FAQs: Glyphosate

Brussels, 29 June 2016

Frequently Asked Questions on Glyphosate.

Memo updated at 14:45 on 29/06/2016 following the Commission's decision to extend the authorisation of glyphosate until the European Chemical Agency issues its opinion.

What is glyphosate?

Glyphosate is an active substance used for the production of pesticides, which has been authorised in the EU since 2002. It is the most frequently used herbicide worldwide and in the EU, and one of several hundred active substances that have been assessed by Member States and the European Food Safety Authority (EFSA) in recent years[1].

Glyphosate-based pesticides (i.e. formulations containing glyphosate and other chemicals) are used in agriculture and horticulture, primarily to combat weeds that compete with cultivated crops.

Does the EU authorise the placing on the market of pesticides?

No, that's the role of the Member States, but active substances in the pesticides have to be approved at EU level.

Once an active substance has been approved or renewed at EU level, the safety evaluation of every pesticide (also referred to as Plant Protection Products PPPs) formulation is done at a later stage by individual Member States before they grant, refuse or restrict – the use of pesticides formulations at national level.

In their authorisation decision, Member States can therefore define the conditions for use of the product, for instance; restricted to certain crops; to professional use; for use in glass houses only.

- **Active substances:**

An active substance undergoes an intensive evaluation and peer-review by Member States and the European Food Safety Authority, before a decision can be made on approval.

Before an active substance can be used within a product in the EU, **it must be approved at EU level.**

- **Pesticides:**

Pesticides and herbicides sold in the market also referred to as Plant Protection Products (PPPs) contain at least one approved active substance.

Before any pesticide can be placed on the market or used, **it must be authorised in the Member State(s) concerned.**

Member States could grant, refuse or restrict the use of a specific product.

Regulation (EC) No 1107/2009 lays down the rules and procedures for authorisation of Plant Protection Products.

What has been the procedure for the extension of approval of glyphosate?

The EU has one of the strictest systems in the world for the assessment of **pesticides**. Hundreds of active substances, like glyphosate, have gone through or are going through a stringent scientific assessment process. The EU approval of an active substance is only granted for a limited period of time (up to 15 years) and must be renewed regularly.

As regards glyphosate, it had been under evaluation, since 2012, for a **possible renewal of the approval**, following the procedures laid down in EU legislation on plant protection products (PPPs).

The EU approval of an active substance means that the Member States can authorise plant protection products on their territory, but they are not obliged to do that. Nonetheless, if there is no EU approval, Member States have no choice.

Timeline:

1. **May 2012:** Assessment of the active substance by the Rapporteur Member State, in this case Germany. Germany's national authority receives dossier for possible renewal of the approval of the active substance glyphosate.
2. **December 2013:** Germany sends report to the European Food Safety Authority (EFSA) so that the peer review by EFSA and all Member States can start (January 2014). It includes a public consultation (March 2014); Additional information requested from applicants (August 2014).
3. **February - March 2015:** Nationalexperts' meetings including risk assessors from all 28 Member States' organized by EFSA.
4. **March 2015:** Publication of a report by the International Agency for Research on Cancer (IARC) on glyphosate - Commission asks EFSA to include it in its peer review.
5. **September 2015:** A new experts' consultation specifically dedicated to carcinogenicity organised by EFSA.
6. **October 2015:** Glyphosate approval provisionally extended until June 2016, pending finalization of the EU peer review.
7. **November 2015**: Publication of EFSA's conclusion.
8. **May 2015**: The Joint UN Food and Agriculture Organisation/ World Health Organisation Meeting on Pesticide Residues (JMPR) publish their risk assessment on glyphosate.
9. **June 2016**: No qualified majority from the Member States at either the Standing Committee (6 June) or the Appeal Committee (24 June).
10. **End June 2016:** End of the provisional extension at EU level of the active substance glyphosate. Commission extends approval of the substance, under certain conditions.

