From:
Sent: Monday, January 25, 2016 8:40 AM
To: PRATS MONNE Xavier (SANTE); MIKO Ladislav (SANTE); JUELICHER Sabine (SANTE);
Cc:
)
Subject: BTO Meeting Commissioner Andriukaitis with on 22 January 2016

Please see the minutes of the meeting as prepared by

BTO Meeting of Commissioner Andriukaitis with on 22 January 2016

Commissioner Vytenis Andriukaitis
Mr Arunas Vinciunas, CAB Andriukaitis
Ms Nathalie Chaze, CAB Andriukaitis

The following topics were discussed during the meeting:

- explained that the concerns of the group were more about the use of science rather than glyphosate as such. All four scientists present took part in the IARC review of glyphosate, albeit in different roles.
- emphasised that IARC and the National Academy of Sciences (NAS) ensure independence through strict policies on conflicts of interest (CoI) and opined that the EFSA process has not been as transparent. In this context he also raised the issue that EFSA does not publish the full data for some of the studies submitted due to confidentiality rules.
- stressed that the group had difficulties understanding what EFSA did in its assessment.
- Commissioner replied that the transparency of EFSA has been debated previously. While a Court of Auditors report identified EFSA as the most transparent among the EU agencies audited, the Commission was still discussing on how to improve further.
- claimed that MS experts participating in the EU process may be biased because they also exercise regulatory functions in their home country, and cited JMPR (WHO/FAO Joint Meeting on Pesticide Residues; the body that provides risk assessment on pesticide residues in the Codex Alimentarius system) as another negative example. This would not be acceptable to IARC when identifying panel members.
- responded to a question of the Commissioner that he offered to discuss with EFSA but was not invited. He suggested that the selection e.g. of EFSA Board members should be done by the Commissioner. He raised several detailed issues regarding the EFSA assessment, including categories and definitions used as well as the choice of statistical approach. agrees with the approach described in

EU guidelines but claimed that EFSA did not follow them. He wondered whether the decision on whether or not to recommend classification of glyphosate as carcinogen may have been influenced by the regulatory consequences of such classification under the EU legislation on plant protection products.

- [redacted] pointed to the scarcity of exposure data on glyphosate and the resulting problems for risk assessment [redacted] suggested that the Commission should address the lack of exposure data, e.g. through a biomonitoring programme for glyphosate and other pesticides. This was even more important because the use of glyphosate had strongly increased in the last 10 years. [redacted] remarked that the human biomonitoring programme of the Commission currently does not include pesticides. [redacted] stressed that such studies must be done systematically, not anecdotally (referring to recent small studies on breast milk, urine and bread that used non-random sampling). [redacted] added that such studies must also be long-term but are expensive.
- Commissioner acknowledged that the meeting was very useful. He conveyed the same message as earlier to IARC, that public allegations among scientists was confusing for the public. He described his role as not a "judge" but an "honest broker". Commissioner asked for suggestions on how to develop a common approach in a collaborative manner.
- [redacted] proposed to bring experts from both sides to the table, with full access to all data on glyphosate.
- [redacted] opined that EFSA should have come to different conclusions due to the big picture emerging from animal studies, even if some individual studies had some deficiencies. He suggested that the approach should change, away from the focus on the active substance only (though he acknowledged that this was the requirement in EU legislation), to inclusion of data on formulations.
- [redacted] stated that in the IARC evaluation, it became clear that effects seen with formulations were due to glyphosate, not the other components. He repeated that IARC was clear, transperant and understandable, while EFSA was less so.
- [redacted] complained that the situation is compromised because EFSA published its Conclusion and publicly responded to the letter co-signed by 96 scientists to the Commissioner. [NOTE: EFSA was mandated by COM to include the (published) IARC evaluation in its assessment and to reply to the open (!) letter of the scientists on concerns regarding the scientific assessment.] He further claimed that the entire EU process was flawed and that it is time to review it.
- It was agreed that the group would send a summary of the issues raised to the cabinet to facilitate follow-up with EFSA, and that both sides should refrain from sending open letters.
- [redacted] advised to assemble an independent panel of 4 to 5 persons to review the process as such, i.e. not specifically on glyphosate. It was imperative that all panellists be free of CoIs. [redacted] added that in the US, the platinum standard for difficult cases of scientific disagreements was to ask the NAS to review, and that NAS's views were generally accepted as the final answer.