EUROPEAN COMMISSION

Chief Scientific Adviser to the President

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Dear Professor Dekant

I refer to your open letter to me which I received on 17th June and I apologise again for the delay in responding to you. As I was not consulted by the Commission services during the review of the regulation on endocrine disrupting chemicals, it was necessary for me to talk with a number of people to be able to address the points you raised in your letter. I have based my response heavily on the information provided to me by my Commission colleagues.

It is also important for you to know that in the meantime other scientists, including Professors Åke Bergman, Ulla Hass, Susan Jobling, Andreas Kortenkamp and Jorma Toppari as well as the Collegium Ramazzini have written letters to me on the matter, indicating to me both the consensus, but also the differing views in the scientific community on endocrine disrupting chemicals.

I would like to make the following specific comments in response to the questions you raised in your letter. I have used italics where I have quoted directly from a Commission service.

In your letter you query whether scientific evidence has been taken into consideration as part of the Commission's review of endocrine disrupter regulation.

I have made enquiries within the Commission regarding the evidence gathering procedure and have received the following response:

DG Environment firstly commissioned a study "State of the art assessment of endocrine disruptors". The study was performed by Prof. Kortenkamp and his team and provided a scientific review of the last 10 years research in the area of endocrine disruptors, an overview of the assessment methods for endocrine disruptors proposed by the Member States and stakeholders, and formulated policy relevant conclusions and recommenda-

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tions. The review focused on the last 10 years, as in 2002 the WHO prepared a state of the art report and the main intention of the Commission study was to determine what advances had been made since the 2002 WHO report. The study was published on the DG ENV website at the end of 2011[1]. The comments received from Member States experts, Commission services and stakeholders on the draft final review were considered in preparation of the final report.

Secondly, DG Environment organised a conference on endocrine disruptors in June 2012 to hold an open and transparent dialogue with all stakeholders[2]. The conference was attended by approximately 300 participants from Member States authorities (both risk assessors and regulators), Commission Services and EU Agencies, academic scientists and representatives of industry associations, non-governmental organisations and unions. The conference concluded that sufficient science had been gathered to start working on regulatory options addressing the concerns of Endocrine Disruptors. For academic scientists the Commission organised a special side event 'Looking Forward to the Next 10 Years of Endocrine Disruptor Research: Challenges and Opportunities', with the aim of identifying research needs in the field.

Thirdly, to provide an open and transparent forum for information exchange on endocrine disruptors and to get orientation on various aspects of endocrine disruptors, DG Environment established in 2011 two consultation groups. One group, the 'ad hoc group' of Commission Services, EU Agencies and Member States, focused on policy issues, was chaired by DG ENV and consisted of policy experts. Representatives of industry associations and non-governmental organisations were invited as observers. The other group, the Endocrine Disruptors Expert Advisory Group, was set up as the sub-group of the 'ad hoc group' to provide detailed reflections on scientific issues relevant to endocrine disrupting substances, not specific to any regulatory framework, including advice/orientation on scientific criteria for the identification of endocrine disrupting substances. The expert advisory group was composed of toxicologists and ecotoxicologists with regulatory and/or endocrinology backgrounds, nominated by the Member States' Competent Authorities for REACH and the Plant Protection Products Regulation (Standing Committee), relevant industry associations and non-governmental consumer/environmental protection organisations. Representatives of relevant Commission services and EU Agencies were invited to attend the meetings as observers. The Commission's Joint Research Centre facilitated and chaired the meetings of the sub-group and prepared the final reports. The final report capturing the experts' opinions on key scientific issues relevant to the identification of endocrine disrupting substances was published in March 2013[3] and the report capturing the experts' opinions on thresholds for endocrine disruptors and related uncertainties has been finalised in June 2013 and is currently awaiting publication.

