SCIENCE AND SOCIETY

GLYPHOSATE CONTROVERSIES

The Production of Risk Assessment Expertise in Europe

a corpus constituted by Thomas Tari

FORCCAST
Formation par la Cartographie de Controverses à l'analyse des sciences et des techniques

SUMMARY

1. Introduction

Guidelines for the readings

• What are controversies made of? Which actors are involved?

• How can the study of controversies help in the analysis of the construction of scientific facts?

• To what extent is the construction of scientific facts impacted by social, political and economic factors? Is it a one-way influence, from society to science?

• What are the rules of the production of scientific knowledge? Can it be criticized or commented? How? Are these rules purely scientific?

• How can a controversy create a feeling of social belonging to a given group?

• How is expertise defined? Who are the experts ? Can lay people become experts, and how?

• Is expertise merely scientific? Or merely legal?

• How does expertise interact with political and economic entities (such as a government or a firm)?

A Short History of Glyphosate

In : *The Detox Project and Sustainable Pulse, "A Short History of Glyphosate" (and updates)*
https://sustainablepulse.com/2017/09/06/a-short-history-of-glyphosate

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1961: Glyphosate was patented in the U.S. as a Descaling and Chelating Agent by the Stauffer Chemical Co. Due to its strong metal chelating properties, glyphosate was initially used as a descaling agent to clean out calcium and other mineral deposits in pipes and boilers of residential and commercial hot water systems. Descaling agents are effective metal binders, which grab on to Calcium, Magnesium and heavy metals to make the metal water soluble and easily removable.

1970: Glyphosate was discovered to be a herbicide (weedkiller) by Monsanto scientist John Franz and was patented as such.

1974: Monsanto brought glyphosate to market in 1974 under the trade name Roundup.

1982: Monsanto was already working on creating Roundup Ready genetically modified crops. So was Luca Comai, a scientist from Calgene (a biotech company that Monsanto would later acquire).

1985: The United States Environmental Protection Agency (EPA) classified glyphosate as a Class C Carcinogen. On February 11, 1985 the carcinogenic potential of glyphosate was first considered by an EPA panel, called the Toxicology Branch Ad Hoc Committee. The Committee, in a consensus review dated March 4, 1985, then classified glyphosate as a Class C Carcinogen. A Class C Carcinogen has "Suggestive evidence of carcinogenic potential" according to the EPA. Monsanto tried to persuade the U.S. EPA that glyphosate was not a possible human carcinogen.

1989: Monsanto strike deal with Asgrow to create Roundup Ready genetically modified crops for commercial market. In 1989, three companies struck a deal: Agracetus, Asgrow and Monsanto. Up until this point, Monsanto had trouble transferring genes into the most valuable crops on the market, corn and soybeans, using its existing method of genetic engineering. Agracetus offered a new method, called a gene gun. In hopes of using it on soybeans, Agracetus had approached Asgrow, a leading soybean seed company. The two approached Monsanto because they needed a gene worthy of engineering into Asgrow's soybeans. Monsanto gave them free access to the Roundup Ready gene.

1991: EPA change classification of glyphosate from Class C "Suggestive evidence of carcinogenic potential" to Class E which suggests "evidence of non-carcinogenicity for humans" The Class C carcinogen classification for glyphosate, which was decided upon in 1985, was changed by the EPA to a Class E category which suggests "evidence of non-carcinogenicity for humans". Mysteriously this change in glyphosate's classification occurred during the same period that Monsanto was developing its first Roundup-Ready (glyphosate-resistant) GM Crops.

1992: Pioneer pay Monsanto for use of Roundup resistance gene. Pioneer (DuPont) paid a one-time payment of half a million dollars for the rights to use Monsanto's Roundup resistance gene in its soybeans forever. Monsanto's profit would come entirely via the additional sales of Roundup it would gain.

1996: Introduction of Roundup Ready Soybeans. Roundup Ready soybeans were commercialized by Asgrow in coordination with Monsanto and separately by Pioneer (DuPont). In 1996, the first year genetically engineered (GE), glyphosate-tolerant crops were planted commercially in the U.S., glyphosate accounted for just 3.8% of the total volume of herbicide active ingredients applied in agriculture (28 million pounds in 1995).

2007: Glyphosate usage is more than double that of the next most heavily sprayed pesticide – Atrazine. By 2007, the EPA reported agricultural use of glyphosate in the range of 180–185 million pounds. In the 20-year timespan covered by EPA sales and usage reports (1987–2007), glyphosate use rose faster and more substantially than any other pesticide. Usage in the range of 81.6–83.9 million kilograms, which occurred in 2007, was more than double the next most heavily sprayed pesticide (atrazine, 73–78 million pounds; ~33.1–35.4 million kilograms). For over a decade, glyphosate-based herbicides have been, by far, the most heavily applied pesticides in the U.S.

2010: Glyphosate was patented in the U.S. by Monsanto as an antibiotic. This patent has led to major concerns about possible harm being caused by glyphosate including the killing of beneficial gut bacteria which causes immune system damage.

2012: Professor Seralini study shows harm being caused by low doses of glyphosate-based herbicides and GM crops. In 2012 the French Professor Gilles-Eric Seralini published his famous toxicity study, which showed how rats fed on a diet containing NK603 Roundup tolerant GM maize or given water containing Roundup, at levels permitted in drinking water and GM crops in the U.S., suffered severe liver and kidney damage. This was not the first independent study showing the possible damage being caused to health by glyphosate-based herbicide but it was the most high profile long-term study.

2014: Glyphosate usage booms even more in the U.S. Since genetically modified crops were introduced in 1996 glyphosate use had increased 9-fold in the U.S. and 15-fold worldwide by 2014. By 2014, annual farm-sector glyphosate usage increased to approximately 240 million pounds (~108.8 million kilograms), based on average annual crop use reported by the NASS. Available use data published by the USDA, USGS, and EPA show that a surprisingly large share (approximately two-thirds) of the total volume of GBH applied since 1974 has been sprayed in just the last decade.

2015: The World Health Organization's cancer agency IARC classified glyphosate as "probably carcinogenic to humans" (Group 2A). This was based on "limited" evidence of cancer in humans (from real-world exposures that actually occur) and "sufficient" evidence of cancer in experimental animals (from studies of "pure" glyphosate). IARC also concluded that there was "strong" evidence for genotoxicity, both for "pure" glyphosate and for glyphosate formulations.

2016: University of California San Francisco (UCSF) discovers glyphosate in 93% of urine samples collected across U.S. In a unique public testing project carried out by a laboratory at the University of California San Francisco (UCSF), glyphosate was discovered in 93% of urine samples during the early phase of the testing in

2015. The urine and water testing was organized by The Detox Project and commissioned by the Organic Consumers Association. Glyphosate was also found at alarming levels in a wide range of best-selling foods across the U.S., Food Democracy Now! and The Detox Project announced in November 2016. The testing project found alarming levels of glyphosate in General Mills' Cheerios and Honey Nut Cheerios, Kellogg's Corn Flakes, Raisin Bran and Frosted Flakes and PepsiCo's Doritos Cool Ranch, Ritz Crackers and Stacy's Simply Naked Pita Chips, as well as many more famous products.

2017: Groundbreaking study shows Roundup causes liver disease at low doses. Internal Monsanto and EPA communications, released during a growing number of Roundup cancer court cases, reveal the reality of the 30+ year glyphosate cover-up. The internal company e-mails show how Monsanto has colluded with the EPA to play down glyphosate safety concerns, admitted that Roundup / glyphosate could possibly cause cancer and other harm to human health and also attempted to silence the work of Professor Seralini.

2018: Monsanto Loses Landmark Roundup Cancer Trial, Set to Pay USD 78 Million in Damages. Monsanto lost a landmark cancer trial in San Francisco and was ordered to pay over USD 289 Million (reduced on appeal to USD 78 Million) in total damages to the former school groundskeeper Dewayne Johnson, a California father who has non-Hodgkin's lymphoma, which was caused by Monsanto's glyphosate-based weedkiller Roundup.

Nov 2023 : Renewal of the approval of glyphosate by the EU Commission (Q&A from their website)

1. Why has the Commission renewed the approval of glyphosate?

As required by EU legislation on pesticides, and in line with the Comitology rules, in the absence of a qualified majority in the Appeal Committee, the Commission was legally obliged to adopt this decision before the expiry of the current approval (15 December 2023). The Commission, based on the assessment made by EFSA of the impact of glyphosate on the health of humans, animals and the environment, and which did not identify critical areas of concern that would prevent a renewal of approval, therefore adopted the proposed Implementing Regulation to renew the approval of glyphosate, subject to certain conditions and restrictions (see Q5). On 16 November 2023, during a vote at the Appeal Committee, Member States did not reach a qualified majority on the Commission's proposal to renew the approval of glyphosate for 10 years. This followed a previous vote at the Standing Committee on Plants, Animals, Food and Feed (SCOPAFF) on 13 October 2023, in which Member States also did not reach the required majority to renew (or reject) the proposal.

2. What is the basis for the Commission's decision?

This decision is based on comprehensive safety assessments carried out by the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA), together with the Member States. This scientific work is the result of a thorough assessment process that started in December 2019 with the work of a group of Member States – France, Hungary, the Netherlands and Sweden, designated as Rapporteur Member States (and which formed the Assessment Group on Glyphosate (AGG)). The assessment made by EFSA on the impact of glyphosate on the health of humans, animals and the environment did not identify critical areas of concern that would prevent a renewal of the approval.

2. Tensions between the Agricultural Production and the Environment

Glyphosate is Everywhere

In : *The Detox Project - Glyphosate in Food and Water, https://detoxproject.org/glyphosate-in-food-water/*

"If Glyphosate Was Listed as an Ingredient on Nutrition Labels, It Would Come Before Vitamins D and B12 in Honey Nut Cheerios"

Glyphosate-based formulations (the most common being Roundup from Monsanto) are the most widely sold and used pesticides globally. They are used on food crops during cultivation, not only to desiccate the crop before harvest (for instance on wheat), but also more intensively during the cultivation of the 80% of genetically modified organisms (GMOs) that are modified to tolerate Roundup. They are also used in parks, gardens, along roads and railway tracks, and in cemeteries. Since glyphosate's main mode of action in plants is absent in animals, it is considered to be one of the safest pesticides – even safer than table salt, according to Monsanto. As a consequence, the presence of glyphosate is tolerated at high levels in food and tap water. After more than 30 years of a "don't look, don't see" policy on glyphosate's secondary side effects, many studies in recent years have suggested that glyphosate has worrying health effects at levels regularly detected in food an tap water.

Understanding the ppb unit.

1 part per billion (ppb) is equivalent to 1 µg/kg or 1 µg/L of a given substance. It represents the concentration of a molecule or a mixture. For a mixture, 1 ppb corresponds to a dilution of 1 billion. 1 ppb of Roundup represents the dilution of a teaspoon of Roundup in the volume of an Olympic swimming pool. 700 µg of glyphosate dissolved in one litre of water corresponds to a concentration of 700 ppb, the level admitted in US tap water. It corresponds to one drop of Roundup in 25 litres of tap water.

