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The glyphosate saga and the fading democratic legitimacy of EU risk regulation.

Giulia Claudia Leonelli *

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This article endeavours to explore the glyphosate saga through the prism of a *socially acceptable risk* approach to the governance of public health and environmental risks in the EU. After a brief overview on the nature and rationale of *socially acceptable* risk approaches, the article analyses the controversial case of glyphosate's renewal of approval, casting light on the position of the agencies and institutions involved throughout the risk assessment and risk management phases. Against this overall backdrop, the article deconstructs the Commission's artificial legal narrative on 'sound' science and glyphosate and contends that the Commission had *scientific* and *legal* grounds, as well as compelling *political* reasons, to accept the requests put forward by the 'Ban Glyphosate' European Citizens' Initiative and the European Parliament. The Commission relied on a narrow evidence-based approach, disregarding the widespread public perception that the uncertain risks posed by glyphosate are *socially unacceptable*, and ignoring the argument that the existing risk management measures are insufficient to achieve the *intended EU level of* public health and environmental *protection*. In so doing, the Commission has ultimately lost a crucial opportunity to re-legitimise and re-democratise EU risk regulation.

Keywords: Democratic legitimacy, risk regulation, glyphosate, pesticides, precautionary principle.

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Abstract

This article endeavours to explore the glyphosate saga through the prism of a *socially acceptable risk* approach to the governance of public health and environmental risks in the EU. After a brief overview on the nature and rationale of socially acceptable risk approaches, the article analyses the controversial case of glyphosate's renewal of approval, casting light on the position of the agencies and institutions involved throughout the risk assessment and risk management phases. Against this overall backdrop, the article deconstructs the Commission's artificial legal narrative on 'sound' science and glyphosate and contends that the Commission had *scientific* and *legal* grounds, as well as compelling *political* reasons, to accept the requests put forward by the 'Ban Glyphosate' European Citizens' Initiative and the European Parliament. The Commission relied on a narrow evidence-based approach, disregarding the widespread public perception that the uncertain risks posed by glyphosate are socially unacceptable, and ignoring the argument that the existing risk management measures are insufficient to achieve the intended level of EU public health and environmental protection. In so doing, the Commission has ultimately lost a crucial opportunity to re-legitimise and re-democratise EU risk regulation.

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What lies at the core of the glyphosate case, and what triggered the heated debate on the EU renewal of approval of this active substance? What course of action did the Commission follow, and how did it ultimately decide to manage the uncertain risks posed by the use of glyphosate? And what role has been played by the 'Ban Glyphosate' European Citizens' Initiative?

This article endeavours to explore the unfolding of the glyphosate saga through the prism of a *socially acceptable risk* approach to EU risk regulation. Section 1. outlines the main features as well as the inner rationale of socially acceptable risk approaches, setting the stage for the following enquiry into the glyphosate controversy. Sections 2. and 3. focus on the risk assessment phase, analysing the position of the agencies involved against the background of the 'sound' science versus scientific uncertainty dichotomy. Sections 4., 5. and 6., on the other hand, provide an overview of the Commission's narrow approach to risk management, emphasising how the latter has ultimately failed in its political task to reconstruct an EU-wide understanding of 'intended level' of health and environmental protection. Against this overall backdrop, section 7. draws some conclusions on the shifting EU balance of functional and democratic legitimacy – highlighting how the Commission's inability to flesh out a truly precautionary approach to the governance of glyphosate risks has undermined the very democratic legitimacy of EU risk regulation.

1. The boundaries and remit of EU risk regulation: the socially acceptable risk approach.

Despite the hegemonic transnational legal narrative on evidence-based risk regulation¹ and the increasing – albeit discontinuous – scientification of the Court's judicial review,² a *socially*

¹ G.C. Leonelli, *The Transnational Law and Governance of GMOs* (under peer review, on file with author); and G.C. Leonelli, 'GMO Risks, Food Security, Climate Change and the Entrenchment of Neo-Liberal Legal Narratives', (forthcoming 2018, on file with author) *Transnational Legal Theory* (Special Issue, Symposium on Transnational Food Security). In a similar perspective, see Maria Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' (2009) 62 *Current Legal Problems* 242, at 242 ff.; and Elizabeth Fisher, 'Framing Risk Regulation: A Critical Reflection' (2013) 4 *European Journal of Risk Regulation* 125, at 125 ff.

² See for instance Maria Lee, *EU Regulation of GMOs* (Edward Elgar 2008), 84-87; Ellen Vos, 'The European Court of Justice in the Face of Scientific Uncertainty and Complexity' in Mark Dawson, Bruno De Witte and Elise Muir (eds.),

acceptable risk approach to the governance of uncertain risks is somehow encoded in the DNA of EU risk regulation. This paradigm lies at the very heart of the ‘constitutional’ nature of EU risk governance,³ as originally envisaged.

If it is certainly true that an evidence-based and a precautionary – or socially acceptable risk⁴ – soul coexist under EU risk regulation,⁵ it is equally true that no plausible legal reason exists for the former to trump the latter. Were the results of technical risk assessment meant to be the only – or the most relevant – factor at stake under EU risk regulation, the EFSA would be an EU version of the US Food and Drugs Administration Agency (FDA); however, this is certainly not the case.⁶ Were technical risk assessors meant to set the relevant threshold of acceptable risk,⁷ there would be no use for the risk managers to politically weigh and balance all interests at stake, identifying the EU-wide intended level of public health and environmental protection.⁸ In fact, as most famously argued in *Pfizer*,⁹ the distribution of authority between technical risk assessors and political risk managers epitomises the EU struggle to complement and reconcile functional and democratic legitimacy.

Against this backdrop, and irrespective of whether evidence-based risk governance is seen in a positive or a negative light, the foundations of EU risk regulation are rooted in a socially acceptable risk approach. This is liable to accommodate a prudential risk assessment as well as a political evaluation of all available risk management options, with a view to ensuring the achievement of the intended level of EU health and environmental protection.

Starting off from the risk assessment phase, socially acceptable risk approaches are epistemologically grounded on a pluralistic – rather than monolithic and universalistic – conception of science.¹⁰ If

Judicial Activism at the European Court of Justice (Edward Elgar 2013), 152 ff.; Patrycja Dąbrowska Klosinska, ‘Risk, Precaution And Scientific Complexity Before the Court of Justice of the European Union’, in Lucasz Gruszczynski and Wouter Werner (eds.), *Deference In International Courts and Tribunals* (OUP 2014), 205 ff.; and Christopher Anderson, ‘Contrasting Models of EU Administration in Judicial Review of Risk Regulation’ (2014) 51 *Common Market Law Review* 424, 432 ff.

³ On the ‘constitutional’ nature of EU risk regulation see Damian Chalmers, ‘Food for Thought: Reconciling European Risks and Traditional Ways of Life’ (2003) 66 *Common Market Law Review* 532.

⁴ The use of this terminology aims at emphasising how socially acceptable risk approaches encompass and do justice to a range of *other legitimate factors* at stake (‘OLFs’), together with the underlying tenets of the *precautionary principle*. See *infra*, in this section.

⁵ On the coexistence of an evidence-based and precautionary soul within EU risk regulation, see Alberto Alemanno, ‘Case C-79/09, *Gowan Comércio Internacional e Servicos Lda v. Ministero della Salute*, Judgment of the Court of Justice (Second Chamber) of 22 December 2010’ (2011) 48 *Common Market Law Review* 1329, 1329-1330; and Alberto Alemanno, ‘Risk Versus Hazard and The Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt’ (2011) 2 *European Journal of Risk Regulation* 169, 169-170.

⁶ For an overview of the specific remit of the EFSA, see Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety [2002] OJ L31, the General Food Law (hereafter, ‘GFL’), articles 22 and 23. Unlike the American FDA, the EFSA is simply entrusted with the task of informing the technical knowledge of political decision-makers.

⁷ For an argument in favour, see Alberto Alemanno, ‘Case C-79/09, *Gowan Comércio Internacional e Servicos Lda v. Ministero della Salute* (n 5), 1342 to 1345.

⁸ On the notions of ‘intended level of protection’, ‘appropriate level of protection’ and ‘high level of protection chosen [in the Union]’, see first and foremost European Commission, Communication from the Commission on the Precautionary Principle, COM (2000) 1 final, at 1 (point 3); 3 (point 6); 7 (section 1); 8 (sections 2 and 3); 12 (section 5) and 16 (section 6.2.). See also the text of Recitals (8), (21) and (32) and Articles 1(1), 5(1), 7(1) and 7(2) of the GFL (n 6).

⁹ Case T-13/99 *Pfizer Animal Health SA v Council* [2002] EU:T:2002:209. See specifically para. 149: ‘[...] It is for the Community institutions to determine the level of protection which they deem appropriate for society. It is by reference to that level of protection that they must then, while dealing with the first component of the risk assessment, determine the level of the risk – i.e. the critical probability threshold for adverse effects on human health and for the seriousness of those effects – which in their judgement is no longer acceptable for society and above which it is necessary, in the interests of protecting human health, to take preventive measures in spite of any existing scientific uncertainty. Therefore, determining the level of risk deemed unacceptable involves the Community institutions in defining the political objectives to be pursued under the powers conferred on them by the Treaty’. See also European Commission, Commission Communication on the General Principles of Food Legislation in the European Union, COM (1997) 176 final; European Commission, Commission Communication on Consumer Health and Food Safety, COM (1997) 183 final; European Commission, White Paper on Food Safety, COM (1999) 719 final.

¹⁰ See Jacqueline Peel, *Science and Risk Regulation in International Law* (CUP 2010) at 94-108.

evidence-based or ‘sound’ science approaches focus on what has been scientifically proved and quantified throughout the phase of technical risk assessment, a socially acceptable risk approach postulates that due consideration should – or may as well – be given to what science cannot prove or measure, in conditions of scientific uncertainty. As testified by the Commission Communication on the Precautionary Principle, a prudential risk assessment¹¹ is perfectly compatible with – if not inherent to – EU risk regulation. The underlying rationale of the precautionary principle, as enshrined in article 191(2) of the Treaty on the Functioning of the European Union (TFEU),¹² is that science should in fact be ‘*consulted less for the knowledge that it has to offer, than for the doubts and concerns that it is in a position to raise*’.¹³

From this perspective, in the face of persisting scientific uncertainty, technical risk assessment is understood as a necessary but not sufficient condition for the enactment of risk regulation¹⁴; in other words, the results of risk assessment are merely meant to inform the technical knowledge of risk managers. This is somehow a logical corollary of the EU model of risk regulation, with all its specificities. If the determination that a risk exists were to be based on ‘sound’ science, political risk managers would have no role to play. If the notion of acceptable risk were deemed to be ‘neutral’, ‘objective’ and ‘universal’¹⁵ – rather than socially embedded¹⁶ – technical experts would be in charge with EU risk management, and fit for the purpose.

