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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

Annex 15 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 15

FOOD SUPPLY AND INTERNATIONAL TRADE

Contents

1. INTRODUCTION	350
2. CONSEQUENCES OF ED CRITERIA ON FOOD SECURITY AND INTERNATIONAL TRADE	351
3. EVIDENCE AVAILABLE AND DATA USED	352
4. METHODOLOGY	354
5. RESULTS OF THE ANALYSIS	360
6. PERFORMANCE OF THE OPTIONS	367
7. CASE STUDIES - IMPACT ON THIRD COUNTRIES	368
7.1. Case Study I - Bananas	369
7.2. Case Study II – Wine	372
7.3. Case Study III - Rapeseed	374
7.4. Case Study IV - Citrus fruit	375

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.

1. INTRODUCTION

Trade is essential to economic growth and job creation in the European Union (EU) and covers exports and increasingly also imports. Two-thirds of EU imports are raw materials, intermediary goods and components needed for companies' production processes. The share of foreign imports in the EU's exports has increased by more than half since 1995, to reach 13%.¹

Food, feed, and treated articles are the three commodity groups used to analyse the impacts of the different options in this impact assessment (IA), and were the basis for MCA-criteria. With these three groups, many products imported to the EU are covered. These three groups are essential for food security, as well as for wellbeing and health. The three categories are also important to a range of trading partners. While feed are mainly imported from the Americas, and food mainly imported from the Americas, Africa and Oceania, treated articles, and especially textiles are heavily concentrated in Asia. The commodities falling under the different groups considered in this IA are briefly described below:

- **Food;** fresh, frozen and dried crops. Processed food and products are, with the exception of wine, not considered in this analysis because the residue monitoring is linked to a higher complexity including several ingredients and origins in one product, as well as processing factors.
- **Feed;** fresh and dried crops. Milled products, such as soya meal, are considered to be impacted to the same extent as the unprocessed products.
- **Treated articles;** a substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products². The article can be a solid object, for instance a bathroom mat that gets an additional value by the treatment of an antibacterial substance.

In 2014, the EU imported agricultural commodities to a value of EUR 105 billion. Agriculture accounts for 6% of total imports from third countries to the EU both in terms of value and volume. Imported crops, especially from tropical countries, constitute a major part of the European diet. Coffee, tea, and bananas are three commodities most Europeans would consider essential to their diet but where Europe would not be able to meet demand without imports. The main trading partners for agricultural commodities, including animals and fish are United States, Brazil, Norway³ and China.

¹ Import into the EU. DG Trade. <http://ec.europa.eu/trade/import-and-export-rules/import-into-eu/>

² See Article 3(1)(l) of BP Regulation (EU) 528/2012.

³ Norway is the largest exporter of animal products to the EU-28, supplying 22 % of the total in 2013. 98 % of the animal products imported from Norway fell under the fish chapter, and represented EUR 4.5 billion.

Source: Extra-EU trade in agricultural goods. Retrieved from: http://ec.europa.eu/eurostat/statistics-explained/index.php/Extra-EU_trade_in_agricultural_goods

Table 1. EU trade in 2014 with countries outside the EU-28.

EU TRADE IN 2014 WITH COUNTRIES OUTSIDE THE EU-28 ⁴		
Commodity	Value in billion EUR	Quantity y in thousand tonnes
Agriculture and food imports	106	99,088
as share of total	6%	6%
TOTAL IMPORTS	1,689	1,635,311

This Annex is outlined as follows. In the next section, the consequences of endocrine disruptor (ED) criteria on food security and international trade are lined out. Then the various data and information sources that have been used in the analysis of the case studies are listed, followed by the definition of each indicator /MCA criterion. In the methodology, it is explained how the IA was carried out, followed by the results and analysis for food, feed, and treated articles respectively. Last, the impacts on third countries' economies are assessed and discussed with case studies for bananas, wine, rapeseed, and citrus fruits.

2. CONSEQUENCES OF ED CRITERIA ON FOOD SECURITY AND INTERNATIONAL TRADE

The bottom line of EU regulation is that countries exporting to EU should meet the safety standards of the EU when producing food to be exported to the EU.

Regarding food and feed (agricultural commodities and processed products), when an active substance used as a PPP is non-approved for use within the EU, it will in extension have an impact on third countries and crops imported to the EU. The impact is due to the lowering of Maximum Residue Levels (MRL) to the limit of determination (LOD), as a consequence of implementation of point 3.6.5 of Annex II of Regulation (EC) No 1107/2009 and in compliance with Regulation (EC) No 396/2005.

What it means in practice for a MRL to be lowered to LOD is that in most cases it cannot be used in the production process of the crop to either fight pests or control diseases. Producers would therefore have to find substitutes or seek alternative practices to grow their crops if they still aim at exporting their products to the EU.

The main problems with losing part of the pesticide portfolio are:

- i. increased risk of crop losses due to pests and diseases where there is no effective plant protection product available;
- ii. increased risk of pests developing resistance to plant protection products due to reduced number of alternatives;
- iii. increased risk of occurrence of mycotoxins in food and feed. These problems are more extensively discussed in Annex 12 on impacts of agriculture and Annex 10 on Human Health (Transmissible diseases and food safety).

⁴ All import data and tables in this annex are extracted from Eurostat considering imports to EU-28 during Jan-Dec 2014, from countries outside the EU. Intra-EU trade is not assessed or analysed.

The consequences for trade and food security in the EU may be:

- smaller quantities of crops and products on the EU market, consequently sold to higher prices;
- food products of inferior quality compared to the quality of fruits and vegetables available on the market today;
- less feed available for animal production within the EU – resulting in feed of less quality and consequently this impacts the entire value chain of animal production.

Regarding treated articles, the BP Regulation foresees that a treated article shall not be placed on the EU market unless all active substances contained in the biocidal products that it was treated with or incorporates are approved. This is expecting to have consequences also on products produced outside the EU and imported.

In the **public consultation** in 2015 (see Annex 2), six public authorities and six governments from non-EU countries gave their comments. One of the main issues authorities from non-EU countries stressed was the potential impact on trade⁵. Countries and crops that may be affected are e.g. wine from Chile, bananas from Latin America, imports for feed such as soybeans, as well as citrus fruit from South Africa, just to name a few.

Further, the topic of ED criteria has raised **increasing attention in the WTO TBT and SPS Committees** during the last years. The issue was raised by the US for the first time in October 2013 and in March 2014 respectively. Since then it has been discussed, in one form or another, at every TBT and SPS Committee meeting. Overall, it is clear that the pressure on the EU is mounting as demonstrated by the growing number of WTO Members taking the floor to express concerns or to question the EU's ongoing work on defining the criteria to identify EDs. Please refer to Annex 8 for more details.

3. EVIDENCE AVAILABLE AND DATA USED

The results of the screening study, identifying which active substances of PPP and BP would be identified under each of the four options, are considered as a basis for the analysis. This information is then combined with the datasets and information sources described below in order to execute the analysis of the impact on trade. Therefore, the analysis underlying this Annex is considered as set of case studies which is based on the identity of substances identified under each option, and the MRLs which would be consequently lowered for a number of imported crops. For BPs, textiles have been selected as case study in order to illustrate potential impacts.

⁵Report on Public consultation on defining criteria for identifying endocrine disruptors in the context of the implementation of the PPP Regulation and BP Regulation. Retrieved from:

http://ec.europa.eu/health/endocrine_disruptors/docs/2015_public_consultation_report_en.pdf

EU Pesticide Database

The EU Pesticide Database⁶ has been used to obtain both the MRLs as well as information on active substances. MRL levels are extracted on an active substance and crop basis. A MRL marked with an asterisk (*) in the database signals that this is the LOD for that crop and active substance. For each active substance there is also a lot of other information listed in the database such as pesticide characteristics, and which sub-group of pesticide an active substance belong to (e.g. herbicide, fungicide, or insecticide).

Eurostat international trade data

The trade data is from Eurostat, COMEXT databases.^{7,8} Imported goods are classified according to the Combined Nomenclature⁹ (CN) and have to be declared stating under which subheading of the nomenclature they fall. For this IA it was necessary to use up to 6-digits of the CN Code, therefore, to match the trade data with the data on MRLs and crops, both the "EU trade since 1995 by HS6" as well as "EU trade since 1988 by HS2-HS4" were used depending on how refined the crop groups were for trade.

Report and list on candidates for substitution

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 R1¹⁰ were flagged and not considered for the impacts on trade in this IA.

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.

For active substances used in BP, it was analysed whether the identified substances as potential ED in the screening would fall under any of the exclusion criteria¹¹ and for which product types the identified substances were approved.

⁶ EU Pesticide Database (2016). Retrieved from: <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>

⁷ Eurostat (2015a) EU trade since 1995 by HS6 (DS-016893)

⁸ Eurostat (2015b) EU trade since 1988 by HS2-HS4 (DS-016894)

⁹ Explanatory notes to the combined nomenclature of the European Union. (2015/C 076/01) Publication made in accordance with Article 9(1) of Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff. Retrieved from: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2015:076:FULL&from=EN>

¹⁰ C1 is a known or presumed human carcinogen, and R1 is a known or presumed human reproductive toxicant, according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

¹¹ Article 5 of the BP Regulation (EU) 528/2012.

