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Editors

The Role of Integrity in the Governance of the Commons

Governance, Ecology, Law, Ethics

 Springer

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Ethics and Pesticides: The Precautionary Principle as Illustrated by Glyphosate

Josef Unterweger

In the course of the approval process for glyphosate eight European environmental organisations—GLOBAL 2000 (Austria), Nature & Progrès Belgique (Belgium), Générations Futures (France), Pesticide Action Network UK, Pesticide Action Network Europe, Pesticide Action Network Germany, WeMove Europe, Umweltinstitut München (Germany)—filed a complaint against Monsanto, the German Federal Institute for Risk Assessment or BfR, and the EFSA, the European Food Safety Authority.

The following looks at the approval procedure for pesticides in the European Union, with the application for approval of glyphosate as an example.

The first part will cover glyphosate, the main pesticide manufacturers that produce it, and the European Union's approval procedures. The second will highlight the timeline of the approval procedure and the various steps taken by the environmental organisations during this procedure.

After that, there will be an insight into the reasons for the complaints and their consequences. This will be followed by a brief résumé.

Glyphosate¹ is known under a number of different brand names, but the most familiar is Roundup. Glyphosate is used all over the world as a weed killer in agriculture, horticulture, industry, and also by private households. It is a broad-spectrum herbicide. In other words it is an herbicide that kills various plant varieties. Glyphosate is non-selective in terms of the plants it affects. Crop plants can be genetically engineered to make them glyphosate-resistant. In these cases glyphosate is used to protect the genetically modified plant, while all other plants are killed off. For years glyphosate has been the most widely used ingredient in

¹<https://en.wikipedia.org/wiki/Glyphosate>.

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herbicides worldwide. In 2014 around 720,000 tonnes of glyphosate were used globally. In Germany, the figure was around 6000 tonnes.²

Monsanto patented glyphosate in 1970 and is one of the world's leading producers of the chemical. The company also has patents for genetically modified glyphosate-resistant plants such as Roundup Ready soybeans and Roundup Ready rape. Glyphosate accounts for around 40% of Monsanto's revenue in Germany.³ In 2011 the company recorded a net profit of 1.6 billion dollars on revenues of 11.8 billion dollars. Around 27% of its revenue comes from herbicide production and sales.⁴

Critical journalists have called Monsanto one of the biggest polluters in industrial history, pointing to a remarkable string of scandals and a number of convictions. Monsanto's history is tied to the sweetener aspartame, polychlorinated biphenyl or PCB, contamination of the area surrounding the Monsanto plants in Anniston in Alabama, the production and distribution of Agent Orange, the chemical spill at Times Beach, Missouri, the bovine growth hormone Posilac, and the production and patenting of genetically modified plants. The company's history is also dotted with accusations of manipulation and corruption, some of which ultimately led to court convictions. Scientists report being pressured after publishing unfavourable papers.

A decisive point in this context is that some studies of glyphosate commissioned by Monsanto resulted in convictions for scientific fraud. For example, Industrial Biotest Laboratories (IBT Labs), which was contracted by Monsanto among others to conduct studies of glyphosate, was closed down by the US Justice Department in 1978.⁵

²Since 1970 when Monsanto the US chemical company filed their patent for the original Roundup herbicide, it has been a wholesale success all over the world. During the past year more than 720,000 tonnes were used worldwide, more than any other herbicide. 6000 tonnes ended up on fields in Germany—for weed control in grain and corn cultivation as well as in vineyards and orchards. To make matters worse, the Germany Railway system uses the herbicide to clear undesirable plants from their tracks (see article July 15, 2015). <http://www.welt.de/wirtschaft/article144015187/Wie-gefaehrlich-ist-C3H8NO5P-wirklich.html>. <http://www.wallstreet-online.de/nachricht/6561010-global-glyphosate-market-is-expected-to-reach-usd-8-79-billion-by-2019-transparency-market-research>.

³junge welt 1/06/2016/Topic/p. 12. Profitable Herbicide: Worldwide Glyphosate is used more and more. The authorities seem unconcerned that experts have announced that the herbicide is »probably carcinogenic “Peter Clausing”. Glyphosate plays a threefold key role: First the chemical is extremely significant for herbicide producers—in Germany alone 40 per cent of Monsanto's sales are due to the sale of herbicides containing Glyphosate. <https://www.jungewelt.de/2016/01-16/054.php?sstr=glyphosat>.