This consideration paves the way for a further analysis of risk management. Under a socially acceptable risk approach, political risk management is meant to encompass the results of the risk assessment phase, the overarching tenets of the precautionary principle¹⁷ and any other legitimate factors (hereafter, ‘OLFs’) at stake.¹⁸ The risk manager is thereafter called upon to establish whether

¹¹ European Commission, Communication from the Commission on the Precautionary Principle (n 8) at 12.

¹² Consolidated Version of the Treaty on the Functioning of the European Union OJ [2012] C326, Article 191(2). As clarified in European Commission, Communication from the Commission on the Precautionary Principle (n 8) at 2 and 9, however, the scope of the precautionary principle extends well beyond the boundaries of EU environmental law.

¹³ Nicolas De Sadeleer, ‘The Precautionary Principle in EC Health and Environmental Law’ (2006) 12 European Law Journal 139, at 159 and 172.

¹⁴ For the use of this definition, see Theofanis Christoforou, ‘The Regulation of Genetically Modified Organisms in the European Union: The Interplay of Science, Law and Politics’, (2004) 41 Common Market Law Review 637, at 680; and Nicolas De Sadeleer (n 13) at 161.

¹⁵ In this perspective, see inter alia Giandomenico Majone, ‘What Price Safety? The Precautionary Principle and Its Policy Implications’ (2002) 40 Journal of Common Market Studies, 89; Cass Sunstein, *Risk and Reason. Safety, Law and the Environment* (CUP 2002); Cass Sunstein, *Laws of Fear. Beyond the Precautionary Principle* (CUP 2005); Cass Sunstein, ‘Precautions Against What? Perceptions, Heuristics and Culture’ in Johnathan Wiener et al. (eds.) *The Reality of Precaution. Comparing Risk Regulation in the United States and Europe* (Routledge 2011) 492; Johnathan Wiener, ‘The Rhetoric of Precaution’ *ibid.* 3; Mark Pollack and Gregory Shaffer, *When Cooperation Fails. The International Law and Politics of Genetically Modified Foods* (OUP 2009); Mark Pollack and Gregory Shaffer, ‘The EU Regulatory System for GMOs’ in Michelle Everson and Ellen Vos (eds.) *Uncertain Risks Regulated* (Routledge, 2009) 269; see also, albeit in a more nuanced vein, Alberto Alemanno, ‘Risk Versus Hazard and the Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt’ (n 5).

¹⁶ The premise of a *socially acceptable risk* approach to risk regulation is that the *threshold of acceptable risk* and the notion of *intended level of protection* are in fact unescapably *socially embedded* – regardless of whether technical risk assessors or political risk managers are in charge with their identification; see G.C. Leonelli, *The Transnational Law and Governance of GMOs* (n 1) and G.C. Leonelli, ‘GMO Risks, Food Security, Climate Change and the Entrenchment of Neo-Liberal Legal Narratives’ (n 1). In a similar perspective, see for instance Sheila Jasanoff, *Designs on Nature. Science and Democracy in the European Union and the United States* (Princeton University Press 2005).

¹⁷ See European Commission, Communication from the Commission on the Precautionary Principle (n 8) at 12, stating that the precautionary principle shall apply ‘*when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy*’; at 13, section 5.1., on the appreciation of scientific uncertainty; and at 16, section 6.2., on the triggering factor for the application of the precautionary principle. For all reference to the precautionary principle in the GFL and PPP Regulation, see *infra*, section 4.

¹⁸ Notably, in this perspective, see recital (19) and articles 5, 6(2), 6(3) and 7(2) of the GFL (n 6). Article 6(3) maintains that ‘*risk management shall take into account the results of risk assessment [...], other factors legitimate to the matter under consideration, and the precautionary principle where the conditions laid down in article 7(1) are relevant [...]*’. For the direct provisions on OLFs in the PPP Regulation see *infra*, section 4.

and how to regulate uncertain risks.¹⁹ At the core of the socially acceptable risk approach is the question whether, in the face of persisting scientific uncertainty, the risk is acceptable and worth running. A variety of different factors will be taken into consideration and weighed and balanced throughout the risk management process. These include the importance of enhanced public health and environmental protection, as postulated by the preventive philosophy underlying the precautionary principle; the intended level of protection, as pursued in the specific regulatory field; the extent and pervasiveness of any potential adverse effects;²⁰ public perception of risk;²¹ an evaluation of the relevant risk management options, including their availability, efficacy and impact;²² the costs and benefits associated with the relevant risk;²³ the underlying socio-economic distributional stakes;²⁴ and any available alternatives to the potentially hazardous product or process, in accordance with the substitution principle.²⁵

On these grounds the results of the risk assessment phase, the margins of scientific uncertainty and the threshold of acceptable risk are *iteratively* interpreted in the light of the intended level of health and environmental protection and of the OLFs at stake.²⁶ Risk management is understood as an inherently value-laden political process, encompassing a range of entangled considerations; the notion of acceptable risk thus unavoidably results from the interaction of cognitive – technical-scientific – assessments and normative – political, socio-economic and ethical – evaluations.²⁷

If this is the legal and policy-making background, there is more to the socially acceptable risk soul of EU risk regulation. In highly controversial cases, where public health and environmental protection stakes are significant and public opinion is in favour of precautionary regulatory standards, evidence-based approaches are liable to undermine the political component of risk governance, dismantling the very democratic legitimacy of EU risk regulation. In turn, this has a range of far-reaching implications.

First of all citizens, whose fights for precautionary standards of protection are frustrated by a narrow adherence to ‘sound’ science, feel increasingly disempowered and disenfranchised. Secondly, a link is automatically established between a narrow evidence-based approach, and pro-market policies.

In the face of persisting scientific uncertainty, ‘sound’ science is liable to affect environmental protection and allocate burdens to consumers, shifting the costs of precautionary risk regulation away

¹⁹ For this distinction, see European Commission, Communication from the Commission on the Precautionary Principle (n 8) at 12, section 5. The two parts of the decision-making process are usually – albeit artificially – distinguished and defined in terms of a ‘precautionary’ (whether to act) and a ‘proportionality’ (how to act) limb.

²⁰ See European Commission, Communication from the Commission on the Precautionary Principle (n 8) at 19 (section 6.3.4.): the precautionary principle embodies a general presumption that the lack of scientific evidence shall not be used as a justification for regulators not to take action, as ‘*a society may be willing to pay a higher cost to protect an interest, such as the environment or health, to which it attaches priority*’.

²¹ European Commission, Communication from the Commission on the Precautionary Principle (n 8) at 15, section 5.2.1.

²² *Ibid.* at 19, section 6.3.4.

²³ Including Impact Assessment (‘IA’) – which may be defined as an EU – nuanced – version of US Cost-Benefit Analysis. For more details, see Alberto Alemanno, ‘Courts and Regulatory Impact Assessment’, in Claire Dunlop and Claudio Radaelli (eds.) *Handbook of Regulatory Impact Assessment* (Edward Elgar 2016), 127.

²⁴ Namely, the specific distribution of the *costs* and *benefits* ensuing from risk regulation across different constituencies – for instance, consumers, market actors or farmers.

²⁵ On the substitution principle, see R. Lofstedt, ‘Risk Versus Hazard. Regulating in the 21st Century’ (2011) 2 *European Journal of Risk Regulation* 149, at 161 ff.

²⁶ G.C. Leonelli, *The Transnational Law and Governance of GMOs* (n 1) and G.C. Leonelli, ‘GMO Risks, Food Security, Climate Change and the Entrenchment of Neo-Liberal Legal Narratives’ (n 1). Elizabeth Fisher, ‘Framing Risk Regulation: A Critical Reflection’ (n 1) has rightfully emphasised the difference between a ‘linear’ and a ‘dialectic-iterative’ approach to risk governance. If the former postulates the compartmentalisation and chronological succession of the risk assessment and risk management phases, the latter relies on a blurred continuum.

²⁷ In this perspective see also Christian Joerges, ‘Law, Science and the Management of Risks to Health at the National, European and International Level – Stories on Baby Dummies, Mad Cows and Hormones in Beef’ (2001) 7 *Columbia Journal of European Law* 1, at 3, arguing that ‘*law cannot resolve the cognitive dimension of risks [and] science cannot provide answers to the normative dimension*’. The – implicit – corollary of the socially acceptable risk approach is that the ultimate authority for setting the threshold of acceptable risk shall rest with political risk managers.

from market actors.²⁸ Most uncertain risks materialise throughout production and trade processes, so that evidence-based risk regulation obviously benefits market stakeholders. Indeed, it is not a case that the Commission Communication on the Precautionary Principle calls upon the political risk manager to strike a fair balance between precautionary public health and environmental protection, and the regulatory burdens placed on market actors.²⁹ For this reason, when in highly controversial cases EU risk managers disregard both scientific uncertainty and vocal public opinion, a straight forward association is made between ‘sound’ science, on the one hand, and corporate power, on the other.

How does this overall analysis connect to the glyphosate case? This article argues that the glyphosate saga epitomises a patent failure by the EU institutions to strike a fair balance between scientific evidence and precautionary health and environmental protection, science and public perception of risk, technical expertise and democratic legitimacy. It thus exemplifies a further shift towards evidence-based risk regulation, and an utter disregard of what EU-wide public opinion clearly held to be the *threshold of acceptable risk* and the *intended level of protection*.

In February 2017, a European Citizens’ Initiative (hereafter, ‘ECI’) was launched with the aim of requesting the Commission to ‘*Ban Glyphosate and Protect People and the Environment from Toxic Pesticides*’.³⁰ Pursuant to Article 11(4) TEU,³¹ at least one million EU citizens from a significant number of EU Member States may request the Commission, within the scope and framework of its powers, to submit a legislative proposal to the Member States ‘*on matters where citizens consider that a legal act of the Union is required for the purpose of implementing the Treaties*’. The ‘*Ban Glyphosate*’ ECI put forward three requests. For the purposes of this article, the first and third requests are most relevant;³² the campaigners respectively asked the Commission ‘*to ban glyphosate-based herbicides, exposure to which has been linked to cancer in humans and has led to ecosystems degradation*’, and ‘*to set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future*’.³³

As the next sections document the Commission, in its answer to the ECI campaigners, concluded that there are currently neither scientific nor legal grounds to submit a proposal to ban the use of glyphosate.³⁴ Further than that, it held that any specific restrictions, conditions or risk management measures should be adopted by the Member States, pending the authorisation process for glyphosate-based plant protection products;³⁵ in other words, the Commission refused to unequivocally commit to enact any EU-wide mandatory reduction targets for glyphosate-based herbicides.