The 2013 European Union report on pesticide residues in food

The European Food Safety Authority (EFSA) report "The 2013 European Union report on pesticide residues in food"¹² was used to get an overview of the current state of MRL compliance with legal limits for imports as well as actual consumer exposure to pesticides for European consumers. The report was used to screen if there were any relevant substances or crops that could be used as case studies, however, none were identified and the selection of case studies was done based on the value of imports and how important the crop or product is for third countries.

4. METHODOLOGY

The purpose of the analysis is to describe potential impacts on trade and to rank the options of each aspect in the multi criteria analysis, in which the following criteria have been defined to assess how the options perform:

- i. Potential impact on imports of agricultural commodities for food related to the lowering of the MRL level to the default value for substances identified as ED. No import tolerances are applied. The analysis considered different regions, e.g. Africa, Asia, US, Latin America, and particular goods; wine, cereal, depending on volume or trade impact.
- ii. Potential impact on imports of agricultural commodities for feed related to the lowering of the MRL level to the default value for substances identified as ED. The analysis will focus on the main agricultural commodities imported as feed, e.g. soya.
- iii. Potential impact on imports of treated articles (biocides). The supply chains for the manufacturing of articles are very complex. It is very difficult to estimate the impacts of a non-approval of a certain biocidal substance of the market (see also Annex 14). Textiles have been used as case study to evaluate of potential impacts.

General Assumptions

The LOD is the lowest amount or concentration of analyte in a sample that can be reliably quantified with an acceptable level of precision and accuracy, and this level can differ between substances. If an active substance has a MRL higher than the LOD for a certain crop in the MRL-database, it was assumed that the substance is needed and consequently used in practice. This assumption is made because it is costly to seek approval for an import tolerance and if it is not used on a specific crop there would be no need to seek approval for it.

However, a recent paper¹³ analysing the impact of MRLs on trade came to the conclusion that the impacts from lowering MRLs are ambiguous. The authors note that the net impact of MRLs is positive on high-income OECD members' imports of plant products, which

¹² European Food Safety Authority (2015). *The 2013 European Union report on pesticide residues in food*. EFSA Journal 2015;13(3):4038, 169 pp. doi:10.2903/j.efsa.2015.4038

¹³ Xiong, B., and Beghin, J., 2014. Disentangling demand-enhancing and trade-cost effects of maximum residue regulations. *Economic Inquiry*. Vol. 52, No. 3, 1190–1203. doi:10.1111/ecin.12082

invalidates the conventional wisdom that stringent food safety will impede trade. However, the impact on least developed countries is more severe due to their lack of financial and technological resources to comply with the MRLs adopted in the high-income OECD countries. The results in this IA are expected to follow the same line with developing countries being more severely impacted than developed countries. However, the effect will be the same over all options and would not contribute to the ranking of the options for the multi-criteria analysis.

There are multiple ways producers and third countries can react to the lowering of MRLs in EU. Expected responses could be; some producers will continue growing the same crop but try to swap to alternative approved substances that fight against the same pests; other producers may continue with their old practice but their produce may be exported to another part of the world or sold domestically; and others will discontinue with the crop they used to export to the EU and instead grow crops that is possible to produce with pesticides that are approved within the EU. This assessment will not delve deeper into the possible responses for each crop and country, instead, the focus is on the total value and volume of crops imported to the EU, and the share of crops in relation to the third country's total exports to the EU. Quantifying the precise welfare loss and socio-economic costs is not attempted and beyond the scope of this IA. However, the negative effects on trade are recognised.

The assessment will rank for PPP the four options against each other based on the number of MRLs lowered for the most valuable crops imported to the EU. It is assumed there will be no import tolerances.

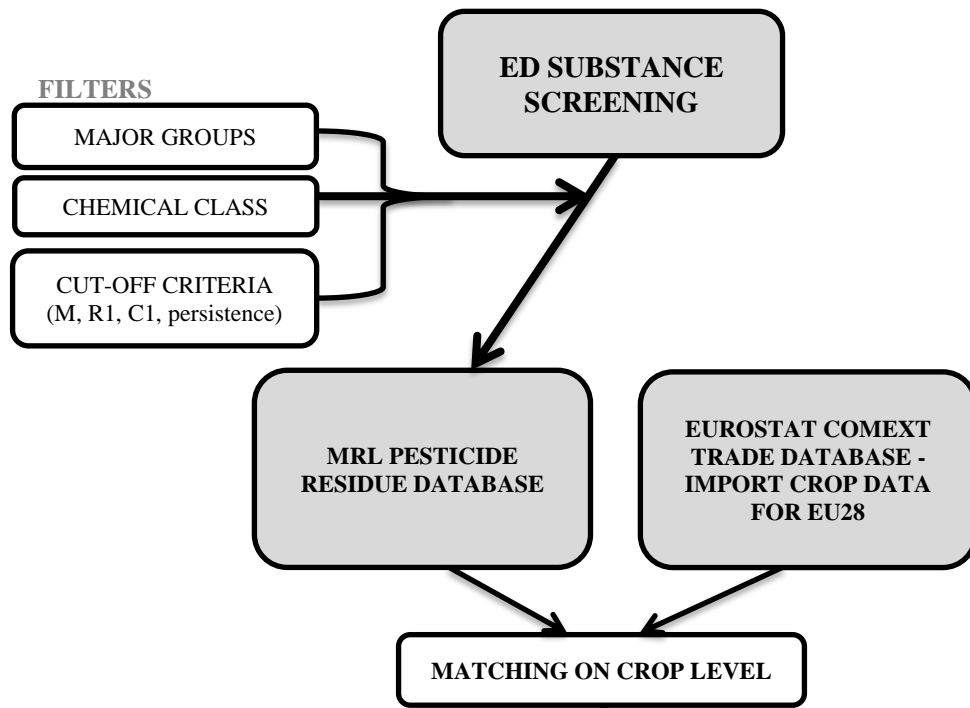
For BP it is assumed that the non-approval of active substances or the approval under strict conditions would probably not initiate replacement of these substances (see Annex 14). Therefore less approved BP substances are expected to be available for treated articles. The impact on trade can be assessed by assuming that the option having the least number of chemicals identified performing relatively the best.

Data extraction and organisation

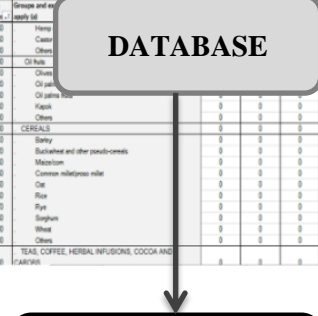
A database was built in order to identify the number of MRLs lowered for each imported crop under the different options. The first step was to combine trade data retrieved from Eurostat with the MRL Pesticide database for each active substance. The data extraction from both Eurostat and the Pesticide database was done in December 2015. The matching was done by identifying which crop or crop group in the trade data best corresponded with the crops in the MRL database. In most cases the matching was straightforward; however, some crops were divided into several categories (such as dried/fresh/frozen) in the trade data while this distinction was not made for the MRLs. In those cases the values of imports were added together for all subcategories of the crop, (e.g., this was the case for apples, CN Code 080810 and 081330). Another issue when matching the two datasets was not only that the trade data was further refined in some cases, in other cases the trade data was coarser in comparison with the crop specific data on MRLs. For trade, several crops were grouped together in the

same category (e.g., cauliflower and head broccoli, CN Code 07041000). In those instances care was taken to e.g., avoid double counting for sums.

To be able to refine the analysis of the impacts on trade, characteristics about the substances were collected from various sources and then added to the database. E.g., what type of pesticide an active substance is, if the substance is a Candidate for Substitution, the chemical class, if the substance would also fall under the cut-off criteria (classified as C1 or R1) in Reg 1107/2009 and hence non-approved regardless the criteria for EDs. The data sources and matching process is depicted in Figure 1. Flow chart describing the steps in which the data was organised



