

EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director-General for Food Sustainability responsible for Directorates E, F and G

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APPEAL COMMITTEE 16 November 2023 at 9h00 SUMMARY REPORT

Chair: Claire BURY

The meeting took place in person.

1. Adoption of the Agenda

The agenda was adopted without amendments.

2. Exchange of views and possible opinion 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/2023/1497)

Legal Basis: Regulation (EC) No 1107/2009 - Article 20(1)

Procedure: Examination procedure

The Commission explained that the draft Implementing Regulation renewing the approval of the active substance glyphosate would be discussed and the vote on it taken during the meeting.

The Commission recalled that the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), Section Phytopharmaceuticals – Legislation had reached no opinion in the vote on the draft Implementing Regulation at its meeting on 13 October 2023. Consequently, the draft had been referred to the Appeal Committee for further deliberation. The Commission also informed the Committee about letters received from one Member State (and the Commission's response thereto) and a civil society group which had been made available to the Member States prior to the meeting of this Committee.

The Commission recalled that its proposal to renew the approval of glyphosate for 10 years, subject to a number of conditions and restrictions, was based on comprehensive assessments carried out by the Assessment Group on Glyphosate (the rapporteur Member States – comprised of FR, HU, NL and SE), the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) together with all Member States. The Commission thanked the Member States and the agencies for their work, which had required significant resources.

The Commission recalled that the content of the proposal in front of the Appeal Committee had been discussed on several occasions with Member States in the Standing Committee. Their comments had been accommodated to the maximum possible extent, always considering the positions of all Member States in view of obtaining maximum support as required by the Comitology Regulation. Some comments or requests could not be accepted because of legal constraints or because they could not be justified based on the outcome of the scientific assessment. The Commission noted that the decision to renew the approval of glyphosate for 10 years does not preclude the possibility to launch an early review at any time if new evidence emerged that would call into question compliance with the approval criteria.

The Commission asked the Member States if they had any comments or questions on the draft Implementing Regulation or if there was a change in their position since the vote taken in the meeting of the Standing Committee on Plants Animals, Food and Feed, section Phytopharmaceuticals - Legislation on 13 October 2023.

No Member State made any comments or raised any questions on the draft Regulation or its Annexes.

One Member State announced that they changed their position from 'in favour' to 'abstain' because in their view the use of glyphosate should be prohibited for use prior to harvest, recalling their declaration made at the SCoPAFF meeting on 13 October 2023.

The Commission recalled that the draft Implementing Regulation contained a prohibition of the use of glyphosate for desiccation to control the time point of harvest or to optimise threshing, but that a general prohibition of all pre-harvest uses at EU level could not be justified because EFSA had evaluated several pre-harvest uses among the representative uses in the application dossier and they were found to be safe. Furthermore, the draft Implementing Regulation contains provisions obliging Member States to consider whether pre-harvest uses for purposes other than for desiccation are in line with good agricultural practices in their territory, thus providing flexibility to Member States to refuse authorisations where they conclude that this is not the case.

No further Member State indicated a change in position compared to the vote taken in the meeting of the Standing Committee on 13 October 2023.

Vote taken: no opinion.

The Commission announced that, since the current approval of glyphosate expires on 15 December 2023 and since it had the legal obligation to take a decision on the renewal in the absence of a qualified majority at the Appeal Committee, it will now proceed to renew the approval of glyphosate in the coming weeks. This is based on the assessment made by EFSA of the impact of glyphosate on the health of humans, animals and the environment, which had not identified critical areas of concern that would prevent a renewal of approval.

The following protocol declarations were made:

Italy:

"L'Italia apprezza lo sforzo collettivo profuso dagli Stati membri, dall'EFSA, dall'ECHA e dalla Commissione per finalizzare una nuova valutazione del glyphosate, avvenuta a pochi anni di distanza dalla precedente e con l'esame di un notevolissimo numero di dati.

Tuttavia, l'Italia ha ritenuto di astenersi considerando essenziale prevedere nel regolamento di rinnovo dell'autorizzazione della sostanza attiva il divieto di utilizzo nella fase pre-raccolta.

L'Italia ritiene infine auspicabile:

- l'avvio, a livello comunitario, di ulteriori studi integrativi finalizzati alla raccolta di dati atti a colmare le lacune conoscitive al fine di tutelare la biodiversità e le diverse matrici ambientali;
- il completamento, senza indebito ritardo, della valutazione dei dossier relativi all'approvazione o al rinnovo dell'approvazione di sostanze attive potenzialmente alternative al glyphosate."

Unofficial translation

Italy appreciates the collective effort made by Member States, EFSA, ECHA and the Commission to finalise a new evaluation of glyphosate, which took place a few years after the previous one and with the examination of a very considerable amount of data.

However, Italy decided to abstain, considering it essential to include a ban on its use in the pre-harvest phase in the regulation for the renewal of the authorization of the active substance.

Finally, Italy deems it desirable:

- to launch, at community level, further integrative studies aimed at collecting data aimed at filling knowledge gaps in order to protect biodiversity and the various elements of the environment;
- to complete, without undue delay, the evaluation of the dossiers relating to the approval or renewal of the approval of active substances that are potential alternatives to glyphosate.

The Netherlands:

"First of all, The Netherlands would like to express its appreciation for all the work that has been done by the AGG consortium, EFSA and the Commission on this dossier.

This resulted in a comprehensive risk assessment, where no critical areas of concern were identified by EFSA. The Netherlands acknowledges this outcome.

On the other hand, in the Netherlands there are concerns present in society and amongst several scientists about the effects of glyphosate on biodiversity and about a possible link between the use of glyphosate and Parkinson's disease. Also, on scientific level, there have been several studies showing associations between the exposure to glyphosate and the development of Parkinson's disease. The concerns about biodiversity and the possible health effects of glyphosate lead to an adopted resolution in the Dutch Parliament to vote against a renewal of glyphosate.

Following these concerns, the Netherlands will initiate a scientific research at our National Institute of Public Health and the Environment (RIVM) on a possible causal link between the use of glyphosate and Parkinson's disease. EFSA will be asked to be involved to ensure the results will be useful to interpret possible risks of the active substance glyphosate.

The Netherlands would like to have an explicit confirmation from the Commission that the approval of glyphosate will be revoked when and if, from this study or from any other scientific information, it can be concluded that glyphosate causes unacceptable risks to humans, animals or the environment; especially in the case of a causal link between glyphosate and Parkinson's disease.

In addition, The Netherlands asks EFSA to give priority to the development of test protocols on neurodegenerative impact of PPP's in order to include such studies in future risk assessments.

The Netherlands also supports the development by EFSA of a risk assessment framework on the indirect effects of PPP's on biodiversity.

Overall, The Netherlands acknowledges both: the outcome of the risk assessment and the concerns from society and the Dutch Parliament on the possible impact of glyphosate on biodiversity and human health. Therefore, The Netherlands will abstain on the current proposal."

<u>Slovenia:</u>

"The Government of SI advocates banning the use of glyphosate on non-agricultural areas.

Regarding the use of glyphosate for agricultural production purposes, the Government of SI advocates that its use be limited as much as it is possible. Use is permitted only where no suitable alternative methods are available.

Since the Commission's proposal goes in the direction of the position of the Government of SI, SI supports the Commission's proposal. Therefore, SI votes in favour of the Commission proposal."

Claire BURY
Deputy Director General *e-signed*