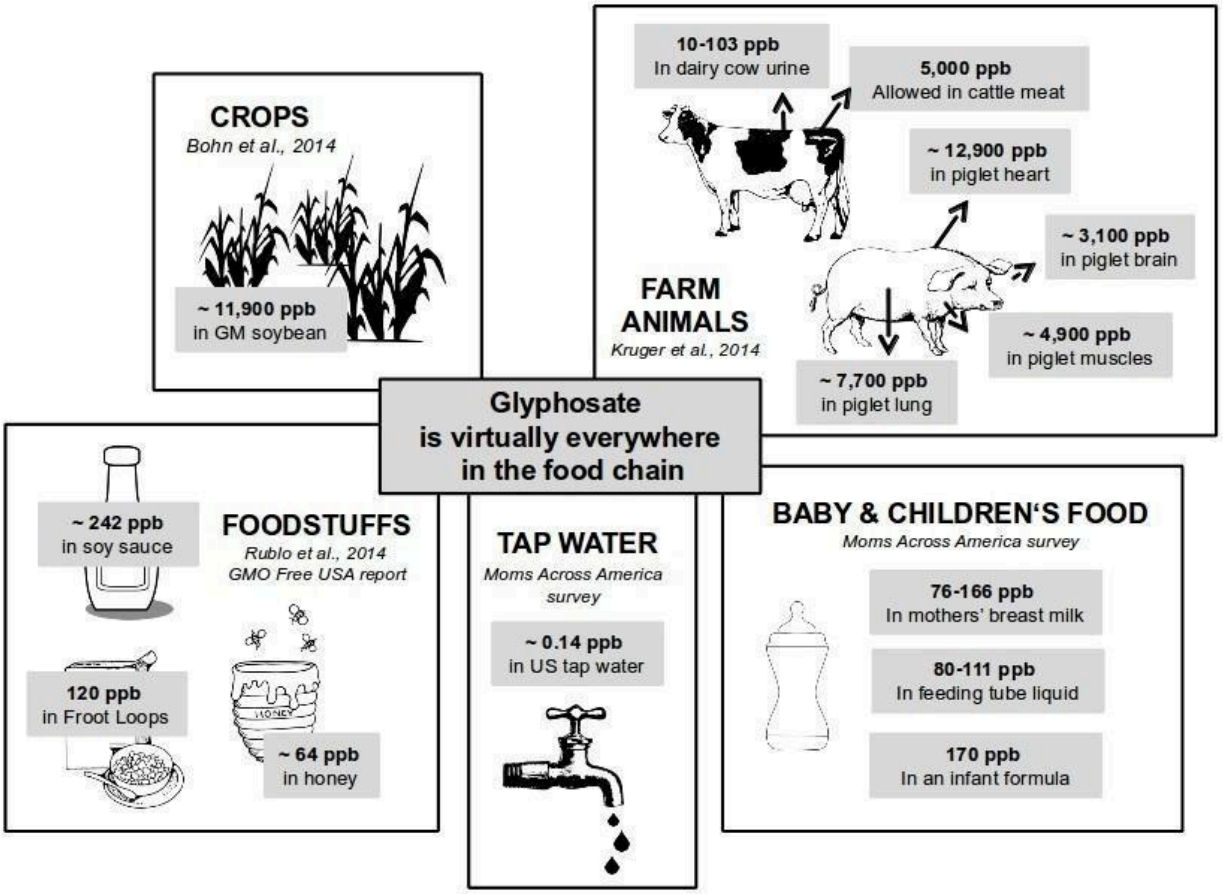
Human contamination and food surveys

Glyphosate has now been found in a range of popular U.S. food products by Anresco Laboratories and also urine of people across America by the University of California San Francisco (UCSF), using validated LC-MS/MS methods.

The cultivation of Roundup Ready GMOs has considerably increased food contamination by glyphosate. Roundup Ready plants do not degrade glyphosate but tolerate it, so they accumulate Roundup residues during their growth. As a consequence, glyphosate has among the highest maximum residue limits for pesticides, with up to 500,000 parts per billion (ppb, see above) authorized in some GM feed. A recent study on 10 batches of GM soybeans from Iowa found glyphosate at an average concentration of 11,900 ppb (maximum of 20,100 ppb). According to Monsanto, residues levels of up to 5,600 ppb in GM soy represent "extreme levels". Since cattle are mostly fed Roundup Ready soybeans, contamination with extreme levels of glyphosate could have serious consequences on cattle health. In a study on Danish dairy cows, elevated glyphosate urinary levels have been linked to a marked increase in biomarkers indicative of damage to liver and kidney function. Another recent study found glyphosate in the organs of piglets born with birth defects.

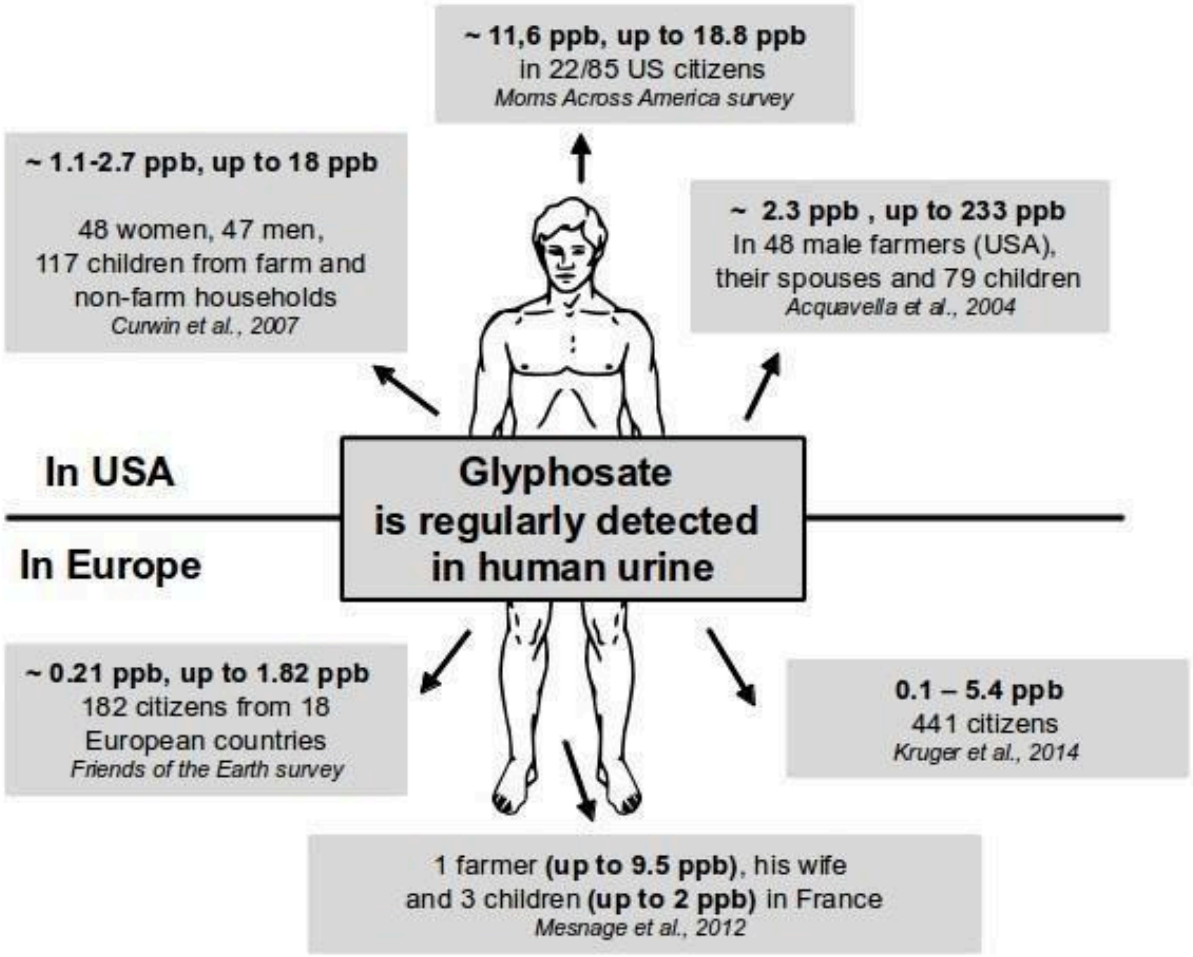
In this case, the highest concentrations were measured in lungs (0.4-80 ppb), heart (0.15-80 ppb), and kidneys (0.1-38 ppb). This strongly suggests bioaccumulation of glyphosate in internal organs, which is contrary to the common belief of rapid elimination.

Permitted levels in tap water reach 700 ppb in USA, which is particularly high for a pesticide. Among 85 tap water samples analyzed by Moms Across America and Sustainable Pulse, glyphosate was found in 35 cases at levels up to 0.3 ppb. Glyphosate contamination in food appears common. UK government testing for glyphosate residues in bread showed frequent glyphosate contamination, sometimes exceeding 500 ppb in wholemeal bread. The global contamination is certainly underestimated. Analysis of 69 honey samples from different origins revealed glyphosate at unexpectedly high levels, around 64 ppb. Some samples were contaminated with 163 ppb, a concentration neurotoxic to honeybees. A recent analysis even documented the presence of glyphosate in Froot Loops at a level of 120 ppb.



Glyphosate is present at all levels of the food chain: in water, plants, animals, and even in humans. Every single study that has measured human contamination with glyphosate has found it. The most recent survey, performed by Moms Across America and Sustainable Pulse, measured glyphosate levels in the urine of 85 US citizens: 17 were recruited in the streets of Washington DC; the others, volunteers among the members of Moms Across America, were spread across the country. Glyphosate was detected in 22 cases at an average concentration of 12.6 ppb. The maximum of 18.8 ppb was measured in the urine of a woman in Oregon. Comparable levels have been detected in a survey performed on farming and non-farming families in Iowa. Glyphosate was detected in the majority of samples, including more than 95% of the children's urine samples (maximum of 18 ppb). In Europe, a survey by Friends of the Earth across 18 countries found glyphosate in 80 out of 182 urinary samples taken from volunteers. Another European survey by Monika

Kruger showed average urinary glyphosate levels of 5.4 ppb (maximum of 40 ppb). In this study, chronically ill humans had higher glyphosate residues in urine than healthy humans.



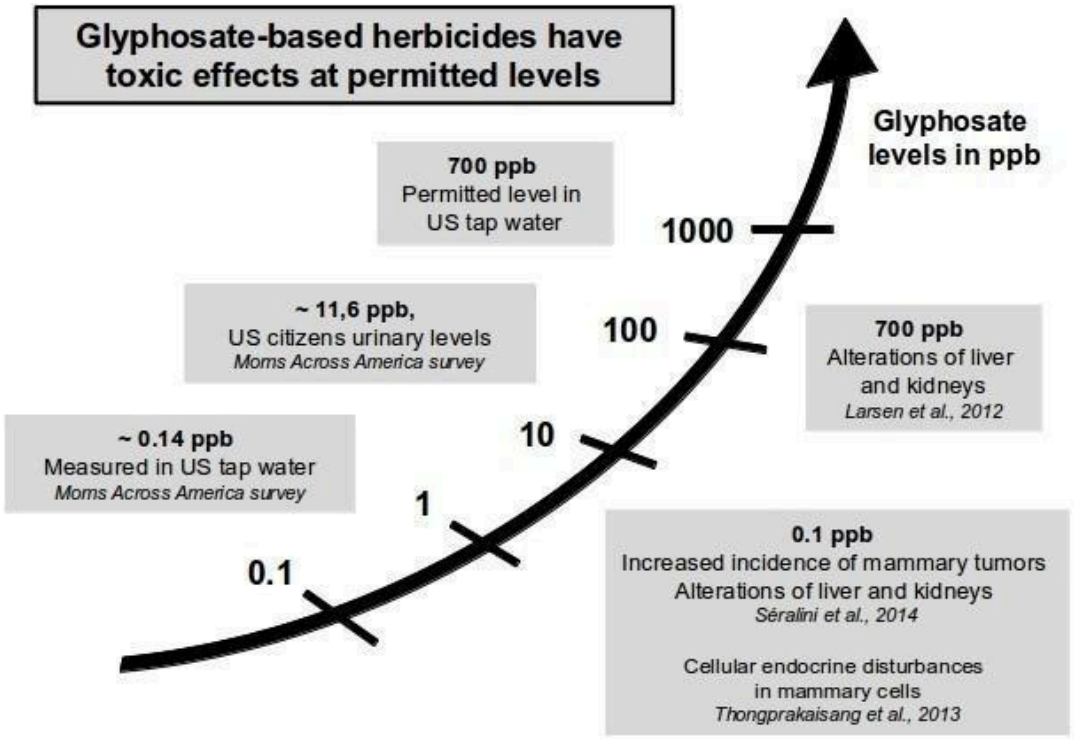
Toxic effects of glyphosate and its commercial formulations

Despite claims that glyphosate has been widely studied by regulatory agencies and industry, little is known about the health effects of glyphosate-based herbicides at levels found in food or water. Indeed, to estimate a safe level of glyphosate for regulatory purposes, glyphosate has been tested in long-term and developmental toxicity tests in rodents. All these tests have been performed with glyphosate alone at very high levels. However, the exposure of animals at doses ranging from around 10,000 ppb during their whole life is not relevant to conclude on the effects of exposures in the much lower dose range of 10-100 ppb. Many pesticides are endocrine disruptors, meaning that they disrupt cell communications and exercise their toxic effects at low doses over long periods of time – even when higher doses do not have these effects. Various studies have found that glyphosate and Roundup can be endocrine disruptors at levels permitted in tap water.

