



## Renewal process for Glyphosate – FAQs

### What is the nature of the EU renewal process?

EU legislation governing the regulation of pesticides dictates that the “active substances” present in these products must be assessed in terms of their safety for humans, animals and the environment at least once every decade. The review of the approval is necessary to take account of progress in science and technology and experience gained since the active substance was last reviewed.

### What is an active substance?

An active substance refers to the biologically active component that produces the intended effects in plant protection products. Glyphosate is the active substance in a range of herbicides which are widely used in both agricultural and non-agricultural situations in order to protect crops and manage weeds.

### What stages are involved in the renewal process?

Companies manufacturing products containing an active substance (applicants) apply for renewal to a designated competent authority (Rapporteur Member State (RMS)) as publically appointed by the European Commission in advance. For Glyphosate, the Rapporteur is Germany. The RMS verifies the admissibility of each application, followed by an independent, objective and transparent assessment of the submitted dossier and prepares a draft assessment report (DAR) based on the information submitted. This report is sent to the European Food Safety Authority (EFSA) and is circulated to all Member States and the applicant. It is published on the EFSA website making it available to all interested parties for comment. EFSA then conducts its own review. The Commission may decide to ask EFSA to carry out a detailed risk assessment involving peer review by scientists from Member States. Based on the final EFSA conclusion, the Commission prepares a Review Report followed by a Regulation that proposes approval, non-approval or amended conditions of approval to the Standing Committee for Food Chain and Animal Health. SCFCAH consists of representatives from relevant ministries of all EU Member States and delivers its opinion by means of qualified majority voting. In the case of a non-approval decision, Member States are required to withdraw authorisation for products containing the active substance within a defined schedule.



## Does the European Parliament have a role to play?

The renewal process is legislated for by means of a Commission Regulation. The European Parliament has no official role in this particular type of legislative procedure. However, MEPs typically engage in the debate surrounding the renewal process in other ways, such as tabling Parliamentary Questions on the issue.

## How can stakeholders engage with the process?

The process for the review of the approval of glyphosate outlined by Commission Regulation (EC) 1141/2010 offers the possibility for to “any person wishing to submit information which might contribute to the assessment, in particular with regard to potentially dangerous effect”, to do so. Any public party can provide comments on the draft assessment report (DAR) prepared by the Rapporteur Member State and during the commenting period managed by EFSA.

## What data is required for the renewal application?

The range of data required includes that on: 1) physical-chemical properties, 2) impact on human health following single, multiple or lifetime exposure, whether for workers, consumers or the general public, and includes consideration of neurotoxic, mutagenic, carcinogenic and reproductive effects; 3) the nature and amounts of residual traces remaining in food; fate and behaviour in soil, surface, ground and drinking water and air; 4) impact on birds and mammals, aquatic species, earthworms and other soil borne organisms, bees and other invertebrate insects, micro-organisms and non-target plants. Furthermore, data on efficacy is requested and peer-reviewed publications have to be searched systematically for evidence of potentially adverse effects.

## How can citizens be assured of the quality and reliability of the data used for the renewal decision?

The prescribed experimental designs have been developed by leading scientists in the fields concerned. They have been subjected to international scientific scrutiny and have been validated by means of an internationally agreed testing procedure involving laboratories around the world, to verify the reliability of the test methods used. All safety tests must be conducted in accordance with the OECD Principles of Good Laboratory Practice (GLP) a system that ensures that tests are conducted by properly trained personnel, that they follow correct procedures and that the procedures used are documented. GLP rules require that audits of tests and testing facilities are conducted.



[www.glyphosate.eu](http://www.glyphosate.eu)

## What is the timeframe for the renewal process?

Current estimates suggest that the decision to renew glyphosate will take approximately 2 years from submission. In this regard, the renewal process could be completed by October 2014. However, if additional information is required completion of the process may be delayed.

Please refer to [www.glyphosate.eu](http://www.glyphosate.eu) for further information