What counts as expertise? The case of glyphosate and Jasanoff’s ‘three-body problem’

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Abstract
In 2015, the International Agency for Research on Cancer of the World Health Organisation published a monograph stating that glyphosate, the active ingredient in Roundup, Monsanto’s leading herbicide, was ‘probably carcinogenic to humans’. Shortly after this, the European Food Safety Authority reassessed glyphosate’s licence for use in the European Union, and deemed it to be safe for human use. Both of these expert advisory bodies faced condemnation and accusations of political bias as a result of these assessments. Employing Jasanoff’s ‘three-body problem’, this article examines the conflicting conclusions of the International Agency for Research on Cancer and the European Food Safety Authority, exploring what the contested assessments of glyphosate reveal about the entangled relationship between scientific expertise and law-making.

Introduction
Glyphosate is the active ingredient in Roundup and Roundup-related products, and is the herbicide with the largest production volume in the world.1 Roundup is produced by the Monsanto Company, one of the world’s most successful life-sciences companies; it is their flagship brand.2 It is currently unclear whether glyphosate poses a health risk to humans. Many researchers claim that glyphosate poses no health risk; studies by Giesy et al (2000) and Williams et al (2000) (two heavily cited studies from respected journals) found that glyphosate poses no health risk, with Williams et al clearly stating that, ‘under present and expected conditions of use, Roundup herbicide does not pose a health risk to humans’.3 However, there have been growing concerns over widespread pesticide and herbicide use and its impact on the environment and on public health.4 Glyphosate has been a focus of this concern. It garnered public attention in 2015, as the cancer research agency of the World Health Organisation (WHO) stated that it was ‘probably carcinogenic to humans’,5 and as its licence for use in the European Union (EU) was due for renewal. The treatment of glyphosate by these various public bodies illuminates the complex interplay between political action, scientific research and public and...
corporate interest that forms the policy-making process and highlights the multiple challenges of evidence-based environmental policy-making.

This article will use Sheila Jasanoff’s ‘three-body problem’ as a frame through which to examine the halting progress of glyphosate licence renewal through the various bodies of the EU. Broadly speaking, the problem Jasanoff’s frame addresses is that rule by the experts is fundamentally incompatible with rule by the people. The relationship between science and the state has grown ever more fraught and complex, moving away from the post-war vision of science-state cooperation set out by Vannevar Bush in 1945. Many factors have influenced this move and have consequently influenced the political accountability of scientific expertise. Jasanoff asks us to consider the problem of expert legitimacy as a ‘three-body problem’, paying attention to each sphere in which scientific knowledge is implicated in the political process. These are:

1. The body of relevant scientific knowledge.
2. The body of the individual scientific expert. 
3. The collective bodies that advise governments.

This analytical framework enables its user to distinguish the various stages at which science and law interact. The potential risk in employing this framework is that it could portray a static vision of the dynamic interactions of scientific knowledge and political process; this article will attempt to avoid this over-compartmentalising. Jasanoff criticises existing accountability mechanisms, stating that:

No national [or supranational] decision-making system has as yet taken on board the fundamental STS insight that experts construct – they do not simply find – the knowledge base on which they rest their hybrid analytic deliberative judgments.

With this failing in mind, this article will examine the role of scientific knowledge, scientific experts and the political bodies through which scientific expertise is adopted in environmental policy-making, using the case study of glyphosate in Europe as a lens through which to consider these science-state interactions. With growing public concern in environmental issues and with the role of scientific expertise in risk assessment and regulation unclear, it is critical that the multiple levels and processes in which scientific expertise and law work together are properly understood, and that possible weaknesses, inequalities and conflicts are identified.

Introducing the concepts: Knowledge, expertise and expert advisory bodies

Science in law: Scientific knowledge

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6 Evidence-based policy denotes an intention to formulate policy around the best available evidence and for it to be informed by expert knowledge. Scientific expertise gains greater prominence in policy areas that rely on complex, modern technology and natural science; there are many such areas in environmental policy. Practitioners contend that a focus on evidence in decision-making has led to an important distinction between values and evidence. There has been a gradual shift in the factors informing decision-making, away from a focus on values and available resources; the expectation in contemporary society is that decisions rely on sound evidence.


10 See Jasanoff, above n. 8 at 163
The regulation of science and technology, whether to further innovation or to control risk, can fruitfully be seen as a kind of story-telling by communities situated in particular times and places who are attempting to deal with unsettling or disruptive changes in their environments.\textsuperscript{11}

The statement above represents the social constructivist view of scientific knowledge, highlighting the influence of public values and the political context on the scientific knowledge that informs policy. If scientific knowledge is understood to be socially constructed, do we still recognise its legitimacy? Certain scientists take the social constructivist approach in science studies as an attack on science, uncomfortable perhaps with this questioning of the positivist worldview; this conflict is ably described by Levine among others.\textsuperscript{12} Scientific knowledge is valued in law-making due to its perceived objectivity. It seems wiser to rely on scientific facts rather than politically motivated actors; truth is better served by ‘impersonal agents’ rather than by ‘fallible human beings’.\textsuperscript{13} This view relies on an understanding of scientific knowledge as Truth, hermetically sealed and ready to be factored into policymaking considerations. It ignores the fact that scientific knowledge used in law-making is sifted, analysed, assessed and compiled. The nuanced findings with which scientists contend are reframed as unambiguous facts, making them more amenable to law-makers. Moreover, as Jasanoff notes, ‘the questions that contemporary policy-makers ask of science are rarely of a kind that can be answered by scientists from within the parameters of their home disciplines’.\textsuperscript{14} Rather, policymakers require interdisciplinary scientific knowledge, thereby intensifying the level of human involvement in the production of scientific knowledge.

