Political influences on biotechnology-based innovation for European agriculture

Political Influences on Biotechnology-based Innovation for European Agriculture: Risk-Assessment and Risk Management

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Abstract

In this paper we explore how the politics of European regulation and risk governance for innovative agricultural biotechnologies, with the continuing emphasis on the precautionary principle, has problematised conventional norms of evidence-based risk-related decision-making. Based on a study we conducted that analysed how the EU regulatory system had operated in practice in the context of two of the company Syngenta's genetically modified (GM) crops (Bt11 and GA21), and through stakeholder workshops, we highlight the tensions in the current regulatory system in Europe, the implications for the future regulation of new and emerging advanced agricultural biotechnologies in the EU, and suggest areas where there may be a need for further regulatory adjustment.

Introduction

The politicisation of European regulatory systems for GM crop development, leading to the EU becoming largely a GM-free zone, has been commented on widely (Davison and Ammann, 2017; Chataway et al, 2006; Tait, 2009). Environmental Risk Assessment (ERA) is one of the areas where the process of politicisation can be observed through the interactions between the company and the regulator, as reported here based on access to relevant documents held by Syngenta plc.

We define the term 'risk' as the combination of the extent of a hazard, and the probability of its occurrence. Controlling the risks arising from innovative technologies also has societal and political dimensions; inevitably, in a plural democracy, there will be a variety of societal perspectives on the acceptability of specific risks and the desirability of related benefits. The overall process of risk management (RM) takes these factors into account when setting parameters and discussing acceptable levels of risk. As part of RM, risk assessment (RA) should be a scientific evaluation of risk that provides good quality evidence on which to base the societal and political judgements about risk acceptability (Renn 2008). The European regulation of GM crops provides an example where this convention has been over-ridden to the extent that scientific evidence is seen by some important actors as irrelevant to both RA and RM.

The case studies and stakeholder workshops we describe in this paper reveal the tensions between evidence-based decision-making and value-based stakeholder demands, and the consequences of not having a system in place to resolve such tensions. These tensions also have implications for the future regulation of new and emerging innovative advanced agricultural biotechnologies (AABs) in the EU.

In this paper we describe the background to the research project and EU regulatory developments relevant to GM crops, and then discuss findings from two case studies and two workshops in the context of the operation in practice of the EU regulatory system. Finally, we consider potential policy solutions to address past and ongoing regulatory constraints on GM crop cultivation, and also broader issues around governance of advanced agricultural biotechnologies that are being shaped by current regulatory approaches.

Methods

Two case studies were undertaken for an ESRC/Syngenta Knowledge Exchange project conducted in 2013-14, showing the progress of Syngenta's GM crops (Bt11 and GA21) in

their passage through the EU regulatory system. The cases were built on published reports, peer-reviewed articles, and access to Syngenta's regulatory submission portfolios. We analysed the responses from member states to the dossiers submitted by Syngenta during the regulatory process, focusing specifically on environmental risk assessment, and noted the different framings and tenor of the questions asked. We categorised these as follows: reference statements suggesting other data thought to be relevant to the analysis, of which Syngenta and/or the European Food Safety Authority (EFSA) should be aware; negative statements disagreeing with some element of Syngenta's submission; neutral requests for more data or clarification of existing data; and direct challenges to the rigour or accuracy of Syngenta's studies or conclusions.

In addition to analysis of these documents, we undertook two site visits to Syngenta (Jealots Hill), interviewed seven Syngenta personnel and other experts, and held meetings with Syngenta scientists and regulatory affairs experts. We also held two one-day workshops to explore different approaches to stakeholder dialogue on AABs. The workshops aimed to take the discussion on GM crops and emerging biotechnologies beyond questions of risk and uncertainty to broader issues of sustainable innovation, smarter regulation, and food security. The first workshop involved 7 potential users of agricultural technologies from the farming community, and science advisory organisations. The second workshop involved 18 stakeholders from industry and policy communities.

Data from the interviews and meetings were recorded and transcribed, preserving participant anonymity.

Background to Risk and the EU Regulatory System

The concept of a 'risk assessment-policy gap' (Evans et al. 2006) was one starting point for this analysis in that, for the ERA, there has been no agreement on the operational definitions of environmental protection goals, and no clarity on the evidence sufficient to satisfy regulators' requirements (Garcia-Alonso 2013; Raybould and Poppy, 2013). According to Evans et al. (2006), RM incorporates a dialogue about societal values and preferences, including what is worthy of protection and the degree to which it should be protected, whereas RA aims to be objective and to reveal factual truths about the world (i.e. RA involves the measurement and delivery of data to help determine the extent to which the objectives specified in the RM can be met).

