Risk

Safety is just the start if we want good regulation

Adrian Ely is a Research Fellow at SPRU, University of Sussex. His areas of interest include environmental impacts of GM crops, frameworks for biotechnology regulation, risk and uncertainty in policy-making around new technologies, and innovation for sustainable development

a.v.ely@sussex.ac.uk

Transgenic crops are being put forward as a solution to the food crisis. The controversies that dogged their introduction, at least in Europe, are being dismissed as dangerous distractions. Difficult lessons about risk regulation, learned over decades of debate, are in danger of being swept aside in the hope of a quick technological fix. Instead of backtracking on advances in European regulation, which have made it increasingly sensitive to scientific uncertainty and social issues, the answer lies in taking them further.

European Food safety regulation was in flux before the GM controversy. A series of food-related scares had stripped away public trust. When research published by Pusztai (transgenic potatoes), Losey *et al* (monarch butterflies) and Quist and Chapela (gene flow in Mexico) called one official assurance about GM crops into question after another, it seemed like the BSE scandal all over again. However, people weren't just concerned about these scientific risks: research at the time showed that they were concerned with broader social and political questions such as who would control and benefit from the new technology and who would carry the risks. [1]

The first response to this catalogue of problems from the EU and many member states was to introduce a new division of labour between government departments responsible for promoting the food industry and those in charge of making sure it was safe. Within the latter came a stricter separation of the 'independent' scientific analysis (risk assessment) function from the value-laden process of political decision making (risk management). However, in practice, it has proved impossible to completely separate the institutions and functions of risk assessment and management. Improving their respective contributions to decision-making is important, but it is also necessary to ensure that the interface between them is organised in an efficient, open and transparent manner. This has led to the recognition of 'risk assessment policy' [2] through which social framing assumptions shape various aspects of risk assessment, and increased attention to divergent values associated with the outputs of risk assessment.

Over the past decade, the ways that the risks of transgenic crops are governed in Europe have evolved considerably in other ways. A wider range of scientific criteria are taken into account and assessment has been opened up to broader considerations. Although some of these changes meant extra burdens for regulators and businesses applying to have GM food, feed or crops approved, they allow more rigorous assessments of potential adverse effects and a more democratically accountable debate (at least within the borders of the EU).

In particular, regulators have begun to look beyond the products themselves to consider the management regimes and social contexts in which they would be used. For example, the principle of 'substantial equivalence', which waived detailed toxicological and analytical studies when transgenic products seemed similar to their conventional counterparts, has been demoted to 'the first step' in a more rigorous process of safety assessment. In the environmental arena the UK farm-scale evaluations, which analysed species differences in fields of conventional and GM herbicide tolerant crops, examined the changes in cultivation practices allowed by GM crops. There is growing consideration of indirect, cumulative effects, and applications for cultivation of GM crops in the EU must now be accompanied by a monitoring plan to identify problems that had not been considered prior to release. [3]

A framework

An EU-funded research project that I've recently been involved with, called Safe Foods, tries to build on such changes[4]. Based on interviews with stakeholders, legal analysis and a series of workshops, our part of the project aimed to develop guidelines for regulators based on a broader notion of 'risk', allowing them to respond not only to risk proper (strictly defined, situations where probabilities and magnitudes of potential outcomes can be quantified) but also to uncertainty (when probabilities are unclear or disputed) and socio-political ambiguity (when the values or the significance of technical or social consequences are in question)[5].

A simplified version of the regulatory framework we suggest is shown in Figure 1. In effect, it formally distinguishes between processes that already go in regulation - framing, assessment, evaluation and management - so that each can be made more robust and transparent.

Conventional risk assessment is still appropriate for most food safety threats, when enough data exist to quantify confidently the probabilities and magnitudes of potential adverse effects and where socio-political concerns are absent. Sometimes, though, additional forms of assessment are needed:

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precautionary assessment to deal more thoroughly with uncertain threats and concern assessment for socio-politically ambiguous threats.

By having a clear framing stage that specifies the most appropriate forms of assessment in the terms of reference to assessors, we can ensure adequate attention is given to the most salient characteristics of a food safety threat, while at the same time guarding against overly burdensome assessments.