	A	B	AV	AUV	AX	AVY	AZ	BA	BC	BD	BX	CC	CH	CH	CO	CP	
Substance			Metabolic	Mycobacta	Quinolone	Penicillin	Polychlor	Polysulfon	Propylam	Prothioconazole	Prothioconazole	Option 1, ALL	Option 2, ALL	Option 4, ALL	Product (CN Code for trade)	Import 2014, Value in EURO	Import 2014 Quantity in 1000G
Option 1 (In/Ya)			1	1	1	1	1	1	1	1	42						
Option 2 (In/Ya)												26					
Option 4 (In/Ya)													11				
Type of pesticide			HB	FU	HB	HB	FU	HB	HB	FU	IN						
Chemical class			TRIAZOLOPYRIDAZINONE	COMBINATION	IMIDAZOPYRIDAZINONE	IMIDAZOPYRIDAZINONE	IMIDAZOPYRIDAZINONE	IMIDAZOPYRIDAZINONE	IMIDAZOPYRIDAZINONE	IMIDAZOPYRIDAZINONE	IMIDAZOPYRIDAZINONE	IMIDAZOPYRIDAZINONE	IMIDAZOPYRIDAZINONE	IMIDAZOPYRIDAZINONE			
Chemical class, NEW CODE			HB_01_01	FA_01_14	HB_01_06	HB_01_02	FB_02_03	HB_01_01	HB_01_07	FA_01_17	HB_13_01						
Genotoxic fungicide (N in the group in total)			1							1							
Code number																	
Group and ex-plant list																	
240	900140	Help								1	0	4	1	0	Help seed	€ 10,911,632	103,299
241	900150	Caster								1	0	4	1	0	Caster seed		
242	900160	Others								1	0	4	1	0	Others for oil production	€ 22,843	113
243	900200	Oil fruits								1	0	0	0	0	Oil fruits	€ 57,425	279
244	900210	Olives								1	0	4	2	0	Olives for oil production	€ 22,843	113
245	900220	Oil palm fruit								1	0	1	0	0			
246	900230	Others								1	0	1	0	0			
247	900240	Kaoli								1	0	1	0	0			
248	900250	Others								1	0	1	0	0			
249	900300	CEREALS								1	0	1	0	0			
250	900310	Barley								1	0	19	9	4	Barley	€ 34,393	189
251	900320	Buckwheat and other pseudo-cereals								1	0	1	3	2	Buckwheat, millet, canary seed and other cereals	€ 14,342,933	742,838
252	900330	Milletium								1	0	4	7	4	Millet	€ 148,296,912	1,006,545
253	900340	Corn and other milium								1	0	2	3	2	Maize or corn	€ 2,858,978,917	142,119,145
254	900350	Oat								1	0	12	9	4	Oats	€ 3,343,889	34,177
255	900360	Rye								1	0	14	9	4	Rye	€ 1,658,739,379	16,426,894
256	900370	Pye								1	0	14	9	4	Pye	€ 14,862,332	1,004,693
257	900380	Sorghum								1	0	2	3	2	Grain Sorghum	€ 31,184,644	1,688,788
258	900390	Wheat								1	0	14	9	4	Wheat and meslin	€ 1,254,028,399	90,489,896
259	900399	Others								1	0	1	3	2			
260	900400	TEA, COFFEE, HERBAL INFUSIONS, COCOA AND FRAGRANCES								1	0	1	3	2			



	A	C	D	E	F	K	L	M	N	O	P	Q
	PARTNER/PRODUCT	Region	LDC	TOTAL	TOTAL	BANANAS	BANANAS	BANANAS	MAIZE OR CORN	MAIZE OR CORN	MAIZE OR CORN	WINE OF FREE GROUPES
				VALUE_IN_EUROS	QTY_1000G	VALUE_IN_EUROS	QTY_1000G	SHARE	QTY_1000G	VALUE_IN_EUROS	SHARE	VALUE_IN_EU
3	EXTRA - EU28, EXTRA			€ 41,688,728,363,334	16,351,819,163	€ 3,053,442,028	50,436,963	0%	€ 2,687,141,844	142,745,140	0%	€ 2,454,230
4	LATIN AMERICA			€ 94,134,235,127	1,977,693,532	€ 2,389,899,935	40,384,381	3%	€ 277,194,384	19,546,342	0%	€ 777,899
5	ECUADOR						14,767,219	31%				€ 1
6	COLOMBIA						10,362,697	9%		459	3%	€ 1
7	COSTA RICA						9,491,796	16%		169	0%	€ 1
8	AFRICA						5,578,496	0%	€ 37,389,420	1,255,041	0%	€ 394,517
9	DOMINICAN REPUBLIC						4,521,848	0%	€ 16,118	263	0%	€ 224
10	DOMINICAN REPUBLIC						3,420,160	31%	€ 77	2	0%	€ 1
11	CAMEROON						2,571,776	9%		4	0%	€ 25
12	COTE D'IVOIRE						2,507,667	5%				€ 1
13	PANAMA (incl. CANAL -1929)	Central America		€ 426,111,924	8,994,530	€ 140,119,281	10,362,697	32%	€ 2,248,794		0%	€ 394
14	BELEZE	Caribbean		€ 121,057,145	2,215,392	€ 56,200,641	1,007,070	46%			0%	
15	PERU	Latin America		€ 4,660,768,499	35,948,739	€ 85,892,379	968,510	1%	€ 7,660,337	48,638	0%	€ 148
16	SURINAME (ex DUTCH GUIANA)	Latin America		€ 289,473,115	5,270,525	€ 38,897,627	725,529	15%			0%	€ 14
17	MEXICO	Latin America		€ 17,660,911,913	145,460,163	€ 31,049,983	797,285	0%	€ 1,177,842	1,108	0%	€ 424
18	SHARIA	Africa		€ 2,894,925,996	31,257,469	€ 30,193,147	494,292	1%			0%	€ 5
19	GUATEMALA	Latin America		€ 691,499,799	7,263,605	€ 15,518,442	291,669	2%	€ 875	1	0%	€ 1
20	BRAZIL	Latin America		€ 30,696,278,693	889,179,432	€ 16,220,182	286,607	0%	€ 121,682,399	7,376,316	0%	€ 4,448
21	ST LUCIA	Caribbean		€ 9,743,462	126,225	€ 5,675,847	88,805	67%			0%	
22	HONDURAS	Latin America		€ 841,251,771	5,927,959	€ 2,084,394	44,954	0%			0%	€ 22
23	ASIA			€ 629,783,332,148	1,977,238,945	€ 1,235,165	5,780	0%	€ 1,638,568	25,316	0%	€ 10,748
24	DOMINICA	Caribbean		€ 1,158,338	1,468,734	€ 369,113	5,382	0%			0%	
25	UGANDA	Africa	1	€ 452,842,256	1,969,505	€ 969,476	4,854	0%	€ 432	2	0%	
26	EUROPE			€ 457,386,962,452	7,140,144,941	€ 206,135	4,458	0%	€ 1,871,680,835	196,388,834	0%	€ 109,492
27	TURKEY	Europe		€ 54,294,899,438	248,177,147	€ 190,842	4,241	0%	€ 22,080,555	168,920	0%	€ 3,782

Figure 1. Flow chart describing the steps in which the data was organised. Data extracted in December 2015.

Analysis of the evidence

To determine how the options rank against each other and their respective impact on trade of food and feed the following rationale was followed for PPP.

- The more MRLs that are lowered for a certain crop, the greater the negative impact. I.e. 10 MRLs are lowered for Bananas under Option 1, 8 MRLs under Option 2 and 3 Category I, and 3 MRLs under Option 4. Thus, Option 4 performs better than Option 2 and 3, which in turn performs better than Option 1.
- The higher value and volume of imports that is expected to be affected, the worse the option performs.
- The higher the number of active substances from the same group of pesticides affected, the worse the option performs, i.e. if 80% of all the fungicides within a subgroup of fungicides are potentially affected, then the impacts are expected to be more severe since there are fewer substitutes available for a specific pest.

The first step in the **analysis for food** was to prioritise the analysis for the most imported commodities in terms of value. Trade is often measured in terms of volume not value, however, in this IA the value of crops was found to be a more relevant unit of comparison rather than volume because such diverse crops as wheat and bananas had to be compared against e.g., spices and nuts. The cut off for the above prioritisation was set at EUR 1 billion for the year 2014.¹⁴ The most imported commodities are in descending order; coffee, nuts, cocoa beans, bananas, maize, wine, citrus fruit, wheat, table grapes, rape seed, and rice.

All commodities except for nuts and citrus fruit are measured individually. For nuts and citrus fruit, the decision to analyse them together is because the active substances that are affected are the same under the four options. Both nuts and citrus are two important crop groups for the European diet. Wine is included in the analysis although it is a product rather than a crop. The reasoning behind is that MRLs are differentiated and set specifically for wine grapes, however the imported product are not wine-grapes but wine, where the corresponding MRL corrected by a processing factor apply. Wine is also an important commodity for the EU as well as an important traded product internationally. Soyabeans are used both as food for humans and feed for animals, with the bulk of imports being used as animal feed. In this IA, soyabeans are assessed in the chapter for feed rather than food.

The second step of the analysis was to see which crops would be most affected in terms of the number of MRLs lowered, irrespective of value of the imports. This gives the absolute number of MRLs affected per crop for each option. Then it can be assessed which group of pesticides will be impacted the most. The four options were then ranked from best performing to worst in terms of the number of MRLs that would be lowered. The greater the number of MRLs affected, the greater the impact on trade, see Section 5.

The **analysis of feed** focusses on the four most important feed products; soyabeans, maize, rapeseed, and cottonseed. The ranking of the four options have been done in the same way as

¹⁴ The cut off EUR 1 billion was chosen in order to include the most valuable food crops imported to the EU in the analysis.

for food with the option having the least number of MRLs lowered performing the best. The main source of information on the value of the feed market and potential impact on feed is taken from the report *Statistics on agricultural markets 2014* by DG AGRI.

