



## **WP2 D.2.3 Glyphosate case study**

**Sabrina Röttger-Wirtz**



The RECIPES project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 824665

## Authors

Sabrina Röttger-Wirtz, Maastricht University

With thanks to:

Laura Drivdal, Rosanne Edlenbosch, Tijs Sikma, Jeroen van der Sluijs, Siebe Rozendal, Ellen Vos for their insightful comments on an earlier draft.

Manuscript completed in [April, 2020]

Document title	D.2.3. Glyphosate case study
Work Package	WP2
Document Type	Deliverable
Date	13 April 2020
Document Status	Final Draft

## Acknowledgments & Disclaimer

This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 824665.

Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the following information. The views expressed in this publication are the sole responsibility of the author and do not necessarily reflect the views of the European Commission.

Reproduction and translation for non-commercial purposes are authorised, provided the source is acknowledged and the publisher is given prior notice and sent a copy.

## Abstract

Glyphosate is the world's most widely used herbicides and the debates surrounding potential risks associated with it have dominated its recent re-approval in 2017 and will continue to play a role in the ongoing renewal procedure which was applied for in December 2019.

Paying attention to the risk assessment and risk management phase at EU level as well as the position of various stakeholders, this case study will analyse the role that the precautionary principle played in the EU procedures for the re-approval of glyphosate. It will also discuss how the application of the precautionary principle in this case interacts with innovation and especially the 'innovation principle' which is recently gaining traction in the EU discourse.

## Table of Contents

<b>1</b>	<b>Introduction</b>	<b>1</b>
1.1	Introduction	1
1.2	Key timeline	2
<b>2</b>	<b>Glyphosate</b>	<b>4</b>
<b>3</b>	<b>Risks and scientific uncertainties</b>	<b>6</b>
3.1	Risk/threat	6
3.1.1	Potential risks	6
3.2	Scientific analysis	9
3.3	Scientific uncertainty	11
3.3.1	Complexity	11
3.3.2	Uncertainty	12
3.3.3	3.3.3 Ambiguity	13
3.4	Relevance of the PP to the case	14
<b>4</b>	<b>Risk governance and the precautionary principle</b>	<b>15</b>
4.1	Political/juridical dynamics	15
4.2	Other governance dynamics	29
<b>5</b>	<b>The precautionary principle and its future</b>	<b>30</b>
5.1	Reflection on the PP in the literature	30
5.2	Effect of the PP on innovation pathways	33
5.3	Innovation principle	34
<b>6</b>	<b>Synthesis</b>	<b>35</b>
<b>7</b>	<b>Conclusion</b>	<b>36</b>
<b>8</b>	<b>References</b>	<b>38</b>
<b>9</b>	<b>Appendix</b>	<b>45</b>

## List of abbreviations

<b>ADI</b>	Acceptable Daily Intake
<b>AMPA</b>	Aminomethylphosphonic
<b>BfR</b>	Bundesinstitut für Risikobewertung /Federal Institute for Risk Assessment
<b>BEUC</b>	Bureau Européen des Unions de Consommateurs
<b>DAR</b>	Draft Assessment Report
<b>ECHA</b>	European Chemicals Agency
<b>EFSA</b>	European Food Safety Authority
<b>EU</b>	European Union
<b>ERF</b>	European Risk Forum
<b>GBH</b>	Glyphosate-based Herbicide
<b>GLP</b>	Good Laboratory Practice
<b>GMO</b>	Genetically Modified Organism
<b>IARC</b>	International Agency for Research on Cancer
<b>NFU</b>	National Farmers Union
<b>NGO</b>	Non-governmental organisation
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>PAFF</b>	Standing Committee on Plants, Animals, Food and Feed
<b>PEST</b>	Special Committee on Pesticides (PEST)
<b>PPP</b>	Plant Protection Product
<b>RMS</b>	Rapporteur Member State
<b>SAM</b>	Scientific Advice Mechanism
<b>WHO</b>	World Health Organisation
<b>WP</b>	Work Package

# 1 Introduction

## 1.1 Introduction

Glyphosate is used as active substance in herbicides (weedkillers) to control unwanted plants and is marketed since the 1970s. Because glyphosate is effective on a very broad range of weeds and not only kills the part of the plant above the surface, but also the plant tissues below the ground level, it quickly became a widely used pesticide in agriculture, landscaping, but also in private households. At the time of its introduction glyphosate was deemed relatively safe to use and even had environmental benefits, as it reduces the need for tillage, which has bad effects on the soil and releases CO<sup>2</sup>. However, increasingly scientific studies and reports of NGOs questioned the safety of glyphosate and glyphosate-based herbicides, raising concerns about risks to human health and the environment.

This case study will examine the complexities and controversies surrounding the application of the precautionary principle in the approval of the active substance glyphosate in the European Union. It will focus on the renewal of the approval of glyphosate as an active substance in pesticides in the EU, which took place between 2012 and 2017.

The renewal of its approval beginning in 2012 was disrupted when the International Agency for Research on Cancer (IARC) published a scientific monograph which presented grounds for concern of carcinogenic potential of glyphosate. Although the European Food Safety Authority, the European Chemicals Agency, as well as other regulatory bodies around the world did not classify glyphosate as carcinogenic, the renewal process was accompanied by public outrage and controversy. The debate concerned studies that have both proven and disproven carcinogenic effects. Additionally concerns arose whether glyphosate might act as endocrine disruptor. Moreover, recently also questions are raised if glyphosate poses unacceptable risks to habitats and biodiversity in farmlands and aquatic ecosystems, because it is non-selective and potentially harmful for a range of non-target organisms.

The glyphosate renewal procedure in 2017, after a long phase of risk assessment by the EFSA and ECHA and contestation through the Member States in the comitology committee, culminated in a renewal of the approval for 5 years. The risk governance in the renewal procedure as well as the legal framework for pesticides will be analysed in this case study, with a specific focus on the application of the precautionary principle.

The main goal of the research in this case study is to understand the complexities and controversies around the application of the precautionary principle in the case of glyphosate in the EU. Therefore, it will describe the specific context of the case study: legal and/or policy discussions (environmental, economic, risk policy), as well as social and cultural context. It will examine how precaution and innovation interact in the case of glyphosate and if they in tension. It will analyse how the risk properties of complexity, uncertainty and ambiguity add to this understanding, and how they been understood by stakeholders (legal, policy makers, risk community). And finally, it will research how glyphosate challenges the innovation/precaution juxtaposition.

## 1.2 Key timeline

Political	Legal	Science/risk assessment	Public debate	Other
Year	Event	Relevance to case study		
1950	Glyphosate creation	N-(phosphonomethyl) glycine, later called glyphosate, was first synthesised by Dr. Martin in Switzerland.		
1960s	Glyphosate sold to Monsanto	Glyphosate is sold by Dr Martin to the chemical company Aldrich in 1959 and resold to Monsanto in 1960.		
1970	Discovery of herbicidal properties	Glyphosate is discovered to be an herbicide by Monsanto chemist John E. Franz.		
1973/74	First marketing of Roundup	The first glyphosate based herbicide is marketed.		
1991	Adoption of Council Directive 91/414/EEC	Plant protection products are subjected to a harmonised authorisation procedures and a EU level approval of active substances.		
2002	Glyphosate approval	Adoption of Commission Directive 2001/99/EC. Glyphosate is now an approved active substance for plant protection products in the EU. Before it was authorised in the Member States via national procedures.		
2009	Adoption of Plant Protection Product Regulation 1107/2009	The legal framework for plant protection products is revised through the adoption of Regulation 1107/2009. Glyphosate remains approved and listed in Part A of the Annex of Commission Implementing Regulation (EU) 540/2011.		
2012	Start renewal of approval procedure	Submission renewal application by the Glyphosate Task Force. The regulatory procedure for the renewal of the approval starts.		
2013	Friends of the Earth briefings	The NGO Friends of the Earth publish briefings raising concerns about risks of glyphosate for human health and the environment.		
2013	BfR Renewal Assessment Report	The BfR concluded that 'glyphosate is devoid of genotoxic potential' and that 'classification and labelling for carcinogenicity is not warranted'.		
2015	IARC hazard assessment	The IARC classified glyphosate as 'probably carcinogenic to humans (Group 2A)', which in the evaluation scheme of the IARC means that there was 'limited evidence of cancer in humans' but 'sufficient evidence of cancer in animals'.		
2015	EFSA risk assessment	Glyphosate is 'unlikely to pose a carcinogenic hazard to humans'. EFSA concluded that glyphosate can be expected to meet the approval criteria.		

2016	European Resolution	Parliament	Referring to the precautionary principle the Parliament called on the Commission to limit the renewal to 7 years and asked for further limiting conditions.
2017	ECHA hazard assessment		ECHA concluded that glyphosate is not to be classified as carcinogenic, moreover it is not mutagenic and also does not disrupt reproduction.
2017	European Citizens Initiative		The European Commission received a European Citizens' Initiative which called for the Commission to ban glyphosate, to reform the regulatory framework for pesticides and to set reduction target for pesticide use.
2017	European Resolution	Parliament	The Parliament again referred to the precautionary principle and called for phasing out the use of glyphosate.
2017	Glyphosate renewal of approval		Approval glyphosate renewal through Commission Implementing Regulation (EU) 2017/2324.
2019	Start renewal of approval procedure		The Glyphosate Renewal Group submitted a renewal application for glyphosate. A new regulatory procedure for the approval has started.
2022	Expiry of approval		The renewal of approval granted in 2017 expires. The ongoing procedure will determine if the approval is prolonged beyond that.



## 2 Glyphosate

The chemical substance **glyphosate [N-(phosphonomethyl) glycine]** was first created in the 1950s by the Swiss chemist Dr. Henri Martin (Dill et al 2016). Its herbicidal properties were discovered by Monsanto (a former US agrochemical company that in 2018 has been acquired by the German chemical company Bayer), which had in the meantime bought the compound, in 1970. Glyphosate is a **pesticide**, which are substances that prevent, destroy, or control a disease or harmful organism, used on plant or plant products during their production, storage or transport. Within pesticides, it classifies as **herbicide** (or weedkiller), which are those pesticides that are used to control unwanted plants, like weeds that would compete with the crops. In the EU, the term **plant protection products (PPPs)** is used: PPPs are pesticides – including herbicides – which are applied to protect crops or other useful plants in agriculture, forestry or home gardens.<sup>1</sup>

Monsanto was the first to market glyphosate as **active substance** of its herbicide Roundup in the early 1970s. The active substance glyphosate is the part of the chemical mixture of the herbicide that acts against the unwanted plants, while the herbicide that is brought to the market contains other chemicals - so-called co-formulants -, like in the herbicide Roundup. Glyphosate was patented by Monsanto from 1971 until 2000, but after the patents had expired, other companies started selling glyphosate-containing herbicides, for example TouchdownTotal by Syngenta. Reportedly in the US alone 750 glyphosate containing products are on the market (IARC 2015, p.322).

Glyphosate-based herbicides are used worldwide to remove unwanted weeds not only in agriculture, but also forestry, gardening and use in public parks, and to remove unwanted weeds from railways. In Europe, the agricultural use is mostly the application to fields before a crop is planted, in order to remove weeds that would otherwise compete with the crop and in some cases it is also sprayed on the crop before harvest to regulate growth.<sup>2</sup> Today, **glyphosate is the most commonly used active substance in herbicides** around the world (Benbrook 2016). It also is the most widely used agrochemical in the world, with a 2008 global sales of 620 000 MT and 8.3 billion US-Dollar (Pollack 2011, p.116). According to a projection made by Benbrook, in the decade between 2005 and 2014, the global use of glyphosate amounted to 6133 million kg (Benbrook 2016, p.7). In Germany, as survey carried out amongst farmers led to the estimation that in 2009, glyphosate-based products were applied to 4.3 million hectares representing 39% of total arable land (Steinmann et al 2012). Moreover, between 1999 and 2010 the use of glyphosate in Germany increased by 100% (Steinmann et al 2012).

Glyphosate works through inhibiting an enzyme which plants (but not animals) need in order to produce the amino acids necessary for the plant metabolism.<sup>3</sup> As this enzyme is essential to the growth of most plants, applying glyphosate leads to the plant wilting and dying. It's wide-spread use is due to its "broad spectrum perennial weed control" (Dill et al 2010, p.2), it works effectively on a very broad range of plants and not only kills the part of the plant above the surface, but also the plant tissues below the ground level. At first, as glyphosate kills all plants that it is applied to including the crops on a field, it first had limited use in traditional agriculture, but began to be more commonly used before planting and also pre-harvest for some crops to facilitate faster harvest.

---

<sup>1</sup> See: [https://ec.europa.eu/food/plant/pesticides\\_en](https://ec.europa.eu/food/plant/pesticides_en), last accessed: 13/4/2020.

<sup>2</sup> European Commission, Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final, p. 6.

<sup>3</sup> Glyphosate inhibits the enzyme 5 - enolpyruvylshikimate - 3 - phosphate synthase (EPSPS).

The use of glyphosate is also closely connected to **biotechnology**. Genetic modification has been used to make crops like maize or soy resistant to the herbicidal effects of glyphosate, which means that a field can be treated with glyphosate and all plants apart from the herbicide resistant GMO crops will be destroyed.<sup>4</sup> This means, that in the US, where glyphosate was already popular before the rise of biotechnology it has become even more widely used, however, in the EU where GMOs are used far less it is a very popular pesticide (Bozzini 2017). Especially in combination with GMOs, glyphosate was claimed to have many advantages, the first being that it leads to a reduction of other chemical and mechanical ways of killing weeds, which were said to be more harmful to the environment (INGSA 2017). Glyphosate was presented as “relatively harmless because it bound tightly to soil constituents with little movement through either soil or groundwater, and had a short environmental half-life with no atmospheric contamination because it is not volatile” (INGSA 2017, p.2).

Bayer presents glyphosate as environmentally friendly, claiming that as shown by regulatory assessments it is not a threat to biodiversity, that it is contributing to conserving land for wildlife by ensuring a productive harvest on the land currently used for agriculture and that through reducing or eliminating the need for tillage it improves soil health and reduces carbon emissions.<sup>5</sup>

Bayer on its website presents glyphosate as a part of modern innovative farming:

*“Introduced as the active ingredient in Roundup® in the 1970s, glyphosate is a non-selective herbicide, which means that it can eliminate almost any type of plant to which it is applied – even desirable plants. It grew in prominence in modern agriculture as an important tool in Integrated Weed Management after the introduction of genetically modified crops, which allowed farmers to use the herbicide in a way that eliminated weeds without harming desirable plants. Today, glyphosate serves as an active ingredient in hundreds of crop protection products currently registered and approved for use in agriculture, vegetation management, lawn care, gardening and more.*

*(...) From data gathered from drones, sensors and other digital technologies to trusted herbicides like glyphosate, there are a host of tools in the crop protection toolbox that are essential for farmers to shape a healthy and sustainable future for agriculture.”<sup>6</sup>*

Farmer’s organisations like the British National Farmers’ Union (NFU) stress that glyphosate is very important in agriculture and that a withdrawal of approval would have many negative consequences, including the increased need for tillage leading to a decrease in earthworms, a decrease in soil organic matter and increasing CO2 emission (NFU 2017). According to the NFU, they would need 49% more labour per hectare without glyphosate and would require 546,000 more hectares to grow the same amount of food (NFU 2017). Finally, Bayer as well as the NFU argues that glyphosate is safe especially because such a

---

<sup>4</sup> The application of the precautionary principle to GMO’s is discussed in a separate case study in the RECIPES project.

