

PP/13/AP/22658 - Rev.3.



## POTENTIAL IMPACT OF CURRENT DRAFT PROPOSAL FOR ENDOCRINE DISRUPTION CRITERIA

### Executive summary

- *The latest version of the endocrine disruption criteria prepared by DG Environment<sup>1</sup> is expected to severely reduce the availability of crop protection products in Europe, with a substantially greater impact than originally expected when Regulation 1107/2009 was adopted.*
- *Based on an assessment made in 2009 by the UK government (PSD/CRD), the market value of products identified as being affected by the ED criteria has been calculated at between €3-4 billion. While the 37 active substances represent 10% of the number of approved active substances currently on the European market, they represent 35-45% of the current European market in terms of formulated plant protection product use.*
- *Looking at the criteria as currently drafted, the number of substances likely to be affected is greater than the 37 active substances that were initially identified by PSD/CRD.*
- *Fungicides in particular are most vulnerable. Applying the PSD/CRD criteria, the 10 most important cereal fungicide plant protection products used in Germany in 2011 would be lost (in France, it would remove 7 of the top 10 products). The loss of the PSD/CRD identified active substances would lead to the removal of approximately 80% of fungicide products currently used across the EU (based on market value)*
- *The final impact on European agricultural output would be substantial. The yield impact on key crops such as wheat, potatoes, oilseed rape and vines are projected to be between 10-20% in an average year – with losses of up to 50% being possible in years of high disease pressure.*
- *The criteria will also impact on innovation. On average, each new solution requires 10 years of research and development activity with an investment of about € 200 Million. Companies could not justify such investment as new solutions could potentially trigger ED criteria.*
- *The use of the endocrine disruption criteria has the potential for far reaching negative impacts on global commerce. The focus on purely hazard based criteria is unhelpful and is not consistent with the WTO's Sanitary and Phytosanitary (SPS) Agreement.*

<sup>1</sup> **Note:** This impact evaluation is based on the draft criteria set out in Commission document: "Revised version of possible elements for criteria for identification of endocrine disruptors" (ED-AD-HOC-6/2013/02).

## Introduction

Under Regulation 1107/2009 active substances considered to have “*endocrine disrupting properties*” will not be approved (i.e. will be banned). Within the Commission, the responsibility for preparing the scientific criteria has been delegated to DG Environment who have been tasked with developing criteria which will be applied to general chemicals (REACH), pesticides (Regulation 1107/2009) and biocides (Regulation 528/2012). On 19 February 2013 DG Environment released a revised proposal for these criteria in their document: “*Revised version of possible elements for the criteria for identification of endocrine disruptors*”. The proposal establishes a system of categories for endocrine disruptors, with Category 1 being confirmed endocrine disruptors, and Category 2 being suspected endocrine disruptors.

While it is not specified in the revised proposal, ECPA’s assumption is that substances placed in Category 1 will be subject to the cut-off criteria in Regulation 1107/2009 (i.e. will be banned).

There are a large number of uncertainties in the current proposal but there is a clear expectation that the proposal would have a substantial impact on the European crop protection market. This evaluation aims to set out in more detail that possible impact on the crop protection market of the endocrine disruption criteria currently under development in DG Environment.

The substantial impact would be expected if the concept of potency is excluded from the criteria; additional elements also have a substantial impact (esp. : no consideration of lead toxicity; reference to read across and no appropriate consideration of relevance for humans and the environment).

From discussions to date, it has been assumed that a number of substances could be affected but this was not expected to impact on all active substances within a particular chemical class. ***However, as currently written, the proposal would now be expected to impact on whole chemical classes.***

This documents aims to evaluate the potential impact on the crop protection market in Europe and focusses in particular on the impact on:

- availability of plant protection products,
- agriculture and crop protection in Europe
- innovation
- international trade

## Substances that could be affected (PSD/CRD evaluation; 2009)

Based on the PSD/CRD evaluation carried out after the adoption of Regulation 1107/2009<sup>2</sup>, the substances set out in Table 1 have been identified as being potentially impacted. Given the current draft proposal of DG Environment, there is a strong likelihood that all these substances would be impacted – as well as a number of other active substances. The table list the identified active substances and highlights the 2011 European market value of these substances.

