

The anglerfish deception

The light of proposed reform in the regulation of GM crops hides underlying problems in EU science and governance

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Anglerfish are predators that live in the eternal darkness of the deep oceans and have a distinctive way of catching their prey. They use a long light-emitting filament that extends from their head to lure organisms in the darkness. Those attracted to the shimmering light and movement are then unwittingly caught in front of the anglerfish's wide-open jaws. Such is the nature of the European Commission (EC)'s proposal for a new European Union (EU) policy on the regulation of genetically modified organisms (GMOs)—it looks alluring at first glance, but there are hidden dangers lurking in the background.

After years of protracted conflict between the EC and several EU member states over the import of GM food and the use of GM crops in agriculture, a new regulatory approach to the approval and cultivation of GMOs is currently moving through the legislative process. In July 2010, the EC proposed the inclusion of a new article (Article 26b) in Directive 2001/18/EC that regulates the deliberate environmental release of GMOs. It would give member states autonomy to make their own decisions about cultivating GM crops, independently of EC authorizations (EC, 2010). However, member states would not be able to make such decisions on the grounds of scientific assessments of health and environmental risk because these are performed by the EU's scientific advisory body, the European Food Safety Authority (EFSA). The EC's rationale for this proposed policy change is to address the bitter resistance to GM crops in some member states and break the resulting long-standing regulatory and policy deadlock.

In July 2011, the European Parliament (EP) overwhelmingly voted to endorse the principle of member-state freedom, but

rejected the EC's attempt to completely prevent member states from using scientific arguments to ban GMOs (Sidebar A). Whereas the EC wished to protect a centralized and singular voice of science for EU policy (namely the EFSA), the EP asserted that the different conditions across the EU could allow a rational scientific approach to reach different conclusions, especially on matters of environmental risk. In its amendments, the EP also implicitly accepted other points of criticism of the EFSA and EC processes; for example, that there are normative choices being made in EU GM policy, but under the false name of science.

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There are inherent dangers with the EC's goal of pursuing a political and economic union for Europe that increasingly depends on claims about a unitary, singular, deterministic and independent quality to scientific risk analysis. We argue that such claims are confused, false and ultimately self-defeating, despite the honourable intent of the original reasons for moving towards political union.

In recent years, several EU member states have used the 'safeguard clause', Article 23 of EC Directive 2001/18, to ban the cultivation of GM crops in their territories, despite safety approvals from the EFSA. Article 23 allows 'temporary' prohibitions if there is new scientific knowledge indicating a potential risk to human health or the environment. However, the EFSA has assessed and declared that all such current

prohibitions by member states lack sufficient scientific support and are therefore illegal under the original EC authorizations. Nonetheless, various member states uphold these bans, thereby formally violating European law and creating an escalating sense of crisis. This has seen the attempt to establish a centralized authority for the regulation of GMOs fall into disarray, as bans are met with EC legal threats, and these are met with further member state intransigence. Disagreement between the EC and member states has typically focused on the EFSA, which acts as scientific authority to its policy client, the EC's Directorate-General for Consumer Health and Protection. The EFSA's central responsibility for risk assessment effectively makes it the EC's scientific authority for GM policy, and it is the risk science of the EFSA's GM panel that has been publicly disputed in member states' justifications of their Article 23 prohibitions.

Disputed science is crucial in disagreements over GMOs, but the dispute is not limited to facts revealed by research

In September 2009, EC President José Manuel Barroso urged a reconsideration of the EU constitutional principle of subsidiarity in GMO policy: "It should be possible to combine a Community authorisation system, based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory" (Barroso, 2009). In July 2010, the EC (2010) proposed amendments to Directive 2001/18 to create a formal basis for member states to restrict or prohibit the cultivation in their territory of GMOs authorized

Sidebar A | Development of the proposal for EU GM regulatory reform

4 December 2008

Council identifies areas for improvement in the European Union (EU) framework for authorizing genetically modified organisms (GMOs), including fuller environmental assessment and socio-economic appraisal.