Nonetheless, was it appropriate on the Commission’s part to argue that there are currently neither scientific nor legal grounds to ban or phase out glyphosate? And was its political choice to elude the ECI’s request for EU-wide mandatory targets at all suitable? The following sections analyse the main events in the glyphosate saga, together with the applicable regulatory framework, through the prism of

²⁸ See G.C. Leonelli, ‘GMO Risks, Food Security, Climate Change and the Entrenchment of Neo-Liberal Legal Narratives’ (n 1). Precautionary risk regulation, on the other hand, is liable to shift a range of economic costs and regulatory burdens onto market actors – which may, for instance, be called upon to develop new and less hazardous products or processes to meet precautionary standards of health and environmental protection.

²⁹ European Commission, Communication from the Commission on the Precautionary Principle (n 8) at 2.

³⁰ For more information see the European Citizens’ Initiative website, <<https://stopglyphosate.org/>> (last accessed 20/03/2018).

³¹ Consolidated Version of the Treaty on European Union [2012] OJ C326, Article 11(4), and in accordance with the procedural requirements of Regulation (EU) No. 211/2011 of the European Parliament and of the Council of 16 February 2011 on the European Citizens’ Initiative [2011] OJ L65/1.

³² Any analysis of the ECI’s second request ‘*to ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry*’ would go beyond the scope of this article.

³³ See supra (n 30).

³⁴ European Commission, ‘Communication from the Commission on the European Citizens’ Initiative “Ban Glyphosate and Protect the People and the Environment From Toxic Pesticides”’, C(2017) 8414 final, at 9 and 14.

³⁵ Ibid., at 8 and 9.

a socially acceptable risk approach. The conclusion is that the Commission had *scientific*³⁶ and *legal* grounds,³⁷ as well as compelling *political* reasons,³⁸ to accept the requests put forward by the ECI campaign.

2. The PPP Regulation and glyphosate's risk assessment.

To begin with, it is worth remarking that glyphosate is an active substance,³⁹ rather than a plant protection product.⁴⁰ In other words, it is a constituent substance and component of a range of plant protection products, commonly known as 'pesticides'. Glyphosate has herbicide features, and is thus used as an active substance in herbicide products – most famously, Monsanto's ubiquitous 'Roundup',⁴¹ Dow AgroSciences's 'Accord',⁴² and Syngenta's 'Touchdown'.⁴³ Indeed, glyphosate is the most used herbicide active substance in the EU and worldwide.⁴⁴

The legal base for its controversial renewal of approval is to be found in Regulation (EC) No. 1107/2009,⁴⁵ concerning the placing of plant protection products on the market (hereafter, 'PPP Regulation'). Active substances are approved at EU level, whereas it is the responsibility of the single Member States to authorise the placing of any specific plant protection products on their national market.⁴⁶ The procedure for EU-wide approval or renewal of approval of active substances is laid out in Chapter II, Section 1 of the PPP Regulation.⁴⁷

Pursuant to Article 4(1) of the PPP Regulation⁴⁸ an active substance shall be approved if, in the light of current scientific and technical knowledge, it may be expected that the plant protection products containing it will meet the requirements of Article 4(2) and 4(3). On the one hand, according to Article 4(2), the residues of the relevant plant protection products shall not have any harmful effects on human or animal health or any unacceptable effects on the environment upon '*an application consistent with good plant protection practice and having regard to realistic conditions of use*'.⁴⁹ On

³⁶ See *infra*, the analysis in section 3.

³⁷ See *infra*, the analysis in section 5.

³⁸ See *infra*, the analysis in sections 6. and 7.

³⁹ See Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 Concerning the Placing of Plant Protection Products on the Market and Repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L309/1, Articles 1(1), 1(2) and 2(2).

⁴⁰ *Ibid.*, see Articles 1(1), 1(2) and 2(2).

⁴¹ See <<https://monsanto.com/products/>> (last accessed 20/01/2018). It is worth noting that Bayer AG and Monsanto Co. have merged into one corporation; on the 7th of June 2018 Bayer AG reported it had completed its purchase of Monsanto. For more information, see <<https://www.nytimes.com/aponline/2018/06/07/world/europe/ap-eu-germany-bayer-monsanto.html>> (last accessed 15/07/2018).

⁴² See <<http://www.dowagro.com/en-us/vm/products/accord-xrt-ii>> (last accessed 20/01/2018).

⁴³ See <<http://www.syngenta-us.com/labels/touchdown-total>> (last accessed 20/01/2018).

⁴⁴ For a statistic on the worldwide increase in use of glyphosate in the years 1994 to 2014, see <<https://www.statista.com/statistics/567250/glyphosate-use-worldwide/>> (last accessed 20/01/2018). In the agricultural sector, glyphosate is used to combat noxious weeds and to facilitate better growth of crops, as a pre-harvesting treatment. Besides these main uses, it is also deployed to control the growth of plants which may cause other problems – for instance, on railway tracks – or by amateur users, for non-professional purposes. See the dedicated page on the European Commission's website: <https://ec.europa.eu/food/plant/pesticides/glyphosate_en> (last accessed 20/01/2018). It is also worth remarking that a significant number of GM crop varieties are genetically engineered to be herbicide-resistant and, specifically, 'Roundup-ready'. For more information, see <<https://monsanto.com/products/seeds/>> (last accessed 20/01/2018).

⁴⁵ Article 20(1) of the PPP Regulation (n 39).

⁴⁶ Through an administrative act of the competent national authority: see Chapter 3 ('Plant Protection Products') of the PPP Regulation (n 39).

⁴⁷ See Sub-sections 1 to 4 of the PPP Regulation (n 39).

⁴⁸ Article 4(1) of the PPP Regulation (n 39).

⁴⁹ Article 4(2) of the PPP Regulation (n 39).

the other hand, as provided for by Article 4(3), the relevant plant protection product⁵⁰ shall be sufficiently effective, shall not have any immediate or delayed harmful effects on human or animal health, shall not cause unnecessary pain and suffering to vertebrates and shall not have any unacceptable effects on plants, plant products and the environment, having particular regard to its distribution and potential contamination of the environment, its impact on non-target species and its effects on biodiversity and the ecosystem.⁵¹ Additionally, the technical assessment shall establish that the relevant active substance satisfies the criteria enshrined in Annex II. to the PPP Regulation.⁵² Thus, an active substance can only be approved if it is not or must not be classified as carcinogenic, mutagen or toxic for reproduction,⁵³ unless the exposure of humans and residue levels are negligible; and if it is not considered a persistent organic pollutant (POP), a persistent bio-accumulative toxic (PBT) or a very persistent and very bio-accumulative (vPvB) substance.

The origins of the glyphosate saga date back to 2012.⁵⁴ In that year the application for the renewal of approval of this active substance was allocated to the BfR (German Federal Institute of Risk Assessment). Pursuant to the PPP Regulation, the competent scientific authority in the so-called ‘Rapporteur’ Member State shall assess the applicant’s dossier⁵⁵ and submit a Draft Assessment Report to the Commission and the EFSA, evaluating whether the active substance is expected to meet the approval criteria.⁵⁶ Upon circulating the Draft Assessment Report to the other Member States and the applicant, and after making it available to the public for the submission of written comments, the EFSA shall adopt its conclusions, stating whether the active substance is expected to meet the criteria enshrined in the PPP Regulation and, if appropriate, addressing any risk mitigation options set out in the Draft Assessment Report.⁵⁷ The BfR’s Draft Assessment Report concluded that, in the light of current technical-scientific knowledge, glyphosate fully complies with the requirements enshrined in the PPP Regulation.⁵⁸ At the end of October 2015 the EFSA adopted its own opinion on glyphosate, concurring with the conclusions of the BfR.⁵⁹

Nonetheless, and just a few months earlier, the World Health Organisation’s (‘WHO’) International Agency for Research on Cancer (hereafter, ‘IARC’) had published its findings that glyphosate may in fact be linked to the development of cancer in humans;⁶⁰ in the light of these results, the IARC decided to classify glyphosate as a Group (2a), ‘*probably carcinogenic to humans*’ substance. Although the Joint Food and Agriculture Organisation (‘FAO’) and WHO Meeting on Pesticide Residues (‘JMPR’) later concluded that there is no direct scientific evidence of glyphosate’s

⁵⁰ Article 4(3): again, upon ‘*an application consistent with good plant protection practice and having regard to realistic conditions of use*’.

⁵¹ As further specified by Article 4(5), the criteria of paragraphs (1), (2) and (3) ‘*shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance*’.

⁵² See specifically points 3.6.2. to 3.6.4. and 3.7. of Annex II., as well as the entire text of points 2. and 3. of Annex II.

⁵³ In accordance with Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on Classification, Labelling and Packaging of Substances and Mixtures, Amending and Repealing Directives 67/548/EEC and 1999/45/EC, and Amending Regulation (EC) 1907/2006 [2008] OJ L353/1 (hereafter, ‘CLP Regulation’).

⁵⁴ Glyphosate has been approved for use since 1 July 2002, pursuant to the provisions of Council Directive 91/414/EEC of 15 July 1991 Concerning the Placing of Plant Protection Products on the Market [1991] OJ L230.

⁵⁵ See Articles 14(1) and 15(1) and (2) of the PPP Regulation (n 39). See also Articles 9(1), (2) and (3).

⁵⁶ See Article 11(1). Article 11(2) reads that ‘*the Rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge*’. The competent national authority must submit its Report within 12 months since the notification of admissibility of the application.

⁵⁷ Article 12(2), supra (n 39).

⁵⁸ For more information concerning the public consultation on the BfR’s draft assessment report, see <<http://dar.efsa.europa.eu/dar-web/provision>> (last accessed 20/03/2018).

⁵⁹ See the conclusions on the peer review of the pesticide risk assessment for the active substance glyphosate on the EFSA Journal 2015;13(11):4302, available at <<https://www.efsa.europa.eu/it/efsajournal/pub/4302>> (last accessed 20/03/2018). For further information, see also <<http://www.efsa.europa.eu/en/corporate/pub/glyphosate151112>> (last accessed 20/03/2018).

⁶⁰ See the IARC’s study published on the 20th of March 2015, available at <<http://monographs.iarc.fr/ENG/Monographs/vol112/mono112.pdf>> (last accessed 20/03/2018).

carcinogenicity,⁶¹ the conclusions drawn by the IARC are structurally different from the ones reached by the BfR and EFSA. On these grounds, and quite clearly, conflicting bodies of scientific opinion coexist on the assessment of glyphosate's carcinogenic potential.

