

Subject: Notes 16 Jan call Ag reprotox and study Ag effects on the biome
Date: Thursday 18 January 2018 at 17 h 39 min 50 s Central European Standard Time
From: Katrien Arijs
To: Buthe, Arno Christian, Olga Lemke, Nissanka RAJAPAKSE, Verberckmoes, Steven, Marie-Laure LEDRICH
CC: France Capon, Mark Raffray
Attachments: PMC_slides_Ag WG_180116_outcome.pdf

Dear all,

Thank you for your contributions during Tuesday's call.

Please find below a brief summary of the discussions:

- The biome study would help in the EOGRTS design and could provide argumentation to 1) further defend our EOGRTS TP and 2) avoid classification. The second point stands even if the TP is eventually denied (i.e. study has fallback value even if not directly useful for EOGRTS design).
- Even after the draft decision on the TP is issued, we still have chances to defend it (through comments on the decision / informal call with ECHA).
- Although the tox experts agreed there is certainly scientific value in a biome study, there are still some concerns, mainly on the timeline.
- Having the biome study as an 'add-on' to the EOGRTS instead of as an enabling study would be difficult: we wouldn't have the biome results before ending the EOGRTS while the results could help in the dose-setting. This point could be raised in our discussion with ECHA on the overall timeline needed for the EOGRTS. The proposal / timeline from Prof. Lison might also be useful in this respect.
- The tox experts agreed to wait for the proposal / timeline from Prof. Lison's lab before making a decision on the biome study. It was noted that we might already have the draft decision on our TP by then.
- The design aspects of the biome study were discussed and are summarized in attached slides.

In the meantime, I have informed Prof. Lison of the study design and he will get back to us with a proposal asap (mentioning the costs for the ancillary investigations separately from the main costs). In addition, I have asked to provide us with a timeline for the study and to inform us on their availability to perform the study.

Kind regards,
Katrien

From: Katrien Arijs <katrien.arijs@arche-consulting.be>
Date: Monday 15 January 2018 at 10:01
To: "Buthe, Arno Christian" <arno.buthe@heraeus.com>, Olga Lemke <olga.lemke@basf.com>, Nissanka RAJAPAKSE <Nissanka.Rajapakse@matthey.com>, "Verberckmoes, Steven" <Steven.Verberckmoes@eu.unicore.com>, Marie-Laure LEDRICH <ledrich@consul-led.com>
Cc: France Capon <france.capon@epmf.be>, Mark Raffray <mark.raffray@btinternet.com>
Subject: Re: Call Ag reprotox and study Ag effects on the biome: Tuesday 16 Jan at 15:30

Dear all,

Please find attached a number of slides for discussion at tomorrow's call. It would be helpful if you could already have a look at the study design slides in advance of the call, to facilitate the discussions.

Thanks and talk to you tomorrow,
Katrien