In all, the EU's assessment of glyphosate has taken 3 years, involving public sector scientific experts from EU's agencies (EFSA and ECHA) and national authorities in all 28 Member States.

27 Member States agree with EFSA's conclusion on carcinogenicity (Sweden was in favour of another classification).

What is the final decision?

The Commission adopted the extension of the current approval of glyphosate for a limited period until the European Chemical Agency (ECHA) has concluded its review - since Member States failed to take responsibility (no qualified majority was reached at either the Standing Committee or the Appeal Committee).

In parallel to the extension of the approval, the Commission has already presented to Member States a series of recommendations on the use of glyphosate. Discussions with the Member States have started at expert level, and the Commission will work to have them adopted as soon as possible. The decision will contain three clear recommendations:

1) ban a co-formulant called POE-tallowamine from glyphosate based products;

2) minimise the use of the substance in public parks, public playgrounds and gardens;

3) minimise the pre-harvest use of glyphosate.

It must be noted that it is primarily the responsibility of Member States to decide upon and enforce such measures.

What will be the European Chemicals Agency work on glyphosate?

The European Chemicals Agency (ECHA) is responsible for managing the harmonised classification (CLH) process for hazardous chemical substances. Active substances in Plant Protection Products (PPPs) are normally subject to harmonised classification and labelling. The CLH process for an active substance is triggered when a proposal for harmonised classification of that chemical substance is submitted by a Member State competent authority to the Agency. As part of the procedure for a possible renewal of glyphosate approval under the PPP legislation, a harmonized classification and labelling proposal has been prepared by the German national competent authority (BAuA), since the country is the Rapporteur Member State for glyphosate. For details on the process please see here: ECHA Harmonised classification and labelling. Once the opinion of the Agency has been adopted by the ECHA's Committee for Risk Assessment (RAC), it will be published and forwarded to the Commission.

Why is the ECHA opinion important?

ECHA is the competent EU agency for the assessment of dossiers for the classification of chemical substances. Moreover, the procedure for harmonised classification of glyphosate was already initiated. The discussions in the Standing Committee on Plants, Animals, Food and Feed on 18 and 19 May 2016 showed that in the specific situation of glyphosate a number of Member States, in their role as risk managers, considered that it was appropriate to have an opinion of the Committee for Risk Assessment of ECHA on the harmonised classification as regards carcinogenicity of glyphosate, before taking a decision. Such an opinion is relevant for the approval based on the criteria set out in EU Regulation (EC) No 1107/2009.

What could be done in particular as regards the *co-formulants*?

Co-formulants are used to produce pesticides, but are neither active substances, safeners, nor synergists. They can already be banned or restricted for use at national level.

POE-tallowamine, one of the *co-formulants* used for glyphosate-based products, has raised concerns regarding its toxicity. **The Commission has proposed to Member States to ban** POE-tallowamine **as a co-formulant** in glyphosate-based products and is currently addressing this issue with them as discussions have started at expert level.

It must also be noted that an EU experts' group has already been put together by the Commission with a view to set up the criteria in order to identify an EU list of banned co-formulants.

Will there be additional scientific work on glyphosate?

Yes. Apart from ECHA's upcoming opinion, EFSA continues its on-going review of the existing Maximum Residue Levels (MRLs) for glyphosate. A Maximum Residue Level is the highest level of pesticide residue that is legally tolerated in, or on food or feed, when pesticides are applied correctly.

Finally, the Commission can review the approval at any time - in case relevant scientific elements are published.

For more information

Approval and use of active substances and pesticides in the EU see:
http://ec.europa.eu/food/plant/pesticides/approval_active_substances/index_en.htm

EFSA's website:
http://www.efsa.europa.eu/interactive_pages/pesticides_authorisation/PesticidesAuthorisation

ECHA's website: http://echa.europa.eu/addressing-chemicals-of-concern/harmonised-classification-and-labelling

[1] Every year, around 40 such active substances are approved or renewed at European level.

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