In the wake of the remarkable impact of the IARC's findings on EU public opinion, and in accordance with the specific provisions on carcinogenic active substances set out in the PPP Regulation,⁶² the Commission rightfully decided to ask the European Chemicals Agency (hereafter, 'ECHA') to assess the potential carcinogenicity of glyphosate, as provided for within the framework of the CLP Regulation.⁶³ On the 15th of March 2017, the ECHA released its opinion.⁶⁴ The ECHA's Risk Assessment Committee concluded by consensus that there is currently no technical-scientific evidence to link glyphosate to the development of cancer in humans; specifically, the Committee decided that glyphosate should not be classified as a carcinogenic, mutagen or toxic for reproduction substance.⁶⁵ On the 7th of September 2017 the EFSA published a further opinion on glyphosate, reaching the conclusion that this active substance does not have any endocrine disrupting properties,⁶⁶ the latter opinion was – appropriately – requested in the face of persisting scientific uncertainty on glyphosate's toxicity for reproduction.

How did the Commission interpret the results of the risk assessment phase, and how did this element reflect on the Commission's narrative on glyphosate?

3. The scientific grounds: 'sound' science... anywhere to be seen?

In its response to the ECI's request '*to ban glyphosate-based herbicides, exposure to which has been linked to cancer in humans and has led to ecosystems degradation*',⁶⁷ the Commission straightforwardly maintained that, as a matter of risk assessment, there are no scientific grounds to justify a ban on glyphosate.⁶⁸

Starting from the environmental risks posed by glyphosate, the Commission emphasised that a full risk assessment had been conducted to take account of the levels of glyphosate in soil, water and air, as well as of its impact on non-target organisms. The Commission concluded that no evidence had emerged to indicate ecosystem degradation, when glyphosate '*is used in accordance with the conditions of authorisation and in line with good agricultural practices*'.⁶⁹ This answer is a clear example of what is technically known as 'boundary work'.⁷⁰ namely, the analysis of a risk in a technical-scientific 'vacuum', whereby the mitigation of complex risks is relegated to the phase of risk management and the availability, efficacy and impact of risk management measures⁷¹ is disregarded. The consequence is that the risks which materialise in practice turn out to be unavoidably neglected. Section 6. will analyse this point in greater detail, explaining how the ECI campaigners

⁶¹ See the Summary Report of the JMPR meeting held on 9-13 May 2016, available at <<http://www.who.int/foodsafety/jmprsummary2016.pdf>> (last accessed 20/03/2018).

⁶² See supra section 1., and specifically the provisions of Articles 4(7) and 14(2) of the PPP Regulation (n 39).

⁶³ Supra (n 53).

⁶⁴ See <<https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa>> (last accessed 20/03/2018).

⁶⁵ For the full text of the ECHA's Risk Assessment Committee ('RAC') Opinion Proposing Harmonised Classification and Labelling at EU Level of Glyphosate (ISO); N-(phosphonomethyl)glycine, see <<https://echa.europa.eu/documents/10162/2d3a87cc-5ca1-31d6-8967-9f124f1ab7ae>> (last accessed 20/03/2018).

⁶⁶ See the conclusions on the peer review of the pesticide risk assessment on the potential endocrine disrupting properties of glyphosate on the EFSA Journal 2017;15(9):4979, available at <<https://www.efsa.europa.eu/en/efsajournal/pub/4979>> (last accessed 20/03/2018).

⁶⁷ European Commission, 'Communication from the Commission on the European Citizens' Initiative [...]' (n 34) at 6 to 9, section 3.1.

⁶⁸ Ibid., at 9 and 14.

⁶⁹ Ibid.

⁷⁰ See infra, the analysis in section 6.

⁷¹ European Commission, Communication from the Commission on the Precautionary Principle (n 8) at 19, section 6.3.4.

claim that the faulty implementation of risk management measures at Member State level affects the environmental risks which glyphosate poses in practice; this factor lies at the core of the ECI's request for EU-wide mandatory targets for the reduction of glyphosate-based herbicides.

Turning to public health risks, the Commission claimed that the available scientific evidence does not support the conclusion that glyphosate is carcinogenic; for this reason, it maintained that there are no scientific grounds to propose a precautionary ban on glyphosate. However, is this position an unquestionable one? Or is the Commission's argument the mere reflection of an evidence-based perspective? A closer look at the Commission Communication on the '*Ban Glyphosate*' ECI suggests that the latter is the case.

The Commission started off by underlining that the IARC is the only scientific authority which has so far reached the conclusion that glyphosate is a potentially carcinogenic substance. Further than that, the Commission maintained that the only reason why the IARC drew such conclusion lies in the latter organisation's choice to '*look at both glyphosate – the active substance – and glyphosate-based plant protection products, [whereas] the EU assessment considered only glyphosate, as Member States are responsible for evaluating each plant protection product*';⁷² and to only consider '*published studies, whereas the EU assessment also considered the studies submitted by applicants as part of their dossiers*'.⁷³ In this light, the Commission contended, the assessment conducted by the EU authorities was more comprehensive than the one undertaken by the IARC.⁷⁴

The Commission's subtle suggestion that the IARC's minority view is not reliable exemplifies a sound science approach to technical risk assessment. By arguing that the studies conducted at EU level are more comprehensive than the findings of the IARC's monograph, the Commission Communication indirectly meant to undermine the scientific validity of the IARC's minority opinion, as if one could clearly discern between 'sound', 'best' or even 'fake' science. This strikes a stark contrast with socially acceptable risk approaches, which rely on a nuanced vision of scientific uncertainty and scientific pluralism.

The way risk is framed and shaped, throughout technical risk assessment, affects all relevant findings and results. A scientist's choice of one model for risk assessment, rather than another – for instance the use of a linear, rather than a threshold model for a dose-response function – is critical to the quantification of a risk and the identification of its acceptable level;⁷⁵ in this perspective, technical risk assessment is neither 'neutral' and 'objective', nor 'universal'. Indeed, the case of glyphosate provides a very good example. The IARC's choice to assess the carcinogenic potential of glyphosate as an active substance and as contained in glyphosate-based PPPs resulted in the classification of glyphosate as '*probably carcinogenic for humans*'; on the other hand, the EU authorities' limited focus on the assessment of glyphosate as an active substance led to the opposite conclusion.

Despite the Commission's hint that the EU assessments were based on 'better' science, it is legitimate to suggest that the IARC's choice to assess both glyphosate and glyphosate-based herbicides, together with the latter organisation's classification of glyphosate as '*probably carcinogenic to humans*', reflect a genuinely *prudential* approach to the uncertain risks posed by the use of this active substance. Indeed, the complex case of neo-nicotinoids – also regulated under the PPP Regulation – shows that serious risks to public health and the environment may only be scientifically proved after years of exposure to hazardous substances.⁷⁶

⁷² European Commission, 'Communication from the Commission on the European Citizens' Initiative [...] (n 34) at 8.

⁷³ Ibid.

⁷⁴ Ibid.

⁷⁵ For this comment and acknowledgment, see Giandomenico Majone, 'Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform' (2010) 1 European Journal of Risk Regulation 5, at 10.

⁷⁶ For more information on the case of neonicotinoids, see https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en (last accessed 20/03/2018). For a very different perspective on the regulation of neonicotinoids, see Alberto Alemanno 'The Science, Law

Against this backdrop, and looking at the case through the prism of a socially acceptable risk approach, it is fair to argue that the margins of scientific uncertainty and the relevant values at stake in the case of glyphosate may have triggered a more thorough reflection, on the part of the Commission, about the entity of the uncertain risks posed by the use of this active substance.

As section 1. has shown, a prudential risk assessment⁷⁷ is perfectly compatible – if not inherent to – the institutional architecture and overarching rationale of EU risk regulation. The precondition for the application of a precautionary approach to risk management is the acknowledgment of scientific uncertainty over a potential risk. In the words of the relevant Commission Communication, *‘the precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inconclusive nature of the scientific data’*.⁷⁸ Further than that, scientific uncertainty is defined as a situation where scientific information is insufficient, inconclusive or uncertain, and where the potential risk may be inconsistent with the chosen level of protection of the values at stake.⁷⁹

Although the technical-scientific assessments conducted by the BfR, EFSA and ECHA did not directly and straightforwardly identify any relevant scientific uncertainties, the Commission could have still legitimately relied on their divergence with the IARC’s opinion. Thus, the margins of scientific uncertainty highlighted by the IARC could have certainly prompted the Commission to ask the WHO to conduct a review of the diverging IARC’s and JMPR’s assessments, as one Member State explicitly suggested during the Comitology process.⁸⁰ Indeed, the level of scientific controversy surrounding the glyphosate case is still very high: in June 2017, for instance, the state of California decided to add glyphosate to its list of carcinogenic chemicals, with Monsanto’s ‘Roundup’ herbicide now being labelled throughout California as ‘cancer causing’.⁸¹

It is also worth getting back to the point that, under EU risk regulation, technical risk assessment is acknowledged to be a necessary and yet not sufficient condition⁸² for regulating uncertain risks, and a necessary but not sufficient component of a more encompassing decision-making process. The results of technical risk assessment are meant to inform the scientific knowledge of risk managers and to underpin, corroborate and substantiate the following phase of risk management; however, and in the face of scientific uncertainty, the precautionary principle mandates that political decision-makers shall ensure enhanced standards of health and environmental protection.⁸³ For this reason, although it could

and Politics of Neonicotinoids and Bees. A New Test Case for the Precautionary Principle (2013) 4 European Journal of Risk Regulation 191.

⁷⁷ See supra (n 11).

⁷⁸ See European Commission, Communication from the Commission on the Precautionary Principle (n 8) at 13 (section 5.1.).

⁷⁹ See the analysis in section 1. (n 8). It is worth noting that at 16 (section 6.2.) the Communication clarifies that *‘the absence of scientific proof of the existence of a cause-effect relationship, a quantifiable dose-response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure should not be used to justify inaction’*, and credible and reputable minority opinions may be legitimately relied on.

⁸⁰ See the Summary Report of the Standing Committee on Plants, Animals, Food and Feed, Section *Phytopharmaceuticals – Plant Protection Products – Legislation*, 25 October 2017, [sante.ddg2.g.5\(2017\)](https://ec.europa.eu/food/rapid-response/summary-report-standing-committee-plants-animals-food-feed-section-phytopharmaceuticals-plant-protection-products-legislation). One Member State specifically proposed that the Commission should ask the WHO to conduct a review of the diverging risk assessments released by the IARC and JMPR. The Member State also proposed that, pending the review, the approval of glyphosate should be merely *extended* for a 3 year period, in accordance with Article 17: however, the Commission straight forwardly rejected this option, claiming that Article 17 of the PPP Regulation would not provide the appropriate legal basis in the specific circumstances.

