will be advantaged compared to companies that have to comply with stricter requirements 2) National legislations diverge significantly entailing costs and unnecessary delay to reach the market 3) Obstacle to the free movement of goods on the internal market, mostly due to the implications of the Mutual Recognition Regulation	1) Presence of low quality products could lead to unfair competition, chaos and market crash 2) Requests for mutual recognition of products would increase which could lead to unfair competition between EU producers	1) Concerns whether it could achieve a reasonable harmonisation of the market 2) Lack of transparency and possible conflict of interests			1) Could lead to a lack of traceability of organic materials of animal or plant origin	
Innovation	Pro:		1) Freedom to place new fertilising products on the market	1) Possibility for emergence of new markets and boost for innovation	1) Better access to a broader range of raw materials	1) Simplification if the raw materials listed can be easily identified	1) Criteria instead of lists would make the scene more open to innovation	1) Flexibility in acco with the needs of sector
	Con:	1) Diverging national requirements restrict innovation 2) The cost and time needed for new products to be listed currently hinders			1) The lengthy procedures for the introduction of new fertilisers is an obstacle to innovation	1) Has the drawback of not being easy to adapt in case of new ingredients or ingredients to be withdrawn 2) Barrier to new		

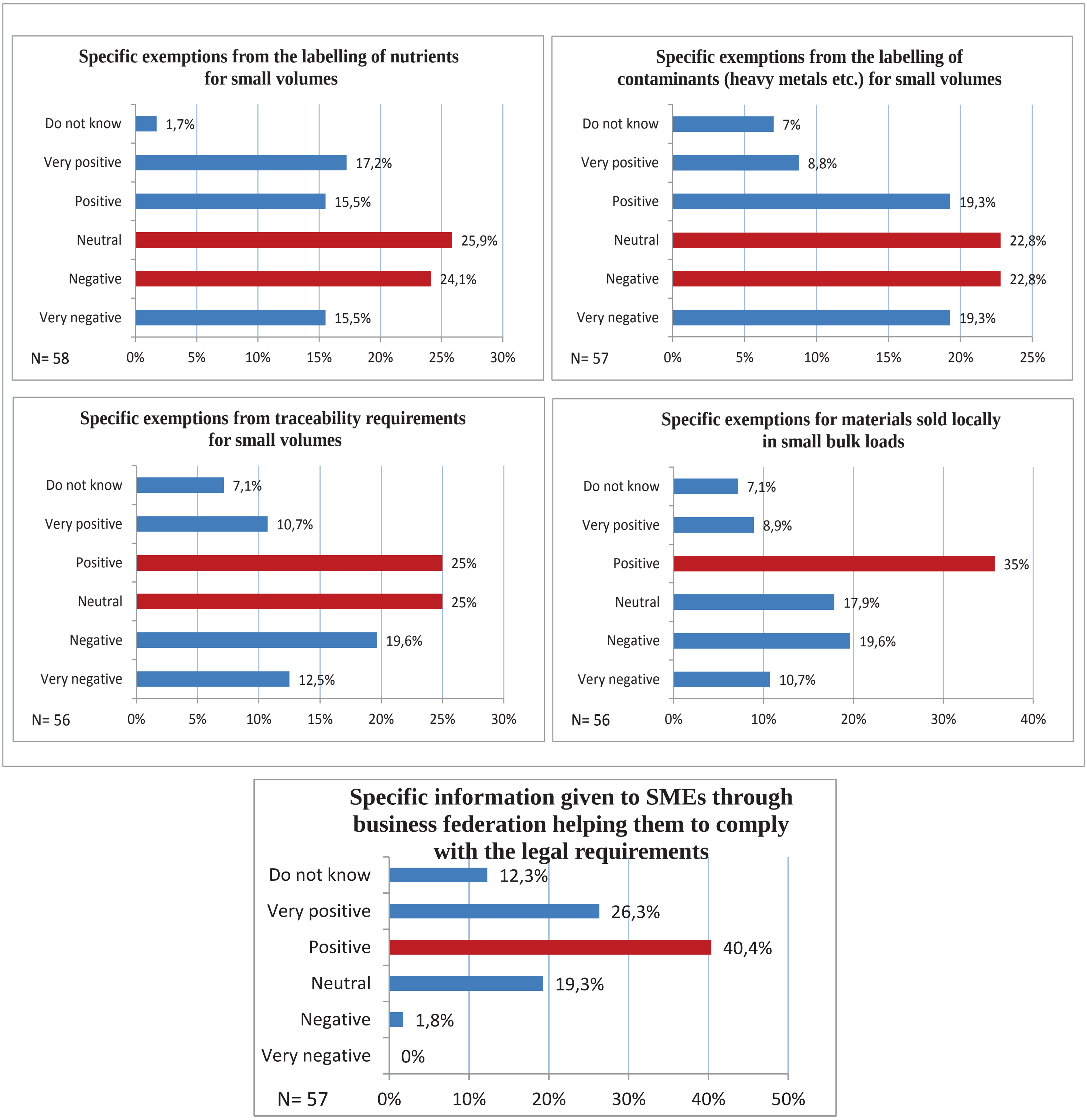
		innovation				ingredients, research and innovation 3) Difficulty to develop new product types		
Compliance	Pro:	1) No change for labelling requirements or other regulatory compliances for existing inorganic fertilisers already on the market			1) Well-known system adopted in many Member States and in the EU Fertilisers Regulation			
	Con:				1) Difficult to define the requirements and evaluation procedures for the application for registration of new products and/or to comply with them		1) Anything that is considered as 'safe' and has a certain agronomic efficacy could be commercialised 2) Could not have the same level of requirements as a complex authorisation registration procedure	1) Considered as too complex and wou require long nego for agreements
Administrative costs	Pro:						1) Transparency and reduction of administrative burden and time frames	1) Transparency and reduction of administrative bu and time frames
	Con:	1) Cost and time needed for new products to be listed in Annex I				1) Cost of registration in Annex I is of concern	1) Fear of rise in the cost of certification and delays to access the market if additional trials are requested	
Efficacy of products	Pro:						1) More claims with proven agronomic efficacy	
	Con:		1) Lack of guarantee for the users	1) Lack of guarantee for users				

Safety of products	Pro:						1) Include all types of safety criteria in generic way	
	Con:		1) Lack of guarantee for the users	1) Concerns whether it can achieve better safety of products				
Legal clarity	Pro:	1) This option could be used as a basis for the preparation of the harmonised legislation on fertilising products				1) Easy to follow as, for each new ingredient, there would exist an obligation to have a technical file		
	Con:		1) Between a restrictive regulation and a deregulation there is plenty of space to work.	1) Fear that only the big industries would have importance in the decision making process. 2) The procedure to draft standards and quality procedures is costly 3) Burdensome and too complex for distributors and users	1) Potential abuse or confusion of lists	1) Potential abuse or confusion of lists	1) Not strict enough 2) Possible confusion for economic operators 3) Difficulty and time to set up harmonised standards	1) Possible difficulti understanding the legal framework

Q12: What do you think about the following measures to reduce the regulatory burden on SMEs?

The Commission proposed several measures to reduce regulatory burden on SMEs (Figures 19 and 20). The proposed measures are listed below as well as the opinions of the respondents. Several responses were allowed.

Figure 20: SMEs opinions on measures to reduce regulatory burden related to small volumes of product. Several replies were allowed



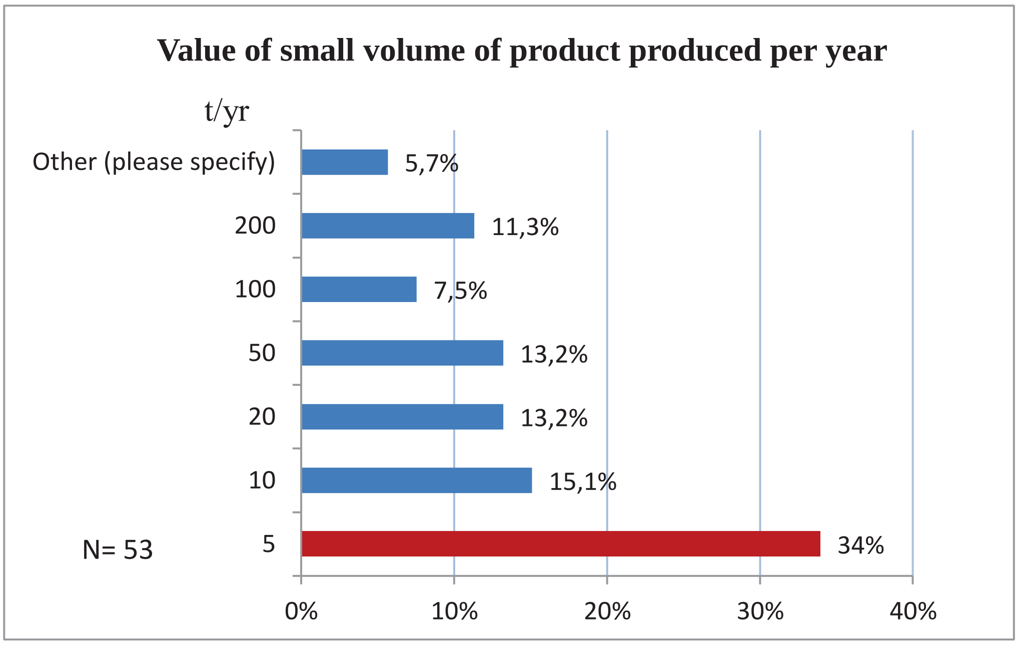
Specific exemptions from the labelling of nutrients or contaminants for small volumes were generally rated as neutral and negative (50%). A remark to the *"specific exemptions from the labelling of nutrients for small volumes"* has been submitted by a Belgian SME about the importance of having both the content and the origin of the nutrients declared on the label in order to guarantee the quality of the product. Exemptions could be only granted to products sold locally in small bulk loads.

Specific exemptions from traceability requirements for small volumes were seen as positive to neutral.

SMEs dealing with imports from other Member States wish easy handling and labelling of these products.

Q13: In relation with Q12, what should be considered a small volume of product produced annually (in tonnes)?

Figure 21: SMEs views on what should be considered a small volume of product produced per year (in tonnes) under which mitigation measures could apply.



One third of the respondent SMEs are in favour of 5 tonnes per year as a threshold for small volumes.

According to some SMEs, allowing a reduced administrative burden for up to 5 tons/year will lead to an influx of deregulated products with unsupported claims on the market. Some SMEs feel that exceptions for small volumes should not be allowed as the same rules should apply for all.

Further comments regarding measures to reduce the administrative burden for SMEs were suggested by the respondents as follows:

1. The harmonisation would play a significant role in reducing the administrative burden and cost for small and medium enterprises, as well as accelerating the placement of new products on the market. Thus, the same rules would apply to all Member States.

2. The lack of a harmonised regulation is seen as a significant drawback when it comes to commercialising fertilisers products. Ready to be commercialised EC Fertilisers products should be regulated by rules enabling quicker access to the market which are flexible enough with respect to innovation of new products and additives. Only products whose efficacy has been scientifically proven should be registered or sold on the internal market to protect both the end users and the market from poor quality products.

3. Having a uniform, harmonised regulation, based on common principle of traceability, would also remove legal interpretations by the Member States. An authority for market surveillance would still be needed in order to judge the compliance of the products with the future legislation.

4. A SME from Ireland proposed creating a centralised registration listing of product available online to all Member States that would contain information about Third party verification.

5. The current cost for registration is viewed as excessively high for the SMEs considering the sales volumes are limited. The cost of registration shared per Kg or L produced can be very high, more so in view of the crisis that has also hit the agricultural sector.

6. An additional burden for small companies is the expense needed to support excessive field, analytical and toxicological studies. The administrative paperwork should be simplified were possible, especially for companies which are just starting their business.

7. A Regulation based on product types, instead of individual permissions, would greatly lighten the administrative burden on the SMEs. Consideration should be given to simplifying the authorisation process of products with clear and guaranteed origin thus facilitating the import of high quality and efficient products.

8. Overall, the revised Fertilisers Regulation could benefit from less complex bureaucracy, which is sometimes difficult to interpret and even contradictory.

9. An additional suggestion concerns bio-agriculture products. All fertiliser products having a certificate for use in bio-agriculture should be exempted from registration in conventional agriculture. There should be an annual fee covering the costs of the National Authority for checking the validity of the certificates for use in bio-agriculture.

Q15: Have you ever suffered from a scarcity of raw materials in the last 10 years? If so what was the main problem and which product was concerned?

Among those who responded positively (37%), 46% were SMEs with 10 to 49 full-time employees and 40% have from 50 to 249 full-time employees. 53% answered negatively and 10% of the responding SMEs did not have any opinion.

The main problems and products concerned were the following:

1. The occurrence of the Bovine Spongiform Encephalopathy (BSE) crisis induced an animal-based raw material crisis, followed by an EU ban on beef meat from the UK from March 1996 through May 2006. During that period animal based raw materials inflow decreased, leading to an increase in prices of the products. The dramatic

increase in cost of animal by-products was also partly due to the subsidised raw material needs of Russia and China.

2. Other problems with scarcity in animal by-products had been registered for blood meal and guano, feather meal and roasted horn. Since the year 2012, a lack of availability (coupled with high prices) of transformed animal proteins has occurred. Shortages were also recorded for pulp grape and olives after a bad crop yield.

3. Other than animal by-products, products mainly concerned by shortage were phosphorus, rock phosphate with low cadmium content and superphosphate fertiliser, due to the political crisis in Northern Africa and the Middle East since the end of 2010. The fertiliser price increases in 2008 was also mentioned.

4. An Austrian SME reported scarcity of N+S products, especially for NPK formulas of high sulphur content. The cessation of the production of manganese sulphate led to difficulties for that particular SME.

5. Shortage of potassium products such as potassium nitrate and potassium chloride, the suppliers of which faced strike movements resulting in long delay periods and consequent problems with crop quality, were also reported.

6. Problems of access to raw materials are often directly related to the import dependence from China. Chinese export taxes are seen as burdensome for a small Spanish producer of fertiliser blends, plant biostimulants and amino acids (e.g. problems with the main provider of specific protein hydrolysing enzymes and specific phosphorus compounds).

7. A short-term shortage of ethylenediamine (EDA), a building block in chemical synthesis, had been also reported during the period.

8. A SME would be interested in having easy access to ammonium based fertilisers from Russia without facing anti-dumping restrictions.

Q17: Have you experienced difficulties to compete with other firms (including from third countries) in the last 10 years?

Half of the SMEs expressed difficulties to compete with other firms (including from third countries) in the last 10 years. SMEs with 10 to 49 employees were the most affected. 27% answered that they have not suffered from competition with other players and 22%did not answer the question.

The following main competitiveness issues were identified by the respondents:

A) Level playing field:

Producers of fertilising products falling outside the scope of the current Fertilisers Regulation suffer from the absence of harmonisation of legislation across the European Union. These products are regulated, if at all, through national legislation, with various levels of stringency as well as differing limit values for contaminants. Some harmonisation has been instilled through the application of the Mutual Recognition Regulation.

SME consultation has highlighted many situation of unfair competition which were not improved through application of the MRR, and sometimes even worsened.

For example, Belgian legislation provides for a traceability obligation which requires substantial investments. As this is not the case in many other MS, it creates unfair competition. Indeed, the fact that some Member states impose costly requirements to the products first marketed in their territory is unfair to these products in the context of mutual recognition as they will have to compete with products legally marketed in other less stringent MS which can enter at lower prices into their market through the application of the MRR.

This problem is particularly blatant for SMEs, which are always more sensitive to distortion in competition, and which are confronted with unfair competition from European companies which do not have to comply with their national legislation. It has in particular been reported that French SMEs are penalised towards many organic products from neighbouring countries like Spain, Belgium and Italy. Such a situation was similarly reported for Slovenia where non EC Fertilisers have to undergo registration and declaration under national law and compete with the same unregistered fertiliser from other Member States.

Finally, situations of dumping in the fertilising sector have been reported. Dumping occurs when manufacturers export a product to another country at a price either below the price charged in its home market, or in quantities that cannot be explained through normal market competition. While it is condemned by the World Trade Organisation, it is not legally prohibited. In the field of fertilisers, Bulgarian SMEs have to struggle against foreign subsidised fertilisers sold at minimum prices, which cause injury to the national market.

B) Administrative costs:

The time currently needed for the authorisation of fertiliser products (e.g. fundamental problem for organic fertilisers and biostimulants) is considered too long and costly in the context of diverging national requirements.

SMEs particularly suffer from that situation, as their position in this regard greatly differs from the economic, financial and political strength which big-scale producers benefit from.

C) Safety and quality requirements:

The introduction of new types of fertilisers for which agronomic efficiency has not been fully demonstrated poses a potential problem.

Humic acids products have to face what is analysed as unfair competition from products containing other substances than available humic acids.

It has in particular been reported that the Spanish market is burdened by low-price products in all categories of fertilising products with unknown composition and for which quality control has not been conducted according to the Spanish regulations.

In Bulgaria, anticompetitive behaviour stems from Romanian and Greek manufacturers offering fertilisers of unknown composition and quality misleading end users.

Comparison of the safety and quality of products offered across the market is impossible as there is no standardised quality system across Europe.

D) Innovation:

There have been complaints that national legislations do not always follow the development of the market.

Additional comments received were as follows:

The harmonisation of the organic fertilisers market is very important for SMEs. It is neither logical nor equitable that organic fertilisers which are often manufactured by SME are not harmonised under European legislation. This harmonisation would develop a fair competition between manufacturers and would also allow having identical rules relating to production, treatment, traceability, innocuousness and efficiency of products. Specific priority therefore should be given to organic fertilisers.

The absence of a harmonised regulation as well as monitoring/surveillance for different categories of products has made possible the emergence of products whose composition and effects do not correspond to the information and claims declared on the label. Control checks in the future should ensure that fertilisers which do not conform to the quality and safety requirements are not placed on the market.

The producers of organic fertilisers fear the harmonisation of the Fertilisers Regulation will allow for unsafe and untraceable products from treated sewage waste to be marketed as organic fertilisers or soil improvers. Therefore it would be a mistake to consider them as one single group of organic fertilisers. Quality and traceability should remain the main parameters when it comes to marketing products.

SMEs also remind the EC to prohibit the use of raw materials of doubtful origin, e.g. hazardous residues from industrial sludge, due to their high content of heavy metals and pharmaceutical chemicals as well as the chemical instability of the nutrients within. The outcome would have an enormous financial impact on the business of the current sector of organic fertilisers. These products could induce a new health or environmental crisis in Europe (e.g. EHEC: entero-haemorrhagic Escherichia coli).

In Belgium, organic fertilisers and soil improvers are still subject to strict requirements such as for example minimum nutrient contents, organic matter contents, traceability, etc. The quality control and traceability of raw materials and final products is not at the same level in all Member States which leads to issues in the application of the mutual recognition procedure.

Planned limit values for heavy metals, especially cadmium, should be chosen in line with the available quantity of rock phosphate of a certain quality. Otherwise, additional costs will arise from higher costs of raw materials and loss of production.

SMEs would also like the minimum NPK level of compound fertilisers to be sufficiently high in order to ensure the efficacy of products and a clear differentiation between organic fertilisers and soil improvers. Although inorganic and organic fertilisers have different characteristics, both need to meet the same guarantees regarding the minimum nutrient contents of N, P and K. On the other hand, high requirements for the analysis of NPK content pose a financial threat to some businesses.

In conclusion, SMEs believe that a new EU regulation on fertilisers with a larger scope which would ensure harmonisation on the legal requirements for the marketing of different types of fertiliser products would be positive. The future regulation will open more opportunities for EC Fertilisers to compete on the global market. It is one of the EC's foremost aims to take into account small producers and their needs in order to facilitate the development of SMEs, rather than hindering them.

<u>Innovation and new products</u>:

New products such as plant biostimulants should get an easier access to the market as those products respond to farmers needs to increase crop yields.

A centralised voluntary registration of new products, supervised by a third party authority and available online across the EU, would allow plant biostimulants with proven claims to be distributed on the internal market.

Given that there is no harmonised legislation at European level specifying which studies should be carried out to demonstrate the safety and efficacy of plant biostimulants, companies are investing time and money in risk assessment and agronomic studies. Those investments should be protected. The use of positive lists of authorised plant biostimulants would not protect innovation as competitors would have the possibility to use existing entries to market the same product without facing the same costs

2. ASSESSMENT OF BUSINESS LIKELY TO BE AFFECTED

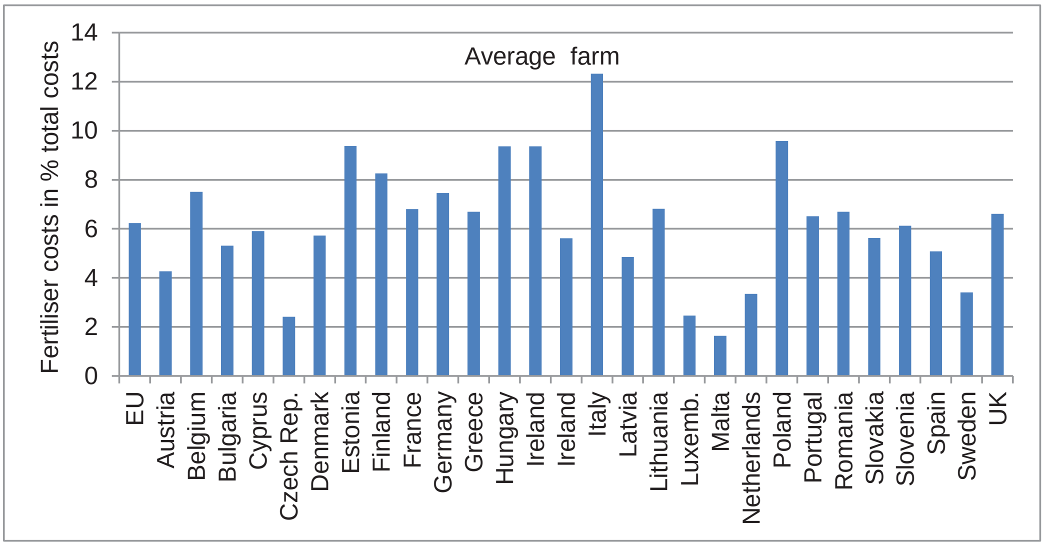
In 2012, an external consultant carried out an assessment of the impacts of the options on competitiveness (hereafter the Competitiveness Report) and proposed corrective and mitigations measures where relevant. Due to budgetary constraints the impacts on producers of three representative fertilising products sectors (NPK inorganic fertilisers[189], animal manure used as organic fertilisers and compost) as well as on farmers were examined qualitatively. According to the market values reported in Annex I, the sectors examined by the consultant represent 80% of the market value of the fertilising products sold on the EU market. The study concluded that the main expected impacts on competitiveness will lie with farmers.

Any reduction in the price of inorganic fertilisers would slightly increase the competitiveness of most EU farmers and, in particular of cereal farmers for whom fertiliser costs are relatively important. Likewise, a reduction in the price of growing media would slightly increase the competitiveness of farms in the horticulture sector.

The consultant reviewed the consumption and costs of fertilising products compared to all input expenditures for various farm types. Fertilisers are important inputs in agriculture to ensure good yields and revenues to farmers. On average fertilising products account for 6.2% of EU farm's annual expenditure – however, the costs vary per farm type and per Member State and range from 12.1% in Italy to only 1.6% in Malta (*see* Figure 4).

[189] Blends of nitrogen (N), phosphorus (P) and potassium (K)

Figure 22: Percentage fertiliser costs versus total input costs for various EU farm types. Average costs of 2007-2009. (*Source: EU farm accountancy Data Network*)



As illustrated in the next table, for most Dutch farms, inorganic fertilisers represent the most important expenditure based on the available data from the Dutch farm accountancy. In horticulture, however, growing media and inorganic fertilisers have the same costs share. Similar trends could be found in other Member States.

Table 54: Costs of fertilising products per farm in the Netherlands in EUR (average 2008-2010). (*Source: the Competitiveness Report)*

	Field crops	Graz. Livestock	Grani-vores	Mixed crops livestock	Horti-culture	Perm. Crops
Inorganic	11,653	5,402	818	7,288	11,633	5,325
Organic	235	13	1	139	299	216
Manure	153	6	3	6	71	121
Growing media	1	4	2	532	11,955	146
Biostimulants	16	21	3	6	12	86
Total costs fertilising products	12,057	5,446	827	7,971	23,970	5,893
Total all costs	207,291	213,147	500,136	306,815	866,075	244,629
% fertilising products vs total costs	5.8	2.6	0.2	2.6	2.8	2.4

3. MEASUREMENT OF THE IMPACTS ON SMES

The main issues for SMEs relate to the time to market new products (diverging and complex regulatory framework, development of standards), the costs of authorisation procedures or certification by third parties, the costs of developing standards and the costs of compliance of products with the requirement of the legislation.

The assessment of each option contains information about the time to market products and the costs of standardisation, authorisation procedure or certification. Some possible mitigation measures are also described where appropriate. Therefore, the analysis below aims to identify the main compliance costs of products (business as usual and administrative burden costs) and propose possible mitigation measures that could apply to Options 2 to 5.

3.1. Composition of 'business as usual costs' as regards compliance check

According to the information collected during the stakeholder consultation in 2012, the costs of nutrient analysis and other quality criteria are relatively low and vary between EUR 15 to EUR 70 per sample. As the analysis and declaration of agronomic quality criteria is the only possibility for producers to differentiate their products from competitors, they will definitely proceed with their analysis. Therefore, they can be considered as 'business as usual' costs.

The costs of keeping records will be also considered as 'business as usual' costs as it is assumed that manufacturers will ensure the traceability of their products even in the absence of legal requirements.

The impacts of the abovementioned costs have not been further evaluated in the policy options.

3.2. Composition of administrative burden costs as regards compliance obligations

The analytical costs of contaminants could be considered as additional administrative burden costs in particular for EC Fertilisers for which the determination of heavy metals is not mandatory so far. Table 54 below summarises the most significant costs for the analytical determination of contaminants. The prices represent the costs charged to companies by accredited laboratories to carry out analysis. The costs of pathogens, plant propagules and inert materials determination are well below EUR 100 and are therefore less significant compared to the costs listed in the next Table.

Table 55: Evaluation of the costs of analysis of heavy metals and organic pollutants in fertilising products (VAT not included) based on information from 9 Member States

	6 Non-nutrient metals	PAHs (16 congeners)	PCBs (7 congeners)	PCDD/Fs (7 PCDDs and 10 PCDFs)
Average costs based on information from nine Member States	EUR 130	EUR 150	EUR 200	EUR 470

It appears that SMEs could be seriously impacted by analytical costs of contaminants (in particular for PCDD/Fs) if the frequency of controls is set at a very ambitious level and/or the whole range of organic pollutants needs to be controlled. For comparison, prices provided for the full package of measurements excluding PAHs varies generally between EUR 350 and EUR 550. The total cost of EUR 950 was however used for the assessment of the costs of Third Party certification under variants 4C and 4D as the costs between laboratories could be huge.

4. ASSESSMENT OF POSSIBLE MITIGATIONS MEASURES

4.1. Reduction of frequency of controls for products deriving from biodegradable waste (applicable to options 2 to 5)

There is a large consensus among stakeholders to require the analysis of heavy metals across the board as their cost of analysis is not too expensive and could be supported by SMEs if the frequency of controls remains reasonable.

Companies involved in the marketing of inorganic fertilisers, liming materials, growing media and plant biostimulants should be exempted from the analysis of organic pollutants because such contaminants are not expected to be found in such products.

However, **companies producing organic fertilisers and organic soil improvers** could be more affected as the presence of organic contaminants in those products cannot be excluded even when segregated source materials are used. Moreover, organic fertilisers and organic soil improvers have very low market value compared to other types of products.

Following the different discussions during the preparation of the EU EoW criteria on biodegradable waste, many calls were made to set a **minimum sampling frequency**, in order to guarantee common standards across Member States. Furthermore, it was generally supported that the measurement frequency should be established depending on the size of the compost or digestate producing plant. At the same time, there was wide support for a **minimization of the burden incurred by frequent sampling and analysis**, by allowing for a reduction in measurement frequency for those parameters that repeatedly are far below the limit values.

The following relaxing sampling and measurement requirements were proposed:

1. During the year of reference, an accredited laboratory should verify that any consignment of compost/digestate complies with agreed safety limits values on organic contaminants to ensure a level playing field among producers.
2. The measurement frequency should be established according to the size of the compost or digestate producing plants. The **minimum measurement frequency should be 4 in the first year** (one sample every season) unless the plant treats less than 3 000 tonnes of input material. In that case, one sample for every 1 000 tonnes of input material rounded to the next integer would be required. This **minimum sampling frequency** should guarantee common standards across Member States.
3. If external sampling shows in the first year that safety parameters (heavy metals and PAH values) are significantly below the threshold value (at 95% confidence level), from the second year, internal sampling could be carried out in accordance with the Table below. The sampling and analysis of PAHs shall always be conducted by a Third Party.
4. In the case of important changes (> 20% of new raw materials) in product formulation, the measurement frequency should be reset at the level of the recognition year. Such major changes should be linked to a change of supplier or the introduction of a new type of input material. Natural seasonal variations of input materials, e.g. those occurring in municipal recycling parks for household green waste are not considered major changes.

Table 56: Overview of proposed minimum sampling frequency and associated costs under the proposed EU EoW criteria for biodegradable waste. External sampling costs: EUR 200, internal sampling costs EUR 50, PAHs analytical costs EUR 150, analytical costs for other contaminants excluding PAHs EUR 450 (costs excluding VAT). Source JRC report on EU EoW criteria for biodegradable waste

	Sampling and analysis frequency (number/year)										Cost			
	Recognition year					Following years					Recognition year		Following years	
	Sampling			Analyses		Sampling			Analyses					
Annual Input (tonne)	Total	External	Internal	All but PAH	PAH	Total	External	Internal	All but PAH	PAH	Total (Euro)	Unit cost (Euro/tonne)	Total (Euro)	Unit cost (Euro/tonne)
<500	1	1	0	1	1	1	1	0	1	0.2	800	1.60	680	1.36
500	1	1	0	1	1	1	1	0	1	0.2	800	1.60	680	1.36
1000	1	1	0	1	1	1	1	0	1	0.2	800	0.80	680	0.68
1500	2	2	0	2	1	2	1	1	2	0.2	1450	0.97	1180	0.79
2000	2	2	0	2	1	2	1	1	2	0.2	1450	0.73	1180	0.59
2500	3	3	0	3	1	2	1	1	2	0.2	2100	0.84	1180	0.47
3000	3	3	0	3	1	2	1	1	2	0.2	2100	0.70	1180	0.39
3500	4	4	0	4	2	2	1	1	2	0.2	2900	0.83	1180	0.34
4000	4	4	0	4	2	2	1	1	2	0.2	2900	0.73	1180	0.30
4500	4	4	0	4	2	2	1	1	2	0.2	2900	0.64	1180	0.26
5000	4	4	0	4	2	2	1	1	2	0.2	2900	0.58	1180	0.24
7500	4	4	0	4	2	2	1	1	2	0.2	2900	0.39	1180	0.16
10000	4	4	0	4	2	2	1	1	2	0.2	2900	0.29	1180	0.12
15000	4	4	0	4	3	3	2	1	3	0.5	3050	0.20	1875	0.13
20000	4	4	0	4	3	3	2	1	3	0.5	3050	0.15	1875	0.09
25000	4	4	0	4	4	4	2	2	4	0.5	3200	0.13	2375	0.10
30000	4	4	0	4	4	4	2	2	4	1	3200	0.11	2450	0.08
40000	5	5	0	5	4	5	3	2	5	1	3850	0.10	3100	0.08
50000	6	6	0	6	5	6	3	3	6	1	4650	0.09	3600	0.07
60000	7	7	0	7	5	7	4	3	7	2	5300	0.09	4400	0.07
70000	8	8	0	8	6	8	4	4	8	2	6100	0.09	4900	0.07
80000	9	9	0	9	6	9	5	4	9	2	6750	0.08	5550	0.07
90000	10	10	0	10	7	10	5	5	10	2	7550	0.08	6050	0.07
100000	11	11	0	11	7	11	6	5	11	2	8200	0.08	6700	0.07
110000	12	12	0	12	8	12	6	6	12	3	9000	0.08	7350	0.07
120000	12	12	0	12	8	12	6	6	12	3	9000	0.08	7350	0.06
>120000	12	12	0	12	9-12	12	6	6	12	3-12	≤9600		≤8700	

Where quality certified compost or digestate is used today under waste regulatory controls, end-of-waste criteria are likely to lead to a **net cost reduction**. The cost reductions accrue to the use sector, and may possibly be transferred back to some extent, through the acceptance of increased compost and digestate prices, to compost and digestate producers, and through reduced gate fees to municipalities or other relevant waste generators.

Where the quality certification of compost and digestate needs to be upgraded for complying with end-of-waste criteria, this creates increased costs for compost and digestate producers, which are not likely to be very significant in relative terms for large scale compost and digestate production, but may represent more than 15 % of total costs in the case of very small-scale production. This may be compensated, at least partly, by increased revenues through higher prices in compost and digestate sale, if users accept that there is a sufficiently high benefit to them in terms of avoided compliance costs and better and more reliable product quality. Finally, clear carbon benefits and other environmental benefits can be reaped from shifting to end-of-waste status.

Nonetheless, it should be clear that **for very small plants**, sometimes operating without the income from gate fees, applying for end-of-waste status **may not be economically feasible**. This group typically comprises small scale community composting systems that work on a voluntary basis or with limited financial means. In this context, some experts had suggested to further relax or lift requirements on mandatory measurements for these small plants, in order to allow them to operate within the end-of-waste framework. However, other experts signalled that such relaxations could undermine the trustworthiness of the proposed end-of-waste system and jeopardize the level playing field. It could also lead to mushrooming of small plants with limited controls. Moreover, opponents of relaxed requirements for very small plants indicated that Member States already have the necessary means at their disposal to recognize the valuable contributions of these plants to the recycling chain, outside of the end-of-waste framework. As such, Article 2(6) and Annex I and II of Commission Decision 2011/753/EU[190] allow Member States to count the input to the aerobic or anaerobic treatment as recycled where that treatment generates compost or digestate which, following any further necessary reprocessing, is used as a recycled product, material or substance for land treatment resulting in benefit to agriculture or ecological improvement. Hence, compost or digestate from small scale plants can be included when calculating recycling levels. Moreover, Article 24 of the Waste Framework Directive enables Member States to exempt composting/digestion operations from permit requirements, allowing for reduced operational costs for small scale plants.

4.2. Certification per group of products (applicable to options 4 and 5 only)

As explained in Annex III, similar to the Biocide Regulation, products presenting the same level of safety and efficacy could be grouped into one family of products under Options 4 and 5.

Notified bodies would verify that the whole product family complies with the relevant safety and agronomic requirements by verifying the compliance of test materials. If during the examination of samples, a product fails to meet the essential safety or agronomic requirements, the whole family would be deemed to fail. This would allow a reduction of the costs of certification for SMEs without reducing the level of protection of human health or the environment.

4.3. No obligation to label the content of contaminant in each fertiliser bag (applicable to options 2 to 5)

The technical meetings organised in 2012 concluded that the mandatory declaration of the contaminant content would entail additional logistic complications and more frequent analysis of the actual content of contaminants in fertiliser lots. Therefore it emerged that – at least for a majority – mandatory labelling of contaminants is not necessary if the limit values described under Annex VI are adopted. If several limits values are adopted for cadmium, producers

[190] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:310:0011:0016:EN:PDF

would have to declare on the bag whether their product comply with one of the permitted maximum limit values.

ANNEX V

List of relevant EU legislation in relation with fertilising products

Regulation (EC) No 1907/2006 OJ L 396, 30.12.2006, p. 1-849 – REACH

- REACH applies to chemical substances, of synthetic origin, contained in fertilisers. Registration in REACH is compulsory for these substances if their volumes exceed 1 tonne per year/per producer or importer when placed on the market.
- Under the REACH Regulation, manufacturers and importers of fertilisers must register the substances contained in their products including also information on impurities above 0,1% at particular deadlines, depending on the quantities they manufacture or import. As part of the registrations for substances placed on the market in quantities above 10 tons/year, companies must submit a chemical safety report. The report must demonstrate that the use of the substances in fertilisers – taking into account impurities above 0,1% - is innocuous to human health and the environment in its intended applications, and must also provide instructions on safe handling, storage etc. Member States and/or ECHA have the possibility to select registration dossiers for fertilisers for further in-depth evaluation, which would also allow addressing specifically certain contaminants (e.g. heavy metals) that might not be included in the chemical safety report as their contamination in fertilisers is well below the limit of 0,1% mentioned above.
- The Fertilisers Regulation sets technical standards for substances and mixtures listed in its Annex I that are allowed to be designated as 'EC Fertilisers'. There are no specific requirements regarding risk assessment as such but economic operators are required to carry out risk assessments and apply appropriate risk management measures under REACH, as part of the registration dossiers, depending on annual tonnage thresholds.
- Risks from fertilisers can be evaluated and be subject to the REACH authorisation or restriction procedures if they contain a substance of very high concern included in Annex XIV of REACH.
- Waste materials in the sense of Directive 2008/98/EC that constitute potential ingredients for the production of organic fertilisers are exempted from registration. (Cf. Art. 2.2 of REACH "*waste as defined in Directive 2006/12/EC of the European Parliament and of the Council* - which has been repealed by Directive 2008/98/EC - *is not a substance, mixture or article within the meaning of Article 3 of this Regulation.*"

Regulation (EC) No 1272/2008 OJ L 353, 31.12.2008, p. 1-1355 – CLP

- The Regulation on Classification, Labelling and Packaging ('CLP Regulation') contributes to the Globally Harmonised Systems (GHS) within the EU. The GHS aims to describe and label the same hazards in the same way around the world. The purpose of the CLP Regulation is to ensure the protection of public health and the environment. Manufacturers have to classify their substances and mixtures by examining available information. In the case of mixtures, all the ingredients have to be compared to the criteria for classification in Annex I and labelled accordingly.
- Only a small number of fertilisers are classified as hazardous (ammonia, nitric acid, phosphoric acid and sulphuric acid, ammonium nitrate of high nitrogen content).

However, many fertilisers could be classified as irritants (skin/eyes) and producers have to comply with Art.31 of REACH on requirements for safety data sheets where appropriate.

- The CLP Regulation will be fully applicable to mixtures in Europe on 1st June 2015.

Commission Regulation (EC) No 1881/2006 OJ L 364, 20.12.2006, p. 5-24 – Setting maximum levels for certain contaminants in foodstuffs

- The Regulation aims at ensuring a high level of protection for consumers from contaminants (e.g. nitrate, arsenic, lead, cadmium, mercury, PCBs and PAHs). These substances may be present in fertilisers. A maximum level approach is appropriate for these contaminants in order to prevent them from entering the food chain.

Regulation (EC) No 1069/2009 OJ L 300, 14.11.2009, p. 1-33 AND Commission Regulation (EC) No 142/2011 OJ L 54, 26.02.2011, p. 1-254 – (ABP Regulation)

- The Animal By-Products (ABP) regulatory framework provides definitions of 'organic fertilisers' and 'soil improvers' restricted to the context of the Regulation.
- When compost is produced from animal by-products, health related requirements have to be respected. Sanitary rules for composting or biogas operations treating animal by-products are laid down in the Implementing Regulation.

Regulation (EC) No 1107/2009 OJ L 309, 24.11.2009, p. 1-50 + Commission Regulation (EC) No 540/2011 OJ L 153, 11.06.2011, p. 1-186 – Plant Protection Products Regulation (PPPR)

- The Regulation provides a definition of Plant Protection Products (PPP) which mainly focus on substances and/or microorganisms exerting an effect on plant pests but also those influencing plant life processes (e.g. growth regulators) which differ from nutrients. Fertilisers are not PPP according to the definition of PPPs. However the sub-category 'Plant Biostimulants' concerns substances and/or microorganisms exerting an effect on plant growth in very similar ways as certain PPPs do.
- The future definitions of Plant Biostimulants and PPPs shall aim to avoid overlap between the scope of the future Fertilisers Regulation and PPPR.
- When the claimed effects on plants are pointing to the definition of PPP and of plant biostimulants, the products shall also fall under the scope of the PPP R and be subject to its provisions and requirements, in particular the authorisation process. PPPR establishes the safety criteria for active substances which are assessed at the EU level as well as the uniform principles for the authorisation of PPP at national or zonal levels. A positive list of active substances (Annex I) which are considered not to pose unacceptable risks to human health and the environment is supplied.
- Any restriction adopted under one legal regime might be triggering question for the recommendations of use under the other regulatory framework.

Directive 2000/29/EC OJ L 169, 10.7.2000, p. 1-112 – Plant Health regime

- This Directive concerns the protective measures against the introduction and spread into the EU of organisms which are harmful to plants or plant products.
- 'Harmful organisms' are defined as "any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products".

- It applies to plants as well as to plant products. As fertilisers, soil improvers or growing media can be produced based on organic plant matters, plant health issues can occur.
- The Directive contains:
  - A ban on importing harmful organisms;
  - Further trade restrictions concerning certain plant and plant products which are potential carriers of harmful organisms;
  - Further measures regarding third-country importers.
- This Directive is under review and is foreseen to become a regulation. The new regulation should have more specific criteria on 'Union quarantine Pests' which poses threats for the entire Union territory. Alongside this, there will be more rules on recognising and monitoring the occurrence of these pests in private and public land.

Commission proposal on preventing and combating invasive alien species

- **Invasive alien species (IAS)** are alien species whose introduction or spread to new habitats has been found, through risk assessment, to threaten biodiversity and ecosystem services, as well as, in some cases, to negatively impact human health, society or the economy.
- Most of the provisions of the proposed Regulation on IAS will apply to species that are recognised to be invasive and of EU concern.
- Pests and diseases affecting respectively plants and animals are regulated through the plant health and animal health legislation and therefore will not be addressed through the proposed IAS Regulation.
- As fertilisers, soil improvers or growing media can be produced based on organic plant matters, IAS can be an issue for these sub-categories.

Commission Decision of 15 December 2006 OJ L 32, 6.2.2007, p. 137-143 AND Commission Decision of 3 November 2006 OJ L 325, 24.11.2006, p. 28-34 – Eco-label for soil improvers and growing media

- This is a voluntary scheme seeking to encourage businesses to market products and provide services with lower environmental impact.
- In order to be awarded the EU Eco-Label for soil improvers and growing media, a product must fall within the product group 'soil improvers' or 'growing media' defined in Article 1 and must comply with ecological criteria set out in Annex I of the respective Decisions. These criteria mainly aim at promoting the reuse of organic matter. Only a very limited range of industrial wastes are authorised for the production of Eco-label products and peat use is banned. Safety criteria such as maximum levels for different metals and metalloids, as well as for pathogens, physical contaminants and viable seeds, apply to eco-labelled soil improvers and growing media.
- A product shall only be considered for the award of the Eco-label if it does not contain peat and its organic matter content is derived from the processing and/or reuse of waste. Materials from Municipal Biological Treatment (MBT) are not excluded from the scope of Eco-label but sewage sludge is banned.

- The Decision on soil improvers also ensures that the final product will have a limited impact on the environment by ensuring that the product shall not contain more than 3% total N (by weight) and that organic N content is above 80%.

Council Directive 86/278/EEC OJ L 181, 4.07.1986, p. 6 – Sewage Sludge

- The Sewage Sludge Directive seeks to encourage the use of sewage sludge in agriculture while preventing harmful effects on soil, plants, animals and human health.
- Sewage sludges can be considered as fertilisers, as their nutrient content is readily available for crops.
- The Directive prohibits the use of untreated sludge on agricultural land unless it is injected or incorporated into the soil. Treated sludge is defined as having undergone "*biological, chemical or heat treatment, long-term storage or any other appropriate process so as significantly to reduce its fermentability and the health hazards resulting from its use*". Some Member States apply specific measures such as stabilisation of sludge with lime.
- The Directive also requires under Article 8 that sludge should be used taking into account plant nutrient requirements and soil, surface and groundwater quality standards. In particular, the Directive lays down limit values for heavy metal content in soils and in sludge for use in agriculture. The maximum permissible annual input of heavy metals during 10 years of sludge application is also described and hence the maximum quantities of sludge that may be applied annually per unit area of soils.
- In 2010, the Commission launched a study for the revision of the Sewage Sludge Directive. The current heavy metal limits are as shown in the following table:

Table 57: Limit values for concentrations of heavy metals (mg/kg dry matter in a representative sample)

	Values for concentration in soils to which sludge is applied (soil with a pH of 6 to 7)	Concentration of heavy metals in sludge for use in agriculture
Cd	1-3	20-40
Cu	50-140	1 000-1 750
Ni	30-75	300-400
Pb	50-300	750-1 200
Zn	150-300	2 500-4 000
Hg	1-1.5	16-25

The **following heavy metals limits** were proposed and are compared to the ECN and JRC Seville limit values for compost.

Table 58: Heavy metals limits discussed as part of a study on the revision of the Sewage Sludge (SS) Directive and various proposals for compost

	Moderate option for SS	*Stringent option for SS*	*ECN proposal for compost*	*JRC proposal for compost*
Cd	*10*	*5*	*1.3*	*1.5*
Cr total	*1 000*	*150*	*60*	*100*
Cu	*1 000*	*400*	*110*	*200*
Hg	*10*	*5*	*0.45*	*1*
Ni	*300*	*50*	*40*	*50*
Pb	*750*	*250*	*130*	*120*
Zn	*2 500*	*600*	*400*	*600*

Directive 2000/60/EC of the European Parliament and of the Council OJ L 327, 22.12.2000 – Water Framework Directive

- The Water Framework Directive aims to prevent negative changes in the biological and chemical composition of aquatic ecosystems and to achieve a good status of all waters in Europe by 2015.
- Fertilisers and related materials (e.g. growing media) are considered as potential issues of concern because they cause diffuse pollution due to the high input of nitrogen or phosphorus to soils (causing eutrophication), or because they affect waterways via the extraction of raw materials (e.g. peat).
- Authorities in areas sensitive to eutrophication define constraints on the use of nitrogen and phosphorus fertilisers. This includes the reduction of nutrient application and the modification of cultivation techniques.
- Furthermore fertilisers can be the source of priority or priority hazardous substances regulated by the WFD because they pose risks to and via the aquatic environment. A list of 33 priority substances is provided in Annex II of Directive 2008/105/EC, recently amended to 45 substances by Directive 2013/39/EU. The selection of those substances is made on the basis of an approach combining comprehensive EU risk assessments carried out under other legislation, targeted risk-based assessment and simplified risk-based assessment based on toxicological studies and monitoring results.
- Among the 33, cadmium, mercury and PAHs have been identified as priority hazardous substances. Lead and nickel compounds are identified as priority substances. For those pollutants, measures shall aim for their progressive reduction and for priority hazardous substances, as defined in Article 2(30), at the cessation or phasing-out of discharges, emissions and losses.

- In the recent amendment (Directive 2013/39/EU), two substances previously listed in Annex III of the EQSD, namely dioxins and dioxin-like compounds/PCBs, have been identified as priority hazardous substances. These substances are also potentially of interest for the revision of the Fertilisers Regulation.
- Another daughter Directive of the Water Framework Directive is the Groundwater Directive 2006/118/EC on the protection of groundwater against pollution and deterioration. This includes criteria for assessing the chemical status of groundwater and for identifying trends in pollution of groundwater bodies. Under this Directive the Member States are required to establish threshold values for a so-called minimum list of pollutants if they identify risks of pollution. This list includes arsenic, cadmium, lead, and mercury. The Groundwater Directive also includes a European quality standard for nitrates based on the Nitrate Directive.

Council Directive 98/83/EC OJ L 330, 5.12.1998, p. 32-54 – Drinking Water Directive

- Without prejudice to their obligations under other EU provisions, Member States shall take the necessary measures to ensure that water intended for human consumption is wholesome and clean.
- Fertilisers and related materials (e.g. organic soil improvers) are considered as potential issues of concern because they cause diffuse pollution to the drinking water caption zones due to high concentration of nitrogen (in a form generating nitrates) of other chemical (e.g. fertilisers...) or biological (organic soil improvers…).
- In the DWD a total of 48 microbiological (among them *Escherichia coli* and Enterococcae) and chemical parameters (among them arsenic, boron, PAHs, cadmium, chromium, copper, lead, mercury, nickel, nitrate, nitrite and selenium) must be monitored and tested regularly. WHO guidelines for drinking water are used as a basis for the standards in the Drinking Water Directive.

Council Directive 91/676/EEC OJ L 375, 31.12.1991, p. 1-8 – Nitrates Directive

- The Nitrates Directive controls the diffuse water pollution caused by excessive anthropogenic nitrogen sources from agricultural practices by designating Nitrate Vulnerable Zones.
- Excess fertilisers escape agricultural fields through leaching, drainage or runoff and can be washed into surface and groundwater bodies, contributing to, or causing, eutrophication in surface waters and the contamination of groundwater.
- The Water Framework Directive refers to the Nitrate Directive for information on diffuse pollution of nitrates from agricultural activities and extends this to phosphates.

Directive 2008/98/EC OJ L 312, 22.11.2008, p. 3-30 – Waste Framework Directive

- According to Article 6 of the Waste Framework Directive 2008/98/EC (WFD), organic waste material can be used as a fertiliser, i.e. a product, if it fulfils end-of-waste status (EoW). It requires that waste be managed without endangering human health and harming the environment, and in particular without risk to water, air, soil, plants or animals, without causing a nuisance through noise and odours, and without adversely affecting the countryside or places of special interest.

- Compost and digestate can be used directly or incorporated into organic soil improvers or fertilisers. They both corresponds to waste transformation products which were identified as candidate waste streams, for which EoW criteria are to be developed. Member States are encouraged to set up measures to promote the separate collection and recycling of biowaste.

- By complying with the EoW criteria, compost and digestate would receive a product status. This means that when they cease to be waste, they must comply with the obligations under REACH, including those relating to registration, authorisation and restrictions. However, according to Article 2.7(b) of the REACH Regulation, substances covered by Annex V of this Regulation where, among others, compost is listed, are exempted from the registration requirements, evaluation and downstream user provisions. The situation with digestate is unclear and needs further clarifications since Annex V lists only biogas, meaning that anaerobic digestate may have to comply with the requirements of the REACH Regulation.

- Material not reaching EoW status according to the WFD is not per se excluded as an input raw material for fertiliser manufacture, but in this case, fertiliser production would be classified as waste management operation according to Article 3(15) of the WFD, and would be governed by waste legislation, e.g. waste permitting, waste shipment regulation (*see* below), unless input material is covered under other legislative acts.

- In the case of animal by-products, Article 2.2(b) of the WFD excludes "animal by-products including processed products" covered by the Animal By-products Regulation (EC) No 1069/2009 (ABP) with the exception of those animal by-products "which are destined for incineration, landfilling or use in a biogas or composting plant", and are thus subject to the waste regime.

Directive 1999/31/EC on landfill

- According to the waste management hierarchy, landfilling is the least preferable option and should be limited to the necessary minimum. Where waste needs to be landfilled, it must be sent to landfills which comply with the requirements of Directive 1999/31/EC on the landfill of waste. The objective of the Directive is to prevent or reduce as far as possible negative effects on the environment, in particular on surface water, groundwater, soil, air, and on human health from the landfilling of waste by introducing stringent technical requirements for waste and landfills.

- The proposal aims at phasing out landfilling by 2025 for recyclable waste (including plastics, paper, metals, glass and bio-waste) in non-hazardous waste landfills, corresponding to a maximum landfilling rate of 25%.

Council Regulation (EC) No 1698/2005 – Rural Development Regulation

- The Common Agricultural Policy regulatory framework provides various financial instruments, one of which, Rural Development Regulation, aims at improving the environment and the countryside by supporting land management.

- Various agri-environmental measures tackle the problem of excess nutrients through reduced fertiliser use. Under the current Rural Development Policy (2007-2013) as well as under the future policy (2014-2020), the baseline for the calculation of agri-environmental payments is composed of various elements, among which cross-compliance standards and minimum requirements for fertiliser and plant protection products use.

Council Regulation (EC) No 834/2007 OJ L 189, 20.7.2007, p. 1-23 AND Commission Regulation (EC) No 889/2008 OJ L 250, 18.9.2008, p. 1-84 – Organic farming

- Organic production outlines that plants shall primarily be fed through soil ecosystems management. Fertilisers, such as ground phosphate rocks, can be used and a cadmium limit value of 90 mg Cd kg/ P_2O_5 applies.

Directive 2012/18/EU of the European Parliament and of the Council OJ L 197, 24.7.2012, p. 1-37 – Seveso III

- The Seveso III Directive is the main EU legislation preventing major accidents in production and storage facilities. The Directive applies to establishments where dangerous substances (such as ammonia and ammonium nitrate) are present in equal quantities to those specified in the Annex of the Directive or in excess thereof.
- After a series of accidents (Baia Mare, Enschede, Toulouse), the Commission decided to amend the Seveso II Directive. Regarding fertilisers, the number of ammonium nitrate entries was increased from 2 to 4, the new entries covering NPK fertilisers capable of self-sustaining decomposition. Entries for potassium nitrate were also inserted.

Directive 2010/75/EU of the EU Parliament and of the Council of 24 November 2010 on Industrial Emissions

- The IED is the successor of the IPPC Directive and aims at minimizing pollution from various industrial sources throughout the European Union. Operators of industrial installations operating activities covered by Annex I of the IED are required to obtain an integrated permit from the authorities in the EU countries.
- The **integrated approach** means that the permits must take into account the whole environmental performance of the plant, covering e.g. emissions to air, water and land, generation of waste, use of raw materials, energy efficiency, noise, prevention of accidents, and restoration of the site upon closure. The purpose of the Directive is to ensure a high level of protection of the environment taken as a whole.
- The permit conditions including emission limit values (ELVs) must be based on the **Best Available Techniques (BAT)**, as defined in the IPPC Directive. BAT conclusions (documents containing information on the emission levels associated with the best available techniques) shall be the reference for setting permit conditions. To assist the licensing authorities and companies to determine BAT, the Commission organises an exchange of information between experts from the EU Member States, industry and environmental organisations. This work is co-ordinated by the Institute for Prospective Technology Studies at the EU Joint Research Centre in Seville (Spain). This results in the adoption and publication by the Commission of the BAT conclusions and BAT REFERENCE DOCUMENTS (the so-called BREFs).
- Composting plants with a capacity of more than 75 tons/day as well as anaerobic digestion plants with a capacity of at least 100 tons/day are covered by the IED Directive.

Council Directive 85/337/EEC OJ L 175, 5.7.1985, p. 40-48 – Environmental Impact Assessment (EIA)

- According to this Directive, human activities, including industrial ones listed in Annex I to the Directive, are considered as having significant effects on the environment and require an EIA.
- This is the case for peat (e.g. used in growing media) production where the surface area of the site exceeds 150 hectares. For areas less than this, Member States have discretion on whether or not to require an assessment, which they determine by the setting of thresholds or criteria. The EIA process involves the public and relevant environmental authorities and is a comprehensive assessment of the potentially harmful environmental effects of a project.

Council Directive 79/409/EEC OJ L 103, 25.4.1979, p. 1-18 – Birds Directive AND Council Directive 92/43/EC OJ L 209, 22.7.1992, p. 7-50 – Habitats Directive

- These Directives aim at protecting all European wild birds and the habitats of listed species, in particular through the designation of special protection areas. The Directives affect the extraction of peat (e.g. used in growing media). Many peatlands across the EU have been designated as Special Protection Areas (SPAs) or Special Areas of Conservation (SACs) and incorporated into the Natura 2000 network (a Europe wide network of protected sites).
- Development, including peat extraction, in such areas is severely constrained and only allowed in exceptional circumstances. When seeking permission to extract peat in such an area, an EIA is likely to be required to assess the impacts on the bird or flora/fauna species in situ. Therefore, any peat extraction project which proceeds has been subject to a comprehensive assessment and will most certainly be subject to conditions regarding the preservation of the relevant bird or flora/fauna species. In many peatlands producers have been entirely precluded from exploiting their lands as a result of designation under these EU conservation Directives.

The 1999 Gothenburg Protocol to abate acidification, eutrophication and ground-level ozone

- The objectives of this protocol are to reduce emissions of ammonia, sulphur, nitrogen oxides, volatile organic compounds and particulate matter caused by anthropogenic activities which are likely to cause adverse effects on human health, the environment, natural ecosystems and the climate.
- Within one year from the data of entry into force of the protocol a Party of the present protocol shall take such steps as are feasible to limit ammonia emissions from the use of solid fertilisers based on urea.

Regulation (EU) No 98/2013 of the European Parliament and of the Council of 15 January 2013 on the marketing and use of explosives precursors

- The Regulation establishes harmonised rules concerning the making available, introduction, possession and use of substances or mixtures that could be used for the illicit production of explosives. The purpose is to limit their availability to the general public while ensuring an appropriate reporting of suspicious transactions for sales both to the general public and to professional users.

- As regards fertilisers, suspicious transactions of the following substances on their own or in mixtures have to be reported in accordance with Article 9 of the Regulation: potassium nitrate, calcium nitrate, calcium ammonium nitrate and ammonium nitrate in concentration of at least 16% by weight of nitrogen in relation to ammonium nitrate.

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Consultative Communication on the sustainable Use of Phosphorus, COM (2013)517

- The objective is to propose environmental requirements for more efficient fertiliser use and a better resource management for phosphorus.
- On phosphorus, the main motivations for future actions are the security of EU supply, consideration to a better use and distribution of phosphorus on arable soils in Europe (under the mandate from the resource efficiency roadmap) and the risks of pollution of surface water (eutrophication). The Council and the EU Parliament will be consulted for their opinion and follow-up will be given as appropriate.

Soil Thematic Strategy (COM (2006) 231) and a proposal for a Soil Framework Directive (COM (2006) 232)

- The objective of the Strategy and the proposal is to ensure a sustainable use of soils while protecting soil functions. In particular, the proposal provides for limiting the intentional or unintentional introduction of hazardous substances in order to avoid accumulation of those hazardous substances on or in the soil that would significantly hamper soil functions or give rise to significant risks to human health or the environment.

ANNEX VI

Background information concerning the proposed list of contaminants levels for the different categories of products

1. SOURCES OF CONTAMINANTS IN FERTILISING PRODUCTS AND AVAILABILITY FOR PLANTS

The heavy metals content in inorganic fertilisers vary largely from one source to another. On average products made from igneous rocks, i.e. formed deep within the earth, have lower heavy metal content (except arsenic) than products made from sedimentary rocks, i.e. formed in the seabed by the decay of organic matter. The possible reduction of the cadmium content of inorganic phosphate fertiliser is a problem that has been discussed in details in an impact assessment report validated in 2011 by the Impact Assessment Board (*see* details under Section 5 of this Annex) and which is annexed to the present report. Many controversial debates occurred about the most appropriate limits to reduce the overall exposure of the general public to cadmium via the environment without entailing disproportionate costs to industry and end-users. Other types of contaminants such as organic pollutant (e.g. perchlorates – ClO_4^-) can also be found in certain types of nitrogen inorganic fertilisers. See point 2.2 below for more details.

During the preparation of the EU EoW criteria on biodegradable waste, the EU Institute for Prospective Technological Studies (IPTS)[191] has organised a survey on different types of biodegradable waste (source segregated and non-source segregated materials) to measure their contaminant level. Participation to the survey was voluntary and samples from 15 Member States (+ CH) were received. In total, 7 heavy metals (Cd, Cr, Cu, Hg, Ni, Pb, Zn) and 5 organic pollutants (PAH_{16}, PCDD/Fs, PCBs, PFCs, polycyclic musk) were analysed. Results show that most of the compost would comply with the safety limits except some sewage sludge and green waste compost (*See* Section 6 below).

