EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2017)

EXTRACT FROM THE SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED

SECTION PHYTOPHARMACEUTICALS - PLANT PROTECTION PRODUCTS – LEGISLATION

5 OCTOBER 2017 – 6 OCTOBER 2017

CIRCABC Link: https://circabc.europa.eu/w/browse/2a806ef7-3337-4dcb-b0fb-fd58c3f28ca2

AGENDA

Section A **Information and/or discussion**

POINT A.21 – GLYPHOSATE

1.1. Summary of events since last PAFF

The Commission summarised the events since the last PAFF meeting in July 2017:

1.1.1. Further allegations in relation to the Monsanto papers

- In August 2017 further documents were released by the lawyer of the plaintiffs in the class action court case in the United States – among others they contain information about studies allegedly showing that dermal penetration of glyphosate when contained in formulated products is higher than for pure glyphosate.
- Again, the Commission asked EFSA and ECHA to consider the issues raised and what impact this may have, if any, on the Agencies' assessments of glyphosate.
- The two Agencies issued statements, which are publicly available and were also made available on CIRCABC on 20 September. They confirmed that these allegations do not have any impact on their assessments.

1.1.2. Plagiarism allegations

- In September 2017, articles appeared in a number of European press outlets casting doubt on the integrity of the EU assessment of glyphosate, in particular the content of the assessment report submitted to EFSA by the German Federal Institute for Risk Assessment (BfR).
- The Commission took these allegations seriously and asked the BfR and EFSA to respond.

- The two bodies issued statements strongly refuting these allegations. The statements can be found on their respective websites.
- Therefore, given the careful and thorough examination of all information as well as the review of all allegations about the quality of their work and the reactions by the two EU agencies and the German BfR, there are no substantiated grounds to call into question the scientific assessments and conclusions on glyphosate carried out in the European Union.

1.1.3. EFSA's conclusion on the potential endocrine disrupting properties of glyphosate

- The conclusion was published on 7 September 2017 and was made available on CIRCABC on 20 September 2017.
- As already indicated in the preliminary information received from EFSA in July 2017, the assessment concluded that the weight of evidence indicates that glyphosate does not have endocrine disrupting properties through oestrogen, androgen, thyroid or steroidogenesis mode of action based on a comprehensive database of toxicological information. The available ecotoxicology studies did not contradict this conclusion.
- The draft Commission Regulation on the renewal of the approval of glyphosate was amended to refer to the publication of this conclusion. The text (revision 1) was made available on CIRCABC on 20 September 2017 and was also published on the Commission's specific webpage dedicated to glyphosate.

1.1.4. European Citizens Initiative

- The Commission has been informed that the organisers of the ECI "*ban glyphosate and protect people and the environment from toxic pesticides*" planned to officially submit the initiative shortly.
- In line with the provisions of the ECI Regulation, the examination of a successful citizens' initiative includes the following steps:
  - The Commission shall first receive the organisers at an appropriate level to allow them to explain in detail the matters raised in their citizens' initiative.
  - Second, the organisers shall be given the opportunity to present the citizens' initiative at a public hearing. The Commission and the European Parliament shall ensure that this hearing is organised at the European Parliament.
  - Finally, the Commission shall set out in a Communication, within three months from the submission date, its legal and political conclusions on the citizens' initiative, the action it intends to take, if any, and its reasons for taking or not taking that action.

1.2. Member States reactions to the Commission's proposal presented in July

The Commission indicated it had received written comments from 10 Member States on the draft Regulation put forward in July, which have been made available to all members of the Committee. In these comments, several Member States had indicated they would have preferred a 15-year renewal period but that they were ready to support a 10-year renewal.

The Commission also informed it had received letters from the companies belonging to the Glyphosate Task Force informing about their intention to initiate judicial proceedings should no decision be taken. The Commission also referred to the possible financial consequences of such a Court case in case the Court decided in favour of the plaintiffs.

The Commission then invited those Member States that had not reacted in writing on the draft Regulation submitted in July to indicate their position.

One Member State supported the proposal for renewal but asked that the requirement that Member States shall ensure that the genotoxic potential of formulations is addressed before granting authorisations for PPPs containing glyphosate, which is currently mentioned only in the review report, be also part of the renewal Regulation (in the Annex). One Member State opposed this suggestion. The Commission indicated it would reflect on this suggestion and explained that the mentioning in the review report did in any case already highlight this issue for Member States.

One Member State requested that the field of use provision *'Only use as herbicide may be authorised*' be not specified in the Annex as this was the standard practice for all renewal of approval decisions, and requested to delete the specific reference an obligation already contained in Directive 2009/128/EC on the sustainable use of pesticides. The Commission explained again that it had proposed to maintain that restriction because a deletion could be wrongly perceived as an enlargement of the possible uses. The Commission also explained that the requirement to minimise use of glyphosate in specific areas, although already part of the Sustainable Use directive, was repeated in the renewal regulation to provide further reassurances to Member States and the public.

One Member State indicated that its Parliament had discussed the draft Commission Regulation and had decided that the government must oppose the renewal of the approval.

One Member State explained that its position with regard to draft Commission Regulation had been discussed at high political level as it is considered very sensitive given that glyphosate is the most used herbicide. The divergence between the IARC and EFSA/ECHA conclusion on the carcinogenic potential of glyphosate, together with the ongoing European Citizens Initiative makes it difficult for this Member State to support the proposal and this is the reason why it will vote against the draft Regulation. When asked whether a shorter renewal period would change its position, this Member State replied that it would not be the case.

The Commission expressed some concern that the outcome of the EU assessment concerning the carcinogenic potential of glyphosate was still questioned. While the political debates about the substance might still be unsettled, the Commission emphasised that the EU agencies ECHA and EFSA, as well as the German BfR had responded satisfactorily to all allegations as to the quality of their work. Furthermore, agencies in practically all Member States and several agencies outside the EU have all concluded that glyphosate is not linked to cancer in humans. IARC remains the only international agency not to share this conclusion.

One Member State indicated that it had no official position yet but stressed that it would probably not be able to support the renewal, even if the renewal period would be shortened.

One Member State explained that the responsible minister had the intention to vote in favour of the renewal of the approval, but while three debates in their national Parliament had already taken place it is not yet clear whether there would be Parliamentary majority to support a vote in favour of the renewal.

One Member State referred to its statement at the July PAFF meeting and indicated it had no final instructions from its government.

Another Member State also indicated it had no official position yet but discussions at national level seem to be pointing towards a vote against the renewal because of concerns related to glyphosate residues found in surface water samples and because of the sensitivity of the topic.

Seven further Member States indicated during the meeting that they would be ready to support the renewal of the approval.

Six other Member States indicated during the meeting that they had no official position yet but two indicated their position would probably be in favour of the renewal.

1 Member State was absent.

One Member State asked whether 6 November was the last date for a possible vote.

The Commission informed that as already explained in the meeting in July, this would be a possible date for a vote that would still enable an appeal committee to be organised, should this be necessary, in view of the expiry date of the current approval (15 December). However, if a qualified majority in favour of the renewal emerges, the organisation of an appeal committee would not be needed. The Commission repeated once again that it would not renew the approval of glyphosate without the support of a qualified majority of Member States.