We suggest that for EU GM crop regulation both RM and RA continue to be strongly influenced by value judgements. Without clear guidance on how scientific evidence should be used in these decisions, evidence can be interpreted differently to support different value positions (Devor et al, 2014). The precautionary principle, which informs European regulatory policy, is part of the structural base that contributes to the existence of these challenges. According to the EC, "…the precautionary principle can be involved when a phenomenon, product or process may have a dangerous effect, identified by scientific and objective evaluation *if this evaluation does not allow risk to be determined with sufficient certainty*," [emphasis added] (European Commission, 2000). The ambiguity around "sufficient certainty" means that there is a degree of openness and interpretive flexibility in how evidence is used during the process.

The EU's incorporation of the precautionary principle throughout its regulatory systems has facilitated the introduction of values into RA (Chataway et al 2006) rather than as a foundational basis for RM, and this is reinforced by the adoption of a voting mechanism in the European Parliament for final approval of GM crops for cultivation in the EU (Zetterberg and Bjornberg, 2017), regardless of results from the RA process. Raybould and Poppy (2012) argue that the RA policy gap is the main reason why accumulated ecological research showing negligible environmental risk of GM crops has failed to expedite EU regulatory approvals for these crops. Others note that, with GMOs presumed as different from other crop counterparts, problems have arisen from the early,

unnecessarily negative framing of citizen preferences (Tait 2001, 2009), facilitated by a permissive policy environment with regard to the dissemination of inaccurate scientific claims. One example of this is the favourable reception the European Parliament gave to misleading claims based on a report that stated that the herbicide glyphosate is a carcinogen, but which was widely criticised and retracted by the journal that published it (Casassus, 2013).

Conflicting values from different stakeholder perspectives involve issues that cannot be dealt with through scientific evidence on a single issue. Therefore, initial RM discussions and the basis for the regulatory system cannot rest on what is "rational scientific evidence" alone. If the variety of issues are ignored, and the focus is only on framing things based on scientific evidence, then broader value-based issues may became "wedged" into the RA process by stakeholders who are left out (Legge and Durant, 2010; Skogstad, 2011; Tait, 2001). Table 1 summarizes the different stakeholders and some of their positions/biases regarding GMOs.

	Group	Position/Bias
Pro	Ag-Biotech firms	• Access to markets and related profit • Seek return on investment on R&D • See deterioration of R&D capacity in Europe • Science-based assessment is only "rational" assessment that should be considered; • GMOs are no different than new plants derived from other methods (i.e. breeding)
	Smaller Biotech	• See GMOs as positive • Worry about negative market perception of GMOs and how may hurt business
	Scientists	• See translation of biotech research into usable products as positive • See GMOs as having low risk based on existing data • Some see GMOs as useful, but perhaps not yet able to declare completely safe (favour further research and trials).
	European States (i.e. UK and Spain)	• Open to GMOs as contributors to agricultural and economic competitiveness.
	Political parties	• Liberal parties, generally in favour of GMOs
	US, Canada, Argentina, Brazil, Egypt, South Africa	• See GMOs as safe, and regulatory system should treat like any other new crop; • See EU regulation as unfair to trade;
	Farmers	• Intensive arable farmers see GMOs as potentially positive • Worry about market perception of GMOs and how may hurt business, therefore hesitate on investment
Anti	Environmental NGOs	• Possibility of gene transfer and unknown environmental consequences; • Parallels with other disasters (e.g. Bhopal, 3 Mile Island, Chernobyl) • GMOs lead to corporate control over food production and distribution; • GMOs lead to intensive farming; • Look at past corporate actions re pesticides – not trustworthy

	European States including France, Germany, Italy, Austria	• Views range from cultural treatment of food and farming, to environmental concerns.
	Political Parties	• Green and Socialist parties see increased corporate control of farming, and of intensive farming
	Consumer Groups	• Increasingly against intensive farming
	Farmers	• Organic farmers see GMOs as directly against their values

Table 1: Positions and Bias amongst stakeholders re GMO, drawing from Herring, 2008; Tait, 2001; Tosun and Schaub, 2017

The EU regulatory system

Regulation of GM crop cultivation in the EU is based on Directive 2001/18/EC, and includes an ERA and post-market monitoring (Mittra et al. 2014). An application for approval to grow a GM crop is submitted to a national authority (e.g. in the UK the Department for Environment, Food and Rural Affairs); the national authority acknowledges receipt within 14 days, and sends the application to EFSA (the lead agency in managing the application process). If it includes a request for permission to cultivate, EFSA delegates it to a national competent authority (CA). The ERA and the RA on health and safety are conducted in parallel over six months, although it may take longer if further information is requested from applicants. If a GM crop is approved by EFSA and by EC members, cultivation would be permitted throughout the EU.