Evaluation gathers the outputs from assessment and allows different stakeholders to deliberate on how tolerable any threats might be. These value-based considerations feed into management, where decisions are made about how to address the issues arising, and those are implemented and monitored by regulators, businesses and civil society. [6]

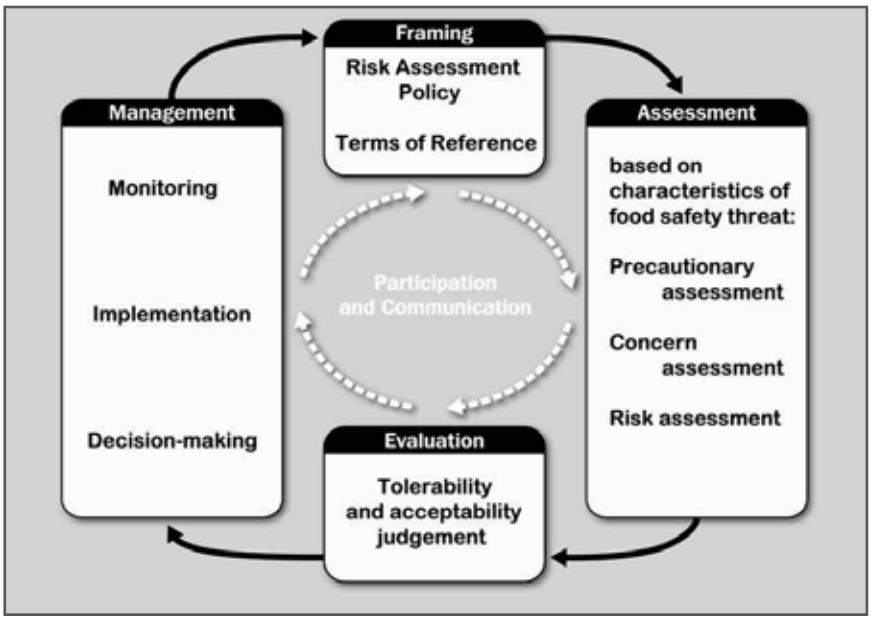

Figure 1. Primary stages in the risk governance framework adopted by Work Package 5 of the Safe Foods project

In Europe, the European Food Safety Authority is responsible for assessment and DG SANCO for management, but our research suggests that the stages of both framing and evaluation require the input of assessors and managers. They also demand wider involvement. The framework provides a structure for engaging stakeholders and members of the public. This is an accepted tenet of good governance in European policy, not least down to the bitter experience of failures to engage well over GM. This wider participation has a different purpose at each stage:

- Framing: to open up risk assessment policy and add legitimacy to the setting of terms of reference.
- Assessment: to broaden the sources of knowledge and information gathered.
- Evaluation: to deliver more legitimate value-based judgements on tolerability or acceptability.
- Management: to select the most appropriate measures and to aid implementation and monitoring.

High levels of scientific uncertainty or socio-political ambiguity require extended participation during assessment, evaluation and management. Of course, one lesson from GM foods is that even that may not be enough: the framework here deals with 'end-of-pipe' product regulation, yet the controversy also revealed a need to transform institutions responsible for agricultural innovation.[7] Along with the attention paid to socio-political ambiguity during concern assessment, that opens up broader questions beyond food safety and nutrition, for example over food security and food sovereignty (peoples' freedom to define and choose their own forms of food provision)

Where next?

At the start of the current French presidency of the European Union, an announcement was made that a "group of friends of the presidency" would be convened in order to consider the remaining problems in the EU system for regulating GM crops. This is an opportunity for Europe to consider the potential role of different forms of agricultural biotechnology globally, rather than just in its own back yard. Any resulting regime should recognise the specificities of the European context, and try to accommodate the concerns of other parts of the world that face radically different challenges and priorities.

Outside Europe, very different approaches to regulating the risks from GMOs have been adopted, with perhaps the most fundamental differences associated with labelling. Labelling GM products, central to food sovereignty concerns, began in Europe in 1998, as retailers sought to preserve consumer trust in their own brands.[8] EU legislation later standardised requirements across different firms and Member States.[9] Europe is still grappling with the co-existence challenges that this legislation raises. Labelling has not become compulsory in the USA, and other countries such as Japan have less stringent thresholds than the EU's 0.9% for adventitious presence. Elsewhere, for example in China, researchers have suggested that GM labelling is not yet a contentious issue and that GM, when commercialised, is likely to receive limited resistance from consumers.[10]

Questions of labelling, traceability and coexistence are probably most significant when considering the introduction of out-crossing transgenic food crop species to developing countries where seed saving and exchange is common. In some such countries strict labellingpolicies are less likely to be meaningfully implemented, and the limited scope for representative, informed concern assessment and evaluation also make the Europe-focussed recommendations outlined above more challenging to put into practice. As a major importer of food products from around the world, Europe has a responsibility to consider these complexities in any emerging governance regime for GMOs.