While the socially constructed nature of scientific knowledge might undermine its legitimacy in the legal sphere, Science’s involvement in the legal sphere similarly damages its own legitimacy. In \textit{The Normative Structure of Science}, Merton identified four norms upon which the ethos of modern science is built: ‘organised skepticism’, communalism, universalism and disinterestedness.\textsuperscript{15} These fundamental norms of scientific endeavour are shaken when science enters the legal system and when it enters the marketplace.\textsuperscript{16} Communalism is undermined when study findings are kept confidential as a form of proprietary knowledge. Moreover, disinterestedness and skepticism can no longer be guaranteed if scientific knowledge is used with a particular aim in mind. Scientific facts, when they are employed in justice or regulatory systems, become evidence.\textsuperscript{17} They are facts viewed in a certain light for a certain purpose.

The objective truth of scientific knowledge is affected by the scientific experts who work with it; it is similarly shaped by the prevailing political and moral context. When scientific knowledge is incorporated in environmental policy-making, for example, it is influenced by social assumptions around nature/culture divisions, around notions of validity, causation, safety and risk.\textsuperscript{18} While reflecting on the norms and assumptions embedded in the production of scientific knowledge, Jasanoff notes that law and science operate according to different notions of truth.\textsuperscript{19} This difference stems from the distinct purposes and contexts of science and law; that legal facts are specific and retrospective, while science facts tend to be more general and forward-looking; that timeliness is

\begin{itemize}
  \item \textsuperscript{12} G. Levine, ‘What is Science Studies for and Who Cares?’ (1996) 46/47 Social Text 113.
  \item \textsuperscript{14} Above n. 8 at 152.
  \item \textsuperscript{15} R.K. Merton, The Sociology of Science: Theoretical and Empirical Investigations (University of Chicago Press, 1973) 268.
  \item \textsuperscript{16} See Jasanoff above n. 13 at 329.
  \item \textsuperscript{17} Ibid, at 329.
  \item \textsuperscript{18} See Jasanoff above n. 11 at 13.
  \item \textsuperscript{19} Above n. 13 at 332.
\end{itemize}
more of a concern for legal facts than it is for science facts; and that the ethics of employing and producing these facts vary in these different contexts.\textsuperscript{20}

Competing considerations of legitimacy can pull science and law-making in different directions. Scientific legitimacy is built on the four norms identified by Merton, within which the objectivity of scientific knowledge is central. The legitimacy of political bodies is dependent on the extent to which they uphold public values and serve the public political will. These legitimacy claims are fundamental to science and to law; does this mean that scientific knowledge and political systems must exist in continual disharmony? Winickoff et al propose that greater public involvement in developing science policy decision-making would help ensure that the ‘epistemic authority of sound science’ is balanced by due consideration of public values, thereby enhancing the legitimacy of legislation dependent on scientific knowledge.\textsuperscript{21} Political processes, typically more attuned to public concerns, should lead on issues that provoke a high level of public concern, as is the case with GM technologies.

\textit{Science in law: Scientific experts}

The legitimacy of scientific expertise in policy-making has faced sustained criticism; Collins and Evans term this investigation the ‘second wave of science studies’.\textsuperscript{22} Theorists have taken different approaches in seeking to address this ‘legitimacy problem’, with some recommending the strict limiting of the role of the scientific expert in policy-making. Bernstein specifies five contingencies in which expertise is useful in policy-making: where data collection and analysis is complex; where discretion is limited; where their focus is narrow and specific; where they are applying set policy to particular contexts rather than creating new policy, and where there is a clearly defined public interest.\textsuperscript{23} These parameters reveal a reluctance to leave scientific experts with scope for policy-making, and strongly suggest that expert input is at its best when it is clearly defined. This reluctance is reinforced by growing concern over the increasing clout of scientific experts in policy-making and over their lack of accountability.\textsuperscript{24} Relevant to environmental policy, activists highlight the proximity of scientific experts and multinational corporations, such as the food and biotechnology industries, viewing this trend as a worrying development for public health and the environment.\textsuperscript{25} Scientific experts can fall prey to the ‘capture paradigm’, where experts and agencies grow too close to the industries they seek to regulate and accept with insufficient independent analysis the case proposed by the regulated industry.\textsuperscript{26} Whilst wary of the growing authority of scientific expertise and over experts’ lack of accountability, the quality of the expert advice and legitimacy of the expert become central concerns for policymakers.\textsuperscript{27} The increasing interdependence of science and political bodies – what Weingart refers to as the ‘scientification of politics and the politicization of science’ –