The ERA may include data from laboratory-based tests, assessments based on risk calculations, and exposure/field studies. It includes a monitoring plan requiring the identification of areas of uncertainty or risk that may not be in the "current knowledge and the limited scope of the environmental risk assessment" (EFSA, 2006).

During the risk assessment, the CAs of other EU member states have the opportunity to ask further questions or to ask for clarification of specific points in the dossier. Once the dossier has been given a positive assessment by EFSA, and a positive ERA opinion by the CA, the EC decision is presented to the Standing Committee of the Food Chain and Animal Health of Member States, which must vote on the decision within three months. If at this stage there is no qualified majority vote in favour of approving the application, the decision is passed to the Council of Ministers. If there is still no qualified majority in favour, it is passed back to the EC (Mittra et al. 2014). A qualified majority is 55% of member states representing 65% of the EU population (EuropaBio, 2013). Member states can prolong this process by requesting further information and evidence, and there are further, potentially indefinite, delays if there is no qualified majority for or against acceptance by the Standing Committee.

In 2015, political deadlock and delays in approvals prompted a change to EU regulations. For GM crops that have been approved for use by the EFSA, member states were permitted to opt out of growing them, but only for political or socio-economic reasons - they were not allowed to justify such a decision on the basis of scientific evidence (EU, 2015; Davison and Ammann, 2017). The expectation was that member states would be more willing to give EU-level approval for GM crops if they individually had the ability to opt-out (EU, 2015; Laaninen, 2015). The legislation was therefore intended to avoid deadlock and to enable member states to reflect their varying democratic preferences on the cultivation of GM crops (EU 2015; Muhlback and Tosun 2017). However, the deadlock has continued (Eriksson et al 2018).

GM Crop Case Studies

Our two cases reveal how the EU RA and RM processes have been applied, and illustrate how the political and normative standpoints of stakeholders may impact regulatory

procedures. Both cases highlight the lack of formal criteria specifying the data necessary to satisfy reviewers, and the degree of rigour required to demonstrate sufficient safety and minimization of risk. The ambiguity from a lack of formal criteria opens up opportunities for repeated requests for additional information and delays in the approval process.

Bt11 maize (resistant to Lepidopteran pests and tolerant to glufosinate herbicide)

The Bt11 dossier was filed by Syngenta with the French authorities in 1996. At that time the crop was approved by the US Department of Agriculture, the US Food and Drug Administration, and the Canadian Food Inspection Agency, and later that year by the US Environmental Protection Agency, Health Canada and the Japanese authorities. It was also approved in 1998 for import of food and feed use in the EU under Directive 90/220/EEC.[1]

Despite being positively assessed, the dossier had to be resubmitted a number of times because of changes in the EU regulatory system – the formation of a French Biosafety Commission in 1998, and the newly formed EFSA in 2002, after Directive 2001/18/EC was approved. It was not until 2003 that the French CA accepted Syngenta's evidence and gave a favourable opinion to the EC and Member States. However, the CAs of other member states raised objections to Bt11 being approved for cultivation during the 3-month consultation period in 2003. Table 1 summarises the 73 questions/statements.

Table 1: Categorized questions from national authorities – Bt11 (author generated)

Member Country	Total questions/ statements	Reference statement	Negative statement	Request for more data or clarification	Question/ request challenging rigour
Austria	5	0	1	3	1
Belgium	10	1	0	0	9
Denmark	3	0	0	3	0
Finland	3	2	0	1	0
Germany	19	5	1	10	3
Ireland	1	0	0	1	0
Italy	14	3	0	7	4
Spain	1	0	0	1	0
Sweden	10	1	0	9	0
Netherlands	3	0	0	3	0
UK	4	1	0	3	0
Total	**73**	**13**	**2**	**41**	**17**

After addressing questions from member states, EFSA in 2005 again published its opinion on the cultivation of Bt11, reiterating the conclusion of the French CA, accepting that the level of scientific uncertainty and potential environmental impacts, surrounding Bt11 was low.

[1] Notification C/GB/96/M4/1

A number of further issues were then raised by Member States on Post Marketing Environmental Monitoring (PMEM). Despite its earlier positive assessment, EFSA requested further improvements and clarification from Syngenta, leading to reiteration of the previous positive conclusion. Some Member States did not accept EFSA's scientific opinions and claimed their concerns were not being adequately addressed, and the EC requested that EFSA provide further information to ameliorate these concerns.