⁴During the 2011 business year Monsanto turned over 11.8 billion US \$, a net gain of 1.6 billion US-\$. The *Agricultural Productivity* division produces herbicides for agriculture, industry, public maintenance, homes and gardens and accounted for 27% of turnover. The best known product of this division is the broad-spectrum herbicide Roundup. <https://de.wikipedia.org/wiki/Monsanto>.

⁵Marshall, E. (1983) “The murky world of toxicity testing”, *Science*. 220 (4602): 1130 – 1132. doi:10.1126/science.6857237, PMID 6857237; Schneider, Keith, “IBT – Guilty” Winter 1983. *Amicus Journal*. Planetwaves.net; Schneider, Keith “Faking it: The Case against Industrial Bio-Test Laboratories”, *Amicus Journal*, Spring 1983; https://en.wikipedia.org/wiki/Monsanto_legal_cases#Roundup.

In 1991 the owners of Craven Laboratories were indicted and convicted. Monsanto explained that the glyphosate studies concerned had been repeated, and that EPA certification of Roundup was no longer based on the studies conducted by Craven Laboratories and IBT Labs.⁶

The European Union's approval procedure is set up in such a way that approval of a pesticide in one member state is valid in all of the other EU countries. Pesticide producers are free to choose the member state to which they submit an application for approval. This means that the manufacturers can basically select any regulatory authority. They can also specify that the application documents remain confidential.

Applicants must provide evidence that their pesticide is not carcinogenic. According to Regulation EC number 1272/2008 a substance is classified as carcinogenic if at least two studies produce positive results.

EC Regulation number 1107/2009 establishes the precautionary principle and a high level of protection.⁷

Recital 8 of the Regulation reads as follows: The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.

These objectives are reinforced by recital 24 of the same Regulation: The provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production. Therefore, it should be demonstrated, before plant protection products are placed on the market, that they present a clear benefit for plant production and do not have any harmful effect on human or

⁶EPA FY1994 Enforcement and Compliance Assurance Accomplishments Report (PDF). United States Environmental Protection Agency; https://en.wikipedia.org/wiki/Craven_Laboratories.

⁷Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC; <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02009R1107-20140630&qid=1475740883425&from=EN>.

Plant protection products may only be authorised if: "industry demonstrates that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment". (Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC und 91/414/EEC, recital 8). "The provisions governing authorisation must ensure a high standard of protection. In particular, when granting authorisations of plant protection products, the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production". (Regulation (EU) No 1107/2009, recital 24).

animal health, including that of vulnerable groups, or any unacceptable effects on the environment.

If the regulatory authority confirms that the requirements for approval have been met, its decision is reviewed by the EFSA and then passed on, together with a draft decision, to the relevant committees of the member states, which then make a final decision. Thus the member states take the decision on approval, and if they cannot agree, the EU Commission takes responsibility.

In order to secure an extension of the authorisation, in May 2012 Monsanto submitted an application to the BfR, which had originally approved the substance in 2002 on behalf of a number of glyphosate producers and retailers. The current BfR president, Professor Andreas Hensel, was involved in the authorisation process. In its draft assessment report published at the end of 2013, the BfR had classified glyphosate as non-carcinogenic. Then, on 20 January 2014 the BfR stated that there were no indications that glyphosate was carcinogenic, toxic to reproduction or embryotoxic, adding that "there was no evidence of carcinogenicity up to the highest dose level".

In a press release published on 20 January 2014 the BfR explained: "In addition to the documents already incorporated in the first test series of active ingredients, more than a thousand new studies were examined and evaluated. These new studies do not suggest that glyphosate has carcinogenic or embryo-damaging properties or that it is toxic to reproduction in test animals. The data do not warrant any significant changes in the limit values of the active ingredient, says Professor Dr. Dr. Andreas Hensel".

On 20 March 2015 the International Agency for Research on Cancer or IARC, part of the WHO, the World Health Organisation, classified glyphosate as "probably carcinogenic to humans".

On 31 March 2015 the BfR published its final assessment report in which it contradicted its original finding that there was "no evidence of carcinogenicity" and noted a slight increase in the occurrence of tumours. However, it pointed out that the "slight increase in the incidence of malignant lymphoma" this was "not statistically significant". No reasoning was given to back up this conclusion.

