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## **PROPOSAL**

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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 17 March 2016

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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Subject: COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY  
OF THE 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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Delegations will find attached document SWD(2016) 65 final.

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EUROPEAN  
COMMISSION

Brussels, 17.3.2016  
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**COMMISSION STAFF WORKING DOCUMENT**

**EXECUTIVE SUMMARY OF THE 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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## **Executive Summary Sheet**

Impact assessment on a proposal for a Regulation of the European Parliament and of the Council  
on the making available on the market of fertilising products

### **A. Need for action**

#### **Why? What is the problem being addressed?**

The conditions for access to the market of fertilising products are only partially harmonised at EU level. The fragmentation of the non-harmonised part of the market is seriously hindering trade opportunities. Moreover, the harmonised legislation does not sufficiently address environmental and human health issues. More specifically, the following operational problems could be identified:

- 1) Companies operating in several Member States on the non-harmonised market are facing the costs of diverging national rules, which often include prior authorisation which is difficult to obtain.
- 2) Serious concerns have been identified relating to health and the environment, in particular the presence of toxic contaminants in certain widely used fertilisers. The current harmonisation legislation provides insufficient protection of health and the environment.
- 3) The current harmonised legislation grants market access through a procedure which has been proven to be too slow in relation to the innovation cycle of industry.

#### **What is this initiative expected to achieve?**

The initiative is expected to:

1. Create a level playing field for all fertilising products at EU level, thereby increasing the industry's opportunities to have access to the Internal Market while maintaining the national regulations in place for products limited to national markets, hence avoiding any market disruption.
2. Increase the level of protection of health and environmental protection by limiting the presence of contaminants in fertilising materials and additives throughout the EU.

Facilitate access to the harmonised market by introducing a proportionate, cost effective, transparent and flexible regulatory framework, thereby responding to the needs of EU farmers for innovative products.

#### **What is the value added of action at the EU level?**

The problems identified in the harmonised market (i.e., insufficient protection of human health and of the environment, and inflexible requirements providing too slow market access), are inherent to the current EU level and can therefore only be corrected by EU level action. An effective EU-wide market for all fertilising products will open up new market opportunities and reduce administrative burdens.

However, in view of the very local nature of the market of certain fertilising products, this EU-harmonised action will be optional and co-exist with national legislations maintained or introduced by Member States and mutual recognition.

### **B. Solutions**

#### **What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?**

Option 1: Baseline scenario – The current EU legislation remains unchanged.

Option 2: The regulatory technique of the Fertilisers Regulation, i.e. type-approval, remains un-changed, and is extended to the harmonisation of fertilisers from organic raw materials and of other fertiliser-related products, such as 'plant biostimulants'.

Option 3: Harmonisation through approval of ingredients, leading to a positive, exhaustive list of materials eligible for intentional incorporation into a fertilising product.

Option 4: Harmonisation through the New Legislative Framework (NLF), which builds on mandatory, quality and safety requirements and voluntary, harmonised technical standards.

Option 5: As under option 4, harmonisation is achieved through the 'New Legislative Framework' with requirements and standards. However, third party involvement in the assessment of conformity with the requirements varies between material categories, and is highest for waste and other secondary materials with potentially variable composition. Option 5 emerges as the preferred option from the analysis.

For options 2 to 5, limit values are introduced for contaminants (including heavy metals) for all fertilising products. Two variants were assessed: full and optional harmonisation as described above.

#### **Who supports which option?**

Option 1 is not supported by any Member States, industry or NGOs.

Options 2 and 3 are each supported by some Member States and some national industry federations, who are used to regulating the fertiliser market by maintaining lists of authorised types or ingredients.

Option 4 is not supported by all Member States, as the NLF is considered a radical change compared to the well-known Option 2 and 3 approaches.

Option 5, especially with the optional harmonisation variant, is generally well accepted by industry (in particular SMEs) and a large number of Member States (including some of the largest) as the best option.

#### **C. Impacts of the preferred option**

##### **What are the benefits of the preferred option (if any, otherwise main ones)?**

Access to the market for fertilising products regulated under the NLF would be eased, and compliance of such products with safety and quality requirements would ensure an increased level of safety in the food chain. The benefits in terms of internal market access and market flexibility of the preferred option (option 5) are very similar to those of option 4. The Impact Assessment estimates that this option will provide lower administrative costs for both public authorities and economic operators than status quo, and significantly lower administrative costs for public authorities than the type-approval option which would significantly increase market flexibility and hence stimulate innovation.

The variant of optional harmonisation would have the additional 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.

##### **What are the costs of the preferred option (if any, otherwise main ones)?**

The costs of the preferred option are proportionate to the expected benefits for businesses and the society. The costs for public authorities are rather neutral. Some additional standardisation work regarding test methods would be required for products subject to the NLF.

Option 5 would imply lower administrative costs than the type-approval option for economic operators. It can, however, be expected that administrative costs will in certain cases be higher than under status quo at the level of individual companies. This would be true in particular for producers of relatively variable materials requiring a high level of third-party involvement in the conformity assessment. SMEs involved in the production of fertilising products subject to third party certification would have to pay fees to a notified body to verify the compliance of their products with the requirements. The variant of optional harmonisation could imply higher costs for national administrations than full harmonisation, since they could be expected to maintain national procedures to some extent. Transition costs would be minimal for fertilising products yet covered by the current Regulation as self-certification of products will be allowed. Member States would also need to ensure the quality of notified bodies.

##### **How will businesses, SMEs and micro-enterprises be affected?**

Companies opting for the harmonised route would benefit from facilitated access to the entire EU market. The administrative costs would also decrease, as there would be less need to register individual products according to diverging national rules. Producers not subject to third party certification procedures would be less affected compared to those supporting the costs of third party certification (e.g. SMEs). Those costs would 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. In this sense 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.

##### **Will there be significant impacts on national budgets and administrations?**

Costs would be rather neutral for national budgets. The costs of governance of national legislation will remain the same but will be reducing over time if more and more companies opt for the harmonised route offered by the Fertilisers Regulation, while the market surveillance costs will remain the same or may slightly increase.

##### **Will there be other significant impacts?**

The proposal is expected to reduce the dependency of non-domestic raw materials, by offering an opportunity for an easier access to the entire EU market for innovative products made, e.g., from organic or recycled materials. EU import flows could be affected, as analysed in detail in a separate impact assessment of 2011 on possible maximum limits for cadmium.

#### **D. Follow up**

**When will the policy be reviewed?**

An ex-post evaluation of the Regulation is foreseen 5 years after its implementation and will be based on the feedback received through various cooperation mechanisms already established under the current Fertilisers Regulation (expert groups). The list of contaminants and their respective limit values could be reviewed at any time, if new scientific evidence would show that soil contaminant inputs from fertilisers have to be reduced.