In 2007, the EC highlighted areas where it believed there was scientific uncertainty around Bt11, and concluded that in light of the precautionary principle Bt11 should not be approved for cultivation, contradicting EFSA's opinion. This decision was influenced by the EC Environment Commissioner Stavros Dimas, who had no technical background in the area but who took the political stance of achieving the lowest possible GM crop residues in seeds. In an attempt to discourage Bt11 cultivation, he clashed with the European Federation of Biotechnology over the interpretation of the studies put forward by the EC (Abbott & Schiermeier, 2007; Hodgson, 2008). EFSA (2008, 21) reviewed all publications and reaffirmed: '*its previous conclusions on the environmental safety of maize Bt11 … expressed on 19 January, 2005, 20 April 2005 and 7 November 2006'*. In 2009, the EC published an updated draft decision on Bt11 agreeing with EFSA's position (D003698/01).

On February 25, 2009, 13 years after the original submission, the Standing Committee on the Food Chain and Animal Health voted on the EC's proposed adoption of Bt11 for cultivation.

Number of Countries	Number of Equivalent Votes	How They Voted
6	91	In favour
12	127	Against
7	95	Abstain
2	32	Did not participate

Table 2: vote results for Bt11 proposal for cultivation

With no qualified majority (which would require 255 votes) the EC was not legally bound to issue a decision thus creating an indefinite further delay.

GA21 maize (tolerant to the herbicide glyphosate)

Following its approval for import into the EU in March 2008, the application for cultivation of GA21 maize was sent to EFSA by the United Kingdom CA in July 2008. EFSA decided the application was valid in October 2008, "starting the clock" on the evaluation process. The ERA was expected to be completed in six months by the CA appointed to carry out the assessment, the Ministry of the Environment of the Czech Republic. The CA asked EFSA to 'stop the clock' three times:

- 3 February to 21 December 2009 (227 working days);
- 12 January to 19 October 2010 (202 working days);
- 26 October 2010 to 29 November 2011 (286 working days) (total 715 working days).

On 21 July 2010, Syngenta delivered an information package that answered questions on non-target organisms, field trials, and surveillance of crops, the areas of inquiry that had prompted the "clock stopping". The CA deemed this sufficient and on 12 October 2010 restarted the clock and submitted their final report on 20 October.

The CA disagreed with Syngenta on the main issue in the report, the impact of cultivation, and whether the management of glyphosate (an herbicide), and prevention of its over-use, should be outlined as part of the process for the crop's approval or as part of the herbicide's (separate) regulatory process. The CA concluded that some of these

responsibilities belonged to Syngenta as part of the crop's approval and requested a fuller description of case specific monitoring, improved general monitoring, and design of a user-guide for farmers using glyphosate.

During the review period, member states were able to review the file and comment/request further information (Table 2).

Member Country	Total questions/ statements	Reference statement	Negative statement	Request for more data/ clarification	Question/ request challenging rigour
Austria	25	0	2	5	18
Belgium	4	2	0	0	2
Finland	1	0	0	1	0
Germany	31	3	2	8	18
Hungary	2	0	0	2	0
Ireland	2	0	0	2	0
Italy	1	0	0	1	0
Norway	6	1	1	3	1
Spain	2	1	0	0	1
Sweden	4	2	0	0	2
Netherlands	2	0	0	1	1
UK	4	1	0	3	0
Total	**84**	**10**	**5**	**26**	**43**

Table 2. Categorized questions from national authorities – GA21 (author generated)

Eighty-four questions/statements were submitted by member states over the evaluation period. Interestingly, 43 directly questioned the rigour or accuracy of Syngenta's studies or of its conclusions. Questions challenging the rigour of Syngenta's studies came mainly from Austria and Germany (18 each), both with long-standing normative opposition to GM crop development (Mittra et al. 2014). Given countries like Austria and Germany's traditional opposition to GM crops (e.g. both have had a ban on GMO cultivation through "safeguard clauses" for a number of years (Butler, 2010), it is understandable that some participants in the regulatory process perceived there to be bias in these responses.

Each question posed by a Member State *must* be addressed by EFSA, and many of its responses pushed back against some of the challenges to the scientific data, although

EFSA did in some instances ask applicants to submit additional data. EFSA's responses ranged from asking for all the available data in terms of specific studies already conducted, to recognising that previous approval had occurred and that citing a previous study was sufficient. EFSA seemed to be attempting to anchor discussion to the scientific evidence, and remain politically neutral despite, as noted above, the lack of criteria specifying what was necessary to demonstrate safety or the absence of harm. Generally, EFSA accepted the hypotheses that Syngenta put forward but also presented the strongest concerns by member states in the final report.