<sup>5</sup> <https://www.bayer.com/en/about-glyphosate-based-herbicides-and-their-role-in-agriculture.aspx>, last accessed: 13/4/2020.

<sup>6</sup> <https://www.bayer.com/en/about-glyphosate-based-herbicides-and-their-role-in-agriculture.aspx>, last accessed: 13/4/2020.

thorough hazard and risk assessment has taken place and because of the sheer volume of studies carried out for this active substance.<sup>7</sup>

However, the benefits presented in the context of glyphosate may be relativized. The weeds which glyphosate is supposed to kill will, over time, become increasingly resistant to it. In turn this leads to an increase in the use of glyphosate-based pesticides, the return to tillage, and an increase in combining the use of glyphosate-based pesticides with other pesticides (Benbrook 2016). Thus, the development of glyphosate-resistant weeds might ultimately take away some of the initial benefits of using glyphosate.

## 3 Risks and scientific uncertainties

Generally speaking, the use of pesticides can entail risks to human health (where humans come in contact with the substance either directly or for example through residues in food) and to the environment (including ecosystems, biodiversity, as well as water and soil quality) (European Court of Auditors 2020). The risks posed by the plant protection products will vary according to the active substance used, the co-formulation with other substances and also when, how and where as well as in which amount they are used (European Court of Auditors 2020). Glyphosate was for the longest time seen as a safe pesticide and used in large quantities all over the world. However, as will be shown in this section, in the last decade concerns with regard to **risks for human health and the environment** have arisen and were simultaneously subject to scientific controversies, as will be discussed in the following.

### 3.1 Risk/threat

#### 3.1.1 Potential risks

From its invention in the 1970s until the 2000s there was little concern over the use of glyphosate-based pesticides and the general public's exposure to them in the scientific and regulatory community. However, in the EU especially in the time surrounding the start of renewal of approval procedure for glyphosate in 2012, concerns about risks of glyphosate to human health and the environment were voiced by scientist and non-governmental organisations (NGOs). The NGO Friends of the Earth Europe for example in July 2013 published a series of briefings raising concerns about risks for human health and the environment.<sup>8</sup>

#### Exposure

Due to the popularity of glyphosate and glyphosate-based herbicides (GBHs), humans are exposed to it in various ways. First of all, obviously the application of a glyphosate based-herbicides exposes humans to it: there is the **occupational exposure** to glyphosate (farmers, workers in garden and landscape maintenance, forestry workers etc.), but also **exposure through household use**, as weedkiller on private properties (IARC 2015). Furthermore, the continuously increasing use of glyphosate has resulted in the fact that glyphosate and aminomethylphosphonic (AMPA, the product into which glyphosate is metabolised) can be **detected in air, water, soil and also food** (Benbrook 2016). This

<sup>7</sup> <https://www.bayer.com/en/is-glyphosate-safe.aspx>, last accessed: 13/4/2020.

<sup>8</sup> <https://www.foeeurope.org/glyphosate-reasons-for-concern-briefing-130613>, last accessed: 13/4/2020.

means that even the average citizen that has never applied glyphosate-based herbicides is exposed to it.

In 2013, the fact that glyphosate residues were found in the urine of European citizens from 18 Member States through a study commissioned by Friends of the Earth caused a public outcry.<sup>9</sup> However, the German competent authority BfR clarified that these concentration levels were not at a level that would cause a risk to human health.<sup>10</sup> In 2016, Benbrook argued that the human exposure estimates through water, soil, air and food remained below the Acceptable Daily Intake (ADI), thus not giving rise to concern (Benbrook 2016, p.11). However, with regard to exposure caused by applying the pesticide, in a more recent article Benbrook claims that the risks that might follow occupational exposure for those mixing and applying the substance, especially through hand held application by sprayers, are higher (Benbrook 2019). In this regard, the application through handheld and backpack sprayers leads to a far higher exposure than the application by tractors with cabins and air filtration systems (Benbrook 2020).

### Risks: Human Health

In June 2011 the NGO Earth Open Source published a report 'Roundup and **birth defects**; Is the public being kept in the dark?', referring to a study (Paganelli et al 2010), which linked glyphosate and glyphosate-based pesticides to birth defects. In 2013 the NGO Friends of the Earth published a media briefing, in which they pointed to the **toxicity** of the substance.<sup>11</sup> The briefing, mostly referring to data from Latin America, also cited studies pointing to **birth defects**, an increased rate of **miscarriages** and a risk of **genotoxicity** (leading to genetic mutation and an increased cancer risk). Furthermore, according to other research, it is estimated that glyphosate exposure poses **risks to the kidney and the liver** (Myers et al 2016).

However, the focal point of the public debate surrounding glyphosate approval was the potential **carcinogenicity** of glyphosate, i.e. the potential of the substance to cause cancer. Although publications by individual scientists began to raise concerns about the potential carcinogenicity of glyphosate and glyphosate-based pesticides (Myers et al 2016), the publication of Monograph 112 by the **International Agency for Research on Cancer (IARC)** in 2015 accelerated the debate concerning carcinogenicity. The IARC classified glyphosate as 'probably carcinogenic to humans (Group 2A)', which in the evaluation scheme of the IARC means that there was 'limited evidence of cancer in humans' but 'sufficient evidence of cancer in animals' (IARC 2015).

Next to the carcinogenicity of glyphosate, other concerns that glyphosate may be an **endocrine disruptor** emerged (Gasnier et al 2009; Krass et al 2020). Endocrine disruptors are chemicals that interfere with the hormonal system and thereby cause cancer and other harms such as birth defects or developmental disorders.<sup>12</sup>

A question that is debated in the scientific analysis of the risks of glyphosate is whether the health risks of glyphosate are the same for all humans or if they differ according to the

---

<sup>9</sup> <https://www.foeeurope.org/weed-killer-glyphosate-found-human-urine-across-Europe-130613>, last accessed: 13/4/2020.

<sup>10</sup> Bundesinstitut für Risikobewertung, Glyphosate in Urine - Concentrations are far below the range indicating a potential health hazard, BfR Opinion No. 014/2013, 14 June 2013.

<sup>11</sup> [https://www.foeeurope.org/sites/default/files/press\\_releases/foee\\_media\\_briefing\\_glyphosate.pdf](https://www.foeeurope.org/sites/default/files/press_releases/foee_media_briefing_glyphosate.pdf), last accessed: 13/4/2020.

<sup>12</sup> Please see the separate case study on endocrine disruptors in the RECIPES project.

**gender** of the exposed person. Many of the case-controlled cancer studies that are used in the IARC assessment were conducted amongst male farmworkers, excluding women from the studies (IARC 2015). Also the EU risk assessment of glyphosate has been criticised for lacking attention to vulnerable groups, for example through not examining the risk of exposure for pregnant women (Arcuri & Hendlin 2019). With regard to the risk of endocrine disruption, a study in 2013 found that glyphosate stimulates breast cancer via the receptors for the hormone estrogen (Thongprakaisang et al 2013). Generally as the male and female hormonal system differ, the harm caused by endocrine disruptors can differ, but currently there is still limited knowledge especially about the effects on females.<sup>13</sup> With regard to animal studies, differences in the impact of glyphosate on animals according to gender have been researched. For example, in the animal studies conducted concerning carcinogenicity the IARC notes a difference in two studies which reported tumours for male but not for female rats (IARC 2015, p.396). A French study reported risks for the gut microbiome specifically of female rats (Lozano et al 2018). Overall, further research is needed to reach more clarity on gender related risks of glyphosate both in humans and animal.

## **Risks: Environmental**

As nowadays, glyphosate is present in soil, water and air it might cause risk to non-target organisms and whole ecosystems. The European Parliament for example in its resolution of April 2016 pointed to: "a high long-term risk found for almost all uses of glyphosate for non-target terrestrial vertebrates, including mammals and birds; whereas use of the non-selective herbicide glyphosate kills not only unwanted weeds, but all plants, as well as algae, bacteria and fungi, thereby having an unacceptable impact on biodiversity and the ecosystem".<sup>14</sup>

Thus, the environmental risks are twofold: first, **specific species are harmed** by glyphosate and, second, it might **endanger the whole ecosystem** through its negative **effects on biodiversity**, which in turn harms many species forming part of the ecosystem. Regarding specific species that are affected by glyphosate, Benbrook for example refers to studies which point to potential harm for microbial communities in the soil as well as for several species (earthworms, monarch butterflies, honeybees, crustaceans) (Benbrook 2016).

With regard to the risks to the ecosystems and biodiversity, the risk assessment on the EU level so far did not point to risks to ecosystems, provided that the substance is used within good agricultural practice and under the conditions under which it was approved.<sup>15</sup> The Commission in this regard points to the possibility of the Member States to impose conditions such as no spray zones or drift reduction technology in the authorisation of glyphosate-based pesticide. Nonetheless, as glyphosate - and any herbicide for that matter - removes unwanted plants, this could disturb interlinked food chains in the relationship

---

<sup>13</sup> Please see the separate case study on endocrine disruptors in the RECIPES project.

<sup>14</sup> European Parliament resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011, P8\_TA(2016)0119, Point R of the resolution.

<sup>15</sup> European Commission, Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final, p. 8.

between different species (so called foodwebs).<sup>16</sup> Two examples in this regard are mentioned by the NGO Friends of the Earth:<sup>17</sup> First of all, the weeds which are removed through the application of glyphosate constitute an important food source for insects, which in turn are the main feed of birds such as the skylark. Second, the use of glyphosate-based herbicides is linked to the decline of Monarch butterflies in the US, not because it would be directly toxic to the butterflies, but because it removes the common milkweed on which the caterpillars of the butterfly are dependent as food source.

More and more, the risk of glyphosate for the environment and, specifically the risks to wildlife in meadows and rivers, is the focus of attention.<sup>18</sup> In an interview by the webportal Politico, Jeroen van der Sluijs (RECIPES partner) warned, concerning the risks of glyphosate, that it leads to an agricultural practice where you have monoculture with no wild plants left in the fields and thus no floral resources for bees and other pollinators, that it harms non-target plants and that it poses risks to aquatic organisms and especially amphibians.<sup>19</sup>

## 3.2 Scientific analysis

### Individual scientific studies

Glyphosate has been the focus of a large and still growing number of scientific studies.<sup>20</sup> Initially, the toxicological testing of glyphosate-based herbicides pointed to a low risk of the substance for non-target species (Myers et al 2016). For example, in 2000 Williams et al. in a review of the safety of glyphosate, based on industry performed regulatory studies as well as published studies, concluded that they found no indication of human health concerns for glyphosate as well as the Roundup formulation (Williams et al 2000). At the time, studies were often carried out by laboratories owned or commissioned by the industry, and also the review of Williams et al. is based on these unpublished studies, while the authors were consultants associated with the industry (Myers et al 2016).

However, since the mid-2000s several animal and epidemiology studies published by non-industry associated scientist seem to call the safety of glyphosate into question (Myers et al 2016). A review of such studies led to a consensus statement of several scientist concerning glyphosate-based herbicides (GBHs) from 2016 which expressed that:

*"Collectively, studies from laboratory animals, human populations, and domesticated animals suggest that current levels of exposure to GBHs can induce adverse health outcomes." (Myers et al 2016, p.3).*

---

<sup>16</sup> European Commission, Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final, p. 8.

<sup>17</sup>

[https://www.foeeurope.org/sites/default/files/publications/foee\\_5\\_environmental\\_impacts\\_glyphosate.pdf](https://www.foeeurope.org/sites/default/files/publications/foee_5_environmental_impacts_glyphosate.pdf), last accessed: 13/4/2020.

<sup>18</sup>

<https://www.politico.eu/article/battle-over-glyphosate-shifts-to-the-environmental-front-pesticides-herbicides/>, last accessed: 13/4/2020.

<sup>19</sup>

<https://www.politico.eu/article/battle-over-glyphosate-shifts-to-the-environmental-front-pesticides-herbicides/>, last accessed: 13/4/2020.

<sup>20</sup> In its assessment the BfR reviewed over 1,000 studies, including epidemiological studies on glyphosate carcinogenicity.



According to this consensus-statement, further studies of the causal link between the exposure to glyphosate-based pesticides and cancer (specifically non-Hodgkin's Lymphoma) are required, while the epidemiological data does provide evidence of heightened cancer risk (Myers et al 2016). They also state that several studies have "reported effects indicative of endocrine disruption." (Myers et al 2016, p.6).

### **The scientific assessment of glyphosate carcinogenicity: The International Agency for Research of Cancer (IARC)**

The IARC is the specialized cancer agency of the World Health Organisation (WHO), which focusses on the carcinogenic properties of different substances. They do not perform their own studies, but base their assessment on compiling publicly available information, the IARC experts critically review and evaluate peer-reviewed and published studies, which they assess in terms of strength-of-evidence (of carcinogenic properties of a substance). The IARC was the first international scientific body identifying carcinogenic properties of glyphosate (Arcuri 2019). The findings are summarised in an article in The Lancet in the following way:

*"There was limited evidence in humans for the carcinogenicity of glyphosate. Case-control studies of occupational exposure in the USA, Canada, and Sweden reported increased risks for non-Hodgkin lymphoma that persisted after adjustment for other pesticides. (...)*

*In male CD-1 mice, glyphosate induced a positive trend in the incidence of a rare tumour, renal tubule carcinoma. A second study reported a positive trend for haemangiosarcoma in male mice. Glyphosate increased pancreatic islet-cell adenoma in male rats in two studies. A glyphosate formulation promoted skin tumours in an initiation-promotion study in mice." (Guyton et. al 2015, pp. 490-491)*

### **The scientific assessment of glyphosate carcinogenicity in EU Agencies: ECHA and EFSA**

In the context of the EU procedures, glyphosate as an active substance was subject to scientific assessment by:

- the Federal Institute for Risk Assessment (BfR) (as rapporteur for EFSA)
- the European Food Safety Authority (EFSA)
- the European Chemicals Agency (ECHA)

In its assessment the BfR reviewed over 1,000 studies, including epidemiological studies on glyphosate carcinogenicity.<sup>21</sup> The BfR also found that there is 'limited' evidence for carcinogenicity in humans based on the epidemiological studies that the IARC also referred to. However, the BfR concluded that the studies in question have certain flaws and do not provide evidence for a link between the exposure to glyphosate and cancer (*non-Hodgkin lymphoma*).<sup>22</sup>

---

<sup>21</sup> Bundesinstitut für Risikobewertung, Assessment of the BfR concerning epidemiological studies on carcinogenic effects of glyphosate in the context of the EU active substance review BfR background information No. 034/2015, 28 September 2015.

<sup>22</sup> Ibid.

In October 2015, based on the assessment of the BfR and the subsequently carried out peer review, EFSA published its 'Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate' in which it concluded that "glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008."<sup>23</sup>

In its opinion of 15 March 2017, ECHA concluded that glyphosate is not to be classified as carcinogenic, moreover it is not mutagenic and also does not disrupt reproduction.<sup>24</sup> However, it did classify glyphosate with: Eye Damage (class 1, Causes serious eye damage) and Aquatic Chronic (class 2; Toxic to aquatic life with long lasting effects). The hazard classifications with regard to eye damage and aquatic toxicity were already in place before the renewed evaluation in 2016.<sup>25</sup>

### 3.3 Scientific uncertainty

This section is about the **scientific uncertainty about the risks** associated with your case.

#### 3.3.1 Complexity

Generally, pesticide risk assessment is complex as they span over a wide range of products from naturally occurring ones to synthetic chemicals (Bozzini 2017). Moreover, pesticides are used in the whole food production chain from farming to trading, as well as in landscaping and forestry (Bozzini 2017). Their use has drastically increased since the 1950s due to the progressive shift towards "the agro-industrial model of farming" (Bozzini 2017, p.2).

A large source of complexity in the risk assessment of glyphosate-based pesticides is that next to glyphosate as active substance they contain other chemicals as well, and this **formulation** will be different for the over 750 different products on the market (IARC 2015, p. 322). For example, concerns were raised regarding the **high toxicity of a co-formulant** of glyphosate, POE-tallowamine (Mesagne et al 2013). After a request from the Commission to EFSA to investigate this further and EFSA concluded that: "Compared to glyphosate, a higher toxicity of the POE-tallowamine was observed on all endpoints investigated."<sup>26</sup> The formulation of the plant protection products are commercial secrets and therefore not accessible to independent scientists (Myers et al 2016).

While the formulation of the different products causes a first level of complexity, this is enhanced through complexities regarding the accumulation and mixing of pesticides that the current scientific methods and regulatory framework is not able to comprehensively address. Myers et al. explain that glyphosate-based pesticides are increasingly applied together with other pesticides, while the safety levels for the active ingredients are calculated separately and without taking into account these mixtures (Myers et al 2016). As stated in a report for the European Parliament, Europe risk assessors also struggle with this issue: "(...) less attention is given to **unintentional mixtures** – like the ones that are formed during the handling of different products on the part of users – or coincidental –

---

<sup>23</sup> EFSA, Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, 13(11) 4302 EFSA Journal (2015), pp. 1-107.

<sup>24</sup> ECHA, Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N-(phosphonomethyl)glycine, CLH-O-0000001412-86-149/F, 15 March 2017.

<sup>25</sup> ECHA, How ECHA is assessing glyphosate, ECHA Newsletter 3/2016, p. 3.

<sup>26</sup> EFSA, Statement of EFSA on the request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine, 13(11) 4303 EFSA Journal (2015), pp. 1-13.



mixtures that get formed in the environment after the use of a variety of active substances. At present there is no systematic and integrated approach across different pieces of legislation. In the pesticide sector, guidelines are currently under development.”<sup>27</sup>

However, not only the mixture of glyphosate with other chemicals poses risk assessment problems. The **physicochemical properties**, make it very difficult to analyse (Huhn 2018). Huhn concluded an article calling for more and enhanced analysis of glyphosate with the statement that: “our understanding of the fate of glyphosate in the environment and its impact on ecosystems and human health are still not fully understood.” (Huhn 2018, p.3043). It is also pointed out that currently studies can only address individual aspects of the fate of glyphosate in the environment and that questions regarding the **bioavailability** when it is absorbed into the soil are unclear, this also leads to gaps in the understanding of its ecotoxicology (Huhn 2018).

### 3.3.2 Uncertainty

Added to the complexities as elaborated in the previous section, is the uncertainty of the ever-evolving **scientific methods**. Since glyphosate is already a relatively old product, it is worth reminding the reader that toxicology as a scientific discipline has rapidly evolved and has become increasingly refined, which means that today scientists are able to conduct a far more sophisticated risk assessment when it comes to toxic, ecotoxic and endocrine disruption risks of a substance (Bozzini 2017). This also influenced the regulatory framework of pesticides which reflects the increasing ability to identify these risks (Bozzini 2017). It should also be taken into account that the science of toxicology will certainly progress further and findings which are now in accordance with the most up-to-date science will be overhauled. Even in an area such as carcinogenicity testing, where a testing standard is already established since the 1960s, the assessment is complex and has been progressively refined, still causing debate.<sup>28</sup>

Another factor that contributes to the scientific uncertainty with regard to glyphosate relates to the **absence of reliable data on the use of glyphosate-based herbicides** (Myers et al 2016). As Benbrook explains, the quantification of risks to human health and the environment is dependent on knowing how much of the substances is applied in a certain region, on which crops and in which other areas (forests, parks, industrial properties etc.), the timing of application and which method was used (Benbrook 2016). However, such a comprehensive dataset is hardly available (Benbrook 2016). Also the Scientific Advice Mechanism (SAM)<sup>29</sup> of the European Commission has noted that: “[i]nformation on non-dietary health risks (e.g. agricultural worker safety) and environmental risks of PPPs is commonly not fully available to all risk assessors and risk managers due to lack of systematic monitoring and data sharing.”(SAM 2018, p.33). Currently, a lot of uncertainty with regard to glyphosate thus originates in a lack of data concerning the exposure to it. This applies to the exposure of citizens through food, water and air; the exposure of people that use glyphosate professionally (often in combination

<sup>27</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, Annex II p. 8.

<sup>28</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, Annex II p. 37-41.

<sup>29</sup> The Scientific Advice Mechanisms (SAM) provides independent scientific advice to the European Commission. It is constituted of 7 Chief Scientific Advisors who work closely with the Scientific Advice for Policy by European Academies (SAPEA) a consortium of over 100 academies and societies across Europe.

with other pesticides); and the exposure of the environment to glyphosate under real world conditions.

### 3.3.3 Ambiguity

Especially regarding the question of carcinogenic risks, ambiguity – difference in interpretation of the scientific data – is a core characteristic of the risk assessment process concerning glyphosate. Next to disputes over the interpretation and methodology of single studies,<sup>30</sup> the **different assessment of the scientific evidence regarding carcinogenicity between the IARC on the one hand and the regulatory agencies in the EU** on the other hand dominated the public and scientific debate.

While the IARC only takes into account publicly available studies, but does not limit its assessment to only the active substance, the regulatory authorities in the EU also use raw data from industry conducted studies but limit their assessment to the active substance. Nonetheless, this is not to say that the IARC and EFSA/ECHA would have carried out their assessment on completely different data sets, on the contrary, the information at their disposal to a large degree was overlapping.<sup>31</sup> What might be surprising given the divergent assessments is that in its 2015 assessment, the IARC did not only take into account peer-reviewed scientific articles but also regulatory reports from the EU and US (IARC 2015). However, what does differ significantly is how the bodies judged the quality, reliability and importance of the different studies.

The IARC, in accordance with its procedures, bases its assessment exclusively on publicly available data, mostly on scientific literature, which is identified by the Agency through systematic literature review and a public call for data. The EFSA conclusion (as well as the ECHA classification), on the other hand, takes into account published studies, but is based on the data submitted by the approval applicant, which contains studies commissioned by the applicants and therefore not publicly available. In examining the submitted studies, EFSA (and the BfR as rapporteur) used a so-called weight-of evidence assessment. According to EFSA guidance, the weight of evidence approach is: “a process in which evidence is integrated to determine the relative support for possible answers to a question.”<sup>32</sup>

In essence for the **weight of evidence assessment**, one asks whether the studies are reproducible, how many studies support a conclusion and also how these studies are designed and conducted.<sup>33</sup> The reason why regulatory authorities place a big emphasis on the studies submitted by the applicant is that those are performed according to the Organisation for Economic Co-operation and Development (OECD) standards of Good Laboratory Practice (GLP). GLP is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. It reduces

---

<sup>30</sup> For example the article ‘Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize’ by Séralini et al. (in Volume 50 of Food and Chemical Toxicology) was retracted and then republished (in 26(14) *Environmental Sciences Europe*), after controversy about its findings.

<sup>31</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, Annex IV p. 89 ff.

<sup>32</sup> EFSA, Guidance on the use of the weight of evidence approach in scientific assessments, 15(8) 4971 EFSA Journal (2017), pp. 1-69.

<sup>33</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p. 87.

the possibilities for fraud and fabrication but it is argued that it does not guarantee that a study has been designed correctly (Maxim & van der Sluijs 2013; Myers et al 2009). Academic studies, on the other hand, are often designed and carried out according to more original and less standardised designs. Most academic labs do not have GLP certificates because this is a standard for industry labs and academic studies rely on the system of peer review for the quality control of the studies. As regulatory authorities apply the so-called Klimisch criteria to assess the reliability of toxicological studies, academic studies are excluded or deemed less reliable as they usually lack the GLP certificate (Myers et al 2016).

While the EU agencies relied on the weight of evidence approach, the IARC uses a so-called strength of evidence approach, which led to different weighting of the studies in question. This is explained by Bozzini:

*"IARC concludes that three studies (out of 14) present evidence of a weak/dubious – but still existent- correlation and classifies such evidence as limited. As a consequence, according to IARC criteria, glyphosate can be classified as 'probably carcinogenic'. Whereas the IARC relies almost exclusively on this evidence, EFSA places it in the context of a much broader set of (unpublished) papers and employs a weight of evidence approach to reach its conclusion. Eventually, EFSA concluded that the evidence is very limited and that, therefore, glyphosate cannot be categorized as carcinogenic." (Bozzini 2017, p.89)*

Thus, the ambiguity in the assessment of glyphosate follows from the "trade-off between regulatory science' and 'research science', that is between the need for standard testing criteria (...) and the need for research designs that are innovative (...)." (Bozzini 2017, p.89)

### 3.4 Relevance of the PP to the case

Glyphosate might be **one of the most intensely studied pesticides on the market**, however as the sections above have shown **this does not exclude scientific uncertainty**. First of all, the discussion in the previous sections has shown that not only people that apply glyphosate-based herbicides, but also average citizens are exposed to the substance. Nonetheless, the absence of systematic monitoring of its herbicide use as well as the exposure via food and water, poses significant uncertainty challenges for the assessment of its risks. These risks concern human health risks, such as carcinogenicity and endocrine disruption, as well as risks to the environment, regarding specific species as well as whole ecosystems. However, the main controversy and source of **ambiguity** surrounding the risk(s) associated with glyphosate in the recently concluded renewal procedure was the **diverging scientific assessment of the substance in terms of its carcinogenic potential**: while in its 2015 monograph the IARC classified glyphosate as probably carcinogenic to humans (Group 2A), EFSA and ECHA did not classify glyphosate as carcinogen.

The causes for this divergence in assessment have been addressed in the literature. From these sources, several factors for the diverging carcinogenicity classification can be identified (Paskalev 2019; Leonelli 2018; Arcuri 2018):

- the mandates and procedures of the bodies in question (regulatory vs non-regulatory);
- hazard identification vs risk assessment;
- approach concerning the data taken into account (published/peer reviewed vs industry composed dossiers);
- assessment of active substance and/or co-formulation;
- diverging methods/interpretations in the 'weight of evidence approach'.

What makes the glyphosate case especially interesting as a case study for the application of the precautionary principle is that not only is the science contested or at least interpreted ambiguously, but that the EU regulators have been criticised for failing to "give any substantial weight to the margins of scientific uncertainty surrounding the glyphosate case"(Leonelli 2018, p.594). For example, the President of BfR in an article in the ZLR, explaining that the precautionary principle does not apply to the risk assessment of glyphosate as there was no unknown risk and no lack of knowledge (Hensel 2016). Concern has been voiced, for example by the Executive Director of EFSA Bernhard Url in Nature, that the public debate surrounding the scientific findings concerning carcinogenicity in the EU risk assessment was driven by political agenda rather than scientific uncertainty. He states that: "It seems to us that some campaigners contest the science of safety assessments in pursuit of greater political arguments. These arguments deserve airing — but they belong with policymaker."(Url 2018, p.381)

Thus, glyphosate represents a case **not only of contestation of science, but also of contestation of scientific uncertainty**. This also warrants the close analysis of the application of the precautionary principle in the EU risk governance concerning glyphosate as discussed in the following section.

## 4 Risk governance and the precautionary principle

The scope of this case study is largely limited to renewal of glyphosate as an active substance in pesticides in the EU, which took place between 2012 and 2017. The glyphosate approval was renewed at the time, however, the precautionary principle still played an important role in the risk governance process as this section will show. First, the political and legal dynamics of the risk governance process will be discussed, including an analysis of the regulatory framework as well as a detailed description of the risk analysis process. In section 4.2. the societal dynamic in the glyphosate risk governance will be introduced.

### 4.1 Political/juridical dynamics

Glyphosate and glyphosate-based pesticides are subject to an **extensive regulatory framework in the EU**. Plant Protection Products have to be approved/authorised before they can be placed on the internal market.<sup>34</sup> The **active substance**, such as glyphosate,

---

<sup>34</sup> For a comprehensive discussion of the regulatory framework for pesticides in the EU see: Bozzini 2017.

is subject to an **approval granted on EU level** by the Commission. However, the actual plant protection products, thus the **commercial formulation** of the active substance with other co-formulants, like the glyphosate containing herbicide Roundup, have to be **authorised on Member State level**.

Pesticides are subject to harmonised European legislation only since the 1990s. A first proposal for a Directive in 1976 was not adopted due to resistance of the Member States.<sup>35</sup> Only with the adoption of Council Directive 91/414/EEC a common procedure for an approval of active substances and the authorisation of plant protection products in the Member States was established.<sup>36</sup> However, the Directive proved unsuccessful in establishing a coherent framework and was inefficient.<sup>37</sup> This led to the adoption of the pesticide package establishing the current regulatory framework: **Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market**,<sup>38</sup> and **Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides**.<sup>39</sup> The following section will examine how the precautionary principle is integrated in the Pesticides Regulation 1107/2009, which applied to the glyphosate renewal.

### The precautionary principle and the regulation of pesticides in the EU

Although in the Treaties the precautionary principle is only mentioned Article 191(2) TFEU on environmental policy, it applies also to other policies especially where they are aimed at the protection of public health and human health, which includes the Pesticides Regulation.<sup>40</sup> Therefore, it is not surprising that also Regulation 1107/2009 refers to the principle. First of all, the precautionary principle is mentioned in Recital 8:

*"(8) 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*

<sup>35</sup> European Commission, Proposal for a Council Directive concerning the placing of EEC-accepted plant protection products on the market, COM (1976) 427 final, OJ C 212, 9.9.1976, p. 3–20.

<sup>36</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ L 230, 19.8.1991, pp. 1–32.

<sup>37</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p. 19.

<sup>38</sup> Regulation (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, OJ L 309, 24.11.2009, pp. 1–50.

<sup>39</sup> Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticide OJ L 309, 24.11.2009, pp.71–86.

<sup>40</sup> See e.g.: C-616/17 *Criminal proceedings against Mathieu Blaise and Others*, ECLI:EU:C:2019:800, paras. 41and 42.

*market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.”(emphasis added)*

This is then included in Article 1 of the Regulation and specifically paragraphs 3 and 4 which state:

*'3. The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.*

*4. The provisions of this Regulation are underpinned by the **precautionary principle** in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.'* (emphasis added)

The regulation aims at the protection of humans, animals and the environment, expressing the precautionary principle in various ways:

- **The prior approval scheme:** Plant protection products can only be placed on the market when they have been authorised by the Member States, and any active substance contained in the PPPs has to be approved on EU level. As stated by Advocate General Sharpston, such a prior approval scheme is in itself an expression of the precautionary principle: “The PPP Regulation is itself a precautionary measure because it establishes a system of *prior approval* affecting a generic product category (plant protection products).”<sup>41</sup> Comparable prior approval schemes are used in several policy areas in the EU, including food, chemicals, and pharmaceuticals.<sup>42</sup> In accordance with the Commission Communication on the precautionary principle, such authorisation schemes are used exceptionally with regard to “substances deemed ‘a priori’ hazardous”<sup>43</sup>.
- **The shift in the burden of proof:** The prior approval scheme also introduces a shift in the burden of proof: in the approval and authorisation procedures the safety of the product had to be proven, and this responsibility is placed on the company that wants to market the product (Bozzini 2017). Such a shift in the

---

<sup>41</sup> Opinion of Advocate General Sharpston in case C-616/17 *Criminal proceedings against Mathieu Blaise and Others*, ECLI:EU:C:2019:190.

