

Joint Press Release

NGOs initiate legal challenge against EU glyphosate re-approval

A consortium of six NGOs - PAN Europe, ClientEarth (EU), Générations Futures (France), GLOBAL 2000 (Austria), PAN Germany, and PAN Netherlands - has officially launched a legal challenge against the European Commission's recent decision to re-approve glyphosate. After conducting a detailed examination of the glyphosate re-approval process and identifying several critical shortcomings, the NGOs submitted a Request for Internal review to the Commission, marking the first step in this legal battle.

The European Commission, the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) have failed to uphold their obligation to protect European citizens and the environment by not adhering to the EU law and case law on Pesticide Regulation and the precautionary principle.

The European Commission re-approved glyphosate for 10 years despite an impressive body of scientific evidence indicating its toxicity to human health and the environment.

Angeliki Lyssimachou, Head of Science and Policy at PAN Europe said: 'We are dismayed by the incredible number of breaches in EU law. Scientific evidence on the important toxicity of glyphosate on health and the environment was not correctly communicated to the Commission by EFSA and ECHA. Farmers are the first victims of this. The Commission reapproved glyphosate despite the available information on its toxicity and the numerous data gaps. This should have led to a ban. "

Pauline Cervan, Toxicologist at Générations Futures said: "The authorities have systematically rejected all data from the independent scientific literature, basing their assessment solely on data supplied by manufacturers. In addition, it appears that some key studies are still missing for different areas of the assessment, which should have led the Commission not to accept the dossier on the grounds of incompleteness".

Helmut Burtscher-Schaden, biochemist at GLOBAL 2000, adds: "Given the evidence uncovered in the US court cases of Monsanto's efforts to influence previous EU approval procedures, we would have expected the authorities to scrutinise the glyphosate manufacturers' studies particularly closely this time. However, the authorities repeated the conclusions of previous approval procedures in a copy-and-paste manner - even when the arguments were based on outdated manufacturer studies that are now generally considered unacceptable."

Margriet Mantingh, chair of PAN Netherlands said: "EFSA's risk assessment of glyphosate neglects the possible effects on the development of Parkinson's disease and autism spectrum disorders in children, while research by independent scientists points to a possible effect. We are very concerned that the Commission is not adequately protecting its citizens. Therefore we demand the Commission to apply the precautionary principle and withdraw the approval of glyphosate."

Peter Clausing, Toxicologist at PAN Germany said: "Disregarding their own guidelines and requirements, the EU authorities have distorted the evidence for the carcinogenic effects of glyphosate in order to come to the false conclusion that the active substance is not carcinogenic."

ClientEarth Senior lawyer Juliette Delarue said: "Glyphosate is a dangerous substance – by re-approving it, the Commission has made a manifest error in the face of the law and of independent and reliable science. Beyond that, the EU treaties require the Commission to act with caution to prevent harm to humans and nature. Our challenge asks the Commission to finally pay heed to the science and withdraw its approval."



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Joint Press Release

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Background information:

In Fall 2023, the European Commission proposed to reapprove glyphosate for 10 years. After 2 rounds of votes among Member States the <u>Commission failed</u> to obtain a qualified majority. In the second vote, only Member States representing 42% of the EU population supported this proposal, but the Commission still decided to move forward and impose the reapproval of glyphosate.

Thanks to a <u>2021 reform of access to justice laws</u>, NGOs and individuals now have the ability to challenge most EU decisions that break environmental law in EU Court. The NGOs sent to the Commission a 'Request for Internal Review", in which they asked the Commission to withdraw the regulation on the reapproval of glyphosate. The Commission now has 22 weeks to reply. If the NGOs consider that the Commission's reply still does not solve the breaches of law, they can challenge the reply before the Court of Justice of the European Union.

Legal arguments - where has the Commission fallen down?

The following findings form the basis of the NGOs' arguments:

1. Cherry-picking of the science

The experts found that the industry provided incomplete dossiers in several areas of the risk assessment. This is not in line with the law, and their dossier should therefore have been rejected by regulators. In some cases, they provided important toxicity studies at a very late stage, preventing regulators from properly assessing them. By failing to request industry actors to provide additional, more comprehensive documentation, regulators ended up producing an incomplete risk assessment.

