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On giving account and taking things into account

The case of Glyphosate

Vesco Paskalev

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Abstract

Risk regulation regimes in the developed world are increasingly 'science-based', that is heavily dependent on scientific assessment of the risk conducted by independent and specialised agencies. In the European Union (EU) these agencies are mostly advisory, and assessments are delivered in the form of 'opinion', yet their pronouncements as for the 'safety' of a novel food, pesticide or chemical are very often judiciously obeyed by the politically accountable risk managers. In this way the locus of decision-making moves upstream, to the risk assessing agencies and in turn this creates strong pressures to make them 'accountable'. The present paper explores the accountability of scientific agencies through a case study of the recent highly salient assessments of glyphosate – a popular herbicide – conducted by the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA). It begins by reframing the notion of accountability as the twin requirements *to give account* as well as *take into account*. The paper argues that the different sides diverge not merely in having opposite views on the one key issue – whether glyphosate is safe – but also in having quite different views *on what matters*, i.e. what factors are relevant for the decision. When some factors cannot be taken into account by the decision-makers while others are made pivotal, the stakeholders are forced into a proxy war on the latter (in this case the alleged carcinogenicity of the herbicide). The other key argument of the paper is that the scientific assessments are always shaped by the legal environment the assessors are embedded into and therefore it is impossible to separate 'legal' and 'political' from 'technical' issues at any level. Thus, even the most trivial or technical-looking detail may have enormous political significance. Sophisticated stakeholders never fail to notice this, so it is necessary for policy makers and academics to acknowledge it too.

Keywords

Accountability, agencies, EFSA, glyphosate, pesticides, public reasons

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'The demand for accountability is a sign of pathology in the social system'.

James March[1]

Introduction[2]

The European Union (EU) is believed to suffer from a number of deficits – democracy, legitimacy, justice – but in the view of the present author (and *pace* Carol Harlow[3]), an accountability deficit is not amongst them. If anything, its institutions seem to be more open, transparent and participatory than their respective counterparts in the Member States. This is even more so with regard to its agencies; indeed they are subject to multiple layers of accountability mechanisms so much so that some authors already speak about accountability overload.[4]

The present paper explores the question of accountability by a case study of the recent reauthorisation of glyphosate[5] – a popular herbicide – amid a heated controversy with the active involvement of a number of regulators across the world, with the key role of the European Food Safety Authority (EFSA) and WHO's International Agency for Cancer Research (IARC). While both of them seem to have been *fairly*[6] transparent, participatory and unbiased, after several years of evaluation and re-evaluation of the available evidence, with independent assessments followed by public exchanges, they remain at odds over key 'scientific' issues, giving the public the impression that there is a foul play somewhere, or everywhere in the system. Thus, one of the arguments that will be advanced in this paper is that even if each of the actors involved in a controversy is accountable, i.e. faithfully fulfils *its own* duties,[7] the interaction between them may

[1] Quoted from Lee Cronbach (1995), 'A Valedictory: Reflections on 60 Years in Educational Testing' (Washington, DC: National Academy Press).

[2] This paper was presented at the TARN Conference on EU Agencies in Brussels, 12-13 April 2018. I would like to thank Alessandra Arcuri, for the opportunity to read her forthcoming manuscript, Paul Anderson, for sharing a treasure trove of materials, as well as Ellen Vos, Michelle Everson, Sabrina Röttger-Wirtz, Merijn Chamon, Andreas Eriksen and all the participants of the TARN-Conference on EU Agencies for the helpful questions and comments.

[3] Carol Harlow (2002), *Accountability in the European Union* (Oxford: Oxford University Press).

[4] Thomas Schillemans and Marc Bovens (2011), 'The Challenge of Multiple Accountability: Does Redundancy Lead to Overload' in Melvin J Dubnick and H George Frederickson (eds), *Accountable Governance: Problems and Promises* (Armonk, NY: ME Sharpe) and more generally Arie Halachmi (2014), 'Accountability overloads' in MAP Bovens, Robert E Goodin and Thomas Schillemans (eds), *The Oxford Handbook of Public Accountability* (Oxford: Oxford University Press).

[5] For the sake of full accountability I would like to disclose my strong views against glyphosate, which may or may not be due to my engagement with a number of environmental organisations, mostly in my native Bulgaria.

[6] One has to choose his words very carefully when discussing the integrity of the regulators, for both sides traded accusations of conflicts of interests and bias. While some of these will be addressed later in the paper, here it is sufficient to say that none of these allegations played a major part in the controversy and no one was fired in disgrace.

[7] Accountability may mean both *a mechanism* and *a virtue*, see Mark Bovens (2010), 'Two Concepts of Accountability: Accountability as a Virtue and as a Mechanism', *West European Politics* 33(5): 946-967. Here I am using the term in the latter sense and shall specify my understanding of these duties in section 2 below.

amount to overall loss of accountability (in the sense that the public is less rather than more clear about the reasons for the decision taken in its name).[8] The other argument that is advanced below is that accountability actually fuelled the controversy; if the scientific advisers were less transparent their conclusion would be much less vulnerable to contestations by the parties unhappy with the outcome.[9] This is not to say that the decisions should be 'black-boxed' – though black boxing in some cases may be necessary.[10] On the contrary, I believe the 'politicisation' of the issue in this case was quite appropriate given the widespread use of the glyphosate and the far-reaching implications of its (non-)authorisation. What was wrong in this controversy was not even the failure of the regulators to reach agreement on whether the herbicide in question causes cancer or not – elsewhere I have argued that contrary to the widespread assumption for universality of science, such questions are very much context-dependent and therefore it is legitimate for different regulators to reach different conclusions on what *appears to be* the same question.[11] In my view *the problem was in the narrow framing of the debate*, where carcinogenicity became pivotal for the decision, obscuring many other factors which may have been even more important for some of the stakeholders.[12] This framing, reliant on arbitrary but nonetheless rigid separation of 'scientific' from 'non-scientific' issues, has been shown in slightly different contexts to be favourable to the industry side.[13]

Unlike other instances of bitter controversies around a 'technical' issue which have the appearance of an irreconcilable difference between 'science' and 'democracy,'[14] in this case the brawl occurred *even within the narrow framework of science-based risk analysis*. Even though each of the agencies involved appears to do science and nothing but science, and even though they have taken into account all scientific evidence that was available to them and was considered reliable, the two key agencies involved – IARC and EFSA – arrived at conclusions at odds with each other. On a closer inspection

[8] Compare with Schillemans and Bovens, see footnote 4 above. They reach the opposite conclusion but with the caveat that it is under the specific circumstances of their cases.

[9] Compare with the effect of the so called Good Science Laws in the US, Annamaria Baba, Daniel M Cook, Thomas O McGarity and Lisa A Bero (2005), 'Legislating "Sound Science": The Role of the Tobacco Industry', *American Journal of Public Health* 95(1): 20-27.

[10] Sheila Jasanoff (2006), 'Transparency in Public Science: Purposes, Reasons, Limits', *Law and Contemporary Problems* 69(21): 21-45.

[11] Vesco Paskalev (2017), 'May Science Be with You: Can Scientific Expertise Confer Legitimacy to Transnational Authority?', *Transnational Legal Theory* 8(2): 202-223.

[12] 'Other factors' must be taken into account by risk managers as a matter of law, but they rarely are – a recent evaluation of the General Food Law states that "EU risk managers have considered *other legitimate factors* in addition to the scientific opinions of EFSA in deciding the appropriate measures to be taken in *very few cases*", see Executive summary of the REFIT evaluation of the General Food Law, {SWD(2018) 38 final}, emphasis of the original. It is unclear whether the European Commission considers this to be a problem or a virtue of the regime.

