FUEHRING Stefan (SG)

From: @ecpa.eu>
Sent: 23 March 2013 11:31
To: JOHNSTONE Duncan (SG)
Cc: @dow.com
Subject: Follow-up: Meeting with Dow AgroSciences and the European Crop Protection Association: Wednesday 20 March at 10.00
Attachments: 3-US-EPA Comments - Commission ED Criteria.pdf; 22658 ECPA agri impact assessment of ED criteria - March 2013.pdf

Dear Duncan

Thanks for taking the time to meet with us on Wednesday. It was very useful to provide perspectives on the subject of endocrine disruption and I hope our meeting can be the beginning of a dialogue over the coming weeks.

As we mentioned, one of the key points for us is the **lack of impact assessment** to accompany the development of criteria which industry believes will have deep impacts *inter alia* on manufacturing, trade, agricultural output and employment. The process to develop criteria to identify and rules to regulate endocrine disruption has been ongoing since 2006 and at NO time has the likely impacts been considered. Further assessment and consideration of the impact would be helpful in understanding the impact on the availability of pesticides for farmers and the impact on food safety – as banning some of these substances will remove important tools that currently control toxins that may develop in our food (e.g. mycotoxins in cereals). Pesticides are not alone, and I believe these points have not be considered for other impacted sectors such as chemicals and plastics.

The **impact on international trade** is also a concern and given the US-EU trade discussions, we would ask that some consideration be given to the ED criteria within this wider context where regulatory cooperation has been identified as a key philosophy to explore. What a great opportunity for the EU to start this engagement, with a concrete work on a policy which will touch on both regions work.

The EFSA opinion was launched on Wednesday afternoon and this **EFSA opinion contains some important points that we believe need to be further considered by DG ENV** (hyperlink to EFSA report for convenience: http://www.efsa.europa.eu/en/efsajournal/doc/3132.pdf). We hope that DG ENV will take EFSA's call for a risk assessment approach, potency and setting thresholds into account when they take forward their proposal.

For information, I also enclose some electronic copies of documents you received as paper copies on Wednesday:

- ECPA comments on ED criteria US EPA comments on ED criteria
- ECPA impact assessment of current draft proposal

Again, thanks for your time. Please let me know if you would like further information.

Regards

, European Crop Protection Association, aisbl
Tel: +32 2 663 (direct); +32 2 663 15 50 (reception)
Tel: +32 (GSM - Mobile)

European Crop Protection

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 1, 2013

Dr. Peter Korytar,

Thank you for the opportunity to provide comment on the draft criteria for endocrine disruptors, issued on November 22, 2012. As the proposed draft criteria presents a preliminary framework to determine specific levels of endocrine activity, considerations summarized below are primarily intended to encourage additional clarity so as to more fully understand the classification scheme, the distinctions between the proposed classification categories and the nature of the data, and data interpretation methods which will inform classification decisions. We appreciate the challenge of integrating biological mechanisms, different types of data and varying levels of scientific evidence in a classification scheme. Our suggestions are intended to assist in further clarification of these specific issues to enhance transparency as you further develop these criteria. To provide some additional context to our suggestions, we also summarize the current status of the U.S. Endocrine Disruptor Screening Program.

Background

Based on US legislative mandate, the U.S. EDSP was developed to screen chemicals using validated test methods for endocrine activity similar to those associated with naturally occurring estrogen; the program has been in existence since 1999 and has evolved to a two-tiered screening and testing program based on the Endocrine Disruptor Screening and Testing Advisory Committee recommendations. The Tier 1 screening battery is intended to determine whether a chemical has the potential to interact with the endocrine system for estrogen, androgen and thyroid pathways, while Tier 2 test methods are definitive studies that would provide quantitative dose response information for use in risk assessments. As a two-tiered testing program, a chemical is advanced for Tier 2 testing only if positive in the Tier 1 battery and weight of evidence analyses warrant further testing.