⁸¹ For an analysis of the June 2017 decision by the state of California to add glyphosate to the list of carcinogenic chemicals and have Monsanto’s Roundup herbicide labelled as ‘cancer causing’, see <<https://www.reuters.com/article/us-usa-glyphosate-california/california-to-list-herbicide-as-cancer-causing-monsanto-vows-fight-idUSKBN19H2K1>> (last accessed 20/03/2018). It is also worth noting that glyphosate is straightforwardly banned – on a precautionary basis – in five countries: these are respectively Argentina, Sri Lanka, Malta, Flanders and the Netherlands.

⁸² Supra (n 14).

⁸³ This still holds true, notwithstanding the gradual evidence-based ‘turn’ of EU risk regulation in the last few years. For the same view see Maria Lee, *EU Regulation of GMOs* (n 2); Maria Lee, ‘Beyond Safety? The Broadening Scope of Risk Regulation’ (n 1); Maria Weimer, ‘The Origins of Risk as an Idea and the Future of Risk Regulation’ (2017) 8 European Journal of Risk Regulation 10.

have – arguably – been difficult for the Commission to enact a straight forward and total ban on glyphosate, there were certainly sufficient scientific grounds for the latter institution to refer to the IARC’s prudential risk assessment and propose a *gradual phasing out* of glyphosate, as recommended by the European Parliament.⁸⁴ This point will be further explored throughout the following sections.

In the light of these considerations, it is fair to conclude that the Commission did not give any substantial weight to the margins of scientific uncertainty surrounding the glyphosate case. The narrative underlying the Commission’s response to the ECI campaigners is permeated by a sound science perspective on the results of EU risk assessment; public perception of the uncertain risks posed by glyphosate and public opinion backlash against the use of this substance in the EU are deemed to be simply irrational.

The Commission’s position that there were no scientific grounds to ban – or phase out – glyphosate is therefore highly questionable, if the case is analysed through the lens of a socially acceptable risk approach. The denigrators of the precautionary principle have defined precautionary approaches as an *‘infantile disease’*⁸⁵ of risk regulation, claiming that *‘regulatory priorities should be directed toward the most important risks – which are not necessarily those that are politically most salient’*.⁸⁶ A similar argument has been formulated by reference to behavioural economics, and developed on cognitive grounds; from this perspective, all precautionary approaches rely on cognitive mistakes and failures which are typical of the individual dimension.⁸⁷ Nonetheless, both ‘sound’ science and precautionary approaches are in fact exposed to biases and inconsistencies.

Any narrow adherence to the results of a ‘sound’ technical risk assessment carries the risk that the applicants, or the industry whose profit-making prospects are at stake, may manipulate scientific data and distort scientific evidence by commissioning ad hoc studies.⁸⁸ In other words, ‘sound’ science

⁸⁴ European Parliament Resolution of 24 October 2017 on the Draft Commission Implementing Regulation Renewing the Approval of the Active Substance Glyphosate in Accordance with Regulation (EC) No. 1107/2009 of the European Parliament and of the Council Concerning the Placing of Plant Protection Products on the Market, and Amending the Annex to Implementing Regulation (EU) No. 540/2011 (D053565-01 – 2017/2904RSP). See *infra*, the analysis in sections 4. and 5. Reliance on technical assessments performed by *international* – rather than *EU* – agencies could be somehow problematic for the Commission; however, this choice could be justified by reference to the precautionary principle, in cases when conflicting bodies of scientific opinion coexist. Moreover, referring to *prudential* risk assessments undertaken by international agencies can trigger a virtuous circle in the EU, fostering inter-institutional cooperation and coordination with a view to ensuring the enactment of precautionary regulatory standards. In the case of dioxins, for instance, the Scientific Committee on Food (predecessor of the EFSA) revised its November 2000 ‘Opinion on the Risk Assessment of Dioxins and Dioxin-Like PCBs in Food’ in May 2001, after the World Health Organisation (WHO) re-evaluated its tolerable daily intake (TDI) for dioxins. This resulted in more stringent EU standards and a lower EU tolerable daily intake than would have otherwise been the case. At that point Council Regulation (EC) No 2375/2001 of 29 November 2001 Amending Commission Regulation (EC) No 466/2001 Setting Maximum Levels for Certain Contaminants in Foodstuff [2001] OJ L32 was enacted. For more information on the regulation of dioxins, see <https://ec.europa.eu/food/safety/chemical_safety/contaminants/catalogue/dioxins_en> (last accessed 15/07/2018).

⁸⁵ Giandomenico Majone (n 75) at 16.

⁸⁶ *Ibid.*, at 14.

⁸⁷ These are argued to encompass loss aversion; the myth of a benevolent nature; the availability heuristics, which outlines a cognitive distinction between lay people and experts; probability neglect; and system neglect, including the potential misallocation of resources which could be more efficiently destined to reduce other risks, as well as trade-off neglect. See Cass Sunstein, ‘The Laws of Fear’ (2001), The University of Chicago Law and Economics Working Paper no. 128/2001. On risk-risk trade-off see already John Graham and Johnathan Wiener, *Risk v. Risk. Trade-Offs in Protecting Health and the Environment* (Harvard University Press 1997). For a powerful criticism of Sunstein, reconnecting Sunstein’s theorisation to a broader *‘fear of democracy’*, see Dan Kahan, Paul Slovic et al., ‘Fear of Democracy: A Cultural Evaluation of Sunstein On Risk’ (2006) 119 *Harvard Law Review* 1071.

⁸⁸ The allocation of the burden to prove the safety of a product or process to the applicant firm or corporation – despite shifting all costs to market actors – unavoidably exposes the risk assessor to the potential bias of any scientific research commissioned by the applicant. This point lies at the core of the second ECI’s request: see the brief mention *supra* in section 1. (n 32). See also point 8. of the European Parliament Resolution of 24 October 2017, *supra* (n 84), whereby the European Parliament called on the Commission and the Member States *‘to ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published peer-reviewed and independent studies commissioned by competent public authorities; considers that the REFIT procedure [...] can potentially be used for that purpose; considers, furthermore, that EFSA and ECHA should be granted sufficient resources in order to increase their capacity, to enable the commissioning of*

approaches are systemically exposed to the risk of market-driven scientific bias. Precaution may be the expression of the *'laws of fear'*⁸⁹ as much as scientific 'soundness' may be directly exploited by market actors; the procedural consistency of both models is thus largely falsifiable. This point is in fact perfectly exemplified by the glyphosate saga. Whilst any in-depth analysis of the allegations against Monsanto,⁹⁰ the BfR⁹¹ or the EFSA⁹² would go beyond the scope of this article, it is still worth noting that both the scientific evidence provided by Monsanto and the risk assessments conducted by these authorities have been fiercely and repeatedly challenged.⁹³ In the face of scientific uncertainty and complexity, 'sound' science is nowhere to be seen in the glyphosate case.

4. Risk management: Comitology and the position of the European Parliament.

Upon risk assessment, the ball is in the Commission's court: the latter must adopt a Regulation providing that the approval of the relevant active substance is renewed, subject to any appropriate conditions and restrictions, or is not renewed.⁹⁴ The Commission must take into consideration, along with the Draft Assessment Report and the EFSA's conclusions,⁹⁵ any *'other factors legitimate to the matter under consideration and the precautionary principle, where the conditions laid out in Article 7(1) of Regulation (EC) No. 178/2002'*⁹⁶ ['GFL Regulation'] *are relevant*⁹⁷. Article 7(1) of the GFL Regulation maintains that when scientific uncertainty persists, following a technical risk assessment, as to the possibility of any harmful effects on health (or the environment),⁹⁸ provisional risk management measures may be adopted with the aim of safeguarding the high level of protection chosen in the Union.⁹⁹

In accordance with the Comitology rules on the examination procedure,¹⁰⁰ the Commission must then submit a draft Implementing Regulation to the Standing Committee on Plants, Animals, Food and

independent scientific studies and to further ensure that the highest scientific standards are upheld and the health and safety of EU citizens protected'.

⁸⁹ Supra (n 15).

⁹⁰ For an overview of the 'Monsanto Papers' issue and for a detailed account of the lawsuits pending in the San Francisco US District Court against Monsanto, see <<https://usrtk.org/pesticides/mdl-monsanto-glyphosate-cancer-case-key-documents-analysis/>> (last accessed 20/03/2018). Approximately 3,500 plaintiffs have sued Monsanto for neglecting to publicise the potential health risks flowing from exposure to 'Roundup' and, specifically, the latter's potential carcinogenicity (the plaintiffs claim that a causal link exists between exposure to 'Roundup' and development of Non-Hodgkin Lymphoma).

⁹¹ For an overview of the accusations of plagiarism raised against the BfR and the latter's response see <http://www.bfr.bund.de/en/press_information/2017/34/glyphosate_assessment_bfr_rejects_plagiarism_accusations-201890.html> (last accessed 20/03/2018).

⁹² For an overview of the allegations against the EFSA and the latter's response, see <<https://www.efsa.europa.eu/en/topics/topic/glyphosate>> (last accessed 20/03/2018).

⁹³ For the Commission's response to the plurality of controversies hitting the headlines of newspapers across the EU and US, see European Commission, 'Communication from the Commission on the European Citizens' Initiative [...] (n 34) at 8: *'Concerns and allegations publicly raised about the quality and robustness of the EU assessment were checked on each occasion at the request of the Commission by ECHA, EFSA and the German Federal Institute for Risk Assessment (BfR), in charge of the assessment of glyphosate in the Rapporteur Member State. In all cases, these bodies concluded that the concerns and allegations were unfounded'.*

⁹⁴ Articles 19 and 20, PPP Regulation (n 39).

⁹⁵ Article 13(1), PPP Regulation (n 39).

⁹⁶ See supra (n 6).

⁹⁷ Article 13(2), PPP Regulation (n 39).

⁹⁸ Article 7(1) of the GFL Regulation (n 6) maintains that *'In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment'.*

⁹⁹ On the notion of 'intended level of protection', see supra section 1. (n 8).

¹⁰⁰ On the scope and application of the examination procedure in Comitology, see Regulation (EU) No. 182/2011 of the European Parliament and of the Council of 16 February 2011 Laying Down the Rules and General Principles Concerning Mechanisms for Control by Member States of the Commission's Exercise of Implementing Powers [2011] OJ L55/13, Articles 2(1) and (2).

