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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection product regulation and biocidal products regulation Annex 2 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

Delegations will find attached document SWD(2016) 211 final - PART 3/16.

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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

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

Annex 2 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 2

Stakeholder consultation

Contents

Besides involvement of stakeholders via the Expert Groups chaired by the European Commission between 2010 and 2013 (see Annex 1), a public consultation and a series of targeted events were carried out in order to involve stakeholders.

What is clear from these consultations is that diverging views and interests exist between NGOs, third countries, farmers, and industry, adding to the scientific and regulatory complexity addressed in this impact assessment.

The events and public consultation are summarised briefly below.

1. DIALOGUE WITH STAKEHOLDERS VIA TARGETED EVENTS

In addition to the minimum standards and in order to involve interested parties, the following events were organised during 2015. The aim was to allow the European Commission to listen to the diverging views of the different stakeholders in preparation of the assessment of impacts.

- A **conference** "EU Conference on EDs: Current challenges in Science and Policy" was carried out in Brussels on 11 and 12 of June 2012. The conference attracted more than 300 participants including policy makers and experts from EU Member States and outside the EU, scientists, academics, industry groups, trade organisations and NGOs.

- **Three roundtables** were organised in 2015: on 25 March with stakeholders, on 24 April with Member States and on 12 May with Members of the European Parliament (MEPs). The aim was to have a targeted dialogue regarding the impact assessment with these parties.

- A **conference** "EDs: criteria for identification and related impacts" was held on 1 June 2015 with the presence of around 300 participants (MEPs, Member States' representatives, advisors to political parties, third countries' representatives, NGOs, industry, trade associations, consumer associations and journalists). At this conference, as well as being informed about the impact assessment process and objectives, key stakeholders were invited to present their respective views (industry, NGOs, third countries, and scientists with divergent views).

- A **technical meeting** took place on 6 November 2015 in Brussels at which the JRC methodology for evidence screening of chemicals developed in the context of the Impact Assessment on criteria to identify EDs was presented. Approximately 140 participants attended including MEPs, representatives from Member States and countries from outside the EU and stakeholders.

For the events carried out since 2015, the respective minutes, video-recordings and presentations are available on the dedicated webpages for EDs.[1]

2. PUBLIC CONSULTATION

A **public consultation**[2] on defining criteria for identifying EDs in the context of the implementation of the PPP Regulation and the BP Regulation took place from 26 September 2014 to 16 January 2015 via an on-line consultation questionnaire (published on the European Commission public consultation page Your Voice in Europe, with a link from the dedicated webpage for EDs). The usual consultation period (12 weeks) was extended to provide stakeholders with sufficient time for comments. Responses were accepted in any official EU language, as well as via e-mail. The report of this public consultation was published on 24 July 2015 on the ED dedicated website.

The objective of this consultation was to gather data (e.g. methodologies used to select endocrine disrupting substances or the socioeconomic impact of identified EDs) and not the views of stakeholders. As a result, none of the questions asked for the opinion of respondents. This objective was reached as many respondents did provide information consisting of scientific articles, studies, reports, views and legal opinions.

Participants were invited to read the roadmap for background information before answering the questionnaire. This on-line consultation was open to all interested parties. In order to ensure all relevant stakeholders were informed the European Commission published a press-release at the launch of the public consultation.[3] The public consultation generated over 27 000 responses which illustrates the significant public interest in this issue and also indicates that all relevant stakeholders had an opportunity to contribute. The submissions received online can be found on DG SANTE's website.[4] Participation in the consultation was acknowledged.

Respondents came from various parts of society and included doctors, farmers, non-governmental organisations, chemical, electronic, food and medical devices industry, water companies and scientists) showing the diversity of use of these chemicals. Individual responses (as opposed to responses of behalf of organisations) accounted for more than 90% of the responses received. Of these individual responses, 88% came from seven Member States (Austria, Denmark, France, Germany, Spain, Sweden and the United Kingdom). 863 responses were made on behalf of an organisation and 64% of these came from one Member

[1] European Commission. Endocrine Disruptors website. Stakeholders' dialogue on endocrine disruptors. Retrieved from: http://ec.europa.eu/health/endocrine_disruptors/stakeholders_dialogue/index_en.htm

[2] The Commission's minimum standards have all been met: the usual consultation period (12 weeks) was extended to provide stakeholders with sufficient time for comments. Submissions were accepted in any official EU language. Responses could be transmitted through the online questionnaire, as well as via e-mail.

[3] European Commission press release. Commission consults the public on criteria to identify Endocrine Disruptors. Retrieved from: http://europa.eu/rapid/press-release_IP-14-1057_en.htm

[4] Public Consultation on defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection product regulation and the biocidal products regulation. Retrieved from: http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food/consultation_20150116_endocrine-disruptors_en.htm#CD and the database for received contributions is available at: https://ec.europa.eu/eusurvey/publication/ED-consultation

State (United Kingdom). Almost 26% of the responses on behalf of an organisation came from an industry or trade organisations and 5% from consumer/non-governmental organisations. Only one health institution and one hospital responded. Three EU-governments as well as 18 national authorities sent comments. Six public authorities and six governments from non-EU countries gave their comments.

The opinions of respondents varied significantly on the options for criteria for determination of endocrine disrupting properties (Options 1, 2, 3, or 4) and for approaches to regulatory decision making (Options A, B or C). The public consultation report provides an overview on the submitted arguments by respondents in favour and against the options as included in the roadmap. In general, respondents expressed diverging views on how to define criteria and how EDs should be regulated. Overall, responses suggested that there is a need for the EU to establish definitive criteria for EDs. Option 1 (no policy change, the interim criteria set in the PPP and BP Regulations continue to apply) was therefore not supported by the consultation.

Many respondents raised issues in relation to food safety, the threat that endocrine disrupting substances might pose to human health and/or the environment and the impact of the different options proposed in the roadmap on agriculture, industry, health and environment. In particular farmers and agri-business highlighted the potential high implications of setting criteria to identify EDs on agriculture. Authorities from non-EU countries stressed the potential impact on trade and noted that any decision on EDs must respect the principles of the World Trade Organisation. A risk-based approach for regulating EDs was proposed by many respondents who identified themselves as farmers, private companies, industrial or trade organisations, or authorities in non-EU countries. Many respondents supported the use of the WHO/IPC 2002 definition as a starting point for defining an ED.

The public consultation provided an overview of the type and size of impacts that may occur if a chemical would be identified as an ED, the methodologies that may be used to obtain this type of information and also data and references to studies and articles to be considered in the impact assessment. The outcome of the public consultation provided useful input for the impact assessment process that addresses the economic, environmental and health impacts of the different policy options.