

Legal Opinion:

On the de-identification exemption included in the draft Commission criteria for the determination of endocrine disrupting properties and the proposed exemption for endocrine disrupting substances on non-vertebrates under Regulation 1107/2009 on the placing of plant protection products on the market

September 25, 2017

An endocrine disruptor is defined by the World Health Organisation as “an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.”¹ The definition also covers “potential” endocrine disruptors, defined as “an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations.”²

Endocrine disruptors are present in our daily life and may cause severe health conditions including diabetes, obesity, neurodevelopmental disorders, and reproductive disorders.³

Under Regulation 1107/2009 on the placing of plant protection products on the market (“Pesticides Regulation”), substances considered to have endocrine disrupting properties that may cause adverse effects in humans and on non-target organisms cannot receive approval.⁴ In order to identify which substances are considered to have endocrine disrupting properties, the European Commission (the Commission) was given a mandate to present “a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties” by December 14, 2013.⁵ The criteria must be adopted in accordance with the regulatory procedure with scrutiny mentioned in Article 79(4) of the Pesticides Regulation.⁶ Pesticides Regulation contains provisions regulating active substances, safeners, and synergists that may have endocrine disrupting properties.

¹ World Health Organization/International Programme on Chemical Safety (WHO/IPCS), 2002. Global Assessment of the State-of-the-science of Endocrine Disruptors. WHO/PCS/EDC/02.2, p. X, http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/

² *Ibidem*.

³ EFSA Scientific Committee, Scientific Opinion on the hazard assessment of endocrine disruptors: Scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment, p.9.

World Health Organization/International Programme on Chemical Safety (WHO/IPCS), 2002. Global Assessment of the State-of-the-science of Endocrine Disruptors. WHO/PCS/EDC/02.2, p. 36, p. 59, p.112, http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/

⁴ Articles 3.6.5 and 3.8.2 of Annex II of Pesticides Regulation.

⁵ Subparagraph 2, Point 3.6.5 Annex II Pesticides Regulation.

⁶ *Ibidem*.

On July 4, 2017, the Standing Committee on Plants, Animal, Food and Feed (SC PAFF) meeting endorsed the European Commission's proposed criteria⁷ for the determination of endocrine disrupting properties.⁸ The Commission notified the European Parliament and Council of the criteria on July 21 and July 20, 2017, respectively.⁹

Should they wish to do so, members of the European Parliament and Council have 3 months after the date of notification to oppose this Commission proposal. The criteria can only be opposed on the following three grounds:

- (1) if they exceed the implementing powers provided for in the basic instrument;
- (2) if the draft is not compatible with the aim or the content of the basic instrument; or
- (3) if the draft does not respect the principles of subsidiarity or proportionality.¹⁰

The Council approved the draft criteria on September 13.

The submission of the criteria may appear to be a step towards the identification of endocrine disruptors and their regulation on the market, but the proposal raises serious concerns in relation to their fitness for purpose and should lead the European Parliament to oppose the Commission proposal on the following grounds:

- An exemption included in the draft criteria exceeds the Commission's implementing power.
- This exemption renders the criteria incompatible with the aim of the basic instrument.¹¹

⁷ SANTE-2016-12020-REV 4 C(2016) 3751 projet Draft Commission Regulation (EU) .../... of XXX amending Annex II to Regulation (EC) 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties ("the criteria").

⁸ "21 MS representing 72.35% of the population voted in favour of the text" Extract from the Summary Report of the SC PAFF held in Brussels on 4 July 2017,

https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/20170704_paff_sum_en.pdf

⁹ Notification for the Commission Regulation (EU) .../... of XXX amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties, No 11470/17, and Annex to the Commission Regulation (EU) .../... amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties, No 11470/17 ADD 1.

¹⁰ Article 5(a) para (3)b, Decision 1999/468/EC.

¹¹ Regulation N°1107/2009 of the European Parliament and 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 (Pesticides Regulation), Article 1.3.

Has the Commission exceeded its implementing powers?

