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Glyphosate: EU Assessment Report Excludes Most of the Scientific Literature from Its Analysis

92% of toxicity studies judged irrelevant or unreliable by preliminary European report

By Claire Robinson
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The preliminary EU report on glyphosate prepared by the Dutch, Hungarian, French and Swedish regulatory agencies fails to take account of the vast majority of recent studies published in the peer-reviewed scientific literature, according to a report by the association Générations Futures.

The preliminary EU report (RAR, for "Renewal Assessment Report") would allow the reauthorisation of the controversial herbicide in Europe at the end of 2022. In an analysis published on 16 November, Générations Futures quantified the failure of the report, prepared by the Dutch, Hungarian, French and Swedish regulatory agencies, to reflect the state of the science on glyphosate.

According to Générations Futures, out of 7,188 studies published in scientific journals, only 30 studies, equivalent to 0.4% of the studies they found, were judged by the RAR to be relevant and reliable without qualification.

None of these 30 studies carried weight in the RAR's evaluation of the exclusion criteria for glyphosate (properties that could lead to a ban on the pesticide) and none was considered as a key study that could lead to the definition of a safe dose.

In total, 92% of the scientific studies published on the toxicity or ecotoxicity of the world's most widely used pesticide were judged as irrelevant or unreliable by the RAR.

On the other hand, notes Générations Futures, the studies conducted by the manufacturers were treated with greater leniency and end up forming the basis of the EU report – in spite of the association's observations that there are "significant methodological flaws" in most of these regulatory tests, which were nevertheless considered reliable by the European evaluators.

The Générations Futures report sheds light on a controversy that has been going on for over five years. In March 2015, the International Agency for Research on Cancer (IARC), the leading authority on the classification of carcinogens, classified glyphosate as "probably carcinogenic to humans". This position is diametrically opposed to that of the EU and US regulatory agencies, which consider the herbicide not to be carcinogenic. Glyphosate was reauthorised in 2017 for five years in the European Union, reduced from the usual 15 years in deference to the huge controversy over the substance.

Differences of opinion

Four years later, the results of the new EU report are identical. According to the conclusions of the RAR, communicated in June, glyphosate is neither carcinogenic, mutagenic, reprotoxic nor an endocrine disruptor. At the same time, the French National Institute for Health and Medical Research (Inserm) expressed a different opinion, concluding that there was a "moderate presumption" of a link between occupational exposure to glyphosate and the occurrence of non-Hodgkin's lymphoma, a type of cancer of the lymphatic system.

Why such divergent views? The report by Générations Futures explains that the EU experts failed to take into account the overwhelming majority of studies published in the scientific literature. Of the 1,550 studies on the toxicity of glyphosate that Générations Futures found had been published in the literature over the last ten years, only 11 were deemed reliable by the RAR. Of the 1,614 ecotoxicity studies identified, once again only 11 were considered reliable. The rate is even lower for endocrine disruption effects: Out of 4,024 published studies, only 8 are considered reliable by the RAR.

On what objective criteria is the bulk of the published science on glyphosate considered irrelevant or unreliable? "Selecting only studies carried out 'on a species relevant to the toxicology of mammals' amounts to excluding all studies carried out on other organisms, such as fish for example," Générations Futures explains in its report. However, an increasing number of studies show that tests on fish could be relevant and exploitable for a risk assessment for humans. The French food safety agency ANSES recommends that data from fish should be considered in assessments of the ability of a substance to damage DNA.

Similarly, Générations Futures criticises the fact that "mechanistic studies examining the effects of glyphosate at the cellular and molecular level were excluded because they 'cannot be linked to the risk assessment'".

Several studies were rejected on the grounds that they were conducted on a mixture of substances, not glyphosate alone. However, closer examination of the studies revealed that in some cases, the study was indeed conducted on glyphosate alone – three studies identified in the RAR fell into this category.

Other academic work is also rejected because it was conducted in a non-European context. Studies from Asia or South America were rejected because the "[experimental] conditions would not be comparable to those in Europe," the report says. This is contrary to all principles of hazard and risk assessment.

Consultation process on glyphosate "not fair" to civil society

Are the studies provided by pesticide manufacturers in support of the glyphosate re-authorisation application subject to the same scrutiny? According to an article by Stéphane

Foucart in Le Monde, the toxicologist Pauline Cervan, the main author of the Générations Futures report, was specifically interested in a specific category of tests (known as "micronucleus tests") designed to identify the genotoxic properties of a substance. Fourteen such studies were submitted by industry to the regulatory authorities, which excluded four of them as unacceptable.

What about the remaining ten, which were considered valid in the RAR? "All these studies have major flaws that should have led the authorities to consider them with reservations," Ms Cervan told Le Monde. According to the toxicologist, who formerly prepared regulatory dossiers for the chemical industry, none of these studies complies with the current recommendations of the Organisation for Economic Cooperation and Development (OECD), which they are supposed to respect. Reasons included an insufficient number of cells analysed, no evidence that the substance being evaluated reached the target tissue (bone marrow), and absence of historical data from the laboratory that conducted the tests.

Questioned by Le Monde, the European Food Safety Authority (EFSA), which oversees the EU assessment, pointed out that the RAR is only preliminary for the time being, and was open to comments in the context of a public consultation that ended on 22 November. "We encourage [Générations Futures] to submit its report to EFSA and ECHA [European Chemicals Agency] so that the rapporteur member states responsible for the RAR can consider the specific points raised," EFSA said. "Certainly, a public consultation has been opened and we will submit our comments, but the process is not fair to civil society," said Pauline Cervan. "The RAR is several thousand pages long and the consultation only lasts two months. For NGOs, the critical work that needs to be done cannot be done in such a short time!"

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