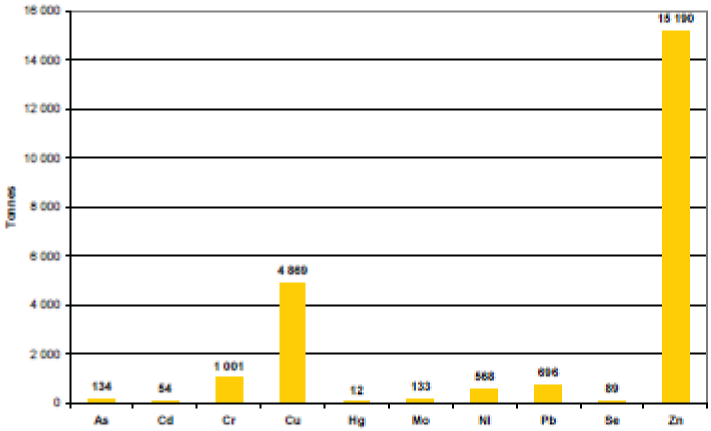
Depending on contaminants, their chemical form, soil conditions, pH etc, only a part of the annual soil contaminant inputs may be biologically available for crops and therefore the effect on human health via the food derived from these soils is difficult to assess. More importantly, there are concurrent factors, including dietary habits, soil type, other sources of contaminant, rate of transfer to plants etc., that affect the way in which soil contaminants may or may not end up in food. Hence, it is recommended by the scientific community to focus on the exposure side and avoid increases in exposure. As underlined by a French study (ADEME 2007), fertilising products are a source of contaminants that negatively impact compliance with environmental and food quality standards.

In France, heavy metal inputs to agricultural soils can be ranked as follows: Zn≫Cu≫Cr>Pb>Ni>As=Mo>Se>Cd>Hg. These results are similar to those obtained in four other European countries for Zn, Pb, Cu and Cd and in China with Zn>Cu>Pb>Cr>Ni>As>Cd>Hg (Luo et al., 2009). For all these countries, it is shown that unprocessed manure is a major source of heavy metals to agricultural soils. In France, it is the predominant (>50%) source of Zn, Ni, As, Cu and Hg and its contribution ranges from 78% for Zn to 23% for Cd. Mineral fertilisers are a major source of Se, Cr and Cd. In particular, phosphate fertilisers have generally high concentrations in Cd and Cr among all inorganic

[191] http://susproc.jrc.ec.europa.eu/activities/waste/documents/ipts_eow_biodegradable_waste_3rd_working_document_wo_line_nr.pdf

fertilizers. This result is in agreement with Nziguheba and Smolders (2008) who recorded higher input fluxes of Cr and Cd from phosphate fertilizers than from atmospheric deposition in European agricultural soils.

Figure 23: Estimations of the total volume of heavy metals added to soils in France (Source ADEME 2007)



2. INFORMATION ABOUT IDENTIFIED RISKS TO HUMAN HEALTH AND THE ENVIRONMENT FROM CONTAMINANTS IN FERTILISERS MATERIALS

2.1. Justification based on existing EU legislation

As regards surface waters, European Union legislation provides for measures against chemical pollution by selecting and regulating priority substances at EU level and by requiring Member States to also regulate substances of national/regional concern (river basin specific pollutants) at national level.

The EU list of priority substances under the Water Framework Directive is a list of substances presenting a significant risk to or via the aquatic environment at EU level. They have to be regularly monitored and measures have to be taken to meet the relevant Environmental Quality Standards (Directive 2008/105/EC, recently amended by Directive 2013/39/EU). The measures should enable to reduce the emissions, discharges and losses of all the substances and lead to complete phase-out of the emissions, discharges and losses of a subset of priority hazardous substances.

Cadmium and mercury have been identified as priority hazardous substances. Nickel and lead compounds are only identified as priority substances so far. PAHs are priority hazardous substances but are only relevant for organic materials. Dioxins and dioxin-like PCBs have also recently been identified as priority hazardous substances.

Directive 2006/118/EC on the protection of groundwater against pollution and deterioration includes criteria for assessing the chemical status of groundwater and for identifying trends in pollution of groundwater bodies as mentioned under Annex V.

The Member States' first River Basin Management Plans, including their assessments of the chemical and ecological status of surface and groundwater, have recently been assessed[192]. Although there are differences between Member States, it is clear that a high proportion of

[192] http://ec.europa.eu/environment/water/water-framework/implrep2007/index_en.htm#third

water bodies are failing to meet the objective of good status, often because of nitrate pollution but in many other cases also because of contaminants, in particular of mercury, cadmium and certain PAHs. Although atmospheric deposition may contribute significantly to many of the exceedance of EQSs for mercury and some PAHs in surface waters, exceedance of the cadmiums EQS appears likely to be mainly linked to fertiliser use.

Council Directive 98/83/EC on the quality of water intended for human consumption laid down the essential quality standards at EU level. A total of 48 microbiological, chemical and indicator parameters must be monitored and tested regularly. Among them, the following parameters are relevant for fertilisers: **arsenic, boron, cadmium, chromium, copper, lead, mercury, nickel, PAHs, Escherichia Coli and Enterococcae**. In general, World Health Organisation's guidelines for drinking water and opinions of the Commission Scientific Advisory Committee on drinking water are used as scientific basis to set up quality standards in the drinking water. It is however difficult to correlate the presence of the targeted substances in fertilisers with their content in drinking water.

When implementing the Drinking Water Directive into their own national legislation, Member States can include additional requirements e.g. regulating additional substances that are relevant within their territory or set higher standards. Member States are however not allowed to set lower standards as the minimum level of protection of human health should be the same throughout the whole European Union.

Member States may depart from chemical quality standards specified in the Directive (Annex I) for a limited time. Derogations can be granted, provided that it does not constitute a potential danger to human health and that the supply of water intended for human consumption in the area concerned cannot be maintained by any other reasonable means.

Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil when sewage sludge is used in agriculture, lays down a number of maximum concentration thresholds for heavy metals (cadmium, lead, mercury, nickel copper and zinc) in sewage sludge and in soils on which the sludge can be applied.

Commission Regulation (EC) No 1881/2006 on maximum limits for certain contaminants in foodstuffs regulates the content of metals (**lead, cadmium, mercury** are relevant for fertilisers) and organic pollutants (**dioxins and dioxin-like PCBs and polycyclic aromatic hydrocarbons (benzo(a)pyrene, perchlorates** are relevant for fertilisers). The enforced limits are based on EFSA[193] opinions.

2.2. Justification based on recent peer-review soil and human health studies

Fertilisers are essential to provide adequate nutrients for crop growth and ensure successful harvests. However, fertilisers can be adulterated products containing raw material sometimes from unknown and/or questionable sources. Besides the certified nutritional ingredients for plants, they may contain, most notably, trace elements that can accumulate into soils through repeated application via fertilisation.

The impact of contaminants on the environment should be of concern in order to minimise the threat of soil and groundwater pollution. Waste disposal and the application of inorganic fertiliser on agricultural lands have been increasingly favoured and, therefore, it should be scrutinised to diminish the risk of introducing pollutants to soils and waters. In general three main factors affect the mobility of heavy metals in soils. These include soil pH (the lower the pH the greater the mobility), soil organic matter and reactive clay surfaces increasing the soil

[193] http://ec.europa.eu/food/food/chemicalsafety/contaminants/cadmium_en.htm.

heavy metal absorption capability and promoting immobilisation of these elements within soils. The following elements have been known to affect human health and contribute to soil contamination through the use of inorganic and organic fertilisers.

Soil microorganisms play an important role in energy flow, in nutrient cycling and organic matter turnover in terrestrial ecosystems. They may act as a nutrient source or sink in soils and are involved in humification processes, degradation of pollutants and the maintenance of soil structure. A well-functioning soil microbial community is therefore vital for soil fertility.

Heavy metals are essential to maintain soil biological functions but are also well known to be toxic to most organisms' when present in excessive concentrations by influencing their growth, morphology and biochemical activities. They can become excessive due to anthropogenic activity such as mining activities, application of sewage sludge, industrial waste disposal and agricultural activities (fertilisers, pesticides).

Heavy metals become toxic to soil microorganisms when they are "bioavailable", e.g. at low soil acidity (pH). They become toxic as a result of them moving freely within the soil environment when in the "bioavailable state", allowing them to cross an organism´s cellular membrane from the medium the organisms inhibit each time (soil solution or soil particles). When a heavy metal enters an organism's membrane it can disturb its chemical equilibrium and deactivate its metabolic activity and severely affect its role in energy flow, organic matter turnover, nutrient cycling and hence the soil fertility status.

A considerable body of information exists on the accumulated effect of heavy metals on soil microorganisms in agricultural soils. A good example is the review article, written by Giller et al (1998) on existing peer reviewed research tackling the toxicity of heavy metals to microorganisms and the microbial processes in agricultural soils. More recent research also shows that the accumulation of Cd in agricultural soils, receiving sewage sludge or in-organic fertilizer, is well known to inflict a negative influence on the soil biota (Smith 2009) and Cd polluted environments have been shown to have an adverse effect on plant growth (Shahabivand et al., 2012), earthworm growth activities (Dominguez-Crespo et al., 2002) and soil microbial biomass (Landi et al., 2000, Vig et al., 2003, Aghababaei et al., 2014

Cadmium (Cd) is a non-essential and toxic element for humans, and has no use for plants or animals, either. It can damage the kidneys, causing excess production of proteins in the urine – the duration and level of exposure to cadmium determines the severity of the effect.

Skeletal damage is another critical effect of chronic cadmium exposure at levels somewhat higher than those where protein in the urine would be an early indicator. Cadmium is also carcinogenic if inhaled. Mainly stored in the liver and kidneys, excretion of cadmium is slow, and it can remain in the human body for decades. Levels of the element tend to build up in most body tissues with age.

Cadmium is associated with skeletal damage, evidenced by low bone mineralisation, a high rate of fractures, increased osteoporosis, and intense bone pain. These were features of itai-itai disease, first described in Japan in the 1940s among people who had eaten rice grown on fields irrigated with cadmium-polluted water. A low calcium diet plus high cadmium exposure led to kidney disease followed by bone disease.

Around 90% of cadmium exposure in non-smokers is through food. Crops take in cadmium from soils and the rate of uptake is influenced by factors such as soil pH, salinity, humus content, crop species and varieties and the presence of other elements (e.g. zinc). Some population groups are especially vulnerable to increased exposure and uptake of cadmium:

- Vegetarians or individuals who consume large amounts of cereals and pulses are likely to have higher exposure than the general population, as agricultural crops (especially irrigated rice) account for most of the cadmium intake;

- Those with a high intake of shellfish and organ meat from marine animals may have a particularly high intake of cadmium;

- People with low body iron stores, especially pregnant women, or low zinc intake have higher rates of cadmium uptake;

- People with other nutritional deficiencies may also be at risk;

- Smokers: tobacco plants absorb cadmium from soil, as other plants do, and are an important source of cadmium uptake. Non-smokers may also be affected through passive exposure to secondary smoke. People living in the vicinity of industrial sources and other point sources of cadmium release can be exposed to an increased level of cadmium.

According to available data, the average weekly intake of cadmium from food in most countries is within the range of 0.7–2.8 μg/kg body weight (UNEP, 2010). Given their smaller size, children may be taking in more cadmium per kilogram of body weight than adults.

In soil, the chemistry of cadmium is largely controlled by pH. Cadmium may be adsorbed on clay minerals, organic material, carbonates or hydrous oxides of iron and manganese or may be precipitated as cadmium carbonate, hydroxide, and phosphate. Under acidic conditions, cadmium solubility increases, and very little adsorption of cadmium by soil colloids, hydrous oxides, and organic matter takes place.

Both toxicity and bioavailability of cadmium are influenced by soil characteristics. Cadmium mobility and bioavailability are higher in more acidic soils, and lower in chalky/lime soils. One way to reduce cadmium bioavailability is to lime the soil to make it less acidic. However, once cadmium is in the soil, it is persistent and cannot be broken down into less toxic substances in the environment.

Cadmium enters agricultural soils from the atmosphere and from application of phosphate fertilisers and sewage sludge (Jiao et al., 2012). In fact, the impact of application of phosphate fertiliser on soil Cd levels has been widely studied (e.g. Taylor, 1997; Mann et al., 2002; McGrath and Tunney 2010). In heavily contaminated areas, re-suspension of dust can cause a substantial proportion of crop contamination and human exposure via inhalation and ingestion, (WHO/UNECE, 2006).

The presence of cadmium in fertilisers and atmospheric deposition has been found to cause increasing amounts of cadmium in topsoil in a number of European countries (ibid). If zinc is present, it can reduce cadmium's availability to plants, by inhibiting calcium uptake and preventing it from moving from the roots to the shoots of the plants.

Although cadmium emissions and concentrations in the air have been reduced, data from 2006 do not show reduced body burden of cadmium in non-smokers (WHO/UNECE, 2006). In the top layers of arable soil, more cadmium is typically being deposited than is being removed: cadmium is accumulating in certain soils, increasing the likelihood of future exposure through food.

Studies in children and pregnant women are still limited, but there is some evidence that elevated cadmium exposure during pregnancy may affect a child's motor skills and perception, and that high cadmium levels in the urine of school children are associated with a weakened immune system (Schoeters et al. 2006). However, more studies are needed to confirm these results. Recent research suggests that the health effects of low-level, chronic exposure to cadmium may be quite different to the high levels that caused itai-itai disease. Exercises mapping the levels of cadmium in Europe suggest correlations between cadmium and age-adjusted prostate or breast cancer rates. (Pan *et al* 2010).

Cd has been reported to be a potentially toxic metal to soil microorganisms.

UNEP's Final Review of scientific information on cadmium (December 2010) identifies the following actions as potential priority ones for reducing cadmium inputs

· Product control actions and regulations for cadmium-containing products, such as phosphate fertilizers – by limiting the allowable content of cadmium present as impurities in high-volume materials.

· The releases to the agricultural soils may be reduced by the use of phosphate rock naturally low in cadmium or to remove the cadmium in the manufacturing of phosphate fertilizers

HTTP://WWW.UNEP.ORG/HAZARDOUSSUBSTANCES/PORTALS/9/LEAD_CADMIUM/DOCS/INTERIM_REVIEWS/UNEP_GC26_INF_11_ADD_2_FINAL_UNEP_CADMIUM_REVIEW_AND_APPENDIX_DEC_2010.PDF

Arsenic (As) is found throughout the Earth's crust, generally in the form of arsenic sulfide, or metal arsenates and arsenides. Key industrial applications of arsenic include antifungal wood preservatives (e.g. for railway sleepers), pharmaceutical and glass industries, manufacture of alloys, sheep dips, leather preservatives, pigments, antifouling paints and poison baits, and agrochemical production (particularly for orchards and vineyards). Arsenic compounds are used in small amounts in the optical and microelectronics industries. Arsenic can also accumulate in soils via organic fertiliser application (Nogueira et al., 2013) and P(hosphate) fertiliser Nziguheba and Smolders 2008; Jio et al., 2012; Hartley et al., 2013).

Much of the evidence for the long-term effects of arsenic on human health comes from south-east Asia, where there is a natural belt of arsenic-rich alluvium or sediments which were deposited millions of years ago in the Bramaputra and Ganges river basins. Bangladesh, parts of India, Myanmar and Nepal are all affected, and mining in areas of Thailand has also caused arsenic contamination. An estimated 30 million people may be at risk from arsenic-related disease as a result of contaminated water in the region (Caussy 2005).

According to WHO research from south-east Asia, humans may be exposed to inorganic arsenic through soil, air, water and food. This typically includes children ingesting soil, certain traditional medicines and foods, and water. In that region, arsenic is present at levels between 0.2 and 40 micrograms per gram (μg/g) of soil. The levels of arsenic in food in affected countries vary, but a far greater threat is considered to be arsenic in drinking water. Arsenicosis (sometimes also called arsenism) is caused by prolonged exposure to low, non-lethal doses of arsenic, in the range of 0.005 to 0.09 milligrams per kilogram (mg/kg) of body weight per day (ibid).

However, arsenic poses serious short and long-term threats to health, and so efforts to reduce exposure to arsenic from all sources are important. When individuals are exposed to arsenic over the long-term, the first changes are usually in skin pigmentation, followed by lesions and hard patches on the hands and soles of the feet. The long list of other long-term exposure effects includes peripheral neuropathy, gastrointestinal symptoms, conjunctivitis, diabetes, renal damage, an enlarged liver, bone marrow depression, destruction of red blood cells, high blood pressure and cardiovascular disease.

Long-term arsenic exposure – for more than ten years – can cause cancer, particularly of the skin, bladder and lungs, and possibly of other organs, such as the kidneys, liver and prostate. Because arsenic can pass through the placenta, pregnant women exposed to arsenic through drinking water are at greater risk of miscarriage, stillbirth and pre-term birth, and there is evidence that exposure to arsenic in the womb or in early life increases the risk of lung cancer and other lung disorders.

Arsenic can be found in food, including fish, shellfish, meat, dairy products and cereals. The type of arsenic found in fish and shellfish is usually organic, which has low toxicity.

The form that arsenic takes in soils depends on a number of factors, including the soil's pH, and biological activity. Where iron, clay and organic matter are present in soils, arsenic's availability becomes restricted. Even where land is contaminated, plants rarely contain much arsenic; cereals and vegetables, especially where soil is sandy, have the greatest concentrations of arsenic.

Natural processes are responsible for polluting wells in locations such as Bangladesh and Taiwan with arsenic, but in other countries the pollution has a human source. Cornwall, UK, was once the world's largest arsenic producer, and soil in some parts of Cornwall has some of the world's highest arsenic concentrations.

Epidemiological studies show that exposure to **lead (Pb)** during the early stages of children's development is linked to a drop in intelligence. Studies suggest that for each 10 µg/dl (microgram per decilitre) of blood lead, IQ is reduced at least by 1-3 points (Morgan, 2013, also see Canfield et al, 2003; and Chen et al, 2005). This small effect on many individuals could be a significant burden to society, with reduced overall intellectual performance and resulting economic losses.

Phasing out lead from petrol has had an effect on levels of lead measured in children's blood in Europe. Soil lead and house dust, but not lead-based paint, are associated with population blood lead levels in children. Most soil lead and house dust are associated with leaded gasoline (Mielke & Reagan, 1998). Levels of lead in the blood began to decline earlier in the western European and Scandinavian countries than in Eastern Europe, largely because the unleaded petrol was introduced earlier in these countries. Lead has been shown to equally accumulate in soils via agricultural activities which include both mineral (Nziguheba and Smolders 2008) and organic fertiliser application (Nogueira et al., 2013).

Besides car exhausts, industrial emissions are important sources of exposure to lead. Data from industrial areas in Bulgaria, Poland, the Russian Federation, the Former Yugoslav Republic of Macedonia and Ukraine show the significant impact of lead emitted by nearby plants on the level of lead in children's blood.

Lead has also been known to accumulate in soils through the application of Pb containing P fertiliser (Strawn and Sparks 200; Kabata 2001; Luo et al., 2009). Lead generally accumulates in soils rich in clay minerals, organic matter, iron-, manganese and aluminium-hydroxides. These characteristics can make Pb be rather immobile in soils. In Southern Spain unusually high concentrations of Pb where detected in farmlands compared to other regions which had not received applications of lead containing industrial wastes and Pb-containing fertilisers (Cabrera et al., 1994).

Exposure to methylmercury, the most harmful form of **mercury (Hg)** to human health, affects brain development, resulting in a lower IQ. The long-term cost to society can be calculated as lifetime earning loss per person, although this estimate does not take into account other aspects of brain toxicity or risks of cardiovascular disease in adults. Once methylmercury is formed, it cycles though the environment for thousands of years, exposing humans and other species to potentially toxic levels for generations.

Large amounts of mainly inorganic Hg have accumulated in the environment, especially in soils and oceans, as a result of past emissions and releases from human activities. Although Hg pollution can occur naturally in the environment through events, such as forest fires, most comes from the burning of fossil fuels. Usually the greatest percentage of harmful exposure to Hg for humans is through eating fish (besides direct ingestion of contaminated soil by young children).

Cement production, mining and smelting, artisanal and small-scale gold mining, burning coal and oil refining are some of the activities emitting Hg which can build up in soils. Consumer products such as electronic devices, switches, batteries, energy-efficient light bulbs and certain cosmetics, dentistry, plastic production, and the chlor-alkali industry are also contributors to Hg emissions.

After it is deposited in soils and sediments, bacteria and microbes are mainly responsible for changing Hg to methylmercury. Over 90% of the Hg found in fish is methylmercury.

Hg can enter the food chain via agricultural products or seafood. Mercury's use in agriculture has led to distressing human health incidents, which have generated data on its effects. At least 459 people died in Iraq when flour was made from grain treated with a fungicide containing Hg in 1971 (Greenwood, 1985). Children whose mothers ate contaminated bread when they were pregnant were the worst affected. Agricultural products used today may still contain Hg.

Rice crops grown in areas with high levels of coal-powered industry, mining or smelting have also shown to be affected recently. A team of Chinese and Norwegian researchers investigated dietary Hg contamination in rural, inland China - a region were few people eat fish. They focused on Guizhou province, which has 12 large mercury-mining and smelting operations, plus other heavy coal-powered industry. The researchers looked at Hg levels in foods eaten by populations from several locations: a village located inside a nature preserve, a region downwind of a major coal plant, people living near a defunct zinc smelter and a community whose air was polluted by mercury-mining operations. Mercury exposures for these communities varied considerably, but in every one of them "*rice accounted for 94-96% of the probable daily intake of methylmercury*". One reason is that rice paddies here contain the types of bacteria that can convert inorganic mercury to its more toxic, methylated form. The levels of contamination of rice grown elsewhere in the world, or exported, need further study. (Zhang *et al*, 2010)

Most Hg contamination sites are concentrated in industrial areas, but Hg can also travel long distances to locations far away from its production or use. Mercury levels in the atmosphere will fall fairly rapidly when emissions cease, but it will take many decades for levels in soils or oceans to also decrease. This is why factors such as industrial legacy and historical mining, as well as geological events such as volcanic eruptions, must be considered alongside modern emissions when looking at the health impacts of mercury in soils. Mercury can also accumulate in agricultural soils in relation to sewage sludge application and fungicide for agricultural purposes (Feng et al., 2009) to fungicides input (Feng et al., 2009), sewage sludge and fertiliser P application (M. de Jesus et al., 2013) leading to Hg being considered as global concern because of its high potential toxicity (Zheng et al., 2008).

Chromium (Cr) can be a naturally-occurring element found in P bearing rocks and released to the environment through natural processes such as geochemical and biological weathering of rocks and soils. Lower to higher Cr containing effluents and solid waste released by activities such as mining, metal plating, wood preservation, ink manufacture, textile industries and corrosion inhibitors in cooling water are also common contributor of Cr to the environment. Chromium can likewise be released to the environment and accumulate in soils via fertiliser P application which can in the long term induce pollution and may cause major health hazards. Cr is one of seven elements which were classified by the fertiliser industry as being harmful to plants and biological systems. Cr can exist in phosphate rocks as Cr (III) or Cr (VI); while Cr (III) is a useful micronutrient, Cr (VI) is a toxic species. The relation between Cr (III) and Cr (VI) strongly depends on the pH and the oxidative properties of the location, but usually Cr(III) is predominant (El-Sheikh et al., 2013). Cr (III) is an essential nutrient for humans: shortages may cause disruptions of metabolisms and diabetes but a high uptake of Cr (III) can cause skin rashes.

Nickel (Ni) occurs naturally in the earth's crust as well as being emitted from volcanic eruptions. It is likewise released to the environment from power plants and incinerators as dry or wet deposition settling eventually on the ground and accumulating in soils and sediments. In general nickel strongly absorbs in soils and sediments rich in iron or manganese hydroxides. Additionally, nickel can be a by-product of fertiliser P application and research have shown nickel increase in soils receiving fertiliser input (Chen et al., 2006; Nziguheba and Smolders 2008; Carbonel et al., 2011).

Food is the major source of exposure to nickel. The population may also be exposed to nickel by breathing air, drinking water, or smoking tobacco. Children can be exposed to nickel by soil eating and both adults and children through skin exposure.

The most serious harmful health effects from exposure to nickel, such as chronic bronchitis, reduced lung function, and cancer of the lung and nasal sinus, have occurred for people who have breathed dust containing certain nickel compounds while working in nickel refineries or nickel-processing plants. The International Agency for Research on Cancer (IARC) has determined that some nickel compounds are carcinogenic to humans and that metallic nickel may possibly be carcinogenic to humans.

Copper (Cu) is a reddish metal which occurs naturally in rock, soil, water, sediment, and, at low levels, air. Copper also occurs naturally in all plants and animals. It is an essential element for all known living organisms including humans and other animals at low levels of intake. At much higher levels, toxic effects can occur.

Copper can enter the environment through releases from the mining of copper and other metals, and from factories that make or use copper metal or copper compounds. Copper can also enter the environment through waste dumps, domestic waste water, combustion of fossil fuels and waste and wood production. Copper in soils is likewise a by-product of copper sulphate fertilisers application (Mclaren and Ritchie 1993) and in soils amended with sewage sludge (Chen et al., 2006).

When copper is released into soil, it can become strongly attached to the organic material and other components (e.g., clay, sand, etc.) in the top layers of soil and may not move very far when it is released. When copper and copper compounds are released into water, the copper that dissolves can be carried in surface waters either in the form of copper compounds or as free copper or, more likely, copper bound to particles suspended in the water.

Norway has launched a study consisting in a risk assessment on copper and zinc from feed to soil and food. Copper and zinc are added to feed as essential nutrients. Samples from manure have shown that there is a high content of copper and zinc in manure. Therefore Norway proposed to study the long-term effects of repeated addition of processed manure to agricultural land. At the same time there is a need to know the risk for animal health and welfare if the amount of copper and zinc in feed is reduced. The results of the study are expected for mid-2014.

Copper is essential for good health. However, exposure to higher doses can be harmful. Long-term exposure to copper dust can irritate your nose, mouth, and eyes, and cause headaches, dizziness, nausea, and diarrhoea. Drinking water containing higher than normal levels of copper, could lead to nausea, vomiting, stomach cramps, or diarrhoea. Intentionally high intakes of copper can cause liver and kidney damage and even death.

Zinc (Zn) is a common element in the Earth's crust as well as being found in the air, soil, and water and being present in all foods. Zinc enters the air, water, and soil as a result of both natural processes and human activities. Most Zn enters the environment as the result of mining, purifying of zinc, lead ores, steel production, coal burning, and burning of waste. The level of Zn in soil increases mainly from disposal of Zn waste from metal manufacturing industries and coal ash from electric utilities.

Sewage sludge P also contributes to increased levels of zinc in the soil (Basta et al., 2005; Lambert et al., 2007). The behaviour of Zn in soils in largely affected by soil properties such as soil pH and soil cation exchange capacity. Food stuff and drinking water can contain Zn. Zinc is a trace element that is essential for human health. When people absorb too little zinc they can experience a loss of appetite, decreased sense of taste and smell, slow wound healing and skin sores. Zinc shortages can even cause birth defects.

Polycyclic aromatic hydrocarbons (PAHs) originate from incineration or combustion processes of biomass and are of concern because of their carcinogenic and mutagenic character. Ashes resulting from those processes can be used in fertiliser production.

PAH compounds are known to be biodegradable, but biodegradation rates may differ widely, depending on the compound and the environmental conditions, with half-lives reported from days to several years (Shuttleworth and Cerniglia, 1995). Furthermore, biodegradation or transformation does not always equal full mineralisation. Meyer and Steinhart (2001) reported that metabolites from PAH breakdown may be very persistent and Lundstedt et al. (2007) indicated that PAHs may be transformed into other toxic compounds such as oxy-PAHs.

Most limit or guide values in legislation refer to a subset or the full set of the 16 principal PAH compounds on the US EPA’s priority pollutants list: naphthalene, acenaphtylene, acenaphtene, fluorene, phenanthrene, anthracene, fluoranthene, pyrene, benzo[a]anthracene, chrysene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, indeno[1,2,3-cd]pyrene, dibenzo[a,h]anthracene and benzo[ghi]perylene.

Perchlorate ion (ClO4 -) is very stable in water, and its salts are highly soluble in water. Perchlorate occurs naturally in the environment, in deposits of nitrate and potash, and can be formed in the atmosphere and precipitate into soil and groundwater. It also occurs as an environmental contaminant arising from the use of nitrate fertilisers and from the manufacture, use and disposal of ammonium perchlorate used in rocket propellants, explosives, fireworks, flares and air-bag inflators and in other industrial processes. Perchlorate can also be formed during the degradation of sodium hypochlorite used to disinfect water and can contaminate the water supply. Water, soil and fertilisers are considered to be potential sources of perchlorate contamination in food.

Following initial findings of perchlorate in fruits and vegetables produced in European Union, a more extensive monitoring indicated that the presence of perchlorate in fruits and vegetables is more widespread than initially expected. From the investigations, evidence was provided that the use of certain fertilisers containing high levels of perchlorate is an important contributor to the presence of perchlorate in fruits and vegetables. However, other sources may also contribute to their presence in the food chain. Further investigations are needed to have a better view of the different sources of contamination of food, in particular fruits and vegetables, with perchlorate. The non-harmonised enforcement approach as regards the presence of perchlorate in food, in particular fruits and vegetables have caused some tension in the market. It was therefore considered appropriate in 2013, to agree on a common provisional enforcement approach for the intra-Union trade for the period awaiting the availability of an EFSA opinion about perchlorate in food. This common provisional enforcement approach was agreed at the Standing Committee on the Food Chain and Animal Health on 16 July 2013. It is to be noted that the agreed levels are applicable on the edible part of the food concerned.

On 30 September 2014 EFSA adopted a scientific opinion[194] on perchlorate: Scientific Opinion on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables.

Based on the outcome of the EFSA opinion, the values as reference for intra-Union trade have been reconsidered, taking into account recent occurrence data and applying the principle that these levels should be set as low as reasonably achievable applying good practices. These levels were endorsed by a very large majority of the delegations in the Standing Committee on Plants, Animals, Food and Feed on 10 March 2015[195] and were updated at the meeting of the Standing Committee on 23 June 2015. These levels apply from 16 March 2015 (except the levels for herbal and fruit infusions which apply from 1 July 2015) and the levels agreed at the Committee on 16 July 2013 are no longer valid.

During the course of 2016, the setting of maximum levels for perchlorate in food/certain foods will be considered, based upon the outcome of the scientific opinion and monitoring data generated in execution of the Commission Recommendation (and other recent monitoring data, i.e. data generated after 1 September 2013).

The limits applicable to fruits and vegetables are currently set as follows:

Levels of perchlorate as reference for intra-Union trade FOOD (*)	**level (mg/kg)**
Fruits and vegetables	0,1
with the exception of	
- *Cucurbitaceae* and leafy vegetables	0.2

[194] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3869.pdf
[195] http://ec.europa.eu/food/safety/docs/cs_contaminants_catalogue_perchlorate_statement_food_update_en.pdf

except	
- celery and spinach grown in glasshouse/undercover	0.5
- herbs, lettuce and salad plants, including rucola, grown in glasshouse/under cover	1.0
Dried spices (except dried herbs and paprika), dried hops	0,5
Tea (*Camellia sinensis*), dried	0,75
Herbal and fruit infusions, dried	0.75
Foods for infants and young children - ready-to-eat	0,02
Other food	0,05

(*) - The levels as reference values for intra-Union trade applies, insofar not specified, to the unprocessed food. For dried, diluted, processed and compound foodstuffs, Article 2 of Regulation (EC) 1881/2006 is of application.
- The levels as reference values shall apply to the edible part of the food concerned.
- The leafy vegetables grown in glasshouse/under cover have to be labelled as such (or be reasonably demonstrated as being from such production in case of non-compliance with the specific level for open air production) for the application of the specific level as reference value established for the leafy vegetables grown in glasshouse/ under cover. In the absence of such a labelling (or subsequent proof of origin), the levels as reference values for intra-Union trade established for leafy vegetables grown in the open air shall apply.

This encourages the setting of maximum limit for the specifically concerned inorganic nitrogen fertiliser (e.g. Chile Nitrate) based on the currently available scientific data regarding the relationship between the presence of perchlorate in such fertilising product and its transfer to crops.

3. PROPOSED LIMIT VALUES AND JUSTIFICATION FOR THE DIFFERENT CATEGORIES OF PRODUCTS

The tables below list for each category of products the list of contaminants to be checked with their corresponding maximum limit values.

Inorganic fertilisers

The limit values proposed below are the results of extensive consultation with Member States and industry representatives.

Table 59: Maximum limit values for heavy metals in primary and secondary nutrient fertilisers

Non-nutrient metals	Maximum permissible content (mg/kg dry matter)
Cd (for products containing less than 5% P_2O_5)	3
Cd for products above 5% P_2O_5	Limits proposed in the IAR Cd
Cr VI	2
Hg	2

Ni	120
Pb	150
As	60

The limit value for perchlorate applies in principle to specific inorganic nitrogen fertilisers taking into account the most recent scientific data establishing transfer rate between such fertilisers and the crops fertilised with them:

Perchlorate	50

Table 60: Maximum limit values for heavy metals in micronutrient fertilisers

Non-nutrient metals	Maximum permissible content (mg heavy metals/kg dry matter) for straight or mixtures of B, Co, Cu, Fe, Mn, Mo or Zn fertilisers
Cd	200
Hg	100
Ni	2 000
Pb	600
As	1 000

The proposed limits for primary and secondary nutrients would be too restrictive when applied directly to micronutrients with the effect of removing a significant proportion of good quality products from the market. In particular, three specific features of micronutrients need to be underlined:

– In nature, ores or minerals of the micronutrients often occurs with one or more of the heavy metals. Furthermore, the chemical similarities between micronutrients and their associated heavy metals makes their separation very difficult e.g. Zn/Cd and B/As and therefore the carry-over of heavy metals into micronutrient fertilisers cannot be avoided.

– Typical application rates of micronutrients fertiliser are rather low (1 to 10 kg/ha/year) which reduces the environmental impact.

– Compliance with limits values are far more difficult to achieve for concentrated micronutrient fertilisers.

Organic fertilisers

The limits proposed below have been established by the expert group of JRC-Sevilla for the preparation of the End of Waste on biodegradable waste. However Cr total has been replaced by Cr VI as being the most hazardous form of Cr.

Table 61: Maximum limit values for contaminants in organic fertilisers

Non-nutrient metals + copper and zinc	Maximum permissible content (mg heavy metals/kg dry matter)
Cd	1.5
Cr VI	0.5
Hg	1
Ni	50
Pb	120

Cu	200 but products containing more than 100 ppm should be labelled
Zn	600 but products containing more than 400 ppm should be labelled

Organic contaminants	Proposed by…	Maximum permissible content
PAH_{16}	EU EoW if only source segregated materials are allowed	6 mg/kg dry matter for 16 congeners

Frequencies of monitoring could be reduced if producers can demonstrate that a significant number of representative samples are not exceeding the limit values proposed above over an initial period of time (*see* Annex VI – Section 4 for the evaluation of the cost reduction potential).

Pathogens	Maximum permissible content
Salmonella	No Salmonella sp. in 25g sample (fresh mass)
Escherichia Coli	1 000 CFU/g fresh mass

The measurements of these parameters should be complemented by a requirement on processing e.g. time-temperature profile as in the ABP Regulation.

Macroscopic impurities	Maximum permissible content (%/kg dry matter)
Glass with size above 2 mm	0.5 (Bleach method)
Metal with size above 2 mm	0.5 (Bleach method)
Plastics with size above 2 mm	0.5 (Bleach method)

The bleach method allows a destruction of organic material and therefore avoids that small impurities remains undetected because they are confused with organic material. The IPTS considered that there is a need to distinguish between natural impurities such as stone and man-made impurities. Therefore no limit for stone was proposed in the EU EoW criteria.

On top of the pollutants mentioned above, the future proposal would make a direct link to the legislation on invasive alien species (IAS). According to the IAR supporting this proposal, IAS have significant consequences for biodiversity and are recognised as being a major cause of species extinction. A list of prohibited species at EU level will be managed by the Commission. Member States will have the possibility to additionally manage their own list of IAS depending on their specific environmental conditions. Compost and digestate producers will be required to ensure that these materials are not contributing to the release into the environment of invasive alien species listed on the EU or national lists via seeds, propagules or any reproducible part of the prohibited species eventually present in the input materials used for the making of compost or digestate. Analytical standards would need to be developed to control that compost and digestate placed on the market fulfil both EU and national requirements.

Organo-mineral fertilisers

As regard heavy metals, the limit values set for inorganic and organic fertilisers would apply to organo-mineral fertilisers as producers would have to ensure that each ingredient used in the manufacture of organo-mineral fertilisers comply with their corresponding maximum limit values for contaminants.

Liming materials

It has been argued in earlier discussions that the limit values for inorganic fertilisers are not suitable for liming materials because the latter are applied in much higher quantities than primary nutrient fertilisers (i.e. 1000 kg/ha vs. 100 kg/ha). However, contrary to primary nutrient fertilisers, liming materials are not applied every year. It has also to be noted that the liming effect (soil pH increase due to liming materials application) reduces the mobility of heavy metals and therefore their uptake by crops.

The limit values below are supported by the technical working groups organised in 2012 by the Commission (*See* Annex XII for more details).

Table 62: Maximum limit values for heavy metals in liming materials

Substance	Maximum permissible content (mg heavy metals/kg dry matter)
Cd	3
Cr VI	Standard in development
Hg	2
Ni	90
Pb	200
As	120

Soil improvers

Same limits as for organic fertilisers.

Growing media

No limit discussed in the working groups. According to some Member States, heavy metals have to be considered as relevant safety criteria for growing media, in particular because GM may consist of compost and are used to grow edible crops. In the study 'Metals and organic compounds from waste used as organic fertilisers (July 2004) carried out for DG Environment (ENV A.2/ETU/2001/0024), a survey on the heavy metal content in commercial GM shows that Cr, Pb, Cu and Zn could be present in relatively high amounts. Therefore the limit values derived from consultations with GM producers are proposed.

Table 63: Maximum limit values for heavy metals in growing media

Substance	Maximum permissible content (mg heavy metals/kg dry matter)
Cd	3
Cr total	150
Cu	230
Hg	1
Ni	90
Pb	150
Zn	500

Plant biostimulants

When applied to soils, plant biostimulants are applied at much lower rates than most inorganic fertilisers, so limits for heavy metals in biostimulants could theoretically be much higher compared to the product weight. However, certain algae are known to be excellent bio-markers of the level of contamination of seas and are considered as accumulating heavy metals. This does not apply for all seaweed extract but it would be preferable to keep this limit even though plant biostimulants are generally mixed with other fertilising material categories for which limit for contaminant would definitively apply as well. It was therefore found advisable to introduce some safety limits for contaminants for this category.

Table 63-a: Maximum limit values for heavy metals in plant biostimulants

Substance	Maximum permissible content (mg heavy metals/kg dry matter)
Cd	3
Cr VI	2
As	60 (inorganic plant biostimulant)
Hg	1 (microbial + organic plant biostimulant) 2 (inorganic plant biostimulant)
Ni	50 (microbial + organic plant biostimulant) 120 (inorganic plant biostimulant)
Pb	150

Zn	500

4. OTHER RISKS IDENTIFIED

Urea based fertilisers emit higher levels of ammonia to air than nitrate based fertilisers. In 2010, according to the GAINS methodology developed by IIASA, ammonia emissions from synthetic fertilisers represented about 15% (570 ktonnes) of total EU emissions levels (3 750 ktonnes). About half of these emissions derived from urea-based fertilisers, while this type of fertiliser only represented about 20% of the total inorganic nitrogen fertilisers used in Europe.

Deposition of ammonia causes acidification of soils and eutrophication of aquatic and terrestrial ecosystems, threatening biodiversity. The main problem is eutrophication, for which NH_3 emissions is an increasingly large contributor, together with nitrogen oxides (NO_x) emissions. In 2010, about 1 million km^2 of ecosystems in Europe were exposed to nitrogen deposition that exceeded critical loads for eutrophication. So far, most of the progress made for limiting eutrophication takes place as a result of decreasing NO_x emissions, while ammonia emissions have remained relatively stable over time despite a large reduction potential. It is estimated that additional ammonia reductions could protect an additional 210 000 km^2 in 2020[196].

Ammonia also reacts as a precursor in the atmosphere to create ammonium and other forms of sulphate and nitrate compounds that condense to become secondary particulate matter (PM2.5 and PM10) with adverse effects on human health[197]. The fact that monitored ambient PM concentrations in the 2000-2010 period have not declined as expected, despite relatively large reductions in emissions of primary PM and secondary PM precursor gases, is partly explained by the limited reductions in NH_3 emissions over time.

Other contaminants could be detected in the future in specific fertilising products through the regular enforcement activities carried out by Member States competent authorities. The safeguard clause will offer the mechanism to review the list of contaminants to be monitored and the level of the maximum limits, where relevant. The scientific information supporting these requests for reviewing will be examined by the Commission scientific bodies such as Scientific Committee on Health and Environmental Risks (SCHER) or the ECHA. Based on their opinion, a delegated act would then be proposed to adapt the essential safety requirements accordingly.

5. SUMMARY OF THE IMPACT ASSESSMENT REPORT ON POSSIBLE LIMITS FOR CADMIUM IN NATIONAL AND EC PHOSPHATE FERTILISERS

It is generally recognised that cadmium accumulates in EU soils because of the use of phosphate fertilisers manufactured from mined rock phosphate naturally contaminated with cadmium. This soil accumulation is raising concerns about human health and environmental damage. In 2002, the Scientific Committee on Health and Environmental Risks concluded that a limit for 40 mg Cd/ kg P_2O_5 or more would lead to cadmium accumulation in most European soils. At the opposite a limit of 20 mg Cd / kg P_2O_5 or less are not expected to result

196 IIASA TSAP report #6.
197 IIASA TSAP report #3.

in long-term soil accumulation over 100 years if other cadmium inputs are not considered. However, it is so far not possible to predict how much cadmium present in the soils will be taken up by crops and will finally end up in foods as this may vary according to various soil and climatic conditions (pH, organic matter and/or clay content …). It remains that when added to soils, cadmium cannot be removed and could eventually be taken up by plants.

Foodstuffs are the main source of cadmium for the non-smoking general population. Cadmium is primarily toxic to the kidney, especially to the proximal tubular cells where it accumulates over time and may cause renal dysfunction. The International Agency for Research on Cancer has classified cadmium as a human carcinogen (Group 1) on the basis of occupational studies and recent data on human exposure to cadmium in the general population have been statistically associated with increased risk of cancer such as in the lung, endometrium, bladder, and breast.

The EFSA CONTAM Panel concluded that the mean exposure for adults across Europe is close to, or slightly exceeding, the tolerable weekly intake. Furthermore, certain subgroups including vegetarians, children, smokers and people living in highly contaminated areas may exceed the tolerable weekly intake by about 2-fold. Although the risk for adverse effects on kidney function at an individual level at dietary exposures across Europe is very low, the CONTAM Panel concluded that the current exposure to Cd at the population level should be reduced.

An IAR Cd finalised in 2011 has tried to balance the negative effects of cadmium to the environment and human health over the longer term with the negative impacts on the competitiveness of the farming sector of a general ban of phosphate inorganic fertilisers containing cadmium.

The conclusions of the IAR Cd covered impacts on international trade as cadmium represents the most pertinent issue in this regard.

This IAR Cd demonstrated that a limit value of 60 mg cadmium/kg P_2O_5 applied to the whole EU would be feasible by selective use of certain mines and/or certain layers within a deposit on the scale needed to supply the EU market in a foreseeable future. Some small producing countries in West Africa such as Togo and Senegal but also Tunisia where cadmium content in phosphate is largely above 60 mg cadmium/kg P_2O_5, would already face severe difficulties to export to the EU.

According to the IAR Cd, any limit below 60 mg cadmium/kg P_2O_5 would endanger the supply of EU farmers at reasonable prices if a technology to remove cadmium from phosphate fertilisers is not in place at industrial level. Decadmiation of high cadmium phosphate fertilisers from Tunisia and Morocco (the current main suppliers of the EU) would also add costs to phosphate fertilisers marketed in the EU (between 10 to 15% according to the IAR Cd). According to some COM services, the average additional costs for wheat farmers compared to the current level of operating costs per hectare would be relatively moderate (no more than 1.5% on average for the whole EU).This has to be put into perspective because wheat is a high profitable crop and the effect might be different for other crops.

However, it is also crucial that, in view of achieving all the intended objectives set out in the IAR Cd, the new Regulation gives an incentive to invest further in decadmiation technologies.

In November 2012, the EU signed a Memorandum of Understanding relating to raw materials with the Tunisian authorities. This document clearly highlighted the need to build up on the

Tunisian experience[198] to develop a reliable technology that would be able to remove cadmium from phosphate fertilisers at industrial scale. The IAR Cd concluded that under the conditions that technically and economically viable decadmiation technologies are available at industrial scale, an option setting clear deadlines for the entry into force of the lowest limit values at EU level would be the most effective in achieving all objectives.

In light of the SCHER opinion 2015[199] the IAR Cd has been adapted to integrate the new conclusion that the accumulation of cadmium in soils is not expected to occur on average in most EU-27 + Norway soils if the concentration of cadmium in inorganic phosphate fertilisers does not exceed 80 mg/kg P_2O_5. In the SCTEE-2002 opinion, the same effect was achieved with a limit value of 20 mg cadmium/kg P_2O_5.

The objective of a strong reduction of human and environmental exposure to cadmium can also be better achieved if progress in the recovery of phosphorous from biomass leads effectively to a progressive replacement of inorganic phosphate fertilisers by organic fertilisers which are less contaminated with cadmium. A future proposal on the revision of the Fertilisers Regulation would support the development of such substitution throughout the EU.

6. ESTIMATION OF THE PERCENTAGE OF PRODUCTS AFFECTED BY THE PROPOSED LIMIT VALUES

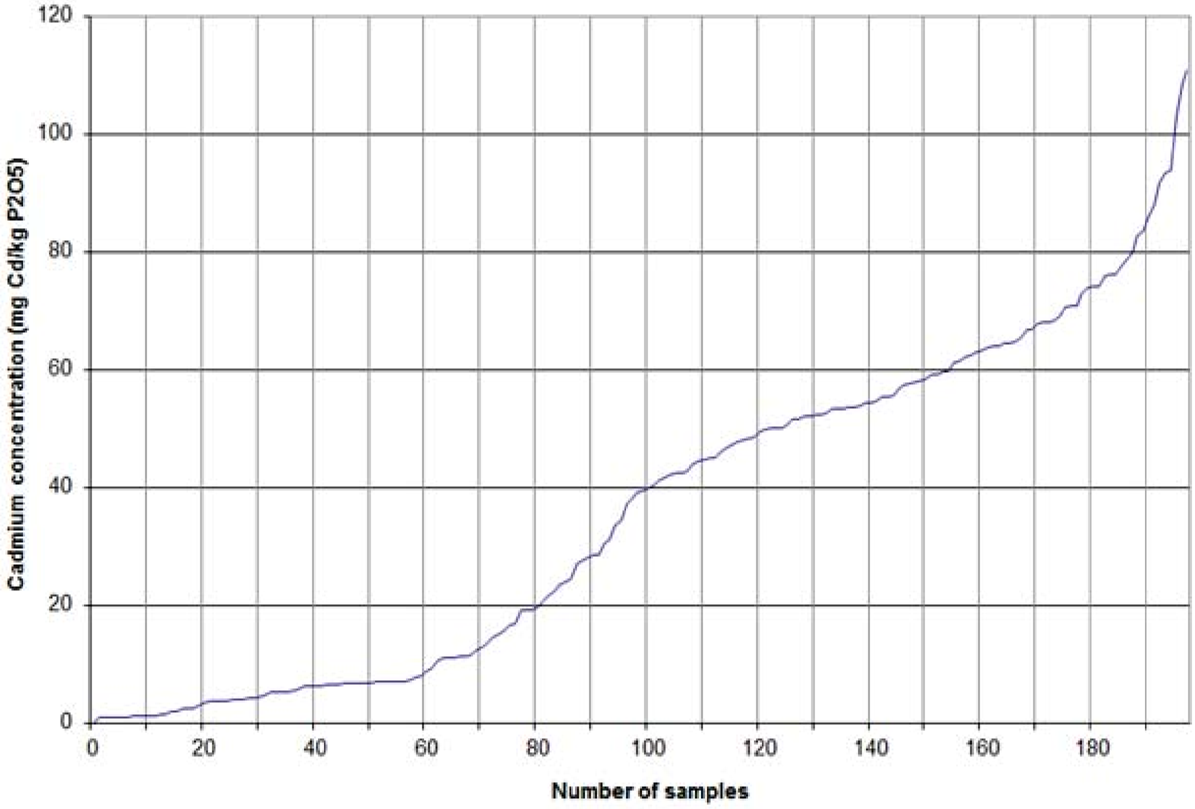
Inorganic fertilisers

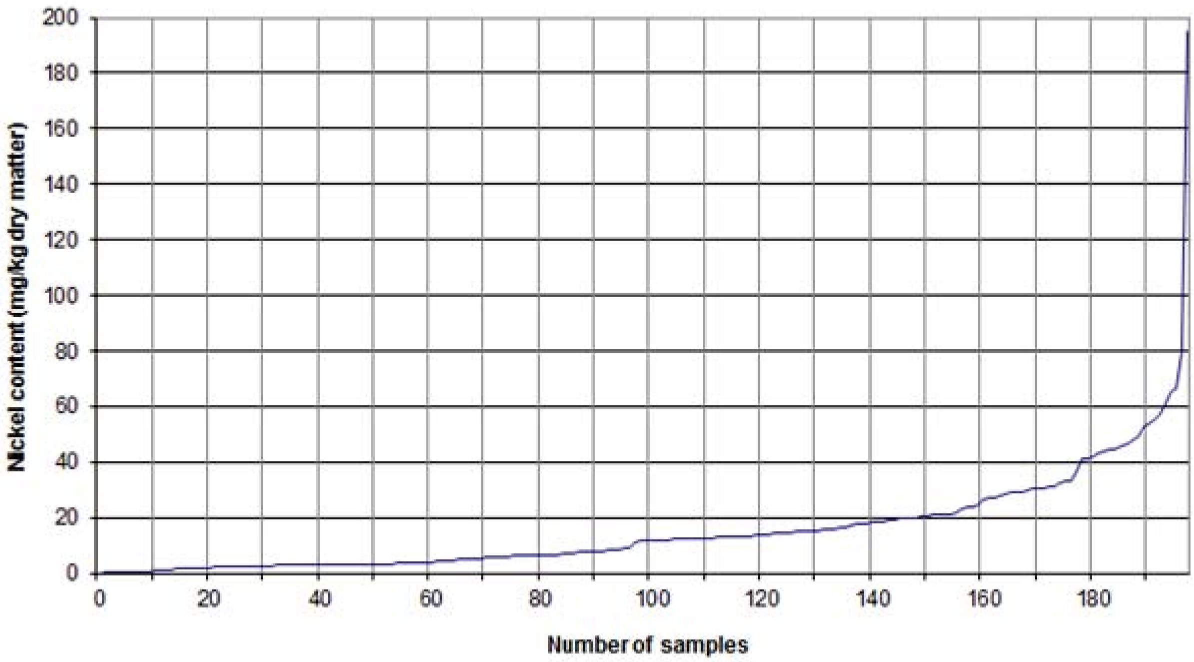
In 2007, Nziguheba and Smolders measured the cadmium content of **197 inorganic phosphate fertiliser** samples provided by 12 Member States (NIPERA study). However, samples have not been weighted for the size of the local market compared to the size of the EU market (e.g. 18 samples from France and 16 from Belgium were analysed) or it was specified which overall volume of fertiliser each sample represents. Data from the study were used to estimate the fraction of inorganic phosphate fertilisers that would be shut out of the market if the proposed limit values mentioned in Table 60 were enforced. The figures show that around 21% of the inorganic phosphate fertiliser would not comply with the 60 mg Cd/kg P_2O_5 proposed for cadmium whereas most of the current products would comply with the limits for Pb, As and Ni. No information for $Cr^{6+}$and Hg were available in the NIPERA study

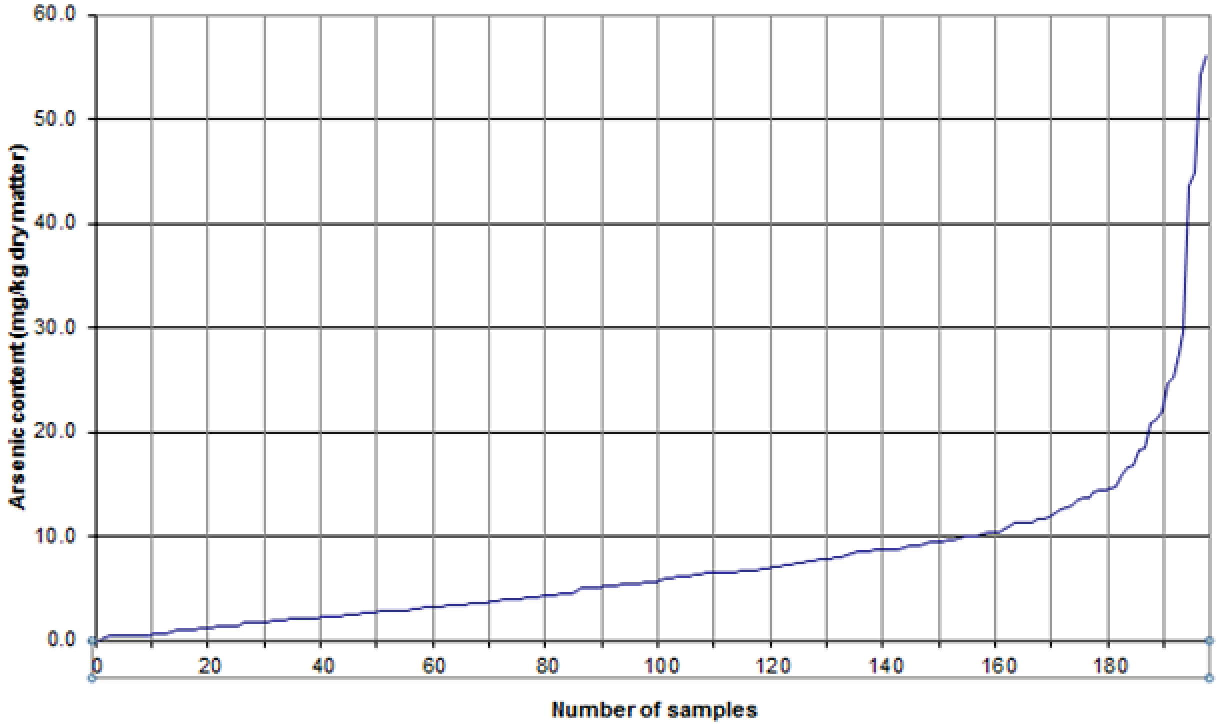
[198] The Tunisian fertiliser industry has developed an industrial process that is able to remove cadmium from phosphate feed grade and that could be applicable to the production of phosphate fertilisers. The Moroccan industry is developing similar technologies.

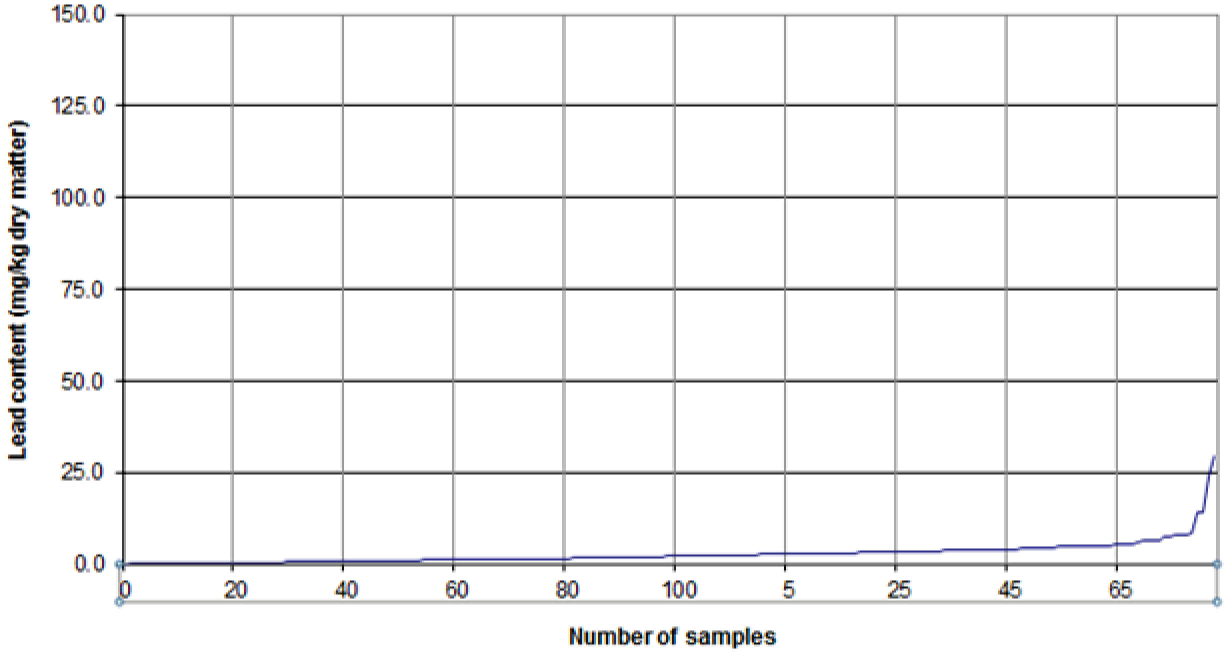
[199] HTTP://WWW.SCIENCEDIRECT.COM/SCIENCE/ARTICLE/PII/S0048969714004495

Figure 24: Results of the NIPERA survey on heavy metals content in 197 inorganic phosphate fertilisers.









A recent survey of inorganic fertilisers and liming materials sold in Portugal shows that around 40% of the inorganic fertilisers would not meet the 60 mg Cd/ kg P_2O_5 limit but all of them would comply with the limit values for the other contaminants mentioned in Section 3above.

However, the figures are given mainly for illustrative purposes as the information provided in the NIPERA study and by the Portuguese authorities do not allow concluding that the data used are representative for the entire EU phosphate fertiliser market.

Organic fertilisers and soil improvers

During the preparation of the JRC report, it emerged that reliable and recent scientific data on the levels of organic and inorganic pollutants in different types of compost and digestate were needed to support the decision-making process for end-of-waste criteria. Therefore, the JRC experts agreed that available and relevant scientific data should be reviewed and complemented by independent recent data generated through a pan-European collaborative screening exercise. Such a screening, consisting of measuring a large series of compost and digestate samples in the best possible standardized way, was therefore carried out in May-December 2011 by the JRC with the collaboration of various industrial networks. More details on the organization of this sampling campaign are available in the JRC report (Chapter 3). The figures below shows which number of compost and digestate would be excluded from the market if the recommendations of JRC for heavy metals and organic contaminants were enforced.

