

The Glyphosate Story so far: Controversy over Science, Lawsuits and Dodgy Lobbying Tactics

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Introduction

In 2015, the WHO's International Agency for Research on Cancer (IARC) concluded that glyphosate – a key ingredient of weed killer Roundup - is probably carcinogenic to humans. Pesticides that can cause cancer must be banned, according to EU rules. However, in 2017, after two years of controversy and scandals, Monsanto's glyphosate weed killer was granted a re-approval by the EU, albeit for the unusually short period of five years, instead of the normal 15 year period. In the US, on the other hand, landmark court cases were taken against Monsanto (based on the IARC's opinion) by thousands of cancer victims, and Bayer (the new owner of Monsanto) was forced to pay billions of US dollars in damages.

In December 2022, the EU permit for glyphosate will expire. A dossier was submitted in December 2019 to the EU authorities by the so-called Glyphosate Renewal Group (a consortium of 8 glyphosate manufacturers, led by Bayer), calling for the chemical to be approved again. This time the re-approval process will be even more closely scrutinised by scientists, media, sustainable farming movements, politicians and civil society.

In this explainer we recap a number of key episodes and events from the glyphosate story over the past six years.

UN cancer institute classifies glyphosate as "probable carcinogen"

In March 2015, the <u>IARC classified glyphosate</u> as "probably carcinogenic to humans". This was based on "limited evidence" of cancer in humans (from real-world exposures that occurred) and "sufficient evidence" of cancer in animals that were experimented on (from studies of "pure" glyphosate). IARC also concluded that there was "strong" evidence that glyphosate can cause damage to DNA (genotoxicity), both for glyphosate alone, and for formulations that contain the chemical.

In Europe, this level of evidence would result in the substance being classified as `carcinogen category 1B', under which the substance is presumed to have

carcinogenic potential for humans. According to the EU Pesticide Regulation (EC 1107/2009) substances with this classification should be banned.

In contrast with IARC however, the EU assessment of glyphosate came to a different conclusion. The <u>German Health Authority BfR</u> and the <u>European Food</u> <u>Safety Authority</u> (EFSA) concluded in November 2015 that the available evidence did not justify the classification of glyphosate as carcinogenic and that the chemical did not pose any other health risk to humans. This gave the green light to the Commission to publish an initial proposal to renew the authorisation of glyphosate for a further fifteen years.

Why such radically different conclusions?

A number of factors <u>can help to explain</u> the striking difference between the European and international assessments of glyphosate.

First, whereas the IARC considered only published scientific studies, BfR and EFSA also took undisclosed industry studies into account. These unpublished studies could only be scrutinised publicly after they were obtained by NGOs and MEPs through freedom of information requests. [see section Secret industry studies]

In 2015, some of the so far undisclosed industry studies were re-analysed by Dr Chris Portier, a leading environmental health and carcinogenicity expert. Portier, along with about 100 scientists, <u>sent a letter</u> to the EU Health Commissioner in November 2015 criticising EFSA's conclusion that glyphosate was not carcinogenic for humans. <u>He stated that EFSA</u> had not done its own analysis of the raw data in the studies. During this time, Dr Portier <u>was attacked</u> by the pesticide industry, and false accusations were made to undermine his reputation as a scientist. In 2020, Dr Portier published a scientific paper showing <u>a total of 37 cases</u> of statistically significant increases in tumours following glyphosate exposure in industry studies that were obtained from EFSA.

The European authorities also used <u>faulty arguments</u> to dismiss certain findings pointing to health risks of glyphosate. One important study was dismissed because of an alleged virus infection in a test animal, which interfered with the development of a particular tumour type (malignant lymphoma). However it later transpired that there was no evidence for such an infection.

