European Commission

Brussels, 7 September 2017

Frequently Asked Questions: Glyphosate

What is glyphosate and what is it used for?

Glyphosate is an active substance which has been used in plant protection products ("pesticides") in the EU for several decades. An active substance is the component of plant protection products that has direct activity against the pest/plant disease. Glyphosate is the most frequently used herbicide worldwide and in the EU, and one of several hundred active substances that have been thoroughly assessed by Member States and the European Food Safety Authority (EFSA) in recent years.

Glyphosate-based pesticides (i.e. formulations containing glyphosate and other chemicals) are used as herbicides in agriculture, horticulture and in some non-cultivated areas, primarily to combat weeds that compete with cultivated crops or present problems for other reasons (e.g. on railway tracks).

Glyphosate-based pesticides are typically applied before crops are sown to control weeds and their root systems and therefore facilitate better growth of crops. This eliminates or minimises the need for ploughing ("zero tillage" farming), thereby reducing soil erosion and carbon emissions. To a lesser extent glyphosate is also used as a pre-harvest or desiccating treatment, accelerating and evening the ripening process (e.g. in cereals grown over the winter months to eliminate weeds and facilitate the harvest, or in oilseed rape to even out ripening before harvest).

What is the current status of glyphosate in the EU?

Glyphosate has been thoroughly assessed by Member States, the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) - to establish whether its use results in any unacceptable effects on human and animal health or the environment.

Following such an assessment, glyphosate was first approved in 2002 according to EU rules on pesticides. Before this time it was authorised for use in Member States according to national rules in place at the time.

Between 2012 and 2015 a comprehensive scientific assessment was carried out by Member States and EFSA according to the rules for renewal of active substance approvals to confirm that glyphosate complies with the new approval criteria laid down in the 2009 EU pesticides legislation, taking into account the latest scientific and technical knowledge. EFSA published its conclusion – that "glyphosate is unlikely to pose a carcinogenic hazard to humans" - following this assessment in October 2015.

The Commission proposed to Member States to renew the approval of glyphosate in early 2016.

No qualified majority in favour of the renewal of the approval of glyphosate could be found. In the light of divergent opinions between the International Agency for Research on Cancer (IARC, an agency of the World Health Organisation) and EFSA on the potential carcinogenicity of glyphosate, it was considered appropriate to ask the European Chemicals Agency (ECHA) to assess the hazard properties of the substance before taking a decision on its potential renewal at EU level. On 29 June 2016[1], following the absence of a qualified majority at either the Standing Committee or the Appeal Committee of representatives of the Member States, the Commission adopted an extension of the approval of glyphosate for a limited period to allow the European Chemicals Agency (ECHA) to conduct its assessment of the carcinogenicity of glyphosate. This extension was limited to 6 months after the receipt of ECHA's opinion or 31 December 2017 at the latest.

Furthermore, Member States also voted in favour of amending the conditions of the existing approval of glyphosate in July 2016, adding further restrictions to ensure the highest safety standards for humans and the environment. The Commission's decision established three conditions for further use of glyphosate in the Member States, as the actual decisions concerning the authorisation of plant protection products containing approved substances for use in their territories are the responsibility of Member States, as the actual decisions concerning the authorisation of plant protection products containing approved substances for use in their territories are the responsibility of Member States:

- Ban a dangerous co-formulant called POE-tallowamine from glyphosate based products;
- Minimise the use in public parks, public playgrounds and gardens;
- Minimise the pre-harvest use of glyphosate.

ECHA sent its opinion to the Commission on 15 June 2017. Therefore, the current approval of glyphosate expires on 15 December 2017.

What are the conclusions in ECHA's opinion?

On 15 March 2017, the Risk Assessment Committee (RAC) of ECHA concluded by consensus that based on the available information there is no evidence to link glyphosate to cancer in humans. Furthermore, the RAC concluded that glyphosate should not be classified as a substance that causes genetic damage (mutagen) or disrupts reproduction.

This confirms the earlier conclusion reached by the European Food Safety Authority (EFSA), supported by experts from 27 EU Member State competent authorities. National authorities outside the EU (e.g. Canada, Japan, Australia, New Zealand and the Joint FAO-WHO Meeting on Pesticide Residues) have also reached the same conclusion. The International Agency for Research on Cancer (IARC) remains the only agency with a divergent view, considering that glyphosate is "probably carcinogenic to humans".

[1] See MEMO/16/2012

What is the Commission now proposing to the Member States?

On 16 May 2017 the Commission agreed that the discussions with the Member States about the possible renewal of glyphosate could restart.