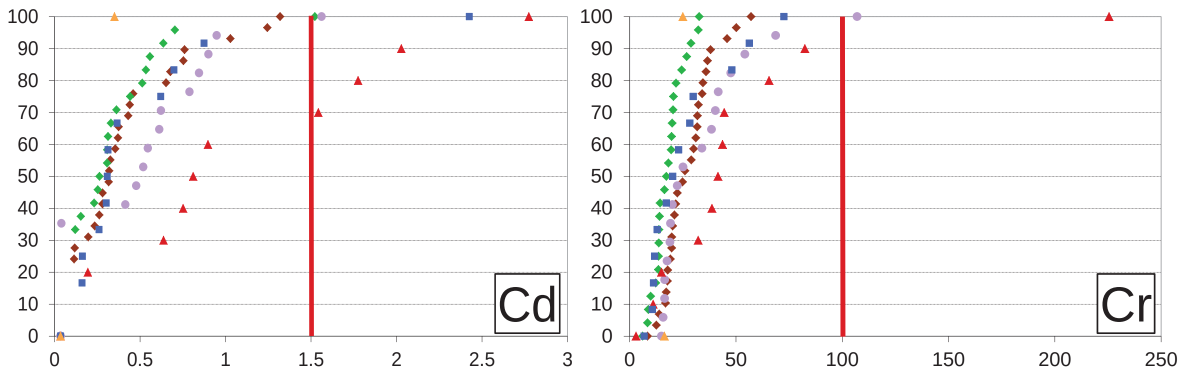
Heavy metals

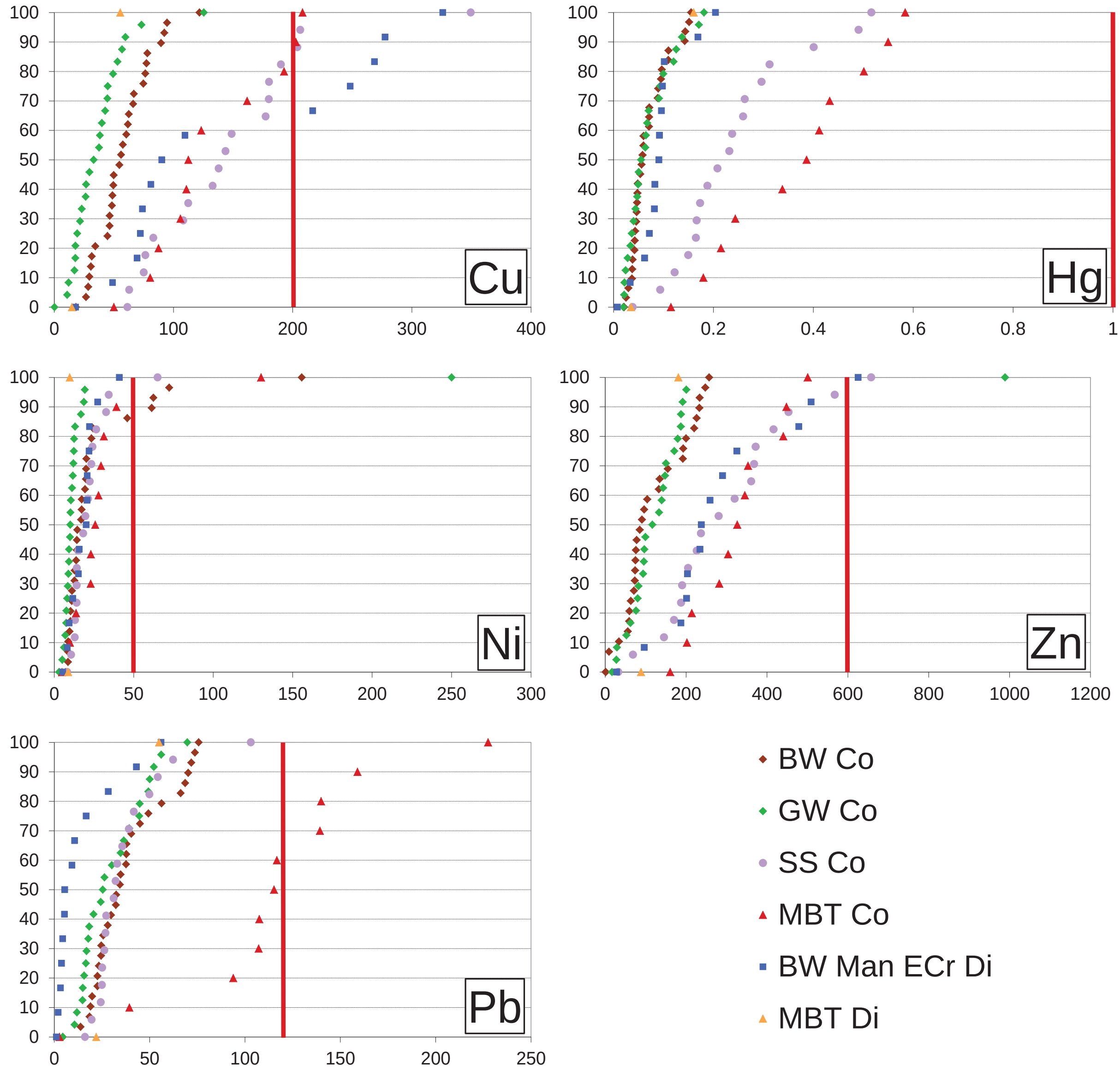
The results of the heavy metal analyses are depicted in the following figure as cumulative graphs scaled from 0 to 100% of the total sample population for a material type, with every concentration data point representing an actual sample measurement. This representation helps visualizing the spread on the data and allows checking how many samples of a compost/digestate type exceed a certain threshold concentration. The graphs also contain red bars, indicating the proposed EU end-of-waste limit values.

It can be derived from the dataset that in general, compost and digestate produced from source separated collection of green waste nearly always meet the proposed limit values for individual heavy metals with sporadic exceedances. Other types of compost generally meet the proposed limit values but tend to have problems in meeting the proposed Cu limits for sewage sludge compost and the proposed limit values for Cd and Pb for MBT compost.

An overview of data carried out at Member States level confirms the JRC conclusions.

Figure 25: Heavy metals in compost and digestate samples collected by JRC. The horizontal axis represents the concentration (mg/kg dry matter) and the vertical axis the cumulative percentage of samples. The red bar represents the proposed maximum values for EU EoW product quality criteria (Co=compost; Di=digestate; BW=source separated bio-waste & green waste; GW= source separated green waste; SS=sewage sludge; MBT=mechanical biological treatment; Man=manure; ECr=energy crops)

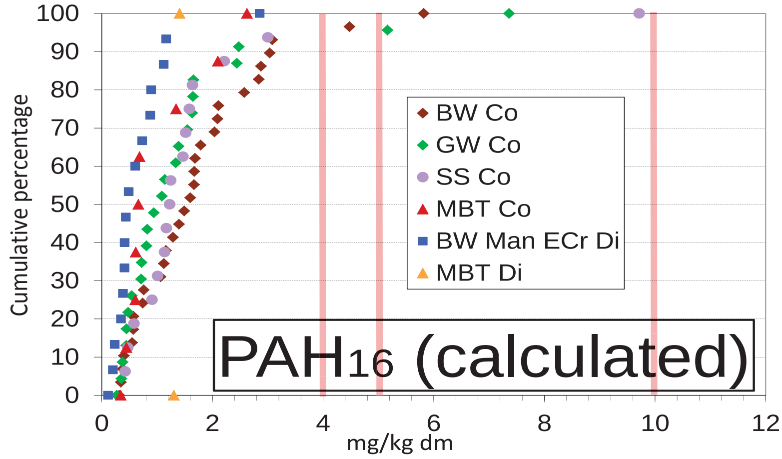




Polycyclic aromatic hydrocarbons (PAHs)

The following figure summarises the results of the survey carried by JRC in 2011

Figure 26: Calculated PAH_{16} in compost and digestate samples collected by JRC and sent by plants. Data are based on measured PAH_{12} values and extrapolated using the 1.073 PAH_{16}/PAH_{12} ratio derived from Brändli et al. (2007a). The horizontal axis represents the concentration (mg/kg d.m.) and the vertical axis the cumulative percentage of samples. The semi-transparent red bars represent existing limit values in different European countries for similar materials (Co=compost; Di=digestate; BW=source separated bio-waste & green waste; GW= source separated green waste; SS=sewage sludge; MBT=mechanical biological treatment; Man=manure; ECr=energy crops. The JRC proposed a limit value of 6 mg/kg d.m.



Data collected by JRC and literature survey suggest that all types of compost and digestate contain PAH congeners, ranking generally from trace levels to and a few mg/kg d.m. Exceedance of existing national PAH limit or guidance values appear to occur and generally represent a few percent to more than a quarter of the sample population, depending on the reference limit value and the type of material (segregated sources or not).

Similar analysis of existing data and literature survey suggest that all types of compost and digestate contain only a few amounts of PCB and PCDD/F compounds. In general, concentration ranges appear well below existing national limit or guidance values for similar materials. Exceedance of existing national limit or guidance values occasionally occur and generally represent zero to a few percent of the sample population, depending on the applicable reference limit value and the type of material.

JRC suggested therefore keeping PAH_{16} as an indicator of organic pollutant contamination in organic soil improver and organic fertiliser.

Liming materials

During the preparation of a Commission Regulation introducing liming materials in Annex I to the Fertilisers Regulation, CEN organised in 2010 a survey to provide information on the actual heavy metal content in liming materials now on the market.

Moreover, CEN analysed national legislation in seven Member States (i.e. Austria, France, the Czech Republic, Germany, Finland, Italy and Belgium) on the maximum admissible content of heavy metals in liming fertilisers. In general, Member States apply the same limit to all types of liming materials except in France, where some limits are type-specific and take into account the use phase. Denmark and the United Kingdom informed that they had not established such limits for liming materials.

Some of the limit values apply to certain types of liming materials, whilst others are applicable to all types. In some Member States, values are also expressed in a form that takes into account the application rates allowed for one (or several) crop growing period(s), which makes comparison difficult as the application rates of liming and fertilising products are not clearly defined in legal texts.

The table below summaries the lowest and highest regulatory limit values reported in the survey:

Table 64: lowest and highest regulatory limit values for heavy metals in liming materials according to seven Member States legislation

Heavy metal	Range of maximum limit values (mg/kg dry matter)	
	Lowest	**Highest**
As	**2** (FR Carbonate sugar factory)	**83** (FR carbonates)
Pb	**4** (FR Mg Burnt Lime)	**150** (Germany : all)
Cd	**1.5** (FR Carbonate Groundwater)	**41** (FR Burnt lime calcium)
Cr (total)	**12** (FR Carbonate Groundwater)	**800** (FR converter lime)
Cr6+	**0.5** (IT : all)	**2** (FI : steel slag)
Ni	**15** (FR: carbonates)	**686** (FR: Magnesium Carbonate)
Hg	**0.3** (FR Converter Lime)	**5** (FR: Burnt lime magnesium)

Even though the information is incomplete, it is obvious that there are significant differences between the limits set by the Member States. It is also not clear on which basis the limits have been set, i.e. a scientific risk assessment or rather analytical data with regard to the heavy metal contents of liming materials currently placed on the market and the quantities used in the Member States.

CEN collected also data on the actual content of heavy metals in carbonates, oxides, hydroxides, silicates, marine and industrial factory limes (including sugar factory limes). More than 4400 samples[200] were analysed. The data were statistically processed to define which fraction of the samples would fit the relevant national limit values and the provisional limit values for inorganic fertilisers.

More than 90% to 95% of the liming materials tested would respectively comply with either the lowest national limits values or the limit values for liming materials proposed in Table 63 above. The level of confidence was considered sufficiently high to allow the inclusion of several types of liming materials of natural origin in the Annex I of the Fertilisers Regulation.

However, silicate limes were not included because of the potential presence of Cr^{6+} although the reduction process in blast furnaces and the presence of metallic iron and ferrous iron in converters actually prevent the formation of Cr6+ according to industry. A more specific method for Cr^{6+} is being developed by CEN which will allow analysing the content of this substance in liming materials in a near future. According to UK authorities more than 100,000 tons/year of such products are marketed every year in the UK.

Growing media

Table 70 in Annex XI show the variations in the limit values for heavy metals enforced by several Member States. Most of them still make use of national standards for the determination of heavy metals in GM products which make comparison between limit values

[200] The samples cover around 90% of the liming materials available on the market.

difficult. However, it is largely accepted that mineral GM or mineral GM constituents do pose somewhat of a problem as they often have higher heavy metal content than organic GM.

ANNEX VII

Description of each possible options envisaged in this impact assessment

	Option 1	Option 2	Option 3	Option 4	Option 5
Description	Status quo	Creating of level playing field for the marketing of fertilising products and additives by listing types of products	Creating a level playing field for the marketing of fertilising products and additives by listing ingredients	Creating a level playing field for the marketing of fertilising products and additives by using the 'New Approach' legislative format	Creating a level playing field by adopting different conformity assessment procedures according to identified risks
Coverage of the EU legislation	Limited to inorganic EC Fertilisers	Full harmonisation of the fertiliser market covering fertilisers, liming materials, soil improver, growing media, plant biostimulants and agronomic additives Partial harmonisation is proposed and analysed as a variant to full harmonisation	Full harmonisation of the fertiliser market covering fertilisers, liming materials, soil improver, growing media, plant biostimulants and agronomic additives Partial harmonisation is proposed and analysed as a variant to full harmonisation	Full harmonisation of the fertiliser market covering fertilisers, liming materials, soil improver, growing media, plant biostimulants and agronomic additives Partial harmonisation is proposed and analysed as a variant to full harmonisation	Full harmonisation of the fertiliser market covering fertilisers, liming materials, soil improver, growing media, plant biostimulants and agronomic additives Partial harmonisation is proposed and analysed as a variant to full harmonisation
Type of regulatory approach	Old approach – fertiliser types containing details about the method of production, specific labelling provisions, specific agronomic quality criteria	Old approach – fertiliser types containing details about the method of production, specific labelling provisions, specific agronomic quality criteria	Old approach – list of authorised ingredients	New approach – the Regulation would specify essential safety and quality requirements for the product categories covered	Mix of variants of option 4
National rules and mutual recognition	Applicable to non EC Fertilisers	Full harmonisation scenario : no more national rules and therefore no possibility to apply mutual recognition anymore Partial harmonisation scenario: mutual recognition of non-harmonised products could still be applied	Full harmonisation scenario: no more national rules and therefore no possibility to apply mutual recognition anymore Partial harmonisation scenario: mutual recognition of non-harmonised products could still be applied	Full harmonisation scenario : no more national rules and therefore no possibility to apply mutual recognition anymore Partial harmonisation scenario: mutual recognition of non-harmonised products could still be applied	Full harmonisation scenario: no more national rules and therefore no possibility to apply mutual recognition anymore Partial harmonisation scenario: mutual recognition of non-harmonised products could still be applied
List of authorised products	Fertiliser types listed in Annex I of the Fertilisers Regulation	Authorised fertiliser types listed in Annexes of the future Regulation	Authorised fertiliser ingredients listed in Annexes of the future Regulation	No more detailed lists of authorised types or ingredients as part of the legislation anymore. Type lists may be used/ elaborated by CEN as part of the standards.	

Registration procedure	Submission of an application dossier by industry. Evaluation procedure involving Member State experts. If the new type is accepted, adaptation of the current list via Comitology procedure	Submission of an application dossier by industry. Evaluation procedure involving Member State experts, EFSA or ECHA. If the new type is accepted, adaptation of the current list via Comitology procedure	Submission of an application dossier by industry. Evaluation procedure involving Member State experts, EFSA or ECHA. If the new ingredient is accepted, adaptation of the current list via Comitology procedure	The registration of products would be replaced by self or third party certification to verify the compliance of the product with relevant safety, quality and labelling criteria	The registration of products would be replaced by self or third party certification to verify the compliance of the product with relevant safety, quality and labelling criteria
Protection of Data (On top of the mechanisms foreseen under REACH	None. New fertiliser type can be used by manufacturers that had no triggered the inclusion in the list of authorised fertiliser types	None. New fertiliser type could be used by any manufacturer even if they did not support the inclusion in the list of types	None. New fertiliser ingredients could be used by manufacturers even if they did not support the inclusion in the list of ingredients	Yes for all categories in particular for data submitted to notified bodies in view of third party certification	Yes for all products, in particular for data submitted to notified bodies in view of their third party certification
Limits for contaminants	No	Yes for all product categories. Same limits as for options 3 to 5	Yes. The limits would apply to commercialised products. Same limits as for option 2, 4 and 5	Yes. The limits would apply to commercialised products. Same limits as for options 2,3 and 5	Yes. The limits would apply to commercialised products. Same limits as for options 2 to 4
Quality criteria	Yes for individual fertiliser type	Yes for individual types	Generic criteria for each category of products	Generic criteria for each category of products	Generic criteria for most product categories but claim and agronomic value shall be demonstrated as part of the registration dossier for plant biostimulants and agronomic additives
EN standards	Mandatory: listed in Annex IV of Regulation (EC) No 003/2003	Mandatory. EN standards would be listed in the Annexes of the future Regulation	Mandatory. EN standards would be listed in the Annexes of the future Regulation	Harmonised methods would be available but there would be other means to verify the conformity to the essential requirements.	Harmonised methods would be available but there would be other means to verify the conformity to the essential criteria. Since standard development can be lengthy, coordination group should be mandated to issue guidance onr how to interpret essential legal requirements until EN standards are available.
Harmonised labelling	Limited to inorganic EC Fertilisers	Yes for all product categories	Yes for all product categories	Yes for all product categories	Yes for all product categories
Surveillance	After the products are placed on the market	Post marketing	Post marketing	Ex-ante evaluations before products are placed on the	Ex-ante evaluations before products are placed on the

				market for certain categories subject to third party certification. Post market surveillance for all products	market for certain categories subject to third party certification. Post market surveillance for all products
Transitional provisions	Not applicable	Sufficiently long transition periods would allow small producers to continue marketing their established products while they adapt product characteristics to new types being included in the annex(es) of a regulation	Sufficiently long transition periods would allow small producers to continue marketing their established products while they adapt product characteristics to new types being included in the annex(es) of a regulation	Shorter transitional provisions could be envisaged in particular under variant 4A (self-certification) provided that the necessary harmonised standards are available. Under the other variants, a reasonable delay could be foreseen to allow Member States to notify the bodies that will be tasked to certify the compliance of products	Products considered as safe will get a quick access to the market as they will follow the self-registration procedure. More risky products will have to wait the designation of notified bodies by the Member States which could be relatively short in Member States that have already implemented quality assurance procedures. The time required by CEN to develop harmonised standards will have to be taken into account.
Role of the Commission and budget implications	No change to the current situation. COM organises the peer-review of application for the registration of new fertiliser types and draft regulatory measures to adapt the lists of authorised products to technical progress. The Commission ensures the correct implementation of the Fertilisers Regulation	Compared to option 1, variants 2A and 2B would not change the current approach. Under Variant 2C, the Commission would have to foresee an EU budget for EFSA to perform its tasks. The Commission would support financially further standardisation work relating to new harmonised products	The role of the Commission would be similar to the those explained under option 2	COM may propose complementary regulatory measures (e.g. restrictions of input materials) to adapt the future Regulation to technical progress. COM sets up and supports an administrative coordination group for national market surveillance authorities (legal base: Article 24 of Regulation (EC) No 765/2008). COM makes publically available the list of conformity assessment bodies notified by the Member States (NANDO database). COM evaluates measures where objections to notified bodies are raised.	The role of the Commission would be similar to the ones described under option 4.

				The Commission would support financially the development of harmonised standards	
Role of the Member States and budget implications	No change to the current situation. Member States competent authorities analyses the requests for registration and perform market surveillance	Under Variant 2A, Member States peer-review the requests for application. Under variants 2 B and 2C, the analysis of the data submitted by industry is analysed either by ECHA or EFSA. Member States are responsible for post market surveillance Member States may comment draft standardisation mandates prepared by the Commission.	The role of the Member States would be similar to the those explained under option 2	Member States would have to designate a national notifying authority which will assess the competence of notified bodies, normally based on accreditation by national accreditation agencies. National notifying authority supervises notified bodies. Member States notify bodies to the COM. Member States continue to ensure the post market surveillance of fertilisers. Member States may comment draft standardisation mandates prepared by the Commission.	The role of the Member States would be similar to the ones described under option 4.
Role of the industry and budget implications	No change to the current situation. Industry prepares and submits data for the registration of new fertiliser types. Industry is liable for the placing on the market of EC fertilisers in accordance with the Fertilisers Regulation	Depending on the variants, industry would submit new application for registration either to the Commission and the Member States or ECHA or EFSA. Industry would have to pay fees to ECHA to carry out its tasks Industry may comment draft standardisation mandates prepared by the Commission.	The role of the industry would be similar to the those explained under option 2	Depending on the type of fertilising products at stake, a manufacturer would have to select the appropriate conformity assessment modules from the range proposed. He would have either to self-certify its products or would need to involve a notified body (and pay fees) to certify that its product complies with the provisions set out in a future Regulation. Products tested against harmonised EN Standards gain a presumption of conformity which eases the conformity assessment	The role of economic operators would be similar to the ones described under option 4.

				procedures. Industry may comment draft standardisation mandates prepared by the Commission.	
Potential implementation and compliance challenges specific to each option.	No change compared to the current situation.	The Commission will ensure that the registration system for all types of fertilising products and agronomic fertiliser additives are effective and timely set up by ECHA or EFSA. Member States would have to conduct the first evaluation of dossiers and participate in peer-review process.	The Commission will ensure that the registration system for ingredients allowed in the manufacture of fertilising products and agronomic fertiliser additives are effective and timely set up by ECHA or EFSA. Member States would have to conduct the first evaluation of dossiers and participate in peer-review process	Member States operating with positive lists will have to ensure an effective and timely transition of the existing structures and institutions to support the marketing of products following the New Approach.. The Commission will ensure that notified bodies are working according to harmonised procedures and quality standards.	The compliance challenges would be similar to the ones described under option 4

ANNEX VIII

Assessment criteria

This annex aims at explaining how the criteria described in Section 6 of the main text have been established for the assessment of each possible option.

1. ECONOMIC IMPACTS

The criteria below are linked to the policy objectives of developing a truly internal market for innovative products sourced from domestic, secondary raw materials. The criteria address the problems of simplification potential, administrative burden reduction and support to innovation.

1.1. Functioning of the internal market and simplification potential

In general terms, it is expected that a more efficient internal market for fertilising products would mean a better level-playing field for businesses and a more transparent and simplified regulatory framework. A well-functioning internal market should benefit end-users (farmers, growers and consumers) as consumer choices should increase and better competition could lead to a reduction in fertiliser prices.

Criterion 1: do the policy options achieve a better level-playing field for product manufacturers? (Qualitative)

Criterion 2: do the policy options lead to administrative simplification? (Qualitative)

1.2. Administrative burden costs

The administrative costs assessment for enterprises, Member States authorities and the Commission for each of the five examined policy options were assessed in the Fertilisers Study and further refined by the Commission using the methodology of the EU Standard Cost Model. Responses from bilateral contacts between the Commission and industry experts and the SMEs survey carried out in 2012 were used to complete the set of data.

Administrative costs include:

1. costs of management of EU and national legislations;
2. costs relating to the placing on the market of EU or national products (e.g. costs of inclusion in annex(es)/authorisation of products) including the costs of standardisation and mutual recognition;
3. costs of market surveillance;
4. costs of compliance

Details about the assumptions, limitations and assessments of the administrative costs are described in Annex III and IV.

Criterion 3: do the policy options minimise administrative and compliance costs? (Quantitative)

1.3. Competitiveness and innovation

The revision of the Fertilisers Regulation is likely to have direct and indirect impacts on competitiveness and profitability of businesses.

Direct impacts relate to the fertiliser industry for which the creation of an internal market is likely to lead to better conditions for investments in research and development which would in turn improve the sector's competitiveness.

However, an important driver for the competitiveness of inorganic nitrogen fertiliser producers is the access to natural gas at a competitive price (natural gas accounts for 50-70% of the price of nitrogen fertilisers). The current high level of natural gas prices in Europe has negative impacts on the competitiveness of the inorganic fertilisers industry. The reduction potential will most likely not allow EU producers to gain significant competitive advantages over third country producers benefiting from much lower gas prices. Nevertheless, it could be considered as a helpful contribution.

As regards international trade impacts, inorganic fertilisers and liming materials are commodities that are traded worldwide and their prices are determined by demand/supply market forces. International trade of other product categories (e.g. organic materials) is limited because of their low market values compared to the costs of transport.

As underlined in the IAR Cd of 2011, the majority of current EU imports of inorganic phosphate fertilisers originate in Northern Africa. Countries such as Morocco and Tunisia are covered by the European Neighbourhood Policy (ENP) which was developed in 2004 with the objective of establishing a deeper political relationship and economic integration between the EU and its immediate neighbours by land or sea. Measures taken in the EU with regard to phosphates, could potentially lead to strong reductions of phosphates exports to the EU, which are today significant sources of revenues (e.g. 20 % of the total Moroccan exports). This would be contrary to the ENP objectives.

Furthermore, the EU is a member of the World Trade Organisation (WTO) and bound by its rules. Consequently, any measures adopted to protect human health or the environment, must be the least trade-restrictive in order to achieve the intended objectives. All possible options therefore have to be assessed with regard to their compatibility with WTO obligations. The proposal accompanied by this impact assessment report will also be notified to the WTO under the TBT agreement, which will allow 3rd countries to comment.

Indirect impacts mainly concern farmers and private consumers for whom improved competitiveness of the fertiliser industry could lead to a reduction in fertiliser prices if more alternatives are available and better crop yields if more efficient products are developed in line with the agricultural needs in different regions of Europe.

Innovation is mainly expected in relation to plant biostimulants and fertiliser additives and in the recycling of biodegradable waste into efficient fertilising products that could partly replace inorganic fertilisers.

More stringent safety requirements can also stimulate innovation by e.g. incentivising the development of decadmiation technologies for mined phosphate rocks or indirectly by orientating research to the production of phosphate based fertilisers from sources other than mined phosphate rock.

Criterion 4: do the policy options support innovation by facilitating the access to the market and by minimising the time to market new products? Could the option lead to significant trade impact? (Qualitative)

2. SOCIAL IMPACTS

The criteria below are linked to the policy objectives of ensuring the safety of fertilising products as regards the protection of human health. It also includes the benefits of establishing more favourable conditions for the development of innovative products that could support the creation of jobs. These criteria are linked to the problems of the lack of environmental protection consideration in the current Fertilisers Regulation, the issue of the mutual recognition and the need for more sustainable products

2.1. Benefits for human health

The social impact analysis will explore the potential health benefits of the various options that might materialise for consumers via the strengthening of the safety requirements for fertilising products. In particular, limits for heavy metal content would eventually lead to reduced levels of such contaminants in the food chain and drinking water. Although the risks for the population and the environment have been clearly identified in relevant EU legislation[201], it is however difficult to quantify what would be the effect of setting limits for contaminants in fertilising products given the very complex relationship between pollutant content in fertilisers, their behaviour in different soil types, different uptake by plants, etc. and even more difficult to monetise those benefits for public health. However, it is clear that fertilising products remain an important contributor to soil contaminant inputs that have not been dealt with so far at EU level. Without regulating their presence, some contaminants brought to the soil by the fertilising products will continue to accumulate in the soils showing the irreversible character of the problem.

It has also to be noted that manufacturers and importers of inorganic fertilisers and agronomic fertiliser additives need to submit a registration dossier under REACH for the substances used in fertilisers. Those selling more than 1000 tons per year of a given substance had to register by 30 November 2010 and the registration dossiers had to include the so called chemical safety report (which is applicable as of 10 tons per year) to demonstrate that all intended uses of the substance(s) are safe. The chemical safety report could also address the presence of contaminants above 0.1%. The registration dossiers are available on ECHA's website and authorities can verify them. For inorganic fertilisers, REACH chemical safety reports are not enough to cover the risks to human health and the environment from the presence of contaminants in fertilising products as contaminants below 0.1% do not need to be declared. Therefore, limit values for contaminants should be described in an appropriate section of the future Fertiliser Regulation.

Likewise other fertiliser materials, such as organic fertilisers and organic soil improvers, which are consisting or deriving from biological materials, are exempted from REACH registration. Therefore, potential safety issues relating to the presence of contaminants in such products need to be defined in the future fertiliser regulation in order to facilitate the enforcement of relevant EU existing environmental or health legislations setting limits for such contaminants.

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[201] A systematic review of the current regulatory framework for food safety, plant and human health and the protection of the environment is proposed in Annex VI to clarify and justify the need for setting limits on contaminants in fertilising products

Criterion 5: can the options effectively contribute to the reduction of contaminant inputs to agricultural soil at EU level and hence decrease contaminant exposure of human beings via the food chain and drinking water? (Qualitative)

2.2. Jobs and Growth

Impacts on employment from the revision of the Fertilisers Regulation will be analysed for each option. For example, options strengthening the organic material sector could lead to more employment and more growth for this sector.

Criterion 6: can the options lead to the creation of jobs and economic growth? (Qualitative)

3. ENVIRONMENTAL IMPACTS

The criteria below are linked to the policy objectives of ensuring the safety of fertilising products, allow a quicker access to products derived from domestic and secondary raw materials and improve the labelling requirements for all product categories and in particular urea-based fertilisers to support the enforcement of other EU environmental legislation.

This includes effects on resource efficiency, reduction of soil contamination, special considerations for the revision of the air quality strategy.

3.1. Resource efficiency and contribution to the circular economy

The production of mineral fertilisers requires the use of non-renewable resources –mineral deposits and/or (fossil) energy. Nitrogen (N) production requires large amounts of natural gas to transform nitrogen from air into forms that can be used by plants. The price of gas is the most important cost factor, and availability and reliability of supply also contributes to investment decisions by companies for production facilities.

Phosphorus-containing mineral fertilisers are produced from mineral phosphate deposits. Currently a 20% efficiency of phosphorus (P) use along the mine-to-fork pathway is calculated, giving room for improvement along each step of the process. 92% of all phosphate fertilisers placed on the EU market are mined in non-EU countries (in particular from Morocco and Russia) or directly imported from those countries.

Potassium (K) from mineral deposits is not a critical resource in the EU, not even in the long term, unlike the previous two elements.

In the perspective of a resource-efficient economy, which is one of the explicit goals of the Europe 2020 strategy, the recycling of nutrients from biowaste (plants, manure, animal by-products, sewage sludge etc.) rather than continuous input of new raw materials should be promoted as well as the efficient use of phosphate throughout the value chain[202]. Some Member States have already established national initiatives, e.g. with voluntary commitments by industry to foster in particular the recycling of phosphorous from struvite for example. However, no harmonised approach is present at EU level.

The draft End-of-Waste criteria developed by JRC-IPTS for compost and digestate could promote high quality recycling for biodegradable waste and ensure that increased compost and digestate production is achieved with minimum risks to the environment. Establishing common compost and digestate production and product standards would also have the

[202] The Commission has recently adopted a Consultative Communication on the sustainable use of phosphorus, COM(2013) 571.

advantage of increasing market confidence in materials that would no longer be considered as waste but valuable quality products.

Fertilisers should be considered as strategic commodities and be treated as such in future international negotiations. Given the existing and future imbalance between the geographic distribution of fertiliser production and fertiliser demand, trade in fertilisers has played and will continue to play an important role in ensuring fertiliser/food security in almost all regions of the world. Practical and geographically adapted solutions in terms of production, access and use of fertilisers should help to support EU agriculture.

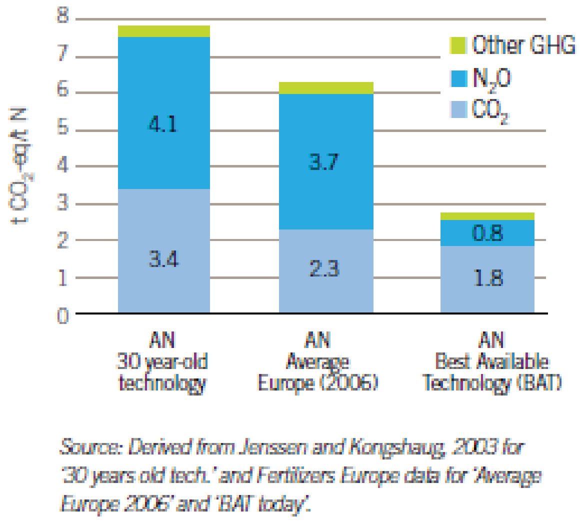
The scenario in which phosphate fertiliser prices continue to increase could be averted in the long term if the demand can be met by improving the recycling of valuable phosphate from biowaste and an overall improved efficiency of farming practices and food chain management.

The following sections illustrate the extent to which the EU fertiliser industry already contributes to the reduction GHG emissions during **production and use** and thus, participates to the circular economy.

3.1.1. Energy performance, carbon foot print and increased sustainability during production

The EU **inorganic N fertiliser** industry is an energy intensive industry and contributes directly and indirectly to GHGs emissions, particularly carbon dioxide (CO_2), ammonia (NH_3) and nitrous oxide (N_2O), through the production, distribution and use of fertilisers. This industry is constantly reducing (Figure 1) its carbon footprint through investments in energy efficiency and emissions control technologies.

Figure 27: Greenhouse emissions of ammonium nitrate production at different levels of production technology *(Source: Fertilisers Europe*).



Energy efficiency in ammonia production is critical, since it accounts for most of the manufacturing cost and has a significant impact on the reduction of carbon dioxide (CO_2) emissions from the sector and, hence, to the contribution of this industry to the EU Emission Trading System (EU ETS). In efficient inorganic fertiliser plants, the steam generated during the production of ammonia and nitric acid can be used elsewhere in the production process to replace the combustion of fossil fuels

Although agriculture accounts only to 3% of overall market for **lime products**, it is still an essential product for agricultural production. Lime production is carbon intensive; however, it is different for many other carbon intensive industries. Its specificity is due to the fact that only a third of emissions come from burning fuels to heat the kilns, but the bulk of emissions come from the chemical reaction that happens during the production process. Given the spilt of emissions, focus has been on reducing energy use and looking into abatement solutions to capture CO_2 during process emissions, even if the Carbon Capture and Storage (CCS) System is not financially viable at this time[203]. It has also to be noted that during the lifetime of products in which lime is applied, CO_2 from the atmosphere is captured basically reversing the reaction in which lime is produced from limestone.

The environmental performance of the production of **organic-based fertilisers** is less documented than inorganic fertilisers or lime. However, this industry is also committed to reduce both energy consumption and GHG emissions. Gain in GHG emissions, energy savings and improvement in the circularity in the sector can be illustrated by the following examples:

[203] A lime producer partnered in the Agical+ research project that aimed at making use of the lime sector CO_2 emissions based on algae culture, biomass production and the production of biofuel that could be used within furnaces during the production process. However, economic analyses revealed that the cost of the biofuel produced would be around EUR 650/Gj or around 100 times more expensive than commercially traditional energy resources.

- The recycling of biodegradable waste (e.g. pig manure, residues of slaughterhouse water treatment plants) often combines biogas production and valorization of digestate residues into organic fertilisers. This contributes to the general EU objectives to secure energy supply but also to reduce ammonia emissions to the environment from landfilling or direct application of raw manure on areas sensitive to eutrophication. Besides energy production, heat and steam recovery at various stage of the production process can help to avoid GHG emission. The final digestate is transformed into highly valuable organic fertilisers exported to regions less sensitive to eutrophication thereby contributing to the objectives of the Nitrate Directive. The whole process could be further improved by separating pig manures into liquids and solids fraction to allow nitrogen and phosphorus to be recycled more efficiently into valuable organic fertilisers. Return on investment is guaranteed by biogas and organic fertiliser sales.

- Martinez-Blanco et al (2009) compared the production and use of compost and inorganic fertilisers on tomato crops through a full life cycle analysis. For treatment with compost, the production stage had the biggest environmental impacts due to the emissions of volatile organic compounds[204] whereas for treatment with inorganic fertilisers, the use phase has the greatest environmental impacts due to N_2O emissions. When all environmental burden of landfilling organic waste is subtracted from the total impacts of compost production and use, the study shows that the compost treatment is more energy effective (circa 20% less in MJ/ton of tomatoes) and avoids the emission of 980 kg CO2 eq/ton tomatoes compared to the treatment with inorganic fertilisers. The compost production results in no differences in terms of agricultural production and quality in that particular case although the efficiency of organic fertilisers pretty much depend on the local soil and climatic conditions[205].

- Biochar is a solid material obtained from the carbonisation of biomass (animal bones or plant residues). In sustainable biochar production, all materials[206], including CO_2 are used to produce energy and valuable materials. Biochar may be added to soils to improve soil functions and soil fertility[207]. It is often combined with conventional inorganic fertilisers or animal manure to reduce GHG emissions from those fertiliser inputs[208]. In that case, biochar has appreciable carbon and nutrients sequestration value regardless of the local soil and climatic conditions and increase soil microbial life. The result is a net reduction of GHG emissions in the atmosphere compared to the production and use of conventional inorganic fertilisers or manure only. Turning agricultural waste into biochar also reduces methane (another potent greenhouse gas) generated by the natural decomposition of the waste.

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[204] The process was compared to a highly efficient inorganic fertiliser plant

[205] The organic nutrients need to be mineralised by the soil biota before being accessible to crops. This can be only realised under moderate soil temperature and humidity conditions.

[206] Oils and gas by-products

[207] Animal Bone biochar (ABC) contains up to 30% P_2O_5 and CaO and traces of K and MgO which are slowly available to the plants. ABC formulated with additional amount of nitrogen and potassium show immediate fertilisation effect on crops resulting in decreased inorganic fertiliser requirements (and hence GHG emissions) and increased crop yields

[208] Under many but not all conditions depending partly on the feedstock materials and pyrolysis conditions during the production of biochar

- Plant biostimulants improve the quality and stock of biological materials in agriculture. Many biostimulants are derived from diverse sources of food and feed waste which are channelled back to producing biostimulants. This conversion of wastes into raw materials for certain biostimulants helps to reduce waste stream which is the main objective of a circular economy.

- Organic-based materials help shift the balance from almost purely industrial inputs into agriculture to a higher percentage of bio-based products.

3.1.2. Carbon footprint and increased sustainability performance during fertiliser use

Due to the capacity of plants to absorb CO_2 and soils to sequester carbon, agriculture has the potential to sequester more CO_2 than it emits. Instead, the agricultural sector is one of the world's most significant sources of anthropogenic greenhouse gas emissions. The activities predominantly responsible for the carbon footprint of food production are the clearing of forests and the conversion of grassland into arable land for biofuels production. Other drivers are the emission of extremely potent greenhouse gases such as nitrous oxide from the decomposition of inorganic fertilisers, as well as methane from unprocessed animal manure and the digestive process of ruminants in livestock farming.

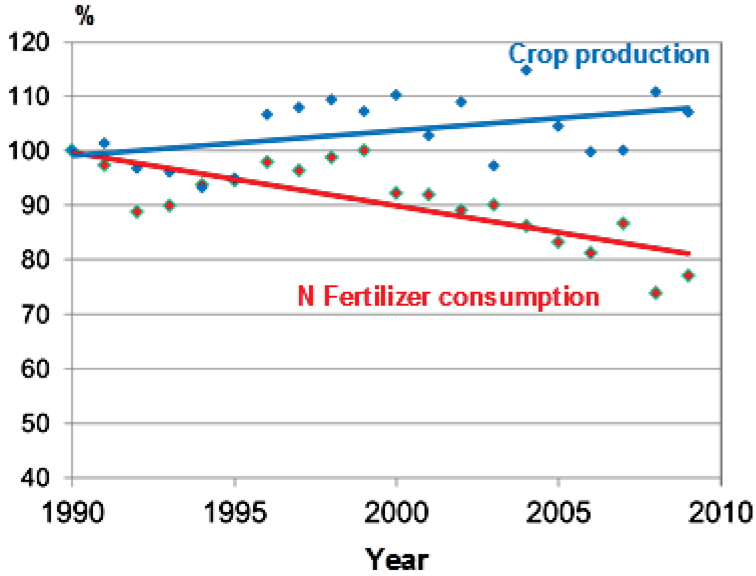
In 2008, total nitrogen losses to the environment from agricultural soils in EU-27 amounted to 13 000 000 tonnes with 53% as N_2, 22% as NO_3, 21% as NH_3, 3% as N_2O, and 1% as NOx. N_2O is an important greenhouse gas, due to its high global warming potential (296 times higher than CO_2) and its relative stability in the atmosphere. It is considered as being responsible for 4% to 5% of global warming. More than a third of all **N_2O emissions** are primarily due to agriculture.

In Europe, approximately half of PM2.5 (particles of less than 2.5 micrometres in size) and a third of PM10 concentrations (particles of less than 10 micrometres) are made up of particles produced by the reactions of three precursor gases—nitrogen oxides, sulphur oxides and ammonia. Worldwide, urban air pollution is estimated to cause about 9% of lung cancer deaths, 5% of cardiopulmonary deaths and about 1% of respiratory infection deaths (WHO, 2011). Atmospheric emissions of all three gases need to be reduced in order to make a meaningful impact on PM concentrations, but **ammonia emissions**, over 90% of which come from agriculture, are not falling as fast as nitrogen oxides and sulphur oxides emissions.

Measures to **reduce N_2O and ammonia emissions** through more efficient use of nitrogen fertilisers can help mitigate climate change and lessen nitrogen losses from agriculture. The available N in the soil is the most important factor in this regard and is directly related to the N-fertilisers application. Therefore if, on the one hand, the use of N –fertiliser is important to provide that plants reach a desirable yield and, on the other hand, a portion of this added N can be lost to the atmosphere[209] as N_2O and ammonia, this is enhancing the greenhouse effect.

[209] As well as in run-off waters

Figure 28: nutrient use efficiency has increased during the last 25 years (*Source IFA*)



Although the soil parameters that could be modified via fertiliser inputs and lead to a modification of GHG emissions or soil carbon storage is not yet fully understood, the following trends[210] are generally well accepted.

The choice of the form of nitrogen, the method of application and the variability of the soil and climate conditions across Europe affect the environmental performance of the fertiliser applied.

Ammonium, ureic and nitrate nitrogen differ not only in terms of their sensitivity to volatilisation, nitrification/denitrification and leaching, but also in terms of their ease of uptake by the plant. Some inorganic fertilisers contain different proportions of these chemical forms.

Nitrate is dissolved in water pore spaces in the soil and cannot be stored over the long term. During the period of crop growth, nitrate is taken up at high rates. Losses of nitrate from the soil occur via the denitrification process of soil bacteria (N_2O emissions).

Ammonium is not mobile and most of it has to be converted into nitrate before crops can take it up. Losses of ammonium from the soil occur via volatilisation of ammonia (NH_3).

Slow and controlled-release as well as nitrification and urease inhibitors can considerably reduce nitrogen losses to water and to the atmosphere, while at the same time significantly improving fertiliser efficiency

A few studies observed lower emissions from organic fertilisers compared to calcium ammonium nitrate and attributed this to the slow release of nitrogen into the soil following favourable environmental conditions such as both moderate temperature and humidity

[210] Although soil temperature and humidity are important factors, their impacts is not described here as fertiliser use cannot influence those factors

conditions. The efficacy of organic fertilisers is therefore dependent on the actual soil structure and conditions available in different parts of the EU.

A range of emission control options is now proven to be effective in practice in more and more countries. Many of these measures are cost-effective and have co-benefits for the farmers, especially when their additional synergistic effects are considered. Adjusting fertiliser application dates to crop requirements, making better use of organic fertiliser, covering manure storage places, using nitrification inhibitors, developping manure and N-fertiliser application techniques are examples of such cost-effective means to cut ammonia emissions in many situations.

While fertilisers and pesticides will always have central roles to play in agriculture, biostimulants can help reduce the flow of the nutrients that fertilisers contain into the biological cycle of agriculture to the amount needed for optimal use.

Biostimulants can improve phosphorus efficiency in agriculture:

Phosphorus is a critical raw material essential for European agriculture. Biostimulants increase phosphorus (P) use efficiency and convert P locked in soils into forms that can be used by plants.

Phosphate fertilizer use in Europe is largely dependent on imports (often from regions that are politically volatile). Increasing the efficiency of the fertilizers used can thus improve the EU's trade balance.

The bulkiness of fertilizers entails significant transport costs (and transport-related GHG emissions), which can be reduced by increasing the efficiency of fertilizer use (and thus the overall amount of materials that need to be transported).

Most sources of phosphorus rock naturally contain cadmium and other contaminants. By improving the efficiency of phosphorus use, more P can be obtained by plants relative to the amount of cadmium added to the soil, thus improving soil management.

Biostimulants can help to better manage the Nitrogen Cycle:

Biostimulants help mitigate the GHG effects linked to the production of inorganic nitrogen fertilisers by increasing nitrogen use efficiency, preventing losses to the environment and allowing for a more resource-effective use of any nitrogen fertilizers that are produced.

The efficiency of fertilisers is documented to be increased by a minimum of 5% (and may go as high as 25% or more) when biostimulants are applied. If the conservative figure (5%) were generalised to the entire EU, it would mean a savings of some 517,000 tonnes of nitrogen fertiliser in a single year.

Nitrogen-fixing micro-organisms are expected to be classified under the umbrella of biostimulants in the future EU regulation. These contribute to the circular economy by offering a bio-based, nonindustrial method of providing nitrogen in forms that plants can use. While this nitrogen can still have unwanted environmental effects, it eliminates impacts related to industrial production and transport.

The rate of build-up of CO_2 in the atmosphere can be reduced by taking advantage of the fact that atmospheric CO_2 can accumulate as carbon in vegetation and soils in terrestrial ecosystems. Any process, activity or mechanism which removes a greenhouse gas from the atmosphere is referred to as a "*sink*". Human activities impact terrestrial sinks, through land use, land-use change and forestry (LULUCF) activities, consequently, the exchange of CO_2 (carbon cycle) between the terrestrial biosphere and the atmosphere is altered.

The role of LULUCF activities in the mitigation of climate change has long been recognized. Mitigation can be achieved through activities in the LULUCF sector that increase the removals of greenhouse gases (GHGs) from the atmosphere or decrease emissions by sources leading to an accumulation of carbon stocks.

Crop yield can play an important role in this regard and an optimum fertiliser application rate can increase the volume of biomass produced and lead to a more important fixation of CO_2 compared to a situation where a lower dose of fertiliser is used. As illustrated in figures 29 and 30, crop production aiming at most efficient utilisation of resources including the agricultural areas, saves GHG emissions by preventing natural areas from having to be converted into cropland

Figure 29: GHG emissions of wheat production (including production and transport of fertiliser) at different N fertilisation intensities (*Source: Fertiliser Europe*).

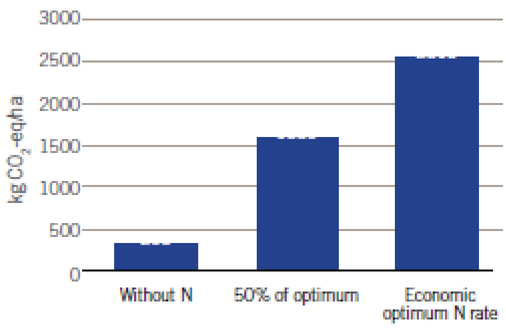
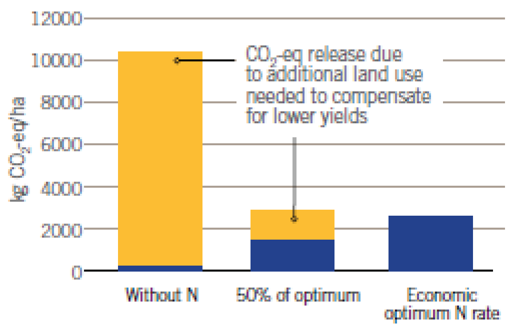


Figure 30: GHG emissions of wheat production (including production, transport and **land use change**) at different N fertilisation intensities (*Source: Fertiliser Europe*).



3.1.3. Other contributions to the circular economy

What are the benefits for plants of a larger use of organic fertiliserss?

The applied organic nutrients will work more slowly and as a consequence they will cause less plant stress. Leaching losses will be strongly reduced and plants will be fed with a more complete nutrition (many naturally present trace elements).

Due to the slow but regular growth, the plants will contain more dry matter, which will make the plants less susceptible to diseases and their fruit will have a longer storage life. So less plant protection products will be needed, both during the culture and post-harvest.

What are the benefits for the soil?

The increase in organic matter will improve the soil structure and his crumb stability. This will guarantee a better yield and healthier crops. Because in a better structured soil, plants will develop more roots and they will become much more resistant to soil-borne pathogens, so less soil pesticides are needed. Organic fertilisers provide a lot of decomposable organic matter, which is very attractive for the beneficial soil micro-organisms, they will become more active and more diversified, what is the best guarantee for a higher protection against harmful soil micro-organisms. Soils with a big microbiological activity will have a self-purifying capacity because they are able to get rid of biodegradable pollutants.

What are the advantages for the society (public health and environment)?

Healthy and well-fed plants will offer a higher nutritional value to food. Lower use of pesticides offers a healthier environment. Lower leaching losses of fertilisers and pesticides will keep our drinking-water safe and accidental soil pollution can - to a certain extent - be microbiologically remedied.

Biostimulants help in the development of beneficial soil microorganisms (and some biostimulants contain microbes) that help retain carbon in the soil and reduce CO_2 emissions form agriculture. Biostimulants foster the development of beneficial soil microorganisms that improve soil structure, among other benefits. Healthier soil retains water more effectively and better resists erosion, meaning less water is needed throughout the agricultural process and there is less runoff into neighbouring ecosystems.

Criterion 7: can the various options foster significantly the recycling of nutrients and support the circular economy? (Qualitative)

3.2. Reduction of contaminant inputs

As reported in the ex-post evaluation, one important gap of the current Fertilisers Regulation is the absence of harmonised limits for contaminants that might be present in fertilisers. As most of the Member States have implemented such limits in national legislation, producers may be tempted to label inorganic fertilisers as EC Fertilisers to circumvent more stringent national rules.

In a series of ad-hoc technical meetings during 2012, experts of the Member States, industry, NGOs and farmers association agreed on a list of contaminants and their corresponding limit values to be controlled in fertilising products in the future legislation. The objective was to reduce as much as possible the potential negative environmental impacts linked to the presence of contaminants in fertilising products thereby ensuring coherence with existing EU legislations. Organic matter degradation and soil structure regulation are highly altered by the presence of soil contaminants because of their negative impacts on soil biodiversity. Consequently, soil functions such as fertility, carbon storage, nutrient cycling as well as water purification are affected and declines with the accumulation of pollutants in the soils.

Criterion 8: can the options effectively contribute to the reduction of contaminant inputs to agricultural soil and hence improve soil function at EU level? (Qualitative)

3.3. Benefits for implementation of the objectives of the air quality strategy

Agriculture is responsible for more than 90% of the total ammonia emissions in the EU. These emissions are responsible for a large part of the excess eutrophication and act as an increasingly important precursor gas for the formation of secondary particulate matter with negative health impacts.

One main source of ammonia pollution is emission from inorganic fertilisers. There has been limited progress in reducing these emissions in the past due to insufficient national action in most Member States, in combination with limited source controls at EU level.

Emissions from the agricultural sector are therefore given high priority in the Commission's air policy review in 2013. The analysis in that review shows that, annual premature mortalities due to particulate matter amounted to over 400.000 and 62% of the EU area was exposed to eutrophication including 72% of protected Natura 2000 ecosystems. Unless additional action is taken, ammonia emissions from agriculture will increase in the coming decades – the only main air pollutant for which this is the case. However, there is a large potential to reduce future ammonia emissions by ensuring a wider uptake of existing best practice in the EU, including by replacing high-emitting inorganic fertilisers such as urea-based fertilisers by less emitting fertilisers or by implementing remediation measures such as urease inhibitors or fast incorporation after application.

Criteria 9: will the options ensure that farmers are correctly informed about the potential release of ammonia from different inorganic fertilisers in order to choose the optimal type of fertiliser and/or implement remediation measures? (Qualitative)

ANNEX IX

Characteristics of plant biostimulants and agronomic fertiliser additives

A. Characteristics of plant biostimulants

Various substances and materials as well as some microorganisms have demonstrated a capacity to modify the physiology of plants, promoting their growth and enhancing their response to abiotic stress when applied directly to plants, growing media or soil. Their action is distinct from nutrients or plant protection products and the term "biostimulants" has been used to describe their function.

A study carried out upon request of the Commission [211] has identified nine categories of plant biostimulants: (1) humic substances, (2) complex organic materials, (3) beneficial chemical elements, (4) inorganic salts (such as phosphite), (5) seaweed extracts, (6) chitin and chitosan derivatives, (7) antitranspirants, (8) free amino acids and other N-containing substances, (9) microorganisms. Some overlap can exist between the various categories.

This study proposed a definition which was further discussed with the stakeholders and which resulted in the final following definition: "a material which contains substance(s) and/or microorganisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to benefit nutrient uptake, nutrient use efficiency, tolerance to abiotic stress, and/or crop quality, independently of its nutrient content".

Categories either include products deriving from materials present in nature or deriving from animal by-products.

The mode of action of plant biostimulants can entail physiological changes in the plants. Their similarity with existing Plant Protection Products (PPP) has been underlined by stakeholders during the consultation phase. In a limited number of cases[212], the same (or very similar) "active ingredients" have been identified as being regulated under the strict regulatory framework of PPP at EU level. However, the nature (e.g. humic acids) or use, as food or cosmetic ingredients (e.g. plant and seaweed extracts…) or in some cases a long history of safe use of most plant biostimulants, are also factors pleading in favour of a flexible regulatory approach. More stringent regulatory measures also correspond to one of the objective driving the revision of the Fertilisers Regulation which is to ensure a high level of protection of human health and the environment from the use of the fertilisers and related product categories, such as plant biostimulants, while fostering innovation by ensuring a swift access to the EU market for new fertilising products.

Plant biostimulants are stimulating by various mechanisms a better use by the plants of the available nutrients present in the soil, hence a reduced use of fertilisers for the farmer. It acts also on the better resistance of the plant to abiotic stress such drought, cold,…allowing plant growth under extreme conditions and less use of water, less investment in cover-crop facilities (e.g. greenhouses) and potentially less energy consumption. Indirect protection towards biotic stress (e.g. pest) has also been reported, hence less use of plant protection products.

B. Characteristics of agronomic fertiliser additives

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[211] The Science of Plant Biostimulants – A bibliographic analysis, by Prof. Patrick du Jardin, available at: HTTP://EC.EUROPA.EU/ENTERPRISE/SECTORS/CHEMICALS/FILES/FERTILIZERS/FINAL_REPORT_BIO_2012_EN.PDF

[212] The group of plant biostimulants include for example microorganisms, as PPP do, which can be responsible for the production of toxins and their related potential risks for plants, animal and human health

In plant nutrition, only a portion of nutrients is taken up and used by the plants while another portion is (temporarily) immobilised in the soil or lost by de-nitrification/volatilisation and leaching (mainly nitrogen). The fertiliser industry has developed special types of fertilisers or additives which reduce such losses such as:

- Slow or Controlled-release fertilisers (SRF or CRF),
- Stabilised nitrogen fertilisers (SNF),
- Nitrification and urease inhibitors (NI and UI),
- Chelating and complexing agents.

As the nutrients applied to the soil will be more available for plants over the longer term, farmers will use less fertiliser to feed crops.

Slow and Controlled-release fertilisers (SRFs and CRFs)

In practice, the main difference between the two types of fertilisers is that for slow-release fertilisers, the nutrient release pattern is fully dependent on soil and climatic conditions and cannot be predicted (or only very roughly). For controlled release fertilisers, the release pattern can be predicted within certain limits.

Slow release fertilisers are dominated by biologically decomposing compounds usually based on urea-aldehyde condensation products such as urea-formaldehyde (UF), and chemically (mainly) decomposing compounds such as iso-butylidene-diurea (IBDU).

Coated or encapsulated products are referred to as controlled-release fertilisers. They are conventional soluble fertilising products whose plant nutrients are rapidly available and which are given a protective coating to control water penetration and hence the rates of dissolution of nutrients release in the soil. Only three types of CRF have gained technical importance:

- Sulphur coatings (e.g sulphur coated urea – SCU)
- Polymer coatings (e.g. PVDC copolymers, polyolefin, polyurethanes, polyethylene, alkyd resins e.g. polymer coated Urea - PCU),
- Sulfur-polymer coatings (hybrid products with a multilayer coating of sulphur and polymer - PSCF).

The production costs of CRF currently prevent their wider use in general agriculture. Their main markets are nurseries, greenhouses, turf, professional lawn care and public consumers.

Nitrification and urease inhibitors (NI and UI)

Many of the primary nutrient fertiliser types containing nitrogen tend to release their nitrogen too rapidly for crops to benefit fully from it. As a result the excess nitrogen may potentially cause harm to the environment. NI and UI reduce losses of nitrogen by interrupting the enzyme activity of soil bacteria.

Addition of a nitrification inhibitor to ammonia containing fertilisers or urea reduces leaching losses of nitrate by stabilisation of ammonia and reduces emissions of the environmentally relevant gases, methane, N_2O and NO. Urease inhibitors reduce ammonia emissions to the atmosphere from urea based fertilisers in particular when urea is not immediately incorporated into the soil.

Chelating and complexing agents

Metal chelate or complexes compounds are common components of fertilisers to provide micronutrients. These micronutrients (manganese, iron, zinc, copper...) are required for the overall health of plants. Most fertilisers contain phosphate salts that, in the absence of chelating agents, typically convert these metal ions into insoluble solids that are of no nutritional value to the plants.

CRFs: Polymer coated or encapsulated controlled release fertilisers can cause environmental problems since undesirable residues of the coating materials may accumulate in the fields. Many types of coating agents have been developed by industry and more information on the possible impacts on the environment would be required. The declaration of the nutrient release pattern of the final products will be made mandatory to ensure that farmers and growers are well informed of the characteristics of the product but the way this information is provided will be left to the producers.

NI and UI: Some nitrification or urease inhibitors might actually kill soil bacteria, some others are liable to hydrolysis which lowers the stability in storage and the activity period on the soil or are highly volatile when applied to fertiliser granules. There is also a need to strengthen the conditions of use of such substances. In New Zealand, traces of dicyandiamide have been recently found in powder milk. In this country, nitrification inhibitors can be applied directly to pasture as a fine suspension to reduce the risk of nitrate losses from the pasture. This practice is not authorised in the current Fertilisers Regulation as nitrification inhibitors must always be mixed with nitrogen fertilisers containing at least 50% nitrogen under the form of ammonia or urea.

Chelating and complexing agents: The behaviour of chelating agents in the environment has received considerable attention for more than 50 years. EDTA (ethylenediaminetetraacetic acid), for example, occurs at higher concentrations in European surface waters than any other identified anthropogenic organic compound and is listed as a possible candidate substance subject to review for possible classification as priority substances or priority hazardous substances under Directive 2008/105/EC. The largest concern is that many chelating agents are only slowly biodegradable and are therefore rather persistent in the environment. They can also extract metals from sediments, and their use is believed to add to the amounts of iron and other heavy metals in waterways.

There are five categories of compounds that are commonly mixed with minerals and used in agricultural foliar and soil applied applications:

1) Synthetic Chelates,
2) Ligno Sulfonates,
3) Humic or Fulvic Acids,
4) Organic Acids,
5) Protein (Amino Acids).

Only synthetic are not always readily biodegradable in the environment and should therefore be subject to specific risk analysis and management measures.

Market outlook

World agricultural crop markets for fertilisers with enhanced nutrient use efficiency have expanded steadily over the past decade with up to 4% CAGR being seen in the US. This has primarily been the result of price decrease and better awareness of farmers about the positive benefits of such additives.