Feed (hereafter, ‘PAFF Committee’), which shall vote by Qualified Majority Voting. If the Standing Committee delivers a positive opinion, the Commission shall adopt the draft Regulation.¹⁰¹ If the Standing Committee delivers a negative opinion, the Commission shall not adopt the draft act: however, if an implementing act is deemed to be necessary, it can either submit the same draft Regulation to the Appeal Committee, or submit an amended draft Regulation to the Standing Committee.¹⁰² Equally, if no Qualified Majority has formed in the Standing Committee either in favour or against the adoption of the draft Regulation, the Commission can either submit the same draft Regulation to the Appeal Committee, or submit an amended draft Regulation to the Standing Committee.¹⁰³ When the draft Regulation reaches the Appeal Committee, the latter shall also vote by Qualified Majority Voting.¹⁰⁴ If the opinion of the Appeal Committee is negative, the Commission is precluded from adopting the Regulation.¹⁰⁵ If the opinion is positive, the Commission shall adopt the draft regulation.¹⁰⁶ If no Qualified Majority has formed in the Appeal Committee, the Commission may adopt the draft Regulation;¹⁰⁷ in other words, and unlike under the Old Comitology rules,¹⁰⁸ the Commission does not find itself under an obligation to adopt the draft Regulation.

How did this complex procedure work out in the case of glyphosate’s renewal of approval? Did the Commission manage to build genuine consensus among Member State representatives in Comitology, and what role did the European Parliament play throughout the process? In March 2016 the Commission expressly proposed to renew the approval of glyphosate for 15 years: however, it failed to build a Qualified Majority in Comitology, and decided to cancel a planned vote.¹⁰⁹ Just a few weeks later, in April 2016, a Resolution of the European Parliament called for the enactment of further restrictions on the use of glyphosate,¹¹⁰ and proposed that the renewal of approval should not cover a period longer than 7 years. Notably, in this first Resolution, the European Parliament called on the Commission to submit a new draft Regulation to better address the sustainable use of herbicides containing glyphosate, ban any non-professional uses of glyphosate and ban any other use in (or close to) public parks, gardens and playgrounds.

In July 2017, after the release of the ECHA’s opinion on glyphosate’s carcinogenicity, the Commission submitted a new proposal for a 10 year renewal of approval of glyphosate – thus disregarding the European Parliament’s indication that glyphosate should not be reapproved for longer than 7 years. However, the Commission did incorporate part of the European Parliament’s recommendations: the Annexes to the proposed draft implementing Regulation¹¹¹ included a set of

¹⁰¹ Ibid., Article 5(2).

¹⁰² Ibid., Article 5(3).

¹⁰³ Ibid., Article 5(4) – this is what happens in the specific case of implementing acts to be adopted in the fields of public health and environmental protection.

¹⁰⁴ Ibid., Article 6(1).

¹⁰⁵ Article 6(3).

¹⁰⁶ Ibid.

¹⁰⁷ Ibid.

¹⁰⁸ That is, under Council Decision 1999/468/EC of 28 June 1999 Laying Down the Procedures for the Exercise of Implementing Powers Conferred on the Commission [1999] OJ L184.

¹⁰⁹ See the Summary Reports of all relevant PAFF Committee meetings, available at <https://ec.europa.eu/food/committees/paff_en> (last accessed 20/03/2018), and the overview on the dedicated European Commission’s webpage on glyphosate, <https://ec.europa.eu/food/plant/pesticides/glyphosate_en> (last accessed 20/03/2018). On the 19th of May 2016, again, the Commission failed to muster a Qualified Majority on a new proposal for a 9-year renewal of approval, and had to cancel a planned vote.

¹¹⁰ European Parliament Resolution of 13 April 2016 on the Draft Commission Implementing Regulation Renewing the Approval of the Active Substance Glyphosate in Accordance with Regulation (EC) No. 1107/2009 of the European Parliament and of the Council Concerning The Placing of Plant Protection Products on the Market and Amending the Annex to Implementing Regulation No. 540/2011 (D044281/01 – 2016/2624RSP). The Resolution also called on the Commission to re-evaluate its approval, in the light of the pending submission of a dossier concerning the harmonised classification of glyphosate under the CLP Regulation.

¹¹¹ The text of Annexes I. and II. can be found – unchanged – in the final Annexes to the Commission Implementing Regulation (EU) No. 2017/2324 of 12 December 2017, Renewing the Approval of the Active Substance Glyphosate in Accordance With Regulation (EC) No. 1107/2009 of the European Parliament and of the Council Concerning the Placing of

provisions and risk mitigation measures to be complied with by Member States, when approving any glyphosate-based herbicides on their national territory. Firstly, the Annexes provide for a ban on any glyphosate-based herbicides containing the POE-Tallowamine co-formulant. Moreover, they maintain that in their overall assessment for the approval of glyphosate-based herbicides Member States shall pay particular attention to the protection of groundwater, the protection of operators, the risk to territorial vertebrates and non-target territorial plants, and the compliance of any pre-harvest uses with good agricultural practices. For this purpose, in particular, the *'conditions of use shall include risk mitigation measures, where appropriate'*.¹¹²

On the 25th of October 2017 a crucial meeting of the PAFF Committee was held: the discussion focused on a set of allegations against the EFSA, the activities of the ECI campaign, and the European Parliament's – second – Resolution on Glyphosate of 24 October 2017.¹¹³ The latter Resolution¹¹⁴ prompted the Commission and the Member States not to approve any non-professional uses of glyphosate, any uses of glyphosate in (or close to) public parks, gardens or playgrounds, any agricultural uses of glyphosate where integrated pest management systems are sufficient for the necessary weed control, and any use of glyphosate for pre-harvest desiccation *after 15 December 2017*. Moreover, and most importantly, it called on the Commission to adopt any necessary measures to *phase out glyphosate* in the European Union *no later than 15 December 2022*, ensuring that *no use of glyphosate is authorised after that date*. In other words the European Parliament – with unprecedented clarity and firmness – exhorted the Commission to radically rethink its position on glyphosate, advocating a gradual but outright phasing out of this active substance and explicitly putting forward a request in this sense. The European Parliament's position thus complemented and strengthened the ECI campaign's request for a precautionary ban on glyphosate.

The opinions expressed by Member State representatives during the 25th of October meeting¹¹⁵ unequivocally showed that the Commission would not be able to muster a Qualified Majority of the PAFF Committee in favour of its draft Regulation.¹¹⁶ The Commission was thus indirectly forced to amend its draft Regulation again. Indeed, this meeting produced an important change: the draft implementing Regulation was amended to limit the renewal of approval of glyphosate to a period of 5 years.¹¹⁷ On the 9th of November 2017 this last draft proposal was submitted to the PAFF Committee, which voted on it. A Qualified Majority of votes was not reached in the PAFF Committee, and the vote did neither result in an opinion in favour of the renewal of approval, nor against it.¹¹⁸

Plant Protection Products on the Market, and Amending the Annex to Implementing Regulation (EU) No. 540/2011 [2017] OJ L333. The requirements enshrined in the Annexes reflect the text of the European Parliament Resolution of 13 April 2016, *supra* (n 110).

¹¹² Further than that, Annexes I. and II. also mention that *'Only uses as herbicide may be authorised'*; *'For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No. 1107/2009, the conclusion of the review report on glyphosate, and in particular Appendices I. and II. thereof, shall be taken into account'*; and *'Member States shall ensure equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the toxicological studies'*.

¹¹³ Summary Report of the Standing Committee on Plants, Animals, Food and Feed, Section *Phytopharmaceuticals – Plant Protection Products – Legislation*, 25 October 2017, *supra* (n 80).

¹¹⁴ European Parliament Resolution of 24 October 2017 on the Draft Commission Implementing Regulation, *supra* (n 84).

¹¹⁵ According to the Summary Report of the Standing Committee, *supra* (n 80), 16 Member States declared they would vote in favour, 9 declared that they would vote against, and 3 claimed they would abstain. It also appeared that the situation would not significantly change if the proposal provided for a 7 year or 3 year renewal of approval.

¹¹⁶ *Ibid.*

¹¹⁷ See the amendments to the Commission's draft Implementing Regulation, in the version available at https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_glyphosate_commission_proposal_revision3_20171109.pdf > (last accessed 20/03/2018).

¹¹⁸ Summary Report of the Standing Committee on Plants, Animals, Food and Feed, Section *Phytopharmaceuticals – Plant Protection Products – Legislation*, 9 November 2017, *sante.ddg2.g.5(2017)*, at 2. 14 Member States (representing 36.95% of the EU population) voted in favour, 9 Member States (representing 32.26% of the EU population) voted against, and 5 Member States (representing 30.79% of the EU population) abstained.

At this point, as already explained, the Commission could either amend its draft implementing Regulation again, submitting it to the PAFF Committee for a new vote, or submit the same version of the draft Regulation to the Appeal Committee. The Commission chose to pursue the latter strategy, disregarding the clear indication that *no EU-wide consensus* exists on the determination that the uncertain risks posed by the use of glyphosate are *socially acceptable*. On the 27th of November 2017 the Appeal Committee voted on the 5 year renewal of approval of glyphosate.¹¹⁹ After the last-minute swing of Germany, which decided to vote in favour, a Qualified Majority was reached and the vote resulted in a favourable opinion.¹²⁰ On the 12th of December 2017, just a few days before the expiry of the extension of approval,¹²¹ the Commission enacted Implementing Regulation (EU) No. 2324/2017, renewing the EU-wide approval of glyphosate as an active substance.¹²²

Despite its final achievement, as this section has briefly explained, the Commission has for almost two years faced the adamant resistance of the European Parliament and of a majority of national representatives in Comitology. How are we to interpret the Commission's approach, then, through the prism of a socially acceptable risk approach?

5. The legal grounds: the notion of 'acceptable risk' and the 'intended level' of health and environmental protection.

Upon establishing that there is currently no unequivocal scientific evidence of a link between exposure to glyphosate, on the one hand, and any specific hazards, on the other, how are the uncertain health and environmental risks ensuing from its use to be managed? Shall glyphosate be banned, phased out, restricted or allowed tout court? Whilst it often occurs that different risk assessments reach diverging conclusions, the glyphosate case epitomises a deeper disagreement. At the core of the glyphosate saga is not only a dispute over the cognitive, technical-scientific elements of the case; but also, and crucially, a profound normative disagreement on the notions of 'intended level' of public health and environmental protection, 'acceptable risk' and 'sustainable' use of pesticides.¹²³

¹¹⁹ It is worth noting that, in its response to the ECI, the Commission claimed that by proposing and enacting a 5 year renewal of approval it gave due consideration to all relevant factors, including the European Parliament's Resolutions and the success of the ECI's campaign: see European Commission, 'Communication from the Commission on the European Citizens' Initiative [...] (n 34) at 9. The 5 year renewal of approval is reminiscent of the provisions of articles 4(7) and 14(2), referring to any active substances which do *not* comply with the requirements of Annex II but which are still – on the basis of documented evidence – necessary to control a serious danger to plant health which may not be contained by other available chemical or non-chemical methods; these active substances may only be approved for a period not exceeding 5 years, subject to the enactment of *specific risk mitigation* measures. Although this may seem reasonable for the Commission to argue, it is still necessary to highlight that such a shift in the Commission's position is the mere effect of persisting Member State opposition in Comitology: the Commission failed to muster a Qualified Majority of votes on a number of occasions and ended up reaching a compromise.