2 March 2009

A Dutch proposal is made to the Environment Council (of EU Member State Ministers) that the decision to cultivate GM crops should be left to individual member states.

24 June 2009

A group of 13 member states requests that the European Commission (EC) give member states the freedom to decide on the cultivation of GM plants based on “relevant socio-economic aspects”.

3 September 2009

EC President José Manuel Barroso suggests “it should be possible to combine a Community authorisation system, based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory” (Barroso, 2009).

13 July 2010

In response to the Council of Ministers, the EC proposes amendments to Directive 2001/18/EC through the addition of Article 26b, allowing member states to restrict or prohibit GMO cultivation on grounds other than adverse effects to health and the environment.

September 2010

Ad hoc working party is established by COREPER (The Committee of Permanent Representatives of Member State Governments) to consider the EC’s proposal, taking into account the recommendation on coexistence.

7 September 2010

Delegates to the ad hoc working party raise concerns about the legality of the proposal within international trade law, as well as the need for enhanced clarity on the proposed acceptable grounds for member state restrictions of GMO cultivation.

27 September and 14 October 2010

Councils on Agriculture and Fisheries and Environment reiterate concerns of the COREPER working party and the opinion of the Council Legal Service is requested.

5 November 2010

Council Legal Service opinion concludes that the EC’s proposal might not be compatible with international treaties or with the General Agreement on Tariffs and Trade (GATT).

23 November 2010

Commission Services disagrees with legal service opinion and argues that the EC’s proposal is a way to ensure smooth functioning of the internal market in accordance with Article 114 of the EU Constitution—the 2009 Treaty of Lisbon—and that grounds other than ethics might be invoked; for example, public order or public interest to preserve cultural traditions, or ‘public morals’ as permitted under GATT.

8 December 2010

COREPER working party argues that a list of grounds that could be used by member states to restrict GMOs under the new proposal needs to be provided by the EC.

9 December 2010

EU Economic and Social Committee (2011) concludes that the proposal will “create more vagueness than certainty and could in practice result in a proliferation of (legally unstable) measures adopted by States” and also calls for more clearly specified grounds for restrictions.

8 February 2011

Commission Services (2011) release an open but not exhaustive list of possible reasons that could be invoked to restrict or prohibit GMO cultivation under the new proposal, including: public morals, public order, avoiding presence in other products, social policy objectives, land-use planning, cultural policy and general environmental policy objectives (other than assessment of adverse effects of GMOs on the environment) such as maintenance of certain types of landscape features, ecosystems or ecosystem services.

12 April 2011

European Parliament (EP) Environment Committee votes to submit to the full EP its amendments to the EC legislative proposal to include scientifically justified environmental impacts complementary to those assessed by the EFSA as legitimate grounds for member state restrictions or prohibitions. This includes prevention of pesticide resistance, invasiveness and/or biodiversity loss; maintenance of seed purity, local biodiversity, unviability of coexistence regimes, ecosystem and agricultural sustainability; and/or presence of persistent uncertainty through data absence or contradictions (Committee on the Environment, Public Health and Food Safety, 2011).

5 July 2011 (originally scheduled for 9 June)

Parliament plenary vote on the EC’s proposal and the EP Environment Committee amendments. Large majority votes in favour of Environment Committee amendments (548 for, 84 against, 31 abstentions). This Parliamentary verdict goes to the Council of Ministers for agreement on a final legal schedule.

at the EU level. The EC proposal turns the existing situation on its head: instead of prohibitions only being permitted on the basis of potential risks to human health or the environment, the new proposal would allow bans only on “grounds other than those related to the assessment of the adverse effect on health and environment” (EC, 2010). The implication is that the EFSA adequately assesses health and environmental risks. Yet, this was, and remains, precisely the main issue for those member states that refuse to accept the scientific adequacy of EFSA authorizations.