The Commission is proposing a renewal of the approval of glyphosate for 10 years. It is now up to the Member States to decide on the Commission's proposal. After the possible renewal of the approval of glyphosate, Member States are actually responsible for the authorisation of plant protection products containing glyphosate (e.g. Roundup).

The proposal put forward by the Commission includes:

- Specific provisions that Member States have to take into account when considering applications for authorisation of glyphosate-based products (e.g. the protection of groundwater and of terrestrial animals e.g. birds and mammals)
- Certain elements that Member States must ensure during assessment and decision making for authorisation (e.g. use in public areas should be minimized).
- The proposal also reiterates the ban of POE-tallowamine (a 'co-formulant' that was previously used in glyphosate-based products) that was put in place in 2016.

Discussions - in the context of meetings with Member States' experts – start on 20 July 2017.

On 17 July, at the Agriculture and Fisheries Council, Commissioner Andriukaitis informed the EU's ministers that the "Commission has no intention to reapprove glyphosate without the support of a qualified majority of Member States", adding that "this is and will remain a shared responsibility".

Commission's Proposal and **Annex**

Why 10 years and not 15 years?

15 years is the maximum period for renewal of active substances foreseen in the EU legislation. This is the period that the Commission usually proposes when all approval criteria are met.
However, glyphosate is not a routine case. It is the most widely used herbicide active substance in the world. There is a large amount of information on glyphosate already available and its assessment lead to the conclusion that the substance is safe and its approval should be renewed. Additional information on glyphosate is being published at an exceptionally high rate compared to other active substances. Therefore, the Commission has taken into account the possibility of rapid future developments in science and technology when deciding on the length of the approval period of glyphosate.

What about the publication of additional scientific work on glyphosate by the end of 2017?

- On 7 September 2017, EFSA published a scientific conclusion on the endocrine activity of glyphosate. This is due to the fact that, in its conclusion of October 2015, EFSA identified a data gap to rule out potential endocrine activity observed in one study. Pertinent data became available too late to be included in the peer review. On 27 September 2016 the Commission asked the Authority to assess that additional information. EFSA concluded that the weight of evidence indicates that **glyphosate does not have endocrine disrupting properties** through oestrogen, androgen, thryroid or steroidogenesis mode of action based on a comprehensive database available in the toxicology area. It must be noted that **all Member States agreed to the conclusion**.

- A review of the Maximum Residue Levels (MRLs) for glyphosate in food and feed items is also currently being carried out by Member States and EFSA. An opinion on the **outcome of this evaluation will be published by EFSA at the end of 2017**, and, if necessary, the Commission will amend the existing MRLs accordingly. Residues of pesticides in food are routinely monitored by EFSA and Member States by taking samples and testing for pesticides. EFSA publishes an Annual Report which summarises the findings of this testing; the reports have consistently shown that the EU protects consumers by controlling the presence of residues in food. The latest report available (2015) more than 99% of food samples collected across the EU in 2015 were within the legal limits established for glyphosate. This result is in line with the one recorded in 2014.

Does the proposal to renew the approval of glyphosate also automatically renew the authorisation of Roundup and other products containing glyphosate?

No.

Only the approval of active substances is decided at EU level. Decisions concerning the authorisation of plant protection products containing approved substances for use in their territories are the responsibility of Member States. This division of responsibility is based on the principle of subsidiarity and reflects the differences in climatic, agronomic and environmental conditions in Member States.

Following renewal of approval, Member States must re-evaluate all existing authorised products containing glyphosate, such as Roundup, to ensure that they comply with the updated conditions of approval and confirm that their use will pose no unacceptable effects on human or animal health and the environment, taking into account the latest scientific and technical knowledge. Based on such assessments Member States can decide to allow for continued authorisation or to amend or withdraw the existing authorisation.

What about access to the studies on glyphosate?

The summary dossier, which contains the summaries and results of the studies for glyphosate submitted by the industry, is publicly available, alongside all of the supporting documents from the peer-review which accompany the EFSA Conclusion; all in all there are over 6000 pages of assessment available.

What about the European Citizens Initiative on glyphosate?

On 25 January 2017 the Commission registered the ECI entitled "Ban glyphosate and protect people and the environment from toxic pesticides".

The Commission is aware that the initiative has reached the 1 million signatures threshold required for such an initiative.

Once the signatures have been verified by Member States the organisers can formally submit the ECI to the Commission who will then have 3 months to reply to it.

More information:

- 'Ban Glyphosate' European Citizens' Initiative
- EFSA page on Glyphosate
- ECHA page on Glyphosate