EFSA gave a positive assessment and recommendation that GA21 is as safe as its natural counterpart, with the caveat that pesticide use should be monitored (EFSA, 2011). However, we could find no record of a vote on its use for cultivation 9 years after the initial submission.

Workshops – the Future for AABs

In addition to the case studies, we undertook two stakeholder workshops, as described earlier. These brought different stakeholders together to discuss and reflect on current and future GMO regulations and their impact on the development and use of new and emerging agricultural technologies such as synthetic biology and gene editing. Synthetic biology is defined by the EU as 'The application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms' and gene editing as 'a process in which DNA is inserted, deleted or replaced in the genome of an organisms using nucleases or 'molecular scissors', resulting in targeted mutations ('edits')' (Tait 2016).

The Impact of Past Regulatory Experience on Current Framings

Workshop participants noted what they considered to be the negativity of the early debates on GM crops, with little regard for the validity of scientific evidence, and the use of emotive terms like 'Frankenfood' that coloured the public debate. The influence of such language prompted one workshop participant to state that "bio is a trashed brand". This raised the question of whether innovative agricultural biotechnologies like synthetic biology and gene editing could also be tainted by this past association. Workshop participants were unsure, and their accounts drew upon notions of 'naturalness'.

> There's … a public sense around GM, around this whole concept of naturalness and going with nature, despite the fact that no plant breeding is totally going with nature. But the idea that something that tends to import a gene from another plant or another completely different species is problematic … Whereas tinkering with the existing genetic structure, which some of these newer techniques … will be able to do very precisely, actually may not face those sorts of almost philosophical barriers.

In discussing synthetic biology, workshop participants noted the current on-going discussion in policy and scientific circles about whether or not such technologies fall under the GMO definition, or whether they should be categorised differently. The argument for AABs not being labelled as GMO is that they are simply more efficient ways of achieving results that could otherwise occur in nature; the counter view among participants was that they still involve genetic modification, even where similar results may be achieved through breeding. The 'naturalness' distinction acquires salience in this context for a particular set of stakeholders, and new technologies are valued, or not, through this prism.

Purposive Change in the Discourse – Benefits and Transparency

The concern expressed by workshop participants for AABs is that, regardless of different risk profiles and new possibilities they may provide, their progress through the system may be prevented by existing regulatory structures and the norms they have established.

They may be perceived simply as a variant of a GMO, and carry with that the negative connotations already documented in the regulatory system.

> Once you tighten regulations, it's very difficult to loosen them again. And the danger is that more and more new technologies just get slipped in under that umbrella… And I think there's a very real danger that we will end up in this, sort of, economic backwater.

Workshop participants considered how to shift the discourse away from risk in order to avoid new biotechnologies becoming trapped in a negative cycle of perception that would affect future regulatory decisions in Europe. Their view was that public engagement should focus more on potential benefits of the technology and the lost opportunities that result from a precautionary approach to hazard and risk. In one workshop it was suggested that the focus from the start should be on the problems that developers and users of the technology are trying to solve, rather than focusing on the technology as if it it can be delineated from this problem context. As some participants reflected, they would want to focus on communicating the benefits of a technology, but not hide the fact that the technology may incorporate biotechnology and may involve some risk. The view was that transparency was necessary, but:

> You can't get away from the fact that actually this is a bio based system… that you're using to give these great benefits. Otherwise, people will turn around and say: “why can't you do it some other way?” And you can then say: “we can't, we can only do it this way. So we're proud of it, it's doing great things, we've looked at all the risks and we've got regulation surrounding it and we'd like you to reflect on this and consider these benefits.”

However, some advocacy groups have already begun to steer public discussion towards threats and possible risks and these values-based arguments may come to dominate broader public discourse, reflecting a pattern noted in the early regulation of GMOs (Tait, 2001).

Despite fears of overly tight regulation and negative views of technologies based on normative rather than evidence-based starting points, the workshop participants *did* want checks and balances, arguing that it is a benefit to have an independent third party to validate the findings around safety of their product. The tendency they wanted to avoid, however, was for a regulatory system that becomes a system of “box ticking”, as well as trying to cover every eventuality. This would lead, in the view of the workshop participants, to overly tight regulation with little flexibility. Some of the workshop participants saw this tendency to focus on risk and hazard as being a difficult, yet typical challenge.

> I think that's where we've gone badly wrong in the past because we've been over precautionary, insufficiently realistic, [with] insufficient balancing of the actual potential of certain risks and hazards to occur versus others. I don't have any confidence in our ability not to focus on some extremely unlikely hazard that will probably never happen and to miss something major that we should actually be thinking about.