[13] Paul Anderson (2004), 'What Rights Are Eclipsed When Risk Is Defined by Corporatism? Governance and GM Food', Theory, Culture & Society 21(6): 155-169. More recently Les Levidow (2017), 'Substituting a Fictional "Science" for Public Accountability: Legitimacy Problems of the EU's Regulatory Framework for GM Products' in Leire Escajedo San-Epifanio (ed.), *Towards a new regulatory framework for GM crops in the European Union* (Wageningen: Wageningen Academic Publishers).

[14] Compare Cass R Sunstein (2005), *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: Cambridge University Press 2005) and Dan M Kahan, Paul Slovic, Donald Braman and John Gastil (2006), 'Fear of Democracy: A Cultural Evaluation of Sunstein on Risk', Harvard Law Review 119(4): 1071-1121.

this should not be surprising. Indeed, the decision of each agency is affected by its own governing documents, terms of reference, set functions and mission statement and this is why even if they all appeared to be considering the same issue – carcinogenicity of a certain substance – they were bound to reach different conclusions. As Alessandra Arcuri pertinently explains:

> Law that has made a call on science to solve certain issues unleashes its [own] authority to frame problems and to admit or exclude scientific evidence. The almost surgical separation between hazard analysis and risk assessment and between formulations and the pure substance resonates with the conceptualisation of risk assessment and risk management as clearly distinct realms. The act of splitting (for example hazard analysis from risk assessment) enables the regulators to exclude arguments.[15]

With regard to the issue explored in the present paper, we could specify that most of the law Arcuri refers to are rules that are put in place to ensure accountability – there are regulations precisely delimiting the competences of the agency, i.e. what issues it may or may not consider, and in turn these reflect the operational principles of the broader system the agency is embedded into; there are the rules defining who can and who cannot sit on the respective panels, letting in certain types of expertise and certain types of interests while excluding others; there are the guidelines to structure experts' discretion to prevent them from choosing or weighing conflicting evidence arbitrarily;[16] there are the requirements for the form and content of the guideline studies provided by the applicant and for the final decision issued by the agency.

Thus, while the decisions are taken by scientific experts, allegedly independent and insulated from any political considerations, the evidence they base their conclusions on is controlled by the law. To demonstrate this, in this paper I shall take a closer look at the two assessments of glyphosate conducted by IARC and EFSA respectively. I shall study the accounts each gave for their acts – and they were plentiful – and will show how the subtle differences in the respective legal frameworks they are set in resulted in significant differences in their 'scientific' conclusions. This delving into the details aims to achieve several goals. The first is to show that the 'scientific' cannot be separated from the 'legal' and 'political'. This has been amply demonstrated by decades of research in Science and Technology Studies (STS) but so far in most cases there *appears* to be a unitary position of 'science' whose political 'implications' are exposed by the researchers. While most such studies – just like the present one - challenge the very possibility of such distinctions – outside of the STS circles they are too often understood to merely show that the line between science and law shall be drawn on a different place or at a different level. The glyphosate case is fairly unique in having two 'purely scientific' bodies reaching opposite conclusions thus showing how law and science are intertwined at *every* level. The second related aim is to show that every scientific assessment is unavoidably political. This does not necessarily mean that assessors self-consciously follow certain agendas (though sometimes they do), but that

[15] Alessandra Arcuri (2019, forthcoming), 'Glyphosate' in Jessie Homan and Daniel Joyce (eds), *Objects of International Law* (Oxford: Oxford University Press).

[16] For example one of the members of the EFSA Management Board, Andres Szekacs, stated that '[EFSA] cannot consider everything for legal reasons', EFSA, 67th Management Board Meeting, 3 December 2015, available at www.efsa.europa.eu/en/events/event/151203#playaudio last accessed on 25 April 2018. I am grateful to Alessandra Arcuri for this reference.

their decisions are inevitably premised on certain hidden choices, either done by the legislator when setting their operational rules or by themselves when they make choices that set them on the firm path to a certain conclusion. Both of these choices appear technical but profoundly affect the outcome of the whole process. This is the case even if there are no overt pressures on the deciding panels, but the links are obvious, so when stakes are high the pressures will not be long to come. The third aim of the case study is to demonstrate how (much) accountability rules discipline decision-makers (risk assessors in this instance) and prevent them from choosing arbitrarily. As we shall see, on the one hand they constrain their discretion, down to the level of choosing which studies to include and which not. On the other hand, this constraint is fairly limited as the choice is by no means removed: tiny 'technical' choices become highly consequential. More importantly, the need to 'explain and justify' exposes the conclusions to reality checks and to contestations from stakeholders who are otherwise disempowered.

Accountability

In Mark Bovens' often quoted definition, accountability is 'a relationship between an actor and a forum, in which the actor has an obligation to explain and to justify his or her conduct, the forum can pose questions and pass judgement, and the actor may face consequences'. [17] While this definition is a common point of departure in the scholarship of EU agencies, different authors tend to focus on different elements and in my understanding we should take a somewhat sanguine view of the bit about the consequences. There are at least two reasons for this, the first being the apparent tension in the case of the agencies whose raison d'être is to be independent.[18] The other reason is that in most cases the consequences are mainly theoretical. Even in the paradigmatic case of an accountability relationship – between a parliament and a government – the practice in the House of Commons provides ample examples of MPs struggling to obtain certain impact studies from their ministers and fighting an uphill battle for the mere opportunity to vote on the most momentous decisions in the recent UK history; the last time the Parliament was able to formally 'pass judgement' on the Government was in 1979.[19] On the other hand, in the same Chamber we can witness ministers explaining and justifying their acts with members approving or contesting these justifications on a daily basis. Whether consequences occur in more subtle ways behind the scenes (they do) and whether this is normatively sufficient is for another

[17] Mark Bovens (2007), 'Analysing and Assessing Accountability: A Conceptual Framework', European Law Journal 13(4): 447-468, p. 450.

[18] For a good attempt to square the circle between independence and accountability see Madalina Busuioc (2009), 'Accountability, Control and Independence: The Case of European Agencies', European Law Journal 15(5): 599-615.

[19] Motion of no confidence in the government of James Callaghan. As a result, the Parliament was dissolved so it had to face the same consequences.

day, but I take it that this justification in the public sphere is the practice at the heart of the accountability relationship.[20]

After taking something out of Boven's definition, I would also add something to it. When everything comes down to justification in the public sphere not any set of reasons will be normatively acceptable. If the reasons that are given by the decision-maker are considered irrelevant by certain stakeholders, while the concerns *they* have against a decision are deemed irrelevant by the decision-maker, the public discourse is devoid of any meaning. Such justification, for these stakeholders is no justification at all. Thus, justifications may be more or less socially robust, depending on the breadth of public reasoning. This would mean that in the process leading to a decision, public authorities should take into account as many considerations raised by the different stakeholders as possible, and when decision is taken they should give account for each of these considerations. This is not to say that the decision needs to *satisfy* all such considerations – such a demand would be absurd[21] – but only that the authority must show that it genuinely reflected on them and even if they were outweighed by some competing claims on this occasion these considerations have a fair chance to carry the day in the future. While giving such account to the losing side may be a small comfort, without it, it would be certain that their considerations will be *always* ignored.