This separation of risk science from other concerns has been misinterpreted by some commentators as allowing EU member states to make “arbitrary” decisions, “without explanation” and “based on irrational criteria” (Sabalza *et al*, 2011). This ignores other rational grounds for decision-making—for example, socio-economic and/or ethical considerations. Moreover, it fails to recognize the contingencies that pervade risk assessment: that is, the possibility for divergent scientific assessments depending on different framing commitments, including the way such commitments define relevant factors, interpretive criteria and implicit burden-of-proof assumptions (Wynne, 1989; Stirling, 1998). The impossibility of separating scientific risk knowledge from normative questions, assumptions and commitments is neither a failing of that science nor those institutions. It is an unavoidable reality that needs to be addressed in an enlightened and accountable way.

Disputed science is crucial in disagreements over GMOs, but the dispute is not limited to facts revealed by research. It is also about the normative commitments that scientists make and how these shape what are deemed to be salient and reliable facts; for example, the choices made concerning the relevant questions to ask, the appropriate methods to employ, the pertinent baselines for comparison and so on. The EC’s proposal embodies a confusion of risk science with an idealized model of pure scientific research unaffected by normative considerations, and which, therefore, supposedly speaks only in the singular voice of Nature. Thus the EC produces a framework that asserts that current scientific and regulatory institutions, namely the EFSA in this case, are sufficiently capable of exhaustively defining and assessing such



risks in an impartial, objective and overarching way. However, not only are there legitimate scientific differences in environmental, agronomic and health risk assessment situations across Europe, there are also unacknowledged social, ethical and political commitments embedded in the supposedly singular EC risk science (Brunk *et al*, 1991; EU, 2007). An unavoidable effect of this confusion is that member states' legitimate differences with EFSA's 'science' (which stands for EC–EU policy), are arbitrarily rendered 'unscientific' and illegitimate.

The EC's proposal embodies a confusion of risk science with an idealized model of pure scientific research...

The conflation of risk, science and rationality into the combined position that risk represents the only legitimate ground for social concern, current scientific and regulatory institutions are capable of defining and assessing such risks in an impartial

This scientism as a form of politics undermines an enlightened, scientifically informed democratic culture

and objective way, and scientific risk assessment as performed by existing institutions is the only rational basis for decision-making, is arguably exactly the institutional mindset that has created the current paralysis in EU GMO regulation and policy, and therefore the need for reform. Thus the same mindset that created the paralysing conflict in the first place is informing the EC's approach to revising legislation.

At first sight, then, the EC's proposal seems to be a positive move to accept different member state policies on GM cultivation, particularly as it includes socio-economic and/or ethical considerations as legitimate grounds for these. Closer examination, however, suggests that it might be a trap. The EC's proposal attempts to create a rigid boundary between a supposed singular, objective, non-contingent and universal scientific knowledge on risk, and

diverse 'non-scientific' social, ethical, religious and/or political concerns. This framing of a rigid division between the scientific and 'non-scientific', corresponding with a 'rational (universal)' over 'irrational (local)' standpoint, ignores that risk science is actually shaped by unacknowledged normative commitments and contingencies, which are manifested through uncertainty, ambiguity, indeterminacy and ignorance (Wynne, 1992; Brunk *et al*, 1991).

The EC proposal draws on ideals of impartiality in research science (Daston & Galison, 2007; Lacey, 2005), but uses these to claim authority for what is a different knowledge culture, namely regulatory science (Jasanoff, 1990). The EC has been here before (Laurence & Wynne, 1989), and its stance seems to express that economic and political union is achievable through scientific authority—as if science can declare unionist policy ends as a revelation of Nature rather than as a reasonably argued but contestable human aim. This scientism as a form of politics undermines an enlightened, scientifically informed democratic culture.

Sidebar B | Legal text of the EC legislative proposal and EP amendments

Original wording of the European Commission proposal

Article 26b

“Member States may adopt measures restricting or prohibiting the cultivation of all or particular [genetically modified organisms, GMOs] [...] in all or part of their territory, provided that:
(a) those measures are based on grounds *other than those related to the assessment of the adverse effect on health and environment* which might arise from the deliberate release or the placing on the market of GMOs”.