The only long-term study at environmentally relevant concentrations was performed with 0.1 ppb of Roundup diluted in drinking water of rats. The incidence of mammary tumors significantly increased in this study. Out of 10 rats treated with Roundup at 0.1 ppb, 9 developed 20 mammary tumors, whereas 5 out of 10 controls only developed 8 tumors. Hormones (Testosterone and estradiol) serum levels were also altered. These results are corroborated by cellular endocrine disturbances found in human mammary cells. Glyphosate was able to replace estrogen and to promote the growth of human mammary cells at around 0.1 ppb. In another study at higher doses, a maternal exposure to a glyphosate-based herbicide during

pregnancy was able to disrupt rat pup development. In the above-cited cases, as for other endocrine disruptors, toxic effects do not always increase in proportion to the dose. In these cases, and contrary to the common industry claim, the dose does not make the poison. These effects are thus not likely to be detected in regulatory tests using only high levels of glyphosate, as has happened in the past for the plastics chemical bisphenol A and other endocrine disruptors.

Converging lines of evidence have demonstrated that Roundup residues pose a risk to the kidneys and the liver. In the study performed by Professor Gilles-Eric Séralini, rats treated with 0.1 ppb of Roundup presented an increased rate of severe chronic kidney disease. This may also explain observed increases in the frequency of chronic kidney disease among farmers. The liver was also affected; rats treated with 0.1 ppb Roundup presented more liver abnormalities such as congestion or necrotic (dead) areas. In another study, Wistar rats were exposed during 30 or 90 days to the highest level (700 ppb) of glyphosate allowed in water for human consumption in USA. While no tissue changes were detected in the study, changes in the biochemistry indicated stress at the level of the kidneys and the liver. All these effects are detected well below regulatory thresholds, in a range of concentrations corresponding to potential human exposures to glyphosate-based herbicide residues.



In conclusion, several converging lines of evidence suggest worrying effects of glyphosate at levels detected in food, water, and even in human bodies. The toxicity tests performed in glyphosate regulatory assessments were unable to detect these effects, because they were performed with too high doses, and did not take into account recent scientific knowledge about toxicology.

Commercial formulations of glyphosate contain other toxicants

Glyphosate is never used alone, but in commercial formulations containing additional toxic agents called adjuvants. They are used to increase glyphosate's toxicity and to allow its penetration into plants. They are in some cases more toxic than glyphosate, but they are never included in glyphosate long-term toxicity tests and are considered to be inert, like water. They constitute a "black hole" in pesticide toxicology,

because they are often kept secret by companies, are never measured in the environment, and are not included in the establishment of pesticide acceptable daily intakes.

Agronomic & Other Benefits of Glyphosate for the EU

In : *Agronomic & Other Benefits of Glyphosate for the EU*
Position Paper of the Glyphosate Task Force (GTF), June 2013

The active ingredient glyphosate present in some of the most widely used broad-spectrum herbicides, accounts for some 25% of the global herbicide market. They are used in both agriculture and domestic situations and are a simple and cost-effective way of controlling weeds that otherwise persist for years or reduce crop yields. The popularity of glyphosate can be attributed to its effectiveness, safety profile and its contribution to the sustainability of European agriculture while providing significant environmental advantages in terms of reduced carbon emissions and soil erosion.

Within the framework of EU legislation glyphosate is being reviewed to renew its approval for a further 10 years. A number of companies formed the Glyphosate Task Force (GTF) to share the work involved in the renewal process.

Crop Protection in Context

World population increased to 6.9 billion in 2010, up from 3.7 billion in 1970 and is projected to reach 9.15 billion by 2050. Food consumption expressed in kilocalories (kcal) per capita per day is a key variable used for measuring the evolution of the global and regional food situation. World average per capita availability of food improved to 2,770 kcal/person/day in 2005-2007 but because of a range of factors some 2.5 billion live in countries with under 2,500 kcal/person/day and 0.5 billion in countries with less than 2,000 kcal/person/day. It is anticipated that by 2050, some 4.7 billion or 52% of world population may live in countries with national averages of over 3,000 kcal/person/day up from 28% at present, while those living in countries with under 2,500 kcal/person/day may fall from 2.3 billion or 35% at present to 240 million or 2.6% of world FAO 2012 population. Achieving such reductions in undernourishment will require that yields continue to rise, that crop losses and food wastage be further reduced and that distribution systems be further improved. The conservation of fertile soils, the development of high yielding varieties, the protection of crops from losses due to weeds, pests and pathogens, the reduction of food wastage and the improvement of distribution systems are essential elements in sustainable crop production at elevated levels necessary for the elimination of undernourishment.

Agronomic Benefits of Glyphosate

Glyphosate works by blocking the shikimic acid pathway, a metabolic pathway that is essential for plant growth. That pathway is present in all plants, but does not occur in animals, which makes glyphosate a very effective broadspectrum herbicide and contributes to its low toxicity in animals.

Unlike the many herbicides that act on either grasses or broad leaved weeds, glyphosate is effective on almost all weeds, providing broad-spectrum control. Glyphosate controls weeds that might otherwise persist for several years, competing with crop plants for water, light and nutrients. The application of glyphosate before the new crop is planted has the potential to improve harvests by up to 30%-60% for many

of Europe's major crops, depending on the weed population and other conditions. Common couch grass, a frequent invader of cereal fields in Europe, can reduce yields up to 60%.

In some countries such as the UK, glyphosate is used as a harvest aid to reduce grain moisture levels, thereby reducing drying costs and accelerating the maturation process of crops like maize, oilseed rape and cereals.

Glyphosate use has facilitated change in farming practices. By chemically controlling a broad spectrum of weeds including their entire root systems, glyphosate has eliminated or reduced the need for ploughing of soils. These reduced tillage practises allow farmers to plant crop seeds directly into stubble fields. A large proportion of Europe's cultivated land is prone to soil erosion and minimal soil disturbance practices are sustainable alternatives that help to protect soil from degradation and reduce greenhouse gas emissions and energy consumption. Several important crops in Europe, including maize, are predominantly managed with these practices in combination with glyphosate making glyphosate a popular tool for farmers in pursuing soil conservation practices.

Glyphosate breaks the "green bridge", removing weeds that might otherwise act as an intermediate host for parasites and disease vectors when crops are emerging. Aphids, for instance, are a common vector of plant viruses such as barley yellow dwarf virus (BYDV) that can destroy up to half of cereal and maize crops. Application of glyphosate removes potential aphid host plants, reducing the risk of virus-carrying aphids transferring from weeds to crop plants when they emerge.

Benefits for Trade

The use of glyphosate has facilitated improvement in crop yields and profitability resulting in the EU being a net exporter rather than a net importer of wheat and course grain while it has led to a reduction in the EU import deficit for oilseed and sugar.

Benefits for Consumers and Taxpayers

Glyphosate use continues to contribute to reduced food prices. Had glyphosate not been discovered and developed for use in agriculture, food prices would be higher, taxpayers would be worse off as a result of increased import taxes and more land would be required for food production

Glyphosate: Too Much of a Good Thing?

In : Cuhra M., Bøhn T. and Cuhra P. (2016) “Glyphosate: Too Much of a Good Thing?”
*Frontiers in Environmental Science*s, 4:28.

Although previously accepted as the less toxic alternative, with low impact on animals, farmers as well as consumers who are exposed to residues in food, glyphosate chemicals are now increasingly controversial as new evidence from research is emerging. We argue that specific aspects of the history, chemistry and safety of glyphosate and glyphosate-based herbicides should be thoroughly considered in present and future re-evaluations of these dominant agrochemicals:

- Glyphosate is not a single chemical, it is a family of compounds with different chemical, physical, and toxicological properties.
- Glyphosate is increasingly recognized as having more profound toxicological effects than assumed from previous assessments.
- Global use of glyphosate is continuously increasing and residues are detected in food, feed, and drinking water. Thus, consumers are increasingly exposed to higher levels of glyphosate residues, and from an increasing number of sources.
- Glyphosate regulation is predominantly still based on primary safety-assessment testing in various indicator organisms. However, archive studies indicate fraud and misbehavior committed by the commercial laboratories providing such research.

We see emerging evidences from studies in test-animals, ecosystems indicators and studies in human health, which justify stricter regulatory measures. This implies revising glyphosate residue definitions and lowering Maximum Residue Limits (MRLs) permissible in biological material intended for food and feed, as well as strengthening environmental criteria such as accepted residue concentrations in surface waters. It seems that although recent research indicates that glyphosates are less harmless than previously assumed and have complex toxicological potential, still regulatory authorities accept industry demands for approving higher levels of these residues in food and feed. […]

The phytotoxic properties of glyphosate were recognized around 1970 and the new compound was enthusiastically embraced as a *good thing*; it was perceived as a *practically non-toxic alternative*, a *safe chemical* and a *benefit to society*. And, best of all, it proved to be an efficient herbicide. After introduction of first commercial formulations around 1975, glyphosate-based herbicides (GBHs) have become globally dominant for eradication of unwanted weed species and lately also have found other use, e.g., as desiccants on agriculture crops. At the moment of writing, glyphosate is the globally dominating herbicide, measured in tonnage, and revenue.

Archive film from a commercial biotechnology laboratory in 1987 shows George H. W. Bush (at that time vice-president of the USA) as he asks the assembled researchers; “this gene of yours, what does it do in the plant?” Before any of the superiors have a chance to answer, a junior scientist excitedly proclaims; “we have this fabulous herbicide…” (Robin, 2008). The fabulous herbicide was glyphosate and the gene in question was the commercially promising EPSPS gene isolated from *Agrobacterium*, which made it possible to modify agriculture crops into *glyphosate-tolerant varieties*. Leading agronomists later described the fabulous herbicide in a widely acknowledged publication bearing the title; “Glyphosate: a once-in-a century

herbicide" (Duke and Powles, 2008). The headline for this present writing also refers to the 2012–2015 detailed evaluation of glyphosate recently completed by the European Food Safety Authority: "Glyphosate: EFSA updates toxicological profile" (EFSA, 2015c), in which EFSA concludes that glyphosate is probably not a human carcinogen, but on the other hand also acknowledges the need for tighter regulation, specifically by adjusting consumer exposure. [...]

A string of previous studies investigated aspects such as toxicity of glyphosate and Roundup toward aquatic invertebrates (Cuhra et al., 2013), accumulation of glyphosate in glyphosate-tolerant soybean (Bøhn et al., 2014) and potential effects of such residues in test animal feed (Cuhra et al., 2014, 2015). Furthermore, we have reviewed reports from industry studies investigating these issues. No studies other than our own were found to specifically assess effects of glyphosate residues (Cuhra, 2015b). We have also published preliminary results from studies of documentation in archives from US FDA and US EPA, obtained via freedom of information act requests (Cuhra, 2015c).