To complement the quantitative analysis, a more qualitative analysis of the most valued imported crops is carried out and presented as **case studies**. EU import data was used to see which continents, regions and countries were most affected. Since EU has a developmental policy objective it is relevant to see if Least Developed Countries, as well as EU main trading partners were affected in particular. It is of importance to identify countries with a heavy dependence on exports of a certain crop. Two examples are Belize and St Lucia whose main exporting goods to the EU are bananas, that make up 46% and 67% of their total exports to the EU respectively.

Assessing the impact on third countries, the focus was not only on the total value and volume but also the share of the value of the affected crops of a country's total exports to the EU. Only data on EU imports and not on third country exports to the whole world have been used. This is because the impact of ED regulation is concerning EU only and may have no impact on crops grown for other markets.

Treated articles, i.e. articles treated with biocides are widely marketed often expressed in terms as anti-mold, anti-bacterial or anti-odour. Articles can be anything from kitchen ware, bathroom accessories, cleaning supplies, to toys and child care articles as well as a wide range of clothing such as sportswear, underwear, shoe insoles, hats, gloves, socks, mattresses, mattress covers, pillows, bedding, towels, rugs, furniture and curtains.¹⁵ One issue assessing the impacts on treated articles is the lack of data on imports. Today there is no distinction between regular and treated articles with special features such as anti-mould. This makes it difficult to quantitatively assess the impacts in terms of value and volume. In 2009 it was noted that non-EU producers represent a non-negligible share of the EU market with treated materials which is estimated at EUR 22.2 billion per year; for example, imports amount to 10-20% of the EU market for treated wood and 25 to 40% of the EU market for wool carpets¹⁶. However, by applying an assumption on the share of treated articles among all imports there are rough estimates on the value of affected products. However, one category that is listed with a unique CN code are disinfectants – which are essential to health care. In 2014, the EU imported 22,000 tonnes of disinfectants to a value of EUR 65 million.

With the non-approval of a biocidal active substance, it can be assumed that manufacturers and importers have to make a considerable effort to adapt to the new requirements. They need to be aware of the obligations to use biocides in articles and gather detailed knowledge about the articles they place on the EU market. As a consequence, the following main impacts are expected:

¹⁵ Chemicals in textiles – Risks to human health and the environment. Report from a government assignment. Swedish Chemicals Agency. Stockholm 2014.

¹⁶ Commission Staff Working Document SEC(2009)773, accompanying document to the Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products - Impact Assessment. Retrieved from: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52009SC0773&from=EN>

- more information exchange in the supply chain is required to make sure suppliers and exporters are aware of EU rules on treated articles;
- implementing control measures will require considerable efforts from manufacturers, importers and authorities alike.

For the purpose of this IA, textiles were used as a case study because their majority, approximately 80% of the textile articles consumed in the EU, are imported from a non-EU country.¹⁵ Biocidal products are used in the textile industry for three main purposes:

1. to improve the storage stability of aqueous raw materials and auxiliaries by preventing microbial material destruction;
2. to preserve fibrous material from microbial deterioration (to prevent rot and mildew);
3. to protect keratin-containing textiles from damage caused by insect pests¹⁷.

In 2014, the EU imported apparel to a value of EUR 73 billion (4.6 million tonnes), and textiles (excl. apparel) to a value of EUR 26 billion (6.8 million tonnes).¹⁵ In total, imported textile are as important in terms of value as the whole agricultural sector imports combined. It therefore constitutes a relevant case study as some textiles are treated with biocides that may fall under one or several of the four options in the screening of EDs.

5. RESULTS OF THE ANALYSIS

MCA-criterion i) volume of imports of food potentially affected by lowering the MRLs

In **Table 2** are the most valuable imported food crops to the EU. These eleven crops are imported to a value of close to EUR 30 billion, which is roughly 30% of all agricultural imports to the EU. The options are ranked in accordance with the number of MRLs that may be lowered under the four options, with the best performing option being the one with the least MRLs being lowered.

Option 4 consistently performs the best for all crops and consequently will have the least disruptive impact on trade and imports of the four options.

Looking beyond the best performing option it is clear that all Options 1, 2 and 3 Category I will have a significant negative impact on trade and food supply in Europe. However, it is not clear which option has the most negative impact on trade, rather it depend on the crop. E.g. citrus fruits will be more heavily impacted by Option 2 and Option 3 Category I with 11 substances potentially removed from the pesticide portfolio, while wheat is more impacted by option 1 compared to 2 and 3. Citrus fruits and wheat are comparable in terms of value of imports; however, it is not obvious which crop is more important to the EU as a whole in terms of food, health, jobs and growth. Therefore, for the purpose of MCA, the performance is considered equal between Option 1 and 2/3 Category I.

These top imported crops to the EU are used as proxy for the full list of crops that will be affected by lowered MRLs. The same pattern re-appears across the entire list. Option 4

¹⁷ Lacasse, K.,Baumann, W. 2004. Textile chemicals, environmental data and facts. Springer, ISBN 978-3-642-62346-2. DOI 10.1007/978-3-642-18898-5

consistently has the least impact on the crops and trade while it varies depending on the crop if Option 1, Option 2 or Option 3 Category I will affect the most MRLs.

Table 2. Most valuable imported food crops in 2014 and how they rank

FOOD - MOST VALUABLE IMPORTED CROPS 2014 AND HOW THEY RANK							
Product	Value in million EUR	Qty in thousand tonnes	Performance	Number of MRLs			
				Opt. 1	Opt. 2	Opt. 3 Cat I	Opt. 4
Coffee	€7,854	2,887	4>2/3>1	3	2	2	0
Nuts	€4,373	791	4>1>2/3	3	5	5	2
Cocoa beans	€3,167	1,384	4>1/2/3	1	1	1	0
Bananas	€3,063	5,041	4>2/3>1	10	8	8	3
Maize	€2,656	14,212	4>1/2/3	4	4	4	3
Wine	€2,454	1,389	4>1>2/3	12	15	15	7
Citrus fruits	€1,485	1,914	4>1>2/3	7	11	11	5
Wheat	€1,294	5,049	4>2/3>1	14	9	9	4
Table grapes	€1,225	598	4>1>2/3	11	13	13	7
Rape seed	€1,170	3,072	4>2/3>1	12	9	9	4
Rice	€1,059	1,643	4>1>2/3	4	7	7	3
TOTAL	€29,800						

A weighted ranking was done to get a better perspective of the difference between the options in terms of value and number of MRLs affected. This was done by multiplying the total import value with the number of MRLs potentially lowered. Thus, the most valuable crops get a high weight but it is also important how many active substances might disappear from the market. The ranking varies slightly between the options with cereals and oilseed more impacted under Option 1 and citrus fruit under Option 2 and 3 Category I (see Table 3).

Table 3. Weighted ranking – most affected crops in terms of value and MRL

WEIGHTED RANKING - MOST AFFECTED CROPS IN TERMS OF VALUE AND MRLS			
Option 1	Option 2	Option 3 Cat I	Option 4
Bananas	Wine	Wine	Wine
Wine	Bananas	Bananas	Bananas
Coffee	Nuts	Nuts	Nuts
Wheat	Citrus fruits	Citrus fruits	Table grapes
Rape seed	Table grapes	Table grapes	Maize
Table grapes	Coffee	Coffee	Citrus fruits
Nuts	Wheat	Wheat	Wheat
Maize	Maize	Maize	Rape seed
Citrus fruits	Rape seed	Rape seed	Rice
Rice	Rice	Rice	Coffee
Cocoa beans	Cocoa beans	Cocoa beans	Cocoa beans

The main ranking is based on the most valuable imported crops to the EU; however, Table 4 lists the most impacted crops with regards to the number of MRLs that may be lowered. Tomatoes is the most impacted food crops in absolute terms with 17 MRLs lowered under

Option 1. This represents 12 % of the total number of MRLs for tomatoes. Another crop highly impacted by Option 1 is barley with 15 MRLs lowered which is 13% of the MRLs set. Crops with high expected impacts under Option 2/3 Cat I are wine and pears with 15 MRLs lowered. This represents 11% and 12% of the MRLs set respectively. Peaches is affected equally by option 1, 2 and 3 Cat I with 14 MRLs lowered, this represents 13% of the MRLs set for peaches.

Table 4. Most affected crops based on the number of MRLs lowered.