C. Possible outline of the conformity assessment procedure for plant biostimulants and agronomic additives

Plant biostimulant is actually a group of fertilising products which covers various type of components: chemical substances, plant or algae extracts, microorganisms.

The composition may be stable in the case of plant or algae extracts obtained by non-disruptive methods but this might not be the case for extracts obtained by chemical methods. Stability of the production batches may also well vary in the case of microbial plant biostimulant as the fermentation or production methods requires a lot of attention to deliver similar quality and safety from one to another production batch.

Similarly among the group of agronomic additives chelating and complexing agents may be considered as not subject to a lot of variation in composition and hence should present smaller risks to deviate from the essential requirements compared to inhibitors which are by nature composed of chemical substances, some of them being very close to the plant protection products functionalities, hence requiring more attention.

That is why agronomic additives, with the exception of urease and nitrification inhibitors should be subject to self-certification by the manufacturers whereas the inhibitors and the plant biostimulants would rather qualify for the EU-type examination and conformity to type based on internal production control (modules B+C) in terms of conformity assessment procedures.

ANNEX X

Regulation (EC) No 2003/2003 relating to fertilisers

Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (hereinafter, 'the Fertilisers Regulation') provides for the harmonisation of EU rules on the placing on the market of **mineral fertilisers** (also referred to as inorganic fertilisers) and thus ensures the uniform application of technical provisions to these fertilisers in order to allow a good functioning of the common market for mineral fertilisers. The Regulation also harmonises the rules on labelling and packaging of mineral fertilisers.

The Regulation lays down rules to be respected by mineral fertilisers if they are to be marketed as **'EC fertilisers'**. A type of fertiliser may be included in Annex I to the Regulation, if:

it provides nutrients in an effective manner;

relevant samplings, analysis, and if required, test methods, are being provided;

under normal conditions of use, it does not adversely affect human, animal or plant health, or the environment.

In order to be so listed in Annex I, manufacturers must constitute a technical file on the characteristics of the fertiliser (safety aspects, agronomic efficacy…).

Annex I to the Regulation includes the type designation and establishes other parameters, such as data on the method of production and essential ingredients, and minimum values for nutrient content.

The inclusion of new fertiliser types in Annex I is discussed in the Fertilisers Working Group. New types of fertilisers are included in Annex I by means of a Commission Regulation.

All fertilisers marked 'EC fertiliser' may **circulate freely** within the European market. The Regulation however provides for a safeguard clause which enables Member States to temporarily prohibit the placing on the market of an EC fertiliser if it believes it constitutes a risk to safety, or health of humans, animals or plants or a risk to the environment. When such a measure is taken, the Commission decides upon the course of action regarding the concerned EC fertiliser.

The Regulation sets out detailed technical provisions regarding the scope, declaration, identification and packaging of four specific types of fertiliser:

primary inorganic nutrient fertilisers: nitrogen, phosphorus and potassium ('NPK'), supplied in substantial quantities for plant growth;

inorganic secondary nutrient fertilisers: calcium, magnesium, sodium and sulphur;

inorganic micro-nutrient fertilisers: boron, cobalt, copper, iron, manganese, etc., required in small quantities

ammonium nitrate fertilisers of high nitrogen content: given the hazardous nature of this type of fertiliser, the Regulation lays down additional measures.

Member States may carry out official controls to verify compliance of fertilisers marked 'EC fertiliser' with the provisions of the Regulation. Penalties for infringements are decided at Member state level.

The most important strength of the Regulation is that it has effectively simplified and clarified the regulatory framework concerning inorganic fertilisers. This is an important achievement and is a point that stakeholders would like to see repeated in any future regulation concerning other categories of fertilisers.

The simplification has also brought some cost savings for manufacturers relating to the packaging and labelling of products and the costs of staying up-to-date with multiple numbers of regulations. In certain cases, economies of scale for firms may also materialise from the more effective management of production.

The overwhelming evidence is that trade barriers in relation to the intra-EU trade of mineral fertilisers have been effectively eliminated. This has not been linked with an evident increase in the level of trade or a reduction of prices but there are other key parameters (price of energy, level of demand) that play a much more important role in this respect.

The implementation and enforcement of the Regulation as far as the surveillance of the market is concerned appears to be both effective and quite efficient. Extensive data are not available to check this conclusion but the feedback of authorities and industry does not indicate any problems in relation to EC fertilisers and surveillance does take place in parallel to that for national fertilisers.

ANNEX XI

Overview of some national fertiliser laws and their discrepancies (Source: the Fertilisers Study[213])

Table 65: overview of national regulatory frameworks

Products regulated at national level

	AT	BE	BG	HR	CY	CZ	DK	FI	FR	DE	GR	IE	IT	LT	LU	MT	NL	PL	PT	ES	SE	UK
Inorganic fertilisers	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
Organic fertilisers	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X
Organo-mineral fertilisers	X		X	X	X	X	X		X	X	X	X	X	X	X			X	X	X		
Liming materials	X	X	X	X		X	X	X	X	X		X	X	X	X		X	X	X	X		X
Soil improvers	X	X	X	X		X	X	X	X	X	X		X	X	X		X	X	X	X		
Growing media	X	X	X	X			X	X	X	X	X		X	X	X		X	X		X		
Plant biostimulants		X	X		X		X		X	X	X		X	X		X	X	X	X	X		
Agronomic additives	X	X					X	X	X	X			X	X	X			X		X		X

Type of registration procedure for the categories of products mentioned above

	AT	BE	BG	HR	CY	CZ	DK	FI	FR	DE	GR	IE	IT	LT	LU	MT	NL	PL	PT	ES	SE	UK
List of authorised types	X	X	X	X	X	X		X		X	X	X	X	X	X	X	X	X	X	X	X	X
List of authorised ingredients	X				X			X		X	X		X	X	X		X	X		X		X
Essential criteria					X	X	X			X	X		X						X			
Individual product registration	X	X	X	X	X	X	X		X	X	X		X		X		X	X	X	X		
Product standards									X													

Rules for contaminants

	AT	BE	BG	HR	CY	CZ	DK	FI	FR	DE	GR	IE	IT	LT	LU	MT	NL	PL	PT	ES	SE	UK
Limits on products and/or application rates	X	X		X		X	X	X	X	X	X		X	X			X	X	X	X	X	

There is no information available for EE, HU, LV, RO, SK and SL in the Fertilisers Study.
In Sweden, inorganic fertilisers must be registered in the Swedish Chemical Agency Register.
In Croatia, only inorganic fertilisers must be registered. The other products need only to be properly declared.

213 Please note that the definitions of products do not necessarily correspond exactly to the definitions proposed in the IAR

Description of national rules for various product categories

The following section gives examples of current national rules for fertilising products in terms of safety requirements, labelling requirements and provisions for the registration of new products. It has to be noted that the market surveillance of the fertilisers market appears to be both effective and efficient. Extensive data are not available to check this conclusion but the feedback of authorities and industry does not indicate big issues in relation with controls of EC and national fertilisers. This section will therefore aim to better illustrate the magnitude of the problem for companies to comply with diverging national rules.

1. INORGANIC FERTILISERS

A fraction of the EU inorganic fertiliser market is still covered by national rules. In most cases, environmental and public safety considerations are utilised to introduce different limits and requirements to serve national or local circumstances. From the point of view of the development of the internal market, these represent trade barriers that, according to almost all stakeholders, and EU wide regulation could effectively address.

The following tables show some examples of diverging national rules that apply to inorganic fertilisers as regards safety and labelling requirements as well as registration procedures.

Table 66: examples of diverging national requirements for national inorganic fertilisers

a) Safety requirements (*Source:* the Fertilisers Study)

During our Technical working group meetings organised in 2012, most Member States supported setting upper limits for heavy metals in inorganic fertilisers. Several Member States having set already national limits that so far affect only national fertilisers insisted on being allowed to continue to apply them to address their specific environmental concerns. The table below contains an overview of the limit values for national inorganic fertilisers (expressed in mg/kg of product as received) that Member States have already introduced in legislation. Additional information on the level of cadmium authorised in 20 Member States is available in Annex I of the IAR Cd

	Arsenic	Lead	Cadmium	Chromium total	Chromium VI	Nickel	Mercury
First figure refers to maximum limit values in products and are expressed in mg/kg dry matter except for cadmium for which the concentration is expressed in mg/kg P_2O_5 *Second figure refers to the maximum permissible application rate for contaminant per hectare and per year.*							
CZ	20	30	50	50	N/A	N/A	0.5
PT	N/A	N/A	N/A	N/A	N/A	N/A	N/A

IT	N/A	N/A	N/A	N/A	N/A	N/A	N/A
EE	50	100	60	50	N/A	100	2
DE	40	150	60	N/A	2	80	1
AT	N/A *N/A*	100 *300*	75 *1.5*	100 *300*	N/A	100 *200*	1 *5*
FI	25	100	22	300	2	100	1
SE	25	100	44	300	2	100	1
GR	N/A	N/A	60	N/A	N/A	N/A	N/A
FR (NF-42-001-1)	60	150	90	120	N/A	120	2
Proposed limit values	60	150	Political decision see IAR Cd	N/A	2	120	2

b) Labelling requirements (*Source: the Fertilisers Study*)

Member States	Name of the producer	Name of distributor	Trade name	Declaration of all nutrients	Declaration of claimed nutrients	Declaration of contaminant	Forms of nutrients to be declared	Condition of use	Quantity	Type designation
LU		X	X		X		X		X	X
DE	X	X	X	X	X	X	X	X	X	X
DK		X	X		X		X	X	X	X
HU	X	X		X			X	X	X	X
NO	X	X	X	X	X	X	X	X	X	X
BG	X		X	X			X	X	X	X
CZ	X		X	X		X				
IE	X	X	X	X			X	X	X	X
PT	X	X	X	X			X	X	X	X
NL	X		X	X	X		X		X	X
CY	X	X	X	X			X	X	X	X
IT	X		X		X				X	X

ES	X	X	X		X		X	X	X	X
BE	X	X	X		X	X	X	X	X	X
AT	X	X	X	X	X		X	X	X	X

c) Examples of diverging registration procedures *(Source: the fertilisers study)*

	List of authorised fertiliser type	List of authorised ingredients	Essential criteria	Individual product registration
UK	X	X		
GR			X	X
NL				
AT	X			X
DK	X		X	X
LU		X		X
HU				X
BE	X			X
NO	X	X		X
BG	X		X	X
CZ	X		X	X
IE	X	X	X	X
DE	X	X	X	X
PT	X		X	X
CY	X	X	X	X
IT	X			

ES	X			

2. SOIL IMPROVERS AND ORGANIC FERTILISERS

In general, national legal frameworks for soil improvers and organic fertilisers have been established by the Member States to manage their potential environmental and human health impacts. However, Member States have adopted different regulatory systems as regards the legal status, the registration procedure and the safety requirements for such materials. The JRC report[214] on EoW criteria for compost and digestate lists the main diverging requirements as shown below.

In practice, there are three main legal bases under which compost is certified or registered:

- fertiliser legislation, with and without specific compost provisions;
- waste legislation, with specific compost or bio-waste ordinances or under general waste treatment licensing procedures;
- soil protection legislation, with minimum requirements for waste derived materials, sludge and compost to be spread on land.

Standards or voluntary agreements based on criteria which are implemented by quality assurance schemes are another category, however, without direct legal status.

Obviously, compost and digestate considered as waste cannot freely circulate in the EU via the mutual recognition regulation that applies only to non-harmonised products.

Table 67: National approaches and criteria defining whether compost produced from waste may be marketed as product or as waste. *Source: ORBIT/ECN (2008) and stakeholder survey December 2010*

	Compost : PRODUCT or WASTE	**Legal basis or standard**	**Main criteria for** compost ceasing to be waste and/or placing on the market and use of compost
AT	**PRODUCT**	Compost Ordinance BGBl. I 291/2001. National environmental legislation	• Central registration of composting plant • Positive list of input materials • Comprehensive documentation of Waste reception Process management and material movement Compost quality criteria Product designation, declaration, labelling and selling of compost • External sampling and product certification

[214] http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=6869

	Compost : PRODUCT or WASTE	Legal basis or standard	Main criteria for compost ceasing to be waste and/or placing on the market and use of compost
			by acknowledged institute If all criteria are met and approved by the external certification system all types of compost can be marketed as PRODUCT.
BE Flanders	**PRODUCT (secondary raw material)**	VLAREA Flemish Regulation on waste prevention and management (B.S. 1998-04-16)	Total quality control of the VLACO-certificate includes: • Positive list of input materials, • Processing parameters, • Standards for product • Correct use • External sampling and product certification by a semi-public organisation If conditions above are met, compost ceases to be waste.
BE Wallonia	**WASTE**	Decree on compost and digestate (currently being examined by the Walloon Government)	Compost does not cease to be waste Four classes (A, B, C, D) and two subclasses (B1, B2) are defined by the Walloon administration for all materials. Compost belong to class B, and are distributed between class B1 and B2 according to the type or origin of the material. Material of class D can not be used on or in the soils; Material of class C can not be used on or in agricultural soils; Material of class A of B can be used on or in agricultural soils. Norms of subclass B2 are those applied for treatment plant sludge that can be recovered in agriculture in accordance with European legislation, i.e. a management at the field level together with a preliminary soil analysis must be undertaken (field level traceability with soil analysis). In order to protect soils from metallic element traces, a maximum quantity of material spreading is defined and the soil is preliminary analysed for metallic element traces (in order to avoid exceeding a defined level) Norms of subclass B1 are less restrictive than subclass B2 due to the lower concentration in metallic element traces and in organic compound traces of certain material (such as waste from food-processing industry, green waste compost, decarbonation sludge, etc), and due to criteria that must be followed within the Water Code on sustainable nitrate management in agriculture. Therefore, preliminary soil analyses are not needed for subclass B1, which simplifies the use of these materials on or in agricultural soils. .
BG	No data	No data	No data
CY	No data	No data	No data
CZ	**PRODUCT**	Act on fertilisers 156/1998 Sb. by the Public	Compost has only to be registered for this group and regular inspections/controls of samples are conducted done by the Control and Test Institute for Agriculture which is the Central

	Compost : PRODUCT or WASTE	Legal basis or standard	Main criteria for compost ceasing to be waste and/or placing on the market and use of compost
		Ministry of Agriculture ČSN 46 5735 Průmyslové komposty Czech Compost Standard defined in the CZ fertiliser law	Institute for Supervising and Testing in Agriculture.
	PRODUCT	Bio-waste Ordinance (In preparation)	All 3 Classes foreseen in the new draft Compost Ordinance are defined as end-of-waste criteria and follow the approach adopted for compost.
DE	WASTE	Fertiliser Ordinance (26. November 2003) Closed Loop Management and Waste Act (KrW-/AbfG); Bio-waste Ordinance (BioAbfV, 1998)	Compost also from source separated organic waste is seen as WASTE due to its waste properties and its potential to pose negative impacts to the environment. (risk of contamination) • Positive list for input materials • Sanitary rules • Limit value for heavy metals • Requirements for environmentally sound application • Soil investigation • Official control and certification by the competent authority • Documented evidence of approved utilisation All classes and types of compost, which are produced from defined source materials under the Bio-waste Ordinance remain WASTE
	WASTE-product (!)	RAL Gütesicherung RALGZ 251	When participating in a voluntary QA scheme relaxations are applied with respect to the regular control and approval protocols under the waste regime although, legally spoken, compost remains waste. The relaxations are: • No soil investigation • No official control of application by the waste authority • No documented evidence of approved utilisation In principle all classes and types of compost, which are

	Compost : PRODUCT or WASTE	Legal basis or standard	Main criteria for compost ceasing to be waste and/or placing on the market and use of compost
			produced from defined source materials under the Bio-waste Ordinance remain WASTE, but in practice, if certified under QAS of the RALGZ 251 compost can be marketed and used quasi like a PRODUCT.
DK	**WASTE**	Stat. Order 1650 of 13.12.06 on the use of waste (and sludge) for agriculture	The use of compost based on waste is under strict regulation (maximum of 30 kg P/year/ha etc. and the concentration of heavy metals in the soil were applied must not exceed certain levels. For this reason the authorities want to know exactly where the compost ends up which is only possible if handled as waste and not as a product (for free distribution). Compost from garden waste is not formally regarded as a product but is treated according to the general waste regulation for which the municipalities are responsible.
EE	**WASTE**	Environmental Ministry regulations 2002.30.12 nr. 78 and in Environmental Ministry regulation 2002.01.01 nr. 269.	Heavy metal limits in compost (sludge compost) No specific regulation on compost from bio-waste and green waste
ES	**PRODUCT**	Real Decree 506/2013 on Fertilisers Products	• Positive list of input materials (Annex IV) • Traceability (Art. 16): declaration of raw materials, description of production processes, declaration of conformity to all legal requirements • Minimum criteria for fertilizer products to be used on agriculture or gardening (Annex I): raw materials, how it shall be obtained, minimum nutrient contents and other requirements, parameters to be included on the label. • Quality criteria for final compost (Annex V): heavy metals content, nitrogen %, water content, Size particle, maximum microorganism content, limitations of use. • Third party verification or certification depending on the regions
FI	**PRODUCT**	Jätelaki (Waste Act) Fertiliser Product Act 539/2006	WASTE status changes to PRODUCT if compost fulfils the criteria of fertiliser regulation and is spread to land or mixed into substrate. No external approval or inspection scheme. Samples can be

	Compost : PRODUCT or WASTE	Legal basis or standard	Main criteria for compost ceasing to be waste and/or placing on the market and use of compost
		Decree of the Ministry of Agriculture and Forestry on Fertiliser Products 12/07	taken by compost producer. The fertiliser product must be produced in an approved establishment.
FR	**PRODUCT**	NF U44-051 Standard	Mixed waste compost – no positive list 4 Product types • "Organic soil improvers - Organic amendments and growing media" • "Organic soil improvers - Compost containing substances essential to agriculture, stemming from water treatment (sludge compost)" • "Organic amendments with fertiliser" • "growing media" Further following quality criteria: • Limit values for: trace metal concentrations and loads (g/ha*y), impurities, pathogens, organic micro-pollutants • Labelling requirements There is no regular external approval or inspection scheme. Samples can be taken by compost producer. However, there exists a legal inspection by the competent authority based on the Industrial Emission Directive procedure which in FR is applied to composting facilities. Compost which is not produced according to the standard is WASTE and has to follow a spreading plan and may apply for a temporary product authorisation
GR	**PRODUCT**	Common Ministerial Decision 114218, 1016/B/17- 11-97. Fertiliser law (Law 2326/27-6-1995, regulating the types of licenses for selling fertilisers).	Compost is considered as product and may be sold, provided it complies with the restrictions of the framework of Specifications and General Programs for Solid Waste Management. No sampling protocol and analysis obligations/ organisations are defined. Compost produced from materials of agricultural origin (olive-mill press cake, fruit stones, tree trimmings, manure etc) are considered products and sold under the fertilisers law
HU	**PRODUCT**	36/2006 (V.18.) Statutory rule about licensing, storing,	Compost are in waste status as long as they are not licensed under the Statutory rule Nr. 36/2006 (V.18.) which defines criteria for waste to be recognised as product.. Criteria:

	Compost : PRODUCT or WASTE	Legal basis or standard	Main criteria for compost ceasing to be waste and/or placing on the market and use of compost
		marketing and application of fertiliser products	• Positive lists of input materials, • External quality approval by acknowledged laboratories, • Physical, chemical and biological quality parameter for final compost.
IE	**PRODUCT**	EPA Waste license or Local Authority waste permit	Product status is based on site specific waste licence or waste permit; compliance with all operational and product requirements laid down in the consent document must be shown by producer. There is currently no legal standard or quality protocol in Ireland which defines when waste becomes a product.
IT	**PRODUCT**	L. 748/84 (law on fertilisers); D.M. 05/02/98 (Technical Regulation on simplified authorization procedures for waste recovery)	Criteria for product status are based on National Law on Fertilisers, which comprises: • Qualitative input list (source segregated organic waste • Quality parameters for final compost • Criteria for product labelling Compost from MBT/mixed waste composting plants may still be used under the old Decree DPR 915/82 - DCI 27/7/84 as WASTE for restricted applications (brown fields, landfill reclamation etc.).
LT	**PRODUCT**	Decree of the Ministry for Environment (D1-57/Jan 2007)	According to environmental requirements for composting of bio-waste, composting plants must provide a certificate of conformity. • Compost sampling is done by the producer • No external approval or plant inspection
LU	**PRODUCT**	Waste licence	The Product Status is achieved only when the statutory Quality Assurance Scheme is fulfilled. EoW criteria are: • Positive list for input materials • Sanitary requirements (Time/temperature profile and indicator pathogens) • Limit value for heavy metals • Requirements for environmentally sound application

	Compost : PRODUCT or WASTE	Legal basis or standard	Main criteria for compost ceasing to be waste and/or placing on the market and use of compost
			• Labelling requirements • Third party certification
LV	**PRODUCT**	Licensing as organic fertiliser (Cabinet Regulation No. 530 " Regulations on identification, quality, conformity and sale of fertilisers" 25.06.2006)	The product status is achieved only when it is registered and tested by certificated laboratory. EoW criteria are: • Sanitary parameters • Limit value for contaminant
MT	**WASTE**	---	NO provisions for compost
NL	**PRODUCT**	Fertiliser act (2008)	• key criteria Records and traceability of the composting process by third party certification Sanitary requirements. Animal manure cannot be used as raw material heavy metal limits declaration & labelling
PL	**WASTE**	Fertiliser law	Ministerial Approval by Min. of Agriculture and Rural Development Criteria: • Limit values for heavy metals (3 classes; also coarse and fine compost) • Test on pathogens • No external verification or certification
PT	**PRODUCT**	NP 1048 – Standard for fertilisers Portaria 672002 pg. 436	Compost is classified as organic soil amendment *"Correctivo organico"*
RO	**---**	---	NO provisions for compost
SE	**WASTE**	Private QAS and SPRC 152 (compost standard)	The compost standard is managed by the Swedish Standardisation Institute
SI	**PRODUCT**	Decree on the	If compost meets the requirements of this Decree, compost is

	Compost : PRODUCT or WASTE	Legal basis or standard	Main criteria for compost ceasing to be waste and/or placing on the market and use of compost
		treatment of biodegradable waste (Official Gazette of the Republic of Slovenia, no. 62/08)	a PRODUCT. If limit values are not met the compost can be used as WASTE. Provided risk assessment is carried out by an accredited laboratory. Criteria: Limit values for heavy metals (3 classes) and AOX, PCBs Maximum levels for glass, plastics, metals Compost sampling is done by the producer
SK	**PRODUCT**	Act No. 223/2001 Col. on waste as amended Slovak technical standard (STS) 46 57 35 Industry compost Act No. 136/2000 Col. on fertilisers Act No. 264/1999 Col. about technical requests for products Regulation of the Government No. 400/1999 Col. which lays down details about technically requirements for products	After bio-waste has gone through recovering process it is considered as compost, but such product cannot be marketed Compost may be marketed in case it is certified by an authorised person according to Act No. 264/1999 Col. Key criteria for the PRODUCT status: • Quality parameter for final compost – STS 46 57 35 • Process parameter (sanitisation) – STS 46 57 35§ • Quality approval by acknowledged laboratory or quality assurance organisation – Act No. 264/1999 Col.
UK	**WASTE**	Waste Management Licensing Regulations Animal By-Products Regulations	England, Wales, Scotland and Northern Ireland: Compost must be sold/supplied in accordance with the Waste Management Licensing Regulation rules for storing and spreading of compost on land (these rules apply whether or not the compost is derived from any animal by-products). There are not any quality criteria / classes but in the application form and evidence (test results for the waste) sent to the regulator, 'agricultural benefit' or 'ecological improvement' must be justified. The regulator makes an evaluation taking account of the characteristics of the soil / land that is intended to receive the waste, the intended application rate and any other relevant issues. Compost derived in whole or in part from animal by-products must be placed on the market and used in accordance with the animal by-products regulations.
	PRODUCT	BSI PAS 100:2005 BSI PAS 100:2005 + Quality Compost Protocol	Scotland: requires certification to PAS 100 (or an equivalent standard), that the compost has certainty of market, is used without further recovery, is not be subjected to a disposal activity and is not be mixed with other wastes, materials, compost, products or additives. Northern Ireland: similar position as Scotland's. England & Wales: both, the Standard and the Protocol have to be fulfilled to sell/supply/use "Quality Compost" as a

	Compost : PRODUCT or WASTE	Legal basis or standard	Main criteria for compost ceasing to be waste and/or placing on the market and use of compost
			PRODUCT. Key criteria: • Positive list of allowed input types and source types • QM system including HACCP assessment; standard process including hygienisation • Full documentation and record keeping • Contract of supply per consignment • External quality approval • Soil testing on key parameters • Records of compost spreading by land manager who receives the compost (agriculture and land based horticulture • N.B.: In each country of the UK, if compost 'product' is derived in whole, or in part from animal by-products, placed on the market, stored, used and recorded as required by the Animal By-Products Regulations.

Other diverging provisions as regard standards on product quality and sanitary rules are available in Annexes 4 and 5 of the JRC report. The following tables list heavy metals and organic pollutant limit values for compost and digestate in various Member States and Switzerland. The information was collected in the ORBIT/CEN study of 2008 and more recently during the stakeholder consultation carried out by JRC Sevilla on the preparation of EU EoW for biodegradable Waste.

Tables 68: Heavy metals and organic contaminant limits in Member States compost and digestate standards

Country	Regulation	Type of standard	Cd	Crtot	CrVI	Cu	Hg	Ni	Pb	Zn	As
			mg/kg d.m.								
AT	Compost Ord.:Class A+ (organic farming)	Statutory Ordinance	0.7	70	-	70	0.4	25	45	200	-
	Compost Ord.:Class A (agriculture; hobby gardening)		1	70	-	150	0,7	60	120	500	-
	Compost Ord.: Class B limit value (landscaping; reclam.) (guide value)*		3	250	-	500 (400)	3	100	200	1,800 (1,200)	-
BE	Royal Decree, 07.01.1998, case by case authorisation, Compost	Statutory decree	2	100	-	150	1	50	150	400	20
	Royal Decree, 07.01.1998, case by case authorisation, **DIGESTATE**	Statutory decree	6	500	-	600	5	100	500	2000	150
BG	No regulation	-	-	-	-	-	-	-	-	-	-
CY	No regulation	-	-	-	-	-	-	-	-	-	-
CZ	Use for agricultural land (Group one)	Statutory	2	100	-	100	1	50	100	300	10
	Landscaping, reclamation (draft Bio-waste Ordinance) (group two)	Statutory Class 1	2	100	-	170	1	65	200	500	10
		Class 2	3	250	-	400	1.5	100	300	1200	20
		Class 3	4	300	-	500	2	120	400	1500	30
	Fertilizer law 156/1998, ordinance 474/2000 (amended)	**DIGESTATE** with dry matter > 13%	2	100		150	1	50	100	600	20
	Fertilizer law 156/1998, ordinance 474/2000 (amended)	**DIGESTATE** with dry matter < 13%	2	100		250	1	50	100	1200	20
DE	Quality assurance RAL GZ - compost / digestate products	Voluntary QAS	1.5	100	-	100	1	50	150	400	-
	Bio waste Ordinance	Statutory decree (Class I)	1	70	-	70	0.7	35	100	300	-
		(Class II)	1.5	100	-	100	1	50	150	400	-

Country	Regulation	Type of standard	Cd	Crtot	CrVI	Cu	Hg	Ni	Pb	Zn	As
			mg/kg d.m.								
DK	Statutory Order Nr.1650; Compost after 13 Dec. 2006	Statutory decree	0.8	-	-	1,000	0.8	30	120/60 for priv. gardens	4,000	25
EE	Env. Ministry Re. (2002.30.12; m° 87) Sludge regulation	Statutory	-	1000	-	1000	16	300	750	2500	-
ES	Real decree 506/2013 on fertilisers										
	Class A	Statutory	0.7	70	0	70	0.4	25	45	200	-
	Class B		2	250	0	300	1.5	90	150	500	-
	Class C		3	300	0	400	2.5	100	200	1000	-
FI	Decree of the Ministry of Agriculture and Forestry on Fertiliser Products 12/07	Statutory decree	1.5	300	-	600	1	100	100	1,500	25
FR	NF U44-051	standard	3	120		300	2	60	180	600	
GR	KYA 114218, Hellenic Government Gazette, 1016/B/17- 11-97 [Specifications framework and general programmes for solid waste management]	Statutory decree	10	510	10	500	5	200	500	2,000	15
HU	Statutory rule 36/2006 (V.18)	Statutory Co: 50; Se: 5	2	100	-	100	1	50	100	--	10
IE	Licensing/permitting of treatment plants by competent authority stabilised MBT output or compost not meeting class I or II	Statutory	5	600	-	600	5	150	500	1500	-
	(Compost – Class I)	Statutory	0.7	100	-	100	0.5	50	100	200	-
	(Compost – Class II)	Statutory	1.5	150	-	150	1	75	150	400	-
IT	Law on fertilisers (L 748/84; and: 03/98 and 217/06) for BWC/GC/SSC	Statutory decree	1.5	-	0.5	230	1.5	100	140	500	-
Luxembourg	Licensing for plants		1.5	100	-	100	1	50	150	400	-
LT	Regulation on sewage sludge Categ. I (LAND 20/2005)	Statutory	1.5	140		75	1	50	140	300	-

Country	Regulation	Type of standard	Cd	Crtot	CrVI	Cu	Hg	Ni	Pb	Zn	As
			mg/kg d.m.								
LV	Regulation on licensing of waste treatment plants (n° 413/23.5.2006) – no specific compost regulation	Statutory =threshold between waste/product	3			600	2	100	150	1,500	50
Netherlands	Amended National Fertiliser Act from 2008	Statutory	1	50		90	0.3	20	100	290	15
PL	Organic fertilisers	Statutory	3	100		400	2	30	100	1500	-
PT	Standard for compost is in preparation	-	-	-	-	-	-	-	-	-	-
Sweden	Guideline values of QAS	Voluntary	1	100	-	100	1	50	100	300	
	SPCR 152 Guideline values	Voluntary	1	100	-	600	1	50	100	800	-
	SPCR 120 Guideline values **(DIGESTATE)**	Voluntary	1	100	-	600	1	50	100	800	-
SI	Decree on the treatment of biodegradable waste (Official Gazette of the Republic of Slovenia, no. 62/08)	Statutory: 1st class*	0.7	80	-	100	0.5	50	80	200	-
		Statutory: 2nd class*	1.5	200	-	300	1.5	75	250	1200	-
		Statutory: stabilized biodegradable waste*	7	500	-	800	7	350	500	2500	-
		* normalised to an organic matter content of 30%									
SK	Industrial Standard STN 46 5735 Cl. 1	Voluntary (Mo: 5)	2	100		100	1	50	100	300	10
	Cl. 2	Voluntary(Mo: 20)	4	300		400	1.5	70	300	600	20
UK	UKROFS fertil.org.farming, 'Composted household waste'	Statutory (EC Reg. 889/2008)	0.7	70	0	70	0.4	25	45	200	-
	Standard: PAS 100	Voluntary	1.5	100	-	200	1	50	200	400	-
	Standard: PAS 110 **(DIGESTATE)**	Voluntary	1.5	100	-	200	1	50	200	400	-

Country	Regulation	Type of standard	Cd	Crtot	CrVI	Cu	Hg	Ni	Pb	Zn	As
			mg/kg d.m.								
EU ECO Label	COM Decision (EC) n° 64/2007 eco-label to growing media COM Decision (EC) n° 799/2006 eco-label to soil improvers	Voluntary [Mo: 2; As: 10; Se: 1.5; F: 200 [only if materials of industrial processes are included]	1	100	-	100	1	50	100	300	10
EU Regulation on organic agriculture	EC Reg. n° 889/2008. Compliance with limits required for compost from source separated bio-waste only	Statutory	0.7	70	-	70	0.4	25	45	200	-

	AT	BE (Fl)	BE (Wal; digestate)	DE	DK	FR (compost)	LU	SI	CH
PAH (mg/kg dm)	**6** (sum for 6 congeners **)	Individual limits for 10 congeners	**5** (PAH_{16})		**3** (sum for 11 congeners***)	Individual limits for 3 congeners	**10*** (PAH_{16})	**3**	**4*** (PAH_{16})
PCB (mg/kg dm)	**0.2** (PCB_6)	**0.8** (PCB_7)	**0.15** (PCB_7)	****	**0.08*** (PCB_7)	**0.8** (PCB_7; only for sewage sludge compost)	**0.1*** (PCB_6)	**0.4** (1st class) **1** (2nd class) (PCB_6)	
PCDD/F (ng I-TEQ /kg dm)	**20**		**100**	****			**20***		**20***
PFC (mg/kg dm)	**0.1**			**0.1**					
AOX (mg/kg dm)	**500**		**250**						
LAS (mg/kg dm)			**1500***		**1300**				
NPE (mg/kg dm)			**25***		**10**				
DEHP (mg/kg dm)			**50***		**50**				

*= guidance value; **=sum of benzo[a]pyrene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[ghi]perylene, fluoranthene and indeno[1,2,3-cd]pyrene; ***=sum of acenaphthene, phenanthrene, fluorene, fluoranthene, pyrene, benzo[b]fluoranthene, benzo[j]fluoranthene, benzo[k]fluoranthene, benzo[a]pyrene, benzo[ghi]perylene and indeno[1,2,3-cd]pyrene; **** Maximum sum of PCDD/F and dl-PCB: 30 ng WHO-TEQ/kg dm, in some cases additional restrictions for PCDD/F only of maximum 5 ng WHO-TEQ/kg dm; PAH_{16}= sum of US EPA 16 priority listed polycyclic aromatic hydrocarbons; PCB_6= sum of PCBs 28, 52, 101, 138, 153 and 180; PCB_7= sum of PCBs 28, 52, 101, 118, 138, 153 and 180; PCDD/F= sum of 17 polychlorinated dibenzo-p-dioxins/furans expressed in International Toxicity Equivalents; PFC= perfluorinated compounds (sum of PFOS and PFOA); AOX= adsorbable organic halogens; LAS linear alkylbenzene sulphonates, NPE= nonylphenol and –ethoxylates; DEHP= di(2-ethylhexyl)phthalates

As mentioned on page 140, PAHs is the only substance that may occur significantly in compost and digestate according to the survey conducted by JRC Sevilla if only source segregated materials are authorised. The future Commission proposal will therefore propose a limit of 6 mg/kg dry matter for PAH_{16}.

3. GROWING MEDIA

In relation to horticultural peat, legislation in this area is at a national level and there are significant variations across Member States as to the contents of horticultural peat products and labelling requirements.

The divergent regulations across the EU pose challenges for producers exporting to other Member States and can amount to barriers to trade as producers must fulfil all national regulations in the Member States to which they export or use mutual recognition. A further issue is that revision of national legislation on growing media forces producers to regularly change their packaging or labelling accordingly (*See* Annex II for examples). The following table gives an overview of the varying legislative standards on growing media across the EU.

Table 69: National barriers to trade in growing media within the EU

FR	GM are included within the French fertilisers regulation. General definitions and market access rules are given by the Code Rural (Art L 255-1 to L255-11), law implemented in 1979. Regular way to access market is a specific authorization, so called "homologation", but there are some exemptions, like by example the conformity to an obligatory standard. The full set of obligatory standards covers all large families of product (fertilizers, soil improver, GM…). French Decree n°80-478 (June 1980) specifies rules in term of labelling and declarations Today, there is not any GM marketed with specific authorization. All GM are marketed through conformity to an obligatory standard (NF U 44-551, and its amendments). NF U 44-551 includes specificities for raw materials, threshold values for some heavy metals and microbiological parameters, specification for quality controls, specifications for labelling. France uses CEN TC 223 standards	Parameters to declare for labelling of GM: Type, composition and declaration of major constituents Minor constituents (e.g. fertilizers, additives). Those constituents should have the authorization to be mixed with GM. Technical specificities: dry matter, pH, conductivity, water capacity + some specific characteristics depending of the type Quantity: volume and weight Company responsible for marketing Recommendations for uses.
SE	No particular legislation for fertilisers but safety requirements are detailed in chemical legislation.	No apparent barrier caused by the Swedish legislation. However Swedish producers mentioned having problems to trade with other Member States as they have to adapt to all national legislations.
LT	Lithuania standard for GM, LST 1957-2006	Characteristics of peat substrate, labelling criteria for packaging and physical and chemical properties of peat products are defined by the Lithuanian standard LST 1957:2006 (which is based on the European standards EN 12579, EN 12580, EN 13037, EN 13038, EN 13039, EN 13040, EN 13041).
DE	German Fertilizer Ordinance (FO) dated 05.12.2012: includes regulations for fertilisers, soil improvers, growing media and soil additives Full German title: Full quotation: „Düngemittelverordnung vom 5. Dezember 2012 (BGBl. I S. 2482)"	Parameters to declare for general labelling of GM: General requirements: Must not contain pathogens: -no Salmonella in 50 g sample, - no hazardous organisms acc. to Directive

		2000/29/EU, - no heat-resistant viruses i.e. TMV, - no fungal plant pathogens with permanent reproduction organs (i.e. Sclerotinia, Rhizoctonia, Plasmodiophora barassicae) - GM must be labelled as GM; - Only bulky constituents listed in the positive list of the FO may be used; - composition and labelling of the bulky constituents; - if necessary labelling of information on transport and proper storage and use; - Name or company and address of the person responsible for marketing in Germany; - Volume in liters or cubic meters (EN 12580); - pH (CaCl2); - salinity (g KCl/liter); - Amounts of As, B, Cd, Co, Cr, Cu, Hg, Ni, Pb, Tl, Zn if certain threshold values are exceeded. Parameters to declare for special labelling of growing media: - Plant available (soluble) nutrients; for N, P2O5, K2O and Mg in mg/l (noting the method), organic matter if the amount exceeds 5 % in dry matter
IT	Legislative Decree No. 75 of 29 April 2010 It includes growing media, liming materials, soil improvers, fertilizers, additives to fertilizer, soil and plant	General criteria: Only organic and mineral components listed in the regulation can be used in growing media; organic materials must respect limits regarding chemical and biological parameters and heavy metals content. Two types of growing media are stated: basic growing media and mixed growing media, as follows: **Basic GM:** **Evaluation criteria. Other required characteristics:** pH (in H_2O) between 3.5 and 7.5 Electrical conductivity: max 0.70 dS/m Organic C min 8% s.s. Dry bulk density max 450 kg/m^3 **Mixed GM:** **Evaluation criteria. Other required characteristics:** pH (in H_2O) between 4.5 and 8.5 Electrical conductivity: max 1.0 dS/m

		Organic C min 4% s.s Dry bulk density max 950 kg/m^3 ***Obligatory labelling:*** Type, Name or company and address of the person responsible for marketing in Italy, quantity: volume in liters ***Parameters to declare:*** pH (in H_2O – IT method) Electrical conductivity (dS/m) Dry bulk density (kg/m^3) Total porosity (% of volume) ***Optional labelling of growing media:*** Recommended use. When declared "for acidophilic species" pH must be between 3.5 and 5.0. Organic C Fertiliser quantity (N: P_2O_5: K_2O – kg/m^3)
BE	Arrêté royal from 28 January 2013	Specific labelling: parameters shall be declared: pH, organic matter, conductivity, dry matter, fertilisers used, composition of substrate
PL	Act on Fertilizers and Fertilization from 10 July 10th, 2007. Regulation of the Minister of Agriculture and Rural Development of 21 December 2009 amending the Act on fertilizers and fertilization	In Poland, manufactures have to require an authorization to the ministry of agriculture for each substrate placed on the market. Every time the composition of the substrate is changed, a new request needs to be introduced. Application for permission takes between 1 year and several years. However, potting soil producers that import substrates in Poland do not need permission from the Polish ministry. Specific labeling: - Full name of product; - pH, salinity, fertiliser content, information about the materials used in the composition of the products. - recommended dose rates an storage information; - Expiry date; - Volume in kg (net weight); - A number of the permission from ministry of agriculture
FI	Decree of the Ministry of Agriculture and Forestry on Fertiliser Products 24/2011 and Decree of the Ministry of Agriculture and Forestry 11/2012	*The main difference between the Finnish law and the legislation of the other EU Member States lays in the level of concentration of heavy metal required that can be found in fertilisers* However the Finnish authorities contacted in February 2014 have confirmed that the analysis results of growing media done by Finnish Food Safety Authority Evira in 2012 and 2013 have not led to withdrawals of GM from the market. Conversely, GM producers mentioned that

		import to Finland is extremely limited.

As regards limit values for contaminants, the table below summarizes the current requirements that applied in various Member States. Only two Member States reported having used EN 13650 for the determination of heavy metals in growing media. The other used national or laboratory methods which makes the comparison of limit values difficult and unreliable and generates costs to verify compliance of products.

Table 70: Heavy metal limits for growing media in different EU Member States

Heavy Metal (mg/kg dry matter)	EU COM proposal	Germany (Fertilizer Ordinance 05.12.2012)	France (FR standard)	Belgium (Belgian Regulation)	Italy[215] (Italian Reg.)	Latvia (Min. of Agr.)	Netherlands		Sweden (no legislation for GM)	Spain [216](legislation)	
							National Comp. standard	Nat. org. products standard		Cat. A	Cat. B
Cd	2,5	1,5 (2,5)	2	1,5	1,5	2	1	0,8 mg/kg OM	X	0,7	2
Cr total	150	(Cr^{VI}) 2,0	150	X	(Cr^{VI}) 0,5	100	50	50 mg/kg OM	X	(Cr) 70	(Cr) 250
Cu	230	X	100	50	230	100	90	50 mg/kg OM	X	70	300
Hg	1	1	1	1	1,5	1	0,3	0,5 mg/kg OM	X	0,4	1,5
Ni	90	80	50	20	100	50	20	20 mg/kg OM	X	50	90
Pb	150	150	100	50	140	100	100	67 mg/kg OM	X	45	150
Zn	500	X	300	200	500	300	290	200 mg/kg OM	X	200	500
As	X	40	X	X	X	20	15	10 mg/kg OM	X	X	X

The use of national standards may undermine the comparison. The limits values proposed by the Commission would apply when the extraction method EN-13651 is used. This method is validated for its practical value and proves to represent the cumulative leaching of contaminants in one year growing season in a worst case scenario. In practical conditions, leaching results will be considerably lower

[215] In Italy, limit values are valid only for organic GM constituents not for commercialised GM
[216] In Spain, GM exceeding the limit values set for category B cannot be used for the growing of edible crops

4. PLANT BIOSTIMULANTS

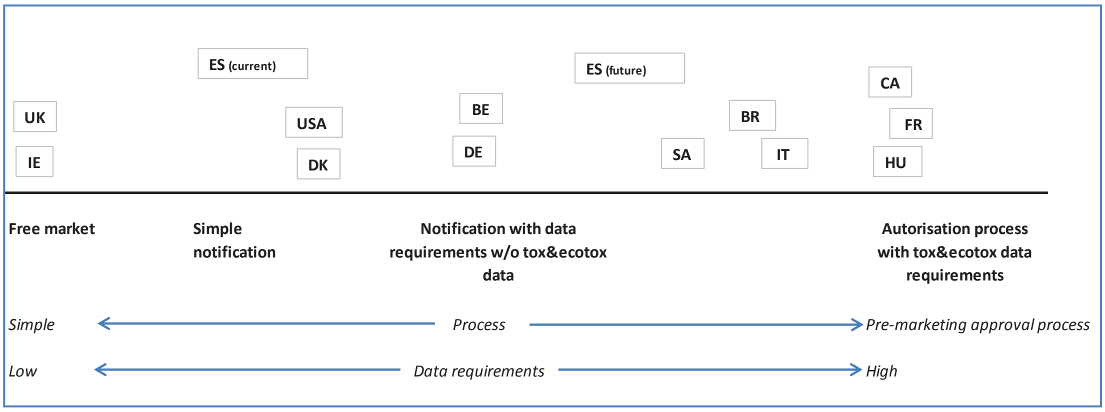
Safety requirements

Only one Member State set limit values for contaminants in plant biostimulants. As mentioned in Annex VI, plant biostimulants are generally added in small quantities to fertilisers to which limit values for contaminants will apply. It is therefore not found necessary to propose limit values for heavy metals in plant biostimulants.

Rules for the placing on the market

According to the analysis of national legislation by Arcadia[217], plant biostimulants can be placed on the market on the basis of variable schemes ranking from simple notification to public authorities to full registration of commercial products. The consultant proposed the following figure summarizing the different registration procedures enforced by the Member States and third countries compared to their various levels of stringency.

Figure 31: EU and third country regulatory processes for placing of PB (and AFA) on the market



Source: Arcadia International (SA: South Africa, BR: Brazil, CA: Canada)

Some Member States do not regulate plant biotimulants or regulate them[218] under other regulatory framework. For example, in The Netherlands, a product may be marketed as a fertiliser only if it satisfies the following general fertiliser requirements: '*the fertiliser provides food for plants or parts of plants in the form of primary or secondary nutrients or micronutrients or improves soil properties by providing organic matter or by maintaining or lowering the acidity in the soil*'. All products which fail to meet this general criterion (such as plant biostimulants) are not subject to national fertiliser regulations but fall, when applied onto the soil, under the Soil Protection Act."

[217] A legal framework for plant biostimulants and agronomic fertiliser additives in the EU. Contract No255/PP/ENT/IMA/13/1112420. March 2014

[218] In accordance with the information provided in Table 67, 14 Member States regulate the placing on the market of such materials

The following table summarizes the registration procedures and their related costs for a plant biostimulant based on seaweed extract in selected EU Member States and third countries.

Table 71: Examples of registration process and data requirements for placing seaweed extract on the market in the EU and in third countries

	EU Member States							Third countries			
Process	BE	DE	DK	ES[219]	FR	IT	HU	BR	CA	SA	USA
Simple notification			Yes	Yes							
Notification with provisions of data	Yes	Yes								Yes	Yes
Data assessment/review	Yes	Yes	No	No	Yes		Yes	Yes	Yes	Yes	
Registration					Yes		Yes	Yes	Yes		
Time for authorisation	<1year	<1year	Case by case	6 months	>1year	>1year	>1year	>1year	>1year	9 months	9 months
Data requirements											
Characterisation & identification	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Analytical method	No	No	No	No	No	Yes	Yes	Yes	Yes	No	No
Manufacturing process	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	No	No
Toxicity data	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No
Ecotoxicity data	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No
Environmental fate data	No	No	No	No	Yes	Yes	Yes	Yes	Yes	No	No
Efficacy data	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Labelling requirements	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fees (in €)											
	1,500	400	400	350	6,000	3,000	340				
Average costs of compiling data for the registration of new products (in €/dossier)											
For applicant[220]	<10,000	<10,000	<2,000	<2,000	>30,000	>30,000	>20,000	>15,000	>15,000	<10,000	<10,000

[219] Current situation. See figure 32
[220] Initial costs only. Cost for providing additional data not included

ANNEX XII

Summary of various stakeholder consultations carried from 2010 to 2015.

1. RESULTS OF THE EX-POST EVALUATION OF REGULATION (EC) NO 2003/2003 AND THE APPLICABILITY OF MUTUAL RECOGNITION FOR NATIONAL FERTILISERS CARRIED OUT IN 2010

Ex-post evaluation of existing legislation is used increasingly by the Commission to assure smart regulation. It consists of an evaluation of the policy framework already in place, its impacts and its efficiency. Any proposals for significant amendments should then be based on the outcomes of the ex-post evaluation. The Commission had signed a contract with an outside consultant to conduct such an ex-post evaluation, who had consulted widely with all relevant stakeholders.

From this evaluation it emerged that the Fertilisers Regulation had been effective in meeting one of its main objectives, namely to simplify and harmonise the regulatory framework in relation to inorganic fertilisers. However, the Regulation appears less effective in meeting two other objectives such as the protection of the environment and the promotion of innovation.

The absence of maximum limits for contaminants is perceived to be a clear limitation of the Regulation and an area where Member States would like to see specific harmonised provisions put in place. Regarding the effects on innovation, the implementation process of the Regulation appears to be slow and not in line with the innovation cycles of industry.

Possible explanations for the above problems include the following: the quality of technical files that are not always being properly prepared by applicants; a lack of resources in the Commission; the delays observed within the Fertilisers Working Group (FWG) that meets only twice a year; and the competence of the FWG, which is not necessarily the most appropriate body to assess technical files. Hence, under certain circumstances, procedures for inclusion of new EC fertiliser types can raise obstacles to innovation.

Another weakness identified in the study concerns the products currently not covered by the Regulation, such as organic fertilisers, growing media and others, for which the market appears to be very fragmented. There is an increasing demand by stakeholders across the board for a more extensive coverage of the fertiliser sector by an EU-wide Regulation.

Thus far, mutual recognition of national fertilisers is limited. Industry is either unaware of or very sceptical about its use, as are the great majority of Member State authorities. The position of almost all stakeholders is that it does not represent an appropriate mechanism to support the development of the Internal Market.

Authorities are concerned by their capacity to ensure the safety of products on national markets through controls of new products and their compliance to national environmental and public safety standards. Almost all authorities also consider that additional work will be created due to the cumbersome task of checking whether a fertiliser, for which mutual recognition is sought, is actually in compliance with the legislation in at least one of the other 26 Member States.

Industry is mainly concerned about unfair competition, in particular from businesses operating in countries where placing on the market or registration is subject to less stringent provisions. A few firms considered that the implementation of mutual recognition could provide a useful alternative to overcome some of the obstacles to the free movement of national fertilisers. Obstacles include the various registration procedures and possible tests required in the different Member States. The Mutual Recognition Regulation will continue to apply to fertilisers until a regulation covering all categories is adopted. It is thus important that a minimum common understanding of the MRR is established during that period.

Independently of the relevance of mutual recognition, there is an overwhelming support for developing an EU-wide regulation to achieve a more comprehensive harmonisation of the market for a broader range of fertilisers, beyond inorganic fertilisers. However, the simple extension of the Fertilisers Regulation is not supported by all stakeholders. Potential difficulties are foreseen in reaching an agreement on particular requirements, such as the presence of pathogens in organic fertilisers or local requirements to demonstrate the efficacy of some fertilisers' categories under different climatic and geological conditions. A separate regulation for each category stands as an alternative approach which the European Peat and Growing Media Association favours.

2. RESULTS OF THE FERTILISERS STUDY CARRIED OUT IN 2011

In 2011, the Commission mandated an outside contractor to analyse a range of policy options in view of the fundamental review of the current Fertilisers Regulation. The study last almost one year to which a broad range of stakeholders contributed.

Study section 1 - Introduction: Background, objectives, methodology

The consultant team carried out five main tasks:

- Review of existing national legislation or standards concerning fertilising products, which are falling inside or outside the scope of Regulation (EC) No 2003/2003.
- Assessment of the relationships and possible synergies in safety assessment with other relevant existing and forthcoming EU legislation.
- Assistance and advice to the Commission in establishing essential safety and – if considered necessary – agronomic efficacy requirements for all types of fertilising products.
- Assistance and advice to the Commission in detailing the formulation of policy options for a revised EU legislation, considering more flexible procedures for the approval of fertilising products and reduced administrative burdens for companies and authorities.
- Evaluating the defined policy options regarding their effectiveness, feasibility and costs (for authorities and the manufacturing sector(s) including SMEs) based in particular on their economic, social and environmental impacts.

The analysis of the existing national regulatory frameworks revealed large differences between Member States. Moreover, national legislations are still in place for mineral fertilisers, which are within the scope of the current Regulation (EC) No 2003/2003.

As estimated by the consultants, further harmonisation efforts concern about 25% of the market value of the fertiliser sector, including mainly organic fertilisers and soil improvers.

In reaction to the presentation of the consultants, some Member States commented on some unintended consequences of the dual legislative systems of European and national legislations: companies wishing to export fertilisers to third countries often ask for national authorisations / registrations for fertilisers even though they are actually marketed as EC fertilisers, as the national authorisations / registrations cover limits for risk factors and hazards. Thus, limit values are an important topic to be discussed in respect to the harmonisation of the future EU Fertiliser Regulation.

The organic fertiliser sector stressed the importance of taking into account the product use in the context of safety requirements, while allowing enough flexibility in the combination of authorised ingredients.

Study section 2 - Safety and agronomic efficacy approach

The study highlighted that apart from a rather general requirement, the current Fertiliser Regulation does not include appropriate methodology to address risk and safety assessments for human health and the environment.

In the study, safety requirements referred to contaminants only (*e.g.* heavy metals, organic pollutants, or microbiological criteria), whereas the term risk assessment referred to all other risks (*e.g.* use conditions and background levels of contaminants in the environment). The term agronomic efficacy was defined as the property of a fertiliser to improve plant nutrition and/or to improve or maintain the physical, chemical, or biological conditions of the soil.

Limits for contaminants are associated in most national legislations with limits on permissible application rates, so as to cover the potential risks from these substances. Limit values apply often to specific groups of products.

Assessments of new products are considered on a case-by-case basis by Member States. Guidelines for the safety assessment of unknown products have been developed in some Member States only (*e.g.* FR, DE, DK). Moreover, agronomic efficacy criteria are applicable in some countries (*e.g.* FR, DE, IT, NL, ES).

The consultants reported that existing EU legislation addresses (at least partly) risk and safety issues of fertiliser materials (*e.g.* REACH, CLP, Plant Protection Products Regulation, Animal By-Products Directive, and Waste Framework Directive).

The consultants presented information on different regulatory systems in third countries:

Most third countries have defined a policy that encompasses all nutrient fertilising products, being mineral or organic. In most countries, compost is also included. Registration of individual products is an obligation in most countries, but in large countries this obligation applies at regional levels (*e.g.* state vs. federal in the U.S.);

Marketing regulations for fertilising products are linked to regulations related to the use of fertilisers, which aim at protecting users of products and the environment. Several countries have developed national plans related to the sustainable use of fertilisers (stewardship plans). In these countries, the way fertilisers are being used is the main concern of regulators;

In several countries, fertiliser regulations are linked to other pieces of legislation, especially chemicals legislations and water quality policies;

In most third countries, thresholds regarding the presence of heavy metals in commercial products as well as the maximum volumes of fertilisers that can be applied yearly in a given field are defined in the legislation;

When registration of individual products is required, safety and agronomic efficacy assessments must be carried out. Labelling is mandatory;

The European approach, based on defining type designations and standards, seems to be rather unique, as countries that have been studied are approaching marketing of fertiliser materials via individual product registration or notifications;

The study concluded that a first approach for regulating safety requirements is to set thresholds for contaminants. Limit values should serve as safeguard principle, but are not enough *per se,* and should be complemented by guidelines on application rates that could be developed at national or regional levels.

Member States suggested that limit values need to be set in such a way that they can be applied by both farmers and industry, while providing adequate protection. Compliance control by analytical means could only be done at the level of the product that is placed on the market.

The consultant and several Member States suggested the principle of splitting fertiliser products into known versus little known products for risks assessment arguing that some products were already risk assessed by Member States. Other Member States and industry representatives expressed concerns about how these distinctions would be applied in practice and therefore risk assessments should be performed for both new and old fertiliser products. For new products, risk assessments should preferably be carried out according to REACH requirements.

Several Member Sates stated that safety requirements should also cover guidelines on "end of waste" criteria for all types of organic waste that could be used in the manufacture of organic fertilisers. Without proper treatment, biological contaminants (*e.g.* nematodes) would remain in these products.

A few Member Stats insisted on the importance of having agronomic efficacy criteria (i.e. the proof that a product brings benefits to farmers) in the future Regulation while others estimated that agronomic efficacy issues that would require field trials should be dealt with by the market. However, minimal product quality criteria such as nutrient content levels should be defined in the future EU Regulation as a 'basic assurance' of efficacy as agricultural practices of farmers also influence the agronomic efficacy of fertilisers.

<u>Study section 3 - Policy options</u>

In 2011, seven different policy options had been developed in order to be compared in the framework of the forthcoming impact assessment.

Policy option 1: Status Quo – baseline scenario

The current Fertiliser Regulation is not modified. For the other categories of fertilisers and fertilising products, national rules and Regulation (EC) No 764/2008 on Mutual Recognition continue to apply. Other pieces of EU legislation such as the REACH Regulation, the Animal By-Products Directive, *etc*, continue to apply.

Policy option 2: Repeal of Regulation (EC) No 2003/2003

The current EU Regulation on fertilisers is repealed and the placing on the market of fertilisers exclusively relies on other relevant pieces of EU legislation: REACH, CLP Regulation, Waste Framework Directive, Animal By-Product Regulation, National legislations and Regulation (EC) 764/2008 on Mutual Recognition.

Policy option 3: Voluntary action by industry

Fertiliser manufacturers, importers and distributors agree to voluntarily establish quality procedures and standards for all fertilising products. All pieces of legislations as described in Option 1 continue to apply. Public authorities are consulted on the definition of the industry standards and they might carry out conformity controls.

Policy option 4: Extension of current approach: listing of fertiliser types

Detailed description of all technical aspects of each authorised type designation for the categories of fertilising products is included in an Annex to the future Regulation. The list will be adapted to technical progress. Maximum limit values for contaminants and specific technical requirements for additives are introduced in the legal text. A risk assessment procedure applies to "new Fertiliser Material type designation". EN standards are used for analytical methods to verify compliance with the type requirements.

Policy option 5: Listing of ingredients

Lists of ingredients and additives that are allowed for the manufacture of fertilising products are included in Annexes to the new Regulation. Limit values for contaminants and other specific technical details are described in the legal text. The lists of authorised ingredients and additives are regularly adapted to technical progress. A risk assessment procedure is applied to "new Fertilising Material ingredients". Further details for the various materials might be developed in EN standards.

Policy option 6: New Approach

The Regulation lays down essential requirements with regard to human and animal safety, as well as protection of the environment, and other criteria such as labelling, traceability, quality control, agronomic efficacy (if considered necessary). All further details are developed in EN standards. Manufacturers, importers and distributors are collectively responsible for ensuring that the products placed on the market are in conformity to the selected criteria. Conformity assessments are carried out by notified bodies. The essential requirements will not be modified without the agreement of the co-legislators.

Policy option 7: Combination of various options for different materials

Different policy options are applied to different categories of fertilisers (but only one policy approach per Fertilising Material category). Framework legislation links the different legal instruments and defines the FM categories. For the purpose of the impact assessment, one option has been selected for each Fertilising Material category, but other approaches may be considered as a result of an agreement between stakeholders and authorities.

Study section 4 – Assessment of the policy options

The assessment of the policy options was performed to address qualitative and quantitative impacts:

Identification – and where possible quantification - of the relevant economic, social and environmental impacts;

Contribution of the different policy options to the general and specific objectives (effectiveness);

Technical feasibility, political acceptance and time-scheduling of the policy options implementation;

Assessment of administrative costs for authorities and industry;

Overall cost-effectiveness assessment based on the addition of the scores of the options obtained for the parameters listed in the indents above.

The study concluded that the policy options 5 (listing of ingredients) and 6 (New Approach) scored best overall, followed closely by option 4. According to the consultants, the selection of the preferred policy option could not be made solely on the basis of the analysis but would ultimately be a political choice.

Options 1, 2 and 3 were clearly rejected by Member States and industry representatives. Several Member States favoured the New Approach arguing that the new system needed to be fast and flexible which was not possible with the current regulatory approach. Other Member States (mainly Mediterranean countries) expressed preference for the current approach and concerns about the role of CEN under the New Approach. CEN mainly represents industry and thus would be biased on issues regarding the protection of human health and the environment. Policy option 7 (option 5 under this report) was seen as being flexible with regard to the wide range of fertilising products that would be regulated in the future at EU level but more information about the procedures under the New Approach were required to help Member States to better understand their roles.

