

# Key Scientific Evidence in EU's Risk Assessment of Glyphosate Herbicide Must Not Remain a 'Trade Secret'

By [Corporate Europe Observatory](#)

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Featured image: EFSA's headquarters in Parma, Italy, 2012 - by CEO

*Companies who make the pesticide glyphosate refuse to disclose key scientific evidence about its possible risks in the name of trade secrets protection. CEO appeals to the European Food Safety Authority (EFSA) to disclose all the possible original elements of three key scientific studies it used in assessing glyphosate as "unlikely" to cause cancer to humans. We also call MEPs to [reject](#) the Trade Secrets Directive in the April 2016 plenary vote on the final text.*

In March 2015 the World Health Organisation's International Agency for Research against Cancer (IARC) [found](#) the world's most commonly used herbicide, glyphosate, "probably carcinogenic to humans". Three months later the EU's official risk assessment of the pesticide, conducted by the European Food Safety Authority (EFSA) and Germany's Federal Risk Assessment Institute (BfR), came to [the opposite conclusion](#) that glyphosate was "unlikely" to cause cancer to humans. A war of words started with, notably, EFSA's director calling scientists critical of its work (including some involved in IARC's review) "facebook scientists" for a petition they had sent to the European Commission... And it continues with, lately, directors of the two organisations engaging in [a public exchange of letters](#), copied to more or less everyone politically involved on this file,[1](#) where both defended the integrity of their respective institution's work. Eventually, a meeting between the two, meant to take place this week, was [cancelled](#), as EFSA did not agree to the IARC's director's requests to change a number of its statements about IARC's work on its website.

One reason behind this almighty mess is the extreme public sensitivity of the topic: behind glyphosate lurks the shadow of US multinational Monsanto, currently one of the most hated companies on the planet, which built its economic development around this wide-spectrum herbicide and GM crops engineered to tolerate it. Monsanto coordinated industry producers into a Glyphosate Task Force (GTF) to facilitate the pesticide's review approval.

But the story has more to it than a political tussle. While conflicts are common in science too, resolving them relies on scientists reviewing and debating the evidence. The problem is this step cannot be taken because parts of this evidence are missing. Three industry-sponsored carcinogenicity studies on mice, in particular, are not accessible to IARC while EFSA insists they played an important role in informing its decision. This situation is unfortunately typical of debates on pesticides regulation.

This is why for years Corporate Europe Observatory and others have been [asking](#) EFSA and the European Commission that, just as with clinical trials for medicines, the data supporting EFSA's scientific opinions should systematically be made public to enable free scientific scrutiny. To find out more about the basis of the glyphosate decision in December 2015 we filed an access to documents request to EFSA to demand the disclosure of these three mouse studies.

EFSA refused, and justified this on the basis that the owners of the studies, all industry producers of glyphosate, said disclosing this evidence would undermine trade secrets and intellectual property rights. Corporate Europe Observatory is appealing that decision by EFSA.

Meanwhile, the political process goes on, with the European Commission expected (according to EU sources) to propose member states start discussing a new EU-wide renewal of glyphosate's market authorisation next March 7-8. To add to the tension, France's food safety agency ANSES published on 12 February an [opinion](#) contradicting EFSA's (even though ANSES officials had contributed to it) by saying that glyphosate could perhaps, after all, be classified<sup>2</sup> as a substance suspected of being carcinogenic to humans – a category which would not imply an EU ban – and that more research should be done, in particular by the European Chemicals Agency (ECHA) in Helsinki.

### **The Mysterious Three**

The starkest difference between the EU's regulatory agencies and the independent scientists who wrote IARC's assessment perhaps lies in their respective interpretation of the animal evidence. The conflict is particularly intense over the EU's use of five industry-sponsored carcinogenicity studies in mice [reviewed](#) by BfR and EFSA. Two of these studies, from 1983 ("A chronic feeding study of glyphosate (Roundup technical) in mice 77-2061! (BDN-77-420)") and 1993 ("Glyphosate: 104-week dietary carcinogenicity study in mice, IRI 438618"), were already included in industry's first EU level request for a market authorisation for glyphosate. But industry sent three new unpublished studies for the EU market authorisation renewal (the "Mysterious Three", as scientific literature reviews specialist Paul Whaley [dubbed](#) them) :

- "Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice" (2001), following OECD Guideline 451 & GLP – study owned by the Israeli pesticides company ADAMA Agan Ltd and was never published;
- "Glyphosate technical: Dietary Carcinogenicity Study in the Mouse" (2009), following OECD Guideline 451 & GLP – study owned by the Australian pesticides company Nufarm and was never published;
- "HR-001: 18-Month Oral Oncogenicity Study in Mice" (1997), following following OECD Guideline 451 & GLP – study owned by the Japanese pesticides company Arysta LifeSciences Corporation and was never published.

