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## STEFANOVA Desislava (ENTR)

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**From:** [REDACTED]@cefic.be>  
**Sent:** 25 June 2013 10:54  
**To:** GIRAL-ROEBLING Anne (ENTR)  
**Subject:** Letter To Commissioner Potocnik  
**Attachments:** Cefic DG letter to Mr. J. Potocnik re Endocrine Disruptors 24 06 2013.pdf; ED Criteria - Cefic Position.pdf

Dear Anne,

As mentioned last week, Cefic has decided to send a letter to Commissioner Potocnik expressing our thinking about Endocrine Disruptors and requesting that a formal Impact Assessment should be undertaken.

The letter has been sent to Mr. Calleja-Crespo for information. If you have any questions, just let me know.

Best regards,

[REDACTED]

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Director General

Mr. Janez Potočnik  
European Commission  
Commissioner for Environment  
Rue de La Loi 200  
B- 1049 Brussels

24 June 2013

## Community Strategy and Criteria for Identifying Endocrine Disruptors

Dear Commissioner Potočnik,

I am writing to raise our serious concerns regarding the approach that your service is taking on the above issue.

Our industry is committed to ensuring that people and the environment are not harmed by exposure to endocrine disrupting substances. To that end, we have been seeking a constructive dialogue with your services and to work with them to develop a coherent regulatory approach to this issue.

Unfortunately, your service appears to have become fixed on a particular proposal without engaging in any meaningful consultation.

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Moreover, your service continues to ignore the scientific opinion of EFSA, and the views of an increasing number of Member States – including the UK, Germany and Italy. We maintain that the technical criteria for identifying endocrine disruptors should be based on evidence and science and not on conjecture and ideology.

I believe that if this ideological blockage could be removed there are no insurmountable obstacles to developing a strategy, and criteria for the identification of endocrine disruptors, that would safeguard people and the environment while commanding the support of all stakeholders.

To this end, I attach a short paper setting out some ideas as to how this matter might be progressed: and would ask you to give these your serious consideration.

Getting this right is of the utmost importance to our industry. Put simply, criteria based on subjective or uncertain grounds will undermine our industry's ability to set the direction for future research, innovation and trade. In the event that you decide to press on with the current proposals, we urge you to undertake a full impact assessment in order to properly evaluate the implications and consequences of doing so.

Yours sincerely,

Chemistry making a world of difference

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## Defining Criteria for Endocrine Disruptors

### Background

DG Environment is currently finalising a proposal for a set of scientific criteria for identifying endocrine disruptors. It is understood that this will be submitted for inter-service consultation at the end of June 2013, and that the horizontal criteria will be used to identify endocrine disruptors for potential regulatory action.

The underlying purpose of all these Regulations is to ensure that people and the environment are protected from exposure to harmful substances. However, the different wording and approach in the various Regulations means that particular care will be needed in establishing and applying criteria horizontally across them to ensure a consistent and coherent Regulatory framework.

It is foreseen that the scientific criteria for the identification of endocrine disruptors are to be applied equally and consistently across all relevant EU regulations, including Article 57(f) of Regulation 1907/2006 (REACH), Paragraph 3.6.5 of Annex II to Regulation 1107/2009 (PPPR), Article 5(1)(d) of Regulation 528/2012 (BPR), and Regulation 1223/2009 (The Cosmetics Regulation).

### Categorisation

Despite the fact that the criteria under discussion are intended to identify or define endocrine disruptors, the discussion to date has focused on the categorisation of endocrine disruptors once they have been identified.

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Industry does not support DG ENV's proposal for categorisation, which follows substantially the same approach that is adopted under the GHS for known adverse effects. In doing so, the Commission appears to assume that all the substances under consideration comply with the definition of endocrine disruptor and to ignore the need to first identify whether a substance is or is not within the WHO/IPCS definition (see further below).

This allocation to categories is not required by any of the above mentioned Regulations – and does not provide, for example, “specific scientific criteria for the determination of endocrine disrupting properties” as required by Regulation 1107/2009 (PPPR).

### Criteria

The approach of the Commission sets out criteria for putting substances into the proposed categories but does not permit any differentiation between substances on the basis of their properties or of their effects. The proposed criteria are based on the quality and nature of the scientific evidence. This approach creates “categories of evidence” but it does not identify “categories of endocrine disruptor”.

Moreover, the criteria that have been suggested by the Commission during this consultation indicate an intention to sort substances into categories by reference to “predicted” and “suspected” effects. Such speculation is neither necessary nor sufficient to permit the effective identification of endocrine disrupting properties; nor is it an adequate basis for sound regulation.

It is, therefore, necessary to reconsider the defining criteria for endocrine disruptors.

## **Emerging consensus for criteria defining Endocrine Disruptors**

### **Definition**

There is a **consensus that the identification of a substance as an endocrine disruptor should be based on the WHO/IPCS definition**, which states that an endocrine disruptor is a *“substance or mixture that alters function(s) of the endocrine system and consequently causes adverse effects in the intact organism, or its progeny, or (sub)-populations”*.

There are three elements to this definition:

- there must be an *adverse effect* in the intact organism;
- there must be an *endocrine mode of action*;
- there must be a *causal link* between the two.

