

Final minutes PSM GRG/AGG June 4th 2020

Pre-ample: this PSM is meant for last minute technical issues.

In reference to the slide numbers as presented by the GRG:

Slide 4: Delay in information on 2 company specific confidential information (document J) due to Covid-19 is accepted. AGG expects that this will be provided for in the updated dossier submitted after the admissibility check;

Slide 5: GRG informed AGG that specific document J from one company will not be included in the submitted dossier. AGG noted that;

Slide 6, 7, 8: Five ongoing studies, with currently expected finalization date of July 2020, and additionally four public literature articles assessed as non-relevant to the risk assessment are delayed due to Covid-19. AGG expects that in case these 5 studies are finalized in time to be included into the updated dossier in July, that the studies are provided for in the updated dossier submitted after the admissibility check. GRG confirms that no other studies will be submitted during the procedure before the commenting round, as advised by AGG during the technical pre-submission meetings between GRG and AGG in October of 2019;

Slide 9: Studies from earlier dossiers not available (anymore) to GRG-members. AGG will request the German BVL to provide AGG with the documents. Those studies owned by GRG-members will be shared with GRG and GRG will be asked to provide AGG with updated summaries. For other studies a legal opinion will be asked to EFSA whether these studies can be shared by AGG, but certainly they have to be checked whether they point to adverse effects. For the CLH-dossier, AGG must consider all available data.

Slide 10: Disclosure and sanitation of confidential information. AGG points out that the basis for confidentiality lies in art 63 of 1107/2009. GRG informs AGG that a telcon is scheduled with EFSA on sanitation where EFSA will inform GRG on the state of play. AGG informs GRG that a letter will be sent requesting GRG to submit a dossier where confidential information is marked and motivated adjacent to submission of the renewal dossier. This has to be prepared for requests of disclosure where timelines are short. GRG takes note and ask AGG to send the letter on short notice so GRG can prepare the dossier. AGG confirms that if there are questions GRG can contact AGG for explanation. The letter is expected to be sent Friday 12th of June;

Slide 11: submission of the dossier on USB hard drive. If any technical issues arise AGG-members can contact Knoell directly;

Slide 12: Fees. GRG is requested to submit proof of payment to ANSES, for Keml this is not necessary, the notification of payment is received.

Slide 14: timeline. GRG informs AGG that the dossier will be sent June 10th. AGG informs GRG that a letter on admissibility will be sent July 10th, giving GRG till July 24th to submit any requested information if necessary (i.e., if it is considered as necessary to make use of the extra 14 days for submission of further data before the dossier is reported as complete). If there is no need to update

the dossier apart from issues mentioned in slides 4, 7 and 8 the timeline for submission of the updated dossier can be set to 31 July.

AOB.

- GRG informs AGG on its consent to provide ANSES with testing material for the ANSES-studies on glyphosate;
- GRG asks AGG what the timeline is of the request for Import tolerance as applied for by GRG. AGG informs GRG that this application will be processed in conformity with the rules, but that it will not be prioritized.
- GRG asks when it can expect the minutes of the PSM on biodiversity. AGG answers that the internal commenting round is not yet finished.