Amendments voted by the European Parliament

“Member States may adopt, after a case-by-case examination, measures restricting or prohibiting the cultivation of particular GMOs or of groups of GMOs defined by crop or trait or of all GMOs [...] in all or part of their territory, provided that:

(a) those measures are based on

(i) duly justified grounds relating to local or regional environmental impacts which might arise from the deliberate release or placing on the market of GMOs, and which are complementary to the environmental impacts examined during the scientific assessment of the impacts on the environment conducted under Part C of this Directive [that is, by the EFSA]; or grounds relating to risk management. Those grounds may include:

- the prevention of the development of pesticide resistance among weeds and pests;
 - the invasiveness or persistence of a GM variety, or the possibility of interbreeding with domestic cultivated or wild plants;
 - the prevention of negative impacts on the local environment caused by changes in agricultural practices linked to the cultivation of GMOs;
 - the maintenance and development of agricultural practices which offer a better potential to reconcile production with ecosystem sustainability;
 - the maintenance of local biodiversity, including certain habitats and ecosystems, or certain types of natural and landscape features;
 - the absence or lack of adequate data concerning the potential negative impacts of the release of GMOs on the local or regional environment of a Member State, including on biodiversity;
- (ii) grounds relating to socio-economic impacts.

Those grounds may include:

- the impracticability or the high costs of coexistence measures or the impossibility of implementing coexistence measures due to specific geographical conditions such as small islands or mountain zones;
 - the need to protect the diversity of agricultural production; or
 - the need to ensure seed purity;
- (iii) other grounds that may include land use, town and country planning, or other legitimate factors”.

Other significant European Parliament amendments

“(2a) The Commission and Member States should ensure, as a priority, the implementation of the Environment Council Conclusions adopted on 4 December 2008, namely a proper implementation of the legal requirements laid down in Annex II of Directive 2001/18/EC for the risk assessment of GMOs. In particular, the long-term environmental effects of GM crops, as well as their potential effects on non-target organisms, should be rigorously assessed; the characteristics of the receiving environments and the geographical areas in which GM plants may be cultivated should be duly taken into account; and the potential environmental consequences brought about by changes in the use of herbicides linked to herbicide-tolerant GM crops should be assessed. More specifically, the Commission should ensure that the new guidelines on GMO risk assessment are adopted. Those guidelines should not be based only on the principle of substantial equivalence or on the concept of a comparative safety assessment, and should make it possible to clearly identify direct and indirect long-term effects, as well as scientific uncertainties. The European Food Safety Authority (EFSA) and the Member States should aim to establish an extensive network of scientific organizations representing all disciplines including those relating to ecological issues, and should cooperate to identify at an early stage any potential divergence between scientific opinions with a view to resolving or clarifying the contentious scientific issues. The Commission and the Member States should ensure that the necessary resources for independent research on the potential risks of GMOs are secured, and that the enforcement of intellectual property rights does not prevent independent researchers from accessing all relevant material”.

The idea is that closed, expert resolution, using the disinterested and supposedly unitary voice of science, will deliver union by abstract revelation...

Public Health and Food Safety, 2011; Sidebar B). On 5 July 2011, the EP followed these recommendations and voted down the original EC proposal (EP, 2011).

The justification for the ‘supplementary’ scientific reasons for member state bans was that environmental issues specific to national, regional or local conditions will require scientific data that might not be sufficiently addressed in a risk assessment at the European level. The EP amendments also stated that a lack of relevant information would constitute legitimate grounds for member states to restrict or prohibit the cultivation of GMOs. Other amendments also restate and reinforce the requirement to implement Directive 2001/18 (Sidebar B), for example, including specific legislative requirements to assess long-term risks. Although this legal requirement already exists under Directive 2001/18, complaints continue that long-term and cumulative risks from GMOs have never been adequately considered by the EFSA and consequent EC authorizations. Significantly, the EP also sought to change the legal basis for the proposed new regulation from Article 114 of the EU Lisbon Treaty, which focuses on the establishment of a single market, to Article 192, which grants member states responsibility for the conservation of fauna and flora, land-use or town and country planning. This change recognizes that GMO cultivation and agriculture are closely linked to issues of land-use, the conservation of flora and fauna, and biodiversity.

Whereas the EP voted with a large majority to amend the EC’s proposal, the EC perspective remains alive and the EP’s recommended amendments are now undergoing political bargaining between the Council of Ministers, the EC and the EP. As one participant informed us, the EP version will not necessarily survive into final EU legislation as it is unlikely that the Council will support all of the amendments. If these negotiations fail to reach agreement, an interagency group with members from the EP and the Council of Ministers will prepare a common statement that will then be voted on again by both bodies. Although the EP’s proposed amendments are promising,

In April 2011, the Environment Committee of the EP recommended significant amendments to the EC’s proposal. These amendments allowed contextually variable definitions of environmental harm, recognized the intertwined character

of nature and culture in agriculture, and acknowledged the significance of scientific uncertainties. In doing so, these proposed amendments permitted non-scientific as well as scientific reasons for bans by member states (Committee on the Environment,

political negotiation continues and the EC's approach, which is fundamentally different from the EP's, might well survive.

While the content of any final EU legislative text remains speculative at this point, it is worth considering the EP's amendments in the light of new EU guidelines for the environmental risk assessment of GM plants, which after a period of feedback and consultation were finalized in May 2011 (EFSA, 2011). It seems that many of the issues that the EP's amendments outline as potentially valid grounds for member state restrictions or prohibitions already fall within the scope of the EFSA. This includes specific environmental risks, such as invasiveness or weed and pest resistance, and general issues such as the specificities of the receiving environment and the potential for changes in agricultural management practices. The EP also calls for the documentation of any scientific uncertainty and disagreement, which has been EU law, although unimplemented, for nine years.

The more controversial that public issues involving science become, the more this aggrandisement of scientific risk assessment becomes appealing

One important and contested issue in the finalized guidelines of the EFSA (2011) is the introduction of a 'Comparative Safety Assessment' by the EFSA GM panel (ENSSER, 2011). If the GM crop under assessment passes this first step, no further questions need be asked. Given that comparative baselines are themselves a point of contention and are normative choices that affect the scientific appraisal, this makes the EC's attempt to assert central singular scientific rule over any possible scientific criticism by member states even more problematic and potentially provocative.

Therefore, if the EFSA follows its own guidelines for environmental risk assessment, the concrete issues described in the EP's amendments could not be considered 'complementary to' those assessed by the EFSA. Should this happen, we would return to a situation in which the EFSA is deemed to sufficiently assess environmental risk, and in which member states would effectively be left with no formal basis to contest the quality or content of the agency's assessment, and therefore could not

prohibit or restrict GM cultivation on the basis of an alternative interpretation of the available science as defined by the EFSA. Consistent with our critical analysis of the EC's proposal, such a final agreement would maintain most of the problematic framing that mistakenly defines 'science' performed by the EFSA and endorsed by the EC to be above and before any other normative commitments with respect to GMO risk assessment and policy.

It is also worth noting that the very language of 'complementary' suggests that EFSA risk assessments might be incomplete, but it does not acknowledge that choices in risk-based science and/or particular framings of a risk assessment might be legitimately different or mutually exclusive between the EFSA and member states. This is true, for example, of the choices of 'normal baseline' comparators for defining harm, of protection goals, of the timescales during which to observe effects, of the chosen endpoints, of the relevant test material, or of the required weight of empirical evidence for defining adequate 'proof' of harm. The language of 'complementary' might be a pragmatic compromise; however, honesty might require 'alternative' and the wider corresponding political debate over the hidden normative issues that this deserves.