Importantly, glyphosate is not one single clearly defined compound, but rather a family of chemicals that can be synthesized through different chemical processes, which in turn will cause various qualitative differences e.g., impurities and byproducts. Glyphosates exist in several chemical mixtures and/or forms, primarily as either glyphosate technical acid or as various salts of glyphosate. [...]

Socioeconomic Aspects

Important societal challenges related to production of glyphosate-tolerant crops such as Roundup-ready soybean include ecological damage through deforestation and degradation of natural habitats (Pengue, 2005) and glyphosate pollution of the environment. The large-scale cultivation of glyphosate-tolerant crops, such as Roundup-ready soy (RR-soy), RR-maize, and RR-canola has also been identified as a main cause for emergence and widespread occurrence of numerous glyphosate-resistant agricultural weeds (Duke and Powles, 2008; Benbrook, 2012). The weed-challenges will be met with alternative and more potent mixes of herbicides (Green, 2009), whereby older and arguably more toxic herbicides, such as atrazine, may be reintroduced (Binimelis et al., 2009). This development has been linked to increased occurrence of severe medical problems in farmers and farm village populations in Argentina, in areas where Roundup-ready soybean is produced (Vazquez and Nota, 2011).

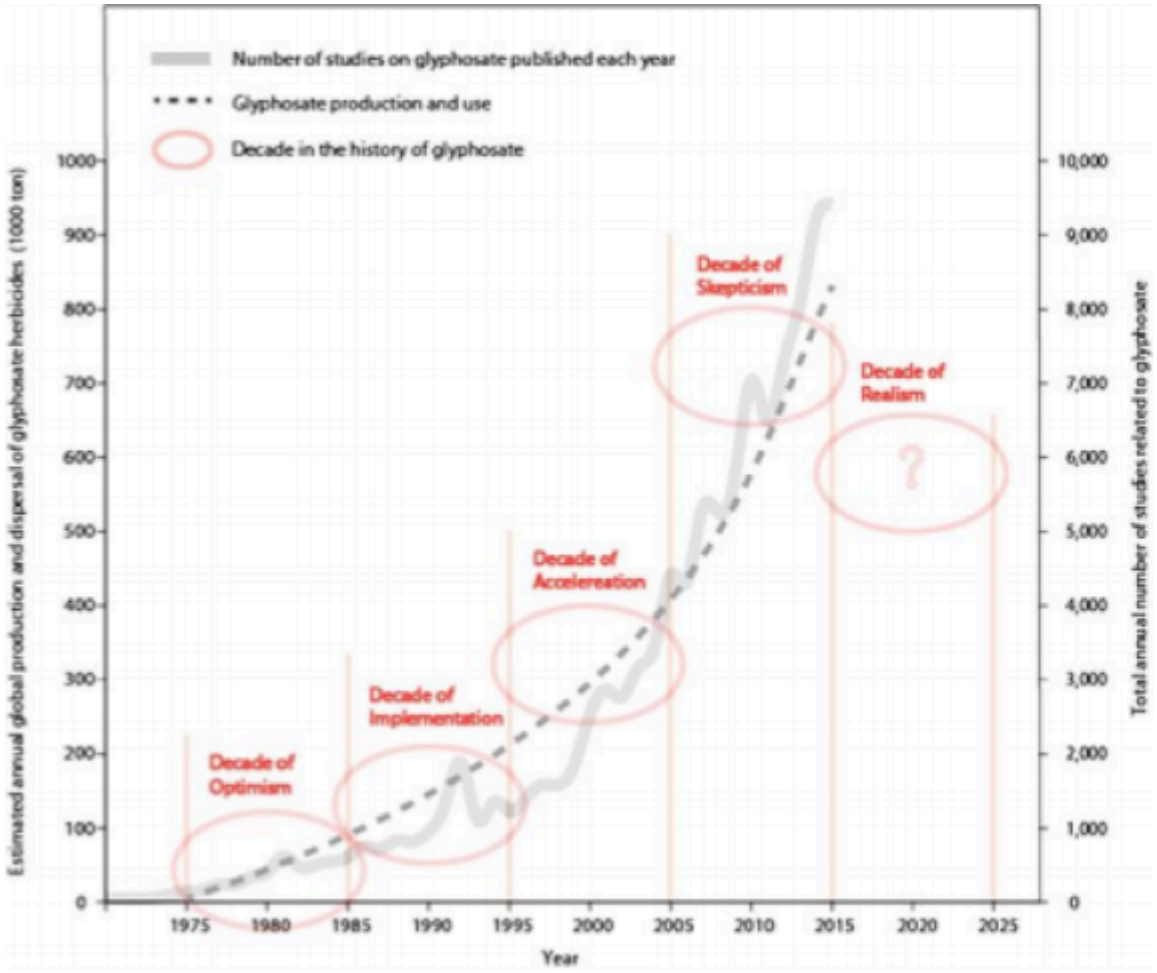
Here, the evolution of glyphosate use and risk-assessment has been defined as five distinct periods (each a decade) following the discovery and commercialization of glyphosate in 1975. The first decade (1975–1985) represents "glyphosate optimism." Glyphosate was discovered as a very efficient herbicide, with a systemic action on a broad spectrum of agriculture weeds. At that time, glyphosate was perceived to have very low toxicity toward users, non-target organisms and consumers of agriculture produce. The following two decades (1986–2005) saw global implementation of glyphosate based herbicides such as Roundup and a dramatic increase in glyphosate use. The introduction and successful commercialization of several glyphosate-tolerant genetically modified crops in 1995 was a development later identified as the most important factor accelerating the use of glyphosate herbicides (Charles, 2001; Duke and Powles, 2008; Benbrook, 2012, 2016). However, although the use of glyphosate has accelerated even further in the following decade (2006–2015) this has also been a decade of increasing and sobering challenges, notably caused by the advent of tolerant and resistant weed species, globally disrupting the efficacy of this agrochemical system. We define this latest decade "the decade of glyphosate skepticism" in our model. Numerous research programs, reviews and laboratory findings have documented that the safety assumptions of glyphosate are mature for revision. The decade culminated with a string of published evidence in 2015 detailing the challenging issues (Mesnage et al., 2015a; Samsel and Seneff, 2015b) even

concluding that glyphosate should be categorized as a probable carcinogen (Guyton et al., 2015), in contrast to previously accepted conclusions concerning these chemicals. EFSA recently reviewed the evidence of glyphosate carcinogenicity and concluded that glyphosate is not a carcinogen (EFSA, 2015c). Other research in 2015 indicated that previous assumptions of safety, have in part been based on flawed evidence or misinterpretations (Cuhra, 2015c; Samsel and Seneff, 2015a).

Future Developments

Agricultural industry in general depends on more-or-less toxic pesticides. This is a generally accepted normality for conventional agriculture, which has developed gradually since the latest great war (Alston et al., 2010) and now constitutes an "agroecological-prison-situation," in which pesticides and other chemicals are now unavoidable in order to make industrial farming cost-effective. Thus, farmers are trapped and dependent on a combination of selected seeds and selected poisons.

Despite the challenges associated with both the continued use of glyphosate as the principal herbicide and the continued cultivation of glyphosate tolerant crops, there are few attractive chemical-biotechnological alternatives at present. Several crop varieties tolerant to herbicidal chemicals glufosinate-ammonium, dicamba, and 2,4-D are currently either in development, awaiting approval or already on the market. But, it is still an unresolved issue whether these crop varieties and agrochemical systems (which are relying on "old" herbicide technology) are as efficient, cost-effective or "better or worse" for the receiving environment, as the existing glyphosate-tolerant varieties currently available. Despite the aforementioned challenges posed by glyphosate-tolerant GMOs, several large biotech firms are now releasing "second-generation" glyphosate-tolerant cultivars touted as being even more efficient. Developing a new herbicide and getting it approved for use is very costly. According to some estimates, the financial investments of industry can amount to US $180 million and the regulatory approval can take a decade (Smith et al., 2008; McDougall, 2010). Furthermore, it is challenging for industry to meet societal demands in such developments; new compounds are expected to have high target specificity and low general toxicity (for the environment, the users and the consumers of agricultural commodities). The biotech-agrochemical industry therefore adheres to two general strategies: it develops and registers new transgenic cultivars and chemical compounds for the market (ISAAA, 2014); and it uses existing chemical compounds in new ways, notably through introduction of transgenic varieties that tolerate higher doses of approved agrochemicals such as glyphosate (e. g., Cao et al., 2012, 2013). The role of glyphosate herbicides can therefore be expected to remain predominant in global industrial agriculture, especially in cultivation of glyphosate-tolerant varieties. As such, it is relevant to consider the possible benefits vs. challenges associated with continued or increased glyphosate use.



Concept model to visualize how societal perception of glyphosate has evolved through five decades (1975–2025), related to trends in glyphosate use and increasing annual rate of publications on glyphosate.

Returning to the history of glyphosate as depicted in the figure above, we suggest that the decade which we are entering at the time of this writing, should be later seen as the period of "glyphosate realism." Hopefully a time when glyphosate will be recognized as a chemical which has to be stewarded carefully and restricted. This would allow that glyphosate can be used sensibly, in moderation, and play a reduced role in global agriculture as the lesser evil, until an alternative is found. […]

3. The Coproduction of Evidence and Victims

In glyphosate review, WHO cancer agency edited out ‘non-carcinogenic’ findings

In : *Kate Kelland, “In glyphosate review, WHO cancer agency edited out ‘non-carcinogenic’ findings”, Reuters (London), 19 octobre 2017.*

The World Health Organization’s cancer agency dismissed and edited findings from a draft of its review of the weedkiller glyphosate that were at odds with its final conclusion that the chemical probably causes cancer.

Documents seen by Reuters show how a draft of a key section of the International Agency for Research on Cancer’s (IARC) assessment of glyphosate - a report that has prompted international disputes and multi-million-dollar lawsuits - underwent significant changes and deletions before the report was finalised and made public.

IARC, based in Lyon, France, wields huge influence as a semi-autonomous unit of the WHO, the United Nations health agency. It issued a report on its assessment of glyphosate - a key ingredient in Monsanto Corp’s top-selling weedkiller RoundUp - in March 2015. It ranked glyphosate a Group 2a carcinogen, a substance that probably causes cancer in people.

That conclusion was based on its experts’ view that there was “sufficient evidence” glyphosate causes cancer in animals and “limited evidence” it can do so in humans. The Group 2a classification has prompted mass litigation in the United States against Monsanto and could lead to a ban on glyphosate sales across the European Union from the start of next year.

The edits identified by Reuters occurred in the chapter of IARC’s review focusing on animal studies. This chapter was important in IARC’s assessment of glyphosate, since it was in animal studies that IARC decided there was “sufficient” evidence of carcinogenicity.

One effect of the changes to the draft, reviewed by Reuters in a comparison with the published report, was the removal of multiple scientists’ conclusions that their studies had found no link between glyphosate and cancer in laboratory animals.

In one instance, a fresh statistical analysis was inserted - effectively reversing the original finding of a study being reviewed by IARC.

In another, a sentence in the draft referenced a pathology report ordered by experts at the U.S. Environmental Protection Agency. It noted the report “firmly” and “unanimously” agreed that the “compound” – glyphosate – had not caused abnormal growths in the mice being studied. In the final published IARC monograph, this sentence had been deleted.

Reuters found 10 significant changes that were made between the draft chapter on animal studies and the published version of IARC’s glyphosate assessment. In each case, a negative conclusion about glyphosate leading to tumors was either deleted or replaced with a neutral or positive one. Reuters was unable to determine who made the changes.

