

Draft minutes pre-submission meeting GRG-AGG Glyphosate and biodiversity

Date: Thursday April 16th, 2020
Time: 14.00 – 17.00
Location: Teleconference

1. Opening

On behalf of Assessment Group of Glyphosate (AGG), the chair of the meeting welcomes all participants. The chair of the Glyphosate Renewal Group (GRG) thanks the AGG for organizing this meeting. All other participants are introduced by a tour de table.

2. Aim of the meeting and disclaimer

This pre-submission meeting (PSM) is intended to discuss issues and questions raised by the applicant in preparing a biodiversity assessment as part of the ecotoxicological assessment for their dossier. The meeting is held to assist the applicant in preparing their dossier and is not legally binding. The advice given does not bind the Member States, EFSA or the European Commission and should not be seen to create any expectations on the part of the applicant concerned. The assistance and advice is solely based on the information made available by the applicant for the meeting. It is the responsibility of the applicant to present a complete picture of the data to be discussed. This does not preclude any other points which may arise after dossier submission. The minutes of this meeting will be finalized after the consent of all parties present. Reference is made to the GRG presentation 'Glyphosate and biodiversity' shown during the teleconference.

3. Questions of slide 3 of GRG's presentation

- **Question 1: We have not tried to develop a "new" approach for the biodiversity assessment. In the AGG's opinion, is the general approach using the core data and lines of evidence clear and fit-for-purpose?**

AGG agrees that a new guidance on such assessment for indirect effects should not be developed by GRG. The GRG proposal is based on already existing lines of evidence. AGG notes that very few proposals were made to address the concern raised during the first renewal, i.e. impact on diversity and abundance of vertebrates and arthropods and their interaction, even if some conditions of the representative uses mentioned during the first PSM could be put forward as risk mitigation measures.

- **Question 2: The proposed Specific Protection Goals (SPGs) largely draw from existing EFSA guidance and the EFSA protection goal workshops. Are the proposed SPGs for the biodiversity assessment fit-for-purpose and if not are there recommendations for how to revise one or more of the SPG's?**

No SPG has yet been defined at EU level. The SPG concepts under development aim at better taking into account biodiversity and ecosystem services in the risk assessment of direct effects. The indirect impacts of a total herbicide on trophic interactions amongst NT organisms is not addressed by the current discussion on SPGs being developed at the EU level.

- **Question 3: Are there any areas the AGG feel have not been sufficiently covered in the proposed approach?**

AGG would have expected some options put forward by the notifiers. GRG's way forward is based on already existing lines of evidence. No proposal was made to address the concern raised during the first

renewal, i.e. impact on diversity and abundance of vertebrates and arthropods and their interaction). This assessment should focus on indirect effects on biodiversity since direct effects are covered by the standard risk assessment. As there is no guidance to assess such effects, recommendation of AGG would be to address this via information from the open literature. It could also be of interest to reinforce the protection of off-crop habitats which are seen as reserve for potential recovery in-field. The risk mitigation measures to compensate from indirect effects may be also found from literature data.

- **Question 4: A strength of the aquatic assessment is that the different trophic levels (e.g., primary producers / consumers and secondary consumers) were tested and show negligible risk. Does the AGG agree that we can follow the approach outlined in the EFSA Aquatic Guidance (Option 1) to address indirect effects through trophic interactions?**

According to AGG, the indirect effects are not covered by the EFSA Aquatic Guidance. However, the EFSA Aquatic Guidance states that protecting against direct effects should not lead to unacceptable indirect effects. The risk assessment of direct effects on aquatic organisms is expected to be acceptable with comparison of tier 1 RAC with step 1-2 PEC_{sw}. Moreover, considering the results of monitoring data in comparison with the RAC, it may be considered in this particular situation that the margin of safety on risk assessment of direct effects should be sufficient to cover most of the indirect effects on aquatic ecosystems. The main concern may be considered to be to terrestrial ecosystems.

AGG considers that for aquatic diversity, because of the mode of action of glyphosate, Lemna sp. tests should be performed with glyphosate sprayed of the tested plants and not only with water contaminated by glyphosate to check if the Lemna study used for the direct effect assessment is covering for the other exposure route.

- **Question 5: Considering the exposure and effects assessment for bees, is there any additional information that should be considered to address indirect effects to bees?**

The basic risk assessment for bees assumes that bees are able to find enough feed resources. Glyphosate being a total herbicide, a diminution of availability of flowering plants in-field can be expected. This indirect effect through trophic interaction is not taken into account in the risk assessment. However performing the risk assessment for pollinators according to the EFSA guidance would be a first step, followed by analysis of the public literature on effects of glyphosate on bees (including non-apis species).

- **Question 6: Based on the exposure and effects assessment for soil organisms, should anything else be considered to address the indirect effects assessment to soil organism functional and compositional biodiversity?**

Given glyphosate ecotox profile regarding soil organisms, AGG may agree that direct effects covered indirect ones in this case. However, given the context of glyphosate and its broad area of use, it is recommended to have a broader consideration of potential for effects on soil macro and microorganisms and soil function. Reference from the open literature, including to the most recent EFSA opinion (Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms adopted in 2016), may be useful

(<https://www.efsa.europa.eu/sites/default/files/consultation/160503.pdf>).