\textsuperscript{20} Ibid 333.
\textsuperscript{22} H. Collins and R. Evans, ‘The Third Wave of Science Studies: Studies of Expertise and Experience’ (2002) 32(2) Social Studies of Science 235 at 239.
\textsuperscript{24} Above n. 8 at 150.
\textsuperscript{25} See Jasanoff, above n 23 at 11.
\textsuperscript{26} Ibid, at 15.
\textsuperscript{27} Scientific research often fails to meet its own criteria for validity. A survey conducted by Nature found that 70 per cent of researchers failed to reproduce their peers’ experiments, and that 50 per cent failed to reproduce their own experiments, See M. Baker, ‘1,500 Scientists Lift the Lid on Reproducibility’ (2016) Nature, 28 July, Available at: http://go.nature.com/1YZAx6R (last accessed 20 June 2017).
complicates this issue.\textsuperscript{28} The legitimacy of the environmental policy being formulated is bound up with the legitimacy of the relevant scientific expert.\textsuperscript{29}

Policy-making is a political process, driven by the values of political actors. What role do scientists, ‘professionally committed to impartiality’, play in this process?\textsuperscript{30} Unsurprisingly, the role of the scientific expert advising on policy is inherently conflicted. Scientific experts are alternately treated with either deference or suspicion by other political actors.\textsuperscript{31} How do scientific experts maintain their disinterestedness (as Merton highlights, fundamental to their legitimacy) while operating in the political sphere? Gieryn coins the term ‘boundary-work’ to describe the strategies undertaken by scientific experts to distinguish their work from the political context, maintaining their intellectual authority and seeking to safeguard the autonomy of scientific research.\textsuperscript{32} The credibility of the scientific experts is inextricably bound to the credibility of the knowledge they produce and ultimately with the credibility of the expert advisory agency to which they are affiliated. The case study section of this article will explore questions of credibility that arose for the European Food Safety Authority (EFSA), the advisory agency that played a key role in glyphosate re-licensing in the EU.

Another concern raised by those questioning the rise of the scientific expert in policy-making is that it restricts the epistemological perspectives that are included in policy-making processes. When a particular decision is framed not as a socially constructed choice but as an objective scientific fact, it becomes much harder to question the underlying normative assumptions that are at play.\textsuperscript{33} The issue has already been framed and it becomes difficult to think beyond the set paradigm.\textsuperscript{34} This is particularly problematic when one recalls the commitment to a ‘greater democratization of global environmental knowledge’ made by the Intergovernmental Panel on Climate Change (IPCC).\textsuperscript{35} The ‘boundary-work’ referred to earlier not only safeguards the authority of scientific experts, it can also withhold authority from other forms of knowledge, devaluing them and impeding their ability to join these policy-making processes. Another solution proposed for the ‘legitimacy problem’ is to extend the field of expertise beyond technical experts to ‘experience-based experts’, to include the input of people who have knowledge and experience specific to the issue at hand.\textsuperscript{36} The reimagining of the ‘expert’ not only addresses the problem of ‘expert legitimacy’; it recognises and challenges the epistemic hierarchy entailed in conventional understandings of scientific expertise.

Science in law: The expert advisory body

The expert advisory body is the final stage in Jasanoff’s ‘three-body’ problem. Mirroring assumptions concerning scientific knowledge and scientific experts, it is assumed that expert advisory bodies, ‘inject a much-needed strain of competence and critical intelligence into a regulatory system that otherwise seems all too vulnerable to the demands of politics’.\textsuperscript{37}

Efforts are often made to protect the expert advisory body from becoming overly politicised; these serve to highlight the fact that the advisory bodies engage in ‘political work’. The advisory agencies

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\textsuperscript{30} Above n. 23 at 7.

\textsuperscript{31} Ibid, at 9.


\textsuperscript{34} Ibid, at 444.

\textsuperscript{35} Ibid, at 451.

\textsuperscript{36} See Collins and Evans above n. 22 at 238.