The quality of the risk assessment process will inevitably remain an issue of debate, as will the significance of particular uncertainties or gaps in knowledge, owing to the inherently normative nature of risk-based choices and assumptions. Here, the key issues are to what extent local, regional and national environmental and social conditions and aims can remain valid grounds for member states' prohibitions; to what extent scientific disagreement over the validity and quality of a risk assessment can be used as valid grounds for member state prohibitions; and whether the knowledge produced and used in risk research and assessment can be acknowledged to be fundamentally different from knowledge as scientific research. This latter admission would also expose the normative public questions that are currently hidden and promoted falsely in the name of science in the EC's attempt to achieve a unified European policy authority.

Recognizing the fundamentally different nature of risk-based regulatory science, particularly the way it makes normative choices

and assumptions, requires that risk assessment as a policy tool include broad-based deliberative quality assurance (Wickson, 2009). This is recognized by the EP in its calls to fully involve member states, competent scientific bodies and other relevant stakeholders in the assessment process. Since the EP, in its amendments, also challenged the appropriateness of the EFSA guidelines to have assessment led by the discredited principle of substantial equivalence (or an undefined 'comparative safety assessment'), it is important that the guidelines themselves also remain open for critical scrutiny.

The EC's constitutional role is that of technical administrator of EU policy. Fearing that the original ideal of political union could disintegrate, the EC has often attempted to sublimate political, institutional and cultural differences into purely technical idioms. The idea is that closed, expert resolution, using the disinterested and supposedly unitary voice of science, will deliver union by abstract revelation rather than by grounded and grinding political negotiation. The tendency to redefine problematic policy issues as scientific questions only, and to assume that public concerns can be correspondingly reduced to scientific unitary terms such as 'risk', is understandable. This typically accompanies the increased framing of policy issues as exclusively questions of risk. Although risk has long been identified as an ambiguous combination of both propositional knowledge and value-commitments (EU, 2007; Brunk *et al.*, 1991; Wynne, 1989)—that is, it can only be scientifically defined by first choosing what is 'at risk' (worth protecting)—a scientific definition of public concerns has been abetted by policy officials who are anxious to avoid or mitigate political confrontation. The more controversial that public issues involving science become, the more this aggrandisement of scientific risk assessment becomes appealing (Wynne, 2001). We are not suggesting that risks are unimportant. Rather, it is that they do not have singular meaning or definition; nor are they the sole definition of public concerns or of public policy issues.

Science for policy cannot be rendered more accountable without also making accountable the policy processes that mutually shape and deploy that science

By seeking to establish a clean and final boundary between the social and scientific aspects of decision-making on GMO cultivation, the EC fails to acknowledge and confront the normative dimensions embedded in risk-based science for policy. This discredits the good name of science and costs its public support. The fact that the EP, led by its Environment Committee, has challenged this particular proposal is significant, but will do little to change matters unless the final legislative document incorporates the suggested EP amendments. More broadly, we argue that the EC's background assumption of apolitical scientific sovereignty over rationally supported policy difference needs to be acknowledged, and altered.

Although the precise form of the legislative amendments voted by the EP remains to be seen, the opening up of the EC's misconceived assertion could be directly pursued through the establishment of more inclusive and plural knowledge assessment processes, under a different understanding of the kinds of knowledge in play. Such developments would increase transparency in political decision-making and its scientific justifications, rather than hiding these under a false mantle of objective, singular and uncontested science. Science for policy cannot be rendered more accountable without also making accountable the policy processes that mutually shape and deploy that science (Jasanoff, 2004). Pursuing this would, however, require a different vision and practice of European political union; one not based on a habit of false scientific determination (Waterton & Wynne, 1996).

Permitting diverse European policy options on GM cultivation and rationally diverse grounds for their justification could improve the potential for a resilient EU socio-agricultural policy portfolio. However, the cultivation of resilient diversity within European agriculture and its supporting sciences depends on the crucial question of whether GM can indeed coexist with alternative approaches, technologies and imaginaries. The scientific and political challenges associated with this, however, are a whole new kettle of fish.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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