In addition to these three main activities, the Commission also requested or got input from additional sources. EFSA's Scientific Committee, which worked in cooperation with other agencies (EEA, EMA and ECHA), the Commission's Scientific Committees and the Joint Research Centre, were asked to provide advice on the definition, criteria and methodologies to identify endocrine disrupting chemicals. The opinion was published in March 2013[4]. Furthermore, the Commission asked the European Chemicals

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[1] http://ec.europa.eu/environment/endocrine/documents/studies_en.htm

[2] http://ec.europa.eu/environment/endocrine/index_en.htm

[3] http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/endocrine_disrupters/jrc-report-scientific-issues-identificationendocrine-disrupting-substances

[4] http://www.efsa.europa.eu/en/efsajournal/pub/3132.htm

Agency to estimate the costs and benefits associated with the possible change of authorisation route under REACH to feed into the impact assessment accompanying a possible proposal to amend REACH in the light of the outcome of the review referred to above.

In addition to these Commission-led activities, regulatory agencies of Germany, the United Kingdom, Denmark and France as well as industry associations and non-governmental organisations made their own proposals for criteria for identification of endocrine disruptors. Finally, in the course of the Commission work, several authoritative studies summarising the state of the science on endocrine disruptors became available and provided further input to the Commission's work.

These included:

- *a technical report of the European Environment Agency (EEA) with an assessment of the impacts of endocrine disruptors on wildlife, people and their environment*[5]*;*
- *a draft detailed review paper of the OECD on the state of the science on novel in vitro and in vivo screening and testing methods and endpoints for evaluating endocrine disruptors;*
- *a report of the WHO on possible developmental early effects of endocrine disruptors on child health*[6]*, and,*
- *a joint report of the UNEP/WHO and the Inter-Organisation programme for the sound Management of Chemicals (IOMC) on the State of the Science of Endocrine Disrupting Chemicals – 2012*[7] *and its Summary for Decision-Makers*[8]*.*

DG Environment stated that they used this input to develop a draft review of the existing strategy, a draft of a new strategy and draft criteria for identifying endocrine disruptors.

Therefore, in my view, the Commission services have consulted with a broad range of scientific authorities and experts on this issue in order to gather an evidence base.

You state that you feel that critical elements of EFSA's opinion were ignored by the Commission.

I have asked DG Environment if that was the case and they said that it was not. DG Environment stated that "*EFSA's opinion was followed and the proposed criteria developed by them are fully in line with the EFSA's opinion. The exact wording of the criteria is still under discussion among the relevant Commission services.*" At the time of writing this letter, I have not been able to consult with EFSA on this issue.

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[5] EEA Technical Report No 2/2012, The impacts of endocrine disrupters on wildlife, people and their environments, The Weybridge +15 (1996-2011) report

[6] Possible developmental early effects of endocrine disrupters on child health, World Health Organisation 2012, ISBN 978 92150376 1

[7] State of the Science of Endocrine Disrupting Chemicals – 2012, United Nations Environmental Programme and the World Health Organisation, 2013, ISBN 978-92-807-3274-0, http://unep.org/pdf/9789241505031_eng.pdf

[8] State of the Science of Endocrine Disrupting Chemicals – 2012, Summary for Decision-Makers, United Nations Environmental Programme and the World Health Organisation, 2013

You ask why the Commission's Scientific Committees have so far not been consulted when drafting the regulation.

As regards criteria for identification of endocrine disruptors, the Commission has consulted EFSA's Scientific Committee which worked in cooperation with other EU Agencies (EEA, EMA and ECHA), the Commission's Scientific Committees and the Joint Research Centre. DG Environment also stated that several opinions over the past years from EU Agencies or Scientific Committees were related to or covered areas of endocrine disruption. These opinions also have been considered by DG Environment.

DG Environment stated that they have identified three main issues of on-going uncertainty in the area of endocrine disruptors:

1. *Non-linear Dose Response Curves*: DG Environment is of the view that there is no doubt that non-linear dose response curves exist for some chemical substances, but there is a scientific debate on the importance of this phenomenon for endocrine disrupting chemicals.
2. *Thresholds*: There is a scientific debate on whether substances having endocrine disrupting effects can be seen as having a threshold or not.
3. *Potency and related considerations*: There is a debate on whether to include potency and some related considerations into the criteria or leave them out of the criteria.