\textsuperscript{37} Above n. 23 at 1.
operating within the EU are guided by the Meroni Doctrine, which states that the agencies, ‘may only perform tasks that have been explicitly attributed to them and do so within the legal boundaries prescribed in the delegating provisions’.\(^{38}\) The European Food Safety Authority (EFSA) was established by the General Food Law, Regulation 178/2002, which states that EFSA assessments will be based on available scientific evidence and undertaken in an independent, objective and transparent manner.\(^{39}\) Notably, the General Food Law makes a distinction between risk assessment, the purview of EFSA, and risk management, a more political process requiring not only scientific considerations but also ‘societal, economic, traditional, ethical and environmental factors’,\(^ {40}\) identified as the responsibility of EFSA, the Commission and the Member States.\(^ {41}\) This reflects a common tendency within policymaking structures to separate risk assessment, seen as neutral, and risk management, seen as value-laden.\(^ {42}\) Similar to scientists’ ‘boundary-work’, it seeks to protect the credibility of the advisory body by limiting its explicitly political function. However, this separation might serve to mask reality, most notably in areas of environmental policy concerning new technologies, where potential risks to public and environmental wellbeing are emerging as the technology develops. In their amicus curiae brief to the Dispute Settlement Panel of the World Trade Organization, Busch et al imagine ‘risk situations’ as falling within a matrix characterised by certainty and consensus; the science surrounding GM technologies, for example, can be classified as having low certainty and low consensus.\(^ {43}\) In practice, the distinction between risk assessment and risk management is much less clearly defined, and the work of expert advisory bodies not as simply limited as Bernstein, in his five points, wishes it to be. The disparity between the theoretical and actual work of expert advisory bodies might account for the rising numbers of ethics or oversight committees, this trend perhaps further underlining the fact that scientific knowledge cannot be taken in isolation, but must be understood by examining the purpose for which it is employed and by mapping its potential benefits.\(^ {44}\)

Despite the distinctions made between risk assessment and risk management, the ‘boundary work’ of experts, and the legislation that limits their capacities, it is evident that expert advisory bodies operate in a political environment and, to a certain extent, engage in political work. They operate within a political culture, defined by Jasanoff as ‘the systematic means by which a political community makes binding collective choices’, informed by a mix of ‘institutionally sanctioned modes’ and ‘unwritten codes’.\(^ {45}\)\(^ {46}\) This includes, but is not limited to: the fundamental values of a particular political context (for example the importance of individual liberty in Western liberal democracies) and the norms that shape the everyday functioning of the legal-political system (for example, the adversarial approach to regulation that exists in the United States,\(^ {46}\) and the concerns regarding democratic legitimacy evident in the EU).\(^ {47}\) Variances in national regulation reveal that similar scientific knowledge does not necessarily produce similar regulations,\(^ {48}\) thus highlighting the influence of different political cultures,


\(^{40}\) Ibid, para 19.

\(^{41}\) Ibid, para 22.


\(^{44}\) Ibid, at 696.

\(^{45}\) Ibid, at 18.

\(^{46}\) Ibid, at 75.

\(^{47}\) Above n. 9.

\(^{48}\) Above n. 11 at 21.
and underlining the socially constructed nature of the scientific knowledge employed in policy-making. Where, as with GM technologies, science has not achieved consensus, this divergence intensifies. Regulations are a response to ‘techno-scientific uncertainty’, in cases where scientific certainty is low, this uncertainty can be used as a political resource by actors seeking to shape policy, for example by lobbying regulators as well as political representatives and by relying on amenable studies while ignoring those that might challenge their agenda. Having introduced the three fields in which law and scientific expertise interact, this article will now turn its attention to the renewal of glyphosate’s licence in the EU, exploring what this recent case reveals about the uneasy relationship between law and scientific expertise in environmental policy.

**Case study: Glyphosate**

*Glyphosate and scientific knowledge*

The preceding section focused on concerns surrounding expert legitimacy, examining how the use of scientific expertise was contested at each level, as scientific knowledge, in the role of the scientific expert and in the functioning of the expert advisory body. The implications of political involvement for scientific integrity and legitimacy were further explored. The following section takes the recent case of glyphosate’s re-licensing in the EU, utilising the frames of scientific knowledge, scientific experts and the expert advisory body to consider the particular challenges facing scientific expertise in policy-making on a topic of low scientific certainty and increased public concern.

Glyphosate-based herbicides, namely Roundup and Roundup-related products, have been in use around the world since the 1970s. Despite their popularity, the impact of glyphosate-based herbicides on human health is uncertain. As was previously noted, the science surrounding genetically modified crops and biotechnologies is particularly contested. It is worth highlighting that the majority of studies investigating the potential health implications of widespread herbicide use have focused exclusively on glyphosate and do not study Roundup, the formulation in which it typically interacts with the public and the environment, contravening EU guidance that states that a ‘whole mixture approach is recommended for any unidentified materials in the mixture and for any interactions among the mixture components’. This is despite the fact that there have been concerns raised over the other ingredients of Roundup, most notably its surface agent, polyoxyethyleneamine (POEA). A study conducted by Benachour and Séralini tested glyphosate alone and with POEA, and found that the formulation of POEA and glyphosate was significantly more toxic; ‘Roundup adjuvants like POEA change human cell permeability and amplify toxicity induced already by Glyphosate, through apoptosis and necrosis’.

