Glyphosate and cancer: Buying science

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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 These are generally unpublished and are kept hidden from the public and independent scientists on the grounds that they are commercial secrets.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 1988.

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.

Introduction

Glyphosate-based herbicides are the most widely used herbicides in the world. The best known glyphosate product is Monsanto's Roundup. The use of glyphosate-based herbicides has massively expanded since the introduction in the mid-1990s of genetically modified (GM) glyphosate-tolerant crops,[1] which are engineered to survive being sprayed with large amounts of the herbicide. Around 85% of GM crops are glyphosate-tolerant.[2]

However, glyphosate has many other uses. It is sprayed to "dry down" or desiccate many types of crops before harvest. It's also used for weed control by farmers, home gardeners, and public authorities on roads, pavements, railway lines, parks, school grounds, and other public areas.

So it's perhaps no surprise that glyphosate turns up everywhere: in rain and air,[3] streams,[4] and people's blood[5] and urine.[6]

Its widespread use also explains why glyphosate is such a lucrative product for the agrochemical industry. The global glyphosate market is expected to cross US$ 10 billion by 2021.[7]

The last patent on glyphosate expired in 2000. The chemical is now manufactured by many companies, including Monsanto, and is included in numerous herbicide brands throughout the globe.[8]

Monsanto maintains its share of the global glyphosate market by packaging and selling its glyphosate-tolerant (Roundup Ready) GM seeds with its own brands of glyphosate herbicides. It's been estimated that in 2015 the company made nearly $4.76 billion in sales and $1.9 billion in gross profits from herbicide products – and most of that was from Roundup. That represents a significant portion of the global glyphosate market.[8]

It is clear that there are huge financial interests in keeping glyphosate herbicide products on the market. However, that market was threatened when in 2015 the World Health Organization's cancer agency IARC, based on a comprehensive review of the peer-reviewed scientific literature, classified glyphosate as a probable human carcinogen.[9]

Monsanto[10] and various regulatory and expert bodies[11,12,13] denied or downplayed the link between glyphosate and cancer. This view has been reinforced by the publication of a series of industry-sponsored and -supported reviews in peer-reviewed scientific journals, which concluded that glyphosate and its commercial formulations do not cause cancer and other serious diseases.

Nearly two years after IARC published its verdict, the row rages on. Yet the question of whether glyphosate and its commercial herbicide formulations cause cancer could affect the health and lives of millions of people.

The public relies on the judgments of regulatory and expert bodies to protect them from the harmful effects of pesticides. They expect these bodies to act objectively in the public interest and to base their opinions on the best science. So it is vital that these bodies strictly guard their independence from industry and carry out their assessments using the most rigorous analytical methods.

This report examines whether these bodies are truly independent and objective in their assessments of glyphosate, as well as looking at the quality of the scientific arguments they rely upon. The report analyzes conflicts of interest of individuals and institutions that have defended the safety of the chemical and asks whether there is any connection between conflicts of interest and scientific practice.

A future report in this series will examine the attacks on IARC, which reached a peak after the agency published its opinion on glyphosate. It will look at the criticisms leveled against IARC and scientists associated with it and examine the issue of conflicts of interest as it relates to individuals on both sides of the debate.

> "Companies often contest scientific evidence of the hazards related to their products, with some even standing accused of deliberately manufacturing evidence to infuse scientific uncertainty and delay restrictions. There are also serious claims of scientists being 'bought' to restate industry talking points."
>
> *– UN Report of the Special Rapporteur on the right to food, 4 January 2017*[1]

Monsanto has a problem – and comes up with a solution

In 2012 the European authorization for glyphosate, the active ingredient of the most widely used herbicides in the world, was due to expire. Monsanto and other companies that market glyphosate herbicides, united in a coalition called the Glyphosate Task Force (GTF), applied to the authorities for re-authorization of the chemical.

But something was getting in the way: science.

To understand why, we need to consider the way that pesticides have been approved in the past and how that has changed.

Historically, applications for pesticide approvals have been almost exclusively based on safety studies sponsored and provided by the pesticide industry.

But in 2009 in Europe, this situation changed. The new pesticides regulation, 1107/2009, specified for the first time that in addition to the industry studies, studies from the "scientific peer-reviewed open literature" must also be included in the dossier submitted by industry to regulators.[2]

This presented Monsanto with a problem. That's because 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.[3] If these studies were taken seriously by the European authorities, glyphosate might be banned.

This was an especially likely outcome in the light of the fact that Europe's pesticide regulation (1107/2009) has hazard-based cut-off criteria for carcinogenicity and genotoxicity (DNA-damaging effects, which can lead to cancer), among certain other serious toxic effects. This means that pesticide active ingredients that are classified under the European system as carcinogens in category 1A (known to have carcinogenic potential for humans, largely based on human evidence[4]) or 1B (presumed to have carcinogenic potential for humans, largely based on animal evidence[4]) or as category 1A or 1B mutagens* are not allowed to be marketed.[2] No negotiation is possible based on arguments that the doses that people are exposed to are believed safe and that therefore the risk is acceptably low.

Monsanto and other glyphosate manufacturing companies duly prepared their dossier of safety studies on glyphosate – including studies from the peer-reviewed scientific literature. They submitted it to the German authorities in May 2012 (see Renewal Assessment Report, p. 3).[5] For both the current re-evaluation of glyphosate and the initial approval in 2002, Germany has been the "rapporteur" member state, responsible for overseeing the application and liaising between industry and the EU authorities in the authorization process. The RAR contains BfR's comments and conclusions on the GTF's summaries of the results of the industry studies.

The RAR reveals that when it came to genotoxicity, Monsanto was faced with a problem. The

* For the purposes of this report we use the terms "genotoxin" and "mutagen" synonymously. The difference is small and most genotoxins cause mutations. A mutagen causes mutations – heritable changes in the DNA (inherited by the next generation through the germ cells of their parents). A genotoxin causes all types of DNA damage, which includes aspects that are not heritable. Thus, a mutagen is a type of genotoxin. EU regulations 1272/2008 and 1107/2009 speak of "mutagens" in category 1A and 1B, but refer to "genotoxicity testing".

RAR lists the findings of a number of peer-reviewed studies identified in industry's literature search that look at the genotoxic effects of glyphosate and its commercial formulations. The majority of studies on both glyphosate and the formulations are positive – in other words, they found that glyphosate can damage DNA (see pages 400–405).[5]

Things did not look good for glyphosate. Monsanto and its allies were badly in need of a strategy to save the chemical and keep it on the market. If science was getting in the way of glyphosate's re-approval, then perhaps another kind of "science" was needed.

By October 2012 Monsanto and other companies that wanted glyphosate to be re-approved had formed the Glyphosate Task Force, which is led by Monsanto.[6] Monsanto also set up a website that makes reassuring claims about the safety of glyphosate.[7] Among them are that glyphosate "is not carcinogenic and does not have mutagenic effects, i.e. it does not alter DNA".[8]

The IARC bombshell

In 2015 a bombshell hit Monsanto and its fellow agrochemical firms when the International

How the regulatory system fails the public

Most members of the public believe that the regulatory system protects them against exposure to unsafe products. Specifically, many people assume that regulators perform or commission independent tests on pesticides to ensure that they are safe. These people are shocked to learn that in order to reach their evaluation, regulators and agencies across the world read industry-commissioned toxicology studies – studies that are classified as commercial secrets and are generally unpublished, meaning that independent scientists cannot assess the data, their interpretation, and the conclusions drawn from them.

This runs counter to the principle of science, which has always progressed through open publication in the peer-reviewed literature. The idea of peer-reviewed publication is that prior to publication, studies are checked for quality ("peer-reviewed") by other scientists. If they are judged worthy of publication, they are openly published. This allows studies in the peer-reviewed literature to be freely discussed and replicated and their findings confirmed, refined, or refuted – a defining feature of science.

Does it matter that safety research is sponsored by industry? The evidence shows that it does. Reviews of the scientific literature on the safety, toxicity, or efficacy of various products show that industry-linked studies are far more likely than studies by scientists working independently of the industry to find the product under examination to be safe and efficacious. That applies to a wide range of risky and controversial products – from tobacco[9,10] to pharmaceutical drugs,[11,12] mobile phones,[13] cognitive or cardiovascular function, hormone levels, symptoms, and subjective well-being and genetically modified (GM) foods[14] and crops.[15] There is no reason to believe that pesticides are an exception to this rule.

It is only fair that industry pays for the studies that are carried out to assess the safety of industrial products, like pesticides. However, industry should pay the money into a fund administered by a public body, which would then commission independent laboratories to carry out the tests. Industry must not directly sponsor or become the "owner" of a study.

The 2009 EU pesticides regulation required industry for the first time to include academic studies from the peer-reviewed literature in the dossiers it submits to regulators.[2] This move attempted to open up the regulatory system to the published discoveries of scientists working outside the industry.

But as this report shows, industry is fighting back by sponsoring reviews in peer-reviewed journals with conclusions that are favourable to its products. It is assisted by regulatory authorities' reluctance to give much weight to the findings of academic scientists and by their preference for industry studies.[16]

Agency for Research on Cancer (IARC), an arm of the World Health Organization, classified glyphosate as a probable human carcinogen. The agency based its verdict on "sufficient" evidence of carcinogenicity in animals and "limited" evidence in humans. It added that there was "strong" evidence that glyphosate is genotoxic (damages DNA).[17] Genotoxicity is one of the mechanisms through which a chemical can cause cancer.

IARC has a policy of only considering studies that are publicly available,[18] unlike pesticide regulators, who consider mainly industry studies that are commercial secrets and mostly unpublished.[19]

IARC is internationally respected for its expertise and independence. Its carcinogenicity classifications are utilized by government agencies worldwide. Clearly, in order to avert bans and restrictions on the herbicide, the industry would have to fight back hard.

The first counterblow came in the media. Hugh Grant, Monsanto's chairman and CEO, dismissed the IARC report as "junk science" that was creating "confusion for consumers".[20] Robb Fraley, Monsanto's chief technology officer, said, "We are outraged with this assessment. This conclusion is inconsistent with the decades of ongoing comprehensive safety reviews by the leading regulatory authorities around the world that have concluded that all labeled uses of glyphosate are safe for human health. This result was reached by selective 'cherry picking' of data and is a clear example of agenda-driven bias."[21]

In reality, however, this claimed decades-long regulatory consensus is false. What Monsanto omits is that in 1985, the US Environmental Protection Agency (EPA) classified glyphosate as a possible human carcinogen, based on experiments showing kidney tumours in glyphosate-treated mice. Input from Monsanto led to a dubious reinterpretation of these studies by the EPA and the reclassification of glyphosate as non-carcinogenic in 1991.[22]

Industry-sponsored reviews reassure on glyphosate safety

Monsanto and other companies financed a series of peer-reviewed scientific reviews, all offering reassuring conclusions about the safety of glyphosate herbicides. Some key reviews are introduced below and a selection is analyzed for scientific quality in Chapter 2. The conflicts of interest of some of the authors are detailed in Chapter 3.

It is significant that industry fought back against the studies finding harm from glyphosate and its formulations with "reviews", not with primary research. That means that Monsanto paid scientists to evaluate the scientific quality of primary research studies. They effectively tell us what is sound science and what is junk science.

History of Monsanto-supported reviews

For at least two decades, Monsanto has financed or otherwise supported the publication of peer-reviewed reviews with conclusions emphasizing the safety of glyphosate and glyphosate-based herbicides.

For example, in 2000 the former Monsanto consultant Gary Murray Williams[23] and colleagues published a Monsanto-supported review in the industry-linked journal* Regulatory Toxicology and Pharmacology that concluded that glyphosate is non-carcinogenic and that "under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans."[24]

Another example was a 2012 review sponsored by Monsanto[25] that appeared to try to counter a growing body of evidence from animal and human studies linking glyphosate and its formulations to adverse reproductive outcomes.[26,27,28,29] This review of developmental and reproductive outcomes in humans and animals after glyphosate exposure concluded, "The available

* See Chapter 3, "Intertek papers published in industry-linked journal"

literature shows no solid evidence linking glyphosate exposure to adverse developmental or reproductive effects at environmentally realistic exposure concentrations."[25]

Below are listed some of the key reviews that Monsanto and other pesticide companies have sponsored and supported that promote the notion of the safety of glyphosate and its formulations.

Key review 1: Kier and Kirkland (2013)[30]

As the IARC report[17] and even BfR's Renewal Assessment Report on glyphosate found, there are a large number of studies in the peer-reviewed scientific literature that indicate that glyphosate and its formulations are genotoxic[5] and thus could be mutagenic. According to the EU pesticides regulation, active substances that are mutagenic in mammals must be banned.[2] Moreover, genotoxicity in general serves as mechanistic evidence for carcinogenic effects.

Kier and Kirkland's review (2013)[30] addressed the question of glyphosate's genotoxicity and concluded that glyphosate and glyphosate-based herbicides do not present "significant genotoxic risk" in normal exposures. The review was funded by the Monsanto-led Glyphosate Task Force.[30] Larry Kier is a former Monsanto employee and David Kirkland is a former consultant to Monsanto.[23]

Thanks to recently released documents,[31] we now know in detail how Monsanto developed a strategic plan for placing industry's opinion, in the form of the Kier and Kirkland review, in the "independent scientific literature".

In 2012, Roger McClellen, editor of the journal Critical Reviews in Toxicology, was approached by Larry Kier, clearly to pave the way for publishing the review. Thought was given to how to create "credibility", in the light of contradictions between industry's confidential study reports "weighing in on negative genotox results vs. the publication record weighing in on positive genotox results".[31] See the excerpt below from email dated 18 July 2012, from David Saltmiras of Monsanto, on p. 185 of the pdf of released documents: 1)

This paper was submitted on 19 December 2012 and published on 12 March 2013, and it had its price. By adding David Kirkland to the manuscript, the estimated cost jumped from US$9,000 to roughly US$30,000, although Kirkland indicated that "his efforts will be less than 10 days"[31] (p. 191 of the pdf), with a daily honorarium of approximately US$2,200 (1,400 British pounds). Monsanto termed this "a fair investment" (p. 183 of the pdf).[31] We call it "buying science". 2)

The reason that Monsanto spent all this money was that the original version (written by Larry Kier alone) "stretched the limits of credibility"

- Larry has briefly discussed with the chief editor of *Critical Reviews in Toxicology* (Roger McClellen), who expressed concern that the GTF member study reports are not public (weighing in on negative genotox results) vs the publication record (weighing in on positive genotox results). This will present itself as an issue with any credible journal. To have credibility, rather than make all study reports public, the GTF may consider submitting all the genotoxicity study Tier II Summaries from the dossier (which may well fall into the public domain) as supplementary data to the journal.

1)

The initial cost estimate for this manuscript was 9k$ (approved by the board).

Adding David Kirkland as a co-author to both review papers would add £14,000 (pounds Stirling) to the project, which split by 25 seems a fair investment.

2)

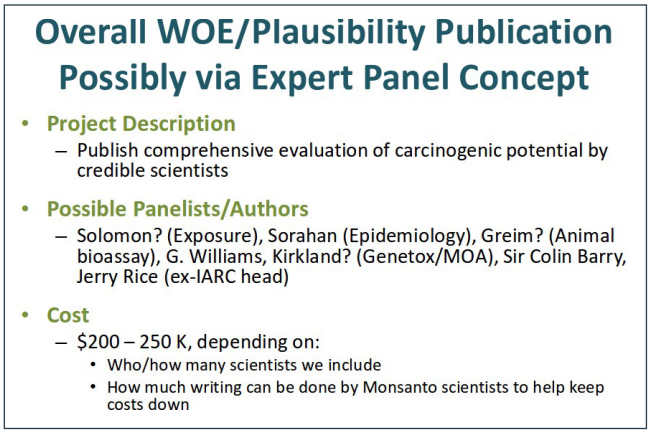
As part of the GTF literature review the RWG and Board agreed to ask Larry Kier (former Monsanto expert and now independent consultant) to write a genetox review paper on technical glyphosate and glyphosate based Plant Protection Products. This paper would pool data from confidential Taskforce Member studies which was the reason why David Saltmiras (MON), chair to the tox-TWG, stepped down as a co-author for this paper. In addition when trying to combine both reviews (on technical glyphosate and PPPs) the manuscript turned into such a large mess of studies reporting genetoxic effects, that the story as written stretched the limits of credibility among less sophisticated audiences. For most 'stories', the approach would have been fine. But even though we feel confident that glyphosate is not genotoxic, this became a very difficult story to tell given all the complicated 'noise' out there. So David Saltmiras, Larry Kier and Bill Heydens consulted by other Monsanto tox experts thought there was a need to re-group & redesign the approach to the manuscript.

