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PART 14/16

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation

Annex 14 out of 16

Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products

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ANNEX 14

SECTORIAL COMPETITIVENESS: PPP, BP AND RELATED INDUSTRIES

Contents

This Annex focuses on the assessment of potential impacts, which build on the results of the screening study explained in Annexes 3 to 5. The results of the screening do not constitute evaluations of individual substances to be carried out under the respective chemical legislations [Regulation (EC) No 1107/2009 on plant protection products and Regulation (EU) No 528/2012 on biocidal products] and in no way prejudge future decisions on active substances to be taken pursuant to these two Regulations. It would thus be erroneous to consider that the substances listed in Annex 5 are considered as endocrine disruptors within the meaning of the EU legislation. The methods and results presented in this Annex are to be interpreted as an estimation of the potential impacts.

Annexes 8 to 15 describe the impacts expected when implementing the criteria to identify EDs (Options 1 to 4) under the current regulatory framework (Option A). In addition, it was assessed whether these expected impacts would remain the same or not under consideration of different regulatory implementations (Options B and C, only applicable to the PPP Regulation). The analyses of the impacts described in these Annexes translate into the "performance" of the options, which is one of the input parameters to the MCAs (Annex 6 and 7).

The MCAs results are not concluding on any preferred option for setting scientific criteria to identify endocrine disruptors, but aim at providing additional information to decision makers with regards to the potential impacts expected when implementing the criteria, after those would have been selected on the basis of science (two MCAs were performed: Options 1 to 4 under the current regulatory context, and Options A compared to Options B and C).

At a preliminary stage of the impact assessment it was anticipated that Option C should be discarded, nevertheless it was maintained for the analysis of the impacts for methodological reasons (see Section 4.2.3 of the main report and Annexes 6 and 7). Option C only applies to the PPP Regulation.

1. IMPORTANCE OF SECTORIAL COMPETITIVENESS

Boosting jobs, growth and investment in the EU is one of the ten priorities of the Juncker Commission, as clearly illustrated in the title of the agenda presented by the President in July 2014 before the European Parliament "*An Agenda for Jobs, Growth, Fairness and Democratic Change*"[1]. This priority also features prominently in the Commission Work Programme[2] for the year 2016. One way legislation in the food and public health sectors, and therefore setting criteria to identify endocrine disruptors (EDs), contributes to this priority is by promoting and protecting health and food safety and adding to a well-functioning single market.

Since the global economic and financial crisis, the EU has been suffering from low levels of investment. Besides, more than six million people lost their job during the crisis and several EU economies are still far away from sustainable growth.[1] One of the key objectives of the Juncker Commission is therefore to put Europe on the path of economic recovery.

The chemical speciality sectors developing and manufacturing plant protection products (PPP) and biocidal products (BP) can help achieving this objective as they can be potential sources of job creation and innovation. This applies also to many – downstream - sectors which rely on the availability of effective and high quality PPP and BP (food and feed industry; agricultural sector, manufacturers of application equipment; healthcare facilities, textile industry, paints and coatings industry, maritime industry etc.). More broadly, the health and food sectors represent about 17% of the EU's GDP and 10% of the EU's workforce. It is important that these sectors are supported by a solid framework based on scientific facts and a high level of protection that supports growth, investment, innovation and competitiveness, which enables them to achieve their economic potential and long-term sustainability.

1.1. Public consultation

The impact of setting criteria for EDs on innovation and competitiveness was pointed out many times in the public consultation, mainly related to the chemical industry and sectors relying on PPP and BP (for example, farming, food industry, paints and coatings industries). The information provided reflected diverging views on how stricter rules may impact innovation and competitiveness.

It was indicated that the positive effects from stricter regulations on innovation should not be underestimated. The setting of criteria for EDs is considered to strengthen businesses seeking to develop better, safer and sustainable alternatives ensuring that the EU industry has its share of the growing market for safer products and move to a more sustainable production. Several companies stated that they avoid the use of suspected EDs in their consumer products. A downstream user indicated that setting ED criteria would facilitate the internal and supply chain management once this group of chemicals is officially identified as such. ED criteria

[1] Jean-Claude Juncker, Opening Statement in the European Parliament Plenary Session. A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change. Political Guidelines for the next European Commission. Strasbourg, 15 July 2014. Retrieved on: https://ec.europa.eu/priorities/sites/beta-political/files/juncker-political-guidelines_en.pdf

[2] Commission Work Programme 2016; No time for business as usual. Retrieved on: http://ec.europa.eu/atwork/pdf/cwp_2016_en.pdf

would also enable the companies to take a long-term perspective on developing products without EDs, instead of facing increased costs by developing new ones at a later stage.

Other respondents considered the setting of ED criteria a significant barrier for innovation as it is adding uncertainty, costs and complexity to the regulatory process. In particular Option 3 (WHO definition + categories) was considered to imply the collection of a significant body of evidence involving considerable cost over time. For small start-up companies, often responsible for technology development, the associated costs and risks are expected to increase, and thus this source of innovation is assumed to be far less common. Many respondents considered the ED issue as adding another level of complexity and uncertainty to the chemical industry in the EU that already struggles to cope with existing legislation. Those respondents indicated that downstream industry continuously assesses trade-offs between performance, health, safety, environmental impacts and economic consequences.

One specific issue raised was the specific requirements of the in-vitro diagnostic manufacturers. It was stressed that the use of EDs are an essential requirement in the positive controls or in biologically active reagents. Furthermore, many respondents stressed that the lack of tools to control pests and diseases is not only a crucial factor for the cultivation of crops, it would compromise also the competitiveness of the entire agri-food chain and supporting industries.

2. SECTORS AFFECTED

2.1. Introduction

The PPP and BP supply chain can be divided into:

- Producers of raw materials (producers of active substances)
- Producers of processed active substances (formulators of PPP and BP)
- Downstream users (industrial end-users, professional end-users, distributors and manufacturers of application equipment)
- Consumers

Legislation on PPP and BP not only influences the companies that manufacture active substances or process active substances (formulators of PPP and BP), but also the downstream users of these products (for example, producers of goods in which or during the production process PPP or BP have been used, for example paints and textiles; farmers; food industry).

The BP (USD 2,6 billion in 2016[3]) and PPP (EUR 8 billion in 2010[4]) markets are relatively small markets compared to the EU markets for human medicines (EUR 228,1 billion, 2011,EFPIA[5]) and the chemical industry (EUR111 billion, value added, Eurostat[6]; sales EUR

[3] Based on the assumption that EU has a 27% share of world market for BP (USD 9,4 billion) as indicated by Markets and Markets. 2016. Biocides Market by Type – Global Trends and Forecasts to 2020. Retrieved from: http://www.marketsandmarkets.com/PressReleases/biocides.asp

[4] ECPA. 2016. Industry Statistics – ECPA Total. Retrieved on: http://www.ecpa.eu/information-page/industry-statistics-ecpa-total

[5] European Federation of Pharmaceutical Industries and Associations (efpia). Industry & Economy. Retrieved on: http://www.efpia.eu/topics/industry-economy

527 billion, EC) (see Figure 1). The market for veterinary medicines is of a similar magnitude as the markets for PPP and BP (veterinary medicines EUR 5 billion (2015, IFAH-Europe[7]).