In 2012, Gilles-Eric Séralini and his colleagues published a paper in Food and Chemical Toxicology setting out the results of their two-year study of the long-term toxicity of Roundup-tolerant maize and

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49 Ibid, at 133
50 Above n. 23 at 6.
52 Roundup is a herbicide developed for use alongside genetically modified crops.
Roundup herbicide formulations. They found that long-term exposure to Roundup damaged the livers and kidneys of rats in the study and led to the development of tumours. Séralini and his colleagues faced sustained criticism after the publication of this paper, with some colleagues accusing them of ‘fraudulent or knowingly inaccurate statements’, of ‘unethical behaviour’, of practising ‘flawed science’, of providing ‘ammunition for extremists’ and of engaging in a ‘transparent attempt to discredit regulatory agencies’. The criticism levelled at Séralini and his colleagues illuminates the tense and tangled relationship between scientific expertise and politics. Their critics condemned the scientists for engaging in ‘bad science’ as a political act, claiming that it was politically motivated. They even claimed that this study was intended to discredit regulatory agencies; clearly demonstrating that scientific objectivity is a value upon which political legitimacy rests. Séralini claimed that the most vocal critics of the study were affiliated with Monsanto, and that their criticisms were motivated by conflicts of interest.

In November 2013, the paper was retracted by the editor-in-chief of Food and Chemical Toxicology, A. Wallace Hayes, on the grounds that the study was ‘inconclusive’. Séralini et al highlight that ‘inconclusiveness’ is insufficient reason for retracting an article, according to the retraction guidelines of the Committee on Publication Ethics. The retraction of the study provoked a strong response within the scientific community. An open letter, with nine authors and 126 signatories, was written in Independent Science News, framing the case of the 2012 Séralini paper as symptomatic of a growing trend of harassment of scientists publishing studies unfavourable to GM technologies. In the letter, they contended that:

> When those with a vested interest attempt to sow unreasonable doubt around inconvenient results, or when governments exploit political opportunities by picking and choosing from scientific evidence, they jeopardise public confidence in scientific methods and institutions, and also put their own citizenry at risk.

In 2014, the study was republished in Environmental Sciences Europe, an open access journal owned by SpringerLink. The response, retraction and republication of the Séralini article highlight potential issues for scientific data as it enters the political sphere. Firstly, it is worth highlighting that Séralini et al were not taking part in a risk assessment of glyphosate with this article. They were not sitting on, or submitting evidence to, an expert advisory committee. There was no explicitly political or policy-focused intent to this article. They were research scientists, publishing a scientific study, in a peer-reviewed scientific journal. However, their critics accused them of engaging in ‘bad science’ and being

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57 Ibid, at 2.
59 Ibid, at 3.
60 Ibid, at 1.
64 Ibid.
65 See Séralini et al above n. 58.
overly influenced by their political beliefs. Séralini et al in turn accused their critics of political bias. This case indicates that the political sphere in which scientists operate is not limited to policy-focused or regulatory bodies. It further justifies Jasanoff’s concern that the four norms underpinning science: scepticism, communalism, universalism and disinterestedness, are compromised when science and politics interact.

One year after the republication of the Séralini article, the International Agency for Research on Cancer Monograph Working Group (IARC), operating under the auspices of the World Health Organization, reclassified glyphosate as being ‘probably carcinogenic to humans’.66 The subsequent section will examine the response to the IARC re-assessment, how the subsequent re-assessment of glyphosate by EFSA was judged in the light of the IARC re-classification, and what these events reveal about the role of scientific experts in law-making processes.

Glyphosate and scientific experts

The very concept of independent scientific advice, on which the EFSA has been built, draws its legitimacy from the level of excellence of the outputs delivered by the international organisations and third country bodies that are active in its environment.67 Groenleer and Gabbi identify in their 2013 article that expert advisory bodies, including EFSA, operate within ‘epistemic communities of reference’.68 The existence of this community is further highlighted by the overlapping events explored in this article. The controversy surrounding Séralini et al’s study, its retraction and eventual republication, the IARC’s re-classification of glyphosate and the re-assessment of glyphosate by EFSA are not directly linked with one another. However, there is an assumption that the Séralini study influenced the IARC’s re-classification,69 and that this would inform the EFSA reassessment. This suggests that the bank of scientific knowledge upon which environmental policy is built is not produced in the imagined silo so integral to scientific authority. Rather, environmental policy and regulation is produced in a process where each step both influences and is influenced by another. This section examines what happens when scientific experts employ scientific knowledge with policy and/or regulatory objectives.

In March 2015, IARC classified glyphosate as ‘probably carcinogenic to humans’.70 In November 2015, EFSA published its risk assessment review, finding that ‘glyphosate is unlikely to pose a carcinogenic hazard to humans’.71 What does this dissonance indicate about the relative objectivity and legitimacy of these agencies and their findings? Despite drawing on ‘about 1000 studies’,72 the IARC’s re-classification of glyphosate was out of step with other research and regulatory agencies. It provoked a strong response from other scientific expert groups, from affected corporations and across the media. This response, and the manner in which their conclusions were discredited, shocked the

66 Above n. 5.
67 See Groenleer and Gabbi above n. 38.
68 Ibid, at 482.
69 The Federation of German Scientists (VDW) and the German Section of the International Association of Lawyers against Nuclear Arms (IALANA), ‘2015 Whistleblower Award, Press Release’ (VDW and IALANA, 17 September 2015). Available at: http://ialana.de/arbeitsfelder/whistleblowing/whistleblowerpreis/whistleblowerpreis-2015 (last accessed 4 March 2016).
70 Above n. 1.
71 European Food Safety Authority, Conclusion on Pesticide Peer Review: Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate (EFSA 13(11) 2015) 11.
scientists who took part in the reclassification. Their shock reflects the gap between the real and idealised roles scientific experts play in policy-making.

