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CHAPTER

# 14 Glyphosate

Alessandra Arcuri

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#### **Abstract**

Glyphosate is the most widely used herbicide in the world. Globally, 6.1 billion kilograms have been applied in the last decade alone. In 2015, the International Agency for Research on Cancer (IARC), classified glyphosate as 'probably carcinogenic to humans'. In stark contrast, regulatory authorities worldwide have attributed non-carcinogenic properties to glyphosate. By charting its recent regulatory history, this chapter demonstrates how glyphosate has been 'subjected' to law through a politics of separation. In the hybrid regulatory space where science and law interact, law retains its authority by cutting-off arguments. This politics of separation is expedient, as law ought to resolve conflicts, to decide. However, by cutting-off debate and discourse, political choices are being backstaged. Glyphosate, as an object of law, has catalyzed contestation of existing regulatory categories (eg risk assessment/hazard analysis). In so doing, glyphosate has brought the politics back to the frontstage, triggering a process of re-politicization of transnational risk regulation.

Keywords: glyphosate, risk regulation, risk assessment, hazard analysis, de-politicization, WHO, IARC,

pesticides, politics of separation, back stage

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#### Introduction

Glyphosate is the rock star of pesticides, albeit a controversial one. With 6.1 billion kilograms applied globally in the last decade alone, it is the most widely used herbicide compound in the world. At the same time, glyphosate is at the centre of an acrimonious controversy relating to whether the substance is carcinogenic to humans and toxic for the environment. The controversy took a sharp legal turn when, in March 2015, the International Agency for Research on Cancer (IARC), which is the specialized cancer agency of the World Health Organization (WHO), classified glyphosate as 'probably carcinogenic to humans'.<sup>2</sup>

The life of glyphosate started in 1950 when Dr Martin, a Swiss scientist working for Cilag, synthetized N-(phosphonomethyl) glycine, later called glyphosate.<sup>3</sup> While molecules are mainly synthetized for utilitarian reasons, for about twenty years the molecule was not put to any use. The 7g of glyphosate initially synthetized by Dr Martin were sold in 1959 to a chemical company, Aldrich, which resold it in 1960 to Monsanto. In 1970, a chemist working for Monsanto discovered the herbicidal properties of glyphosate and fours years later Monsanto commercialized Roundup, a glyphosate-based herbicide. <sup>6</sup> While glyphosate appears mainly as 4 a product of science and technology (a molecule synthetized by a chemist), its fate is tightly bound to law.

Glyphosate has been 'judged' by law as innovative and gained patent protection. International diplomacy has enlisted it as a valuable weapon in the 'war on drugs', in the context of the concerted action between the US and Colombia, known as Plan Colombia, during which glyphosate has been aerially sprayed on illegal coca plantations. Most notably, regulatory authorities worldwide have attributed non-carcinogenic properties to glyphosate and have subsequently authorized its use as an active substance in pesticides. Finally, laws in the US (and other countries) have magnified the potential for glyphosate's use by authorizing the genetic engineering of plants. Most Genetically Modified Organisms (GMOs), in fact, have been engineered to be resistant to glyphosate; since the opening of the market to GMOs, the use of glyphosate has exponentially increased.<sup>7</sup>

Fig 14.1



Farmers spraying pesticide in a paddy field, 2015

Source: Rapeepong Puttakumwong/Alamy Stock Photo.

In an illuminating essay on 'Scientific Objects and Legal Objectivity', Bruno Latour posits that the latter is 'object-less'. Bruno Latour posits that the latter is 'object-less'. Glyphosate, by contrast, is a vibrant example of the object-ness of (international) law. The peculiarity of glyphosate is that  $\ \ \ \ \$  it is an object of law and science at the same time and in the same space. This chapter sets out to show how glyphosate has been 'subjected' to law through a politics of separation. In the hybrid regulatory space where science and law interact, law retains its authority by cutting off arguments from the decision-making process. At the same time, glyphosate has catalyzed contestation, triggering a process of re-politicization of the realm of transnational risk regulation.

## **Glyphosate as a Matter of Law**

The story of glyphosate is being co-written by a variety of legal institutions, from patent protection to counter-narcotics policies. <sup>10</sup> Given the limited scope of this chapter, the focus is on transnational risk regulation. At the core of risk regulation is the idea that public and (increasingly) private regulatory bodies are to regulate 'risky' products, technologies, and other activities. Under this regulatory paradigm, the risk properties (such as carcinogenicity) of the to-be regulated objects become the focal point of regulation. The problem, though, is that law in itself is not endowed with the authority of attributing these properties to the objects. To solve this problem, conceptual and institutional categories enabling law to acquire the authority and the powers to ascribe the risk properties to products have been created. In numerous jurisdictions around the world, it is today common to distinguish a risk assessment from a risk management phase. 11 The risk assessment is an institutionalized set of practices by which scientists enlisted by law assess certain properties of the to-be regulated object. Risk assessment lends cognitive legitimacy to the regulators, which are then entrusted with the 'management' of risks. Various guidelines on risk assessment (eg Codex guidelines) attest to this division. <sup>12</sup> A lot has been written about the need to organize the risk assessment/risk management process as iterative, dialogical, non-linear, and much has been written to attest to the interconnectedness of risk assessment and management. <sup>13</sup> Yet, risk analysis, as embedded in 4. risk regulation, tends to be stranded in dichotomies, where science is juxtaposed to politics, risk assessment to management, etc. 14

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It is through these conceptual categories and concrete institutions that objects, like glyphosate, can be (and have been) 'subjected' to law. These categories and institutions have spread globally through the field of international law. <sup>15</sup> The IARC is an interesting example of a scientific body that is entrusted by the WHO to assess cancer risks. While the opinions of the IARC are non-binding, they do produce effects in the legal realm and, more generally, it can be said that the IARC exercises a form of public authority at the global level.

In the legal universe, authority is commonly conceptualized as 'solid', meaning formal, binding, hierarchical. <sup>16</sup> Authority grounded in informal and non-binding means has been characterized by Nico Krisch as 'liquid authority'. <sup>17</sup> This chapter endorses a broad conception of authority where both solid and 'liquid' models are included. From this perspective, the IARC can be said to exercise a form of 'liquid authority'. As will be shown below, the report of the IARC is influencing the international, transnational, and domestic legal realm in a variety of ways. While the report of a scientific body may not qualify as law, international legal scholars have started to conceptualize international law in ways that go beyond the traditional sources doctrine. According to this view, the practices and institutions that *de facto* exercise international public authority should be considered as part of international law, or better 'informal international law'. <sup>18</sup> Reports of internationally recognized and institutionally embedded scientific bodies may qualify as part of informal international law making.

The IARC March 2015 Monograph 112<sup>19</sup> is the first assessment of an international scientific body attributing carcinogenic properties to glyphosate. The publication of the Monograph has triggered a number of regulatory and quasi-regulatory responses, at different levels of governance. These responses may lead, and in certain cases have already led, to strict limitations on the use of glyphosate.

On the international plane, the IARC Monograph further triggered the re-evaluation of glyphosate by the Joint Meeting on Pesticide Residues (JMPR), an expert body, established in 1963 to assess the safety of pesticides residues in food. 20 4 JMPR is jointly 'administered' by the UN Food and Agricultural Organization (FAO) and the WHO and it is embedded in the work of the Codex Alimentarius Commission (Codex Commission). The JMPR produces reports regarding the safety of pesticides (expressed as Maximum Residues Levels (MRL) and Allowable Daily Intakes (ADIs)), which are typically adopted as international standards by the Codex Commission. Codex standards gained quasi-binding authority with the establishment of the World Trade Organization (WTO). <sup>21</sup> To oversimplify, when JMPR reach a conclusion similar to the one of the IARC, any WTO Member that sought to adopt regulations restricting the use of glyphosate (and consequently its trade) could justify its measures before the WTO on the basis of the JMPRdriven Codex standard. When the JMPR, by contrast, reach different conclusions to the IARC, it may be more problematic for WTO Members to adopt glyphosate-trade-restrictive measures. JMPR published its Report in May 2016, reaching the conclusion that 'glyphosate is unlikely to pose a carcinogenic risk to humans via exposure from the diet. '22 Given the apparent contradiction between the IARC and the JMPR report, the question of what will happen should a legal dispute on trade restrictive measures concerning glyphosate be brought before a WTO adjudicatory body remains unsettled.<sup>23</sup>

The IARC has also triggered action in the European Union. The European Food Safety Authority (EFSA) received a mandate from the European Commission 'to consider' the findings of the IARC in its process of re-evaluation of glyphosate.<sup>24</sup> This request of the Commission came when the review process was already ongoing. The review process of glyphosate within the EU was initiated by the Federal Institute for Risk Assessment (BfR) in Germany and the IARC was aware of this process when it conducted its own assessment. While the European Commission is not bound by the release of an IARC Monograph, it promptly reacted by asking EFSA to conduct its own re-evaluation of the IARC assessment. In spite of its non-binding nature, the IARC Monograph became a document to be 'considered' by the scientists at EFSA. The final conclusions of EFSA are different from those of the IARC  $\, \, \mathrel{\displayskip} \, \,$  Monograph. These two different assessments led to a regulatory compromise by the European Commission. With a positive assessment by EFSA, the compound could have been easily re-approved for another fifteen years. However, in June 2016, the Commission decided to only temporarily re-authorize glyphosate for an additional eighteen months, pending other reviews. Moreover, the Commission has adopted an implementing regulation mandating Member States to ban the surfactant POE-tallowamine from glyphosate-based plant protection products and recommending Member States to pay particular attention to the use of the substance in public parks, public playgrounds, and gardens as well as to the pre-harvest use of glyphosate. <sup>25</sup> Meanwhile, in January 2017, a group of concerned citizens launched a European Citizens' Initiative (ECI) to ban glyphosate, which draws on the legal relevance of the IARC classification. <sup>26</sup> The ECI is a new legal institute enabling a critical

mass of EU citizens to formally demand that the European Commission launch a legislative proposal. In March 2017, the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) concluded that glyphosate should not be classified as carcinogenic. This decision may lead to a reauthorization of glyphosate for at least the next ten years. <sup>29</sup>

In the US, at the federal level, the Environmental Protection Agency (EPA) has also started a process to reassess the safety of glyphosate. The process is pending, amidst a very polarized debate. In the meanwhile, and as a direct consequence of the IARC Monograph, as of 7 July 2017, Glyphosate is listed as carcinogenic in the State of California. 1

Finally, several legal suits against Monsanto are pending in the US. These disputes share the claim that Roundup has caused non-Hodgkin lymphoma, leading to several deaths. One of the questions that the American judges will have to decide in coming to a verdict is whether the IARC analysis and findings are relevant to prove causation. In the course of the trial, a number of Monsanto internal emails have been disclosed, revealing that some of the studies which found no genotoxic potential of glyphosate may have been written under the influence of Monsanto itself and, accordingly, lose credibility. This matter, labelled by the media as the 'Monsanto papers', has led a group of EU parlamentarians to ask, inter alia, for a new assessment of the validity of some the studies used by EFSA and ECHA in their assessment and the adoption of tougher rules to control undue influence of industry on agencies' decision-making processes. A

The legal initiatives and proceedings spurred by and related to the publication of the IARC Monograph are a clear illustration that glyphosate is an object of law, or better of informal international law (or global law). The Monograph of an international scientific body has not only triggered legal action at the transnational and domestic level but it has initiated an intertwined set of legal procedures, in which evidence discovered in one jurisdiction (in this case the US) may influence the regulatory process of another jurisdiction (in this case Europe).

### **Glyphosate and the Politics of Separation**

On 12 November 2015, EFSA published its conclusions and, in apparent contrast with the IARC Report, it found that glyphosate is 'unlikely to pose a carcinogenic hazard to humans.'<sup>35</sup> As mentioned above, the JMPR has followed suit releasing a Report in May 2016, which is also dismissive of the carcinogenic risk.<sup>36</sup> How to explain these different findings? And what do the differences between these assessments tell about glyphosate-related law-making processes? According to one JMPR \( \sigma \) scientist the differences between IARC and JMPR are more 'apparent than real' because:

we serve different functions ... IARC is about identifying carcinogens and determining whether the evidence is strong, moderate or weak; they don't look into the implications for human health. JMPR is mandated to advise Codex Member States on the safety of residues in food ... IARC does not look at exposure ... it does not conduct a risk assessment ... it [is] for JMPR to assess the risks to the consumers from residues in food.<sup>37</sup>

In short, IARC conducts hazard classification, which looks only at causation and not at the exposure to residues in food. From this vantage point, the evaluations do not differ in their findings but rather ask different questions. The distinction between hazard analysis and risk assessment is well established in risk regulation. The former is commonly considered the first step in the process of risk analysis. Its main aim is to establish causation. Risk assessment integrates hazard analysis with the analysis of exposure to risk. The Codex Alimentarius guidelines on risk analysis fully subscribe to the risk analysis grammar. IARC, by its own account, conducts 'hazard classification' only. Only.

Next to this issue, the differences between the assessments have been traced to the scope of the matter analysed. EFSA has published a short document, which explains to the layman the reasons underpinning the difference with the IARC Monograph. <sup>41</sup> On p 2, we read:

... the IARC report looked at both glyphosate – an active substance – and glyphosate-based formulations, grouping all formulations regardless of their composition. The EU assessment, on the other hand, considered only glyphosate. Member States are responsible for evaluating each plant protection product that is marketed in their territories. ... This distinction between active

substance and pesticide formulation mainly explains the differences in how EFSA and IARC weighed the available data.  $^{42}$ 

The decision of EFSA and, incidentally, of many other scientific agencies, not to consider formulations has been criticized by one IARC scientist in the following way:

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So, you are a lawyer. Everywhere in the world, the pesticide agencies review the pure product ... and the reason is a legal one; if you are going to ban a product ... unless you want to sit down and evaluate every formulation all the time ... it will make you crazy, you will get \$\Gamma\$ challenged in courts, there is all kinds of problems associated with it, so they all go for the pure product ... they are all wrong, but I can get past it because *it's a legal issue*. ... Did EFSA at least make a decent attempt to look at this? In my opinion the answer is no. ... First of all, all of the epidemiology data is formulations; none of it is pure glyphosate; so most of the pesticide reviewing agencies around the world ignore the epidemiology data.<sup>43</sup>

There is one point of convergence among the reasoning of the interviewed scientists: the assessment of glyphosate, albeit scientific, is embedded in law. This issue was made explicit during the discussion at one EFSA Management Board meeting; as put by one participant: 'it should be emphasized also that it is *legally-binding* evidence-based *risk assessment* [that EFSA is following] ... that EFSA, by its mandate, will not take into consideration all available information for *legal reasons*.'<sup>44</sup>