Table 1: Active substances identified in PSD/CRD evaluation (2009)					
ASs most likely to be eliminated			ASs which may be eliminated		
Substance	Expiry of approval	Market value	Substance	Expiry of approval	Market value
<b>Insecticides</b>			<b>Insecticides</b>		
• Thiacloprid	12/2014	61	• Deltamethrin	10/2016	47
<b>Fungicides</b>			• Dimethoate	09/2017	38
• Cyproconazole	05/2021	65	<b>Fungicides</b>		
• Epoxiconazole	04/2019	208	• Difenconazole	12/2018	38
• Fenbuconazole	04/2021	2	• Folpet	09/2017	46
• Iprodione	10/2016	16	• Fluquinconazole	12/2021	4
• Mancozeb	06/2016	130	• Fuberidazole	02/2019	-
• Maneb	06/2016	5	• Metiram	06/2016	12
• Metconazole	05/2017	63	• Myclobutanil	05/2021	29
• Tebuconazole	08/2019	151	• Penconazole	12/2019	31
<b>Herbicides</b>			• Prochloraz	12/2021	56
• Amitrole	12/2015	-	• Propiconazole	01/2017	108
• Ioxynil	02/2015	15	• Prothioconazole	07/2018	304
• Molinate	07/2014	5	• Tetraconazole	12/2019	16
			• Thiram	07/2014	13
			• Triadimenol	08/2019	22
			• Triticonazole	07/2017	3
			<b>Herbicides</b>		
			• 2,4-D	12/2015	49
			• Carbetamide	05/2021	3
			• Chlorotoluron	02/2016	20
			• Fluometuron	05/2021	3
			• Metribuzin	09/2017	32
			• Picloram	12/2018	7
			• Tepraloxym	05/2015	6
			• Triflurosulfuron	12/2019	42
			<b>Other</b>		
			• Metam	06/2022	34
European market value 2011		621	European market value 2011		963

<sup>2</sup> This report also included a general agronomic impact assessment which is further referred to in this document.  
[http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/Q/Outcomes\\_paper\\_-\\_summary\\_impact\\_assessment\\_\(Jan\\_09\).pdf](http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/Q/Outcomes_paper_-_summary_impact_assessment_(Jan_09).pdf)

### Market value<sup>3</sup>

The European market value of the endocrine active substances identified by PSD/CRD is €1.58 billion. In considering formulated products containing these active substances, the current market value on the European market would be €3-4 billion (accounting for nearly 35-45% of the current market). Looking in particular at fungicides, the European market value of the identified active substances is €1.2 billion. ***The current market value of the affected products is estimated to be €2.5 billion – accounting for 80% of the current European fungicide market!***

### Impact on product availability

The main sector that would be affected is cereal fungicides, especially given the major impact on the availability of triazole fungicides. Looking at the PSD/CRD evaluation and comparing those against the actual products in use, tables 2 & 3 in the annex show the impact on the availability of cereal fungicides in both Germany and France. ***Assuming a ban of all active substances identified by PSD/CRD, all of the top ten products in Germany would be lost*** as they each contain an active substance identified by the report. 7 out of the top 10 products would be affected in France.

## Latest draft criteria: Potential impact greater than identified by PSD/CRD

The latest draft criteria raise a number of concerns and it is presumed that the impact would be substantially greater than that previously estimated (e.g. PSD/CRD assessment). While a detailed evaluation of each active substance has not been carried out, it can be presumed that particular chemical classes will be severely impacted. Two areas of particular concern are highlighted below:

- ***Pheromones and insect growth regulators (IGRs)***

Pheromones and insect growth regulators are used in plant protection products specifically for their endocrine disrupting mode of action, by creating confusion to disrupt mating or by inhibiting the life cycle of insects. The provisions of Regulation 1107/2009 taken with the current draft criteria would impact on the availability of Pheromones and IGRs.

- ***Further impact on chemical classes (e.g. from read-across)***

Table 4 (annex) sets out details of those chemical classes that have been highlighted in the PSD/CRD evaluation. However, without reference to potency, severity or weight of scientific evidence, but with reference to 'read-across', the impact on particular classes may be substantially greater and all active substances in certain chemical classes could be affected. The chemical classes most affected by the current draft criteria are listed at the start of the table and it is presumed that the remaining substances from those classes could be at risk based on the current draft criteria.