The glyphosate debate in the global public sphere

Glyphosate is a broad spectrum herbicide introduced in the 1970s by Monsanto and is by now the most widely used weed-killer throughout the world. It is normally used in mixtures - Monsanto's own Roundup as well as a number of generic compounds. Glyphosate blocks the ability of plants and bacteria to produce certain vital amino acids in the so called shikimate pathway which is present in plants and bacteria but not in animals; thus, it is deadly for the former but not so for the latter. This makes it a 'non-selective' herbicide, meaning that it kills most plants it is sprayed onto. Generally, it is applied before the crops are planted, but sometimes also just before harvest in order to dry the crop out and facilitate harvesting (desiccation).[22] Importantly, since the 90s there are a number of plant varieties which are genetically modified to be tolerant to glyphosate and which are now very common outside of Europe. Due to its widespread use glyphosate residues are ubiquitous – most produce in our supermarkets contain some, and tests have found glyphosate in the urine of 44% of a sample of some 180 people from 18 European countries.[23] In the US glyphosate was detected in 59% of 470 surface

[20] Some authors consider that accountability includes also the existence of some 'checks and balances'. In my view the concept should not be stretched that far – checks and balances belong to another concept, separation of powers (or institutional balance in the EU) and the latter does not necessarily involve elements of accountability: for instance the US president may veto a bill without much of an explanation.

[21] Besides unrealistic, it may not be normatively desirable to satisfy all – justice may require that the concerns of some groups – too marginal or too extravagant – are *not* taken into account.

[22] In Colombia it is sprayed from the air on illegal coca fields, in an US supported program to combat drugs trafficking. After the IARC classification in 2015 the Colombian Health Minister suspended the spraying.

[23] Medizinisches Labor Bremen (2013) 'Determination of Glyphosate residues in human urine samples from 18 European countries', Report Glyphosate MLHB-2013-06-06. Available at: https://www.foeeurope.org/sites/default/files/glyphosate_studyresults_june12.pdf.

water sites and 50% of the soil sites from across 38 states.[24] Notwithstanding this, there are 'profound gaps' in the estimates of human exposure to glyphosate across the world.[25]

In 2015 the news broke that glyphosate is probably carcinogenic for humans as the International Agency for Research on Cancer (IARC) classified it in its 2A group of substances. Although environmental NGOs have been voicing concerns long before that, the carcinogenicity was not central even in their complaints. For example, a report by Friends of the Earth (FoE) from 2013 mentioned it only once along with a number of other serious issues: endocrine disruption, loss of farmland biodiversity, water contamination, soil health (leading to increased need for fertilisers), etc.[26] At that point in time FoE were highly concerned about glyphosate, but their demands did not include a ban on its use. Instead, they insisted that its levels in food and environment are regularly monitored, that the EU Member States adopt glyphosate-reduction programmes; only the use for desiccation was to be prohibited.

There are other reasons for the environmentalists to dislike glyphosate not explicitly mentioned in the FoE report. The first that comes to mind is the complementarity between glyphosate and GMOs.[27] The increasing dependence of the farmers and food chains on a single corporation, Monsanto, is another. Further, glyphosate allows *simplified weed management* which favours the development of large scale industrial farming; many objections are raised against this – monocultures ('green deserts') are detrimental to biodiversity, displace small scale farmers and whole communities, etc. Instead, environmentalists advocate *integrated weed management* and along with its concerns against glyphosate FoE published a report on the available green alternatives. There is also the concern about the 'pesticide treadmill' – heavy use of pesticides is known to breed resistance. According to one estimate 'superweeds' now infest 25 million ha of US farmland[28] – so a 'safe' herbicide-resistant crop locks farmers, biotech

[24] US Geological Survey, 'Weed Killer is Widespread in the Environment', available at http://toxics.usgs.gov/highlights/2014-04-23-glyphosate_2014.html, quoted in Olivier de Schutter (2017) 'Why the Commission's renewal of the authorization to place glyphosate on the EU market should be annulled', a note presented by the Greens/EFA group in the EP on 07.12.2017, available at http://extranet.greens-efa-service.eu/public/media/file/1/5422, last accessed 8 January 2019.

[25] John P. Myers, Michael N. Antoniou, Bruce Blumberg et al. (2016) 'Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement', *Environmental Health* 15(19), doi: 10.1186/s12940-016-0117-0.

[26] Friends of the Earth Europe (2013) 'Glyphosate – Media Briefing. Reasons for concern', available at http://www.foeeurope.org/glyphosate-reasons-for-concern-briefing-130613, last accessed on 27 March 2018. See also the accompanying more detailed documents available there.

[27] It is worth to note that the use of glyphosate worldwide skyrocketed only with the introduction of Monsanto's Roundup-ready GMO crops.

[28] Brandon Keim (2015) 'Monsanto's Newest GM Crops May Create More Problems Than They Solve', *Wired*, 2 February 2015. Available at: https://www.wired.com/2015/02/new-gmo-crop-controversy/. According to another study, 10,000 ha in Argentina are now covered by glyphosate-resistant weeds and the farmers have entered a treadmill where overuse of a single product leads to tolerance and tolerance is overcome with more product, see Rosa Binimelis, Walter Pengue and Iliana Monterroso (2009) '"Transgenic treadmill": Responses to the emergence and spread of glyphosate-resistant johnsongrass in Argentina' *Geoforum* 40(4) 623-633. See also Natasha Gilbert (2013), 'Case studies: A hard look at GM crops', *Nature*, 1 May 2013. Available at: https://www.nature.com/news/case-studies-a-hard-look-at-gm-crops-1.12907.

industry and regulators in a cycle of competition between evolution and innovation.[29] The self-sustaining growth of demand for pesticides is much welcome for the industry but progressively increases the effect on the environment well beyond the initial estimates.[30] Next, the risk for the residents in the vicinity of the sprayed fields – in Argentina or in the UK – seems to be completely outside of the radar of both researchers and regulators.[31] Last but not least, many people would consider the presence of glyphosate in our bodies as an issue of its own: even if it were completely harmless, we may not want it thrusted upon each of us without our consent.[32]

Now, one can imagine that the decision for its reauthorisation for the next 15 years in the EU would be informed by a debate on some or all of these concerns, yet they were hardly ever mentioned in the public space, especially after 2015. This is not, however, a case of NGOs stoking fear or of intellectual laziness of the media; all actors were wise to focus on carcinogenicity because in the existing regulatory framework its 'safety for human health and the environment' is the only factor that really matters. Pursuant to Regulation 1107/2009 concerning the placing of plant protection products on the market (the Pesticide Regulation), if a pesticide is carcinogenic to humans it cannot be authorised.[33] While on the face of it such automatism is plausible, it exhibits a high degree of what van Asselt and Vos call risk intolerance.[34] This means the culture, and in the present case, the law, that makes it impossible for the industry, for the regulators, and for the environmentalists all alike to accept that certain products create some risks that we have to live with. Instead the former will go out of their way to show that there is no risk at all, while the latter will not accept any degree of it to be permitted. Thus, the environmentalists seized the opportunity IARC has unexpectedly provided to contest the re-authorisation of glyphosate on one specific ground. On the other hand, the producers – The Glyphosate Task Force (GTF) lead by Monsanto – had to do all they could to undermine IARC's claim (and did not have to bother very much to address any of the other concerns; nor did they have to extol any of its benefits).

Thus, both sides in the controversy were forced to make carcinogenicity a proxy for everything else. This was acknowledged by EFSA's head, Bernhard Url, who complained in a recent opinion piece in *Nature* that scientific assessment suffers when 'questions about a society's values are thrust onto scientific agencies rather than elected

[29] The consequences of the spread of glyphosate-resistant weeds are quite unlike the other herbicide resistant weeds and require major changes in tillage and cropping patters, see John P. Myers et al., footnote 25 above, at p. 4 and the literature they refer to.

[30] Such concerns are voiced not only by environmentalists. In a recent report the UN special rapporteurs on the right to food and on toxics elaborated on a number of problems and called pesticides a 'global human rights concern', UN Human Rights Council (2017) 'Report of the Special Rapporteur on the right to food', A/HRC/34/48. Available at: https://undocs.org/en/A/HRC/34/48.