<sup>42</sup> See also: European Commission, Communication from the Commission on the European Citizens' Initiative “Ban Glyphosate and Protect People and the Environment from Toxic Pesticides”, C(2017) 8414 final, p. 11.

<sup>43</sup> European Commission, Communication from the Commission on the precautionary principle, COM(2000)0001 final, p.20.



burden of proof is exceptional and not the general rule for all risks.<sup>44</sup> In the case of pesticide approvals, the manufacturers are required to provide scientific evidence of the safety of their product. Next to performing own tests, manufacturers are required to also compile peer-reviewed scientific literature for the active substance in question (Bozzini 2017).

- **The authorisation criteria:** With the adoption of Regulation 1107/2009, the EU introduced a hazard-based approach as opposed to a risk-based approach.<sup>45</sup> This entails that a substance is first examined for certain intrinsic hazardous characteristics, the so-called 'cut-off criteria'. If in the hazard identification stage, it becomes evident that a pesticide meets one of the cut-off criteria, for example as it is carcinogenic, a risk assessment concerning the likelihood of the harm to occur is not necessary to take precautionary measures. With regard to the approval of active substances, the hazard-based approach is enshrined in Article 4(1) of Regulation 1107/2009 and the cut-off criteria are listed in Annex II points 3.6.2 to 3.6.4 and 3.7. According to this cut-off criteria system, an active substance will be banned if it is: carcinogenic; mutagenic; toxic for reproduction; persistent, bioaccumulative and toxic for the environment; a persistent organic pollutant; very persistent and very bioaccumulative; or an endocrine disruptor.
- **The limited approval periods:** In accordance with Article 5 of the Pesticide Regulation, if an active substance is approved for the first time, the approval cannot be granted for a longer period than 10 years. If the approval of an active substance is subsequently renewed, the maximum period is 15 years (Article 14(2)). This ensures that the scientific evidence for the safety of the substance is reviewed regularly, considering new scientific findings and evolving technology.
- **The review of approval:** In accordance with Article 21 the Commission can review the approval at any time should new scientific findings and technical knowledge point to doubts that the approval criteria are still fulfilled.
- **Emergency measures:** If an authorised product (or a substance contained in it) or approved active substance is likely to cause serious risks to human or animal health or the environment, the Commission – also on proposal of a Member State – can immediately take measures to restrict the use/sale as an emergency measure (Article 69).

Thus, the **precautionary principle is integrated in the regulatory framework applicable to pesticides**. Especially the use of a hazard-based approach is quite unusual, not only compared to pesticide regulation around the world, but also compared to other risk regulation areas in the EU, which generally are risk based (Bozzini 2017). It is argued that the hazard-based approach is not only an expression of the precautionary principle, but that choosing a hazard, rather than risk based approach is "a strong version of the principle by calling for precautions to avoid serious and possibly irreversible harm".<sup>46</sup> As was stated before, already the existence of the prior-approval scheme in the regulatory

---

<sup>44</sup> European Commission, Communication from the Commission on the precautionary principle, COM(2000)0001 final, p. 4.

<sup>45</sup> For a discussion of the hazard-based approach see: Bozzini 2017, p. 29 ff.; SAM 2018, p. 42; European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p.43.

<sup>46</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p. 21.

framework for pesticides is based on the precautionary principle. In the following section the approval procedure will be introduced, before examining the approval procedure of glyphosate.

### The approval procedure for active substances

Active substances like glyphosate have to be approved before they can be used in plant protection products in the EU. An application will have to be submitted to a competent authority of a Member State, which becomes the Rapporteur Member State (RMS).<sup>47</sup> The RMS together with another co-rapporteur from another Member State, produces a draft assessment report (DAR), carrying out an “**independent, objective and transparent assessment** in the light of current scientific and technical knowledge” of the documents submitted by the applicant.<sup>48</sup> The purpose of these assessments is to establish ‘whether the active substance can be expected to meet the approval criteria, as provided for in Article 4 of Regulation (EC) No 1107/2009.’<sup>49</sup> The following risk assessment steps are coordinated by EFSA Panel on Plant Protection Products and their Residues, including a peer review of the application by the other Member States and a public consultation.<sup>50</sup> EFSA’s Conclusion is subsequently sent to the Commission, which has the decision-making power concerning the approval of active substances.

Taking into account the EFSA Conclusion, the European Commission will draft a review report and a Draft Implementing Regulation.<sup>51</sup> This Draft Implementing Regulation will approve or not approve the active substance, based on “the review report, other factors legitimate to the matter under consideration and the **precautionary principle**”.<sup>52</sup> However, the European Commission’s decision-making power is still subject to control by the Member States through comitology, as the comitology committees are composed of representatives of the Member States (van den Brink 2020), often being employees of national ministries. This means that the Member States will vote on the Commission proposal to approve a substance in the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee), and more specifically in the PAFFs section on phytopharmaceuticals. In case of a positive opinion of the committee, the Commission adopts an Implementing Regulation approving the substance, it will be included in the list of approved active substances in the Annex of Commission Implementing Regulation (EU) No 540/2011.<sup>53</sup>

---

<sup>47</sup> Regulation (EC) No 1107/2009, Art. 7.

<sup>48</sup> Regulation (EC) No 1107/2009, Art.11(2).

<sup>49</sup> Regulation (EC) No 1107/2009, Art 11. Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market OJ L 252, 19.9.2012, pp. 26–32.

<sup>50</sup> Regulation (EC) No 1107/2009, Art. 12. See also: European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p. 21.

<sup>51</sup> Regulation (EC) No 1107/2009, Art. 13.

<sup>52</sup> Regulation (EC) No 1107/2009, Art. 13(2). Emphasis added.

<sup>53</sup> In case of approval of active substances the examination procedure is followed in accordance with Article 5 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by



In case of glyphosate, the procedure applicable in this case study was not an initial approval, but a renewal of an existing approval, which is governed by Articles 14 until 21 and further detailed in Commission Implementing Regulation (EU) No 844/2012.<sup>54</sup> As the first approval of an active substance is only granted for a maximum of 10 years,<sup>55</sup> while the maximum renewal period is 15 years,<sup>56</sup> such renewals are reoccurring regularly. The procedure follows similar steps as the approval procedure with an assessment by a Rapporteur MS and a subsequent peer review by EFSA. However, a core difference is that the Rapporteur Member State is not chosen by the applicant but has been assigned in the Commission Implementing Regulation.<sup>57</sup> Like in the case of an initial approval, the applicant company will have to provide scientific evidence that the approval criteria are fulfilled given the current scientifically and technical knowledge. The Commission again is the final decision-maker, together with the comitology committee.

### **Glyphosate in the EU: the timeline of glyphosate approval procedures**

Glyphosate was first approved in the EU in 2002, after the introduction of the harmonised procedures through Council Directive 91/414/EEC. Before, glyphosate was used in the European Union in products authorized in Member States under their national regulatory framework. With the adoption of the Directive, a gradual work programme was set up in order to examine and approve the active substances on the market.<sup>58</sup> In the context of this work programme glyphosate was approved in 2002,<sup>59</sup> based on the scientific and technical knowledge of human health and environmental risks at the time.

In 2009, after a revision of the Plant Protection Product legislation in the EU, a new general legislative framework was introduced through the adoption of Regulation (EC) 1107/2009. The previously granted approval of glyphosate remained valid.<sup>60</sup> This approval originally expired in 2012 but, together with other approval dates, was prolonged to 31 December 2015,<sup>61</sup> in order to clarify the framework for and carry out the renewals under the new Regulation. In accordance with the applicable procedure,<sup>62</sup> the renewal was applied for on

---

Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, pp. 13–18.

<sup>54</sup> Commission Implementing Regulation (EU) No 844/2012.

<sup>55</sup> Regulation (EC) No 1107/2009, Art. 5.

<sup>56</sup> Regulation (EC) No 1107/2009, Art. 14(2).

<sup>57</sup> Annex of Commission Implementing Regulation (EU) No 844/2012.

<sup>58</sup> Council Directive 91/414/EEC, art 8(2).

<sup>59</sup> Commission Directive 2001/99/EC of 20 November 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include glyphosate and thifensulfuron-methyl as active substances OJ L 304, 21.11.2001, pp. 14–16.

<sup>60</sup> All the active substances included in Annex I to Directive 91/414/EEC were also deemed to be approved under Regulation (EC) No 1107/2009.

<sup>61</sup> Commission Directive 2010/77/EU of 10 November 2010 amending Council Directive 91/414/EEC as regards the expiry dates for inclusion in Annex I of certain active substances Text with EEA relevance OJ L 293, 11.11.2010, pp. 48–57.

<sup>62</sup> Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances, OJ L 322, 8.12.2010, pp. 10–19.

25 May 2012 by the so-called Glyphosate Task Force, a collective of 24 glyphosate producing companies which included Monsanto Europe.<sup>63</sup>

The **Rapporteur Member State (RMS) was Germany** and its German Bundesinstitut für Risikobewertung (BfR), which was supported by Slovakia as co-rapporteur. The Renewal Assessment Report (RAR) will form the basis of the risk assessment. On 20 December 2013 the BfR provided the Renewal Assessment Report to EFSA, in which it stated that “glyphosate is devoid of genotoxic potential” and that **“classification and labelling for carcinogenicity is not warranted”**.<sup>64</sup> Upon receiving the RAR, EFSA sent it out for consultation to the Member State and the applicant – the Glyphosate Task Force. Based on the comments received, EFSA identified “that expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology” should be carried out.<sup>65</sup> After consultation with experts from other Member States and the approval applicants as well as a public consultation, the BfR incorporated the comments and additional studies and submitted a revised report in December 2014.<sup>66</sup>

While the assessment in the EU was ongoing, on **20 March 2015 the International Agency for Research on Cancer (IARC) published a monograph which contained findings of a carcinogenic potential of glyphosate**. Based on a mandate by the European Commission, the BfR made an addendum to the RAR on 31 August 2015 to evaluate the IARC Monograph. The BfR reassessed the studies taken into account by the IARC, but did not change its conclusion.<sup>67</sup> Therefore, **EFSA in October 2015 published its Conclusion**, stating that **“glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008.”**<sup>68</sup> Overall, **EFSA concluded that glyphosate can be expected to meet the approval criteria**.<sup>69</sup>

However, the EFSA Conclusion mentioned a data gap concerning the fate and behaviour in the environment, stating that further information is required to assess the “contamination route through run off (especially in situations where application to hard surfaces might occur) and subsequent surface water contamination and bank infiltration to groundwater”.<sup>70</sup> Also concerning **“ecotoxicology, two data gaps** were identified to provide an assessment to address the long-term risk for small herbivorous mammals and for insectivorous birds.”<sup>71</sup> The ecotoxic risk for aquatic organisms as well as bees,

---

<sup>63</sup> Bundesinstitut für Risikobewertung, Renewal Assessment Report, Glyphosate, Volume 1 Report and Proposed Decision, Volume 1, p.3.

<sup>64</sup> Bundesinstitut für Risikobewertung, Renewal Assessment Report, Glyphosate, Volume 1 Report and Proposed Decision, Volume 1, p.139.

<sup>65</sup> EFSA, Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, 13(11) 4302 EFSA Journal (2015), pp. 1-107, p. 2.

<sup>66</sup> This Renewal Assessment Report was revised twice (29 January 2015 and 31 March 2015). Bundesinstitut für Risikobewertung, Frequently asked questions on the procedure for the re-assessment of glyphosate within the framework of the EU active substance review, BfR FAQ, 12 November 2015.

<sup>67</sup> Bundesinstitut für Risikobewertung, The BfR has made a comprehensive check of the epidemiological studies on glyphosate, BfR Background Information No. 033/2015, 22 September 2015.

<sup>68</sup> EFSA, Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, 13(11) 4302 EFSA Journal (2015), pp. 1-107.

<sup>69</sup> Ibid.

<sup>70</sup> Ibid., p.3.

<sup>71</sup> Ibid.

arthropods and soil micro- and macro-organisms was considered low.<sup>72</sup> The risk for non-target plants was considered low, given that mitigation measures are taken.<sup>73</sup> The EFSA opinion had also pointed out that one study showed **potential endocrine activity** and that, while data had become available there was no time to assess this information. This led the Commission to ask for an assessment of the endocrine disruption potential through EFSA.

However, when the EFSA Conclusion was presented to the Member States, as represented in the **comitology committee**, they considered it was appropriate to have an opinion of the Committee for Risk Assessment of the European Chemicals Agency.<sup>74</sup> ECHA and more specifically its Committee for Risk Assessment was asked to form an opinion on the hazard classification of glyphosate.<sup>75</sup>

In April 2016 the **European Parliament** adopted a resolution concerning ongoing glyphosate approval.<sup>76</sup> At the time the European Commission had drafted a proposal for the maximum period of 15 years. In its resolution the Parliament stated that the Commission proposals “fails to apply the precautionary principle”<sup>77</sup> and called on the Commission to limit the renewal to 7 years.<sup>78</sup>

In the meantime, in August 2016, the **conditions of approval of the active substance were amended** in the light of new scientific and technical knowledge by Commission Implementing Regulation (EU) 2016/1313, which the PAFF has agreed to.<sup>79</sup> In its opinion from October 2015 the EFSA had voiced concerns regarding the toxicity co-formulant POE-tallowamine, which is often used in plant protection products containing glyphosate. Based on these findings, the conditions of approval for glyphosate were changed and Member States had to ensure that pesticides containing glyphosate do not contain POE-tallowamine. Moreover, the changed conditions of approval now stated that Member States in their assessment of PPPS should pay particular attention to (i) the protection of groundwater in vulnerable areas (particularly regarding non-crop use); (ii) risks from use

---

<sup>72</sup> Ibid.

<sup>73</sup> Ibid.

<sup>74</sup> In January 2016, the EFSA report was presented to the PAFF and in May the PAFF asked for an opinion of the Committee for Risk Assessment of the European Chemicals Agency on the carcinogenic potential of glyphosate. When the Commission in June 2016 called for a vote on the renewal proposal, neither a qualified majority for nor against the renewal could be reached. See: [https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment\\_en](https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment_en), last accessed: 13/4/2020.

<sup>75</sup> Such a hazard assessment is carried out in accordance with Article 37 of Regulation (EC) No 1272/2008. With regard to pesticides, the Pesticides Regulation 1107/2009 prohibits the placing on the market of a hazardous pesticide that is classified as human carcinogen or as mutagen, and this classification is carried out through the procedure prescribed by the CLP Regulation 1272/2008. See Annex II Regulation 1107/2009.

<sup>76</sup> European Parliament resolution of 13 April 2016 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011, P8\_TA(2016)0119.

<sup>77</sup> European Parliament resolution of 13 April 2016, Point 1.

<sup>78</sup> Ibid., Point 3.

<sup>79</sup> Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate, OJ L 208, 2.8.2016, pp. 1–3.

in areas used by the general public and vulnerable groups (like parks, playgrounds etc.); and (iii) compliance of the pre-harvest use with good agricultural practice.

