EUROPEAN COMMISSION

Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
22 September 2023

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SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Commission informed that the summary report of the meeting of this Committee in May is published. The full summary report of the meeting in July is under finalisation while an extract of it concerning the discussions on glyphosate held at this meeting has already been published on the Commission's website dedicated to glyphosate.

A.02 Date of next meeting(s).

The Commission confirmed that the next meeting of this Committee will take place in person on 12 and 13 October 2023 and that interpretation will be provided. The Member States were reminded that if they cannot participate, they should provide voting delegation to another Member State.

A.03 AoB.

The Commission informed that it had received a request for access to the documents containing the Member States comments on the draft renewal report for glyphosate made available after the meeting of the Committee in July and how it intended to respond to the request.

A Member State asked how the proposed renewal of approval of glyphosate would affect ongoing procedures to decide on applications for (re-)authorisation of plant protection products (PPP) under the current approval expiring 15 December 2023. The Commission explained that it considers that following a renewal of approval new applications for renewals of existing authorisations (even if these are extended ones granted under the earlier approval) would need to be submitted and assessed under the new applicable conditions of approval. Another Member State explained that under their national administrative law, on-going administrative procedures should be completed under the rules applicable at the time when the application was made.

A Member State asked if the Commission could provide further guidance how the ruling on Case-162/21 should be applied for products containing metalaxyl-M. The Commission replied that as restrictions under Art. 49(2) of Regulation (EC) No 1107/2009 apply for this active substance, it is not possible to grant emergency

authorisations for uses that are not permitted by the applicable restriction in the approval of the substance. This had already been confirmed at previous meetings of the Committee.

Section C Draft(s) presented for a discussion

C.01 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011

(PLAN/1497/2023)

The Commission explained that the postponement of the meeting from the initial date intended (15 September 2023) to 22 September 2023 was needed to finalise the internal validation of the relevant documents. It thanked all the Member States which submitted comments on the draft Renewal Report made available in July.

The Commission also drew the attention of Member States to letters received from various stakeholders, which had been made available prior to the meeting: from Pesticide Action Network (PAN) Europe, Health and Environment Alliance (HEAL), several third countries, as well as a recent report from Générations Futures. The Commission informed it asked EFSA and ECHA to reply to the arguments raised by PAN Europe and Générations Futures by 6 October 2023.

The Commission presented the updated draft Renewal Report section by section, highlighting the changes made based on the comments received to the previous version of the draft Report. The Commission also explained why certain comments had not led to changes. Member States were invited to comment on each section and the amendments presented. A Member State indicated that at this stage it had a scrutiny reservation on all the draft documents.

In relation to the proposed ban of uses of glyphosate for pre-harvest desiccation, two Member States explained that pre-harvest uses are important for some agricultural systems, in particular to eliminate cover crops in conservation agriculture, which lead to reduction of green-house gas emissions and use of nitrogen. Another Member State questioned the necessity of such prohibition, as each individual PPP must be authorised at national level, and this is the moment where evaluation for compliance with good agricultural practises should take place. The Commission proposed to amend the relevant parts in the various texts to better specify which desiccation uses are not allowed, which Member States found acceptable.

One Member State questioned whether the co-formulant for which a data gap was identified in the EFSA Conclusion should be prohibited in glyphosate-containing products as had been done in 2016 for tallow amines and suggested that co-formulants should be assessed in a harmonised way at EU level. The Commission recalled that the EFSA Conclusion did not identify a concern for this co-formulant that would justify a prohibition. It also recalled that according to Regulation (EC) No 1107/2009, Member States have the responsibility to evaluate all co-formulants when assessing applications for the authorisation of PPP and that the draft Regulation under discussion referred to the criteria for identification of unacceptable co-formulants set in Commission Implementing Regulation (EU) 2023/574, which has established a mechanism for

adding unacceptable co-formulants to Annex III of Regulation (EC) No 1107/2009. Three other Member States asked for clarifications and suggested minor redrafting in the draft renewal report for better clarity; these suggestions were implemented.

One Member State expressed concerns that the extensive explanations in the draft renewal report related to indirect impacts on biodiversity creates a precedent that might require similar treatment for other active substances. The Commission agreed that similar explanations might be necessary for other substances for which the EFSA Conclusion contains comparable findings.

Two Member States stated that references to non-professional users are not justified as products authorised for such users are evaluated at national level. The Commission recalled that reference to non-professional users is already present in the current approval and seemed justified as such users are not specifically trained in plant protection.

Several Member States were concerned that the requirement to consider alternative methods for weed control during the assessment of applications for product authorisation would create a large burden for the national authorities and that it is not clear what will be the effect during the zonal authorisation processes. In addition, these Member States indicted that the evaluation of the requested confirmatory information on indirect effects of glyphosate on biodiversity, may overlap with the next renewal. Doubts were also expressed whether additional monitoring on biodiversity will be of any further value. In general, some Member States thought that the existing biodiversity legislation and strategic documents (e.g. Biodiversity Strategy) are sufficient and that addressing indirect effects on biodiversity in the context of the renewal of approval of glyphosate is not justified – such topic should be addressed at a horizontal level because of its broad scope and the fact that the situation varies significantly among Member States.