[31] 'This means that pesticides have been approved for decades without first assessing the health risks for people who actually live in crop sprayed areas which obviously includes babies, children, pregnant women, the elderly, and people already ill and/or disabled', Georgina Downs (2015), 'It's not just glyphosate and neonicotinoids! Why we need a pesticide-free future', *The Ecologist*, 30 April 2015. Available at: https://theecologist.org/2015/apr/30/its-not-just-glyphosate-and-neonicotinoids-why-we-need-pesticide-free-future.

[32] Damian Chalmers (2005), 'Risk, Anxiety and the European Mediation of the Politics of Life', European Law Review 30(5): 649-674.

[33] See the Pesticide Regulation, Annex II, 3.6.3.

[34] Marjolein B. A. van Asselt and Ellen Vos (2006), 'The Precautionary Principle and the Uncertainty Paradox', Journal of Risk Research 9(4): 313-336.

officials'. He believes that 'when campaigners allege that EFSA did not follow due scientific process when assessing glyphosate, … they are really railing against bigger issues: the role of modern agricultural practices and multinational biotech firms in our food supply'. I suspect that this is true, but I part company with Mr. Url where he insists that elected officials and regulatory agencies have separate jobs which can and should be insulated from each other.[35] In the remainder of this paper I will study how the scientific agencies conducted their 'scientific job' to show that, contrary to the wide-spread perception, there is no single outcome which scientific agencies are bound to reach if only they were left alone.[36]

International agency for research on cancer

The International Agency for Research on Cancer (IARC) is an independent organisation within the framework of the World Health Organisation (WHO) based in Lyon, France. A panel of experts sets assessment priorities for certain substances (and sometimes practices like working night shifts), then an ad hoc Working Group is set up, its members selected on the basis of their expertise and vetted for conflicts of interests; they review the available scientific literature for a year, and at the end of it convene for a week-long workshop where they aim to reach conclusions by consensus as for the possible carcinogenic effect of the object of the assessment.[37] Its detractors are keen to point out that it has classified as possible carcinogen red meat and hairdressing, and that during its entire history it classified as safe (i.e. probably not carcinogenic) only one substance. This appears to be rhetorically very effective, but it may show not the bias it is meant to, but only that the substances that were prioritised for assessment were selected wisely. IARC is not a regulator, and its decisions are not binding on anyone. Yet as Arcuri notes, it exercises a form of liquid authority and its opinions have significant effects in the legal realm.[38]

In 2014 an IARC committee identified glyphosate along with four other pesticides as a substance of interest and assigned the review to a working group of 17 scientists; its concluding meeting was held 3-10 March 2015 and the *consensus* conclusions were publicly announced on 20 March. A summary of the findings was published in *The*

[35] Indeed, the predominant understanding of the established framework for risk analysis is that risk assessment is strictly separate from risk management and that non-scientific factors may be considered only in the latter. However, this is contested, see for example Mihail Kritikos (2009), 'Traditional Risk Analysis and Releases of GMOs into the European Union: Space for Non-Scientific Factors?', European Law Review 34(3): 405-432.

[36] For this reason I set aside the entire 'Monsanto papers' scandal, for a good coverage see Philip Bethge (2017), 'Monsanto Faces Blowback Over Cancer Cover-Up', *Der Spiegel International*, 24 October 2017, available at http://www.spiegel.de/international/world/monsanto-papers-reveal-company-covered-up-cancer-concerns-a-1174233.html, last visited on 1 May 2018.

[37] There are five categories: carcinogenic to humans; probably carcinogenic; possibly carcinogenic; not classifiable as carcinogenic; and probably not carcinogenic. Details of the procedure available on the IARC website, see 'Working procedures', available at: monographs.iarc.fr/ENG/Preamble/currenta6work0706.php.

[38] Arcuri, 'Glyphosate', see footnote 15 above.

Lancet[39] and the full review was published as *Monograph 112*.[40] The conclusion was that there is a limited evidence of carcinogenicity in humans, sufficient evidence for carcinogenicity in animals and strong evidence for genotoxicity. This warranted classification of Glyphosate as 'probably carcinogenic for humans'.

There are several specific features of IARC that are worth to note. First, its opinions are based only on published peer-reviewed studies. Regulators are often provided with studies conducted by the industry which remain hidden from public scrutiny; as a rule these are not available to IARC. However, it may be able to take such studies into account if there are published summaries of their main findings. The other specific feature is that its task is only to *identify hazards*, i.e. the mere possibility for a substance to cause cancer. The different groups – possible, probable, etc, reflect only how certain the evidence for causal effect is, not the actual risk the substance present. For the latter to be assessed, account must be taken not only of the causal relationship but also of the *exposure*, i.e. the amount that is needed for the effect to materialise. This is what is done in *risk assessment* and it is usually conducted by regulatory bodies like EFSA.[41] The third important feature of IARC's assessments is that it considers both studies of the active substances and of compounds. This is in stark contrast with the regulators which normally consider only active substances. In the EU there is a division of labour between Union and national authorities with the former – EFSA – assessing the active substances and the latter – the mixtures. While in theory this is a good example of subsidiarity[42] (and epistemic subsidiarity[43]) taken seriously, in practice the national assessment process is impaired by the dearth of research on each of the hundreds of individual mixtures that are available in the local shops.[44] All these details might appear trivial, but the whole controversy pivoted on which studies could be taken into account and which not; it is important to note that these questions are pre-determined by the regulatory framework each scientific advisor is embedded into. While this framework allows the scientific advisor to be robustly accountable, here it should be apparent how inseparable law and science are. It is worth to note that these differences do not reflect apparent political choices; contrary to EFSA's director cited

[39] K. Z. Guyton, D. Loomis, Y. Grosse et al. (2015) 'Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate', IARC Monograph Working Group, *The Lancet Oncology*, 16(5): 490-491.

[40] IARC/WHO (2017) 'Some Organophosphate Insecticides and Herbicides' *IARC Monographs on the evaluation of carcinogenic risks to humans*, vol. 112. Available at http://monographs.iarc.fr/ENG/Monographs/vol112/index.php, last accessed on 1 May 2018.

[41] Soon after the glyphosate classification IARC's work was attacked in a number of ways, including questioning the value of *hazard classification*, Alan R. Boobis, Samuel M. Cohen, Vicki L. Dellarco et al. (2016) 'Classification schemes for carcinogenicity based on hazard-identification have become outmoded and serve neither science nor society' *Regulatory Toxicology and Pharmacology* 82: 158-166. The authors of this paper, however, were allegedly connected to Monsanto, see Environmental Health News (2017), 'The Monsanto Papers, Part 1 and 2', 20 and 21 November 2017. Available at http://www.ehn.org/monsanto-glyphosate-cancer-smear-campaign-2509710888.html, last accessed 7 March 2018.

[42] Art. 5, Treaty on European Union (TEU).

[43] Sheila Jasanoff (2013) 'Epistemic Subsidiarity – Coexistence, Cosmopolitanism, Constitutionalism', European Journal of Risk Regulation 4(2): 133-141, and Paskalev, 'May Science Be with You', see footnote 11 above.

[44] An excellent example of undone science, compare with Scott Frickel, Sahra Gibbon, Jeff Howard et al. (2010) 'Undone Science: Charting Social Movement and Civil Society Challenges to Research Agenda Setting', Science, Technology & Human Values 35(4): 444-473.

above, IARC's selection of studies does not reflect any values or bigger issues which may or may not be shared by its members. It merely reflects its foundational documents; the resulting differences, however, have huge political importance.