## Availability of plant protection products and agronomic impact

The number of crop protection products available to European farmers has already decreased by more than 60 percent during the last two decades. **The current proposal by DG**

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<sup>3</sup> Note regarding market value:

- The market values given are estimates for each AS. Many products on the market are mixtures and the market value of those products are broken down to give a value per AS. While the allocated market value is given for each AS, the market value of the impacted products would be much higher (probably more than double).
- The market value figures are given for Europe; the EU market represents over 80% of that market.

Environment will lead to a further significant decrease and we give some detailed examples on the agronomic impact below. In general, this will cause severe disadvantages for European farmers and will discriminate them in a global economy. European farmers will have no access to technologies which can be safely used elsewhere. The consequences of DG Environments proposal would highly effect cereal production in the EU leading to a potential estimated welfare loss of \$ 5.6 billion.<sup>4</sup>

The increasing impact of fungal diseases would have a negative impact on the trade balance, with the EU moving from being a substantial net exporter of wheat to a net importer. This would impact the profitability and the livelihoods of European farmers, it would also result in a corresponding rise in prices for basic foodstuffs such as bread and pasta. Furthermore, less wheat grown for European livestock would mean both an increase in imports, but also an increase of pork and poultry prices in local supermarkets.

**A key environmental consideration** is the impact on the environment and the efficient use of scarce resources. With reduced levels of disease control, the amount of wheat produced per unit of water and per unit of applied nitrogen would decrease substantially. As a consequence, greenhouse carbon footprint and gas emissions per tonne of wheat produced would increase<sup>5</sup>.

If the criteria were to remove complete classes of chemicals from the market, it is projected that both the quantity and frequency of fungicide applications would have to be increased in order to sustain of yields.

## Potential impact on insecticides, fungicides and herbicides

The following sets out the potential impact of the ED criteria on different groups of pesticides, and the agronomic effect of the loss of many current solutions.

### • *Insecticides*

The removal of pyrethroid insecticides, together with DG SANCO's proposal of January 2013 to restrict the use of neonicotinoid seed treatments, would have a serious impact on the ability of European farmers to control a broad range of important agricultural pests, including:

- wheat bulb fly (*Delia coarctata*), a major pest of wheat,
- cabbage stem flea beetle (*Psylliodes chrysocephala*) and pollen beetle (*Meligethes aeneus*), major pests of oil seed rape, and
- Corn root worm (*Diabrotica vergifera*), an important invasive pest on corn.

Potential removal of the two main classes of foliar insecticides, pyrethroids and organophosphates, would leave European farmers with little or no choice to manage many pest species on minor crop uses (including off-label approvals), with little or no options for resistance management.

### • *Fungicides*

Removal of triazole fungicides from the European market, would have the greatest impact on European farmers.

- Cereal farmers would be left without adequate or sustainable control of leaf blotch (*Septoria tritici*), the most important cereal pathogen. On average, this would result in

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<sup>4</sup> Source: "Restricted availability of azole based fungicides: impact on EU farmers and crop agriculture"; Schmitz, M. et al. (2001)

<sup>5</sup> Source: Paverley, 2010

wheat yield reductions of 10-20%<sup>6</sup>, but much greater reductions could be experienced in wet summers.

- For oil seed rape, triazoles are the most effective products for the control of stem canker (*Leptosphaeria maculans*) and light leaf spot (*Pyrenopeziza brassicae*). A recent study has shown that the loss of azoles alone would lead to an yield impact of 8-10%<sup>7</sup> - but yield reductions of up to 50% would be possible given favourable conditions for disease development.
- Horticulturalists would also experience significant problems as withdrawal of triazoles would leave few if any replacements.

Withdrawal of dithiocarbamates would be especially challenging for potato growers. These multisite inhibitor fungicides are important components of resistance management programmes, especially in wet climates such as Ireland, where late blight (*Phytophthora infestans*) is capable of destroying entire harvests.

Removing dithiocarbamate fungicides from the market would also be challenging for growers of grapevines, apples, tomatoes, potatoes as well as several minor crops, where dithiocarbamate fungicides are a standard resistance management tool to control plant pathogens showing a high risk of resistance development to classical single-site fungicides. In minor crops like onions, for example, downy mildew (*Peronospora destructor*) can reduce yields by 50%. For that reason FRAC (Fungicide Resistance Action Committee) recommends that several compound classes should only be used in combination with multi-site fungicides, with the dithiocarbamates as one fundamental cornerstone.

- **Herbicides**

Withdrawal of linuron and ioxynil would have a significant impact on minor crops, such as carrots, parsnips and onions. This situation would be made worse if, as indicated by PSD/CRD, further important herbicidal active ingredients were to trigger other regulatory exclusion criteria (e.g. PBT).

