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HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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

SECTION *PHYTOPHARMACEUTICALS - PLANT PROTECTION PRODUCTS - LEGISLATION*

19 JULY 2017 - 20 JULY 2017

CIRCABC Link: *https://circabc.europa.eu/w/browse/726e71b2-23c2-4cf3-ad04-480dbc372284*

AGENDA

Section A Information and/or discussion

A.21 Glyphosate

The Commission started by summarising the events since the last PAFF meeting in May 2017 before moving on to discuss the proposal concerning the renewal of approval of glyphosate that had been made available to Member States two weeks prior to the meeting.

1.1. Summary of the events that took place since the last PAFF meeting in May 2017

1.1.1. "Monsanto papers"

- In view of the intense debate over the last months, and whilst the Commission is neither party to the legal proceedings in the US nor has any proof that the allegations are correct, it asked EFSA and ECHA to indicate which impact the allegations in the so-called "Monsanto papers", if confirmed, would have on the overall assessment and the EFSA and ECHA conclusions and opinions on glyphosate.

- Both ECHA and EFSA confirmed that the information contained in the "Monsanto papers", even if confirmed, would not have an impact on their overall assessment of glyphosate. This is because the articles mentioned were study reviews. The EU experts had access to the raw data and produced their own conclusions on the original studies. Therefore, the study reviews have limited weight in the scientific assessment. Furthermore, the interests of the authors of the review reports had actually been declared and known to ECHA and EFSA.

- Both statements (ECHA's and EFSA's) are publicly available and were also made available to Member States on CIRCABC on 6 July.

- The same issue was tackled in the European Parliament's June Plenary session on 13 June 2017 – in response to an Oral Question from several MEPs, Commissioner Andriukaitis clarified the issue of the Monsanto papers, answered on the planned REFIT evaluation of the pesticides legislation, answered on the recent Court rulings on access to information and on the measures taken by the Commission with regard to alternative sustainable and cost efficient solutions for plant protection.

- The Commission also informed that some MEPs have decided to bring EFSA to Court for their refusal to disclose some parts of the raw studies in the context of an access to documents requests.

1.1.2. Letter and article from Mr Christopher Portier

- Mr Christopher Portier had sent a letter to President Juncker on 28 May 2017, in which he questioned the assessments by ECHA and EFSA on glyphosate.

- The Commission asked the two agencies to reply. Their joint answer, also made in collaboration with the German BfR, is publicly available on their websites and was also made available to Member States on CIRCABC on 6 July.

- Overall EFSA and ECHA are of the opinion that all the findings in the chronic rodent carcinogenicity studies referred to in the letter have been adequately considered and therefore see no need for their evaluations to be revisited.

- Furthermore, Mr Christopher Portier and Mr Peter Clausing published an article in response to the article published in Archives of Toxicology by EFSA staff, containing similar criticisms of the EU review as in Mr Portier's letter to Commission President Juncker. EFSA's response will shortly be published by the journal. The EFSA reply as accepted by the journal has been added to CIRCABC for Member States.

➢ Therefore, currently, given the thorough scrutiny of all available information by the two EU agencies, there are no grounds to call into question the scientific assessments and conclusions on glyphosate carried out in the European Union. This was clearly stated by Commissioner Andriukaitis at the AGRIFISH Council on 17 July 2017. At this occasion, Commissioner Andriukaitis also made clear that "*the Commission has no intention to reapprove glyphosate without the support of a qualified majority of Member States*". As stated by him, "*this is and will remain a shared responsibility*".

1.1.3. Global 2000 Report from July 2017

- Global 2000 has just published a report authored by Mr Peter Clausing that criticises the ECHA assessment of glyphosate. This report has been made available on CIRCABC on 13 July.

- ECHA is in the process of considering this report and will respond in due course, publishing its reply.

1.1.4. Pesticides Peer Review Expert meetings on ED properties

- In its Conclusion of October 2015, EFSA identified a data gap to rule out potential endocrine activity observed in one animal study. Pertinent data became available too late to be included in the peer review. Consequently, on 27 September 2016 the Commission tasked the Authority to assess the additional information.

- The minutes of the Pesticides Peer Review expert meetings 159 (toxicology) and 160 (ecotoxicology), held respectively on 6-9 June 2017 and 14-16 June 2017, were made available on CIRCABC on 6 July.

- Experts concluded that "*the weight of evidence indicates that glyphosate is not an endocrine disruptor*". The draft focussed EFSA Conclusion on endocrine disruption has now been made available to Member States for comments before finalisation by EFSA.

- EFSA also submitted a letter to DG SANTE informing about the conclusions of the meetings – this letter is available on CIRCABC.

