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IMPACT ASSESSMENT

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

Annexes 12 and 13 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 12

SECTORIAL COMPETITIVENESS: EU AGRICULTURE

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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. Agriculture in the EU

Agriculture plays an important role in the EU: it supplies nutritious and high quality food to the 508.2 million Europeans¹, but also jobs. The farming and food sectors together provide 7% of all jobs and generate 6% of European gross domestic product².

The EU is the largest wine and olive oil producer in the world. It is also one the largest producers of cereals at global level (the harvested production of cereals, including rice, in the EU-28 was estimated to be around 334.2 million tonnes in 2014). The EU is a major actor in the international trade of agricultural product as it is a leading exporter (mostly processed and high-value-added products).³

According to the Agriculture, forestry and fishery statistics - 2014 edition⁴, there were 12.2 million farms in the EU-28 in 2010, with the vast majority of these (96.9%) classified as family farms⁵. Altogether, their utilised agricultural area (UAA) encompassed 176 million hectares (ha), or 1.76 million km². The land used by farms in the EU-28 accounted for approximately 40% of the total land area.

Around four fifths (80.3% in 2010) of all farms in the EU-28 had less than 10 hectares of utilised agricultural area, and together these smaller farms cultivated some 12.2% (of the utilised agricultural area. By contrast, only 5.9% of the farms in the EU-28 cultivated 50 hectares or more of land for agricultural purposes, however, these larger farms collectively cultivated 66.6% of the total utilised agricultural area.⁴

In addition, based on the “Annual Working Unit per holding” which gives the number of full-time equivalent jobs per holding for different farm size categories, nowhere in the EU can we find agricultural holdings with more than 250 employees. Even in the highest size class of holdings (100 ha and more) the highest number of full-time equivalent jobs per holding is 20.5 AWU/holding (Slovenia). The idea that larger holdings are more likely to employ several people than smaller holdings is therefore not verified.

As a consequence, if the definition for SMEs “less than 250 employees” is applied⁶, all agricultural holdings qualify as SMEs and it can be assumed that the higher the impacts on

¹ EUROSTAT, News release 124/2015, 10 July 2015. Retrieved from: <http://ec.europa.eu/eurostat/documents/2995521/6903510/3-10072015-AP-EN.pdf/d2bfb01f-6ac5-4775-8a7e-7b104c1146d0>

² European Commission. 2014. The European Union explained. Agriculture - The EU's common agricultural policy (CAP): for our food, for our countryside, for our environment. Retrieved from: http://europa.eu/pol/pdf/flipbook/en/agriculture_en.pdf

³ EUROSTAT, Statistics explained. Agricultural production – Crops. Retrieved from: http://ec.europa.eu/eurostat/statistics-explained/index.php/Agricultural_production_-_crops#Further_Eurostat_information

⁴ EUROSTAT. 2015. Agriculture, forestry and fishery statistics, 2014 edition. Retrieved from: <http://ec.europa.eu/eurostat/documents/3217494/6639628/KS-FK-14-001-EN-N.pdf/8d6e9dbe-de89-49f5-8182-f340a320c4bd>, (p 12)

⁵ According to the FAO definition, the term ‘family farm’ is used to refer to any farm under family management where 50 % or more of the regular agricultural labour force was provided by family workers.

⁶ Definition of an SME according to tool 19 of the better regulation toolbox: http://ec.europa.eu/smart-regulation/guidelines/tool_19_en.htm "Businesses can be characterised as Small and Medium Enterprises (SMEs) by looking at the number of employees: micro companies have 0-9 employees, small companies have 10-49 employees, medium-sized companies have 50-249 employees while large companies have 250 or more employees."

farmers, the more difficult it will be for them to cope with these impacts as they are all SMEs. These difficulties might translate into loss of revenues, the need to change agricultural production, loss of jobs in the farming sector, etc.

Table 1. Distribution of holdings and utilised agricultural area by size and class (UAA), EU, 2005 and 2010

Size classes in hectares	Number of holdings			Utilised agricultural area		
	EU-27		EU-28	EU-27		EU-28
	2005	2010	2010	2005	2010	2010
	(thousands)			(thousand hectares)		
Total	14 482	12 015	12 248	171 996	174 499	175 815
	(% share within total) (%)			(% share within total) (%)		
0	2.0	2.2	2.1	0.0	0.0	0.0
> 0 to < 2	48.3	46.9	47.0	3.0	2.4	2.4
2 to < 5	21.2	20.1	20.2	5.6	4.4	4.4
5 to < 10	10.9	10.9	10.9	6.4	5.2	5.3
10 to < 20	7.1	7.5	7.5	8.4	7.3	7.3
20 to < 30	2.8	3.1	3.1	5.8	5.3	5.3
30 to < 50	2.9	3.3	3.3	9.3	8.8	8.8
50 to < 100	2.8	3.3	3.2	16.4	15.9	15.9
100 or more	2.0	2.7	2.7	45.2	50.9	50.7

(¹) Shares may not sum to 100 % due to rounding.
Source: Eurostat (online data code: ef_kvaareg)

Table 2. AWU/holding, 2010 (Calculations done by DG AGRI on the basis of data from Eurostat)

GEO/AGR AREA	Total	Zero ha	Less than 2 ha	From 2 to 4.9 ha	From 5 to 9.9 ha	From 10 to 19.9 ha	From 20 to 29.9 ha	From 30 to 49.9 ha	From 50 to 99.9 ha	100 ha or over
Belgium	1.44	1.21	1.22	1.17	1.16	1.34	1.45	1.54	1.74	2.12
Bulgaria	1.10	1.17	0.88	1.27	1.58	1.83	2.13	2.10	2.70	7.65
Czech Rep.	4.72	16.00	1.05	1.46	1.14	1.31	1.49	1.66	2.37	17.40
Denmark	1.24	1.98	2.63	1.54	0.47	0.56	0.69	0.86	1.28	2.90
Germany (u)	1.82	3.98	1.64	1.57	0.88	1.14	1.46	1.72	2.07	4.60
Estonia	1.28	7.47	0.62	0.59	0.68	0.76	0.88	1.10	1.29	6.24
Ireland	1.18	2.00	0.67	0.64	0.79	1.00	1.18	1.36	1.59	1.93
Greece	0.59	1.38	0.31	0.67	0.94	1.18	1.34	1.48	1.69	2.06
Spain	0.90	1.14	0.52	0.59	0.78	1.03	1.19	1.31	1.62	2.75
France	1.51	1.71	0.73	0.83	1.12	1.41	1.57	1.67	1.80	2.32
Croatia	0.79	5.22	0.44	0.81	1.14	1.52	2.02	1.94	2.23	9.13
Italy	0.59	0.96	0.29	0.53	0.80	1.09	1.38	1.64	2.06	3.24
Cyprus	0.48	1.65	0.25	0.71	1.15	1.80	2.08	2.21	2.73	4.17
Latvia	1.02	2.09	0.45	0.65	0.83	1.06	1.28	1.53	1.77	4.88
Lithuania	0.73	11.92	0.38	0.48	0.64	0.92	1.15	1.27	1.64	5.90
Luxembourg	1.68	1.00	0.65	1.44	1.86	1.29	1.08	1.33	1.77	2.52
Hungary	0.73	0.66	0.50	0.79	0.97	1.21	1.38	1.57	2.01	8.84
Malta	0.39	0.68	0.31	0.78	1.30	2.25	0.00	:	:	:
Netherlands	2.24	3.07	2.22	2.09	2.06	2.07	2.06	2.08	2.56	4.11
Austria	0.76	0.37	0.38	0.40	0.63	0.85	1.04	1.20	1.31	1.46
Poland	1.26	1.49	0.73	1.04	1.41	1.73	1.98	2.11	2.20	5.92
Portugal	1.19	2.36	0.98	1.10	1.25	1.55	1.83	2.17	2.49	3.44
Romania	0.42	0.20	0.29	0.62	0.89	1.21	1.52	1.77	2.16	5.41
Slovenia	1.03	1.26	0.57	0.85	1.19	1.61	1.99	2.37	2.82	20.50
Slovakia	2.29	2.16	0.61	0.72	0.85	1.04	1.00	1.40	1.94	16.95
Finland	0.94	1.35	1.75	0.48	0.43	0.55	0.80	1.06	1.43	2.07
Sweden	0.80	1.32	1.48	0.34	0.38	0.48	0.61	0.78	1.16	2.34
United King.	1.43	1.17	1.29	1.08	0.74	0.84	1.06	1.19	1.56	2.63
EU-28	0.81	0.68	0.41	0.73	1.01	1.26	1.42	1.56	1.82	3.62
EU-27	0.81	0.68	0.41	0.73	1.01	1.26	1.42	1.55	1.82	3.61
EU-15	0.94	1.42	0.44	0.67	0.86	1.09	1.29	1.48	1.78	2.81
EU-N12	0.72	0.47	0.40	0.78	1.17	1.53	1.76	1.87	2.11	7.84
EU-N13	0.72	0.47	0.40	0.78	1.17	1.53	1.77	1.88	2.11	7.86

2. of plant protection products (PPP)

The use of PPP plays an important role in EU agricultural production. Farmers use PPP to ensure less weed and pest damage to crops and a consistent yield. Therefore, as the availability of PPP is expected to be impacted by the future endocrine disruptors (EDs) criteria as these might result in the non-approval of substances, farmers are one of the main stakeholders that will be impacted as they use PPP for their production.

There are three main types of PPP:

- fungicides⁷: used for the control of fungi.
- herbicides⁷: used for the control of unwanted plants or weeds.
- insecticides⁷: used for the control of insects.

In the EU, since the 90s, PPP are regulated products that need to be authorised before being placed on the market (Regulation (EC) No 1107/2009, which replaced Directive 91/414/EC). This pre-market approval system is considered as one of the strictest worldwide: any PPP must be authorised before it can be placed on the market and used. Only PPP which contain active substances placed on a "positive list" can be authorised for use in the EU, if the use has been considered not to cause adverse effects on human or animal health or unacceptable effects on the environment.