In its opinion of 15 March 2017, **ECHA concluded that glyphosate is not to be classified as carcinogenic**, moreover it is not mutagenic and also does not disrupt reproduction.<sup>80</sup> However, it did classify glyphosate with: Eye Damage (class 1, Causes serious eye damage) and Aquatic Chronic (class 2; Toxic to aquatic life with long lasting effects). The hazard classifications with regard to eye damage and aquatic toxicity were already in place before the renewed evaluation in 2016.<sup>81</sup> It should be stressed that the ECHA carries out a hazard assessment, which does not consider the exposure.

In May 2017 the Commission, therefore, restarted the discussion, which also took into account the **EFSA opinion** published on 7 September 2017, that concluded that on the basis of the data assessed, **weight of evidence indicates that glyphosate is not an endocrine disrupter**.<sup>82</sup> The Commission proposed the renewal for glyphosate for 10 years, and the proposal also included certain conditions of approval.<sup>83</sup> A **second European Parliament resolution** was adopted on 24 October 2017, one day before the meeting of the PAFF Committee, in which the Commission proposal foreseeing a renewal for 10 years was to be discussed.<sup>84</sup> In this resolution the Parliament again referred to a breach of the precautionary principle,<sup>85</sup> and also called for phasing out the use of glyphosate in the EU until 15 December 2022.<sup>86</sup>

In the **comitology committee**, some Member States questioned why the renewal period was shortened to 10 years and the meeting ended with the Commission requesting written comments. The discussions in the comitology committee continued throughout October, however, no majority for or against could be found.<sup>87</sup> On 9 November 2017, the PAFF was asked again to vote, this time the Commission had proposed a renewal for 5 years. Again, no majority could be found and the Committee delivered no opinion. The **division in the position of the Member States** becomes visible in the summary report:

*'Several Member States voting in favour indicated that they would have preferred a longer period of renewal but agreed to the shorter period of renewal in the spirit of compromise. (...) Two Member States voted against as they wanted a renewal or extension of approval for*

---

<sup>80</sup> ECHA, Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N-(phosphonomethyl)glycine, CLH-O-0000001412-86-149/F, 15 March 2017.

<sup>81</sup> ECHA, How ECHA is assessing glyphosate, ECHA Newsletter 3/2016, p. 3.

<sup>82</sup> EFSA, Conclusion on the peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate', 15(9) 4979 EFSA Journal (2017), pp.1-20.

<sup>83</sup> See: [https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment\\_en](https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment_en), last accessed: 13/4/2020.

<sup>84</sup> European Parliament resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 (D053565-01 – 2017/2904(RSP)), P8\_TA(2017)0395.

<sup>85</sup> Ibid., Point 1.

<sup>86</sup> Ibid., Point 6.

<sup>87</sup> See: [https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment\\_en](https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment_en), last accessed: 13/4/2020.

*a maximum period of 3 years. (...) Three Member States voted against due to political and societal sensitivity and environmental concerns. (...) One Member State voted against as its national parliament had adopted a formal position against any period of renewal or extension of approval. Three Member States abstained as they considered a 5-year renewal period too short and because they saw no scientific or legal reasons justifying such a short period of renewal. One of them indicated that the resources needed at national level to review the existing authorisations of glyphosate-containing products were of concern in particular in the light of the short period of renewal proposed.*<sup>88</sup>

Finally, on 27 November an Appeal Committee voted in favour of a 5 year renewal,<sup>89</sup> after Germany had changed its position from an abstention to a positive vote.<sup>90</sup> On 12 **December 2017 the renewal of the glyphosate approval was adopted by the European Commission.**<sup>91</sup> This approval of glyphosate will expire on 15 December 2022.

On 12 December 2019 a group of companies referring to themselves as the Glyphosate Renewal Group<sup>92</sup> has submitted an application for renewal of the glyphosate approval. In deviation from the normal renewal procedure, the application will be assessed by a group of 4 Member States consisting of France, Hungary, the Netherlands and Sweden, forming the Assessment Group on Glyphosate (AGG).<sup>93</sup>

### **The precautionary principle in the glyphosate approval**

As the previous sections have shown, the precautionary principle is deeply embedded in the regulatory framework for pesticides in the EU. Submitting glyphosate to an approval procedure based on the hazard-based approach, which is continuously repeated in each renewal, is an expression of the precautionary principle in itself. Therefore, it is important to stress that according to the finding of a study carried out for the European Parliament, “did not find evidence that, in the case of glyphosate, the national and EU authorities

---

<sup>88</sup> European Commission, Summary Report of the Standing Committee on Plants, Animals, Food and Feed held in Brussels on 17 July 2017, [sante.ddg2.g.5\(2017\)4119844](https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment_en).

<sup>89</sup> See: [https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment\\_en](https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment_en), last accessed: 13/4/2020.

<sup>90</sup> <https://euobserver.com/environment/140042>, last accessed 13/4/2020; <https://www.politico.eu/pro/glyphosate-renewal-shakes-germany-france-italy/>, last accessed 13/4/2020.

<sup>91</sup> Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, OJ L 333, 15.12.2017, pp. 10–16.

<sup>92</sup> <https://glyphosate.eu>, last accessed: 13/4/2020.

<sup>93</sup> Commission Implementing Regulation (EU) 2019/724 of 10 May 2019 amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur Member States and co-rapporteur Member States for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin and amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the rapporteur Member State, OJ L 124, 13.5.2019, pp. 32–35.

involved in the evaluation process did not comply with the relevant procedures under the approval (renewal of approval) of substances.”<sup>94</sup>

In the case of glyphosate, after a **scientific risk assessment** by EFSA (and hazard assessment by ECHA), the **Commission as risk manager** - in accordance with the comitology committee vote - decided that a ban was not necessary, even in the face of large public pressure. The decision to grant the renewal shows that the **threshold of damage** that would have triggered a ban/non-renewal has not been met. This is due to the fact that in the risk assessment process neither ECHA nor EFSA classified the substance as carcinogenic, or meeting any of the other cut-off criteria. To a certain degree this also explains why carcinogenicity became the focal point of the glyphosate renewal procedure: Had glyphosate been classified as carcinogenic in the EU, it would have met a cut-off criterion and would have been banned immediately.

When considering the role of **cost effectiveness/ proportionality**, as glyphosate has been renewed, no cost-effectiveness assessment of a ban has taken place. The same also holds true with regard to the absence of an **impact assessment**. In this regard it can be added that for the measures taken under the Regulation, such as the approval or renewal of an active substance, no impact assessments of the risk management measures are routinely carried out in the regulatory process (Bozzini 2017).

With regard to **reversibility** of the glyphosate renewal in 2017, one has to refer to the possibility to review any approval under Article 21 of the Pesticide Regulation where this is warranted by new scientific findings and technical knowledge. Also the European Commission stressed in its answer to the European Citizens Initiative that “the Commission can, at any time, review the approval of glyphosate if new scientific evidence emerges that indicates that the substance no longer fulfils the approval criteria laid down in the Plant Protection Products Regulation.”<sup>95</sup> Moreover, in case of glyphosate, the renewal was only granted for 5 year, which entails that the new dossier had to be submitted until December 2019. Thus, there is very quick review of the measure. As the Commission explains: “This renewal period is significantly shorter than the maximum of 15 years foreseen in EU legislation but the Commission also took into account the views of the European Parliament and other legitimate factors when setting the appropriate period of renewal. In fact, the Commission has taken into account possibilities of rapid future developments in science and technology: while a large amount of inform.”<sup>96</sup>

## Court of Justice of the European Union

The glyphosate approval has kept the Court of Justice of the European Union quite busy, which for a technical issue like the approval of an active substance is relatively uncommon. The glyphosate approval was dealt with by the General Court and the Court of Justice in the cases:

---

<sup>94</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p. 47.

<sup>95</sup> European Commission, Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final, p. 9.

<sup>96</sup> Ibid.



- T-545/11 *Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe) v European Commission*, ECLI:EU:T:2013:523
  - C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe*, ECLI:EU:C:2016:889
  - T-545/11 RENV *Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe) v European Commission*, ECLI:EU:T:2018:817
- T-12/17 *Mellifera eV, Vereinigung für wesensgemäße Bienenhaltung v European Commission*, ECLI:EU:T:2018:616
  - Currently under appeal: C-784/18 P *Mellifera v Commission*
  - T-383/18 *Mellifera v. Commission*
- T-178/18 *Région de Bruxelles-Capitale v European Commission*, ECLI:EU:T:2019:130 (Order of the General Court)
  - Currently under appeal: C-352/19 P *Région de Bruxelles-Capitale v European Commission*
- T-125/18 *Associazione Nazionale Granosalus vs. European Commission*, ECLI:EU:T:2019:92
  - Currently under appeal: Case C-313/19 P *Associazione GranoSalus v Commission*
- T-716/14 *Tweedale v EFSA*, ECLI:EU:T:2019:141
- T-329/17 *Hautala v EFSA*, ECLI:EU:T:2019:142
- C-616/17 *Criminal proceedings against Mathieu Blaise and Others*, ECLI:EU:C:2019:800

Most cases related to access to documents, where third parties requested to see certain studies that were part of the dossiers of the original glyphosate approval procedure in 2002 as well as the renewal procedure. This line of case law has significantly contributed to the balancing of **transparency of the authorisation procedure** and the scientific assessment and commercially confidential information contained in the authorisation dossier. These developments are not directly related to the precautionary principle. However, the **Court clearly connected the increasing transparency with regard to documents to constitutional values such as democracy, accountability and participatory openness** (Morvillo 2019; Korkea-aho & Leino 2017). The Court was thus concerned with making the risk assessment stage visible to the broader public, to enhance the citizens trust in the process and also to allow for an open debate. Ultimately, this led to a reform of the transparency rules with regard to studies submitted to EFSA in the context of the approval of new active substances and in other fields of activity of the Agency.<sup>97</sup> The adopted Regulation now provides for publication of all studies submitted in the risk assessment process and also requires all studies commissioned to be registered, in order to prevent that unfavourable studies can go unnoticed (de Boer 2019).

In the case brought by the government of the region Brussels (T-178/18 *Région de Bruxelles-Capitale v European Commission*), it was **pleaded that the glyphosate**

<sup>97</sup> Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, OJ L 231, 6.9.2019, pp. 1–28.

**renewal infringed the precautionary principle** claiming that the renewal fails to ensure a high level of protection of human health and of the environment, as the risk assessment would fail to fulfil the conditions of the precautionary principle. In an article published by the webportal Politico, an official of the region bringing the claim was cited to have stated: "As long as the causal link between glyphosate and harmful effects is not 100% proven, it cannot be banned. This is diametrically opposed to the precautionary principle."<sup>98</sup> However, as the case was declared **inadmissible** due to strict rules on standing and an absence of direct concern, the position of the Court concerning this line of argumentation is not available.

However, in the *Blaise case*, ruled by the Grand Chamber of the Court of Justice in October 2019, the Court was asked in a **preliminary reference to assess if Regulation 1107/2009 is compatible with the precautionary principle**. In the case the Court clarified the requirements of the correct application of the precautionary principle in the regulation of pesticides, stating that it should entail (i) the identification of potential risks of active substances and PPPs for health and (ii) a comprehensive risk assessment "based on the most reliable scientific data available and the most recent results of international research".<sup>99</sup> The Court stated the benchmark laid by the precautionary principle for the validity of the Regulation is the question whether the legislation ensures that the competent authorities have enough information to adequately assess the risk of the active substances and PPPs under review.<sup>100</sup> Importantly, however, the Court stressed that a finding of non-compliance of the Regulation with the precautionary principle could not be based - solely - on the circumstances of a particular case, here the alleged errors in the glyphosate approval procedure.<sup>101</sup> Overall, none of the questions raised in the procedure led to a finding that challenged the validity of the Regulation.

## Measures taken by Member States

When looking beyond the active substance glyphosate, the plant protection products – including their formulation, are assessed on Member State level. With regard to PPPs the EU operates a specific version of **mutual recognition**: the territory of the EU is divided in three zones: north, centre and south, which is based on comparability of agricultural, plant health and environmental (including climatic conditions). If a product is authorised in a Member State belonging to one zone, e.g. North, then the authorisation should also be granted in the other Member States of this zone based on the risk assessment carried out by the other Member State.<sup>102</sup> However, the criteria on which the authorisation procedure in the national competent authorities are based are **subject to EU harmonisation**, to ensure the same level of safety across the Union and in order to facilitate mutual recognition.<sup>103</sup> Nonetheless, a recent study conducted for the European Parliament, concluded that there are still significant **differences** between the standards and

---

<sup>98</sup> <https://www.euractiv.com/section/agriculture-food/news/brussels-government-takes-commission-to-eu-court-over-glyphosate/>, last accessed: 13/4/2020.

<sup>99</sup> C-616/17 Criminal proceedings against Mathieu Blaise and Others, ECLI:EU:C:2019:800, para. 48.

<sup>100</sup> Ibid., para. 74.

<sup>101</sup> Ibid., paras 48-49.

<sup>102</sup> Annex 1 Regulation (EC) No 1107/2009. The North Zone includes Denmark, Estonia, Latvia, Lithuania, Finland, Sweden; the Centre Zone is composed of Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia; and the South Zone is made up of Bulgaria, Greece, Spain, France, Croatia, Italy, Cyprus, Malta, Portugal.

<sup>103</sup> The data requirements for the dossier are set in Implementing Regulation (EU) No 284/2013 and Regulation (EU) 546/2011 establishes uniform principles for evaluation and authorisation of PPPs.



procedures in national risk assessments, which creates obstacles to the mutual recognition of authorizations.<sup>104</sup>

With regard to the authorisation of glyphosate-based herbicides in the Member States, it should be noted that **several states have communicated their plans to ban glyphosate-based herbicides**. The French competent authority in December 2019 announced that after a review of the renewal applications for PPP authorisation, 36 out of the 39 glyphosate containing products available in France will be prohibited from the end of 2020 onwards, "due to a lack or absence of scientific data ruling out any genotoxic risk."<sup>105</sup> Next to France,<sup>106</sup> there has been debate about glyphosate-bans (more precisely: bans on glyphosate containing pesticides) in several EU Member States. In Austria, the Parliament in July 2019 voted positively on a glyphosate ban from 1 January 2020 onwards. However, the ban until the time of writing has not been signed into law.<sup>107</sup> In Germany, the government in the so-called 'Agrarpaket' decided to ban glyphosate containing pesticides until the end of 2023 in order to protect insects,<sup>108</sup> but also here no binding law has been adopted yet. Only Luxemburg has adopted legislation to ban glyphosate/glyphosate-based herbicides, withdrawing the marketing authorization from 1 February 2020 onwards.<sup>109</sup>

### Glyphosate risk governance around the world

In the literature it is argued that the European regulatory framework for pesticides is one of the strictest in global comparison and the regulatory measures taken in the EU, including both the authorizations and conditions of use of pesticides, are stricter and more precautionary than comparable decisions in the US (Bozzini 2017).

When it comes to glyphosate, it should be mentioned that its **carcinogenicity was reviewed also by other regulatory bodies outside the EU**. As stated by the Commission in its answer to the citizens' initiative the conclusion of EFSA and ECHA "is shared by other national and international bodies (from Canada, Japan, Australia and New Zealand, and also the Joint UN Food and Agriculture Organisation/World Health Organisation Meeting on Pesticide Residues."<sup>110</sup>

---

<sup>104</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018.

<sup>105</sup> <https://www.anses.fr/en/content/anses-announces-withdrawal-36-products-containing-glyphosate>, last accessed: 13/4/2020.

