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The Classification of Glyphosate by the ECHA

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Report Highlights:
The proposal for an up to 18-month extension for the authorization of Glyphosate is now scheduled to be voted at the Appeal Committee on June 24, but it is very likely that the positions of the Member States have not changed in order to reach a qualified majority. The College of Commissioners is then expected to approve the proposal through written procedure on June 27.
The short-term option prolongs the current authorization of Glyphosate, allowing the European Chemicals Agency (ECHA) to finalize its classification exercise in the second half of 2017, a move pushed by a number of countries. This report clarifies the legal basis and the content of the ECHA classification process.

General Information:
On June 6, 2016, Member States were unable to reach a qualified majority in order to approve a proposal for an up to 18-month extension for the authorization of Glyphosate at the Standing Committee for Plants, Animals, Food and Feed (PAFF). Malta was the only country that voted against, Germany, France, Italy, Greece, Austria, Portugal and Luxemburg abstained, while the other 20 Member States voted in favor.

It is now scheduled be voted at the Appeal Committee on June 24. If the positions of the Member States have not changed by then, which is highly likely, the Commission College will approve the extension under its own authority on June 27 through written procedure. The European Commission has already contacted all the companies holding a registration under the current approval for their comments to the amended terms of the current approval

The aim of the proposal for the 18-month extension is to allow the European Chemicals Agency (ECHA) to complete its classification exercise of glyphosate. The Commission would like to have their opinion to join the already available assessments from the Rapporteur Member State (Germany) and the Food Safety Authority (EFSA) before proceeding to approve a new registration.

The ECHA review process

Q. What is the legal basis for considering an ECHA opinion in the context of renewal of a pesticide authorization?

- Active substances in Plant Protection Products (PPPs) are subject to the harmonized classification and labelling process (CLH) by Article 31 of Regulation 1107/2009 on PPPs.

- Member States, manufacturers, importers, and downstream users may propose the classification and labelling of a substance to be harmonized across the European Union. The European Chemicals Agency (ECHA) is responsible for managing the harmonized classification process for chemical substances according to Regulation (EC) No 1272/2008 (CLP Regulation).

Q. What is the ECHA review process?

- The CLP process for an active substance is triggered when a proposal for harmonized classification of that chemical substance is submitted by a Member State competent authority to ECHA.

- In the case of glyphosate, under the PPP legislation, a harmonized classification and labelling proposal has been prepared by the German Federal Institute for Occupational safety and health (BAuA), since the country is the Rapporteur Member State for glyphosate. This initial proposal for harmonized classification and labelling of glyphosate, posted on the ECHA website, confirmed once more that glyphosate is not carcinogenic "based on the epidemiological data as well as on data from long-term studies in rats and mice, taking a weight of evidence approach, no hazard classification for carcinogenicity is warranted for glyphosate according to the CLP criteria."

Q. How is it different than the EFSA assessment and why now do they have a role?

- The proposal posted by ECHA looks beyond the carcinogenicity of the active substance. ECHA's review also includes considerations about mutagenicity and reproductive toxicity. The scope of ECHA includes all toxicological effects, routes of exposure and environmental protection targets identified from the hazards assessed. (http://echa.europa.eu/view-article/-/journal_content/title/echa-publishes-new-guidance-on-the-scope-of-exposure-assessment)

- The RMS, in this case, Germany, requested the classification on March 17, 2016. [Comment: Several Member States agreed that an ECHA review was needed in order to vote in favor and justify the extension of glyphosate authorization].

Q. What are the next steps in the ECHA review process?

- Under the standard ECHA process, this proposal must undergo a public consultation and review by ECHA's Risk Assessment Committee (RAC), which was launched on June 2, 2016 until July 18, 2016 (45 days).

- If the initial proposal is confirmed, it would support official conclusions of the German Federal Institute for Risk Assessment (BfR), the European Food Safety Agency (EFSA), and most recently the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and also the finalized Cancer Assessment Review Committee (CARC) evaluation conducted by U.S. EPA. Once ECHA's opinion has been adopted by the RAC, which should occur within 18 months of receipt of the initial proposal, it will be published and forwarded to the European Commission.

Q. Is this now a new body we are going to have to deal with on a regular basis?

- It is hard to say at this point. Normally, ECHA's review does not determine the reauthorization of an active substance. However, in this particular case, the Commission included the ECHA's review due to the MS request for additional scientific evidence. Our sources indicate that this requirement was added as a compromise to the MS in order to move forward with the Commission's proposal. However, any dossier submitter (companies) or Member State can request an ECHA review for classification.