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Committee on Sanitary and Phytosanitary Measures

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**REPORT ON 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**

COMMUNICATION FROM THE EUROPEAN UNION

The following communication, received on 1 October 2015, is being circulated at the request of the Delegation of the European Union.

1. This communication provides a summary of the report of the 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 which was launched by the European Commission in September 2014. The report was published on 24 July 2015 and is available on the website¹ of the Directorate General for Health and Food Safety of the European Commission.

2. In the European Union open public online consultations are systematically part of the consultation strategy for initiatives subject to impact assessments. A public consultation on defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and the biocidal products regulation took place from 26 September 2014 to 16 January 2015 by means of an on-line consultation questionnaire.

3. The usual consultation period (12 weeks) was extended by three weeks to provide interested stakeholders with sufficient time for comments. Submissions were accepted in any official EU language. Responses were received through the online questionnaire or via e-mails.

4. The public consultation generated over 27,000 responses. This illustrates the significant public interest in the EU's policy on endocrine disruptors. The submissions received online can also be found on the website² of the Directorate General for Health and Food Safety of the European Commission.

5. Respondents came from various parts of society and included doctors, farmers, non-governmental organizations, chemical, electronic, food and medical devices industry, water companies and scientists. This shows how widely these chemicals are used.

6. Submissions from individuals accounted for more than 90% of all the responses received. Of these individual responses, 88% came from seven EU member States, i.e. Austria, Denmark, France, Germany, Spain, Sweden and the United Kingdom.

7. 863 responses were made on behalf of an organization and 64% of them came from one EU member State, i.e. the United Kingdom. Almost 26% of responses on behalf of organizations came from industry or trade organizations and 5% from consumer/non-governmental organizations. Only two health institutions and hospitals responded. Three EU-governments as well as 18 EU public authorities have sent comments.

¹ http://ec.europa.eu/health/endocrine_disruptors/docs/2015_public_consultation_report_en.pdf.

² http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food/consultation_20150116_endocrine-disruptors_en.htm.

8. Six public authorities and six governments in non-EU countries sent their comments: the Australian Government, the Kenya Plant Health Inspectorate Service; the Norwegian Food Safety Authority, le Ministère de l'Agriculture de Côte d'Ivoire; the Government of Canada; Health Canada; Instituto Colombia Agropecuario (ICA); the Ministry of Agriculture, Livestock and Supply of Brazil; the Ministry for Primary Industries, Environmental Protection Authority and Ministry of Foreign Affairs and Trade of New Zealand; República Argentina and the United States Government.

9. The objective of this consultation was to gather information for the impact assessment on the establishment of criteria to identify endocrine disruptors. This objective was reached as there were many respondents that provided information. The public consultation generated a great deal of data consisting of scientific articles, studies, reports, views and legal opinions.

10. The opinions of respondents varied significantly on the options proposed in the road map³ for defining criteria for identifying endocrine disruptors and for approaches to regulatory decision making. The report provides an overview on the submitted arguments by respondents in favour or against the options as included in the roadmap. In general, respondents expressed diverging views on how to define criteria and how endocrine disruptors should be regulated. Overall, responses suggested that there was a need for the European Union to establish definitive criteria by the European Union for endocrine disruptors. The option of no policy change (the interim criteria set in the plant protection products and biocidal products regulations continue to apply) was therefore not supported by the consultation.

11. 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 endocrine disruptors on agriculture. Authorities from non-EU countries stressed the potential impact on international trade. A risk-based approach for regulating endocrine disruptors was proposed by many respondents who identified themselves as farmers, private companies, industrial or trade organizations, or authorities in non-EU countries. Many respondents supported the use of the WHO/IPC 2002 definition as a starting point for defining an endocrine disruptor. Authorities in non-EU countries noted that any decision on endocrine disruptors must respect the principles of the World Trade Organization.

12. The public consultation provided an overview on the type and size of impacts that may occur if a chemical would be identified as an endocrine disruptor, 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 impact assessment process that addresses the economic, environmental and health impacts of the different policy options.

³ http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf.