

## **Why the Commission's renewal of the authorization to place glyphosate on the EU market should be annulled\***

**On 27 November 2017, the EU Member States, acting by a qualified majority within the appeal committee of the Standing Committee on Plants, Animals, Food and Feed, approved the proposal of the European Commission for an implementing regulation renewing the approval of the active substance glyphosate for a period of five years. The Implementing Regulation that the Commission is intent on adopting on 12 December 2017, on the basis of that authorization, should be immediately challenged before the Court of Justice of the European Union.**

**The European Parliament as well as the nine Member States which voted against the proposal are called to file an action for annulment of the implementing regulation. Article 263 of the Treaty on the Functioning of the European Union provides that any EU Member State or the European Parliament, *inter alia*, may seek the annulment of acts adopted by the Council or the Commission "on grounds of lack of competence, infringement of an essential procedural requirement, infringement of the Treaties or of any rule of law relating to their application, or misuse of powers". This note argues that there are a number of reasons why such an action for annulment should be filed against this Implementing Regulation.**

### **I. Background**

In accordance with Article 20 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market,<sup>1</sup> the Commission proposed to adopt an Implementing Regulation renewing the authorization to place glyphosate on the market for a period of five years (for the period 16 December 2017-15 December 2022), for use as a herbicide (hereafter referred to as the "draft Implementing Regulation").<sup>2</sup>

On 27 November 2017, this proposal was agreed to by the appeal committee, acting pursuant to Article 5(4) of Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.<sup>3</sup> The appeal committee was seized after the Standing Committee on Plants, Animals, Food and Feed failed to agree on an earlier proposal of the Commission, arriving at an inconclusive "no opinion" on 9 November 2017 (sante.ddg2.g.5(2017)) (only 14 Member States voted in favour (representing 36.95 % of the EU population) of the proposal of the Commission on that occasion; 5 other Member States abstained (representing 30.79 % of the EU population)).

At the appeal committee meeting of 27 November 2017, a qualified majority appeared in support of the proposal by the European Commission. 18 Member States voted in favour, representing 65.71% of the EU population: these were Bulgaria, Germany, Czech Republic, Denmark, Estonia, Ireland, Spain,

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<sup>1</sup> OJ L 309, 24.11.2009, p. 1.

<sup>2</sup> Available on:

[https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_glyphosate\\_commission\\_proposal\\_revision4.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_commission_proposal_revision4.pdf) (last consulted on 3 Dec. 2017).

<sup>3</sup> The application of this procedure results from a combined reading of Article 79(3) of Regulation No. 1107/2009 and Article 13(1)(c) of Regulation No. 182/2011. As regards glyphosate, it is further detailed in Commission Regulation 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.

Latvia, Lithuania, Hungary, Netherlands, Poland, Romania, Slovakia, Slovenia, Finland, Sweden and the United Kingdom. 9 Member States voted against (Belgium, Greece, France, Croatia, Italy, Cyprus, Luxembourg, Malta, Austria, representing together 32.26 % of the EU population), and Portugal abstained (representing 2.02 % of the EU population).

Among the votes in favour of the proposal of the Commission was the vote cast by the German agriculture minister Christian Schmidt. This vote took the German government by surprise. Germany had abstained from voting in all previous deliberations on glyphosate in previous months, and the coalition partners of Mr Schmidt's political party, the CSU, had publicly opposed the renewal of the authorization of glyphosate. This sudden change of opinion was all the more surprising considering that Germany acted as the rapporteur Member State on glyphosate.<sup>4</sup> Its position was therefore expected to stand on firm scientific ground and not depend on short-term internal electoral considerations.

The decision appears to meet with strong opposition from the general public, as well as from the European Parliament. On 25 January 2017, the European Citizens' Initiative "Stop Glyphosate" was registered (ECI(2017)000002). It called on the Commission "to propose to member states a ban on glyphosate, to reform the pesticide approval procedure, and to set EU-wide mandatory reduction targets for pesticide use". On 6 October 2017, the European Commission officially received the submission of the ECI, since at that date, the ECI had been supported by 1,070,865 citizens from at least 7 Member States. (In addition, 116,879 citizens signed the ECI after that cut-off date, bringing the total number of signatories to 1,187,744).

On 24 October 2017, the European Parliament adopted a resolution in which it considers that "the Commission's draft implementing regulation fails to ensure a high level of protection of both human and animal health and the environment, fails to apply the precautionary principle, and exceeds the implementing powers provided for in Regulation (EC) No 1107/2009".<sup>5</sup>

The European Parliament and the Member States which opposed the proposal of the Commission should now be prepared to file annulment proceedings against the implementing regulation that the Commission shall adopt, based on the vote that took place on 27 November 2017. This is essential to preserve the faith of the European public in the integrity of decision-making within the EU institutions, to protect the health of the population in Europe, and to protect the environment, as required by the European Treaties.

## **II. Grounds for annulment**

Six arguments in particular would justify the annulment of the Implementing Regulation.

### **1. Violation of Regulation No. 1107/2009**

Regulation No. 1107/2009 is violated on two grounds. First, the Regulation seeks to ensure that no pesticides shall be authorized unless they have no harmful effects on human health (a). Second, it seeks to contribute to the good functioning of the internal market (b). Neither of these two conditions are fulfilled by the Implementing Regulation.

a) According to Article 4(2) of Regulation No. 1107/2009 :

The residues of the plant protection products, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the

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<sup>4</sup> See Annex I of Commission Regulation No. 1141/2010. Slovakia was the co-rapporteur.

<sup>5</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, para. 1.

following requirements:

- (a) they **shall not have any harmful effects** on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, or on groundwater;
- (b) they shall **not have any unacceptable** effect on the environment. (emphasis added)

Article 4(3) of the same Regulation provides further that :

A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:  
(...)

- (b) it shall **have no immediate or delayed harmful effect** on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater; ... (emphasis added)

According to these requirements, only plant protection products which do not have *any* harmful effect on human and animal health or unacceptable effect on the environment should be authorised in the internal market, irrespective of any cost-benefit analysis. Through such criteria, Article 4 of Regulation No. 1107/2009 turns into a legal requirement a political orientation already expressed in Recital 24 to the Preamble, which states that "when granting authorisations of plant protection products, **the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production**" (emphasis added).

It is an undisputed scientific fact that glyphosate does have at least *some* harmful effect on human and animal health, though the precise magnitude of such harm may remain disputed. Indeed, the Commission Implementing Regulation itself acknowledges the existence of such harm by calling upon the Member States to "pay particular attention to: the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses; the protection of operators and amateur users; the risk to terrestrial vertebrates and non-target terrestrial plants; the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions" and to "minimise" the "use of plant protection products containing glyphosate (...) in the specific areas listed in Article 12(a) of Directive 2009/128/EC [of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides]".

Therefore, by renewing the approval of an active substance whose harmful effects are amply demonstrated (and acknowledged), the Commission breached the requirements imposed by Article 4(2) and (3) of Regulation.

b) The Implementing Regulation also violates Regulation No. 1107/2009 insofar as it does not contribute to the objective of this Regulation, which is to ensure the good functioning of the internal market.

Regulation No. 1107/2009 aims to contribute to the establishment of the internal market by harmonising the approval of active substances and the marketing of plant protection products. Its main legal basis is, therefore, Article 95 EC (now Article 114 TFEU). While this Regulation is also based on Article 37(2) and Article 152(4)(b) of the EC Treaty, which relate respectively to the common agricultural policy and to the competence of the European Union in the field of public health, public health and agricultural productivity are just ancillary concerns. This finding is supported by the procedure followed for the adoption of that Regulation (the so-called codecision procedure, now ordinary legislative procedure), which corresponds to the exercise of the EC's internal market powers. CAP- and public health-related measures would have been adopted following other types of procedure.

It appears from this procedural route that the authors of that Regulation took the view that its "centre of gravity" was the good functioning of the internal market.

The Implementing Regulation does not seem to be in line with this main objective insofar as it only very partially harmonises the market access of glyphosate. Indeed, in accordance with Article 14 of Regulation No 1107/2009, which refers back to the conditions that may be imposed for the approval of an active substance under the Regulation (Art. 6), it recommends that the Member States pay particular attention to: "the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses; the protection of operators and amateur users; the risk to terrestrial vertebrates and non-target terrestrial plants; the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions; compliance of pre-harvest uses with good agricultural practices. Conditions of use shall include risk mitigation measures, where appropriate. Member States shall ensure that use of plant protection products containing glyphosate is minimised in the specific areas listed in Article 12(a) of Directive 2009/128/EC [of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides]".<sup>6</sup>

Thus, the Implementing Regulation leaves it up to the Member States to take all the necessary measures to, *inter alia*, protect the groundwater in vulnerable areas; protect operators and amateur users; and to manage the risk to terrestrial vertebrates and non-target terrestrial plants. By so doing, the Regulation opens the door to the adoption of a variety of national (or even subnational) regulatory regimes that would defeat its harmonisation purpose.

Therefore, it appears that the Implementing Regulation breaches Regulation No. 1107/2009 insofar as it does not enhance the good functioning of the internal market.

## **2. Violation of the requirement to ensure a high level of protection of human health**

According to Article 9 TFEU, "In defining and implementing its policies and activities, the Union shall take into account requirements linked to the (...) protection of human health". Article 12 TFEU states further that "Consumer protection requirements shall be taken into account in defining and implementing other Union policies and activities". Article 168(1) TFEU provides in turn that "A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities". The requirement to ensure a high level of human health protection also follows from Article 35 of the Charter of Fundamental Rights.<sup>7</sup>

The Court of Justice has confirmed that the EU institutions "must take account of the precautionary principle, according to which, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures".<sup>8</sup>

Yet, the decision to renew the authorization of glyphosate constitutes a serious threat to the health of

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<sup>6</sup> Proposal for a 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 (SANTE/10440/2017 Rev. 1 (POOL/E4/2017/10440/10440R1-EN.doc)).

<sup>7</sup> According to Article 35 of the Charter, "A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities".

<sup>8</sup> See judgment of 9 June 2016, *Pesce and Others*, Joined Cases C-78/16 and C-79/16, EU:C:2016:428, para. 47. See also Case C-236/01, *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 111; judgment of 10 April 2014, *Acino AG v. Commission*, Case C-269/13 P, EU:C:2014:255, para. 57 ("in accordance with that principle, as interpreted by the Court's case-law, where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent"); judgment of 17 December 2015, *Neptune Distribution*, C-157/14, EU:C:2015:823, paras. 81 and 82.

consumers in the European Union.

In 2015, the International Agency for Research on Cancer (IARC), the World Health Organization's cancer agency, basing itself on the review of a total of about 1000 studies, classified the key ingredient in Roundup, glyphosate, as 'probably carcinogenic to humans' (Group 2A, a ranking corresponding to international standards based on the strength of the scientific evidence available). This classification was made on the basis of "limited evidence" of cancer in humans (from studies of real-world exposure of farmworkers and forest workers exposed to spraying, including case-control studies suggesting that people exposed to glyphosate had a higher incidence of non-Hodgkin's lymphoma, a rare type of cancer that could not be explained by other pesticides), "sufficient evidence" of cancer in laboratory animals (from two feeding studies of mice with "pure" glyphosate, providing evidence in both studies of the emergence of rare cancers, some of which were malignant), and "strong evidence" of mechanistic information related to carcinogenicity (for genotoxicity, i.e., damage to the DNA, and oxidative stress) for both "pure" glyphosate and glyphosate formulations.<sup>9</sup>

To ensure the full impartiality of its review and for the sake of transparency, the IARC committee only considered publicly available studies from scientific journals and government sources. In its Monograph 112 on glyphosate, released on 11 August 2016 and detailing its findings, the IARC confirmed its classification of glyphosate as "probably carcinogenic to humans", concluding that "There is strong evidence that exposure to glyphosate or glyphosate-based formulations is genotoxic based on studies in humans in vitro and studies in experimental animals".<sup>10</sup>

Instead of taking the IARC findings as its starting point, the Commission relied on the conclusions reached by the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA). The main difference between EFSA and ECHA on the one hand, and IARC on the other hand, is that EFSA and ECHA take into account industry data providing toxicological studies that are not available in the public domain -- in fact, that appears to constitute their main source of information. In contrast, as regards "epidemiological studies, cancer bioassays, and mechanistic and other relevant data", the IARC considers "only reports that have been published or accepted for publication in the openly available scientific literature are reviewed. The same publication requirement applies to studies originating from IARC, including meta-analyses or pooled analyses commissioned by IARC in advance of a meeting (...). Data from government agency reports that are publicly available are also considered. Exceptionally, doctoral theses and other material that are in their final form and publicly available may be reviewed".<sup>11</sup>

On 15 March 2017, based on the proposal of the German Federal Institute for Occupational Safety and Health / Federal Office for Chemicals,<sup>12</sup> the Risk Assessment Committee (RAC) of the European Chemicals Agency took the view that there is no evidence to link glyphosate to cancer in humans, based on the available information, and that glyphosate should not be classified as a substance that causes genetic damage (mutagen) or disrupts reproduction.

This assessment is based, "Apart from the published studies on glyphosate", on "the original reports of studies conducted by industry".<sup>13</sup> The Risk Assessment Committee of the European Chemicals Agency solely pronounces itself, moreover, "on the hazard classification of the substance. The classification is based solely on the hazardous properties of the substance. It does not take into

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<sup>9</sup> Kathryn Z Guyton, Dana Loomis, Yann Grosse, Fatiha El Ghissassi, Lamia Benbrahim-Tallaa, Neela Guha, Chiara Scoccianti, Heidi Mattock & Kurt Straif, on behalf of the International Agency for Research on Cancer Monograph Working Group, "Carcinogenicity of Tetrachlorvinphos, Parathion, Malathion, Diazinon, and Glyphosate," 16(5) *Oncology* (2015) 490.

<sup>10</sup> Available on: <http://monographs.iarc.fr/ENG/Monographs/vol112/index.php>

<sup>11</sup> Preamble to the *IARC Monographs* (last updated in 2006), available from <http://monographs.iarc.fr/ENG/Preamble/index.php>.

<sup>12</sup> CLH report Proposal for Harmonised Classification and Labelling based on Regulation (EC) 1272/2008 (CLP Regulation), May 2016, available on: <https://echa.europa.eu/documents/10162/9fb5d873-2034-42d9-9e53-e09e479e2612> (last consulted on 3 Dec. 2016).

<sup>13</sup> See <https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa> (last accessed on 3 Dec. 2017).

account the likelihood of exposure to the substance and therefore does not address the risks of exposure."<sup>14</sup> In describing how it assessed glyphosate, the ECHA emphasizes that "The classification is based solely on the hazardous properties of the substance. It does not take into account risk or exposure because the assessment does not evaluate the quantities used, nor the way in which it is used. Such aspects are considered later on, as part of further risk management measures when assessing if a certain use can be authorised. For example, the use of glyphosate as a pesticide is covered by the Plant Protection Products Regulation, which is managed by the European Food Safety Authority (EFSA)."<sup>15</sup>

In October 2015, the European Food Safety Authority (EFSA) 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 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006]". That finding was made on the basis of a peer review of the initial risk assessments carried out by the German Federal Institute for Risk Assessment (BfR), the competent authority of the rapporteur Member State Germany, for the pesticide active substance glyphosate. It appears that significant portions of that review were simply copy-pasted from documents provided by Monsanto. Against that background, the statement by EFSA that it "assessed more evidence including additional key studies that were not considered by IARC" is deeply disingenuous, as it would tend to imply that the assessments performed by the independent experts working under the IARC umbrella are less comprehensive; for the reasons indicated they are, on the contrary, far more trusted within the scientific community.<sup>16</sup>

The EFSA's findings prompted 96 independent scientists to send an open letter to the European Commission, urging the Commission to reject the EFSA's findings because they "do not reflect the available science."<sup>17</sup> It also appears that the findings are largely based on information provided by Monsanto, the firm that dominates the market for glyphosate-based herbicides, with its flagship product Roundup. As noted by the European Parliament in its resolution of 24 October 2017, the internal documents by Monsanto concerning Roundup, the herbicide produced by Monsanto, which the company was forced to release in the context of litigation in the US brought by plaintiffs who claim to have developed non-Hodgkin's lymphoma as a result of exposure to glyphosate, "cast doubts on the credibility of some studies, both Monsanto-sponsored and presumably independent ones, which were among the evidence used by EFSA and ECHA for their evaluation of the safety of glyphosate".<sup>18</sup>

Following a request by the European Commission that it assess the potential endocrine disrupting properties of glyphosate, EFSA presented a second assessment (approved on 17 August 2017 and published on 7 September 2017), in which it reached the conclusion that "the weight of evidence indicates that glyphosate does not have endocrine disrupting properties through oestrogen, androgen, thyroid or steroidogenesis mode of action based on a comprehensive database available in the toxicology area".<sup>19</sup>

The assessments provided by EFSA and ECHA are highly controversial. The Commission acknowledges this by stating that :

While a large amount of information on the active substance glyphosate already exists and has

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<sup>14</sup> See <https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa> (last consulted on 3 Dec. 2017) (emphasis by the European Chemicals Agency).

<sup>15</sup> <https://newsletter.echa.europa.eu/home/-/newsletter/entry/how-echa-is-assessing-glyphosate> (last consulted on 3 Dec. 2017).

<sup>16</sup> In a letter dated Feb. 5th, 2016, addressed by Christopher Wild, the Director of IARC, to Dr Bernhard Uhl, the Executive Director of EFSA, IARC formally requested that EFSA correct that misleading statement it had made about the work of IARC. The annex to the letter details other inaccuracies and misrepresentations about IARC's work made by EFSA. See [https://www.efsa.europa.eu/sites/default/files/Letter\\_from\\_Dr\\_Wild\\_to\\_Bernhard\\_Uhl.pdf](https://www.efsa.europa.eu/sites/default/files/Letter_from_Dr_Wild_to_Bernhard_Uhl.pdf) (last consulted on 4 Dec. 2017).

<sup>17</sup> Christopher J. Portier, et al., Open letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR, 27 Nov. 2015, available at: [https://www.efsa.europa.eu/sites/default/files/Prof\\_Portier\\_letter.pdf](https://www.efsa.europa.eu/sites/default/files/Prof_Portier_letter.pdf) (last consulted on 3 Dec. 2017).

<sup>18</sup> Preamble, para. K.

<sup>19</sup> See <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4979/epdf> (last consulted on 3 Dec. 2017).

been assessed leading to the conclusion that the approval of the active substance glyphosate should be renewed, additional information on glyphosate is being published at an exceptionally high rate compared to other active substances. Therefore possibilities of rapid future developments in science and technology should be taken into account when deciding on the length of the approval period of glyphosate, also bearing in mind the fact that glyphosate is one of the most widely used herbicides in the Union.<sup>20</sup>

That, however, is the opposite of what should have been done. In the face of scientific uncertainty, the correct attitude is not to deliberately accept to put the European population at risk. It is to abstain from taking such a risk, until any doubt is alleviated and until convincing answers are provided to the concerns raised about the toxicity of the products that are to be placed on the market. This is required under the precautionary principle, referred to above. As confirmed by the Court of Justice, "where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures".<sup>21</sup> It is also in violation of the principle of sound administration.<sup>22</sup>

It deserves notice in this regard that the Implementing Regulation authorizes glyphosate, without even imposing restrictions as to its use in combination with co-formulants, and without planning the gradual phasing out of the use of glyphosate. In other terms, despite the serious concerns that exist as regards the impact of glyphosate use on human health, no mitigation measure whatsoever are included in the Implementing Regulation. This is not to act with precaution, and it does not constitute sound administration.

### **3. Violation of the requirement to aim at a high level of protection of the environment**

According to Article 11 TFEU, "Environmental protection requirements must be integrated into the definition and implementation of the Union's policies and activities, in particular with a view to promoting sustainable development". Article 191(2) TFEU provides, moreover, that the European Union's policy on the environment "shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union", and that it shall be "based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay." The stated purpose of Regulation (EC) No 1107/2009 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".

Despite these clear legal obligations, the requirement to ensure a high level of protection of the environment appears to have been entirely disregarded in the decision to renew the authorization to place glyphosate formulations on the market. Indeed, the use of glyphosate also poses a number of threats to the environment, and although some controversies do remain, the requirement under Article 191(2) TFEU is to abstain from taking measures that might cause damage to the environment, even though the certainty about such damage is not absolute.

It is precisely because of the damage to the environment that could be caused where glyphosate-based herbicide is applied to targeted crops aerially, that this practice has been outlawed in the EU by

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<sup>20</sup> Preamble to the draft Implementing Regulation, para. 19.

<sup>21</sup> Judgment of 10 April 2014, *Acino AG v. Commission*, Case C-269/13 P, EU:C:2014:255, para. 58; judgment of 17 December 2015, *Neptune Distribution*, C-157/14, EU:C:2015:823, para. 82.

<sup>22</sup> Article 41 of the Charter of Fundamental Rights guarantees the right to a good administration, which imposes in particular "the obligation of the administration to give reasons for its decisions" (para. 2, a) and c)).

directive 128/2009, except under very specific conditions<sup>23</sup>: indeed, glyphosate drift onto untargeted crop species is largely inevitable where aerial spraying is practised.<sup>24</sup> Studies have found that plants within a certain downwind distance were injured, with symptoms of injured plants including chlorosis of the youngest leaves, necrosis, stunted growth, and plant death within a week of exposure.<sup>25</sup> A number of other studies have confirmed that aerial spray of glyphosate-containing herbicides results in drift of the product causing damage to non-target plants.<sup>26</sup>

The environmental impacts of glyphosate formulations use are not limited to the practice of aerial spraying, however. The U.S. Geological Survey (USGS) reports that glyphosate is transported out from agricultural sources and is widely presented in other ecosystems. The USGS took 3,732 environmental samples from 2001 to 2010 in 38 states. They found that glyphosate was detected in 59% of 470 surface water sites and 50% of the soil sites.<sup>27</sup> Glyphosate can have serious environmental consequences for aquatic habitats.<sup>28</sup> The fact that glyphosate can travel from farms into other soils and streams may result in severe impacts on the environment. Guilherme, Gaivo, Santos & Pacheco (2010) find that the extensive application of Monsanto's Roundup has been detected in many aquatic ecosystems and its presence poses a serious threat to aquatic organisms. "Due to its extensive use, it has been widely detected in aquatic ecosystems representing a potential threat to non-target organisms, including fish."<sup>29</sup> Even short-term exposure to Roundup can cause long-term adverse impact on fish reproductive systems and increase the likelihood of carcinogenic illness of fish.<sup>30</sup> Similarly, Annett, Habiibi & Hontela (2014) find that "[t]he creation of glyphosate tolerant crop species has significantly increased the demand and use of this herbicide and has also increased the risk of exposure to non-target species," and that acute toxicity occurs in numerous fish species as a result of exposure to glyphosate.<sup>31</sup> A number of other studies have documented in detail that Monsanto's glyphosate-containing herbicides move from the soil into water sources, and cause damage to aquatic species.<sup>32</sup>

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<sup>23</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 pesticides, OJ L 309, 24.11.2009, p. 71 (see Art. 9 of the directive).

<sup>24</sup> KN Reddy, W Ding, RM Zablutowicz, SJ Thomson, Y Huang & LJ Krutz, Biological Responses to Glyphosate Drift from Aerial Application in Non-Glyphosate-Resistant Corn," 66 *Pest Management Science* (2010) 1148.

<sup>25</sup> *Ibid.*

<sup>26</sup> See, e.g., SL Bird, DM Esterly & SG Perry, "Off-target Deposition of Pesticides from Agricultural Aerial Spray Application," 25 *Journal of Environmental Quality* (1996) 1095; NW Buehring, JH Massey & DB Reynolds, "Shikimic Acid Accumulation in Field-grown Corn (*Zea mays*) Following Simulated Glyphosate Drift," 55 *Journal of Agricultural Food Chemistry* (2007) 819; N Ballaloui, KN Reddy, RM Zablutowicz & A Mengistu, "Simulated Glyphosate Drift Influences Nitrate Assimilation and Nitrogen Fixation in non Glyphosate-Resistant Soybean," 54 *Journal of Agricultural Food Chemistry* (2006) 3357; IW Kirk, "Aerial Spray Drift from Different Formulations of Glyphosate," 43 *Trans ASAE* (2000) 555; NJ Payne, "Spray Dispersal From Aerial Silvicultural Glyphosate Applications," 12 *Crop Protection* (1993) 463; KN Reddy, RE Hoagland & ME Zablutowicz, "Effect of Glyphosate on Growth, Chlorophyll, and Nodulation in Glyphosate-Resistant and Susceptible Soybean (*Glycine max*) Varieties," 2 *Journal of New Seeds* (2000) 37.

<sup>27</sup> United States Geological Survey, Weed Killer is Widespread in the Environment, available at [http://toxics.usgs.gov/highlights/2014-04-23-glyphosate\\_2014.html](http://toxics.usgs.gov/highlights/2014-04-23-glyphosate_2014.html) (last visited 10 May 2016) ("Many studies indicate that commercial glyphosate formulations can be more toxic than pure glyphosate due to the toxicity and/or action of additives, such as surfactants (detergents).").

<sup>28</sup> *Id.*

<sup>29</sup> S Guilherme, I Gaivão, MA Santos & M. Pacheco "European Eel (*Anguilla Anguilla*) Genotoxic and Pro-Oxidant Responses Following Short-Term Exposure to Roundup®—a Glyphosate-Based Herbicide," 25(5) *Mutagenesis* (2010) 523.

<sup>30</sup> *Ibid.*

<sup>31</sup> Robert Annett, Hamid Habiibi & Alice Hontela, "Impact of Glyphosate and Glyphosate-based Herbicides on the Freshwater Environment," 34(5) *Journal of Applied Toxicology* (2014) 458.

<sup>32</sup> See, e.g., CL Achiorno, C de Villalobos & L Ferrari, "Toxicity of the Herbicide Glyphosate to *Chordodes nobilii* (Gordiida, Nematomorpha)," 71(10) *Chemosphere* (2008) 1816; WA Battaglin, DW Kolpin, EA Scribner, KM Kuivila & MW Sandstrom, "Glyphosate, other Herbicides, and Transformation Products in Midwestern Streams," 41(2) *Journal of the American Water Resources Association* (2002) 323; OK Borggaard & AL Gimsing, "Fate of Glyphosate in Soil and the Possibility of Leaching to Ground and Surface Waters: A Review," 64(4) *Pest Management Science* (2008) 441; F Botta, G Lavison, G Courturier, F Alliot, E Moreau-Guigon, N Fauchon, B Guery, M Chevreuil & H Blanchoud, "Transfer of Glyphosate and its Degradate Ampa to Surface Waters Through Urban Sewerage Systems," 77(1) *Chemosphere* (2009) 133; RB Bringolf, WG Cope, S Mosher, MC Barnhart & D Shea, "Acute and Chronic Toxicity of Glyphosate Compounds to Glochidia and Juveniles of *Lampsilis siliquoidea* (Unionidae)," 26 (10) *Environmental Toxicology Chemistry* (2007) 2094; JL Frontera, I Vatnick, A Chaulet & EM Rodriguez, "Effects of glyphosate and polyoxyethylenamine on growth and energetic reserves in the freshwater crayfish *Cherax quadricarinatus* (Decapoda, Parastacidae)," 61(4) *Archives Environmental Contamination and Toxicology*. (2011) 590; CM Howe, M Berrill, BD Pauli, CC Helbing, K Werry & N Veldhoen, "Toxicity of Glyphosate-Based Pesticides to Four North American Frog Species," 23(8) *Environmental*