We were doing our job. We understood there were other issues . . . economic consequences. But none of us had a political agenda. We simply acted as scientists, evaluating the body of evidence, according to the IARC criteria.

Francesco Forastiere, Lazio regional health service

We were independent and just looked at the science. We had strict rules on what was admissible and came to a conclusion based on that evidence. We made the right decision based on the evidence.

Lin Fritschi, Curtin University

Both scientists draw upon notions of ‘boundary-work’ in their justifications; they reiterate that they were free from political bias, and simply looked at the evidence in front of them. They underline that their expert opinion was based on the available data. Both further highlighted the narrow parameters to which they were required to adhere.

When, in turn, EFSA conducted an assessment of glyphosate and found that it posed no risk to humans, they too met with criticism from scientific experts and from the public. Ninety-six scientists, including those who were part of the IARC panel, wrote a letter to Mr. Vytenis Andriukaitis, Commissioner for Food and Public Health in the European Commission, questioning the credibility of the EFSA review and pointing to shortcomings in its assessment procedures. In this letter, scientific experts directly compared the methods of the IARC review with that of EFSA, or to be more specific, the methods of the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) which compiled the Renewal Assessment Report upon which the EFSA decision was based. The scientists questioned BfR’s reliance on industry studies, the lack of transparency in their approach, and the lack of references and authors listed in the report. They contended that the IARC research adhered more closely to the accepted standards for scientific research; that their procedures were open, that there were no links with industry and that they relied on peer-reviewed studies. The independence of EFSA was further questioned. Critics highlighted the regulatory bodies’ history of conflicts of interest; a report published in 2013 found that 59 per cent of its members had links to companies under its assessment. These reported conflicts of interest and the condemnation of EFSA’s approach by 96 scientists call into question the legitimacy of the scientific experts commissioned by EFSA. Many of the criticisms surrounding EFSA’s decision on glyphosate highlight the agencies’ proximity to the bio-technology and GM-industry companies that they regulate, suggesting that EFSA might be a victim of the ‘capture paradigm’, briefly described in Section II. The probability of the ‘capture paradigm’ affecting expert advisory bodies increases in contemporary society, as scientific experts work across multiple institutional contexts. This is evidenced by the 25


75 EFSA works with Member State food safety agencies and scientific organisations to produce scientific opinions and advice as requested by European Union decision makers. The BfR has frequently conducted risk assessments on behalf of EFSA.

76 See Portier et al above n. 74.

scientific experts currently sitting on the EFSA’s scientific committee who are required to declare their interests on the EFSA website. All members have multiple connections to universities, scientific journals, nongovernmental organisations, national and supranational agencies, including national food agencies, national environmental agencies, the WHO, FAO, OECD and so on. A fifth of the membership declared potential conflicts of interest with industries regulated by EFSA (companies such as Syngenta, Merck and Boehringer) through funding their own research or that of their home university. There were no declarations of interest evident on the BfR website.

Lastly, and briefly, it is interesting to assess the scope of knowledge or of epistemological perspective, evidenced in these assessments. As the EFSA report does not provide references, we cannot evaluate the knowledge upon which their decision is based. The IARC Monograph includes approximately 300 references; five of these are neither drawn from scientific journals nor government agencies. Two of the references focus on Monsanto’s pesticide market dominance, one focuses on glyphosate use in forestry and two are concerned with national regulation of glyphosate outside of the EU. The monograph does not cite community groups, activists, or any other group with an overtly political interest in this topic. Touching upon notions of legitimacy and objectivity discussed in earlier sections, this relatively narrow selection of data serves to reinforce the importance of maintaining credibility, and of keeping scientific knowledge within pre-ordained, acceptable parameters.

As previously highlighted, the credibility of scientific knowledge directly affects the credibility of the advisory bodies employing that knowledge. In this final section, this article will consider the role of EFSA as an expert advisory body, and how their expertise was employed by the various political bodies involved in the renewal of glyphosate’s license in the EU.

**Glyphosate and expert advisory bodies**

Before assessing the role of EFSA in the re-authorisation of glyphosate in the EU, this article will first consider how expert advisory bodies typically operate within the EU, focusing on EFSA. Many expert advisory bodies operate within the broad institutional framework of the EU. Their responsibilities are delimited by the Meroni Doctrine, which states that advisory agencies ‘may only perform tasks that have explicitly attributed to them and do so within the legal boundaries prescribed in the delegating provisions’. Clearly defined boundaries are set in order to foster unity in the EU and to enable a coherent strategy across the various institutions. The prominence of advisory bodies in EU decision-making is further reinforced by comitology, the process through which EU law is modified within comitology committees. This approach is intended to strengthen the role of the scientific expert in decision-making. However, it is unclear whether comitology truly favours scientific knowledge over political expedience. While Weiher contends that comitology depoliticises decision-making, Paskalev argues that it is merely a ‘disguised politicisation’, and that delegates tend to adhere to the positions of their Member States. Klika, Kim and Versluis’ 2013 study of GM technology authorisation in the EU supports Paskalev’s contention.