As well as potential adverse effects (or 'risks' in the broadest sense), Europe needs to take into account, transparently, the possible relative benefits of GMOs. Those need to be compared not only against other products, but also with alternative processes or practices that achieve the same ends. This presents a crucial challenge when considering some GM traits such as

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drought-tolerance in staple varieties which might, if they proved effective in practice, bring benefits for the economy and public health in some developing countries. As with risks, uncertainty over these possible benefits, and socio-political ambiguity (for example around their distribution) are vitally important.

Yet none of this comes from having less regulation of GM foods in Europe, or by trying to prune assessment back until it is once again confined to narrow technicalities.

By building in public participation, an alertness to uncertainty and greater space for assessing the social implications of new technology, Europe will be increasingly well-equipped to make sound decisions that build food safety, food security and food sovereignty. ■

[1] Marris, C. (2000) EMBO reports 2: 545-548.

[2] Millstone, E., P. et al. (2008) 'Risk-assessment policies', Joint Research Centre.

[3] EC (2001) Directive 2001/18/EC, OJ (17.4.2001): L 106/1.

[4] This article draws significantly on work conducted by Work Package 5 of the Safe Foods project (www.safefoods.nl) - Ortwin Renn, Marion Dreyer, Adrian Ely, Andy Stirling, Ellen Vos and Frank Wendler. The research will soon be published in Dreyer, M. and Renn, O. (Eds.) (2008) 'Food Safety Governance: Integrating Science, Precaution and Public Involvement', Springer.

[5] Stirling, A. (2007) EMBO Reports 8: 309-315.

[6] These steps in the management process are akin to those put forward by the International Risk Governance Council - see IRGC White Paper No1 "Risk Governance - Towards an Integrative Approach", IRGC, Geneva, 2005.

[7] Levidow, L. and Marris, C. (2001) Science and Public Policy 28: 345-360.

[8] Levidow, L. and Bijman, J. (2002) Food Policy 27(1): 31-45.

[9] EC (1998) Council Regulation 1139/98, OJ L159 (3 June), 4.

[10] Huang, J. et al. (2006) Appetite 46: 144-151.

Risk amplification

When consumers think about the risks involved with food products, they will usually make judgements that either amplify or attenuate those risks, effectively rejecting or accepting them.

Amplification factors include: involuntary consumption; a novel, man-made food product characteristic with unknown but probably long-term effects; a danger to vulnerable groups; and contradictory statements by scientists.

In contrast, attenuating factors present the opposite picture: a voluntary risk over which the consumer has control and can avoid; a natural source with well-understood short term effects distributed evenly throughout the population.

The consequence is that we find consumers much more concerned about technological man-made hazards in food products than over lifestyle hazards, which they believe they understand and are voluntary.

GM foods ascribe almost perfectly to the amplification of food risks model. Research at Newcastle University placed "eating genetically modified food" as fifth (behind hormones, antibiotics, pesticides and animal welfare) out of 16 potential food safety hazards in answer to the question "How worried are you about ...?" Consumers were much "less worried" about hazards associated with diet and health and food hygiene.

Claims are often made about consumer needs and desires. But consumer attitudes to food are very heterogeneous. In a study specifically directed towards GM foods we concluded that the population could roughly be divided into four groups in relation to attitudes to GM foods. [1]

The first, relatively small, group ('the refusers') rejected GM foods on moral, ethical or welfare grounds, rejecting purchase under all circumstances. At the other extreme many more people were very willing potential consumers, being 'enthusiastic triers' - young and keen on modern technology; or 'traditional triers'- low income consumers who saw GM foods as a cheaper alternative. But the majority were 'undecided' and, for them, the decision to accept or reject consumption of GM food products depended on various factors.

Christopher Ritson is Professor of Agricultural Marketing in the School of Agriculture, Food and Rural Development, University of Newcastle. He is a member of the Food Ethics Council

christopher.ritson@newcastle.ac.uk

It all depends

The perceived beneficiaries of a new technology dominate its acceptability to consumers. There is a widespread view that producers and 'big business' will reap the benefit of GM technology. But, identify a consumer benefit, and the technology becomes more acceptable. Societal benefits - "feeding the world" - or environmental implications are seen as remote; the impact on the individual consumer counts most.

We see too a 'scale of acceptance', with modification in fruit and vegetables more acceptable than fish, poultry and red meat (in that order). The perceived nature of the modification is also important: interspecies gene transfer is viewed as more acceptable than intraspecies transfer. ■

[1] Ritson, C. and Kuznesof, S. (2005) in Eilenberg and Hokkanen (Eds) An ecological and societal approach to biological control. Springer.