

# *Glyphosate: The European Controversy – A Review of Civil Society Struggles and Regulatory Failures*

Peter CLAUSING\*

**Keywords:** accountability, EFSA, health protection, pesticides, regulation

## I. INTRODUCTION

Getting a pesticide banned often takes a long time, even if the evidence of its negative effects on health and the environment is strong and well-documented. Typically, such negative effects become obvious when the pesticide is widely used in large parts of the world. By that point, however, it is particularly difficult to achieve a ban on such a pesticide due to the powerful economic interests at stake. A prime example from the past of the protracted effort required to ban a pesticide is the case of the insecticide DDT, which was finally banned for agricultural use in various countries in the 1970s. A prime example from the present, meanwhile, is the herbicide glyphosate.

Glyphosate was first marketed in the mid-1970s and is currently the most widely used pesticide in the world with an annual global use of more than 800,000 tons.<sup>1</sup> A large share of glyphosate is marketed as a ‘package’ together with genetically modified seeds of glyphosate-resistant crops. Yet, even in countries without genetically modified crops, e.g., Germany, glyphosate is used extensively. In Germany, the annual use is above 5,000 tons,<sup>2</sup> representing approximately 12 per cent of the total amount of pesticides used in the country per year, while the remaining 88 per cent is divided between 250 different other compounds. Although the focus of this paper is on glyphosate in the European Union (EU), it should be kept in mind that in South America, glyphosate use per hectare is at least four times higher than in Europe.<sup>3</sup> At the same time, pesticide regulation is much weaker in South America compared with the EU.

The current European pesticide regulation – Regulation (EC) 1107/2009<sup>4</sup> – is commonly considered to be one of the most stringent regulations in the world. It resulted from a decade-

---

\* Pesticide Action Network Germany (PAN Germany), Nernstweg 32, 22765 Hamburg, Germany. Email: [peter.clausing@pan-germany.org](mailto:peter.clausing@pan-germany.org)

<sup>1</sup> Charles M Benbrook, ‘Trends in Glyphosate Herbicide Use in the United States and Globally’ (2016) 28:3 *Environmental Science Europe*.

<sup>2</sup> Schwarz et al, ‘Bewertung des Inlandsabsatzes von Pflanzenschutzmitteln im Ackerbau unter besonderer Berücksichtigung von Glyphosat’ (2014) 447 *Julius Kühn Archiv* 556.

<sup>3</sup> Daniel E Meyer and Christel Cederberg, *Pesticide Use and Glyphosate-Resistant Weeds – A Case Study of Brazilian Soybean Production*, SIK Rapport No. 809 (Göteborg: The Swedish Institute for Food and Biotechnology, 2010).

<sup>4</sup> EUR-Lex, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&from=EN> (accessed 30 October 2017); note that this legislation regulates the market approval of active ingredients (here: the chemical glyphosate), while the approval of formulated products (in case of glyphosate, for instance, Roundup) is regulated at the level of EU member states.

long legislative evolution, accompanied by civil society struggles for better protection of the environment and human health. The EU pesticide regulation has three special features:

- it recommends a precautionary approach be used in cases of scientific uncertainty;
- it requires that knowledge from existing scientific literature be considered in addition to studies submitted by industry actors; and
- it applies the so-called ‘hazard-based’ approach to certain health concerns, meaning that if a pesticide is knowingly or probably carcinogenic, mutagenic or harmful to the unborn child, it cannot be approved for marketing on principle, rendering any ‘risk assessment’ superfluous.<sup>5</sup>