3. INFORMATION ABOUT THE RESULTS OF THE TECHNICAL WORKING GROUPS ESTABLISHED TO PREPARE THE REVISION OF THE FERTILISERS REGULATION

Following a suggestion from Germany, the Fertiliser Working Group agreed in April 2011 to set up several expert working groups in order to discuss a range of technical topics that will be relevant in the preparation of the revision of the fertiliser legislation.

The Commission set up the following 4 ad-hoc working groups:

1. WG 1: OVERALL STRUCTURE OF THE FUTURE PROPOSAL

In particular WG1 was tasked to:

1.1. develop a common set of definitions for all the categories of fertilising products and additives currently placed on the European market..

1.2. develop proposals on how the necessary safety requirements and relevant mechanisms / structures for their verification should be put into practice**.**

2. WG 2: NUTRIENT CONTENT, PRODUCT COMPOSITION, AND AGRONOMIC EFFICACY

WG 2 reflected on whether and how the revised Regulation should set criteria for nutrient content and agronomic efficacy of the various product categories, where relevant.

3. WG3: CONTAMINANTS, HYGIENE, AND OTHER RISKS

This working group examined the need for setting appropriate conditions with regard to the presence of contaminants (such as heavy metals or organic pollutants), pathogens, or other risk factors.

4. WG4: LABELLING, ENFORCEMENT AND CONTROL

WG 4 worked on a range of horizontal topics such as labelling requirements for each product category, monitoring and traceability by manufacturers and importers, particular obligations/ recommendations to Member States authorities concerning market surveillance of products.

The ad-hoc working groups were composed of experts from the Member States, industry, other stakeholders (such as CEN and one NGO) and the Commission. They were co-chaired by a representative of the Commission and a Member State expert. Information exchange were organised via specific CIRCA Groups for each WG. Working Groups met up to three times in the period January to December 2012. WG1 met four times.

In December 2012, the Commission presented the main outcomes of the work of the ad-hoc technical working groups during a meeting of the Fertilisers Working Group offering an opportunity for participants to comment. The text below summarizes the main outcomes of the discussions in the WG.

Concerning the definition of inorganic fertiliser the working group concluded that the proposed definition of inorganic fertiliser was overall supported (See glossary) and that, if a maximum limit of organic carbon (or matter) should at the end be defined, this should be set rather low to allow for the presence of trace quantities of organic materials whereas exempting additives as a point of principle.

As regards the minimum nutrient content for inorganic fertilisers the Working Group reported about the difficulty to find a compromise value to reconcile the views of those Member States (IT, ES, CY, PL) and industry, who supported a higher minimum content to guarantee efficacy to the professional users (e.g. farmers) with those Member States, who supported lower values to cover also specialty-products for plants (such as aquatic plants, orchids, cactus,…) which require only low nutrient amounts per application.

UK (supported by IE, AT, BE) expressed the concern that with a high minimum content, low-concentration fertilisers would be excluded from the market. Industry suggested to raise the proposed minimum content (namely for fluid fertilisers) without consequences as the users (professional or amateurs) can always dilute to satisfy plant needs. The Commission mentioned the possibility that an exemption from (somewhat higher) minimum nutrient contents could be foreseen for specific consumer products (i.e. for orchid), if Member States can confirm that there is a distinction between products for consumers and for professionals (i.e. orchid breeders).

As regards the forms of nutrients (N, P, K, secondary- and micro-nutrients) to be declared, the Commission noted an overall consensus based on the technical working group proposals.

The Commission presented some general principles as regards contaminants which were broadly supported by the Working Group:

- impracticability to regulate material flows (i.e. application rates of fertilisers) at EU level;
- limit values need to be defined for the different product categories based on their specific application rates. Higher application rates will trigger stricter limits.
- no need to require the declaration of all contaminants on the label at EU level – except possibly for Cu and Zn – while flexibility could be allowed for Member States to request labelling of contaminants in light of particular conditions such as relatively high background levels of certain contaminants to facilitate farmers' choice;
- as regards enforcement activities, the responsibilities of the various actors (industry, officials) would be clearly defined; obligations shall apply equally to manufacturers and importers; the appropriate monitoring frequencies for contaminants could be discussed in a so-called Administrative Co-ordination Group (ADCO) among market surveillance authorities and stakeholders (e.g. modulated depending on which input materials are used)

and relaxed after a while if analytical results show consistently that the limit values are not exceeded;

- possibility to allow Member State(s) – on the grounds of specific reasons - to grant upwards derogation from the general limit values for products which shall then be limited to be placed on the local or national market only unless other Member State(s) accept the product as well. When taking such action, Member States should provide quantitative information on the share of products that would be excluded from the market due to the fact that they cannot comply with the general limit values;

- possibility for Member States to introduce certain specific lower national limit values for cadmium in phosphate fertilisers. For other contaminants, derogation for lower limits can be requested by Member States in accordance with Art.114 of the Treaty on the Functioning of the European Union.

Copper, zinc and selenium are considered both, contaminants or plant nutrients (Cu and Zn) or as an additive with a human/animal health benefit (Se). The Working Group agreed that the rules for micro-nutrients should apply for Cu and Zn when they are intentionally added. When Cu and Zn are not intentionally added their concentration should not exceed limit values proposed by the EU End-of-waste criteria for biodegradable waste.

As regards the proposed maximum limit values for heavy metals in primary and secondary nutrient fertilisers, it was agreed that the limit for cadmium should be expressed in mg/kg P_20_5. Several Member States (PL, FR, PT, ES) said that the limit of 60 mg Cd/kg P_2O_5 for phosphate fertilisers containing more than 5% P_2O_5 is too stringent and should be raised up to 90 mg Cd/kg P_2O_5. The Commission mentioned the outcome of a recent EUROMED conference where a representative of the major phosphates producer in Tunisia had provided encouraging information on the perspective of decadmiation of phosphate fertilisers..

As regards the compulsory labelling of inorganic fertilisers, the Working Group agreed to the items as proposed by WG 4. The Commission replied to a question of industry that other indications might be voluntarily provided by the manufacturer/importer/distributor, such as the fact that the product is compliant with the organic farming rules (if it fulfils the provisions of the appropriate Regulation).

The definition of organic fertiliser presented during the meeting gained support by a majority of Member States. ES remarked, however, that the proposed version is actually covering fertilisers made only out of microorganisms (e.g. from microbial biomass production), hence it proposed to specify that the organic materials should be of "animal or plant origin" instead of "biological origin". The ES opinion was adopted.

As regards the quality requirements for organic fertilisers the Working Group discussed mainly the need for setting a minimum organic matter content. ES supported by industry indicated that this parameter was not really justified as the main function of fertilisers is to provide nutrients. However, following the discussion ES indicated that it could accept to have a minimum value in a spirit of compromise, but it has to be lower that the corresponding limit for soil improvers. PT considered this parameter important and preferred 30% (instead of 20% as presented).

As regards the maximum limit values for non-nutrients metals, the Commission indicated that the proposed values are similar to those which are discussed in the context of the End-of-Waste criteria for the biodegradable waste. Upwards derogations could be necessary to address specific local situations for nickel (IT and FR in compost, DE in digestate) and for lead (UK in compost). IT (supported by PL, DE) explained that setting a limit for total chromium (Cr) does not make sense because it means the sum of Cr(III) plus Cr(VI).

Cr(III) is a micronutrient for humans and animals, it is not mobile in soil solution and it has a low coefficient of translocation from soil to plant (i.e. it is not dangerous in soil, and its presence is not a matter of concern). Cr(VI) is not a micronutrient, it is carcinogenic, it is mobile in soil solution and it has high coefficient of translocation from soil to plant (i.e. Cr(VI) compounds are the only possibly dangerous). For these reasons IT proposes a limit exclusively for Cr(VI) for all kind of fertilisers. Safety towards productions and environmental protection are guaranteed with fertilisers not containing detectable amounts of Cr(VI). The presence of Cr(VI) in organic materials means that those products are polluted. Moreover there is no correlation between the potential presence of Cr(VI) and total chromium. Cr(III) content is insignificant in relation to toxicity and therefore no limit value is necessary. This proposal reflects the Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production. Official method to determine Cr(VI) in organic-based fertilisers is already available in Italy (D.M. 08/05/2003, G.U. 21/05/2003 n. 116, Suppl. n. 8 of the Italian Republic), as well as a method for determination Cr(VI) in organic and organo-mineral substances is being validated by CEN (*EN ISO 17075:2007*). . Other Member States considered that due to the presence of organic matter Cr(VI) will always be reduced and only a Cr total determination made sense.

As regards the maximum limit values for organic contaminants, the Commission explained that it could be foreseen that they would apply only to relevant product categories. Application of the limit values could be made selective to products for which certain waste streams have been used as input materials or be limited to PCBs only (as marker substances). The frequency of monitoring could be reduced (or further verification waived) if producers can demonstrate that a significant number of representative samples are not exceeding the limit values proposed in the EoW criteria scheme over an initial period of time. The Working Group supported the proposed approach, as well as the one presented for maximum limit values for microorganisms.

As regards the compulsory labelling of organic fertilisers, the Working Group discussed the need to define a threshold above which the origin of the components used in the manufacture of the product should be mentioned. ES underlined that the origin of each ingredient should be labelled by using for example the EU Waste List codification. DE indicated that the Animal By-Products Regulation has shown that traceability should be implemented in a thorough way in order to limit the spread of animal disease, hence the importance of mentioning the animal origin above a certain threshold.

As regards the minimum quality requirement for organo-mineral fertilisers, IT pointed out that the minimum values for organic N in the IT legislation are 1 and 0.3 % for solid and fluid products, respectively. Two Member States sent other proposals after the meeting.

EL, BE and UK commented on the definition of liming materials. The UK requested the possibility to market silicate slags as liming materials, as otherwise about 100,000 tons/year will not have access to the market anymore. This was opposed by EL and BE - although BE indicated some flexibility for the future.

The minimum neutralising value presented (20) as well as the list of parameters to be declared obtained overall support of the Working Group. UK pointed out that a minimal NV of 15 had been proposed for sugar lime in the 7th ATP and should be used as the benchmark for the whole category. CEN clarified that the minimum NV of 15 was applicable for sugar factory lime suspensions, while the NV of 20 should apply to solid sugar factory lime.

Definition of "soil improvers": PT, BE and IT would favour the definition of two sub-categories, inorganic soil improvers (including liming materials and "acidifying products") and organic soil improvers. According to ES (supported by PT, BE, UK) the definition of both sub-category should not contain the origin of the materials but only be based on their main function (e.g. increasing soil organic matter content for organic soil improver).

Quality criteria for organic soil improvers: the Working Group discussed the need for a maximum nutrient content (upper limit) as a "cut-off" value to avoid overlapping with organic fertilisers where a minimum nutrient content was discussed. It was recognised that some flexibility should be applied to the producers which could prefer to market a given product in the organic soil improvers category despite the fact it is complying with the minimum nutrient content criteria of the organic fertiliser category. However, the actual content should always be declared.

Growing media: the points reported in the presentation prepared by the Commission were not discussed, except the proposed safety criteria which should be aligned with the values of the future End-of-Waste criteria for compost and digestate.

Plant biostimulants: the Commission presented the proposed definition and the guiding principles and concept of "registration" for plant biostimulants (NOTE: the NLF was finally favoured) according to an approach similar to that of the Feed Materials Regulation and in a way to the REACH Regulation. The Commission reacted to the question raised by ES about the completeness of a dossier by saying that the dossier should be submitted and checked (by an official body to be determined and according to a procedure, also to be determined) before it would be declared as complete. Industry indicated that they will be making some proposals on how to make this completeness check the least burdensome as possible for the designated official bodies.

As regards the waste materials (neither composted nor digested), such as animal meals, oil cake meal, which will not be addressed by the future EU End-of-Waste criteria for compost and digestate, a similar approach as for 'upwards derogation' discussed earlier could be implemented: waste materials compliant with national EoW criteria can be used as ingredients but the derived fertilisers shall then be limited to be placed on the local or national market only unless other Member State(s) accept the products as well. When taking such action, Member States should provide quantitative information on the share of products that would be excluded from the market due to the fact that they are not included in the EU EoW criteria. Alternatively, the animal by-products regulation already foresees the placing on the market of soil improver and organic fertilisers made of animal by-products and could be used as criteria for EU end-of-waste.

Policy options: the Commission noted that the situation compared to the discussion one year ago had evolved as several Member States had realised that extending the procedure of type listing to all new fertilisers categories to be covered by the future Fertilisers Regulation would not be realistic as thousands of types have already been identified on the market in the Member States. Therefore, the Commission highlighted to possible advantages of combining option 5 (positive and negative lists) for the most sensitive ingredients such as agronomically relevant active additives and plant biostimulants with option 6 (new approach) for the other main product categories. (NOTE: the NLF was finally adopted in 2015 as the preferred option)

DE indicated that due to negative experiences in the past few years (e.g. with waste products) they have implemented at national level a system which is similar to the presented combination of options 5 and 6. DE commented that negative lists would not be that easy to establish in the initial proposal and could be easily by-passed, so that DE would now for organic materials be more in favour of a positive listing of ingredients which would be more transparent for users and manufacturers. The Commission repeated that a negative list would be implemented as a safeguard mechanism for ingredients which are found to constantly lead to non-conformity of products with the essential requirements.

ES stated that, considering the previous investment for type designation of inorganic fertilisers, option 4 should continue to apply for this category, while ES recognised that this option is not adapted to the other categories considering the high number of new type designations to handle. Option 5 (ingredient listing) could be an alternative for these categories.

PL, IT, FR supported ES and expressed concerns about the amount of work related to CEN standards if option 6 would be implemented. The Commission repeated that types or ingredients listing will also be an immense task – in particular for describing precisely acceptable ingredients for organic materials.

FR indicated that "bigger groups" of ingredients could be constituted which could reduce the amount of work and ease the identification of problematic ingredients. The Commission considered that grouping ingredients in view of their listing will not provide the necessary level of safety information to the manufacturers, nor to the users. There would probably also be many questions regarding correct interpretation of these descriptions during actual implementation of the revised Regulation, hence missing the objective of simplification.

Industry indicated that a better understanding of option 7 following the presentation by the Commission at the last meeting of technical working group 1 had increased the industry's support for this option.

4. OUTCOMES OF THE PUBLIC CONSULTATION ON THE RENEWED CIRCULAR ECONOMY PACKAGE IN RELATION WITH FERTILISERS (SUMMER 2015)

As a reminder the Circular Economy package as published in July 2014 included

- the European Commission's communication document "Towards a Circular Economy: A zero waste program for Europe" as well as

- a Proposal for a Directive which would revise several pieces of legislation such as the Waste Framework Directive (Directive 2008/98/EC) and introduced the vision of a 'Circular Economy'.

However, a 'Circular Economy' further aims to maintain the value of the materials and energy used in products in the value chain for the optimal duration, thus minimising waste and resource use. By preventing losses of value from material flows, it creates economic opportunities and competitive advantages on a sustainable basis.

This is one of the reason why, in December 2014, the new Commission announced the withdrawal of the 2014 legislative proposal for the review of waste legislation. A new initiative promoting the Circular Economy was announced by the end of 2015.

The new and more ambitious Circular Economy strategy would have to be fully aligned with the priorities of the new Commission and comprise a revised legislative Proposal on waste acquis, and a Communication setting out an action plan on the Circular Economy covering – as it is often called - the 'other side of the circle', which means covering the whole value chain of a product instead of focussing on its end of life state as waste.

To develop a more ambitious Circular Economy strategy and create the necessary conditions to "close the loop" in the value chain and promote actions at all stages of the life-cycle of products, the input from stakeholders and the public was identified as one key factor to spot main barriers and gather views on measures to be taken at EU level to overcome such barriers. Therefore, the new Commission initiated the exchange of information at European level with three initiatives:

1. In early 2015, the Commission announced that it will conduct a public, online stakeholder consultation on the Circular Economy over the summer. The consultation was published on 28th May 2015 and lasted until 20th August 2015 at midnight. All interested stakeholders such as citizens, organisations and public authorities have been invited to contribute to the online consultation. The survey consisted of eight sections, including short background information and addressing different fields: introduction, general information about respondents, production phase, consumption phase, markets for secondary raw materials, sectoral measures, enabling factors for the Circular Economy, including innovation and investment, and upload documents. Many questions allowed for specific remarks and upload of additional papers was possible.

2. In addition, the Commission consulted the 28 Member States through a separate questionnaire dedicated to issues not covered by the public stakeholder consultation (as described above) or of specific interest to the Member States. This questionnaire was distributed electronically to the relevant administrations (in English) and included a maximum of 10 open questions. The consultation was started from July 2015 and ended in September 2015.

3. Organisation of the Circular Economy Conference in Brussels on 25 June 2015: The Commission organised the conference "CLOSING THE LOOP – Circular Economy: boosting business, reducing waste" which was open to all stakeholders wishing to contribute in shaping the European economy policy making. The conference consisted of an opening plenary (keynote and panel discussion), a series of break-out sessions addressing specific aspects of the Circular Economy (and discussing questions of the online stakeholder consultation as described above), and a closing panel with institutional representatives. All documents, speeches and web streams of the conference have been published on the Commission's website and are publicly available.

Based on a comprehensive analysis of the stakeholder input, the outcome of the three initiatives as described above has formed part of the final Circular Economy initiative.

Under the section "Market for secondary raw materials", the results of the consultation identified 9 problem descriptions, each followed by a list of the three top priority-fields selected by stakeholders.

"Bio-nutrients" holds the "Priority 1"-place in 6 of the 9 priority lists, and the "Priority 2"-place in another 1 of the 9 lists.

This underlines the strong support received during this last public consultation, for a regulatory initiative such as the revision of the Fertilisers Regulation enabling the development of a market for the so-called bio-nutrients which have to be understood as the recycled nutrients from secondary raw materials.

The results of the consultation are available on the following website:

HTTPS://EC.EUROPA.EU/EUSURVEY/PUBLICATION/CIRCULAR-ECONOMY

The Commission has presented a new, more ambitious circular economy strategy in December 2015, to transform Europe into a more competitive resource-efficient economy, addressing a range of economic sectors, including waste. The strategy will be fully aligned with the priorities of the new Commission. It will comprise a revised legislative proposal on waste and a Communication setting out an action plan on the circular economy for the rest of this Commission's term of office. The action plan will cover the whole value chain, and focus on concrete measures with clear EU added value, aiming at 'closing the loop' of the circular economy.

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PART 2/2

Circular Economy Package

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Limits for cadmium in phosphate fertilisers

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009

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1. Introduction

Concerns regarding the risks posed by cadmium to human health and the environment were addressed by the Council already in its Resolution of 25 January 1988[1] which emphasized the importance of reducing inputs of cadmium into soils from all sources including diffuse sources (e.g. atmospheric deposition, phosphate fertilisers, sewage sludge…) by among others *"appropriate control measures for the cadmium content of phosphate fertilisers based on suitable technology not entailing excessive costs and taking into account environmental conditions in the different regions of the Community"*. Among the possible actions (reduced atmospheric emissions, limit values for sewage sludge), cadmium in phosphate fertilisers remains the main point not having been dealt with so far at EU level.

The EU fertiliser market is only partly harmonised. Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers[2] (hereinafter referred to as "the Fertilisers Regulation") aims to ensure the free circulation on the internal market of "EC fertilisers" i.e. those fertilisers that meet certain requirements for their nutrient content, their safety, and their lack of adverse effect on the environment. The Fertilisers Regulation does not affect the so-called "national fertilisers" placed on the market of the Member States in accordance with national legislation. Producers can choose to market fertiliser as "EC fertiliser" or as "national fertiliser". Depending on agricultural practices in the Member States, "EC fertilisers" have, on average, market shares from 60 to 70 %[3].

Twenty Member States have already introduced or intend to introduce diverging limits for cadmium in national fertilisers. On the other hand, there is currently no limit value for cadmium in the Fertilisers Regulation. However, Recital 15 of the Fertilisers Regulation specifies that "*Fertilisers can be contaminated by substances that can potentially pose a risk to human and animal health and the environment. Further to the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE), the Commission intends to address the issue of unintentional cadmium content in mineral fertilisers and will, where appropriate, draw up a proposal for a Regulation, which it intends to present to the European Parliament and the Council*".

1 OJ C 30, 4.02.1988, p. 1.
2 OJ L 304, 21.11.2003, p. 1.
3 Evaluation of Regulation (EC) No 2003/2003 to fertilisers. Centre for Strategy and Evaluation Services. Final Report. November 2010. HTTP://EC.EUROPA.EU/ENTERPRISE/SECTORS/CHEMICALS/FILES/FERTILIZERS/FINAL_REPORT_2010_EN.PDF

Commission Regulation (EC) No 889/2008[4] on organic products sets an upper limit of 90 mg/kg P_2O_5[5] for cadmium in two phosphate fertiliser types (soft ground rock phosphates, aluminium-calcium phosphate) that may be used in organic production. Those fertiliser types also fall under the scope of the Fertilisers Regulation.

2. CONSULTATION OF INTERESTED PARTIES AND EXPERTISE

The various consultations conducted as part of this impact assessment report have been carried out in compliance with the Commission's minimum standards on consultation[6].

2.1. Consultation of other Commission services

An impact assessment steering group (IASG) was established in May 2008 to which the following Directorates-General were invited: Enterprise and Industry, Environment, Health and Consumer Protection, Agriculture, Trade, External Relations, Research, Development, Economic and Financial Affairs, Internal Market, Secretariat General and Legal Service. The members of the steering group were also invited to participate in meetings with experts in decadmiation, stakeholders and Member States representatives.

The IASG met six times between June 2008 and May 2010 in order to accompany the preparation of the impact assessment. Directorates-General Enterprise and Industry, Environment, Health and Consumer Protection, Agriculture and Trade were the most active participants.

2.2. Consultation of the Member States and EU fertiliser industry in the frame of the Fertiliser Working Group

During the Fertilisers Working Group meeting of 5 November 2007, most Member States supported setting upper limits for cadmium for all phosphate fertilisers (EC and national fertilisers). Several Member States having set already national limits that so far affect only national fertilisers insisted on being allowed to continue to apply them to address their specific environmental concerns. Annex I contains an overview of the limit values for national fertilisers that Member States have already introduced or intend to introduce in legislation.

In October 2009, representatives of the Member States, producing countries of phosphate rocks and fertilisers, EU fertiliser manufacturers, environmental NGOs, trade unions, farmers and consumers organisations[7] were consulted at a specific workshop on potential policy options for implementing cadmium limit(s). The advantages and drawbacks of the options

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4 Commission Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. OJ L 250, 18.09.2008, p. 1.

5 See Glossary of terms and abbreviations.

6 Available at: HTTP://WWW.CC.CEC/HOME/DGSERV/SG/STAKEHOLDER/INDEX.CFM?LANG=EN&PAGE=GUIDANCE

7 BEUC (European Consumers Organisation), COPA COGECA, CEN (European Committee for Standardisation), European Environmental Bureau (EEB), IMPHOS (World Phosphate Institute), OCP (Office Chérifien des Phosphates), EFMA (European Fertilisers Association), EFBA (European Fertilisers Blenders Association), EFIA (European Fertilisers Imports Association), IFA (International Fertilizers Association), ETUC (European Trade Union Confederation), EMCEF (European mine, chemical and energy workers' federation).

developed in this impact assessment (except Option 2)[8] were presented in detail and stakeholders were requested to provide their views on the options. The preferences expressed during that meeting are provided in Annex II.

In summary, a majority of stakeholders supported the following approach:

– Introduction of an upper limit of 60 mg cadmium/kg P_2O_5 decreasing progressively to more stringent limits because of sufficient scientific evidence establishing a conclusive link between soil cadmium concentration, transfer to plants, dietary intake and possible human health risks. Some Member States advocated starting with a limit value of 75 mg cadmium/kg P_2O_5 and decreasing to 60 mg cadmium/kg P_2O_5 after 3 years.

– However, the adoption of limits lower than 60 mg cadmium/kg P_2O_5 would be conditional on the successful implementation of a decadmiation technology at industrial scale which is so far unproven as low cadmium phosphate sources will not be sufficient to cover all needs of EU farmers.

– The setting of low limits needs to be mindful of the problem that not all the current fertiliser types placed on the market can be decadmiated, in particular decadmiation would not be possible for the phosphate fertilisers currently authorised in organic farming.

– The timing of a progressive decrease in cadmium limits will therefore mainly depend on progress in decadmiation technology and/or on the availability of phosphate fertiliser alternatives containing less cadmium (e.g. from manure, sewage sludge, bio-waste, industrial by-products…).

In addition to this consultation, an earlier public consultation via internet had been conducted in 2003 regarding the possible introduction of Community limits on cadmium in fertilisers below 60 mg cadmium/kg P_2O_5. The distribution of the 65 replies received by the Commission, which may be broadly classified as for, against and neutral, was as follows:

- 7 broadly approved the Commission's proposal;
- 54 expressed strong concerns in particular concerning the introduction of uniform limits below 60 mg cadmium/kg P_2O_5;
- 4 replies did not directly express an opinion on the proposal, but sent studies relating to the subject of cadmium in fertilisers.

Further details are contained in Annex III. A renewed public consultation via internet was not considered necessary, as based on the available knowledge through direct contacts the positions of those who participated in the earlier consultation have not changed. All key stakeholders were represented at the workshop in October 2009 referred to above.

2.3. SMEs consultation

In the framework of the implementation of the Small Business Act, requests for input on the various options (except option 2) developed in the impact assessment were also submitted to Small and Medium Size Enterprises (SMEs) on the basis of a specific questionnaire supported by a background note clarifying the technical and economical aspects of the proposal. 40 companies in 14 Member States participated in the consultation. This might represent around 5% of the SMEs active in the production and trade of mineral fertilisers across

[8] Option 2 (market-based incentives) was not part of the earlier consultations because it was included in the analysis only after the first review of the draft impact assessment report by the Commission's Impact Assessment Board.

Europe. In general, SMEs producing only mineral fertilisers or producing mineral fertilisers plus organic fertilisers and soil improvers commented mostly on possible negative impacts on the competitiveness of the sector from measures restricting the supply in phosphate fertilisers. Further information on the SMEs replies is incorporated in the analyses in section 6 and is available in Annex IV.

2.4. Scrutiny by the Commission impact assessment board

The impact assessment board (IAB) [9] of the European Commission assessed a draft version of the impact assessment and issued its first opinion on 2 July 2010. The impact assessment board made several comments and, in the light of those suggestions, the revised impact assessment report:

– **provides a broader description of the problem** by presenting in more detail the current supply conditions and related economic issues such as incentives for developing decadmiation technologies;

– **explains in the description of the problem why long term risks for the population** and for the environment cannot be assessed more quantitatively and why it is impossible to directly correlate soil cadmium inputs from mineral phosphate fertilisers and their effects on public health and the environment;

– **clarifies the objectives** pursued with the legislative proposal accompanied by this impact assessment;

– **indicates more clearly the trade-offs between the different objectives** and specifies why choices are limited by political constraints such as trade obligations and external relations;

– **introduces and analyses a new option on market-based incentives including fiscal incentives (hereinafter option 2)** to increase the use of fertilisers with low cadmium content and a new annex explaining the calculations carried out;

– **analyses for each option** the incentives to trigger the development and implementation of decadmiation technologies;

– **provides additional explanations why the most ambitious option** of an immediate EU limit of 20 mg cadmium/ kg P_2O_5 has been discarded at an early stage and clarifies that this option is implicitly contained in one of the options that has been fully analysed.

The Impact Assessment Board issued its final position on a revised draft impact assessment report on 26 July 2011 and, based on those comments, the final impact assessment report:

– **Better present the time dimension of the problem** in terms of long term health impacts and technological developments

– **Clarifies how the trade-offs between the objectives** have been taken into account in the formulation of objectives and why a complete harmonisation of the cadmium limit value is not envisageable

– **Provides clearer arguments to disguard the option of immediately imposing a 20 mg limit**

9 HTTP://EC.EUROPA.EU/GOVERNANCE/IMPACT/IAB_EN.HTM.

3. PROBLEM DEFINITION

3.1. Why is the presence of cadmium in phosphate fertilisers an issue?

Cadmium is a non-essential element that has a high transfer rate from soil to plants compared to other non-essential elements. Certain plants (e.g. sunflowers, colza, triticale, tobacco...) tend to accumulate larger amounts of cadmium. Cadmium is naturally present in phosphate rocks which are mined for the manufacture of phosphate fertilisers.

The additional annual cadmium accumulation rate from various anthropogenic sources such as atmospheric deposition, mineral fertilisers, manure and sewage sludge is generally small but quantitative estimates vary. In 2002, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE-2002[10]) considered that annual net accumulation from all sources is typically in the order of about 1 % of the amount already present in agricultural soils[11], whilst several Member States having conducted specific risk assessments concluded that annual net accumulation would be in the order of 0.4-1.25 % from phosphate fertilisers alone if their cadmium content is at 60 mg/kg P_2O_5[12].

Once present in soil, cadmium cannot be removed and might accumulate and migrate to pore solution where plant roots take up their nutrients. Quantification of the net contribution of phosphate fertilisers to transfer to plants is extremely complex and depends on soil and climatic conditions. Cadmium solubilisation and bioavailability are affected by soil pH – acidic soils favour the solubility of cadmium – and are also largely controlled by the presence of organic matter, sand, clay or micro-nutrients such as zinc, iron and manganese. Other factors such as crop variety, rainfall and farming practices may also affect cadmium bioavailability. However, soil pH and soil cadmium accumulation are considered as the main factors controlling the availability of cadmium for uptake by plants.

The presence of cadmium in plants and cadmium intake from foodstuffs could eventually lead to adverse effects on human health in the longer term. In addition to human health impacts, further cadmium accumulation in soils could have negative effects on soil biodiversity and therefore on soil functions (e.g. decay of organic matter) and on groundwater quality via leaching in soils.

In 2002, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE - 2002)) was asked by the Commission for its opinion[11] on the likelihood for accumulation of cadmium in soils through the use of phosphate fertilisers. Based on risk assessment studies carried out by 8 Member States (+ Norway) and additional analysis, the SCTEE-2002 estimated that phosphate fertilisers containing 60 mg cadmium/kg P_2O_5 or more are expected to lead to cadmium accumulation in most EU soils whereas phosphate fertilisers containing 20 mg cadmium/kg P_2O_5 or less are not expected to cause long-term soil accumulation over 100 years, if other cadmium inputs are not considered. A similar trend is expected for cadmium uptake in crops although the actual increase would be much smaller. The SCTEE-2002 was also of the opinion that the derivation of a limit exclusively based on soil accumulation does not take into account the level of risk for human health and the environment associated with the current situation and considered that such a limit should be derived on a more solid risk assessment basis using a probabilistic approach and taking all cadmium sources into consideration.

10 Now renamed SCHER.

11 HTTP://EC.EUROPA.EU/HEALTH/PH_RISK/COMMITTEES/SCT/DOCUMENTS/OUT162_EN.PDFI.

12 HTTP://EC.EUROPA.EU/ENTERPRISE/SECTORS/CHEMICALS/DOCUMENTS/SPECIFIC-CHEMICALS/FERTILISERS/CADMIUM/RISK-ASSESSMENT_EN.HTM

In 2015, the Commission mandated the Scientific Committee on Health and Environmental Risks (SCHER-2015) to evaluate a new mass-balance analysis[13] (hereinafter the "new analysis") based on new information about atmospheric deposition of cadmium, use of inorganic phosphate fertilisers and new and more accurate models to estimate the cadmium leaching from the soil. The main objective was to compare the results of the new analysis with the SCTEE-2002 opinion in order to assess whether new trends in soil cadmium accumulation can be observed based on the most up-to-date data.

The SCHER released its final opinion on 27.11.2015[14] and concluded that, on average, cadmium accumulation is not likely to occur in EU 27 + Norway arable soils when using inorganic phosphate fertiliser containing less than 80 mg Cd/kg P_2O_5. According to SCHER, the new conclusion is justified by the significant decrease in the level of cadmium actually present in the environment since the last assessment of 2002 which was based on data from the nineties.

The SCHER-2015 highlighted however that an average scenario does not reflect the various soil and climatic conditions in the EU. In extreme conditions (high fertiliser consumption, critical soil conditions), SCHER showed that cadmium soil accumulation could still happen at a concentration of 20 mg Cd/kg P_2O_5.

As the new conclusion from SCHER-2015 came during the interservice consultation on a draft Commission proposal for a revision of the Fertilisers Regulation, the assessment of the impacts have been construed based on the conclusions of SCTEE-2002. However, the opinion of SCHER-2015 should be considered as a new important scientific element and therefore its impact on the choice of the preferred option is discussed in Section 8 of this impact assessment.

The most important conclusions of recent risk assessments concerning cadmium are presented in the following section. Summaries of previous mass-balance calculations and risk assessments are available in Annex V.

3.1.1. *Toxicity of cadmium for human health via the diet*

In the framework of Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances[15], cadmium and cadmium oxide were identified as priority substances for evaluation in accordance with Commission Regulations (EC) No 1179/94[16], (EC) No 2268/95[17] and (EC) No 143/97[18], respectively. Belgium was designated as Rapporteur Member State and completed a risk evaluation for cadmium and cadmium oxide to the environment and human health in accordance with Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances[19]. The EU Risk

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13 HTTP://WWW.SCIENCEDIRECT.COM/SCIENCE/ARTICLE/PII/S0048969714004495

14 HTTP://EC.EUROPA.EU/HEALTH/SCIENTIFIC_COMMITTEES/ENVIRONMENTAL_RISKS/OPINIONS/INDEX_EN.HTM

15 OJ L 84, 5.04.1993, p. 1.

16 Commission Regulation (EC) No 1179/94 of 25 May 1994 concerning the first list of priority substances as foreseen under Council Regulation (EEC) No 793/93.OJ L 131, 16.05.1994, p. 3.

17 Commission Regulation (EC) No 2268/95 of 27 September 1995 concerning the second list of priority substances as foreseen under Council Regulation (EEC) No 793/93.OJ L 231, 28.09.1995, p. 18.

18 Commission Regulation (EC) No 143/97 of 27 January 1997concerning the third list of priority substances as foreseen under Council Regulation (EEC) No 793/93.OJ L 25, 28.01.1997, p. 13.

19 OJ L 161, 29.06.1994, p. 3.

Assessment Report[20] (hereafter EU RAR) on cadmium and cadmium oxide was issued in December 2007.

The EU RAR on cadmium found that the most sensitive toxicological/ecotoxicological endpoint is kidney toxicity through repeated oral exposure (intake via the diet). Cadmium in food is the second factor after smoking that contributes to cadmium human body burden. For the general non-smoking population, food is actually the main source of cadmium intake. Although cadmium absorption through the gastrointestinal tract is relatively low (3-6 %), cadmium is efficiently retained in kidneys and liver. Once absorbed, cadmium is not easily excreted (biological half life between 10 and 30 years) and tends to accumulate in humans and may eventually cause renal dysfunction.

The food groups that contribute most to adult dietary cadmium intake are, in decreasing order of importance: cereals and cereal products; vegetables; meat, meat products and offal (inner organs); as well as fish and seafood. Vegetables and wheat are the crop categories with the highest inputs of phosphate fertilisers (market shares of 17.8 % and 16.4 %, respectively).

The EU RAR found that the contribution of dietary cadmium constitutes about half the tolerable intake and concluded that there is a need for limiting the risks to human health from cadmium via the environment from all sources of cadmium combined because, at current level of exposure, health risks cannot be excluded for adult smokers and people with depleted iron body stores and/or living near industrial sources.

Based on the conclusions of the EU RAR, the Risk Reduction Strategy for cadmium and cadmium oxide recommended concrete measures to reduce cadmium content in foodstuffs, tobacco blends and for phosphate fertilisers taking into account the variety of conditions throughout the Community[21].

In 2007, the Commission asked the European Food Safety Authority (EFSA) to assess the risks to human health related to the presence of cadmium in foodstuffs[22]. The Panel on Contaminants in the Food Chain of EFSA (CONTAM Panel) issued its scientific opinion[23] in January 2009. Based on updated exposure assessments from foodstuffs and on statistical review of available information, the CONTAM Panel concluded that a value of 1 µg cadmium/g creatinine for urinary cadmium (Cd-U) would be an appropriate biomarker value to protect 95 % of the general population by the age of 50. The dietary exposure that corresponds to the value of 1 µg cadmium/g creatinine after 50 years corresponds to a tolerable weekly dietary intake of 2.5 µg cadmium/kg body weight (TWI).

The current average weekly dietary exposure across Europe – 2.3 µg cadmium/kg body weight – is very close to the TWI proposed by the CONTAM Panel and may be exceeded about 2-fold for certain sub-groups of the population such as vegetarians, children, smokers and people living in contaminated areas. Quantitative data on the size of these high risk groups, the distribution of risks within these groups, their risk increase in relation to the

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20 HTTP://ECB.JRC.EC.EUROPA.EU/DOCUMENTS/EXISTING-CHEMICALS/RISK_ASSESSMENT/REPORT/CDOXIDEREPORT302.PDF and HTTP://ECB.JRC.EC.EUROPA.EU/DOCUMENTS/EXISTING-CHEMICALS/RISK_ASSESSMENT/REPORT/CDMETALREPORT303.PDF.

21 OJ C 149, 14.06.2008, p. 6.

22 For exposure assessments, dietary intake included only cadmium in food but not in drinking water.

23 Scientific Opinion of the panel on contaminants in the Food Chain on a request from the European Commission on cadmium in food. The EFSA Journal (2009) 980, p. 1-139. HTTP://WWW.EFSA.EUROPA.EU/EN/SCDOCS/DOC/980.PDF

general population and the potential impact on public health costs were not assessed by EFSA as such data is not available and the calculation of public health costs is outside the remit of EFSA. Furthermore, a more detailed estimate of risk to establish relations between certain risk levels and the percentages of the population exposed to given risk levels would require a probabilistic risk assessment, for which not enough information is available.

Although the risk for adverse effects on kidney function at an individual level and at dietary exposures across Europe is very low, EFSA concluded that the current exposure to cadmium at population level should be reduced. EFSA evaluated qualitatively the impact of the uncertainties associated with their risk assessment according to EFSA and international guidelines. The outcome of this evaluation was that "*the impact of the uncertainties on the risk assessment of exposure to cadmium is limited*" and "*that its assessment of the risks is likely to be conservative- i.e. more likely to overestimate than to underestimate the risk*". This approach is in line with the precautionary principle. In fact, although early signs of kidney dysfunction may be reversible, it is difficult for people to decrease their exposure as most of the exposure to cadmium for the general population is via the food chain. These early signs mostly appear at the age of 50 when kidneys are supposed to function still for several decades.

Furthermore, according to the SCHER, the vulnerability of diabetics and patients with kidney disease needs to be ascertained with regard to cadmium effects on kidney function.

In June 2010 the Joint FAO/WHO expert Committee on food additives (JECFA)[24] evaluated the toxicology of dietary cadmium and revised its earlier provisional tolerable intake downwards from 7 µg cadmium/kg body weight **per week** to the slightly lower value of **25 µg cadmium/kg body weight per month**. JECFA considered that the current cadmium ingestion through the diet for all age groups, including consumers with high exposure and subgroups with special dietary habits (e.g. vegetarians) does not lead to increased health risks. The limit value set by JECFA is rather close to that of the EU-RAR which is **21 µg cadmium/kg body weight on a monthly basis**, whereas the corresponding EFSA value is significantly different at **10 µg cadmium/kg body weight per month**.

In July 2010, EFSA was asked by the European Commission to confirm whether the current TWI of 2.5 µg cadmium/kg body weight is still considered appropriate or whether any modification are needed in view of the opinion of JECFA. In February 2011, the CONTAM Panel confirmed its TWI limit[25]. The assessments of the CONTAM Panel and the JECFA were based on the same indicator of cadmium induced kidney damage (i.e. the beta 2-microglobulin B2M) and the same epidemiological studies. However, the statistical approaches to quantify the variations between those studies were different and lead to different values of permitted tolerable weekly intake.

Annex VI provides further information on the differences in the calculations made in the various assessments[26].

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[24] HTTP://WWW.WHO.INT/FOODSAFETY/PUBLICATIONS/CHEM/SUMMARY73.PDF. Summary report of the 73rd meeting of JEFCA. JECFA is the Joint FAO/WHO Expert Committee on Food Additives. FAO is the Food and Agriculture Organization of the United Nations. WHO is the World Health Organisation.

[25] EFSA Panel on Contaminants in the Food Chain (CONTAM); Statement on tolerable weekly intake for cadmium. EFSA Journal 2011;9(2):1975. [19 pp.]. doi:10.2903/j.efsa.2011.1975. Available online at: http://www.efsa.europa.eu/en/efsajournal/pub/1975.htm#

[26] In 2001 the US State of California proposed a maximum limit for dietary intake of cadmium of 0.7 µg/kg/day, which would correspond to 0.49 µg/kg/week – hence even considerably lower than EFSA. The value has been derived under California's Proposition 65, which applies to chemicals that

In January 2011, the German Federal Institute for Risk Assessment (BfR) has released a report[27] on the current levels of cadmium, lead, mercury, dioxins and polychlorinated biphenyls (PCBs) intakes by the general population through the food chain. The report concludes that, on average, the current cadmium ingestion via the diet for all age groups is below the Tolerable Weekly Intake recommended by EFSA. However some specific groups with specific dietary habits (e.g. teenagers and vegetarians) might occasionally exceed the EFSA limit.

In conclusion, for the general population the main exposure to cadmium is through food ingestion and the most critical endpoint is kidney toxicity. Two reports (EU RAR 2007 and JECFA 2010) indicate that intake via food constitutes about half the tolerable intake for 95 % of the population, and a third report (EFSA 2009) that food constitutes the whole tolerable intake for the average adult. The EU-RAR concludes that exposure via the environment to cadmium from all sources combined constitutes a risk, and that there is a need for specific measure to limit the risk. EFSA is also of the opinion that exposure to cadmium at the population level should be reduced. The negative impacts of cadmium on human health are only gradual and could appear after 50 years of exposure.

Due to the very complex relation between cadmium content in soil and cadmium content in plants, which is influenced by a range of parameters (as described above), it is not possible to derive a specific limit value for cadmium in fertilisers that would ensure that the cadmium content in food stays below a desired value. However, the general relation that increasing amounts of cadmium in soil will lead to increasing cadmium content in plants – and conversely decreasing cadmium content in soil will eventually lead to decreasing cadmium content in plants – is valid. In order to protect human health from adverse effects of cadmium via dietary intake, it is, therefore, important to decrease cadmium input into soils.

3.1.2. Environmental concerns about the presence of cadmium in soils

The EU RAR concluded that there is a need for specific measures to limit the risks to terrestrial ecosystems in the vicinity of cadmium production and plating sites and in one region in the UK based on the 90th percentiles of measured cadmium concentrations of European soils.

The EU RAR did not conclude that there is a need to limit the risks from cadmium in the environment in general. However, the SCTEE-2002[28] criticised the choice of the Predicted environmental concentration (PEC) and the Predicted no-effect concentrations (PNEC) mentioned in the EU-RAR and suggested creating PEC/PNEC probabilistic distributions to improve insights and information for potential risk management decisions. This probabilistic element was eventually not included in the final version of the EU-RAR. Furthermore, more recent scientific evidence shows that accumulation of cadmium in European soils threatens the long term sustainability of water and soil functions such as storing, filtering and

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are carcinogenic or toxic to reproduction. The legislation requires dividing the No-Observed Effect level (NOEL) for reproductive toxicity by 1.000 to establish the maximum allowable dose level and does not account for other toxic effects, such as renal toxicity. This explains why the limit derived in California is significantly low than even the limit established by EFSA, even though kidney toxicity is actually more sensitive than reproductive toxicity.

27 HTTP://WWW.BFR.BUND.DE/CM/238/AUFNAHME_VON_UMWELTKONTAMINANTEN_UEBER_LEBENSMITTEL.PDF

28 HTTP://EC.EUROPA.EU/HEALTH/PH_RISK/COMMITTEES/SCT/DOCUMENTS/OUT228_EN.PDF

transforming nutrients and water, biodiversity and carbon pools[29]. The influence of heavy metals, including cadmium, and their bioaccumulation by earthworms has been the subject of many studies in the past[30]. Heavy metals (including cadmium) have been shown to cause mortality and reduce fertility, cocoon production, cocoon viability and growth of earthworms. Negative effects on the aquatic ecosystem in Spain have been reported in a recent study[31].

Cadmium inputs from anthropogenic sources, e.g. emissions from industry and intensive agriculture, affect the natural background concentration of cadmium and the residence time of cadmium could be several decades. The relative annual contributions from various sources to soil cadmium inputs are described in Annex VII for 11 Member States and Norway (phosphate fertiliser contribution ranges from just 3 % in certain regions up to 86 % in others).

The current cadmium concentration in the plough layer of Member States is shown in Figure 1. The cadmium concentration in soil solution (the cadmium fraction that could be assimilated by plants) is not reflected on this map.

All mathematical models[32] predict a net accumulation of cadmium over the long term (60 to 100 years) with current cadmium inputs. However, the historical increase of the last century – which results in important cadmium reservoirs as illustrated in Figure 1 – is unlikely to continue at the same rate because of the decrease in air emissions from different anthropogenic sources and the reduction in the overall consumption of mineral phosphate fertilisers in Europe (See example for France in Figure 7).

EU legislation already restricts atmospheric deposition through emission limits for cadmium from major anthropogenic sources such as coal-fired power stations, waste incinerators and metal refineries. Other EU legislation is also in place to limit the content of cadmium in several products and waste, as well as to reduce and prevent the emissions of cadmium to the environment. Annex VIII contains a list of relevant legislation.

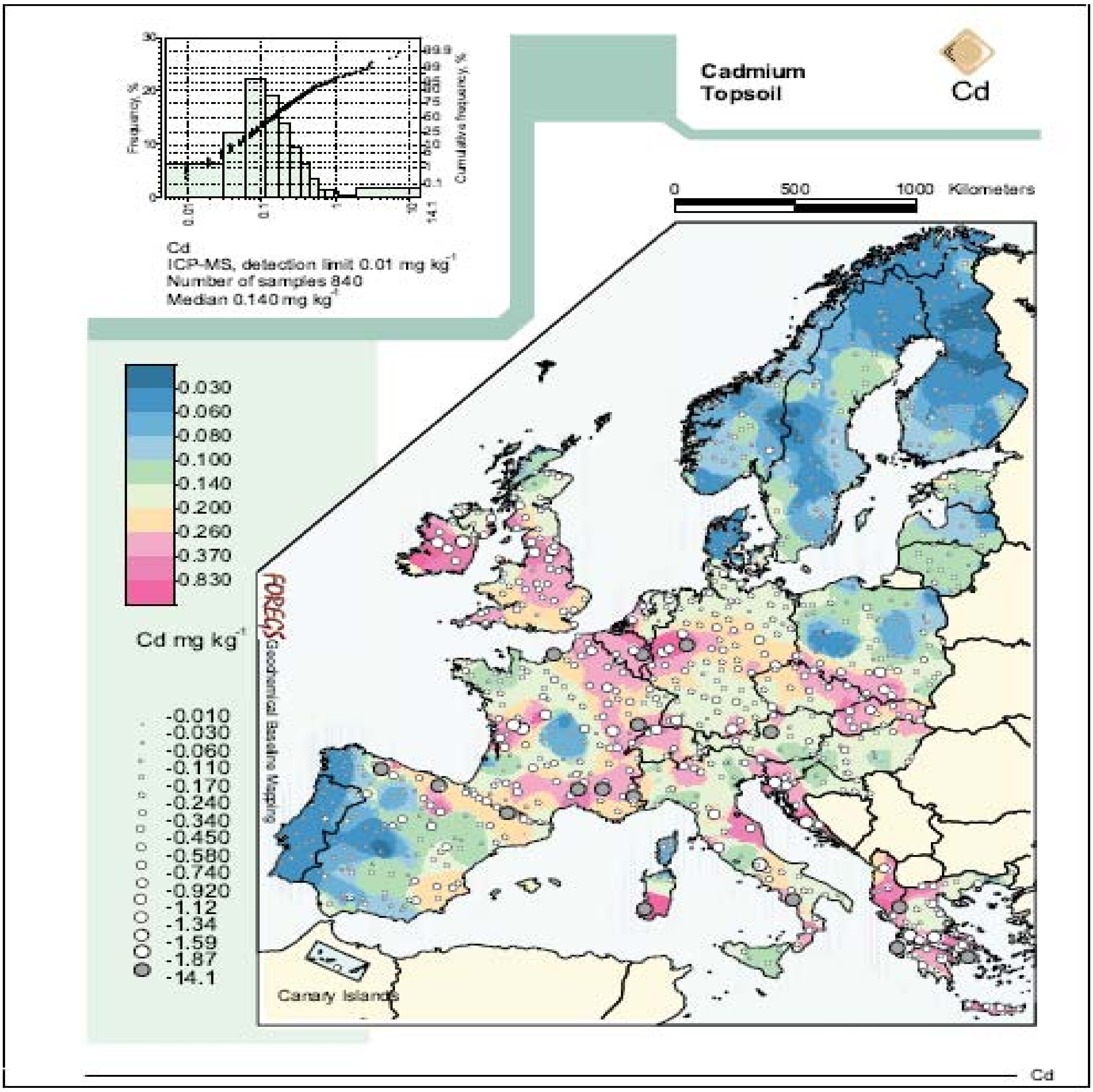
Figure 1: *Current cadmium concentration (mg/kg) in European topsoil including natural background and human sources (Source: Geochemical Atlas of Europe – Soil data and information system – FOREGS and JRC Ispra)*

[29] *'Soil biodiversity, functions; threats and tools for policy makers'*, available at: HTTP://EC.EUROPA.EU/ENVIRONMENT/SOIL/BIODIVERSITY.HTM

[30] For example: Bouche 1994, Morgan and Morgan 1999, Kennette et al. 2002.

[31] E. Dopico, A.R. Linde and E. Garcia-Vasquez (2009). Traditional and modern practices of soil fertilisation: effects on cadmium pollution of river ecosystems in Spain. Human Ecology, 37(2), 235-240.

[32] Algorithm of Anderson and Christensen (1988), algorithm of Christensen (1989), algorithm of Mac Bride (1997), algorithm of Römkens (2000), algorithm of Smolders (2007).



As regards surface water[33], an EU Environmental Quality Standard for cadmium has been recently adopted under the Water Framework Directive together with an obligation for Member States to cease or phase-out emissions, discharges and losses, as well as maximum concentration limits in rivers and lakes depending on the local water hardness level.

As regards groundwater[34], quality standards have been adopted taking into account local or regional conditions together with measures to prevent or limit the input of cadmium into groundwater. Based on recent surveys, the competent authorities responsible for the groundwater Directive have reported the following data in 2009:

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33 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/178/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 200/60/EC of the European Parliament and of the Council. (OJ L 348, 24.12.2008, p. 84-97).

34 Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration. (OJ L 372, 27.12.2006, p. 19-31).

– 11 Member States indicated that they have groundwater bodies at risk of not complying with their environmental objectives because of cadmium,

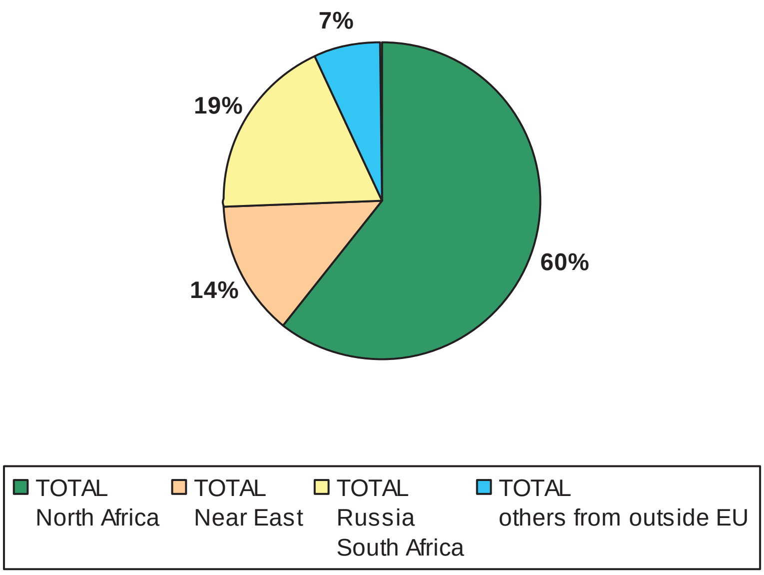
– 6 Member States already declared at this stage that they have groundwater bodies that fail the cadmium standards.

3.2. Current EU supply in mineral phosphate fertilisers

Mineral phosphorous is a non-renewable resource. According to the statistics of Fertilisers Europe, EU farmers applied on their land on average around 2.7 million tonnes of phosphate fertilisers (expressed as P_2O_5) over the last three years which correspond to approximately 38 kg P_2O_5/year for each hectare of arable land.

The main suppliers of phosphate rock, phosphoric acid or phosphate fertilisers to the EU are Morocco, Tunisia, Syria, Egypt, Israel, Jordan, South Africa and Russia. Morocco is one of the world's main suppliers and holds the most important phosphate rock reserves in the world. Figure 2 presents a breakdown by origin of imports.

Figure 2: *Phosphate rock imports to EU-27 in 2007, share of different producer countries (source: IFA – International Fertiliser Industry Association)*



The EU market takes up about 25 % of the Moroccan phosphate production and phosphate exports represent about 20 % of the total Moroccan exports (ERM 2001). The only commercially viable source of phosphate rock in the EU is located in Finland.

The cadmium content of phosphate rock varies considerably from one source to another (an overview for the main producing countries is contained in Annex IX). The phosphate rocks which are mined in Finland, Russia and South Africa are igneous rocks i.e. they were formed deep within the earth, and have very low cadmium contents (sometimes below 10 mg cadmium/kg P_2O_5). In contrast, those found in North and West Africa and the Middle East are sedimentary rocks i.e. they formed on the seabed by the decay of organic matter, and generally have much higher cadmium levels. In North and West Africa (Tunisia, Togo, Senegal), the levels are frequently above 60 mg cadmium/kg P_2O_5 while Morocco, the most important EU supplier, does have deposits which lead to cadmium content in fertilisers above or lower the 60 mg cadmium/kg P_2O_5 (see Annex IX for further details). In the Middle East

(Jordan, Syria, Egypt), the rocks are also sedimentary but the cadmium content is lower at about 20-40 mg cadmium/kg P_2O_5.

Global demand for phosphate fertilisers is forecast to grow at an annual rate of 3 % although demand in Europe is expected to continue to be weak (see Figure 7). Over the next five years, close to 40 new units producing various phosphate fertilisers (MAP, DAP and TSP) are expected to be constructed in ten countries, half of them in China alone. New facilities are planned in Africa (Algeria, Morocco and Tunisia), Middle East (Saudi Arabia), Asia (Bangladesh, China, Indonesia and Viet Nam), and Latin America (Brazil and Venezuela). For the period 2010 to 2014, it is estimated that all new supply additions will be absorbed by global growing demand for food, feed, fibres and bioenergy and that prices of phosphate fertilisers will experience upward pressure.

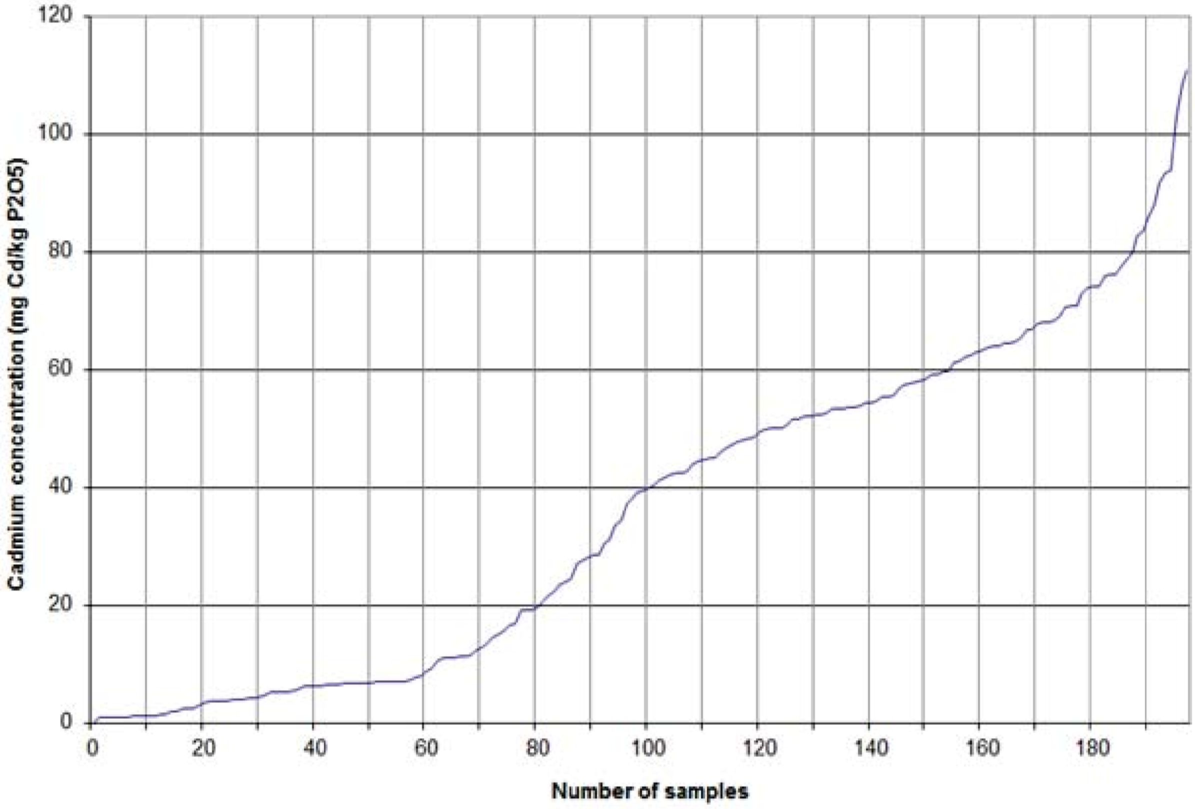
Very few data are available on the actual cadmium content of mineral phosphate fertilisers placed on the market in the EU as this parameter is not routinely monitored by either manufacturers or importers. Annex X gives information about the content of cadmium in phosphate mineral fertilisers from various sources. In 2007, Nziguheba and Smolders[35] measured the cadmium content of 197 phosphate fertiliser samples provided by 12 Member States (see Figure 3).

About 21 % of those samples contained more than 60 mg cadmium/kg P_2O_5. Samples have not been weighted for the size of the local market compared to the size of the EU market (e.g. 18 samples from France and 16 from Belgium) nor is it specified which overall volume of fertiliser each sample represents. If the data from the study were used to calculate the cumulative cadmium content contained in phosphate fertilisers as a function of the concentration contained in the samples analysed, the curve in Figure 3 would emerge.

However, it has to be underlined that the figure is given mainly for illustration purposes, as information provided in the study does not allow concluding that the data used are representative for the entire EU phosphate fertiliser market. Despite this limitation, the figure will be used in the analysis of the policy options to provide an indication of which reduction in cadmium input could potentially be achieved through the implementation of the options.

[35] Nziguheba G., Smolders E. Inputs of trace elements in agricultural soils via phosphate fertilizers in European countries, Sci Total Environ (2007).