3)

and "this became a very difficult story to tell given all the complicated 'noise' out there"[31] (p. 183 of the pdf). 3)

On 19 February 2015, in a similar move, Monsanto strategically planned to counter the results of the IARC meeting. For that, they were willing to pay US$250,000 or more, "depending on what comes out of the IARC meeting"[31] (p. 203 of the pdf). The results were the "Intertek papers" of 2016 (see "Key reviews 3–7: The Intertek papers (2016)", below). Monsanto was just not sure in which science disciplines the money should be invested. To keep the cost down, Monsanto considered ghost-writing papers so that the "expert" nominal authors "would just edit & sign their names so to speak". Monsanto's remark, "Recall that is how we handled Williams Kroes & Munro, 2000"[31] (a much cited review), indicated that this had worked before (see p. 204 of the pdf). 4)

cations to the IARC monograph (see below) and yet did not contact the nominal authors of these papers. It is, of course, possible that the contact between Monsanto and the nominal authors was indirect, but nonetheless it would have been ultimately controlled by Monsanto. 5)



5)

For the overall plausibility paper that we discussed with John (where he gave the butadiene example), I'm still having a little trouble wrapping my mind around that. If we went full-bore, involving experts from all the major areas (Epi, Tox, Genetox, MOA, Exposure - not sure who we'd get), we could be pushing $250K or maybe even more. A less expensive/more palatable approach might be to involve experts only for the areas of contention, epidemiology and possibly MOA (depending on what comes out of the IARC meeting), and we ghost-write the Exposure Tox & Genetox sections. An option would be to add Greim and Kier or Kirkland to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000.

4)

This strategy appears to be in stark contrast with the claim that the nominal authors of the Intertek papers "were not directly contacted by the Monsanto Company" (Williams and colleagues, 2016[32]). It is hard to believe that Monsanto was strategically planning counter-publi-

In the light of this strategy, another statement by Williams and colleagues also appears difficult to believe: "Neither any Monsanto company employees nor any attorneys reviewed any of the expert panel's manuscripts prior to submission to the journal."[32] Alternatively, the

statement may be technically true, but it does not rule out the possibility that Monsanto employees actually wrote the manuscripts or parts of them. If that were the case, there would have been no need for them to "review" their own work.

It seems that these investments in Monsanto- and Glyphosate Task Force-sponsored "independent" publications have paid off well. BfR's Renewal Assessment Report refers to Kier and Kirkland's paper of 2013 to emphasize "the overwhelming preponderance of negative results in well-conducted bacterial reversion and in vivo mammalian micronucleus and chromosomal aberration assays", which indicate "that glyphosate and typical GBFs [glyphosate-based formulations] are not genotoxic".[33, 5] Moreover, the more recent evaluation by the US EPA made major reference to Kier and Kirkland and followed their conclusions.[34]

The "Intertek papers" also made it into the evaluation conducted by the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) of the US EPA's report on glyphosate. The panel recommended that "several relevant papers" which "have been published… should be reviewed…. These manuscripts include reviews by Acquavella et al., 2016, Williams et al., 2016, and several others that will be readily identified by US EPA when it updates its literature search."[35]

Key review 2: Greim and colleagues (2015)[36]

This review, an evaluation of the carcinogenic potential of glyphosate, was published in 2015 and was co-authored by (among others) Helmut Greim, MD, Professor Emeritus, Toxicology and Environmental Hygiene, Technical University Munich, and a former consultant to Monsanto.[23] A co-author was David Saltmiras, a Monsanto employee. Greim was paid by Monsanto for providing his expertise. The review concluded that "glyphosate does not present concern with respect to carcinogenic potential in humans".[36]

The timing of this review is worth noting. It was published online on 26 February 2015.[36] This was three weeks before the initial publication in The Lancet of IARC's classification of glyphosate as a probable carcinogen.[37] It was also in time to influence the final draft of the Renewal Assessment Report,[5] which was submitted by the BfR via BVL to EFSA on 31 March 2015. Greim and colleagues may have been aware of that date, since in their review they cite the previous draft of the Renewal Assessment Report (dated 29 January 2015). That draft was not publicly available, so it appears that Greim and colleagues were given privileged access. Also, Greim and colleagues' review is cited in BfR's Renewal Assessment Report (version of 31 March 2015, p. 947).

Key reviews 3–7: The Intertek papers (2016)

A major aspect of Monsanto's strategy against the IARC verdict was to sponsor a series of five scientific reviews,[38, 39, 32, 40, 41] which were all published in late 2016 in the same peer-reviewed journal. As stated in the declarations of interest in each paper, all were funded by Monsanto via Intertek. The lead review carries the following statement: "This article is part of a supplement, sponsored and supported by Intertek Scientific & Regulatory Consultancy. Funding for the sponsorship of this supplement was provided to Intertek by the Monsanto Company, which is a primary producer of glyphosate and products containing this active ingredient."[32]

For the purposes of this report we call these reviews the Intertek papers.

All of these reviews defended the safety of glyphosate with regard to key health effects. Their specific aim was to counter IARC's evaluation of glyphosate as a probable human carcinogen and as genotoxic (damaging to DNA), as the articles themselves explicitly state. In addition, an accompanying commentary by the editor of the journal stated that the Intertek papers were intended to counter IARC's verdict.[42]

Conclusion

In 2009 a new regulation was passed in Europe that required industry to include studies from the peer-reviewed scientific literature in the dossiers submitted in support of pesticide approvals.

Taken together with studies from industry, many of these studies link glyphosate and its commercial formulations with harmful effects, including carcinogenicity and genotoxicity. As pesticide active ingredients with carcinogenic potential are not allowed to be marketed in Europe, a proper evaluation of the science would necessarily lead to glyphosate being banned.

The onslaught of scientific articles showing problems with glyphosate reached a peak in 2015 with the publication of a report by IARC, the World Health Organization's cancer agency, classifying glyphosate as a probable carcinogen and pointing to evidence that it is genotoxic.

For the past two decades, Monsanto and other companies have countered such developments by financing and supporting the publication of scientific reviews in peer-reviewed journals. These reviews reach reassuring conclusions about the safety of glyphosate and its commercial formulations.

In Chapter 2 we analyze the scientific quality of some of these publications. In Chapter 3 we detail the conflicts of interest of the authors – including links to Monsanto and other agrochemical firms; the industry-funded International Life Sciences Institute (ILSI); and testing and consultancy firms that serve industry.

Chapter 2

Bad science of industry-sponsored papers defending glyphosate

In Chapter 1 we saw how, in response to a growing number of peer-reviewed scientific studies finding serious health risks from glyphosate and its commercial formulations, Monsanto and other companies and industry-linked bodies commissioned or otherwise supported the publication of counter-reviews that defended the safety of the chemical.*

Many of the authors of these reviews had conflicts of interest with industry or industry-linked bodies. These are analyzed in detail in Chapter 3.

However, some might argue that such conflicts of interest do not matter as long as the scientific quality of the reviews is sound. With that in mind, we offer the following analysis of several of the Monsanto-sponsored Intertek papers, along with some additional reviews sponsored by glyphosate manufacturers that also defend glyphosate-based herbicides.

Bad scientific practice no. 1: Flood the reader with irrelevant data, but omit the important data

Greim and colleagues (2015)[1]

This evaluation of the carcinogenic potential of glyphosate by Greim and colleagues (2015), which had Monsanto employee David Saltmiras among the authors and which was supported by Monsanto and the Glyphosate Task Force, concluded that "glyphosate does not present concern with respect to carcinogenic potential in humans".[1]

Greim and colleagues presented incidence tables of several types of tumour. However, these were irrelevant for the assessment because they were clearly not related to treatment with glyphosate. This can be seen from the pattern of the tumour incidences – there is no increase as compared to the control groups, no significance in the increases, and/or no dose-dependence. They comprised lung adenomas, lung adenocarcinomas, broncho-alveolar adenomas, broncho-alveolar carcinomas, and pituitary adenomas in mice.[1]

It would be fully appropriate to include these tumours in the tables if it were done to provide the complete picture. But Greim and colleagues did something very different. They listed these irrelevant tumours – yet failed to mention those tumours that were significantly increased in incidence in glyphosate-treated animals (as revealed by BfR's Addendum to the Renewal Assessment Report[2]).

To sceptical members of the public and scientific community, this may at the very least appear to be misleading and at worst may appear to be fraud. For example, this applies to the following studies:

- Mouse study of 1993 (sponsor: Cheminova). Greim and colleagues did not mention the statistically significant increase in haemangiosarcomas (blood vessel cancers) in glyphosate-treated animals.
- Mouse study of 1997 (Arysta Life Science). Greim and colleagues did not mention the statistically significant increase in haemangiosarcomas and kidney tumours in glyphosate-treated animals.
- Mouse study of 2001 (Feinchemie Schwebda). Greim and colleagues did not mention the statistically significant increase in kidney tumours in glyphosate-treated animals.
- Mouse study of 2009 (Nufarm). Greim and colleagues presented the data on malig-

* This appears to be a standard industry tactic in cases where a chemical becomes controversial: for example, it has been extensively used to defend the herbicide atrazine. See Hayes TB. There is no denying this: Defusing the confusion about atrazine. Bioscience. 2004;54:1138-1149.

nant lymphoma in males but did not mention that these date indicate a highly significant (p=0.0037) and dose-dependent increase in malignant lymphoma. Instead, they claimed that there were "no treatment-related effects".

Similarly the pancreatic tumours in male rats in the 1981 study by Monsanto were not listed by Greim and colleagues, although they were significantly increased in glyphosate-treated animals, while data for pituitary tumours were presented in detail, even though they are not relevant because no statistically significant increase was identified. Likewise the significantly increased incidence in liver cell tumours in the 1990 rat study by Monsanto was not mentioned by Greim and colleagues.

It is worth noting that Greim and colleagues had access to BfR's internal documents, as they referred to an interim version of several volumes of the Draft Renewal Assessment Report (the 29 January 2015 revision),[1] which the public never had access to. The question arises as to why BfR apparently gave Greim and colleagues (including Monsanto's Saltmiras) privileged access to non-public regulatory documents. This might be justified with a claim that chemical producers should receive an advance copy, but it seems to us that on principle, industry should not have access to draft regulatory documents.

Bad scientific practice no. 2: Take facts out of context to dismiss inconvenient evidence

Williams and colleagues (2016)[3] (Intertek paper)

After introducing a reasonable concept for scientific reviews ("In any review, if any studies are to be ignored, the reasons for this should be provided"), the former Monsanto consultant[4] Gary Murray Williams and colleagues expressed their "opinion that the IARC evaluation showed selectivity in the choice of data reviewed, with some omissions for which reasons were not clearly presented".[3]

As proof of this claim, they offer "the paper of Greim et al (2015),[1] who evaluated 14 carcinogenicity studies, nine chronic/carcinogenicity studies in the rat, including one peer-reviewed published study, and five carcinogenicity studies with glyphosate in mice." In contrast, Williams and colleagues point out, "The IARC Monograph reviewed only six rat and two mouse studies."

The latter statement is true, but ignores IARC's policy as stated in the Preamble attached to each of its Monographs: "With regard to epidemiological studies, cancer bioassays, and mechanistic and other relevant data, only reports that have been published or accepted in the openly available scientific literature are reviewed. … Data from government agency reports that are publicly available are also considered."[5]

Industry generally refuses to make its study reports publicly available. So it is ironic that industry's paid authors criticize IARC for not including these unpublished studies.

"Industry generally refuses to make its study reports publicly available. So it is ironic that industry's paid authors criticize IARC for not including these unpublished studies."

Williams and colleagues argued that the data from these studies would in fact have been available to IARC because they were "detailed in a supplement to the Greim et al (2015) paper".[3] What they omitted to mention is that IARC did evaluate this publication, but decided not to include it. The sound scientific reason for non-inclusion is described in IARC's report: "because the information provided in the review article and its supplement was insufficient (e.g. information lacking on statistical methods, choice of doses, body weight gain, survival data, details on histopathological examination and/or stability of dosed feed mixture)."[6]

In other words, relevant information was held back by industry.

Bad scientific practice no. 3: Industry-friendly experts re-evaluate data until it no longer threatens the approval of a pesticide

Williams and colleagues (2016)[3] (Intertek paper)

In March 1985 the US Environmental Protection Agency (EPA) classified glyphosate as a group C carcinogen[7] ("possible human carcinogen"[8]).

Williams and colleagues address this episode in their paper, referring to "the renal neoplasms [kidney tumours] that occurred in the first two-year, oral chronic toxicity, and carcinogenicity study in CD-1 mice (Monsanto 1983).[3] Glyphosate had caused renal (kidney) tubule adenomas, a rare kind of tumour, in a dose-dependent manner. There were 0, 0, 1, and 3 incidences of this tumour in the control, low-dose, mid-dose, and high-dose groups respectively.[9]

The crucial story that follows is omitted by Williams and colleagues in their paper, thus giving a misleading impression that the carcinogenicity concerns were laid to rest on a scientific basis.

In the second half of 1985 the US EPA classification of glyphosate as a possible carcinogen came under pressure after the original tumours were (as reported by Williams and colleagues) "re-evaluated by a pathology working group (PWG)… and peer review experts including Dr Marvin Kuschner M.D., Dean, School of Medicine, State University of New York at Stony Brook".[3]

According to his biographical entry in Prabook, from 1979 Kuschner was also a member of Monsanto's Biohazards Commission[10] (see Chapter 3). Williams and colleagues do not include any information on Kuschner's interests.

It is unclear who convened and instructed the PWG.

Kuschner re-evaluated the original ḱidney sections from Monsanto's mouse study and claimed to have found a new renal tumour in a control mouse, no. 1028.[9,11]

This was an important tumour for Monsanto. If its existence were confirmed, an age-adjusted statistical analysis would demonstrate no tumour-causing effect of glyphosate using the controls within the experiment.[12] Thus glyphosate would have been exonerated from suspicion of being a carcinogen.

But initially, Kuschner seemed to be the only one who could see the alleged new tumour in the control mouse. The EPA pathologist Louis Kasza stated that the alleged tumour "does not represent a pathophysiologically significant change".[9, 13]

To be on the safe side, the EPA arranged for additional kidney sections to be cut from the male mice in all groups of the feeding study. The new sections were then examined on slides under the microscope by "a number of pathologists", including Kasza. The pathologists confirmed the presence of all the tumours reported in the original study. But not one of them could find Kuschner's claimed extra control mouse tumour.[13, 9]

Therefore Kuschner's claimed tumour could not be recognized as such in the original slide or in any of the new sections cut by the US EPA scientists.

Reporting to Monsanto: the Pathology Working Group

In parallel, Monsanto commissioned a group of four consultants to review Kuschner's alleged tumour finding and evaluate the significance of the kidney tumours. The re-evaluation took place in the summer or autumn of 1985.

In their report to Monsanto, these consultants, together with the five pathologists that formed the pathology working group (PWG), contradicted the US EPA pathologists. They stated that they were able to confirm Kuschner's tumour finding in the original slide of control mouse no. 1028. They also claimed that they were convinced that the tumours in three high-dose males were not related to glyphosate treatment, but due to chance.[11]

In February 1986 a Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA-SAP) recommended to the US EPA that it accept the control tumour because "the vast majority of the pathologists… agreed that the lesion represented a renal adenoma".[12]

The FIFRA-SAP also noted: "In addition, the statistical analysis shall be age-adjusted; when this is done, no oncogenic [carcinogenic] effect of glyphosate is demonstrated using concurrent controls."[12]

The FIFRA-SAP recommended that the EPA re-classify glyphosate as Category D (not classified regarding carcinogenicity) and order further studies in rats or mice "to clarify unresolved questions".[12]

In September 1988 the EPA followed the recommendation of the FIFRA-SAP and classified glyphosate as Category D.14 In October 1991 the EPA classified glyphosate in Category E• (evidence of non-carcinogenicity).[15] •

While Williams and colleagues used the supposed lack of significance of the renal tumours in the Monsanto 1983 study, they remained silent about the study's troubled history and the conflicts of interest involved in its re-evaluation.[3]

Bad scientific practice no. 4: Make false statements and hope that neither the reviewer of the manuscript nor the majority of readers pays attention to detail

Williams and colleagues (2016)[3] (Intertek paper)

According to Williams and colleagues, four other chronic toxicity and carcinogenicity mouse studies with glyphosate did not produce kidney neoplasms. They refer to the studies sponsored by Cheminova 1993a; Arysta Life Sciences 1997; Feinchemie Schwebda 2001; and Nufarm 2009.[3]

But this is incorrect. As can be seen from Table 1, with data derived from the CLH Report,[16] two of the four studies mentioned by Williams and colleagues revealed kidney neoplasms in the high and/or mid-dose. The increases were even statistically significant when using the Cochran-Armitage Trend Test, which is explicitly recommended for the assessment of tumour incidences by OECD Guidance 116.[17]

Table 1: Significant increases in kidney neoplasms and p-value based on Cochran-Armitage Trend Test. Data from draft CLH-Report[16]

Study owner/year	Control	Low-Dose	Mid-Dose	High-Dose	p-value
Monsanto 1983	(1)*	0	1**	3***	0.0339 0.0370#
Arysta Life Science 1997	0	0	0	2	0.0078
Feinchemie Schwebda 2001	0	0	1	2	0.0390

* an adenoma was identified by Marvin Kuschner ("peer review expert"[3]) when re-examining the slides of the control group, while subsequent additional kidney sections from this mouse study prepared at the request of the EPA did not reveal "additional tumors, but confirmed the presence of the tumors identified in the original study report".[13]

** carcinoma

*** 1 adenoma, 2 carcinomas

p-value (error probability; a value of 0.05 represents a 5% error probability), if only carcinoma were considered

• More details will be provided in the book, Die Akte Glyphosate (Orac/K & S) by Helmut Burtscher-Schaden, one of the authors of this report, which is expected to appear in late summer 2017.