IARC did not respond to questions about the alterations. It said the draft was “confidential” and “deliberative in nature.” After Reuters asked about the changes, the agency posted a statement on its website advising the scientists who participate in its working groups “not to feel pressured to discuss their deliberations” outside the confines of IARC.

Reuters contacted 16 scientists who served in the IARC expert working group that conducted the weedkiller review to ask them about the edits and deletions. Most did not respond; five said they could not answer questions about the draft; none was willing or able to say who made the changes, or why or when they were made.

The chairman of the IARC sub-group tasked with reviewing evidence of glyphosate's effect on laboratory animals was Charles Jameson, an American toxicologist. In testimony as part of personal-injury lawsuits against Monsanto in the United States, Jameson told lawyers for Monsanto he did not know when, why or by whom the edits had been made.

Monsanto is facing multiple legal claims in the U.S. from plaintiffs who allege glyphosate gave them or their loved ones cancer. Jameson is an expert witness for the plaintiffs. He did not respond to questions for this article.

Scott Partridge, Monsanto's vice president of global strategy, told Reuters the changes to the draft showed how "IARC members manipulated and distorted scientific data" in their glyphosate assessment. IARC declined to comment.

Numerous national and international agencies have reviewed glyphosate. IARC is the only one to have declared the substance a probable carcinogen. Compared with other agencies, IARC has divulged little about its review process. Until now, it has been nearly impossible to see details, such as draft documents, of how IARC arrived at its decision.

The European Food Safety Authority (EFSA) said that in its assessment of the weedkiller, the scientific decision-making process "can be traced from start to finish." Jose Tarazona, head of EFSA's pesticides unit, told Reuters: "Anyone can go to EFSA's website and review how the assessment evolved over time. So you can see clearly how experts … appraised each and every study and also how comments from the public consultation were incorporated into the scientific thinking."

In the United States, the Environmental Protection Agency published a full 1,261-page transcript of a three-day scientific advisory panel meeting on its ongoing evaluation of the carcinogenic potential of glyphosate in December 2016.

No such record of the deliberations behind IARC's monographs is published.

In a previous response to questions about the transparency of the IARC process, the agency's director, Chris Wild, referred Reuters to a letter in which he said his agency's assessments are "widely respected for their scientific rigor, standardized and transparent process." Wild also said IARC's methods are intended to allow scientists to engage in free scientific debate at its monograph meetings.

Deletions and additions

IARC says its working group scientists are selected for "their expertise and the absence of real or apparent conflicts of interest." For the panel that evaluated glyphosate and four other pesticides in what is known as IARC's Monograph 112, scientists from 11 countries met at the agency's headquarters in Lyon for a week-long meeting starting on March 3, 2015. The meeting "followed nearly a year of review and preparation" by IARC staff and working group members, "including a comprehensive review of the latest available scientific evidence," IARC said in a statement at the time.

In June, Reuters reported how the chairman of the IARC working group was aware of new data showing no link between glyphosate and cancer in humans, but the agency did not take it into account because it had not been published.

No drafts of IARC's glyphosate assessment have surfaced before. However, a draft was obtained by Monsanto as part of the legal proceedings in the United States. Reuters reviewed chapter 3, the section on animal studies, which is the only section no longer covered by a confidentiality order of the court.

The glyphosate review in IARC's Monograph 112 runs to 92 pages; the chapter on animal studies consists of just over 10 pages. Reuters has not seen any other sections of the draft and cannot say whether they also underwent significant edits.

In comparing draft and final versions of chapter 3, Reuters found that in several instances comments in the draft were removed; the comments noted that studies had concluded glyphosate was not carcinogenic. They were replaced in the final version with the sentence: "The Working Group was not able to evaluate this study because of the limited experimental data provided in the review article and supplemental information."

This sentence was inserted six times into the final version. Each time it replaced a contrary conclusion, noted in the draft, by the original investigators on the study being considered, such as: "The authors concluded that glyphosate was not carcinogenic in Sprague Dawley rats"; "The authors concluded that glyphosate technical acid was not carcinogenic in Wistar rats"; and "The authors concluded that glyphosate was not carcinogenic in CD-1 mice in this study."

Reuters also found changes to the conclusions and statistical significance of two mouse studies. These studies were cited in IARC's ultimate finding of "sufficient" evidence that glyphosate causes cancer in animals.

One edit concerned a 1983 study in mice. IARC's published monograph contains a fresh statistical analysis calculation as part of its review of that study. The original investigators found no statistically significant link between glyphosate and cancer in the mice. IARC's new calculation reached the opposite conclusion, attributing statistical significance to it.

This new calculation was inserted into the final published assessment, but was not in the draft version seen by Reuters. The change gave the working group more evidence on which to base its conclusion that glyphosate was probably carcinogenic.

In further discussion of the same 1983 study, IARC's final published report refers to expert pathologists on a panel commissioned to reanalyze the work of the original investigators. The IARC draft notes that these pathologists "unanimously" agreed with the original investigators that glyphosate was not related to potentially precancerous tissue growths in the mice. IARC's final report deletes that sentence.

Reviewing a second mouse study, the IARC draft included a comment saying the incidence of a type of animal cancer known as haemangiosarcoma was "not significant" in both males and females. IARC's published monograph, by contrast, inserts a fresh statistical analysis calculation on the data in male mice, and concludes that the findings were statistically significant.

[…] IARC answered none of Reuters' specific questions about changes to the draft.

IARC rejects false claims in Reuters article

In : *International Agency for Research on Concer, "IARC rejects false claims in Reuters article ("In glyphosate review, WHO cancer agency edited out "non-carcinogenic" findings")", 24 octobre 2017.*

In a Reuters article published on 19 October 2017, Kate Kelland reports on IARC Monograph draft documents "obtained by Monsanto as part of the legal proceedings in the United States". Reuters states IARC "edited out "non-carcinogenic" findings" and "dismissed and edited findings from a draft of its review of the weedkiller glyphosate that were at odds with its final conclusion that the chemical probably causes cancer", adding that the Agency "won't say who made the changes or why". IARC rejects these false claims.

As IARC explained to Ms Kelland, changes made to draft documents are the result of deliberation between IARC Monograph Working Group members and therefore cannot be attributed to any particular scientist. It is usual procedure that drafts prepared before a Monograph meeting form the basis of open scientific debate during the eight-day meeting in Lyon and are revised as a result of those deliberations. The Working Group makes its own assessment of the available scientific literature and may conduct additional analyses of the data therein. The Working Group does not have to take account of prior national regulatory assessments in making its own, independent evaluation.

Ms Kelland refers to differences between the draft document she obtained and the published Monograph text. Most of these differences specifically relate to a review article 1 co-authored by a Monsanto scientist.

The conclusions included in the draft Monograph document were those of the authors of this review article. During the meeting in Lyon, the Working Group considered that the review article did not provide adequate information for independent evaluation of the conclusions reached by the Monsanto scientist and other authors; consequently, the draft was revised, and the text in the published Monograph is the consensus opinion of the Working Group. However, the Monograph does factually describe the review article and the reported findings (see Monograph, pages 34–35 and 40–41).

The Reuters article is ambiguous as to precisely who is alleged to have "edited out "non-carcinogenic" findings". IARC staff do not draft or revise the Monograph text. Only the Working Group writes and revises the text, as described in the Preamble to the IARC Monographs. The final Monograph evaluation represents the scientific consensus of the whole Working Group. Full details of the scientific report and the process for the classification of glyphosate are available online.

Deliberative drafts are not made public, in order to protect the Working Group from interference by vested interests. The position of IARC and the World Health Organization concerning the public release of deliberative documents, or records of deliberative scientific discussions, is consistent with standard practice in scientific committees. This was already clearly explained to Reuters after an earlier misleading report, in October 2016. 2 Observers, however, are permitted to attend the Monograph meetings and have access to all draft documents. Monsanto had an observer at the Monograph evaluation of glyphosate. This observer was quoted in the media as saying: "The meeting was held in accordance with IARC procedures. Dr. Kurt Straif,

the director of the Monographs, has an intimate knowledge of the rules in force and insisted that they be respected."

Members of the Working Group expressed concern at being pressed to respond to allegations about the scientific debate that took place at IARC. In response, IARC was compelled to issue a reminder to all parties not to pressure or intimidate scientists in relation to their role as Working Group members. Reuters approached 16 members of the Working Group to ask them to justify their edits and deletions and claimed "none was willing or able to say who made the changes, or why or when they were made". In an email seen by IARC, one Working Group member who did respond to Ms Kelland stated that all the procedures were transparent, with many witnesses to the discussions during the eight-day meeting, including various stakeholders.

IARC will not respond to baseless, defamatory statements about IARC or its Working Group, whether these are issued by Monsanto or other interested parties, directly or through third parties, including media contacts. IARC will not comment on the transparency of the evaluation processes of other agencies. IARC notes the context of ongoing legal proceedings and regulatory decision-making processes regarding glyphosate, but is not involved in these processes.

In summary, the cancer hazard classifications made by the IARC Monographs are the result of scientific deliberations of Working Groups of independent scientists, free from conflicts of interest. The resulting Monograph represents the Working Group's consensus conclusions, based on their critical review of the published scientific literature, agreed upon by all Working Group members in plenary sessions. The principles, procedures, and scientific criteria that guide the evaluations are described in the Preamble to the IARC Monographs.

Becoming a Victim of Pesticides

In : Jean-Noël Jouzel and Giovanni Prete, "Becoming a Victim of Pesticides: Legal Action and Its Effects on the Mobilisation of Affected Farmworkers", *Sociologie du travail*, Vol. 57, Nov.2015.
Translated by Christopher Hinton

Thwarted entry into the trajectory of a farmworker victim of pesticides

The trajectory of farmworkers victim to pesticides began well before their first legal action. The prerequisites for their entry into the law governing work accidents and occupational diseases appear to have acted as powerful filters which limited recognition of the effects of pesticides on their health. For the very few farmers who applied for recognition of a pesticide-related occupational disease over the last decade, this was almost never an obvious decision. Given that they fell ill when they considered themselves as being in good health and leading an active life, chronic disease was experienced as a "biographical rupture" (Bury, 1982) and their initial reaction to their health problems – and that of their families — was to concentrate their efforts on finding an effective therapy which would allow them to "return to normal" as quickly as possible, particularly as far as work was concerned. Generally speaking, the question of a possible link with pesticides only arose later on, when they had come to accept that their health would be affected on a long-term basis and that they needed to engage in a lengthy process of medical treatment. In most cases, this etiological hypothesis was first mentioned by a third party (spouse, neighbour, etc.) who was already concerned about the potential dangers of pesticides. In other cases, it was through interaction with healthcare personnel — with doctors in specialist departments in particular (haematology, neurology) — that the sick farmworkers became aware of the possible link between their suffering and the pesticides they had been handling throughout their working lives.

Yet when this link was taken into consideration, it did not automatically lead to a request for recognition of an occupational disease. As far as the farmworkers were concerned, perceiving themselves to be sick as a result of exposure to pesticides did not mean taking on the identity of victim of a harm which entitled them to compensation. Very often they first blamed themselves and their own negligence for their suffering. Some of them felt "responsible for their suffering", that they had "been a bit stupid" in not taking sufficient precautions. This conception of one's intoxication is a powerful obstacle to entry into the work accident and occupational disease recognition procedure, and is one of the underlying reasons for the very low number of applications for recognition filed in relation to pesticide exposure. […]

More than a cultural reading focusing on the special relationship people might have with the body in the rural world, this observation calls for an understanding of how, over the long term, policies designed to prevent occupational intoxication from pesticides have framed this type of bodily harm. Since 1943, pesticides have been subject to a marketing authorisation granted by the French Ministry of Agriculture on the basis of an *a priori* risk assessment which, for each pesticide, uses models to measure the occupational exposure that is expected and determines an "acceptable" threshold. This risk assessment is carried out by the manufacturers who market the product […]. If the estimated exposure level remains too high, the manufacturer has the possibility of reducing it by making recommendations for the use of protective clothing (gloves, masks, suits). In this respect, prevention policies have for a long time emphasised the fact that users' protection from pesticides depended on their own capacity to follow a set of recommendations

provided for their attention on the product labelling. The implicit consequence of this framing is to blame any product-related bodily harm on insufficient vigilance on the part of the farmworker victims, and to urge the latter to accept their fate.

