including non-governmental organizations (NGOs) [6] to discuss GMO topics. That the EFSA is neither a centralized nor a singular voice of science in the EU is clear, because the initial report on the ERA is delivered by a MS, not the EFSA; all MSs can comment on the ERA; and EFSA GMO Panel Opinions respond transparently to every concern raised by each MS. Following publication, the EFSA regularly attends the SCFAH Committee (comprising MS representatives) to account for its Opinions. The involvement of all MSs in the evaluation process ensures that concerns relating to their environments are addressed in the ERA. Subsequently, MSs can contribute to decisions on the management and monitoring of GM plants in their territories if cultivation is approved.

In recent years, several MSs have used the 'safeguard clause', Article 23 of 2001/18/EC, to attempt to ban the cultivation of specific GM plants in their territories, despite earlier EFSA Panel Opinions on those plants. But the claim that "the risk science of the EFSA's GM Panel has been publicly disputed in Member State's justifications of their Article 23 prohibitions" needs to be placed into context [1]. When a safeguard clause (SC) is issued by a MS, the EFSA GMO Panel is often asked by the EC to deliver an Opinion on the scientific basis of the SC. The criteria on which to judge the documentation accompanying a SC are whether: (i) it represents new scientific evidence—and is not just repetition of information previously assessed—that demonstrates a risk to human and animal health and the environment; and (from the guidance notes to Annex II of 2001/18/EC) (ii) it is proportionate to the level of risk and to the level of uncertainty. It is pertinent that on 8 September 2011, the EU Court of Justice ruled that 'with a view to the adoption of emergency measures, Article 34 of Regulation (EC) No 1829/2003 requires Member States to establish, in addition to urgency, the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health or the environment'. Scientific literature is monitored continually by the Panel and relevant new work is examined to determine whether it raises any new safety concern. In all cases where the EFSA was consulted by the EC, there has been no new scientific information presented that would invalidate the Panel's previous assessment.

Throughout [1] the text demonstrates a fundamental misunderstanding of the distinction between ERA and risk management. ERA is the responsibility of the EFSA,

although it is asked for its opinion on risk management methodology by the EC. Risk management implementation is the responsibility of the EC and MSs. Hence, the setting of protection goals is an issue for risk managers and might vary between MSs. However, the ERA GD [2], through its six-step approach, makes it mandatory for applications to relate the results of any studies directly to limits of environmental concern that reflect protection goals and the level of change deemed acceptable. Indeed, the recent EFSA GMO Panel Opinions on *Bt*-maize events [for example, 7] have been written specifically to provide MSs and risk managers with the tools to adapt the results of the quantified ERA to their own local protection goals. This enables MSs to implement risk management and PMEM proportional to the risks identified in their territories.

The EFSA GMO Panel comprises independent researchers, appointed for their expertise following an open call to the scientific community. The Panel receives able support from staff of the EFSA GMO Unit and numerous *ad hoc* members of its working groups. It has no agenda and is neither pro- or anti-GMOs; its paramount concern is the quality of the science underpinning its Guidance Documents and Opinions.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest. All the authors except M. Nuti are members of the EFSA GMO Panel; M. Nuti was a member of the Panel from 2003 to 2006 (declarations of interest available on efsa.europa.eu/en/gmo/gmomembers).

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REFERENCES

1. Wickson F, Wynne B (2012) *EMBO Rep* **13**: 100–105
2. EFSA Panel GMO (2011) Guidance on the environmental risk assessment of genetically modified plants. *EFSA J* **8**: 1879–1989
3. Royal Society (2002) *Genetically modified plants for food use and human health—an update*. London, UK: The Royal Society. http://royalsociety.org/uploadedFiles/Royal_Society_Content/policy/publications/2002/9960.pdf
4. Kearns P, Mayers P (1999) No GM conspiracy. *Nature* **401**: 640–641
5. EFSA Panel GMO (2011) Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. *EFSA J* **9**: 2316–2355
6. *Stakeholder initiatives*. <http://www.efsa.europa.eu/en/networks/stakeholders.htm>
7. *EFSA updates advice on environmental safety of GM maize 1507* (2011) <http://www.efsa.europa.eu/en/press/news/111118.htm>

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Reply to J.N. Perry *et al*

Our respondents, eight current or former members of the EFSA GMO panel, focus on defending the EFSA's environmental risk assessment (ERA) procedures. In our article for *EMBO reports*, we actually focused on the proposed EU GMO legislative reform, especially the European Commission (EC) proposal's false political inflation of science, which denies the normative commitments inevitable in risk assessment (RA). Unfortunately the respondents do not address this problem. Indeed, by insisting that Member States enjoy freedom over risk

management (RM) decisions despite the EFSA's central control over RA, they entirely miss the relevant point. This is the unacknowledged policy—normative commitments being made before, and during, not only after, scientific ERA. They therefore only highlight, and extend, the problem we identified.

The respondents complain that we misunderstood the distinction between RA and RM. We did not. We challenged it as misconceived and fundamentally misleading—as though only objective science defined RA, with normative choices cleanly confined to

RM. Our point was that (i) the processes of scientific RA are inevitably shaped by normative commitments, which (ii) as a matter of institutional, policy and scientific integrity must be acknowledged and inclusively deliberated. They seem unaware that many authorities [1–4] have recognized such normative choices as prior matters, of RA policy, which should be established in a broadly deliberative manner “in advance of risk assessment to ensure that [RA] is systematic, complete, unbiased and transparent” [1]. This was neither recognized nor permitted in the proposed EC reform—a central point that our respondents fail to recognize.