The claim by Williams and colleagues that "In an 18-month diet study in CD-1 mice, histopathological evaluations of groups dosed up to 4200 mg/kg/d of GLY [glyphosate] (HD [high dose]), did not show any evidence of renal [kidney] neoplasms in male or female mice (Arysta Life Sciences 1997)"[3] is a repetition of the false statement cited above. Likewise, with regard to the study of Feinchemie Schwebda (2001), it is incorrect to state that "GLY produced no statistically significant neoplastic lesions",[3] because the incidence was dose-dependent and statistically significant (see Table 1 above).

Thus the conclusions about kidney tumours in glyphosate-treated mice drawn by Williams and colleagues[3] are invalid, as they are based on false statements and distorted facts.

The misleading statements by Williams and colleagues are not restricted to renal tumours. Regarding the studies on haemangiosarcoma (blood vessel cancer), they state: "There were no statistically significant increases in the incidence of any tumors when compared with the control groups and no dose response was evident."[3]

However, the Addendum to the Renewal Assessment Report (RAR), prepared by the German Federal Institute for Risk Assessment (BfR) and published in November 2015, would have been available for the authors. As can be seen in this Addendum,[2] two out of five mouse studies showed a statistically significant increase in the incidence of haemangiosarcoma in male CD-1 mice when using the Cochran-Armitage Trend Test.

Bad scientific practice no. 5: Favour publications that fit the pre-ordained conclusion, even if they are weak, and dismiss publications that do not fit, even if they are of high quality

Acquavella and colleagues (2016)[18] (Intertek paper)

The above approach was the principal method used by Acquavella and colleagues to reach the conclusion that "only one study in the glyphosate literature… deserves the highest weight in our assessment". In contrast, they stated, "The other studies have so many validity concerns that they cannot be interpreted at face value."[18]

This "weight of evidence evaluation" was the basis for the authors' conclusion that "the application of commonly applied causal criteria do not indicate a relationship with glyphosate exposure and NHL [non-Hodgkin lymphoma, a type of cancer]". They added, "Our conclusion for NHL differs from that of the IARC workgroup seemingly because we considered the null [no effect of glyphosate herbicides] NHL findings from the AHS [Agricultural Health Study] to be more convincing than the case control studies, in aggregate, with their major limitations."[18]

The AHS is a cohort study, where the participants are selected and then followed over many years to see whether tumours develop or not. Case control studies select tumour patients and analyze, on the basis of interviews and questionnaires, past exposure to the chemical in question.

However, the AHS (published as DeRoos and colleagues, 2005[19]) suffers from crucial limitations, which Acquavella and colleagues even admit to. These were the "relatively short duration of followup for AHS cohort members, the relatively small number of NHL cases, and the likelihood of some degree of exposure misclassification in the various analyses."[18]

Crucially, however, they forgot to acknowl-

edge that the first of these factors essentially makes the study invalid. As the epidemiologist Dr Peter Infante explained,[20] the median followup time of 6.7 years "is unlikely to be long enough to account for cancer latency".[21] In addition, the time of initial exposure was not reported in DeRoos and colleagues' 2005 study,[19] making an estimate of the latency period (time since first exposure to glyphosate) impossible. Further, Infante pointed out that the control group itself had an elevated risk for NHL, thus underestimating the risk of NHL for glyphosate-exposed people.[20]

On the other hand, Acquavella and colleagues make a blanket dismissal of all case control studies,[18] largely based on limitations that apply to case control studies in general, although three of them were ranked high (Eriksson and colleagues, 2008[22]) or medium (McDuffie and colleagues, 2001;[23] DeRoos and colleagues, 2003[24]) quality by the US EPA. These three studies showed a significantly higher NHL risk for glyphosate exposure. For two of them (Eriksson and colleagues, 2008; McDuffie and colleagues, 2001), an exposure-response relationship was demonstrated. In addition, the study by Eriksson and colleagues (2008)[22] was able to evaluate latency – which the AHS study was unable to do – and an increase in risk related to the latency period was found.

Even a recent Monsanto-funded meta-analysis admitted that there were positive associations between Non-Hodgkin Lymphoma (NHL) and glyphosate in the five of the six studies analyzed, resulting in a statistically significant overall association between glyphosate and NHL and an even stronger association between glyphosate and the B-cell subtype of NHL.[25]

These results clearly support IARC's assessment of "limited" (but existing) evidence "in humans for the carcinogenicity of glyphosate".[6] "Limited" evidence, in IARC's classification system, is only one class below "sufficient" evidence. It means that "A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence."[5]

But the authors of the Monsanto-funded meta-analysis dismissed these results on the grounds that the data did not establish a "causal relationship" between glyphosate and NHL.[25]

Finally, it seems obvious that a "weight of evidence evaluation" should pay attention to the results of controlled animal studies. However, Acquavella and colleagues simply forgot to take into consideration existing evidence from animal studies when evaluating the results from epidemiology. More precisely, they omitted three mouse studies finding significantly increased incidence of malignant lymphoma in glyphosate-treated animals.[26, 27] But Acquavella and colleagues were not the only ones who excluded malignant lymphoma from consideration altogether, as can be seen in the following section.

Bad scientific practice no. 6: Claim to have considered everything, but keep quiet about inconvenient facts

Williams and colleagues (2016)[3, 28]

(two reviews, both Intertek papers, by these authors are considered here)

Williams and colleagues stated that they "evaluated all available scientific data including the results of a number of unpublished reports, some of which have been submitted to and reviewed by regulatory authorities".[28] Thus they claim to have performed a more thorough review than the IARC.

However, they neglected the observation of increased malignant lymphoma in glyphosate-treated male mice – despite their high relevance, given the fact that increased lymphoma (non-Hodgkin lymphoma) in glyphosate users have been reported in each of the case-control studies carried out (Eriksson and colleagues, 2008[22]; McDuffie and colleagues, 2001[23]; and DeRoos and colleagues, 2003[24]). Although this tumour type was not evaluated by IARC because the agency had no access to the original data of these industry studies, it is reasonable to assume that in contrast, Williams and colleagues,[3, 28] sponsored by Monsanto, did have full access to the data.

In case they did not, the data would have been available from the RAR[26] and its Addendum.[2] In contrast, IARC's report was published more than three months before the RAR and its Addendum became publicly available in mid-November 2015. So IARC did not have the opportunity to evaluate the data of these industry studies in their final form.

Failing to mention malignant lymphoma is a crucial omission on the part of Williams and colleagues, because this cancer type was seen in all five mouse carcinogenicity studies, three of which showed significant increases. Of the other two studies, one was of limited quality and the other was invalid with regard to malignant lymphoma.[2, 16] These studies comprise the most convincing evidence for the carcinogenicity of glyphosate in experimental animals.[29] Therefore it is illegitimate for William and colleagues to draw the conclusion "that glyphosate is not a carcinogen in laboratory animals".

Thus while Williams and colleagues accused IARC of "selectivity in the choice of data reviewed",[3] it was they themselves who were guilty of this practice.

Bad scientific practice no. 7: Make your argument looking scientific by referencing the peer-reviewed literature, but turn the evidence upside-down

Williams and colleagues (2012)[30]

In this Monsanto-sponsored paper, Williams and colleagues (2012) performed a "critical analysis" of the developmental and reproductive outcomes in humans and animals after glyphosate exposure.[30]

One of the papers they criticized is that of Beuret and colleagues (2004), who observed an increase in lipid peroxidation (oxidative degradation of lipids, a process that leads to cell damage) in the liver of pregnant rats and of their fetuses after exposure to a glyphosate-based formulation.[31] Because these glyphosate-exposed rats consumed less food than the control animals, Williams and colleagues questioned the validity of this observation by citing literature that "showed that dietary restriction may affect lipid peroxidation and glutathione peroxidase activity levels", concluding that "therefore, it is not known whether the effects observed resulted from [the glyphosate formulation] treatment or reduced food and water intake".[30]

While it is correct that the cited papers (e.g. Kim and colleagues, 1996[32]; Rao and colleagues, 1990[33]) report the effects of food restriction on lipid peroxidation, Williams and colleagues[30] forgot to mention that the effect of food restriction shown these and other (Xia and colleagues, 1995[34]) studies was a decrease in lipid peroxidation.

In other words, a comparison with a pair-fed control group (mimicking the reduced food consumption of glyphosate-treated dams) would probably have shown an even more pronounced increase in lipid peroxidation caused by the glyphosate-based formulation.

Bad scientific practice no. 8: Dismiss evidence by comparing apples with oranges

Williams and colleagues (2016)[3] (Intertek paper)

Table 1 collates tumour incidences in eight rat studies,[3] suggesting a comprehensive review. Referring to this data collation, the authors concluded, "The incidence of tumors shows no clear or consistent pattern, either across dose or individual study. Such a distribution of findings strongly indicates that these incidences represent spontaneous variations."

This data collation ignores the fact that rats of considerable genetic difference were used in the different studies. The different types of rat commonly used in laboratory toxicology studies (for example, Sprague-Dawley and Wistar), differ genetically from one another, and it is well known that they can react differently to a

particular test substance.[35] Making direct quantitative comparisons (e.g. of tumour incidences) between these different strains of rats is like comparing the training results of carthorses and racehorses and concluding that the training method is inconsistent.

There are also differences in response between sub-strains of the same "super-strain" of rat (e.g. Sprague-Dawley or Wistar) bred at different laboratories.[35]

Collating data from a variety of experiments performed on rats of different genetic makeup widens the range of variability of tumour incidence. Thus it increases the "data noise" in the dataset, masking the effect of the glyphosate treatment.

Therefore it is good scientific practice to be very restrictive when it comes to making direct comparisons between different experiments and to confine the dataset to results from the same strain of rat and from the same laboratory. Essentially the rules laid out by the Organization for Economic Cooperation and Development (OECD)[17] and the European Chemicals Agency (ECHA)[36] for the use of historical control data – data from control animals from different experiments potentially conducted under varying conditions – should be applied also for such comparisons as those that Williams and colleagues are attempting to make.

These rules were heavily violated by Williams and colleagues in the comparisons made in Table 1 of their review. Thus the highly variable tumour incidences as presented in this table is not proof that the effect of glyphosate is inconsistent, but is simply proof of the genetic variability of the animals used. Therefore it does not provide an excuse to dismiss the tumour incidences as "spontaneous" and as not related to glyphosate exposure, as Williams and colleagues did.

While the authors do not conceal that different strains of rat were used in different studies (the strains are identified in the footnotes to the table), they group together study data from different rat types in a way that constitutes bad scientific practice. Of the eight studies presented in their table, three are from studies performed with Wistar rats and five with Sprague-Dawley rats.

They also incorrectly equate data on different sub-strains of the same type of rat (e.g. Wistar) but bred at different laboratories – the laboratory is identified in the prefix to the name "Wistar". For example, they equate data from Alpk:APfSD Wistar rats with data from Han Crl:WI Wistar rats.

Williams and colleagues have introduced so much "data noise" into their dataset by including results from experiments on different strains and sub-strains of rat that it is almost guaranteed that no effect will be seen from the glyphosate treatment and the tumour incidences will be put down to chance ("spontaneous variations").

Bad scientific practice no. 9: Avoid a true scientific debate by failing to address the evidence

Brusick and colleagues (2016)[37] (Intertek paper)

Oxidative stress was one of the two modes of action through which the IARC considered that glyphosate might cause cancer – the other was genotoxicity. While oxidative stress is known to have genotoxic potential by itself, it is also involved in intracellular and molecular processes that are potentially carcinogenic but non-genotoxic (Klaunig and colleagues, 2010;[38] Kakehashi and colleagues, 2013[39]).

The IARC judged that there is strong evidence that glyphosate causes both genotoxicity and oxidative stress.[6] In contrast, Brusick and colleagues attempted to deny that oxidative stress is a mechanism for carcinogenicity, stating, "The evidence for oxidative stress/damage as a mechanism or predictor of carcinogenesis is unconvincing"[37]. With this blanket statement, Brusick and colleagues largely avoided dealing with the existing evidence for the generation of oxidative stress by glyphosate. They also failed to provide evidence for their deviating view.

Brusick and colleagues' denial that oxidative stress is a mechanism for carcinogenicity is in clear contradiction to the opinion expressed by

a number of scientists who have reviewed oxidative stress as a mechanism of carcinogenicity in recent years.

For example, Klaunig and colleagues stated that oxidative stress "may cause DNA, protein and/or lipid damage leading to changes in chromosome instability, genetic mutation and/or modulation of cell growth that may result in cancer."[38] Deferme and colleagues emphasized that they "demonstrated the eminent role of oxidative stress in chemical carcinogenesis".[40] And Cacciapuoti wrote that recent research in oxidative stress and tumour genesis suggests that "free radicals control various aspects of tumor development including inflammation, transformation, survival, proliferation of cancers' cells, invasion, angiogenesis, and metastasis".[41]

In fact, an increase of oxidative stress parameters associated with the administration of glyphosate (the active ingredient) has been reported in seven publications using zebrafish, mice, rat and human (in vitro) test systems.

In total, the IARC reviewed 32 papers concerning the effects of glyphosate and/or glyphosate-based formulations (GBFs) on oxidative stress, seven of them on only the active ingredient, glyphosate. Almost all of the 32 papers demonstrated an increase in oxidative stress after exposure to glyphosate or GBFs. In contrast, Brusick and colleagues reviewed only 13 such publications.

While Brusick and colleagues themselves missed 22 papers taken into consideration by IARC, they criticized IARC for missing three papers in their review (one of them actually supporting IARC's conclusion). Clearly they were following the central theme of this Monsanto-sponsored series of publications – accusing IARC of "selectivity" in their review.

Conclusion

Our analysis shows that the key industry-sponsored reviews defending glyphosate's safety suffer from a number of scientific shortcomings. Specifically, they utilize manipulations such as apparently calculated omissions, misrepresentation of facts, and the introduction of irrelevant data to confuse the picture and deny the scientific evidence.

For example, the Intertek papers prominently accuse IARC of being selective with the data. But we show that the authors of these papers ignore IARC's transparent and carefully justified approach for study selection, use hair-splitting examples to construct a biased selectivity by IARC, but then make a biased selection themselves. And even more importantly, they distort and/or conceal inconvenient facts and turn evidence upside-down to support their arguments.

These authors claim to have used a "weight of evidence" approach to assess whether glyphosate is carcinogenic or not. However, in reality they avoid a true weight of evidence approach, which would take a holistic view on the different lines of evidence. These different lines of evidence are:

- The results of animal studies
- The outcome of epidemiological data
- Considerations of possible mechanisms of carcinogenesis.

The case is particularly strong if these 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 (farmers and private users).

Altogether evidence exists in all three areas of consideration:

- Animal studies: Significantly increased tumour incidences were seen in male mice (for renal tumours, three studies;

for haemangiosarcoma, two studies; and for malignant lymphoma, three studies). This – according to the CLP regulation (EC 1272/2008)[42] – qualifies glyphosate as a category 1B carcinogen, which would result in a ban in the EU.

- Epidemiology: Limited but available evidence points to a positive association between glyphosate exposure and non-Hodgkin's lymphoma.

- Mechanisms: Genotoxicity and oxidative stress caused by glyphosate have been identified as possible mechanisms of carcinogenicity.

A holistic consideration of the existing 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, while claiming to strengthen their arguments.

As will be seen in Chapter 5, this approach is remarkably similar to that used by the German Federal Institute for Risk Assessment (BfR) and the European Food Safety Authority (EFSA) to conclude that glyphosate is not carcinogenic. It is legitimate to question where this similarity comes from.

That is especially the case as these incorrect and misleading conclusions in turn became the basis for the CLH proposal[16] that lays the scientific basis for ECHA's conclusion on the carcinogenicity and mutagenicity of glyphosate, expected as early as March 2017.

Chapter 3

Individual conflicts of interest among defenders of glyphosate

Individuals who have played key roles in defending the safety of glyphosate and its commercial formulations include:

- Members of the Monsanto-financed Glyphosate Expert Panel[1]
- Alan Boobis and Angelo Moretto, the chair and co-chair of the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Meeting on Pesticide Residues (JMPR) for glyphosate, which decided that that glyphosate is "unlikely to pose a carcinogenic risk to humans from exposure through the diet"[2] (see Chapter 5 for details)
- Roland Solecki, currently head of the "Safety of Pesticides" department responsible for the health assessment of glyphosate at BfR[3] (see Chapter 5 for details).

However, these individuals have serious conflicts of interest with industry, which are often not clear to members of the public and media. Details are below.

The Glyphosate Expert Panel

As we have seen in the previous chapters, the Intertek papers defending the safety of glyphosate[4, 5, 6, 7] specifically aimed to counter the findings of the World Health Organization's cancer agency IARC that glyphosate is a probable carcinogen and that evidence for its genotoxicity is "strong".

