

From: [REDACTED] (SANTE)
Sent: 18 March 2016 09:31
To: MIKO Ladislav (SANTE); JUELICHER Sabine (SANTE)
Cc: [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE)
Subject: FW: BTO - Discussion re access to glyphosate information, 17.03.2016

Dear all,

Please find below the BTO, approved by [REDACTED] of yesterday's conference call with EFSA and industry on access to full studies on carcinogenicity of glyphosate. I also copy unit 02, see last sentence on communication.

Best regards,

[REDACTED]

BTO, Discussion re access to glyphosate information, 17.03.2016

Participants:

- [REDACTED], Glyphosate Task Force (GTF)
- [REDACTED], GTF
- [REDACTED], European Crop Protection Association (ECPA)
- [REDACTED], EFSA
- [REDACTED], SANTE.E.4

EFSA has received a public access to documents (PAD) request for three carcinogenicity studies on glyphosate. Three principle ways forward were discussed:

1. Send sanitised studies to PAD applicant, after formal consultation of originator of document and decision by EFSA on confidentiality => standard PAD procedure
2. Publish the studies, if agreed by industry
3. Give access in a reading room, if agreed by industry

Industry has strong concerns on options 1 and 2, as they fear misuse of the raw data. Not much difference between the two options, since experience shows that release to PAD applicant, even with disclaimer in accompanying letter, frequently leads to web-publication of the obtained documents.

Industry willing to consider reading room. EFSA suggested that reading room could be physical, but also virtual, whereby studies are accessed under request but on line to everybody without need to come to Parma, and in a format that does not allow to copy/paste. Industry will consider this as well.

Industry enquired about the letter from Commissioner to the GTF, and whether a reading room access would address the request of the Commissioner. They were aware due to Commissioner's remarks at recent AGRI Council. I replied along the lines given in Michael's and Sabine's e-mails (cannot take position as to the Commissioner's reaction, at technical level seen as improvement over status quo, but doubts whether it will address NGO's requests and public perception).

As regards precedent setting, I explained that confidentiality requests have to be justified and decided upon for each PAD request, on a case-by-case basis.

If a reading room is agreeable, there will be a need to communicate on the approach chosen and agreed in this exceptional case, and EFSA Communication unit will coordinate with SANTE Communication unit. Industry may do their own, but independent, communication.

From: JUELICHER Sabine (SANTE)
Sent: Thursday, March 17, 2016 10:53 AM
To: [REDACTED] (SANTE)
Cc: MIKO Ladislav (SANTE); SCANNELL Michael (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE)
Subject: Re: Discussion with ECPA on the disclose of the glyphosate studies

[REDACTED]

I agree that we basically listen in but we need to flag the intention of the Commissioner to write (we can refer to the meeting with CEO, Greenpeace where Commissioner announced his intention).

Sabine

Sent from my iPhone

On 17 Mar 2016, at 11:28, [REDACTED] (SANTE) <[REDACTED]> wrote:

Ladislav, Sabine, Michael

We have been invited by EFSA to attend a telcon between them and the applicants of Glyphosate, facilitated by ECPA. This telcon is to be seen in the context of the request for access to the tox studies, where EFSA has now to deal with a confirmatory request (they refused access as applicant did not give permission).

For this you should also take into account that the note for C SSR Andriukaitis asking applicants to release the studies is now with XPM for his approval, before it goes to Cabinet.

We can attend, but any input/reaction would be at technical level. I cannot assess how this possible offer of a reading room will be perceived by C SSR, neither by NGOs. The proposal of a reading room is at least an improvement over the status quo, where we have no access to raw data at all.

However, the proposal will however not be sufficient to address the requests from NGOs, as they would want access to data in an electronic format that allows re-analysis of the data; for this purpose a reading room or even a PDF document are not sufficient.

I suggest that we listen on this basis to the telcon, unless you tell us to do otherwise.

[REDACTED]

From: [REDACTED] [[mailto:\[REDACTED\]](mailto:[REDACTED])]
Sent: Wednesday, March 16, 2016 6:07 PM
To: [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE)
Subject: Discussion with ECPA on the disclose of the glyphosate studies

Dear colleagues,

This is just to inform you following a PAD request we are going to have tomorrow at 12:30 a phone call with the applicants facilitated by ECPA on the disclosure of three glyphosate studies. The options we want to discuss are the disclosure of a sanitised version and having the full study reports available for consultation in a reading room.

Considering the announcement of the Commissioner, ECPA has informed us now that they will invite you ([REDACTED] was mentioned) to attend.

Please let me know if you want to have a short bilateral before.

Kind regards,

[REDACTED]



<image001.gif>

Via Carlo Magno 1/A

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Italy



www.efsa.europa.eu

twitter.com/EFSA_EU <image002.png>

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