The chemical industry producing and developing PPP and BP could be considered as specialty chemicals sector (see Table 1). The High Level Group on the Competitiveness of the European Chemical Industry concluded that the European chemicals industry is facing strong competition from emerging countries notably in Asia, the Middle East and Russia[8] (see Table 2)

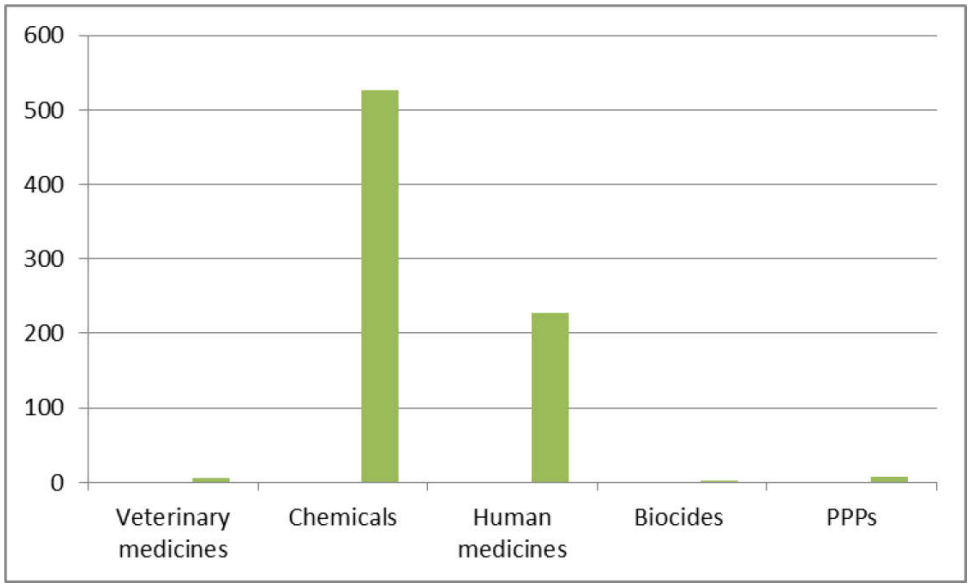

Figure 1. Market values of different chemical sectors (in millions EUR)[6]

Table 1. Weight of speciality chemicals in chemical industry (excluding pharmaceuticals)[9]

Chemical sub-sector	Weight (%)		Weight (%)
Petrochemicals	26,6		
Basic inorganics	13,7		
Polymers	21,5		
Speciality chemicals	26,5		
		Dyes and pigments	9,5
		Crop protection	7,0
		Paints and inks	29,4
		Auxiliaries for industry	54,1
Consumer chemicals	11,7		

[6] Eurostat archive. Manufacture of chemicals and chemical product statistics. Retrieved on: http://ec.europa.eu/eurostat/statistics-explained/index.php/Archive:Manufacture_of_chemicals_and_chemical_products_statistics_-_NACE_Rev._2
[7] IFAH Europe. About the industry. Retrieved on: http://www.ifaheurope.org/about/about-the-industry.html
[8] CEFIC Final Report of the High Level Group on Competitiveness of the European Chemicals Industry. Retrieved from:.http://www.cefic.org/Documents/PolicyCentre/HLG-Chemical-Final-report-2009.pdf
[9] The European Chemical Industry Council (CEFIC). Facts and figures 2016. Retrieved on: http://www.cefic.org/Facts-and-Figures/

Table 2. Chemical sales, exports and imports in the world (in billion Euro)[9]

	2013	Share
EU28	527	16,7%
Rest of Europe	103	3,3%
NAFTA	528	16,7%
Latin America	144	4,6%
Rest of Asia	408	12,9%
China	1047	33,2%
Japan	152	4,8%
South Korea	132	4,2%
India	72	2,3%
Rest of the World	44	1,4%
World	3156	100,0%

2.2. PPP and BP industries

The companies that manufacture active substances or formulate PPP or BP and place these on the market are directly affected by the setting of ED criteria. In

Table 3, key data are provided on these industries. In the following subparagraphs the particularities of the PPP and BP industries (active substance manufacturers and product formulators) are described in more detail. Downstream users are discussed in the next section 2.3.

Table 3. Key data of the PPP and BP market

	PPP	BP
Market value	Global market USD 34 billion; market value in Europe USD 8 billion in 2010[10;11] USD 59 billion forecast for world market in 2016[12] (Freedonia group) Pesticide sales by product category (USD million): fungicides 9.910, herbicides 17.321, insecticides 9.982, others 1.100[11]	Global market: EUR 3 billion in 2000[13], USD 7,2 billion in 2010, USD 9,4 billion forecast for world market in 2016[14] USD 10 billion in 2012[15] USD 7,9 billion in 2014[16] European market: EUR 890 million in 2000[17]
New product introductions	1980-1990 four agrochemical active ingredient introductions per year, now 1.2 per year[18]	
Share of global R&D focussed on European markets	33% in the 1980s, 7.7% 2012[18]	
Jobs	26,223 in 2010 (5,431 in R&D, 11,236 in production/logistics, 6,541 sales/marketing, 3,016 administration)[10]	

[10] ECPA. 2016. Industry Statistics – ECPA Total. Retrived from http://www.ecpa.eu/information-page/industry-statistics-ecpa-total

[11] Library briefing of the European Parliament 29/03/2012. Pesticide legislation in the EU. Towards sustainable use of plant protection products. Retrieved from: http://www.europarl.europa.eu/RegData/bibliotheque/briefing/2012/120291/LDM_BRI(2012)120291_REV1_EN.pdf

[12] Freedonia. 2016.World Agricultural Pesticides. Found on: http://www.freedoniagroup.com/industry-study/2902/world-agricultural-pesticides.htm

[13] Commission Staff Working Document SEC(2009)773. Impact Assessment for a proposal for a Regulation concerning the placing on the market and use of BP: http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2009_en.htm#env.

[14] Markets and markets. 2016. Biocides Market by Type – Global Trends and Forecasts to 2020. Retrieved from: http://www.marketsandmarkets.com/PressReleases/biocides.asp

[15] BusinessWire. Research and Markets: Global Biocides Market 2013 Report. Retrieved from: http://www.businesswire.com/news/home/20130709005713/en/Research-Markets-Global-Biocides-Market-2013-Report

[16] Grand View Research. Biocides Market Analysis by product, by application and segment forecasts to 2022. Retrieved from: http://www.grandviewresearch.com/industry-analysis/biocides-industry

[17] Commission Staff Working Document SEC(2009)773, Impact Assessment for a proposal for a Regulation concerning the placing on the market and use of BP: http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2009_en.htm#env.