This concern of being overly cautious and focused on hazards was also linked to perceptions that anti-GMO values are often the starting point, which were also viewed by workshop participants as anti-science, anti-innovation and anti-profit for large businesses. This same view was also expressed by Davison and Ammann (2017) in their description of the EU’s regulatory system for GMOs and its possible impact on new technologies.

Some of the caution, as argued by NGO representatives in our workshops, however, comes from their assessing new technologies or crop products based on current farming practices and uses. There was a hesitation expressed in terms of accepting that farming practices would necessarily change with a new product. While they have more hesitation

with some technologies such as GM, it would be helpful to see how a new technology was situated within whole farming practice, rather than treating it as a separate technology. From a farmer's perspective, a workshop participant stated that they naturally look at sustainability, "I know I will lose the land if I do something that's going to [cause] damage and we want to try and improve it. So that's the actual easy bit, looking at the environmental and the economical and the technical." Overall, the grounded experience and expertise of the different practitioner stakeholders were seen as necessary to consider; one challenge in this regard, however, was how to assess different voices' expertise in a broader forum: "I think one of the worst things about the internet is that everybody's opinion is equal. And yet somebody's got 30 years' experience compared to somebody who writes a blog, the same weight is given."

Discussion and Conclusions

Bias perceived in the current EU regulatory system

Both the cases and the workshops provided insights into the challenges facing those participating in the current regulatory structures in the EU, as well as the challenges that will likely become evident as new technologies emerge. Specifically, the case studies illustrated that regulation of GM crops in the EU was unable to avoid the intrusion of delaying tactics that were interpreted as ideology-based into the scientific evaluation process of RA; and these delaying tactics were facilitated by the absence of clear criteria, standards and end-points defining the evidence needed to justify approval of a GM crop. In regards to the latter, we noted disagreement amongst CAs and EFSA regarding what is sufficient or rigorous evidence. EFSA was faced with trying to maintain scientific rigour while also navigating member state challenges about the nature and meaning of data, and politically influenced requests for clarification or further studies. In addition, grey literature highlighted cancellations of meetings, which extended the time period of a crop candidate moving through the regulatory process, and the EC's refusal to make a decision in the event of no qualified majority. EuropaBio noted that the Commission has formally admitted that it regularly fails to comply with legal timelines when it comes to GM authorizations (2013, pg. 1).

Davison and Ammann (2017), in their discussion of EU GMO regulation highlight that EC votes on GMO crop decisions after they pass through EFSA tend to align with member states' political stances on GMOs, rather than any evidence presented. They also note, amongst other things: EFSA being criticized, or its recommendations ignored by the European Commission and Parliament, despite the scientific evidence; and legislation presented by the EU leadership which is openly anti-GM on an ideological basis. Eriksson (2018), in a similar vein, notes that the initial intent of EU regulation around GMOs was that it would adapt as more evidence of their safety became available. With over three decades of evidence of safe use accumulated internationally, Eriksson implies a wilful disregard of evidence for political and/or value-based reasons.

GMO regulation and its impact on new technologies

Scientists are concerned that the EU regulatory systems may lead to delays or the prevention new technologies developing, such as AABs. Defining them as GMOs would enable their capture by GM regulation, and the EU has held open this possibility in the reports of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) (Tait 2016, p31-33). However, these products remain in a state of regulatory limbo, to the frustration of those who see the EU as falling behind the rest of the world in commercialising scientific research.

For example, and discussed to some extent in the workshops, different national European governments are taking contrasting views on gene editing technologies based on whether new or 'foreign' DNA is introduced into the plant. According to the Dutch, German and Swedish responsible organizations, no new DNA means the technology should not be

regulated as GM because the same results could be achieved through normal breeding techniques, albeit at a very low probability level (Laaninen, 2016). Others view gene editing as falling under the definition of a GM crop because it involves purposeful changes in genetic structures, regardless of whether they could occur in nature. In the case of synthetic biology where novel DNA can be introduced into the plant genome, it will be more difficult to make a case that this is different in a regulatory sense from the preceding generation of GM technologies. While developers of these technologies hope to achieve a regulatory system that is more proportionate to the properties of the final product, organic lobbyists and NGOs favour regulatory categorization as GM crops because of the risk they perceive "to the environment and human health" (quotation from Beyond-GM, an NGO website).

Tait et al (2017) have identified a general problem in that the initial choice of regulatory system for an innovative biotechnology often proves impossible to adapt later when it is found to have a disproportionate impact on commercialisation of the product. Davison and Ammann (2017) also argue that the current regulatory system is incapable of properly accommodating new AABs, as they are quite different from the GM technologies the regulation was created to address.