1. Under the very last paragraph of the Commission's proposal, the proposed criteria specify that: "[i]f the intended plant protection mode of action of the active substance being assessed, consists of controlling target organisms other than vertebrates via their endocrine systems, the effects on organisms of the same taxonomic phylum as the targeted one, shall not be considered for the identification of the substance as having endocrine disrupting properties with respect to non-target organisms."¹²
2. Specific endocrine effects are thus deliberately excluded from the considerations to identify substances having endocrine disrupting properties. As a result, substances demonstrating clear and intentional endocrine mode of action are automatically exempted from being recognized as substances having endocrine properties, without proper scientific justification. This paragraph, which is an integral part of the criteria to identify endocrine disruptors proposed by the Commission, preventively exempts substances with endocrine disrupting properties from identification and is routinely referred to as a de-identification exemption.
3. The presence of such an exemption in the proposed criteria for the identification of endocrine disruptors raises concerns about whether the Commission is exceeding its implementing powers provided for in the Pesticides Regulation.
4. The Commission has a mandate to present "a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties."¹³
5. The mandate is framed by procedural rules for amendments under Article 78.1 (a) of the Pesticides Regulation, enabling the amendment of "non-essential elements" of the Regulation.
6. The identification of a substance as having endocrine disrupting properties carries important consequences for the approval process, as such substances cannot receive approval pursuant to the Pesticides Regulation (except in limited circumstances set in the Regulation).¹⁴
7. By unilaterally exempting certain substances with endocrine mode of action from being identified as substances with endocrine disrupting properties, the proposed criteria therefore modify the conditions of approval of such substances.
8. Approval criteria for active substances are included in the "subject matter" of the Pesticides Regulation¹⁵ and should therefore be considered "essential" elements of the regulation. The procedure for adopting criteria does not allow the modification of essential elements of the

¹² Point (2) paragraph 3, of the Proposed Commission Regulation to amend Point 3.8.2. Annex II to Regulation (EC) No 1107/2009. Emphasis added.

¹³ Subparagraph 2, Point 3.6.5 Annex II Pesticides Regulation.

¹⁴ Article 3.6.5 and 3.8.2 Annex II Pesticides Regulation.

¹⁵ Article 1 Pesticides Regulation.

regulation. A change of essential elements of the Pesticides Regulation can only be introduced via ordinary legislative procedure.¹⁶

9. The exemption proposed in the last paragraph of the criteria therefore interferes with the scope of substance approval of the Pesticides Regulation and goes beyond the Commission's mandate to present "measures concerning specific scientific criteria for the determination of endocrine disrupting properties."¹⁷
10. It follows that the proposed criteria exceed the implementing powers provided for in the Pesticides Regulation and should therefore be opposed.

Are the criteria compatible with the aim and content of the Pesticides Regulation?

1. In order to assess compatibility one must consider Article 1 and Recital 8 of the Pesticides Regulation.
2. According to Article 1, the Pesticides Regulation aims at ensuring "a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving the agricultural production".¹⁸
3. Recital 8 indicates that "the purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment."
4. The combination of these provisions read in light of the jurisprudence from the European Court of Justice in case *S.P.C.M. SA and Others v. Secretary of State for the Environment*,¹⁹ indicates the prominence of the first of those three objectives, namely to ensure a high level of protection of human health and the environment.
5. The exemption described in Section 1 above allows for continued environmental exposure of substances with endocrine disrupting properties for invertebrates, which is inconsistent with a high level of protection of animal health and the environment mandated by Article 1 of the Pesticides Regulation.

¹⁶ Article 298 of the Treaty of the Functioning of the EU.

¹⁷ Subparagraph 2, Point 3.6.5, and 3.8.2 Annex II Pesticides Regulation.

¹⁸ Article 1.3 Pesticides Regulation.

¹⁹ Case C-558/07 on the application of S.P.C.M. SA C.H. Erbslöh KG, Lake Chemicals and Minerals Ltd and Hercules Inc. v Secretary of State for the Environment, Food and Rural Affairs.

6. The exemption, which forms an integral part of the Commission's proposed criteria, also appears to be incompatible with the aim of the Pesticides Regulation and should therefore be opposed.

Conclusion

The criteria proposed by the Commission exceed the implementing powers given to the Commission and are incompatible with the aim and content of the basic instrument (the Pesticides Regulation) and should thus be opposed.

Opposing this proposal would force the Commission to propose other criteria that do not exceed its powers and are compatible with the aim and content of the Pesticides Regulation.