The case of glyphosate illustrates that science-based law is in fact legally-embedded-science-based law. The relationship between science and law is circular, not linear. Law that has made a call on science to solve certain issues unleashes its authority to frame problems and to admit or exclude scientific evidence. The almost surgical separation between hazard analysis and risk assessment and between formulations and the pure substance resonates with the conceptualization of risk assessment and risk management as clearly distinct realms. The act of splitting (eg hazard analysis from risk assessment) enables the regulators to exclude arguments and decide more expeditiously; risk assessment is the basis for regulation, not hazard analysis; pure substances are to be appraised not formulations; arguments in, arguments out. This politics of separation is expedient, as law ought to resolve conflicts, to decide. To decide comes from the Latin words de- and caeděre: to cut-off. Law needs to 'cut-off'. In resorting to science, law risks being lost in the 'thousands of ways' by which scientists 'manipulate, transform and test phenomena'; through the politics of separation, law regains one of its main traits, that is the ability of 'saying the last word'. 45

These political choices are made when the institutions for the scientific appraisal of risks are shaped and tend to remain unquestioned in the subsequent regulatory process; they are back-staged. Glyphosate, however, has become a catalyst for contesting existing dichotomies. In so doing, glyphosate brings the politics back to the front-stage of the decision-making forum.

Glyphosate has gained this role because of its unique features in the universe of pesticides. The words of one scientist working on glyphosate are eloquent: 'we were interested in glyphosate because it is the main pesticide of the world and also because it is associated (sic) to GMOs and we were working on toxicity of pesticides in food ... and the use and consumption of GMOs is a major factor of pesticide exposure, because almost all GMOs are made to tolerate a pesticide.'

Glyphosate is not just any other pesticide, it is the most widely used pesticide in the world, it is the 'first billion dollar product' of the pesticide industry, <sup>49</sup> and it is the pesticide used to treat GMOs. The boundary work through which the legitimacy and the legality of arguments are established is now under scrutiny

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because the stakes are so high. The IARC Report has triggered a number of review procedures for the assessment of glyphosate safety, which have led to the questioning of a set of practices underpinning the regulatory process. Distinctions that were previously normalized are being destabilized. In short, glyphosate has the potential of re-politicizing the field of science-based law.

By having decided to classify as hazardous *the very same object* that other agencies worldwide had considered safe, the IARC triggered a process of destabilization of the normal practices by which 'risk' properties are attributed to a wide category of compounds. The IARC deviates from the practice of other agencies that have so far assessed only the pure compound. At the same time, while considering the studies on formulations, the IARC frames its analysis as an assessment of glyphosate, not of formulations. One scientist has explained this choice in the following terms:

... on the last day, after we argued constantly over the science for 8 days, then we decide what actually are we going to make a decision on; is it glyphosate formulations that we are making a probable call on? Or is it glyphosate that we are making a probable call on? And that argument then goes to the mechanistic data, because that was the only place where we had lots of studies with both pure glyphosate and the formulations ... and we concluded that there is enough evidence ... that it was glyphosate that was really causing the problem ... not all the \$\mathbb{L}\$ adjuvants, not formulations, glyphosate ... so the IARC review is that glyphosate is a probable human carcinogen ... and it was a *conscious decision*. <sup>50</sup>

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After the IARC Monograph had been released, scientists started to engage in a debate over the 'normal' practices that 'legally-embedded science' employs to ascribe risky properties to objects. For example, a group of scientists published a 'consensus statement' on the concerns over using glyphosate-based pesticides. The article is 'directed to scientists, physicians, and regulatory officials around the world' and contends, inter alia, that many of the toxic effects that have been established by scientific studies 'would likely not be detected in experiments adhering to traditional toxicology test guidelines promulgated by pesticide-regulatory authorities'. 51 Making a quite different point, other scientists have criticized the '[c]lassification schemes for carcinogenicity based solely on hazard-identification such as the IARC monograph process and the UN system adopted in the EU' as 'outmoded' and have contextually advocated for incorporating 'principles and concepts of existing international consensus-based frameworks including the WHO [International Programme for Chemical Safety] IPCS mode of action framework'. 52 These scientists advocate for a much stricter reliance on risk assessment and for greatly limiting the role of hazard classification. This is an important issue because some regulations rely on risk assessment as a legally relevant criterion, while others rely on hazard classification. NGOs and industry groups alike have joined the chorus raising critiques of the practices by which risks are commonly assessed in current regulatory science. The critiques touch upon a wide variety of issues, ranging from the institutional features of the decisionmaking process (such as conflict of interests; over/under-reliance on studies by industry) to the scientific methodologies that ought to be used.<sup>53</sup> What is peculiar about this case, and all those at the intersection of science and law, is that the politics underpinning the law unfolds in scientific and legal realms at the same time. For example, the arguments contesting the methodologies normally used in risk assessment or the use of hazard classifications for regulatory purposes have been published in scientific journals.<sup>54</sup> At the same time, the arguments used by the scientists adhere to a rhetoric that is not purely scientific. Both groups of authors, albeit 🖟 defending different views, resort to consensus, an ideal central to the field of international law rather than science.