[18] Phillips McDougall. 2013.R&D trends for chemical crop protection products and the position of the European market. A consultancy study undertaken for ECPA. Retrived from: http://www.ecpa.eu/files/attachments/R_and_D_study_2013_v1.8_webVersion_Final.pdf

	PPP	BP
Pre-market approval/authorisation system	In EU: 482 approved substances, 792 non-approved and 37 substances for which approval is pending[19].	In EU: 159 approved active substance-product type combinations, 548 under review and 22 non-approved[20]
Total costs for discovery, development and registration	USD 152 million in 1995, USD 184 million in 2010, USD 256 milllion (25 million registration, 146 million development and 94 million research in 2005-8)[21]	EUR 0.2-2.0 million for a biocidal product; the time for gaining return in investment: biocidal products 3-10 years, active substances 2-15 years[22]
Product development time (of a new product)- time lag between discovery and commercialization	9,8 years in 2005-8[6]	5-15 years for an active substance, biocidal product 1-3 years[22]
Direct costs for approval/authorisation	The fee for the substance evaluation of one product type (PT) varies considerably from one Member State to another,	EUR 0,2-0,7 million;[23] active substance EUR 3-10 million;[24] biocidal product EUR 0,15-1 million[25]. The fee for the substance evaluation of one product type (PT) varies considerably from one Member State to another, ranging from less than EUR 150.000 to above EUR 200.000[26]
Industry consolidation	The number of companies involved in the research and development of new agrochemical active ingredients worldwide	

[19] European Commission. EU pesticides database (state of play February 2016). Retrieved from: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN

[20] European Chemical Agency (ECHA) database on Biocidal Active Substances. Found on: http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances

[21] Philips McDougal. 2010. The cost of new agrochemical product discovery, development and registration in 1995, 2000 and 2005-8. A consultancy study for Crop Life America and the European Crop Protection Agency.

[22] Ecorys. 2016. Background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision. Draft Final Report

[23] Costs consist of preparing dossier for a biocidal product, Letter of Access for the use of BPR fees: impact on the active substance and product authorisation fee; The future of biocidal products, Aise. Biocides 2015, 18th Annual Conference, Vienna, November 2015.

[24] Costs to develop and submit an approval dossier for an active substance (including fees), not including R&D costs for developing a new substance. Cefic-EBPF information for the socio-economic analysis part of the impact assessment on criteria to identify endocrine disruptors (2016).

[25] Costs to develop and submit an authorisation dossier for a biocidal product or a family (including fees). Cefic-EBPF information for the socio-economic analysis part of the impact assessment on criteria to identify endocrine disruptors (2016).

[26] 58th meeting of representatives of Members States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. Report on the fees payable to Members States Competent Authorities pursuant to Article 80(2) of the Biocidal Product Regulation. Retrieved from: https://circabc.europa.eu/sd/a/896cf317-7b62-4604-a736-c18e02fc3ead/CA-Nov14-Doc.7.2%20-%20Report%20on%20fees.doc

	PPP	BP
	has halved, from 34 companies in 1995 to 17 in 2012. [18]	
Patents		Most of the patents associated with the active substances on the market have expired[27]

2.3. PPP industry

Between 2003 and 2011 Europe was the leading regional agrochemical market worldwide; in 2012 it was overtaken by Asia.

Competitive pressure has fuelled consolidations as companies seek economies of scale to cover the global market and to generate funds for research and development. This has resulted in the situation that a small number of companies dominate the industry.

Generic pesticide products (companies making off-patent products) increased their share of the market. In 1996 generics had a market share of the world market of about 20%. This increased gradually to about 30% in 2008[28]. It appears that a product being off-patent does not automatically mean that the main producer loses the share of the market.

In the EU a new PPP has to displace in general existing products to generate revenue as markets in EU are saturated for major crops. A new PPP must therefore be superior to be successful.

In the EU the number of PPP available for minor uses is decreasing[29]. Many PPP are not anymore available on the EU market because they either do not comply any more with regulatory standards or the regulatory costs do not allow them to be considered a profitable product. The review programme of existing active substances carried out between 1993 and 2009 led to the withdrawal of approximately 70% of the active substances that were on the market before 1993.[29] It is clear that the withdrawn substances were not all substituted by new active substances: before 1993 almost 1000 active substances had been approved and currently 482 approved active substances are included in the EU PPP database. Also a substantial decrease in the number of efficacious PPP authorisations for minor crops in the period 1990-2010 was found, supporting the view that innovation is targeted at major crops.

The value of the manufacturing of PPP in Europe was EUR 9,9 billion in 2014 (see Table 4), an increase in value of 50% compared to 1995.

Table 4. The value of the manufacture of PPP in the EU (EUROSTAT-PRODCOM data).

Year	1995	1998	2002	2006	2010	2012	2013	2014
Value (in EUR millions)	6675	6879	6333	5441	6326	7533	7116	9990

[27] Most of the biocidal active substances on the market are on the market for decades. Cefic-EBPF information for the socio-economic analysis part of the impact assessment on criteria to identify endocrine disruptors (2016).

[28] Phillips McDougall (2010). Trends in crop protection R&D, Bratislava, Slovakia. Retrieved from: http://www.ecpa.eu/files/gavin/presentation_Matthew_Phillips.pdf.

[29] Report from the Commission on the establishment of a European fund for minor uses in the field of plant protection products: http://ec.europa.eu/food/plant/pesticides/legislation/docs/com_2014_82_en.pdf.

2.4. BP industry

BP is a wide category of products including amongst others disinfectants, pest control products, wood preservatives and antifouling products. They are widely employed in water treatment, wood preservation, paints, food and beverage production, and as disinfectants to kill or inhibit hazardous organisms. Professional use is prevalent for all preservatives, some pest control products, antifouling products and embalming and taxidermist products. Non-professional use (consumers) prevails for some pest control products (rodenticides, insecticides, repellents and attractants) and some disinfectants. The BP Regulation sets out a two-tiered system of approving active substances at EU level and authorising BP (containing one or more active substances) at EU or national level, following a similar approach as the PPP Regulation.

No detailed, consolidated data is available on the BP market in the EU. By the use of several information sources an indication of the size and the structure of this market is provided. The value of the global market is about USD 8 billion (

Table 3). In 2000 North America was representing about 43% and Europe 27% of the world market.

In the EU the market is dominated by three companies that held 25% of the market in 2000[30]. Also the global BP market share is concentrated with top three participants accounting for over 45% of total demand in 2014. Companies require significant amount of investment at the start up stage due to stringent regulations regarding testing and labelling of these products. This discourages entry of new players[31].

In the EU the BP market is fragmented on Member State (MS) level as there is a difference on the number of BP allowed on the national markets.

[30] Commission Staff Working Document SEC(2009)773, Impact Assessment for a proposal for a Regulation concerning the placing on the market and use of BP. Retrieved from: http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2009_en.htm#env.

