S.14

SPEER Suzanne (BEPA)

From: [redacted]@efsa.europa.eu>
Sent: Tuesday 13 August 2013 15:57
To: MUELLER Jan Marco (BEPA)
Cc: GLOVER Anne (BEPA)
Subject: RE: Reply to open letter regarding endocrine disrupters (sent on 17 June, 2013)

Dear Jan,

Thanks for the copy of this well-written letter. In light of your upcoming discussions in September, a few comments (following input from EFSA colleagues involved in either the ED opinion or EFSA's pesticide work):

1. The legislation on both Plant Protection Products and Biocides requires the Commission "to develop scientific criteria for the determination of endocrine-disrupting properties" (see e.g. Article 5(3) of the Biocides Regulation). In developing these hazard criteria, the Commission consulted EFSA, and the current draft criteria developed by DG Environment are indeed fully consistent with the EFSA opinion. Debate remains however on the strength of evidence needed to establish the "plausible causal relationship" between the endocrine activity and the adverse effect.

2. The hazard-based approach for EDs developed in the regulations gives
   - a special status to substances acting via a specific mode of action.
   - focuses on substance classes that have been grouped by their use (e.g. pesticides, biocides), leaving aside also naturally occurring compounds (e.g. isoflavones) that also display an endocrine-related mode of action (and potentially more potent than some of the man-made chemicals considered).

3. The EFSA opinion also states: "Furthermore, to inform on risk and level of concern for the purpose of risk management decisions it is the opinion of the SC that risk assessment (taking into account hazard and exposure data/predictions) makes best use of available information. EDs can therefore be treated like most other substances of concern for human health and the environment, i.e. be subject to risk assessment and not only to hazard assessment."
   I understand that, unlike EDs to be authorised under REACH, the pesticide legislation has no 'control route' or 'socio-economic route' to permit EDs to possibly remain on the market. However, I also understand that the pesticide legislation foresees on the other hand an exception if the exposure is negligible. In this regard, EFSA has been invited to join a DG SANCO group which is being initiated to try and ascertain what is to be considered 'negligible exposure'. I interpret that the Scientific Committee's opinion would lead to the consideration that 'negligible exposure' is to be seen in relation to the outcome of the hazard characterisation through which a health-/ecotoxicology-based guidance has been established.

Kind regards,[redacted]

[redacted]
European Food Safety Authority

Tel +39 0521[redacted]
[redacted]@efsa.europa.eu

Via Carlo Magno 1/A, I-43126 Parma, Italy

From: Jan.MUELLER@ec.europa.eu [mailto:Jan.MUELLER@ec.europa.eu]
Sent: 13 August 2013 12:23
To: [redacted]
Subject: FW: Reply to open letter regarding endocrine disrupters (sent on 17 June, 2013)

Dear [redacted]
It was nice to talk to you.
Find enclosed the response Anne has given to Prof. Dekant et al.
As you can see she has left some question marks on which she is going to follow up with ENV and SANCO. She will have a meeting on EDs with people from both DGs on 13 Sep (followed by another one with Mr Seychell on 25 Sep).
For info: Anne is on leave until 25 August.
All the best, Jan

Dr. Jan Marco MÜLLER
Assistant to the Chief Scientific Adviser / Assistent der Wissenschaftlichen Chefberaterin /
Assistant de la conseillère scientifique principale

European Commission / Europäische Kommission / Commission européenne
Bureau of European Policy Advisers (BEPA) / Büro europäischer Politikberater (BEPA) /
Bureau des conseillers de politique européenne (BEPA)

Berlaymont 08/364
Rue de la Loi 200
B-1049 Brussels / Brüssel / Bruxelles
Belgium / Belgien / Belgique
Tel.: +32 2 2992883
e-mail: jan.mueller@ec.europa.eu
Internet: http://ec.europa.eu/commission_2010-2014/president/chief-scientific-adviser/index_en.htm

From: SPEER Suzanne (BEPA) **On Behalf Of** GLOVER Anne (BEPA)
Sent: Thursday, August 01, 2013 4:44 PM
To: 'dekant@toxi.uni-wuerzburg.de'
Subject: Reply to open letter regarding endocrine disrupters (sent on 17 June, 2013)

Dear Professor Dekant,

Please find enclosed my comments in response to your questions.

Best regards,

Professor Anne Glover, CBE