



Brussels, 14 February 2017

To: Mr Frans Timmermans, European Commission First Vice-President

Cc: Mr Vytenis Andriukaitis, European Commissioner for Health and Food Safety

Subject: Call to implement Better Regulation principles in EU action on Endocrine Disrupting Chemicals

We are contacting you about Better Regulation issues in the EU's policy on Endocrine Disrupting Chemicals. First, we would like to express our appreciation to the European Commission for its stated commitment to "*listen to the European Parliament, listen to all Member States, and listen to the people*" (1). The harm caused by endocrine disrupting chemicals ("**EDCs**") on EU citizens' health and their environment is one of these "big problems" that the European Commission has been mandated to tackle as early as 1998 (2). However, although laws and policies adopted since then show the EU institutions have been trying to address EDCs, citizens continue to be concerned and scientists continue to sound the alarm (3) (4) (5) (6):

The Commission's proposals for criteria to identify EDCs, as required by the Pesticides and Biocides Regulations, are a necessary first step towards better protecting citizens and the environment from these harmful substances. However, because the proposals are currently at odds with the founding principles of Better Regulation, which aims at ensuring that the EU *delivers high quality legislation*, we bring the following concerns to your attention:

- (1) **NOT EFFICIENT NOR COHERENT: The Commission is not adhering to existing EU political commitments for horizontal identification criteria enshrined in the Seventh Environment Action Programme (7), commitments which were recently reaffirmed by Council conclusions (8).** Currently the proposed identification criteria are only designed to work specifically for and in the Pesticides and Biocides Regulations (see Annex).
- (2) **NOT EFFECTIVE: The Commission proposal on derogation conditions changes the overall Risk Management balance between protection and competitiveness enshrined in the Pesticides Regulation for EDCs and thereby exceeds the Commission's legal mandate:** the Commission was required to adopt scientific criteria to *identify* EDCs, not to soften the conditions for *approval* of EDCs in pesticides (see Annex).
- (3) **NOT BASED ON EVIDENCE: The Commission is using a misinterpretation of science to justify changing the overall Risk Management balance.** The Commission's justification to make a change to the derogation conditions for pesticides' authorisation is actually based on a flawed selective reading of the EFSA Scientific Opinion (see Annex).

(4) **NOT COHERENT: The Commission's criteria proposal is inconsistent with international practices in chemicals classification** which jeopardises the adoption of harmonised criteria worldwide and thus creates further uncertainty for businesses and policy makers (see Annex).

(5) **NOT TRANSPARENT: There is insufficient transparency and openness** in the recent amendments made to the initial proposed criteria text. Substantial changes in the identification criteria have been made that lack any publically available scientific reasoning or justification and make it a daunting task for stakeholders to follow the process and the impacts of such major changes (see Annex).

As they stand now, the proposed criteria to identify EDCs are a **perfect counter-example of Better Regulation**. That is why, **we call on you**, as First Vice-President of the European Commission, in charge of coordinating the work on Better Regulation and the rule of law, and ensuring horizontal responsibility for sustainable development, **to act to "break down silos" and adhere to existing EU political commitments** (9). Your action within the Commission to ensure better EDC criteria can send a strong signal to European citizens about what Better Regulation can and ought to be on the big things that concern them, protecting people's health and the environment from harmful chemicals.

Yours sincerely,

Genon K. Jensen, Health and Environment Alliance (HEAL) Executive Director on behalf of the **EDC-Free Europe** NGO coalition

Jorgo Riss, Greenpeace European Unit Director on behalf of **the Green 10** as current Chair

EDC-Free Europe is a coalition of more than 70 environmental, health, women's and consumer groups across Europe who share a concern about endocrine disrupting chemicals (EDCs) and their impact on our health and wildlife.

The **Green 10** are ten of the largest environmental organisations and networks active on the European level. They coordinate joint responses and recommendations to EU decision makers. Membership of the Green 10 alone is more than 20 million people.

Annex:

1. **The Commission is not adhering to existing EU political commitments for *horizontal* identification criteria** enshrined in the Seventh Environment Action Programme (10), commitments which were recently reaffirmed by Council conclusions (11). Currently the Commission's proposed criteria are only designed to work specifically for and in the Pesticides and Biocides Regulations. As explained in the EDC Criteria Roadmap (12),

one of the challenges that the Commission is meant to overcome is to set identification criteria **workable under all the relevant EU legislation**. With the current proposal, EDCs may be identified inconsistently depending on the applicable legislation. But the Commission has so far refused to establish a ranking system with categories consistent with the identification of CMRs. This is despite the fact that such a ranking would allow coherent *identification* of EDCs irrespective of the applicable law and thus irrespective of the sector. In addition, in December the Commission reformulated the criteria to exempt from identification a group of EDCs that relates solely to pesticide and biocide uses, and runs counter to the commitment to 'horizontal' criteria. If the Commission believes that a group of chemicals needs to be exempted from the authorisation prohibition, it should propose a derogation in the basic acts applicable to the relevant sector (here the Pesticides Regulation).