The EU pesticides database⁸ on active substances summarises the active substances assessed so far (both approved and not approved). Currently, there are 482 active substances approved on the EU market which can be used in PPP and which include low risk substances and microorganisms: 147 fungicides, 123 herbicides, 98 insecticides, and 114 other type (e.g. repellent, rodenticide, attractant, etc.) (Figure 1).

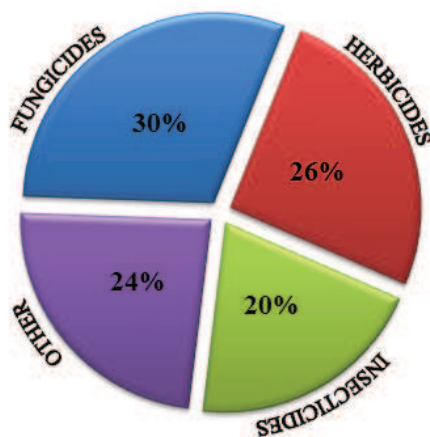


Figure 1. Approved active substances to be used in PPP in the EU, by 01/01/2016.

⁷ Stephenson G.R., Ferris I.G., Holland P.T., Nordberg M., 2006. Glossary of terms relating to pesticides (IUPAC Recommendations 2006), Pure Appl. Chem., Vol. 78, No. 11, pp. 2075–2154. doi:10.1351/pac200678112075. Retrieved from:

<http://www.iupac.org/publications/pac/2006/pdf/7811x2075.pdf>

⁸ EU pesticides database on active substances. Available on: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>

3. Assessment of potential impacts on agriculture

In the public consultation carried out in the context of this impact assessment (IA) (September 2014 to January 2015) many farmers and agricultural producers responded. In total 488 web-based and 33 email responses were received from agricultural producers/farmers.

About 57% of web-based responses submitted on behalf of an organisation came from agricultural producers/farmers. A high proportion of those who answered expressed concerns about the potential disappearance of key PPP and the high yield losses that would result from this. They also mentioned the linked resistance problem, i.e. if only a few similar types of PPP remain available, the development of resistance of diseases to these products will take place faster and more frequently, creating a problem for agricultural production. In addition, they mentioned the fact that there might be no suitable substitutes for some of the substances that may no longer be available.

Given the feedback received from farmers and the importance of agriculture for the EU, the criteria illustrated under section 3.2 were chosen to compare how the different options (1 to 4 and A to C) would impact the competitiveness of EU agriculture.

All criteria are based in first instance on the results of the screening study (see Annex 5) and consider the impacts derived from the regulatory consequences (a non-approval of the active substance in the worst case) on other aspects. The results of the screening were filtered for other "cut off" criteria 1) none of the substances identified as ED were classified or to be classified as M1 nor persistent in the environment (see Annex 5), 2) substances which are classified or to be classified as C1, or R1 were flagged and not considered for the assessment of the impacts on agriculture. In this way, substances which are already having regulatory consequences under Regulation (EC) No 1107/2009 under consideration of other "cut off" criteria are not double counted.

The assessment focused on PPP used in agriculture (including horticulture), while forestry and amenity areas were not considered. A series of additional data have been considered for this assessment. In section 3.1 below, the additional data used and the selected criteria are briefly described. In first instance the analysis will be used to assess the performance of options 1 to 4. Options A to B are linked to the decision making, with Option C affecting less active substances than B and A in all cases.

3.1. Additional Data used for the assessment

In order to carry out the analysis of the impacts on EU agriculture, the following datasets and information sources have been used.

1) EU Pesticide Database

The EU Pesticide Database⁸ has been used to obtain information on active substances. For each active substance the database also indicates to which sub-group of pesticides it belongs (e.g. herbicide, fungicide, or insecticide).

2) Data supplied by Member States (MS)

The PPP Application Management System (PPPAMS) was developed by the European Commission to support MS in fulfilling their legal obligations under Regulation (EC) No 1107/2009, notably Article 57(1) and (2). The objectives of the PPPAMS are harmonisation of the formal requirements for application of PPP, streamline mutual recognition of authorisations to speed up time to market, improve the management of the evaluation process for authorisation of PPP, and deliver correct and timely information on authorised or withdrawn PPP to stakeholders.

The process on building up the PPPAMS is on-going. In its context, in June 2015 and in order to compile data for the IA, the European Commission sent a request to MS to provide information on existing authorisations of PPP and their use at national level for the IA. This data should be kept available by MS according to article 57 of Regulation (EC) 1107/2009.

Complete datasets on existing authorisations of PPP and their use at national level were available by 1 January 2016 for Estonia, Germany, Austria, Belgium, the Netherlands, Czech Republic, Slovenia, and Greece⁹. With exception of Estonia representing the Northern zone and Greece representing the Southern zone, all other data are from the Central zone.

The data were processed by the Commission services. After receiving the data from the MS (in most of the cases, the data were provided in their national language), they were checked by the Commission services to ensure conformity with a common language (EPPO codes for crops and pests).¹⁰ However, a final quality check by the corresponding MS has not been done yet.

3) Eurostat data

Regulation (EC) No 1185/2009 requests MS to submit data on sales and use of pesticides to the Commission (Eurostat). This regulation also provides that for confidentiality reasons the Commission aggregates the data before publication.

The data on sales of actives substances for the following 11 MS that have agreed to the disclosure of the documents in an earlier case (GestDem 2015/2182) was available for the assessment: Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Italy, Luxembourg, Malta, Slovenia and Sweden. After assessing the data for these 11 MS, it was analysed if they correlate with the data for EU 27 based on the complete set of data. However, as Regulation 1185/2009 does not allow the Commission to produce any statistics on active substance level, the annex containing these data is kept separate and confidential (Annex 13).

⁹ According to Regulation (EC) 1107/2009, there are three zones in the EU. The following MS belong to:

Zone A (North): Denmark, Estonia, Latvia, Lithuania, Finland, Sweden;

Zone B (Centre): Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom;

Zone C (South): Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal

¹⁰ European and Mediterranean Plant Protection Organization (EPPO) Global Database. Available on: <https://gd.eppo.int/>

3.2. Selection of Criteria

(a) **Number of PPP that would be affected**

Because of the two step approach of the EU legislation concerning PPP (approval of active substances at EU level, authorisation of PPP uses at national level) there may be more or less PPP uses authorised at EU level for each active substance, and this may also vary across MS.

In order to assess the number of PPP that would be affected, a "worst case scenario" is used as a starting point: PPP active substances that would be identified as ED would not be approved and would therefore no longer be available on the EU28 market for use in PPP. The application of derogations, which would actually reduce the impacts, under the provisions of negligible exposure or Article 4.7 of Regulation 1107/2009 are assumed to apply equally (in the same proportion) to all options and therefore not considered to play a role for a relative ranking of the options. They were as a consequence not considered for the purposes of simplification.

For each non-approved active substance at EU level, the number of PPP authorisations at national level that would be affected has been assessed. It is assumed that the higher the number of PPP that would potentially disappear from the market, the higher the likely impacts for farmers. As mentioned before, farmers are considered SMEs. Since evidence to quantitatively assess the impacts in terms of yield losses of the potential disappearance of one single substance is lacking, a more detailed analysis of the agricultural impacts could not be carried out.

The potential disappearance of certain PPP active substances, and consequently of certain PPP, may result in the rising production prices of some crops and agriculture commodities. This might be passed on to consumers who may find it difficult to manage any significant increase in food prices and may reduce their consumption of fresh products. It might also result in a change of diet for consumers (they could for instance consume more substitute products).

Consumption expenditure *“is what people, acting either individually or collectively, spend on goods and services to satisfy their needs and wants. A household’s economic well-being can be expressed in terms of its access to goods and services. The more that can be consumed, the higher the level of economic well-being, though the relationship between the two is not a linear one. Measuring consumption expenditure might, therefore, be a way of measuring economic well-being.”*¹¹

There are different household consumption habits across the EU; culture, income, weather, household composition, economic structure and degree of urbanisation are all factors that can have an impact on habits in each MS.¹¹

In national accounts, the final consumption expenditure of households *“is the biggest component of the expenditure approach to GDP. Its evolution allows an assessment of*

¹¹ EUROSTAT. 2013. Statistics explained. Household consumption expenditure - background. Available on: http://ec.europa.eu/eurostat/statistics-explained/index.php/Household_consumption_expenditure_-_background

purchases made by households, reflecting changes in wages and other incomes, but also in employment and in savings behaviour.”¹¹

According to Eurostat, in 2012 food represented on average 16% of household expenditure in the EU 27. Bread and cereals, meat, fish and dairy products represented on average 17%, 25%, 3 % and 19 % of household expenditure on food respectively for 2012.¹²

- Oils and fats, fruits, vegetables and potatoes as well as other food products represent on average 5%, 20% and 12% of household expenditure for food respectively.¹²
- Bread and cereals therefore represented on average 2.72% of household expenditure in 2012 in the EU 27.¹²
- Fruits, vegetables and potatoes represented on average 3.2% of household expenditure in 2012 in the EU 27.¹²

It can be assumed that the higher the impact on agricultural production resulting from the potential loss of some PPP, the higher the likelihood of having impacts on the end consumer.

(b) Crops affected

Based on the available MS data, the number of crops for which PPP authorisations would be affected has been identified. This assessment was done at genus level¹³ due to the fact that this level of information was considered as the most reliable and consistent one given the data collected. It is assumed that the longer the list of crops concerned by the disappearance of certain active substances, the higher the impacts for EU agriculture and farmers will be.

This criterion is considered important because some of the main problems with losing part of the PPP portfolio are an increased risk of yield losses due to pests and fungi where there is no other effective PPP available, and an increased risk of pests developing resistance to PPP due to reduced number of alternatives (this is discussed under the third criterion). Farmers might react in different ways to these impacts: they could either go out of business or might decide to change crops. The price of their products might also increase and this could eventually impact end consumers (see previous section).