Throughout its existence, EFSA has had to contend with contentious, value-laden issues. It was formed with the intention of re-building public trust after the BSE crisis of the early 1990s. The biotechnology

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79 Above n. 5 at 79
80 Above n. 38.
82 Ibid, at 328.
83 Ibid.
84 Ibid, at 329.
crises in Europe of the 1990s, which were understood to have their own ethical implications, further fell under the remit of EFSA. As previously discussed, issues that are scientifically uncertain require greater political involvement; issues concerning GM technologies have typically fallen into this category. Despite ostensibly being an apolitical expert advisory body, EFSA has frequently played a decisive role in politically contentious issues, including in the re-authorisation of GM technologies. It is also worth highlighting EFSA’s role as a member of a global epistemic community of reference, a community shaped by international organisations such as WHO and FAO. Groenleer and Gabbi contend that EU agencies like EFSA are ‘political entrepreneurs’, who have developed their own relationships with these international organisations, and who take their positions into account in their deliberations. It is interesting to take note of the influence of this ‘epistemic community’ when considering the diverging positions taken by EFSA and IARC.

As has been previously discussed, GM technologies lie in a region of low scientific certainty and low political consensus. Member States have failed to reach an agreement in the comitology committees; the authorisation of GM technologies is therefore left to the European Commission, which tends to follow EFSA’s recommendation on this issue. This indicates a failure in the procedure for GM technology regulation. EFSA, a nominally objective advisory body, thus becomes the ‘de facto decision-maker’ for a scientifically and politically uncertain topic upon which Member States are deeply divided. Klika, Kim and Versluis found that EFSA had, up until that date, issued 39 opinions on applications for GM technology authorisations. These opinions were all positive; in other words, they recommended to the European Commission that they authorise the GM product.

The position taken by EFSA does not reflect Member States’ concerns with GM technology, neither does this position reflect the lack of consensus within the scientific community. This is perhaps understandable; it is, after all, an advisory body, not an explicitly political body. EFSA’s risk-assessment procedures are said to be intolerant of scientific uncertainty; in the case of GM technologies, it is evident that competing scientific opinions are not effectively represented. EFSA’s decisions, and consequently those of the European Commission, have been taken to be politically provocative, frustrating those Member States whose positions are entrenched and run counter to the position consistently taken by EFSA and the European Commission. This challenging set of circumstances throws into sharp relief the tensions inherent in working with different forms of knowledge, when there is no space for debate around scientific knowledge, and when a lack of political consensus leads to greater political responsibility being given to scientific experts, with any ethical concerns ignored in favour of scientific legitimacy.

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85 Above n. 11 at 89.
86 See Groenleer and Gabbi, above n. 80 at 479.
87 Ibid, at 482
88 See Jasanoff above n. 9.
89 See Klika, Kim and Versluis above n. 81.
90 Ibid, at 327
91 Ibid.
92 Ibid, at 330.
93 Ibid, at 327.
94 Ibid.
95 This issue is somewhat relieved by EU Directive 2015/412 11 March 2015 that enables Member States to restrict the cultivation of genetically modified organisms in their own territories. Note that responsibility for decisions concerning GMO import and export remain at the EU level, ‘to preserve the internal market’; similarly, the Directive warns that this extension of Member States’ decision-making authority should not compromise the role of EFSA. (Directive (EU) 2015/412, preamble s. 6).
96 Above n. 81 at 330.
Echoing concerns over the various entanglements that exist between regulated industry and the scientific experts who sit on regulatory bodies (previously referred to as the ‘capture paradigm’) there are concerns that the increasing number of public-private sector research partnerships has compromised the integrity and independence of regulatory bodies;97 this is particularly relevant to bodies whose functions affect public health and the environment.98 While the EU has tended to be more risk-averse than the US around GM technologies,99 and has relied more heavily on the precautionary principle,100 the position of EFSA and the European Commission points to a weakening of the precautionary principle in food and chemical safety. Diminishing state activity has encouraged the growth of co-regulation, where public and private actors collaborate in their regulatory processes.101 Co-regulation poses a potential threat to transparency and independence in the regulatory processes; for the 96 scientists who criticised the BfR and EFSA’s reliance on industry studies, this threat is evident in EFSA’s recommendation to re-license glyphosate. These concerns were intensified by the publication of Monsanto’s internal e-mails, which seemingly reveal close ties between the company and scientific researchers. As a result of these allegations, a group of MEPs have called on Commission President Jean-Claude Juncker to delay the Commission decision on glyphosate until the validity of the studies upon which their decision relies can be verified.102