Figure 3*: cadmium distribution 197 samples of phosphate fertilisers (From the data of Nziguheba and Smolders (2007) – communicated directly by the authors. The data are not necessarily representative of the EU phosphate fertiliser market situation)*



3.3. Possible alternatives to mineral phosphate fertilisers with high cadmium content and their availability

Mineral phosphates containing high levels of cadmium (> 60 mg/kg P_2O_5) could be replaced by the following alternatives:

– phosphates from igneous or sedimentary sources with (very) low cadmium content,

– decadmiation of phosphate rocks during the production process of fertilisers,

– phosphates from organic fertilisers.

The different possibilities and their limitations are reviewed in the following sections.

3.3.1. Use of igneous rocks or sedimentary rocks of low cadmium content

Some 85 % of the world phosphate production is derived from sedimentary phosphate deposits and reserves of igneous rocks, in the neighbourhood of the EU, are limited to Russia. Instead of exporting igneous rocks as such, Russia prefers to export transformed products like DAP and MAP. There are also doubts whether Russia will be able to increase its capacity from existing deposits. The current operations are not particularly efficient and would require huge investments to maintain or even increase production.

Although notable investments in new capacity are coming on-stream in Brazil and South Africa, a sufficient supply in phosphates from igneous rock in these countries is not expected at affordable prices due to high costs of transport. Moreover, the main investments have been developed to support national farming in these countries.

In addition, the characteristics of igneous-based SSP and TSP (higher free acidity, higher moisture) would require the EU fertiliser producers to bear significant technological adjustment costs for using different raw materials.

In 2007, 18 % of overall EU-27 imports (9 000 ktons) of phosphate rocks for all purposes (fertilisers, food industry, etc) came from sedimentary rocks of low cadmium content mined in the Middle East[36]. Imports of phosphate fertilisers from this region represented only 3.2 % of the total EU consumption. Given their overall shares in world phosphate reserves and fertiliser production (see Annex XI), it is unlikely that exports of sedimentary phosphate rocks of low cadmium content could increase to such quantities as to replace the current imports of sedimentary phosphates from sources with high cadmium content that are used in the production of phosphate fertilisers.

In conclusion, it is not feasible to supply the EU market with phosphate fertiliser solely from igneous origins or from sedimentary phosphates with low cadmium content.

3.3.2. Decadmiation of phosphate rocks

Without a specific decadmiation treatment, the final fertiliser retains most of the original cadmium content of the phosphate rocks. So far, two decadmiation technologies have been developed at laboratory scale, which can be applied in production processes where phosphoric acid is an intermediate. Further details concerning the processes are contained in Annex XII.

Figure 4 contains a schematic representation of phosphate fertiliser production pathways. All currently known decadmiation processes can only be used for fertilisers being produced via the phosphoric acid route. Consequently, several EU manufacturers (BASF, Belgium; YARA, Norway; AMI, Austria; Azomures, Romania; Lovochemie, Czech Republic), who in order to address growing environmental concerns about the generation of gypsum wastes produced in the conventional phosphoric acid route have opted for the production of NP and NPK[37] fertilisers via the nitrophosphate route, are not in a position to use the known decadmiation technologies. Single superphosphate, double superphosphate, partially solubilised rock phosphate production which do not follow the phosphoric acid route can also not be decadmiated.

Based on overall cost structure (price of phosphoric acid, ammonia, sulphur and phosphate rock) and estimated decadmiation running costs between EUR 12-32/t P_2O_5[38] as suggested for one of the decadmiation processes, experts of the International Fertilisers Association (IFA) have estimated a possible price increase for phosphate fertilisers derived from sedimentary rock phosphate with high cadmium content in the range of 2 to 7 %. However, these economic figures must be considered with caution as the costs for decadmiation and their impact on fertiliser prices have not been confirmed at industrial scale. During the stakeholder consultation of October 2009, experts in decadmiation commented that the minimum increase in fertiliser prices would be most likely in the range of 5 to 15 %. The current state of development of the various technologies does not allow any certain prediction as to the future decadmiation costs (including the costs for a sound disposal of cadmium containing waste,

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36 Egypt (200 kt), Syria (1 100 kt) and Jordan (300 kt). Source EFMA.

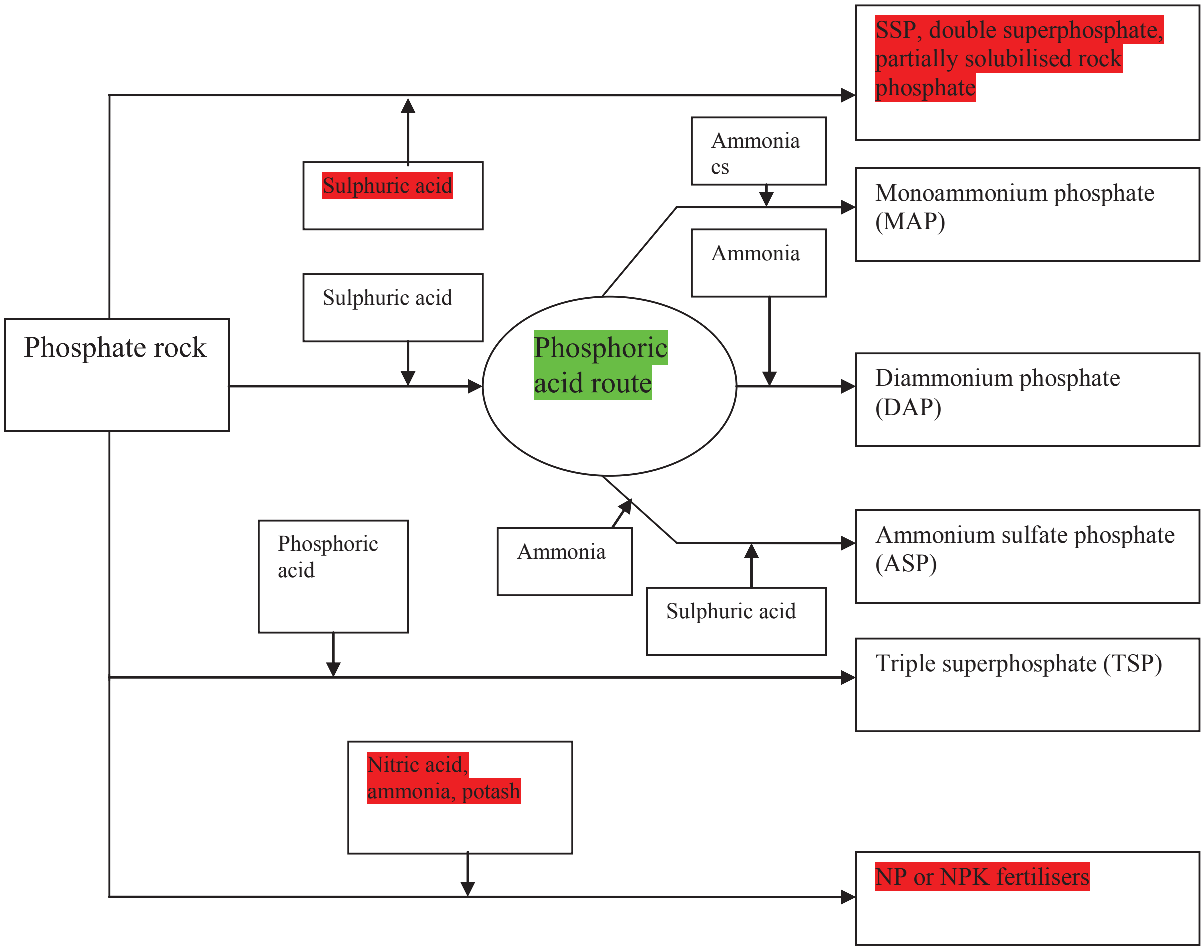
37 30% of the volume of NP and NPK fertilisers marketed in the EU follow the nitrophosphate route.

38 Exchange rate: EUR 1 = USD 1.25.

which would be generated as by-products) and the possible income from the marketing of added-value by-products (such as certain other heavy metals).

In any case, costs due to decadmiation would become a structural disadvantage for phosphate producers mining deposits with high cadmium content. Producers from Russia or Syria, Jordan and Egypt would have no decadmiation costs to bear since the cadmium content of their ores is (very) low. This would be different for producers based in Northwest Africa, which today produce the bulk of phosphates imported in the EU.

Figure 4: *schematic representation of phosphate fertiliser production pathways*



Decadmiation technology for high-quality phosphates for human and animal consumption, which are sold at much higher prices than phosphate fertilisers, is already in operation in two phosphate production plants in Tunisia[39] to reduce the level of cadmium impurities below very strict regulatory limits in food and feedstuffs. The development and installation of the technology came in response to this regulatory drive, in combination with the economic consideration that the additional cost due to decadmiation would still be preferable than a restriction of phosphate sources or export possibilities.

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39 *The precipitation process SIAPE is used by the Groupe Chimique Tunisien in Gabès and Skhira. Annual phosphoric acid production capacity: Gabès: 470 000 tons P_2O_5; Skhira: 375 000 tons P_2O_5. In October 2012, the Tunisian producer stated that the existing decadmiation process could be applied to the production of fertilisers at reasonable costs. This statement was unfortunately not confirmed later on.*

In conclusion, in the present circumstances, there is no reason why decadmiation for phosphate fertilisers would be developed on industrial scale: producers have not been required to do so, e.g. through the setting of limit values in important phosphates markets, neither is there a financial incentive as phosphate fertiliser prices are not correlated with cadmium content. Several attempts started earlier – probably in response to the long-standing debates in the EU for setting a limit in phosphate fertilisers – have not gone beyond laboratory scale. For example, in 1993, the EU signed a contract of ECU 1 million with CERPHOS for the development of a decadmiation process at laboratory scale. The results were positive, but CERPHOS was unwilling to develop a pre-industrial pilot plant without additional funding of ECU 7.5 million by the EU.

Further details concerning the state of development of the various processes and their future perspectives are contained in Annex XII.

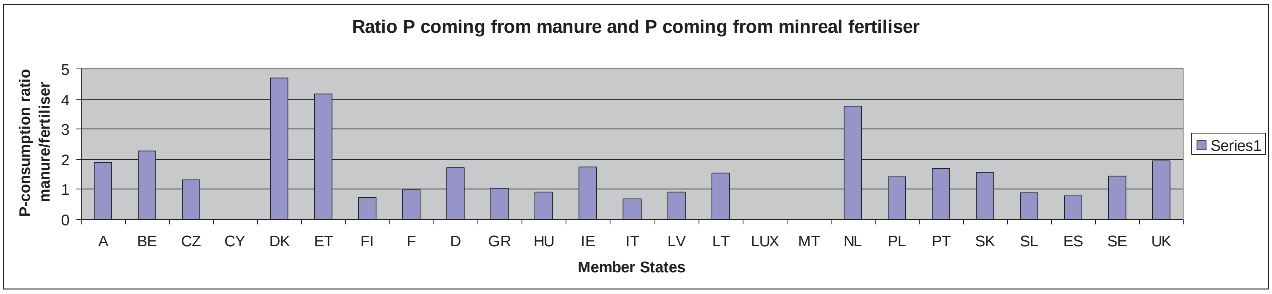
3.3.3. Organic fertilisers

Most experts estimate reserves of mineral phosphorous to last little more than one hundred years. The highest quality reserves will be depleted more rapidly and current use of phosphates is not in line with the principles of sustainable development (only 20 % of the phosphorous mined end up in crops).

Mineral phosphates are not the only possible source of this indispensable nutrient for plant growth. Manure and to a lesser extent sewage sludge and biowaste are potential sources of phosphorous. In fact, animal manure is the main source of phosphorous in the EU and 4.7 million tonnes of manure are applied as fertilisers annually in the EU[40].

Figure 5 illustrates that for 15 Member States out of 22 (no data available for Cyprus, Luxembourg, Bulgaria, Romania and Malta), the main source of phosphorous in agricultural land is manure. In Denmark, Netherlands and Estonia the amount of phosphorous coming from manure is more than three times that coming from mineral fertilisers – but those Member States have a surplus of manure due to the high density of animal farms – whereas in Finland, France, Greece, Hungary, Italy, Latvia, Slovenia and Spain, mineral phosphate fertilisers are the main source of phosphorous.

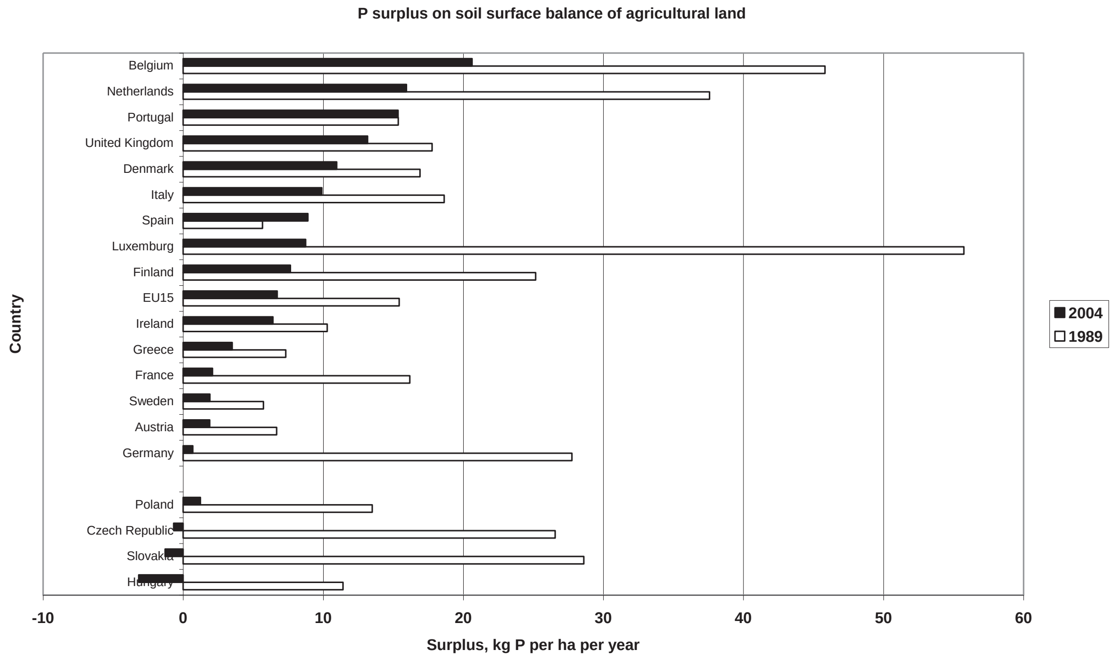
Figure 5: *ratio of the use of manure and mineral fertiliser in EU-25 (Source: Study addressing phosphorous related problems in farm practice. Soil Service of Belgium – 2005)*



Furthermore, among the 22 Member States, only the Czech Republic, Slovakia and Hungary have a negative balance in phosphorous as illustrated in Figure 6. The others have a phosphorous surplus which means that the input of phosphorous to soil is higher than the output.

40 *Richards, J.R. & D.J. Dawson (2008). Phosphorous imports, exports, fluxes and sinks in Europe. Proceedings 638, International Fertilizer Society. York, UK: 1-28.*

Figure 6: *phosphorous surplus in 1989 and 2004 (kg P per ha UAA (Utilised Agricultural Area) (Source OECD))*



In comparison to mineral phosphate fertilisers, a complete recovery of phosphate from organic fertilisers (e.g. manure, sewage sludge, and bio-waste) would also have the advantage of not increasing the overall cadmium mass present in the European ecosystem. Cadmium impurities in manure, bio-waste and, to a lesser extent, sewage sludge mainly come from food and feedstuffs produced in Europe which in turn contain cadmium absorbed from European soils.

EU environmental legislation has been the main driver for the development of phosphorous recovery technologies. Alternatives to mineral phosphate fertilisers in agriculture are promoted by several EU environmental instruments:

- Generation of energy from renewable sources[41] and use of remaining solid fractions as fertiliser. The characteristics of the end product are a function of the relative ratio between the different sources of organic wastes.
- The Sewage Sludge Directive has established the conditions to ensure a safe use of sludge on agricultural lands although the maximum limit values for cadmium therein are rather high. 16 Member States have adopted more stringent standards than those given in the Directive. Therefore the amount of sewage sludge applied on land is currently limited and represents only 40 % of the volume of sludge produced in EU-15 Member States.
- The Landfill Directive[42] requires Member States to progressively reduce landfilling of municipal biodegradable waste by 35 % in 2016 compared to 1995 which will instead be used for biogas production or compost. The Directive has led to a very significant increase in the recycling of bio-waste to produce biogas and nutrients for soil improving and agriculture.

[41] Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources. OJ L 140, 5.06.2009, p. 16-62.

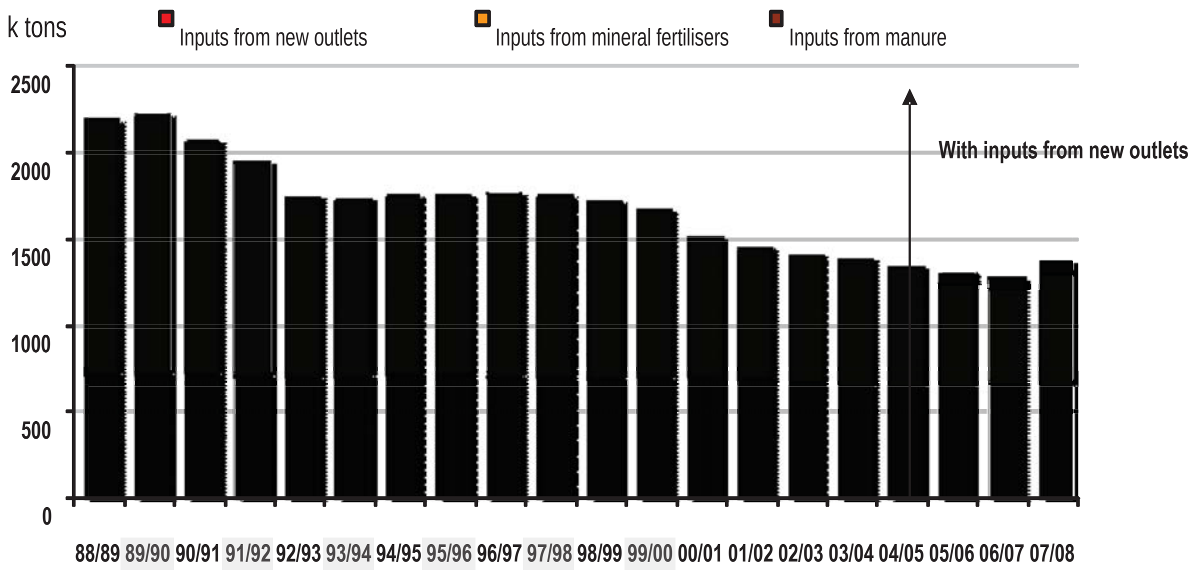
[42] Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste. OJ L 182, 6.07.1999.

- The Water Framework Directive which requires Member States to reduce discharge, emissions and losses of phosphorous in the environment.

Although many industrial phosphorous recovering technologies are already on-stream, there is no common strategy to promote the use of such renewable sources by farmers. The price of recycled fertilisers is commonly much higher than mineral phosphate fertiliser prices. Annex XIII contains further details on the various sources of phosphorous available in the EU and their relative efficiency in relation to mineral fertilisers, the cadmium content of those sources and a description of the EU fertiliser industry.

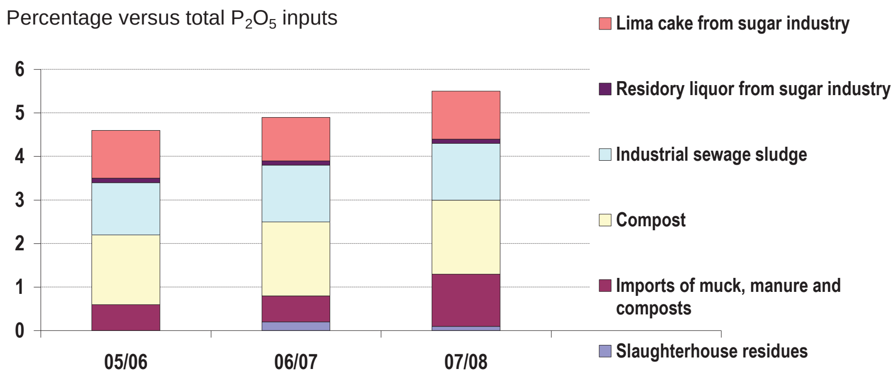
Possibilities to stimulate further substitution of mineral phosphates by alternatives have been examined by in the Commission Communication on future steps in bio-waste management in the EU[43]. Priority actions include rigorous enforcement of the targets on diverting bio-waste away from landfills (the Landfill Directive requires MS to progressively reduce landfilling of municipal biodegradable waste by 35 % in 2016 compared to 1995), proper application of the waste hierarchy and other provisions of the Waste Framework Directive to introduce separate collection systems as a matter of priority. Compost collection and treatment could substitute 10 % of phosphate fertilisers, 9 % potassium fertilisers and 8% of lime fertilisers. Supporting initiatives at EU level – such as developing standards for compost – will be crucial to accelerate progress.

Figure 7: *Total phosphorous inputs in France for the last 20 years (Source: UNIFA)*



[43] COM (2010) 235

Figure 8: *Inputs from new phosphate sources (versus total phosphorus inputs for the three last growing seasons – Source UNIFA)*



Still, whilst the need for mineral phosphates fertilisers is presently slightly decreasing, the complete recycling of phosphorous from organic fertilisers will not be able to replace them completely in the foreseeable future. In France, where fertilising patterns have been recorded for more than 20 years, the amounts of phosphorous coming from the recovery of manure and other organic inputs covered about 55 % of the French farmers' needs in 2008 as illustrated in Figures 7 and 8.

According to an Austrian Company active in the recovery and treatment of manure, sludge and slaughterhouse residues, more than 50 % of the current phosphate fertilisers imports could theoretically be replaced by recycled phosphates, if all available phosphate resources were managed sustainably (e.g. increase of biomass-to-energy technologies for manure) as a pathway to a more efficient use of phosphorous in the EU and a lesser reliance on mineral phosphate fertilisers imports. Today, this volume ends up in landfills, cement, ashes of power plants and waste incinerators.

The Commission has contracted work to a consultant to assess the sustainable use of phosphorus[44]. The result of this study will contribute to possible development and promotion of other alternatives to the current phosphate products provided that environmental and economical benefits emerge i.e. that the general characteristics (phosphorus and cadmium content) and prices of organic wastes fertilisers and mineral phosphate fertilisers are comparable.

In summary, whilst recycling of phosphates from organic waste will increase, it is not certain, that within the foreseeable future the available quantities will be sufficient to replace imports of mineral phosphates with high cadmium content.

3.4. Trade obligations and external relations

As explained in section 3.2, the majority of current EU imports of mineral phosphates originate in Northern Africa. Countries such as Morocco and Tunisia are covered by the European Neighbourhood Policy (ENP) which was developed in 2004 with the objective of establishing a deeper political relationship and economic integration between the EU and its

[44] HTTP://EC.EUROPA.EU/ENVIRONMENT/FUNDING/PDF/CALLS2009/SPECIFICATIONS_EN09025.PDF

immediate neighbours by land or sea. Measures taken in the EU with regard to phosphates, could potentially lead to strong reductions of phosphates exports to the EU, which are today significant sources of revenues (e.g. 20 % of the total Moroccan exports). This would be contrary to the ENP objectives.

Furthermore, the EU is a member of the World Trade Organisation (WTO) and bound by its rules. Consequently, any measures adopted to protect human health or the environment, must be the least trade-restrictive in order to achieve the intended objectives. All possible options therefore have to be assessed with regard to their compatibility with WTO obligations. The proposal accompanied by this impact assessment report will also be notified to the WTO under the TBT agreement, which will allow 3rd countries to comment.

3.5. Fragmentation of the internal market and administrative burden

Every Member State is concerned to a greater or lesser extent by the threat that accumulation of cadmium poses to the long-term sustainability of crop production. Twenty Member States have already introduced or intend to introduce rules limiting the cadmium content in national fertilisers under their obligations to reduce emissions of cadmium in the environment and thereby the cadmium exposure to humans. Depending on the Member State, between 30 to 40 % of total mineral fertilisers are marketed as national fertilisers.

Based on the former Article 95(4) of the EC Treaty (now Article 114 TFEU), the Commission has granted derogation to the free circulation of "EC fertilisers" to Austria, Finland, and Sweden[45] to apply national limits for cadmium also to "EC fertilisers". Such requests need to be accompanied by appropriate justification and the Commission has to take a decision within 6 months. This process constitutes significant administrative burdens for both Member States and the Commission. For example, efforts by the Czech Republic to provide appropriate justification for their intention to set a limit value also for EC Fertilisers at 50 mg cadmium/kg P_2O_5 have been ongoing for several years. When a first request was submitted in 2006, several Commission services have been involved in the examination in order to deal with it within the prescribed time period (including consultation of SCHER). Following the withdrawal of the request in the light of SCHER's negative opinion on the quality of the submitted justification, the Czech Republic has worked for more than a year with several experts on a re-submission, which has ultimately not happened, as an EU proposal is now expected instead.

The diversity of rules concerning the cadmium content of phosphate fertilisers marketed in the EU has a negative effect on the internal market of phosphate fertilisers which is more and more fragmented and fertiliser manufacturers have to be aware of and comply with an increasing number of diverging limit values, e.g. by sourcing appropriate raw materials and conducting the necessary quality analyses.

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45 Commission Decision 2006/349/EC of 3 January 2006 on the national provisions notified by the request of the Republic of Austria under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers. Cadmium limit: 75 mg cadmium/kg P_2O_5.
Commission Decision 2006/348/EC of 3 January 2006 on the national provisions notified by the request of the Republic of Finland under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers. Cadmium limit: 22 mg cadmium/kg P_2O_5.
Commission Decision 2006/347/EC of 3 January 2006 on the national provisions notified by the request of the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers. Cadmium limit: 44 mg cadmium/kg P_2O_5.

Furthermore, in accordance with Regulation (EC) No 764/2008 on mutual recognition[46], Member States are obliged to accept fertilisers lawfully placed on the market of another Member State unless they can demonstrate that there are specific reasons to the contrary. The cadmium content of mineral fertilisers can be used as an argument by competent authorities to refuse the marketing of products within their territories if their specific soil conditions require action. However, Member States authorities have limited resources for market surveillance and if they fail to notify their decision within the period foreseen in Regulation (EC) No 764/2008, products are considered as lawfully placed on the market, even though the Member States might have legitimate reasons to be more restrictive.

3.6. Regulatory failures

As a direct consequence of the EFSA report and the recommendations in the Risk Reduction Strategy, the Commission is envisaging revising the maximum levels for cadmium in food as set in Regulation (EC) No 1881/2006[47]. However, the setting of more stringent limits in food could become impossible as the cadmium content of foodstuff is dependent on soil cadmium concentration, which confirms the need for an overall action to reduce cadmium inputs to soils through the use of phosphate fertilisers.

Furthermore, limit values for national fertilisers can actually be circumvented by industry through marketing phosphate fertilisers as 'EC fertilisers', which benefit from the free movement clause in the current EU Regulation on fertilisers, except for the three Member States that have obtained derogation in accordance with Article 114 TFEU. The current EU legislation could thus be used to undermine the efforts of Member States who have set limits for national fertilisers to achieve a high level of protection of human health and the environment.

3.7. Who is affected, how and to what extent by the current situation?

In the current situation, fertilisers with high cadmium content can be used and the following stakeholders are affected:

– The general population for which current exposure is very close to the current safety limit recommended by EFSA. For some parts of the population current exposure might already exceed this safety limit twofold, and they are, therefore, at risk of unacceptable cadmium exposure via food with possible adverse effects in the longer term.

– The European fertilisers industry which, without a harmonised market for phosphate fertiliser, has to comply with different values for cadmium in the Member States and thereby faces extra compliance costs.

– Phosphate producing companies in third countries and the European fertiliser industry have no incentives to develop and implement decadmiation technologies at industrial scale, nor are there incentives to promote the recycling of phosphates as an alternative to mineral fertilisers.

46 Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member States and repealing Decision No 3052/95/EC. OJ L 218, 13.08.2008, p. 21.

47 Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. OJ L 364, 20.12.2006, p. 5-24.

- EU farmers have no information[48] on the cadmium content of EC phosphate fertilisers and are currently not able to take action to control cadmium inputs to agricultural soils.
- Food safety authorities have difficulties to implement safe maximum levels of cadmium concentration in foodstuffs without unduly restricting the supply of food commodities that are beneficial and essential for human health (fruit and vegetables, cereals…). The limits are set taking into account the recommended daily intake but also considering pragmatically the current load of contaminants in the environment.
- National public administrations in Member States having established limit values for cadmium in phosphate fertilisers to avoid soil contamination by cadmium have difficulties to enforce their limit values under their obligations on mutual recognition of 'national fertilisers' from other Member States and due to the possibility for the industry to circumvent the national rules by marketing fertilisers as 'EC fertilisers'.

3.8. How would the situation evolve if no action is taken?

In the longer term, cadmium levels in EU agricultural soils from phosphate fertiliser inputs would probably increase. The production of food complying with safe limit values for cadmium that would guarantee that the TWI recommended by EFSA would be respected in the EU could therefore become impossible, and certain sub-groups of the population would continue to be at risk.

Most soils would see an increase in cadmium concentrations, thus threatening soil functions and the aquatic environment. The objectives of the Water Framework Directive with regard to the chemical status of groundwater might also not be achieved.

EU farmers would not get any means to limit the cadmium input into their soils from mineral fertilisers.

The internal market for phosphate fertilisers would continue to be fragmented, with increasing tendency, as more and more Member States might take legislative action at national level and convergence towards lower limit values would not be a realistic outcome of the current situation. The European fertilisers industry would continue to face extra compliance costs. There would be no incentive for industry or phosphate producing countries to invest in decadmiation technologies or the technical recycling of phosphates from manure, sewage sludge and bio-waste.

Additional Member States wishing to set limit values for cadmium in EC fertilisers would have to request derogations based on Article 114(6) TFEU. This will create administrative burdens for the Member States – examples from the past have shown that gathering the necessary data requires significant resources – and for the Commission to evaluate and decide on the requests. National public administrations in Member States having established limit values for cadmium in phosphate fertilisers to avoid soil contamination by cadmium will have increasing difficulties to enforce their limit values under their obligations on mutual recognition of 'national fertilisers' from other Member States and due to the possibility for industry to market fertilisers as 'EC fertilisers' rather than national fertilisers.

[48] Only the Czech Republic authorities have introduced a mandatory labelling of the cadmium content of national mineral phosphate fertilisers.

3.9. The EU right to act

3.9.1. Legal basis

The legal basis of the proposal accompanied by this impact assessment is Article 114 of the Treaty on the Functioning of the European Union (TFEU). Article 114 has the objective to establish an internal market while ensuring a high level of protection of human health and the environment.

3.9.2. Subsidiarity and proportionality

Legislation relating to fertilisers is already partly harmonised by the Fertilisers Regulation: "EC fertilisers" complying with the requirements of that Regulation can circulate freely in the internal market and Member States cannot hamper their free movement based on their composition. If a Member State wants to impose limits to the content of cadmium in "EC fertilisers" used in their territory it has to request derogation based on Article 114(6) TFEU. So far, such derogations have been granted by the Commission to three Member States.

Many Member States have also introduced national rules limiting the cadmium content in national phosphate fertilisers, setting limit values that are widely diverging. However, in accordance with the recent legislation on mutual recognition, Member States would be obliged to accept fertilisers lawfully placed on the market of another Member State unless they can demonstrate that the fertilisers in question present a serious risk to the environment or human health.

Moreover, the Council in its Resolution of 25 January 1988[49] has explicitly called on the Commission to reduce inputs of cadmium into soils from all sources including diffuse sources such as phosphate fertilisers.

Consequently, Member States cannot achieve a functioning internal market for phosphate fertilisers by themselves. As a result of the stakeholder consultation, Member States support broadly the setting of a harmonised EU limit with the possibility by individual Member States to impose stricter limits or to gradually impose stricter EU limits under the condition that decadmiation technologies become available. Action at EU level to set an overall limit can, therefore, be considered proportionate.

4. OBJECTIVES

4.1. General objective

The general objective is to ensure a high level of protection of human health and the environment from the potential adverse effects of cadmium in phosphate fertilisers while ensuring a well functioning internal market for such fertilisers.

4.2. Specific objectives

- Reduction of cadmium inputs to European agricultural and pastoral soils, contributing to the overall reduction of cadmium inputs to the environment to supplement existing environmental legislation affecting several other industrial sectors.
- Reduction of the exposure of humans to cadmium through food ingestion.
- Reduction of the exposure of soil organisms and maintaining soil biodiversity which provide essential ecological services and are important elements of soil fertility.

[49] OJ C 30, 4.02.1988, p. 1.

- A secure and adequate supply of the EU from diverse sources of phosphate fertilisers at reasonable costs and minimisation of negative economic impacts on third countries and on EU farmers.
- Improvement of the functioning of the internal market for phosphate fertilisers through a reduction of the divergence of existing limit values for cadmium in such fertilisers. Harmonisation of cadmium limit(s)[50] is seen by most of the Member States as the only way to reduce the environmental problems caused by the mutual recognition of national fertilisers.
- Reduction of the burden for public administrations for developing and justifying national measures in the absence of harmonised measures at the level of the European Union.

The proposed objectives highlight that choices to reduce the exposure to cadmium are limited by constraints as regards trade obligations and external relations.

5. POLICY OPTIONS

5.1. Possible options which have been discarded at an early stage

5.1.1. Voluntary commitment by the fertiliser industry

Fertiliser manufacturers and importers could agree to establish voluntarily a limit value for cadmium in phosphate fertilisers and would then make only such fertiliser available on the EU market. Additionally, they could agree to work with farmers (or farmer associations) to reduce cadmium input to agricultural soils by implementing good agricultural practices.

In 2000, in an effort to avoid legislation, EFMA (today called “Fertilisers Europe”) members tried to adopt an overall upper limit of 60 mg cadmium/kg P_2O_5. In 2007, a survey on the cadmium content of phosphate fertilisers[51] showed that 21 % of phosphate fertilisers placed in the EU market are still exceeding the 60 mg cadmium/kg P_2O_5 limit (see also Figure 3).

Members of Fertilisers Europe cover only 60 % of the EU phosphate fertilisers market and full harmonisation by voluntary commitment is unlikely to be achieved for the whole sector.

Furthermore, those Member States that have already set legally binding limit values for national fertilisers (see Annex I) and in some cases also for EC fertilisers would most likely not modify these limit values when faced with a voluntary commitment by industry.

5.1.2. Setting directly an EU limit of 20 mg cadmium/kg P_2O_5 without intermediate steps

In the absence of a reliable and cost efficient decadmiation process at industrial scale, the immediate introduction of a limit of 20 mg cadmium/kg P_2O_5 would have disastrous economical consequences for almost all producing countries in Northern Africa and the Middle East (see section 3.2) who would be shut out of the European market, as their phosphate deposits contain significantly higher amounts of cadmium. It would thus be utterly incompatible with the ENP objectives. As these countries are the main suppliers of the European phosphates fertilisers market, sufficient supply of EU farmers at reasonable prices would be endangered. Whilst such a low limit value would be a very strong incentive to invest in decadmiation, the construction and operation of plants at industrial scale is yet unproven

50 A complete harmonisation would not take into account the diverging soil and climatic conditions among the Member States.

51 Nziguheba G., Smolders E. Inputs of trace elements in agricultural soils via phosphate fertilizers in European countries, Sci Total Environ (2007).

and will not be feasible in the short term. As a consequence, practically the entire EU supply would depend on one single phosphates exporting country, in the current circumstances Russia, which mines igneous rocks with low cadmium content. However, igneous rock, which is much harder, requires different machinery for transformation than softer sedimentary rocks. Most EU producers would have to invest heavily to modify their equipment and it is uncertain whether Russia will be able to increase its production to levels necessary to make up for the no longer available sedimentary rocks.

On the other hand, this option would be fully in line with the opinion of the SCTEE-2002 according to which a limit of 20 mg cadmium/kg P_2O_5 or less is not expected to result in long-term soil accumulation over 100 years. The ultimate goal of achieving a cadmium limit of 20 mg/kg P_2O_5 is, therefore, not discarded, but is part of option 4 (albeit with a longer timer horizon), which will be examined in full. Although there is still no firm and clear commitment from Third countries to invest in decadmaition, technical solutions are currently being investigated in Morocco. The Commission signed in 2012 a political agreement with Tunisia on raw materials. The developemnt of a decadmiation technology for the production of phosphate fertilisers was part of the deal.

5.2. Description of the examined options

5.2.1. Option 1: No action

The status quo would continue: no maximum limit for cadmium in phosphate fertilisers would be adopted at EU level (with the exception of the already existing limits for phosphate fertilisers authorised in organic farming). Member States having established limit values for national or EC phosphate fertilisers will maintain them, whilst others might do so in the future.

5.2.2. Option 2: Market incentives

Options based on market incentives include taxation of fertilisers on the basis of cadmium content, subsidies for low-cadmium containing fertilisers, quotas on imports and/or the use of fertilisers containing cadmium, or combinations of these elements. Adopting either of these options would in turn make decadmiation more attractive and send a market signal to that effect.

5.2.3. Option 3: A new Regulation setting an upper limit of 60 mg cadmium/kg P_2O_5 in phosphate fertilisers while allowing Member States to impose a limit value of 40 or 20 mg cadmium/kg P_2O_5 for the placing on the market and use depending on the conditions prevailing in their territories

The new Regulation would define a maximum level of 60 mg cadmium/kg P_2O_5 for the entire EU to enter into force after an appropriate transition period (e.g. 2 to 3 years) and Member States would be allowed to establish a lower limit by choosing from two possible values when there are reasons in the light of soil and climatic conditions. Fertilisers would be labelled with the information of whether they comply with the limit of 60 mg cadmium/kg P_2O_5 or 40 mg/kg, or 20 mg/kg, respectively.

Concerning the level of justifications to derogate from the 60 mg limit value, a formal notification under the procedures of Article 114(6) TFEU would no longer be necessary. A notification under Directive 98/34/EC on the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations[52] would be sufficient to inform the Commission and the other Member States.

5.2.4. *Option 4: A new Regulation setting a Community limit value for cadmium content in phosphate fertilisers at 60 mg cadmium/kg P_2O_5 decreasing over time to 40 and eventually 20 mg cadmium/kg P_2O_5, if decadmiation becomes available on industrial scale*

The new Regulation would set a Community upper limit for cadmium in phosphate fertilisers at 60 mg cadmium/kg P_2O_5 after an appropriate (e.g. 2 to 3 years) transition period.

Five years after the end of the transition period, the Commission would reassess the technical and economic feasibility of decadmiation, taking into consideration the socio-economic aspects but also the need to protect the EU citizens against cadmium inputs in the environment. If considered feasible and proportionate, the upper limit value would be decreased to 40 mg cadmium/kg P_2O_5 and, after a further review at a later point in time, would be decreased to 20 mg cadmium/kg P_2O_5.

The three Member States who have been granted derogations to apply national limits for the cadmium content of phosphate fertilisers would continue to benefit from them until an equivalent level is reached by EU action. Other Member States wishing to reduce the cadmium inputs to agricultural land will have to request derogation under Article 114(6) of the TFEU as long as the EU level stays higher as what they consider necessary for their territories.

5.2.5. *Option 5: A new Regulation setting an upper limit of 40 mg cadmium/kg P_2O_5 in phosphate fertilisers while allowing Member States to set a limit value of 60 or 20 mg cadmium/kg P_2O_5 for the placing on the market and use depending on the conditions prevailing on their territories*

This option would be similar to Option 3 except that the normal upper limit for cadmium in phosphate fertilisers would be set at 40 mg cadmium/kg P_2O_5 after an appropriate transition period (e.g. 2 to 3 years). By way of derogation, Member States would be allowed to opt for setting a higher limit of 60 mg cadmium/kg P_2O_5 or a lower limit of 20 mg cadmium/kg P_2O_5 throughout their territories where acceptable or necessary in the light of prevailing soil and climatic conditions. Fertilisers would be labelled with the information of whether they comply with the limit of 40 mg cadmium/kg P_2O_5 or 60 mg, or 20 mg, respectively, as foreseen for Option 3.

As explained in Option 3, Member States wishing to derogate from the 40 mg limit value would have to inform the Commission and the other Member States of their decision by using Directive 98/34/EC on the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations.

6. IMPACT ANALYSIS

Effects of the various policy options on food prices will not be analysed in the assessment, as for end-consumers, the estimated costs increase due to higher costs for low cadmium content fertilisers would be negligible because cultivated products are mostly commodities, i.e. easily

[52] OJ L 204, 21.07.1998, p. 37-48.

tradable and therefore prices are defined by the overall market situation rather than on an "additional cost" basis[53].

6.1. Option 1: No action

Risks to human health and the environment from cadmium in fertilisers depend very much on soil properties, agricultural practices and dietary habits, which vary significantly between the Member States. They are therefore well placed to determine which limit values would be the most appropriate for them. As mentioned before, 20 Member States have already set or intend to set limit values for national fertilisers placed on their markets. Three Member States (Sweden, Finland and Austria) have obtained authorisation under Article 114 TFEU (the former Article 95 of the Treaty) to set limit values also for EC fertilisers at 44, 22, and 75 mg/kg P_2O_5, respectively.

In the absence of an EU limit of cadmium content in phosphate fertilisers and if not all Member States take action to set appropriate limit values, there is a risk that in the longer term, cadmium levels in EU agricultural soils from phosphate fertilisers inputs would increase. Furthermore, national limits apply only to national fertilisers, which on average make up between 30 and 40 % of total consumption in the Member States. In the absence of an EU limit, there would be a risk that phosphate fertilisers with high cadmium content will be sold primarily in those Member States not setting limit values, leading to faster cadmium accumulation in their agricultural soils with possible adverse consequences on the cadmium content in food, groundwater and surface water. Sub-groups of the population would continue to be at risk. The long term preservation of soil functions and the protection of soil biodiversity would be in jeopardy. The objectives of the Water Framework Directive with regard to the chemical status of groundwater might also not be achieved.

According to a recent report from the Commission on the implementation of the Nitrates Directive[54], the consumption of mineral phosphorous fertilisers has gone down by 9 % in the EU-15 in the reporting period 2004 to 2007 and by only 1 % for the EU-27 as compared with the last reporting period (2000-2003). According to earlier forecasts by Fertilisers Europe, the EU-27 consumption of mineral phosphate fertilisers could fall by 4.3 % over the next ten years which in turn will lead to reduced cadmium input regardless of the introduction of regulatory cadmium limit values (by either Member States or the EU). However, in the light of the available information, it is not possible to conclude that this decrease in overall consumption of phosphate fertilisers would be sufficient to stop or reverse cadmium accumulation from mineral fertilisers. Conversely, growing food production needs and decrease in available production areas from urban sprawl or competition with bio-fuel production may cause a reverse trend in mineral phosphate consumption. In fact, in its latest forecasts in the 2009 Annual Report, Fertiliser Europe notes that for the first time in several decades an increase of 3.9 % in the consumption of mineral phosphates fertilisers is expected for the next ten years, with significant growth in Sweden, Spain and the UK.

Impacts on industry, producing countries – and hence the secure and adequate supply of phosphates – as well as farmers would be limited in the short-term and there would be no

53 For example, high food prices during 2007/2008 were mainly caused by a drastic reduction of worldwide cereals stocks and not necessarily by higher fertiliser prices, which had raised in line with energy and raw material costs.

54 Report on the implementation of Council Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources based no member States reports for the period 2004-2007 (HTTP://EC.EUROPA.EU/ENVIRONMENT/WATER/WATER-NITRATES/PDF/COM_2010_47.PDF).

particular incentive to invest in decadmiation. However, impacts could increase if more and more Member States introduced different limit values – in particular if those limit values cannot be met by the main producing countries without decadmiation. Fragmentation of the internal market would increase and EU industry would have to adapt to a multitude of different limit values applicable in various Member States which would create additional compliance costs, e.g. for sourcing appropriate raw materials, supply chain management, and conducting the necessary quality analyses.

Member States wishing to introduce more stringent limit values for cadmium in EC fertilisers would have to ask for authorisation by the Commission in accordance with Article 114 (5) of the Treaty on the Functioning of the European Union (TFEU), which would create significant administrative burdens as described in section 3.5. Likewise, correct implementation of Regulation (EC) No 764/2008 on mutual recognition might be a problem for Member States wishing to enforce existing low national cadmium limits, as they will have to justify refusal of placing on the market of national fertilisers with higher cadmium content that are lawfully placed on the market in Member States having established higher limits or no limits at all. In addition, limit values for national fertilisers could be circumvented by industry through marketing phosphate fertilisers as 'EC fertilisers', as described in section 3.6.

Conclusions:

This option would not achieve most of the intended objectives, as neither the input of cadmium into soils through mineral fertilisers, nor the uptake of cadmium by crops and human exposure to cadmium through the diet would be significantly reduced, unless all Member States adopted appropriate national limits. However, not all Member States have taken action to reduce cadmium inputs from the use of national fertilisers and only three Member States have obtained derogation for EC fertilisers.

Conversely, if more and more Member States introduced specific cadmium limits, the internal market would be more and more fragmented and the EU fertilisers industry will have to meet a multitude of cadmium limits leading to additional compliance costs.

There would be no immediate impacts on the security of supply. No action at EU level would lead to significant administrative burdens for Member States authorities in relation with their obligations concerning Regulation (EC) No 764/2008 on mutual recognition, or for requesting derogation under Article 114 TFEU and for the Commission to decide on such requests.

6.2. Option 2: Market incentives

Currently, prices of phosphate fertilisers do not reflect their cadmium content. Consequently, there are no price signals giving incentives to manufacturers or farmers to increase the share of phosphates with low cadmium content. Moreover, the supply of phosphates with a low cadmium content is limited (see section 3.3.1), whilst decadmiation during the production process is associated with certain costs and is currently unavailable at industrial scale (see section 3.3.2 for details).

There are different sub-options to provide market incentives for increasing the use of low-cadmium containing phosphate fertilisers, and their impacts will be analysed separately. Adopting either of these options would in turn make decadmiation more attractive and send a market signal to that effect. Numerical examples will illustrate how high a tax (or conversely a subsidy) would need to be to compensate for the additional costs of decadmiation.

6.2.1. *Sub-option A: Fiscal incentives for stimulating substitution of current mineral phosphate fertilisers with suitable alternative sources or for creating a separate market for low-cadmium mineral phosphate fertilisers*

This option has been studied by Oosterhuis et al.[55] who examined charges of EUR 1.00 per gram of cadmium per ton of fertilisers applied across the board, or charges of EUR 0.25 per gram of cadmium per ton of fertiliser applied to fertilisers with more than 60 mg cadmium per kg P_2O_5 in combination with lowering the latter threshold to 40 mg/kg after two years and to 20 mg/kg after four years. Member States would in all cases be able to impose higher charges nationally to reflect different soil characteristics and other national circumstances. The purpose of a tax would be to incentivise users of high-cadmium fertilisers to switch to organic or low-cadmium mineral fertilisers. The purpose would not be to raise revenue.

In terms of benefits, the perceived tax revenues could theoretically be redistributed to the farming and fertiliser industries (in the form of support for developing decadmiation technologies, training and awareness raising for farmers, etc.), although based on the experience in other areas, it is more likely that the revenues will become part of the general Member States budgets. The sub-option is potentially easy to implement and run, as a tax system would impose limited additional administrative burden on users, producers and importers.

Provided the tax level would be set at the appropriate level so that decadmiation becomes advantageous above a certain cadmium content (see section 6.2.5 and Annex XIV), the overall reduction of cadmium content in phosphate fertilisers (and hence the input into agricultural soils) would be comparable to that achieved by setting a regulatory limit value. These are further examined in sections 6.3, 6.4, and 6.5.

Two critical parameters for the success of this sub-option are the price and substitution elasticities of phosphate fertilisers. Estimates in existing literature suggest that the demand for phosphate fertilisers has low price elasticity, around 0.1 in absolute terms[56]. Therefore even doubling the price by imposing a tax of 100 % would only reduce demand by about 10 %. Substitution elasticities appear to be slightly higher in absolute terms, meaning that the purpose of making users shift to organic or low-cadmium mineral fertilisers would be achieved to a greater extent by the introduction of a tax than the purpose of reducing the overall use of fertilisers.

On the other hand, taxation of phosphates containing high levels of cadmium would push up demand for low-cadmium mineral phosphate fertilisers, the demand for which may exceed maximum production capacity in the absence of viable decadmiation technology at industrial scale. If technical, economical or social constraints would not allow an increase in the use of untapped sources of organic phosphorous (e.g. from biowaste or sewage sludge), overall prices would thus go up and constitute a burden on EU farmers. Taxation of phosphates with high cadmium content would sour relations between the EU and (mainly African) exporting countries. There could be stockpiling of high-cadmium fertilisers in anticipation of the tax and

[55] A possible EU wide charge on cadmium in phosphate fertilisers: economic and environmental impacts". Final report to the European Commission, April 2000 (Report no E-00/02).

[56] Low price elasticity is confirmed by recent data for the growing seasons 2007/2008 and 2008/2009: Despite a very strong price increase in the season 2007/2008 (prices for some fertiliser types almost tripled – see Annex X), consumption of phosphate fertilisers showed only a small decrease in line with long-term trends. However, in the season 2008/2009, prices went down strongly but consumption in EU-27 actually dropped by 40 % (according to the 2009 Annual Report of Fertilisers Europe) due to difficulties for farmers to have access to finance.

there would be a risk of illegal imports to avoid the tax. EU-wide taxes would not reflect the true externalities of cadmium in fertilisers, which can vary regionally or even locally depending on different soil characteristics. Last but not least, unanimity in the Council would be needed for the adoption of any legal act on EU cadmium taxes.

The existing fragmentation of the internal market would not be reduced. Member States wishing to maintain or introduce more stringent limit values for cadmium in EC fertilisers would have to ask for authorisation by the Commission in accordance with Article 114(4) or (5) of the Treaty on the Functioning of the European Union (TFEU), which would create significant administrative burdens as described in section 3.5. Likewise, correct implementation of Regulation (EC) No 764/2008 on mutual recognition might be a problem for Member States wishing to enforce existing low national cadmium limits, and limit values for national fertilisers could be circumvented by industry through marketing phosphate fertilisers as 'EC fertilisers', as described in section 3.6.

6.2.2. Sub-option B: Subsidies for the use (or production) of suitable alternatives to high-cadmium mineral phosphate fertilisers

This sub-option would involve rewarding users (or producers) financially when purchasing (producing) any fertilisers (including those with organic phosphorous) defined as preferable to mineral phosphate fertilisers with high cadmium content. The purpose would be to use the price mechanism to steer consumption (production) away from fertilisers with high cadmium content, but not to reduce overall use of fertilisers.

As virtually all phosphates producers are located outside the EU (apart from a modest production in Finland), giving financial support to producers would mean channelling public funds from the EU into the fertiliser industry in non-EU countries, which is probably politically difficult. Financial support to users can be given either at the point of purchase (the user would pay only part of the price, the remainder being covered by the subsidy) or *ex-post*, for instance annually in the form of tax credits. In the latter case the user would pay the full price at the point of purchase and be compensated later.

There would be a shift from non-subsidised fertilisers with high cadmium content to subsidised fertilisers, within the limits of availability of fertilisers with low cadmium content. This sub-option is likely to appeal more to users than taxation. If combined with a tax on fertilisers with high cadmium content, the revenues from the tax could be returned to the user community in the form of subsidies.

On the other hand, it is also possible that due to the limited availability of low cadmium-containing phosphates, producers would increase their profit margins on subsidised fertilisers in order to get a share of the subsidy. Provided the subsidy would be set at the appropriate level so that decadmiation becomes advantageous above a certain cadmium content (see section 6.2.5 and Annex XIV), the overall reduction of cadmium content in phosphate fertilisers (and hence the input into agricultural soils) would be comparable to that achieved by setting a regulatory limit value. These are further examined in sections 6.3, 6.4, and 6.5.

As for sub-option A, the fragmentation of the internal market and the administrative burden related to maintaining or setting limit values in the Member States and those related to mutual recognition would persist. The entire system would be difficult to administrate and run, and there would be a high risk of fraud. The actual amounts of the subsidies are difficult to calibrate to different soil characteristics.

6.2.3. *Sub-option C: Quotas on imports of mineral phosphate fertilisers with high cadmium content*

Import quotas on fertilisers with high cadmium content would limit their availability in the EU, thereby pushing up prices to the point where the demand of the users with the highest willingness to pay for such fertilisers would match the limited supply. Users with insufficient willingness to pay would be excluded from the market for fertilisers with high-cadmium content and would need to turn to organic or mineral fertilisers with low cadmium content, the prices of which would also go up as a result.

As a consequence, the overall amount of phosphates with high cadmium content imported and used in the EU would go down. Provided the quotas could be set at the appropriate levels so that decadmiation becomes advantageous above a certain cadmium content (see section 6.2.5 and Annex XIV), the overall reduction of cadmium content in phosphate fertilisers (and hence the input into agricultural soils) would be comparable to that achieved by setting a regulatory limit value. These are further examined in sections 6.3, 6.4, and 6.5.

However, import quotas would probably fall foul of WTO rules and would be detrimental to relations between the EU and (mainly African) exporting countries. It would be extremely difficult to calculate appropriate quotas – balancing the overall needs of EU agriculture, the different soil characteristics that vary on regional and even local scale, and the availability of low cadmium-containing phosphates. All users and some producers would suffer welfare losses. There is a risk of stockpiling of fertilisers with high cadmium content in anticipation of the quotas and of illegal imports to circumvent them.

As for sub-option A, the fragmentation of the internal market and the administrative burden related to maintaining or setting limit values in the Member States and those related to mutual recognition would persist.

6.2.4. *Sub-option D: Quotas on the use of mineral phosphate fertilisers containing cadmium*

In analogy to the European emissions trading scheme for greenhouse gas emissions, "cadmium permits" could be distributed to users of fertilisers in relation to the size of the productive farming area and taking into account its soil characteristics. Users could choose to use several permits at once to buy fertilisers with high cadmium content, fewer permits to buy fertilisers with low cadmium, or no permits at all to buy organic fertilisers or 'recycled phosphates' with low cadmium content. Users running out of permits would need to either buy additional permits or refrain from buying mineral phosphate fertilisers. Users with more permits than needed would be able to sell them on a special exchange. Member States would be able to control the total number of permits and the use of cadmium, by buying or selling on the exchange and by limiting the validity of permits so that they expire after a number of years and then issue new permits, possibly in smaller numbers.

The scheme would guarantee a genuine market equilibrium in which the users with the highest marginal benefit of high-cadmium fertilisers end up using the permits. Assuming that the number of available permits is such that all permits will be used, Member States would be able to calculate with accuracy the actual total use of cadmium and fine-tune it by making available fewer (or more) permits. In calculating the amount of permits, it would be possible to take account of different soil qualities.

However, the development and administration of such a permit system would potentially be very burdensome and expensive. It would impose a heavy administrative burden on participants. In fact, the latest draft internal proposal discussed in the Commission in 2005 foresaw the labelling of phosphate fertilisers as being in one of three classes (up to 20, 40, 60 mg/kg, respectively) and the possibility that Member States designate 'vulnerable zones' according to certain criteria and that in these zones only fertilisers with low cadmium content could be used. However, this was rejected by many other Directorates-General as too bureaucratic, complicated, and unenforceable. Furthermore, due to inelastic demand the market for permits may not work. There is a risk of stockpiling of fertilisers with high cadmium content in anticipation of the trading scheme, illegal imports to circumvent it, and a high risk of fraud.

In line with the total amounts of permits, the overall cadmium input into agricultural soils will decrease, but it is not possible to forecast, whether this will lead to reduced exposure of humans and the environment, as farmers, who should use low-cadmium containing fertilisers in the light of the soil characteristics on their farms and/or the plants they wish to grow, would still be able to buy permits and high-cadmium containing phosphates. As for sub-option A, the fragmentation of the internal market and the administrative burden related to maintaining or setting limit values in the Member States and those related to mutual recognition would persist.

6.2.5. Incentives for investing in decadmiation

Decadmiation is expensive to invest in, which is one reason why no full-scale industrial decadmiation plants have been built so far for the production of fertilisers. Moreover, the two existing technologies that could be cost-effective have not yet been proven feasible at industrial scale. However, given the right incentives, using one of the four sub-options outlined above, producers may decide it makes business sense to make the investment. Changing circumstances such as a breakthrough in decadmiation technology would have the same effect.

In the case of an incentive for decadmiation in the form of a tax on fertilisers with high cadmium content, Oosterhuis et al. showed that under a set of simplifying assumptions[57], investing in decadmiation can be profitable. Building on that approach, an analysis is made in Annex XIV, in which a simple tax is introduced that needs to be paid on every gram of cadmium per ton of phosphate fertiliser brought on the EU market. Every producer of phosphate fertilisers then has to decide whether it is cheaper to pay the tax or to decadmiate the phosphates in the fertiliser production process, which costs money but also leads to tax savings.

In this model, for a given cost of the decadmiation technology, it is possible to calculate the tax rate that induces producers to decadmiate phosphate fertilisers above a certain desired threshold (in terms of cadmium content), while for phosphate fertilisers below the threshold it is cheaper to pay the tax. In summary, the lower the desired threshold is, the higher the tax rate needs to be.

Data for the two most-promising decadmiation technologies (CERPHOS and ELICAD) have been used in order to estimate which tax rates would be required per gram of cadmium in order to provide the appropriate incentives for decadmiation. For a full description of the model, the data used, the results and some sensitivity analysis, please refer to Annex XIV.

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[57] Note that the model may be over-simplified and that the results therefore need to be interpreted with care.

Figure 9 compares the most promising decadmiation technologies in terms of tax effect to stimulate decadmiation for the cadmium content in the phosphate fertilisers (using the data with regard to cadmium content from Figure 3). Figure 10 illustrates the effect of a tax on the average cadmium content of phosphate fertilisers (using the data with regard to cadmium content from Figure 3). For the ELICAD process, tax effects have been calculated on the basis of estimated low and high operative costs.

The main conclusions are that:

1. The necessary tax rate depends on several essential parameters that characterise a decadmiation technology (notably costs, process effectiveness and production capacity). The two technologies examined produce different results (see figure 9): a tax rate of EUR 0.5 has a break-even for Cerphos at around 57 mg cadmium whereas the same tax rate would provide a break-even between 37 to 44 mg cadmium for Elicad depending on its final operative costs.

2. The sensitivity analysis (see Annex XIV) shows that the effectiveness of the decadmiation process (how much cadmium can be removed by it) is the most important factor, while various other parameters do not significantly change the results for a given technology. The choice of the discount rate is also important.