¹²⁰ Summary Report of the Appeal Committee, Section *Phytopharmaceuticals – Plant Protection Products – Legislation*, 27 November 2017, *sante.ddg2.g.5(2017)*, at 2. 18 Member States voted in favour (representing 65,71% of the EU population), 9 Member States voted against (representing 32,26% of the EU population) and 1 Member State abstained (representing 2,02% of the EU population).

¹²¹ Given that the Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 Amending Implementing Regulation (EU) No 540/2011 as Regards the Extension of the Approval Period of the Active Substance Glyphosate [2016] OJ L173 had extended the approval period of glyphosate, in accordance with Article 17 of the PPP Regulation, for a period of six months since the receipt of the ECHA's opinion, or until the 31st of December 2017 at the latest. It is worth noting that – even on this occasion – the Commission did not manage to muster a qualified majority in Comitology, and had to unilaterally enact the extension.

¹²² Commission Implementing Regulation (EU) No. 2017/2324 of 12 December 2017, Renewing the Approval of the Active Substance Glyphosate in Accordance with Regulation (EC) No. 1107/2009 of the European Parliament and of the Council Concerning the Placing of Plant Protection Products on the Market, and Amending the Annex to Implementing Regulation (EU) No. 540/2011 [2017] OJ L333.

¹²³ In this perspective, see Christian Joerges (n 27). See also Sheila Jasanoff, *Designs on Nature. Science and Democracy in the European Union and the United States* (n 16); and Sheila Jasanoff and Kim Sang-Hyun, *Dreamscapes of Modernity. Sociotechnical Imaginaries and the Fabrication of Power* (Chicago University Press 2015).

Section 3. has argued that the Commission had sufficient *scientific* grounds to take a *prudential* stance on the uncertain risks posed by glyphosate, as emerging from conflicting technical assessments. This section explores whether the Commission had any *legal* grounds to follow a *precautionary* approach to glyphosate's risk management. In other words, was the Commission in fact legally unable to enact a ban or a phasing out plan?

To begin with, an overview of the criteria enshrined in the PPP Regulation can provide a helpful basis to assess the standards of protection that active substances and plant protection products are expected to meet. Article 1(3) of the PPP Regulation maintains that the overarching aim of the regulatory framework is to ensure a high level of human and animal health as well as environmental protection;¹²⁴ article 1(4) further reads that, for this very purpose, the provisions of the PPP Regulation '*are underpinned by the precautionary principle [...]*'.¹²⁵ Articles 4(2) and 4(3), as explained in section 2., provide that the relevant plant protection products and their residues shall not have any harmful – immediate or delayed – effects on human or animal health or any unacceptable effects on the environment and biodiversity.¹²⁶ These requirements are then substantiated by a range of further technical¹²⁷ specifications. These encompass, for instance, the requirement that the assessment of the impact on public health shall include a consideration of the effects on vulnerable groups or animal health, directly or through drinking water, food, feed or air, as well as any consequences in the workplace or other indirect effects, taking into account any known cumulative and synergistic impacts;¹²⁸ moreover, the assessment of any residues with toxicological, ecotoxicological, environmental or drinking water relevance shall be taken into consideration.¹²⁹ It is thus fair to conclude that the 'benchmark' standards of protection incorporated in the applicable regulatory framework are highly protective ones.

Secondly, it is worth getting back to the text of Article 13(2), mandating that when deciding on the approval of an active substance the Commission shall take into account the results of the risk assessment, *other factors legitimate* to the matter under consideration, and the *precautionary principle* – whenever scientific uncertainty persists as to the possibility of harmful effects which would not comply with the *high level of protection chosen* in the Union.¹³⁰ The text of this article unequivocally reflects a *socially acceptable risk* approach to the governance of PPPs, whereby the risk manager is called upon to *politically* weigh and balance the relevant margins of risk, precautionary public health and environmental protection and a range of other legitimate factors (OLFs)¹³¹ – including *public perception* of risk, *environmental sustainability* goals and *enhanced consumer protection*.

In the light of these provisions, there can be little doubt as to the point that the Commission had sufficient *legal* grounds to enact – at least – a plan to gradually phase out glyphosate. If any such doubt persisted, the text of the second European Parliament's Resolution would make it fade: in remarkably explicit language, the Resolution states that the Commission's Regulation '*fails to ensure a high level of protection of both human and animal health and the environment [and] fails to apply the precautionary principle*',¹³² thereupon calling on the Commission to '*withdraw the [...] Regulation and submit a new draft implementing Regulation in line with the requirements laid down*

¹²⁴ Article 1(3) of the PPP Regulation, supra (n 39).

¹²⁵ Article 1(4).

¹²⁶ See supra, the analysis of section 3.

¹²⁷ See supra (n 52).

¹²⁸ Art. 4(2) and 4(3) of the PPP Regulation, supra (n 39).

¹²⁹ See art. 4(2) as well as points 3.7.1.1., 3.7.1.2., 3.7.1.3., 3.7.2., 3.7.3. and 3.8. of Annex II of the PPP Regulation, supra (n 39).

¹³⁰ Article 13(2) of the PPP Regulation, referring to Article 7(1) of the General Food Law – see supra (n 97) and (n 98).

¹³¹ See European Commission, Communication from the Commission on the Precautionary Principle, supra (n 8) and particularly at 12 (section 5) and 16 (section 6.2.). See also Recitals (8) and (21) and Article 5(1) of the GFL, supra (n 8).

¹³² Supra (n 84), point 1.

by [the PPP Regulation], *i.e. including not only the EFSA's opinion, but also other legitimate factors and the precautionary principle*'.¹³³

In the light of these considerations, the Commission's renewal of approval of glyphosate appears to be nothing but a reflection of the latter's reliance on a narrow evidence-based approach. The Commission's decision¹³⁴ has disregarded the ECI's powerful argument that the uncertain risks posed by the use of glyphosate are publicly perceived as unacceptable; in turn, this has triggered a heated debate on the available risk management measures, which are regarded as insufficient to safeguard the intended –precautionary – EU level of health and environmental protection.

Further than that, by straightforwardly interpreting the lack of unequivocal *scientific* evidence as a *legal* obstacle to the implementation of precautionary measures, the Commission's response to the ECI campaigners has signposted a highly debatable shift in the understanding of the boundaries and remit of risk management. Under a socially acceptable risk approach, as enshrined in EU risk regulation, setting out the acceptable level of risk for society is an '*eminently political responsibility*';¹³⁵ EU risk managers have the political responsibility to decide whether to act, when is 'safe' safe enough¹³⁶ and how safe is 'safe'.¹³⁷ As already explained, this enshrines the superiority of democratic legitimacy and politics over functional legitimacy and technical expertise.¹³⁸ If the opposite were the case, the EFSA would be a European version of the American FDA. Nonetheless, the Commission has clearly taken a very different perspective throughout its handling of the glyphosate case.

The conclusion is that the Commission has fallen short of its political responsibility to consider whether glyphosate risks are socially acceptable, evaluating whether the use of this active substance complies with the intended level of EU health and environmental protection and enacting appropriate risk management measures. From a socially acceptable risk perspective, this approach is both disputable and highly unsatisfactory.

6. Eluding the ECI's third request: from EU-wide mandatory targets to the national implementation of the SUD Directive.

Before any conclusions are drawn on the glyphosate saga, a few remarks on the Commission's reaction to the ECI's proposal '*to set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future*'¹³⁹ must be sketched.

How did the Commission answer this proposal? Specifically, did the Commission – upon rejecting the request for an EU ban or phasing out plan for glyphosate – consider the option of enacting EU-wide mandatory reduction targets for the use of glyphosate-based pesticides?

In its Communication on the glyphosate ECI, the Commission emphasised that EU policy does not aim at the total elimination of pesticides, but rather at achieving a sustainable use of plant protection products.¹⁴⁰ On the one hand, the Commission noted that '*mandatory volume reduction targets alone do not necessarily reduce the risk from pesticide use*';¹⁴¹ this occurs because pesticides obviously

¹³³ Supra (n 84), point 2.

¹³⁴ See the further comments supra (n 119).

¹³⁵ European Commission, Communication from the Commission on the Precautionary Principle (n 8), particularly at 15, section 5.2., '*the appropriate response in a given situation is thus the result of an eminently political decision, a function of the risk level that is 'acceptable' to the society on which the risk is imposed*'.

¹³⁶ Maria Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation', supra (n 1) at 244.

¹³⁷ Nicolas De Sadeleer, 'The Precautionary Principle in EC Health and Environmental Law', supra (n 13) at 147.

¹³⁸ See para. 149 of Case T-13/99 *Pfizer Animal Health SA v Council*, supra (n 9).

¹³⁹ See supra (n 30).

¹⁴⁰ European Commission, 'Communication from the Commission on the European Citizens' Initiative [...] (n 34) at 12.

¹⁴¹ *Ibid.*

have different levels of toxicity, so that *'the focus of the Member States and of the Commission's work is on the reduction of risk from pesticide use, rather than a simple volume reduction of all pesticides'*.¹⁴² On the other hand, it remarked that many limitations on the use of pesticides – including the recommendation that non-chemical methods should always be preferred whenever they provide satisfactory pest control, and that the use of pesticides must be as specific as possible to target and have the least side effects – are enshrined in the SUD Directive.¹⁴³

Upon these preliminary clarifications, the Commission turned to the specific request of the ECI campaigners. To begin with, whilst rightfully remarking that EU policy aims at reducing the risks posed by pesticide use, rather than the volume of any pesticides used, the Commission did neither clearly and unequivocally commit to propose EU-wide reduction targets on the grounds of pesticide risk,¹⁴⁴ nor to enact any mandatory targets for the specific reduction of glyphosate-based herbicides.¹⁴⁵ Despite vaguely mentioning that it would in the future establish harmonised risk indicators for different pesticides,¹⁴⁶ the Commission fell short of proposing any measures; indeed, it concluded that at this stage it *'does not envisage to submit a proposal to establish EU level reduction targets for pesticide uses'*.¹⁴⁷

Secondly, building on the argument that all necessary conditions and limitations are already enshrined in the SUD Directive,¹⁴⁸ the Commission turned the ECI's request for *EU-wide* targets upside down, claiming that the responsibility to ensure a truly sustainable approach to the use of pesticides lies with the *Member States*. Notably, the Commission expressly mentioned the findings of its own 2017 Report to the European Parliament and the Council,¹⁴⁹ acknowledging that the national implementation of the SUD Directive *'remains patchy, [...] improvement is needed in particular as regards the use of all tools available under Integrated Pest Management [and] national plans are still very diverse in their completeness and coverage'*.¹⁵⁰ However, and despite this admission, the Commission merely committed to assist the Member States in the implementation of the eight principles of Integrated Pest Management ('IPM principles') set out in Annex II to the SUD Directive, facilitating their conversion and standardisation into specific benchmarks and monitoring national performance.¹⁵¹

Is the Commission's answer to the third request of the ECI campaigners *politically* appropriate and satisfactory? This does not appear to be the case. On the one hand, the Commission deliberately eluded the ECI's request to take action at EU level; it did neither commit to enact EU-wide mandatory targets for the reduction of glyphosate-based herbicides, nor to put in place a harmonised system for the reduction of pesticide use on the grounds of their toxicity level. Thus, the Commission ultimately washed its hands of any potential reform of the SUD Directive system.