The Intertek papers were authored by members of the Glyphosate Expert Panel, convened by the industry consultancy firm Intertek under commission from Monsanto. Monsanto paid Intertek to convene and facilitate the panel's work.[1]

The authors of the Intertek papers are listed on Monsanto's web page on the Glyphosate Expert Panel under their public affiliations[1] – for example, with universities or research institutes.

Twelve out of the 16 panel members have served as consultants to Monsanto and/or have been employed by the company.[1] Others have different conflicts of interest with industry or industry-linked bodies, as revealed by the panel members' personal CVs (curriculum vitae), which can be downloaded from Monsanto's website,[1] and other sources given below.

For one member of the panel, Michele Burns, we were unable to find any conflicts of interest apart from the fact that she was a member of the Glyphosate Expert Panel.

Links with the International Life Sciences Institute (ILSI)

Some Glyphosate Expert Panel members have links with the International Life Sciences Institute (ILSI), an organization funded by industry, including Monsanto, Dow, and BASF[10] – all companies that manufacture and/or market glyphosate herbicides. ILSI promotes industry-friendly "scientific" concepts and methodologies to be used in the risk assessment of foods, chemicals, and other industrial products.[11]

ILSI has proved highly controversial. People who have worked for ILSI on certain substances are no longer allowed on expert panels dealing with those substances at the European Food Safety Authority (EFSA), after the authority instituted new independence rules.[12] In 2012 EFSA carried out a partial purge of experts with strong ILSI links, though some collaborations with ILSI are still tolerated, according to a report by Corporate Europe Observatory.[13]

"Independent" yet convened with Monsanto money

In spite of the clear pro-industry bias of the Glyphosate Expert Panel and the fact that it was convened by Intertek with Monsanto money, the panelists were claimed in the Intertek papers to be "independent".[6, 4] The panel was also characterized as "independent" in a media attack on the IARC verdict on glyphosate.[14]

One of the Intertek papers carries the disclaimer: "Neither any Monsanto company employees nor any attorneys reviewed any of the Expert Panel's manuscripts prior to submission to the journal."[6] However, this does not rule out the possibility that an Intertek employee or another person trusted by Monsanto performed this role.

And with people who have formerly served as consultants to, and employees of, Monsanto among the Intertek papers' authors, it is questionable as to whether any current Monsanto employees or attorneys were needed in order to ensure that the conclusions were favourable to the company.

Intertek papers published in industry-linked journal

All of the Intertek papers, as well as the review by Greim and colleagues (2015)[16] claiming that glyphosate was non-carcinogenic, were published in the same journal: Critical Reviews in Toxicology.

Sixteen years previously, another journal, Regulatory Toxicology and Pharmacology, published a paper defending glyphosate as non-carcinogenic[17] by the former Monsanto consultant and recent Glyphosate Expert Panel member Gary Murray Williams[1] and colleagues.

Both Critical Reviews in Toxicology and Regulatory Toxicology and Pharmacology are notorious for their industry ties.

Together with the scientific consulting firm, the Weinberg Group (see "Douglas Weed" in "Individual conflicts of interest: The Glyphosate Expert Panel"), Regulatory Toxicology and Pharmacology was investigated in 2008 by US Congressional Representative John Dingell over its role in the Food and Drug Administration (FDA) decision allowing the endocrine-disrupting chemical bisphenol A in infant formula and other foods. Dingell wrote that "several scientists" had noted "apparent conflicts of interests, lack of transparency, and absence of editorial independence" at the journal.[18, 19]

An investigation by the Center for Public Integrity in 2016 noted that both Regulatory Toxicology and Pharmacology and Critical Reviews in Toxicology have been accused by critics of peddling "junk science". The Center stated that these journals publish "misleading, industry-backed articles that threaten public health by playing down the dangers of well-known toxic substances such as lead and asbestos. The articles often are used to stall regulatory efforts and defend court cases."[20]

What is a conflict of interest?

In order to analyze the role of conflicts of interest in re-evaluations of glyphosate, we first need to define what a conflict of interest is. For the purpose of this analysis we agree with the definition of conflicts of interest of the Association of the Scientific Medical Societies (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V.) in Germany:

"Conflicts of interest are defined as circumstances that create a risk that professional judgment or action that relates to a primary interest is unduly influenced by a secondary interest."[15]

In the context of different scientists' evaluations of a pesticide, primary interests can be understood as scientific rigour and objectivity. Secondary interests may include corporate affiliations, dependencies, and loyalties. These may or may not involve financial incentives, as well as social motives such as career advancement or scientific recognition. The conflict of interest occurs when the primary and secondary interests collide.

The Center found that half of all review articles written by scientists employed by the industry consulting firm Gradient since 1992 were published either in Critical Reviews in Toxicology or in Regulatory Toxicology and Pharmacology. No other journal came close.[20]

Canadian anti-asbestos activist Kathleen Ruff called both journals "egregious examples" of the problem of industry influence. She said, "You'd have to be delusional to not recognize that the issues they're dealing [with] and policies they're setting won't affect the profits of very powerful sources. Creating doubt is an endless activity and, in the meantime, people die unnecessarily."[20]

Jennifer Sass, a senior scientist at the Natural Resources Defense Council, an environmental group, commented on the apparent pro-industry bias at the two journals: "The harm is that it actually muddies the independent scientific literature. They're stacking their weight on their side of the scale."[20]

That is arguably the aim of the Monsanto-sponsored onslaught against the IARC verdict on glyphosate.

Conflicts of interest of Glyphosate Expert Panel members

Marilyn Aardema

Marilyn Aardema has her own consultancy firm, which provides "expert solutions" to chemical companies and industry associations, among others, "in support of human safety assessments".[1] She is the former chief scientific officer at BioReliance Corporation,[1] which provides testing and manufacturing services to pharmaceutical, biotechnology, and chemical companies.[21]

Aardema is a co-author on two of the Intertek papers defending the safety of glyphosate.[5, 6]

Aardema's ILSI roles include:

- 1999–2004: ILSI Health and Environmental Sciences Institute (HESI) Subcommittee on Application of Genomics to Mechanism Based Risk Assessment, Rapporteur, Genotoxicity Working Group
- 2006–present: Invited member, Steering Committee ILSI Risk Science Institute, HESI Emerging Issues Subcommittee on the Relevance and Follow-up of Positive Results in In Vitro Genetic Toxicity Testing, now Genetic Toxicology Technical Committee.[1]

John Acquavella

John Acquavella is a former employee of Monsanto[1] (1989–2004[7]), where he "served as a member of Monsanto's executive scientist core", "led industrywide programs with funding by relevant trade associations", and "did original research in support of Monsanto's businesses". Other former industry posts include head of epidemiology at the biopharmaceutical company Amgen and at the oil, gas, and chemical giant Exxon. He has won two awards from Monsanto and one from the pesticide industry association CropLife America.[1]

As part of his employment at Monsanto, he published peer-reviewed data on glyphosate.[1] Together with other Glyphosate Expert Panel members David Garabrant, Gary Marsh, Tom Sorahan and Douglas L. Weed, Acquavella was first author on an Intertek paper concluding that there was no causal link between glyphosate and the cancer types non-Hodgkin's lymphoma and multiple myeloma.[7] The paper specifically contradicted the IARC's findings of "limited evidence" of carcinogenicity and a "positive association" with non-Hodgkin's lymphoma.[22]

Sir Colin Berry

Sir Colin Berry has previously served as a consultant to Monsanto.[1] He is a co-author on one Intertek paper concluding that "glyphosate is not a carcinogen in laboratory animals"[4] and another concluding that "glyphosate is unlikely to pose a carcinogenic risk to humans".[6]

Berry is a member of the American Council on Science and Health,[1] a front group for the tobacco, agrochemical, fossil fuel, pharmaceutical and other industries,[23, 24] which has

received funding from Monsanto and other agrochemical firms.[23, 25] He sits on the advisory board for the Scientific Alliance,[1] a UK-based organization which was set up by the lobbying firm Foresight Communications and which promotes anti-environmentalist and pro-industry views.[26, 27]

Berry is also a member of the advisory council of Sense About Science,[1] a UK-based charitable trust which says its aim is to challenge "the misrepresentation of evidence in public life",[28] but which has consistently lobbied in favour of genetically modified (GM) crops[29] and defended the safety of glyphosate.[30]

In 2009 Sense About Science was exposed as failing to disclose the industry links of some of the authors of its guide to GM foods, "Making sense of GM"[31] – and as failing to disclose that one author was Andrew Cockburn, Monsanto's former director of scientific affairs.[32]

Sense About Science has received funding from firms and organizations with interests in biotechnology – for example, AstraZeneca, the John Innes Centre, and Rothamsted Research.[29, 33]

David Brusick

David Brusick has previously served as a consultant to Monsanto; to "major pharmaceutical and chemicals companies"; to the chemical manufacturers' trade association, the American Chemistry Council; and to ILSI.[1] He is a co-author on two of the Intertek papers defending glyphosate's safety.[5, 6]

From 1985 to 1986 he occupied a senior position at Hazleton Biotechnologies,[1] a subsidiary of Hazleton Laboratories, a company that provided animal testing services for new drugs, cosmetics, pesticides, and industrial chemicals and that analyzed new compounds for the pharmaceutical, chemical, and food industries.[34]

Brusick moved to the parent company, Hazleton Laboratories, in 1986,[1] remaining there after it became Corning Hazleton in 1987. In 1995 Corning spun off a section of its business as Covance Laboratories.[34] As well as drug development services, Covance offers toxicology testing to the chemical, agrochemical and food industries.[35] In the 1990s, Covance performed studies sponsored by the tobacco industry claiming that even extreme exposure to second-hand smoke was safe for humans.[36, 37]

From 1995 to 2005 Brusick occupied senior positions at Covance. According to his CV, he managed its global toxicology business and "increased the productivity and operating profits of Covance toxicology businesses by 200% during a 5 year period from 1995–2000."[1]

Michele Burns

Michele Burns is a co-author on two of the Intertek papers defending glyphosate's safety.[4, 6]

Joao Lauro Viana de Camargo

Joao Lauro Viana de Camargo has previously served as a consultant to Monsanto.[1] He is a co-author on two of the Intertek papers defending glyphosate's safety.[4,6]

De Camargo is a member of the Scientific Consulting Committee of ILSI/Brazil. He has also served as a consultant or ad hoc referee to the following chemical companies: BASF, Bayer, DuPont, Monsanto, Ihara, and Adama.[1] All of these companies manufacture and/or market glyphosate herbicides.

Moreover, De Camargo has served as a consultant or ad hoc referee to the Brazilian government agency CTNBio,[1] which as at March 2014 had approved fifty GMOs for cultivation in the country, the most widely planted being glyphosate-tolerant soy.[38] Brazil is the second largest grower of GM crops after the US.[39] It could therefore be argued that if De Camargo were to come up with an unfavourable verdict on glyphosate's safety, he would be condemning the prior decision of an agency in which he has served, perhaps even a decision that he contributed to, and that he could potentially share moral responsibility for the consequences of that decision.

Serving in CTNBio could in itself be considered a conflict of interest, given the reportedly extreme pro-GMO attitude of the agency. In his book, The Politics of Precaution: Genetically Modified Crops in Developing Countries, Robert L. Paarlberg notes, "Unfortunately, CTNBio

is still required by the 1995 law to include representatives from the private biotechnology companies, so the corporate conflict of interest issue remains."[40]

Paarlberg adds, "Because CTNBio retains its reputation as a cheerleader for GM crops, it has had trouble finding independent representatives from Brazil's consumer protection movement" to sit on the commission.[40]

David Garabrant

David Garabrant has previously served as a consultant to Monsanto.[1] He is a co-author on two of the Intertek papers defending the safety of glyphosate.[6,7] He serves on a scientific advisory board to Dow AgroSciences, which markets pesticides including glyphosate, and has consulted on behalf of Bayer Corporation on litigation matters concerning glyphosate and leukemia.[7] He has received research grants from Dow Chemical Company and Dow AgroSciences.[41]

Helmut Greim

Helmut Greim is Professor Emeritus at the Technical University Munich, Germany. He has previously served as a consultant to Monsanto and, as part of that consulting relationship, published peer-reviewed data regarding glyphosate.[1] He is a co-author on two of the Intertek papers defending glyphosate's safety.[4, 6]

Greim has been awarded the Order of Merit of the Federal Republic of Germany, the country's highest honour, for his contribution to the protection of people and the environment.[42]

From 1998 to 2008 Greim was an affiliate of ILSI's Health and Environmental Safety Institute (HESI) and from 2001–2002 he was chair of board of trustees for that organization.[1]

On 28 September 2015 Greim appeared before the Agriculture Committee of the German Parliament as a supposedly independent expert, invited by the CDU/CSU parliamentary group. The committee was discussing glyphosate, following the IARC's classification of the chemical as a probable carcinogen. Greim gave it the all-clear.[42]

Greim told the committee, "I must say, I really don't understand at all what all the fuss is about… It [glyphosate] does not cause cancer."[42]

But an investigation by the German political TV programme Monitor, which is broadcast monthly on the public TV channel ARD, revealed that Greim is not independent and has close links to industry.[42]

In 2015 Greim co-authored a review on the carcinogenic potential of glyphosate with David Saltmiras, an employee of Monsanto.[16] The review concluded, "glyphosate does not present concern with respect to carcinogenic potential in humans". Greim was paid by Monsanto for providing his expertise[16] yet claimed that this fact did not influence the results.[42]

Oliver Krischer, Member of the German Parliament (Alliance 90/The Green Party – Bündis90/Die Grünen) and deputy leader of the parliamentary group, commented: "Anyone who writes paid reports for the agricultural corporation Monsanto cannot, to my mind, be considered an independent expert in the field of glyphosate and plant pesticides."[42]

So how did Greim come to be invited to a parliamentary committee as an independent expert? Hermann Färber, Member of the German Parliament (CDU), Committee for Nutrition and Agriculture, said: "The scientists we invite from the EU are independent – otherwise there's no way we'd invite them."[42]

The Monitor reporter pointed out, "Mr Greim is being paid by Monsanto and fully represents the views held by that company. So it is difficult to see how he is independent." But Färber dodged the questions about Greim's independence, stating: "It's not what Mr Greim says that's the deciding factor, anyway – what matters is what the regulatory authorities have to say."[42]

Long before Greim took to defending glyphosate, he did the same for dioxins and PCBs, substances that are now accepted as highly toxic. Professor Erich Schöndorf, an environmental lawyer and a former prosecuting attorney in a court case on the issue, said of Greim: "He was a phoney expert. He didn't deserve to be recognized as an 'expert' or 'subject specialist'.

He clearly stood on the manufacturer's side and had nothing to do with impartial scientific methodology."[42]

In 2013 Greim co-authored a scientific paper defending the "azole" class of fungicides,[43] which have endocrine disrupting properties.[44] The paper was supported by BASF (which manufactures an "azole" fungicide) through the consultancy firm RJKA.[43] Greim has also co-authored a paper defending the safety of fragrance ingredients as part of research supported by the Research Institute for Fragrance Materials, an industry body funded by the manufacturers of fragrances and consumer products containing fragrances.[45] And he co-authored a Monsanto-funded paper defending the company's MON863 genetically modified maize against the findings of a re-analysis of the company's own data.[46] The re-analysis, by scientists working independently of the GMO industry, had reported potential signs of liver and kidney toxicity in rats fed the GM maize.[47]

In February 2017 it emerged that Greim is a member of a key European committee that is responsible for setting limits for workers' exposure to carcinogenic substances, the Scientific Committee on Occupational Exposure Limits (SCOEL). An investigation for the French newspaper Le Monde found that the majority of the SCOEL's experts (15 out of 22) have links with industrial sectors directly involved with substances evaluated by the committee. But according to the European Commission, Greim had "no" conflicts of interest, in spite of his membership of the Glyphosate Task Force and his role as a consultant for the chemical company BASF.[48]

Larry Kier

Larry Kier was employed by Monsanto from 1977 to 2000 and held a number of senior posts at the company. As part of that employment, he published peer-reviewed data regarding glyphosate.[1] He is a co-author on two of the Intertek papers defending the safety of glyphosate.[5, 6]

Together with another Glyphosate Expert Panel member, David Kirkland, in 2013 Kier published a review of the scientific literature that concluded that glyphosate and glyphosate-based herbicides "do not appear to present significant genotoxic risk under normal conditions".[49] The review was published in the industry-linked journal Critical Reviews in Toxicology (see below).

