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Page: 1/2

Committee on Sanitary and Phytosanitary Measures Committee on Technical Barriers to Trade

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INFORMATION TO WTO MEMBERS ON THE LATEST DEVELOPMENTS ON ENDOCRINE DISRUPTORS

COMMUNICATION FROM THE EUROPEAN UNION

The following communication, received on 18 December 2017, is being circulated at the request of the Delegation of the <u>European Union</u>.

The European Union (EU) would like to inform WTO Members of the latest developments as regards the setting of scientific criteria to identify endocrine disruptors (EDs) in the context of the implementation of the plant protection products¹ and biocidal products² Regulations.

1 BACKGROUND

1.1. On 15 June 2016, two draft legal acts setting criteria to identify endocrine disruptors under the plant protection products and biocidal products Regulations were issued by the European Commission (Commission). Both proposals were notified to the WTO in notifications G/SPS/N/EU/166, G/TBT/N/EU/383 and G/TBT/N/EU/384. The EU reply to the comments received on the SPS notification was sent to all WTO Members on 24 February 2017. The EU replies to the comments received on the TBT notifications were sent to each commenting Member on 22 February 2017.

1.2. During the consultation and decision making process that took place after the publication of the draft legal acts the Commission introduced changes in the drafts taking into account the comments received from EU member States, stakeholders and non-EU countries. These changes were considered non-substantial compared to the texts notified to the WTO.

1.3. In December 2016, the draft Regulation setting criteria for identifying endocrine disruptors for plant protection products was split into two parts without any change in content: one text containing the criteria for identifying EDs, and the other containing a proposed amendment to the derogation possibility based on negligible exposure. This allows EU member States and colegislators (the European Council and the European Parliament) to express their opinion on each act separately and in sequence.

1.4. The draft act on the derogation possibility was put on hold until agreement is reached on the criteria by the EU co-legislators.

1.5. As reported by the European Union at the last SPS Committee meeting, the draft Regulation setting criteria for plant protection products was endorsed by EU member States on 4 July 2017 and was then subjected to the scrutiny of the co-legislators.

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24 November 2009, p. 1–50).

² Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27 June 2012, p. 1–123).

- 2 -

1.6. On 4 October 2017, the European Parliament objected to this draft Regulation on the basis that a specific provision related to active substances with an intended endocrine mode of action exceeded the Commission's implementing powers.

2 LATEST DEVELOPMENTS AND NEXT STEPS

2.1. At a meeting on 13 December 2017, EU member States endorsed a new version of the draft Regulation on setting criteria for plant protection products, recently proposed by the Commission, which takes into account the views of the European Parliament. The text endorsed does not differ significantly from the text notified to the WTO in 2016.

2.2. The endorsed draft criteria will now be sent to the co-legislators for their scrutiny. It will be eventually adopted by the Commission if there are no objections from any of these institutions.

2.3. As far as the proposed Regulation setting criteria to identify endocrine disruptors under the biocidal products Regulation is concerned, it was adopted on 4 September 2017 and following the completion of the scrutiny period of co-legislators, it was published on 17 November 2017 as Regulation (EU) $2017/2100^3$. The criteria entered into force on 7 December 2017 and will be applicable from 7 June 2018, including for substances still under evaluation at that time.

2.4. Finally, the European Union would like to report that the European Chemicals Agency and the European Food Safety Authority have launched a public consultation on the draft technical Guidance document to implement the criteria once they become applicable for biocides and pesticides. The public consultation is open until 31 January 2018 and WTO Members are invited to submit comments⁴.

2.5. The European Union remains committed to keeping its trade partners fully informed of further developments.

2.6. All relevant information on the matter is available on the Commission's website⁵.

³ Commission Delegated Regulation (EU) 2017/2100 of 4 September setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17 November 2017, p. 1–5).

⁴ <u>https://comments.echa.europa.eu/comments_cms/PC_ED_Guidance.aspx</u>.

⁵ http://ec.europa.eu/health/endocrine_disruptors/next_steps_en.