The IARC commissioned some of the world's top scientists to evaluate glyphosate—the world's most widely used pesticide. The evaluation was performed by scientists who have already published research into glyphosate and other pesticides, and who are recognised in scientific circles as experts on this substance. The finding that glyphosate is probably carcinogenic to humans reflects a consensus among the scientists involved. The statement of 20 March 2015 classifying glyphosate as "probably carcinogenic to humans" was included in an IARC monograph published in July of last year.

Of the five studies on mice that the BfR deemed to have produced negative results in its interim report, two were examined by the IARC, and the Agency's monograph states that the studies provided sufficient evidence for carcinogenicity. In response the BfR released an addendum to its final assessment report on the pesticide on 31 August 2015. However, in the addendum the BfR concluded that there was a "dose-dependent, statistically significant increase" in malignant lymphoma. The

BfR explained that it had relied on industry data submitted by Monsanto in its findings. The Institute also said that the discrepancy between the opinions of the IARC and the BfR was down to data supplied by the glyphosate industry, adding that the statistical analyses of the industry and the IARC were both appropriate. At the same time, the BfR declared that the studies on which the IARC based its findings—all of which had been peer-reviewed and published—were “not reliable”. Therefore the Institute concluded that glyphosate was not carcinogenic.

On 12 November 2015 the EFSA also classified glyphosate as non-carcinogenic, and as a result recommended its continued use in the European Union for the next 15 years.

A few days later, on 27 November Professor Christopher J. Portier sent an open letter to the EU’s Health and Food Safety Commissioner Vytenis Andriukaitis, who is ultimately responsible for the approval of glyphosate. In his letter Professor Portier made serious accusations against the BfR and the subsequent evaluation by the EFSA. In a nutshell, the letter condemned the BfR’s risk assessment as “scientifically unacceptable”, “fundamentally flawed” and “misleading”. In his open letter, Professor Christopher J. Portier and the co-signatories made serious accusations against the BfR and the subsequent evaluation by the EFSA. The authors explained that “the BfR decision is not credible because it is not supported by the evidence”, adding that the BfR’s conclusions were misleading, as was its language, which in turn was not internationally acceptable and as a result failed to meet EU Guidelines.

Professor Portier continued that “it is clear that BfR differed from standard scientific practices in order to reach their conclusions”. He also accused the Institute of inappropriate use of historical data. The scientists concluded that the studies “in fact document the carcinogenicity of glyphosate”.

A further accusation was that the BfR used testing guidelines to exclude substantive scientific evidence from its cancer risk assessment and also ignored OECD guidelines. The arguments put forward by the BfR were found to be “fundamentally and scientifically flawed”. Furthermore, according to Professor Portier, the evaluations carried out by the BfR and the EFSA did not reflect the available science.

The BfR—the regulatory authority selected by the pesticide industry and pesticide producers—gradually changed its assessment of the studies submitted by the applicants. The original finding was that “there was no evidence of carcinogenicity up to the highest dose level” was replaced by a “slight, but statistically insignificant increase in the incidence of malignant lymphoma” and ultimately “a statistically significant increase in malignant lymphoma that could be seen as treatment-related”. In spite of this opinion, the BfR stood by its finding that there were no indications of carcinogenicity.

In justifying these discrepancies and corrections, the BfR pointed out that it had originally based its assessment on statistical analyses and data provided by the glyphosate industry. The EFSA accepted BfR’s incorrect assessment without hesitation.

GLOBAL 2000 asked toxicologist Peter Clausing and epidemiologist Eberhard Greiser to prepare an expert opinion on the evaluation of the studies submitted by the glyphosate industry. Mr. Clausing and Mr. Greiser confirmed the accusations made in the open letter. They found that in the approval application, the industry claimed that there were no indications of carcinogenicity. However, the studies that accompanied the application, which were intended to prove that glyphosate was harmless, actually showed a rising incidence of tumours at increasing dosages of the substance. It further emerged that the application for extension of the approval was based on animal studies that had not been properly or professionally evaluated and interpreted. As a result, significant carcinogenic effects that appeared in all five of the studies submitted by the industry were concealed.

Regulation 1272/2008⁸ states that carcinogenic pesticides must not be approved for use in the European Union. A substance is classified as carcinogenic if at least two studies produce positive results for cancer. The approval application submitted by the glyphosate industry was based on five studies of carcinogenicity in laboratory mice. In all five, tumours developed in the kidneys, blood veins or lymph glands.