In dismissing our criticism that comparative safety assessment appears as a ‘first step’ in defining ERA, according to the new EFSA ERA guidelines, which we correctly referred to in our text but incorrectly referenced in the bibliography [5], our respondents again ignore this widely accepted ‘framing’ or ‘problem formulation’ point for science. The choice of comparator has normative implications as it immediately commits to a definition of what is normal and, implicitly, acceptable. Therefore the specific form and purpose of the comparison(s) is part of the validity question. Their claim that we are against comparison as a scientific step is incorrect—of course comparison is necessary. This simply acts as a shield behind which to avoid our and others’ [6] challenge to their self-appointed discretion to define—or worse, allow applicants to define—what counts in the comparative frame. Denying these realities and their difficult but inevitable implications, our respondents instead try to justify their own particular choices as ‘science’. First, they deny the first-step status of comparative safety assessment, despite its clear appearance in their own ERA Guidance Document [5]—in both the representational figure (p.11) and the text “the outcome of the comparative safety assessment allows the determination of those ‘identified’ characteristics that need to be assessed [...] and will further structure the ERA” (p.13). Second, despite their claims to the contrary, ‘comparative safety assessment’, effectively a resurrection of substantial equivalence, is a concept taken from consumer health RA, controversially applied to the more open-ended processes of ERA, and one that

has in fact been long-discredited if used as a bottleneck or endpoint for rigorous RA processes [7–10]. The key point is that normative commitments are being embodied, yet not acknowledged, in RA science. This occurs through a range of similar unaccountable RA steps introduced into the ERA Guidance, such as judgement of ‘biological relevance’, ‘ecological relevance’, or ‘familiarity’. We cannot address these here, but our basic point is that such endless ‘methodological’ elaborations of the kind that our EFSA colleagues perform, only obscure the institutional changes needed to properly address the normative questions for policy-engaged science.

Our respondents deny our claim concerning the singular form of science the EC is attempting to impose on GM policy and debate, by citing formal EFSA procedures for consultations with Member States and non-governmental organizations. However, they directly refute themselves by emphasizing that all Member State GM cultivation bans, permitted only on scientific grounds, have been deemed invalid by EFSA. They cannot have it both ways. We have addressed the importance of unacknowledged normativity in quality assessments of science for policy in Europe elsewhere [11]. However, it is the ‘one door, one key’ policy framework for science, deriving from the Single Market logic, which forces such singularity. While this might be legitimate policy, it is not scientific. It is political economy.

Our respondents conclude by saying that the paramount concern of the EFSA GMO panel is the quality of its science. We share this concern. However, they avoid our main point that the EC-proposed legislative reform would only exacerbate their problem. Ignoring the normative dimensions of regulatory science and siphoning-off scientific debate and its normative issues to a select expert panel—which despite claiming independence faces an EU Ombudsman challenge [12] and European Parliament refusal to discharge their 2010 budget, because of continuing questions over conflicts of interests [13,14]—will not achieve quality science. What is required are effective institutional mechanisms and cultural norms that identify, and deliberately address, otherwise unnoticed normative

choices shaping risk science and its interpretive judgements. It is not the EFSA’s sole responsibility to achieve this, but it does need to recognize and press the point, against resistance, to develop better EU science and policy.

REFERENCES

1. FAO (2007) Codex Alimentarius, <http://www.fao.org/docrep/007/y5817e/y5817e04.htm>
2. Millstone EP, Ibarreta D (2008) *Risk Assessment Policies: Differences Across Jurisdictions*. Joint Research Centre, Institute for Prospective Technological Studies
3. US National Research Council (1996) *Understanding Risk*. National Academy Press
4. European Commission (2000) European Commission Communication on The Precautionary Principle.
5. EFSA (2011) *EFSA J* **8**: 1879–1989
6. ENSER (2011) ENSER Comments on the EFSA Guidance on the Environmental Risk Assessment of Genetically Modified Plants. European Network of Scientists for Social and Environmental Responsibility. <http://www.enser.org/activities/projects/reforming-the-gmo-approval-system/>
7. Royal Society of London (2002) *Genetically modified plants for food use and human health—an update*, Policy document 4/02. <http://royalsociety.org/policy/publications/2002/genetically-modified-food-update/>
8. British Medical Association (1999) The Impact of Genetic Modification on Agriculture, Food and Health: An Interim Statement.
9. Royal Society of Canada (2001) Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada: An Expert Panel Report on the Future of Food Biotechnology.
10. Christoforou T (2004) The regulation of genetically modified organisms in the European Union: the interplay of science, law and politics. *Common Law Market Rev* **41**: 637–709
11. Wickson F, Wynne B (2012) *Ethics, Policy & Environment* (in press)
12. Testbiotech (2012) Independence of EFSA’s GMO risk assessment challenged. <http://www.testbiotech.org/en/node/638>
13. EFSA (2012) FAQ on EFSA’s 2010 budget discharge. <http://www.efsa.europa.eu/en/faqs/faq2010budgetarycontrol.htm>
14. GM Watch (2012) Independence of EFSA challenged by European Parliament. <http://gmwatch.org/latest-listing/1-news-items/13797-independence-of-efsa-challenged-by-european-parliament>

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