2. **The Commission's proposal concerning the Pesticides derogation contradict the will of the co-legislators by exceeding the Commission's legal mandate** which was limited to setting scientific *identification* criteria. The Commission proposes to amend the conditions of *approval* of EDCs in pesticides by widening the derogation from the prohibition on EDCs in the Pesticides Regulation, thereby weakening the health and environmental protection from EDCs that the 'cut off conditions' were designed to deliver. The terms of the original derogation form part of the **risk management** measures adopted democratically by the co-legislators, and have nothing to do with setting scientific criteria for **identification** of EDCs, and therefore the proposal exceeds the Commission's legal mandate (13).
3. **The Commission is using a misinterpretation of science to justify changing Risk Management measures**. The Commission's justification for changing the derogation conditions for pesticides' authorisation is based on a flawed selective reading of the EFSA Scientific Opinion. The Commission argues that a legal article in the Pesticides Regulation which permits adjustments according to "current scientific and technical knowledge" enables them to change the conditions of approval for pesticides with Endocrine Disrupting properties. But the European Food Safety Authority ("EFSA") (14) **does not provide any new scientific and technical knowledge**. The EFSA Opinion merely sets out, as context, what the well-known science of "Risk Assessment" entails. Changing the conditions of approval for pesticides with Endocrine Disrupting properties in actual fact constitutes a change to the Risk Management measures set by the co-legislators. The EFSA Opinion **even acknowledges that risk management considerations are "beyond the scope of [its] opinion"** (15). Therefore the EFSA Opinion cannot be used to make a change to Risk Management measures adopted democratically by the co-legislators (16).
4. **The Commission's proposal creates inconsistencies with international practices in chemicals classification**. The United Nations Globally Harmonised System of Classification and Labelling of Chemicals ("GHS"), on which EU classification of chemicals is based, identifies chemicals not only on the basis of their "hazard class" (e.g. carcinogenicity), but also ranks them according to the strength of evidence available (i.e. "hazard category") to facilitate harmonizing classifications between countries and between sectors. Thus legislators can choose the hazard classes and categories to set the desired level of protection for the various populations (e.g. workers, children, general population). Because EDCs are not yet covered by the GHS system, the Commission needed to draft criteria for identification that could then be ratified worldwide. The current approach however, by failing to define categories, impedes international harmonisation and will thus create uncertainties both for businesses and policy makers.
5. **There is insufficient transparency and openness** in the recent amendments made to the initial proposed criteria text. Substantial changes have been made without the publication of any scientific reasoning or

justification and this makes it a daunting task for stakeholders to follow the process and the impacts of such major changes. One substantial change seems to directly exempt from identification a whole class of endocrine disruptors without plausible scientific justification (17). This addition also confuses identification with risk management: if the Commission believes that a group of chemicals needs to be exempted from being banned, it should add derogations in the basic acts, if scientifically justified.

Notes:

- (1) Speech, "2016 State of the Union", September 2016, SPEECH/16/3043.
- (2) European Parliament Resolution on Endocrine Chemicals (OJ C 341, 9.11.1998, p. 37).
- (3) e.g. the 7th Environmental Action Programme, the Pesticides Regulation 1107/2009 and the Cosmetics Regulation, among others.
- (4) Eurobarometer: http://ec.europa.eu/public_opinion/archives/ebs/ebs_416_en.pdf; also the very high public participation rates in the Public Consultation on the EDC criteria finishing in January last year, see: http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food/consultation_20150116_endocrine-disruptors_en.htm#CD.
- (5) A. C. Gore, V. A. Chappell, S. E. Fenton, J. A. Flaws, A. Nadal, G. S. Prins, J. Toppari, R. T. Zoeller, 2015, EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals; 36 (6):E1-E150. See: <https://www.ncbi.nlm.nih.gov/pubmed/26544531>.
- (6) World Health Organization, United Nations Environment Programme (WHO-UNEP), 2012, In: Bergman, A., Heindel, J.J., Jobling, S., Kidd, K.A., Zoeller, R.T. (Eds.), State of the Science of Endocrine Disrupting Chemicals. See: <http://www.who.int/ceh/publications/endocrine/en/>.
- (7) Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet'.
- (8) The Council "NOTES the Commission Communication accompanying its proposal for scientific criteria to identify Endocrine Disruptors; CALLS UPON the Commission to comply with the relevant 7th EAP provisions 19 when further developing those criteria in order to better protect humans and the environment from endocrine disruptors; and INVITES the Commission to subsequently update as appropriate the 1999 EU endocrine disruptors strategy", Council Conclusions of 19 December 2016, 15673/16.
- (9) Speech, 17 September 2015, "Remarks by First Vice President Timmermans at the European Parliament's Plenary Session on 16/09/2015 concerning the UN Sustainable Development summit and development-related aspects of COP 21".
- (10) Decision No 1386/2013/EU of the European Parliament and of the Council of 20 November 2013 on a General Union Environment Action Programme to 2020 'Living well, within the limits of our planet'.
- (11) The Council "NOTES the Commission Communication accompanying its proposal for scientific criteria to identify Endocrine Disruptors; CALLS UPON the Commission to comply with the relevant 7th EAP provisions 19 when further developing those criteria in order to better protect humans and the environment from endocrine disruptors; and INVITES the Commission to subsequently update as appropriate the 1999 EU endocrine disruptors strategy", Council Conclusions of 19 December 2016, 15673/16.
- (12) Roadmap "Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation", 06/2014; available at: http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf (see page 4).
- (13) As found by the Legal Service of the European Parliament.
- (14) Proposal amending points 3.6.5. and 3.8.2. of Annex II to Regulation (EC) 1107/2009 taking into account current scientific and technical knowledge, Explanatory Memorandum, Recital 3.
- (15) "Scientific Opinion on the hazard assessment of endocrine disruptors" EFSA Journal 2013; 11(3):3132; available at: <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3132/epdf> (see page 10 and 43).
- (16) As acknowledged by the Legal Service of the European Parliament.
- (17) The proposed exemption: http://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/ppp_criteria_en.pdf.