Thus, in terms of accountability IARC seems perfect (at least as far as intellectual robustness is concerned) – *we, the public* have full access to all information the panel members had (although we differ in the ability to understand and interpret it), we know the members and any conflict of interests they may have (more on this below), we know their epistemic policy – identify potential causality, possibly preferring false positives to false negatives (as in contrast to bodies which set standards or prescribe a course of action which might prefer the opposite). Thus, we may know their reasons to interpret the data the way they did. Notwithstanding this, their conclusions on glyphosate were far from universally accepted. It is hardly surprising that they were challenged by the industry, but they were also contested by the scientific regulators all over the world and the controversy with EFSA was particularly bitter. In the Republic of science, one could naively expect that scientific advisors will be ready to accept each other's findings, and disagree only when an error is found. Any such disagreement would be temporary, only until publicly exposed and the error corrected. Scientific accountability would facilitate this process of correction of errors and agreement. Yet in the real world the opposite seems to happen – the accountability rules of each agency – those of EFSA will be discussed below – make sure that they will have different evidence bases. Moreover, they may have different epistemic policies – that is preference for false negatives or false positives, depending on the known consequences of their decisions. As was already pointed out IARC does not consider exposure, and as its decisions do not have *direct* policy consequences it is also uniquely in position not to face any trade-offs; it does not need to balance economic, social and health concerns.

Thus, IARC is likely to rank quite high on the scorecard of any scholar of accountability. Alas, when stakes are high no authority is contestation-proof and even the strongest accountability mechanisms show cracks. In post-2015 IARC at least two alleged conflicts of interest were identified (the use of passive voice is deliberate to avoid naming the source of these contestations). Christopher Portier is an expert in environmental health and carcinogenicity who in 2014 chaired the IARC Advisory Group panel that prioritised substances for subsequent assessment; later he served as 'invited specialist' in the Working Group on glyphosate. As it turned out he was also working as consultant to the Environmental Defence Fund (EDF), a US NGO with a clear anti-pesticide stance. Subsequently to the classification he actively engaged in promotion of the IARC's assessment and urged the European Commission to ignore EFSA's study.[45] Also subsequently he became a paid consultant for the plaintiffs in a class action against Monsanto in the US. IARC insists that there was no conflict of interest as, because of his involvement with the EDF, Dr. Portier acted only as an 'invited specialist' who was not allowed to participate in the evaluation or drafting of

[45] He was the lead author of an elaboration of the issues EFSA failed to appreciate in IARCs monograph, see C.J. Portier, B.K. Armstrong, B.C. Baguley et al. (2016) 'Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)', *J Epidemiol Community Health* 70(8): 741-745, p. 743. He was also the first author of an open letter, signed by some 100 scientists, which called upon the Commission to set aside the assessment by EFSA and decide for itself, see C.J. Portier (2015) 'Open letter: Review of the carcinogenicity of glyphosate by EFSA and BfR', available at https://www.efsa.europa.eu/sites/default/files/Prof_Portier_letter.pdf.

the monograph. More importantly, the Working Group consisted of 17 members who reached a consensual conclusion so any undue influence by any single member can be expected to be counterbalanced.

The other issue raising questions was the exclusion of a major study. The Agricultural Health Study (AHS) is a decade long prospective research project conducted in the US with nearly 90,000 farmers. An early publication (2005) based on it found that 'glyphosate exposure was not associated with cancer incidence overall'. Since then quite a lot of further data was gathered, adding more power to this finding; by 2013 this was clear to the investigators, but it was not published until 2018. Crucially, one of the researchers, Dr. Aaron Blair was the chair of the IARC Working Group on glyphosate. Yet, the new findings were not taken into account by the Working Group as the study was not published at the time, which is a key condition under its rules. Dr. Blair did not even orally report the findings to his colleagues. While publishing results does take years, and such a huge research project yields many different results competing for researchers' attention, an investigation by Kate Kelland of Reuters hints that it might be the case that Dr. Blair was in position to set the priorities and may have delayed this one to prevent its inclusion in the IARC review.[46] As will be seen below, this study was key for the other regulatory agencies who do not have to limit themselves to published studies only.[47] Interestingly, if there was a foul play in this case at all, it would have been made possible by a rule meant to increase the accountability of IARC; on the other hand, the other regulators appear to have been proof to this trick, yet it may be that the trick became visible only because of the rules; elsewhere games could go on unnoticed. After all, how can regulators become aware of studies which are not published?

Finally, IARC's critics claim that its approach is lacking scientific rigour because its working groups include scientists who are reviewing their own research. Now, in the field of regulatory science this has an air of conflict of interests indeed, but does not withstand a second look. It is almost by definition that the experts on an issue will have conducted key studies of this issue themselves. Removing them, or the studies, will either deprive the decision-making body of the best experts or from the most important research. In any event, the head of IARC's monograph programme Kurt Straif claims that this is controlled for by IARC's rules. They ensure, first, that the authors cannot directly evaluate their own studies and, second, the involvement of 20 to 30 people in the discussions should neutralise any such interests.[48] I think this shows where the outer limits of accountability should be and any rule barring the author from partici-

[46] Kate Kelland (2017) 'Cancer agency left in the dark over glyphosate evidence', *Reuters*, 14 June 2017. Available at https://www.reuters.com/investigates/special-report/glyphosate-cancer-data/, last accessed 8 March 2018. For a thorough analysis of Kelland's investigations see Stacey Malkan (2017), 'Reuters' Kate Kelland Again Promotes False Narrative About IARC and Glyphosate Cancer Concerns' *US Right To Know*, 20 October 2017. Available at https://usrtk.org/our-investigations/acc_loves_katekelland/.

[47] Note however that the AHS is also far from being decisive evidence for the safety of glyphosate. As Portier and colleagues were quick to note, 'the median follow-up time in the AHS was 6.7 years, which is unlikely to be long enough to account for cancer latency', see Portier et al. (2016), footnote 45 above, p. 743.

[48] Kate Kelland (Reuters), see footnote 46 above.

pation in the working group altogether would amount to accountability overload, achieving more harm than benefit.[49] In any event, IARC stands behind its classification, but remained isolated. Regulators around the world conducted their own assessments – some prompted by IARC's classification, others due anyway – and reached opposite conclusions. The same year the US Environment Protection Agency (EPA) decided that it is not carcinogenic and so did the German Federal Institute for Risk Assessment (BfR), conducting preparatory work for EFSA. For lack of space, I will focus on the latter only.

European Food Safety Authority

The EFSA was the other key player in the glyphosate saga. It is one of the stronger agencies in the EU, set up to advise the Commission on a wide variety of issues, some of which may be only indirectly related to food and feed (e.g. Bisphenol A). Upon request it conducts risk assessments, which inform the decision of the Commission and/or comitology committees who act as risk managers. Although its opinions are not binding, the Commission tends to follow them, and often claims that it is obliged to do so.[50]

Its independence is contested. Perhaps it is the most *institutionally independent* of all EU agencies, as the 14 members of its Management Board are not representatives of the Member States (which is the case for most newer agencies).[51] There is one Commission representative, 4 representatives of consumer or other stakeholder organisations, and the remaining 9 are independent experts. Yet its independence from the market players was questioned on many occasions, and generated at least one major scandal. On the one hand, EFSA's internal rules and procedures for dealing with conflicts of interests have been strengthened progressively (with the latest round of amendments adopted in June 2017) and appear to be quite rigorous. Thus, in a recent review of the General Food Law, the Commission boasted that 'EFSA has one of the most advanced and robust systems ensuring its independence'.[52] On the other hand, there were a number of examples of revolving doors, one of which made headlines across the world in 2012. It turned out that Diána Bánáti, chair of EFSA's Management Board, failed to disclose that she was a member of the board of International Life Sciences Institute (ILSI)-Europe, an industry-sponsored association promoting the products EFSA is called upon to assess. She left ILSI after the link was exposed by a Green MEP, but the pressure in the European Parliament continued, so she resigned from EFSA to become … a director of ILSI.[53]

[49] Interestingly, in the same report where the Reuters investigator decries that authors are reviewing their own work, she also complains about Dr. Blair not using his own AHS work. This cannot help striking me as incredibly disingenuous.