Figure 9: Comparison Elicad/Cerphos. Break-even between tax and cost of decadmiation

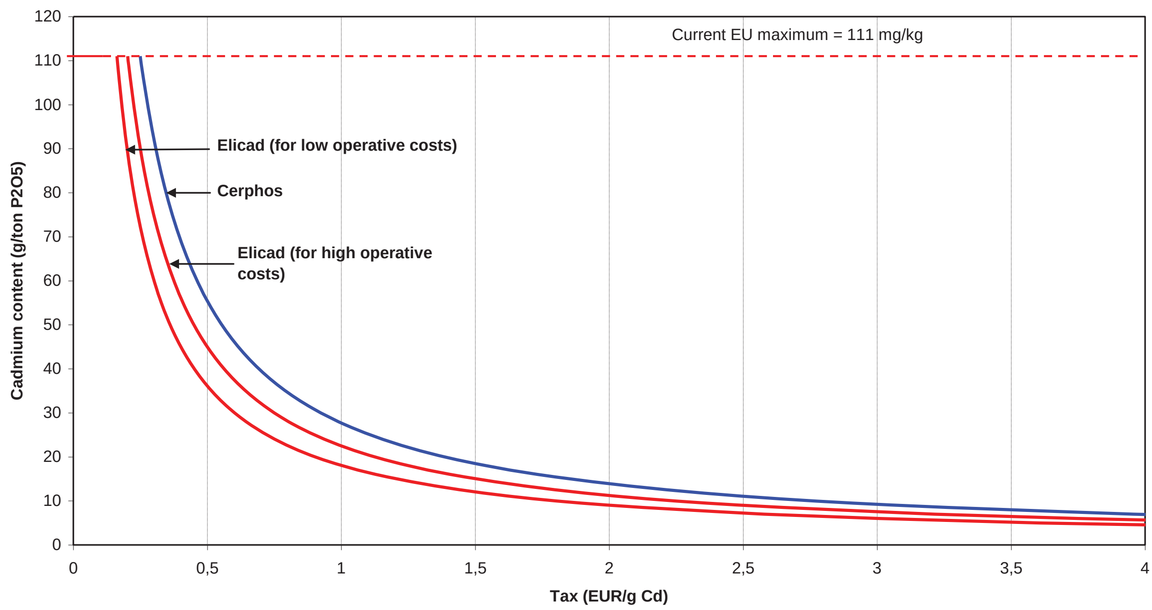
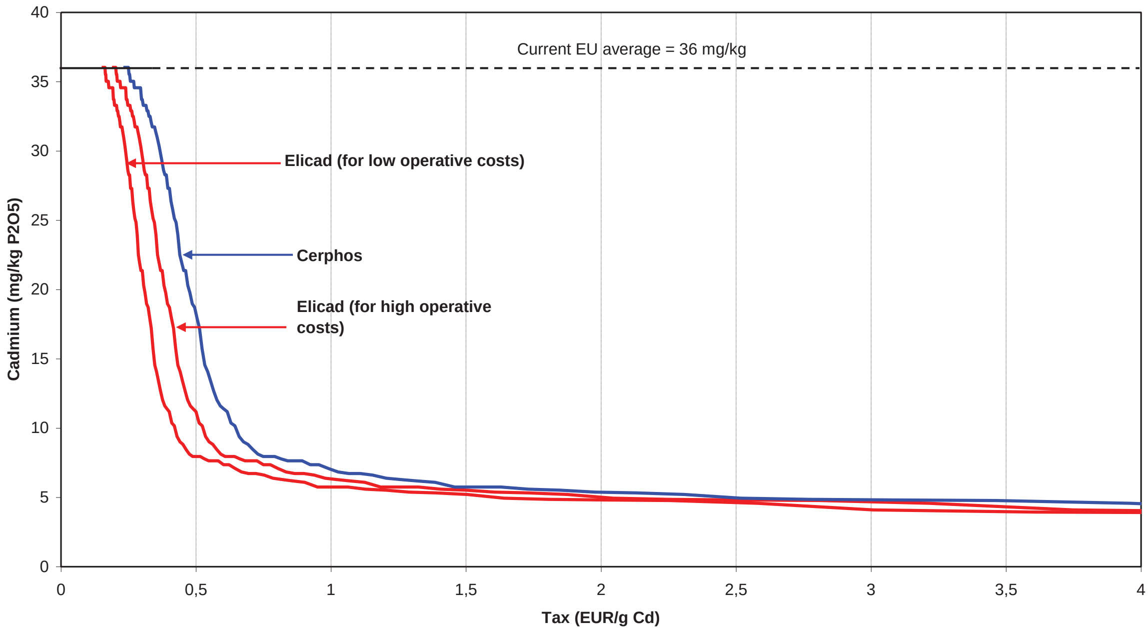


Figure 10: Comparison Elicad/Cerphos. Effect of tax on average Cd content



Based on the figures presented in Figure 9, an estimation of the level of the tax needed to stimulate decadmiation for a given desired limit can be made as well as its influence on the increase of fertilisers costs.

Results for the ELICAD process:

Desired maximum cadmium content per ton of fertiliser [g/ton]	Tax per gram of cadmium [EUR/g] for lower cost estimate	Tax per gram of cadmium [EUR/g] for higher cost estimate
60	0.3	0.37
40	0.45	0.56
20	0.90	1.12

Irrespective of the threshold chosen, this would increase the price of a ton of fertiliser close to or slightly above the desired threshold by approximately EUR 18 to 22.5 (sum of decadmiation costs and tax to be paid on remaining Cd content), which at a price of USD 250 per ton – a price observed during much of 2007 – and an exchange rate of USD 1.25 per EUR would correspond to an increase of 9 to 11 %. If the initial Cd content is higher, the price increase would also be higher – for example for an initial content of 100 g Cd/ton phosphate, the increase would be 10-16 % (See Annex XIV for details).

Results for the CERPHOS process:

Desired maximum Cadmium content per ton of fertiliser [g/ton]	Tax per gram of cadmium [EUR/g]
60	0.5
40	0.7
20	1.4

Irrespective of the threshold chosen, this would increase the price of a ton of fertiliser close to or slightly above the desired threshold by approximately EUR 28 (sum of decadmiation costs and tax to be paid on residual Cd content), which at a price of USD 250 per ton – a price observed during much of 2007 – would correspond to an increase of 14 %. If the initial Cd content is higher, the price increase would also be higher – for example for an initial content of 100 g Cd/ton phosphate, the increase would be 15-20 % (See Annex XIV for details).

The same results can be used to determine the required subsidies – as an alternative to a tax. The available information does not allow to model the system of quotas and/or permits, which would make decadmiation financially attractive.

Conclusions:

At least two of the sub-options (taxation or subsidies) have the potential to stimulate investment in decadmiation and provided the taxes/subsidies could be set at the appropriate levels, the overall reduction of cadmium content in phosphate fertilisers (and hence the input into agricultural soils) would be comparable to that achieved by setting a regulatory limit value.

However, politically it will be rather impossible to get unanimity in the Council for the adoption of a tax or subsidies at EU level. All sub-options will have significant impacts on farmers – in fact decadmiation (triggered by taxation) and paying the tax on the remaining cadmium content will lead to significant price increases – for phosphates containing originally 100 mg cadmium/kg P_2O_5 from about 10 to 20 % for the ELICAD or CERPHOS processes which would be passed on as additional costs to farmers – see Annex XIV for details. If the raw material contains more cadmium, or if the efficiency of the decadmiation process is lower than assumed, price increases would even be higher, while they would be lower for raw material containing less cadmium or for more efficient decadmiation processes.

There would also be potentially negative effects on phosphates producing countries (in particular if their deposits contain high cadmium levels) and security of supply. None will lead to a reduction of the fragmentation of the internal market, nor to a reduction of administrative burdens linked to Article 114 requests for derogation or mutual recognition, as Member States will keep their legislation setting limit values (or introduce new one). Quite on the contrary, there will be additional administrative burdens to introduce and administer the sub-options, which will be particularly high for a system of import quotas or tradable permits.

6.3. Option 3: A new Regulation setting an upper limit of 60 mg cadmium/kg P_2O_5 in phosphate fertilisers while allowing Member States to impose a limit value of 40 or 20 mg cadmium/kg P_2O_5 for the placing on the market and use depending on the conditions prevailing in their territories

An EU limit of 60 mg cadmium/kg P_2O_5 combined with the possibility for Member States to set a lower limit at either 40 or 20 mg cadmium/kg P_2O_5 will lead to some reduction of new cadmium input into soils. However, it is uncertain whether this will result in a significant decrease in soil cadmium accumulation and hence lower cadmium levels in food since the SCTEE-2002 considered that in most European soils, cadmium accumulation will likely continue if a 60 mg cadmium/kg P_2O_5 limit was implemented. On the other hand, the flexibility foreseen in this option as an element of subsidiarity will allow Member States to opt for limit values at either 40 or 20 mg cadmium/kg P_2O_5 in the light of prevailing conditions and it would therefore not be totally inconsistent with the SCTEE-2002 opinion.

As already set out in section 3.2, the actual cadmium content of the fertilisers placed on the market in the EU is not well studied, and it is therefore difficult to quantify the reduction in new cadmium input into agricultural soils that this option would entail. Phosphate fertilisers with cadmium concentrations higher than 60 mg cadmium/kg P_2O_5 could no longer be marketed in the EU and would be replaced by others with lower cadmium content. It is not possible to know precisely the cadmium content of the phosphate fertilisers that would replace the prohibited quantities with cadmium content above 60 mg/kg P_2O_5, but this will have a strong influence on the reduction that can be achieved. On the basis of the data contained in Figure 3, which are, however, not necessarily representative for the EU, the introduction of an upper limit at 60 mg cadmium/kg P_2O_5 could reduce the annual input of cadmium on EU agricultural soils by around 30 % if all fertilisers with cadmium content above the limit were to be replaced by fertilisers with a cadmium content of 25 mg cadmium/kg P_2O_5 (which is the average of those currently on the market below 60 mg cadmium/kg P_2O_5). However, if all replacement quantities had a cadmium content of exactly 60 mg cadmium/kg P_2O_5, the overall cadmium reduction would only be at around 10 %, whereas replacement with phosphates at 0 mg cadmium/kg P_2O_5 would lead to an overall reduction of 45 %. Further details of the analysis are contained in Annex XV.

In terms of impacts on third countries, the main supplier of phosphates to the EU, Morocco, has a number of different mines, each with different average cadmium content, and the fertilisers produced from these mines also have different cadmium contents (see Annexes IX and X). The deposits within each mine are several meters thick and are layered rather uniformly. Some of these layers have higher cadmium content than others. By selective use of certain mines (e.g. Khourbiga) and/or of certain layers within a deposit, an upper limit of 60 mg cadmium/kg P_2O_5 appears to be feasible for Moroccan phosphate producers on the scale needed to supply the EU market for the foreseeable future without the need for decadmiation. In fact, selective mining for quality purposes in relation to P_2O_5 content is already in place in a majority of mines. Further sedimentary phosphates with low cadmium content are available in Syria, Jordan and Egypt. Thus, sufficient production capacity of sedimentary rock with cadmium content at or below 60 mg cadmium/kg P_2O_5 from existing sources seems to be available, and a significant increase of rock price is unlikely. Some smaller phosphate producing countries in Africa, such as Togo and Senegal, where cadmium content in phosphates is higher than 60 mg kg P_2O_5, would face difficulties – however, for more than 10 years there have not been any exports to the EU from these countries.

Consequently, the European fertiliser industry could meet an upper limit of 60 mg cadmium/kg P_2O_5 using their current supply chains without decadmiation through the selective mining and blending of sedimentary phosphate rock deposits with appropriate cadmium content. The European Standard EN 14888[58] has been developed to determine the cadmium content of fertilisers. The related analytical costs are around EUR 60 per sample.

16 out of 26 European SMEs consulted on the potential impacts of the different policy options developed in this impact assessment (except Option 2) reported that the economical impacts would be smallest if a cadmium limit of 60 mg cadmium/kg P_2O_5 was to be adopted. A more stringent limit would inevitably make the supply of adequate sources of phosphate fertilisers and the management of the different stocks of raw material more problematic. Annex IV provides details of the SMEs consultation.

58 Determination of cadmium content by flame atomic spectroscopy (AAS) and by inductively coupled plasma-optical emission spectroscopy (ICP-OES) after extraction in nitric acid.

Labelling fertilisers with the cadmium content could be a measure to facilitate enforcement of limit values and would increase awareness of farmers about the cadmium content of fertilisers. So far, only one Member State having introduced legislation to limit the cadmium content of phosphate fertilisers requires such labelling, but one company does this voluntarily. Consultation with industry revealed that the determination of cadmium content and labelling fertilisers with the exact content (i.e. per individual batch of production) would lead to high costs, whereas the sole indication on the label that fertilisers respect the limit value of either 60, 40 or 20 mg cadmium/kg P_2O_5 would not entail significant costs.

Given that the main suppliers of phosphates could meet an EU limit of 60 mg cadmium/kg P_2O_5 without decadmiation, this option will not provide a direct incentive to invest in developing such technologies. However, if over time more and more Member States would choose to allow only marketing and use of fertilisers with a cadmium content of 40 or 20 mg cadmium/kg P_2O_5, Morocco and other producing countries of phosphate rock with high cadmium content would have to invest into decadmiation or the EU fertiliser industry would have to increase its supply from phosphate sources with low cadmium content, which could lead to an increase in costs for mineral phosphate fertilisers. As the majority of Member States seem to be satisfied by the upper limit of 60 mg cadmium/kg P_2O_5 as evidenced by the outcome of the consultations described in section 2, such a development is not expected in the near future.

Impacts on conventional farmers are expected to be limited as the main producing countries can supply the EU market at the 60 mg cadmium/kg P_2O_5 limit without additional costs except costs for analysis and raw material stock management. No phosphate fertiliser type will be shut out of the market.

Organic farming represents approximately 4 to 5 % of the cultivated land in the EU; organic crop production is therefore currently limited. In organic farming, phosphorous generally comes from organic sources e.g. composted farmyard manure, but use of mineral phosphate fertilisers (soft ground rock phosphate, aluminium-calcium phosphate) as described in Regulation (EC) No 889/2008 occurs. Soft ground phosphate rocks cannot be decadmiated, but sources of low cadmium phosphate rocks are available in Jordan and Syria, which could comply with a limit value of 60 mg cadmium/kg P_2O_5. Some Member States have adopted action plans to increase organic farming. In particular Germany, Austria, Slovenia, UK (Wales) have committed to increase this area up to 20 %[59]. It is therefore likely that organic production will increase in the future and all phosphorous sources need to be available in particular for areas where organic sources are less available. As this could lead to increasing demand for soft ground phosphate rock with low cadmium content, it might be necessary in the future to consider appropriate measures for organic agriculture, including further recycling of organic materials.

An upper limit of 60 mg cadmium/kg P_2O_5 would satisfy the needs of a majority of Member States (see Annex I). Allowing Member States to restrict placing on the market and use to 40 or 20 mg cadmium/kg P_2O_5, would satisfy those Member States wishing to reduce further the cadmium emissions in their environment due to specific prevailing conditions. This would be fully in line with the subsidiarity principle and the fact that there are divergent conditions among the Member States. There would be no administrative burden linked to mutual recognition or the need for Member States wishing to set one of the two lower limit values to request derogation under Article 114 TFEU. In fact, an upper limit of 60 mg cadmium/kg

59 Source FP6. ORGAP (The Consortium partners of the European Research Project) – 2008.

P_2O_5 would make the existing derogation for Austria (with a limit value of 75 mg cadmium/kg P_2O_5) redundant, whereas the current derogations for Sweden and Finland could be fully accommodated by imposing the possible lower limits of 40 or 20 mg /kg P_2O_5 – the existence of the former derogations would be a sufficient justification. Industry could no longer circumvent national limit values by marketing fertilisers as ‘EC fertilisers’. Overall, fragmentation of the internal market would be reduced compared to the situation today, as instead of complying with a multitude of different limits, there would be only 3 different values and companies could choose themselves whether they want to produce only fertilisers respecting the EU limit of 60 mg cadmium/kg P_2O_5 and hence forego marketing in those Member States having set lower limits, or whether they want to produce also fertilisers complying with the lower limit values.

Conclusions:

Setting an upper limit of 60 mg cadmium/kg P_2O_5 would lead to some reduction of new cadmium input into agricultural soils from phosphate fertilisers throughout the EU. This effect would be more pronounced in Member States opting for one of the lower limits of either 40 or 20 mg cadmium/kg P_2O_5. Due to the limited availability of data, quantification of the reduction of new cadmium input to soils is difficult – using the available but not necessarily representative data shown in Figure 3, the reduction could be in the order of 30 % (possible range 10-45 %).

However, in the light of the SCTEE-2002 opinion, cadmium accumulation will likely continue in most soils with the implementation of the 60 mg cadmium/kg P_2O_5 limit. A possible decrease of soil cadmium accumulation and, hence transfer from soil to foodstuffs, will therefore depend on the number of Member States using the flexibility of this option to set lower limits at either 40 or 20 mg cadmium/kg P_2O_5.

An EU limit of 60 mg cadmium/kg P_2O_5 could be met without a major disturbance of the EU supply in phosphate fertilisers as the main supplying country, Morocco, could provide sufficient quantities by selective mining and blending, but would not be a sufficient incentive for producing countries to develop and invest in a reliable decadmiation technology, unless a growing number of Member States chose to set one of the two lower limits. Given that supply would not be strongly affected, the transition period for introducing the limit value could be relatively short, between 2 and 3 years after entry into force of the legislation.

It would improve the functioning of the internal market for phosphate fertilisers, by reducing the already existing fragmentation with a multitude of different limit values and would also avoid further fragmentation in the future. No Member State would be required to request authorisation for derogation under Article 114 TFEU and there would be no future administrative burden related to such requests for either the Member States or the Commission.

6.4. Option 4: A new Regulation setting a Community limit value for cadmium content in phosphate fertilisers at 60 mg cadmium/kg P_2O_5 decreasing over time to 40 and eventually 20 mg cadmium/kg P_2O_5 if decadmiation becomes available on industrial scale

When fully implemented, i.e. when decadmiation is available at industrial scale, this option would be fully in line with the opinion of the SCTEE-2002 concluding that, in most European soils, a limit of 60 mg cadmium/kg P_2O_5 in mineral phosphate fertilisers would not be sufficient to avoid accumulation of cadmium, whilst a limit of 20 mg cadmium/kg P_2O_5 would be appropriate to achieve that goal. Consequently, this option would lead to a decrease of cadmium concentrations in soil in the long term and hence a clear reduction of risks to the environment and to human health via the diet provided that it is fully implemented, i.e. that further reductions to 40 mg and 20 mg cadmium/kg P_2O_5 become effective.

As already set out in section 3.2, the actual cadmium content of the fertilisers placed on the market in the EU is not well studied, and it is therefore difficult to quantify the reduction in new cadmium input into agricultural soils that this option would entail. On the basis of the data contained in Figure 3, which are, however, not necessarily representative for the EU, and with the same calculations as set out for Option 3 (see Annex XV for details), setting the limit value at 60 mg cadmium/kg P_2O_5 could lead to a reduction of cadmium inputs in the order of 30 % (possible range 10-45 %) compared to today, whilst a further decrease to 40 mg cadmium/kg P_2O_5 could lead to a reduction of cadmium input by 69 % (possible range 30-84 %), and a decrease to 20 mg cadmium/kg P_2O_5 could bring a reduction of about 81 % (possible range 60-92 %).

As explained in the analysis of Option 3, an initial limit value of 60 mg cadmium/kg P_2O_5 could probably be met by phosphates exporting countries (except for some smaller African producers, which do, however, not export to the EU) and the EU fertiliser industry without excessive costs and disturbance of supply, by using raw material from selective mining of sedimentary phosphate rock from mines with sufficiently low cadmium content. As for option 3, an appropriate transition period to set this limit could be of the order of 2 to 3 years after entry into force of the legislation.

As the entry into force of stricter cadmium limits would be conditional on the existence of a suitable decadmiation technology, producers would still not have any immediate reason for developing such technology (see also section 3.3.2). Conversely, the impacts of a reduction of the EU limit to 40 or 20 mg will strongly depend on the availability of alternatives to phosphates as described in section 3.3. Given that the availability of natural deposits of phosphates with low cadmium content and the potential for increased recycling of phosphates from waste streams is limited, the feasibility of decadmiation at industrial scale will be decisive.

In the absence of decadmiation at industrial scale and at reasonable costs, the consequences of a reduction of the EU limit will be very negative for a broad range of phosphates producing countries in Northern Africa, who effectively will not be able to export to the EU anymore – including also the main producer Morocco. Consequently, there will be a disruption of the supply of the EU fertiliser industry and farmers, who will also face strongly increased prices due to very high demand for the limited amounts of alternative phosphates with low cadmium content. At the same time, countries such as Morocco and Tunisia are covered by the European Neighbourhood Policy (ENP) which was developed in 2004 with the objective of establishing a deeper political relationship and economic integration between the EU and its immediate neighbours by land or sea. Without proven feasibility of decadmiation, both could see their exports of phosphates to the EU being severely limited, which are today significant sources of revenues. This would be contrary to the ENP objectives.

As a further consequence, producers in Northwest Africa would probably seek to export phosphates with high cadmium content that could no longer be sold to the EU to other third countries, in particular to developing countries, as several other developed countries have already introduced restrictions on cadmium content in fertilisers[60].

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[60] Several third countries have introduced restrictions on cadmium content in fertilisers: Switzerland (21 mg Cd/kg P_2O_5), Norway (43 mg Cd/kg P_2O_5), Japan (146 mg Cd/kg P_2O_5).

Many of the soils in developing countries are naturally acidic with little opportunity of being limed to raise their pH and thereby cadmium applied to these acidic soils will be likely to enter the food chain. The EU imports in turn agricultural produce from developing countries, the cadmium content of which could then possibly increase. In that context, the Kenyan authorities notified in mid October 2010 to the World Trade Organisation their intention to impose limits on heavy metals, including cadmium[61], in rock phosphate for use in manufacture of fertilisers and common phosphate fertiliser types. The main objective of the Kenyan authorities is to ensure a safe use of fertilisers for consumers and environment protection. No member of the WTO objected or submitted comments on the Kenyan notification.

On the other hand, implementation of stringent limits for cadmium in phosphate fertilisers would constitute a clear signal from the EU to phosphates producing countries to invest in decadmiation technologies in order to ensure continued access to the EU market in the long term future. For example, construction of the existing installation with decadmiation for food-grade phosphates in Tunisia was probably motivated by the EU's setting of stringent limits for cadmium in food and feedstuffs. Further research and development could bring down the costs of such processes, and would allow these countries to remain competitive also on other third country markets where limit values for cadmium are already in place or might be established in the future.

In June 2010 and in January 2011, the European Investment Bank has received applications to finance two projects in Tunisia (EIB 21 276 2010) and Morocco (EIB 21 05 2011) concerning the modernisation or construction of new phosphate fertiliser plants. In its comments, the Commission has recommended that the investors also consider developing and installing an industrial decadmiation process in the light of possible future limits for cadmium in phosphate fertilisers.

Still, whilst successful decadmiation would restore a sufficient supply base for the European fertiliser industry and farmers, third countries mining phosphates with high cadmium content would face some structural disadvantage due to the costs associated with decadmiation – as set out in the analysis of Option 2, price increases due to decadmiation could be in the order of 10 to 20 % – and for certain fertiliser types that are not produced involving phosphoric acid as an intermediate, decadmiation technologies are not yet available, even at laboratory scale.

As long as no decadmiation at industrial scale is available, the fragmentation of the internal market will persist, as 60 mg cadmium/kg P_2O_5 will remain the *de facto* EU limit. Member States wishing to maintain or introduce more stringent limit values for cadmium in EC fertilisers would have to ask for authorisation by the Commission in accordance with Article 114 TFEU, which would create significant administrative burdens as described in section 3.5. However, once decadmiation is available and the EU limit can be decreased, fragmentation will be reduced and eventually the Internal Market will be fully harmonised.

Conclusions:

Full implementation of this option would strongly reduce the cadmium content in phosphate fertilisers throughout the EU, which would reduce the input of cadmium to agricultural soils and hence transfer into food and ultimately also intake by humans through the diet. It would eventually be fully in line with the opinion of the SCTEE-2002 indicating that, at a limit value of 20 mg cadmium/kg P_2O_5, no further cadmium accumulation from phosphate fertilisers is

[61] Maximum cadmium content in rock phosphate: 30 ppm cadmium on dry matter i.e. around 90 mg Cd/kg P_2O_5 for phosphate content of 32 % (wt % P_2O_5).

likely to occur in most European soils. Due to the limited availability of data, quantification of the reduction of new cadmium input to soils is difficult – using the available but not necessarily representative data shown in Figure 3, the reduction could be in the order of 30 % (possible range 10-45 %) for the initial limit of 60 mg cadmium/kg P_2O_5, whilst a further decrease to 40 mg cadmium/kg P_2O_5 could lead to a reduction of cadmium input by 69 % (possible range 30-84 %), and a decrease to 20 mg cadmium/kg P_2O_5 could bring a reduction of about 81 % (possible range 60-92 %).

Feasibility of the full implementation of this option will largely depend on the availability of a decadmiation process at industrial scale. If stringent cadmium limits were to be adopted even though no industrial decadmiation process is available, there would likely be a rush to either sedimentary low-cadmium phosphate rock or to a lesser extent to igneous rocks leading to severe effects on producing countries, EU fertiliser industry and farmers. In the mid term at least, the recovery of nutrients from organic wastes such as manure, sewage sludge and bio-waste will not cover the phosphate needs of EU farmers. On the other hand, drivers such as this option could stimulate decadmiation and phosphorous recycling technologies and if a workable timetable for implementation of the lower limits were foreseen, these adverse effects on supply could be mitigated.

With a single EU limit value for cadmium in phosphate fertilisers – decreasing over time – fragmentation of the internal market would eventually disappear and enforcement by national authorities would be easier. However, as long as the EU limit would stay at 60 mg cadmium/kg P_2O_5 several Member States wishing to maintain lower national limits would have to submit requests for derogation under Article 114 TFEU with the related administrative burdens and fragmentation of the internal market would persist.

6.5. Option 5: A new Regulation setting an upper limit of 40 mg cadmium/kg P_2O_5 in phosphate fertilisers while allowing Member States to impose a limit value of 60 or 20 mg cadmium/kg P_2O_5 for the placing on the market and use depending on the conditions prevailing on their territories

This option might be considered as a variant of Option 3. An upper limit of 40 mg cadmium/kg P_2O_5 after an appropriate transition period would better address the concerns about cadmium accumulation in European soils by limiting the input of cadmium from the application of phosphate fertilisers and would be more in line with the opinion of the SCTEE-2002. However, it is not certain that this will result in a significant decrease in soil cadmium accumulation and hence lower cadmium levels in food since the SCTEE-2002 considered that in most European soils, cadmium accumulation will be avoided only if a 20 mg cadmium/kg P_2O_5 limit was implemented.

As already set out in section 3.2, the actual cadmium content of the fertilisers placed on the market in the EU is not well studied, and it is therefore difficult to quantify the reduction in new cadmium input that this option could entail. On the basis of the data contained in Figure 3 which are, however, not necessarily representative for the EU, and using similar calculations as for the previous options (for details see Annex XV), setting the limit value at 40 mg cadmium/kg P_2O_5 could lead to a reduction of new cadmium inputs by 69 % (possible range 30-84 %).

Compared to Option 3, this option would have significant economic impacts on the fertiliser industry and producing countries, unless a majority of Member States would opt to deviate from the default value of 40 mg/kg P_2O_5. This is not guaranteed because many Member States – although actually satisfied with a limit value of 60 mg/kg P_2O_5 (see Annex I) – would have to act to allow the marketing and use of phosphate fertilisers containing 60 mg cadmium/kg P_2O_5 if an EU limit value was set at 40 mg/kg P_2O_5. With regard to labelling, the same considerations as for Option 3 apply.

As explained in the analysis of Option 4, there will be a strong negative impact on producing countries mining sedimentary rocks containing a high amount of cadmium. In particular Morocco, as the main supplier of phosphate to the EU, will also be immediately affected. Indeed, as Morocco, Tunisia and Israel will not be able to supply the European market with phosphate fertilisers with an upper limit of 40 mg cadmium/kg P_2O_5 without decadmiation technology, there will be a rush to low cadmium phosphates sources which will most likely lead to strong price increases for such phosphates. The same supply constraints as discussed for Option 4 apply.

No Member State would be required to request authorisation for derogation under Article 114 TFEU and there would be less administrative burden, in comparison with option 1, related to such requests for either the Member States or the Commission. In fact, an upper limit of 40 mg cadmium/kg P_2O_5 would make the derogation for Austria (with a limit value of 75 mg cadmium/kg P_2O_5) and Sweden (with a limit value of 44 mg cadmium/kg P_2O_5) redundant, whereas the derogation for Finland (with a limit value of 22 mg cadmium/kg P_2O_5) could be fully accommodated.

However, according to the results of the stakeholder meeting of 28 October 2009 (see Annex II for details) the number of Member States that might adopt the 60 mg cadmium/kg P_2O_5 limit instead of the EU limit of 40 mg cadmium/kg P_2O_5 would be significantly higher than those opting for lower limits in Option 3. This would create administrative burdens for a higher number of Member States.

Conclusions:

Compared to Option 3, this option would reduce the cadmium content in phosphate fertilisers throughout the EU, which would further reduce the input of cadmium into agricultural soils and hence transfer into food. Due to the limited availability of data, quantification of the reduction of new cadmium input to soils is difficult – using the available but not necessarily representative data shown in Figure 3, the reduction could be in the order of 69 % (possible range 30-84 %).

However, in the light of the SCTEE-2002 opinion, cadmium accumulation might still continue in some soils with the implementation of the 40 mg cadmium/kg P_2O_5 limit and more so, if Member States opt to increase the limit to 60 mg cadmium/kg P_2O_5. A possible decrease of soil cadmium accumulation and, hence transfer from soil to foodstuffs, will therefore depend on the number of Member States using the flexibility of this option to set either a higher limit at 60 mg cadmium/kg P_2O_5 or a lower limit at 20 mg cadmium/kg P_2O_5. In the absence of a technically and economically feasible decadmiation technology at industrial scale, there would be very high economic impacts on producing countries that currently supply the bulk of phosphate fertilisers imported into the EU. On the other hand this option would provide a clear signal to invest in the development of decadmiation or phosphates recycling.

The option would improve the functioning of the internal market for phosphate fertilisers, by reducing the already existing fragmentation of the internal market with a multitude of different limit values and would also avoid further fragmentation in the future but the number of Member States deviating from the EU limit would be higher than in Option 3.

Lastly, the Legal Service of the Commission considers that, according to Article 114 TFEU, economic reasons are not recognised as possible grounds to justify deviation from harmonised measures, in particular when less strict measures are adopted, which seems to preclude Member States from opting for a limit value of 60 mg cadmium/kg P_2O_5. This effectively rules out an implementation of this option in practice.

7. COMPARING THE OPTIONS

The comparison of the various policy options has been conducted taking into account the criteria of:

– **effectiveness** of the option in achieving the objectives (reduction of cadmium inputs into agricultural soils, reduction of exposure of humans via food and reduction of the exposure of soil organisms, secure supply and minimisation of negative impacts on third countries producing phosphates, reduction of internal market fragmentation, reduction of administrative burden). Overall effectiveness has been calculated as an average across achievement of the individual objectives, assigning, however, double weight to the objectives linked to human health and the environment;

– **efficiency** of the option in achieving the objectives. Efficiency aims at comparing the costs of the implementation of a particular policy option to its effectiveness in reaching the objectives. In the absence of reliable quantitative estimates, the costs of implementation are interpreted as adverse economic impacts on producing countries, fertiliser manufacturers or farmers[62];

– **coherence** of the option with other EU objectives (e.g. European Neighbourhood Policy) and trade obligations including WTO rules .

While the following tables represent a qualitative analysis of the arguments developed in section 6, the quotation presented is a necessary simplification to facilitate comparison and identify trade-offs and should be therefore treated as purely indicative.

The options have been assessed as being "strongly negative (---)", "negative (--)", "slightly negative (-)", "neutral (=)", "slightly positive (+)", "positive (++)" or "strongly positive (+++)" compared to the no EU action option (baseline scenario). The selected options have been assessed according to two scenarios:

Scenario 1: technologically and economically feasible decadmiation for large scale processing is not available;

Scenario 2: technologically and economically feasible decadmiation for large scale processing is available.

[62] ***Nota bene:*** for the purpose of this indicative comparison and in the absence of reliable quantitative estimates, the costs of the development and investment in the decadmiation technology are not taken into account.

Scenario 1: technologically and economically feasible decadmiation for large scale processing is not available:

Criteria	Option 1	Option 2	Option 3	Option 4	Option 5
Reduction of cadmium input into soils	=	=/+	+	+	++
Reduction of human exposure to cadmium	=	=/+	=/+	=/+	+
Reduction of exposure of soil organ-isms / Maintaining soil biodiversity	=	=/+	=/+	=/+	+
Security of supply and minimisation of negative impacts on 3rd countries	=	=	=	=	---
Reduction of Internal market fragmentation	=	=	++	=	++
Reduction of burden for public administration	=	--	+++	=	++
Overall effectiveness	=	=	+	=/+	+
Costs of implementation	=	--	-	-	---
Efficiency	=	-	=	- /=	--
Coherence	=	-	++	++	---
Explanatory comments	=	If no decadmiation is available, incentives will not change very much which fertilisers will be available or bought. A tax would cause adverse economic impacts on producing countries, industry and/or farmers through price increases. Fragmentation of internal market and related administrative burdens will remain unchanged – still need for Art. 114 TFEU requests for Member States wishing to set limits. In addition administrative burdens for developing and implementing any of the sub-options. Incoherent with neigh-bourhood and trade policies.	Some reduction of new cadmium inputs into agricultural soils. Uncertain whether this will result in decrease of total soil cadmium and hence reduced exposure of humans via food or reduced exposure of soil organisms. Reduced fragmentation of internal market as only 3 limit values will be possible. No need for Art. 114 TFEU requests Some negative economic impacts. Coherent with neighbourhood and trade policies.	Some reduction of new cadmium inputs into agricultural soils - the 60 mg limit would remain the de facto limit value. Uncertain whether this reduction will result in decrease of total soil cadmium and hence reduced exposure to humans via food or reduced exposure of soil organisms. Some Member States will wish to maintain or introduce lower limits, which necessitates Art. 114 TFEU requests as today. No reduction of fragmentation of internal market. Some negative economic impacts. Coherent with neighbourhood and trade policies as long as limit stays at 60 mg Cd/kg P_2O_5.	Significant reduction of new cadmium inputs into soils and some reduction of soil cadmium accumulation. Consequently, some reduction of the exposure of humans via food and some reduction of exposure of soil organisms. Reduced fragmentation of internal marked as only 3 limit values possible. No need for Art. 114 TFEU requests, but more Member States would wish to opt for 60 compared to those opting for 40 or 20 in option 2. Strong negative economic impacts. Incoherent with several EU policies (neighbourhood and trade policies, intentions of Art. 114 TFEU).

Scenario 2: technologically and economically feasible decadmiation for large scale processing is available

Criteria	Option 1	Option 2	Option 3	Option 4	Option 5
Reduction of cadmium input and reduction of risks to human health	=	+++	+	+++	++
Reduction of human exposure to cadmium	=	+++	+/=	+++	+
Reduction of exposure of soil organ-isms and maintaining soil biodiversity	=	+++	+/=	+++	+
Security of supply and minimisation of negative impacts on 3rd countries	=	=	=	=	=
Reduction of Internal market fragmentation	=	=	++	+++	++
Reduction of burden for public administration	=	--	+++	+++	++
Overall effectiveness	=	++	+	+++	++
Costs of implementation	=	--	-	--	-
Efficiency	=	=	=	+	+
Coherence	=	-/=	++	-/=	--
Explanatory comments	=	If incentives are set at appropriate level, reduction of cadmium input and hence risk to human health and the environment will be similar to regulatory limits. Some adverse economic impacts on producing countries, industry and/or farmers. Fragmentation of internal market and related administrative burdens un-changed – still need for Art. 114 TFEU requests for Member States wishing to set limits. Administrative burdens for developing and implement-ting all sub-options. Disadvantages for countries with phosphates of high cadmium content, otherwise coherent with neighbourhood and trade policies	Some reduction of new cadmium inputs into agricultural soils. Uncertain whether this will result in decrease of total soil cadmium and hence reduced exposure of humans via food or reduced exposure of soil organisms. Reduced fragmentation of internal market as only 3 limit values will be possible. No need for Art. 114 TFEU requests. Some negative economic impacts. Coherent with neighbourhood and trade policies.	Strong reduction of new cadmium input into soils and of soil cadmium accumulation. Reduction of exposure to humans via food of soil organisms. Eventually full harmonisation and no need for Article 114 TFEU requests. Some adverse economic impacts – in particular on producers not using the phosphoric acid route. Some structural disadvantages for third countries mining phosphates with high cadmium content, otherwise coherent with neighbourhood and trade policies.	Reduction of new cadmium inputs into soils and some reduction of soil cadmium accumulation. Consequently, some reduction of the exposure of humans via food and some reduction of exposure of soil organisms. Reduced fragmen-tation of Internal Marked as only 3 limit values possible. No need for Art. 114 TFEU requests, but more Member States would wish to opt for 60 compared to those opting for 40 mg or 20 mg in option 2. Some negative economic impacts. Incoherent with Art. 114 TFEU.

8. PREFERRED POLICY OPTION

From the comparison of the different options, it emerges that in the current situation where technically and economically viable decadmiation at industrial scale is not available, overall effectiveness and efficiency are better for option 3 compared to option 4 and even more so compared to option 5. This is due in particular to the reduced fragmentation of the internal market and lower administrative burdens for option 3, and not to better achievements of the objectives to reduce cadmium exposure for humans and the environment. In the absence of a decadmiation technology, both options 3 and 4 have only limited effects in achieving those objectives as, in the light of the SCTEE-2002 opinion, cadmium accumulation could actually still continue in most European agricultural soils unless lower limits are adopted. However, under the condition that a technically and economically viable decadmiation process becomes available at industrial scale, option 4 will be clearly preferable, as it would be the most effective in achieving all objectives.

It is not possible to estimate with confidence the effectiveness of option 2 in achieving the objectives because of the limitation of the economic model used to derive the level of the tax and the uncertainties of the parameters introduced in the model. However, this option would not result in a reduction of the fragmentation of the internal market and would increase significantly administrative burdens. Whilst it will provide an incentive to invest in decadmiation technologies it would also increase phosphate fertiliser prices.

It is therefore crucial in view of achieving all the intended objectives that the proposed new Regulation gives an incentive to invest in further developments of decadmiation technologies. This would be in line with the opinion of the SCTEE-2002 with regard to potential cadmium accumulation in soil and would respond to the desire of many stakeholders to achieve a further decrease of the cadmium content of phosphate fertilisers.

A new Regulation should therefore be adopted that would establish an EU limit value of 60 mg cadmium/kg P_2O_5 as a starting point. This limit would take effect after an appropriate transition period of e.g. 2 to 3 years. Flexibility should be given to allow Member States to set limit values at either 40 or 20 mg cadmium/kg P_2O_5 in the light of specific conditions in their territories. Fertilisers would be labelled to provide an indication which limit value for cadmium they comply with.

In order to provide incentives for further developments in decadmiation technologies and their implementation at industrial scale, different alternatives could be chosen:

– to include in the legislative proposal a clause triggering a review of the situation 5 to 10 years after the date of application of the 60 mg cadmium/kg P_2O_5 limit based on biannual reporting by manufacturers and importers of phosphates fertilisers on the efforts undertaken to develop a decadmiation process and on statistical data about the cadmium content of mineral phosphate fertilisers. The review should also address further developments in the supply situation for phosphates with low cadmium content and the availability of recycled phosphates;

or

– to set, in the legislative proposal, a timetable for implementation of lower limit values, e.g. 40 mg cadmium/kg P_2O_5 5 to 10 years after the date of application of the 60 mg/kg limit, and 20 mg cadmium/kg P_2O_5 after 15 to 20 years. The Commission would, nevertheless, need to monitor the actual development at industrial scale of a decadmiation process, the evolution of phosphate imports into the EU, and the availability of alternative phosphate sources through recycling to avoid shortages of supply of phosphates in the EU and/or disproportionate effects on phosphates exporting countries.

The selection of the incentive to be included in the final legislative text will be a political choice.

As mentioned in section 3.1, the SCHER-2015 opinion estimated that the current actual cadmium level in the environment justifies the revision of the CSTEE-2002 opinion and concluded that the accumulation of cadmium in soils is not expected to occur on average in most EU-27 + Norway soils if the concentration of cadmium in inorganic phosphate fertilisers does not exceed 80 mg/kg P_2O_5. In the SCTEE-2002 opinion, the same effect was achieved with a limit value of 20 mg cadmium/kg P_2O_5.

Despite the new assessment of future trends in soil cadmium accumulation, the conclusions of experts assessing the toxicology of cadmium through the food chain (See Section 3.1.1) remain valid i.e. that in order to protect human health from adverse effects of cadmium via dietary intake[63], it is important to decrease cadmium input into soils. Such reduction seems in light of the SCHER-2015 opinion more rapidly achievable than expected in 2002.

The overall approach would:

- achieve a reduction of new cadmium inputs to soils thereby reducing, in the long term, the presence of cadmium in the environment and in crops harvested in Europe and therefore the cadmium exposure of humans via food, depending on the actual development of technically and economically feasible decadmiation at industrial scale;
- achieve initially a rather harmonised internal market with an upper EU limit while allowing Member States to set with low administrative burdens one of two possible lower limits to reduce the cadmium content of phosphate fertilisers marketed in their territories proportionate to their specific conditions. Full harmonisation will be achieved when a technically and economically feasible decadmiation at industrial scale will be available;
- have limited and gradual economic impacts on phosphate producing countries, fertiliser manufacturers and farmers and on the economy as a whole;
- reduce the administrative burden for the Commission and the Member States as requests for derogation in accordance with Article 114 TFEU will not be necessary any longer.

9. MONITORING AND EVALUATION

The proposal, once adopted, is going to be implemented in close cooperation with all stakeholders concerned. To this end, the Committee and the Working Group on Fertilisers have provided for a valuable forum for the past and will be used in the future.

As long as a decadmiation technology is not available at industrial scale, Member States wishing to impose limits of 40 or 20 mg/kg P_2O_5, respectively, within their territories will notify those measures to the Commission accompanied by justification in terms of particular conditions. The Commission will make the information received from Member States publicly available, to increase awareness of operators and facilitate enforcement.

[63] As mentioned in section 3.7, food safety authorities are not able to implement today safe maximum levels of cadmium concentration in staple food as these limits take also into account the actual cadmium concentration currently present in the environment.

Under their obligations of market surveillance set in Regulation (EC) No 765/2008, Member States will have to collect data on cadmium limit values in phosphate fertilisers after implementation of this legislation through the determination of the cadmium content of phosphate fertilisers that are representative of their national markets. This information will be available from manufacturers and importers of phosphate fertilisers, who will have to determine the cadmium content of the fertilisers placed on the market in order to label them with the correct limit value that they comply with.

As one important objective of the proposal is to reduce exposure to cadmium through the food chain, the Commission should continue to request EFSA to periodically review new toxicological studies and/or the occurrence of cadmium in foodstuffs. However, as the residence time of cadmium into the soil is very long, effects of the adopted measure are not likely to emerge in the short term.

The Commission also intends to review the situation of the European market supply (recycling of organic waste and their cadmium content, better availability of low cadmium sedimentary rocks sources, better availability of phosphorous to plant roots leading to reduced application of phosphorous) and other parameters that affect the proposal (development of decadmiation technology).

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11. GLOSSARY OF TECHNICAL TERMS AND ABBREVIATIONS

- **AP** means ammonium phosphate (or triammonium phosphate). A substance which is used used as ingredient in some fertilisers as source of nitrogen and phosphorous.

- **Bioavailability** is the proportion of a substance capable of being absorbed by plants and available for use or storage.
- **B2M** stands for beta-2-microglobulin a low molecular weight protein recognised as useful bio-marker in relation with cadmium body burden.
- **Cadmium** is a heavy metal that is found as an environmental contaminant both from natural occurrence and from industrial sources. Food is the major source of exposure to cadmium for the non-smoking general population.
- **Cd-U** is the quantity of cadmium excreted in urine. It is often expressed in relation with a molecule totally excreted by the kidneys (creatinine).
- **COPA COGECA:** European farmers and agri-cooperatives association.
- **Decadmiation:** an industrial process by which cadmium could be removed from phosphoric acid. The two main processes that could be suitable for the fertiliser industry are described in Annex XII.
- **EC fertilisers:** fertilisers complying with the provisions of Regulation (EC) No 2003/2003.
- **EFBA:** European Fertilisers Blenders Association.
- **EFMA:** European Fertilisers Manufacturers Association. Recalled Fertilizers Europe as of 1 January 2010.
- **EU RAR:** EU Risk Assessment Report.
- **Eutrophication:** an increase in available nutrients or nutrient enrichment of a water body.
- **HEA:** Health and Environmental Alliance.
- **IFA:** International Fertiliser Industry Association.
- **IMPHOS:** the World Phosphate Institute represents six phosphate producing countries: Algeria, Jordan, Morocco, Senegal, Togo and Tunisia.
- **MAP and DAP:** monoammonium phosphate and diammonium phosphate respectively. Ammonium salts of phosphoric acid are those days the most largely used phosphate fertilisers.
- **mg cadmium/kg P_2O_5** is the way the cadmium content in phosphate fertilisers is expressed. 1 kg P is equivalent to 2.29 kg P_2O_5.
- **National fertilisers:** fertilisers complying with national rules.
- **NP, PK and NPK** are fertilisers having a declarable content of at least two of the primary nutrients (Nitrogen, Phosphorous and/or Potash). Whenever figures are mentioned, they indicate the content of each nutrient.
- **OCP:** Office Chérifien des Phosphate. A leading Moroccan company for the production of phosphate rocks and derivatives.
- **P_2O_5:** phosphorous oxide. A way to express the content of phosphorous in fertilisers.
- **Phosphate fertilisers:** fertilisers containing mineral phosphate fertilisers in amounts greater than 5 % P_2O_5 equivalent.

- **PEC:** Predicted Environmental concentration. This is the estimated concentration of a chemical in an environmental compartment calculated from available information on its properties, its use and discharge patterns and the quantities involved.
- **PNEC:** Predicted Non-Effect Concentration. It can be defined as the concentration below which a specified percentage of species in an ecosystem are expected to be protected or the content below the level of which soil function are not impaired by the effect of hazardous substance.
- **Reserve:** that part of the reserve base which could be economically extracted or produced at the time of determination.
- **Reserve base:** that part of an identified resource that meets specified minimum physical and chemical criteria related to current mining and production practices, including those for grade, quality, thickness, and depth. The reserve base is the in-place demonstrated (measured plus indicated) resource from which reserves are estimated. It may encompass those parts of the resources that have a reasonable potential for becoming economically available within planning horizons beyond those that assume proven technology and current economics. The reserve base includes those resources that are currently economic (reserves), marginally economic (marginal reserves), and some of those that are currently subeconomic (subeconomic resources).
- **SCTEE:** Scientific Committee on Toxicity, Ecotoxicity and the Environment. One of the scientific committees managed by DG SANCO.
- **SCHER:** Scientific Committee on Health and Environmental Risks. The former SCTEE
- **Solubilisation:** to make or become a substance soluble or more soluble in water.
- **SSP and TSP:** single super phosphate and triple superphosphate respectively. The advantage of those fertilisers is their high phosphorous content.
- **Technical Guidance Document (TGD):** is the document issued in 1996 by the Institute for Health and Consumer Protection in support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances.
- **Topsoil** is the upper, outermost layer of **SOIL**, usually the top 5 cm to 20 cm. It has the highest concentration of **ORGANIC MATTER** and **MICROORGANISMS** and is where most of the **EARTH**'s **BIOLOGICAL** soil activity occurs. **PLANTS** generally concentrate their **ROOTS** in and obtain most of their **NUTRIENTS** from this layer.
- **UNIFA, Assofertilizzanti and IVA** are respectively the French, Italian and German fertiliser producers associations.
- **Welfare loss:** A situation where marginal social benefit is not equal to marginal social cost and society does not achieve maximum utility.

ANNEX I: OUTCOME OF A MEMBER STATES AND INDUSTRY CONSULTATION ON LIMITS FOR CADMIUM IN NATIONAL PHOSPHATE FERTILISERS

Member State represented	*Maximum limits for cadmium in national fertilisers containing more than 5 % P_2O_5* *mg cadmium/kg P_2O_5*
Austria	75
Belgium	90
Czech Republic	50
Denmark	48
Finland	22
France	60
Germany	60
Poland	50
Hungary	20
Italy	50
Cyprus	60
Lithuania	60
Spain	60
Romania	60
Slovenia	60
Slovakia	20
Bulgaria	50
Greece	60
Sweden	44
Latvia	60

ANNEX II: SUMMARY OF MEMBER STATES AND INDUSTRY CONSULTATION ON THE OPTIONS PRESENTED AT THE WORKSHOP IN OCTOBER 2009[64]

Option 1	Option 3	Option 4a*	Option 4b*	Option 4c*	Option 5
OCP	*UK*	*IE*	*FR*	*SE*	
IMPHOS	*BG*	*FI*	*BE*	*HEA*[65]	
	RO	*LT*	*IT*		
	PT	*SI*	*SP*		
	PL[66]	*DK*[67]	*UNIFA*		
	CZ	*HU*	*Assofertillizzanti*		
	LV	*GR*			
	EE	*LU*			
		AT			
		DE			
		IVA			
		Copa Cogeca			

* **Option 4a:** Option 4 as proposed by the Commission in this Impact Assessment.

** **Option 4b:** Option 4 with a cadmium limit starting from 75 mg and decreasing to 60 mg after 3 years of entry into force of the proposal. Further reduction would be then dependent on the availability of a reliable and cost-effective decadmiation technology that would be suitable for fertiliser production.

*** **Option 4c:** Option 4 with a lower starting limit (40 mg).

64 *Nota bene*: Option 2 had not been discussed during the stakeholder consultation, as it was only included into the analysis after the first review of the draft impact assessment report by the Commission's Impact Assessment Board.

65 HEA suggested starting from 40 mg and decreasing rapidly to 20 mg. This proposal was supported by other NGOs like Greenpeace, the European Environmental Bureau and WWF.

66 Subject that the starting limit would be 75 ppm.

67 Subject to the condition that DK can maintain a lower national limit of 48 ppm.

ANNEX III: SUMMARY OF AN EARLIER INTERNET CONSULTATION ON LIMITS FOR CADMIUM IN PHOSPHATE FERTILISERS

In 2003, DG Enterprise and industry ran an Internet consultation on a first draft proposal relating to cadmium in fertilisers. This proposal introduced a phasing out approach with an initial limit for the cadmium content in phosphate fertilisers starting from 60 mg cadmium/kg P_2O_5 and decreasing stepwise to 40 and 20 mg cadmium/kg P_2O_5 over a period of 15 years during which decadmiation technology would have been introduced to supply the whole EU market with low cadmium-content phosphate fertilisers (*Nota bene*: this is very similar to option 4 examined in this impact assessment).

Stakeholders were invited to comment on the text of a Draft Proposal and on an accompanying impact assessment which were available on-line[68].

The EU fertiliser manufacturing industry replied that 60 mg would be the lowest limit that could be applied. A maximum limit of 90 mg was proposed by some stakeholders to be consistent with the provisions of Commission Regulation (EC) No 889/2008 of 5 September 2008[69] laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.

Some replies suggested waiting for the completion of the European risk assessment report on cadmium oxide and cadmium metal. The final report of the EU RAR on cadmium was published in December 2007[70].

Many replies stated also that the proposal was not based on an adequate risk assessment and questioned the assumptions on which the proposal was based concerning cadmium input into agricultural soils. In particular questions were raised relating to the following issues:

- many experiments have shown that most phosphate fertilisers used for long periods did not increase crop cadmium concentration as these fertiliser treatments have not increased the bioavailability of cadmium;
- the validity and type of algorithm or model for soil accumulation used;
- the overall phosphate fertiliser consumption in the EU (the proposal mentioned 3.5 million tons per year, which was considered too high).

All replies concerning decadmiation possibilities pointed out that no decadmiation technology was yet implemented at industrial scale and that the related additional costs would therefore be uncertain but that they were probably considerably underestimated in the impact assessment of the proposal. Some of these replies also stressed that decadmiation could pose a risk to the environment due to the waste generated and the problem of its disposal.

All but two companies (KEMIRA in Finland and PHOSAGRO in Russia) argued that the impact on the EU industry and farmers as well as some high cadmium content sedimentary phosphate rock producing countries could be severe due to the creation of a quasi

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68 See: HTTP://EC.EUROPA.EU/ENTERPRISE/NEWSROOM/CF/DOCUMENT.CFM?ACTION=DISPLAY&DOC_ID=2968&USERSERVICE_ID=1&REQUEST.ID=0.

69 OJ L 250, 18.09.2008, p. 1.

70 European Union Risk Assessment Report on cadmium and cadmium oxide. Vol. 72 and 74. JRC Ispra (2007). HTTP://ECB.JRC.EC.EUROPA.EU/DOCUMENTS/EXISTING-CHEMICALS/RISK_ASSESSMENT/REPORT/CDOXIDEREPORT302.PDF

monopolistic position of the Russian producer of low cadmium igneous rock. Moreover, the nature of the Russian phosphate rock is not suitable for the production of simple and triple super-phosphates according to Amsterdam Fertiliser and OCP[71]. Several replies, and in particular those of two agricultural cooperatives, indicated that the farmers would not be able to bear the additional costs resulting from decadmiation.

[71] Office Chérifien des Phosphates.

ANNEX IV: SUMMARY OF THE SMEs CONSULTATION ON LIMITS FOR CADMIUM IN PHOSPHATE FERTILISERS

The Commission ran a SMEs consultation from 24 October 2009 to 11 January 2010 by using the European Enterprise Network. The purpose of the consultation was to receive information from industry on their estimated compliance costs from a potential Commission proposal setting limit values for cadmium in mineral phosphate fertilisers.

In addition to technical and scientific arguments regarding the contribution of phosphate fertilisers to cadmium exposure through the environment, the Commission intended to investigate the socio-economic consequences on EU SMEs from possible limits on cadmium content in phosphate fertilisers in order to identify the most proportionate and adequate course of action.

The questionnaire was divided into three sections asking SMEs to provide information on the company (section 1), their local market situation (section 2) and the possible impacts on business from possible harmonised limits on cadmium for phosphate fertilisers (section 3).

75 % of the participating companies declared less than 49 workers. 14 companies registered as mineral fertiliser retailers, 11 as mineral fertiliser producers, 4 as importers and 12 as being also active in the production of organic fertilisers and liming material. A majority of enterprises were present on their national markets and in neighbouring countries.

Price, value for money and the quality of service are currently the three main sales arguments. Human health and environmental concerns are regarded as less important.

In section 3 (economical impacts of cadmium limits on business), one of the questions put forward was about whether limit values of 60, 40 or 20 would have detrimental, neutral or beneficial consequences on business.

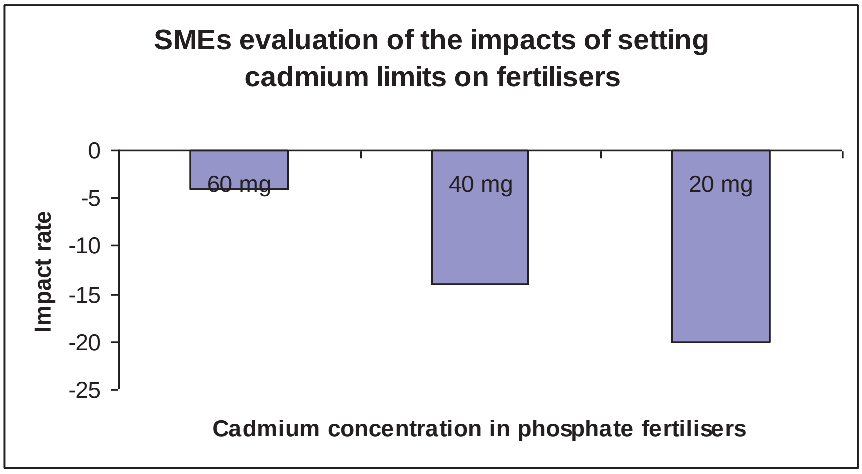
Companies located in countries already applying cadmium limits below 60 mg/kg P_2O_5 (Norway, Denmark) would have less difficulties to implement stricter limits. EU-10 companies worried more than EU-15 companies about the possible implementation of cadmium limits in phosphate fertilisers.

52 % of the respondents declared that they already suffered from a disruption in the supply of mineral fertilisers in the past. However, companies having less than 10 workers did not claim to have more difficulties than larger enterprises to be correctly supplied in phosphate fertilisers.

In general, SMEs producing only mineral fertilisers or having a wider portfolio (organic fertilisers, liming material) were most concerned about the possible negative impacts on the competitiveness of the sector from measures restricting the supply in phosphate fertilisers. Importers and retailers expressed less concerns about the possible economical impacts of the policy options.

Relatively few companies provided quantitative estimates of price increases if the limit value was set below 60 mg cadmium/kg P_2O_5 and these ranged from 0-220%. However, as no real justification was provided for these estimates, it has not been possible to make quantitative estimates for the entire sector.

The following figure provides the results of a semi-quantitative analysis determining an 'impact rate'[72] and shows that stringent limits are seen as potentially detrimental for the competitiveness of the sector.



Summary of the SMEs Test

(1) Consultation with SMEs representatives	See sections 2.3, as well as Annex IV.
(2) Preliminary assessment of businesses likely to be affected	See sections 2.3., as well as Annex IV.
(3) Measurement of the impact on SMEs	See sections 6.2, 6.3, 6.4, and 6.5 as well as Annex IV.
(4) Assess alternative options and mitigating measures	See sections 6.2, 6.3, 6.4, and 6.5.

72 The impact rate is the score achieved by rating the replies according to the following table and summing up the result:
Strongly beneficial: +2
Slightly beneficial: +1
No effect: 0
Slightly detrimental: -1
Strongly detrimental: -2
The maximum achievable impact rate for a total of 40 companies would therefore be ± 80.

ANNEX V: SUMMARY OF PREVIOUS RISK ASSESSMENTS ON CADMIUM

Environmental concerns caused by cadmium in fertilisers were raised at Community level during the negotiations for the accession of Austria, Finland and Sweden in 1995. The three Member States were granted temporary derogation from Community legislation on fertilisers pending a careful Community evaluation of the risks from cadmium in fertilisers.

In this context, the Commission first gathered all available data and information on the exposure situation. As not enough data was available in all Member States, the Commission mandated two studies to elaborate a methodology and procedures[73] with a view to assessing the risks to the environment from cadmium in fertilisers. Member States were subsequently invited to carry out nation-wide risk assessments by making use of the above methodology and procedures.

In 2000, eight Member States (plus Norway) submitted reports[74] in line with the agreed methodology. In each case, these assessments showed that soils and climatic conditions strongly affect the rate of soil cadmium accumulation. Those nine countries did not represent the whole EU – Mediterranean countries were not among them – nor did they address the actual risk to human health or the environment, focusing instead only on cadmium accumulation in soil.

In 2002, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) was asked for its opinion[75] on the results of the reports submitted by those eight Member States (+ Norway) and in particular on the likelihood for slow build-up of cadmium in soils through the use of phosphate fertilisers. The SCTEE criticized the mass balance approach chosen by the consultant and used by the nine countries. The main uncertainty associated with this methodology was the estimation of leaching output which has never been confirmed in a real-world environment. This led to some significant variability in the prediction of the long-term soil accumulation sometimes leading to opposing trends. Nevertheless, the SCTEE estimated that despite the differences in values for input and output variables, the various assessments suggested some consistent trends: phosphate fertilisers containing 60 mg cadmium/kg P_2O_5 or above are expected to lead to cadmium accumulation in most European soils and application of 20 mg cadmium/kg P_2O_5 or less would lead to slow increase and even decrease of cadmium accumulation. A similar trend is expected for cadmium accumulation in crops although the actual increase is much smaller.