Kier was a member of an ILSI Risk Science Institute Working Group on Transgenic Animals in Carcinogenicity Testing (1995).[1]

David Kirkland

David Kirkland has previously served as a consultant to Monsanto and, as part of that consulting relationship, published peer-reviewed data regarding glyphosate.[1] He is a co-author on two of the Intertek papers defending the safety of glyphosate.[5, 6]

Like David Brusick, Kirkland is a veteran of divisions of the drug development and industry toxicity testing firms Hazleton Laboratories and Covance. Between 1990 and 1997 he occupied senior positions at Hazleton Microtest and Hazleton Europe; from 1997 to 2009 he was "Vice President of Scientific and Regulatory Consulting" at Covance Laboratories Europe (CLE), "responsible for the pharmaceutical regulatory affairs group and expert reviews (consultancy). This includes developing and promoting the regulatory and scientific expertise within CLE to 'add value' to client projects."[1]

Kirkland was the chair of the Peer Consultation Workshop on Genotoxicity for Categorization of "Inherent Toxicity" to Humans under the Canadian Environmental Protection Act (CEPA '99), co-sponsored by ILSI and Health Canada, in 2002.[1]

Gary Marsh

Gary Marsh is a co-author on two of the Intertek papers defending glyphosate's safety.[6, 7] He has a long history of conducting research for polluting industries on the health effects of risky or known toxic substances, such as formaldehyde and man-made mineral fibre. In the 1970s and 1980s he received research funding from the chemical companies Monsanto, DuPont, and American Cyanamid, all of which market or have marketed (in the case of the

latter) glyphosate products, as well as oil and energy giants Shell and Mobil. He has served as a consultant to industry (including the glyphosate manufacturer Dow Chemical) and other bodies since the 1990s.[1]

In 1980 he received research funding from Monsanto to investigate deaths among chemical workers exposed to formaldehyde. In 1989–91 he received funding from the Formaldehyde Institute,[1] an industry organisation with members including Monsanto and Dow Chemical,[50] to re-analyse[1] a National Cancer Institute study of industrial workers that found a link between exposure to formaldehyde and cancer.[51, 52, 53] Marsh was the first listed author on a series of papers, published in the industry-linked journal Regulatory Toxicology and Pharmacology (see below), that attempted to counter, dismiss, or minimize the National Cancer Institute's findings.[54, 55, 56] One of these papers[56] specifically challenges the IARC's 2004 decision to classify formaldehyde as a known carcinogen, which was based in part on the National Cancer Institute's data.[57]

In 2010 Marsh wrote to the National Toxicology Program's (NTP) Report on Carcinogens (RoC) Center protesting against the expert panel's recommendation to list formaldehyde as a known human carcinogen. Marsh castigated the panel for its "blatant and unsubstantiated omission" of his papers from its report.[58] Marsh's lobbying did not succeed and in 2011 the NTP published its "Twelfth report on carcinogens", upgrading formaldehyde from "reasonably anticipated to be a human carcinogen" to "known to be a human carcinogen".[59]

Ashley Roberts

Ashley Roberts has previously served as a consultant to Monsanto and is currently an employee of Intertek.[1] He is a co-author of one of the Intertek papers defending the safety of glyphosate.[6]

For ten years until 2001 he was the scientific and regulatory affairs manager for the food giant Tate & Lyle,[1] which uses "innovative technology to turn raw materials into distinctive, high quality ingredients". It operates primarily in two areas: corn wet milling and high-intensity sweeteners.[60]

Roberts is, or has been, a member of the Acceptable Daily Intake and Food Chemical Intake task force at ILSI. For his PhD research, he collaborated with a research programme sponsored by ILSI and the Calorie Control Council, an international association representing the low- and reduced-calorie food and beverage industry.[1] He is a member of the International Society of Regulatory Toxicology and Pharmacology (ISRTP), which the Center for Media and Democracy's Sourcewatch website flagged up for its "list of presidents and vice presidents" who are "mostly tireless workers for the tobacco industry. This organisation was often run by tobacco's favourite scientists who were willing to work for them on the quiet."[61]

Keith Solomon

Keith Solomon has previously served as a consultant to Monsanto and, as part of that consulting relationship, published peer-reviewed data regarding glyphosate.[1] He is the author[8] and co-author[6] of two of the Intertek papers defending the safety of glyphosate. He was a member of the ILSI Technical Committee on Aggregate Exposure from 2000 to 2004 and is a member of the ILSI HESI committee (July 1998–present). He is currently a member of the ILSI subcommittee on Cumulative Risks and Problem Formulation for Cumulative Risks.[1]

Solomon was a member of the CropLife America Science Forum and Panel on Weight of Evidence (May 2012).[1] CropLife America is a "trade association that represents the manufacturers, formulators and distributors of pesticides".[62] In 2004, CropLife poured funding into a campaign to try to defeat a Mendocino County ballot initiative – known as Measure H – that would make the country the first to ban genetically modified (GM) crops[63] (around 85% of GM crops are engineered to tolerate glyphosate herbicide[64]). In the lead-up to the vote, CropLife contributed over $500,000 – more than seven times that of the initiative supporters – in an (ultimately unsuccessful) attempt to defeat the proposal.[63]

Tom Sorahan

Tom Sorahan has served as a consultant to Monsanto and, as part of that consulting relationship, published peer-reviewed data re-

garding glyphosate. He is a co-author on two of the Intertek papers defending the safety of glyphosate.[6, 7] His research has been sponsored by Monsanto to the tune of over £50,000.[1]

Douglas Weed

Douglas Weed is a co-author on two of the Intertek papers defending the safety of glyphosate.[6, 7] He is the founder and managing member of DLW Consulting Services, LLC, a consultancy firm that specializes in providing expert advice and guidance on problems at the interface of science, law, commerce and public policy.[1]

DLW Consulting Services, LLC was one of the participating organisations, alongside chemical and GM seed giants Bayer, Dow Chemical, DuPont, Monsanto, and Syngenta, in the ILSI HESI Subcommittee on Evaluating Causality in Epidemiologic Studies (2012–13).[65] The scientific paper produced by this subcommittee was authored by employees of Dow Chemical, Monsanto, Bayer, DuPont, Syngenta, and Exxon Mobil, as well as an affiliate of ILSI HESI and employees of the US Environmental Protection Agency (EPA).[66]

The paper, titled "Evaluating uncertainty to strengthen epidemiologic data for use in human health risk assessments",[66] is ostensibly about improving the strength of epidemiological studies for use in human risk assessments. However, it appears to be heavily focused on manufacturing doubt about the reliability of epidemiological studies. It makes the criteria for acceptability so unrealistically stringent that no epidemiological study would be judged acceptable for informing risk assessments.

Christopher J. Portier, an invited specialist to the IARC Working Group on glyphosate and former director of the Agency for Toxic Substances and Disease Registry, USA, commented on this paper, "Quantification of uncertainty is itself uncertain, so where do you stop the process? If I do not know something precisely, I must make assumptions about the uncertainty in that thing in order to characterize the overall uncertainty. That makes the uncertainty estimate itself very uncertain. And none of that has anything to do with whether or not the association [between exposure to a certain chemical and a disease] really exists.

"The bottom line is that I could almost get any outcome I want from an uncertainty analysis. Certainly, Blair and colleagues (2009) suggest this is the case and, I believe, also correctly point to the fact that this is likely to increase the false negative rate"[67] [a false negative is when a toxic effect exists but is missed due to poor analytical methodology].

Weed occupied "advisory positions" at ILSI HESI from 2004 to 2005 and at ILSI from 2000–2003.[1]

From 2007 to 2008 Weed was Vice President for Epidemiology and Biostatistics at the Weinberg Group in Washington DC.[1] The Weinberg Group is a scientific consulting firm that, in the words of David Roberts in a 2008 article for Vanity Fair, "works for chemical companies to manufacture uncertainty about the health and environmental effects of chemicals, with the aim of fighting off regulatory and legal challenges. Lest you think that description melodramatic, it's worth reading the letter Weinberg sent DuPont on that company's battle over Teflon [a substance used in non-stick cooking pans that gives off toxic fumes when heated[68]]. It describes how Weinberg would 'harness, focus and involve the scientific and intellectual capital of our company with one goal in mind – creating the outcome our client desires.'"[69]

The Weinberg Group, together with several other industry-linked outfits (see "Glyphosate-defending papers published in industry-linked journals" below), was the subject of an investigation by US Congressional Representative John D. Dingell (D-Mich.), chairman of the House Energy and Commerce Committee, over its role in the Food and Drug Administration (FDA) decision allowing the endocrine-disrupting chemical bisphenol A in infant formula and other foods. In a statement, Dingell said, "The tactics apparently employed by the Weinberg Group raise serious questions about whether science is for sale at these consulting groups, and the effect this faulty science might have on the public health."[69]

Gary Murray Williams, MD

Gary Murray Williams has served as a consultant to Monsanto and, as part of that consulting relationship, published peer-reviewed data regarding glyphosate.[1] Williams is a co-author on three[5,4,6] of the Intertek papers defending the safety of glyphosate.[5, 4, 6, 7, 8]

Williams has a long history of publishing articles defending glyphosate. In 2000 he was the first author of a review that concluded, "Glyphosate is noncarcinogenic… the use of Roundup herbicide does not result in adverse effects on development, reproduction, or endocrine systems in humans and other mammals… under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans."[17] Interestingly, a co-author of the review was Ian C. Munro of industry consultancy Cantox[17] (now Intertek[70]).

Funding is not mentioned in the review but Monsanto employees are credited for their "significant contributions" and "scientific support". Monsanto is thanked for giving access to its toxicological data,[17] which has generally been kept hidden from the public and scientific community as a commercial secret.

Williams's many ILSI roles stretch over 27 years, from 1983 to 2010. They include:[1]

- 1993–2005: Member, Board of Trustees, ILSI Health and Environmental Sciences Institute (HESI). Chair, Membership Development Committee, 2002–2003.[1]

- 2006–2007: Member, Expert Group on the Application of the Margin of Exposure (MOE) Approach to Genotoxic Carcinogens in Food. ILSI – European Branch.[1] MOE is a concept promoted by ILSI in risk assessment that would allow genotoxic (DNA-damaging) substances to remain on the European market even though the EU authorities aim to eliminate exposures because no safe level is known.[11]

- 2009–2010: Corresponding member, Expert Group of the Risk Assessment of Genotoxic Carcinogens in Food Task Force. Data selection for BMD modelling of genotoxic and carcinogenic substances. ILSI – European Branch.[1]

The JMPR panel

Alan Boobis and Angelo Moretto

Alan Boobis is a professor at the Faculty of Medicine at Imperial College London.[71] He was chair of the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Meeting on Pesticide Residues (JMPR) for glyphosate, which decided that that glyphosate is "unlikely to pose a carcinogenic risk to humans from exposure through the diet".[2] The co-chair was Professor Angelo Moretto,[72] an associate professor at the Department of Biomedical and Clinical Sciences "Luigi Sacco", University of Milan.[73]

Soon after the JMPR published its opinion, it became embroiled in a bitter row about conflicts of interest. It emerged that Boobis was the vice-president of ILSI Europe. In 2012 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. Moretto was a board member of the ILSI Health and Environmental Sciences Institute (HESI), and of its Risk21 steering group, which Boobis also co-chairs.[72] See further details of this story in Chapter 5.

The consultant pathologist

Marvin Kuschner: Saviour of glyphosate?

Marvin Kuschner, MD was Dean of the School of Medicine, State University of New York at Stony Brook,[4] from 1972 until 1987.[74]

Kuschner was a key actor in the US EPA's decision[75] not to classify glyphosate as carcinogenic (see the full story in Chapter 2). He is referred to in a Monsanto-sponsored Intertek paper by Williams and colleagues that concluded, "glyphosate is not a carcinogen in laboratory animals". Williams and colleagues named Kuschner as one of the "peer review experts" who in 1985 re-examined the renal (kidney) tumours found in mice in a Monsanto study on glyphosate.[3] Kuschner claimed to have found a new renal tumour in a control mouse, no. 1028.[77, 78]

Neither the US EPA's pathologist, nor the pa-

thologists of the laboratory that had conducted Monsanto's mouse study, could confirm the existence of Kuschner's alleged new tumour.[79] If confirmed, it would effectively remove the significant increase found in Monsanto's original study in tumour incidence between glyphosate-exposed and control groups of animals, thus exonerating glyphosate from the accusation of carcinogenicity. Kuschner's claimed finding enabled three more individual pathologists hired by Monsanto and a "Pathology Working Group" (PWG), who all reported directly to Monsanto, to conclude that the renal tumours were not related to glyphosate treatment but were due to chance.[78] It is not known on whose orders the PWG members were recruited or who paid them, if anyone. Finally, in 1991, the EPA classified glyphosate as non-carcinogenic.[76]

Williams and colleagues carefully note Kuschner's academic affliliation.[4] But sources available on the Internet raise the question of whether Kuschner also had conflicting interests and allegiances with industry, which are undeclared by Williams and colleagues.

According to his biographical entry in Prabook, by 1979 Kuschner was a member of Monsanto's Biohazards Commission[76] (possibly the same body as the company's "biohazards committee", referred to in a lawsuit[77]).

The same source lists Kuschner (date unspecified), who was a specialist on lung cancer, as a consultant to the asbestos manufacturer Johns Manville Company,[76] which faced hundreds of thousands of lawsuits relating to asbestos-related diseases.[78] In 1994, along with the former Monsanto consultant and Glyphosate Expert Panel member Gary Murray Williams and others, Kuschner co-published a scientific paper defending the safety of asbestos in the air of public buildings. The paper, which does not declare the conflicts of interest of the authors, concluded, "leaving well-maintained asbestos in place is considered to be the best course."[79] This would certainly be the least expensive course for the industry, enabling it to avoid liability for the costs of removal.

Kuschner was an expert witness in a lawsuit (the judgment was handed down in 1979) brought by the widow of a former Johns Manville employee, in which he argued that the employee's death from cancer was not caused by exposure to asbestos.[80]

Kuschner was also reportedly a trusted ally of another polluting company. A newspaper report about an Eastman Kodak-owned plant that severely polluted groundwater in Rochester, New York noted that Kuschner was chair of a panel convened by the company to review the evidence on methylene chloride, the chemical at the centre of the controversy, and to judge whether it posed a health risk to residents.[81]

Confusing anecdote with scientific evidence, Kuschner stated, "The bottom line is that when the panel members were asked if they would be content to live in an atmosphere that contained what Rochester's contained, the answer was 'absolutely'." Presumably this claim was never tested, insofar as the panel members were not forced to live in the area.[81]

Head of pesticide safety at BfR

Roland Solecki

Roland Solecki is head of the "Safety of Pesticides" department responsible for the health assessment of glyphosate at BfR. He has also been a member of the Scientific Committee of the European Food Safety Authority (EFSA) since 2015. He was involved in the first European approval procedure for glyphosate in Germany and at the EU level as an employee of the then Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV). He was one of the JMPR experts who adopted a 2004 report setting limits for the acceptable daily intake of glyphosate, in which it was classified as non-carcinogenic. See Chapter 5 for details.

Solecki has worked with industry representatives for years – until at least 2015 – and has long-standing links with ILSI (see Chapter 5).

Conclusion

There is clear evidence of strong conflicts of interest among people who have defended glyphosate and glyphosate-based herbicides, while downplaying or hiding evidence of the risks of these chemicals.

Because we cannot read people's minds, it is difficult to prove that someone's view of glyphosate's safety has been influenced by their industry interests.

However, as seen in Chapter 1 ("How the regulatory system fails the public"), there is a great deal of evidence showing that industry-linked scientific papers are more likely to find that the product in question is safe.

In addition, in Chapter 2, we showed that many of the scientific papers defending glyphosate's safety are based on bad scientific practices. The conclusions of these papers consistently exonerate glyphosate herbicides from suspicion of harmfulness, in contradiction to the conclusions of many studies authored by scientists working independently of the industry.

Therefore we conclude that conflicts of interest have led to bad scientific practices, which are closely correlated with conclusions of "no harm" from glyphosate herbicides.

Chapter 4

Bad science of the regulatory authorities

On 20 March 2015 the World Health Organization's cancer agency IARC published its verdict that glyphosate is a probable human carcinogen and that there is strong evidence that it is genotoxic.[1] Monsanto quickly hit back with strong denials.[2,3]

The company gained support from several regulatory agencies and expert bodies, including:

- BfR (Germany's Federal Institute for Risk Assessment), which concluded on 31 August 2015 that "no hazard classification for carcinogenicity is warranted"[4]
- The European Food Safety Authority (EFSA), which, based on BfR's report, concluded on 12 November 2015 that glyphosate is "unlikely to pose a carcinogenic hazard to humans"[5]
- The Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Meeting on Pesticide Residues (JMPR), which announced in May 2016 that glyphosate is "unlikely to pose a carcinogenic risk to humans from exposure through the diet"[6]
- The US Environmental Protection Agency (EPA), which in May 2016 published a document on its website stating that glyphosate was "not likely carcinogenic" before removing it, stating that it had been published in error prior to finishing the agency's review of the chemical.[7]

In the current chapter we examine the quality of the scientific arguments used by these agencies in their assessments.

In order to understand the argument that follows, we first need to define hazard and risk. There is a difference between the two. As the World Health Organization's (WHO) cancer agency IARC explains: "An agent is considered a cancer hazard if it is capable of causing cancer under some circumstances. Risk measures the probability that cancer will occur, taking into account the level of exposure to the agent."[8]

In lay terms, a hazard is something that can potentially cause harm, such as falling off a ladder. A risk is the likelihood that this will really happen.