The European pesticide regulation requires that each pesticide undergo review and reapproval every 10–15 years, taking into consideration new scientific knowledge. For glyphosate, this process lasted from May 2012 to November 2017. It started when the Glyphosate Task Force, a consortium of 26 chemical companies led by Monsanto, submitted their dossier for the reapproval of glyphosate to the reporting member state (RMS). The RMS (Germany) was responsible for preparing the Renewal Assessment Report (RAR), which forms the basis of a two-step decision-making process. First, the European Food Safety Authority (EFSA) and its (anonymous) experts, recruited from an approved pool of representatives from all EU member states, draw a conclusion on whether the pesticide in question can be recommended for reapproval. This is done after a public consultation on the RAR (in the case of glyphosate, performed in April/May 2014) and a peer review of the RAR performed by the experts. Thereafter, the Standing Committee for Plants, Animals, Food and Feed (SCoPAFF), a committee of the Directorate General for Health and Food Safety of the European Commission (DG SANTE), decides on the reapproval of the pesticide.

This paper analyses the regulatory background for a ban on the pesticide glyphosate as well as the EU authorities’ breach of their own rules and civil society’s struggle against this breach. It reviews the legal basis for prohibiting pesticides classified as ‘probable human carcinogens’ in the EU and shows how relevant EU authorities violated their own rules to keep glyphosate on the market. The article concludes with an assessment of civil society’s successes and disappointments in claiming the human right to health as related to glyphosate.

## II. THE GLYPHOSATE STRUGGLE

In essence, the struggle to ban glyphosate is about realizing the human right to ‘the highest attainable standard of physical and mental health’ by protecting people from exposure to dangerous substances through their food or environment.<sup>6</sup> A multitude of actors have a stake in this struggle, including public servants, legislators, the chemical industry, the agriculture industry (both conventional and organic), civil society, journalists, lawyers, prosecutors and judges. In contrast to other situations in which only civil society is at

---

<sup>5</sup> A ‘hazard’ is an intrinsic characteristic of a chemical (e.g., it is carcinogenic), whereas a ‘risk’ involves an assessment of the *likelihood* that this characteristic will affect human health.

<sup>6</sup> International Covenant on Economic, Social and Cultural Rights, Article 12.

loggerheads with profit-seeking corporations, the quarrel over glyphosate has a unique feature: a controversy between authorities. Although the EU regulatory authorities sided with industry in the opinion that glyphosate is harmless, a highly esteemed agency of the World Health Organization, the International Agency for Research on Cancer (IARC), classified glyphosate as a 'probable human carcinogen'. This became a main point of reference for glyphosate critics and had a significant impact on the pesticide's EU reapproval process.

While scientific reports on health and environmental problems caused by glyphosate frequently mention birth defects,<sup>7</sup> detrimental effects on biodiversity,<sup>8</sup> and chronic kidney failure,<sup>9</sup> the most important and best-documented effect is that of being a probable human carcinogen.<sup>10</sup> In March 2015, IARC announced its classification of glyphosate as a category 2a hazard on its scale of carcinogenicity, identical to category 1B in the EU system, further fuelling the existing public controversy over its safety and creating a serious obstacle for the pesticide's ongoing European reapproval process.<sup>11</sup> According to EU regulation 1107/2009, category 1B (presumed human hazard, based on evidence from animal studies) represents a cut-off criterion that prohibits the marketing of such a pesticide in principle. Following the announcement, industry actors boldly tried to discredit the IARC findings by calling their assessment 'junk science', while EU authorities confused the public by blurring the debate about 'risk' and 'hazard' (note: carcinogenicity category 1B makes a risk assessment superfluous). A growing number of scientific publications criticized the EU authorities' regulatory failure concerning glyphosate<sup>12</sup> and parliamentary hearings were convened on the topic in Berlin and Brussels. Meanwhile, a multi-layered civil society campaign challenged the EU authorities' position.

