Appropriate Governance of the Life Sciences - 3

Regulating GM Crops: lessons for next generation technologies

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This policy brief is one of a series describing Innogen's research on strategic innovation issues in life sciences, the governance and regulation of innovation and the resulting innovation trajectories determining which products are developed and which companies take the lead in developing them.

GM crops were the first technology to be regulated on a precautionary basis from the earliest stages of its development

Genetically Modified (GM) crops occupy a unique place among risk governance approaches for modern innovative technologies. They were the first such technology to be regulated on a precautionary basis from the earliest stages of a development process that began in the 1980s and is still evolving. Today, there are distinctively different risk governance regimes in the European Union (EU) and the USA and the roots of these differences can also be traced back to the 1980s.

The development of regulatory regimes for GM crops has implications for the governance of innovative technology in the life sciences more generally, where any new technology carries with it the automatic presumption that it will be regulated, but where there may not be a clear regulatory precedent on which to build (Note 1).

GM crop regulation is referred to as either a positive or a negative precedent in discussions about life science regulation. For environmental organisations the European system is seen as an archetype, a paradigm shift in regulatory processes which has changed fundamentally the way we will regulate innovative technologies from now on. More usually it is seen as counter-productive from the perspective of risk governance, with discussions focusing on making sure it is **not** repeated for other new and emerging areas of innovation.

Both perspectives refer to the need to learn from the past, but the lessons proposed are usually too simplistic, focusing solely on the need for more public and stakeholder engagement at an earlier stage in the development of science and technology ('upstream engagement' (Note 2)). This policy brief builds on a series of research projects since the 1980s, exploring the complex antecedents of the European GM crops regulatory system and suggests a broader and more robust set of policy lessons to be drawn from the experience (Note 3).

PRODUCT VS PROCESS BASED REGULATION

In the USA and many other countries, GM crops have been commercialised in a straightforward and relatively swift manner through the regulations for comparable products (i.e. product-based). The EU regulations, on the other hand, have been 'process-based', assuming that a radically new, path-breaking set of innovations would require a similarly path-breaking approach to regulation (Note 4).

Devising the EU regulatory system has been a complex and politicised process, involving a temporary moratorium on GM crop approvals in the late 1990s, followed by the Deliberate Release Directive 2001/18/EC. Regulators assumed in the 1990s that the precautionary regulatory system which they were developing would

subsequently be relaxed as experience with GM crops accumulated. However, the reverse has been the case.

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The EU regulatory system for GM crops is now more complex and demanding than that for any other technology. Few GM crops are grown in or imported into Europe, and yet GM crops are grown on millions of hectares in the rest of the world, and GM foods are consumed on a daily basis by millions of people, under much less demanding regulatory regimes. There is no evidence of *direct* environmental or health risks from approved GM crops, and considerable evidence of their benefits.

There are acknowledged *indirect* environmental impacts, some beneficial and some damaging, as a result of changes in farming systems that can arise from the adoption of GM crops. There are also likely to be changes in the relative economic positions of different farm types. However, risk regulation is not the most appropriate policy instrument to deal with indirect impacts of a technology.

UPSTREAM ENGAGEMENT

To avoid future damaging conflicts over the regulation of innovative life science technology, 'earlier and better public and stakeholder engagement' is the widely presumed remedy. This is indeed an important aspect of modern democratic risk governance and it is particularly effective in reaching consensus in some circumstances, for example in planning and land use decisions, where there is an identifiable local population whose interests are directly and immediately affected by a proposed development. However, for novel technologies, particularly in life sciences with very long product gestation times (10-20 years) this can never be more than a partial solution.

Earlier public engagement Is a necessary but insufficient solution to a complex problem.

- It is impossible to predict the outcomes of today's scientific research in terms of new knowledge and discoveries, and equally impossible to predict the practical developments that will result from these discoveries over a period of 10-20 years (Note 5). Where the properties, benefits and risks of the objects of engagement are all highly uncertain, discussions are more likely to focus on political agendas and positioning of stakeholder groups with competing values and ideologies.
- Public opinion is notoriously volatile and subject to media and a variety of other influences. It is legitimate to question the extent to which opinions relevant to today's circumstances should determine the technological options available to meet society's needs in the quite distant future.
- Given the uncertainty about the benefits and risks of new technology, discussions about future developments require a prior process of 'framing' the technology and its products for a public audience, and this will necessarily be based on conjecture rather than evidence. Public views about the technology are therefore likely to be influenced mainly by stakeholder groups competing to frame it to suit their interests and values, with the attendant risk of generating conflict rather than mitigating it.
- For a technology with an uncertain future and unknown benefits and risks, most members of the public will not be motivated to take up engagement opportunities. Those willing to take part are likely to have specific agendas and to be motivated by a desire to shape the future, rather than to explore it in an open-ended manner.