## **Concluding Remarks: Glyphosate and Re-Politicization**

In global governance, science has been used as a vehicle to harmonize policies and as a means of depoliticization. The WTO has empowered a number of international standardization bodies (such as JMPR) that, by subscribing in various ways to the risk analysis grammar, have accordingly fostered global technocracy. The authority entrusted to these bodies by the international trade regimes is only likely to increase in the future, as evidenced by the negotiations of mega-regional agreements (such as the Comprehensive Economic and Trade Agreement between Canada, and the European Union, CETA) which aspire to enhance regulatory coherence by subscribing to 'science-based' regulatory processes. The subscribing to 'science-based' regulatory processes.

Glyphosate as an object of international law has proved a powerful means to re-politicize this field. Re-politicization in this case means that the political choices back-staged in a normalized risk regulation

decision-making process are brought back to the front stage. Given the high stakes attached to its use, glyphosate has become a powerful catalyst of contestation.

Glyphosate, as an object of international law, is also bearing witness to the evolution of a hybrid space between science and law, where claims to authority are made in unconventional sites (such as scientific journals) and scientific epistemic communities resort to the language of law (such as consensus) to make their case stronger. The way the EFSA has rationalized the differences between its and the IARC's evaluation — 'it is not glyphosate, it is formulations'—and the way the IARC has responded—'it is glyphosate, not formulations'—brings to mind Magritte's painting(s) 'The Treachery of Images' where we see a pipe with the hand-written caption, *Ceci n'est pas une pipe*.

Art historians have asked: 'Where is the authority? Do we believe what we're seeing in the veracity of the illustration, the sort of perfect representation of the almost platonic pipe, or do we believe the text underneath, which tells us this is 4 not a pipe?' In Magritte's painting there is a tension between the authority of the platonic representation of the pipe and the (equally platonic) handwriting-language denying it. Likewise, the glyphosate case is a story about the *tensions* between the abstractions instrumental to categorize, separate, and *decide* and the alliance between the object and the people denying the authority of those acts of separation.

#### **Notes**

- This figure corresponds to '71% of total use worldwide from 1974–2014'. See Charles M Benbrook, 'Trends in Glyphosate Herbicide Use in the United States and Globally' (2016) 28(3) Environmental Sciences Europe. I would like to thank Jessie Hohmann, Daniel Joyce, and the participants of the Queen Mary Workshop on International Law's Objects: Emergence, Encounter and Erasure through Object and Image for insightful comments as well as Marjolein Schaap-Rubio Imbers, Federica Violi, Michela Salamone, and the interviewed scientists who generously shared their time and experience with me.
- Technically this is called Group 2A; see IARC Monograph 112, 2015, <a href="https://monographs.iarc.fr/iarc-monographs-on-the-evaluation-of-carcinogenic-risks-to-humans-4/">https://monographs.iarc.fr/iarc-monographs-on-the-evaluation-of-carcinogenic-risks-to-humans-4/</a> accessed 3 August 2018.
- Robert L Zimdahl, A History of Weed Science in The United States (1st ed, Elsevier 2010) 105; Vijay K Nandula (ed), Glyphosate Resistance in Crops and Weeds (1st ed, Wiley 2010) 1. Today, the molecule of glyphosate can be bought at Sigma-Aldrich (part of Merk), see their website <a href="http://www.sigmaaldrich.com/catalog/search?">http://www.sigmaaldrich.com/catalog/search?</a> term=glyphosate&interface=All&N=0&mode=match%20partialmax&lang=en&region=NL&focus=product> accessed 3 August 2018.
- 4 Philip Ball, 'Chemistry: Why Synthesize?' (2015) 528(7582) Nature 327.
- 5 Zimdahl (n 3) 105.
- 6 Benbrook (n 1); Stephen O Duke and Stephen B Powles, 'Glyphosate: A Once-In-A-Century Herbicide' (2008) 64(4) Pest Management Science 319.
- 7 Benbrook (n 1).