IARC restricts its assessment of pesticides, including glyphosate, to a hazard evaluation. Risk assessments are performed by regulatory or other expert bodies. They take exposure into account, but they must be based on a prior hazard evaluation.* Hazard evaluation is the vital first step to better inform the risk assessment.

In Europe the process ends with the hazard assessment and no risk assessment is done, in cases where a pesticide is classified as a 1A or 1B carcinogen.[9] This is because known or presumed human carcinogens are considered so dangerous that human exposure is not allowed at any dose.

Based on its hazard evaluation, IARC judged glyphosate to be a probable human carcinogen.[1] But BfR[4] and EFSA[5] disagreed, giving glyphosate a clean bill of health with regard to carcinogenicity. The BfR stated that "no hazard classification for carcinogenicity is warranted" (p. 92)[4] and EFSA concluded that glyphosate is "unlikely to pose a carcinogenic hazard to humans".[5] The JMPR concluded that glyphosate is "unlikely to pose a carcinogenic risk to humans from exposure through the diet".[6] And the US EPA concluded that glyphosate was "not likely carcinogenic" in its cancer assessment[10] that was published in error in May 2016.[7]

Why did BfR, EFSA, the JMPR, and the US EPA disagree with IARC?

The first and fundamental problem with BfR's and EFSA's assessment is that, in contrast with

* Not all countries around the world conduct their own hazard evaluation; many countries in the Global South rely on the WHO. That is why they often classify pesticides as harmless although they are classified as mutagenic, reprotoxic or carcinogenic in Europe (and sometimes the US).

IARC, they failed to perform a proper hazard evaluation for glyphosate. This has important implications, because if a carcinogenic hazard is acknowledged, the risk assessment will be fundamentally different. By omitting the fact that glyphosate is carcinogenic, the authorities can continue to allow the use of glyphosate and declare it "safe". If glyphosate were labelled as a category 1B carcinogen, its authorization in the EU would be forbidden.[9]

BfR confuses hazard and risk

BfR's and EFSA's denial of the carcinogenic hazard of glyphosate essentially invalidated their risk assessment. They seem to try to conceal this shortcoming by blurring the difference between risk assessment and hazard evaluation.

For instance, in a statement published on its website, BfR claimed that the difference between IARC's and their own assessment was because "IARC only made the first step of an assessment of the health risk, which in case of glyphosate has been completed by the European authorities as well as the JMPR by relating the potential health hazards to the anticipated glyphosate exposure from agricultural use"[11] (our emphases).

This is clearly misleading. In reality, IARC's hazard evaluation was fundamentally different from that of BfR's and EFSA's. That is why those authorities did not "complete" the hazard evaluation made by IARC, but simply denied it. They claimed that glyphosate does not pose a carcinogenic hazard, and performed a risk assessment that ignores the carcinogenic hazard.

BfR also confused hazard and risk in attempting to dismiss the results of rodent carcinogenicity studies, the majority of which showed that glyphosate did cause an increase in cancer (see below). BfR claimed: "In summary, based on the data from five carcinogenicity studies in mice and seven chronic toxicity and carcinogenicity studies in rats, the weight of evidence suggests that there is no carcinogenic risk"[4] (emphasis by BfR).

But according to Regulation (EC) 1272/2008 (p. 104, Table 3.6.1) the results of rodent carcinogenicity studies are the basis for the hazard evaluation.[12] Risk assessment may follow, based on exposure assessments and other considerations, if legislation allows the marketing of carcinogenic compounds. In Europe, in principle, it does not for category 1A or 1B carcinogens,[9] as explained above.

If BfR had used the rodent carcinogenicity studies for a rigorous hazard evaluation, it would have had no choice but to admit that glyphosate poses a category 1B carcinogenic hazard – thus triggering a ban in Europe.

"If BfR had used the rodent carcinogenicity studies for a rigorous hazard evaluation, it would have had no choice but to admit that glyphosate poses a category 1B carcinogenic hazard – thus triggering a ban in Europe."

BfR's and EFSA's assessment mired in contradictions

The hazard evaluation made by BfR and EFSA (EFSA based its conclusion on BfR's report) is entangled in contradictions, making it a prime example of bad science. First BfR acknowledged and did not deny IARC's judgments, but then flatly stated that "There was no evidence for a carcinogenic potential of glyphosate noted in any of the studies performed in rats and mice" (p. 24) and that "classification and labelling for carcinogenicity is not considered appropriate" (p. 28).[13]

The steps involved in some of the contradictions are below.

Step 1: BfR admits significant increase in tumour incidence in animal experiments

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)[1] in which BfR had previously not been able to detect any evidence of cancer activity, the German

authority had to re-evaluate its report[14] and amend its inadequate statistical analysis of the animal carcinogenicity studies.

> "BfR admitted the existence of three lines of evidence for glyphosate's carcinogenicity: animal, mechanistic, and epidemiological studies. But instead of considering the whole picture in a true "weight of evidence" fashion, BfR separated out the lines of evidence, pretending they were isolated phenomena, to deny them individually, one by one."

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. Overall, BfR reported a total of 11 statistically significant increases of tumour incidences in glyphosate-treated animals in five mouse and two rat studies.[4] BfR's amended analysis was detailed in an Addendum to its initial report dated 31 August 2015.[4] In the Addendum, BfR finally agreed with IARC: "The statistical analysis by IARC was confirmed" (p. 44).[4]

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" (p. 36).[4] The statistical analysis provided by industry was not in accord with current Organization for Economic Cooperation and Development (OECD) guidance[15] and therefore had found statistical significance only in a single mouse study.

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.[9]

Step 2: BfR admits mechanism for glyphosate's carcinogenicity

BfR identified a mechanism through which glyphosate could cause cancer –oxidative stress. It stated that the "uncoupling or inhibition of mitochondrial oxidative phosphorylation also represents an established mechanism for ROS [reactive oxygen species] generation. Notably, uncoupling of oxidative phosphorylation by glyphosate has been reported in rat liver microsomes."[4]

This is in agreement with IARC, which also identified oxidative stress as a mechanism for glyphosate's carcinogenic effects.[1]

Step 3: BfR agrees with IARC on epidemiological evidence for carcinogenicity

Regarding the epidemiological data on glyphosate-based herbicides and cancer, BfR stated: "Based on the studies on cancer in humans IARC concluded: 'There is limited evidence in humans for the carcinogenicity of glyphosate'." It should be noted that under the IARC classification system, "limited" is the second strongest category of evidence, after "sufficient".

BfR continued, "RMS [Rapporteur member state] agrees with IARC that the other IARC categories (evidence suggesting lack of carcinogenicity, inadequate evidence of carcinogenicity and sufficient evidence of carcinogenicity) are not suitable for the classification of the evidence from studies in humans."[4] More specifically, BfR stated, "Following the logic of the classification system of IARC, the RMS can accept this interpretation."[4]

Thus BfR agreed with IARC's conclusion that epidemiological studies provided "limited" evidence for glyphosate's carcinogenicity. That means, in IARC's definition, that "A positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence."[16]

Step 4: Reverse gear: BfR denies what it has already admitted

BfR admitted the existence of three lines of

evidence for glyphosate's carcinogenicity: animal, mechanistic, and epidemiological studies. But instead of considering the whole picture in a true "weight of evidence" fashion, BfR separated out the lines of evidence, pretending they were isolated phenomena, to deny them individually, one by one.

The process was as follows:

- Animal studies: BfR acknowledged that five mouse and two rat studies demonstrated a statistically significant increase in one or more tumour incidences per study. It even listed these studies, together with the error probabilities showing statistical significance, in its Addendum.[4] Yet in spite of all this, BfR still concluded, "It should be avoided to base any conclusion only on the statistical significance of an increased tumour incidence identified in a single study without consideration of the biological significance of the finding"[4] (our emphasis). Exactly how BfR could redefine seven studies showing statistically significant increases of tumour incidences in glyphosate-treated animals as "a single" study is a mystery. It has nothing to do with science.

> "Exactly how BfR could redefine seven studies showing statistically significant increases of tumour incidences in glyphosate-treated animals as "a single" study is a mystery. It has nothing to do with science."

- Mechanistic studies: BfR also admitted the existence of a mechanism for carcinogenicity of glyphosate. But then, in a statement that is so confused as to be meaningless, BfR claimed that "the mechanistic and other studies do not provide further evidence for a carcinogenic mechanism" because of "the absence of sufficient evidence for a carcinogenic risk related to the intended herbicidal uses".[4] BfR also stated with regard to the mechanistic evidence: "From **the sole observation** of oxidative stress and the existence of a plausible mechanism for induction of oxidative stress through uncoupling of mitochondrial oxidative phosphorylation alone, genotoxic or carcinogenic activity in humans cannot be deduced for glyphosate and glyphosate based formulations"[4] (our emphasis). BfR omits the fact that this is not a "sole observation" – it is well supported by animal and epidemiological evidence.

- Epidemiological studies: BfR acknowledged the existence of "limited" epidemiological evidence that glyphosate herbicides are carcinogenic. It also acknowledged a mechanism that can explain glyphosate's carcinogenic action. Yet turning its back on the evidence, it followed the industry-sponsored review by Acquavella and colleagues (2016)[17] in denying the significance of this evidence, based on the "no effect" finding from a single study, the Agricultural Health Study.[18] However, as explained in Chapter 2, this study had too short a followup period to allow the necessary time for the cancer in question (non-Hodgkin lymphoma) to develop from glyphosate exposure.

BfR's reasons for mixing the concepts of hazard evaluation and risk assessment are unclear, but the resulting confusion has two effects:

1. It distracts the reader from drawing the inevitable and correct conclusion – that glyphosate poses a carcinogenic hazard.

2. Blurring the distinction between hazard and risk opens an "escape route" in the scientific debate and enables a contra-factual conclusion. The irrefutable evidence coming from carcinogenicity and mechanistic studies, as well as epidemiology, are admitted – yet at the same time they are denied with references to "risk". The implication is that the hazard is insignificant because the risk is supposedly negligible. However, this is an upside-down argument, since as we have seen, the risk can only be properly calculated on the basis of a prior hazard assessment.

BfR's genotoxicity contradictions

IARC concluded that there was "strong" evidence that glyphosate and glyphosate-based

formulations are genotoxic (damage DNA). In Tables 4.1–4.6 of its report, IARC summarized the findings of 59 published studies on glyphosate, its formulations, and its metabolite AMPA. Unequivocal results were obtained in 105 tests described in these publications and 65 demonstrated genotoxic effects. IARC concluded that there is "strong evidence that glyphosate causes genotoxicity".[1]

BfR, in its Addendum to the Renewal Assessment Report (RAR), listed the results of 41 industry studies (not accessible to the public, including IARC) and 17 published studies, 16 of which were also considered by IARC. According to the Addendum, none of the industry studies showed any genotoxicity, while 62% of the 34 test results for glyphosate described in these 17 publications did show genotoxicity. However, despite this evidence, BfR concluded "that glyphosate does not induce mutations in vivo and no hazard classification for mutagenicity is warranted"[4] (p. 49).

How did BfR reach this conclusion? Apparently through a technical dodge that allowed it to exclude damning evidence.

According to Regulation 1272/2008, for categorization of a substance as a **mutagenic hazard**, in vivo evidence **in mammals** is needed, while for the assessment of **mutagenic activity** as a mechanism for carcinogenicity, such a requirement does not exist.[12]

Neither in the RAR14 nor in the Addendum[4] did BfR take a position on the mutagenic potential of glyphosate as mechanistic evidence for carcinogenicity. Instead BfR hid behind the hazard classification for mutagenicity, with its specific requirement for positive effects in mammals. This made it possible for BfR to exclude eight studies listed by IARC that demonstrated in vivo genotoxic effects of glyphosate in fish, fruit flies, and plants (Table 4.5)[1] – as they were not conducted in mammalian systems.

> "To the public's detriment, BfR, once again entangled in contradictions, reached an opposite conclusion to IARC on the genotoxicity of glyphosate, using exactly the same arguments as the Monsanto-linked and Glyphosate Task Force-funded Kier and Kirkland study."

Surprisingly, however, even after BfR concluded that "glyphosate does not induce mutations in vivo"[4] (p. iii),[4] it still stated that it "strongly recommends further genotoxicity studies in compliance with OECD test guidelines in general and for representative formulations" (p. iv)[4] – perhaps suggesting that it lacked confidence in its own conclusion.

BfR made prominent reference to the Glyphosate Task Force-sponsored review by Kier and Kirkland (2013).[19] In Volume 1[20] (p. 57) as well as in Volume 3 Annex B.6[14] (p. 405) of the Renewal Assessment Report, BfR echoed the conclusion drawn by Kier and Kirkland: "The authors concluded that an overwhelming preponderance of negative results in well-conducted bacterial reversion and in vivo mammalian micronucleus and chromosomal aberration assays indicates that glyphosate and typical GBFs [glyphosate-based formulations] are not genotoxic in these core assays."

The "preponderance of negative results" does not seem to be that overwhelming, given that BfR "strongly" recommended further genotoxicity studies in the Addendum. While such a precautionary approach is welcome, the question arises as to why this did not translate into BfR's acceptance of the evidence of a mechanism for glyphosate's carcinogenicity.

An important aspect of the "preponderance" is the "negative results in well-conducted bacterial reversion" assays, i.e. 16 negative Ames Tests using *Salmonella typhimurium*. While dismissing the genotoxic effects of in vivo studies in rodents because of too-high dose levels, BfR gave no consideration to the fact that glyphosate is a broad-spectrum antibiotic (US patent number 7771736[21]) and an "antimicrobial agent" (US patent number 20040077608 A1[22]). It has been known for over 30 years that "the testing of antibiotics in bacteria is a very dubious procedure".[23] Moreover, the Ames Test is not considered suitable for testing antibiotics.[24]

BfR ignored these important issues and accepted bacterial tests as evidence of a presumed lack of glyphosate's genotoxic potential, without qualifying or questioning its conclusion. In addi-

tion, BfR did not hesitate to reproduce industry's (unproven) opinion that it "is "due to cytotoxicity rather than DNA interaction" when "DNA damage effects at high (toxic) dose levels" were observed (Volume 1,[20] p. 57).

Thus to the public's detriment, BfR, once again entangled in contradictions, reached an opposite conclusion to IARC on the genotoxicity of glyphosate, using exactly the same arguments as the Monsanto-linked and Glyphosate Task Force-funded Kier and Kirkland study.[19]

EPA fails to report significant results of malignant lymphoma

The "final report" of the US EPA's Cancer Assessment Review Committee (CARC) on the "Evaluation of the Carcinogenic Potential of Glyphosate"[25] was posted on the EPA's website for a short time in May 2016.[7] The CARC was chaired by a top-ranking EPA official, Jess Rowland.[25] Its report offers insights into how the EPA handled scientific data to come to the conclusion that glyphosate is "not likely to be carcinogenic in humans". The way in which it dealt with a specific type of cancer, malignant lymphoma, in mouse studies can be considered emblematic.

Looking at the data of the available mouse studies leads clearly to the conclusion that glyphosate causes an increase in malignant lymphoma, a tumour affecting the lymphatic system, as does non-Hodgkin lymphoma in humans.

The EPA's CARC itself pointed out that in one study (cited as Nufarm 2009b and referred to as Wood 2009 by the European authorities) "for the malignant lymphomas there was a trend and pairwise significance".[25]

The reported incidence of malignant tumours in this study was:

- control group: 0/51 (0%)
- low dose group: 1/51 (2%)
- medium dose group: 2/51 (4%)
- high dose group: 5/51 (10%)

Statistical evaluation of the study revealed a significant increase in the incidence of malignant lymphoma when a trend test is applied (p=0.006633) and also a significant increase by pairwise comparison (p=0.02820), according to the EPA's own evaluation (Fisher's Exact Test and Exact Trend Test Results).

This seemingly posed a problem to the CARC, and the way the CARC dealt with it was similar to the way it was dealt with in Europe. In essence, the other mouse studies and historical control data (data from untreated animals in other studies) were used to discredit the crystal-clear result in the Nufarm study, on the claimed basis that "malignant lymphomas were not seen in the other three studies in this strain of mice".[25]

A fourth study in a different strain of mice (Swiss Webster), which also showed a dose-dependent and significant increase in malignant lymphomas (Feinchemie Schwebda 2001), was excluded from further consideration because of an alleged virus infection in the colony.25 However, the European authorities came to the conclusion that "in the study report itself, there was no evidence of health deterioration due to suspected viral infection and, thus, the actual basis of EPA's decision is not known"[26] (p.72). Neither does the CARC report offer a basis for this decision.