(c) Existence of alternatives / risk of resistance of pests (see Annex 10)

Regulation (EC) No 1185/2009 classifies the active substances by chemical class. In order to carry out an analysis on the existence of alternatives (both chemicals and micro-organisms falling under Regulation (EC) No 1107/2009), in a first step, the proportion of active substances identified as ED under each of the options by chemical class and major group (fungicide, herbicide, insecticide) was calculated.

¹² EUROSTAT. 2012. Statistics explained. Comparative price levels for food, beverages, and tobacco.

Available on: http://ec.europa.eu/eurostat/statistics-explained/index.php/Comparative_price_levels_for_food_beverages_and_tobacco

¹³"A genus is a principal taxonomic category that ranks above species and below family, and is denoted by a capitalized Latin name, e.g. Leo. " Retrieved from <http://www.oxforddictionaries.com/definition/english/genus>

It is assumed that the higher the percentage of chemical class affected, the lower the number of alternatives existing. It is acknowledged that for some crops, only one particular active substance is effective/efficient and therefore its loss might lead to higher impacts for the crop production than the data shown. However, the level of detail and of reliability of additional data at the disposal of the Commission did not allow for a more detailed analysis.

It is assumed that the lower the number of alternatives existing for a crop/pest, the higher the potential risks of resistance appearance in pests are. This could decrease sustainability of agriculture as farmers would not have at their disposal a wide range of PPP to make it possible to select and rotate products that are appropriate for the crop/pest situation, avoiding thus resistance development through repeated use of the same active substances. This aspect is important from an agricultural point of view, as recognised by on-going international activities focusing on this topic and done by the European and Mediterranean Plant Protection Organisation (EPPO¹⁴) and the Food and Agriculture Organisation of the United Nations (FAO).

Other crop management methods (e.g. resistant varieties) are not mentioned in this analysis because they can vary significantly from one MS to another, depending on the climatic/agronomic and the market expectation in a given MS. Therefore, no general conclusion for a particular crop could be drawn, however the analysis is considered suitable to illustrate a general outcome.

Similar calculations were performed for the volumes of sales of these active substances for 11 MS¹⁵ for which Eurostat data were available for the years 2011; 2012 and 2013. The analysis and results of these data is kept as confidential due to the provisions of Regulation (EC) No 1185/2009 (Annex 13).

3.3. Expected impacts of the different options on agriculture Results of the screening

The substances identified as ED under any of the options considered for the screening are listed below in Table 3.

The substances identified as EDs in the screening were filtered for other "cut off" criteria 1) none of the substances identified as ED were classified or to be classified as M1 nor persistent in the environment (see Annex 5), 2) substances which are classified or to be classified as C1, or R1 were flagged and not considered for the impacts on agriculture.

Figure 2 summarises the number of active substances identified as ED under each of the four options with regulatory consequences by PPP major group (excluding substances which are also classified as C1 or R1, or substances being identified as candidate for substitution because of persistency) as follows:

¹⁴ EPPO 2015. PP 1/213 (4) Resistance risk analysis. Bulletin OEPP/EPPO Bulletin (2015) 45 (3), 371–387
ISSN 0250-8052. DOI: 10.1111/epp.12246.

¹⁵ An average was calculated for the years 2011;2012;2013 for the following MS: BE, BG, CZ, DK, FI, FR, IT, LU, MT, SE, SI

- under Option 1, 13.6% of the fungicides, 13% of the herbicides, and 3% of the insecticides currently on the market would be non-approved;
- under Option 2 and 3 Category I, these percentages are reduced to 8.8%, 7.3% and 4.1%, respectively;
- under Option 4, fungicides and herbicides are further reduced to 4% and 0.8 %, while the percentage for insecticides remains as for Option 2 and Option 3.

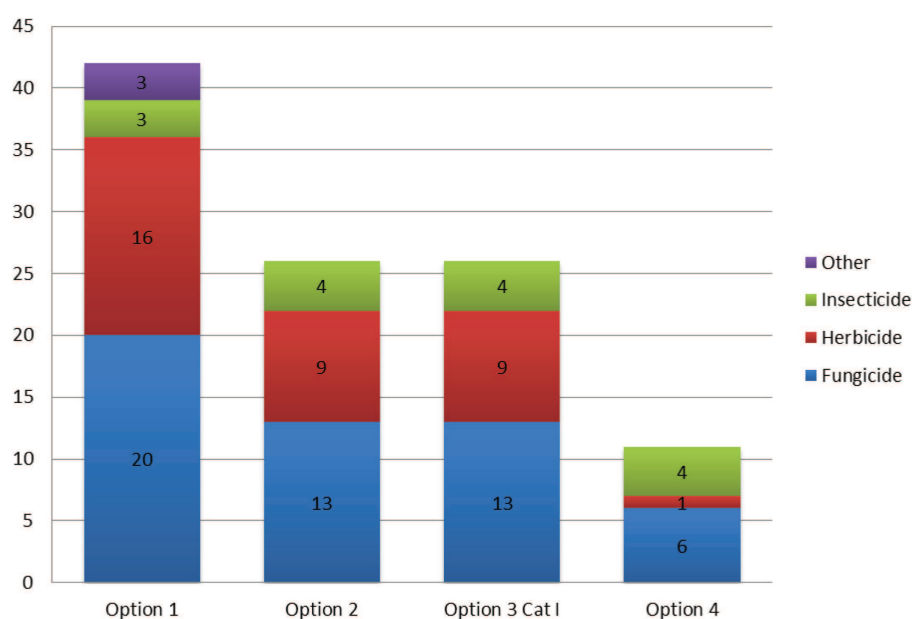


Figure 2. Number of substances identified as ED by PPP major group excluding substances which are also C1 or R1

Table 3. Active substances currently approved for their use in PPP identified as ED under the different options (excluding substances which are also C1, R1):

Option 1 (42)	Option 2 and 3 Category I (26)	Option 4 (11)
1-Naphthylacetamide	2,4-D	8-hydroxyquinoline
1-Naphthylacetic acid	8-hydroxyquinoline	Cypermethrin
8-hydroxyquinoline	Boscalid	Fenamidone
Abamectin	Cypermethrin	Flubendiamide
Benthiavalicarb	Desmedipham	Malathion
Bromoxynil	Fenamidone	Mancozeb
Captan	Flubendiamide	Metiram
Chlorotoluron	Iprodione	Pendimethalin
Cycloxydim	Lenacil	Spirodiclofen
Cymoxanil	Malathion	Tetraconazole
Dazomet	Mancozeb	Ziram
Dimoxystrobin	Maneb	
Fenbuconazole	Metiram	
Fenpropimorph	Myclobutanil	
Fluazifop-P-butyl	Oxadiazon	
Fluazinam	Pendimethalin	
Flupyrsulfuron-methyl	Propyzamide	
Halosulfuron methyl	Spirodiclofen	
Hymexazol	Tebuconazole	
Indolylbutyric acid	Tepraloxydim	
Ipconazole	Tetraconazole	
Isoproturon	Thiophanate-methyl	
Isopyrazam	Thiram	
Isoxaflutole	Tralkoxydim	
Maneb	Triflurosulfuron	
Metam	Ziram	
Metconazole		
Metribuzin		
Myclobutanil		
Prochloraz		
Profoxydim		
Prothioconazole		
Pymetrozine		
Quinoclamine		
Quizalofop-P		
Spirotetramat		
Spiroxamine		
Tebuconazole		
Tembotrione		
Tepraloxydim		
Thifensulfuron-methyl		
Triadimenol		

3.4. Number of PPP that would be affected

Figure 3 indicates the number of PPP that would potentially be affected¹⁶ at national level following the non-approval of the active substances that would be identified as ED under the different options at EU level. Table 7 to Table 14 provide details of the number of PPP authorisations by active substance for the eight MS for which data was available.

One authorised product at national level could contain several active substances identified as ED. This is the reason why the total number of authorisations per option may differ from the sum of occurrences for the active substances under the same option.

It is assumed that the higher the number of PPP that will potentially disappear from the market, the higher the likely impacts for farmers. In addition, it is also assumed that the impact on SMEs would be higher, as farmers are mainly SMEs. Intuitively, one would think that the higher the number of actives substances identified as ED, the higher the number of PPP authorisations that would be affected. Such an assumption would lead to Option 1 (the one identifying the highest number of active substances as ED) being the one performing the worst but the evidence available for the 8 MS which provided data did not confirm this in most of the cases. Figure 3Figure 3 summarises the number of PPP that would be affected per option for all the MS for which data was available. Table 4 illustrates the performance of the options for each MS analysed and the overall performance.

In all analysed MS, Option 4 is the one performing the best as it would lead to the potential disappearance of the lowest number of PPP. The second best option is Option 1 (interim ED) for all countries, except for the Czech Republic and the Netherlands, as it is the one that would lead to the potential disappearance of the second lowest number of PPP. The third best option is Option 2 and Option 3 Category I. In summary, Option 4 performs better than Option 1, which performs better than Option 2 and 3, i.e. $4 > 1 > 2/3$.

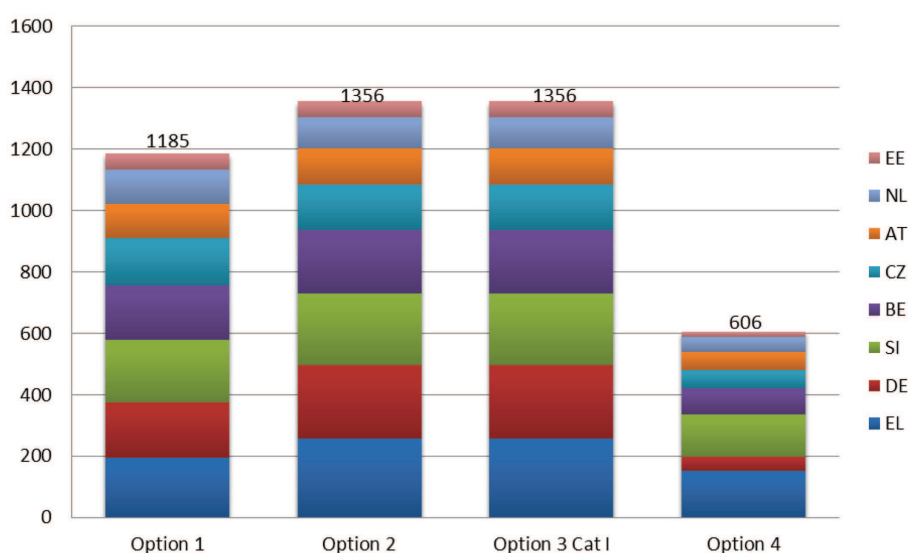


Figure 3. Number of PPP that would be affected under Option 1, Option 2, Option 3 Category I, and Option 4, divided by MS.