### **The dangerous life of Monsanto employees**

The names of the authors of all five studies are redacted in EFSA's publications. In a Twitter exchange on the matter, Monsanto Europe [explained](#) this was for security reasons: "If you get scientists' names what's stopping people going after them/families?" The company later

[added](#) to its first reply saying: “It’s a sad fact that some activists target Monsanto employees for harassment,” but this seems simply irrelevant in this case given that not a single Monsanto employee seems to have been involved in the conduct of these studies.

Despite the first two studies, from 1983 and 1993, also not having been published, IARC could access [3](#) them. Indeed it [interpreted](#) the 1983 study as showing “a significant increase in the incidence of rare tumours, with a dose-related trend, which could be attributed to glyphosate”, in stark contrast with EFSA and BfR’s review of the same study. IARC’s interpretation of the 1993 study is on the other hand consistent with EFSA and BfR’s. But it could not evaluate the three more recent studies, even though it was able to access summaries which its scientists commented showed incidence of various tumours.

### **“Key” and “pivotal” evidence**

The Mysterious Three are an essential element of the conflict. This is particularly so because EFSA heavily referred to them to explain its assessment, with José Tarazona, the Head of EFSA’s Pesticides Unit in charge of the assessment, calling them “key” and “pivotal”. Similar comments can be found from various member states’ experts, [4](#) with Belgium insisting that “it was unfortunate that IARC did not take into account 3 guideline studies in both mice and rats, since this could have put the overall conclusions in another perspective”. This very unfair sentiment (IARC could not access these studies) was echoed by Ireland: “IARC’s failure to evaluate the 3 other studies is not helpful.”

Since EFSA’s publication, the agency has been arguing that there is enough detailed information in its [documentation](#) to perform a good analysis, but IARC scientists respond that the descriptions and summaries published miss key elements and cannot replace original data. *Among these missing elements, IARC said, [5](#) are “the historical control data from the reporting laboratory for all tumours with statistically significant positive increases, by either test recommended by OECD; another is the survival of the animals”. More generally, IARC [pointed](#) to its list of attention points for all studies it assesses. [18 February 2016 addition]*

### **Secret perfection or convenient argument?**

So what is in these Mysterious Three? How can only three studies explain such a striking contrast? Would they be so strong as to convince IARC to reverse its stance? Would they on the contrary confirm it? Or, given the strong political interest in this file and the fact that the EU’s Pesticides Regulation would force glyphosate out of the market were its cancer-causing properties confirmed, isn’t referring to these secret studies a convenient argument for all those willing to keep glyphosate on the EU market anyway?

In its [response](#) to Corporate Europe Observatory on 5 February 2015 explaining why it would not release the information, EFSA said that the studies’ owners (who, by law, must be consulted) refused any disclosure because they considered their studies to contain trade secrets and intellectual property which if released would harm their industrial and commercial interests as well as their “competitive position”. EFSA agreed with this analysis and explained that, according to the exception foreseen in the EU’s Public Access to Documents Regulation 1049/2001 as well as in the EU’s Pesticides Regulation 1107/2009, it was entitled to not disclose the documents.

### **Abusive use of the trade secrets protection argument**

However, both regulations only protect commercial interests and, in the case of the Pesticides Regulation, a limited list of elements within the studies, not the whole document – it is difficult to believe that everything in a scientific study would be a trade secret. Moreover, the EU’s Pesticides Regulation stipulates that any data owner refusing disclosure of its material must provide a verifiable proof that disclosure would harm him, which was apparently not done. Finally, glyphosate has been off-patent for 15 years and most pesticide companies now producing glyphosate [belong](#) to the Monsanto-led Glyphosate Task Force, the group that bundled all these studies together and sent them to the BfR and EFSA: how would disclosing these studies harm any of these companies’ competitive position if they were already shared among the main competitors?

As a consequence, CEO is appealing this decision, hoping that EFSA will use the opportunity of this major file and controversy to demonstrate its good faith in actually acting upon its declared [intentions](#) on data transparency and providing a level of openness that enables this conflict to evolve into a more productive, evidence-based discussion. The ongoing court case on the same issue at the European Court of Justice already provides useful insights into what can actually be disclosed by the agency (see “Additional Information” section below).