DG Environment considers the two first issues as being scientific and do not expect this uncertainty to be resolved over the next year. Given this controversy, DG Environment proposes in its draft new strategy to focus research on these two topics. The draft criteria which DG Environment has developed are, in their view, not affected by this scientific debate, as the criteria are evidence-based, are to be applied on a case-by-case basis and do not treat substances differently depending on the presence or absence of non-linearity or thresholds.

I invite you to comment on whether you are in agreement with the statement of these three areas of uncertainty.

You raise the concern that a departure from existing principles – in particular the definition of safe thresholds for substances that are classified as endocrine disruptors, i.e. going from a risk to a hazard-based assessment – is intended.

DG Environment states that this is not correct.

However, although I accept the statement from DG Environment that existing legislation contains both hazard- and risk-based provisions for endocrine disruptors, they also state that "*they are working on the development of scientific criteria for identification of endocrine disruptors, which are criteria for identification of an intrinsic property of a substance and are therefore based on hazard identification and not on risk assessment. The Commission is required to develop these criteria by December 2013 under the Regulation for Plant Protection Products and under the Regulation for Biocidal Products. However, horizontal criteria applicable across all relevant legislation are needed to ensure a harmonised and coherent way in dealing with endocrine disruptors and to ensure legal coherence and certainty, regulatory consistence, and predictability to all players.*"

The evidence base for this approach is not clear to me and I will be discussing this matter further with colleagues in the Commission.

For your information, in support of their approach, DG Environment states "*At the same time, we are working on reviewing the authorisation routes (adequate control or socioeconomic) applicable to endocrine disruptors to gain an authorisation under REACH and whether authorisation of such chemicals should be granted using the socio-economic route only. Currently if the substance is considered to be an endocrine disruptor for which it is possible to establish a threshold value, the use of the substance can be authorised via the so called adequate control route. If no threshold value can be established or in case an authorisation cannot be granted because the risk is not adequately controlled, an authorisation may only be granted via the so-called socio-economic route. The scope of the review is to evaluate whether all substances that are identified under REACH as having endocrine disrupting properties are to be subject to the authorisation procedures via socio-economic route irrespective of whether or not they have a threshold, based on the latest developments in scientific knowledge. The argumentation being considered in the review is based on the knowledge on the functioning of the hormonal system, based on the uncertainties related to the determination of safe threshold and based on socio-economic considerations.*"

Although the Commission was required to perform the review by 1 June 2013, the work and consultations are still on-going and DG Environment and DG Enterprise and Industry have not yet communicated their views externally.

You raise the issue whether the intended legislation would allow classifying a substance as endocrine disruptor based on *in vitro* tests only.

DG Environment state that this is not the case and say that *"it is not correct that the intended criteria developed by DG Environment have this effect – however the current legal requirements in Biocides and Plant Protection Products are interpreted by some to allow such a classification. The proposed criteria define endocrine disruptors using a WHO/IPCS definition. According to this definition, an endocrine disruptor "is 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." This definition requires that endocrine disruptors are defined by three criteria:*

i) an adverse effect in an intact organism or a (sub)population;

ii) an endocrine activity; and

iii) a biological plausible causal relationship between the two."

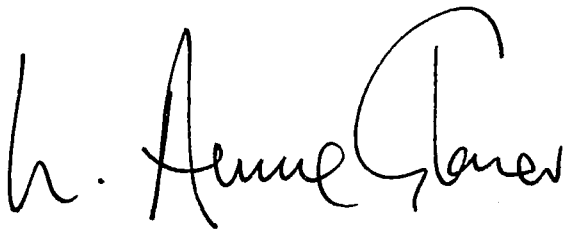
In my view, adherence to the above criteria will not allow classifying a substance as an endocrine disrupter based on *in vitro* tests only.

I hope that this letter addresses your concerns. In my view it is evident that policy-makers are operating here in an area where there is still some significant scientific uncertainty which makes it all the more important to be able to gather evidence from opposing points of view and to reflect these in any change in regulation.

I have offered my own services to Commission colleagues to help in outlining scientific consensus on the matter to try and ensure that any change in regulation is evidence-based.

I hope I can count on your support as well as that of the other scientists that have written to me.

Yours sincerely



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