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- 8 Bruno Latour, 'Scientific Objects and Legal Objectivity', a chapter of *La Fabrique du droit* translated by Alain Pottage in Alain Pottage and Martha Mundy, *Law, Anthropology, and The Constitution Of The Social: Making Persons And Things* (1st ed, CUP 2004). Latour acknowledges that there are situations in which science bears 'the imprint of law'; yet, in his article he mainly draws attention to the important distinctions between the two.
- 9 Glyphosate-based pesticides were protected by patents in the US from 1974 until 2000; when the compound went offpatent, production increased with prices going down.
- After the IARC report, the government of Colombia decided to stop spraying the illegal coca plantations with glyphosate-based products; this decision has been was met with opposition in the US. See 'Colombia Suspends Spraying Illegal Coca Fields with Herbicide over Cancer Link', *The Guardian* (2015)
  <a href="https://www.theguardian.com/world/2015/may/15/colombia-herbicide-glyphosate-coca-fields-cancer">https://www.theguardian.com/world/2015/may/15/colombia-herbicide-glyphosate-coca-fields-cancer</a> accessed 27
- For an overview of the evolution of these practices, see Alessandra Arcuri, 'Risk Regulation', in Roger J van den Bergh and Alessio M Pacces, *Regulation and Economics (Encyclopedia of Law and Economics)* (2nd ed, Edward Elgar 2012).
- 12 Codex Alimentarius Commission, 'Working Principles for Risk Analysis for Food Safety for Application by Governments' (FAO and WHO 2007) *CAC/GL 62-2007* and Codex Alimentarius Commission, 'Procedural Manual' (25th ed, FAO and WHO 2016).
- See National Research Council, 'Risk Assessment in the Federal Government: Managing The Process' (National Academy Press 1983); Important Reports for the evolution of these debate are: National Research Council, 'Science and Judgment in Risk Assessment' (National Academy Press 1994); Paul C Stern and Harvey V Fineberg (eds), 'Understanding Risk: Informing Decisions in a Democratic Society' (National Academy Press 1996); Royal Commission on Environmental Pollution, 'Setting Environmental Standards' (21st Report 1998). For an overview and an analysis, see Elizabeth Fisher, 'Framing Risk Regulation: A Critical Reflection' (2013) 4(2) European Journal of Risk Regulation 125.
- 14 Warner North, 'Reflections On The Red/Mis-Read Book, 20 Years After' (2003) 9(5) Human and Ecological Risk Assessment:

- An International Journal 1145; Fisher (n 13). David Demortain, 'The Many Meanings of "Standard": the Politics of the International Standard for Food Risk Analysis' (2010) London School of Economics and Political Science Discussion Paper no 58 <a href="http://www.lse.ac.uk/accounting/CARR/pdf/dps/disspaper58.pdf">http://www.lse.ac.uk/accounting/CARR/pdf/dps/disspaper58.pdf</a> accessed 27 February 2017.
- David Demortain, 'Enabling Global Principle-Based Regulation: The Case of Risk Analysis in the Codex Alimentarius' (2012) 6(2) Regulation and Governance 207.
- Nico Krisch, 'Liquid Authority in Global Governance' (2017) 9(2) International Theory 237–60.
- 17 ibid.
- 18 Joost Pauwelyn, Ramses Wessel, and Jan Wouters (eds), *Informal International Lawmaking* (1st ed, OUP 2012).
- 19 See IARC Monograph 112 (2015) <a href="http://monographs.iarc.fr/ENG/Monographs/vol112/">http://monographs.iarc.fr/ENG/Monographs/vol112/</a> accessed 27 February 2017 (hereafter IARC 'Monograph 112').
- The functions and institutional characteristics of the JMPR are briefly presented on the JMPR website; 'Plant Production And Protection Division: The Joint FAO/WHO Meeting On Pesticide Residues (JMPR)' (Food and Agriculture Organization of the United Nations) <a href="http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/en/">http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/en/</a> accessed 27 February 2017.
- Frode Veggeland and Svein Ole Borgen, 'Negotiating International Food Standards: The World Trade Organization's Impact on the Codex Alimentarius Commission' (2005) 18(4) Governance 675; Tim Büthe, 'The Globalization of Health and Safety Standards: Delegation of Regulatory Authority in the SPS Agreement of the 1994 Agreement Establishing the World Trade Organisation' (2008) 71(1) Law and Contemporary Problems 219; David E Winickoff and Douglas M Bushey, 'Science And Power In Global Food Regulation: The Rise Of The Codex Alimentarius' (2009) 35(3) Science, Technology & Human Values
