

## Cooperation of Member States on the renewal assessment of glyphosate: governance model

For the renewal assessment of glyphosate a group of Member States will jointly act as Rapporteur Member State: the **Assessment Group on Glyphosate (AGG)**, in accordance with Implementing Regulation (EU) No 686/2012. Participating Member States are France, Hungary, the Netherlands and Sweden.

Working together as RMS means that a supporting governance is necessary to cover the following issues:

- Deliver on regulatory assignment
- Project management
- Communication (between the Member States of the AGG, the applicant, the Authority (EFSA), the Commission and other EU Member States as well as the general public)

The governance relies on a steering committee with a representative from each of the Member States in the AGG. The mandate of the representative of the Member States can differ depending on the organizational situation in the Member State.

Representatives ascertain the coordination within their Member State and the commitment of the participating Member State when applicable.

### Formal governance structure

- The AGG is responsible for the assessment of the renewal dossier, which is presented in a draft Renewal Assessment Report (dRAR), and that the assessment is performed in an independent, objective and transparent way, based on current scientific and technical knowledge.
- The steering committee is responsible for managing the project with regard to planning the evaluation of the dossier and for meeting the legal deadlines.
- The different tasks related to the assessment of the application and the dossier for the renewal of glyphosate will be divided among the AGG members. Quality assurance throughout the entire evaluation process will be the responsibility of each Member State of the AGG, tacit agreement throughout the entire process will apply. As a result, the steering committee is collectively responsible for ensuring the quality of the complete dRAR.
- For the day-to-day management of the project, the steering committee is supported by a secretariat (including project managers).

- Chairing the steering committee will be done by one of the Member States of the AGG and will be alternated after a period of 6 months.
- Admissibility and confidentiality are formal decisions. Per section of the application and corresponding dossier a decision will be proposed by the Member States of the AGG actively involved in that part of the assessment. These proposals are reported to the steering committee. The steering committee will take one decision, to be signed by all AGG members and covering the whole application and dossier. The admissibility check will be performed according to the "Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances".
- The steering committee aims for scientific consistency of the assessment. In case opinions differ on certain issues during the assessment, the steering committee should endeavor to reach consensus and report it in a balanced way in the draft RAR.
- The steering committee is responsible for aligning as far as possible the communication about the glyphosate renewal assessment before it is released, including external communication, e.g. to general public. The already existing glyphosate webpages on the website of the European Commission will be used as a platform for communication.
- Each Member States of the AGG shall separately charge a fee from the applicant for their part of the work, as stated in Regulation (EC) No 1107/2009.
- As necessary, the steering committee should liaise with the Commission and the Authority in due time, especially for legal affairs and communication.
- An opinion on classification and labelling from the Risk Assessment Committee (RAC) of ECHA is necessary in order to complete the renewal assessment and finalise the EFSA conclusion. Therefore, a proposal for harmonized classification and labelling according to Regulation (EC) no 1272/2008 will be submitted by one member of the AGG on behalf of the AGG, at the latest 12 months after the supplementary dossier has been received.
- According to legislation and regular procedure, which is also applicable for this renewal procedure, the subsequent risk management and decision taking on approval or non-approval of the active substance is the responsibility of the European Commission. The scientific opinion on classification and labelling (RAC opinion) is the responsibility of ECHA and the decision on classification and labelling is taken by the European Commission.