MOST AFFECTED CROPS BASED ON THE NUMBER OF MRLS LOWERED							
MRL	Option 1	MRL	Option 2	MRL	Option 3 Cat I	MRL	Option 4
17	Tomatoes	15	Wine	15	Wine	8	Tomatoes
15	Barley	15	Pears	15	Pears	7	Wine
14	Peaches	14	Tomatoes	14	Tomatoes	7	Pears
14	Wheat	14	Peaches	14	Peaches	7	Table grapes
14	Rye	14	Apples	14	Apples	7	Strawberries
13	Capsicum	14	Apricots	14	Apricots	7	Capsicum
13	Melons	14	Cherries	14	Cherries	7	Cucumbers
12	Wine	14	Plums and sloes	14	Plums and sloes	7	Gherkins
12	Cucumbers	13	Table grapes	13	Table grapes		
12	Apples	13	Pumpkins	13	Pumpkins		
12	Courgettes	13	Quinces	13	Quinces		
12	Rape seed	13	Medlars/Loquats	13	Medlars/Loquats		
12	Oats	13	Strawberries	13	Strawberries		

MCA-criterion ii) volume of imports of feed potentially affected by lowering the MRLs

Four imported commodities that is mainly used for feed are listed in Table 5; soyabean, maize, rapeseed and cottonseed. They represent the bulk of EU feed imports and crucial to the animal husbandry sector. Roughly five million EU farmers raise animals for food production with a value of about EUR 130 billion. Every year, they need approximately 450 million¹⁸ tons of feed, most of which are roughages grown and used on the farm of origin. The balance includes cereals grown and used on the farm as well as feed purchased by livestock producers to supplement their own feed resources¹⁹ (such as maize, soyabean, rapeseed, and cottonseed). The EU is a major importer and dependent on imports of agricultural commodities for feed use. It is therefore relevant to evaluate the impact of ED criteria on feed imports and in extension the entire livestock sector in the EU.

The four options are ranked in accordance with the number of MRLs that will be lowered with the best performing option being the one with the least MRLs being lowered. In the next

¹⁸ European Commission, DG SANTE. Accessed on:
http://ec.europa.eu/food/food/animalnutrition/index_en.htm

¹⁹ Feed & food Statistical Yearbook 2014. European Feed Manufacturers Federation (FEFAC).

paragraphs, feed products and the importance of imported feed to EU is explained, followed by a discussion of the performance of the options.

In the event of an interruption of soy product exports to the EU, the EU meat markets, poultry and pork in particular, would be affected due to the more costly and limited feed alternatives.²⁰ The increase in feed costs could weaken the competitiveness of the EU livestock sector and reduce the EU shares in domestic and world markets. A trade disruption would amplify the current EU protein deficit for the livestock sector and the need for alternative sources. These alternatives may come from increased production of oilseeds, such as rapeseed and sunflower seeds, or protein crops, such as field peas, field beans and sweet lupines.²⁰ Given the low level of EU competitiveness, the European Commission estimates that an increase in oilseed and protein seed acreage could replace at most 10–20% of EU imports of soyabeans and soyabean meal²¹, but in that case farmers would need to be able to protect their crops with plant protection products and may face similar situations with respect to the residue levels as the imported commodities.

The EU production of soyabean, rape and sunflower seeds, as well as pulses and other legume crops, compensates to a limited extent the EU dependence on soyabean and soymeal imports. However, for now these products cannot, on their own, meet the EU protein needs for feed.²² The low self-sufficiency (of e.g. soya) exposes the EU to possible trade distortions, sustainability problems, scarcity and price volatility of soyabean on the global market.²³

Table 5. Feed imports 2014 and how the options perform.

FEED IMPORTS ²⁴ 2014 AND HOW THE OPTIONS PERFORM							
Product	Value in million EUR	Quantity in thousand tonnes	Performance	Number of MRLs			
				Opt 1	Opt 2	Opt3 Cat I	Opt 4
Soyabeans ²⁵	€5,264	13,079	4>2/3>1	7	4	4	0
Maize	€2,656	14,212	4>1/2/3	4	4	4	3
Rape seed	€1,170	3,072	4>2/3>1	12	9	9	4
Cotton seed	€19	69	4>2/3>1	10	5	5	2
TOTAL	€9,109						

²⁰ Henseler, M., Piot-Lepetit, I., Ferrari, E., Gonzalez Mellado, A., Banse, M., Grethe, H., Parisi, C., H elaine, S. 2013. On the asynchronous approvals of GM crops: Potential market impacts of a trade disruption of EU soy imports. *Food Policy* 41: 166-176

²¹ DG AGRI of the EC. 2007. Economic Impact of Unapproved GMOs on EU Feed Imports and Livestock Production. European Commission, DG AGRI Report.

²² EIP-AGRI Focus Group Protein Crops: final report. <http://ec.europa.eu/eip/agriculture/en/content/eip-agri-focus-group-protein-crops-final-report>.

²³ Visser, C.L.M., Schreuder, R., and Stoddard, F. (2014) The EU's dependency on soya bean import for the animal feed industry and potential for EU produced alternatives. *Oilseeds & fats Crops and Lipids (OCL)* 21(4). DOI: [10.1051/ocl/2014021](https://doi.org/10.1051/ocl/2014021)

²⁴ EUR 9 billion is the total value of soyabeans, maize, rapeseed and cotton seed considering beans and seeds only, not milled products. This figure should therefore be considered as a lower bound value of the imports for feed. Note that feed imports are generally not estimated in value but in volume.

²⁵ Note that this figure is for soyabean imports only which constitute less than half of the total share of soya feed, the rest (roughly 18 million t) are imported as soyameal. In total, the EU imports on a yearly basis on average 36.1 million tonnes of soyabean equivalent.

Soy

Soyabeans are one of the most important feedstuffs for the EU due to their high protein content and is used by livestock producers in the EU to achieve a balanced diet, particularly for pigs and poultry. The EU has a self-sufficiency rate of only 3% for its soyabean and soyameal needs.^{26;27} Since the overall import volumes of soyabeans and soyabean meal are much higher than EU domestic production, they are crucial for the EU animal sector. Few alternatives exist to replace these protein rich crop imports in the short term.²⁸

Around two thirds of soyabeans used in the EU feed industry are imported, mostly from Argentina, Brazil and the US.²⁰ In the last three years, the EU has imported on average 36.1 million tonnes of soyabean equivalent²⁹ on a yearly basis. On average, 12.7 million tonnes of soyabeans are imported into the EU for crushing into soyabean oil and meal; and 18.5 million tonnes of soyameal (i.e. 23.4 million tonnes of soyabean equivalent) are directly imported into the EU. Commodity imports are concentrated in a few EU ports, from where they are traded to other Member States. The total value of soybean and soymeal imports to the EU mounted to EUR 10.6 billion in 2014-2015.

Between 0.43 and 0.56 million hectares of soyabean crops have been cultivated in the EU in the last three years, producing between 0.96 and 1.85 million tonnes of soyabeans. In the EU, soyabeans are mainly produced in Italy (around half of the EU production), Romania, France, Hungary and Austria.²⁰

Maize

The EU has imported, in the last three years, between 8 and 14 million tonnes of maize per year. In addition, the EU has also imported between 0.2 and 0.7 million tonnes of Corn Gluten Feed CGF which is a by-product of the starch industry used as an animal feedstuff.

More than 9 million hectares of maize crop are cultivated in the EU per year producing between 60 and 78 million tonnes of maize. The EU self-sufficient rate on maize depends on the year, fluctuating between 82% and 102% in recent years.³⁰

²⁶ The Self-Sufficiency Ratio (SSR) expresses the magnitude of EU production in relation to domestic use, i.e. $SSR = \text{production} / (\text{production} + \text{imports} - \text{exports} \pm \text{changes of stock})$.

²⁷ Statistics on agricultural markets 2014, DG AGRI. http://ec.europa.eu/agriculture/markets-and-prices/market-statistics/index_en.htm

²⁸ DG AGRI of the EC. 2007. Economic Impact of Unapproved GMOs on EU Feed Imports and Livestock Production. European Commission, DG AGRI Report.

²⁹ Soyabeans are crushed to extract oil. The remaining by-product is soymeal, which is used for feed. One tonne of soyabean grains produces 0.20 tonne of oil and 0.79 tonne of meal. Data on soyabeans and soymeal have to be expressed into the same equivalent unit to allow adding them up. In order to compare EU imports of soyabeans and soymeal versus EU production of soyabean crops, data have been expressed in soyabean equivalent (SOE). A conversion factor of 0.79 has been applied.

³⁰ Statistics on agricultural markets 2014, DG AGRI. Retrieved from: http://ec.europa.eu/agriculture/markets-and-prices/market-statistics/index_en.htm

Rapeseed

The EU imports, on average, 3.5 million tonnes of rapeseeds per year, and between 0.2 and 0.47 million tonnes of rapeseed meal. In total, on average, the EU imports 4.2 million tonnes of rapeseed equivalent. More than 6 million hectares of oilseed rape are cultivated in the EU on a yearly basis, producing between 19 and 21 million tonnes of rapeseed. The EU self-sufficiency rate on rapeseed reaches about 85%.³⁰ For more information on rapeseed, see case study III in this annex.

Cottonseed

On average, the EU imported 0.054 million tonnes of cottonseeds and 0.009 million tonnes of cottonseed meal in recent years. In total this equals 0.76 million tonnes of cottonseed equivalent.³¹ The EU cultivates around 0.3 million hectares of cotton, producing around 0.5 million tonnes of cottonseed per year. There is no data on EU self-sufficiency of cottonseed.