¹⁶ PPP affected imply PPP authorisations affected at MS level.

Table 4. Ranking of options - criterion I: No of PPP affected**RANKING OF OPTIONS CRITERION I**

Zone	Member State	Performance	No of PPP affected		
			Option 1	Option 2 and 3 Category I	Option 4
Northern	ESTONIA	4>1/2/3	51	51	18
Central	GERMANY	4>1>2/3	179	240	47
Central	AUSTRIA	4>1>2/3	112	121	58
Central	SLOVENIA	4>1>2/3	204	233	136
Central	CZECH REPUBLIC	4>2/3>1	154	146	59
Central	BELGIUM	4>1>2/3	178	206	88
Central	NETHERLANDS	4>2/3>1	112	101	49
Southern	GREECE	4>1>2/3	195	258	151
-	Total (8 MS)	4>1>2/3	1185	1356	606

3.5. Crops affected

The information on the crops affected in each of the MS for which data is available is given at genus¹⁷ level in Table 15 to Table 22 at the end of this annex.

It can be assumed that the longer the list of crops concerned by the disappearance of certain active substances, the higher the impacts for EU agriculture and farmers will be. Intuitively, one would think that the higher the number of actives substances identified as ED, the higher the number of crops that would be affected. Such an assumption would lead to Option 1 (the one identifying the highest number of active substances as ED) being the one performing the worst but the evidence available for the 8 MS which provided data did not confirm this in most of the cases. For certain crops, no or very few possibilities will remain to control pests and diseases with pesticides. The yields could be reduced. In all these potential cases, end consumers would also be affected (see remarks on consumers in Section 3.2 (b)).

In all these MS, Option 4 is the one performing the best as it would affect the lowest number of crops at genus level.

For all the countries for which data is available, except for Austria and the Netherlands, the second best option is Option 1 (interim ED) as it is the one that would affect the second lowest number of crops at genus level and the third best option is Option 2 and Option 3 category I. In summary, Option 4 performs better than Option 1, which performs better than Option 2 and 3, i.e. $4 > 1 > 2/3$

¹⁷ For further information on what each genus refers to the European and Mediterranean Plant Protection Organization (EPPO) Global Database, available on: <https://gd.eppo.int/>

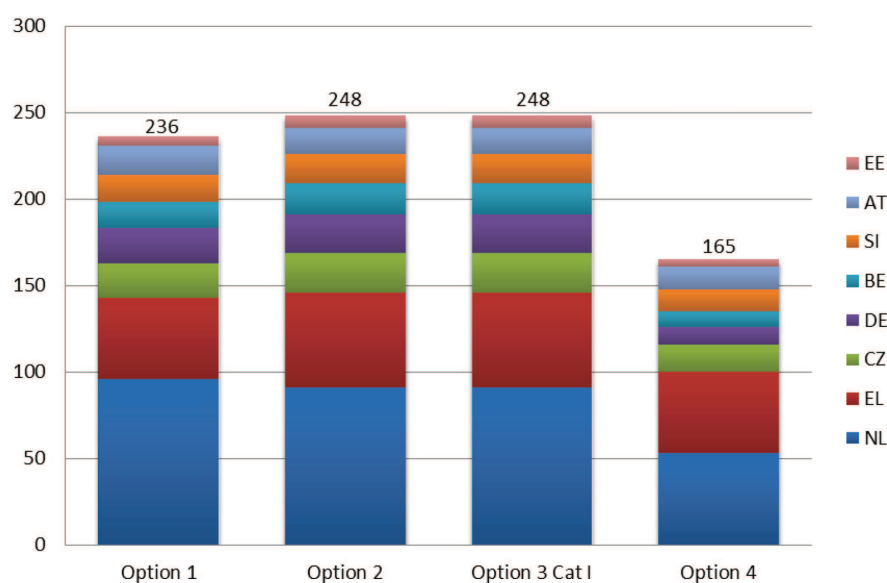


Figure 4. Number of crops (genus level) that would be affected under Option 1, Option 2, Option 3 Category I, and Option 4, divided by MS.

Table 5. Ranking of options - criterion II: No of crops (genus level) affected

RANKING OF OPTIONS CRITERION II					
Zone	Member State	Performance	No of crops affected (genus level)		
			Option 1	Option 2 and 3 Category I	Option 4
Northern	ESTONIA	4>1>2/3	5	7	4
Central	GERMANY	4>1>2/3	20	22	10
Central	AUSTRIA	4>2/3>1	17	15	13
Central	SLOVENIA	4>1>2/3	16	17	13
Central	CZECH REPUBLIC	4>1>2/3	20	23	16
Central	BELGIUM	4>1>2/3	15	18	9
Central	NETHERLANDS	4>2/3>1	96	91	53
Southern	GREECE	4/1>2/3	47	55	47
	TOTAL (8 MS)	4>1>2/3	236	248	165

3.6. Existence of alternatives and the risk of resistance of pests

In order to carry out an analysis on the existence of alternatives (both chemicals and micro-organisms falling under Regulation (EC) No 1107/2009), in a first step, the chemical classes that would be affected by the potential non approval of the active substances identified as EDs under the different options were assessed. Chemical classes are defined in Annex III to Regulation 1185/2009, as last updated by Commission Regulation No 656/2011.

This information was first analysed in terms of percentage of active substances that would be affected per chemical class and major group (e.g. herbicides, fungicides, and insecticides) – Table 6 based on the number of active substances that would be identified as ED.

It is assumed that the higher the percentage of chemical class affected, the lower the number of alternatives existing. It is acknowledged that for some crops, only one particular active substance is effective/efficient and therefore its loss might lead to higher impacts for the crop production than the data shown. However, the level of detail and of reliability of additional data at the disposal of the Commission did not allow for a more detailed analysis.

It is assumed that the lower the number of alternatives existing for a crop/pest, the higher the potential risks of resistance appearance in pests are. This could decrease sustainability of agriculture as farmers would not have at their disposal a wide range of PPP to make it possible to select and rotate products that are appropriate for the crop/pest situation, avoiding thus resistance development through repeated use of the same active substances.

Other crop management methods (e.g. resistant varieties) are not mentioned in this analysis because they can vary significantly from one MS to another, depending on the climatic/agronomic and the market expectation in a given MS. Therefore, no general conclusion for a particular crop could be drawn because a method that is valid for one crop in a given MS is not necessarily valid for the same crop in another MS.

Similar calculations were performed for the volumes of sales of these active substances for 11 MS¹⁸ for which Eurostat data was available for the years 2011; 2012 and 2013. An average was calculated for the three years and used as a basis for the analysis. Further, the correlation of the average volume of sales for the years 2011; 2012 and 2013 and the whole EU 27 was calculated to assess whether the trends observed for the 11 MS were valid for the EU27.

When looking at the percentage of each chemical class identified as EDs during the screening, the data show for instance that for a total of four active substances belonging to the cyclohexanedione herbicides chemical class being on the market, under Option 1, 75% of them would be affected. Under Option 2 and Option 3 Category 1, 50% of them would be affected and under Option 4, this chemical class would not be affected at all. The lowest impact for this chemical class would therefore be under Option 4 as it would not be affected at all.

Figure 5 indicates the percentage of chemical class affected per option, based on the number of active substances. Option 1 (interim ED criteria) is the one affecting the chemical classes the most heavily. It has the highest number of occurrences where it would affect between 67 and 100% of a given chemical class. It has the highest number of occurrences where it would affect between 34 and 66% of a given chemical class. The same trend is observed for chemical classes affected in a proportion going from 0 to 33%. Option 1 is therefore the worst performing option under this criterion as it implies that there would be fewer alternatives available on the market to control pests.

Option 4 (WHO definition and inclusion of potency as element of hazard characterisation) would be the best performing one under this criterion as it would affect the lowest number of chemical classes. Besides, even within the chemical classes it would affect, it would affect them to a lower degree: there are no cases in which Option 4 affects between 67 and 100% of

¹⁸ An average was calculated for the years 2011;2012;2013 for the following MS: BE, BG, CZ, DK, FI, FR, IT, LU, MT, SE, SI

a chemical class. There are only 5 cases in which Option 4 affects between 34 and 66% of a chemical class and only 4 cases in which it affects a chemical class between 0 and 33%.

Similar calculations were performed for the volumes of sales of these active substances for 11 MS¹⁹ for which Eurostat data was available for the years 2011; 2012 and 2013. They are reported in a confidential annex (Annex 13) due to the provisions of Regulation (EC) No 1185/2009. The results of this annex confirm the same trend.

Option 4 is the one affecting the less heavily the chemical classes, even when looking at the average volumes of sales for the years 2011; 2012 and 2013 in the 11 MS.

To summarise, the performance of the four options would be $4 > 2/3 > 1$.