[50] For a discussion see Vesco Paskalev (2017) 'Losing the Battle, but Winning the War? Standing to Challenge GMO Authorisations and Other Acts Concerning the Environment', *European Journal of Risk Regulation* 8(3): 580-585.

[51] Many studies found that the EU agencies, EFSA included, are subject to much tighter control by the Commission than the formal rules provide, see Busuioc (2009) in footnote 18 above, and more recently Ellen Vos (2016) 'EU Agencies and Independence' in Dominique Ritleng (ed.), *Independence and Legitimacy in the Institutional System of the European Union* (Oxford: Oxford University Press).

[52] Executive summary of the REFIT Review, footnote 12 above.

[53] As a follow up of this scandal EFSA amended its rules to include a two year cooling-off period.

This might be only the tip of the iceberg. Corporate Europe Observatory (CEO), an NGO, identified that nearly half of the EFSA staff has some links to the industry.[54] While this is very worrisome, perhaps it should be taken with a pinch of salt. As Vos notes 'it is at the same time also evident that in practice scientists of good repute who could serve on staff committees of agencies will always be likely to be or have been involved in industry or national affairs'.[55] Indeed, often with the expertise comes the interest so much so that it may be difficult to find a microbiologist with expertise on GMOs who has not been involved in the development of one; even if there is someone who conducted their research in the academia only, the nature of their occupation is very likely to prejudice them to favour commercialisation of the product they have spent years of their lives on. Similarly, it would be very difficult to find a biologist researching certain animal species who has no strong feelings for the conservation of these species. Thus, one may wonder whether 'an independent expert' really exists, and it may be futile to look for one; in the opinion of the present author the best we can do is to make all dependencies visible (i.e. account for them) and to seek their diversification on the relevant boards and panels. Rather than insulating such panels we should be seeking to reconstruct a 'view from everywhere' within them.[56] In any event, for the purposes of this paper I will set these issues aside and focus only on the account required and given by EFSA for its opinion on glyphosate. To anticipate the conclusion, it seems fairly robust (that is, in terms of intellectual robustness). Below I will identify the evidential basis on which the assessment was done and discuss the reasons EFSA gave for deciding the way it did.

The differences between the set of studies that are taken into account by IARC and EFSA were already discussed but now we need to reconsider them with regard to EFSA's rules and aims. Perhaps the most widely discussed difference was that EFSA possesses and must take into account proprietary studies conducted by the applicant. Paradoxically, while this is the biggest source of criticism of EFSA decision, this is also its main defence: it might be that as a matter of law these studies ought to have greater weight than any academic literature and in any event this is how the Commission interprets the law. A very recent review conducted on the General Food Law (GFL)[57] states:

> As regards risk assessment in the context of authorisation dossiers, EFSA is bound by **strict confidentiality rules** and by the legal requirement to primarily base its assessment **on industry studies,** laid down in the GFL Regulation and in the multiple authorisation procedures in specific EU food legislation. These elements **lead civil society to perceive a certain lack of transparency and independence,** having a **negative impact on the acceptability of EFSA's scientific work by the general public.** There is therefore a need to address these issues in order to protect the reputation of EFSA's work.[58]

[54] CEO, 'Recruitment Errors', 17 June 2017, available at https://corporateeurope.org/efsa/2017/06/recruitment-errors.

[55] Vos (2016), see footnote 51 above.

[56] The careful reader would notice that besides this pragmatic reason, there is also a normative one – a panel with a view from everywhere is more likely to be able to provide socially robust justifycations.

[57] Regulation 178/2002 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.

[58] REFIT evaluation, see footnote 12 above, emphasis of the original.

I have difficulties to find where the GFL *requires* EFSA to base its assessment *primarily* on industry studies but systematic interpretation of the Pesticide Regulation suggests this might be the case for pesticides. Art. 8 of the latter provides quite comprehensive requirements for the content of the application dossiers, and is clearly focused on the data that is to be gathered by the applicant. Only its very last paragraph says that 'scientific peer-reviewed open literature … published within the last 10 years … shall be added by the applicant to the dossier'. While this may be understood to give certain priority to the industry studies to provide the minimum baseline data, it is far from certain that these studies should be given *preference* when other data is available. Furthermore, this article is addressed to the applicant as to the information they have to provide, and need not affect the way scientific panels – who are provided with information from variety of other sources – form their opinions. Notwithstanding these disagreements of mine, if this is how priorities are understood by the Commission in its REFIT report, there is little reason to doubt that this is also what EFSA panels are actually doing. As we shall see below, in the case of glyphosate five industry studies were 'key' and 'pivotal' for EFSA's conclusion.[59] Thus, it turns out that one particular interpretation of an obscure article in the relevant law pre-determines which scientific study will carry the day. Anyone still believing in the separation between science and politics? Thus, whatever one thinks of the industry studies, EFSA was fully accountable – to its principal and to the general public – for its relying on it.

My studies vs. your studies

There are five such pivotal studies provided by the industry. The first of them[60] was conducted as early as 1983 in preparation for the initial authorisation application in the US. The competent authority there – the EPA – initially understood it to show 'a significant increase in the incidence of rare tumours, with a dose-related trend, which could be attributed to glyphosate' so it classified glyphosate as 'possibly carcinogenic to humans'. Three years later the EPA – after some exchanges with Monsanto – agreed that the findings were not unequivocal, so they agreed to classify glyphosate as safe, but insisted that the study is repeated. Monsanto balked, and by 1991 EPA dropped its demand thus clearing glyphosate completely. As IARC obtained the study through EPA it could take it into account and interpreted it as showing carcinogenic effect.[61] As a social scientist I cannot help pointing at this wonderful example of 'hard science' being subject to different interpretation and genuine disagreement between scientists (presumably all acting in good faith.) The same study was interpreted favourably in

[59] Words of José Tarazona, the Head of EFSA's Pesticides Unit quoted in Corporate Europe Observatory (2016) 'Key evidence withheld as "trade secret" in EU's controversial risk assessment of glyphosate', 17 February 2016. Available here: https://corporateeurope.org/efsa/2016/02/key-evidence-withheld-trade-secret-eus-controversial-risk-assessment-glyphosate, last accessed on 9 March 2018.

[60] A. Knezevich and G. Hogan (1983) A Chronic Feeding Study of Glyphosate (Roundup Technical) in Mice: Project No. 77-2061: BDN-77420. Final rept. (Unpublished study received Aug 17, 1983 under 524-308; prepared by Bio/dynamics, Inc., submitted by Monsanto Co., Washington, DC; CDL:251007-A; 251008; 251009; 251010; 251011; 251012;251013;251014; (MRID 00130406).

[61] IARC (2017), Monograph 112, see footnote 40 above, p. 394. If one wonders, the reason why two diametrically opposing interpretations of the same study are possible is that the mice were given glyphosate at doses of 150, 1500, or 4500 mg/kg bw per day, and negative effects were observed in males at the highest dose only. Thus one can validly conclude both that 'glyphosate is carcinogenic' and that 'lower doses are safe.'

EFSA's assessment. The second proprietary study, from 1993[62] did not raise such differences, IARC and EFSA seem to be in agreement that no significant carcinogenic effect was shown.