#### 4. Violation of the duty to examine carefully and impartially all the relevant facts of the individual case

The Courts of Justice of the European Union take the view that "in particular where EU institution enjoys a wide discretion, in order to verify whether it has committed a manifest error of assessment", they "must verify whether [the institution] has examined carefully and impartially all the relevant facts of the individual case, facts which support the conclusions reached".<sup>33</sup>

The Commission has not demonstrated that it has thus carefully and impartially examined all the relevant facts. In particular, it refused to question the assessments provided by EFSA and ECHA, despite the important concerns raised by the scientific community about the integrity of these assessments, and although the evidence is now unfolding of the considerable efforts deployed by Monsanto to manipulate the scientific evidence -- in particular, by "ghost-writing", i.e., paying scientists to sign studies that have been prepared by Monsanto staff scientists, and by encouraging its own staff to influence the scientific debate in the interests of the corporation.<sup>34</sup>

#### 5. Violation of the principle of institutional balance

In its above-mentioned resolution of 24 October 2017, the European Parliament took the view that "the Commission's draft implementing regulation [renewing the authorization to place glyphosate on the EU market for a period of five years]... exceeds the implementing powers provided for in Regulation (EC) No 1107/2009".<sup>35</sup>

The decision to re-authorize the use of glyphosate is a highly political issue, requiring in particular that a delicate balance be struck between competing economic interests and public health and environmental considerations. In Case C-355/10, *European Parliament v. Council*, the Court of Justice of the European Union considered that "provisions which, in order to be adopted, require political choices falling within the responsibilities of the European Union legislature cannot be delegated. It follows from this that implementing measures cannot amend essential elements of basic legislation or supplement it by new essential elements. Ascertaining which elements of a matter must be categorised as essential is not – contrary to what the Council and the Commission claim – for the assessment of the European Union legislature alone, but must be based on objective factors amenable to judicial review. In that connection, it is necessary to take account of the characteristics and particularities of the domain concerned."<sup>36</sup> This is an issue that can deeply affect fundamental rights of

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*Toxicology Chemistry* (2004) 1928; VC Langiano & CBR Martinez, "Toxicity and Effects of a Glyphosate-Based Herbicide on the Neotropical Fish," 147 *Comparative Biochemistry and Physiology Part C: Toxicology and Pharmacology* (2008) 222; KA Modesto & CBR Martinez, "Roundup® Causes Oxidative Stress in Liver and Inhibits Acetylcholinesterase in Muscle and Brain of the Fish *Prochilodus lineatus*," 78 *Chemosphere* (2010) 294; AH Mohamed, "Sublethal Toxicity of Roundup to Immunological and Molecular Aspects of *Biomphalaria alexandrina* to *Schistosoma mansoni* Infection," 74(4) *Ecotoxicology and Environmental Safety* (2011) 754; AG Oliveira, LF Telles, RA Hess GAB Mahecha & CA Oliveira, "Effects of the Herbicide Roundup on the Epididymal Region of Drakes *Anas platyrhynchos*," 23(2) *Reproductive Toxicology* (2007) 182; KR Soloman & DG Thompson, "Ecological Risk Assessment for Aquatic Organisms from Over-Water uses of Glyphosate," 6(3) *Journal of Toxicology and Environmental Health – Part B – Critical Review* (2003) 289.

<sup>33</sup> Judgment of the General Court of 10 December 2015, *Front Polisario*, Case T-512/12, EU:T:2015:953 (citing judgments of 21 November 1991 in *Technische Universität München*, C-269/90, ECR, EU:C:1991:438, paragraph 14, and 22 December 2010 *Gowan comércio Internacional e Servios*, C-77/09, ECR, EU:C:2010:803, paragraph 57).

<sup>34</sup> See Stéphane Foucart and Stéphane Horel, "'Monsanto Papers': la guerre de Monsanto pour défendre son produit phare, le glyphosate", *Le Monde*, 1 June 2017.

<sup>35</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, para. 1.

<sup>36</sup> Judgment of the Court of 5 September 2012, paras 65-68.

the persons affected; it is one that, according to the Court, may therefore require the involvement of the European legislature.<sup>37</sup>

### **6. Violation of Article 11 (4) TEU, of the principle of democracy, of the principle of sound administration and of the principle of sincere cooperation**

It is finally striking that the proposal of the Commission for an Implementing Regulation, and the adoption of such Implementing Regulation following the vote of the appeal committee, occurred after the Commission has officially received the European Citizens' Initiative "Stop Glyphosate".

