Minutes pre-submission meeting GTF2-AGG
Fate & Behaviour, Ecotoxicology, Endocrine Disruption

Date:	Thursday, October 17th, 2019
Time:	10.00 – 17.00 h

Present on behalf of the AGG:

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1. **Opening**
   On behalf of Assessment Group of Glyphosate (AGG), the chair of the meeting welcomes all participants. The chair of the Regulatory Working Group of the Glyphosate Taskforce 2 (GTF2) 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 their dossier in the field of Fate and Behaviour, Ecotoxicology and Endocrine Disruption.
   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.

3. **General topics**
   GTF2 proposed two new topics for discussion:
   1) How to deal with studies that will not be finalized by the time of dossier submission?
      Answer AGG: Those studies can be submitted in the peer review process provided that they are requested by EFSA.
   2) How to present (old) literature studies in the dossier?
      Answer AGG: Reference is made to the advice document 'How to present the literature search in the dossier to be submitted in June 2020' dated October 2019 which was made available to the GTF2. Furthermore, it was confirmed that a separate meeting (teleconference) is to be scheduled on this topic.

4. **Fate and Behaviour**
   Reference is made to the GTF2 presentation 'Environmental Fate / Modelling' (attachment 1).

   Slide 6 (degradation in soil – laboratory, active substance):
   Regarding recovery and microbial biomass, the <90% recovery and <1% of OC are not considered cut-off criteria. It depends on the data set whether or not to eliminate a data point/experiment. Will be decided on a case by case basis.
   Regarding pH range, all values should be reported for the same matrix (CaCl2 or water) to ensure that a sufficient range has been tested and to provide a robust check of pH dependency. It is usually considered that the range indicated in OECD 307 refers to $CaCl_2$ matrix.

   Slide 8 (degradation in soil – laboratory, metabolite AMPA):

The new degradation study might not be sufficient to address the issue as the presence or absence of pH dependence is not definitively demonstrated. AGG recommends GTF2 to further address the issue with more soils with pH values in the acidic range. GTF2 asked as follow-up if the use of the worst-case would defensible, AGG responded that considering the limited data set, it is not known whether the worst-case value is actually the worst-case.

Slide 12 (degradation in soil – field data):
If GTF2 can demonstrate that the US/Canada soils are representative for EU soils (properties, climate), then the US/Canada soils should be included in the data set.

Slide 16 (adsorption to soil – active substance):
The applicant should present a detailed assessment of the adsorption studies according to the criteria of the OECD 106 guideline and of the OECD 106 evaluators checklist (latest version). If these criteria are met, the (new) adsorption data can be taken into account.

Slide 20 (adsorption to soil – metabolite AMPA):
Although 4 soils fulfil the data requirement AGGs prefers to have a new study with additional soils to enable some conclusions regarding adsorption in relation to soil properties. At least GTF2 should consider a new study.

Slide 22 (degradation in water – active substance and metabolite AMPA):
Although GTF2 considers experimental aqueous photolysis studies as supplemental, AGG is of the opinion that it would be part of the dossier. It is therefore advised to present the route of degradation.

Slide 24 (further existing studies – active substance):
AGG has no comments on GTF2 proposal to column leaching and behaviour in air.

Slide 26 (potential effects of water treatment – active substance):
In the absence of guidance regarding this point, consideration regarding the potential degradation products formed by ozonation / chlorination processes of glyphosate and its metabolites and/or data from literature may be of interest. GTF2 is encouraged to investigate the effects of water treatment.

Slide 38 (public monitoring):
A clear and transparent evaluation and summary of the monitoring data is required from the GTF2. Depending on the type of monitoring locations the relevant thresholds should be regarded (i.e. do not compare SW monitoring only to the RAC but also include drinking water and water framework directive thresholds).
The inclusion of monitoring data from literature would also be of interest. AGG indicates that additional monitoring data (groundwater and surface water) might be found in the European Environmental agency database. It is noted though that exceedance of aquatic threshold values cannot be linearly extrapolated to effects on other types of organisms

Slide 43 (PEC calculations – risk envelope):
See answers to slides 44-48.

Slide 44 (PECsoil calculations – relevance of new EFSA guidance):

AGG reiterates that all guidance that is applicable (into force) at the time of dossier submission will be applicable for the dossier.

Slide 45 (PECsoil calculations – proposed risk envelope):
The proposed scenarios seem appropriate and there is no need to consider the split application in Tier 1 simulations.

Slide 46 (PECgw calculations – proposed risk envelope):
The proposed scenarios seem appropriate and there is no need to consider the split application in Tier 1 simulations if significant safety margins are obtained when considering single application.

Slide 47 (PECsw calculations – proposed risk envelope FOCUS steps 1-2):
The proposed scenarios seem appropriate and there is no need to consider the split application in Tier 1 simulations.

Slide 48 (PECsw calculations – proposed risk envelope FOCUS step 3):
The proposed scenarios seem appropriate. Split application might be needed to consider for FOCUS step 3.

5. Ecotoxicology

Reference is made to the GTF2 presentation 'Glyphosate EU Annex I Renewal – Ecotoxicology' (attachment 2).

