

Helsinki 22. 07. 2016

Umweltinstitut München e.V.

By email [info@umweltinstitut.org](mailto:info@umweltinstitut.org)

**Subject: Glyphosate**

Dear Sir/Madam,

Thank you for your email and your interest in the work of ECHA in assessing glyphosate. You raise a number of important issues.

ECHA has received a proposal from the German Federal Institute for Occupational Safety and Health (BAuA) that glyphosate should have an additional harmonised classification (it already has several). The proposal is now being processed in accordance with the European Union's Classification, Labelling and Packaging Regulation (CLP). The proposal was subject to a public consultation which closed on 18 July. The comments are now being considered by the German Authority. The next step will be consideration of the proposal and opinion development by ECHA's Committee for Risk Assessment (RAC). The RAC is an ECHA scientific committee, composed of experts nominated by the Member States of the European Union and appointed by ECHA. The provisions of REACH and CLP legislations and the published rules of procedure guarantee the objectivity and transparency of the opinion making.

RAC will adopt an opinion on the need for a harmonised classification for glyphosate based solely on its hazardous properties, regardless of how it is used. In its opinion, RAC takes the scientifically relevant data submitted during the public consultation (including those provided by NGOs and independent experts) into account. RAC will also take into account the key information that was previously analysed by other bodies and will also consider the differing views on how some of those studies have been evaluated. The opinion will be submitted to the European Commission who will take the final decision on the need for a further harmonised classification for glyphosate.

ECHA will focus on adopting a scientific opinion on what the harmonised classification and labelling of glyphosate should be, as it does with all substances for which Member States or industry submit proposals. In assessing whether a substance meets the criteria for harmonised classification, ECHA performs an assessment of whether the intrinsic hazardous properties of the substance meet the hazard criteria set out in the CLP Regulation. In doing so, ECHA does not assess the risks associated with the different individual uses of the substance.

When conducting their assessments, regulatory agencies rely on a combination of data from the public domain, as well as data from toxicological studies that are not available to the public. Under EU law, there is a legal requirement on industry to ensure the safe use of chemical substances that they place on the market. Industry, therefore, has to conduct toxicology studies to identify the hazardous properties of these substances. These studies are paid for by industry. Specialised laboratories that perform such studies have to follow strict guidelines, which are laid down in EU legislation and related guidance documents. The studies must be performed in accordance with agreed methodology and meet quality requirements (OECD or equivalent technical guidelines and good laboratory practice). This is the same process used, for example, for medicines. The reports from these studies are made available to the relevant regulatory authorities, including ECHA's Risk Assessment Committee, for their evaluation.

The results of the studies included in the classification process, the responses to comments received and RAC's opinion on the classification of glyphosate will be published on ECHA's website once the opinion has been adopted. The dossier submitted by the German competent authority as well as the comments provided during the public consultation are already available there.

ECHA is committed to implementing the EU's chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. In the process of developing the opinion on the harmonised classification and labelling of glyphosate, we seek to do justice to all parties affected, by following our processes transparently and arriving at a well-founded opinion.

I trust this helps to clarify the issues you raised. Further information can be found at the following link:

- Harmonised classification and labelling:  
<http://echa.europa.eu//addressing-chemicals-of-concern/harmonised-classification-and-labelling>
- ECHA's role in assessing glyphosate:  
<http://echa.europa.eu/chemicals-in-our-life/hot-topics/glyphosate>.

I intend to publish this letter on our website in order to respond to the many citizens who followed your lead in raising these questions with us.

Yours sincerely,

*Signed*

Geert Dancet  
Executive Director