As an important aside, CEO also calls MEPs to [reject](#) the so-called Trade Secrets Directive, whose final vote in the European Parliament is announced for next April 12. As a matter of fact, one of the numerous problems with this text is that it would give companies additional arguments to fight public interest disclosures in court by threatening public authorities with massive financial penalties would they dare to disclose information they consider a trade secret.

## **ADDITIONAL INFORMATION**

### **The European Commission and the pesticides industry fighting Greenpeace Netherlands and Pesticides Action Network Europe at the European Court of Justice on glyphosate documentation**

The data used by the European Commission to grant a market authorisation to glyphosate has been a much-debated issue for a long time. Disclosure of industry’s dossier has been at the core of a court case started in October 2011 between the European Commission and Greenpeace Netherlands and Pesticides Action Network Europe at the European Court of Justice. The Court’s General Court [condemned](#) in October 2013 the European Commission to disclose large sections of the documents, but the European Commission has lodged an [appeal](#) which is ongoing. From March 2015 onwards, the European Commission has received support from numerous industry groups in this appeal:

- the European Crop Protection Association (‘ECPA’), which [argues](#) that “an adequate protection of confidential business information (‘CBI’) is essential in order to preserve and stimulate innovation and thus competitiveness and growth in the EU crop protection sector”;
- CropLife International, the international lobby group of the pesticides industry, whose members “account for approximately 75% of sales across the crop protection industry worldwide” and whose interest [consists](#) in “promoting the interests of its members as regards, inter alia, the protection of intellectual property and, in particular, confidential business information”.
- A delegation of US industry, composed of CropLife America, Inc., the National Association

of Manufacturers of the United States of America and the American Chemistry Council, Inc., who [argue](#) that “the present appeal, since it concerns a conflict between the right of access to documents concerning the environment and the protection of confidential business information that manufacturers of chemical products are required to submit to the competent authority, raises a question of principle which is liable to affect the interests of [their] members”.

– the European Chemical Industry Council, the EU’s chemicals industry, [arguing](#) that “it has for many years underlined the importance of an adequate protection of confidential business information (‘CBI’) for the competitiveness of the EU chemicals industry.”

– the European Crop Care Association, an association representing small and medium-sized enterprises operating in the generic pesticides industry, who [says](#) that “the Court’s judgment in the present appeal will have a significant impact on the small and medium-sized enterprises which it represents, which rely heavily on industrial secrets to protect their intellectual property and innovation.”

### Notes:

1. The EU Agriculture and Health Commissioners P. Hogan and V. Andriukaitis, the European Commission’s DG SANTE’s Director and Vice-Director X. Prats-Monné and L. Miko, the chair of the European Parliament’s ENVI Committee G. La Via, Germany’s Federal Minister of Food and Agriculture C. Schmidt, etc.
2. They suggested glyphosate could be placed in CLP Category 2, for substances suspected of being carcinogenic to humans.
3. Thanks to the US’ Environmental Protection Agency, where the 1983 study is [detailed](#) as follows:
4. Knezevich, A. and Hogan, G. (1983) A Chronic Feeding Study of Glyphosate (Roundup Technical) in Mice: Project No. 77-2061: BDN-77420. Final rept. (Unpublished study received Aug 17, 1983 under 524-308; prepared by Bio/dynamics, Inc., submitted by Monsanto Co., Washington, DC; CDL:251007-A; 251008; 251009; 251010; 251011; 251012;251013;251014). (MRID 00130406)
5. And a 2006 review by the Joint WHO/FAO Meeting on Pesticides Residue where the 1993 study is [detailed](#) as follows:
6. Atkinson, C., Martin, T., Hudson, P. & Robb, D. (1993a) Glyphosate: 104 week dietary carcinogenicity study in mice. Unpublished report No. 7793, IRI project No. 438618, dated 12 April 1991, from Inveresk Research International, Tranent, Scotland. Submitted to WHO by Cheminova A/S, Lemvig, Denmark.
7. Whose names are also redacted, with more than 80% of them [refusing](#) to be identified in a later request by CEO.
8. Interview by CEO, 17 February 2016

### [EFSA](#)

### References:

 [efsa\\_ref.15252298\\_pad\\_2015\\_143\\_reply\\_your\\_request\\_of\\_10\\_december\\_2015.pdf](#)

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