[All redactions made under Art. 4.1(b)]

From: [redacted] (GROW)
Sent: 10 April 2015 09:37
To: [redacted] (SANTE); [redacted] (JRC-ISPRA); [redacted] (JRC-ISPRA)
Cc: [redacted] (GROW); [redacted] (GROW); [redacted] (GROW); [redacted] (JUST); [redacted] (JRC-SEVILLA); [redacted] (SANTE); [redacted] (SANTE); [redacted] (GROW); [redacted] (ENV); [redacted] (SANTE); [redacted] (EMPL); [redacted] (SG); [redacted] (AGRI); [redacted] (SANTE); [redacted] (ENV); [redacted] (SANTE); [redacted] (SG); [redacted] (SANTE); [redacted] (SANTE); [redacted] (ENV); [redacted] (GROW); [redacted] (AGRI); [redacted] (JRC-SEVILLA); [redacted] (ENV); [redacted] (GROW); [redacted] (TRADE); [redacted] (SANTE); [redacted] (TRADE); [redacted] (ENV); [redacted] (RTD); [redacted] (JRC-SEVILLA); [redacted] (TRADE); [redacted] (SANTE); [redacted] (SJ); [redacted] (JRC-GEEL); VANDER [redacted] (SANTE); [redacted] (JRC-ISPRA)
Subject: RE: Draft ED screening methodology
Attachments: DRAFT Substance inventory GROW.xlsm; Selection of substances in the field of cosmetic products for the impact assessment.docx

Dear All,

Firstly I'd like to thank you for your work on the draft screening methodology .

According to your request please to find in attach the DG GROW - Unit Health Technology and Cosmetics' document that includes comments regarding the selection made in the draft report and additional criteria to limit the amount of cosmetics substances for the screening process.
We attached as well the excel file modified to add the 77 cosmetic substances candidate for the screening process. We worked in collaboration with DG GROW- Reach unit but, as our colleague [redacted] already explained, it was not possible to coordinate to send you one document.

In case you have any question please to let us know.

Best regards,

[redacted]

[redacted]

European Commission
Directorate General for Internal Market, Industry, Entrepreneurship and SMEs
Health Technology and Cosmetics

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From: [redacted] (GROW)
Sent: Thursday, April 09, 2015 11:07 PM
To: [redacted] (SANTE); [redacted] (JRC-ISPRA); [redacted] (JRC-ISPRA)
Cc: [redacted] (GROW); [redacted] (JUST); [redacted] (JRC-SEVILLA); [redacted] (SANTE); [redacted] (SANTE); [redacted] (GROW); [redacted] (ENV); [redacted] (SANTE); [redacted] (EMPL); [redacted] (SG); [redacted] (GROW); [redacted] (AGRI); [redacted] (SANTE); [redacted] (ENV); [redacted] (SANTE); [redacted] (SG); [redacted] (SANTE); [redacted] (SANTE); [redacted] (ENV); [redacted] (GROW); [redacted] (AGRI); [redacted] (JRC-SEVILLA); [redacted] (ENV); [redacted] (GROW); [redacted] (TRADE); [redacted] (SANTE); [redacted] (TRADE); [redacted] (ENV); [redacted] (RTD); [redacted] (JRC-SEVILLA); [redacted] (TRADE); [redacted] (SANTE); [redacted] (SJ); [redacted] (JRC); [redacted] (SANTE); [redacted] (JRC-ISPRA)
Subject: RE: Draft ED screening methodology

Dear all,

First of all, many thanks for sending us the draft screening methodology, and congratulations for the work done.

I have to point out that - due to the Easter time - it was not possible to fully coordinate our response and the selection of substances with our colleagues from ENV and with colleagues from the unit responsible for the Cosmetic Products Regulation. Further coordination on the selection of substances might therefore be necessary.

I am attaching several documents to this email:

- An Excel-file listing the selected substances and an additional document providing explanations on the selection
- Comments to the draft screening methodology, and the draft screening methodology itself with some further comments

Karin had attached several questions, for which we will give some answers below.

Best regards,

[redacted]

1. Scope of the screening methodology. .[…] is the scope of the screening methodology, and in particular the selection of pathways (EATS), ED-relevant endpoints and test species, considered realistic and adequate? → **YES**

2. Selection of chemicals for each regulatory sector. → **see attached files**

3. Steps proposed for selection of substances → **see attached files**

4. Sources of information. Are the sources cited (see Appendix A) appropriate and sufficient for the purposes of this IA? → **see changes made to Appendix A**

5. Rules for assessing the toxicological data. Are the proposed rules logical and consistent with the roadmap options?
   Answer: As outlined in the comment no. 9 (see attachment, general comments), more consideration should be given to the evaluation of the strength of evidence when assigning chemical substances to the categories. The availability of studies according to a certain level of the OECD Conceptual Framework is not sufficient for evaluating the strength of evidence. It should be considered whether it is possible to add elements to the methodology focusing further on the strength of evidence.

6. How should compounds be treated that – mainly based on literature research and (potentially) ToxCast data – clearly show activity on a non-EATS endocrine pathway, e.g. activity on the Retinoic Acid Receptor (RAR) or the Peroxisome Proliferator-Activated Receptor (PPAR) ? Even though the in vivo relevance of these is less clear at the moment, should this data be captured? And if so, should these compounds be automatically classified as inconclusive?
   Answer: The draft methodology suggests focusing on EATS endocrine pathways (which will be already challenging, especially for thyroid hormone disruption and the

steroidogenesis pathway). Taking the limited time into account available for carrying out the IA, and the fact that the in vivo relevance for non-EATS endocrine pathways is less clear, we suggest not to include this pathways in the screening.

European Commission
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DG GROW REACH pages are available at:
http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en htm
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From: (SANTE)
Sent: 25 March 2015 17:41
To: (GROW); (JUST); (JRC-SEVILLA); (SANTE); (SANTE); (GROW); (ENV); (SANTE); (EMPL); (SG); (GROW); (AGRI); (SANTE); (ENV); (SANTE); (SG); (SANTE); (SANTE); (ENV); (GROW); (AGRI); (JRC-SEVILLA); (ENV); (GROW); (TRADE); (SANTE); (JRC-ISPRA); (TRADE); (ENV); (SANTE); (RTD); (JRC-SEVILLA); (TRADE); (SANTE); (GROW); (SJ); (JRC); (SANTE); (JRC-ISPRA); (JRC-ISPRA)
Subject: FW: Draft ED screening methodology

Dear colleagues,

As announced at the last ISG meeting, please find attached the draft methodology developed by the colleagues of JRC for the screening of chemical substances in the context of the IA.

Attached you will find:

- The revised methodology document
- A zip file containing three Excel files associated with the methodology document
- The list of questions to be addressed by IASG and Agency (ECHA and EFSA) contacts to help us finalise the methodology

Responses to the questions (see file attached) and additional comments are welcome by 10th of April. They should be sent directly to Andrew Worth and Sharon Munn.

Best regards

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