Subject: Glyphosate Classification Review

Dear Mr Vollenweider,

Thank you for your letter of July 11 and your interest in ECHA’s work in assessing glyphosate. You raise a number of important issues. May I thank you also for your kind words about ECHA and our accomplishments. We do indeed have an inspiring and momentous task and we pursue our goals with determination and passion.

You make a point about the source of the data that we take into account in making assessments about chemicals and, in particular, your concerns about using data generated by companies. In reality, when conducting our assessments, regulatory agencies like ECHA rely on a combination of data from the public domain, as well as data from toxicological studies that are not available to the public because they have been conducted and paid for by individual companies.

Under the EU’s regulations on chemicals, there are legal requirements on companies to conduct certain (eco)toxicological studies in order to identify the hazardous properties of their substances. The regulatory agencies have set down strict guidelines which have to be followed by the specialised laboratories that perform the studies. They must be performed in accordance with the agreed methodology and meet quality requirements (OECD or equivalent technical guidelines and good laboratory practice). On demand, the complete reports from these studies are also made available to the relevant regulatory authorities, including ECHA’s Committee for Risk Assessment (RAC), for their evaluation.

You mention data gaps in particular on glyphosate, and the need for further studies as well as to make sure that we evaluate all the available data. In line with the Classification, Labelling and Packaging regulation, ECHA’s RAC will carry out a scientific evaluation of the proposal by Germany for a harmonised classification of the active substance glyphosate. That evaluation will be based on the weight of the available evidence, and make a recommendation on the hazard classification accordingly. The opinion will take into account all the scientific data on glyphosate available to RAC, including any data and comments from concerned parties received during the public consultation which has just ended. 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 were 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. It will not contain any recommendation for further studies, which is not within the competence of ECHA under the CLP regulation.

The results of the studies considered 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.

RAC and ECHA’s assessment is solely based on the hazardous properties of the active substance glyphosate – which harmful effects can it cause? It does not take into account the risk or the extent to which people and the environment are exposed to the substance. This of course depends on how the substance is used and how much of it is used. Those detailed risks are therefore considered under the Plant Protection Products Regulation which is assessed by the European Food Safety Agency, who can also assess the need for further testing of glyphosate or other substances with which it is formulated in commercial herbicidal products.

Towards the end of your letter, you appeal for us to work with rigour, feedback, transparency and proactivity. I can assure you that we will be doing our best to meet those standards – as we do with all our work. The published rules of procedure of RAC set out the process and standards that will be followed in arriving at the scientific opinion. I can also assure you that we are in dialogue with the Agencies who have previously evaluated glyphosate and that we are actively explaining our process to them so that they are able to offer input from their experience where that is appropriate.

Finally, you asked to meet or contact me directly. Perhaps your secretary would be in touch with mine to arrange a mutually convenient time.

I hope that you find my explanations reassuring and I thank you once again for your letter and for your proactivity in supporting our mutual objective of safer chemicals.

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