[31] Grand View Research. Biocides Market Analysis by product, by application and segment forecasts to 2022. Retrieved from: http://www.grandviewresearch.com/industry-analysis/biocides-industry

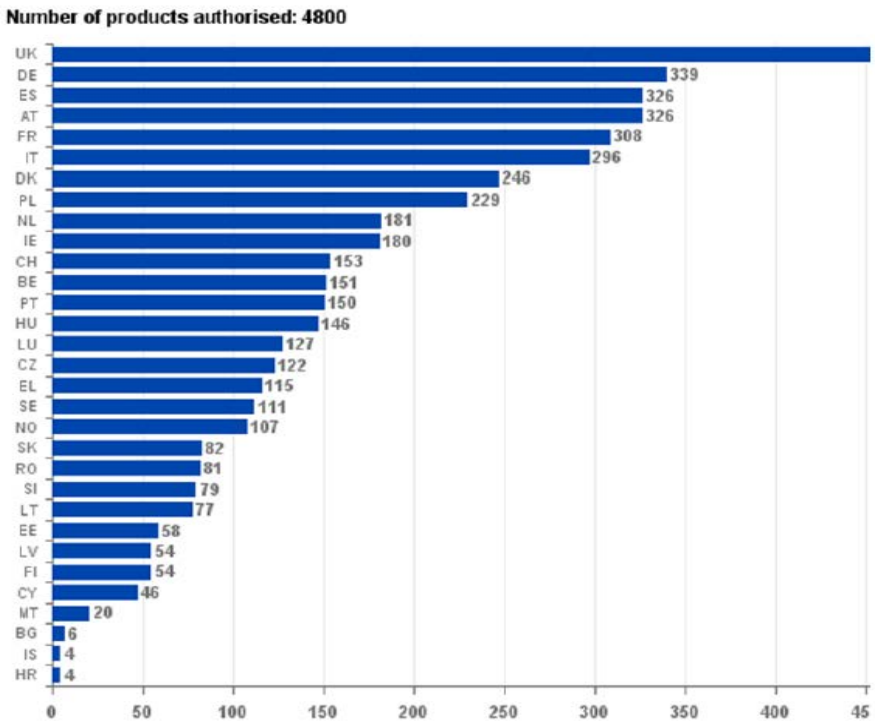

Figure 2. Number of BP authorisations per MS by 15th of January 2016[32].

The BP market is further fragmented because approvals for active substances are provided for product types (the BP Regulation defines 22 product types, (see Figure 2). For example, an active substance approved for use in a disinfectant for the product type veterinary hygiene cannot be used for disinfecting sites in healthcare facilities.

[32] ECHA-report on product authorisations to the 15th meeting of the co-ordination group of competent authorities for BP.

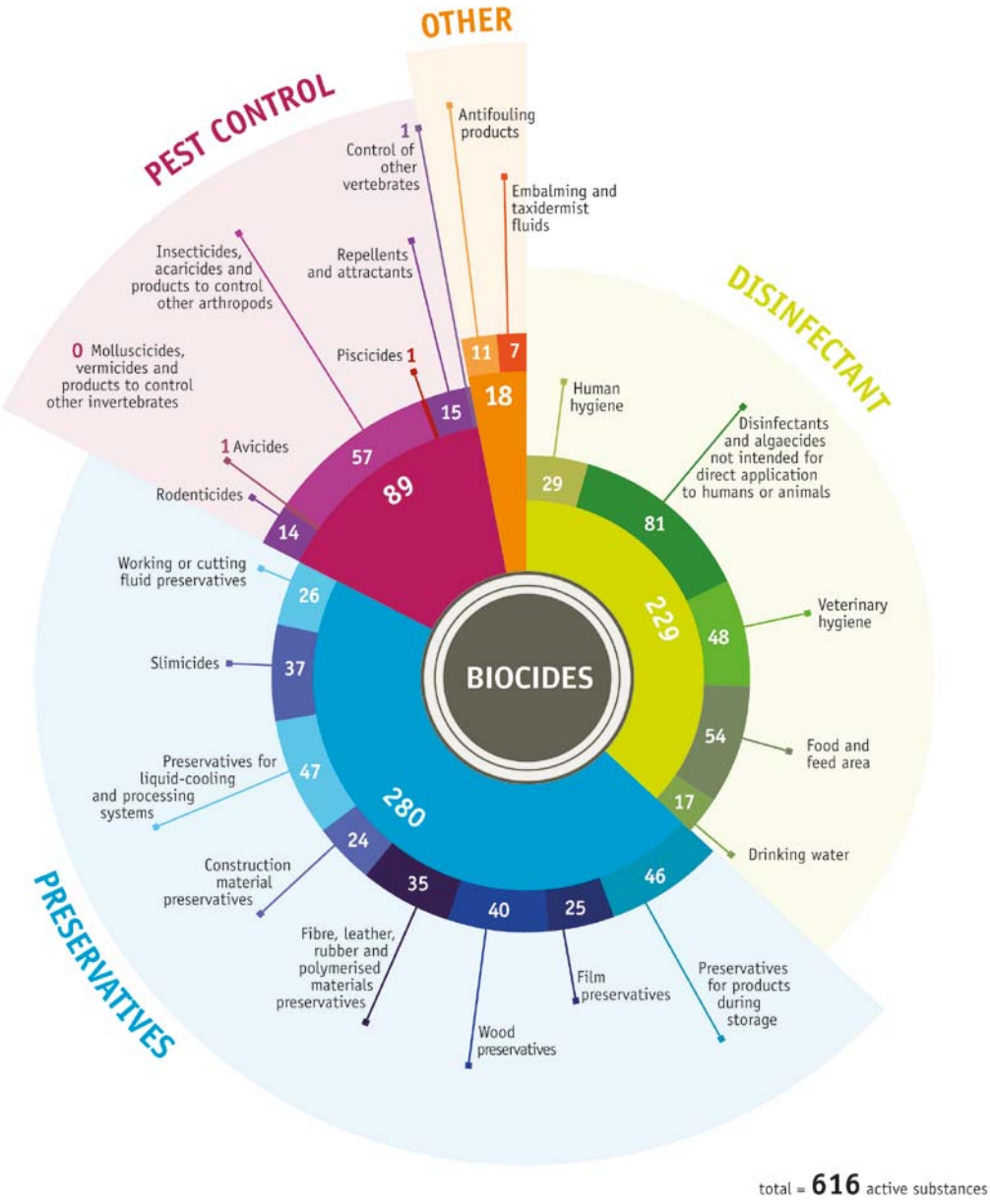

Figure 3. BP market structure, number of approved active substances per product type.

2.5. Related and downstream industry

The use of PPP plays an important role in the EU agricultural production. Farmers use PPP (mainly herbicides, fungicides, insecticides) to ensure less weed and pest damage to crops and a consistent yield. PPP have played a major role in increasing farm productivity[33]. The agricultural sector is characterised by small enterprises (farms), and is described in more details in the Annexes 12 and 13. In addition to agriculture, other professional users and

[33] Headley, J.C. 1968. Productivity of agricultural pesticides. Journal of Farm Economics 50: 13-23.

consumers use PPP for non-agricultural purposes, for example weed control in public areas and private gardens.

