From: [redacted] (ECHA)
Sent: 23 May 2016 17:25
To: [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE)
Cc: [redacted] (ECHA); [redacted] (ECHA); [redacted]
Subject: RE: Glyphosate ED properties

Follow Up Flag: Follow up
Flag Status: Flagged

Dear [redacted],

Many thanks for your prompt reply (in the midst of a busy day)!

That all seems clear enough, but we will get back to you if further clarification/ information is needed. Concerning point 3, in assessing whether a substance meets the criteria for a reproductive toxicity classification, the committee for risk assessment (RAC) takes into account any study results that provide relevant information regarding toxicity to reproductive and related endocrine organs.

Thanks again

With kind regards

[redacted]

From: [redacted]@ec.europa.eu [mailto:[redacted]@ec.europa.eu]
Sent: 23 May 2016 18:00
To: [redacted]
Cc: [redacted]
Subject: RE: Glyphosate ED properties

Dear [redacted]

Sorry if my reply is brief, but it is a busy day today:

ad 1) See EFSA Conclusion, p. 12, and in particular:
"Glyphosate is not classified or proposed to be classified as carcinogenic or toxic for the reproduction category 2 in accordance with the provisions of Regulation (EC) No 1272/2008 (harmonised classification supported by the present assessment), and therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. Apical studies did not show adverse effects on the reproduction, however signs of endocrine activity, even if appearing at parental toxic doses, could not be completely ruled out regarding delay in preputial separation in F1 males and decrease in homogenisation resistant spermatids (cauda epididymis) observed in the most recent multi-generation study. Glyphosate was selected by the US EPA Endocrine Disruptor Screening Program's (EDSP) to undergo a full battery of Tier I screening assays for evaluation of glyphosate's potential to interact with the oestrogen, androgen and thyroid endocrine pathways. The RMS mentions that the first published data revealed no effects on the androgenic and oestrogenic pathways (from the Hershberger and

Uterotrophic assays), that glyphosate did not show evidence of endocrine disruption in male and female pubertal assays and no impact on steroidogenesis was observed in the in vitro assays. However these studies were not submitted for the renewal procedure and a data gap has been identified for the full battery of Tier I screening assays on the hazard assessment of endocrine disruptors in accordance with the EDSP, or the Level 2 and 3 tests currently indicated in the OECD Conceptual Framework (OECD, 2012b), and analysed in the EFSA Scientific Opinion (EFSA SC, 2013). Although the experts agreed that there is no evidence for endocrine-mediated effects for glyphosate, a firm conclusion cannot be reached now and a data gap was proposed. No potential for neurotoxicity or immunotoxicity was detected in glyphosate-administered rats."

ad 2) The submitted information would be evaluated by the RMS, in accordance with the "Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009" (SANCO/5634/2009 rev. 6.1, dated December 2013). All other MS are then invited to comment on that evaluation. If COM considers it appropriate, EFSA may be mandated to peer-review the evaluation and publish a conclusion. The GD also outlines the possible procedural outcomes and impact on approval (keep, restrict, non-approve).

ad 3) In my view this would not be relevant for harmonised classification, as endocrine disruption is not a hazard class under CLP (while acknowledging that the ED interim criteria in Reg 1107/2009 make use of existing hazard classes, i.e. C2 and R2).

Best regards,

Policy Officer

European Commission
DG Health and Food Safety
Unit SANTE/E4

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From: @echa.europa.eu]
Sent: Monday, May 23, 2016 1:23 PM
To: (SANTE); (SANTE); (SANTE); (SANTE)
Cc: (ECHA); (ECHA);
Subject: Glyphosate ED properties

Dear [redacted] and Colleagues,

We would like to raise the following issue with you.

We note that in document SANTE/10026/2016 ANNEX Rev. 2 (ANNEXES to the COMMISSION IMPLEMENTING REGULATION (EU) .../... renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009) it is stated (both in Annex I and Annex II) that:

"The applicant shall submit confirmatory information as regards the absence of endocrine disrupting properties that may cause adverse effect in humans to the Commission, the Member States and the Authority by 1 August 2016."

Could you indicate to us
(1) specifically what information you would like to receive from the applicant,
(2) how you intend to use the information and
(3) whether this is something which would be relevant to the harmonised classification proposal which is anticipated to be submitted to public consultation next week?

The dossier submitter has noted in the issue in their current (draft) version of the CLH report (but which is currently being reviewed by the dossier submitter) that glyphosate was found to be devoid of a potential for endocrine disruption in recent testing on request of the U.S. EPA.

Please do not hesitate to contact us should further clarification be needed.

With kind regards

[redacted]

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