- See FAO/WHO, Report of the special session of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 9–13 May 2016,
- 23 IARC Monographs have been used by WTO Courts to assess the legality of certain health and safety measures. See Appellate Body Report, European Communities—Measures Affecting Asbestos and Asbestos-Containing Products, WT/DS135/AB/R (12 March 2001).
- 24 European Commission, Health and Food Safety Directorate-General, 'Request to consider the findings by IARC as regards the potential carcinogenity of glyphosate or glyphosate containing plant protection products in the ongoing peer review of the active substance', 30 April 2015, Brussels, SANTE/E3/DVB/Wv/np.
- See 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 C/2016/4896 [2016] OJ L208. For a press release on the regulation, see the Commission dedicated webpage <a href="http://europa.eu/rapid/press-release\_MEMO-16-2012">http://europa.eu/rapid/press-release\_MEMO-16-2012</a> en.htm> accessed 7 July 2017.
- See European Commission, 'Press Release-Commission Registers 'Ban Glyphosate' European Citizens' Initiative' (Europa.eu, 2017) <a href="http://europa.eu/rapid/press-release\_IP-17-28\_en.htm">http://europa.eu/rapid/press-release\_IP-17-28\_en.htm</a> accessed 27 February 2017; the ECI was registered on January 25 <a href="http://ec.europa.eu/citizens-initiative/public/initiatives/open/details/2017/000002/en">http://ec.europa.eu/citizens-initiative/public/initiatives/open/details/2017/000002/en</a> accessed 7 July 2017.
- 27 See 'European Citizens' Initiative' (Ec.europa.eu) <a href="http://ec.europa.eu/citizens-initiative/public/welcome?lg=en">http://ec.europa.eu/citizens-initiative/public/welcome?lg=en</a> accessed 27 February 2017. For an insightful analysis, see Anastasia Karatzia, 'The European Citizens' Initiative and the EU Institutional Balance: On Realism and the Possibilities of Affecting EU lawmaking' (2017) 54(1) Common Market Law Review 177
- 28 ECHA press release 17/06 <a href="https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa">https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa</a> accessed 3 August 2018.
- Stephen Gardner, 'EU to Consider Reauthorizing Glyphosate Pesticide Through 2027' (Reuters, 17 May 2017)
  https://www.bna.com/eu-consider-reauthorizing-n73014451143/> accessed 7 July 2017; Sarantis Michalopoulos,
  'Commission says 10-year glyphosate extension is a "starting point" for debate' (Euractiv.com, 17 May 2017)
  http://www.euractiv.com/section/agriculture-food/news/commission-says-10-year-glyphosate-extension-is-a-starting-point-for-debate/> accessed 7 July 2017.
- See Carey Gillam, 'Cancer Questions, Controversy And Chorus At EPA Glyphosate Meetings', *The Huffington Post* (2016) <a href="http://www.huffingtonpost.com/carey-gillam/cancer-questions-controve\_b\_13679052.html">http://www.huffingtonpost.com/carey-gillam/cancer-questions-controve\_b\_13679052.html</a> accessed 27 February 2017; PJ Huffstutter, 'EPA Says Glyphosate, Used In Monsanto Herbicide, Likely Not Carcinogenic' (*Reuters*, 2016) <a href="http://www.reuters.com/article/us-usa-epa-glyphosate-idUSKCN11M28X">http://www.reuters.com/article/us-usa-epa-glyphosate-idUSKCN11M28X</a> accessed 27 February 2017.
- 31 Monsanto has tried to halt this decision by the Office of Environmental Health Hazard Assessment, but it has so far been unsuccessful before the Court: <a href="https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer">https://oehha.ca.gov/proposition-65/crnr/glyphosate-listed-effective-july-7-2017-known-state-california-cause-cancer</a> accessed 7 July 2017; Dave Simpson, 'Monsanto Can't Nix Calif.'s Add Of Herbicide To Cancer List' (Law360, 26 June 2017) <a href="https://www.law360.com/articles/938732/monsanto-can-t-nix-calif-s-add-of-herbicide-to-cancer-list">https://www.law360.com/articles/938732/monsanto-can-t-nix-calif-s-add-of-herbicide-to-cancer-list</a> accessed 7 July 2017.
- In United States District Court Northern District of California, Case No 3:16-md-02741-VC, the submissions by both claimants and defendant have engaged with the question whether the IARC Monograph is relevant to establish causation. The submission by the claimant can be downloaded at <a href="https://goo.gl/6tFRL4">https://goo.gl/6tFRL4</a> and the submission by Monsanto can be downloaded at <a href="https://goo.gl/yddHNT">https://goo.gl/yddHNT</a> both accessed 27 February 2017.
- 33 Le Monde, 'Ce que les « Monsanto Papers » révèlent du Roundup' (18 March 2017)