One Member State opined that herbicides have advantages under certain geographic conditions: for instance, ploughing is leading to significant soil erosion (i.e., losing soil cover) in hilly areas and under such circumstances the use of herbicides is preferable in order to maintain soil. Another Member State asked if similar requirements to assess indirect impacts on biodiversity will be included in the approvals of other active substances.

As regards the provision setting confirmatory data to the applicant to submit information once a guidance document is available, one Member State proposed to set a timeline for the development of such a guidance document and to shorten the time for applicants to supply the confirmatory information to 1,5 years after the finalisation of the guidance document.

The Commission explained that the proposed approach aims to provide maximum flexibility to the Member States until a harmonised methodology for assessment of indirect effects on biodiversity becomes available. The development of such guidance will be a complex task and therefore it is not possible to set a deadline in the Regulation. However, the Commission is committed to mandate EFSA to develop such guidance as soon as possible after adoption of the renewal Regulation. As to the time needed for applicants to then deliver confirmatory information, it is likely that field studies will be needed, which are expected to last for more than one season and thus be longer than one year. Thus, the timing set for submitting data after the guidance is available needs to be sufficient to generate the data needed and longer that the standard timing given in

such cases which is two years. The Commission also recalled that each substance is assessed on a case-by-case basis and noted that a similar approach may be followed if the peer review and the EFSA Conclusion would identify such necessity.

One Member State requested that if indirect effects on biodiversity are identified and if practical alternative methods for weed control exist, refusal of authorisations for PPP containing glyphosate should be obligatory. Several Member States stressed that glyphosate does not fulfil the criteria to be a candidate for substitution and there is no legal basis to require a mandatory comparative assessment. The Commission recalled the wording in Article 50(2) of the PPP Regulation as to comparative assessment, but suggested to include an obligation to set appropriate conditions and restrictions in authorisations in case Member States find indirect impacts on biodiversity.

Seven Member States expressed concern about the proposed prescriptive wording in relation to risk mitigation measures to reduce drift and to protect terrestrial plants, in particular because they found them not flexible enough and not cover all situations. As an example, one Member State indicated that its usual approach was to require smaller no-spray buffer zones but more effective drift-reducing nozzles, to ensure overall low drift. The Commission explained that the risk mitigations measures specified result from the findings in the EFSA Conclusion. One Member State suggested to add a reference to other equivalent measures to allow for alternative solutions, which was accepted.

One Member State suggested setting maximum application rate in response to the risks identified for small herbivorous mammals, but did not make any proposal as to the level of such maximum rate nor the wording to be included in the draft Regulation. The Commission noted that in the EFSA Conclusion there was no justification for setting such maximum application rate. The Commission also noted that if maximum rates were to be set in the Implementing Regulation, there might be a need for frequent amendments, i.e., every time a higher application rate is found safe during product authorisations. Eight Member States strongly opposed the proposal as incompatible with the principle enshrined in Regulation (EC) No 1107/2009 that Member States have the responsibility for authorisations on their territories. The Commission invited the Member State proposing maximum application rates to provide a specific wording together with a justification for the chosen rate(s) for further consideration.

After finalising the discussion on the review report, the draft Implementing Regulation and its Annex were discussed; changes were implemented to ensure coherence with the amended draft renewal report.

Several Member States noted that the draft Regulation and its Annex are unusually detailed and at places repeat existing legal provisions which Member State implement on a routine basis. Some Member States stressed that this approach should not be understood to set a precedent for future approvals / renewals of approval of active substances.

The Commission noted that most Member States who sent comments supported 15 years as renewal period and explained its reasoning for proposing 10 years as set out in recital 30 of the draft Regulation. Several Member States indicated that they could accept 10 years despite their preference for 15 years. One Member State thought that 10 years is too long in the light of the uncertainties identified but did not propose a specific time period. The Commission recalled the high resource needs in Member States authorities and EFSA for the current renewal procedure and invited all Member

States who advocate for a shorter renewal period to volunteer to become rapporteur Member State for the upcoming renewal procedure. The Commission also noted that the development of guidance and the provision of confirmatory information on potential indirect impacts on biodiversity will take several years – if the renewal period is too short and considering that applications for renewal need to be submitted 3 years in advance of the expiry of the approval, new data might not yet be available to inform the next renewal process if the period would be shorter than 10 years.

One Member State reiterated that it would have preferred 15 years renewal, due to the fact that there are no critical areas of concern identified, that glyphosate is not classified under CLP Regulation, and that its use is essential for direct-drilling technologies which plays an important role to achieve a climate neutral Europe and for which farmers need predictability in order to invest in expensive new drilling machinery. This Member State also stressed that the focus of resources on assessing alternative (low risk) active substances should be given higher priority than reassessing for a third time glyphosate, given the fact that two assessments have led to similar results with no critical areas of concern.

The Commission informed that it would make available the agreed updated versions of the draft Renewal Report and Implementing Regulation on 22 September 2023. Member States were invited to send comments by 27 September 2023 14.00 CET, in order to make available revised drafts which consider the comments received 14 days before the vote at the next meeting of this Committee.