Since 1999, the EDSP program has validated 11 Tier 1 screening assays; issued Tier 1 test orders for 67 pesticide chemicals and is currently in the process of evaluating the incoming EDSP Tier 1 data. The program is also in the process of validating Tier 2 test methods; all test method development activities are conducted in conjunction with OECD to enhance global harmonization of test guidelines and performance standards. In conjunction with these various efforts, in 2013, the EDSP is undertaking the following external peer reviews through the Agency's Scientific Advisory Panel (1-4) and the National Academy of Sciences (5):

(1) Use of Computational Toxicology to Prioritize the EDSP Universe of Chemicals for Tier 1 Screening
(2) EDSP Tier 1 assay and battery performance evaluation
(3) EDSP Tier 2 test methods validation for multi-generation reproduction studies on invertebrates, birds and fish and amphibian growth and development study.
(4) EDSP weight of evidence analyses based on Tier 1 screening data and other scientifically relevant information to determine if a chemical has the potential to interact with estrogen, androgen and/or thyroid systems.
(5) State of the science on non monotonic dose response curves for endocrine disrupting chemicals.

Based on recommendations from these external scientific peer reviews, the agency will advance the EDSP to reflect the current state of the science, using validated screening and testing methodologies and data evaluation processes. The agency is required to ensure strong scientific rigor in the applied test methods, transparency in the data review and regulatory processes with full and open public participation, broad stakeholder engagement and international partnerships through OECD.

General Considerations:

1. As the US EDSP has engaged in public participation, will the EC anticipated providing a formal public comment period for the next version of the document and any supporting documents?
2. Is there going to be a support document(s) prepared that provides additional information as to how best available information will be evaluated to determine the assignment of specific categories? What are the minimum data quality standards for different types of information for each category?
3. How will a chemical be classified if there is no endocrine related data available? How will a chemical be classified if there is sufficient data indicating it does not have endocrine effects? It seems at least two more categories are needed, a) Insufficient data to make a determination and b) sufficient data to determine the chemical does not have endocrine effects.
4. The classification scheme seems to correlate with the OECD EDTA Tiers that progress from prioritization through definitive testing, but the OECD Tiers are not designed to provide a categorization scheme. Does the EC anticipate using the OECD Tiers in a process to require data submission from manufacturers to the appropriate authorities and/or as a process to gather and evaluate existing data.
5. If a chemical has, for example, appropriately vetted in silico or in vitro data to indicate it has the potential to interact with an endocrine system, if subsequently additional, more definitive data is generated and it indicates a chemical does or does not interact with the endocrine system, will the chemical be re-classified?
6. The difference between the suspected (may alter functions of the endocrine system) and potential (might be expected to lead to endocrine disruption) categories is unclear. Additional detail is needed, perhaps with hypothetical examples of data sets, to provide a

better understanding of the differences between these categories. Additional clarification is also needed to ascertain the difference between category 1B and 2.

7. Category 1A requires clear evidence of an effect independent of other effects or an ED effect that is not secondary to other effects. This implies an extensive in vivo data set that addresses dose response information for a wide variety of endpoints will be required to make a determination for this category. Additional descriptions of the data sets required to make a determination for this category would be helpful.
8. Category 1A also indicates human data/evidence is needed. What data/evidence is envisaged – human epidemiological studies or intentional human dosing studies? We assume the former, not the latter, but clarification is needed. With regard to human epidemiological data, additional information is required to understand how cause-effect relationships from an epidemiological study will be ascertained (e.g., control of confounding effects or effect modifiers, etc.)
9. The definitions for categories 2 and 3 are unclear. For example, for category 2 the term "suspected" is used in the definition of the data types that could be used to make a determination of a "suspected" endocrine chemical. However, the word "suspected" is never defined; hence, it is difficult to understand the attributes of a data set that would result in a determination of suspected endocrine activity. The same circular description occurs for category 3. This lack of clarity makes it difficult to ascertain the difference between these two categories as well as the nature of the data that would support a classification. Examples of hypothetical chemicals with hypothetical data sets that illustrate how a chemical could be suspected or could have potential is needed to ascertain the differences between these categories and the nature of the data that would support a classification in either category.