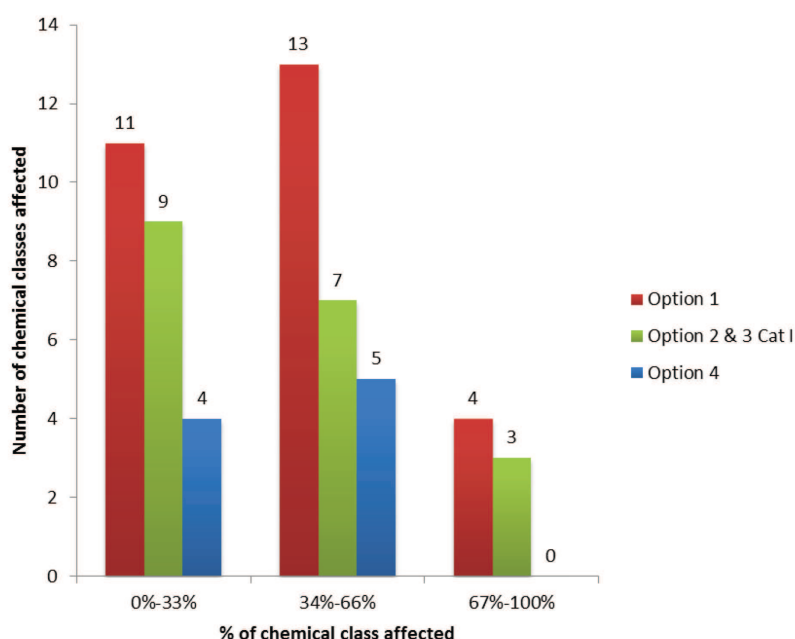


Figure 5.²⁰ How many chemical classes and to which extent each of the options (in percentages) affects the PPP chemical classes, based on the number of active substances identified as EDs

¹⁹ An average was calculated for the years 2011;2012;2013 for the following MS: BE, BG, CZ, DK, FI, FR, IT, LU, MT, SE, SI

²⁰ Figure 5 is a graphical explanation of Table 6. Each bar represents the share of identified EDs within the chemical class, i.e. to which extent a chemical class is affected by the options. If there are two active substances in a chemical class and one of them is identified as an ED it would mean that 50% of the chemical class is affected and will be counted in the bin 34%-66%. This is calculated for each chemical class for each option. The aggregated result is presented in the graph. The higher the bar, the more chemical classes are affected to that certain extent (bin).

Table 6. Percentage of each chemical class²¹ identified as EDs during the screening performed in the framework of this IA for each of the four options.

	Chemical class	Approved AS	Option 1	Option 2 and 3 Category I	Option 4
FUNGICIDES	ALIPHATIC NITROGEN FUNGICIDES	2	50%		
	AMIDE FUNGICIDES	7	14%	14%	
	ANILIDE FUNGICIDES	13	8%		
	BENZIMIDAZOLE FUNGICIDES	3		33%	
	CARBAMATE FUNGICIDES	3	33%		
	CONAZOLE FUNGICIDES***	20	35%	15%	5%
	DICARBOXIMIDE FUNGICIDES	1		100%	
	DINITROANILINE FUNGICIDES	1	100%		
	DITHIOCARBAMATE FUNGICIDES	6	17%	83%	50%
	IMIDAZOLE FUNGICIDES	3		33%	33%
	MORPHOLINE FUNGICIDES	3	33%		
	OXAZOLE FUNGICIDES	2	50%		
	PHTHALIMIDE FUNGICIDES	2	50%		
	QUINOLINE FUNGICIDES	2	50%	50%	50%
	STROBILURINE FUNGICIDES	7	14%		
	UNCLASSIFIED FUNGICIDES	13	8%		
HERBICIDES	AMIDE HERBICIDES	8		13%	
	ANILIDE HERBICIDES	6	17%		
	ARYLOXYPHENOXY- PROPIONIC HERBICIDES	10	20%		
	BIS-CARBAMATE HERBICIDES	3		33%	
	CARBAMATE HERBICIDES***	1			
	CYCLOHEXANEDIONE HERBICIDES	4	75%	50%	
	DINITROANILINE HERBICIDES	3		33%	33%
	ISOXAZOLE HERBICIDES	2	50%		
	NITRILE HERBICIDES	1	100%		
	PHENOXY HERBICIDES	7		14%	
	SULFONYLUREA HERBICIDES	21	10%	5%	
	TRIAZINONE HERBICIDES	2	50%		
	TRIAZOLE HERBICIDES***	1			
	TRIKETONE HERBICIDES	3	33%		
	UNCLASSIFIED HERBICIDES***	8	13%	13%	
	URACIL HERBICIDES	1		100%	
	UREA HERBICIDES***	5	40%		
INSECTICIDES	INSECTICIDES PRODUCED BY	5	20%		
	ORGANOPHOSPHORUS INSECTICIDES	9		11%	11%
	PYRAZOLE (PHENYL-) INSECTICIDES	5		20%	20%
	PYRETHROID INSECTICIDES	13		8%	8%
	PYRIDINE INSECTICIDES	2	50%		
	PYRIDYLMETHYLAMINE INSECTICIDES***	3			
	TETRONIC ACID INSECTICIDES	2		50%	50%
	UNCLASSIFIED INSECTICIDES-ACARICIDES	27	4%		
OTHER	OTHER PHYSIOLOGICAL PLANT GROWTH	9	33%		
	OTHER SOIL STERILANTS	3	67%		
	RODENTICIDES***	5			

(Chemical classes identified with *** include substances identified as ED, which are falling under the "cut-off" criteria and were excluded from the calculation of the percentages).

²¹ as defined in Regulation EC No 1185/2009

3.7. Performance of options A to C for all criteria related to EU agriculture

While all options applied under the current legislative framework in the PPP sector (Option A) may lead to an impact on agriculture because of a decision making based mainly on hazard, Option B would allow proportionate decision making based on more risk elements and would thus have less impact on agriculture than Option A. Option C would allow consideration of socio-economic aspects during the regulatory decision making, which is so far the case only for limited derogations of reduced scope. Thus, the options would perform this way: C>B>A.

3.8. Tables - Number of PPP that would be affected

Tables 7 to 14 provide information on which active substances will be affected under each option and how many authorisations they have in each MS for which data was available. The number of authorisations per active substance is listed as 'occurrences per active substances (AS)'. Note that the total number of authorisations per option may differ from the sum of occurrences because one authorisation may contain more than one active substance. The order of the tables is:

- Table 7 Estonia
- Table 8 Germany
- Table 9 Austria
- Table 10 Slovenia
- Table 11 Czech Republic
- Table 12 Belgium
- Table 13 Netherlands
- Table 14 Greece

Table 7. Number of PPP authorisations that would be affected in Estonia²².

ESTONIA					
Option 1		Option 2 & 3 Category I		Option 4	
Authorisations	51	Authorisations	51	Authorisations	18
Active Substance	Occurrences per AS	Active Substance	Occurrences per AS	Active Substance	Occurrences per AS
Tebuconazole	15	Tebuconazole	15	Mancozeb	9
Prothioconazole	10	Mancozeb	9	Pendimethalin	6
Prochloraz	5	Boscalid (formerly nicobifen)	7	Cypermethrin	2
Fluazinam	5	2,4-D	7	Fenamidone	1
Metconazole	5	Pendimethalin	6		
Fenpropimorph	4	Cypermethrin	2		
Spiroxamine	2	Thiophanate-methyl	1		
Metribuzin	2	Desmedipham	1		
Dimoxystrobin	2	Iprodione	1		
Pymetrozine	1	Thiram	1		
Abamectin (aka avermectin)	1	Fenamidone	1		
Isoproturon	1				
Chlorotoluron	1				
Triadimenol	1				
Fluazifop-P	1				
Cycloxydim	1				

²² One authorised product at national level could contain several active substances identified as ED. This is the reason why the total number of authorisations per option may differ from the sum of occurrences for the active substances under the same option.

Table 8. Number of PPP authorisations that would be affected in Germany²².

GERMANY					
Option 1		Option 2 & 3 Category I		Option 4	
Authorisations	179	Authorisations	240	Authorisations	47
Active Substance	Occurrences per AS	Active Substance	Occurrences per AS	Active Substance	Occurrences per AS
Tebuconazole	39	2,4-D	102	Mancozeb	21
Bromoxynil	18	Tebuconazole	39	Pendimethalin	9
Prothioconazole	16	Mancozeb	21	Cypermethrin	5
Fluazinam	11	Propyzamide	14	Tetraconazole	5
Thifensulfuron-methyl	10	Pendimethalin	9	Metiram	4
Cymoxanil	10	Myclobutanil	8	Fenamidone	2
Myclobutanil	8	Boscalid (formerly nicobifen)	8	Spirodiclofen	1
Chlorotoluron	8	Desmedipham	6		
Abamectin (aka avermectin)	8	Thiophanate-methyl	5		
Prochloraz	8	Tetraconazole	5		
Isoproturon	7	Cypermethrin	5		
Fenpropimorph	7	Thiram	5		
Metribuzin	6	Metiram	4		
Isopyrazam	5	Triflusulfuron	3		
Metconazole	4	Fenamidone	2		
Flupyrifluor-methyl (DPX KE 459)	4	Maneb	2		
Triadimenol	4	Iprodione	2		
Spiroxamine	4	Lenacil	1		
Captan	3	Spirodiclofen	1		
Maneb	2				
Benthiavalicarb	2				
Dimoxystrobin	2				
Quinoclamine	2				
Tembotrione	2				
Cycloxydim	1				
Fluazifop-P	1				
Hymexazol	1				
Spirotetramat	1				
Pymetrozine	1				
Isoxaflutole	1				

Table 9. Number of PPP authorisations that would be affected in Austria²².