<sup>106</sup> <https://www.euractiv.com/section/agriculture-food/news/french-mayors-ban-glyphosate-weedkiller-defying-government/>, last accessed: 13/4/2020.

<sup>107</sup> [https://www.parlament.gv.at/PAKT/VHG/XXVII/E/E\\_00004/fname\\_775803.pdf](https://www.parlament.gv.at/PAKT/VHG/XXVII/E/E_00004/fname_775803.pdf), last accessed: 13/4/2020;

[https://www.parlament.gv.at/PAKT/PR/JAHR\\_2019/PK0808/index.shtml](https://www.parlament.gv.at/PAKT/PR/JAHR_2019/PK0808/index.shtml), last accessed: 13/4/2020; <https://kontrast.at/glyphosat-verbot-oesterreich/>, last accessed: 13/4/2020.

<sup>108</sup> <https://www.zeit.de/wissen/umwelt/2019-09/tierwohl-label-nutztiere-insekten-glyphosat-julia-kloeckner>, last accessed: 13/4/2020.

<sup>109</sup> [https://gouvernement.lu/en/actualites/toutes\\_actualites/communiqués/2020/01-janvier/16-interdiction-glyphosate.html](https://gouvernement.lu/en/actualites/toutes_actualites/communiqués/2020/01-janvier/16-interdiction-glyphosate.html), last accessed: 13/4/2020.

<sup>110</sup> European Commission, Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final, p. 7.

However, it should also be mentioned that in the US, and specifically in California, Monsanto/Bayer and other producers of glyphosate-based herbicides have faced **litigation**, mostly by professional users of these herbicides who developed cancer later on (Arcuri & Hendlin 2019). For example in the case *Hardeman v. Monsanto* (Case No 16-cv-00525-VC) from the United States District Court Northern District of California, found in favour of the applicant that Monsanto had negligently failed to place sufficient cancer warnings on Roundup bottles. Also in the cases brought by Dewayne Johnson (*Dewayne Johnson v Monsanto* (case No CGC-16- 550128)) and Alva and Alberta Pilliod v. Monsanto (Case No. RG17862702, JCCP No. 495), were won by the applicants as the court agreed that the exposure to glyphosate has caused them to develop cancer. However, the task of the courts in such cases significantly differs from the risk assessment of a regulatory authority, which means that the judgment regarding the scientific evidence by the courts is not easily transferred to a risk assessment (Benbrook 2020).

## 4.2 Other governance dynamics

Generally the **risk perception of pesticides has changed over time**: Whereas initially the early 1900's the use of chemicals in farming was embraced as it helped to alleviate hunger, this changed in the 1960s when the risk for human health and the environment associated with pesticides became clearer (Bozzini 2017). When it comes to plant protection products, Regulation (EC) 1107/2009 aims to protect human and animal health as well as the environment, while improving agricultural production.<sup>111</sup> These aims and whether the Regulation succeeds in achieving them is contested, as shown in a study for the European Parliament: while some stakeholders including NGOs, but also national regulators, said that the aim of improving production and trade "are no longer relevant"<sup>112</sup>, a pesticide manufacturers association expressed their concern that the Regulation is unnecessarily burdensome in terms of health and environmental protection measures and negatively impacts on the Unions agricultural industry on the global market.<sup>113</sup>

It should be made clear that the **debate surrounding glyphosate is deeply entangled with a bigger societal, political, ecological and economical question on the future of agriculture**.<sup>114</sup> As Alexandra Brand (Syngenta) told Politico: "A lot of what we talk about pesticides is a symbol for an agriculture we are not happy with."<sup>115</sup> The discussion surrounding glyphosate was certainly politicised due to its connection to the very contested issue of GMOs. For example the Parliament Resolution from April 2016 in paragraphs AC and AD mentioned the connection between glyphosate and GMOs, and that the Parliament had objected to four different draft GMO authorisations.<sup>116</sup> Arguably, at the time Monsanto as one of the most prominent glyphosate-based herbicide producers, attracted normative critique being "the symbol of industrialized agriculture" (INGSA 2017, p.6).

---

<sup>111</sup> Regulation (EC) No 1107/2009, Art. 1(3).

<sup>112</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p. 34.

<sup>113</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p. 34.

<sup>114</sup> See: Section 4.2. of this report.

<sup>115</sup> <https://www.politico.eu/article/battle-over-glyphosate-shifts-to-the-environmental-front-pesticides-herbicides/>, last accessed: 13/4/2020.

<sup>116</sup> EP Resolution P8\_TA(2016)0119.

Glyphosate itself is a catalyst of the shift to large industrial-style farming, which has been criticized for creating 'green deserts' of monocultures, which in turn are detrimental to biodiversity (Paskalev 2019). This concern with broader questions of agricultural policy is also very visible in the European Citizens Initiative which called on the Commission to "set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future".<sup>117</sup> In its answer the Commission made clear that the EU is not in pursuit of a zero-pesticide policies, but that it is aiming at sustainable use of pesticides.<sup>118</sup> As expressed by the NGO Corporate Europe Observatory:

*"In our opinion, one of the most important – but less discussed – stakes in this process has been the possibility to put an end to the use of one the most used and efficient plant-killer on Earth while we're experiencing the fastest biodiversity collapse ever measured. The glyphosate saga could have been an opportunity to at last discuss and regulate the use of wide-spectrum herbicides in agriculture, but this is yet to happen."*<sup>119</sup>

## 5 The precautionary principle and its future

### 5.1 Reflection on the PP in the literature

The use of the precautionary principle in the approval procedure of glyphosate and the pesticides framework in general have been extensively reflected on and criticised. Many criticisms were already mentioned in the previous analysis, however, in this section some of the central reflections on the use of the precautionary principle in the glyphosate renewal procedure will be discussed.

Although the Pesticides Regulation presents the **hazard-based cut-off criteria**, like carcinogenicity, as binary 'fulfilled or not fulfilled' criteria, the reality is different: although some of the criteria are subject to such a black-or-white assessment with clear scientific indicators, most of these criteria are more openly defined and require an expert judgement, often using a weight of evidence approach (SAM 2018). Already in the section 3.3.3 discussing ambiguity of scientific findings, it was discussed that the IARC and the EU agencies assigned different importance to scientific data, and especially studies published by academics which lack GLP certification. The **weight of evidence** that EFSA and ECHA gave to certain studies and the fact that it dismissed others is not undisputed. A group of scientists led by Prof. Portier (who has also acted as invited specialist during the IARC meeting) send a letter to the European Commission in November 2015 criticising the BfR assessment for errors in their assessment and for incorrectly dismissing certain evidence.<sup>120</sup> Concerned scientists including Prof. Portier and Dr. Clausen (affiliated with

<sup>117</sup> European Commission, Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final, p. 12.

<sup>118</sup> Ibid.

<sup>119</sup> <https://corporateeurope.org/en/food-and-agriculture/2016/06/glyphosate-one-pesticide-many-problems>, last accessed 13/4/2020.

<sup>120</sup> <https://www.baumhedlundlaw.com/pdf/monsanto-documents/johnson-trial/DX-2735-Portier-Letter-EFSA-BfR-Glyphosate.pdf>; last accessed: 13/4/2020. Portier followed up with another letter in 2017 after the Monsanto papers:

the Pesticide Action Network) also voiced criticisms in scientific articles regarding the application weight of evidence standards and the risk assessment in the case of glyphosate (Clausing et al 2018; Robinson et al 2020). Moreover, in other articles comparing the IARC and EFSA assessment, they identified flaws in the risk assessment carried out by EFSA (Portier et al 2016; Portier et al 2017).

With regard to the glyphosate risk assessment, another core criticism relates to the **reliability of the studies provided for by the industry** in the renewal of approval procedure. Generally, concerns have been raised whether the shift of the burden of proof that requires the applicant to submit the safety evidence, guarantees correct data and an independent and transparent risk assessment.<sup>121</sup> The information asymmetry between the applying companies and the risk assessing public authorities raised concerns.<sup>122</sup> The **Monsanto papers scandal**, where Monsanto was forced to release documents including emails, peer review reports, drafts of manuscripts as well as power point presentations, in the context of tort litigation against the company in California,<sup>123</sup> has contributed to the questions concerning the reliability of industry financed studies (McHenry 2018). The publication of these documents showed that Monsanto actively interfered in the supposedly objective scientific debate by ghost-writing scientific articles and intruding in peer review process (McHenry 2018). McHenry (2018, p.202) in this regard concludes that Monsanto has "poisoned the [scientific] well by flooding the scientific journals with ghost-written articles and interfering in the scientific process at multiple levels."

Moreover, **the lack of transparency of the approval process** and the confidentiality of the submitted studies was criticized.<sup>124</sup> To address some concerns raised by shifting the burden of proof on the industry the Commission promised to enhance the auditing of the studies and their compliance with the GLP, to increase the transparency concerning the studies taken into account and to create the possibility to exceptionally commission studies in case of serious doubts.<sup>125</sup> These measures were taken through adoption of Regulation 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain.<sup>126</sup>

Not only the risk assessment process was criticized for a lack of transparency, but also the **risk management process was deemed to lack transparency**. These transparency

---

<https://corporateeurope.org/sites/default/files/attachments/letterjuncker28may2017.pdf>, last accessed: 13/4/2020.

<sup>121</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p. 40f.

<sup>122</sup> Ibid., p. 41.

<sup>123</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, Annex II p. 58.

<sup>124</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, Annex II p.73 and Annex IV p. 57; Korkea-aho & Leino, 2017.

<sup>125</sup> European Commission, Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final, p. 12.

<sup>126</sup> Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, OJ L 231, 6.9.2019, pp. 1–28.

concerns are important with regard to the application of the precautionary principle as it is in the risk management stage that the principle is applied, in accordance with Article 13 of the Pesticide Regulation. A report for the European Parliament for example points out: "Evidence shows that there is a need for a more transparent and comprehensive risk management stage since most of the time the reasoning behind risk management decisions, the regulatory criteria adopted and how the discussions among decisions-makers unfolded is not made explicitly public."<sup>127</sup> This concern is also voiced by stakeholders.<sup>128</sup>

However, the transparency of the application of the principle is in practice challenged by two factors: first of all, the **criteria for decision-making in the risk management task are not clearly laid down**. While this allows for flexibility and a wide margin of appreciation in the decision-making, which may be necessary in the face of complex risks, it also hinders legal certainty and the meaningful accountability for the decision made (Bozzini 2017; Morvillo 2020). Second of all, the actual reasons for concrete decisions made in the approval of an active substance, like glyphosate, are not openly communicated.<sup>129</sup> The Scientific Advice Mechanism therefore recommended that the goals protected by a measure and factors that were taken into account should be clearly communicated (SAM 2018). Also the European Parliament called for transparency of the comitology procedure.<sup>130</sup>

In the aftermath of the glyphosate renewal the European Parliament decided to investigate the functioning of the pesticides approval and authorization procedures through a committee devoted to this topic, the **Special Committee on Pesticides (PEST)**.<sup>131</sup> Based on this report, the European Parliament on 16 January 2019 adopted a resolution, which amongst many other issues also addresses the role of the precautionary principle in the pesticides procedures. The Parliament asked the Commission and the Member States to "in their role as risk managers to duly apply the precautionary principle when, following an assessment of the available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, by adopting provisional risk management measures necessary to ensure a high level of protection of human health."<sup>132</sup>

Finally, in an article in King's Law Journal, Arcuri and Hendlin (2019), argue that the regulatory approach taken in the case of glyphosate **fails to sufficiently protect vulnerable populations and non-human organisms**. They argue (Arcuri and Hendlin 2019, p. 236) that in the risk determination of environmental toxicology "legal frameworks (...) frequently minimise risks and overestimate the certainty and accuracy of assessments, leading to downplaying the exposures of those populations most threatened by toxic chemicals." The risk assessment of glyphosate, and pesticides in general, according to their view is flawed as it suffers from compartmentalisation and anthropocentrism (Arcuri and Hendlin 2019). They criticise that, with the regulation being anthropocentric, vulnerable

---

<sup>127</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p. 50.

<sup>128</sup> Ibid.

<sup>129</sup> Ibid.

<sup>130</sup> European Parliament resolution of 16 January 2019 on the Union's authorisation procedure for pesticides, P8\_TA(2019)0023, Point 79.

<sup>131</sup> European Parliament, European Parliament decision of 6 February 2018 on setting up a special committee on the Union's authorisation procedure for pesticides, its responsibilities, numerical strength and term of office, P8\_TA(2018)0022.

<sup>132</sup> European Parliament resolution of 16 January 2019 on the Union's authorisation procedure for pesticides, P8\_TA(2019)0023, Point 6.

groups in the human population as well as animals are not adequately protected in the current exposure and harm thresholds.

## 5.2 Effect of the PP on innovation pathways

As far as pesticides are concerned, next to weeds becoming resistant to certain pesticides, the **increasingly demanding regulatory framework and the banning of substances has led to innovation** (Bozzini 2017). While the sector remains very profitable, it is argued that research and development costs have dramatically increased (Bozzini 2017). As explained in an article by the legal scholars Garnett, van Calster and Reins (2018, p.6): although no piece of EU legislation directly and exclusively addresses innovation, general rules such as the precautionary principle and sector specific legislation, like the Pesticides Regulation, has an effect on how innovation is approached in certain sectors and companies. The balance that is struck in the legislation between protection human health and the environment and promoting trade industrial interests, and therefore innovation, is a core struggle in the innovation pathway for pesticides.

Whether the debate surrounding the risks of glyphosate will lead to innovation in changing the product or leading to its replacement is currently not foreseeable. Concerns have been voiced that in case of a ban, glyphosate might not be easily substituted. Euractiv published an article citing Bayer official Dr. Bob Reiter as referring to glyphosate as a 'once in a lifetime product' and that it has properties that even after intensive research so far have not been discovered in another substance.<sup>133</sup> According to this interview, Bayer is aiming to prevent a complete replacement of glyphosate and instead is trying to advocate to complement it with other substances.<sup>134</sup>

However, as was already discussed in section 4.2., the glyphosate debate is very much influenced by border concerns of agricultural policy and the questioning of the future use of pesticides. Stakeholders call for new objectives in the pesticide regulation, including: "developing new technologies, investing in the use of naturally occurring substances and the protection of farm ecosystems, stimulating use of substances with low risk, or promoting non-animal methods for assessment of risks of substances and mixtures".<sup>135</sup> Also the **European Green New Deal** promoted by the von der Leyen Commission in this regard states:

*"The strategic plans will need to reflect an increased level of ambition to reduce significantly the use and risk of chemical pesticides, as well as the use of fertilisers and antibiotics. The Commission will identify the measures, including legislative, needed to bring about these reductions based on a stakeholder dialogue. The area under organic farming will also need to increase in Europe. The EU needs to develop innovative ways to protect harvests from pests and diseases and to consider the potential role of new innovative techniques to improve*

<sup>133</sup> <https://www.euractiv.com/section/agriculture-food/news/no-magical-alternative-to-glyphosate-in-the-next-5-years-bayer-official-says>, last accessed: 13/4/2020.

<sup>134</sup> <https://www.euractiv.com/section/agriculture-food/news/no-magical-alternative-to-glyphosate-in-the-next-5-years-bayer-official-says>, last accessed: 13/4/2020.

<sup>135</sup> European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018, p. 34-35.