As the organ of representative democracy in the European Union,103 it is unsurprising that the European Parliament is especially attuned to shifts in public opinion; in the case of glyphosate, public interest influenced the progress of glyphosate re-approval through the European Parliament, building local protest against the use of glyphosate.104 On 2–4 March 2016, members of the European Parliament heard expert testimony on this issue from academics and interest groups.105 Later that month, the Environment Committee of the European Parliament passed a resolution urging the European Commission not to renew authorisation of glyphosate,106 followed by a resolution in April 2016, seeking restrictions on the scope and duration of glyphosate’s licence in the EU.107 In June 2016, after Member States failed to reach a qualified majority in the Standing Committee (6 June) or in the Appeal Committee (24 June), the European Commission adopted the extension of glyphosate’s

98 Ibid, at 168.
99 Above n. 9.
100 The precautionary principle, championed by Dr Frances Kelsey in the 1960s in blocking the approval of thalidomide in the US, assumes the onus is on the producer to demonstrate the absence of risk and not the presence of risk, and that appropriate action should be taken limited but credible evidence of harm be proven. P. Vineis (2005). ‘Scientific basis for the Precautionary Principle’ in Toxicology and Applied Pharmacology Vol 207 (Amsterdam: Elsevier) 68.
107 Anon, ‘Glyphosate: authorise for just seven years and professional uses only, urge MEPs’ Available at: http://bit.ly/2IEcfFn (last accessed 7 February 2017).
authorisation for 18 months, ostensibly to wait for the review conducted by the European Chemical Agency (ECHA). As the European Commission had indicated that they postponed their decision in order to include the findings of ECHA, it seems reasonable to imagine that these might be reflected in the position of the European Commission. The ECHA report states that they agreed to ‘maintain the current harmonised classification of glyphosate as a substance causing serious eye damage and being toxic to aquatic life with long-lasting effects’. This wording indicates a desire to appear neutral and depoliticised. However, the ECHA review has not persuaded glyphosate’s critics; sides have become entrenched and the tone of the debate has, at times, become quite heated. Christopher Portier, former director of the US National Institute of Environmental Health Sciences and consultant to IARC, criticised EFSA’s approach to their review of glyphosate in an open letter to Commission President Jean-Claude Juncker. Vytenis Andriukaitis, EU Commissioner for Health and Food Safety, excited criticism when he appeared to assume scientific consensus regarding the safety of glyphosate: ‘I am not a scientific expert, but it seems to me that political opinions cannot outweigh broadly agreed scientific opinions.’

The notable difference between the European Parliament and the European Commission’s approach to glyphosate’s re-authorisation reveals the distinct cultures shaping these institutions, a fascinating area for research, but an area beyond the remit of this article. However, it serves to underline that the regulation of GM technologies, a process reliant on scientific data, assessed by scientific experts and compiled by expert advisory bodies, remains a political process, shaped by political actors. It has been interesting to note that concerns around the legitimacy of democratic processes and the production of scientific knowledge have remained central to current debates around glyphosate. As highlighted by Green food safety and public health spokesperson Bart Staes:

There is a wider issue of the lack of transparency in the EU’s assessment of active substances. Assessment of potentially harmful substances by EU agencies must be based on fully independent and public studies so that they are open to proper scrutiny. Not only would this improve the robustness of the assessment, it would also help increase public trust in the important work these agencies do.

Where scientific knowledge is uncertain, political influence becomes more dominant. Where science and law are both contested, what happens? Which comes to the fore? Are we left with less effective law, with less ‘true’ science? The case of glyphosate from May 2015 until time of writing provides a valuable opportunity to explore an example of particularly divisive topic. The delayed progress of glyphosate’s re-authorisation through the EU further enables the researcher to explore and to apply theory to an unfolding public concern. It is hoped that this article highlighted some key areas of concern in this divisive and highly relevant political and scientific debate.

110 See ECHA above n. 109.
111 Above n. 74.
Conclusion
Jasanoff’s ‘three-body’ problem equips the legal researcher with a clear, useful framework with which to consider the interactions of science and law. It enables a deeper analysis of glyphosate, the politically contested topic that serves as the focus of this article. The article discussed scientific knowledge, identifying the ways in which the four norms upholding science are compromised as scientific knowledge is incorporated in the legal and political sphere. The case of glyphosate, and in particular the strong reaction to the Séralini study in 2012, serves as a strong reminder that this spreads far beyond legislative and regulatory institutions. Illuminating theoretical tools, such as ‘boundary work’ and the ‘capture paradigm’, aid analysis of the role of scientific experts in law-making. They are highly relevant to the case of glyphosate; evident when the IARC scientists, alarmed by the perceived politicisation of their work, strongly reassert the boundaries laid between science and politics. Boundary work is further evident in the narrow range of sources that qualify as scientific knowledge. It would seem that science as understood by law-makers comes from a specific particular epistemological perspective. Lastly, in examining the role of expert advisory bodies in law-making, and in particular the role of EFSA in the re-assessment of glyphosate’s licence, we observe the impact of the political culture on how scientific expertise is applied. The ‘capture paradigm’ is revisited, highlighting concerns with the growth of co-regulation and its impact on the integrity of bodies like EFSA. Noting the role of epistemic communities of reference further serves to highlight the entangled nature of the institutions included in this case study, and underlines the expanded form of the political sphere in which they operate.

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