In its dossier lobbying for renewal, the glyphosate manufacturers proposed assessing all published academic studies on glyphosate using a highly disputed rating system which had been developed by three BASF employees in 1997 - the so-called <u>Klimisch Criteria</u>. As a result, <u>none of the published academic studies</u> demonstrating carcinogenic or genotoxic effects were assessed as "reliable". BfR and EFSA followed the industry's preferred approach and came to exactly the same conclusion.

In fact, a scandal broke in 2017 when it became clear that major sections of the EU assessment report were copy-pasted directly from industry's original application. The Commission is required by EU law to provide its own independent assessment, which it does not appear to have done. A study commissioned by the European Parliament concluded in 2019 that half of the text in the chapters about the academic studies which reported health risks was copied directly from the industry dossier. The chapter assessing published studies on the genotoxicity of glyphosate consisted of up to 96% of text that was copy-pasted directly from Monsanto's application. Apart from anything else, this is plagiarism.

Finally, what about the independence of the experts involved in the assessments? The authors of the IARC opinion are named, and the institute has a strict and transparent conflict of interest policy in place. The BfR and EFSA assessments, on the other hand, <u>were carried out by anonymous public officials</u>. It is therefore not possible to assess their independence.

Secret industry studies – citizen action leads to transparency

As indicated above, the EU pesticide risk assessment is to a large extent based on unpublished studies provided by the industry itself. Keeping these studies secret meant that the glyphosate risk assessment was not objective, transparent or independent - a legal requirement of EU law.

Both the Commission and EFSA have in the past refused to give public access to industry's secret glyphosate studies, arguing that disclosure would violate pesticide manufacturers' commercial interests and intellectual property rights.

However, in 2016 and again in 2019 the <u>European Court of Justice (ECJ) ruled</u> that, according to the Aarhus Convention on access to environmental information, an EU institution is obliged to disclose such documents, especially when there is an 'overriding general interest' in disclosing the information.

Following these rulings, EFSA provided the studies to organisations requesting access to them, including the genotoxicity studies.

A <u>European Citizens Initiative (ECI) on glyphosate</u> was started in January 2017 by a coalition of NGOs. It demanded:

- (1) a ban on glyphosate
- (2) to ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, commissioned by competent public authorities instead of the pesticide industry, and
- (3) to set EU-wide mandatory reduction targets for pesticide use.

The ECI was the most successful ever - over one million signatures were collected across Europe in seven months, instead of the foreseen one year timeline. In response to the ECI, <u>the EU adopted a new Transparency Regulation</u>. Although it only partly addresses the second demand, it nevertheless obliges companies, as of 27 March 2021, to publish any studies they submit when applying for a pesticide (re-)authorisation. This development is a game changer.

The Glyphosate Renewal Group, which is lobbying to secure re-approval next year, has already provided access to the glyphosate studies that it funded and submitted to EU authorities via its website, but only by individual request and with a requirement for personal data to be provided.

Bayer faces avalanche of court cases, resulting in Monsanto Papers

In the US, the IARC opinion on glyphosate led to thousands of cancer victims across the country initiating lawsuits against Monsanto, claiming that the company's weed killer caused their non-Hodgkin lymphoma. The US legal system (via the so-called Discovery Procedure) allowed the cancer victims' lawyers to obtain substantial access to internal records (including emails, text messages, company reports, etc) from Monsanto about glyphosate and its harmful properties.

These documents became known as the <u>Monsanto Papers</u>, and can be accessed via the website of US Right to Know, a non-profit organisation. The disclosed records painted a bleak picture of Monsanto's manipulation of science, regulators and media alike. One key finding from the Monsanto Papers is <u>the company's</u> <u>practice of ghost-writing of academic papers</u>. A <u>case in point</u> was Monsanto's involvement in the paper published in 2000 by Williams, Munroe and Kroes, which the company then used to defend glyphosate. Press articles published in Forbes by Henry Miller, a scientist, were also <u>ghost-written</u> by Monsanto employees.

Journalist <u>Carey Gillam's book about the Monsanto Papers</u> describes how the company also tried to block a US government toxicity review of Roundup products, had cozy relationships with certain regulators, and had strategies in place to discredit independent scientists who highlighted the dangers of the weed killer.