A related industry are manufacturers of pesticide application equipment (agricultural, horticultural and forest machinery). Most PPP are applied by professionals using sprayers of different type (boom sprayers, orchard sprayers) which may be also specialised machines built on demand for specific crop situations. Accessory parts to these machines are often specialised, as for instance drift reducing nozzles which reduce impact to the environment. This market has a window of opportunity to innovate, as shown by e.g. innovations which lead to more precise application of PPP, avoiding unnecessary exposure of the environment and/or operators to PPP.

The BP downstream market consists of major industrial sectors relying on the use of BP (see Table 5), either because they manufacture goods in which BP are incorporated (for example paints and detergents in which BP are used to preserve the products) or because BP are required in the manufacturing process (for example, use of biocidal disinfectants to ensure microbial safety of food).

Downstream users of BP may be indirectly affected by changes in prices of products, the disappearance of certain products and the need to switch to alternatives or other suppliers of the product. An important feature of the BP market is the diversity of end-users reflected in the product types that are acting independently of each other (for example, companies providing professional disinfection services to the food industry and others providing professional application of antifouling paints in shipyards). This implies that the BP market consists of multifaceted submarkets, which partly are relatively small and include many small and medium-sized enterprises (SMEs).

Table 5. Examples of sectors relying on BP in manufacturing process or manufacture treated articles[34].

INDUSTRY MANUFACTURING SECTOR	VALUE ADDED (EMPLOYEES) EUROSTAT DATA	PRODUCT TYPES MAINLY USED IN THE MANUFACTURING SECTOR
Food/feed	EUR150 billion VA (4.8 million)	3; 4; 6; 11; 12; 14; 18
Motor vehicles	EUR141 billion VA (2.2 million)	2; 6; 9; 11; 13
Paper	EUR 41 billion VA (646 million)	2; 6; 7; 9; 11; 12; 18
Household and professional cleaning and hygiene	~ EUR 15 billion (VA)	1; 2: 4; 6; 11; 12; 18; 19
Paints & coatings	~ EUR 10 billion (VA)	2; 6; 7; 8; 10; 11; 12; 21

In some industries the proportion of goods in which BP are being used can be close to 100% (for example aqueous based paints, detergents). Other industries in which BP are often used in the manufacturing process produce end-products which do not contain BP, or if they do so only at very low, unavoidable levels (for example use of disinfectants in food industry). The most relevant product types for these industries are the product types 2 (disinfectants), 6 (preservatives for product during storage), 7 (film preservatives) and 9 (fibre, leather, rubber and polymerized materials preservatives) (see Table 6).

According to research companies three developments are expected to have a positive impact on demand for BP over the next years:

1. Rising demand from industrial applications, particularly in paints and coatings and water treatment;
2. Rising need to control microbial growth in food and drinks, along with increasing use of preservatives in ready-to-eat food; and
3. Increasing use in personal care products such as liquid soap, shower gel, cream and shampoo for inhibiting growth of fungus and bacteria, and to improve shelf life.[16]

The best growth opportunities for the BP are in the Asia-Pacific and Eastern Europe region, whereas the mature North American and West European markets are expected to register a modest growth.[15] The availability of approved active substances is critical for companies to develop BP[35]. The prices for BP vary and appear to be linked to the type of good in which it is being used or the aim of the use of biocide.

[34] Cefic-EBPF information for the socio-economic analysis part of the impact assessment on criteria to identify endocrine disruptors (2016).
[35] BPR fees: impact on the future of BP. Aise. Biocides 2015, 18th Annual Conference, Vienna, November 2015.

3. IMPACT ON SINGLE MARKET

Both the PPP and BP Regulations work in a two-step process: approval of active substances at EU level and authorisation of products at national level. Also both regulations provide the possibility, notwithstanding a substance is identified as an ED, to authorise it with restrictions for a fixed time period (see also Annex 8). However, these approvals and authorisations will be MS specific (see Table 6).

Table 6. Conditions for approval of substances identified as ED and conditions of authorisation at MS level for products containing such substances.

	Plant Protection Product Regulation (EC) 1107/2009 (PPPR, 2009)	**Biocides Product Regulation (EU) 528/2012 (BPR, 2012).**
Procedure for approval	Commission Implementing Regulation (Article 13) Examination procedure by standing Committee (Article 79(3) of PPP Regulation in combination with Article 13 of Regulation 182/2011)	Commission Implementing Regulation (Article 9) Examination procedure by Standing Committee (Article 82(3))
Cases in which approval is allowed	- Annex II, section 3.6.5: […] the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005. - Annex II, section 3.8.2: […] the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible. Article 4(7): An active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods MS may authorise PPP containing active substances approved in accordance with this paragraph only when it is necessary to control that serious danger to plant health in their territory.	- Article 5(2):At least one of the following conditions is met: -The risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment; -It is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; -Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance. When deciding whether an active substance may be approved, the availability of suitable and sufficient alternative substances or technologies shall be a key consideration.

	Plant Protection Product Regulation (EC) 1107/2009 (PPPR, 2009)	**Biocides Product Regulation (EU) 528/2012 (BPR, 2012).**
Risk-mitigation measures	Article 4(7): The use of the substance approved in accordance with Article 4(7) is subject to risk mitigation measures to ensure that exposure of humans and environment is minimised	- Article 5(2): The use of a BP containing active substances approved in accordance with this paragraph shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment to those active substances is minimised. - Article 5(2):The use of the BP with the active substance concerned shall be restricted to MS in which at least one of the conditions set out in this paragraph is set. - Article 19(4): Not for use by general public
Approval period	- In case of derogations under Annex II, sections 3.6.5 - 3.8.2, approval (and renewal) for maximum 7 years as candidate for substitution (Article 24 read in combination with section 4, 7th indent, of Annex II) - Five years for the substance approved in accordance with Article 4(7)	Approval five years as candidate for substitution (Article 4(1))
Other conditions	For candidates of substitution MS shall carry out a comparative risk assessment before authorising a PPP use. In case of the derogation under Article 4(7), MS shall draw up a phasing out plan concerning the control of the serious danger by other means, including non-chemical methods, and shall without delay transmit that plan to the Commission (Article 4(7))	For candidates of substitution MS shall carry out a comparative risk assessment before authorising a BP use.

The co-legislators introduced these provisions to ensure that the applied derogation will occur only where it is necessary and subject to specific conditions. However, it will create new complexity in the EU market as regards the specific conditions linked to the derogations that will apply in each MS and the interpretation and the enforcement of those conditions. Therefore the availability of PPP and BP to related and downstream users (farmers, professional users, health care sector and food chain producers, industry, etc.) may differ between MS, creating different competitive situations also to the related and downstream industry.

With respect to the impact of the different options on this criterion, the more substances are identified as ED, the more likely that substances would be taken out of the market or approved only under restricted conditions, leading consequently to higher negative impacts on the single market. Because both the PPP and BP Regulations are recent, no relevant experience exist with the derogations for active substances, being for substances with ED properties or other kind of properties which are subjected to similar derogations (e.g.

cancerogenic). Therefore, it is not possible to extrapolate form existing data or experiences. Thus, the best indicator for assessing the impact is the number of substances identified. Option 4 would rate better than Options 2 and Option 3 Category I, and these better than Option 1 (performance of the options is 4 > 2/3 > 1). With respect to regulatory decision making options, Option C would rate better than B, and this better than A as it is expected that less MS specific derogations would occur when less substances are identified as EDs, leading to the following performance of the options C > B > A.