Specific Comments by Section:

10. Section 4.1: The WHO definitions seem appropriate and consistent with those adopted by the US EDSP.
11. Section 4.2: An elaboration of exposure is critical, including the route and level of exposure. The need for this information is implied in the category definitions (e.g., dose-response information is needed in evaluating whether or not a chemical falls into category 1).
12. Section 4.3: Option 2 is needed to provide transparency.
13. Section 4.4: A definition of mode of action is needed as this concept is at least implicitly required to make a classification – such a definition will provide transparency. In addition, it would be helpful to better understand how the AOP concept or IPCS MOA WOE approach would be considered in the proposed classification scheme.
14. Section 4.5: Causality needs to be elaborated to provide transparency; doing so may help explain the distinction between categories 1A, 1B, 2, and 3, which is presently not clear.
15. Section 4.7: Option 3 would be optimal for clarity and transparency. Option 1 should not be used.
16. Section 4.8-4.11: These sections have options to provide additional information and in all cases the options for expanded descriptions and detail should be implemented. More detailed descriptions are needed for these terms to provide clarity and transparency in the distinctions between the categories.

17. Section 4.12: The four steps seem reasonable. There may, however, be a need for additional steps once there is elaboration of the issues previously highlighted. Also, a discussion of the process for data and evaluation, as well as an estimated timeline by which the EC regulatory authorities will undertake this effort would be helpful.

Thank you again for the opportunity to provide comments on the draft proposed criteria. If you have any additional questions, please feel free to contact me at (202) 564- or @epa.gov. I look forward to our continued partnership and collaboration on endocrine disrupting chemicals.

Sincerely,

U.S. Endocrine Disruptor Screening Program

PP/13/AP/22658 - *Rev.1.*

European
Crop Protection

POTENTIAL IMPACT OF CURRENT DRAFT PROPOSAL FOR ENDOCRINE DISRUPTION CRITERIA

Executive summary

- ***The latest version of the endocrine disruption criteria prepared by DG Environment[1] 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 substancial. 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.***

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[1] **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

Market value[3]

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 by €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 substances 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 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**

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[3] **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.

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

Based on the PSD/CRD evaluation carried out after the adoption of Regulation 1107/2009[2], 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

Substance	Expiry of approval	Market value
Insecticides		
• Thiacloprid	12/2014	61
Fungicides		
• Cyproconazole	05/2021	65
• Epoxiconazole	04/2019	208
• Fenbuconazole	04/2021	2
• Iprodione	10/2016	16
• Mancozeb	06/2016	130
• Maneb	06/2016	5
• Metconazole	05/2017	63
• Tebuconazole	08/2019	151
Herbicides		
• Amitrole	12/2015	-
• Ioxynil	02/2015	15
• Molinate	07/2014	5
European market value 2011		*621*

ASs which may be eliminated

Substance	Expiry of approval	Market value
Insecticides		
• Deltamethrin	10/2016	47
• Dimethoate	09/2017	38
Fungicides		
• Difenoconazole	12/2018	38
• Folpet	09/2017	46
• Fluquinconazole	12/2021	4
• Fuberidazole	02/2019	-
• Metiram	06/2016	12
• Myclobutanil	05/2021	29
• Penconazole	12/2019	31
• Prochloraz	12/2021	56
• Propiconazole	01/2017	108
• Prothioconazole	07/2018	304
• Tetraconazole	12/2019	16
• Thiram	07/2014	13
• Triademenol	08/2019	22
• Triticonazole	07/2017	3
Herbicides		
• 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
• Tepraloxydim	05/2015	6
• Triflusulfuron	12/2019	42
Other		
• Metam	06/2022	34
European market value 2011		*963*

[2] http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/O/Outcomes_paper_-_summary_impact_assessment_(Jan_09).pdf . Please not that this report also included a general agronomic impact assessment which is further referred to in this document.

- 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 wheat yield reductions of 10-20%[6], 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 (*Pyrenopepziza brassicae*). A recent study has shown that the loss of azoles alone would lead to an yield impact of 8-10%[7] - 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 Resistence 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

[6] CRD/PSD evaluation (2009)
[7] ADAS & JKI (2011)

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.[4]

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[5].

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.

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

[5] Source: Paverley, 2010

prohibitive for innovation that the definition on endocrine disrupters is broader in scope than the generally accepted WHO definition.