Bayer, which had just bought Monsanto, was faced with no less than 125,000 plaintiffs, with more to come and no end in sight. To date, <u>three cases</u> against Monsanto have been won by cancer victims. In August 2018, in the very first case, a jury ruled that Roundup <u>was a substantial contributing factor</u> to DeWayne "Lee" Johnsons' cancer, and that Monsanto should pay \$289.25 million in damages. This was later reduced by the court to around \$78 million. In 2020 Bayer agreed to pay close to \$11 billion to resolve roughly 75 per cent of the cases. The company

is still attempting to get a settlement accepted, in order to limit its ongoing liability.

In Europe, where it is not possible for individuals to claim punitive damages in court, only two known cases have been taken against Monsanto, one about Roundup and one regarding another herbicide, Lasso. The latter <u>was filed in 2007</u> by a French farmer, Paul François, who <u>won his case</u> in 2017, and again in 2020 when Monsanto's appeal was rejected.

Bayer-Monsanto merger

Bayer bought Monsanto for \$63 billion, aiming to increase its dominance on the world seed market, in the midst of the glyphosate upheaval in 2017. The Bayer-Monsanto merger was the last in a wave of mega-mergers, following Dow and DuPont's merger and ChemChina's acquisition of Syngenta. At the time two hundred NGOs signed <u>an open letter</u> to the European Commission opposing the merger, but they <u>cleared the deal</u> in March 2018.

However the Bayer-Monsanto merger turned out to be one of the worst corporate deals ever. Bayer's shares have <u>dropped 45 per cent</u> since it lost its first Roundup court case in the US in 2018. German shareholders <u>are now suing Bayer</u> for damages following the company's decline in value due to acquiring Monsanto.

EU's bumpy road to a decision on glyphosate reapproval

By 2017, following the growing doubts about the EU pesticide authorisation procedure, the Commission had a difficult time securing an agreement on the renewal of glyphosate among EU Member States. The Commission's health department DG SANTE had to come up with several new proposals on glyphosate's re-approval, negotiating on the duration of the authorisation period and conditions of use.

The European Parliament for its part adopted <u>a resolution in October 2017</u> that demanded a full ban of glyphosate by December 2022. The five year phase out they proposed included some immediate restrictions, such as a ban on all household uses of the chemical, and full transparency and independence regarding the studies used to undertake the risk assessment.

In autumn 2017, DG SANTE, in a last attempt to reach consensus, very exceptionally proposed to reduce the glyphosate renewal period down to five years from the usual 15, meaning the renewal would run until December 2022. On 27 November 2017 a qualified majority of Member States (reaching 65.71 per cent of EU population) voted in favour of the proposal. In a final twist, the German Agriculture Minister, instead of following his government's directions to abstain,

<u>supported the proposal</u>. Nine countries voted against the proposal: Belgium, Greece, France, Croatia, Italy, Cyprus, Luxembourg, Malta, and Austria.

Calls to strengthen the EU pesticide approval procedure

The glyphosate license was ultimately renewed for five years, but the concerns about industry malpractices that were revealed in the process remained. The European Parliament decided to respond to citizens' concerns and investigate all the evidence documenting this malpractice by setting up a Special Committee (called the PEST Committee). This initiative was supported by civil society groups.

The Committee undertook nine months of investigations, consisting of six public hearings, three fact-finding missions to EFSA, IARC and INRA (National Institute for Agricultural Research) and the commissioning of studies to examine every step of the pesticide authorisation procedure. Following its investigations, the PEST Committee concluded that the current system was failing to achieve its purpose, ie to ensure protection from the harm caused by pesticides in Europe, and highlighted the need for urgent change. The <u>PEST report</u>, and its 114 recommendations for improving the current system, <u>received full support</u> from the Parliament in 2019.