In summer 2015, under pressure from IARC's findings, the German Federal Institute for Risk Assessment (BfR) re-evaluated its own carcinogenicity assessment and had to admit that it had initially 'relied on the statistical evaluation provided with the [industry-produced] study reports' instead of making its own judgement.<sup>13</sup> In its original assessment, BfR had only acknowledged the increased incidence of one tumour type in a single study, which it considered an 'outlier' because no further increases seemed to exist in other studies. After a

---

<sup>7</sup> Michael Antoniou et al, 'Roundup and Birth Defects. Is the Public Being Kept in the Dark?' *Earth Open Source* (2011), <http://earthopensource.org/wp-content/uploads/RoundupandBirthDefectsv5.pdf> (accessed 30 October 2015); Monika Krüger et al, 'Detection of Glyphosate in Malformed Piglets' (2014) 4:5 *Journal of Environmental Analytics and Toxicology* 230.

<sup>8</sup> Umweltbundesamt, 'Glyphosat' (05 February 2016), <http://www.umweltbundesamt.de/themen/chemikalien/pflanzen-schutzmittel/glyphosat> (accessed 30 October 2015).

<sup>9</sup> Channa Jayasumana et al, 'Drinking Well Water and Occupational Exposure to Herbicides is Associated with Chronic Kidney Disease in Padavi-Sripura, Sri Lanka' (2015) 14:6 *Environmental Health* 1.

<sup>10</sup> IARC, 'Some Organophosphate Insecticides and Herbicides', 112 *IARC Monographs* (Lyon, France: World Health Organization, 2017).

<sup>11</sup> Kathryn Z Guyton et al, 'Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon, and Glyphosate' (2015) 16:5 *Lancet Oncology* 490.

<sup>12</sup> For example, Christopher J Portier et al, 'Differences in the Carcinogenic Evaluation of Glyphosate Between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)' (2016) 70:8 *Journal of Epidemiology and Community Health* 741.

<sup>13</sup> RMS Germany, 'Renewal Assessment Report Glyphosate', Addendum 1 to RAR, Assessment of IARC Monographs Volume 112 (2015): Glyphosate' (31 August 2015), [http://gmwatch.org/files/Renewal\\_Assessment\\_Report\\_Glyphosate\\_Addendum1\\_RAR.pdf](http://gmwatch.org/files/Renewal_Assessment_Report_Glyphosate_Addendum1_RAR.pdf) (accessed 30 October 2017).

re-evaluation of its own database, however, using IARC's preferred statistical method, BfR had to acknowledge that there were altogether 11 significantly increased tumour incidences in seven out of 12 studies instead of only one in a single study. Surprisingly, this result did not change the EU authorities' general conclusion that glyphosate lacks carcinogenic potential. They dismissed all of BfR's significant findings based on a 'weight of evidence' approach that, if applied properly according to the rules laid down in guidance documents, is a legitimate scientific procedure. However, the authorities' use of these rules as a benchmark for EFSA's assessment was heavily flawed,<sup>14</sup> a fact that was criticized as early as September 2015.<sup>15</sup> Consequently, an Austrian non-governmental organization (NGO), Global2000, together with other NGOs, filed a criminal complaint alleging scientific fraud against Monsanto, BfR and EFSA.<sup>16</sup> Regrettably, the case was not taken up by the legal authorities in the end, but it did serve as a tool for raising public awareness around this issue.

Concerning the reapproval of glyphosate, on 12 November 2015, EFSA published its conclusion stating that 'glyphosate did not present genotoxic potential and no evidence of carcinogenicity was observed in rats or mice'.<sup>17</sup> For industry actors, this was the ticket they had been waiting for, as it set them up to get the envisioned 15-year reapproval of glyphosate in the EU. From there, however, the ride did not go as smoothly as industry actors, BfR and EFSA had hoped.

