



EUROPEAN COMMISSION
SECRETARIAT-GENERAL

The Secretary General

Brussels, 020713
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**NOTE FOR THE ATTENTION OF
MR K. FALKENBERG, DIRECTOR-GENERAL, DG ENV
MS P. TESTORI COGGI, DIRECTOR-GENERAL, DG SANCO**

Subject: Endocrine disruptors – Next steps

By the end of 2013, the Commission has to establish criteria that will be used to identify substances with endocrine disrupting properties which will subsequently be largely phased out under the Plant Protection and Biocides Regulations. The elaboration of these criteria is sensitive because of the diverging views held by the stakeholder community and the potential impacts on parts of the chemical industry and international trade. It is important, therefore, that the Commission be able to demonstrate that it has followed a sound process in developing these legal acts and is able to defend robustly whatever decision it takes. With this in mind, we would like to make the following comments.

- (1) DG ENV is developing a delegated act establishing criteria for identifying endocrine substances and envisages in addition a Commission Recommendation, a Communication with a revised endocrine strategy and a Commission staff working document assessing the current endocrine strategy. SANCO must also prepare an implementing act establishing criteria for identifying endocrine substances. There is substantial overlap between these tasks so it is important that your services work together to present a single package for adoption at the end of 2013 or early 2014 whose key elements should be a delegated act (ENV) and an implementing act (SANCO) which has been voted by the relevant Standing Committee and which can be adopted by the College. Whilst the legislator has decided upon two separate proposals to implement the relevant legislation, the substance of these proposals should be identical and ENV and SANCO should ensure there is no divergence caused by having to present one of the measures to the Standing Committee. The two proposals should be supported by an impact assessment including a public consultation on the various options for the criteria and their impact in the context of the regulation of biocides and plant protection products. We suggest that as other DGs have done, you consider making a joint single impact assessment to cover all the proposals.
- (2) We do not think it is necessary to prepare a Commission Recommendation on the criteria to identify endocrine disrupting substances which is independent from, and comes in advance of the two legislative proposals.

- (3) We do, however, believe there is value in preparing a Commission Communication to explain the Commission's approach to the identification of endocrine disrupting substances in the two legal acts. This Communication should draw on the analysis presented in the impact assessment and can also be used to signal future steps in the Union's approach to the management of endocrine disrupting substances if appropriate.

My services are ready to offer all necessary assistance and would like to be associated with the development of the package.



Catherine Day

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A. Glover (CSA)

From: THEVENARD Eric (SANCO)
Sent: Tuesday, March 12, 2013 5:01 PM
To: SLEATH William (SG)
Subject: RE: Couple of questions

Discussions are on-going. Let's see where this leads both DGs.
I don't think an intervention from SG is needed at this stage.
Eric

From: SLEATH William (SG)
Sent: Tuesday, March 12, 2013 12:57 PM
To: THEVENARD Eric (SANCO)
Subject: RE: Couple of questions

Thanks Eric – but you think progress? I guess the question for us is whether this needs SG intervention.....

Thx
William

From: THEVENARD Eric (SANCO)
Sent: Tuesday, March 12, 2013 12:03 PM
To: SLEATH William (SG)
Subject: Couple of questions

On endocrine disrupters, I checked.
There is no agreement for the time being.
Eric

Début du message transféré :

Expéditeur: "SLEATH William (SG)"
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Date: 11 mars 2013 17:31:14 UTC+01:00
Destinataire: "THEVENARD Eric (SANCO)"
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Objet: Couple of questions

Eric

Could I follow up on a couple of points from the planning meeting we had on 20 Feb?

- On endocrine disrupters, we had the equivalent meeting with ENV and they gave us the impression

that agreement had been reached on ensuring consistent approaches. Is this right?

- On the hygiene legislation, could you give us a slightly more precise idea of where this is, and when the CIS might come. Don't think we have seen it yet.

Many thanks!

William

William Sleath
Head of Unit



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- **Amendments** to the criteria (particularly as regards **potency**) should be foreseen in the written commenting round, as no ad-hoc WG meeting is scheduled after the publication of the EFSA opinion.
- **Category 2** (suspected ED) will **stigmatize** many chemicals for which uncertain evidence exists.

Other points

- **SANCO reminded that criteria will be subject to the scrutiny of the European Parliament. Substantial deviations from the original intention of legislators drafting Reg 1107/2009 (i.e. hazard based cut-off criteria) will probably be unacceptable.**
- **2 of the authors of the EEA e WHO/UNEP reports (Prof Kortenkamp and prof Susan Jobling – both from Brunel University), together with few other scientists, presented their position on ED in a document titled "The Berlaymont Declaration on ED", available on PAN-Europe website.**
- **CEFIC and ECPA points out that the 3 reports (Kortencamp report, EEA report and WHO/UNEP report) on which DG ENV bases its proposal are actually a single report, as they are drafted by the same authors.**