In the meantime, EU and national civil society organisations joined forces and created the "<u>Citizens for Science in Pesticide Regulation</u>" coalition, which calls for a strengthening of the EU pesticide regulation. The <u>coalition manifesto</u> was signed by more than 140 civil society organisations and scientific institutions. A "<u>White Paper</u>" developed by the coalition identified 15 shortfalls of the EU pesticide authorisation system. It also proposed solutions to these problems, including ensuring that safety studies are carried out independently from the manufacturers, requiring a strict conflict-of-interest policy for all experts involved in the procedure, and using pesticides only as a last resort when all alternatives have failed.

More dodgy lobby tactics: scaremongering and fake grassroots campaigns

During this period, Monsanto and its lobby groups did not shy away from using various questionable lobbying tactics. For example, in 2017 the firm <u>hired Irish</u> <u>lobby firm Red Flag Consulting</u> to stage a fake grassroots campaign, mobilising farmers to support glyphosate at agricultural fairs and other events in "the eight most important EU countries".

A similar lobby manoeuvre was seen the night before a key hearing of the PEST committee, when Monsanto's lobby group ECPA (now renamed Croplife Europe) and farming lobby Copa-Cogeca jointly <u>invited MEPs to a posh dinner</u>.

ECPA also delivered "<u>factsheets</u>" featuring dramatic claims of potential agricultural crop losses if glyphosate was banned, to scaremonger MEPs. The figures were provided by <u>Steward RedQueen</u>, a consultancy firm hired by ECPA, based on 'data' provided by ECPA and Copa-Cogeca member organisations, among others.

Revelations in the French media showed that during 2016 and 2017, Monsanto hired lobby firm FleishmanHillard to compile a vast list of its opponents (the 'stakeholder lists'), an action which was potentially illegal in France. The list contained the names of some 200 journalists and politicians and other personalities. It soon became clear that the campaign extended to various other EU countries, as well as Brussels itself. Monsanto paid FleishmanHillard no less than €14.5 million for this campaign, far more than both companies declared to the EU Lobbying Transparency Register.

Cities, Regions, and Countries ban glyphosate

In the mean time, following the multiple controversies, many countries, regions and cities across Europe have enacted (plans for) bans and restrictions on numerous glyphosate-based products. This is possible because while active ingredients in pesticides, like glyphosate, are authorised at EU level, the formulated pesticide products like Roundup are authorised at member state level. For instance, <u>Luxembourg</u> banned glyphosate-based herbicides in 2020; <u>Austria</u> attempted to do the same but has not succeeded yet.

Germany <u>plans to ban glyphosate</u> from 2024. France has indicated it has similar plans. In 2019 <u>French authorities banned</u> a specific formulation, Roundup Pro 360, and numerous municipalities have put in place <u>local bans</u>. Flanders <u>banned the use</u> of glyphosate-based herbicides for private use, and the Netherlands banned the chemical's use in public grounds and parks.

Internationally, glyphosate has been banned in various countries including Sri Lanka, Vietnam and Thailand - Mexico is also considering a ban. In the US, several states and cities have put in place restrictions or bans on the use of Roundup on public grounds and rail tracks.

What next?

The next re-approval process for glyphosate being now in full swing, all eyes are again on the EU authorities. The independent review by Dr. Armen Nersesyan and Prof. Siegfried Knasmueller provides new evidence that the EU authorities' earlier assessment concluding, based on industry's studies, that glyphosate is not genotoxic, is not justified. This raises a question about the credibility of all safety studies provided by the industry, most of which conveniently downplay the cancer potential or other adverse effects of glyphosate. With the announced target of a 50% reduction in the use of pesticides in the EU Farm to Fork Strategy, the stakes for the pesticide industry have risen even higher, as their business model is in jeopardy. Both for the protection of biodiversity and the ecosystems that sustain life on earth, and for human health, the phasing out of toxic pesticides like glyphosate-based herbicides from agriculture, is of the utmost urgency.

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