The European Commission's proposal for a 15-year reapproval of glyphosate still needed the endorsement of SCoPAFF. However, between 8 March and 24 June 2016, SCoPAFF failed on three different occasions to reach a qualified majority on the issue.<sup>18</sup> Thereafter, DG SANTE of the European Commission could have made the decision on its own, but instead opted to extend the existing approval until the end of 2017, as a safety assessment of glyphosate by another European authority, the European Chemicals Agency (ECHA), was still pending. ECHA's task was to perform a hazard assessment according to Regulation (EC) 1272/2008.<sup>19</sup> On 15 June 2017, based on a similarly flawed 'weight of evidence' approach, ECHA announced the same conclusion as EFSA: that glyphosate does not pose a carcinogenic or mutagenic hazard.<sup>20</sup> This opinion was met with the same critique by NGOs as that voiced earlier in relation to EFSA's conclusion and triggered a fierce exchange of open letters between ECHA and the NGOs.<sup>21</sup>

---

<sup>14</sup> Peter Clausing, Claire Robinson and Helmut Burtscher-Schaden, 'Glyphosate and Cancer: Authorities Systematically Breach Regulations' (2018) *Journal of Epidemiology and Community Health*, EPub ahead of print.

<sup>15</sup> Peter Clausing, 'The Glyphosate Renewal Assessment Report. An Analysis of Gaps and Deficiencies' (2015), [http://www.pan-germany.org/download/Glyphosat-Studie\\_Campact\\_PAN\\_korrigiert.pdf](http://www.pan-germany.org/download/Glyphosat-Studie_Campact_PAN_korrigiert.pdf) (accessed 5 April 2018).

<sup>16</sup> Josef Unterweger, 'Statement of Facts' (2 March 2016), [https://www.welt-ernaehrung.de/wp-content/uploads/2017/10/Strafanzeige-Glyphosate-Berlin-160302\\_en.pdf](https://www.welt-ernaehrung.de/wp-content/uploads/2017/10/Strafanzeige-Glyphosate-Berlin-160302_en.pdf) (accessed 31 October 2017).

<sup>17</sup> EFSA, 'Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate' (2015) 13:11 *EFSA Journal* 4302.

<sup>18</sup> According to EU rules, a 'qualified' majority of member countries (i.e., more than 14 countries) representing at least 65 per cent of the population need to support the move.

<sup>19</sup> EUR-Lex, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R1272&from=EN> (accessed 30 October 2017); ECHA's assessment procedure is explained in Clausing, note 14.

<sup>20</sup> ECHA, 'Opinion Proposing Harmonised Classification and Labelling at EU Level of Glyphosate' (17 March 2017), <https://echa.europa.eu/documents/10162/2f8b5c7f-030f-5d3a-e87e-0262fb392f38> (accessed 4 April 2018).

<sup>21</sup> Clausing, note 14.

Towards the end of glyphosate's 18-month extension period, SCoPAFF was again charged with making the decision about the pesticide's future in the EU. In contrast to 2016, when SCoPAFF considered a proposal for the 15-year reapproval of glyphosate, on 27 November 2017, the decision finally taken by the body's appeal committee was to reauthorize glyphosate for a five-year period only.<sup>22</sup> Although the NGOs did not achieve their goal of banning glyphosate entirely in the EU, the significant reduction of its reapproval period to only five years still marks an important achievement. As a result, countries like France announced they would 'phase-out' glyphosate over the next few years.

### III. ASSESSMENT AND CONCLUSION

Banning glyphosate in the EU would contribute to protecting the human right to the highest attainable standard of physical and mental health, and would send an important signal to other countries where the herbicide's use is even more prevalent. Despite not achieving such a ban on glyphosate, however, the reduction of its potential 15-year EU reapproval to a much shorter re-authorization period of only five years still amounts to an important success. This outcome did not come about by itself, but was the result of a multi-faceted, Europe-wide campaign that can provide valuable lessons for similar efforts in the future.

