EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability, and Innovation
Pesticides and biocides

Brussels,
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Discussion at the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), section Phytopharmaceuticals - Legislation on Agenda item B.03.00

Exchange of views and possible opinion on a draft Commission Implementing Regulation 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

12-13 October 2023

Summary Report

The Commission informed that several Member States had submitted comments on the draft Renewal Report and draft Implementing Regulation that were made available after the meeting of the Committee on 22 September 2023. All these comments had been made available to the other Member States.

The Commission also drew the attention to letters received from stakeholders, which had been made available prior to the meeting and about statements published by EFSA and ECHA in response to criticism from NGOs, which had been published on the Commission's dedicated glyphosate webpage. In the statements the agencies concluded that the points and findings in the letter and report by the NGOs do not have any impact on the overall conclusions adopted by EFSA and ECHA.
The Commission also mentioned that on the day before the meeting it had met 4 NGOs who had handed over a petition signed by 2.5 million citizens since 2017 from all over the world, including third countries, calling for a ban of glyphosate.

The Commission presented the updated draft Renewal Report section by section, explaining the changes made to address the comments received to the previous version of the draft Report, as well as some small editorial changes and corrections. The Commission also explained why certain comments from Member States had not been taken up. Member States were invited to comment on each section.

The Commission explained that to accommodate a proposal of one Member State it had proposed to set maximum annual application rates at the highest values where no unacceptable risk for small herbivorous mammals was concluded, while allowing Member States to set higher rates for specific plant protection products (PPPs), if additional data is submitted and their risk assessment at national and/or zonal level indicates that no unacceptable risks is identified. This Member State insisted that absolute maximum rates should be set, and if higher levels are found to be safe for certain uses, the limit in the approval regulation should be raised. The Commission explained that the EFSA

Conclusion does not give any justification for such absolute limits because the relevant risk assessment had not considered possible refinements. Several Member States strongly opposed setting of any maximum application rates as deviating from the usual practice, having little added value with respect to safety, while expecting to cause implementation difficulties at national and zonal level. They stated that while they could support the current proposal as a compromise and with reluctance, they could not accept any further changes, and this should not set any precedent. One Member State expressed preference that either no maximum application rates or absolute ones are set to ensure legal certainty. Despite this preference, they could support the Commission proposal. Another Member State found the proposal compatible with current practises at national level.

The Commission explained that it had not modified the proposal as requested by one Member State to require mandatory comparative assessment and refusal of authorisations when non-chemical alternatives are available. In its view the EFSA Conclusion did not provide grounds to overrule Article 50(2) of Regulation (EC) No 1107/2009 according to which Member States may conduct comparative assessments for products that contain active substances that are not candidates for substitution but are not obliged to do so. The Member State who had made the proposal noted that both this and their proposal for maximum application rates aim to harmonise the processes across the Member States and support the ambition to reduce the use of chemical pesticides in Europe. In addition, they believed that the existing legal framework allows such measure to be adopted. Several Member States who took the floor opposed the proposal and no other Member State supported it. The Commission recalled that it (and all Member States) supports the reduction of the use and risk of pesticides. However, the tools to achieve this are set specifically in other legal frameworks such as the Sustainable Use Directive and reminded that it had proposed to reinforce these tools in its proposal for a Sustainable Use Regulation currently under discussion.

After finalising the discussion on the draft renewal report, the draft Implementing Regulation and its Annexes were discussed. The Commission explained some editorial and typographic changes (in line with changes made in the draft Renewal Report) that were supported by Member States.

The Commission explained again the reasoning for its proposal for a renewal period of 10 years as set out in recital 30 of the draft Regulation. It noted that most Member States who sent comments supported 15 years as the appropriate renewal period, while one had requested a shorter period. That Member State reiterated its request for a shorter period considering the existing uncertainties, however, without proposing any specific length. No other Member State supported an approval period shorter than 10 years. Several Member States recalled their proposal for a longer renewal period but stated that the proposal of Commission is acceptable. One Member State expressed that it could not accept less than 10 years.

The Commission and several Member States taking the floor expressed their appreciation for the enormous work and efforts of the Rapporteur Member States, EFSA and ECHA, and Commission.

The Commission proceeded to vote during the meeting. The Member States voting against or abstaining invoked the precautionary principle, political reasons, public opinion, and/or absence of agreement at national level.

Outcome: no opinion.