4. IMPACT ON INNOVATION AND RESEARCH

Under the current PPP and BP Regulations, substances identified as ED will be either withdrawn or approved under strict conditions for a fixed period of time.

Before analysing the impacts on the different sectors it is important to refer to the general discussion about the impact of stricter rules on innovation. Many companies and industry organizations consider stricter rules as having a negative impact on innovation and competitiveness as it diverts personnel and resources away from R&D and production activities. On the other hand, it is argued that regulation can have a positive effect on innovation and growth, for example, requirements could promote innovation by encouraging the replacement of hazardous chemicals with newer, more sustainable alternatives[36]. Both views were expressed by respondents in the public consultation. For the EU rules that apply for the registration of chemicals (REACH) it was found that the rules led to an increase of R&D. However, it is important to underline that the scope and the approach of REACH differs substantially of the PPP Regulation and the BP Regulation (for example, no pre-market approval system applies), so that extrapolation is subject to uncertainties[37].

Competitiveness and innovation in companies in the supply chain is driven by a wide range of factors (energy prices, labour costs and productivity, infrastructure, taxation, regulatory environment etc.). It is stressed that setting criteria for EDs is just one issue that may affect the innovative capacity or competitiveness of EU companies. Information is lacking in order to compare the size of the impact of setting EDs in relation to those other factors impacting innovation. Also should be considered that in general, not linked to the setting of criteria for EDs, a decrease takes place of the number of active substances and BP and PPP available on the market in the EU.

[36] World Wildlife Fund (WWF). 2003. Innovation in the Chemicals Sector and the New European Chemicals Regulation, a WWF chemicals and health campaign report. Retrieved from: http://www.wwf.org.uk/filelibrary/pdf/innovationreport.pdf

[37] Monitoring the impacts of Reach on Innovation, Competitiveness and SMEs (CSES)-2015. In the report on the monitoring of the impacts of REACH on innovation it was concluded that the implementation of the REACH Regulation has led to an increase in R&D activity for some 26% of companies surveyed. The report pointed out that there are different views as regards the extent to which that has led to innovation, as opposed to regulatory compliance. The same report analysed the response of companies that had experienced withdrawals of substances; 62,2% of those companies indicated that they carried out research to identify an alternative substance, and over a third said that they changed their manufacturing process to avoid the need to use the substance withdrawn.

4.1. PPP industry and downstream users

The process of developing new PPP and obtaining an authorisation to place these on the EU market is lengthy and costly. Researchers have found positive relationships between R&D spending and the rates of technological innovation and it was shown that pesticide research expenditures relate positively to new pesticide registrations[38].

In PPP the driver of new product development for the EU-15 markets is improved solutions for existing problems, particularly where pest, weed or disease resistance has become an issue. The industry focusses for R&D on major crops. In Europe the focus for new product development are cereals. The next major crop is maize, however, R&D in this area has been reduced because of the shift of this market to biotech solutions of genetically modified races. The third major crop in Europe is oilseed rape.

Higher development and regulatory costs discourage some types of innovation because a product must generate greater revenue in order to be profitable: analysing historical data a 10% increase in the anticipated cost resulted into a 15% decline in innovation for PPP.[38] Therefore an increase in regulatory costs may affect R&D spending and thus also influence innovation. It may also result in some uses of PPP becoming unprofitable because of the regulatory costs to maintain a product on the market, or deter firms from initiating research for minor crop market uses. This is confirmed by the fact that regulatory costs encouraged firms to register PPP only for major crop market usages[39]: a 10% increase in regulatory costs caused an 8% increase in the proportion of PPP for major crops.

The number of new active substances in development worldwide is falling. In 2000 there were 70 new active substances in the development pipeline. In 2012 there were only 28. This is primarily due to fewer companies being involved, it is scientifically more challenging to find new active substances, a greater share of R&D investment being spent on defending products as they come off patent, and a greater focus by these companies on plant breeding. Companies with sufficient resources are maintaining research departments and development expertise in house. However, even the largest companies recognise that research is being carried out outside the company. Partnering, in-licensing, collaborations with universities and research institutions are all part of the innovation mix. There are a number of small, often start-up companies involved in technology development. The majority of these small companies do not have the financial capability of bearing the cost of bringing a new active substance from discovery through the market development. As a result the major way for products developed by these companies to get to market is for the product or the company, to be acquired by one of the major industries in the sector.

The share of crop protection R&D investments attributable to products being developed for the European market has fallen from 33.3% in the 1980s to 7.7% in the 2005-14 period.[18] The number of companies involved in the research and development of new agrochemical active

[38] Ollinger, M. 1995. Innovation and regulation in the pesticide industry. CES 95-14.
[39] Gianess. L.P. and Puffer, C.A. 1992. Registration of minor pesticides: some observations and implications. In: Inputs Situation and Outlook Report, U.S. Dept. Agri. Econ. Res. Serv.: 52-60.

ingredients worldwide has halved, from 35 companies in 1995 to 18 in 2012, of which the number of European companies also halved from 8 in 1995 to 4 in 2012 (Japan 11, USA 3)[40].

For PPP it can be concluded that the withdrawal of active substances in the EU will probably not trigger substantial innovation for replacing these by other substances on the EU market. The main reason for this is that the 18 companies involved in research and development of PPP are multinationals that focus their innovation on growth markets outside the EU or on one major crop in the EU. Moreover, less new potential active substances are in the pipeline. This provides companies with lesser opportunities to develop new PPP for crops in the EU.

Regulatory action on PPP may promote innovation in non-chemical methods like plant breeding for resistance. The rewards for resistance research can be great, for example USD 9.3 million on developing resistance in wheat, alfalfa and corn against some pests resulted in saving to farmers at several hundred million dollars annually[41].

Innovation in application technology of PPP may be also triggered by regulatory action on pesticides demanding less exposure of the environment and operators. Better technology may improve targeting of application of PPP and minimising human and environmental risks during application. Besides evidence on the development of safer application technology like e.g. sprayers classified as spray-drift-reducing-technology (SDRT), band field crop sprayers, shielded band field crop sprayers, sensor field crops sprayers, automatic boom height control, weed wipers, GPS controlled machinery, or drift reducing nozzles, no overview data are available. Non-approval of substances, with no or very limited possibility of restricted approval, is expected to discourage innovations in application technology.

An overview of the impact of setting ED criteria on the different types of companies is provided in Table 7. The term "input" is used to indicate the availability of resources, products or services required to make a product or deliver a service. The term "demand" indicates the market demand for the product made or service delivered by this type of companies. The analysis is on group/sector level, so not on individual company level.