While some campaign activities directly targeted corporations, such as the October 2016 Monsanto Tribunal held in Den Haag<sup>23</sup> and the criminal complaint mentioned earlier in this piece, most activities targeted the relevant EU authorities' insufficient transparency and lack of compliance with their own rules and guidance documents. IARC's 2015 report classifying glyphosate as a 'probable human carcinogen' and numerous NGO reports analysing various aspects of the EU authorities' failures and collusion with corporations were important points of reference for the campaign.<sup>24</sup> Several parliamentary hearings were conducted at the national and the European level, and an inquiry committee of the European Parliament did its work in 2018 looking into possible flaws to avoid them during the next reapproval process for glyphosate. Over the course of the campaign, such efforts were amplified by significant media coverage and a successful European Citizens Initiative that handed in more than one million validated signatures to the European Commission on 23 October 2017.<sup>25</sup>

Overall, it was the manifold and coordinated nature of civil society action that led to the campaign's substantial, even if incomplete, success in the case of this 'system-relevant' pesticide. While it is probably fair to say that civil society's efforts would have been less successful without IARC's competing and authoritative hazard assessment of glyphosate,

---

<sup>22</sup> European Commission, 'Summary Report of the Standing Committee on Plants, Animals, Food and Feed: Section Phytopharmaceuticals - Plant Protection Products - Legislation' (25 October 2017), [https://ec.europa.eu/food/sites/food/files/plant/docs/sc\\_phyto\\_20171025\\_pppl\\_summary.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20171025_pppl_summary.pdf) (accessed 31 October 2017).

<sup>23</sup> International Monsanto Tribunal, 'Tribunal', <http://www.monsanto-tribunal.org/How> (accessed 30 October 2017); Unterweger, note 16.

<sup>24</sup> Helmut Burtscher-Schaden, Peter Clausing and Claire Robinson, 'Glyphosate and Cancer: Buying Science' (March 2017), [http://www.pan-germany.org/download/Glyphosate\\_buying\\_science-EN.pdf](http://www.pan-germany.org/download/Glyphosate_buying_science-EN.pdf) (accessed 30 October 2017).

<sup>25</sup> Euractiv, 'More than 1.3 Million Demand EU Glyphosate Ban' (23 October 2017), <http://www.euractiv.com/section/agriculture-food/news/more-than-1-3-million-demand-eu-glyphosate-ban/> (accessed 30 October 2017).

the Agency's report would likely have been filed without much fanfare or impact had it not been for the 'sounding board' of civil society. Moreover, when assessing the role of civil society, it is important to recognize that it was not just the high number of NGOs participating in this campaign that made it so effective, but also the diversity of NGOs involved and acting in a coordinated and complementary fashion. This included:

- NGO networks with large memberships in different countries (e.g., Friends of the Earth) being able to fund expert opinions (e.g., on the BfR's plagiarism) and pay for lawyers (e.g., when filing the criminal complaint against BfR, EFSA and Monsanto);
- NGOs with offices in Brussels and other European capitals being well-positioned to convince parliamentarians and the media of the appropriateness of their stance;
- NGOs with sufficient expertise to participate in and sometimes even drive the scientific debate; and
- NGOs specialized in online campaigns, capable of mobilizing many citizens.

Notably, attempts to hold EU authorities directly accountable for dismissing their own standards in favour of industry preferences were unsuccessful. It was not legal decisions against the authorities, but public pressure that enabled the campaign's partial victory over commercial interests, for the benefit of human rights. Although accountability could not be legally enforced, the 'glyphosate battle' still shows the importance of clear, binding criteria as a reference for directing public pressure at companies and regulatory authorities alike.

In relation to glyphosate's reapproval, EU authorities either ignored or distorted recommendations and requirements laid down in their own guidance documents. This represents a 'soft form' of impunity compared with the situation in the Global South, where regulations similar to those in the EU often do not exist. Creating sufficient political pressure to enforce respect for laws, regulations and, ultimately, human rights, is an important issue in both parts of the world. Logically, access to highly visible media facilitates the creation of this political pressure. In the case of glyphosate in the EU, this was achieved in large part thanks to a broad coalition of actors supporting clearly defined demands. The joint and coordinated action of diverse NGOs enabled a 'non-linear' amplification of their impact and offers a promising example to others of how to promote a common cause.