

Minutes of the Glyphosate Renewal Group (GRG) - Assessment Group on Glyphosate (AGG)
teleconference on sanitization and disclosure timelines, 26 August 2020

10.00 – 12.00 h CET

	Issue	Discussion/Conclusion
1		<p>Aim of the meeting: to give GRG information about the practices in the member states in case there is a specific disclosure request, in addition to the sanitisation performed according to Reg. 844/2012.</p> <ul style="list-style-type: none"> • No predictions can be given how a request is being handled; this depends on the member state and the way the request is addressed . • On EU and national level are court rulings how the member states should handle a request. Because of these, the given information is only provided as indicative guidance on a general level and according the present situation.
2	Rules of sanitization questions from GRG	<p>Review AGG’s general comments to CBI form (document “General comments to CBI form_Docs A-I_LCA_MCA_N1-N5 and CBI form_Docs LCP and MCP” provided by AGG to GRG in July 2020, see Appendix 1).</p> <p>GRG agree to the rules of sanitization as mentioned in the document with the following precaution on location data: GRG considers that it is important to blacken the locations / GPS coordinates in field studies in order to protect the physical integrity of farmers, personnel and supporting persons.</p> <p>AGG: point of discussion during the final sanitization.</p> <p>It is the responsibility of the individual authorities to decide on sanitization according to the rules in place.</p>
3	Timelines relevant in the four member states in case of a disclosure request	<p>The AGG emphasizes to the GRG the importance to be clear which parts of the current dossier have already been disclosed. Disclosure of parts of the glyphosate dossier were based on earlier requests and these have not to be reopened again.</p> <p>Timelines</p> <p>Depending on the scope and wording of a request, the individual member states may have different timelines and responses. The AGG agreed to have internal coordination, but 100% is not possible.</p> <p>KEMI</p> <p>Need to start immediately if there is a request for access to documents in the dossier and do not ask for the opinion of GRG. If there is a comment it will be considered.</p> <p>Disclosure has to be asap, there are no legal timelines. Access to a marked version (information blackened) of the dossier from GRG would be helpful. It could be offered to the requestor as a quicker alternative of getting access to the dossier. In that case, KEMI will only check if additional information has to be sanitised. As to more information on the Swedish legislation on public access to official documents, KEMI refers to the documents that were sent out ahead</p>

	<p>of the meeting (documents “Public Access to Information and Secrecy Act” and “Public access to official documents in Sweden” provided by KEMI to GRG in August 2020, see Appendix).</p> <p>Anses</p> <p>A request will be analysed and the response will be tailored depending on the scope, wording and legal basis triggered. The legal framework in France may offer room for harmonization with work performed by other AGG members.</p> <p>The GRG will be asked to provide a CBI form and red marked documents highlighting what is confidential. A signed statement will also be requested stating that no changes in the red-marked documents were made compared to the initial documents submitted to Anses. The final decision is by Anses.</p> <p>A request targeting a large volume of documents can be decided upon and released in batches. The first batch of feedback should be within a month (this can be a formal answer as well). Other batches will be released as soon as they are available in their sanitized version</p> <p>Ctgb</p> <p>Pursuant to national law, the Ctgb must, on request, disclose documents in its possession, unless there are legal grounds to keep (parts of) these documents confidential. After receiving a request for disclosure of documents submitted by an applicant of an active substance or plant protection product dossier, the Ctgb consults the data owner. The data-owner should submit a reasoned opinion indicating why certain parts of documents should be kept confidential. In doing so, the data-owner must invoke the statutory grounds for non-disclosure with well specified reasons. The data owner must also provide blackened versions of the documents and a version in which the information to be kept confidential is marked. The Ctgb critically assesses this view of the data owner and then decides to publish the documents fully or partially. It is also important whether the documents contain information about emissions into the environment as there are fewer statutory grounds for keeping such information confidential and refuse disclosure.</p> <p>The time limit for deciding on a disclosure request related to environmental information is two weeks. This can only be delayed if the size or complexity of the information justifies it. The terms of Directive 2003/4 may not be exceeded. Disclosure of large requests for information in batches can be helpful.</p> <p>If the Ctgb does not take a decision within these time limits, the applicant can lodge an appeal with the competent court for failing to take a timely decision on the disclosure request. The judge can then set a term, linked to a penalty.</p>
--	--

		<p>Once the Ctgb has taken a decision on the disclosure request, stakeholders such as the applicant and the data owner can submit a notice of objection within 6 weeks. The Ctgb must then take a decision on the notice of objection within 12 weeks. Parties that do not agree with the decision on the notice of objection can then appeal to the competent court.</p> <p>NÉBIH Because Nébih does not have any disclosure requests yet, there is no specific or practical information available. General timelines: 30 days which can be extended by 30 days. The total amount is 2 months to disclose the requested information. Because of lack of resources Nébih would merely rely on the sanitisation work of the applicant.</p> <p>Conclusion: there are differences between the member states, basically it is important for all to act swiftly. Timelines depend on actual work to be done. Issue raised by Anses of handling disclosure in batches can be taken in to consideration. With regard to the Netherlands, there are uncertainties how the Dutch court will react when timelines are not met.</p>
4	<p>Organisation and alignment of workload (GRG)</p>	<p>GRG confirm that sanitization work of safety related K-documents has already been started with tox studies to be followed by the ecotox studies etc. (900-1000 studies in total). It is expected that the work will be finalised by the end of October. Access to the studies for any interested person is provided on the GRG website via online-order (www.glyphosate.eu). Additional studies will only be sanitised if there is a disclosure request. The effective related studies will be done later.</p> <p>Alignment of workload AGG: without a request there is no obligation for the GRG to deliver a sanitised version of the dossier, but we should be prepared and not await a disclosure request to avoid mistakes.</p> <p>GRG ask if they will be informed by the MS if there is a disclosure request. KEMI: will not inform GRG actively, only if the GRG is asking this information. Anses: Such a request will not be put forward to data owner. When a request is submitted and no sanitization form available (and a sanitised dossier ready), Anses contacts the data owner to ask for that form and a sanitized dossier Ctgb: GRG is regarded as an interested party and will be informed of a request and also of decisions.</p>

		AGG consider it very helpful if the GRG provide the already sanitised (blackened) dossier items batchwise. Anses would only need a red marked version.
7	<p>AOB</p> <ul style="list-style-type: none"> • Procedure questions (GRG) • Admissibility check (GRG) 	<p>Timeline of feedback: NL on behalf of the AGG will send the final version of CBI form in 2 weeks to EFSA.</p> <p>GRG: with reference to the letter of 18 August 2020, many points regarding timelines were not accepted by the AGG. They ask if delayed studies can be submitted before the commenting period. AGG confirms that the existing deadline for delayed studies cannot be extended.</p> <p>Remarks on the table: Point 24, request for additional literature: will be sent end of August by AGG to GRG. Point 29, general; old studies and summaries submitted by the previous taskforce and not submitted by the GRG : AGG will send a separate request to Germany.</p> <p>AGG: there is no need to reply on the final letter, response by GRG is only required when they cannot meet the timelines in the table.</p> <p>GRG will send two versions of the dossier (non-sanitised and sanitised) together with the CBI forms to the AGG.</p>