Slide 24 (acute mammal risk assessment – endpoint selection):
Provided that the available studies on acute oral toxicity are comparable regarding their test design, AGG may consider the geomean LD50 for the risk assessment (note that the geomean per species is calculated first, and thereafter the overall geomean between species). However, this alternate approach must be properly motivated; GTF2 needs to address the concerns raised in the previous evaluations.

Slide 32 (chronic mammal risk assessment – endpoint selection):
The chronic endpoint for mammals will be carefully re-considered based on all available data. At this stage therefore, AGG cannot give an answer whether GTF2 proposal for a revised endpoint (NOAEL revised from 50 to 150 mg/kg bw d) will be accepted or not.

Slide 41 (Higher Tier common vole semi-field effects study):
A 50% reduction in rate applied for use in risk assessment cannot the accepted in advance, and is not generally accepted for the acute risk assessment. The proposal will be carefully considered during the evaluation.

AGG agrees to review all available residue decline studies, also those which have been previously reviewed at EU level. Reference is made to the *Outcome of the Pesticide Peer Review Meeting on general recurring issues in ecotoxicology, approved: 28 June 2019, doi:10.2903/sp.efsa.2019.EN-1673*.
Where the broadleaf data set is not considered useful for EU risk assessment, GTF2 needs to provide further options for risk assessment and AGG will evaluate them.

Regarding an enclosure study, AGG does not support the generation of new vertebrate studies, unless they are unavoidable. Furthermore, it is not possible at this stage to assess the study design as presented,

so the relevance is questionable. Information from literature and population modelling can be submitted and will be taken into account. However, please note that generic statements regarding the population dynamics of voles are not generally accepted, as it is not possible to make an extrapolation to no risk simply based on a high baseline reproductive rate. This is of particular importance from the stand-point of biodiversity, as voles (and other small mammals covered by voles in the risk assessment) form the basis of several food webs including higher predatory bird and mammal species.

Slide 44 (aquatic fish chronic endpoint selection):
The GTF2 proposed to consider the *Brachydanio rerio* chronic study as invalid. During the previous peer review, the choice of the chronic endpoints was already discussed. AGG indicates that the argumentations will be (re)checked. However, the study summary available in the RAR contradicts the arguments provided by the GTF2 regarding the unreliability of the endpoint. Moreover, the choice of the chronic endpoint was part of previous peer review discussions. Thus, an update of the endpoint to be considered for chronic risk assessment of fish seems unlikely in the light of the relatively recent discussions in the last peer review.

Slide 47 (pollinators):
The GTF2 indicated that new studies are available compared to the previous RAR and proposes a weight of evidence for risk assessment, as done for Art 43 submissions. For the available studies, AGG recommends performing a risk assessment considering the EFSA bee guidance (EFSA Journal 2013;11(7):3295), although the guidance is not yet noted, as it is the current practice at EU level for DAR/RARs. Please refer to the agreements in the *Outcome of the Pesticide Peer Review Meeting on general recurring issues in ecotoxicology, approved: 15 Dec 2015, doi: 10.2903/sp.efsa.2015.EN-924.* Note that implementation refers only to those areas of the Guidance for which adequate data is available, according to the agreement.

Slides 55-57 (biodiversity):
The GTF2 did not propose new information nor assessment. The GTF2 only reminds the outcome of the risk assessment and highlights the benefits of the use of glyphosate (control of invasive / alien species). The arguments are seen as purely qualitative and not fully addressing the concern as stated by the EU Commission *("risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic inter-actions"*).
It is agreed that no validated tools nor methodology for a EU harmonized risk assessment are available. Still, AGG would like to suggest to GFT2 to explore more deeply the current state of the art in order to identify potential new data/information or new approach or tools that may help to provide some quantitative information to address this specific concern. AGG also advises to use monitoring data to address the point.

The use of glyphosate is decided upon product/application level and not on the active substance level, but due to the magnitude of use, glyphosate is omnipresent. Even if biodiversity is not affected by glyphosate alone, its effects on biodiversity should be addressed in the dossier.

6. Endocrine disruption (ED)
Reference is made to the GTF2 presentation 'Glyphosate EU Annex I Renewal – Ecotoxicology' (attachment 2) and to GTF2 presentation 'Glyphosate EU Annex I Renewal – Toxicology' (attachment 3).

GTF2 indicates that the conclusions in the EFSA conclusion on ED properties of glyphosate are still valid*: Peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate, approved 17 August 2017, doi: 10.2903/j.efsa.2017.4979.*

AGG reminds that after 2017, new guidance on ED has come into force (*Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, adopted 5 June 2018, doi: 10.2903/j.efsa.2018.5311*) so that a new up-to-date dossier on ED has to be built.

GTF2 agrees to present a new dossier and to follow the new EFSA/ECHA guidance, including submission of Appendix E.

AGG does not consider Level 1 data unnecessary given the significant quantity of higher Tier data. All information available should be submitted and evaluated, including Level 1 data. Therefore QSAR-data and all peer reviewed literature relevant for ED endpoints (e.g. mechanistic studies; epidemiology and field studies) should be provided for the ED assessment.

In the light of the substantial use of glyphosate AGG advises GTF2 to pay specific attention to data on epidemiology. Considering the level of public concern, there is a need to evaluate these data thoroughly at the level of the active substance assessment.