AUSTRIA					
Option 1		Option 2 & 3 Category I		Option 4	
Authorisations	112	Authorisations	121	Authorisations	58
Active Substance	Occurrences per AS	Active Substance	Occurrences per AS	Active Substance	Occurrences per AS
Cymoxanil	21	2,4-D	38	Mancozeb	33
Fluazinam	11	Mancozeb	33	Cypermethrin	11
Prochloraz	11	Cypermethrin	11	Pendimethalin	8
Metribuzin	9	Desmedipham	9	Ziram	2
Spiroxamine	8	Pendimethalin	8	Metiram	2
Captan	8	Myclobutanil	7	Malathion	1
Myclobutanil	7	Lenacil	4	Spirodiclofen	1
Bromoxynil	6	Thiram	4		
Isoproturon	4	Triflurosulfuron	3		
Tembotrione	4	Metiram	2		
Quinalofop-P	3	Ziram	2		
Isoxaflutole	3	Spirodiclofen	1		
Cycloxydim	3	Maneb	1		
Ipconazole	2	Malathion	1		
Fluazifop-P	2				
Fenpropimorph	2				
Spirotetramat	2				
Isopyrazam	2				
Dimoxystrobin	1				
Dazomet	1				
Pymetrozine	1				
Hymexazol	1				
Maneb	1				

Table 10. Number of PPP authorisations that would be affected in Slovenia²².

SLOVENIA					
Option 1		Option 2 & 3 Category I		Option 4	
Authorisations	204	Authorisations	233	Authorisations	136
Active Substance	Occurrences per AS	Active Substance	Occurrences per AS	Active Substance	Occurrences per AS
Tebuconazole	49	Mancozeb	73	Mancozeb	73
Thifensulfuron-methyl	18	Tebuconazole	49	Pendimethalin	22
Captan	15	Pendimethalin	22	Tetraconazole	13
Metribuzin	15	Thiram	16	Metiram	11
Triadimenol	10	Tetraconazole	13	Spirodiclofen	9
Cycloxydim	9	Metiram	11	Ziram	8
Dazomet	9	Spirodiclofen	9		
Tembotrione	8	Propyzamide	8		
Fluazinam	8	Ziram	8		
Prochloraz	7	Boscalid (formerly nicobifen)	8		
Pymetrozine	6	Tepraloxydim	5		
Chlorotoluron	6	Thiophanate-methyl	5		
Fenbuconazole	6	Iprodione	4		
Fenpropimorph	5	Myclobutanil	2		
1-Naphthylacetamide (1-NAD)	5				
Tepraloxydim	5				
Isoproturon	4				
Abamectin (aka avermectin)	4				
Metconazole	3				
Quinoclamine	3				
Cymoxanil	3				
Indolylbutyric acid	3				
Myclobutanil	2				
Isoxaflutole	1				

Table 11. Number of PPP authorisations that would be affected in Czech Republic²².

CZECH REPUBLIC					
Option 1		Option 2 & 3 Category I		Option 4	
Authorisations	154	Authorisations	146	Authorisations	59
Active Substance	Occurrences per AS	Active Substance	Occurrences per AS	Active Substance	Occurrences per AS
Tebuconazole	42	Tebuconazole	42	Mancozeb	28
Cymoxanil	19	Mancozeb	28	Pendimethalin	16
Prothioconazole	13	Pendimethalin	16	Tetraconazole	5
Isoproturon	12	2,4-D	14	Cypermethrin	4
Thifensulfuron-methyl	9	Desmedipham	11	Fenamidone	3
Metribuzin	9	Thiram	6	Metiram	2
Prochloraz	8	Tetraconazole	5	Ziram	1
Fluazinam	7	Cypermethrin	4	Malathion	1
Spiroxamine	7	Thiophanate-methyl	4		
Bromoxynil	7	Propyzamide	4		
Fenpropimorph	6	Fenamidone	3		
Captan	4	Myclobutanil	3		
Metconazole	4	Lenacil	2		
Isopyrazam	3	Metiram	2		
Myclobutanil	3	Iprodione	2		
Triadimenol	3	Triflusalufuron	2		
Isoxaflutole	3	Ziram	1		
Tembotrione	2	Malathion	1		
Dimoxystrobin	2				
Iponazole	2				
Benthiavalicarb	2				
Pymetrozine	1				
Hymexazol	1				
Spirotetramat	1				
Quinoclamine	1				
Dazomet	1				

Table 12. Number of PPP authorisations that would be affected in Belgium²².

BELGIUM					
Option 1		Option 2 & 3 Category I		Option 4	
Authorisations	178	Authorisations	206	Authorisations	88
Active Substance	Occurrences per AS	Active Substance	Occurrences per AS	Active Substance	Occurrences per AS
Cymoxanil	31	Mancozeb	44	Mancozeb	44
Prothioconazole	20	2,4-D	38	Cypermethrin	16
Tebuconazole	18	Tebuconazole	18	Flubendiamide	11
Fluazinam	17	Cypermethrin	16	Pendimethalin	9
Prochloraz	10	Desmedipham	13	Tetraconazole	4
Isoproturon	9	Flubendiamide	11	Fenamidone	3
Myclobutanil	8	Propyzamide	10	Metiram	1
Metribuzin	7	Pendimethalin	9	Spirodiclofen	1
Abamectin (aka avermectin)	6	Iprodione	9		
Captan	6	Myclobutanil	8		
Thifensulfuron-methyl	6	Thiram	7		
1-Naphthylacetamide (1-NAD)	6	Boscalid (formerly nicobifen)	6		
Fenpropimorph	5	Tetraconazole	4		
Isopyrazam	4	Oxadiazon	3		
Tembotrione	4	Lenacil	3		
Spiroxamine	4	Fenamidone	3		
Profoxydim	3	Thiophanate-methyl	2		
Quinoclamine	3	Maneb	2		
Triadimenol	3	Tepraloxydim	2		
Isoxaflutole	3	Spirodiclofen	1		
Bromoxynil	3	Metiram	1		
Tepraloxydim	2				
Dimoxystrobin	2				
Maneb	2				
Hymexazol	1				
Ipconazole	1				
Benthiavalicarb	1				
Spirotetramat	1				
Pymetrozine	1				
Dazomet	1				
Cycloxydim	1				

Table 13. Number of PPP authorisations that would be affected in the Netherlands²².

NETHERLANDS					
Option 1		Option 2 & 3 Category I		Option 4	
Authorisations	112	Authorisations	101	Authorisations	48
Active Substance	Occurrences per AS	Active Substance	Occurrences per AS	Active Substance	Occurrences per AS
Cymoxanil	17	Mancozeb	29	Mancozeb	29
Tebuconazole	15	Tebuconazole	15	Pendimethalin	9
Abamectin (aka avermectin)	13	2,4-D	12	Flubendiamide	3
Fluazinam	8	Pendimethalin	9	Cypermethrin	3
Metribuzin	7	Boscalid (formerly nicobifen)	8	Spirodiclofen	2
Captan	7	Propyzamide	6	Fenamidone	2
Prochloraz	7	Iprodione	5	Metiram	1
Dazomet	6	Flubendiamide	3		
Bromoxynil	5	Cypermethrin	3		
1-Naphthylacetamide (1-NAD)	4	Maneb	3		
Pymetrozine	3	Thiram	3		
Profoxydim	3	Spirodiclofen	2		
Maneb	3	Fenamidone	2		
Thifensulfuron-methyl	2	Lenacil	1		
Metam (incl. -potassium and -sodium)	2	Metiram	1		
Isoprazam	2				
Isoproturon	2				
Tembotrione	2				
Benthiavalicarb	2				
Cycloxydim	1				
Hymexazol	1				
Spirotetramat	1				
Quinoclamine	1				

Table 14. Number of PPP authorisations that would be affected in Greece²².

GREECE					
Option 1		Option 2 & 3 Category I		Option 4	
Authorisations	195	Authorisations	258	Authorisations	151
Active Substance	Occurrences per AS	Active Substance	Occurrences per AS	Active Substance	Occurrences per AS
Tebuconazole	28	Mancozeb	77	Mancozeb	77
Cymoxanil	27	Pendimethalin	29	Pendimethalin	29
Abamectin (aka avermectin)	23	Tebuconazole	28	Cypermethrin	27
Myclobutanil	22	Cypermethrin	27	Metiram	6
Captan	18	Myclobutanil	22	Ziram	5
Metam (incl. -potassium and -sodium)	8	2,4-D	15	Fenamidone	3
Fluazinam	7	Iprodione	15	Tetraconazole	3
Bromoxynil	7	Boscalid (formerly nicobifen)	8	Flubendiamide	1
Metribuzin	7	Metiram	6	Spirodiclofen	1
1-Naphthylacetamide (1-NAD)	6	Maneb	6		
Maneb	6	Ziram	5		
Triadimenol	5	Desmedipham	4		
Prochloraz	4	Tetraconazole	3		
Thiencarbonyl-methyl	4	Thiram	3		
Profoxydim	3	Fenamidone	3		
Isoxaflutole	3	Propyzamide	3		
Prothioconazole	2	Thiophanate-methyl	2		
Tembotrione	2	Spirodiclofen	1		
Spiroxamine	2	Lenacil	1		
Hymexazol	2	Flubendiamide	1		
Benthiavalicarb	2				
Fenpropimorph	2				
Halosulfuron methyl	1				
Fenbuconazole	1				
Cycloxydim	1				
Spirotetramat	1				
Pymetrozine	1				
Dazomet	1				

3.9. Tables - Number of crops that would be affected (genus level)

Tables 15 to 22 provide information on which crops (genus level) would be affected under each option in each MS for which data was available. The EPPO database²³ can be used to see what species are represented within the genera. The order of the tables is the following:

- Table 15 Estonia
- Table 16 Germany
- Table 17 Austria
- Table 18 Slovenia
- Table 19 Czech Republic
- Table 20 Belgium
- Table 21 Netherlands
- Table 22 Greece

Table 15. Number of crops (genus level) affected in Estonia.

ESTONIA					
Option 1		Option 2 and 3 Category I		Option 4	
1BEAG	Beta	1BEAG	Beta	1SOLG	Solanum
1BRSG	Brassica	1BRSG	Brassica	1TRFG	Trifolium
1GLXG	Glycine	1FRAG	Fragaria	1TRZG	Triticum
1SOLG	Solanum	1SOLG	Solanum	1TULG	Tulipa
1TRZG	Triticum	1TRFG	Trifolium	TOTAL	4
TOTAL	5	1TRZG	Triticum		
		1TULG	Tulipa		
		TOTAL	7		

²³ <https://gd.eppo.int/>

Table 16. Number of crops (genus level) affected in Germany.

