

Meeting between DG SANCO and DG ENV

Subject: Involvement of EFSA and scientific committees in the process for development of scientific criteria for identification of endocrine disruptors

Date 19th September 2012. Time: 17:30 to 18:30. Location B 232-7/108.

██████████'s notes from the meeting

Participants: SANCO – Paola Testori (DG), Martin Seychell (DDG), ██████████, ██████████, ██████████, ENV – Karl Falkenberg (DG), Gustaaf Borchardt (Director), ██████████, ██████████, ██████████.

DG SANCO explained that the criteria for endocrine disruptors will have a significant impact on their legislation, particularly on the number of substances being authorised under the Plant Protection Products Regulation. DG SANCO expressed the view that the impact on their legislation (plant protection products, cosmetics, medicines, additives etc.) would be much bigger than on DG ENV legislation on biocides and pointed out that the number of active substances used in plant protection products in Europe has been already reduced from 800 to 250 and that there is great sensitivity to reduce it further. In order for the criteria to be defensible (including under the WTO), the process for defining the criteria must be independent, transparent and excellent. According to DG SANCO, the DG ENV lead process is biased and not excellent. The bias is related to the fact that the process involves interested parties and that we work with a paid contractor. The lack of excellence is due to the capacity of the contractor and the non-involvement of the EFSA and DG SANCO scientific committees and panels. The only way to rectify the current deficiencies in the process was to ask EFSA and the scientific committees and panels to provide their opinion on the criteria. DG SANCO also noted that EFSA experts and members of the scientific committees had declined to participate in the JRC lead expert meetings arguing that the group was mixing risk assessment and risk management. DG SANCO asked DG ENV to slow down the process in order to be able to take into account the EFSA opinion. If DG ENV was unable to accommodate this request, DG SANCO would be obliged to pull out of the DG ENV-lead process.

DG ENV explained that since 2009 there has been agreement between DG SANCO and DG ENV that DG ENV would lead the process for development of the criteria which was confirmed in several meetings and written exchanges at DG level. The process has been endorsed by DG SANCO, fully included DG SANCO and should be seen as joint process. DG ENV disagreed with the conclusion of DG SANCO that the current process is biased and argued that the process is transparent and inclusive for all stakeholders including industry and NGOs. The process is running well and it would be very unfortunate as well as detrimental to the Commission's reputation to disrupt/stop the process at this stage. In addition, slowing down the on-going process in order to allow time for a consultation of EFSA risked to miss the deadlines for finalisation of the criteria. Further, DG ENV expressed its concern that EFSA will focus only on the wording in Plant Protection Product regulation and will not be able to describe criteria which could be applicable horizontally for all the relevant EU legislation.

DG SANCO first contested that there was an agreement regarding the leadership of the process for development of the criteria. However, it was recognized that DG SANCO should have made its objections to the nature of the DG ENV lead process much more explicit and much sooner. Nevertheless, SANCO prefers to be late with the criteria than to go without the opinion of EFSA.. Depending on the criteria, DG SANCO is ready to change entirely Annex II of PPP Regulation by Comitology, i.e. including the current wording on endocrine disruptors and did not oppose even the idea to go back to regulating based on risk assessment.

Nothing concrete has been agreed except:

- DG ENV will explore whether there would be a possibility to slow down the current process to take into account the delays resulting from the consultation of EFSA

- SANCO will talk with EFSA to try and accelerate the preparation of the opinion(s).
- The JRC chair of the expert group will be participating in the EFSA working group to ensure the proper linkages.