The other three industry studies are more recent and remain unpublished.[63] Crucially, they were made available to EFSA (and EPA) but could not be taken into consideration by IARC. As they were not subject to any peer review, their only quality imprimatur is the compliance with the OECD Guideline 451 & Good Laboratory Practice (GLP) guidelines. While it is far from certain whether peer review per se is a guarantee of quality and reliability,[64] the publication and availability of the raw data is a key factor assuring that misinterpretation, errors and fraud – especially in a case that is so contested – will be discovered. The compliance with certain protocols – even if they were very strict – cannot substitute the critical eye. Thus, EFSA's conclusion came under fire immediately. Dr. Christopher Portier and some 100 colleagues published an open letter and an accompanying paper urging the European Commission to disregard EFSA's assessment because of, inter alia, its reliance on these unverifiable studies.[65] As every lawyer knows, compliance with cumbersome legal procedures is a prerequisite but not a guarantee for substantive correctness of the decision. However, this criticism misses to note that these studies – presumably with the raw data – were subject to review by the peers sitting in EFSA's scientific panels. Thus, in my view – the formal requirements provided by the GLP guidelines *when combined* with the critical eye of the members of a regulatory committees could, in principle, provide a strong accountability mechanism while still respecting the need for protection of trade secrets.[66] What derails the mechanism in this case is that as was shown earlier, the integrity of the EFSA scientists is not accepted by all.

Further to these three sequestered studies, there are some studies that were available to EFSA (and the public) but were not taken (sufficient) account of. When assessing toxicity there are two major types of studies – animal studies where a group of lab animals are exposed to the substance under investigation and their wellbeing is

[62] C. Atkinson, T. Martin, P. Hudson and D. Robb (1993) 'Glyphosate: 104 week dietary carcinogenicity study in mice'. Unpublished report No. 7793, IRI project No. 438618, dated 12 April 1991, from Inveresk Research International, Tranent, Scotland. Submitted to WHO by Cheminova A/S, Lemvig, Denmark.

[63] 'Carcinogenicity Study with Glyphosate Technical in Swiss Albino Mice' (2001), owned by the Israeli company ADAMA Agan Ltd (unpublished);

'Glyphosate technical: Dietary Carcinogenicity Study in the Mouse' (2009), study owned by the Australian company Nufarm (unpublished);

'HR-001: 18-Month Oral Oncogenicity Study in Mice' (1997), owned by the Japanese company Arysta LifeSciences Corporation (unpublished).

[64] A spoof paper with obvious mistakes submitted to some 200 peer-reviewed journals was accepted by nearly half of them, see John Bohannon (2013) 'Who's Afraid of Peer Review?',*Science Magazine* 342(6154): 60-65.

[65] Portier et al., see footnote 45 above, at p. 743 (with a reference to J.P. Myers, F.S. vom Saal, B.T Akingbemi et al. (2009) 'Why public health agencies cannot depend on good laboratory practices as a criterion for selecting data: the case of bisphenol A', *Environmental Health* Perspectives 117(3): 309-315).

[66] This need is itself dubious in this case – glyphosate is now generic, and produced by hundreds of companies worldwide; the biggest of them joined forces in the Glyphosate Task Force which submitted the studies in the re-authorisation dossier. So one cannot help wondering what are the secrets that are being protected, and from whom?

compared to a control group of animals in the same environment with the only difference that they are not subject to the treatment. This is accepted to prove causal relationship. The trouble is that not all effects that are observed in animals will affect humans. As it would be unethical to make similar experiments with humans, adverse effects on humans are observed through the so called epidemiological studies where the conditions of a large group of people who are exposed to the substance anyway is compared with a similar group of people who are not so exposed. The problem with this is that the similarity of the two groups is never sufficient to prove causality – even if we control for factors like age, smoking etc., still the differences between the two groups may be attributed to factors other than the investigated substance.

In the glyphosate assessment IARC relied on both types of studies. As was mentioned above, it concluded that there was sufficient evidence for carcinogenicity in animals and limited evidence for humans. As the subject of its assessment was not the active substance only, but also any compounds based on it, there were a few epidemiological studies available, enough to conclude that there is 'limited' evidence for carcinogenicity for humans.[67] When EFSA is to consider the same studies additional difficulty arises. While the animal studies can be conducted with pure glyphosate, the epidemiological studies are mostly of compounds as glyphosate is always used in compounds. This adds further differences to control for and makes epidemiological studies less conclusive for the purposes of the regulators. The broader subject of IARC's assessment allows the accumulation of the studies of the different mixtures; for EFSA the other chemicals in the mixtures became confounding factors and it becomes more difficult to cumulate studies of different mixtures: is this weak adverse effect due to glyphosate, or is it attributable to another chemical in a particular mixture which was not present in another study of another mixture that showed yet another effect?[68] As it turns out, the subject of assessment determines the selection and the weight of the different type of evidence.

Finally, the subtle difference between hazard identification and risk assessment plays a hugely significant role. IARC which considers whether glyphosate, or glyphosate-based compounds, can cause cancer, would count as positive all findings, regardless of the exposure level at which they are observed. On the other hand, EFSA which considers whether glyphosate presents actual risk to humans may discount studies where the positive effect is found only on exposure levels which no human is realistically exposed to.[69] Again, the detailed prescriptions for each regulator controls what is to be

[67] Note that the wider scope of assessment allows to IARC's experts a certain discretion. As one of Arcuri's interviewees explains: 'we had lots of studies with both pure glyphosate and the formulations … and we concluded that there is enough evidence … that it was glyphosate that was really causing the problem … not all the adjuvants, not formulations, glyphosate … so the IARC review is that glyphosate is a probable human carcinogen …and it was a conscious decision'. See Arcuri (2019 forthcoming), see footnote 15 above.

[68] Note however that one of the key studies 'exculpating' glyphosate - the AHS discussed above - is epidemiological.

[69] Note however that it is a bit misleading to say that EFSA considers 'exposure'. It does consider *dose response* to the substance, but it does not monitor or take into account what the actual exposure of farmers or citizens to glyphosate is at the moment. It only prescribes safe exposure thresholds. Thus, it allows the industry to boost that it is harmful only if you consume, say, 1000 portions of veggies in a day. Such statements may sound reassuring, but skirt the question whether we have not been exposed already to the equivalent of 999 units from a variety of other sources (water, soil, etc). This is by no means a hypothetical concern for the people whose homes are adjacent to the fields but whose exposure is not considered in any of the assessments, see footnote 31 above.

taken into account and how much. By now it should be obvious, that the decisions whether an agency should assess active substances or mixtures, whether it can include unpublished studies or not, etc. are by no means 'technical'. Their political nature requires that they are addressed at the appropriate political level.

Glyphosate endgame

EFSA issued its opinion on 12 November 2015.[70] It was followed by a number of explanatory statements or letters to respond to critics – above all IARC's chair and Dr. Portier – and in 2017 it issued a separate opinion on the potential endocrine disruptions caused by glyphosate (this was also negative).[71] Weary of the strong opposition against reauthorisation, but unable (or unwilling) to take any of the 'other' concerns into account, the Commission did not move on as soon as it could, but mandated the European Chemicals Agency (ECHA) to opine on glyphosate's carcinogenicity too. On 15 March 2017 the latter announced its conclusions that glyphosate is not carcinogenic.[72] In the meantime the European Parliament adopted a (non-binding) resolution calling for the phasing out of glyphosate.[73] Under the existing regulations the risk management decision is taken jointly by the Commission and a 'comitology committee', where national experts from each Member State vote on a proposal by the Commission. Comitology is a famously consensual procedure[74], but on this occasion a number of Member States remained opposed (or abstained) so that the Standing Committee on Plants, Animals, Food and Feed failed to reach a decision either way. The Commission's rhetoric changed. While the Committee's failure to agree opens the gate for it to approve (as per its proposal and as it always does), it sought 'support' among Member States to proceed. It also decreased the duration of the proposed reauthorisation, from the 15 years initially sought, down to 10 and eventually to 5 years only.[75] Such sensitivity on the part of the Commission is very much welcome and is in stark contrast to its approach on GMOs where lack of support does not prevent it from proceeding with the authorisations, even in the face of the opposition of the EP and sometimes as many as 15 Member States.