Thus three other studies remained which were used to claim that observation of a dose-dependent, significant increase in malignant lymphomas in the Nufarm-study was irrelevant, because of an alleged absence of malignant lymphomas.[25] First of all it needs to be stressed that contrary to CARC's claim, malignant lymphomas were seen in two of the other three studies. The third study (Knezevich and Hogan 1983) was of limited use, because their classification of tumours of the lymphatic system was less specific and therefore could not be compared. All this can easily be derived from the documents of the European authorities.[14,20,26] However, in common with the European authorities, CARC failed to acknowledge that the Atkinson and colleagues 1993 study was severely compromised because the histopathological assessment of malignant lymphomas suffered from restricting it to lymph nodes with macroscopic changes (p. 68).[25]

Finally, for the Arysta 1997 study, CARC shied away from using applicable OECD guidance.[15] The CARC report actually shows that the incidence of lymphoma in males was statistically significant when the trend test was used, but focused on pairwise tests, emphasizing in its conclusion that "there were no statistically significant pairwise differences"[25] (p. 73). It should be remembered that OECD Guidance No. 116 explicitly recommends the use of a trend test for such comparisons and in addition points out that "either kind of test" (i.e. trend or pairwise) is considered sufficient to accept statistical significance.[15]

Perhaps for added certainty, CARC also used historical control data to dismiss the significant and dose-dependent increase in malignant lymphoma in the Nufarm study. In similar fashion to the European authorities, CARC ignored the strong recommendation by the OECD and other guidance documents of a highly restrictive use of historical control data. According to these guidance documents, historical control data should be derived from studies performed in the same laboratory, in the same strain of mice, within the last five years prior to the study in question. None of these criteria was fulfilled for the Nufarm study, because such data were not available. Instead CARC used a large pool of historical control data assembled from studies conducted in various laboratories over a large period of time.

In summary, the US EPA's CARC used similar methods as the European authorities to "cleanse" a database which otherwise would have led to the conclusion that glyphosate is carcinogenic in laboratory animals. In contrast with Europe, the interference of the industry (i.e. Monsanto) in the US EPA's decision-making process is well documented (see Chapter 5).

Lack of detail in JMPR report

Last year the results were published of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), held from 9–13 May 2016 in Geneva, Switzerland.[6] Interest groups in favour of a continued authorization of glyphosate refer to this document as "the other WHO" document, which, in contrast to IARC's report, contends that glyphosate does not pose a carcinogenic risk.

The 123-page report contains a 10-page section on glyphosate, of which less than one page is dedicated to results of animal carcinogenicity testing and another page to epidemiological results concerning non-Hodgkin lymphoma.[6] Citations and references to the scientific literature or other data sources are not provided.

The report was published in May 2016, but the corresponding monograph on glyphosate is still pending. The report did not specify details of the studies relied on, such as tumour incidences or error probabilities. It offered just two sentences concerning the increased incidence of malignant lymphoma in glyphosate-treated mice: "The Meeting concluded that there is equivocal evidence of induction of lymphomas in male mice in three out of seven studies and in female mice in one out of seven studies at high doses (5000–40,000 ppm, equal to 814–4348 mg/kg bw [bodyweight] per day). The Meeting also noted that in the other three studies in which even higher doses (up to 50,000 ppm, equal to 7470 mg/kg bw per day) had been used, no effect was observed."[6]

No further explanations or references were given.

The lack of detail in the JMPR report demonstrates its low quality. It also demonstrates an absence of transparency, since the lack of references means that independent scientists cannot examine the JMPR's sources and assess how the panel members reached their conclusions.

Nevertheless, unlike BfR and EFSA, JMPR did not completely deny the carcinogenic hazard posed by glyphosate. In its conclusion, the JMPR panel stated: "The Meeting concluded that glyphosate is not carcinogenic in rats but **could not exclude the possibility that it is carcinogenic in mice** at very high doses"[6] (our emphasis).

Conclusion

BfR agreed with IARC on the three lines of evidence for the carcinogenic potential of glyphosate (human, animal, and mechanistic evidence).

Notably, BfR agreed with IARC's judgments that rodent carcinogenicity studies showed significant increases in malignant lymphoma in

glyphosate-treated animals, and that human epidemiological studies show an association between exposure to glyphosate herbicides and Non-Hodgkin lymphoma. Thus these two lines of evidence support one another in that they indicate glyphosate's carcinogenicity in the same organ, lymphatic tissue. In addition, BfR agreed with IARC that oxidative stress was a plausible mechanism for glyphosate's carcinogenic effects.

But then, contradicting the totality of evidence, BfR denied the chemical's carcinogenicity.

In this process, BfR blurred the distinction between risk and hazard, drawing a veil of confusion over its claims on glyphosate.

Both BfR and EFSA failed to perform a proper hazard evaluation for glyphosate – an omission that enabled them to sidestep the data from rodent carcinogenicity studies showing a link between glyphosate exposure and cancer.

These bad scientific practices have led to scientifically inaccurate conclusions on glyphosate. These conclusions put public health at risk by enabling the continued use of glyphosate herbicides.

Chapter 5

Institutional conflicts of interest in regulatory and expert bodies

In the previous chapter, we saw that industry's contention that glyphosate is not carcinogenic gained support from several regulatory agencies and expert bodies, including the BfR (Germany's Federal Institute for Risk Assessment),[1] the European Food Safety Authority (EFSA),[2] the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Meeting on Pesticide Residues (JMPR),[2] and the US Environmental Protection Agency (EPA).[3]

However, reports on glyphosate issued by these bodies are marred by serious conflicts of interest, dating back to the time of the chemical's first European approval and before.

First glyphosate approval in the EU

Research by the NGO BUND (Friends of the Earth Germany) shows how glyphosate was approved for the European market and how subsequent approvals allowed it to remain there. The following history is condensed and translated from BUND's report, which at the time of writing is only available in German.[4]

The environmental and health risks of the pesticide "active substance" glyphosate were examined for the first time under an EU-wide framework from 1993 to 2002. Glyphosate was already on the market at the time. It was subjected to the EU's new assessment procedure and allowed onto the EU market from 2002 for ten years. After the licence expired in 2012 the EU adopted several extensions without a risk assessment, prolonging the approval until mid-2016. Then the Commission further extended the approval for a limited period until the European Chemicals Agency (ECHA) concludes its review of glyphosate's carcinogenicity.[5]

The chronology of the 1993–2002 approval procedure was as follows.

In 1993, several companies, including Monsanto, Zeneca, Feinchemie Schwebda and Dow, submitted an application for the European approval of glyphosate. Germany was appointed by the EU Commission as the rapporteur member state, responsible for reviewing the documentation submitted by the companies. The core questions posed in this review were whether there were health or environmental risks which indicated that the substance should not be placed on the market. Germany forwarded the results in the form of a draft report to the relevant EU authorities. The rapporteur country thus played – and continues to play – a central role in the entire approval process.

In Germany, the following authorities were responsible for the risk assessment of glyphosate and for compiling the draft assessment report:

- The Federal Biological Research Centre for Agriculture and Forestry (Biologische Bundesanstalt für Land- und Forstwirtschaft, or BBA)

- The Federal Institute for Consumer Health Protection and Veterinary Medicine (Bundesinstituts für gesundheitlichen Verbraucherschutz und Veterinärmedizin, or BgVV), responsible for health assessment, and

- The German Environment Agency (Umweltbundesamt, or UBA, responsible for environmental assessment.

The German report on glyphosate was completed in 1999, with a recommendation to authorize glyphosate in the EU. From 1999 to 2000, the draft report was subjected to a European peer review procedure under the ECCO (European Community Co-ordination for the Evaluation of Active Substances) project. Ultimately in 2001, the EU Commission's Standing Committee on Plant Health decided to include glyphosate in the list of authorized pesticide active substances.

BUND identified three main problems with this review process:

1. Closeness of the BBA to industry: The BBA had a close relationship with industry, collaborating with agrochemical companies on the development of commercial products and on applications for patents on products. BUND commented, "We do not know whether or in which way the BBA cooperated with the companies that wanted to market glyphosate. But the clearly visible, fundamentally lacking demarcation with industry suggests that there was little awareness in the authority about possible conflicts of interest."

2. Double roles in committees: After Germany had completed its draft report in 1999, it was submitted to the ECCO team. The team had the task to coordinate the European peer review process for the evaluation of pesticide active ingredients, to prepare appropriate meetings and to pass the results from the peer review procedure to the EU Commission in the form of a report.

   The problem with this arrangement from the public interest point of view was that most of the ECCO managers consisted, in addition to representatives from the UK's Pesticide Safety Directorate or PSD, of BBA and BgVV employees. Both German authorities, together with the British PSD, also chaired the ECCO meetings in which the evaluation reports from the rapporteur were discussed by experts.

   BUND reports, "The representatives of German authorities involved in the ECCO project were the former President of the BBA, Prof Fred Klingauf, Hans-Gerd Nolting (BAA), Henning Bruno (BBA), Martin Streloke (BBA), Rudolf Pfeil (BgVV) and Roland Solecki (BgVV)."

   BUND points out, "Overall, there is a problematic situation with regard to the evaluation of the active substance glyphosate: Employees of the BBA and BgVV assessed a plant protection product as representatives of a German authority and subsequently assessed the plausibility and quality of their own assessment as employees of an EU project."

   These double roles of committee members constitute a clear conflict of interest, as employees of these agencies are highly unlikely to contradict and invalidate their own previous decision.

3. Studies showing harmful effects from glyphosate were dismissed: In a report published in June 2011,[6] a group of scientists coordinated by the organization Earth Open Source (EOS) raised serious accusations against the EU and above all the German authorities over their role in the review process of glyphosate. Thus, according to EOS research, several industry animal feeding studies from the 1980s and 1990s show that glyphosate causes malformations in fetuses – not only at high, but also at medium and low doses. The authors of the study demonstrated that the BBA and the EU Commission knew of these studies during the initial authorization procedure. However, the results were either ignored or rejected by the German authorities during the approval process for unscientific reasons. The results of the studies did not appear in the final report of the EU Commission on glyphosate.[7] Also, the BBA recommended a high acceptable daily intake (ADI) for glyphosate (0.3 mg/kg of bodyweight per day), even higher than that recommended by one of the industry applicants (0.05 mg/kg of bodyweight per day.). A peer-reviewed version of EOS's report was published in 2012.[8]

   In July 2011 BfR responded to the report, calling it "a challenging document raising a lot of questions that should be taken very seriously. An adequate response to the criticism and the many accusations in the report would require a general discussion of the established paradigms for the toxicological evaluation of chemicals… These general discussions should be initiated by the Commission before we start with the re-evaluation of glyphosate."[9] However, these discussions did not take place.

> "Overall, there is a problematic situation with regard to the evaluation of the active substance glyphosate: Employees of the BBA and BgVV assessed a plant protection product as representatives of a German authority and subsequently assessed the plausibility and quality of their own assessment as employees of an EU project."
> – BUND (Friends of the Earth Germany)

BUND concluded, "The proximity to industry, the non-inclusion of critical study results as well as the double roles of personnel cast a shadow over the EU's first authorization procedure for glyphosate. There is doubt as to whether the authorization was, as required, actually based on an independent and unbiased assessment of all scientific findings on the environmental and health risks of the active substance."[4]

Current re-evaluation of glyphosate: The German authorities

The EU re-registration process for glyphosate has been ongoing since 2012. The EU has postponed its final decision until the European Chemicals Agency (ECHA) comes up with its verdict on glyphosate's carcinogenicity.[10]

As in the first European approval procedure, industry chose Germany as the rapporteur member state in the re-evaluation – thus generating a major conflict of interest for an authority and individual experts if they should find mistakes in their first "clean bill of health" for glyphosate.

The 24 companies that want glyphosate to be re-approved have joined together to form the Glyphosate Task Force. Monsanto submitted the dossier of studies and documents on behalf of the Glyphosate Task Force to the German authorities in support of the re-approval of glyphosate.[4]

In Germany, this time the following authorities are responsible for the re-evaluation of glyphosate:

- The Federal Office of Consumer Protection and Food Safety (BVL) as the lead agency (risk management). The BVL performs the tasks of the former Federal Biological Research Centre for Agriculture and Forestry (BBA)
- The Federal Institute for Risk Assessment (BfR), which evaluates the health aspects of the active substance. In 2002 it became the most important successor of the Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV)
- The German Environment Agency (UBA), which assesses the impact on the ecosystem
- The Julius Kühn Institute (JKI), which assesses practical application and benefits as well as efficacy.[4]

In an Addendum to the Renewal Assessment Report, dated 31 August 2015, the German authorities concluded that a carcinogenic classification for glyphosate was not warranted.[1]

EFSA then carried out a peer review of the German authorities' report, which it published in November 2015. EFSA concluded that glyphosate is "unlikely to pose a carcinogenic hazard to humans" and that the acceptable daily intake (ADI) level could be raised from 0.3 to 0.5 mg/kg of bodyweight per day.

Lack of transparency may hide conflicts of interest

In light of the double roles played in the 2002 evaluation of glyphosate by individuals in the German authorities and subsequently at the EU level, in which these individuals effectively reviewed their own decisions, it is essential that the names of those responsible for the current evaluation in the different authorities are made public. However, such transparency has been lacking in the current re-evaluation. Corporate Europe Observatory (CEO) reported that in response to its access to documents request, more than 80% of the national experts involved in EFSA's assessment of glyphosate refused to have their names disclosed to the public.[11]

CEO noted, "The most striking outcome of this access to documents request was perhaps that not a single expert from the rapporteur state, Germany, was named. This is all the more problematic given that BfR has a policy allowing industry employees on its committees (its current pesticides committee for instance includes employees of chemical giants Bayer and BASF[12])."

CEO added, "BfR refused to comment on the identity of the five officials contributing to EFSA's peer review (an anonymous source had sent five names to CEO, all BfR officials), stating that 'BfR assessments in general are made by BfR staff' and that 'external experts from the BfR Committees merely advise BfR […] and were not involved at any stage in the re-assessment of the active substance glyphosate'."[11]

Why such secrecy? CEO said, "No reason was provided."[11]

Previous research by the journalist Stéphane Horel in collaboration with CEO found that almost 60% of experts sitting on EFSA's panels had direct or indirect links with industries regulated by the agency.[13] Horel's and CEO's 2013 report, "Unhappy meal: The European Food Safety Authority's independence problem", identified major loopholes in EFSA's independence policy and found that EFSA's rules for assessing its experts, implemented in 2012 after several conflicts of interest scandals, had failed to improve the situation.[14]

Since "Unhappy meal" was published, EFSA has revised its independence policy. However, CEO noted that "the worst problems remain".[15]

Continuity of personnel and closeness to industry creates conflicts of interest

Research by BUND shows how key people in the 2002 evaluation of glyphosate were still in place for the current re-evaluation, leading to a situation in which these individuals were effectively reviewing their own previous decisions in favour of glyphosate. BUND commented: "There is a potential conflict of interest here, since the revision of one's own assessment could jeopardize the credibility of the initial assessment. In addition, personnel continuity raises the question of whether a changed view of the active substance is possible or whether individual assessment criteria influence the entire assessment process."[4]

The details of these personnel continuity situations in different agencies are explored in this chapter.

Federal Office for Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, or BVL)

The BVL, founded in 2002, is responsible for the authorization of pesticides in Germany. It acts as coordinator in cases – including glyphosate – where Germany is the rapporteur member state for a pesticide "active substance". It controls the procedure and the partial evaluations of the other participating authorities, the Federal Institute for Risk Assessment (BfR), the Federal Environment Agency (UBA) and the Julius Kühn Institute (JKI).[4]

The BVL performs the tasks of the former Federal Biological Research Centre for Agriculture and Forestry (BBA). Today the BVL's department for plant protection products, which coordinates evaluations of active substances (including glyphosate), is the successor to the former BBA department for plant protection products. This results in a strong continuity of personnel who are central to the re-evaluation of glyphosate. The current Head of the Plant Protection Unit, Dr Martin Streloke, was involved in the first European approval procedure for glyphosate at both German and European level. His predecessor, Hans-Gerd Nolting, the BVL department head from 2002 to 2014, took part in the first approval procedure in the 1990s both as a BBA and as an ECCO employee.[4]

Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, or BfR)

The Federal Institute for Risk Assessment (BfR) is a scientific institution under the authority of the Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft, or BMEL). In addition to its statutory task of assessing the health risks of food and feedstuffs, consumer goods and chemicals, BfR also conducts its own research. In 2002 it became the most important successor of the Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV).[4]

In the re-evaluation procedure for glyphosate, BfR is responsible for the health assessment of the active substance. Since IARC classified glyphosate as "probably carcinogenic",[16] BfR's previous safety assessment of glyphosate in the 1990s has been publicly discussed – and questioned – in Germany.[17]

BfR's new safety assessment of glyphosate for the current evaluation has also been severely criticized. The German toxicologist and co-author of this report Dr Peter Clausing said that BfR – and the European Food Safety Authority (EFSA), which based its evaluation of glyphosate[2] on BfR's report[18, 1] – appear to have committed scientific fraud in order to force the conclusion that glyphosate is not a carcinogen.[17] Details of the scientific problems with BfR's report were presented in Chapter 4.