  <a href="http://www.lemonde.fr/planete/article/2017/03/18/ce-que-les-monsanto-papers-revelent-du-roundup\_5096602\_3244.html">http://www.lemonde.fr/planete/article/2017/03/18/ce-que-les-monsanto-papers-revelent-du-roundup\_5096602\_3244.html</a> accessed 3 August 2018. See also, Le Monde, '« Monsanto Papers »: des eurodéputés veulent la révision de l'expertise du glyphosate' (24 March 2017)

- <a href="http://www.lemonde.fr/planete/article/2017/03/24/monsanto-papers-des-eurodeputes-veulent-la-revision-de-lexpertise-du-glyphosate\_5100479\_3244.html">http://www.lemonde.fr/planete/article/2017/03/24/monsanto-papers-des-eurodeputes-veulent-la-revision-de-lexpertise-du-glyphosate\_5100479\_3244.html</a> accessed 3 August 2018.
- 34 Letter by EU parlamentarians to the President of the European Commission Jean-Claude Juncker, Bruxelles, 24 March
- 35 See European Food Safety Authority, 'Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate' (2015) 13 EFSA Journal 4302 <a href="http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4302/epdf">http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4302/epdf</a> accessed 27 February 2017 (emphasis added).
- 36 JMPR Report 2016 (n 22).
- 37 Interview 3; 3.'38'.
- The practice of risk assessment has its roots in the US, in *Industrial Union Department, ALF-CIO v American Petroleum Institute*, 448 US 607 (1980) (USSC). On the origin of risk assessment, see Brian Israel, 'An Environmental Justice Critique Of Risk Assessment' (1995) 3(1) New York University Environmental Law Journal 469, 477; WA Thomas, 'Supreme Court Review of the OSHA Benzene Standard' (1982) 36 The American Statistician (Part 2: Proceedings of the Sixth Symposium on Statistics and the Environment) 264.
- 39 See National Research Council, 'Risk Assessment In The Federal Government: Managing The Process' (National Academy Press 1983).
- 40 See Q&A on glyphosate published by the IARC on its website <a href="https://www.iarc.fr/en/media-centre/iarcnews/2016/glyphosate\_IARC2016.php">https://www.iarc.fr/en/media-centre/iarcnews/2016/glyphosate\_IARC2016.php</a> accessed 27 February 2017.
- 41 EFSA, 'EFSA explains risk assessment' (2015)
  <a href="https://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/efsaexplainsglyphosate151112en\_1.pdf">https://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/efsaexplainsglyphosate151112en\_1.pdf</a>
  accessed 27 February 2017.
- 42 ibid 2.
- Interview 2, Part B. Some of the IARC scientists, joined by other scientists, have further explained the differences between the IARC and EFSA assessments of glyphosate, see Christopher J Portier et al, 'Differences in the Carcinogenic Evaluation of Glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)' (2016) Journal of Epidemiology Community Health 1.
- 44 EFSA, 67th Management Board Meeting, 3 December 2015, Discussion EFSA progress report <a href="http://www.efsa.europa.eu/en/events/event/151203#playaudio">http://www.efsa.europa.eu/en/events/event/151203#playaudio</a> (quoted passage can be listened to at *c.* minute 51) accessed 3 August 2018.
- 45 Latour (n 8).
- 46 See Sheila S Jasanoff, 'Contested Boundaries in Policy-Relevant Science' (1987) 17 Social Studies of Science 195.
- For a discussion of itemization, see Veerle Heyvaert, 'Governing Climate Change: Towards A New Paradigm For Risk Regulation' (2011) 74(6) Modern Law Review 817.
- 48 Interview 4.
- 49 András Székács and Béla Darvas, 'Forty Years with Glyphosate' in Mohammed Nagib Hasaneen (ed), *Herbicides: Properties, Synthesis and Control of Weeds* (Intech 2012).
- 50 Interview 2.
- John Peterson Myers et al, 'Concerns Over Use Of Glyphosate-Based Herbicides And Risks Associated With Exposures: A Consensus Statement' (2016) 15 Environmental Health <a href="https://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0">https://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0</a> accessed 27 February 2017.
- Alan R Boobis et al, 'Classification Schemes For Carcinogenicity Based On Hazard-Identification Have Become Outmoded And Serve Neither Science Nor Society' (2016) 82 *Regulatory Toxicology and Pharmacology* 158.
- For example, the organization launching the ECI is asking that 'Regulatory studies to support EU pesticide approvals must be commissioned by public authorities, not the industry itself'; see the ECI Initiative and, in particular its Annex, at 1 <a href="http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002">http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002</a> accessed 16 October 2018. On its part, the American Chemistry Council industry body has launched a project to reform current practices of risk analysis as well as a reform of the IARC <a href="http://campaignforaccuracyinpublichealthresearch.com/">http://campaignforaccuracyinpublichealthresearch.com/</a> accessed 27 February 2017.
- 54 Myers et al (n 51); Boobis et al (n 52). See also Kai Kupferschmidt, 'High-Profile Cancer Reviews Trigger Controversy' (2016) 352 Science 1504.
- For recent work on understanding the phenomenon of depoliticization in risk governance, see David Demortain, 'Depoliticization by Design? The OECD and Risk Governance' (2015) paper presented at the SKAPE-Net workshop, Monitoring and the Politics of Ignorance, 19 May 2015, Geneva (unpublished paper, on file with the author).
- However, as I have argued in my previous work, some dimensions of this system are evolving and possibly leading to change. See Alessandra Arcuri, 'Global Food Safety Standards: The Evolving Regulatory Epistemology at the Intersection of the SPS Agreement and the Codex Alimentarius Commission' in Panagiotis Delimatsis (ed), *The Law, Economics and Politics of International Standardisation* (CUP 2015); Alessandra Arcuri, 'The Coproduction of the Global Regulatory Regime for Food Safety Standards and the Limits of a Technocratic Ethos' (2014) Robert Schuman Centre for Advanced Studies Research Paper No RSCAS 2014/97 <a href="http://ssrn.com/abstract=2500705">http://ssrn.com/abstract=2500705</a> accessed 27 February 2017.
- 57 See further Alberto Alemanno, 'The Regulatory Cooperation Chapter of The Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences' (2015) 18 Journal of International Economic Law 625.
- Conversation between art historians, Dr Beth Harris and Dr Steven Zucker on Magritte's painting 'The Treachery of Images' <a href="https://www.khanacademy.org/humanities/art-1010/art-between-wars/surrealism1/v/magritte-the-treachery-of-images-ceci-n-est-pas-une-pipe-1929">https://www.khanacademy.org/humanities/art-1010/art-between-wars/surrealism1/v/magritte-the-treachery-of-images-ceci-n-est-pas-une-pipe-1929</a> accessed 27 February 2017.