Monsanto has been linked with scientific fraud and falsification of studies several times. It even has a number of convictions in connection with studies of glyphosate. Although it was aware of these circumstances, the BfR accepted the data and conclusions provided by the glyphosate industry in the approval application without the necessary review. The Institute only reviewed the cancer studies submitted by Monsanto after the IARC had classified glyphosate as probably carcinogenic to humans.

In spite of these results, the BfR did not withhold approval, but instead continued to adopt the position put forward by the pesticide industry. After the open letter had indicated yet again that incorrect conclusions had been reached, and statistically significant carcinogenic effects had been obscured, the BfR not only revised the obviously incorrect findings, it also ruled in favour of extending the authorisation for glyphosate when this clearly ran counter to the facts.

In spite of the evidence of shortcomings in the BfR's assessment, EFSA accepted their arguments and conclusions and contradicted the available study results by announcing that glyphosate was not carcinogenic. EFSA recommended its continued use in the European Union for 15 years. It is unusual for complaints to be filed against public bodies such as the BfR, and its unusual nature will be shown a little later.

On 2 March 2016 GLOBAL 2000 and seven other environmental organisations filed complaints against Monsanto on, which had overall responsibility for the glyphosate

⁸Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance), 3.6. Carcinogenicity; <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1475741055994&uri=CELEX:02008R1272-20160401>.

approval application, and against the BfR and the EFSA both in Austria⁹ and in Germany¹⁰. The complaints were based on suspicion of serious commercial fraud, because incorrect or falsified data had been used to generate profit, thus giving consumers and businesses the erroneous idea that the pesticide was not harmful to human and animal health or to the environment, as provided for in EC Regulation No. 110/2009.

The statement by the International Agency for Research on Cancer on 20 March 2015, the responses of the BfR, and Professor Christopher J. Portier's open letter to the EU Commissioner for Health and Food Safety, also signed by 96 renowned scientists, have brought to light a number of extremely suspicious circumstances. Expert opinions commissioned by the environmental organisations have confirmed and also strengthened these suspicions, as have the BfR's reactions, especially those of the Institute's president. The BfR president had made unilateral comments favouring the pesticide industry by stating: "Glyphosate has been used in agriculture for over 40 years and there has never been any serious evidence of damaging side-effects". In addition, his statement contained misleading advertising slogans used by Monsanto.

GLOBAL 2000 filed another complaint on 20 April 2016 after an expert opinion disproved the BfR's claims once again. The Vienna public prosecutor's office demanded that Monsanto respond to the complaint. Monsanto interceded and demanded to bar GLOBAL 2000 from access to the files. In March 2016 the prosecutor gave access to the files but revised this decision in July 2016. In October 2016 the prosecutor considered to investigate fraud and intended to nominate an expert witness. In November 2016 the prosecutor dismissed the complaint and refused to give grounds for the dismissal.

For 3 months the Berlin public prosecutor's office was unable to confirm receipt of the complaints, and in late June 2016 it stated that they had been passed on to the Düsseldorf public prosecutor's office for reasons of jurisdiction. The prosecutor decided more than 5 months after submission of the complaint to dismiss the complaint without investigation.

So what was the outcome of the environmental organisations' efforts? The vote by the EU member states on extending glyphosate's approval was postponed several times, and even a third vote on 6 June this year did not produce a qualified majority in favour of an extension. However, the European Commission has extended the approval for glyphosate until the end of 2017.

Several studies have shown that the serious accusations against the BfR and the EFSA made by Professor Christopher J. Portier in his open letter are correct. As a result of the complaints filed in Vienna, Monsanto will be obliged to respond to the accusations.

Another outcome was that in April 2016 the environmental organisations had problems finding a room for a press conference held after the initial complaint had been submitted. On three successive occasions, after revealing the subject of the

⁹Case Nr: Staatsanwaltschaft Wien 32 St 17/16z.

¹⁰Case Nr: Staatsanwaltschaft Düsseldorf 10 UJs 1993/16.

press conference, the organisations were refused access to rooms for which they had confirmed bookings.