GERMANY					
Option 1		Option 2 and 3 Category I		Option 4	
1ALLG	Allium	1AATG	Actaea	1AVEG	Avena
1BEAG	Beta	1ALLG	Allium	1BRSG	Brassica
1BRSG	Brassica	1AVEG	Avena	1FRAG	Fragaria
1CUMG	Cucumis	1BEAG	Beta	1HUMG	Humulus
1FOEG	Foeniculum	1BRSG	Brassica	1SECG	Secale
1HORG	Hordeum	1CUUG	Cucurbita	1SIPG	Silphium
1HUMG	Humulus	1FOEG	Foeniculum	1SOLG	Solanum
1LACG	Lactuca	1FRAG	Fragaria	1TRZG	Triticum
1MABG	Malus	1HORG	Hordeum	1TTLG	Triticosecale
1PIBG	Pisum	1HUMG	Humulus	1VITG	Vitis
1PYUG	Pyrus	1MABG	Malus	TOTAL	10
1QUEG	Quercus	1MLSG	Melissa		
1ROSG	Rosa	1PARG	Petroselinum		
1SECG	Secale	1ROSG	Rosa		
1SOLG	Solanum	1SECG	Secale		
1SORG	Sorghum	1SIPG	Silphium		
1TRZG	Triticum	1SOLG	Solanum		
1TTLG	Triticosecale	1TRZG	Triticum		
1VITG	Vitis	1TTLG	Triticosecale		
1ZEAG	Zea	1VICG	Vicia		
TOTAL	20	1VITG	Vitis		
		1ZEAG	Zea		
		TOTAL	22		

Table 17. Number of crops (genus level) affected in Austria.

AUSTRIA					
Option 1		Option 2 and 3 Category I		Option 4	
1AGARG	Agaricus	1ALLG	Allium	1ALLG	Allium
1ALLG	Allium	1ASPG	Asparagus	1ASPG	Asparagus
1BEAG	Beta	1BEAG	Beta	1BRSG	Brassica
1BRSG	Brassica	1BRSG	Brassica	1CICG	Cichorium
1CICG	Cichorium	1CICG	Cichorium	1CPSG	Capsicum
1FRAG	Fragaria	1CPSG	Capsicum	1HORG	Hordeum
1HORG	Hordeum	1HORG	Hordeum	1MABG	Malus
1HUMG	Humulus	1HUMG	Humulus	1SOLG	Solanum
1MABG	Malus	1MABG	Malus	1TRZG	Triticum
1PAPG	Papaver	1SOLG	Solanum	1TTLG	Triticosecale
1PHSG	Phaseolus	1TRZG	Triticum	1VICG	Vicia
1SECG	Secale	1TTLG	Triticosecale	1VITG	Vitis
1SOLG	Solanum	1VICG	Vicia	1ZEAG	Zea
1TRZG	Triticum	1VITG	Vitis	TOTAL	13
1VICG	Vicia	1ZEAG	Zea		
1VITG	Vitis	TOTAL	15		
1ZEAG	Zea				
TOTAL	17				

Table 18. Number of crops (genus level) affected in Slovenia.

SLOVENIA					
Option 1		Option 2 and 3 Category I		Option 4	
1APUG	Apium	1ALLG	Allium	1APUG	Apium
1AVEG	Avena	1APUG	Apium	1BRSG	Brassica
1BRSG	Brassica	1BRSG	Brassica	1CUMG	Cucumis
1HORG	Hordeum	1CICG	Cichorium	1DAUG	Daucus
1MABG	Malus	1CUMG	Cucumis	1HORG	Hordeum
1MISG	Miscanthus	1DAUG	Daucus	1MABG	Malus
1PHSG	Phaseolus	1HORG	Hordeum	1PIBG	Pisum
1PRNG	Prunus	1MABG	Malus	1PRNG	Prunus
1PYUG	Pyrus	1PHSG	Phaseolus	1PYUG	Pyrus
1SECG	Secale	1PIBG	Pisum	1SOLG	Solanum
1SOLG	Solanum	1PRNG	Prunus	1TRZG	Triticum
1SPQG	Spinacia	1PYUG	Pyrus	1VITG	Vitis
1TRZG	Triticum	1SOLG	Solanum	1ZEAG	Zea
1TTLG	Triticosecale	1TRZG	Triticum	TOTAL	13
1VITG	Vitis	1TTLG	Triticosecale		
1ZEAG	Zea	1VITG	Vitis		
TOTAL	16	1ZEAG	Zea		
		TOTAL	17		

Table 19. Number of crops (genus level) affected in Czech Republic.

CZECH REPUBLIC					
Option 1		Option 2 and 3 Category I		Option 4	
1ANUG	Annona	1ALLG	Allium	1ALLG	Allium
1AVEG	Avena	1ARHG	Arachis	1BEAG	Beta
1BEAG	Beta	1AVEG	Avena	1BRSG	Brassica
1BRSG	Brassica	1BEAG	Beta	1CPSG	Capsicum
1CAUG	Carthamus	1BRSG	Brassica	1HORG	Hordeum
1CPSG	Capsicum	1CPSG	Capsicum	1MABG	Malus
1DAUG	Daucus	1DAUG	Daucus	1MEUG	Melilotus
1HELG	Helianthus	1HORG	Hordeum	1PHLG	Phleum
1HORG	Hordeum	1HOTG	Houttuynia	1PIUG	Pinus
1HUMG	Humulus	1LACG	Lactuca	1ROSG	Rosa
1LACG	Lactuca	1LIUG	Linum	1SECG	Secale
1MABG	Malus	1MABG	Malus	1SOLG	Solanum
1PAPG	Papaver	1MEUG	Melilotus	1TRZG	Triticum
1PRNG	Prunus	1PHLG	Phleum	1TTLG	Triticosecale
1SECG	Secale	1PIUG	Pinus	1VITG	Vitis
1SLYG	Silybum	1PRNG	Prunus	1ZEAG	Zea
1TRZG	Triticum	1ROSG	Rosa	TOTAL	16
1TTLG	Triticosecale	1SECG	Secale		
1VITG	Vitis	1SOLG	Solanum		
1ZEAG	Zea	1TRZG	Triticum		
TOTAL	20	1TTLG	Triticosecale		
		1VITG	Vitis		
		1ZEAG	Zea		
		TOTAL	23		

Table 20. Number of crops (genus level) affected in Belgium.

BELGIUM					
Option 1		Option 2 and 3 Category I		Option 4	
1AOYG	Astrocarvum	1BEAG	Beta	1CLKG	Cladium
1BEAG	Beta	1BRSG	Brassica	1PYUG	Pyrus
1BRSG	Brassica	1CLKG	Cladium	1ROSG	Rosa
1HORG	Hordeum	1IUNG	Juncus	1SOLG	Solanum
1LIUG	Linum	1PIBG	Pisum	1TRZG	Triticum
1MABG	Malus	1PRNG	Prunus	1VICG	Vicia
1PAVG	Pastinaca	1PYUG	Pyrus	1VITG	Vitis
1PIBG	Pisum	1RHEG	Rheum	1VLLG	Valerianella
1PYUG	Pyrus	1ROSG	Rosa	1ZEAG	Zea
1ROSG	Rosa	1SCVG	Scorzonera	TOTAL	9
1SOLG	Solanum	1SOLG	Solanum		
1TRZG	Triticum	1SPQG	Spinacia		
1VITG	Vitis	1TRZG	Triticum		
1VLLG	Valerianella	1VALG	Valeriana		
1ZEAG	Zea	1VICG	Vicia		
TOTAL	15	1VITG	Vitis		
		1VLLG	Valerianella		
		1ZEAG	Zea		
		TOTAL	18		

Table 21. Number of crops (genus level) affected in the Netherlands.