Performance of the options for feed

Option 4 consistently performs the best for all the four feed products and consequently will have the least negative impact on trade and imports. Option 1 is the worst performing option with the most MRLs potentially affected. Therefore, compared with the impact on food, it is possible to draw the conclusion that Option 1 is performing worse than Option 2 and Option 3 Category I. The ranking for feed is 4>2/3>1.

Both the number of MRLs and which chemical class they belong to differ between the four options. The main impacted major group are fungicides, and this is a general conclusion not just for soyabeans, maize, rapeseed and cottonseed but for all crops. Among the four feed crops evaluated, rapeseed has an even more pronounced impact on fungicides than the others.

MCA-criterion iii) volume of imports of goods which may be affected as a consequence of implementing the Biocidal Products Regulation in relation to treated articles

Biocides are used to control harmful organisms from causing health and environmental risks, or damaging products. The EU legislation relating to biocides is aimed at improving the functioning of the internal market and to ensure a high level of protection of human and animal health as well as of the environment. The EU biocides rules apply to articles placed on the market, either produced within the EU or imported.

The term treated article means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.³² A treated article may only be placed on the market if the active substances contained have been approved in the EU, or are included in the corresponding review programme of active substances.

³¹ The conversion factor applied between cottonseed and cottonseed meal is 0.45.

³² Article 3(1)(l) of BP Regulation

TEXTILE IMPORTS

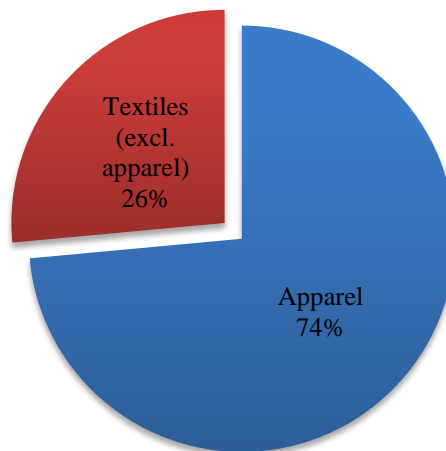


Figure 2. Textile imports to the EU divided into textiles and apparel.

The analysis of this IA focuses on textiles, since their majority, approximately 80%, of the textile articles consumed in the EU are imported from a non-EU country.³³

If a biocide is non-approved in the EU, it means it cannot be used on or incorporated in any article imported to the EU as well. It applies to all goods falling in the scope of the definition of treated article, not only those goods with a claim to be a biocidal treated article. However, unless a specific claim that the product is treated with a biocide is made, it is difficult to find out if an article has been treated or not.³⁴

There are two ways in which textile could be designated as a treated article in statistics:

- 1) to prevent growth of mould during storage and transport;
- 2) to create special functions of clothes or garments, such as anti-odour in tops and sportswear. Treated textile materials are for instance pure or blended cotton, wool, polypropylene, acrylics, polyamide and polyester.³⁵

Not all textiles imported to the EU are treated articles. Currently, there is no reliable data on the share of treated articles with respect to all imported textiles. This is because treated articles do not have a separate CN Code for trade and imports. With the Biocides Products Regulation, applying from 1 September 2013,³⁵ data will be collected to get a better overview of the volumes and values of treated articles. Due to the current lack of data, the assumption is made that 5% of all imported textiles could be considered a treated article. This is based on

³³ Chemicals in textiles – Risks to human health and the environment. Report from a government assignment. KEMI Swedish Chemicals Agency. Stockholm 2014. Retrieved from:

<https://www.kemi.se/files/8040fb7a4f2547b7bad522c399c0b649/report6-14-chemicals-in-textiles.pdf>

³⁴ KEMI PM 2/12 Biocide treated articles - an Internet survey (2012). Retrieved from:

<https://www.kemi.se/global/pm/2012/pm-2-12-biocide-treated-articles.pdf>

³⁵ The transitional measure for treated articles will apply until 1 March 2017.

the estimate of 25% for wool carpets and taking into account the relatively low percentage of chemicals used for treatment of textiles.^{16,36} This is a conservative estimate; however, considering the total value and volume of textiles, the market value for treated textile articles would still be more than EUR 3.5 billion. So the potential impact from removing certain biocidal products from the EU market may affect EUR 3.5 billion worth of imports.

Table 6. Top EU-28 import of apparel in 2014.

TOP EU-28 IMPORT OF APPAREL 2014		
Partner	Value billion EUR	Qty (tonnes)
China	€28.35	2,035,743
Bangladesh	€11.04	928,687
Turkey	€9.19	412,632
India	€4.64	262,962
Cambodia	€2.23	146,927
Vietnam	€1.64	84,351
Morocco	€1.63	53,668
Tunisia	€1.47	50,141
Pakistan	€1.06	85,973

The main trading partners for textiles are Asian countries with China being the biggest exporter by far. In contrast with food and feed, the textile industry is heavily concentrated in Asia.

As with the downstream use of biocidal products in general (see annex on competitiveness and innovation), it is difficult to estimate the impact of the setting the criteria for EDs. For example, it will depend on the alternatives available for the biocidal active substance not any more allowed on the EU market. For textiles an EU Ecolabel³⁷ exist including restrictions on the use of biocides in textiles. This shows that alternatives for biocidal substances may be available. One outcome could be higher prices of treated articles in an initial phase before a substitute is found. In 2015 the EU Ecolabel was awarded to 2501 textile products (in total of 44711 EU Ecolabel products on the market). One impact of withdrawing a biocidal substance from the market could be higher prices of treated articles as a limited number of companies would be able to supply treated articles of the same quality. Another possible impact may be the removal of certain treated articles from the EU market, either indefinitely or temporary.

6. PERFORMANCE OF THE OPTIONS

From the analysis of the evidence illustrated in previous sections of this annex (based on the screening study results, MRL and trade data), it can be concluded, that for all MCA-criteria

³⁶ See Windler, L., Height, M., and Nowack, B. 2013. Comparative evaluation of antimicrobials for textile applications. *Environment International* 53: 62-73. <http://dx.doi.org/10.1016/j.envint.2012.12.010>

³⁷ EU Ecolabel Textile Products User Manual. Retrieved from: http://ec.europa.eu/environment/ecolabel/documents/User_manual_textile.pdf

considered (import of food, import of feed, and import of treated articles) the ranking of the Options 1 to 4 would be $4 > 1/2/3$.

Less substance would be affected for PPP in Option B (introducing elements of risk assessment) compared to Option A (basically based on hazard). Option C introduces in addition socio-economic elements, which are however not applicable for MRL setting (food and feed) which is the driver for trade impacts. Thus, Option C and B could be considered to be ranked equally. The ranking of the Options A to C would be, as a consequence, $C/B > A$ for both import of food and feed indicators. For treated articles the options A, B and C were not evaluated as these options are only relevant for PPP.

7. CASE STUDIES - IMPACT ON THIRD COUNTRIES

The EU's main trading partners are the United States (US), China, and Japan. The EU is also committed to support Least Developed Countries (LDC)³⁸ and special attention is given to these countries when assessing any potential negative impact that new criteria for EDs may have. The EU market is the world's most open market toward developing countries. If fuels are excluded, the EU imports more from Least Developing Countries than the US, Canada, Japan and China together.³⁹

The EU is the fifth largest export market for US agricultural products, while the US is the largest export market for EU agricultural products. US agricultural producers rely on a variety of plant protection products to control pests and plant diseases, improve quality and yield, and limit human disease outbreaks associated with rodent and insect populations. Without the availability of viable pest mitigation alternatives, the elimination of important pesticides could significantly limit the quantity and quality of US agricultural goods intended for export to the EU.⁴⁰

Emerging and developing countries face the stringent European legislative requirements on safe food production, which restricts opportunities for exports. Developing or transition countries accounted for more than 88% of all EU food and feed rejections between 2002 and 2008. As roughly 70% of the imports of agricultural produce originate from developing

³⁸ **Least Developed Countries:** Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Congo Dem Rep., Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Guinea, Guinea-Bissau, Haiti, Kiribati, Lao PDR, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Sudan, Sudan, Tanzania, The Gambia, Timor-Leste, Togo, Tuvalu, Uganda, Vanuatu, Yemen, and Zambia. The World Bank IBRD-IDA, Least developed countries: UN classification.

Retrieved from: <http://data.worldbank.org/region/LDC>

³⁹ EU position in world trade. <http://ec.europa.eu/trade/policy/eu-position-in-world-trade/>

⁴⁰ Comments of the US Government. European Commission's Public Consultation on Defining Criteria for Identifying Endocrine Disruptors (EDs) in the Context of the Implementation of the Plant Protection Product Regulation and Biocidal Products Regulation.

countries it can be expected that the rejections are mainly related to products from developing countries.⁴¹

In the EU, imports have to comply with several safety and quality standards – pesticide residues being one of them.⁴¹ Another example is the obligation to treat or incorporate in articles biocidal products containing only active substances approved in the EU. This might be quite challenging for some of the exporting countries. In addition, the economic consequences for complying with EU legislation by the exporting third countries are high. Several studies have demonstrated that investments in infrastructure, training and capacity building or workers and implementation of food safety management systems are demanding economical efforts from exporting countries.⁴¹

1.1. Case Study I - Bananas

Bananas⁴² are one of the world's most important food crops in terms of gross value of production and the most commonly eaten fruit in the world.⁴³ It is a staple food and a key export commodity for many low-income countries.⁴⁴ Every year, more than 100 million tons of bananas are produced in around 130 countries.⁴⁵ The EU is the largest importer of dessert bananas in the world, followed by the United States. In 2014, 5 million tonnes of bananas were imported to the EU from Third Countries.