- **Question 7: Considering the current in-field and off-field protection goals for non-target arthropods, and meeting those protections goals with the existing assessment is there anything else to consider to maintain relevant nontarget arthropod functions in-crop and protecting species abundance and richness (i.e., insect biodiversity) off-crop?**

The risk assessment is based on direct effects. The potential loss of habitats for foliage dwelling arthropods should be considered, especially if acceptability of in-field risk assessment is based on

recovery of in-field non-target arthropods populations. Given the discussion during the first renewal and the concern raised in the approval regulation of glyphosate, it is recommended to have a broader consideration of potential effects on NTAs. Reference to the most recent EFSA opinion (Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods) together with findings from the literature search may be useful (<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.3996>).

The option to model recovery at the landscape level was discussed. Recovery modelling should take into account the indirect impact of glyphosate on NT habitats and not recovery from the direct effects. However, GRG highlighted that there is still a lack of acceptance for such modelling studies, which was acknowledged by the AGG.

- **Question 8: Currently, there are no in-crop protection goals for non-target terrestrial plants. Therefore, comprehensively addressing indirect effects from in-crop weed control, is best addressed outside the PPP framework and under other policies (e.g., common agricultural policy (CAP)). Does the AGG agree that the best solution to address indirect effects from in crop weed control is best handled by risk management options under other policies (e.g., CAP)? For example, does the AGG agree that protecting farmland birds, from indirect through trophic interactions that may result from in-crop weed control, can be addressed independently by MS via risk management options and using the provisions of the new CAP?**

This could be addressed at the level of product authorisation and to some extent by other policies than PPP approval/Authorisation scheme. However, given the efficacy spectrum of glyphosate (total herbicide), the in-crop protection goals for non-target plants should be considered depending on the crop groups and accounting for good agricultural practices. For example, in orchards and vineyards, application is generally made in the rows, below trees. The space between the rows should ideally be vegetated to allow the use of the part of the field by herbivorous vertebrates and arthropods and offer flowering resources for bees. The notifier is therefore encouraged to also address how the scope of use of glyphosate based on the GAPs in question, and also based on yearly use estimates, may impact non-target plants. In addition, if argumentation is presented that other types of weed removal have an equal or greater impact on ecosystems and biodiversity, this should be supported by data. We note that comparing only the area of land use is not an adequate comparison.

The more recent EFSA opinion on NTPs (Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target terrestrial plants) might also be consulted (<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3800>).

Closely related to point 7.

- **Additional comments on slides**

Slide 8: AGG reminds GRG that all claims should be substantiated in the supplementary dossier and will be assessed according to the standard approach.

Slide 9: the GRG aims at comparing the monitoring data with the RAC, however other thresholds, eg. drinking water and surface water according to the respective directives (directive [98/83/EC](#) and directive 2000/60/EC) should also be taken into account.

Slide 19: AGG comments that effects on birds and mammals should be described and taken into account by applying the guidance documents in place and considering the relevant information identified in the literature search.

Slides 20 -24: AGG reminds GRG that the quotes date back to 2008 and over the last 12 years the state of play evolved. However, the B&M GD revision is still not bringing insights on how to address the question, and there is currently no EU level guidance to address indirect effects to birds and mammals through trophic interactions.

Slide 27: AGG notes that functional redundancy makes ecosystem more resilient. Protection of biodiversity as an enabler for that redundancy should be taken into account.

Slide 40: AGG adds that taking into account the relevant literature data will complement the assessment of active substance data.

Slide 41: AGG notes that the literature reports potential effects on earthworms which should be documented in the supplementary dossier. GRG adds that an earthworm study with the representative formulation will be performed and that some studies from the literature may have scientific flaws. GRG will focus their dossier on protection of the structure and function of soil organism communities.

Slide 42 : GRG asks for clarification about the quantitative approach. AGG replies that the risk assessment is one quantitative approach. Ranking (transitional) effects observed in all data, including in the literature and higher tier studies, is another way to document the possible impact in a quantitative way.

Slide 43: When it comes to modelling, it is clarified that information is provided in the EFSA opinion on non-target arthropods from 2016 and this should be read in conjunction to the opinion on modelling published in 2014.

Slide 46: When it comes to non-target plants, AGG notes that GRG identified policy options outside of the regulation for plant protection products, like the CAP, that could be used to address impacts of pesticides on biodiversity at the landscape level. They consider such tools as a holistic approach to assess which should be preferred over a specific approach developed for a specific a.s. However, studies with glyphosate compiled with relevant pieces of scientific literature should be used to inform such an assessment.

Slide 51: AGG feels that there is no need to develop new approaches as discussed at the beginning of the call under Question 1. Rather, the GRG should use existing literature, concepts, models and approaches from other parts of the globe. AGG notes that the ecosystem services approach is useful, but wonders if it is sufficient to fully address the biodiversity question (gaps to be identified). Finally, the AGG mentions that they are missing a holistic approach for the whole environment e.g. long-term biomonitoring of fields where glyphosate is used and see how biodiversity changes with it. However, the GRG mentions that it will be difficult to identify the contribution of glyphosate vs. other stress factors in such studies.