On the other hand, as already explained, it committed to assist the Member States in their implementation of the Directive; however, this is by no means an answer to the different question

¹⁴² Ibid.

¹⁴³ Ibid., at 13. See also 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 [2009] OJ L309.

¹⁴⁴ Ibid. See also at 14.

¹⁴⁵ This is all the more disappointing in that a clear commitment by the Commission would have triggered issues of *substitution*: in this specific respect, see Annex II, Point 4, and Article 24 of the PPP Regulation, *supra* (n 39). It is reasonable to suggest that, in the face of a phasing out plan or mandatory reduction targets, the industry would be likely to allocate economic and human resources with the aim of developing *less hazardous* active substances and/or plant protection products. This point goes directly to the heart of the *distributional implications* of different approaches to risk regulation.

¹⁴⁶ European Commission, 'Communication from the Commission on the European Citizens' Initiative [...]' (n 34) at 13.

¹⁴⁷ Ibid., at 13 and 14.

¹⁴⁸ Ibid.

¹⁴⁹ Report from the Commission to the European Parliament and the Council on Member State National Action Plans and on Progress in the Implementation of Directive 2009/128/EC on the Sustainable Use of Pesticides, COM(2017) 587 final.

¹⁵⁰ European Commission, 'Communication from the Commission on the European Citizens' Initiative [...]' (n 34) at 5.

¹⁵¹ Ibid.

raised by the ECI. The ECI asked the Commission to propose the enactment of EU-wide mandatory reduction targets, whereas the Commission claimed that the regulatory system delegates the Member States to enact and implement national plans. Rather than answering the question, arguably, the Commission decided to adhere to the status quo.

The ECI campaigners perceive the faulty implementation of the SUD Directive at Member State level as a problem, and asked the Commission to solve it through an EU-wide response: namely, the enactment of mandatory targets. At the heart of this ECI's proposal lies the acknowledgement that the availability, efficacy and effectiveness of risk management measures¹⁵² directly impact on the risks which are run in practice;¹⁵³ for this reason, the ECI advocated the enactment of different risk management measures – and specifically, EU-wide mandatory reduction targets – to safeguard the intended level of EU public health and environmental protection. The Commission, deploying a somehow circular argument, committed to assist the Member States in the enactment and implementation of their national plans: nonetheless, can the problem become part of the solution? Whilst this scenario cannot be aprioristically ruled out, it is certainly difficult to envisage any prospective margins of success. Further than that, and most importantly, by eluding the explicit ECI's request for EU-wide targets, the Commission disavowed all political responsibility on the matter.

This section concludes the overview of the glyphosate saga. Against this overall backdrop, and pulling the strings of the whole analysis, the next and final section will argue that the Commission has – throughout its handling of the glyphosate case – failed to address the ECI's powerful arguments and lost a significant political opportunity.

7. The political grounds. Re-legitimising EU risk regulation? A missed political opportunity.

Shall uncertain health and environmental risks be run until science has unequivocally proven them, as the hegemonic – evidence-based – transnational legal narrative suggests?¹⁵⁴ Section 1. has explained that reconciling functional legitimacy, as provided for by technical risk assessment, and democratic legitimacy, as dialectically constructed throughout the phase of political risk management, lies at the very heart of EU risk regulation. The rationale for this regulatory choice was to enhance the political nature of risk governance and the democratic accountability of decision-makers, while safeguarding the independence of technical experts.

The analysis of the glyphosate saga through the prism of a socially acceptable risk approach triggers one question: where has the *political* and *democratic* component of EU risk regulation gone? Is it anywhere to be found?

Whilst consumer concerns and public aversion to glyphosate have certainly been magnified by the remarkable media coverage of the matter, the Commission has completely ignored the public view that the uncertain risks posed by glyphosate are *not* socially acceptable; in so doing, it has failed to consider how the existing risk management measures are deemed to be insufficient to safeguard the intended level of EU health and environmental protection. By eluding the ECI's requests and by ignoring the European Parliament's position the Commission has ultimately disregarded its own

¹⁵² European Commission, Communication from the Commission on the Precautionary Principle, supra (n 8) at 19, section 6.3.4.

¹⁵³ On the notion of 'boundary work', see supra (n 70) and Marjolein Van Asselt and Ellen Vos, 'Wrestling with Uncertain Risk: EU Regulation of GMOs and the Uncertainty Paradox' (2008) 11 Journal of Risk Research 281, at 288 ff.

¹⁵⁴ See G.C. Leonelli, *The Transnational Law and Governance of GMOs* (n 1) and G.C. Leonelli, 'GMO Risks, Food Security, Climate Change and the Entrenchment of Neo-Liberal Legal Narratives' (n 1).

political role, underplaying the democratic component of EU risk regulation and altering the underlying balance of power in the field.

Moreover, by emphasising that risk management and risk mitigation measures are the sole responsibility of the Member State level, the Commission has reinforced the perception that EU decision-making has a mere ‘technical’ remit. On the one hand, in its proposal to renew the approval of glyphosate, the Commission deliberately relied on a technocratic, ‘sound’ science approach. On the other hand, by refusing to propose mandatory reduction targets for pesticide use, it left all ensuing risk management burdens to the national level; indeed, Member States are entrusted with the politically charged tasks of authorising glyphosate-based herbicides, enacting risk mitigation measures, adopting national plans under the SUD Directive and monitoring their implementation. Ultimately, and despite the ECI’s requests that the EU level shall take action, the regulation and monitoring of ‘sustainable’ use of pesticides is still delegated to the national level.

What lessons are taught by the glyphosate saga? In this case the EU procrastinated taking a decision, and finally mustered a Qualified Majority through compromising. However, this is not the time for compromises. As the answer of the ECI’s organisers suggests, the vague proposals of the Commission and its rhetorical emphasis on transparency and procedures are nothing but a partial and misleading response to the ECI’s campaign.¹⁵⁵ The case of glyphosate in fact epitomises a powerful clash and disagreement on the *substantive* issues at stake, rather than on any of the relevant *procedures*.

The time has long been ripe for a re-legitimation of EU risk regulation. The Commission had compelling political grounds to listen to the ECI’s – transnational and EU-wide – message, and should have enacted stringent measures to comply with precautionary standards of public health and environmental protection. By refusing to acknowledge that the uncertain risks posed by glyphosate are publicly perceived as socially unacceptable the Commission has lost an important opportunity to re-legitimise and re-democratise EU risk regulation, disregarding a set of – controversial – risk assessments and listening to widespread public demand for enhanced levels of protection.

At a time of resurging nationalism, technocracy and ‘output legitimacy’¹⁵⁶ will not save the EU; rather, a paradigm shift is urgently needed. Taming anti-EU, anti-globalisation and ‘sovereignty-enhancing’ movements will be impossible if the EU keeps on relying on a technocratic model, privileging regulatory convergence and trade liberalisation over *democratic* legitimacy and *political* values – such as consumer protection and environmental sustainability.¹⁵⁷ Equally, it will be impossible as long as the engagement with political and socio-economic demands is left to the Member State level, away from the ivory tower of EU technicians. In a totally different vein, and well beyond the ‘output legitimacy’ paradigm, the EU needs to fight *both* technocracy *and* ‘sovereignty-enhancing’ movements through its own, transnational *re-legitimation* and *re-democratisation*.¹⁵⁸

¹⁵⁵ Available at <<https://stopglyphosate.org/wp-content/uploads/2017/12/12122017PR.pdf>> (last accessed 20/03/2018).

¹⁵⁶ For the terminology of ‘input’ and ‘output’ legitimacy – with the former referring to the model of representative democracy, and the latter to the advent of efficiency-driven, functional forms of legitimacy, see Fritz Scharpf, *Governing Europe. Effective and Democratic?* (OUP 1999); and Fritz Scharpf, ‘Monetary Union, Fiscal Crisis and the Disabling of Democratic Accountability’, in Wolfgang Streeck and Armin Schäfer (eds.) *Politics in the Age of Austerity* (Polity 2013), 108. See also Giandomenico Majone, (ed.) *Regulating Europe* (Routledge, 1996).

¹⁵⁷ G.C. Leonelli, *The Transnational Law and Governance of GMOs* (n 1). See also Christian Joerges’s ‘Conflicts Law Constitutionalism’ (‘CLC’) theory, drawing on a procedural legal paradigm and on Habermas’s theory of deliberative action: see inter alia C. Joerges and J. Neyer, ‘From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology’ (1997) 3 *European Law Journal* 273; C. Joerges and M. Everson, ‘Reconfiguring the Politics-Law Relationship in the Integration Project Through Conflicts-Law Constitutionalism’ (2012) 18 *European Law Journal* 644; C. Joerges, ‘Legitimacy Without Democracy in the EU? Perspectives on the Constitutionalisation of Europe Through Law’, in M. Maduro, K. Tuori and S. Sankari (eds.) *Rethinking European Law and Legal Thinking* (CUP 2014), at 248 ff.; C. Joerges and C. Gliniski (eds.) *The European Crisis and the Transformation of Transnational Governance: Authoritarian Managerialism Versus Democratic Governance* (Hart Publishing 2014); C. Joerges and C. Kreuder-Sonnen, ‘European Studies and the European Crisis: Legal and Political Science Between Critique and Complacency’ (2017) 23 *European Law Journal* 118.

¹⁵⁸ See G.C. Leonelli, *The Transnational Law and Governance of GMOs* (n 1).

The glyphosate case and the EU-wide, transnational ECI campaign offered a superb occasion for the EU to reshape its own transnational identity, getting back to the democratic and political foundations of EU risk regulation. Whilst it may not be too late for the EU to change its overall direction it is, unfortunately, too late for the Commission to look back at its decision in the glyphosate case.