Moreover, the SCTEE was of the opinion that the derivation of a limit exclusively based on soil accumulation does not take into account the level of risk for human health and the environment associated with the current situation and considered that such a limit should be derived on a more solid risk assessment basis using a probabilistic approach and taking all cadmium sources into consideration.

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73 Environmental Resources Management (ERM), March 1999, contract No **ETD/98/501711** and (ERM), February 2000, contract No **ETD/99/502247**. HTTP://EC.EUROPA.EU/ENTERPRISE/SECTORS/CHEMICALS/DOCUMENTS/SPECIFIC-CHEMICALS/FERTILISERS/CADMIUM/RISK-ASSESSMENT_EN.HTM.

74 Available at: HTTP://EC.EUROPA.EU/ENTERPRISE/SECTORS/CHEMICALS/DOCUMENTS/SPECIFIC-CHEMICALS/FERTILISERS/CADMIUM/RISK-ASSESSMENT_EN.HTM#H2-%0A-RISK-ASSESSMENTS-FROM-THE-MEMBER-STATES%0A--------

75 Scientific Committee on toxicity, ecotoxicity and the environment (SCTEE) – Brussels, 24 September 2002. HTTP://EC.EUROPA.EU/HEALTH/PH_RISK/COMMITTEES/SCT/DOCUMENTS/OUT162_EN.PDF.

In 2004, the opinion of the SCTEE[76] was requested on the results of a first draft EU Risk Assessment Report on cadmium and cadmium oxide (EU RAR). In general, the SCTEE considered that the EU RAR contained satisfactory scientific information to assess the environmental benefit of potential risk management decisions but indicated that probabilistic assessment techniques would enhance the risk characterization and would provide improved insights and information for the risk management. This point was subsequently partly addressed in the revised EU RAR which based its approach on the use of 90^{th} percentiles to introduce a probabilistic element in its assessment.

The lowest dose with observed adverse effects (LOAEL[77]) proposed in the EU RAR for urinary cadmium concentration (Cd-U) is 2 µg cadmium/g creatinine because it has been demonstrated in several studies that this limit is predictive of the age related decline of the kidney filtration rate. However, the SCTEE[78] considered that the proposed LOAEL (Cd-U) of 2 µg Cd/g creatinine is uncertain and not sufficiently conservative.

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[76] Scientific Committee on toxicity, ecotoxicity and the environment (SCTEE) – Brussels, 28 May 2004. HTTP://EC.EUROPA.EU/HEALTH/PH_RISK/COMMITTEES/SCT/DOCUMENTS/OUT228_EN.PDF.

[77] Lowest Observed Adverse Effect Limit.

[78] Scientific Committee on toxicity, ecotoxicity and the environment (SCTEE) – Brussels, 8 January and 28 May 2004. (HTTP://EC.EUROPA.EU/HEALTH/PH_RISK/COMMITTEES/SCT/DOCUMENTS/OUT228_EN.PDF, HTTP://EC.EUROPA.EU/HEALTH/PH_RISK/COMMITTEES/SCT/DOCUMENTS/OUT220_EN.PDF.

ANNEX VI: COMPARISON OF CADMIUM TOLERABLE INTAKES MADE BY EFSA, JECFA AND EU-RAR

Parameter	**EFSA (Issued in 2009)**	**JECFA (Issued in 2010)**	**EU- RAR (Issued in 2007)**	**Comment**
Criterion for the threshold of toxicological concern (effects assessment)	5 % incidence of elevated Beta-2-microglobulin in the sub-population aged >50 years compared with whole population	Any increase in the mean Beta-2-microglobulin level for individuals who were 50 years or older	Elevated levels of low MW proteins in urine	The studies do not give the 'normal' value of the biomarker. It is not known if EFSA and JEFCA take the same value for B2M
Urinary Cd concentration corresponding to the threshold of concern	4 µg Cd/g creatinine	5.24 µg Cd/g creatinine	2 µg Cd/g creatinine	
Adjustment factors applied to above value	3.9 (for inter-individual variations in creatinine/B2M correlation)	None – confidence interval 4.94-5.57	NOAEL=LOAEL/3	
Max safe Cd level in urine	1 µg Cd/g creatinine	5.24 µg Cd/g creatinine	0.66 µg Cd/g creatinine	
Criterion for calculating dietary intake needed for max safe urine level	Safeguard 95th percentile of the non-smoking population after 50 years exposure	Safeguard 95th percentile of the whole population	Safeguard 95th percentile of the non-smoking population after 53 years exposure	JEFCA do not mention the smoker/non-smoker issue
Tolerable intake	2.5 µg Cd/kg body weight/**week**	25 µg Cd/kg body weight/**month**	0.67 µg Cd/kg body weight/**day**	
Tolerable monthly intake (TMI)	**10µg** Cd/kg body weight	**25 µg** Cd/kg body weight	**21 µg** Cd/kg body weight	
Monthly dietary exposure	≥ 10 µg Cd/kg body weight. Mean value for adults, subgroups may be twice as high	No JEFCA assessment, but JEFCA claims that no exposure estimate exceeds 25 µg Cd/kg body weight, even for sensitive groups	4.6-8.5 µg Cd/kg body weight (Norway) 9.3-12 µg Cd/kg body weight (Belgium) 8.9-11.2µg Cd/kg body weight (Italy). Mean values for adults	Additional study from Germany (published in 2010): mean values for adults: 6.0-7.2 µg Cd/kg body weight high consumption groups (teenagers and vegetarians): 12.5-15.0 µg Cd/kg body weight

ANNEX VII: RELATIVE CONTRIBUTION OF VARIOUS SOURCES TO TOTAL CADMIUM INPUT IN SOIL FOR VARIOUS MEMBER STATES

(Source: Environmental and Human Health Risk Reduction Strategy-Cd metal and Cd oxide. Addendum to report of March 2006.04/09307/KDV-April 2007)

		Total Cd input	*Relative contribution of various sources to total cadmium input in soil*					
		g Cd/ha/yr	*Atmospheric deposition*	*Phosphate fertiliser*	*Manure*	*Sewage sludge*	*Lime*	*Other organic wastes*
Austria	Arable land	3,43	61,22 %	22,94 %	13,50 %	1,17 %		1,17 %
	Grassland	3,353	62,63 %	10,44 %	24,55 %	1,19 %		1,19 %
Belgium	Region 1	3,89	38,56 %	27,25 %	33,93 %	0,26 %		
	Region 2	6,04	60,43 %	17,55 %	21,85 %	0,17 %		
	Region 3	38,89	93,85 %	2,73 %	3,39 %	0,03 %		
Czech Republic		1,66	78,31 %	15,66 %	6,02 %			
Denmark	Cereals	4,144	9,89 %	33,59 %	11,78 %	34,99 %	9,65 %	0,10 %
	Root crop	3,552	11,54 %	22,52 %	13,74 %	40,82 %	11,26 %	0,11 %
	Grassland	3,448	11,89 %	20,19 %	14,15 %	42,05 %	11,60 %	0,12 %
Finland		0,605	33,06 %	4,13 %	53,22 %		5,79 %	3,80 %
France		5,35	31,78 %	68,22 %				
Germany		7,94	21,41 %	70,53 %	8,06 %			
Greece	Kopaida	0,971	3,19 %	82,39 %	4,12 %		10,30 %	
	Koropi	0,955	4,71 %	73,30 %	9,42 %		12,57 %	
	Thessaloniki	0,981	4,18 %	71,36 %	14,27 %		10,19 %	
	Lorissa	0,771	4,02 %	64,85 %	18,16 %		12,97 %	
	Biotia	1,324	3,32 %	86,10 %	3,02 %		7,55 %	
	Chalkidiki	0,59	6,78 %	74,58 %	1,69 %		16,95 %	
	Biotia-Kopaida	0,721	4,30 %	83,22 %	5,55 %		6,93 %	
Ireland		4,0747	36,81 %	40,98 %	22,09 %	0,12 %		
Sweden	Min	0,96	67,71 %	27,08 %	5,21 %			
	Max	1,47	44,22 %	52,38 %	3,40 %			
UK		3,98	45,23 %	54,77 %				
Norway	Min	0,88	56,82 %	13,64 %	4,55 %	22,73 %	2,27 %	
	Max	0,97	51,55 %	21,65 %	4,12 %	20,62 %	2,06 %	

ANNEX VIII: LIST OF EU LEGISLATION DEALING WITH CADMIUM

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs	OJ L 364, 20.12.2006, p. 5-24
Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment	OJ L 37, 13.02.2003, p. 19-23
Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles	OJ L 269, 21.10.2000
Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture	OJ L 181, 4.07.1986, p. 6
Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy	OJ L 348, 24.12.2008, p. 84-97
Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy	OJ L 327, 22.12.2000
Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators	OJ L 266, 26.09.2006, p. 1-14
European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	OJ L 365, 31.12.1994, p. 10-23
Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption	OJ L 330, 5.12.1998, p. 32-54
Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration	OJ L 372, 27.12.2006, p. 19-31
Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste	OJ L 332, 28.12.2000, p. 91-111
Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control	OJ L 24, 29.01.2008, p. 8-29
Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Annex XVII	OJ L 396, 30.12.2006, p. 1-849
Directive 2008/50/EC of the European Parliament and of the Council of 21 May 2008 on ambient air quality and cleaner air for Europe	OJ L 152, 11.06.2008, p. 1-44

ANNEX IX: CADMIUM CONTENT IN PHOSPHATE ROCK (MG CD/KG P_2O_5)

Origin	Davister, 1996	Oosterhuis et al, 2000
Igneous rock		
Russia (Kola)	< 13	0,25
Russia (Pharlaborwa)	< 13	0,38
Sedimentary rock		
USA (Florida)	23	24
Jordan	> 30	18
Morocco (Khouribga)	46	55
Syria	52	22
Algeria	60	
Egypt	74	
Morocco (Boucraa)	100	97
Israel	100	61
Morocco (Youssoufia)	121	120
Tunisia (Gafsa)	137	173
Togo	162	147
USA (North Carolina)	166	120
Senegal (Taiba)	203	221

ANNEX X: CADMIUM CONTENT IN CERTAIN FERTILISER TYPES

Trace elements concentration in Triple Superphosphate (TSP). The cadmium concentration is expressed as mg per kg P_2O_5 whereas the concentration of the other elements is expressed in relation to the dry mass of fertilisers. (Source IMPHOS)

			Elements (in mg cadmium/ kg P_2O_5)					
Country	**Deposit**	**P205(%wt)**	**As**	**Cd**	**Cr**	Hg	Ni	Pb
Sediment deposits								
Algeria	Djebel Onk Djebel Onk	28,8 27,9	7,4	53,2 29,3	285,7	0,3		2,3
Australia		28,8	23,0	9,9	57,5	0,1		7,7
Burkina Fasso		25,4	11,2	5,4	54,0	0,2		1,7
China	?	31,1	39,5	5,5	50,2	7,6		1,4
	Kaiyang	35,9	11,9	3,8	23,7	0,3		3,7
Colombia	Media Luna Sardinalia	30,1 36,2		20,3 29,1				
Egypt	Abu Tartur	29,9	55,4	13,0	39,5	0,1		14,1
	Hamrawen	22,2	55,4	46,0	370,6	0,2		1,0
	West Makamid	26,5	10,7	15,4	133,8	0,2		12,5
India	Mussoorie Rajasthan	25,0 36,7	149,4	21,8 1,9	105,9	3,2		22,2
Israel	Arad	32,4	8,0	30,0	189,7	0,2	58,4	1,4
	Zin	**31,1**	15,2	67,4		0,3		3,6
	Oron	33,6	11,3	10,1	150,6	0,2		0,7
	?	32,8		50,2	327,3			3,4
Jordan	El Hasa Ruseife	32,4 30,8	11,7 16,9	11,3	134,3 353,1	0,1	24,8	1,4
	Shidyia	30,5	14,0	13,4	76,0	0,1		1,5
Mali		28,8	18,1	18,9	37,8	0,0		15,4
Morocco	Boucraa	35,1		72,7			25,6	
	Khourbiga	32,6	19,4	31,5	290,1	1,2	46,4	6,8
	Youssoufia	32,1	13,6	61,9	374,2	0,2		9,7
	?	32,4	17,8	54,6	407,2	0,1		
Nauru		37,5	3,8	154,6				
Niger		34,3	5,5	7,9	67,6	0,1		5,2
Peru		30,1	20,9	56,5	201,1	0,2		8,8
Senegal		35,9	22,9	164,3	184,4	0,4	69,8	3,7
Syria		31,9	5,9	6,4	155,6	0,0	37,1	2,1
Tanzania		28,6	13,2	2,4	26,5	0,1		1,6
Togo		36,7	12,9	108,3	130,1	0,5	45,1	4,8
Tunisia		29,3	7,3	139,3	232,4	0,2	25,8	3,0
USA	Central Florida	31,9	16,8	19,4	88,9	0,3	59,3	11,8
	North Florida	31,2	10,6	13,3	98,5		33,3	8,5
	North Carolina	29,9	17,7	86,9	249,9	0,4		5,9
	Idaho	31,7	35,4	198,1	950,2	0,4	126,8	8,4
Venezuela		27,9	6,8	9,8	55,9	0,1		1,6
Mean		**31,2**	**20,0**	**45,4**	**195,5**	**0,6**	**53,0**	**5,7**
Igneous deposits								
South Africa		38,2	16,1	2,3	1,2		43,3	6,4
Brazil	Araxa	37,0	22,4	4,6	38,3	0,1		13,2
	Catalão	37,4	19,0	3,6	45,5	0,1		17,2
Burundi		40,4	2,3	3,4	36,3	0,0		5,5
Finland		39,5	3,6	3,4	16,8	0,0		2,2
Uganda		38,6	4,9	1,8	13,5	0,0		20,7
Russia	Kola	35,9	13,2	2,3			2,6	20,4
Sri Lanka		36,4	34,7	4,1	129,9	0,3		7,3
Sweden	Grangesburg	37,8	469,1	1,8	25,0	0,1		11,7
	Kjiruna	37,2	945,7	0,0		0,2		6,0
Zimbabwe		33,1	8,6	2,1	14,3	0,1		4,0
Mean		**37,4**	**153,0**	**2,7**	**34,1**	**0,1**		**8,9**

Trace elements in Mono Ammoniumphosphate (MAP). The cadmium concentration is expressed as mg per kg P_2O_5 whereas the concentration of the other elements is expressed in relation to the dry mass of fertilisers. (Source IMPHOS)

			Elements (in mg cadmium/ kg P_2O_5)					
Country	**Deposit**	**P205(%wt)**	**As**	**Cd**	**Cr**	**Hg**	**Ni**	**Pb**
Sediment deposits								
Algeria	Djebel Onk Djebel Onk	28,8 27,9	8,6	51,6 28,4	334,3	0,4		1,5
Australia		28,8	26,9	9,6	67,2	0,2		5,1
Burkina Fasso		25,4	13,1	5,2	63,2	0,2		1,1
China	?	31,1	46,3	5,3	58,7	8,9		0,9
	Kaiyang	35,9	13,9	3,7	27,7	0,3		2,4
Colombia	Media Luna Sardinalia	30,1 36,2		19,8 28,3				
Egypt	Abu Tartur	29,9	64,8	12,6	46,3	0,1		9,3
	Hamrawen	22,2	64,8	44,6	433,7	0,2		0,7
	West Makamid	26,5	12,5	15,0	156,6	0,2		8,2
India	Mussoorie Rajasthan	25,0 36,7	174,8	21,1 1,8	123,9	3,7		14,6
Israel	Arad	32,4	9,4	29,2	222,0	0,2	68,3	0,9
	Zin	31,1	17,8	65,4		0,4		2,3
	Oron	33,6	13,2	9,8	176,2	0,2		0,4
	?	32,8		48,8	382,9			2,2
Jordan	El Hasa Ruseifa	32,4 30,8	13,7 19,8	11,0	157,1 413,2	0,1	29,0	0,9
	Shidyia	30,5	16,3	13,0	88,9	0,1		1,0
Mali		28,8	21,1	18,4	44,2	0,1		10,1
Morocco	Boucraa	35,1		70,6			29,9	
	Khourbiga	32,6	22,7	30,6	339,4	1,5	54,3	4,5
	Youssoufîa	32,1	15,9	60,1	437,8	0,2		6,4
	?	32,4	20,8	53,0	476,4	0,1		
Nauru		37,5	4,4	150,1				
Niger		34,3	6,5	7,7	79,0	0,2		3,4
Peru		30,1	24,4	54,9	235,3	0,2		5,8
Senegal		35,9	26,8	159,6	215,8	0,4	81,7	2,4
Syria		31,9	6,9	6,2	182,1	0,1	43,4	1,4
Tanzania		28,6	15,5	2,3	31,0	0,1		1,0
Togo		36,7	15,1	105,1	152,3	0,5	52,8	3,2
Tunisia		29,3	8,5	135,3	271,9	0,2	30,2	2,0
USA	Central Florida	31,9	19,6	18,8	104,1	0,3	69,4	7,8
	North Florida	31,2	12,4	12,9	115,3		39,0	5,6
	North Carolina	29,9	20,7	84,4	292,4	0,4		3,9
	Idaho	31,7	41,4	192,4	1111,8	0,5	148,4	5,5
Venezuela		27,9	7,9	9,5	65,4	0,1		1,0
Mean		**31,2**	**23,4**	**44,1**	**228,8**	**0,7**	**62,1**	**3,7**
Igneous deposits								
South Africa		38,2	18,8	2,2	1,4		50,7	4,2
Brazil	Araxa	37,0	26,2	4,5	44,9	0,2		8,7
	Catalão	37,4	??,2	3,5	53,3	0,1		11,3
Burundi		40,4	2,7	3,3	42,5	0,0		3,6
Finland		39,5	4,2	3,3	19,6	0,1		1,5
Uganda		38,6	5,7	1,7	15,8	0,1		13,6
Russia	Kola	35,9	15,4	2,2			3,1	13,4
Sri Lanka		36,4	40,6	4,0	152,0	0,4		4,8
Sweden	Grangesburg	37,8	548,9	1,7	29,3	0,1		7,7
	Kjiruna	37,2	1106,6	0,0		0,2		3,9
Zimbabwe		33,1	10,0	2,0	16,7	0,1		2,6
Mean		**37,4**	**179,0**	**2,7**	**39,9**	**0,1**		**5,8**

Trace elements concentrations in Diammonium Phosphate (DAP). The cadmium concentration is expressed as mg per kg P_2O_5 whereas the concentration of the other elements is expressed in relation to the dry mass of fertilisers. (Source IMPHOS)

			Elements (in mg cadmium/ kg P_2O_5)					
Country	**Deposit**	**P205(%wt)**	**As**	**Cd**	**Cr**	**Hg**	**Ni**	**Pb**
Sediment deposits								
Algeria	Djebel Onk Djebel Onk	28,8 27,9	7,3	49,7 27,4	280,6	0,31		1,3
Australia		28,8	22,6	9,3	56,4	0,13		4,2
Burkina Fasso		25,4	11,0	5,0	53,0	0,16		1,0
China	?	31,1	38,8	5,1	49,3	7,45		0,8
	Kaiyang	35,9	11,6	3,5	23,3	0,27		2,0
Colombia	Media Luna Sardinalia	30,1 36,2		19,0 27,3				
Egypt	Abu Tartur	29,9	54,4	12,1	38,8	0,12		7,8
	Hamrawen	22,2	54,4	43,0	364,0	0,17		0,6
	West Makamid	26,5	10,5	14,4	131,4	0,16		6,9
India	Mussoorie Rajasthan	25,0 36,7	146,7	20,4 1,7	104,0	3,10		12,2
Israel	Arad	32,4	7,9	28,1	186,3	0,19	57,3	0,8
	2n	31,1	14,9	63,1		0,30		2,0
	Oron	33,6	11,1	9,5	147,9	0,18		0,4
	?	32,8		47,0	321,4			1,9
Jordan	El Hasa Ruseife	32,4 30,8	11,5 16,6	10,6	131,9 346,8	0,07	24,4	0,8
	Shidyia	30,5	13,7	12,5	74,6	0,08		0,8
Mali		28,8	17,7	17,7	37,1	0,05		8,5
Morocco	Boucraa	35,1		68,0			25,1	
	Khourbiga	32,6	19,1	29,5	284,9	1,22	45,6	3,7
	Youssoufia	32,1	13,3	57,9	367,4	0,17		5,3
	?	32,4	17,5	51,1	399,9	0,09		
Nauru		37,5	3,7	144,7				
Niger		34,3	5,4	7,4	66,3	0,14		2,9
Peru		30,1	20,5	52,9	197,5	0,19		4,9
Senegal		35,9	22,5	153,8	181,1	0,35	68,6	2,0
Syria		31,9	5,8	6,0	152,8	0,04	36,4	1,1
Tanzania		28,6	13,0	2,2	26,0	0,06		0,9
Togo		36,7	12,7	101,3	127,8	0,46	44,3	2,7
Tunisia		29,3	7,1	130,4	228,2	0,16	25,4	1,7
USA	Central Florida	31,9	16,4	18,2	87,3	0,29	58,2	6,5
	North Florida	31,2	10,4	12,4	96,7		32,7	4,7
	North Carolina	29,9	17,4	81,3	245,4	0,36		3,3
	Idaho	31,7	34,7	185,4	933,1	0,42	124,5	4,6
Venezuela		27,9	6,7	9,1	54,9	0,10		0,9
Mean		**31,2**	**19,6**	**42,4**	**192,0**	**0,57**	**52,1**	**3,1**
Igneous deposits								
South Africa		38,2	15,8	2,2	1,2		42,5	3,5
Brazil	Araxa	37,0	22,0	4,3	37,7	0,14		7,3
	Catalão	37,4	18,6	3,4	44,7	0,05		9,5
Burundi		40,4	2,3	3,2	35,6	0,02		3,0
Finland		39,5	3,5	3,2	16,5	0,05		1,2
Uganda		38,6	4,8	1,6	13,2	0,05		11,4
Russia	Kola	35,9	12,9	2,1			2,6	11,2
Sri Lanka		36,4	34,1	3,8	127,6	0,32		4,0
Sweden	Grangesburg	37,8	460,7	1,7	24,6	0,07		6,5
	Kjiruna	37,2	928,7	0,0		0,19		3,3
Zimbabwe		33,1	8,4	1,9	14,0	0,06		2,2
Mean		**37,4**	150,2	**2,6**	33,5	0,07		4,9

ANNEX XI: GLOBAL PHOSPHATES PRODUCTION AND RESERVES

World production of phosphate rock[79] in 2005 *(Source US Geological Survey)*

Country	Production (10^6 kg)	World share (%)
United States	36 300	24,69
China	30 400	20,68
Morocco	25 200	17,14
Russia	11 000	7,48
Tunisia	8 000	5,44
Jordan	6 230	4,24
Brasil	6 100	4,15
Syria	3 500	2,38
Israel	2 900	1,97
Egypt	2 730	1,86
South Africa	2 577	1,75
Australia	2 050	1,39
Senegal	1 520	1,03
Togo	1 215	0,83
India	1 200	0,82
Canada	1 000	0,68
Algeria	878	0,60
Finland	825	0,56
Others	3 396	2,31
Total	147 021	100

79 The P_2O_5 content varies with the origin of the rock.

World phosphate rock reserves and reserves base *(Source: US Geological Survey 2007 and 2008)*

	Mean grade (wt % P_2O_5)	Mine production 2005 (1 000 tons)	Mine production 2006 (1 000 tons)	Reserves[80] (1 000 tons)	Reserve base[81] (1 000 tons)
United States of America	31,2	36 300	30 100	1 200 000	3 400 000
Australia	31,2	2 050	2 300	77 000	1 200 000
Brazil	35 to 38	6 100	5 800	260 000	370 000
Canada	37,5	1 000	550	25 000	200 000
China	35,9	30 400	30 700	6 600 000	13 000 000
Israel	32,5	2 900	2 200	180 000	800 000
Syria	31,9	3 500	3 850	100 00	800 000
Jordan	31,2	6 230	5 870	900 000	1 700 000
Egypt	26,2	2 730	2 200	100 000	760 000
Morocco	32,2	25 200	27 000	5 700 000	21 000 000
Senegal	35,9	1 520	600	50 000	160 000
South Africa	36 to 40	2 580	2 600	1 500 000	2 500 000
Togo	36,7	1 220	1 000	30 000	60 000
Tunisia	30	8 000	8 000	100 000	600 000
Russian Federation	39 to 40	11 000	11 000	200 000	1 000 000
Other countries		6 500	7 740	890 000	2 200 000
World total		147 000	142 000	18 000 000	50 000 000

[80] Assuming a production cost of USD 36/ton.

[81] Assuming a production cost of USD 90/ton.

ANNEX XII: DECADMIATION PROCESSES

The CERPHOS (Centre d'Etudes et de Recherches des Phosphates Minéraux) and a Dutch start-up[82] have developed on laboratory scale two decadmiation processes that could be suitable and economically viable for the fertilisers industry. The feasibility of both processes has not yet been demonstrated at industrial scale and the environmental and economic aspects will have to be carefully investigated when they will be available.

- The CERPHOS process[83] (co-crystallisation):

This co-crystallisation process is based on the addition of sulphate ions in the form of gypsum to the diluted phosphoric acid before a concentration step. The following crystallisation is influenced by many impurities and must be adjusted to the phosphate rock processed. The removal of cadmium requires a temperature between 80 °C to 100 °C and takes place at a phosphoric acid concentration above 56.6 % P_2O_5. A purity level of 87 % could be achieved (corresponding to a reduction from 75 to 10 mg Cd/kg P_2O_5) but requires investment costs of around USD 4.56 million. In 2007, CERPHOS estimated that the increase in DAP fertiliser prices is expected at around USD 30/ton P_2O_5 if this process is introduced. The process generates also an important amount of cadmium salts that must be disposed of and the post-treatment of those salts should have an important impact on the final costs. The figures will have to be refined by CERPHOS when data from a pilot plant – the construction of which remains uncertain – will be available.

- The ELICAD process:

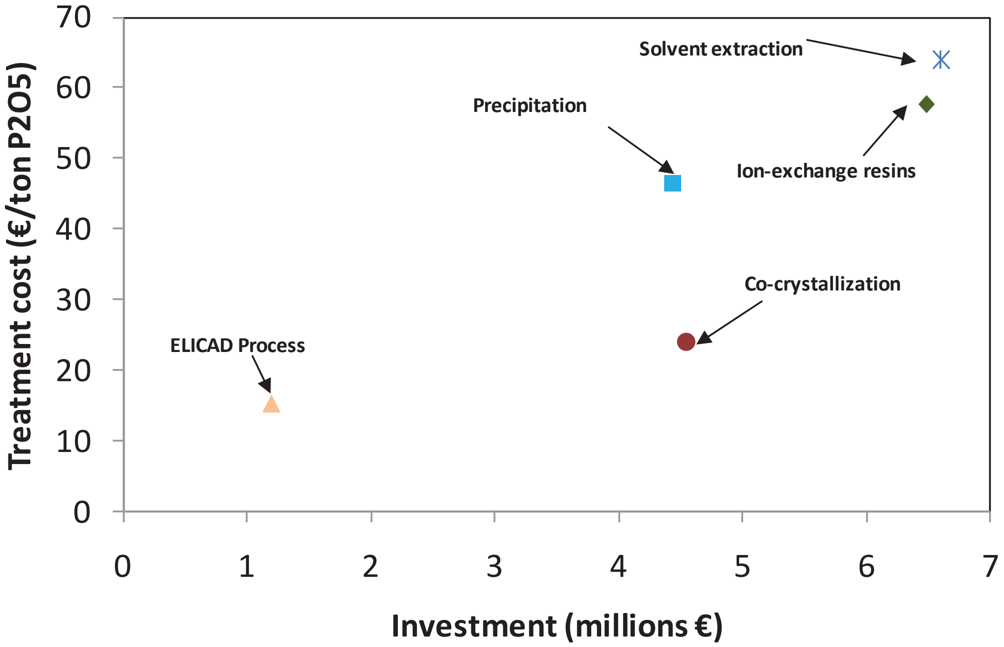
This process would eliminate cadmium from a continuous flow of phosphoric acid by a selective adsorption of cadmium on an active material. When this material is saturated, it can be regenerated five times by a physico-chemical treatment. The process allows also the removal of other heavy metals like arsenic, mercury, nickel, copper, zinc, vanadium, chromium and lead and most probably uranium. The investment costs should be below EUR 1.2 million for an installation treating 1200 tons of phosphoric acid per day. Fertiliser price increase from the use of this technology would be around EUR 12 to 32/ton P_2O_5 (figures from 2009) for a 90 % effectiveness. The figures need to be refined when data from a pilot plant will be available. This was expected by mid 2010, however no project for constructing a pilot plant found the necessary funding and it is uncertain when this will happen. The objective of the Dutch start-up is to make the process eventually available to fertilisers and mining companies.

Compared to other decadmiation processes, the ELICAD process would be more cost effective as illustrated in the following figure.

[82] INOS: Innovative Engineering System.

[83] Promoting the development and semi-industrial application of a potentially high performing process for removing cadmium from phosphoric acid. CERPHOS issue paper to OECD Cd Workshop – Stockholm 1995.

Costs estimations of different decadmiation processes (Source INOS).



Based on the potential cost increases from the use of the ELICAD process, the increase in mineral phosphate fertilisers prices has been estimated by IFA as presented in the following table. Further calculations conducted by the Commission are contained in Annex XIV.

Potential increase in price for several phosphate fertiliser types from Morocco related to the implementation of a decadmiation process (Source: IFA)

Fertiliser name	**Decadmiation costs of phosphoric acid** EUR/t P_2O_5	**Fertiliser prices in September 2009** EUR/t fertiliser	**Average price increase if the ELICAD process is introduced** EUR/t fertiliser	**Average percentage increase in fertiliser price if the ELICAD process is introduced** %
DAP	0	**305**	-	*0,0*
Diammonium phosphate	12 (= USD 15)	311,5	6,5	*2,2*
	32 (= USD 40)	324,5	19,5	*6,4*
MAP	0	**283**	-	*0,0*
Monoammonium phosphate	12 (= USD 15)	289,7	6,7	*2,4*
	32 (= USD 40)	303	20	*7,1*
TSP	0	**242**	-	*0,0*
Triple superphosphate	12 (= USD 15)	247,1	5,1	*2,1*
	32 (= USD 40)	257	15	*6,2*

As worldwide demand for cadmium metal is decreasing due to growing restrictions on its use, it will most likely not be possible to sell the recycled cadmium metal in order to reduce costs. Therefore, there is little incentive to recover cadmium at all and the initial residues will have to be disposed of which will create risks of inappropriate disposal and contamination of the environment in producing countries. However, the capture and possible recovery of several other heavy metals in the ELICAD process would allow a reduction of the costs for the treatment of the saturated product and its final destruction.

Currently, 130 million tons of phosphogypsum are produced each year worldwide as by-product of the production of phosphoric acid. The costs for treatment and management of phosphogypsum reach up to EUR 5/ton. The introduction of a decadmiation technology could partly reduce this volume and make phosphogypsum more available as raw material product for construction. The management of the cadmium-rich waste generated by the decadmiation process would need to be properly addressed to avoid environmental pollution.

ANNEX XIII: CURRENT SUPPLY OF THE EU IN PHOSPHATE FERTILISERS

In the EU, phosphorous is supplied to agricultural land either by mineral fertilisers (natural rock phosphate, superphosphates and NPK mixtures) or by organic fertilisers (mostly animal manure and slurry as well as to a lesser extent, sludge and bio-waste).

The rationale for phosphorous application is to maintain soil phosphorous concentration in readily available soil reserves sufficiently high to ensure a correct crop yield. This is achieved by replacing the quantity of phosphorous that is removed from soil in the harvested crops (maintenance and replacement application). At farm level, an analysis of soil samples is conducted every 4 or 5 years to determine the needs in fertilisers for a particular crop.

In European agriculture, environmental concerns related to the use of phosphate fertilisers (eutrophication in surface and marine waters as a consequence of run-off of phosphates from agricultural land) and a better understanding of the plant nutrition mechanisms have allowed a substantial decrease in the consumption of phosphate fertiliser in recent years.

For example, the French fertiliser manufacturers association has reported on average a strong decrease in the consumption of chemically processed phosphate fertilisers since 1972 from 72 kg P_2O_5/ha/year to approximately 23 kg P_2O_5/ha/year for the growing season 2007-2008.

1. Mineral fertilisers

The worldwide primary market for phosphate rock derivatives is agriculture (79 %) followed by animal feeds (11 %), detergents (7 %) and specific applications (3 %). Mined phosphate rock is not commonly used directly as fertiliser because the solubility of the phosphate in the rock is rather low. In order to increase the bioavailability of rock phosphate on neutral and alkaline soils, phosphate fertilisers are manufactured from the rock by dissolution in acid and subsequent precipitation. In the past, phosphate rock was imported into the EU for conversion to fertilisers but producing countries now generally prefer to export either the phosphoric acid intermediate product or even the finished fertiliser (mainly in the form of ammonium phosphate) which offers significant technical and economic advantages. This trend is likely to continue for all producing countries.

Currently, only one European fertiliser producer can be supplied with igneous rocks from Finland and Russia at affordable price as Russia prefer to export to the high added value feed supplements market. All others rely mainly on the sedimentary rocks, the phosphoric acid or the final products coming from North Africa to produce phosphate fertiliser. The current cadmium content of the most largely used phosphate fertilisers are described in Annex X in relation to their origin.

Morocco and China hold the most important phosphate reserves in the world (See Annex XI).

Jordan, Syria and Egypt have substantial reserves of sedimentary phosphate rock of low cadmium content (1.7 Gt, 0.8 Gt and 0.75 Gt respectively – US Geological Survey Minerals Yearbook 2000) but their phosphate fertiliser production capacity is limited and can not cover all the EU farmers needs in the short term. EU organic farmers needs could however be covered, but the Jordan and Syrian ores are very dusty and some European ports have already banned their unloading in bulk shipments.

Current world reserves of phosphate rocks are estimated to last 100 years (at current consumption and production costs) but this could be extended to more than 300 years if proven phosphate deposits become economically viable in the future. (See Annex XI). Large phosphate resources have been identified on the continental shelves and on seamounts in the

Atlantic Ocean and the Pacific Ocean, but cannot be recycled economically with current technology.

2. Other sources of nutrient phosphorous

Organic fertilisers are another source of phosphorous supply. However, whilst mineral fertilisers (with the exception of natural ground phosphate) are readily available for plants, only a fraction of the phosphates in organic materials can be assimilated by crops (See table). The organically bound phosphorous mineralises slowly through the activity of soil microorganisms and becomes thereby available for plants.

Indicative phosphate levels and the relative distribution of mineral phosphorous and organically bound phosphorous in different organic wastes in relation to the mineral fertiliser TSP (triple superphosphate). (Source Alterra report 991, 2004)

Manure Type	Total phosphate content (kg P_2O_5 ton^{-1})	Mineral Phosphorous. Readily available for plants (% on mass)	Organic Phosphorous. Slowly available for plants (% on mass)
Solid cattle manure	3,3	60	40
Cattle slurry	1,5	90	10
Chicken slurry	6,7	80	20
Fixed pig slurry	11,8	85	15
Pig slurry	2,6	95	5
Compost	4,4	70	30
Urban sludge[84]	1,8	50	50
Garden turf	0,6	20	80
Triple superphosphate (TSP)	460	100	0

The amount of phosphorous mineralised (and hence bioavailable) show great variability and depend not only on climatic conditions, storage, handling but also on the farming system and the nature of the soil.

3. Cadmium content in various organic waste

The next table shows the average cadmium content in different organic wastes in 13 Member States.

Cadmium content in different organic wastes (mg cadmium/kg P_2O_5) (Source: Annex to the Report from the Commission to the Council and the European Parliament on the implementation of community waste legislation – Directive 75/442/EEC on waste, Directive 91/689/EEC on hazardous waste, Directive 75/439/EEC on waste oils, Directive 86/278/EEC

[84] According to data provided by UNIFA.

on sewage sludge and Directive 94/62/EC on packaging and packaging waste, Directive 1999/31/EC on the landfill of waste – for the period 2001-2003 {COM(2006) 406 final) SEC(2006)972)

Compost	25
Cattle manure	11
Pig manure	10
Sewage sludge	23

Despite its low cadmium concentration, urban sludge is often applied in such quantities that the annual cadmium input to the soil might exceed the cadmium input from the use of mineral phosphate fertilisers as illustrated in the following example from Belgium. In 2006, farmers in the Walloon Region have applied on average 4 tons of urban sludge per hectare containing on average 1.5 mg cadmium/kg dry matter. This means an average annual input of 6 g cadmium per hectare. In comparison the average annual input from the application of phosphate fertiliser containing 60 mg cadmium/kg P_2O_5 and applied at an annual rate of 40 kg per hectare is of 2.5 g cadmium per hectare. Urban sludge is prohibited for use as fertiliser in Flanders.

Consequently, when setting limit values for cadmium in mineral phosphate fertilisers other sources of cadmium, such as urban sludge, also need to be addressed. A revision of the sewage sludge Directive is under preparation and more stringent Community values for heavy metals content in sludge might emerge.

4. Organic or inorganic: which nutrient source is better for plants?

Mineral fertiliser contains precise, guaranteed levels of nutrients, in forms that are readily available for plant uptake and use. Their application can be timed to meet crop requirements, assuring efficient nutrient use and minimizing any potential impact on the environment if used correctly. Because of their high nutrient content, mineral fertilisers are easy and economical to ship to great distance from their point of production. However the reserves of mineral phosphate are finite and located in a limited number of countries. They also contain certain amounts of hazardous substances such as heavy metals (including cadmium).

Organic fertilisers such as manure, urban sludge and bio-waste contain varying amounts of plant nutrients and provide organic carbon. They improve the biological, chemical and physical properties of the soil. There are, however, concerns associated with their use:

– They are low in nutrient content making impractical the transport of organic sources over long distances.

– It is also virtually impossible to time the release of the nutrients they contain so as to match the needs of the growing crop and minimize residual amounts that can impact the environment. For example, the nitrogen content of manure and human waste (sewage sludge) is often the factor determining the rate of application. Their relative fixed nutrient ratios can result in excessive phosphorous loading in heavily manured soils because crops require much less phosphorous compared to nitrogen contained in the manure. This can pose a threat of excessive phosphorous moving into surface waters though runoff.

– Nutrient content of livestock manures and other organic material varies considerably. The phosphorous content in manure and urban sludge might decrease somewhat in the future following the continuous decrease of phosphorous in animal feedstuffs and detergents. The quantity of animal husbandry is now stabilised in EU 27 after a significant decrease for the period 2003-2007.
– Indiscriminate use of animal manures and urban sludge can create human health hazards through the accumulation of heavy metals (including cadmium), pathogens and organic compounds.

Therefore, the quality of municipal sewage sludge, manure and meat and bone meal as regards their heavy metals and nutrient content should be improved and projects under the Sixth EU Research Framework Programme have aimed at increasing their use in agriculture and thereby at reducing the EU dependence on mineral phosphate fertilisers.

According to an Austrian engineering company which has developed a process for treating urban sludge and slaughterhouse residues, 15 EU plants could be equipped with such technology to produce around 650 000 tons of phosphorous (as P_2O_5) annually within a period of 5 to 7 years.

This company has recently put on the German and Austrian markets two compound fertilisers (NPK and PK) to assess the reaction of farmers. Both products were accepted as valuable alternatives to traditional mineral fertilisers. However, recycled phosphate fertilisers are currently sold at EUR 0.85-0.90/kg P_2O_5 when triple superphosphate is sold at EUR 0.55-0.60/kg P_2O_5. This disadvantage is currently overcome by selling specialities.

5. Accessibility of mineral phosphate fertilisers for EU farmers during the last three years

During the season 2007/2008, prices for all kind of fertilisers have surged worldwide (see next table). Phosphate rock prices have multiplied by 9 in 12 months from around EUR 32/ton to EUR 272/ton. The reasons for this price increase are the global demographic pressure, high energy prices and the demand for renewable fuels, thereby pushing the demand for fertilisers which cannot be immediately balanced by a production increase of the phosphate rock producers. Prices decreased again in 2009 as a consequence of the global economic crisis.

In 2009, access to finance remained a key problem in the current economical situation and certain categories of farmers were unable to take out loans to buy fertilisers because banks refused to provide credits in the light of the financial and economic crisis.

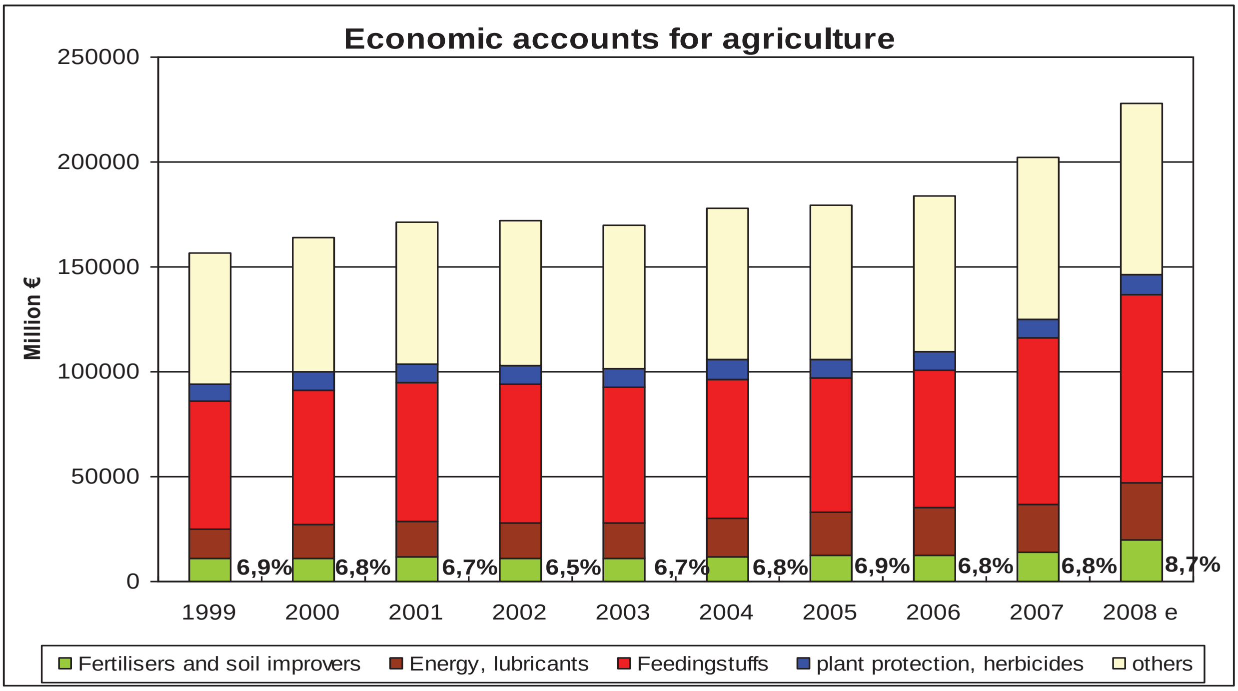
Fluctuations in prices for DAP (Diammonium Phosphate), TSP (Triple Superphosphate) and NPK (compound fertiliser) during the last two years in EUR/ton. (Source World Bank and EFMA)

Fertiliser name	January-December 2007	January-December 2008	January-October 2009
DAP (bulk, fob US Gulf)	290	315	215
TSP (bulk, fob US Gulf)	225	590	175

NPK 16-16-16 (fob Baltic)	250	600	280

By the end of 2009, prices of agricultural produce were at historical low level – cereals prices largely depend on cereals worldwide stocks. This had an impact on the purchase of fertilisers by EU farmers who already reduced their fertiliser purchase in spring and autumn and intend to adopt a very cautious approach for 2010. This negative environment had consequences on the production and turnover of some SMEs producing mineral fertilisers.
The current share of costs for fertilisers and soil improvers in cereal farmers' input costs was around 8.1 % in 2008, slightly higher than the long term average of 6.8 % (see figure below for further details).

EU Farmers input costs for the last ten years (Source EFMA)



6. Description of the EU fertiliser industry

EU fertiliser producers are organised in two different categories:

- large companies transforming the basic elements (nitrogen from air, phosphorous and potassium from mines) into a small range of fertilisers that are used for cereals, colza and maize crops,
- Small and Medium Size Enterprises which blend fertilisers produced by the majors for specific needs of their local market (vineyards, fruits, vegetables…).

Fertiliser manufacturing plants are distributed throughout the EU. Major producing Member States are France, The Netherlands, Germany, Poland and Spain, being close to the market because transport costs constitute a significant part of the cost of the finished product. Together with energy costs, the other main factor affecting the competitive position of fertiliser manufacturers and importers will be the price and the availability of the phosphate-based raw materials and intermediate products. Since cadmium has not yet become a determining factor for the price of phosphate rock and fertilisers, the price of igneous or sedimentary rocks are roughly the same.

ANNEX XIV: MODELLING THE INCENTIVES FOR DECADMIATION BY TAXATION / SUBSIDIES

Incentives to invest in decadmiation can be steered by imposing a tax on the cadmium content of phosphate fertiliser. The same results can be used to determine an appropriate subsidy, as essentially, a subsidy is a negative tax. Therefore, only taxation will be analysed here, the discussion of subsidies would be analogous.

The basic model[85] consists of a simple tax per gram of cadmium per ton of phosphate expressed in P_2O_5 put on the market. The tax rate is denoted by t [in EUR/g] and needs to be paid by the manufacturer[86].

The model assumes that fixed costs are required to build a decadmiation plant and that constant variable costs are incurred for the decadmiation of a ton of phosphate. The fixed costs are denoted by C^f and the variable cost by c. Both are measured in EUR.

Furthermore, the cadmium content of the non-decadmiated fertiliser is denoted by x and measured in [g/ton].

Finally, the model assumes that decadmiation cannot remove all cadmium from the phosphates but that a fraction remains. That fraction is denoted by β. Note that in the model, the tax is still to be paid on the remaining cadmium content after decadmiation[87]. It further assumes that the variable cost is independent of the original cadmium content of the input phosphate.

In this model, producers of fertilisers are only interested in profit maximisation. Therefore, they will invest in decadmiation and decadmiate phosphates if (and only if) this is cheaper than paying the tax for the entire cadmium content of the non-decadmiated phosphate fertiliser. It is clear that a necessary (but not sufficient) condition that needs to be met if decadmiation is to be stimulated is that the variable cost of decadmiating a ton of fertiliser are lower than the tax savings that can be realised by it.

Mathematically, this can be described as follows:

(1) if $c + x \cdot \beta \cdot t > x \cdot t$, then it is cheaper to pay the tax than to pay c per ton of fertiliser in order to save $(1 - \beta) \cdot x \cdot t$. Therefore the following condition needs to be met to make decadmiation interesting for given cadmium content of phosphate:

(2) $c + x \cdot \beta \cdot t \leq x \cdot t$. This can be rewritten as follows:

(3) $$c/t + x \cdot \beta \leq x \Leftrightarrow c/t \leq x \cdot (1-\beta) \Leftrightarrow \frac{c}{t \cdot (1-\beta)} \leq x$$

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85 This model is based on several assumptions that need not necessarily be met in reality. Most importantly, it uses cost estimates for decadmiation that are based on laboratory scale processes or at best pre-commercial pilot plants. None of these technologies is currently used at industrial level. Therefore the cost estimates may not reflect what can be realised in practice.

86 This is the simplest way of collecting the tax. Other ways are possible and should not lead to radically different conclusions.

87 There are other ways how the tax system could be designed. One could for instance think of a tax that is only payable for fertiliser with a cadmium content above a certain threshold, while for fertiliser below it, no tax needs to be paid at all. This would limit price increases for decadmiated fertiliser to the same level as a regulatory limit. However, such a tax system would be so similar to introducing a regulatory limit that the additional administrative cost of setting up and enforcing a tax system does not appear justifiable.

Furthermore, this condition is not sufficient to induce decadmiation *ex-ante*, since it is also necessary to recover the investment costs over the lifetime of a decadmiation plant (C^f and the cost of capital).

Therefore, the model is extended by the following:

A decadmiation plant has initial investment costs of C^f [in EUR] and an expected lifetime of L years. Furthermore, it has a daily capacity of decadmiating R tons of phosphate and operates on d days per year. Finally, cost of capital is described by i.

In order to operate profitably, a plant must generate sufficient margins to recover the cost of capital over time. The (constant) margin per ton required is denoted by π. This condition is met if the margin allows realising a positive net present value (NPV, see also Annex 11.6 of the Commission IA guidelines).

This can be written as

(4) $$-C^f + \sum_{n=1}^{L} \frac{\pi \cdot R \cdot d}{(1+i)^n} > 0 \Leftrightarrow R \cdot d \cdot \sum_{n=1}^{L} \frac{\pi}{(1+i)^n} > C^f$$

We will calculate the minimum margin required to just generate a zero net present value in a first step, using parameters for two known decadmiation technologies. In a second step, we can then calculate the tax rate that is necessary to induce decadmiation for all fertiliser exceeding a desired threshold in terms of cadmium content per ton of fertiliser.

ELICAD process:

For the so-called ELICAD process, the following values are known:

C^f = EUR 1 200 000   R = 1 200 tons P_2O_5/day   L = 20 years

c = EUR 16 to 20 per ton P_2O_5

The number of operating days (d) is assumed to be 300 per year. The required return on investment is assumed to be 4 % (i). Finally, β is assumed to be 0.1 (90 % of cadmium can be removed).

In order to achieve a positive NPV, the annual operating profit must be greater than EUR 88 300, which translates into a margin of π = EUR 0.25 per ton.

In a second step, the tax rate (t) can be calculated, which incentivises decadmiation for a given level of maximum cadmium content desired in fertilisers (Cd^{max}), while still allowing generating the required margin per ton of fertiliser that is decadmiated.

From equation (3) it can be seen that the following must hold:

(5) $$t \geq \frac{c}{x \cdot (1-\beta)}$$ but this equation needs to be amended to also incorporate the margin per ton required to make the initial investment worthwhile.

This can be done by simply replacing the term c by the term c + π, such that

(6) $$t \geq \frac{c+\pi}{x \cdot (1-\beta)}$$

For the maximum levels discussed in the options in this impact assessment, the required tax rates for the ELICAD technology would be:

Cd^{max}	t [EUR/g] for low c	t [EUR/g] for high c	tax per ton [EUR] for low c	tax per ton [EUR] for high c
60	0.3	0.37	18	22.5
40	0.45	0.56	18	22.5
20	0.90	1.12	18	22.5

At a price level of USD 250/ton phosphate fertiliser – as observed for example during 2007 (see Annex XIII) – and an exchange rate of USD 1.25 per EUR, this would mean a price increase of 9-11 % for a ton of phosphate with a cadmium content close to the desired maximum level. If the initial cadmium content is higher, the price increases would also be higher – see illustrative example below.

CERPHOS process:

For the so-called CERPHOS process, the following values are known:

C^f = EUR 4 560 000   R = 1 200 tons P_2O_5/day   L = 20 years

c = EUR 24 per ton P_2O_5

The number of operating days (d) is assumed to be 300 per year. The required return on investment is assumed to be 4 % (i). Finally, β is assumed to be 0.1 (90 % of cadmium can be removed).

In order to achieve a positive NPV, the annual operating profit must be greater than EUR 335 600, which translates into a margin of π = EUR 0.93 per ton.

For the maximum levels discussed in the options in this impact assessment, the required tax rates for the CERPHOS technology would be:

Cd^{max}	t [EUR/g]	tax per ton [EUR]
60	0.5	28
40	0.7	28
20	1.4	28

At a price level of USD 250/ton phosphate fertiliser – as observed for example during 2007 (see Annex XIII) – this would mean a decadmiation cost of 14 % for a ton of phosphate with a cadmium content close to the desired maximum level. If the initial cadmium content is higher, the price increases would also be higher – see illustrative example below.

Illustrative example

In order to illustrate how the model works, we choose the case of a producer who sells phosphate with a cadmium content of 100 g/ton (which corresponds to 100 mg cadmium/kg P_2O_5). If a tax on cadmium is introduced, the producer would have to pay a tax of $T = t \cdot$ EUR 100 per ton if he decides not to use decadmiation. On the other hand, if the producer decides to decadmiate, he incurs the decadmiation costs and he would need to pay a tax on the remaining cadmium content after decadmiation. This would amount to $c + \pi + \beta \cdot t$.

The following table reports the additional financial burden on the manufacturer for the scenarios described above, once for simply paying the tax and once for decadmiating and paying a tax on the remaining cadmium content (for β we use the 10 % as above).

ELICAD process:

Cd^{max}	t [EUR/g] for low c	t [EUR/g] for high c	Cost for simply paying the tax (low c)	Cost for simply paying the tax (high c)	Cost for decadmiating and paying tax on remaining Cd (low c)	Cost for decadmiating and paying tax on remaining Cd (high c)
60	0.3	0.37	30	37	19.25	23.95
40	0.4	0.56	40	56	20.25	25.85
20	0.9	1.12	90	112	25.25	31.45

At a price level of USD 250/ton phosphate fertiliser – as observed for example during 2007 (see Annex XIII) – and an exchange rate of USD 1.25 per EUR this would mean a price increase of 10-16 % for decadmiation and payment of tax on remaining cadmium content, and 15-56 % for simply paying the tax.

CERPHOS process:

Cd^{max}	t [EUR/g]	Costs for simply paying the tax	Costs for decadmiating and paying tax on remaining cd
60	0.5	50	30
40	0.7	70	32
20	1.4	140	39

At a price level of USD 250/ton phosphate fertiliser – as observed for example during 2007 (see Annex XIII) – this would mean a price increase of 15 to 20 % for decadmiation and payment of tax on remaining cadmium content, and 25-70 % for simply paying the tax.

What can be seen from this example is that for this producer it is under all scenarios cheaper to decadmiate than to simply pay the tax over the total cadmium content. It can also be seen that for the different maximum cadmium levels desired, the choice of the corresponding tax rate has a large impact if the producer decides to simply pay the tax but that it has a relatively small impact if he decides to decadmiate. This is due to the fact that with higher tax rates, the tax is due on the entire cadmium content in the one case but only on 10 % of the original cadmium content in the case of decadmiation.

Conclusion

It can be concluded that the results depend on the decadmiation technology that is used. For ELICAD, lower tax rates would induce fertiliser producers to decadmiate compared to the CERPHOS process.

It has to be noted also that decadmiation (triggered by taxation) and paying the tax on the remaining cadmium content will lead to price increases – for phosphates containing originally 100 mg cadmium/kg P_2O_5 from about 10 to 16 % for the ELICAD process and 15 to 20 % for CERPHOS, which would be passed on as additional costs to farmers. If the raw material contains more cadmium, price increases would even be higher, while they would be lower for raw material containing less cadmium.

Sensitivity analysis:

In order to check the robustness of the results, several rounds of calculations have been carried out with varying parameters.

a) capacity utilisation

One assumption that is implicit and the model above is that the decadmiation plant can be run at 100 % capacity utilisation. This is probably overly optimistic and the calculations have been re-run with a different value for R (which is the same as taking the original capacity and assuming an utilisation rate of less than 100 %).

For ELICAD 80 % utilisation results in:

Cd^{max}	t [EUR/g] for low c	t [EUR/g] for high c	tax per ton [EUR] for low c	tax per ton [EUR] for high c
60	0.30	0.38	18.12	22.56
40	0.45	0.56	18.12	22.56
20	0.91	1.13	18.12	22.56

and for CERPHOS 80 % utilisation would result in:

Cd^{max}	t [USD/g]	tax per ton [USD]
60	0.47	28
40	0.70	28
20	1.40	28

It can be seen that the required tax rate is not significantly higher for ELICAD and CERPHOS.

b) number of operating days

The number of operating days per year used in the basic model might be overly optimistic, and the model has been re-run with only 250 operating days per year (50 weeks with 5 working days a week).

For ELICAD the results are:

Cd^{max}	t [EUR/g] for low c	t [EUR/g] for high c	tax per ton [EUR] for low c	tax per ton [EUR] for high c

60	0.30	0.38	18.1	22.55
40	0.45	0.56	18.1	22.55
20	0.91	1.13	18.1	22.55

And for CERPHOS:

Cd^{max}	t [USD/g]	tax per ton [USD]
60	0.47	28
40	0.70	28
20	1.40	28

Consequently, the number of operating days per year does not change the results significantly for ELICAD and CERPHOS.

c) Cost of capital

The basic model uses an internal discount rate of 4 % (to note: the model assumes constant prices and does not capture inflation). To test for robustness, a higher rate of 8 % has been used.

For ELICAD and CERPHOS, an increase of 4 % in the discount rate will require an increase of 40 % of the annual operating profit to ensure a positive NPV. This might lead to a significant fertiliser price increase.

d) effectiveness of decadmiation process

Finally, calculations have been re-run with a higher value for $\beta = 20\,\%$ (the cadmium portion that cannot be removed by decadmiation) to see how this would influence the results.

For ELICAD, it results in:

Cd^{max}	t [EUR/g] for low c	t [EUR/g] for high c	tax per ton [EUR] for low c	tax per ton [EUR] for high c
60	0.34	0.42	20.3	25.3
40	0.51	0.63	20.3	25.3
20	1.02	1.27	20.3	25.3

And for CERPHOS in:

Cd^{max}	t [USD/g]	tax per ton [USD]
60	0.52	31.2
40	0.78	31.2
20	1.56	31.2

A less effective decadmiation process means that the tax rate needs to be higher (as expected). It also means that total price increases (i.e. cost for decadmiation + tax on remaining cadmium) would be somewhat higher.

Conclusion:

The underlying assumptions do not change the results dramatically. For all processes, the choice of the discount rate and the effectiveness of the decadmiation process are important factors. The results for ELICAD and CERPHOS are close to each other.

ANNEX XV: POTENTIAL REDUCTION OF TOTAL QUANTITY OF CADMIUM INPUT INTO AGRICULTURAL SOILS FOR THE VARIOUS POLICY OPTIONS

As set out in section 3.2, the actual cadmium content of the fertilisers placed on the market in the EU is not well studied, and it is therefore difficult to quantify the reduction in new cadmium input into agricultural soils that the various policy options would entail.

Phosphate fertilisers with cadmium concentrations higher than the overall limit set in the policy options could no longer be marketed in the EU and would be replaced by others with lower cadmium content. It is not possible to know precisely the cadmium content of the phosphate fertilisers replacing the prohibited quantities.

On the basis of the data contained in Figure 3, the following table summarises the results of calculations for the overall cadmium input reduction, if the quantities of phosphate fertilisers that could no longer be marketed, were to be replaced in their entirety with other phosphate fertilisers of a given cadmium concentration. The shaded fields correspond to the situation where the fertilisers replacing the prohibited quantities contained the average concentration of the fertilisers currently on the market below the limit value.

Limit 60 mg Cd/kg P_2O_5 (43 out of 197 fertiliser samples above the limit)		Limit 40 mg Cd/kg P_2O_5 (96 out of 197 fertiliser samples above limit)		Limit 20 mg Cd/kg P_2O_5 (117 of 197 fertiliser samples above limit)	
Replacement Cd content	Net Cd reduction, %	Replacement Cd content	Net Cd reduction, %	Replacement Cd content	Net Cd reduction, %
0	45,20	0	83,89	0	92,32
10	39,43	10	70,36	6,8	81,21
20	33,65	11,3	68,61	10	75,98
25,2	30,65	20	56,84	20	59,64
30	27,88	30	43,32		
40	22,10	40	29,80		
50	16,32				
60	10,55				