*the sustainability of the food system, while ensuring that they are safe.*"<sup>136</sup>

Thus, some form of innovation will have to occur in the pesticides industry, given the public and political pressure. In this regard, **the application of the precautionary principle - through the strict regulatory framework for pesticides- can be seen as fostering innovation.** The Bureau Européen des Unions de Consommateurs (BEUC) more generally expressed it in the following way: "The precautionary principle pushes industry to research and innovate in safer or greener alternatives, which benefits both consumers and the economy."<sup>137</sup>

### 5.3 Innovation principle

This study **has not found evidence that the innovation principle has been invoked** formally in the context of the debate surrounding glyphosate. However, when in 2013 12 CEOs wrote a letter to the Presidents of the Commission, European Council and European Parliament to introduce and promote the innovation principle the CEOs of several companies producing glyphosate-based pesticides were amongst the signatories Bayer, BASF, Dow AgroScience, and Syngenta.<sup>138</sup> Many companies participating in the **European Risk Forum (ERF)**, which is central in proposing and lobbying for the innovation principle are producers of pesticides and biotechnology.<sup>139</sup> Although not specifically referring to pesticides a joint position of the ERF, BusinessEurope and the European Roundtable of Industrialists states:

*"Regulation which solely concentrates on risk avoidance and removal of scientific uncertainty and fails to consider both risks and benefits, stifles technological innovation. This type of regulation tends to result in companies directing limited budgets towards 'defensive R&D', for compliance, at the expense of more innovative and discovery oriented research."*<sup>140</sup>

Thus, the argument is advanced that strict regulatory frameworks, like the approval and authorization scheme for pesticides with heavy scientific data requirements hinders innovation, as money is spent on proving safety for the regulatory procedures rather than innovating.

As argued by Garnett, van Calster and Reins (2018, p.11), large biotech companies would use the innovation principle to side-line the precautionary principle, where they "have been finding it increasingly hard to see their products approved for use in the EU and in some

<sup>136</sup> European Commission, Communication from the Commission – The European Green Deal, COM(2019) 640 final, 11.12.2019, p. 12.

<sup>137</sup> [https://www.beuc.eu/publications/beuc-x-2018-112\\_precautionary\\_principle\\_under\\_attack\\_please\\_delete\\_so-called\\_innovation\\_principle.pdf](https://www.beuc.eu/publications/beuc-x-2018-112_precautionary_principle_under_attack_please_delete_so-called_innovation_principle.pdf), last accessed: 13/4/2020.

<sup>138</sup> [https://corporateeurope.org/sites/default/files/corporation\\_letter\\_on\\_innovation\\_principle.pdf](https://corporateeurope.org/sites/default/files/corporation_letter_on_innovation_principle.pdf), last accessed: 13/4/2020.

<sup>139</sup> [http://www.riskforum.eu/uploads/2/5/7/1/25710097/business europe-erf-ert\\_innovation\\_principle\\_joint\\_statement.pdf](http://www.riskforum.eu/uploads/2/5/7/1/25710097/business europe-erf-ert_innovation_principle_joint_statement.pdf), last accessed: 13/4/2020.

<sup>140</sup> [http://www.riskforum.eu/uploads/2/5/7/1/25710097/business europe-erf-ert\\_innovation\\_principle\\_joint\\_statement.pdf](http://www.riskforum.eu/uploads/2/5/7/1/25710097/business europe-erf-ert_innovation_principle_joint_statement.pdf), last accessed: 13/4/2020.

cases are fighting long legal battles to see their product licenses renewed (such as with glyphosate, bisphenol A or endocrine disruptors).” They point out that the industry, like in the case of glyphosate, has to go through lengthy and demanding risk assessment procedures which still might not disperse doubts with regard to the safety of the products, which explains why those companies might be inclined to shift the focus of the debate to innovation and job creation (Garnett, van Calster and Reins 2018).

Also Corporate European Observatory (CEO) warns that: “(...) these industries are trying to use this principle to undermine EU laws on chemicals, novel foods, pesticides, nano-products and pharmaceuticals, amongst others, as well as legal principles of environmental and human health protection which are enshrined in the EU Treaty.”<sup>141</sup> CEO refers to an event organized by the ERF and cites a representative of the pesticides industry as arguing that there is an incompatibility between regulations promoting innovation and those regulations that prohibit innovative or indispensable substances.<sup>142</sup> The ‘indispensable substances’ is interpreted by CEO to refer to glyphosate.<sup>143</sup>

## 6 Synthesis

The glyphosate case study illustrates very well that a **relatively old technology**, widely used around the world since the 1970s, can with new scientific findings become the center of an extensive controversy. In the last decade, concerns have been raised with regard to glyphosate and risk for human health, such as carcinogenicity and endocrine disruption, as well as risks to the environment, regarding specific species as well as whole ecosystems. However, these risks are subject to **scientific uncertainty** even decades after its invention. This is caused by uncertainty through absence of systematic monitoring of glyphosate use and exposure. Moreover, the case clearly illustrates that scientific uncertainty also can exist and persist, in case of an **intensely studied** chemical substance, with over 1,000 studies performed and continuous scientific interest leading to an ever-increasing number of studies. In the glyphosate case, the scientific uncertainty is mostly fueled by **normative and interpretative ambiguity**: the reliability of industry studies is questioned, and, regulatory authorities apply a **weight of evidence** approach that leads to academic studies being of limited significance to the risk assessment performed, leading to opposing findings concerning the highly contested carcinogenicity of glyphosate.

What is remarkable about the **risk governance on EU level** is that the **existence of scientific uncertainty is not recognized**. As the hazard and risk assessment performed by EFSA and ECHA concluded that glyphosate is not a carcinogen, from the perspective of these Agencies and the Commission, there is no scientific uncertainty on this question. This leads to the conclusion that in the EU assessment of the glyphosate debate, the legislation and the regulatory framework, with the weight of evidence approach as operated in the scientific assessment, has significantly influenced and shaped the risk assessment process (Paskalev 2020; Morvillo 2020). As explained by Paskalev (2019, p.3) who compared the IARC and EFSA/ECHA findings: “the decision of each agency is affected by its own governing documents, terms of reference, set functions and mission statement and this is why even if they all appeared to be considering the same issue – carcinogenicity of a certain substance – they were bound to reach different conclusions.” Thus, **the uncertainty with regard to the glyphosate risk is presented less as a clash of scientific findings but rather a problem of conflicting regulatory scientific choices in the hazard identification/risk assessment stage**. This has brought to the forefront

<sup>141</sup> <https://corporateeurope.org/en/environment/2018/12/innovation-principle-trap>, last accessed: 13/4/2020.

<sup>142</sup> Ibid.

<sup>143</sup> Ibid.



that in framing the risk analysis process through regulation, political choices are made and that “[g]lyphosate (...) has become a catalyst for testing existing dichotomies” and that “glyphosate has the potential of re-politicizing the field of science based-law” (Arcuri, p.243).

As was shown in this case study, although not all of **main components of the precautionary principle** as defined in the **WP1 Report: Taking stock as a basis for the effect of the precautionary principle since 2000**,<sup>144</sup> including scientific uncertainty and risk, scientific evaluation, threshold of damage, cost-effective measures/proportionality and burden of proof, were directly applicable in the case of glyphosate as the substance was not banned. However, in principle **the regulatory framework applicable to glyphosate does incorporate these characteristics**. Nonetheless, it also became clear that the **application of the precautionary principle in the risk management stage is not clearly regulated**. Although the legislation specifically mentions taking into account the PP in the decision on approval and renewal of active substances, how this should happen is not clearly defined and also not well communicated.

In the case of glyphosate, after a hazard and risk assessment by EFSA and ECHA, it was decided that a ban was not necessary, even in the face of large public pressure. While this is criticized by some stakeholders, it is also a **sign that innovation and innovative industries do not need to be specifically protected** against ‘laws of fear’<sup>145</sup>. The build-in mechanisms in the process leading to the application of the principle, like the thorough risk assessment, in itself protected against a disproportionate precautionary measure.

The glyphosate case also shows how a very technical and scientific debate – surrounding the carcinogenicity assessment and the underlying scientific methods, can be easily **politicized**. With regard to the glyphosate, this is caused, first of all, by the fact that **exposure** is in essence unavoidable for everyone, given the residues of glyphosate in food and water. On the other hand, the **debate surrounding glyphosate is deeply entangled with bigger questions on the future of agriculture and GMOs**.

This also has an impact on how the application of the precautionary principle interacts with **innovation**. While glyphosate has not been banned on EU level, a ban of the substance or the further limitation of its use will pose challenges to the chemical industry and farmers. It is debated if glyphosate would be (easily) replaceable and how innovation with regard to the substance or a possible substitute will look. What is clear is that the glyphosate controversy, together with the debate surrounding other pesticides such as neonics,<sup>146</sup> has reinvigorated the public and political pressure to rethink the use of pesticides in European agriculture. In this regard, the **precautionary principle has been a catalyst for innovation**.

## 7 Conclusion

The safety of glyphosate, and especially its effects on human health and the environment, have been called into question in the recent decade by scientific studies. However, these

---

<sup>144</sup> E. Vos & K. de Smedt, ‘Taking stock as a basis for the effect of the precautionary principle since 2000’, RECIPES WP 1 Report, available via: <https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20as%20a%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf>, last accessed: 13/04/20.

<sup>145</sup> The term was coined by Sunstein (2005).

<sup>146</sup> Please see the RECIPES case study on neonicotinoids.

studies are debated in terms of their methodology and in how far they should be taken into account in the risk assessment by regulatory bodies. In the EU, the assessment of glyphosate in the context of the renewal of approval procedure ended with a re-approval of the substance for 5 years in 2017. This decision was based on the risk assessment carried out by EU agencies, which came to the conclusion that glyphosate is not carcinogenic and also does not pose other risk that would justify banning the substance. However, this finding is contested by individual scientists and also opposes the finding of the IARC. This creates scientific uncertainty through ambiguity.

The precautionary principles shapes the approval procedure and regulation of pesticides as such, however, as in the risk assessment of glyphosate on EU level no risk was determined, no precautionary measure in the form of a ban was taken. This is contested by various stakeholders. The politicisation of the glyphosate renewal procedure has to be seen in the context of the larger debate surrounding the future of EU agriculture and the use of pesticides. In this regard, the application of the precautionary principle has led to increased political pressure, which is highly likely to result in some form of innovation in this area in the long run. As for glyphosate itself, whether innovation will be necessary will be determined in the currently ongoing renewal procedure.

## 8 References

### EU legislation and non-legislative acts

Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, pp. 13–18.

Regulation (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, OJ L 309, 24.11.2009, pp. 1–50.

Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, OJ L 231, 6.9.2019, pp. 1–28.

Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, OJ L 230, 19.8.1991, pp. 1–32.

Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticide OJ L 309, 24.11.2009, pp.71-86.

Commission Directive 2001/99/EC of 20 November 2001 amending Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market to include glyphosate and thifensulfuron-methyl as active substances OJ L 304, 21.11.2001, pp. 14–16.

Commission Directive 2010/77/EU of 10 November 2010 amending Council Directive 91/414/EEC as regards the expiry dates for inclusion in Annex I of certain active substances Text with EEA relevance OJ L 293, 11.11.2010, pp. 48–57.

Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances, OJ L 322, 8.12.2010, pp. 10-19.

Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market OJ L 252, 19.9.2012, pp. 26–32.

Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate, OJ L 208, 2.8.2016, pp. 1–3.

Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017 renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, OJ L 333, 15.12.2017, pp. 10–16.

Commission Implementing Regulation (EU) 2019/724 of 10 May 2019 amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur

Member States and co-rapporteur Member States for the active substances glyphosate, lambda-cyhalothrin, imazamox and pendimethalin and amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the rapporteur Member State, OJ L 124, 13.5.2019, pp. 32–35.

## **Other EU documents**

ECHA, Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N-(phosphonomethyl)glycine, CLH-O-0000001412-86-149/F, 15 March 2017.

ECHA, How ECHA is assessing glyphosate, ECHA Newsletter 3/2016.

European Commission, Proposal for a Council Directive concerning the placing of EEC-accepted plant protection products on the market, COM (1976) 427 final, OJ C 212, 9.9.1976, p. 3–20.

European Commission, Communication from the Commission on the precautionary principle, COM(2000)0001 final.

European Commission, Communication from the Commission on the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", C(2017) 8414 final.

European Commission, Summary Report of the Standing Committee on Plants, Animals, Food and Feed held in Brussels on 17 July 2017, [sante.ddg2.g.5\(2017\)4119844](#).

European Commission, Communication from the Commission – The European Green Deal, COM(2019) 640 final, 11.12.2019.

European Court of Auditors, Sustainable use of plant protection products: limited progress in measuring and reducing risks, Special Report 05/2020.

EFSA, Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, 13(11) 4302 EFSA Journal (2015), pp. 1-107.

EFSA, Statement of EFSA on the request for the evaluation of the toxicological assessment of the co-formulant POE-tallowamine, 13(11) 4303 EFSA Journal (2015), pp. 1-13.

EFSA, Guidance on the use of the weight of evidence approach in scientific assessments, 15(8) 4971 EFSA Journal (2017), pp. 1-69.

EFSA, Conclusion on the peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate', 15(9) 4979 EFSA Journal (2017), pp.1-20.

European Parliament resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011, P8\_TA(2017)0395.

European Parliament, European Parliament decision of 6 February 2018 on setting up a special committee on the Union's authorisation procedure for pesticides, its responsibilities, numerical strength and term of office, P8\_TA(2018)0022.

European Parliament resolution of 16 January 2019 on the Union's authorisation procedure for pesticides, P8\_TA(2019)0023.

European Parliament Research Service, Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market – European Implementation Assessment, PE 615.668, April 2018.

Scientific Advice Mechanisms, Group of Chief Scientific Advisors, EU authorisation processes of Plant Protection Products, Scientific Opinion 5/2018, June 2018.

### **Judgements Court of Justice of the European Union**

T-545/11 *Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe) v European Commission*, ECLI:EU:T:2013:523.

- C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe*, ECLI:EU:C:2016:889.
- T-545/11 *RENV Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe) v European Commission*, ECLI:EU:T:2018:817.

T-12/17 *Mellifera eV, Vereinigung für wesensgemäße Bienenhaltung v European Commission*, ECLI:EU:T:2018:616.

- Currently under appeal: C-784/18 P *Mellifera v Commission*.
- T-383/18 *Mellifera v. Commission*.

T-178/18 *Région de Bruxelles-Capitale v European Commission*, ECLI:EU:T:2019:130 (Order of the General Court).

- Currently under appeal: C-352/19 P *Région de Bruxelles-Capitale v European Commission*.

T-125/18 *Associazione Nazionale Granosalus vs. European Commission*, ECLI:EU:T:2019:92.

- Currently under appeal: Case C-313/19 P *Associazione GranoSalus v Commission*.

T-716/14 *Tweedale v EFSA*, ECLI:EU:T:2019:141.

T-329/17 *Hautala v EFSA*, ECLI:EU:T:2019:142.

C-616/17 *Criminal proceedings against Mathieu Blaise and Others*, ECLI:EU:C:2019:800

- Opinion of Advocate General Sharpston in case C-616/17 *Criminal proceedings against Mathieu Blaise and Others*, ECLI:EU:C:2019:190.

### **Literature**

A. Arcuri, 'Glyphosate', in J. Hohmann & D. Joyce, *International Law's Objects* (Oxford University Publishers, 2018), pp. 234-246.

A. Arcuri & Y. Hendlin, 'The Chemical Anthropocene: Glyphosate as a Case Study of Pesticide Exposure', 30(2) *King's Law Journal* (2019), pp. 234-253.