The contrasting positions on such issues go beyond different interpretations of data or disagreement based on interests; they involve a perception of bias in others and a low level of trust amongst stakeholders in GM-related debates. Earlier issues with pesticide regulation and slow recall of harmful products, and mismanagement of communication around "mad cow" disease, led to distrust of corporate and government sharing and interpretation of scientific information (Tait, 2001; Herring, 2008). This is reflected in the examples in the grey literature, and in interviews/workshops, where groups holding differing normative positions may not accept the evidence from those with whom they disagree. How does a regulatory process allow for evidence to be presented and used in decision-making in a way that would avoid compromising its quality, increase transparency, while still democratically addressing the normative positions of organizations and citizens?

A proposed approach to policy and regulatory structuring

The approach to regulatory policy we propose here builds on the case studies and the workshop discussions. From this basis, three points could usefully be addressed for any agricultural biotechnology, existing or new:

- Equal consideration of benefits and hazards in policy and regulatory discussions, avoiding unnecessary negative societal framing of an innovation.
- More adaptive regulatory systems to accommodate new technologies or new evidence regarding current technologies, to support the delivery of societal benefits while continuing to ensure safety, quality and efficacy.
- Greater transparency on the values and incentive structures underlying the contributions of all stakeholders involved in regulatory discussions and decisions.

Relevant to these discussions is the proposed framework Proportionate and Adaptive Governance of Innovative Technologies (PAGIT) (Tait et al, 2017), combining the EU innovation principle – where the impact of political/policy/regulatory decisions on innovation are fully assessed – and the related principles of proportionality and adaptation in the delivery of regulatory requirements. PAGIT proposes a more creative use of standards and guidelines throughout regulatory processes to continue to ensure safety, quality and efficacy of new technologies. The overall aim is to enable societally beneficial innovations to be developed within a manageable time-scale and at an affordable cost, particularly for small and medium sized companies, while taking account of "the

synergistic or competing requirements of innovators, regulators, policymakers and stakeholders".

Our workshop participants noted the challenges that issues of trust and perception create for stakeholder engagement, the interpretation of evidence, and perception of bias in others. This concern is shared by Davison and Ammann (2017) in terms of policymakers, and (for example) their biases against GM. Further, the range of positions and biases held by the different stakeholders noted earlier (Table 1), and the lack of trust in corporate and government evidence by citizens, means that continuing calls for transparency throughout the regulatory process need to be addressed (Tait, 2001; Skogstad, 2011; Legge and Durant, 2010). These issues related to bias and the possibility of value conflicts, from the agenda and discourse setting stage to the more operational levels of RM and RA, have raised still-unresolved questions for the effective conduct of stakeholder engagement and dialogue, despite very considerable investment in EU Horizon 2020 and Framework programmes (Tait 2017).

The EU Transparency Register may contribute to resolving such issues. It is a database listing organizations that try to influence EU lawmakers and institutions(including NGOs), and requires disclosure of *what interests are being pursued, by whom and with what budgets (https://ec.europa.eu/info/about-european-commission/service-standards-and-principles/transparency/transparency-register_en)*. Adding sources of income and requesting evidence requirements would fit in well with the information regarding the organizations' leadership, amount of funds used to lobby the respective EU institutions, and how many FTE equivalents are used. At the very least, a stronger culture of transparency and quality of evidence may to be established.

In conclusion, in this paper we have presented our analysis of the politicisation of the current European regulatory system for GM crops, and considered its implications for future innovative biotechnologies. We have suggested two initiatives that could begin to address these challenges, the PAGIT framework and a transparency register but these are far from being complete answers. There is a need for further research and analysis on how to regulate future innovative technologies and how to enable the productive and effective stakeholder dialogue and engagement that will be needed to deliver societal acceptance of these technologies.

References

Abbot, A. and Schiermeier, Q. (2007). Showdown for Europe. *Nature* **450**, 928-929 (2007).

Butler, D. (2010). A new dawn for transgenic crops in Europe? *Nature*, March 9.

Cassasus, B. 2013 Study linking GM maize to rat tumours is retracted. *Nature 28 Nov.* doi:10.1038/nature.2013.14268

Chataway, J., Tait, J., & Wield, D. (2006). The governance of agro-and pharmaceutical biotechnology innovation: public policy and industrial strategy. *Technology Analysis & Strategic Management*, 18(2), 169-185.

Davison, J., & Ammann, K. (2017). New GMO regulations for old: Determining a new future for EU crop biotechnology. *GM crops & food*, 8(1), 13-34.

Devos, Y., Sanvido, O., Tait, J., & Raybould, A. (2014). Towards a more open debate about values in decision-making on agricultural biotechnology. *Transgenic research*, 23(6), 933-943.