Personnel continuity at BfR

As with BVL, a high level of continuity of personnel in the evaluation procedure for glyphosate is found in BfR, according to BUND. Persons who have previously been responsible for assessment of glyphosate at BfR's predecessor in the 1990s are also currently responsible in the authority. This is the case for Roland Solecki, currently head of the "Safety of Pesticides" department responsible for the health assessment of glyphosate at BfR, as well as for Rudolf Pfeil, the head of the Toxicology Group of Active Substances and their Metabolites in Solecki's Division. Both were involved in the first European approval procedure for glyphosate in Germany and at the EU level as employees of the then Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV).[4]

BfR's closeness to industry

On its website, BfR gives detailed information on the internal handling of conflicts of interest. According to the agency, the "independence of the experts from economic, political and social interests is a fundamental prerequisite for an objective, purely scientific fact-based risk assessment."[19]

In order to ensure this independence, additional activities must be reported by the employees to the BfR and "are subject to authorization by the authorities in accordance with the relevant legal provisions". If an activity leads to a conflict of interests, BfR states that the employee must refrain from the activity.[19]

However, according to BUND, BfR does not consistently implement this policy: "Our research has shown that Roland Solecki has worked with industry representatives for years and until at least 2015. In 2006, an influential publication by the ILSI Health and Environmental Sciences Institute (HESI) was published, in which Solecki was named as co-author.[20] The publication is about simplifying testing procedures for pesticides. Other authors include representatives of all the major agricultural and genetic engineering companies (BASF, Bayer CropScience, Dow, DuPont, Monsanto, and Syngenta) and industry scientists."[4]

Solecki was a workshop leader at an event organized by the European Center for Ecotoxicology and Toxicology of Chemicals (ECETOC).[21] ECETOC is an association of chemical, agricultural and oil companies,[22] where industrial scientists develop (among other activities) toxicological concepts for the evaluation of chemicals.[23]

Solecki was also a member of the Risk21 technical committee of ILSI HESI until at least 2014.[24] This industry-financed project aims to develop new procedures for the risk assessment of chemicals.[25] ILSI HESI was specifically designed to represent "such firms and corporations that are within or suppliers to the chemical, petrochemical, automobile and pharmaceutical industries".[26]

Also present on the ILSI HESI technical committee on which Solecki served are scientists from Monsanto, Syngenta and Dow Chemical[24] – representatives of companies that are applying to have glyphosate re-approved, the records of which have been evaluated by Roland Solecki's department.

BUND commented: "There is a clear conflict of interest in the fact that a leading public agency responsible for the independent assessment of company records is cooperating with representatives of the companies submitting these documents on new methods for verifying pesticide risks. The fact that BfR permits this cooperation is unacceptable and is in breach of its own internal rules for the prevention of conflicts of interest. Solecki has also been a member of the Scientific Committee of the European Food Safety Authority (EFSA) since 2015. In his conflict of interest statement for EFSA, his involvement with ILSI HESI does not appear."[27]

The question arises as to whether BfR's ability to fulfill its legal mandate is not only hampered by its institutional conflicts of interest – but also by the obviously strong personal conflict of interest of the head of its pesticide department.

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JMPR is not independent of BfR

Since the evaluation of glyphosate as a probable carcinogen by IARC,[16] BfR has substantiated its own safety assessment by referring to other European or international bodies which have also classified glyphosate as non-carcinogenic.[28] Among them is the joint working group of the WHO and the World Food Organization FAO, the Joint Meeting on Pesticide Residues (JMPR), which concluded that glyphosate is "unlikely to pose a carcinogenic risk to humans from exposure through the diet".[29]

JMPR has a history of performing glyphosate assessments that are favourable to industry. In 1986, just one year after the US EPA had classified glyphosate as a possible human carcinogen, JMPR also performed a cancer assessment and concluded, "There is no evidence of carcinogenicity."[30]

Research by BUND[4] found that BfR representatives have been sitting for years in the JMPR – and even wrote JMPR assessment reports on glyphosate. This was the case for the 2004 JMPR report setting limits for the acceptable daily intake of glyphosate, in which it was classified as non-carcinogenic. The report was drafted for the JMPR by two BfR employees, Rudolf Pfeil and Lars Niemann.[31] Among the JMPR members who adopted the report were the BfR staff members Roland Solecki and Ursula Banasiak, former head of BfR's chemical safety department and Solecki's predecessor.[32] Also participating in a second JMPR report on glyphosate and its degradation product AMPA in 2011 (evaluation: glyphosate has no toxic effects)[33] was Rudolf Pfeil of BfR.[34] Roland Solecki and Ursula Banasiak of the BfR participated in the report as JMPR experts.[33]

BUND commented, "If the BfR calls the JMPR an institution independent of the BfR, this is partly misleading." The NGO added that the two organizations are interdependent, due to the fact that "the same persons in national and international committees repeatedly confirm their own judgment".[4]

Interestingly, in the middle of September 2015, an expert task force of the WHO found that the JMPR had failed to consider "many studies, mainly from the published peer reviewed scientific literature" in its assessment.[35, 36] The task force's remit was to clarify how different assessments could be made within the WHO regarding the carcinogenicity of glyphosate, with the JMPR concluding that it was unlikely to pose a carcinogenic risk through diet and the IARC concluding that it was probably carcinogenic.

The head of the task force was (remarkably) BfR department head Roland Solecki, according to an email from Dr Philippe Verger MD, PhD, Department of Food Safety and Zoonoses, World Health Organization, sent to the WHO to the freelance researcher Almut Gaude.[37] The task force's recommendations to the JMPR in-

cluded (again remarkably) a complete re-evaluation of glyphosate, as well as revision of its previous guidelines on the inclusion of independent studies.[35] BUND called the task force's findings "a serious admission of a huge blind spot in the evaluation process for glyphosate".[4]

However, there is no sign that the task force's highly critical advice is being taken on board by the JMPR.

JMPR chair and co-chair in conflict of interest scandal

Soon after the JMPR published its opinion that glyphosate is "unlikely to pose a carcinogenic risk to humans from exposure through the diet",[29] it became embroiled in a bitter row about conflicts of interest. It emerged that 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's 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.[38]

Alan Boobis said: "My role in ILSI (and two of its branches) is as a public sector member and chair of their boards of trustees, positions which are not remunerated. The boards of trustees are responsible for oversight of the organisations and their scientific programmes."[38]

But even if Boobis received no money for his ILSI work, it still represents a conflict of interest since ILSI is an industry-funded organization that promotes industry-friendly methods of risk assessment.[39]

This news sparked furious condemnation from green MEPs and NGOs, intensified by the report's release two days before an EU relicensing vote on glyphosate, which was worth billions of dollars to industry.[38] As it happened, a qualified majority was not reached in the vote and the Commission intervened, granting its temporary licence to keep glyphosate on the market, without the support of a majority of EU countries, pending the decision of ECHA on the chemical's carcinogenicity.[40]

In a previous conflicts of interest scandal, Boobis refused to leave ILSI in 2012 and as a consequence could not be reappointed to an expert panel at EFSA. And Moretto had to resign from EFSA's pesticides panel in 2011 after it was found he had omitted to declare his interests at ILSI.[41]

In spite of this latter development, in February 2017 it emerged that Moretto is a member of a key European committee that is responsible for setting limits for workers' exposure to carcinogenic substances, the Scientific Committee on Occupational Exposure Limits (SCOEL).[42, 43] During the EFSA conflict of interest episode of 2011, Moretto had failed to declare his ownership of 17% of a toxicology consulting firm he co-founded, Melete. He still had 10% of these shares when he was nominated a member of the SCOEL in May 2015, but the Commission did not find these conflicts of interest problematic.[43] In fact an investigation by the journalist Stéphane Horel for the French newspaper Le Monde found that the majority of the SCOEL's experts (15 out of 22) have links with industrial sectors directly involved with substances evaluated by the committee.[43]

Of the sixteen collaborations with industry that Moretto declared in the context of his SCOEL role, half consisted of expert witness opinions in the context of lawsuits. In other words, industries used the services of Moretto to defend themselves in court against their own employees, in cases that were often brought by people who were close to the victims when they died. Such cases were brought to claim compensation for diseases related to victims' exposure to asbestos, benzene, and other chemicals.[43]

Questions over US EPA collusion with Monsanto over glyphosate

In May 2016 Monsanto gained support for its claims that glyphosate is non-carcinogenic when the US Environmental Protection Agency (EPA) briefly published a document from its Cancer Assessment Review Committee (CARC)

stating that glyphosate was "not likely carcinogenic" before removing it. The agency said that the document had been published in error prior to finishing its review of the chemical.[3]

However, the leaked document had an effect: it was cited by Monsanto as evidence that the IARC classification of glyphosate as a probable carcinogen was flawed.[44]

In February 2017 a new court filing made on behalf of dozens of people claiming that Monsanto's glyphosate herbicide gave them cancer included information about alleged efforts within the US Environmental Protection Agency (EPA) to protect Monsanto's interests and unfairly aid the agrichemical industry.[44]

The filing included what the attorneys represented to be correspondence from Marion Copley, a 30-year career EPA scientist, accusing top-ranking EPA official Jess Rowland of playing "your political conniving games with the science" to favour pesticide manufacturers such as Monsanto.[44]

Rowland oversaw the EPA's cancer assessment for glyphosate and was a key author of a report finding glyphosate was not likely to be carcinogenic. But in the correspondence, longtime EPA toxicologist Marion Copley cited evidence from animal studies and writes: "It is essentially certain that glyphosate causes cancer." Copley accused Rowland of having "intimidated staff" to change reports to favour industry.[44]

The plaintiffs, all of whom are suffering from non-Hodgkin lymphoma (NHL) or have lost a loved one to NHL, asserted in court filings that Monsanto wielded significant influence within the EPA's Office of Pesticide Programs (OPP) and had close ties specifically to Rowland, who until 2016 was deputy division director within the health effects division of the OPP.[44]

Rowland managed the work of scientists who assessed the health effects of exposures to pesticides like glyphosate and he chaired the EPA's Cancer Assessment Review Committee (CARC) that in 2016 determined that glyphosate was not likely to be carcinogenic to humans. Rowland left the EPA in the same year, shortly after the CARC report was leaked.[44]

Political and commercial interference with science at US EPA

If the authenticity of Copley's correspondence is verified, it will be just the latest episode in a long history of political and commercial interference in science at the EPA. In a survey carried out by the Union of Concerned Scientists, hundreds of current and former EPA scientists reported political interference in their work, significant barriers to the free communication of scientific results, and concerns about the agency's effectiveness. Out of 1,586 scientists who responded to the survey:

- 7% said they had frequently or occasionally been "directed to inappropriately exclude or alter technical information from an EPA scientific document"
- 16% had personally experienced frequent or occasional "situations in which scientists have actively objected to, resigned from, or removed themselves from a project because of pressure to change scientific findings"
- 18% had personally experienced frequent or occasional "changes or edits during review that change the meaning of scientific findings."
- 22% had personally experienced frequent or occasional "selective or incomplete use of data to justify a specific regulatory outcome"
- 43% knew of "many or some" cases where EPA political appointees had inappropriately involved themselves in scientific decisions
- 42% knew of "many or some" cases where "commercial interests have inappropriately induced the reversal or withdrawal of EPA scientific conclusions or decisions through political intervention."[45]

Such interference undermines the role of science in regulatory decision-making.

IARC: Strict policy on conflicts of interest

In contrast with organizations that have issued reassuring verdicts on glyphosate's safety, IARC has a strict policy of excluding experts with conflicts of interest from its decision-making processes. It states, "Working Group Members are selected on the basis of (a) knowledge and experience and (b) absence of real or apparent conflicts of interests."[46]

While it has been alleged that IARC's glyphosate evaluation was marred by a conflict of interest,[47] the allegations are unconvincing and largely emanate from industry-linked sources.[48] They will be dealt with more fully in a subsequent report in this series.

Conclusion

Glyphosate's previous and current evaluations in Europe have been marred by conflicts of interest and a lack of transparency. As the "rapporteur" member state for glyphosate, the German authorities were responsible for assessing the industry safety studies on the chemical and forwarding their report to the relevant EU authorities.

The initial EU approval in 2002 was compromised by conflicts of interest among people serving in the regulatory authorities of Germany, leading to institutional conflicts of interest on the part of these authorities.

One important type of conflict of interest is the closeness to industry of the various regulatory authorities involved in the glyphosate approval.

One authority, the BBA, has collaborated with agrochemical companies on the development of commercial products and on applications for patents on products. Another authority, BVL, considers itself a "service provider" to industry in pesticide applications. Strong conflicts of interest with industry are also found in individuals within the authorities, such as Roland Solecki, who is currently head of the "Safety of Pesticides" department responsible for the health assessment of glyphosate in BfR and who has worked with industry representatives for years.

Some committee members served double roles in different committees, leading to a situation where they reviewed their own previous decisions on glyphosate. Also, some officials currently serving in the German authorities responsible for the current evaluation of glyphosate were also involved in the 2002 evaluation, resulting in a strong continuity of personnel who are central to the re-evaluation of glyphosate.

Such double roles of committee members constitute a clear conflict of interest, as employees of these agencies are highly unlikely to contradict and invalidate their own previous decision.

The current evaluation of glyphosate has been marked by a lack of transparency. Over 80% of the national experts involved in EFSA's assessment of glyphosate refused to have their names disclosed to the public, so any conflicts of interest are effectively being hidden.

The overlapping of staff between different regulatory and expert bodies means that independent scrutiny of the decisions of these bodies is lacking. BfR has claimed support for its claim that glyphosate is not carcinogenic from an apparently separate expert body, the JMPR. Yet BfR representatives have been sitting for years in the JMPR – and have even written JMPR assessment reports on glyphosate. This places in question the independence of both bodies in their assessments of glyphosate.

We conclude that the bad scientific practices of the regulatory and expert bodies as detailed in the previous chapter are strongly correlated with conflicts of interest.

Conclusion and recommendations

In 2009 a new regulation was passed in Europe that required industry to include studies from the peer-reviewed scientific literature in the dossiers submitted in support of pesticide approvals.

Taken together with studies from industry, many of these studies link glyphosate and its commercial formulations with harmful effects, including carcinogenicity and genotoxicity. As the new pesticide regulation includes hazard cut-off criteria for carcinogenic and genotoxic pesticides, a proper evaluation of the science would necessarily lead to glyphosate being banned in Europe.

The onslaught of scientific articles showing problems with glyphosate reached a peak in 2015 with the publication of a report by IARC, the World Health Organization's cancer agency, classifying glyphosate as a probable carcinogen and pointing to evidence that it is genotoxic.

Monsanto and other companies have countered such developments by financing and supporting the publication of scientific reviews in peer-reviewed journals. These include what we call the "Intertek papers", which were sponsored by Monsanto via the industry consultancy Intertek and were published in 2016. These reviews reach the reassuring conclusions that glyphosate and its commercial formulations are non-carcinogenic and do not pose other serious health risks.

Many of the authors of these reviews had conflicts of interest with industry or industry-linked bodies. Some have strong links to the International Life Sciences Institute (ILSI), an organization funded by industry, including companies that manufacture and/or market glyphosate herbicides, such as Monsanto, Dow, and BASF. ILSI specializes in developing and promoting industry-friendly concepts and methods of testing and risk assessment.

While some might argue that such conflicts of interest do not matter as long as the scientific quality of the publications is sound, we found that the reviews suffer from serious scientific shortcomings. For example, they utilize manipulations such as apparently calculated omissions, misrepresentation of facts, and the introduction of irrelevant data to confuse the picture and deny the scientific evidence of glyphosate's harmful effects.

These authors claim to have used a "weight of evidence" approach to assess whether glyphosate is carcinogenic or not. However, in reality they avoid a true weight of evidence approach, which would take a holistic view on the different lines of evidence. These different lines of evidence are:

- The results of animal studies
- The outcome of epidemiological data
- Considerations of 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.

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, while claiming to strengthen their arguments.

Monsanto and other pesticide companies gained support for their contention that glyphosate does not cause cancer from 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), which in May 2016 published a document on its website stating that glyphosate was "not likely

carcinogenic" before removing it, saying it had been published in error prior to the agency's completing its assessment.

However, reports on glyphosate issued by these bodies are marred by serious conflicts of interest, dating back to the time of the chemical's first European approval and before. These conflicts of interest have been accompanied by bad scientific practices in these bodies' reports claiming that glyphosate is safe. For example, BfR admitted statistically significant increases in tumours in glyphosate-treated animals in five mouse and two rat studies – but then claimed that only a "sole" study had shown such increases. Also, BfR separated out the various lines of evidence of glyphosate's carcinogenicity in order to deny them individually, rather than evaluating the evidence as a whole. When the whole picture is considered, evidence of glyphosate's carcinogenicity becomes clear.

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.

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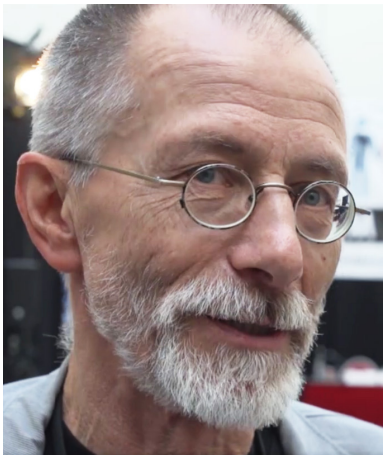

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