C. Benbrook, 'Trends in glyphosate herbicide use in the United States and globally', 28(3) *Environmental Sciences Europe* (2016), pp. 1-15.

C. Benbrook, 'How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides?', 31(2) *Environmental Sciences Europe* (2019), pp. 1-16.

C. Benbrook, 'Shining a Light on Glyphosate-Based Herbicide Hazard, Exposure and Risk: Role of Non-Hodgkin Lymphoma Litigation in the USA', *forthcoming in European Journal of Risk Regulation* (2020), available via: <https://doi.org/10.1017/err.2020.16>, last accessed: 13/4/2020.

A. de Boer, 'Transparency and consumer trust in scientific assessments under European food law', in A. Urazbaeva, et al. (Eds.), *The functional field of food law: Reconciling the market and human rights* (Wageningen Academic Publishers, European Institute for Food Law, Vol. 11), pp. 245-255.

E. Bozzini, *Pesticide Policy and Politics in the European Union: Regulatory Assessment, Implementation and Enforcement* (Palgrave Macmillan, 2017).

T. van den Brink, 'Danger! Glyphosate may Expose Weaknesses in Institutional Systems: EU Legislation and Comitology in the Face of a Controversial Reauthorisation' *forthcoming in European Journal of Risk Regulation* (2020), available via: <https://doi.org/10.1017/err.2020.2>, last accessed: 05/08/2020.

F. Chang et al., 'Occurrence and fate of the herbicide glyphosate and its degradate aminomethylphosphonic acid in the atmosphere', 30(3) *Environmental Toxicology and Chemistry* (2011), pp. 548-555.

P. Clausen et al., 'Pesticides and public health: an analysis of the regulatory approach to assessing the carcinogenicity of glyphosate in the European Union', 72 *Epidemiol Community Health* (2018), pp. 668-672.

A. De Roos et al., 'Integrative assessment of multiple pesticides as risk factors for non-Hodgkin's lymphoma among men', 60(9) *Occupational Environmental Medicine* (2003), p. 1-9.

G. Dill et al., 'Glyphosate: discovery, development, applications, and properties' in V. Nandula (ed.), *Glyphosate resistance in crops and weeds: history, development, and management* (John Wiley & Sons; 2010), pp. 1-33.

K. Garnett, G van Calster & L. Reins, 'Towards an innovation principle: an industry trump or shortening the odds on environmental protection?', 10(1) *Law, Innovation and Technology* (2018), pp. 1-14.

C. Gasnier et al., 'Glyphosate-based herbicides are toxic and endocrine disruptors in human cell lines', 262(3) *Toxicology* (2009), pp. 184-191.

K. Guyton et. al, 'Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate', 16(5) *The Lancet Oncology* (2015), pp. 490-491.

A. Hensel, 'Zwischen Wissen und Metaphysik – Wo steht das Vorsorgeprinzip im Streit um die Risikobewertung des Pflanzenschutzmittelwirkstoffs Glyphosat? ', 43(4) *Zeitschrift für das gesamte Lebensmittelrecht* (2016), pp. 447-450.

C. Huhn, 'More and enhanced glyphosate analysis is needed', 410 *Analytical and Bioanalytical Chemistry* (2018), pp. 3041-3045.

L. Hardell et al., 'Exposure to Pesticides as Risk Factor for Non-Hodgkin's Lymphoma and Hairy Cell Leukemia: Pooled Analysis of Two Swedish Case-control Studies', 43(5) *Leukemia & Lymphoma* (2002), pp. 1043-1049.



- E. Korkea-aho & P. Leino, 'Who owns the information held by EU agencies?: Weed killers, commercially sensitive information and transparent and participatory governance, 54(4) *Common Market Law Review* (2017), pp. 1059-1092.
- L. Krass et al., 'Relationship between agrochemical compounds and mammary gland development and breast cancer', 508 *Molecular and Cellular Endocrinology* (2020), pp. 1-9.
- G. Leonelli, 'The glyphosate saga and the fading democratic legitimacy of European Union risk regulation', 25(5) *Maastricht Journal of European and Comparative Law* (2018), pp. 582-606.
- V. Lozano et al., 'Sex-dependent impact of Roundup on the rat gut microbiome', 5 *Toxicology Reports* (2018), pp. 96-107.
- L. McHenry, 'The Monsanto Papers: Poisoning the Scientific Well', 29(3) *International Journal of Risk and Safety in Medicine* (2018), pp. 193-205.
- R. Mesagne et al., 'Ethoxylated adjuvants of glyphosate-based herbicides are active principles of human cell toxicity', 313(2-3) *Toxicology* (2013), pp. 122-128.
- L. Maxim and J. van der Sluijs, 'Seed-dressing systemic insecticides and honeybees', in European Environmental Agency, *Late lessons from early warnings: science, precaution, innovation*, EEA Report 1/2013, pp. 369-406, available via: <https://www.eea.europa.eu/publications/late-lessons-2/late-lessons-2-full-report/part-b-emerging-lessons-from-ecosystems-1/view>, last accessed: 13/4/2020.
- M. Morvillo, 'The General Court Orders Disclosure of Glyphosate-related Scientific Studies: Tweedale, Hautala, and the Concept of Environmental Information in the Context of Plant Protection Products', 10(2) *European Journal of Risk Regulation* (2019), pp. 419-427.
- M. Morvillo, 'Glyphosate Effect: Has the Glyphosate Controversy Affected the EU's Regulatory Epistemology?', *forthcoming in European Journal of Risk Regulation* (2020), available via: <https://doi.org/10.1017/err.2020.11>, last accessed: 05/08/2020.
- J. Myers et al, 'Why public health agencies cannot depend on good laboratory practices as a criterion for selecting data: the case of bisphenol A', 117(3) *Environmental Health Perspectives* (2009), pp. 309-315.
- J. Myers et al., 'Concerns over use of glyphosate-based herbicides and risk associated with exposures: a consensus statement', 15(19) *Environmental Health* (2016), pp. 1-13.
- A. Paganelli et al., 'Glyphosate-based herbicides produce teratogenic effects on vertebrates by impairing retinoic acid signaling', 23(10) *Chemical Research in Toxicology* (2010), pp. 1586-1595.
- V. Paskalev, 'On Giving Account and Taking Things into Account: The Case of Glyphosate', TARN Working Paper Series 1/2019, available via: [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3316949](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3316949), last accessed: 13/4/2020.
- V. Paskalev, 'The Clash of Scientific Assessors: What the Conflict over Glyphosate Carcinogenicity Tells Us about the Relationship between Law and Science', *forthcoming in European Journal of Risk Regulation* (2020), available via: <https://doi.org/10.1017/err.2020.59>, last accessed 05/08/2020.
- P. Pollak, *Fine chemicals, the industry and the business*, (2<sup>nd</sup> edition; John Wiley & Sons, Hoboken; 2011).



C. Portier et al., 'Glyphosate toxicity and carcinogenicity: a review of the scientific basis of the European Union assessment and its differences with IARC', 91 *Archives of Toxicology* (2017), pp. 3195–3197.

C. 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)', 70 *Journal of Epidemiology and Community Health* (2016), pp. 741–745.

C. Robinson et al., 'Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions', *forthcoming in European Journal of Risk Regulation* (2020), available via: <https://doi.org/10.1017/err.2020.18>, last accessed: 05/08/2020.

G. Séralini et al., 'Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize', 50 *Food and Chemical Toxicology* (2012), pp. 4221–4231, Retracted.

G. Séralini et al., 'Republished Study: Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize', 26(14) *Environmental Sciences Europe* (2014), pp. 1–17.

H. Steinmann et al., 'Uses and benefits of glyphosate in German arable farming', 42 *Crop Protection* (2012), pp. 164–169.

C. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge University Press, 2005).

S. Thongprakaisang et al., 'Glyphosate induces human breast cancer cells growth via estrogen receptors', 59 *Food and Chemical Toxicology* (2013), pp. 129–136.

B. Url, 'Don't attack science agencies for political gain', 553 *Nature* (2018), p. 381.

E. Vos & K. de Smedt, 'Taking stock as a basis for the effect of the precautionary principle since 2000', RECIPES WP 1 Report, available via: <https://recipes-project.eu/sites/default/files/2020-03/Report%20Taking%20stock%20as%20a%20basis%20for%20the%20effect%20of%20the%20precautionary%20principle%20since%202000.pdf>, last accessed: 13/04/20.

G. Williams et al., 'Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans', 31 *Regulatory Toxicology and Pharmacology* (2000), pp. 117–165.

## Other

Bundesinstitut für Risikobewertung, Glyphosate in Urine - Concentrations are far below the range indicating a potential health hazard, BfR Opinion No. 014/2013, 14 June 2013.

Bundesinstitut für Risikobewertung, Renewal Assessment Report, Glyphosate, Volume 1 Report and Proposed Decision, available via: <http://www.efsa.europa.eu/en/consultations/call/public-consultation-active-substance-glyphosate>, last accessed: 13/4/2020.

Bundesinstitut für Risikobewertung, The BfR has made a comprehensive check of the epidemiological studies on glyphosate, BfR Background Information No. 033/2015, 22 September 2015.

Bundesinstitut für Risikobewertung, Assessment of the BfR concerning epidemiological studies on carcinogenic effects of glyphosate in the context of the EU active substance review, BfR background information No. 034/2015, 28 September 2015.

Bundesinstitut für Risikobewertung, Frequently asked questions on the procedure for the re-assessment of glyphosate within the framework of the EU active substance review, BfR FAQ, 12 November 2015 .

International Network for Government Science Advise (INGSA), Roundup Ready? Regulating Glyphosate Amidst Health, Economic and Public Concerns about GM, Case Study by T. Buklijas & S. de Saille, (2017), available via: <https://www.ingsa.org/wp-content/uploads/2017/06/Glyphosate-v2.0-final.pdf>, last accessed: 13/4/2020.

Friends of the Earth, Glyphosate briefings: reasons for concern (2013), available via: <https://www.foeeurope.org/glyphosate-reasons-for-concern-briefing-130613>, last accessed: 13/4/2020.

Friends of the Earth, Glyphosate briefings: Media Briefing Reasons for concern (2013), available via: [https://www.foeeurope.org/sites/default/files/press\\_releases/foee\\_media\\_briefing\\_glyphosate.pdf](https://www.foeeurope.org/sites/default/files/press_releases/foee_media_briefing_glyphosate.pdf), last accessed: 13/4/2020.

Friends of the Earth, The environmental impacts of glyphosate, available via: [https://www.foeeurope.org/sites/default/files/publications/foee\\_5\\_environmental\\_impacts\\_glyphosate.pdf](https://www.foeeurope.org/sites/default/files/publications/foee_5_environmental_impacts_glyphosate.pdf), last accessed: 13/4/2020.

International Agency for Research on Cancer (IARC), Some Organophosphate Insecticides and Herbicides - IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 112 (2015), available via: <https://publications.iarc.fr/549>, last accessed: 13/4/2020.

National Farmers Union (NFU), Glyphosate is vital, (2017) available via: <https://www.nfuonline.com/glyphosate-leaflet-feb-2017-final/>, last accessed: 13/4/2020.

## Websites

<https://www.anses.fr/en/content/anses-announces-withdrawal-36-products-containing-glyphosate>, last accessed: 13/4/2020.

<https://www.baumhedlundlaw.com/pdf/monsanto-documents/Hardeman/Hardeman-Jury-Verdict-Form-Phase-2.pdf>, last accessed: 13/4/2020.

<https://www.baumhedlundlaw.com/pdf/monsanto-documents/johnson-trial/DX-2735-Portier-Letter-EFSA-BfR-Glyphosate.pdf>; last accessed: 13/4/2020.

<https://www.bayer.com/en/about-glyphosate-based-herbicides-and-their-role-in-agriculture.aspx>, last accessed: 13/4/2020.

<https://www.bayer.com/en/is-glyphosate-safe.aspx>, last accessed: 13/4/2020.

[https://www.beuc.eu/publications/beuc-x-2018-112\\_precautionary\\_principle\\_under\\_attack\\_please\\_delete\\_so-called\\_innovation\\_principle.pdf](https://www.beuc.eu/publications/beuc-x-2018-112_precautionary_principle_under_attack_please_delete_so-called_innovation_principle.pdf), last accessed: 13/4/2020.

[https://corporateeurope.org/sites/default/files/corporation\\_letter\\_on\\_innovation\\_principle.pdf](https://corporateeurope.org/sites/default/files/corporation_letter_on_innovation_principle.pdf), last accessed: 13/4/2020.

<https://corporateeurope.org/en/food-and-agriculture/2016/06/glyphosate-one-pesticide-many-problems>, last accessed 13/4/2020.

<https://corporateeurope.org/sites/default/files/attachments/letterjuncker28may2017.pdf>, last accessed: 13/4/2020.

[https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment\\_en](https://ec.europa.eu/food/plant/pesticides/glyphosate/earlier-assessment_en), last accessed: 13/4/2020.

<https://www.euractiv.com/section/agriculture-food/news/brussels-government-takes-commission-to-eu-court-over-glyphosate/>, last accessed: 13/4/2020.

<https://www.euractiv.com/section/agriculture-food/news/french-mayors-ban-glyphosate-weedkiller-defying-government/>, last accessed: 13/4/2020.

<https://www.euractiv.com/section/agriculture-food/news/no-magical-alternative-to-glyphosate-in-the-next-5-years-bayer-official-says>, last accessed: 13/4/2020.

[http://www.riskforum.eu/uploads/2/5/7/1/25710097/businessseurope-ert\\_innovation\\_principle\\_joint\\_statement.pdf](http://www.riskforum.eu/uploads/2/5/7/1/25710097/businessseurope-ert_innovation_principle_joint_statement.pdf), last accessed: 13/4/2020.

<https://euobserver.com/environment/140042>, last accessed 13/4/2020.

<https://www.foeeurope.org/weed-killer-glyphosate-found-human-urine-across-Europe-130613>, last accessed: 13/4/2020.

<https://glyphosate.eu>, last accessed: 13/4/2020.

[https://gouvernement.lu/en/actualites/toutes\\_actualites/communiques/2020/01-janvier/16-interdiction-glyphosate.html](https://gouvernement.lu/en/actualites/toutes_actualites/communiques/2020/01-janvier/16-interdiction-glyphosate.html), last accessed: 13/4/2020.

<https://kontrast.at/glyphosat-verbot-oesterreich/>, last accessed: 13/4/2020.

[https://www.parlament.gv.at/PAKT/VHG/XXVII/E/E\\_00004/fname\\_775803.pdf](https://www.parlament.gv.at/PAKT/VHG/XXVII/E/E_00004/fname_775803.pdf), last accessed: 13/4/2020.

[https://www.parlament.gv.at/PAKT/PR/JAHR\\_2019/PK0808/index.shtml](https://www.parlament.gv.at/PAKT/PR/JAHR_2019/PK0808/index.shtml), last accessed: 13/4/2020;

<https://www.politico.eu/pro/glyphosate-renewal-shakes-germany-france-italy/>, last accessed 13/4/2020.

<https://www.politico.eu/article/battle-over-glyphosate-shifts-to-the-environmental-front-pesticides-herbicides/>, last accessed: 13/4/2020.

<https://www.zeit.de/wissen/umwelt/2019-09/tierwohl-label-nutztiere-insekten-glyphosat-julia-kloeckner>, last accessed: 13/4/2020.

## 9 Appendix

n/a