So it is often through interaction with third parties that this definition of the situation can evolve. The family, in particular, might encourage the farmer to start a recognition procedure by explaining the material advantages which may be gained. They might emphasize the threats that the disease leaves hanging over the continuity of the farm. This road to legal action is initially conceived less from a standpoint of repair than as one of the several windows available to the farmworker and his/her family in order to obtain material and financial "aid" which will allow them to continue their professional activity in spite of the disease.[...]

When the trajectory makes the combatant

The difficulties that they encountered during their recognition trajectories often caused farmworkers and their families to set out on a quest for information, for "tips" which would allow them to play "with the law" (Ewick et Silbey, 1998) and thus maximise their chances of success. To this end they mainly consulted the Internet and both the trade and general press, where they found two types of possible support. First of all, their quest for information sometimes led them to identify cases of farmworkers who were suffering from similar pathologies to their own and who had obtained recognition due to their exposure to pesticides. In addition to the fact that such discoveries encouraged them to persevere with their own recognition procedures, they also more fundamentally strengthened their belief that there was indeed a link between their suffering and the pesticides that they had used. Additionally, some of the individuals and families concerned entered into contact with one another, thus constituting the first steps in a shift from individual engagement in a quest for recognition, towards a structured collective action. Their search for information in the media also led farmworkers and their families to identify resource actors: scientists who had worked on the links between pesticides and their diseases, journalists or environmental activists who could help them strengthen their cases. These actors provided farmworkers with information on the specific scientific data available or on other cases similar to theirs. But above and beyond such practical information — often decisive in the success of recognition procedures –, they provided the farmworkers who contacted them with interpretative frameworks that encouraged them to perceive their disease as a genuine injustice.

[…] These encounters gradually led them to see themselves as legitimate victims and strengthened their belief that their problems were caused by pesticides. Above all, they helped them to give moral meaning to this causal link: whilst work accident and occupational disease legislation attempts to marginalise the notion of fault, the obstacles it places in the farmworkers' way end up having the opposite effect, putting the latter on the track of the actors responsible for their situation. These encounters punctuated the creation of a more and more dense and combative network of sick farmworkers' families, environmental activists, lawyers and scientists. This network was to gradually take the form of a structured collective action to denounce the dangers that pesticides presented to farmworkers in their fields. In January 2010, a dozen families met for the first face-to-face meeting in Ruffec in the Charente region, on Paul François' farm. A year later, in March 2011, these same families met again at the same place to officially found the Phyto-Victims Association, which has ever since been fighting for greater recognition for pesticide-related occupational diseases, for stricter control of products and for the banning of the most dangerous among them. The difficulties that these farmworkers have encountered in trying to gain recognition for their occupational diseases have been a major vector for their commitment to a cause which is, a priori, far removed from their political socialisation.

From the individual to the collective: the Phyto-victims cause taken up by the law

The choice of the name "Phyto-victims" is significant. The farmworkers are sending out the message that above and beyond the diverse nature of their pathologies and individual trajectories, they share the same experience and the same identity which they will defend in the public space and in legal arenas: that of having used pesticides during the course of their professional activities, and of now suffering from the pathologies caused by those products. [...]

Recourse to judicial institutions greatly strengthened the adherence of the founders of the Phyto-Victims Association to their victimary identity, by helping them to see their suffering as the consequence of criminal acts committed by third parties, from whom compensation could legitimately be demanded. The law gave Phyto-victims frameworks which allowed them to consider and formulate their diseases as an injustice, and their experience of the legal proceedings directly and indirectly favoured their conversion into accusing victims (Barbot and Fillion, 2002). Phyto-victims who engage in legal action are directly led to see themselves as victims of the actors against whom the procedures are initiated. In this respect the P. François case is illuminating. When he followed his lawyer's advice and began a civil action against Monsanto in 2007, he was still far from convinced that the company was responsible for his suffering. His complaint was therefore essentially linked to the fact that a legal limitation period was about to expire. It was only as proceedings moved ahead that he began to see himself as a victim of the American firm's lie about the toxicity of the product he had inhaled.[…] The civil action thus influenced the construction of P. François' identity as a victim not only of pesticides, but also of the manufacturers who marketed them. […]

More indirectly, farmworkers who have not yet taken any legal action outside the law on work accidents and occupational diseases are reconsidering their situation in the light of their observations of the procedures initiated by other members of the association. In their eyes, the first instance successes of P. François and Dominique M. are proof of the liability of the pesticide companies concerned, and several other association members are thinking about taking similar steps, particularly before the Civi [the commission for compensation of victims of criminal offences]. […] From a legal standpoint, the increasing number of cases brought before the Civi might encourages the fund which compensates victims to try to identify the perpetrators of the offences in question and to take action against them through subrogatory actions. […]

The law therefore encourages Phyto-victims to frame their suffering as an experience of moral prejudice and offense. Yet this framing is relatively limited given the complexity of pesticide occupational risk prevention systems. In addition to the manufacturers, numerous other actors are involved in the chain through which information relating to the dangers of pesticides and to means of protection should reach the end users of these products; as such, they might be considered to have some responsibility for the deficiencies in the information provided. This is particularly true of the government: theoretically speaking, product labelling meets the regulatory requirements for the marketing authorisations granted by the ministry of agriculture, based on a risk assessment carried out by an independent agency, Anses (French national agency for food, environmental and occupational health safety). However, these requirements have for a long time proven to be extremely limited in terms of health and safety at work. Until 2006 for example, labels contained no details on "re-entry intervals", i.e. the period to be respected before farmworkers could return to fields where pesticides had been used. [...]

Finally, it should be noted that as long as legal action focuses on misleading or inadequate information to pesticide end-users, it ultimately reinforces the idea that farmworkers who are properly

informed of the dangers of pesticides should be able to effectively protect themselves. In so doing, it runs the risk of implicitly validating a highly questionable orientation of public policies. Regarding pesticide-related occupational diseases, prevention policies make product labelling and the observance of safety instructions the cornerstone of protection for farmworkers. Several recent works have nevertheless suggested that such “controlled use” (Décosse, 2013), based on information relating to the dangers of pesticides and to protective equipment, is pure fiction. In particular, ergonomics and metrology studies demonstrate that the protective equipment recommended on product labels is neither effective (Grillet et al., 2004; Garrigou et al., 2008), nor suited to the practical realities of agricultural work (Mohammed-Brahim and Garrigou, 2009). These data suggest that even if available information on the dangers of pesticides was improved, and even if the available means of protection were optimised, truly effective protection would remain highly theoretical. In making lack of information the main option for examining the responsibilities at play in occupational diseases, legal action tends to push aside such reflexion. Paradoxically, it therefore constitutes an element which tends to reinforce the *status quo* surrounding modalities of pesticide control.

Urine testing for pesticides: new dodgy science straight out of France

In : Bill Wirtz, “Urine testing for pesticides: new dodgy science straight out of France” in *Comment Central (Consumer Choice Center)*, December 20, 2019

If you’ve never heard of “glyphosate pissers,” then picking up French newspapers will take you on a wild ride. As the glyphosate debate captivatestalking heads in Europe – a saturated amount of activists in lieu of scientists – French environmentalists have taken their assassination of the weedkiller one step further.

Since April 2018, 5,500 farmers have found glyphosate in their urine at levels above the average allowed in drinking water, which is 0.1 na/ml. “Only three participants scored below this average,” a 66-year-old environmentalist activist told the French newspaper Libération. These activists have convinced French farmers that there could potentially be big money in the effort to sue pesticide producers. Nothing could be more appealing than trying to replicate million-dollar lawsuits as those scraped together in the United States. Over 1,500 complaints of “glyphosate pissers” have been filed for “endangering the lives of others,” “aggravated deception” and “environmental damage”. A few hundred Euros, the environmentalists who organise these lawsuits say, would cover both the costs of the lab testing “and the presence of a bailiff to certify the results,” since nothing screams unbiased scientific research more than bringing your lawyer to the lab. On its website, the French campaign group “Campagne glyphosate” says that 100% of the tests have tested positive for glyphosate. No risks at all, dear farmers, just sign here. If the 100% figure rings a bell, then you’d be right in feeling reminded, as Gil Rivière-Wekstein, editor of the French agriculture media outlet “agriculture & environment” points out in an editorial.

In June 2015, the German Green Party had 16 samples of breast milk analysed in Germany, with 100% positive results for glyphosate. The story was in the news across the Rhine, triggering a wave of panic among breastfeeding mothers. Curious. Shortly after that, 2000 urine samples from German citizens were analysed as part of the “Urinale,” a campaign led by the anti-pesticide association Bürgerinitiative Landwende. This time, 99.6% of the results were positive. So close, yet so far. In May 2016, the Green Group in the European Parliament had the urine of 48 MEPs (Members of the European Parliament) tested, again with 100% positive results. Shocking. In March 2017, 27 urine samples were analysed from Danish mothers and children, again with 100% positive results. You get the gist.

Heavily involved in the current tests is a research lab called BioCheck, based in Germany and founded in 1997 by Monika Krüger. Madame Krüger is herself an anti-pesticide activist. Not necessarily the right pre-condition for a sound and objective researcher. In fact, their results have already been debunked. Remember the 16 samples of breast milk that were 100% contaminated? The German Federal Institute for Risk Assessment (BfR) affirmed that there was no evidence whatsoever that proved that glyphosate levels in breast milk were above the legal limits. The two independent studies that the BhR commissioned were put together in an article for the Journal of Agricultural and Food Chemistry. They used liquid chromatography coupled with mass spectrometry (LC-MS/MS) or gas chromatography coupled with mass spectrometry (GC-MS/MS) – processes that are, according to the risk assessment institute, 10 times more trustworthy than regular tests for detecting pesticides, and 75 times more trustworthy than those used by BioCheck.

BioCheck had been employing the ELISA test to reach its conclusions. This enzyme-linked immunosorbent assay is a test that detects and measures antibodies in your blood. The German Federal Institute for Risk Assessment said that detecting glyphosate in itself is a fundamentally complicated endeavour, and that the ELISA is not an adequate way of going about finding it. Marcel Kuntz, Research Director at the CNRS (Centre national de la recherche scientifique) in Grenoble, also confirms that ELISA not an accurate test to detect pesticides. That's probably why BioCheck charged a mere €75 for their urine tests. You always get what you pay for.

Headlines like "Results of Glyphosate Pee Test Are in 'And It's Not Good News" have already been written and published, without retraction, so what's the big deal? The problem is that we are looking at a thorough perversion of the scientific method.

In easy swipes, years of technological innovation in agriculture are thrown overboard for the convenience of political ideologues. We know that glyphosate is safe: when looking through the scientific literature, we see that it is a herbicide that is safe to use, and necessary for modern agriculture. Scare stories about "toxic residues" in our body are supposed to make us anxious and suspicious,with unfortunate success. Many governments are succumbing to the pressure, and have introduced bans products at the expense of both farmers and consumers.

To these activists, re-considering more exhaustive testing isn't of interest. They would rather pursue fanatic unproven convictions for special interests to use in the world of lawsuits. That's a shame.