As noted by the General Court in a judgment of 10 May 2017, "far from amounting to an interference in an ongoing legislative procedure, ECI proposals constitute an expression of the effective participation of citizens of the European Union in the democratic life thereof, without undermining the institutional balance intended by the Treaties".<sup>38</sup> Indeed, the ECI mechanism, which according to the Court "consists in improving the democratic functioning of the European Union by granting every citizen a general right to participate in democratic life" specifically seeks to implement "the principle of democracy, which, as it is stated in particular in the preamble to the EU Treaty, in Article 2 TEU and in the preamble to the Charter of Fundamental Rights of the European Union, is one of the fundamental values of the European Union".<sup>39</sup>

It is contrary to the principle of good administration, to the principle of democracy,<sup>40</sup> and to Article 11(4) TEU itself which establishes the European Citizens' Initiative, to table a proposal to renew the authorisation of glyphosate before the "Stop Glyphosate" ICE is adequately responded to. Just like a refusal to register an ECI, the adoption of a measure that constitutes an implicit rejection of the ECI, without clearly providing reasons justifying the rejection, cannot be allowed, since this undermines "the effective exercise of the right enshrined in the Treaty".<sup>41</sup>

### **III. Conclusion**

There are serious reasons to believe that the use of herbicides based on glyphosate shall further threaten the health of European consumers and cause further damage to the environment. Although the proposal of the Commission to renew the authorization to place glyphosate on the market is taken "bearing in mind the fact that glyphosate is one of the most widely used herbicides in the Union", the fact that formulations using glyphosate were extensively used until now cannot constitute a valid reason for such a decision. The new evidence which emerged, concerning both the health risks of glyphosate-based formulations and the environmental impacts of glyphosate spreads, and the decision-making procedures within EFSA -- including the manipulative practices of Monsanto --, would have required a far more careful assessment of the evidence by the Commission. And if doubts remain, they should have led to deny the renewal of the authorization, as required by the precautionary principle.

The European Parliament and the Member States which opposed the proposal to renew the authorization to place glyphosate formulations on the market (consistent with the views they held within the Standing Committee on Plants, Animals, Food and Feed and the appeal committee) should file annulment proceedings before the Court of Justice of the European Union.<sup>42</sup> Such actions should be accompanied with a request from the Court to grant interim measures, to avoid further irreparable

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<sup>37</sup> Comp. Judgment of 5 September 2012, *European Parliament v. Council of the European Union*, Case C-355/10, EU:C:2012:516, para. 77.

<sup>38</sup> Judgment of 15 May 2017, *M. Efler v. European Commission*, Case T-754/14, EU:T:2017:323, para. 47.

<sup>39</sup> *Id.*, para. 37.

<sup>40</sup> See also Art. 2 TUE.

<sup>41</sup> See Judgment of the General Court of 19 April 2016, *B. Costantini v. European Commission*, Case T-44/14, EU:T:2016:223, paras. 72-73; and Judgment of the General Court of 3 Feb. 2017, *Bürgerausschuss für die Bürgerinitiative Minority SafePack — one million signatures for diversity in Europe v. European Commission*, Case T-646/13, EU:T:2017:59, paras. 17-18.

<sup>42</sup> An action for annulment filed by a Member State would be filed before the General Court (Art. 256 TFEU and Art. 51, al. 1 of the Statute of the Court of Justice).

harm to the caused.<sup>43</sup>

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<sup>43</sup> Article 278 TFEU (ex Article 242 TEC) provides that : "Actions brought before the Court of Justice of the European Union shall not have suspensory effect. The Court may, however, if it considers that circumstances so require, order that application of the contested act be suspended." Article 279 TFEU (ex Article 243 TEC) provides for the possibility for the Court of Justice of the European Union to prescribe any necessary interim measures in any case before it. Such interim measures may be granted where four conditions are satisfied: the main action for infringement appears *prima facie* well founded; the interim measure requested relates to the case; the measure requested is required in order to avoid serious and irreparable harm, thus guaranteeing "the full effectiveness of the definitive future decision [of the CJEU]" (C-76/08 R, *Commission v Malta*, Order of the President 24 April 2008, para. 31 (interim order against authorising hunting of protected birds)); and the awardance of the provisional measure is justified based on a balance of all interests involved (Article 160 of the *Rules of Procedure of the Court of Justice* of 25 September 2012 (OJ L 265, 29.9.2012), as amended on 18 June 2013 (OJ L 173, 26.6.2013, p. 65) and on 19 July 2016 (OJ L 217, 12.8.2016, p. 69)).