## **Impact on Innovation**

Plant protection active ingredients have been removed from the European market at a rate five times that of the rate at which new active ingredients have been approved. This has already left European farmers with access to a significantly reduced plant protection tool box.

Without reference to potency, severity or weight of scientific evidence, criteria for endocrine disruption, as currently proposed by DG Envi, this would not only further deplete the diminished tool box, it would also create another significant barrier for innovation. The cost of new active substance development has increased sharply in order to meet new regulatory requirements. On average, each new solution requires 10 years of research and development activity with an investment of about € 200 Million. In order to justify such investments, the crop protection industry needs a reliable and predictable regulatory environment.

Faced with additional barriers, the crop protection industry would not be able to justify developing novel active ingredients which could potentially trigger ED criteria, even if it could be demonstrated that in use they would not pose an unacceptable risk to human or environmental health. In this regard it is prohibitive for innovation that the definition on endocrine disrupters is broader in scope than the generally accepted WHO definition.

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<sup>6</sup> CRD/PSD evaluation (2009)

<sup>7</sup> ADAS & JKI (2011)

The size of the innovation challenge can be demonstrated when one considers that in the last 30 years, no new class of broad leave herbicide has been discovered and brought to market. During this period, only three new biochemical modes of action were discovered and brought to market for control of *Septoria*, with the development of resistance rendering one of these (strobilurins) it largely ineffective against *Septoria* throughout the region, in just four years.

A new series of fungicides (from the class SDHI) are under development, representing a new highly effective tool in *Septoria* control. In order to reduce the risk of *Septoria* developing resistance to the SDHIs, as occurred with the strobilurins, these new products will only be marketed in combination with other classes of established and effective *Septoria* fungicides. The remaining highly effective triazoles are therefore not only important for controlling *Septoria* today, but they are also required to reduce the risk of resistance developing to new class of SDHI fungicides.

Resistance management is therefore now more challenging and important than ever before. Each time a mode of action is restricted or removed from the market, the life expectancy of the remaining active ingredients is reduced, and farmers are forced to manage with less cost effective solutions.

## Impact on trade

Trade issues between the EU and major trading partners including the US, would arise were the EU to restrict approvals or withdraw uses for substances with endocrine disrupting properties. Based on the very fact that the two regulatory systems are so different is in itself a cause of concern for trade.

The use of hazard based cut off criteria, enabled by the categorization of compounds as endocrine disrupters, has the potential for negative and far reaching impacts on global commerce, and given the increased focus on purely hazard based criteria we have compelling reasons to believe that this approach is not consistent with the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) Agreement to which the EU is a signatory.<sup>8</sup>

Most importantly, exported food and feed containing detectable residues of substances identified as endocrine disrupters in the EU could be prohibited from entering the European market. While trade impact is impossible to quantify at this stage, industry is keen to raise these considerations in the context of a constructive dialogue. It is critical to stress that the actual impact will depend on the final adoption of specific ED regulatory criteria for pesticides and that any definition which is not proportionate and adequate will lead to trading barriers which are not justified under the SPS or TBT provisions.

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<sup>8</sup> We would in particular highlight Article 5 of the SPS Agreement:

1. *Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.*
2. *In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest — or disease — free areas; relevant ecological and environmental conditions; and quarantine or other treatment.*

## ANNEX

**Table 2: Product Data (Top Ten) for France, Cereals, Fungicides (2011) €**

Brand	Containing active Ingredient identified in PSD/CRD report:	Product Area Treated (000 ha)	Product Volume (000 kg)	Product Value (€m)
FANDANGO S 150	Prothioconazole			
SOPHISM	Epoxiconazole			
JOAO 250EC	Prothioconazole			
CELEST NET 25 SC	N/A			
MENARA BRAVO PACK 910EC	Cyproconazole / Propiconazole			
PROSARO 250EC	Prothioconazole / Tebuconazole			
OPUS 125SC	Epoxiconazole			
ACANTO	N/A			
Comet 250 EC	N/A			
MADISON 375EC	Prothioconazole			
Total of 7 affected products		7,007.48	4,020.95	168.42
Top Ten Total		10,999.43	5,980.89	235.14
Grand Total		23,071.79	13,015.17	423.86
Seven affected products %		30%	31%	40%
Top Ten products %		48%	46%	55%