THE NETHERLANDS					
Option 1		Option 2 and 3 Category I		Option 4	
1ALLG	Allium	1AAOG	Aconitum	1AAOG	Aconitum
1AMYG	Amaryllis	1ABGG	Arum	1ABGG	Arum
1ANHG	Ananas	1ALLG	Allium	1ALLG	Allium
1ANMG	Anemone	1ANRG	Anthriscus	1APUG	Apium
1AODG	Anisodonteia	1ANUG	Annona	1ASPG	Asparagus
1ASPG	Asparagus	1AOYG	Astrocaryum	1BRSG	Brassica
1ASTG	Aster	1APUG	Apium	1CEAG	Ceanothus
1AVEG	Avena	1ARWG	Armoracia	1CHYG	Chrysanthemum
1BEAG	Beta	1ASPG	Asparagus	1CICG	Cichorium
1BELG	Bellis	1AVEG	Avena	1CPSG	Capsicum
1BOUG	Bougainvillea	1BEAG	Beta	1CUMG	Cucumis
1BRSG	Brassica	1BRSG	Brassica	1CUUG	Cucurbita
1CEMG	Cestrum	1CEAG	Ceanothus	1CVBG	Cupressus
1CEOG	Celosia	1CHYG	Chrysanthemum	1DAUG	Daucus
1CHYG	Chrysanthemum	1CICG	Cichorium	1ECHG	Echinochloa
1CICG	Cichorium	1CIEG	Cicer	1ERUG	Eruca
1CING	Cinnamomum	1CITG	Citrullus	1ESAG	Escallonia
1CITG	Citrullus	1CPSG	Capsicum	1FESG	Festuca
1CLDG	Calendula	1CRYG	Carum	1FOEG	Foeniculum
1CLVG	Clematis	1CUMG	Cucumis	1FRAG	Fragaria
1CMUG	Calophyllum	1CUNG	Calluna	1HECG	Helichrysum
1CNKG	Convallaria	1CUUG	Cucurbita	1HSTG	Hosta
1CPSG	Capsicum	1CVBG	Cupressus	1IRIG	Iris
1CUMG	Cucumis	1DAUG	Daucus	1IRISG	Iris
1CUNG	Calluna	1DING	Dianthus	1LACG	Lactuca
1CUUG	Cucurbita	1ECHG	Echinochloa	1LGNG	Lagenaria
1CVOG	Crocus	1ERUG	Eruca	1LILG	Lilium
1DAHG	Dahlia	1ESAG	Escallonia	1LOLG	Lolium
1DAUG	Daucus	1EUOG	Euonymus	1LUPG	Lupinus
1DING	Dianthus	1FESG	Festuca	1MABG	Malus
1DORG	Doronicum	1FOEG	Foeniculum	1OEOG	Oenothera
1EYOG	Euryops	1FRAG	Fragaria	1PAOG	Paeonia
1FATG	Fatsia	1GLAG	Gladiolus	1PAVG	Pastinaca
1FESG	Festuca	1HECG	Helichrysum	1PHSG	Phaseolus
1FRAG	Fragaria	1HELG	Helianthus	1PIBG	Pisum
1GADG	Gardenia	1HORG	Hordeum	1PIPG	Piper
1GEBG	Gerbera	1HSTG	Hosta	1POAG	Poa
1GLAG	Gladiolus	1HUMG	Humulus	1PYUG	Pyrus
1GLXG	Glycine	1HYAG	Hyacinthus	1RBIG	Rubia
1HEEG	Hedera	1IRIG	Iris	1RHEG	Rheum
1HELG	Helianthus	1IRISG	Iris	1RHOG	Rhododendron
1HEOG	Heliotropium	1LACG	Lactuca	1ROSG	Rosa
1HORG	Hordeum	1LGNG	Lagenaria	1SCVG	Scorzonera
1HYAG	Hyacinthus	1LILG	Lilium	1SJNG	Senna
1HYEG	Hydrangea	1LIUG	Linum	1SOLG	Solanum
1IRIG	Iris	1LOLG	Lolium	1TRZG	Triticum
1IRISG	Iris	1LUPG	Lupinus	1TTLG	Triticosecale
1KANG	Kalanchoe	1MABG	Malus	1TULG	Tulipa
1LACG	Lactuca	1MEDG	Medicago	1VIBG	Viburnum
1LANG	Lantana	1MUAG	Mauritia	1VICG	Vicia
1LAVG	Lavandula	1OEOG	Oenothera	1VITG	Vitis

THE NETHERLANDS					
Option 1		Option 2 and 3 Category I		Option 4	
1LILG	Lilium	1OLVG	Olea	1XCHG	Xerochrysum
1LIUG	Linum	1PAOG	Paeonia	1ZEAG	Zea
1LOLG	Lolium	1PARG	Petroselinum	TOTAL	53
1MABG	Malus	1PAVG	Pastinaca		
1MUAG	Mauritia	1PHSG	Phaseolus		
1NARG	Narcissus	1PIBG	Pisum		
1NRIG	Nerine	1PIPG	Piper		
1OLVG	Olea	1POAG	Poa		
1OSPG	Osteospermum	1POPG	Populus		
1PARG	Petroselinum	1PRNG	Prunus		
1PELG	Pelargonium	1PYUG	Pyrus		
1PEUG	Petunia	1RAPG	Raphanus		
1PHSG	Phaseolus	1RBIG	Rubia		
1PIBG	Pisum	1RHEG	Rheum		
1PIPG	Piper	1RHOG	Rhododendron		
1POPG	Populus	1RIBG	Ribes		
1PRIG	Primula	1ROSG	Rosa		
1PRNG	Prunus	1RUBG	Rubus		
1PYUG	Pyrus	1SCVG	Scorzonera		
1RANG	Ranunculus	1SECG	Secale		
1RAPG	Raphanus	1SING	Sinapis		
1RHOG	Rhododendron	1SJNG	Senna		
1RIBG	Ribes	1SOLG	Solanum		
1ROSG	Rosa	1SPQG	Spinacia		
1RUBG	Rubus	1TOPG	Tropaeolum		
1SALG	Salvia	1TRFG	Trifolium		
1SCVG	Scorzonera	1TRZG	Triticum		
1SECG	Secale	1TTHG	Trichosanthes		
1SENG	Senecio	1TTLG	Triticosecale		
1SING	Sinapis	1TULG	Tulipa		
1SJNG	Senna	1VACG	Vaccinium		
1SOLG	Solanum	1VALG	Valeriana		
1SPQG	Spinacia	1VIBG	Viburnum		
1SQFG	Spathiphyllum	1VICG	Vicia		
1TNCG	Tanacetum	1VIGG	Vigna		
1TOPG	Tropaeolum	1VISG	Viscum		
1TRZG	Triticum	1VITG	Vitis		
1TTLG	Triticosecale	1XCHG	Xerochrysum		
1TULG	Tulipa	1ZEAG	Zea		
1VACG	Vaccinium	1ZIPG	Ziziphus		
1VICG	Vicia	TOTAL	91		
1VIGG	Vigna				
1VIOG	Viola				
1VITG	Vitis				
1ZEAG	Zea				
TOTAL	96				

Table 22. Number of crops (genus level) affected in Greece.

GREECE					
Option 1		Option 2 and 3 Category I		Option 4	
1AFEG	Anethum	1ABMG	Abelmoschus	1ABMG	Abelmoschus
1ALLG	Allium	1AFEG	Anethum	1AFEG	Anethum
1APUG	Apium	1ALLG	Allium	1ALLG	Allium
1ARHG	Arachis	1APUG	Apium	1APUG	Apium
1ARTG	Artemisia	1ARHG	Arachis	1ARHG	Arachis
1ASPG	Asparagus	1ASPG	Asparagus	1ASPG	Asparagus
1AVEG	Avena	1ATIG	Actinidia	1AVEG	Avena
1BARG	Barbarea	1AVEG	Avena	1BEAG	Beta
1BEAG	Beta	1BEAG	Beta	1BRSG	Brassica
1BRSG	Brassica	1BRSG	Brassica	1CICG	Cichorium
1CICG	Cichorium	1CICG	Cichorium	1CIDG	Citrus
1CIDG	Citrus	1CIDG	Citrus	1CIEG	Cicer
1CITG	Citrullus	1CIEG	Cicer	1CITG	Citrullus
1CNSG	Consolida	1CITG	Citrullus	1CORG	Coriandrum
1CPSG	Capsicum	1CORG	Coriandrum	1CPSG	Capsicum
1CUMG	Cucumis	1CPSG	Capsicum	1CUMG	Cucumis
1CUUG	Cucurbita	1CSNG	Castanea	1CUUG	Cucurbita
1CYDG	Cydonia	1CUMG	Cucumis	1CYLG	Corylus
1CYLG	Corylus	1CUUG	Cucurbita	1CYUG	Cynara
1CYUG	Cynara	1CYDG	Cydonia	1DAUG	Daucus
1DAUG	Daucus	1CYLG	Corylus	1FOEG	Foeniculum
1DING	Dianthus	1CYUG	Cynara	1FRAG	Fragaria
1EIOG	Eriobotrya	1DAUG	Daucus	1GLXG	Glycine
1FRAG	Fragaria	1DING	Dianthus	1GOSG	Gossypium
1GLXG	Glycine	1EIOG	Eriobotrya	1HELG	Helianthus
1GOSG	Gossypium	1FOEG	Foeniculum	1HORG	Hordeum
1HORG	Hordeum	1FRAG	Fragaria	1IUGG	Juglans
1IUGG	Juglans	1GLXG	Glycine	1LACG	Lactuca
1LACG	Lactuca	1GOSG	Gossypium	1LENG	Lens
1LEPG	Lepidium	1HELG	Helianthus	1LTHG	Lathyrus
1MABG	Malus	1HORG	Hordeum	1MABG	Malus
1NIOG	Nicotiana	1IUGG	Juglans	1NIOG	Nicotiana
1OLVG	Olea	1LACG	Lactuca	1PARG	Petroselinum
1ORYG	Oryza	1LENG	Lens	1PHSG	Phaseolus
1PHSG	Phaseolus	1LTHG	Lathyrus	1PIBG	Pisum
1PIBG	Pisum	1MABG	Malus	1PRNG	Prunus
1PRNG	Prunus	1NIOG	Nicotiana	1PYUG	Pyrus
1PYUG	Pyrus	1OLVG	Olea	1RAPG	Raphanus
1RUBG	Rubus	1PARG	Petroselinum	1SECG	Secale
1SECG	Secale	1PHSG	Phaseolus	1SOLG	Solanum
1SOLG	Solanum	1PIAG	Pistacia	1SORG	Sorghum
1TRZG	Triticum	1PIBG	Pisum	1SPQG	Spinacia
1TTLG	Triticosecale	1PRNG	Prunus	1TRZG	Triticum
1VACG	Vaccinium	1PYUG	Pyrus	1TTLG	Triticosecale
1VITG	Vitis	1RAPG	Raphanus	1VICG	Vicia
1VLLG	Valerianella	1SECG	Secale	1VITG	Vitis
1ZEAG	Zea	1SOLG	Solanum	1ZEAG	Zea
TOTAL	47	1SORG	Sorghum	TOTAL	47
		1SPQG	Spinacia		
		1TRZG	Triticum		
		1TTLG	Triticosecale		
		1VICG	Vicia		
		1VITG	Vitis		
		1VLLG	Valerianella		
		1ZEAG	Zea		

GREECE		
Option 1	Option 2 and 3 Category I	Option 4
	TOTAL	55

ANNEX 13

SECTORIAL COMPETITIVENESS: EU AGRICULTURE

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This Annex complements Annex 12 and contains data on the sales of pesticides compiled under Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides. The article 3.4 of this regulation states that the Commission (Eurostat) must aggregate the data before publication, taking due account of the protection of confidential data at the level of individual Member States. The confidential data can be used by the Commission (Eurostat) exclusively for statistical purposes. Therefore, this data cannot be published in this impact assessment report.

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 prejudice 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.