[40] If otherwise stated the data in this section are based on Phillips McDougall. 2013. R&D trends for chemical crop protection products and the position of the European market. A consultancy study undertaken for ECPA. Retrieved from: http://www.ecpa.eu/files/attachments/R_and_D_study_2013_v1.8_webVersion_Final.pdf

[41] Pesticide innovation and the economic effects of implementing the Delaney Clause (1987). Retrieved from: http://www.ncbi.nlm.nih.gov/books/NBK218035/

Table 7. Impact of setting ED criteria for companies active on the PPP-market.

Pesticides Market										
Description of the EU-market					**Potential impact of ED criteria**					
Type of business		Input	Demand/sales	Number of products or services	Number of firms	Input	Demand/sales	Innovation on EU market	Number of products or services	Competitiveness
Manufacturers and developers of active substances	Multinationals	Not relevant	World		→	Not relevant	→	→	↘	→
Formulators of PPP	Multinationals and SMEs	Europe	Europe		→	↘	→	→ or ↗	↘ → ↗	↘ or →
Downstream users PPP										
Manufacturers of application technology	Many SMEs	Europe	Europe	>>>> many	→	→	→ or ↘	→ or ↘	→ or ↘	→
Professional end-user	Many SMEs	Europe	Europe	>>>> many	→	→ ↘	→	→	→ or ↘	→
Consumer		World	Not relevant	Not relevant	Not relevant		→	Not relevant	Not relevant	Not relevant

4.2. BP industry and downstream users

During the last 15 years less than 10 new biocidal active substances have been developed.[34] In a recent survey conducted by the International Association for Soaps, Detergents and Maintenance products (AISE) and the European Chemical Industry Council (CEFIC), the following main obstacles for innovation had been reported: (1) The costs for authorisation of a product are considered too high to justify R&D efforts, (2) Regulatory compliance is taking a lot a companies' resources, and as a consequence no resources remain for innovation, (3) The timelines for authorisation are too long and the process involves much uncertainty, and (4) The number of active substances is decreasing which directly impacts the possibilities for innovation in BP.[34]

It is expected that the withdrawal of active substances in the EU will probably not trigger innovation for replacing it by another substance. The main reason for this is that the companies involved in research and development of biocidal active substances are multinationals that will probably focus their innovation on growth markets outside the EU or will not refocus their R&D in Europe because of the disappearance of one specific substance. Formulators of BP have the focus on Europe. Those companies, of which many SMEs, may try to develop new products in order to respond the market demand of effective BP. However, this type of innovation may have to compete with the additional compliance costs linked to the approval process of identified EDs under the derogations as included in the BP and pesticides legislation. For companies these derogations will trigger additional costs and personal resources.

As mentioned before, many major industrial sectors are relying on the use of BP, either because they manufacture goods containing BP or because BP are required in the manufacturing process. These sectors may be impacted by the disappearance of active substances on the EU market and the associated BP. It is difficult to judge whether this will lead to additional innovation at downstream users level as it depends on many factors. Firstly, it can be expected that the many different types of downstream users will respond differently. The market is segmented and a highly diverse group of enterprises and downstream users participate in market activities. In view of this complexity, a disadvantage for one company might be an advantage for another and vice versa. Secondly, it can be questioned whether non-EU suppliers are prepared to invest in compliance with the BP Regulation. It may be challenging for EU importers to get the information from non-EU companies about the composition of substances, articles or mixtures that are bought. This will imply the need for increased investments in supply chains, especially in countries outside the EU, in order to have an adequate information flow in the supply chain for ensuring compliance with the BP Regulation. This means that it will be generally more difficult to switch to other suppliers in the short term. Consequently, this reduces flexibility in the supply chain choice for those EU based companies and may reduce their competitiveness.[34] However, some EU companies may benefit from this situation as companies may decide, or have to, switch from non-EU to EU BP Regulation-compliant suppliers. In the context of the information flow in the supply chain, it is important to stress that companies, from 1 March 2017, have to comply with the regulatory requirement that in treated articles only biocidal active substances can be used that

are approved or under review in the EU. So, downstream users will have also to invest in the information flow in supply chains in order to comply with this regulatory requirement.

Thirdly, it will depend on the substance in question and the type of supply chain. For example, for key substances in the supply chain, and high value added substances, probably quicker increased R&D will occur as key substances have a shorter return of investment (this return of investment varies from 2 up to 15 years, see Table 3). It is important to note that replacing a chemical in an article or mixture can imply that companies need to significantly change their technologies or processes. It can also affect their business model or supply chain as they need to establish new relations with suppliers. The screening of biocidal substances on ED properties is not representative for the biocidal active substances on the market (see Annex 5 on results of the screening study). This implies it is not possible to determine what type of biocidal substances would be in particular impacts and whether key substances will be affected by the setting of ED criteria. It is important to underline that the BP Regulation provides the possibility to approve an active substance if it is shown that it is essential to prevent or control a serious danger to human health, animal health or the environment (for example, key disinfectants) or not approving the active substance would have a disproportionate impact on society when compared with the risk (see also Table 7 for further details). No experiences exist with the application of this possibility in the legislation, so it is unclear under which circumstances MS would agree to apply these possibilities.

The same impacts are expected on domestic and foreign companies for products placed on the EU market as the same ED criteria will apply. It is noted that companies may use for exports a withdrawn substance in the EU for manufacturing a mixture or an article (if the substance is allowed in the country of destination). However, a company conforming to two standards must manage substances sourcing, production and logistics separately for two standards, and this is expected to created additional costs.

For downstream users it is expected that the setting of criteria will not affect the level of innovation or additional R&D or may lead to an increase. However, this activity is driven by the need to comply with the legislation. As indicated at the section on the results of the public consultation there are different views whether this will lead to an increase in competitiveness in terms of having more and/or higher quality products. The companies may gain competitive advantages by producing safer products and benefitting from a green and innovative image[42]. This positive marketing effect is less obvious if products are meant to be used by commercial actors or for complex articles.[37]

An overview of the impact of setting ED criteria on the different types of companies is provided in Table 8. The term "input" is used to indicate the products or services required to make a product or deliver a service. The term "demand" indicates the market demand for the product made or service delivered by this type of companies. The analysis is on group/sector level, so not on individual company level.

[42] Nidumolu, R., Prahalad, C.K., and Rangaswami, M.R. 2009. Why sustainability if now the key driver of innovation. Harvard Business Review. September issue 2009. Retrived from: https://hbr.org/2009/09/why-sustainability-is-now-the-key-driver-of-innovation

Table 8. Impact of setting ED criteria for companies active on the BP market.