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 strobiliurins, 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. [8]

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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[8] 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	1,310.20	1,467.42	49.07
SOPHISM	Epoxiconazole	1,844.20	1,277.97	38.80
JOAO 250EC	Prothioconazole	894.29	456.09	28.85
CELEST NET 25 SC	N/A	2,235.72	782.50	20.26
MENARA BRAVO PACK 910EC	Cyproconazole / Propiconazole	862.66	319.18	17.80
PROSARO 250EC	Prothioconazole / Tebuconazole	599.83	425.88	17.25
OPUS 125SC	Epoxiconazole	1,032.80	485.41	16.65
ACANTO	N/A	786.69	341.38	16.20
Comet 250 EC	N/A	969.54	239.66	15.15
MADISON 375EC	Prothioconazole	463.50	185.40	15.12
Top Ten Total		**10,999.43**	**5,980.89**	**235.14**
Grand Total		**23,071.79**	**13,015.17**	**423.86**
Top Ten %		**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	870.50	1,055.11	43.59
Champion + Diamant	Epoxiconazole	886.60	1,221.75	39.77
Capalo	Epoxiconazole	886.12	1,060.37	28.12
Osiris	Epoxiconazole / Metconazole	525.53	837.51	14.74
Input	Prothioconazole	488.88	366.53	14.18
Input Xpro	Prothioconazole	399.58	362.76	13.14
Prosaro	Tebuconazole / Prothioconazole	351.73	307.87	12.64
Taspa	Propiconazole / Difenoconazole	517.43	197.16	9.62
Juwel Top	Epoxiconazole	244.66	193.98	9.53
Gladio	Propiconazole / Tebuconazole	410.21	219.98	8.94
Top Ten Total		**5,581.24**	**5,823.03**	**194.26**
Grand Total		**16,146.18**	**10,863.3**	**313.13**
Top Ten %		**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	*Value*	*May be affected*	*Value*	
Triazoles *2011 sales: €801m*	Cyproconazole Epoxiconazole Fenbuconazole Metconazole Tebuconazole **Total**	64.85 208.35 1.67 63.23 151.14 **489.24**	Difenoconazole Fluquiconazole Myclobutanil Penconazole Propiconazole Tetraconazole Triademenol Triticonazole **Total**	37.68 4.30 29.20 30.74 107.81 15.79 21.78 3.40 **250.70**	5 ASs *2011 sales: €61m*
Other Azole *2011 sales: €371m*			Prochloraz Prothioconazole **Total**	55.57 303.99 **359.56**	5 ASs *2011 sales: €11m*
Dithiocarbamate *2011 sales: €178m*	Mancozeb Maneb **Total**	129.86 5.16 **135.02**	Metiram Thiram **Total**	12.35 13.17 **25.52**	2 ASs *2011 sales: €17m*
Cyclohexandione *2011 sales: €63m*	Tralkoxydim	4.49	Tepraloxydim	6.26	3 ASs *2011 sales: €52m*
Pyrethroid *2011 sales: €333m*			Deltamethrin	46.82	11 ASs *2011 sales: €286m*
Urea *2011 sales: €82m*			Chlorotoluron Fluometuron **Total**	20.41 3.44 **23.85**	4 ASs *2011 sales: €58m*
Triazine *2011 sales: €182m*			Metribuzin	32.02	2 ASs *2011 sales: €150m*
Phthalimide *2011 sales: €137m*			Folpet	45.73	2 ASs *2011 sales: €91m*
Benzimidazole *2011 sales: €45m*			Fuberidazole	0.07	2 ASs *2011 sales: €45m*
Phenoxy acetic acid *2011 sales: €120m*			2,4 D	49.12	5 ASs *2011 sales: €71m*
Carbamate *2011 sales: €212m*	Molinate	4.89	Carbetamide	3.02	4 ASs *2011 sales: €204m*
Pyridine *2011 sales: €224m*			Picloram	7.02	5 ASs *2011 sales: €217m*
Organophosphorous *2011 sales: €141m*			Dimethoate	37.62	9 ASs *2011 sales: €104m*
Sulfonylurea *2011 sales: €826m*			Triflusulfuron	41.88	22 ASs *2011 sales: €785m*
Acaricide	Amitrole (Amitraz)	0.09			
Dicarboxamide	Iprodione	15.93			
Fumigant			Metam Sodium	34.35	
	Total	*633.73*	*Total*	*963.54*	

Source of data: © AMIS Global

Table 5: Total European sales in 2011

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

Source: © AMIS Global

ECPA
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