In addition, the NGOs have identified that the EU assessment systematically discards non-industry studies. Their systematic approach allows them to neglect major scientific findings from academia, that often provide a better insight on the toxicity of pesticides, as regulatory studies are often less sensitive.

2. Cancer risk: new scientific findings confirm again the that glyphosate is a carcinogen

Previously, the NGO experts had already identified that ECHA did not present to the European Commission a carcinogenicity assessment carried out according to its own rules, resulting in failing to classify glyphosate as 'Carcinogen 1B' classification, which would have led to the ban of glyphosate

For example, a <u>new scientific study</u> from the renowned Ramazzini institute confirmed that long-term exposure of rats to supposedly acceptable doses of the representative formulation can lead to the development of blood cancers. Blood cancers (non-Hodgkin's lymphoma) are the main reason plaintiffs are suing Monsanto/Bayer in the US.

3. Genotoxicity shown in non-industry studies

The 2021 ECHA assessment on genotoxicity failed to prove that glyphosate is not genotoxic, while nonindustry studies based on the most sensitive tests show that the herbicide is in fact genotoxic. The



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assessment is still based on old industry studies, which are less sensitive, and many were found to be unreliable from a methodological point of view. No new studies have been requested by the authorities to assess genotoxicity, and many of the copy-paste from industry dossiers scandal identified in the 2017 assessment still remains. The most recent independent scientific literature indicating the genotoxic potential of glyphosate to specific organs has been dismissed from the evaluation. The industry studies indicating that glyphosate can cause chromosome damage on DNA lesions have been declared "supportive/supplementary or unacceptable" instead of "acceptable". This means that they were not taken seriously enough to have an impact in the overall assessment of glyphosate's genotoxicity.

4. Neurotoxicity not properly assessed

The potential of glyphosate to compromise the brain and nervous system has not been properly assessed. All industry studies provided are based on acute or short-term toxicity in adults, and are unfit to assess neurotoxicity via maternal exposure or neurotoxicity in the form of degenerative diseases such as Parkinson's disease.

The industry also omitted to submit a Developmental Neurotoxicity (DNT) study performed in 2001 on glyphosate-trimesium (one of the glyphosate salts), which showed offspring developed adverse effects. The industry also omitted to provide the full independent literature available in the last 10 years, including studies that were submitted during the previous 2015 evaluation. Additional evidence from relevant studies submitted during the public consultation were again discarded by the EU authorities.

5. Glyphosate affects the microbiome

Glyphosate has also been patented as an antibiotic agent and it also affects the microbiome of humans, birds, bees and other species. It has been shown that 50% of human microbiome species are affected by glyphosate. Considering the important role of gut-brain axis indicated in scientific literature, glyphosate-induced alterations may explain the neurotoxicity or reproduction toxicity of glyphosate indicated in scientific literature. Despite the legal obligation to use the most recent and reliable science, the EU risk assessment disregarded evidence on the impacts of glyphosate on the microbiome of humans and other species for the legally unacceptable reason "that standardised regulatory guidance is currently not available for the assessment of microbiome".

6. EFSA failed to disclose vital information on insect, bird and amphibian toxicity

The investigations carried out by the NGOs have shown that while the regulatory studies sometimes showed an unacceptable toxicity of glyphosate for insects (100% mortality, according to industry studies), the EFSA did not even communicate this information to the European Commission in its peer review. In addition, major toxicity studies from academia, showing that glyphosate and glyphosate-based herbicides decimate amphibians or harm the reproduction of birds, were dismissed from the assessment by the EFSA, thus preventing regulators from making a sound decision.

7. No test on complete and representative pesticide formulation provided

EU law and EU case law demands that at least one glyphosate-based herbicide (a 'representative formulation') is tested for its impact on human health and the environment. The aim is to assess the toxicity of the other ingredients of a pesticide formulation, and potential toxicity synergies between the 'active ingredient' glyphosate and co-formulants.

Not a single long-term mammalian toxicity study (such as the Ramazzini institute study mentioned previously) was provided. In the environmental risk assessment, a similar situation was observed: the industry failed to provide many crucial mandatory studies for the representative formulation.

In addition, the EFSA acknowledged that they were not able to assess all the co-formulants from the representative formulation, which is, again, contrary to the pesticide legislation.



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