Biocides Market										
Description of the EU-market					**Potential impact of ED criteria**					
Type of business		Input	Demand/sales	Number of products or services	Number of firms	Input	Demand/sales	Innovation on EU market	Number of products or services	Competitiveness
Manufacturers and developers of active substances	Multinationals	Not relevant	World		→	Not relevant	→	→	↘	→
Formulators of BPs	Many SMEs	Europe	Europe		→	↘	→	→ or ↗	↘ → ↗	↘ or →
Downstream users of BPs										
Industrial end-user	Multinationals and SMEs	World	World and Europe	>>>> infinite	→	↘ or →	→	→ or ↗	↘ → ↗	→
Professional end-user	Many SMEs	Europe	Europe	>>>> infinite	→	↘ or →	→	→	↘ → ↗	→
Consumer		World	Not relevant	Not relevant	Not relevant		→	Not relevant	Not relevant	Not relevant

4.3. Summary and performance of the options

Competitiveness and innovation in companies in the supply chain is driven by a wide range of factors (energy prices, labour costs and productivity, infrastructure, taxation, regulatory environment etc.).It is emphasised that setting criteria for EDs is just one issue that may affect the innovative capacity or competitiveness of EU companies in the PPP and BP supply chain. Moreover, the information is lacking in order to determine the size of the impact of setting criteria for EDs compared to other factors affecting innovation.

The criteria for EDs may lead to additional costs and increase the time-to-market for PPP and BP as more tests and data may be required in order to fulfil the regulatory requirements. It is expected that the ED criteria would imply that some active substances incorporated in PPP or BP will be withdrawn of the market or approved under strict conditions (see Annex 5). The withdrawal of active substances contained in PPP and BP in the EU will probably not trigger substantial innovation for replacing these by other substances. The main reason for this is that the multinational companies involved in R&D would probably not refocus their R&D. Moreover, the higher development and regulatory costs (for obtaining approval for an active substance and maintaining it on the market), will consume part of the investments available for R&D for new active substances and products.

For downstream users and formulators of PPP and BP it is very difficult to judge whether the proposal will lead to additional innovation because of the many factors involved. For downstream users it is expected that that the setting of criteria does not affect the level or may lead to an increase in innovation. However, this innovation will be driven by the need to comply with legislation. Different views exist whether this increase in innovation will lead to an increase in competitiveness in terms of having more and/or higher quality products.

Taking into account the impacts on the different and many actors involved in the supply chain ,and the lack of information on the supply chain, overall ranking of the four options for innovation and research can be only done assuming that the option having the less number of chemicals identified, will be performing the best. As a consequence, the options would perform 4>2/3>1. With respect to the options related to regulatory decision making, Option C would have less impacts than Option B and A, respectively (C>B>A), because they would respectively lead to the non-approval of less substances.

5. IMPACT ON SMES (EXCLUDING FARMERS)

The agricultural sector is constituted by SMEs, impacts on this sector are discussed in Annexes 12 and 13.

Small and medium-sized enterprises (SMEs) operate in the supply chain of PPP (importers, distributors). No specific data are available on these SMEs. SMEs are important for the BP market as more than 60% of the companies are SMEs (see Figure 4).

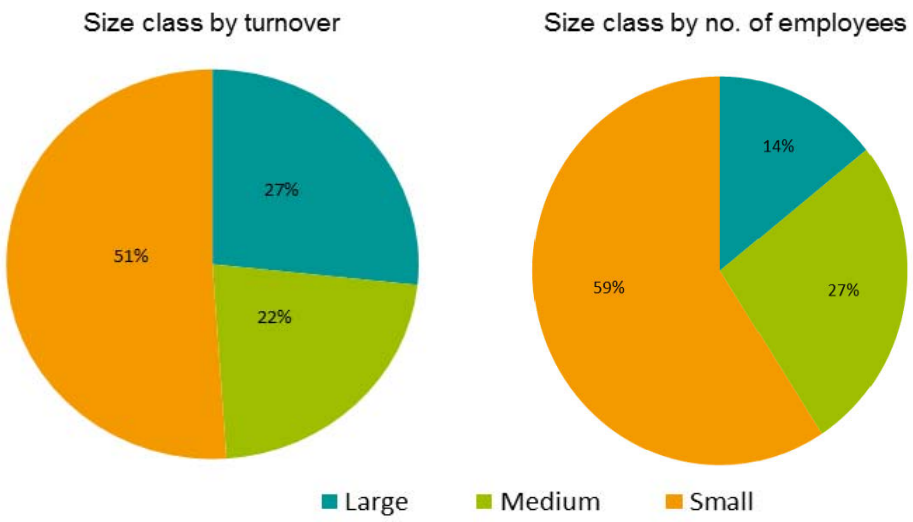

Figure 4. The percentage of SMEs in the EU biocides market[43].

Several economists assert that high cost research, as that required for PPP and BP, favour larger firms because of their greater financial capacity[44]. Larger firms are also better able to take advantage of their research because they have more market outlets[45]. Contrarily, SMEs have more difficult access to capital and their cost of capital is often higher than for larger businesses. Finally, to comply with detailed legislation does not match with the success factors of an innovative SME: an informal organisational structure with high flexibility, and less overhead and bureaucracy[46]. Therefore, SMEs, due to their specificities, can be affected by the ED criteria options assessed in this report more than their bigger competitors. In addition, under both the PPP and BP Regulations SMEs have to comply to the same rules as larger companies.

In general SMEs have products based on less active substances in their portfolio than larger companies, making them more vulnerable to the withdrawal of substances linked to the setting of ED criteria. However, the PPP and BP Regulation provide both the possibility, notwithstanding a chemical is identified as an ED, to approve the substance with restrictions for a fixed time period (see Table 7). A company would have to support this with additional data (for example for the comparative assessment whether suitable alternative substances and technologies are available). In order to prepare the additional data SME probably have to outsource it because of the limited personal resources and expertise in a SME. It is clear that applicants would need to invest and would be uncertain about the status of the substance for some time as the provided evidence for using the specific derogations has to be evaluated and the conditions for approval need

[43] Ecorys, Background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision. Draft Final Report (2016).
[44] Schumpeter, J.A. 1961. Theory of economic development, New York, Oxford University Press.
[45] Teece, D.J., 1982. Towards an economic theory of the multiproduct firm. Journal of Economic Behavior and Organisation 3: 39-63.
[46] European Commission. 2012. Interim Evaluation, Impact of the REACH regulation on the innovativeness of the EU chemical industry, Annexes, 2012 (Ares (2015)3396029).

discussion. In case of an approval, it would be for a shorter time than the normal period, so it will be re-assessed earlier increasing the cost to maintain the active substance on the market. These additional costs and demand on expertise and personal resources will constitute a, comparatively, higher burden to SMEs than for larger companies.

It is clear that the criteria will trigger additional costs and resources. In general it can be concluded that an increase in costs and a further demand in personal resources would favour bigger companies and negatively affect the market position of SMEs as bigger companies have greater financial capacity and can better spread risks. Moreover, SMEs are considered to be relatively more vulnerable than larger companies to the withdrawal of an substances because their portfolio consist of less substances. The options result to different levels of additional costs and resources and are expected to be related to the number of substances identified as ED. In general it can be concluded that the ranking of the options for SMEs can be done in the same way as innovation and competitiveness, but that the size of the impacts on SMEs will be expected to be larger. The impacts can lead to a reduction of SMEs, even a further concentration in the PPP and BP-sector, and less competition. Summarising the options would perform 4>2/3>1. With respect to the options related to regulatory decision making, Option C would have less impacts than Option B and A, respectively (C>B>A), because they would respectively lead to the non-approval of less substances.