A window of opportunity appeared in November 2017 when the coalition talks between the Christian Democrats and the Greens collapsed, so Germany, which had previously abstained, voted for reauthorisation. Thus, glyphosate was saved – in the 11th hour, just

[70] EFSA (2015) 'Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate', *EFSA Journal* 13(11): 4302.

[71] EFSA (2017) 'Peer review of the pesticide risk assessment of the potential endocrine disrupting properties of glyphosate', *EFSA Journal* 15(9): 4979.

[72] ECHA (RAC) (2017) Opinion proposing harmonised classification and labelling at EU level of glyphosate (ISO); N-(phosphonomethyl)glycine, 15 March 2017, CLH-O-0000001412-86-149/F, available at https://echa.europa.eu/documents/10162/2f8b5c7f-030f-5d3a-e87e-0262fb392f38, last accessed on 1 May 2018.

[73] European Parliament resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate (D053565-01 – 2017/2904(RSP)). Available at: http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2017-0395&language=EN, last accessed on 7 January 2019.

[74] Christian Joerges and Jurgen Neyer (1997) 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology', *European Law Journal* 3(3): 273-299.

[75] This coincides with the duration of the phase-out period proposed by the EP.

before its license was about to expire on 15 December 2017, and for 5 years only. This is hardly long enough for the current controversy to subside before the new one erupts. Indeed, the EP already established a temporary committee to look further into the issue. Meanwhile France and Italy announced that they will not authorise glyphosate-based products on their territories. As Alberto Alemanno notes, the reauthorisation, in the way it happened, was a Pyrrhic victory for the industry and glyphosate is now living on borrowed time.[76] This may appear to be far too optimistic to the environmentalists who would rather see it as yet another snub by the unresponsive industry-captured bureaucrats. Yet I agree with Alemanno that the case demonstrates that the interactions between democratic participatory mechanisms and the formal structures are growing.[77] However one should beware that this was a rather exceptional case, greatly facilitated by the involvement of another scientific advisor with a differing position, therefore it could happen *despite* the existing regime which provides plenty of formal openings for participation but is substantively closed for participants' most important concerns.

While the scientific arguments were going on, a European Citizens Initiative (ECI) was launched, with proposals (1) glyphosate to be banned, (2) risk assessments to be based not on industry studies but on such commissioned by the authorities, and (3) mandatory targets for decreased pesticide use to be set by law. Although it gathered the necessary million signatures, the Commission rejected the first of these on the ground that pesticide authorisations are executive acts under the existing regulations rather than a legislative issue of the kind ECI is meant for.[78] The second proposal was taken a little more seriously and in April 2018 the Commission did announce proposals for reforms of the risk assessment process.[79] While they do propose to make industry studies more transparent and open to contestation their pivotal place in risk assessment seems to be intact.[80]

[76] Alberto Alemanno (2017) 'Glyphosate renewal is a Pyrrhic victory for Monsanto', *EU Observer*, 28 November 2017, available at https://euobserver.com/opinion/140058, last accessed on 19 April 2018.

[77] Ibid.

[78] Communication from the Commission on the ECI 'Ban glyphosate and protect people and the environment from toxic pesticides' C(2017) 8414 final, available at: http://ec.europa.eu/transparency/regdoc/rep/3/2017/EN/C-2017-8414-F1-EN-MAIN-PART-1.PDF, last accessed on 1 May 2018.

[79] See European Commission (2018) 'Commission's proposal on transparency and sustainability of the EU risk assessment model in the food chain', 11 April 2018, available at http://europa.eu/rapid/press-release_MEMO-18-2942_en.htm. For the initial reactions see Sarantis Michalopoulos (2018) 'Commission efforts to build trust in food safety receives mixed reviews', *Euractiv*, 11 April 2018, available at https://www.euractiv.com/section/agriculture-food/news/commission-efforts-to-build-trust-in-food-safety-receives-mixed-feelings/, last accessed on 1 May 1, 2018.

[80] The analysis of the Commission's response to the European Citizen Initiative and the new transparency proposals is beyond the scope of this paper. For a comprehensive early analysis, see Natassa Athanasiadou (2018) 'Towards more public control of scientific studies? Revisiting the independence of expertise in the glyphosate era', presented at the TARN-Conference on EU Agencies: Performance, Operability & the Accountability Overload: Squaring the Impossible Circle? Brussels, 12-13 April 2018.

Conclusion

Thus, in the long and controversial assessment of glyphosate the basic requirements to 'explain and justify' were seemingly satisfied by both IARC and EFSA. Yet neither of the two agencies was able to take into account the 'other' concerns stakeholders have against glyphosate which in view of the present author should be added for the justification to be socially robust. Thus, the established regime of science-based regulation prioritises certain concerns – in this case about carcinogenicity – and marginalises all others. Those who care for the spread of green deserts, the corporate grip on the food chain etc. have the unenviable choice to either engage in a proxy war over carcinogenicity or to have their voices left out completely. There are a few other things that the glyphosate saga made clear. The first is that different scientific assessors can arrive at different conclusions on seemingly the same scientific question while giving intellectually robust accounts for their decisions. Actually, the divergence seems to be not despite the strong accountability rules, but at least to some part because of them. It was because each of the agencies was following its own epistemic policies – which significantly differed – that they decided as they did; at least they very well could justify their choices by reliance on the respective rules. Now, this is not to say that the advisors did not have any discretion, and were just mouthpieces of 'Science' or 'The Law'; in my view the opposite is more likely to be the case.

This brings us to the case study's second finding, namely that seemingly trivial, 'technical' differences in the respective rules can bring about huge differences in the outcome. It is important to note however, that the way the tiny details can reverse the outcome is transparent for any sophisticated observer – that is, assessors and stakeholders – so much so that they all focus their attention on the 'technical' details and fight what I called proxy wars. The epistemic rules give leverage to seemingly technical arguments to bring about politically significant changes of the outcomes; *this* rather than the behaviour or the parties is what brings about 'politicisation' of science. On the other hand, while it is true that the legal framework forces the assessor into a certain pathway and determines their evidential base, this does not remove their discretion; it only moves the choice from the apparently political to what appears 'technical'. No matter how precise the regulations are it would always be for the assessor to *choose* what is permissible to be taken into account, when findings are inconclusive – as they always are – how to interpret them, and when different studies contradict each other – as they inevitably do – how to weigh them. The choice remains whether to report an unpublished study or not, whether an epidemiological study is less telling than a lab experiment, whether some tiny dots in the tissues of a few mice dead since 1983 are malign or not. In the current risk regulation paradigm these technical choices have become very consequential and have substituted the choices of whether to allow or hinder the spread of certain types of agriculture, whether to increase the dominance of certain companies over the global food chains or whether certain chemicals will be thrusted into our bodies. While this shift towards the 'technical' may be unavoidable if we want governance to be informed by science, we can at least face it with eyes wide open for the highly political nature of the 'technical'. Accountability – as the basic requirement for the decision-makers (or risk assessors in this case) to explain and justify their choices – simultaneously enables them to present their decisions as 'objective' and inevitable, but also allows us to trace where a space for discretionary choice was opened. The final contribution this case study claims is to have shown that the right question is not whether we have too much or too little accountability, but how any given accountability rule shifts the locus of the power to choose.