The Commission informed that it would refer the draft Regulation to the Appeal Committee that would take part in the first half of November 2023 in accordance with the comitology rules.

The following protocol declarations were made:

Croatia:

"Considering that application restrictions are necessary, and taking into account the precautionary principle, and the negative attitude of part of the public regarding the use of glyphosate, as well as the Commission's strategy from "Farm to fork", as part of the European Green Plan, which emphasizes the need to move to a fair, healthy and ecologically acceptable food system without the use of synthetic chemical products for plant protection Croatia will not support the proposal of the Commission."

Denmark:

"Denmark support banning the desiccation of crops before harvest and that the member states must introduce buffer zones where glyphosate may not be sprayed along streams and nature areas of either 5 or 10 m, depending on the dosage of glyphosate on the fields.
Denmark welcomes the change in the proposal about use on sealed and very permeable areas where the Member States should pay particular attention to these areas.
Denmark would have liked a ban of concentrated products containing glyphosate to non-professionals, but find it covered by the Member States possibilities to non-approval of this use.
With this remarks Denmark can support a renewed approval period of a maximum of 10 years."

France:

La France prend acte des améliorations apportées par la Commission européenne à son projet de règlement renouvelant l'approbation du glyphosate, notamment l'interdiction d'utilisation pour la dessiccation en vue de la récolte et l'obligation pour les demandeurs de soumettre des données confirmatives en ce qui concerne les effets indirects sur la biodiversité via la chaine trophique.
La France invite la Commission à mandater sans délai l'EFSA pour élaborer le document guide qui permettra d'évaluer ces données confirmatives.
Cependant, la France considère que le glyphosate est une substance dont l'utilisation doit être réduite à l'échelle européenne et limitée aux utilisations pour lesquelles il n'existe pas d'alternatives. Le règlement d'approbation devrait traduire cet objectif et contribuer à la trajectoire de réduction européenne. En l'état, ce règlement renvoie aux États membres la mise en œuvre éventuelle de mesures de réduction de l'utilisation, alors qu'une approche portée par la Commission permettrait de renforcer la cohérence du marché intérieur et d'éviter de possibles distorsions de concurrence.
De plus, la France avait demandé à ce que la durée de l'approbation soit beaucoup plus courte que les 10 ans proposés compte tenu des incertitudes soulignées par les scientifiques.
Pour ces raisons, la France ne peut pas soutenir la proposition de règlement de la Commission européenne et s'abstient.
La France invite la Commission à modifier sa proposition pour répondre aux préoccupations de la France et de nombreux Européens, en restant ouverte à des échanges en ce sens.

Unofficial translation

France notes the improvements made by the European Commission to its draft regulation for renewal of the approval of glyphosate, notably the ban on use for desiccation for harvest and the obligation for applicants to submit confirmatory data with regard to indirect effects on biodiversity via the trophic chain.
France invites the Commission to mandate the EFSA without delay to develop the guide document which will make it possible to evaluate this confirmatory data.
However, France considers that glyphosate is a substance whose use must be reduced on a European level and limited to uses for which there are no alternatives. The regulation for approval should reflect this objective and contribute to the European path towards reduction. As it stands, this regulation refers to the Member States the possible implementation of the measures to reduce the use, whereas an approach led by the Commission would make it possible to strengthen the coherence of the internal market and avoid possible distortions of competition.
In addition, France had requested that the duration of approval be much shorter than the 10 years proposed given the uncertainties highlighted by scientists.
For these reasons, France cannot support the regulation proposed by the European Commission and is abstaining.
France invites the Commission to modify its proposal to respond to the concerns of France and many Europeans, while remaining open to discussions in this direction.

Germany:

" Glyphosat ist mit Abstand das meist eingesetzte Totalherbizid. Glyphosat wirkt systemisch, d.h. aufgenommen über die Blätter gelangt es in alle Bestandteile der Pflanze und führt zum Absterben der Pflanze.*
** Seit 2017 sollen die Mitgliedstaaten bei ihren nationalen Zulassungsentscheidungen über glyphosathaltige Pflanzenschutzmittel die Auswirkungen auf die Biodiversität einbeziehen und gegebenenfalls Anwendungsbedingungen zur Risikobegrenzung festlegen.*
** In Deutschland haben wir bereits national auf dem Verordnungsweg bestimmte Anwendungen von glyphosathaltigen Herbiziden verboten/beschränkt.*
** Allerdings fehlen auch über 10 Jahre nach Inkrafttreten der VO (EG) Nr. 1107/2009 weiterhin eine anerkannte harmonisierte Bewertungsanleitung und konkrete Anforderungen an ein Risikomanagement, um die indirekten Auswirkungen auf die Biodiversität und insbesondere die Effekte auf Nahrungsnetze in den Zulassungsverfahren einheitlich bewerten und regulieren zu können.*
** Auch die EFSA hat festgestellt, dass insoweit mangels verfügbarer Informationen keine eindeutigen Schlussfolgerungen gezogen werden können und mögliche negative Effekte nicht ausgeschlossen werden können.*
** Deutschland fordert weiterhin, dass der EFSA ein Mandat zur Verwendung der von Deutschland bereits vorgestellten Interimsmethode zur Bewertung der Biodiversität erteilt wird.*
** Deutschland wird deswegen der erneuten Genehmigung des Wirkstoffs Glyphosat nicht zustimmen, sondern sich enthalten."*

Unofficial translation

Glyphosate is by far the most commonly used total herbicide. Glyphosate has a systemic effect, i.e. when absorbed through the leaves it gets into all parts of the plant and causes the death of the plants.
Since 2017, Member States have been required to take into account the effects on biodiversity in their national authorization decisions for plant protection products containing glyphosate and, if necessary, establish conditions of use to limit the risk.

In Germany we have already banned/restricted certain uses of herbicides containing glyphosate through national regulations.
However, even more than 10 years after Regulation (EC) No. 1107/2009 came into force, there are still no recognized harmonized assessment guidelines and specific requirements for risk management to assess uniformly for regulatory purposes during the approval procedures the indirect effects on biodiversity and in particular the effects on food webs.
The EFSA has also determined that, due to a lack of available information, no clear conclusions can be drawn, and possible negative effects cannot be ruled out.
Germany continues to demand that EFSA is mandated to use the interim method for assessing biodiversity that already exist in Germany.
Germany therefore does not agree with the renewal of approval of the active substance glyphosate, but will rather abstain.

Italy:

"L'Italia apprezza il grosso 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, in relazione ad alcuni punti di ulteriore approfondimento evidenziati dal parere dell'EFSA ed emersi nella discussione finalizzata all'adozione del regolamento di rinnovo l'Italia ritiene opportuno sottolineare che sia auspicabile:

- *che l'utilizzo della sostanza attiva non sia autorizzato in fase di pre-raccolta*
- *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 gliphosate."*

Unofficial translation

Italy appreciates the great collective effort made by Member States, EFSA, ECHA and the Commission to finalize a new evaluation of glyphosate, which took place a few years after the previous one and involved the examination of a very considerable amount of data.
However, regarding some issues for further investigation as highlighted by the EFSA opinion and which emerged in the discussions to adopt the renewal regulation, Italy deems it appropriate to underline that it is desirable:

- to launch, at community level, of further integrative studies for collection of data to fill data gaps in order to protect biodiversity and the various environmental matrices;
- to complete, without undue delay, of the evaluation of the dossiers relating to the approval or renewal of the approval of active substances that are potential alternatives to glyphosate;
- that the use of the active substance is not authorized in the pre-harvest phase.

Latvia:

"*Latvia supports the Commission's Implementation Regulation draft PLAN/2023/1497 with the following reservation:*
Considering the evaluation of the EU's scientific and competent authorities EFSA and ECHA and the Commission's proposal, Latvia supports the draft Regulation for renewal of the approval of glyphosate for a shortened period, but at the same time encourage to set at least 30 days interval between the use of glyphosate and harvesting."

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.

Portugal:

"Portugal supports the proposal for renewal of glyphosate as it has been established from the scientific risk assessment that glyphosate meets the approval criteria provided for in article 4 of Regulation 1107/2009 as no critical areas of concern were identified during the peer review of the substance.
Although we acknowledge that there are issues that need further consideration including at Member State level when (re)authorizing plant protection products we find that the overly prescriptive approach and setting of redundant conditions that dismiss the role of MS as Risk Managers will mostly contribute to unharmonized approaches from applicants and competent authorities to (re)authorization of glyphosate based plant protection products at zonal and national level, uncoherent decision making and increased administrative workload."

Slovenia:

"The Government of Slovenia 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 Slovenia, Slovenia supports the Commission's proposal. Therefore, Slovenia votes in favour of the Commission proposal."