1.1.5. Opinion of the European Chemicals Agency's Risk Assessment Committee (RAC)

- The RAC Opinion on the classification of glyphosate was officially transmitted to the Commission on 15 June 2017. As a reminder, in its opinion, RAC concluded by consensus that the available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen.

- The opinion is publicly available and was made available to Member States on CIRCABC on 6 July.

- COM published a notice in the Official Journal of the EU on 28 June 2017 acknowledging receipt of this opinion. In line with the provisions of Regulation (EU) 2016/1056[1], the approval of glyphosate expires on 15 December 2017.

1.1.6. European Citizens Initiative (ECI)

- On 15 June 2017, the organisers of the ECI "*ban glyphosate and protect people and the environment from toxic pesticides*" informed the Commission that they reached the 1 million signatures of support required – the number is now over 1.3 million and the organisers want to see this number further increase.

- The European Citizens' Initiative Regulation requires that the organisers submit the signatures to Member States authorities for verification.

- The Commission was informed on 5 July 2017 that the organisers of the ECI had submitted that same week the signatures to the Member States for certification/verification. Member States have three months to do so, from the time of submission by the organisers.

[1] Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate. OJ L 173, 30.6.2016, p. 52-54.

- After verification of the signatures, the organisers can submit them to the Commission. The Commission will then have three months to react. The Commission can decide either to follow the request or not follow the request and in both instances would be required to explain its reasoning.

- The Commission recalled that the ban of glyphosate is only one of the three aims pursued by the ECI. The second one is a call to ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry, and the third one is a call to set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future.

1.2. The Commission's proposal

The Commission explained that given the sensitivity of the file and the call for transparency there is now a dedicated webpage and Q&A document on glyphosate on the Europa pesticides pages[2] (the special webpage went live on 19 July 2017) and that the draft proposal is also available on this page.

The Commission informed that the minutes of the PAFF meetings on the specific agenda point "glyphosate" will be published rather quickly after the meetings on this webpage.

1.3. Member State comments

One Member State supported the Commissioner's view that the scientific controversy with regards to the carcinogenic potential of glyphosate should be regarded as settled. From a health assessment perspective, there are no reasons not to renew the approval of the substance. They nonetheless indicated that they have no final position for the moment but that the responsible Minister was in favour of a renewal. Discussions were still ongoing on whether a condition for Member States to pay attention to impacts on biodiversity should be included. They questioned the shortening of the renewal period to 10 years.

The Commission explained the rationale behind the 10-year renewal period proposed, referring to the relevant Recital in the draft Regulation setting out the reasons.

One Member State supported the renewal of approval but had no final position yet on the period of renewal. They pointed to the high cost that a procedure as called for in the second aim of the ECI (to ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry) would entail and questioned who would pay for this.

Another Member State would favour a 15-year renewal period as they see no reason to limit the period to 10 years. They also wondered why the

[2] https://ec.europa.eu/food/plant/pesticides/glyphosate_en

restriction to “herbicides uses only” had been maintained given that for other renewals such restrictions were routinely removed.

The Commission explained that as there is no other foreseen or possible use of glyphosate, it had proposed to maintain that restriction because a deletion could have been wrongly perceived as an enlargement of the possible uses.

One Member State indicated that they did not have a position yet as the responsible Minister wanted to debate this in their Parliament before the summer. Their Minister strongly supports all actions to ensure transparency on this dossier (and for other substances) to create more public trust in the system.

Another Member State welcomed the creation of the webpage, and asked about IARC’s reaction to the recent answers provided by ECHA and EFSA to the letter of Mr Portier. They indicated that they could not support the proposed renewal for 10 years. Following a request from the Chair for clarification they did not specify whether it was because they oppose the 10 year renewal period or because they oppose any renewal of glyphosate as such.

EFSA mentioned the offer to IARC to meet to discuss their assessments and divergent opinions and to collaborate on the article published in Archives of Toxicology which explains the differences between both assessments, which so far had not been accepted by IARC. EFSA also stressed the high level of transparency on glyphosate at EU level including the 6000 pages of background documents that are publicly available to support the assessment.

The Commission concluded by asking for written comments on the proposal by 4 August 2017, or if not possible given the summer holidays, by 1 September. The Commission also indicated that the proposal would be revisited after the summer, either at the next PAFF Pesticides Legislation meeting on 5/6 October or already at the PAFF Residues meeting on 21/22 September. The Commission also clarified that it would like to vote as soon as possible and that the latest date to hold a vote on the proposal in the context of a PAFF meeting is 6 November 2017.

Two Member States indicated not being in favour of holding discussions on this sensitive file in a PAFF Residues' Committee and strongly insisted to keep the discussions for the PAFF Pesticides Legislation meeting so that the appropriate experts would be present.