A further outcome is that the European Union's approval procedures for pesticides could be overhauled. The goal should be to establish an independent EU-wide authority, a step that would end the "race to the bottom" among the national regulatory authorities. The approval process should be transparent and science-based, and should be subject to independent supervision. The public should also play a part in the process. Explaining the precautionary principle is not enough—it also needs to be applied.

At present, the BfR is taking decisions that may impact the health of 500,000,000 EU citizens and their children. Belgians, Hungarians, Italians, French and British will be affected by the BfR's decisions, but have no say in the matter. And that needs to change.

1 Addendum: "Salt"

The BfR responded swiftly to the complaints brought by the environmental organisations. A study by environmental associations found glyphosate residues in beer and foodstuffs, as well as in urine samples taken from a large number of people.

BfR president Andreas Hensel responded by saying: "Glyphosate has been used in agriculture for over 40 years and there has never been any serious evidence of damaging side-effects".¹¹ This comment was made on 12 March 2016—after the IARC had classified glyphosate as probably carcinogenic to humans and had published the corresponding monograph. Professor Christopher J. Portier's open letter to EU Commissioner Andriukaitis contained some serious accusations against the BfR.

Professor Hensel explained that "the lethal dose of glyphosate is comparable to that of table salt".¹² This statement is astonishing given that Monsanto used this comparison to advertise glyphosate in the US.

In 1996, the Attorney General of the State of New York Consumer Frauds and Protection Bureau and Environmental Protection Bureau instigated proceedings against Monsanto based on this and similar advertising slogans. That same year, Monsanto was obliged to cease and desist from making statements such as "Glyphosate is less toxic to rats than table salt following acute oral ingestion".¹³ "Pesticide

¹¹<http://www.spiegel.de/spiegel/vorab/behoerdenchef-wirft-umweltverbaenden-und-gruenen-panikmache-vor-a-1081815.html> (German only).

¹²<http://www.spiegel.de/spiegel/vorab/behoerdenchef-wirft-umweltverbaenden-und-gruenen-panikmache-vor-a-1081815.html> (German only).

¹³<http://www.mindfully.org/Pesticide/Monsanto-v-AGNYnov96.htm>; Attorney General of the State of New York. Consumer Frauds and Protection Bureau. Environmental Protection Bureau. 1996. In the matter of Monsanto Company, respondent. Assurance of discontinuance pursuant to executive law 63(15). New York, NY, Nov. False Advertising by Monsanto Regarding the Safety of Roundup Herbicide (Glyphosate).

products containing glyphosate or any component thereof are safe, non-toxic, harmless or free from risk” and “glyphosate-containing pesticide products or any component thereof are safer or less toxic than common consumer products other than herbicides”.

2 Addendum: “Unreliable Studies”—Professor Eberhart Greiser

In light of the criticism of the BfR sparked by Professor Portier’s open letter in November 2015, the environmental organisations asked German epidemiologist Professor Eberhart Greiser of the University of Bremen to provide an expert opinion on the way BfR dealt with human evidence. The BfR had dismissed numerous peer-reviewed studies as unreliable that had appeared in respected journals. The open letter described this as “fundamentally flawed”, “scientifically unacceptable” and “misleading”. Some of the studies were mentioned by the pesticide producers in the approval application, which alleged that they contained methodological errors, even though they were peer-reviewed. The BfR accused eighteen epidemiological studies of failing to collect the necessary information on the risk of disease. Professor Greiser looked into this accusation and concluded that all of the studies had been published in renowned medical journals and peer-reviewed. Three of the studies described as “inconclusive” by the BfR were carried out by the National Cancer Institute in the US. Professor Greiser found that all of the studies contained the requisite information on the risk of disease—the exact opposite of the BfR’s claims. While the BfR asserted that key data—such as exposure to glyphosate, smoking behaviour and previous illnesses—had not been collected, the review showed that all of this information had actually been compiled in detail, in line with the latest epidemiological methods.

In view of the statements made by the BfR and in particular by its president, as well as the scientists’ conclusions in the open letter, the environmental organisations filed a supplementary complaint with the Berlin public prosecutor’s office, because it had been shown that the BfR president had unilaterally made comments favouring the pesticide industry.

The BfR’s comments that studies on the health-related effects of glyphosate were “unreliable” and “irrelevant” were obviously off the mark. These comments were also only made in connection with studies that identified the health risks posed by glyphosate. The supplementary complaint was submitted in view of all of these facts.