4. The Making of Risk Assessment Expertise

How industry strategized and regulators colluded

In : *Helmut Burtscher-Schaden, Peter Clausing, and Claire Robinson, "Glyphosate and Cancer : Buying Science. How industry strategized (and regulators colluded) in an attempt to save the world's most widely used herbicide from a ban", Global 2000, March 2017. (Summary)*

In this report we show how Europe's pesticide regulation, introduced in 2009, threatened the survival of glyphosate herbicides, the most widely used in the world, and how industry fought back to save its chemical from a ban.

Chapter 1 describes the challenges that confronted manufacturers of glyphosate-based herbicides in 2012 when they had to apply for re-approval in the EU of their active ingredient, glyphosate. Under the 2009 law, pesticide active ingredients are not allowed to be marketed if they have the potential to cause cancer, damage DNA, or have toxic effects on reproduction. This is known as a hazard-based approach. It means that if the pesticide has these effects, in principle, it must be banned. The inherent properties of the chemical are crucial, rather than the – often difficult to predict – risk to humans under certain exposure scenarios.

The reasoning that if the pesticide is properly used, people would only be exposed to "safe" doses – the "risk-based approach" – is not permitted for such substances. This change in law posed a problem for Monsanto and other companies that manufacture or market glyphosate herbicides, because several of the industry's own animal studies show statistically significant and dose-dependent carcinogenic effects from glyphosate.

Another aspect of the 2009 regulation also posed a problem for industry. In the past, the regulatory assessment of pesticide active ingredients has been based on industry-sponsored studies. These are generally unpublished and are kept hidden from the public and independent scientists on the grounds that they are commercial secrets. But the regulation mandated for the first time that studies from the peer-reviewed open scientific literature must be included in the dossier of documents that the industry submits to regulators in support of the approval of a pesticide.

The challenge to the pesticide companies lay in the fact that while industry studies generally conclude that glyphosate is safe for its proposed uses, many studies conducted independently of the industry disagree. In recent years, a growing number of peer-reviewed studies in the published scientific literature have pointed to the harmful effects of glyphosate and its commercial formulations. Notably, while most industry studies indicate that glyphosate is not genotoxic (damaging to DNA), the majority of independent studies find the opposite.

In 2015 a severe blow hit the industry when the World Health Organization's cancer research agency IARC published its verdict that glyphosate was probably carcinogenic to humans and that there was strong evidence that it was genotoxic. Glyphosate products represent a lucrative global market that is expected to cross US$ 10 billion by 2021. So the industry had to come up with a strategy to save its chemical.

Monsanto and other glyphosate companies responded to these cumulative threats to their business by sponsoring scientific reviews, published in peer-reviewed journals, which conclude that glyphosate and its commercial formulations are not harmful to health.

In 2016 a series of reviews with favourable conclusions on glyphosate's safety (we call them the "Intertek papers") were published in a peer-reviewed journal. The authors were members of the Glyphosate Expert Panel, convened by the commercial consultancy firm Intertek under commission from Monsanto. Monsanto had paid Intertek to convene and facilitate the panel's work. The specific and stated aim of the Intertek papers was to counter IARC's evaluation of glyphosate. They unanimously conclude that glyphosate in humans does not harm genetic material or trigger cancer.

In Chapter 2 we identify nine major scientific flaws in the Intertek papers and other industry-sponsored and -supported review articles on glyphosate's health risks. Specifically, they utilize manipulations such as apparently calculated omissions and the introduction of irrelevant data, confusing the picture and denying the scientific evidence of glyphosate's harmful effects.

Most importantly, the authors claim to have used a "weight of evidence" approach to assess whether glyphosate is carcinogenic or not, yet in reality, they avoided such an approach. A weight of evidence approach takes a holistic view of the different lines of evidence, namely:

- Animal studies
- Epidemiological data
- Possible mechanisms of carcinogenesis.

In the case of glyphosate, the different lines of evidence complement each other. For instance, the finding of a significantly increased incidence of malignant lymphoma in three mouse studies is complementary to the association between glyphosate exposure and non-Hodgkin lymphoma in humans. These lines of evidence are in turn supported by convincing evidence for genotoxicity and oxidative stress as possible underlying mechanisms for cancer development.

Altogether evidence exists in all three areas of consideration. A holistic consideration of this evidence inevitably leads to the conclusion that glyphosate is carcinogenic. Instead, the Monsanto-sponsored authors considered the different lines of evidence separately, used false arguments, and concealed or distorted the facts, concluding that glyphosate is not carcinogenic.

One episode that is not objectively addressed in the Intertek papers took place in 1985, when the US EPA classified glyphosate as a possible human carcinogen. The EPA had based its verdict on a significant and dose-dependent increased incidence of a rare kidney tumour in a mouse study submitted by Monsanto. But Marvin Kuschner, a consultant pathologist who was reportedly a member of Monsanto's Biohazards Commission, re-evaluated the data and claimed to find such a tumour in a control mouse (which did not receive glyphosate), thus removing the statistically significant increase in the incidence of this tumour in glyphosate-treated animals. This finding, if confirmed, would have exonerated glyphosate from suspicion of causing kidney cancer.

Pathologists tasked by the EPA with re-examining the original kidney sections and new sections of the same organs were unable to identify the alleged new tumour. However, four consultants commissioned by Monsanto stated that they were able to confirm Kuschner's extra tumour. After a long back-and-forth

discussion, the EPA moved glyphosate from class C (possible human carcinogen) into class D (not classified for carcinogenicity) in 1998.

In addition to the fact that the Intertek papers themselves were commissioned by Monsanto, many of the authors of these and other industry-sponsored or industry-supported reviews have conflicts of interest with the pesticide and chemical industries. This is shown in Chapter 3. Twelve of the 16 members of the Glyphosate Expert Panel have served as consultants to Monsanto and/or have been employed by the company. Others have different conflicts of interest with industry or industry-linked bodies, notably the International Life Sciences Institute (ILSI), an organization funded by (among others) companies that manufacture and/or market glyphosate products, including Monsanto, Dow, and BASF. These conflicts of interest have often not been made clear to members of the public and media.

Only in the case of one panel member were we unable to find any conflicts of interest, apart from her participation in the Intertek papers. In spite of all this, members of the Glyphosate Expert Panel were claimed in the Intertek papers to be independent.

The notion that glyphosate is not carcinogenic has found backing in the verdicts of several regulatory agencies and expert bodies, including BfR (Germany's Federal Institute for Risk Assessment), the European Food Safety Authority (EFSA), the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Meeting on Pesticide Residues (JMPR), and the US Environmental Protection Agency (EPA). However, the assessments of BfR and EFSA suffer from fundamental scientific weaknesses and the JMPR's conclusions are marred by a severe lack of transparency and scientific clarity, as shown in Chapter 4.

As an example of the problems with BfR's assessment, after the cancer research agency IARC found "sufficient" evidence of a carcinogenic effect of glyphosate in the same four industry studies (two studies with rats and two with mice) in which BfR had previously not been able to detect any evidence of cancer activity, the German authority had to evaluate the assessments of the IARC. As a result, BfR was forced to confirm the statistically significant tumour findings noted by IARC in all four studies. Also, in the remaining three mouse studies of the manufacturers, BfR had to admit the existence of statistically significant and dose-dependent increases in tumours, which it had previously overlooked. As an explanation for its colossal error, the BfR admitted that "initially", it had "relied on the statistical evaluation provided [by the glyphosate manufacturers] with the study reports".

This failure of the German authority is particularly explosive because the hazard-based approach in the EU pesticide regulation forbids the authorization of an active substance as soon as there are positive cancer findings in at least two independent animal studies.

In addition, BfR repeatedly confused hazard with risk, apparently deliberately. Our presumption is that this was intended to divert attention from the hazard-based approach of EU law, which, in light of the positive cancer findings in mice and rats in the industry cancer studies, would require a ban for glyphosate.

The whole of the evidence on glyphosate, taken together – animal studies, human epidemiological evidence, and mechanistic evidence – provides ample confirmation of glyphosate's carcinogenicity. Yet in a similar fashion to the Intertek papers, rather than evaluating the evidence as a whole, BfR separated out the various lines of evidence of glyphosate's carcinogenicity in order to deny them individually, and finally to

discard the isolated evidence as a single random result. It concluded that glyphosate does not warrant a carcinogenic classification.

In parallel with these scientific shortcomings, the regulatory and expert agencies' reports on glyphosate are also compromised by conflicts of interest, as detailed in Chapter 5. For example, the same people who were involved in the European evaluation of glyphosate in Germany in the 1990s are also involved in the current re-evaluation. Some have evaluated glyphosate for national agencies and then re-evaluated their own previous decisions at the EU and international level, in different positions. This is a problem because if individuals are asked to assess their own earlier assessment, they will not be inclined to admit any mistakes – particularly regarding a politically and economically sensitive issue like the re-approval of glyphosate.

Some people who have evaluated glyphosate for regulatory and expert bodies also have conflicts of interest with industry. For instance, the chairman of the JMPR for glyphosate, Alan Boobis, was also the vice-president of ILSI Europe. In 2012 – the year Monsanto submitted the dossier for the re-approval of glyphosate – the ILSI group received a $500,000 (£344,234) donation from Monsanto and a $528,500 donation from the industry group Croplife International, which represents Monsanto, Dow, Syngenta, and others. The co-chair of the JMPR glyphosate sessions was Professor Angelo Moretto, a board member of the ILSI Health and Environmental Sciences Institute (HESI), and of its Risk21 steering group, which Boobis also co-chairs.

Even the EPA's forthcoming report on glyphosate – which was widely expected to give the chemical a clean bill of health – has become mired in controversy. According to court filings by people who believe that their cancer was caused by exposure to glyphosate herbicides, a former long-time EPA scientist, Marion Copley, accused former top-ranking EPA official Jess Rowland of colluding with Monsanto to protect the company's interests and deny that glyphosate was carcinogenic. Copley cited evidence from animal studies and wrote to Rowland: "It is essentially certain that glyphosate causes cancer." Rowland left the EPA in 2016, shortly after the agency's favourable report on glyphosate was leaked.

In sum, attempts by agencies and individuals to defend glyphosate and its formulations against evidence that they cause cancer and damage DNA are scientifically unsound and undermined by serious conflicts of interest.

In the light of our findings, we recommend that the evaluations of glyphosate and its formulations by individuals and institutions compromised by conflicts of interest are set aside. If these institutions and individuals wish to address their flawed evaluations, they must openly address the scientific points and evidence raised in this report. For the sake of transparency, they should use only studies available in the public domain.

In the meantime, glyphosate-based formulations should be phased out as a precautionary measure. The continuation of the European authorization of glyphosate would lead to an unacceptable risk of cancer, which would be avoided by correctly observing the laws and respecting scientific integrity.

Cleaning the scientific house

In : Naomi Oreskes, 'Cleaning the scientific house: Rebuilding trust in science requires confronting the harms of ghostwriting', *Science*, 30 Oct 2025, Vol 390, Issue 6772

American science is under attack. Recent cuts to funding and staffing of federal agencies, layoffs of scientists, and rescission of billions of dollars in grants are unprecedented in US history and threaten the stability of the scientific infrastructure that, since World War II, has made the US the world's global scientific leader. So this might not seem the right time to raise questions about scientific integrity. When someone is burning down your house, it is probably not the right time to worry about cleaning it. But if someone is trying to dismantle your house, then it is a good time to shore up its foundations. Consider the problem of ghostwriting in science. Recently, a colleague and I published a paper analyzing the impacts of a peer-reviewed paper, published in 2000, that purported to be an independent, objective, and comprehensive review of the safety of the pesticide, glyphosate. The paper found no convincing evidence for toxicity, genotoxicity, carcinogenicity, or endocrine disruption. However, documents made public through legal proceedings in 2017 showed that the paper was not, in fact, independent, but had been conceptualized and largely written by Monsanto employees. We wanted to know: How much of an impact has this ghostwritten paper, which asserts the safety of glyphosate, had? The answer is: a lot. It is cited in more than 800 academic papers and dozens of government documents and used as a source in several Wikipedia articles (upon which the large language models that inform ChatGPT rely). Many of these citations occurred after it had been revealed that the paper was ghostwritten; only a handful discuss the paper's ethically questionable pedigree. [NB. The paper was withdrawn because of "serious ethical concerns" and questions about the validity of the research findings, on 28 November 2025.]