Most bananas are consumed domestically. However, around 20 % of the world production of bananas is traded internationally. The banana sector is a very dynamic industry. World production more than doubled since 1990, from around 47 million tonnes, to 107 million tonnes in 2013; bananas traded internationally show a similar growth, increasing from 9 million tonnes in 1990 to 20 in 2013.⁴⁵

⁴¹ Uttendaele, M. 2014. "Issues surrounding the European fresh produce trade: a global perspective". Global Safety of Fresh Produce: A Handbook of Best Practice, innovative commercial solutions and case studies. Ed. Hoorfar, J. Woodhead Publishing. Cambridge, UK.

⁴² Bananas comprise a diverse group, including cooking types such as plantains and a wide range of dessert types.

⁴³ Banana is the eighth most important food crop in the world and the fourth most important food crop among developing countries according to the UN agency FAOSTAT.

⁴⁴ Jaime de Melo. 2015. "Bananas, the GATT, the WTO and US and EU domestic politics", Journal of Economic Studies, Vol. 42 Iss: 3, pp.377 - 399

⁴⁵ Anania, G., 2015. The role of trade policies, multinationals, shipping modes and product differentiation in global value chains for bananas. The case of Cameroon. International Conference of Agricultural Economists. Milan 29th May, 2015, published on the African Journal of Agricultural and Resource Economics 2015; 10(3): 174-191. Retrieved from: <http://ageconsearch.umn.edu/bitstream/211666/2/1%20Anania.pdf>

BANANAS

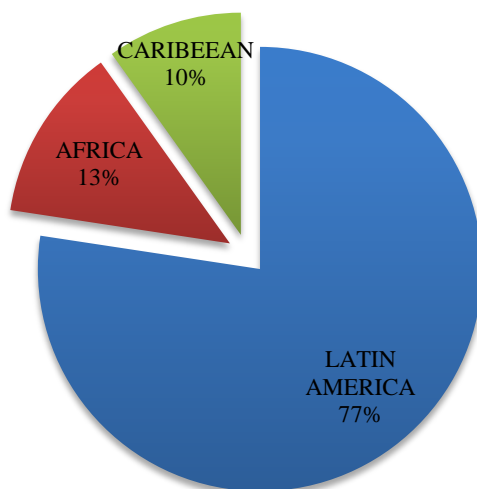


Figure 3. Banana imports to EU-28 based on region of production.

In 2013 the six main producers of bananas accounted for almost two thirds of global production; they were, in order of importance: India, China, the Philippines, Brazil, Ecuador, and Indonesia. The largest net exporters of bananas and their ranking do not coincide with those based on production, as India and China, the two largest producers, are marginal international traders and net importers. The largest net exporter in 2013 was Ecuador (27.7% of total world exports), followed by the Philippines (17.2%), Guatemala (16.3%), Costa Rica (9.8%) and Colombia (8.2%).⁴⁵ In 2013 the top five exporting countries alone accounted for 79% of the world market. Market concentration for imports is even higher than for exports.

The EU is supplied by three different groups of origins for bananas:

- Most Favoured Nation (MFN) countries, mainly Central and Southern America countries.
- Africa, Caribbean and Pacific (ACP) countries.
- EU own production.

In total, there are 61 MRLs set for bananas and depending on the option, more or less substances will be affected. Option 1 will have the greatest impact on bananas, since it will affect the most substances, 16% of all MRLs currently set. Option 4 will have the least impact on the production of bananas, with only 5% of total MRLs possibly affected. This is the general trend for all crops; however, the long term impact on availability, prices, welfare, and production techniques is not clear cut. In some cases there may be good crop protection alternatives available but in other cases not, and this has to be assessed on a region and pest level basis at the respective third countries.

Table 7. Banana imports and the share of potentially affected MRLs under the four options.

BANANAS - IMPORTS TO EU-28 AND POTENTIALLY AFFECTED MRLS						
Value in million EUR	Quantity in thousand tonnes	Total number of MRLs set	Share of MRLs			
			Opt 1	Opt 2	Opt3 Cat I	Opt 4
€ 3,063	5,041	61	16%	13%	13%	5%

The removal of some pesticides could possibly benefit the health of workers in banana plantations and in sorting factories in third countries. Furthermore, the removal of some pesticides may also spur innovation or lead to a change in farming technique or crops. This type of legislation may promote an increase in the organic banana supply in the EU. Although organic bananas currently target higher income consumers,⁴⁵ an increase in supply may put downward pressure on prices.

Main impacts

- Latin America, Caribbean and African countries most affected
- Lower volumes imported sold to higher prices
- Some very small countries, such as St Lucia, are heavily dependent on their banana exports and will be impacted.
- May imply a shift towards other crops and affect farming practice.

Table 8. Banana imports to EU-28 in 2014 by main trading partner.

RANK	PARTNER/PRODUCT	VALUE IN EUR	QTY 100KG	SHARE OF EXPORTS TO THE EU
1	ECUADOR	€ 812,050,918	14,767,219	31%
2	COLOMBIA	€ 698,644,569	10,862,897	9%
3	COSTA RICA	€ 549,230,124	9,401,766	15%
4	DOMINICAN REPUBLIC	€ 239,456,233	3,420,160	31%
5	CAMEROON	€ 189,199,034	2,571,778	9%
6	COTE D'IVOIRE	€ 169,301,183	2,527,657	5%
7	PANAMA	€ 140,518,280	2,248,794	32%
8	BELIZE	€ 56,290,641	1,007,070	46%
9	PERU	€ 65,882,379	966,510	1%
10	SURINAME	€ 38,687,927	725,929	15%
11	MEXICO	€ 31,049,068	707,835	0%
12	GHANA	€ 30,160,147	464,282	1%
13	GUATEMALA	€ 15,518,442	291,669	2%
14	BRAZIL	€ 16,220,182	286,607	0%
15	ST LUCIA	€ 5,875,847	88,805	67%

Fair Trade and organic banana production constitutes the most important single factor explaining the rapid increase in recent years of volumes exported and market shares of some of the relatively smaller banana exporters, such as the Dominican Republic (today the largest

supplier of Fair Trade bananas), and Peru.⁴⁵ Other large exporters of Fair Trade bananas are Colombia and Ecuador.

Assuming a reduction in number of active substances will impact the quality of bananas due to the smaller range of pesticides available to fight certain pests, the EU may have to accept imports of lower quality. A potential scenario is also that if the quality of bananas decrease, more fruit will be sold domestically as they are seen unfit for exports.⁴⁵ The result would be a decrease in volumes of bananas exported to the EU, consequently sold to higher prices.

Another assumption is that new stringent criteria for ED will have the same impacts as new private standards. Thus, only prices will change due to costlier production processes, however, availability and quantity will not be significantly impacted.⁴⁵⁴⁵

Looking at the different chemical classes between the options, it is clear that fungicide is the most impacted major group.

1.2. Case Study II – Wine

The EU is the world's leading producer of wine; however, the EU is also a major importer of wine. Grapes used for wine are very susceptible to various pests and a whole range of pesticides are used on grapes. In total there are 137 MRLs set and grapes will be one of the crops most affected by the four different options, especially Option 1, 2 and 3 will impact the wine and grape industry considerably.

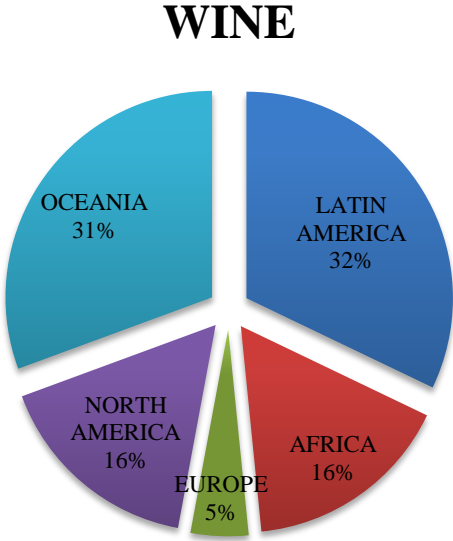


Figure 4. Wine imports to the EU-28 in 2014, based on region of production.

Looking at imports of wine and grapes, they are of considerable importance to the exporting countries as can be seen from the share of wine and grapes out of the total exports from the exporting country to the EU. For example Chile and New Zealand are highly dependent on EU as a trading partner for their wine sectors, and taking also the table grape exports into

account it is 10% of Chile's exports that will be impacted by changing regulation for plant protection products.