Source: © AMIS Global

**Table 3: Product Data (Top Ten) for Germany, Cereals, Fungicides (2011) €**

Brand	Containing active Ingredient identified in PSD/CRD report:	Product Area Treated (000 ha)	Product Volume (000 kg)	Product Value (€m)
Aviator Xpro Duo	Prothioconazole			
Champion + Diamant	Epoxiconazole			
Capalo	Epoxiconazole			
Osiris	Epoxiconazole / Metconazole			
Input	Prothioconazole			
Input Xpro	Prothioconazole			
Prosaro	Tebuconazole / Prothioconazole			
Taspa	Propiconazole / Difenconazole			
Juwel Top	Epoxiconazole			
Gladio	Propiconazole / Tebuconazole			
Top Ten Total		5,581.24	5,823.03	194.26
Grand Total		16,146.18	10,863.3	313.13
Top Ten products %		35%	54%	62%

Source: © AMIS Global

**Note:** The majority of products listed in tables 2 & 3 are mixture products. Active substances that have not been identified in the PSD/CRD report are not mentioned in the second column.



Table 4: Chemical classes most affected by the current draft criteria

Chemical class	Substances identified in PSD/CRD report		Other ASs approved under Reg 1107/2009
	Likely to be affected	May be affected	
<b>Triazoles</b> 2011 sales: €801m	Cyproconazole Epoxiconazole Fenbuconazole Metconazole Tebuconazole	Difenoconazole Fluquiconazole Myclobutanil Penconazole Propiconazole Tetraconazole Triadimenol Triticonazole	5 ASs
<b>Other Azole</b> 2011 sales: €371m		Prochloraz Prothioconazole	5 ASs
<b>Dithiocarbamate</b> 2011 sales: €178m	Mancozeb Maneb	Metiram Thiram	2 ASs
<b>Cyclohexandione</b> 2011 sales: €63m	Tralkoxydim	Tepraloxydim	3 ASs
<b>Pyrethroid</b> 2011 sales: €333m		Deltamethrin	11 ASs
<b>Urea</b> 2011 sales: €82m		Chlorotoluron Fluometuron	4 ASs
<b>Triazine</b> 2011 sales: €182m		Metribuzin	2 ASs
<b>Phthalimide</b> 2011 sales: €137m		Folpet	2 ASs
<b>Benzimidazole</b> 2011 sales: €45m		Fuberidazole	2 ASs
<b>Phenoxy acetic acid</b> 2011 sales: €120m		2,4 D	5 ASs
<b>Carbamate</b> 2011 sales: €212m	Molinate	Carbetamide	4 ASs
<b>Pyridine</b> 2011 sales: €224m		Picloram	5 ASs
<b>Organophosphorous</b> 2011 sales: €141m		Dimethoate	9 ASs
<b>Sulfonylurea</b> 2011 sales: €826m		Triflurosulfuron	22 ASs
<b>Acaricide</b>	Amitrole (Amitraz)		
<b>Dicarboxamide</b>	Iprodione		
<b>Fumigant</b>		Metam Sodium	
	<b>Total sales: €634m</b>	<b>Total sales: €964m</b>	<b>Total sales: €2152m</b>

Source of data: © AMIS Global

**Table 5: Total European sales in 2011**

<b>Crop Group</b>	<b>Herbicides (€m)</b>	<b>Insecticides (€m)</b>	<b>Fungicides (€m)</b>	<b>Others (€m)</b>	<b>Total (€m)</b>
<b>Cereals</b>	1,334	148	1,439	145	3,066
<b>Maize</b>	900	109	2	1	1,012
<b>Rice</b>	49	3	5	0	57
<b>Soybean</b>	78	1	1	0	80
<b>Rape</b>	418	119	211	5	753
<b>Sunflower</b>	240	5	16	0	261
<b>Cotton</b>	14	19	0	8	40
<b>Sugarbeet</b>	375	27	40	1	442
<b>Potato</b>	124	68	261	11	464
<b>Vine</b>	106	111	580	17	815
<b>Pome fruit</b>	40	150	207	21	418
<b>Other F and V</b>	254	312	317	49	932
<b>Other crops</b>	188	101	107	32	429
<b>TOTAL</b>	<b>4,121</b>	<b>1,173</b>	<b>3,186</b>	<b>290</b>	<b>8,769</b>

Source: © AMIS Global