One example is particularly revealing. In 2011, the Canadian Forest Service published an FAQ addressing public concerns about pesticide safety. One question read: "I've read on the Internet that glyphosate causes cancer and is an endocrine disruptor. Is that true?" The answer cites the paper (as reference 24) at issue as a credible and reliable source in support of glyphosate safety: *No. Based on the weight of available scientific evidence, several regulatory and independent scientific review panels conclude that glyphosate is non-carcinogenic, does not cause birth defects or genetic alterations, and does not act as an endocrine disruptor… (24, 25). Such reviews conducted by highly qualified professional toxicologists and risk assessment specialists provide the most credible and reliable sources of information.*

This "answer" points to the most troubling aspect of this story: that the paper has likely played a substantial role in the US EPA's conclusion that glyphosate does not pose a human cancer risk, even though the International Agency for Research on Cancer (IARC) concluded that it probably does (the IARC also concluded that there was strong evidence for glyphosate genotoxicity; the EPA did not). And the damage continues: The New York Times recently published an opinion piece insisting that glyphosate is "fine, really," based in part on the accusation that concerns about the pesticide are "pseudoscience" (The piece also ridiculed the IARC for classifying red meat as probably carcinogenic. In fact, red meat is carcinogenic.).

Ghostwriting is a form of scientific fraud because a paper is falsely presented as the work of people other than its actual authors. We have asked the journal that published the paper in question to retract it on those

grounds. At the time of this writing, they were reviewing the matter. Ghost-writing also threatens the integrity of scientific research: When a paper is ghostwritten by a corporation with a clear interest in promoting or exonerating a profitable product, the paper may have been inappropriately influenced by that interest. One might therefore think that academics would be motivated to expose and expunge such practices, especially when lives are potentially at stake. But the truth seems to be otherwise.

For decades, the prominent British psychiatrist David Healy has tried to call attention to ghostwriting by pharmaceutical companies, which he believes has grossly distorted the scientific landscape regarding drug efficacy. In 2004, he testified in the British parliament that as many as 50% of articles dealing with therapeutics were ghostwritten. In 2009, a lawsuit involving the Pharma giant, Wyeth, showed that 26 papers in medical journals on hormone replacement therapy were wholly or in part ghostwritten. These papers supported the benefits of hormone replacement therapy (HRT) and minimized its risks. (at the time, Wyeth was earning nearly $2 billion a year selling HRT drugs). Another lawsuit showed that Parke Davis had sponsored papers intended to encourage the use of its anticonvulsant drug, gabapentin. Company employees planned a set of 24 papers to be written by "guest" authors; Out of the planned 24 papers, 11 appeared in the intended medical journals, and none disclosed the company's role in this plan.

In 2012, physicians Xavier Bosch and Joseph S. Ross explained how ghostwriting works and why it is so problematic. Typically, an industry employee or contract writer prepares the paper and then solicits an academic expert to put their name on it, perhaps after a bit of minimal editing, and submit it for publication. The academic gets paid—sometimes a little, sometimes a lot—but, in most cases, has no access to the clinical data, so they are in little position to judge whether the study was done properly or the claims of the paper are true. A chilling example was reported in 2007: A paper published in the Annals of Internal Medicine, reporting on clinical trials of the analgesic Vioxx, omitted some participants' deaths. The paper's first author confessed that Merck "designed the trial, paid for the trial, ran the trial," and asked him after the fact to be its "author." All he did was edit it. Vioxx was taken off the market after studies showed that it increased the risk of heart attack and stroke. One FDA investigator concluded that the drug may have caused 60,000 excess deaths. Some studies place the number even higher.

The purpose of producing ghostwritten papers, Bosch and Ross conclude, is to "manage and shape the medical literature" in ways that advance corporate interests. Sergio Sismondo, a Canadian science studies researcher, argues that ghostwriting is part of a larger pattern that he calls "ghost management," wherein corporations manipulate the scientific research agenda and communication in diverse and creative ways, all intended to promote their products to doctors and patients, irrespective of the best interest of those patients. Despite these disturbing examples, many academics do not take ghostwriting seriously. Bosch and Ross observed that their colleagues typically view it as a "slight, easily comprehensible moral failing" rather than a profoundly unethical practice. Others justify it as offering the opportunity to work with industry, improve the quality of industry studies, or earn academics justified remuneration. Even when exposed, academics are rarely punished. One of the authors involved in the Wyeth scandal was investigated by her university. She was "reprimanded" but suffered no sanction.

Aside from the obvious problem of academics lending their reputations to papers that, like the Vioxx study, may actually put lives at risk, turning a blind eye to malfeasance in our ranks gives the public legitimate reason to distrust our work. And this brings us back to our present moment.

There's a lot of concern right now about low levels of public trust in science; commentators typically recommend the remedy of better communication. Good communication is never a bad thing, per se, but consider this: A 2021 study by the Pew Research Foundation found that only 11% of Americans believe that medical research scientists face serious consequences for misconduct, and barely more (12%) think that researchers are consistently transparent about conflicts of interest and take responsibility for their mistakes. From the evidence that I have reviewed, it's hard to conclude that they are wrong. If we are to rebuild our scientific enterprise, we will need the support of the American people, and that means cleaning up our house. Policies to forbid ghostwriting and strong sanctions for researchers who violate those policies would be a good place to start.

“A fundamental lack of understanding of the EU pesticides assessment framework”

In : *EFSA statement addressing allegations on the renewal assessment report for glyphosate*
22 September 2017

Recent reports in the media have alleged that parts of the EU assessment of glyphosate were plagiarised from information provided to regulatory authorities by the companies applying for the re-authorisation of this active substance. These allegations are unfounded and based on a fundamental lack of understanding of the EU pesticides assessment framework.

“To be clear, the process for the EU assessment of glyphosate was carried out properly, transparently, and in the same way as the assessment of all other pesticides involving EFSA, regardless of whether they lead to market authorisations or to restrictions and bans,” said EFSA’s Executive Director, Bernhard Url. “In the EU regulatory system for pesticides, which is set out in EU law, the starting point for any risk assessment is a dossier compiled by the company seeking to place an active substance on the market.” Dr Url added: “It is natural and necessary that parts of the company’s dossier appear in sections of the draft assessment report prepared by the rapporteur member state.”

The dossier submitted by a company to regulatory authorities contains mandatory safety studies, commissioned by the company, and peer-reviewed literature relevant to the active substance in question. Companies are required to summarise the safety studies and peer-reviewed literature according to set guidelines and provide this information to the regulatory authorities. In a first step, this information is assessed by a rapporteur member state (RMS), which was Germany in the case of glyphosate. The RMS checks all information provided by the applicant and, where relevant, corrects and amends the applicant’s study summaries and evaluation. If the RMS agrees with a particular summary or evaluation it may incorporate the text directly into the draft assessment report. A close reading of the renewal assessment report (RAR) for glyphosate reveals numerous examples of amendments, modifications and corrections by the RMS of the text submitted by the applicant. The completion of this first step results in a comprehensive independent evaluation of the applicant’s dossier by the RMS and includes the RMS’s own assessment of the safety of the substance.

Once the RMS has completed the initial risk assessment, it is provided in the form of the draft RAR to EFSA to begin the peer review process, which includes public and expert consultations. The draft RAR has been available on EFSA’s website since November 2015. “Unfortunately, the recent claims appear to be part of an orchestrated campaign and the latest in a series of efforts to discredit the scientific process behind the EU assessment of glyphosate,” Dr Url said. “While of course we welcome all interested parties to scrutinise our work, it is important that the integrity of the legally prescribed scientific process is not purposefully undermined for short-term political gain.”

In 2014, EFSA launched a public consultation on the draft RAR provided by Germany, in which all interested parties and the general public were invited to provide comments and additional scientific information pertinent to the safety of glyphosate. [...] The results of the public consultation and the expert peer review were incorporated by EFSA into its final conclusion, which was published in November 2015 and provided to the European Commission and Member States to inform the decisions they take as risk managers at European level.

Transparency and Sustainability of the EU Risk Assessment

In : *European Parliament Press Releases – March 2019; General Court of the EU*

March 2019 - General Court of the European Union - PRESS RELEASE No 25/19 Luxembourg

Glyphosate is a chemical product used in pesticides which are plant protection products and is one of the most widely used herbicides in the EU. Glyphosate was included on the list of active substances for the period from 1 July 2002 to 30 June 2012. That listing was temporarily extended until 31 December 2015. In view of the renewal of approval of the active substance glyphosate, Germany, as Rapporteur Member State, submitted to the Commission and to the European Food Safety Authority (EFSA) a 'draft renewal assessment report', published by EFSA on 12 March 2014.

In Case T-716/14, Mr Anthony C. Tweedale submitted to EFSA a request for access to documents pursuant to the regulation on public access to documents1 and the regulation on the application of the provisions of the Aarhus Convention on access to information2 ('the Aarhus Regulation'). That request concerned two toxicity studies: 'the two "key studies" used in order to set glyphosate's acceptable daily intake (ADI)'.

In Case T-329/17, Ms Heidi Hautala, Ms Michèle Rivasi, Mr Benedek Jávor and Mr Bart Staes, Members of the European Parliament, submitted to EFSA a request for access to documents pursuant to the same regulations. Their request concerned the parts relating to 'material, experimental conditions and methods' and to 'results and discussion' of the unpublished studies on the carcinogenicity of glyphosate. In their request, the applicants pointed out that, in March 2015, the International Agency for Research on Cancer had concluded that glyphosate was potentially carcinogenic and that, nevertheless, in November 2015, the EFSA peer review had concluded that glyphosate would be unlikely to pose a carcinogenic hazard to humans.

In both cases, EFSA refused access to the documents, basing its decision, inter alia, on the following reasons: (i) disclosure of that information might seriously harm the commercial and financial interests of the companies which had submitted the study reports; (ii) there was no overriding public interest justifying disclosure; (iii) there was no overriding public interest justifying disclosure of the parts of the studies to which the applicants sought access, since those parts do not constitute information which 'relates to emissions into the environment', and (iv) EFSA considered that access to the parts of those studies was not necessary to verify the scientific assessment of the risks carried out in accordance with Regulation No. 1107/2009. The applicants then brought an action before the General Court seeking annulment of the decisions refusing access. [...]

Thus, the public must have access not only to information on emissions as such, but also to information concerning the medium to long-term consequences of those emissions on the state of the environment, such as the effects of those emissions on non-targeted organisms. The public interest in accessing information on emissions into the environment is specifically to know not only what is, or foreseeably will be, released into the environment, but also to understand the way in which the environment could be affected by the emissions in question.

The concept of information which 'relates to emissions into the environment' must therefore be interpreted as covering not only information on emissions as such, namely information concerning the

nature, composition, quantity, date and place of those emissions, but also data concerning the medium to long-term consequences of those emissions on the environment. The General Court concludes that the requested studies must be regarded as constituting information which ‘relates to emissions into the environment’ and that an overriding public interest in disclosing the studies is deemed to exist. EFSA could not therefore refuse to disclose them on the ground that that would have an adverse effect on the protection of the commercial interests of the owners of the requested studies.