The volumes and values of the wine imports are quite significant with more than EUR 2 billion of imports from just the top five exporting countries. In total, close to EUR 2.5 billion of imported wine may be affected to a varying extent under the four options with relatively equal impact under Option 1, 2, and 3, while Option 4 would impact the least number of active substances.

Table 9. Wine imports to the EU-28 and the share of potentially affected MRLs under the options.

WINE - IMPORTS AND POTENTIALLY AFFECTED MRLS						
Value in million EUR	Quantity in thousand tonnes	Total number of MRLs set	Share of MRLs			
			Option 1	Option 2	Option 3 Cat I	Option 4
€2,454	1,389	137	9%	11%	11%	5%

Assessing which type of pesticide groups will be most impacted under the four options, the results are similar for wine as they are for bananas, with fungicides being the most impacted major group.

Main impacts

- The availability and price of wine in Europe unlikely to be affected by reduced imports, as countries within the EU are producing the bulk of wine in the world.
- Australia, Chile and South Africa will be affected the most as they are major wine producers, exporting a large share of their wine to the EU.
- May imply a shift towards other crops and affect farming practice.

Table 10. Wine imports to the EU-28 in 2014 by main trading partner

WINE				
RANK	PARTNER/PRODUCT	VALUE IN EUR	QTY 100KG	SHARE OF EXPORTS TO THE EU
1	AUSTRALIA	€ 427,793,357	3,301,999	5%
2	CHILE	€ 606,283,902	3,012,903	7%
3	SOUTH AFRICA	€ 385,725,654	3,003,289	2%
4	UNITED STATES	€ 396,734,529	2,269,743	0%
5	NEW ZEALAND	€ 313,459,969	675,184	9%
6	ARGENTINA	€ 164,813,730	613,082	2%
7	MACEDONIA	€ 31,441,151	529,274	1%
8	MOLDOVA	€ 23,103,104	211,636	2%
9	MOROCCO	€ 6,239,209	40,500	0%
10	KOSOVO	€ 2,021,519	35,633	2%

1.3. Case Study III - Rapeseed

Rapeseed is a member of the Brassica family and rapeseed oil is, after palm and soyabean oil, the most produced vegetable oil in the world.⁴⁶ Depending on the variety, rapeseed can be used in a wide range of purposes; from salad dressing, margarines and sauces to technical purposes, such as bio-degradable lubricating oil as an alternative to mineral oil based lubricants. Rapeseed can also be a substitute for diesel fuel, and the increasing demand for rapeseed oil over the last decade is due to its use in the biodiesel industry (non-food use).⁴⁷

EU imports of rapeseed are dominated by Australia and Ukraine⁴⁸ which exported 1.5 and 1.2 million tonnes of rapeseed to the EU in 2014, representing approximately 50% and 40% of the import shares respectively. The EU has become the largest importer in recent years due to increasing needs related to the expansion of biofuels.⁴⁹

The impacts under the various options are similar for rapeseed and other cereals. The impacts will be most severe under Option 1 with the highest number of pesticides affected. Fungicides are the most affected major group across all options, see Table 11.

Table 11. Rapeseed imports to EU-28 in 2014 and the share of potentially affected MRLs under the options.

RAPESEED - IMPORTS AND POTENTIALLY AFFECTED MRLs						
Value in million EUR	Quantity in thousand tonnes	Total number of MRLs set	Share of MRLs			
			Option 1	Option 2	Option 3 Cat I	Option 4
€1,170	3,072	75	16%	12%	12%	5%

An important feature of the rapeseed market is that the crop is not only used for foodstuffs but also as lubricants for machinery and as biofuels. The imports of rapeseed for industrial purposes may thus be affected via a lowering of the MRL, set considering consumption as food or feed. So far, there is not different treatment foreseen in the legislation for treating imports for food/feed or for industrial purposes differently.

Main impacts

- Ukraine and Australia most heavily impacted; the total imports from just these two countries reach more than EUR 1 billion, which is close to all imports of rapeseed to the EU.
- For all cereals and oilseeds, Option 1 will have the highest impact

⁴⁶ Gunstone, F. 2011. Vegetable Oils in Food Technology: Composition, Properties and Uses. 2nd Ed. Wiley Blackwell. ISBN 978-1-4443-3268-1

⁴⁷ National Edible Oil Distributor Association's website: <http://www.neoda.org.uk/rapeseed-oil>

⁴⁸ Canada dominates the world market for rapeseed but is a minor exporter to the EU in comparison with Australia and Ukraine.

⁴⁹ Carré, P., Pouzet, A. (2014) Rapeseed market, worldwide and in Europe. Oilseeds & fats Crops and Lipids (OCL) 21(1). DOI: [10.1051/ocl/2013054](https://doi.org/10.1051/ocl/2013054)

Table 12. Rapeseed imports to EU-28 in 2014 by main trading partner

RAPESEED				
RANK	PARTNER/PRODUCT	VALUE IN EUR	QTY 100KG	SHARE OF EXPORTS TO THE EU
1	AUSTRALIA	€ 605,711,127	15,230,239	7%
2	UKRAINE	€ 444,461,896	12,699,294	3%
3	KAZAKHSTAN	€ 34,597,728	685,721	0%
4	CANADA	€ 25,763,121	644,898	0%
5	ARGENTINA	€ 24,583,262	589,363	0%

1.4. Case Study IV - Citrus fruit

During the summer months, the only source of citrus in the EU comes from the southern hemisphere. The major supplier of citrus fruit to the European market from June until October is South Africa (SA), followed by Egypt and Turkey.⁵⁰ Imports from South America, including Brazil, Argentina, Uruguay and Peru are also important. Fungicides are particularly important to the citrus industry because of the freight times overseas. It takes approximately three weeks for citrus fruit to reach a European port from SA and to avoid fungal diseases, pesticides need to be applied.

Table 13. Citrus fruit imports to EU-28 in 2014 and the share of potentially affected MRLs under the options.

CITRUS FRUIT - IMPORTS AND POTENTIALLY AFFECTED MRLS						
Value in million EUR	Quantity in thousand tonnes	Total number of MRLs set for oranges	Share of MRLs			
			Option 1	Option 2	Option 3 Cat I	Option 4
€1,485	1,914	86	8%	13%	13%	6%

The EU accounts for approximately 40% of SA citrus exports⁵⁰ and these exports are considered worth close to EUR 0.5 billion. The whole citrus growing industry in SA is considered to be worth around EUR 1 billion and in 2013 it employed around 100,000 people.⁵¹ It can therefore be assumed an impact on the number of pesticides used on citrus may have a significant impact on the citrus industry in SA. The impact on citrus fruits will be most severe under Option 2 and Option 3.

A major concern for the SA citrus industry in recent years have been the occurrence of the fungal disease Citrus Black Spot (CBS), which resulted in a temporary ban of citrus imports from South Africa to EU during the winter season 2013/2014. However, in reality this had relative little impact on total imports because the temporary ban only came into effect when

⁵⁰ Source: USDA Citrus Semi-annual Report. Retrieved from: http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Citrus%20Semi-annual_Pretoria_South%20Africa%20-%20Republic%20of_6-15-2015.pdf

⁵¹ ENCA. 2013. Tight squeeze for SA citrus industry. Retrieved from: <https://www.enca.com/south-africa/tight-squeeze-sa-citrus-industry>

the citrus exporting season was almost over. Thus, it is difficult to draw any robust conclusions on the impacts on the South African economy due to decreased exports to the EU.

In order to control Citrus Black Spot, fungicides can be applied. In the latest Food and Veterinary Office (FVO) audit regarding citrus fruit exports from SA⁵², one of the recommended active substances to use combat CBS is Mancozeb, a substance that falls under option 2, 3 and 4 for the ED criteria.

Table 14. Citrus imports to the EU-28 in 2014 by main trading partner

CITRUS FRUIT				
RANK	PARTNER/PRODUCT	VALUE IN EUR	QTY 100KG	SHARE OF EXPORTS TO THE EU
1	SOUTH AFRICA	€ 432,931,860	5,790,272	2%
2	TURKEY	€ 158,182,660	2,407,821	0%
3	EGYPT	€ 86,544,050	1,847,098	1%
4	MOROCCO	€ 123,476,193	1,679,824	1%
5	ARGENTINA	€ 178,520,047	1,621,450	2%
6	ISRAEL	€ 93,732,880	952,592	1%
7	BRAZIL	€ 90,596,818	936,324	0%
8	CHINA	€ 48,566,545	759,208	0%
9	URUGUAY	€ 54,749,977	756,342	5%
10	PERU	€ 53,274,718	582,315	1%

Main impacts

- South Africa will be most heavily impacted with imports to EU worth close to EUR 0.5 billion affected.
- Option 2 and 3 Category I will cause the greatest negative impact.
- The disappearance of certain pesticides may reduce the quality and availability of citrus fruit during the European summer.

⁵² Final report of an audit carried out in South Africa from 24 February to 06 March 2015. In order to evaluate the system of official controls and the certification of citrus fruit for export to the European Union. Retrieved from: http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=3483