EFSA, (2006). Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed. European Food Safety Authority, May 2006.

EFSA (2008) *Request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507,* EFSA Journal, 851: 1-27.

EFSA Panel on Genetically Modified Organisms (GMO). (2011). Scientific Opinion on application (EFSA-GMO-UK-2008-60) for placing on the market of genetically modified herbicide tolerant maize GA21 for food and feed uses, import, processing and cultivation under Regulation (EC) No 1829/2003 from Syngenta Seeds. *EFSA Journal*, 9(12), 2480.

Eriksson D, de Andrade E, Bohanec B, Chatzopolou S, Defez R, Eriksson NL, van der Meer P, van der Meulen B, Ritala A, Sági L, Schiemann J, Twardowski T, Vaněk T. (2018). Why the European Union needs a national GMO opt-in mechanism. *Nature Biotechnology*. Jan 10;36(1):18-19. doi: 10.1038/nbt.4051.

EU (2015). Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015: amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. Official Journal of the European Union.

Europabio (2013). Failures of the EU Authorisation System for GMOs: Causes Impacts and Solutions, Update March 2013.

European Commission, 2000. Communication from the Commission on the precautionary principle COM(2000) 1 final of 2 February.

Evans, J., Wood, G. and Miller, A. 2006. The risk assessment-policy gap: an example from the UK contaminated land regime. Environment International, 32, 1066-1071.

Garcia-Alonso, M., & Raybould, A. (2014). Protection goals in environmental risk assessment: a practical approach. *Transgenic research*, 23(6), 945-956.

Herring, R. J. (2008). Opposition to transgenic technologies: ideology, interests and collective action frames. *Nature Reviews Genetics*, *9*(6), 458.

Hodgson, J. (2008) 'Scientists cry foul as Europe plays politics with GM crops', *Nature Biotechnology,* 26: 139 - 140

Laaninen, T. (2015). At a Glance: Member States' possibility to 'opt out' from GM food and feed import authorisations. European Parliamentary Research Service.

Laaninen, T. (2016). New plant-breeding techniques: applicability of GM rules. European Parliamentary Research Service.

Legge Jr, J. S., & Durant, R. F. (2010). Public opinion, risk assessment, and biotechnology: Lessons from attitudes toward genetically modified foods in the European Union. *Review of Policy Research*, *27*(1), 59-76.

Mittra, J., Mastroeni, M. and Tait, J. 2014, *Engaging with Uncertainty and Risk in Agricultural Biotechnology Regulation: Delivering Safety and Innovation.* Report from ESRC Knowledge Exchange Project with Syngenta, Jan. 2014.

Mühlbock, M. and Tosun, J. (2017). How EU member states have tried (and failed) to reach agreement on GMOs – and what it could mean for EU decision-making. LSE blog, November 2017.

Raybould, A. and Poppy, G. (2012) Commercialising GM crops under EU regulations: objectives and barriers. *GM Crops Food,* Jan-Mar, *3(1),* 9-20

Renn, O. 2008 *Risk governance:coping with uncertainty in a complex world,* London: Earthscan.

Skogstad, G. (2011). Constructing a transnational policy paradigm in the European Union: the case of GMO risk regulation. *Policy paradigms, transnationalism, and domestic politics*, *35*, 91.

Tait, J. 2001. More Faust than Frankenstein: the European Debate about Risk Regulation for Genetically Modified Crops. *Journal of Risk Research, 4(2),* 175-189

Tait, J. (2009) Upstream Engagement and the Governance of Science: the shadow of the GM crops experience in Europe. *EMBO Reports.* Vol 10, Special Issue, pp 18-22.

Tait, J. (2016) *Environmental Regulation of Advanced Innovative Biotechnologies: Anticipating future regulatory oversight.* Report to ShARE Group of Environment Agencies of the UK and Republic of Ireland.

Tait, J. 2017 From Responsible Research (RR) to Responsible Innovation (RI): challenges in implementation. *Engineering Biology.* doi: 10.1049/enb.2017.0010

Tait, J., Banda, J., and Watkins, A. (2017). Proportionate and Adaptive Governance of Innovative Technologies (PAGIT): A framework to guide policy and regulatory decision-making. 17 July, Innogen Institute, Edinburgh.

Tosun, J., & Schaub, S. (2017). Mobilization in the European Public Sphere: The struggle over genetically modified organisms. *Review of Policy Research*, *34*(3), 310-330.

Zetterberg, C., & Björnberg, K. E. (2017). Time for a new EU regulatory framework for GM crops?. *Journal of Agricultural and Environmental Ethics*, 30(3), 325-347.