To determine whether a substance falls within this definition of an endocrine disruptor, “defining criteria” should allow the regulator to determine whether these three elements are present. For example, given the almost limitless number of ways in which a substance might interact with the endocrine system it would be misleading to assume that all these possible effects are “adverse”. Therefore, the identification of “endocrine disruptors” requires criteria for the identification of “adversity” (See Annex 1 for definition of ‘adversity’).

### **The Scientific Criteria Proposed by DG ENV**

The ideas tabled by DG Environment in the current consultation do not provide defining criteria for endocrine disruptors, as outlined above, for two reasons:

- (a) In mirroring the approach taken under the GHS they assume a specific, clearly defined adverse effect. However, before that approach could be applied it would be necessary to introduce a clear definition of “endocrine disruption”; and when one tries to do so it becomes clear that the range of possible effects is too broad to permit a simple classification.
- (b) The approach turns on the quality and nature of the evidence and not on the properties of the substance or the nature of the effect.

In short, that approach does not assist in determining whether a substance is an endocrine disruptor because the categorisation assumes it.

### **A Way Forward Towards Sound Regulation**

The fundamental objective of the future ED regulatory framework is to ensure that people and the environment are not exposed to substances which could cause them harm.

The criteria for identifying endocrine disruptors should therefore enable authorities and manufacturers to adopt the appropriate and proportionate measures to ensure that people do not suffer harm from exposure to endocrine disruptors. In this regard, all parties endorse the need for a systematic and transparent set of criteria, based on the weight of evidence, to clearly identify those substances that can produce adverse effects via an endocrine mode of action.

Scientific criteria for the identification of endocrine disruptors should respect the principle of legal certainty, which requires a clear determination as to whether a substance is, or is not, an endocrine

disruptor; and the principle of proportionality, which requires the regulatory consequences to be proportionate to the risk of adverse effects.

## Hazard Assessment

“Hazard identification is only the first step of hazard assessment, with hazard characterisation being the next...”<sup>1</sup> Thus, hazard characterisation is an essential element in a full hazard assessment, and is necessary in order to fully interpret and apply the WHO/IPCS definition as a basis for European regulation. It will focus regulatory actions on substances that could pose a significant risk of harm to people or the environment and ensure a proportionate regulatory response.

A growing number of stakeholders (including EFSA, JRC, some Member States and the European Parliament) have indicated that determining whether a substance is an endocrine disruptor will require a **comprehensive hazard assessment**, which requires both “**hazard identification**” and a “**hazard characterisation**”.<sup>2</sup> The former considers the adverse effect caused by exposure. The latter considers the severity of the possible effect, its (ir)reversibility, and the likelihood that it will be caused given the inherent properties, including potency, of the substance.

A proportionate regulatory response will involve consideration of both the likelihood of an adverse effect and the severity of that effect should it occur. To achieve this, both hazard identification and hazard characterisation should be conducted **before** substances are considered to be within the definition of endocrine disruptors, as “causing adverse effects in the intact organism...”.

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## Concluding Remarks

In order to ensure legal certainty, and an appropriate and proportionate regulatory approach which helps to avoid the unnecessary stigmatisation of products, only substances within the definition of an endocrine disruptor should be capable of meeting the defining criteria. This implies only one category of endocrine disruptor. The decision whether a substance is in that category should be based on a full ‘**weight of evidence**’ analysis of the relevant scientific data and a **full hazard assessment**, including both elements of hazard identification and hazard characterization.

So far as the quality of the evidence is concerned, where there is insufficient evidence to conclude that a substance falls within the definition, then those substances should **not** be considered to be endocrine disruptors nor should they be given that name.

Where there is sufficient evidence to conclude that a substance has endocrine disrupting properties, a simple horizontal regulatory solution is to be preferred: being one in which only those substances that present a regulatory concern for human health and the environment due to their hazard characteristics (e.g. potency, irreversibility, severity..) are treated as endocrine disruptors. This can best be achieved by including an element of “hazard characterisation” in the criteria for identifying endocrine disruptors and to exclude substances that do not have probable serious effects from that definition. This could be achieved, for example, by including elements of “probability” (eg potency) and “severity” and ‘(ir)reversibility’ in the criteria for determining adversity.

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<sup>1</sup> 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. EFSA Scientific Committee

<sup>2</sup> According to IPCS, hazard characterization is “The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties.

## **Annex 1**

### **Adverse Effects**

Endocrine activity on its own does not trigger identification as a disruptor. For a substance to come within the definition of an “endocrine disruptor” it is necessary to demonstrate that it has an adverse effect. In the absence of an adverse effect a substance that affects the endocrine system is not an endocrine disruptor.

There are no current criteria for identifying “adversity” or “adverse effects”. The UN Globally Harmonised System on Classification and Labelling (GHS) considers substances with clearly identified adverse effects, for example carcinogens, mutagens, and reproductive toxicity: and then considers criteria for classifying these substances.

Unlike a cancer, endocrine disruption is not an end point but a mode of action. It is therefore necessary to characterise an effect as “adverse”: and this requires a definition and criteria for identifying adversity.

The WHO defines an adverse effect as, *“A change in morphology, physiology, growth, reproduction, development or lifespan of an organism which results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increased susceptibility to the harmful effects of other environmental influences.”*

Once again, there are three elements to this definition. It requires a “change in morphology, physiology etc” that “results” in an “impairment of functional capacity etc.”