All of these challenges have been evident in the development of regulations for GM crops and they are unlikely to be resolved, and may even be exacerbated, by moving the engagement process further upstream. Earlier engagement is a necessary but insufficient solution – more sophisticated approaches to the

engagement process itself are needed, and also a better understanding of the conduct of fundamental science, and the processes of translation of that science to products and processes that are safe, publicly useful and commercially viable.

MORE ROBUST FUTURE POLICY OPTIONS

We do not yet have robust policy procedures and decision rules to deal with innovative technologies that are publicly contentious. In the case of GM crops themselves, it is becoming urgent to revise the European regulatory system to bring it closer to normal standards of good risk governance practice. Likewise for new life science based technologies such as nano-biotechnology, stem cells, synthetic biology and novel pharmaceutical products, policy makers may feel they would benefit from having better guidance to help them to make decisions on the best available evidence, from both social and natural sciences, rather than routinely building stakeholder engagement into the risk governance of new technology in a manner that may actually increase the democratic deficit in decision making.

Stakeholder engagement itself could be managed so as to lessen the likelihood of negative outcomes.

- The rules of engagement should include requirements to comply with good quality standards for evidence brought to the discussion and avoid unsubstantiated conjecture.
- Discussions should be open and accommodating of the full range of relevant opinions (general public/citizens, scientists, industry, users of the technology, consumers) and no single perspective should expect to dominate other opinions.
- Engagement will not necessarily lead to consensus and expectations that **all** stakeholder views can be accommodated will generally not be met.
- Engagement should be carefully timed – too early and its value will be undermined by the level of uncertainty around the nature of future developments; too late and stakeholder opinions and political positions may have become entrenched so that accommodation will be more difficult to achieve.

Beyond the engagement process, one of the values of a democratic governance process lies in its ability to prevent vested interests from dominating policy decision making, particularly when this imposes unnecessary disadvantages on others.

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- An example from the development of the EU regulatory system for GM crops has been the setting of the standard for the permitted level of contamination by GM produce in organic and non-GM foods. The organic farming lobby has been able to influence the setting of this standard to a level which is more closely related to their political opposition to GM crops than to any attendant risks from the consumption of GM food. This outcome disadvantages farmers who would like to grow GM crops and companies that would produce them.
- Where there is no evidence of risks to health or the environment, but strongly held ideological views about the acceptability of particular technologies such as GM crops, it is more democratic to resolve the conflict by allowing choice in a market place, rather than imposing blanket prohibitions which restrict the choices available to all. Thus, where GM food is labelled so as to allow consumer choice, additional restrictions such as local bans to accommodate the views of pressure groups may be understandable from a political point of view but they cannot be justified on grounds of good risk governance.
- There may sometimes be a choice between adopting a ‘social fix’ (policy or

regulation) for a particular problem or a 'technological fix'. The latter approach is often derided, but historically, technical fixes have been at least as effective as social fixes. An example of a future opportunity in this category would be the policy requirement to incorporate a genetic use restriction technology (GURT) in any GM crop that could potentially spread by pollen or seed, thereby preventing any cross-contamination of genomes from related species.

Given the uncertainties described here about future innovations in life sciences, one useful general rule for policy makers would be to avoid unnecessarily foreclosing on the future – our foresighting abilities will probably never be good enough to enable us to predict what new technology will emerge from new knowledge in life sciences or elsewhere.

If we continue with a risk governance mode which attempts to predict today which products will be publicly acceptable in ten years' time along with the nature of their risks and benefits, we will miss out on some major public and commercial benefits and we will not avoid future mistakes.

NOTES

Note 1. See Innogen Policy Briefs: Appropriate Governance of the Life Sciences – 1 and 2. *Multinational Company Innovation Strategies* and *The Case for Smart Regulation.*

Note 2. Willis, R. and Wilsdon, J. (2004) *See-through Science – Why Public Engagement Needs to Move Upstream.* London: Demos, 71pp

Note 3. See the following publications:

Tait, J. and Levidow, L. (1992) Proactive and Reactive Approaches to Risk Regulation: the Case of Biotechnology, *Futures*, April, 1992, pp 219-231.

Tait, J. (1993) Written evidence on behalf of ESRC to Report of House of Lords Select Committee on Science and Technology on *Regulation of the United Kingdom Biotechnology Industry and Global Competitiveness*, 7th Report, Session 1992/93. London: HMSO HL Paper 80-I, pp187-196.

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. and Bruce, A (2001) Globalisation and Transboundary Risk Regulation: Pesticides and Genetically Modified Crops. *Health, Risk and Society. 3(1),* 99-112.

Tait, J. 2007. Risk Governance of Genetically Modified Crops – European and American Perspectives. In eds. O. Renn and K. Walker, *Global Risk Governance: Applying and Testing the IRGC Framework.* Dordrecht, NL. Springer Science and Business Media. See also www.irgc.org

Note 4. The case for path-breaking, process based regulation was made in: Royal Commission on Environmental Pollution, 1989, *Thirteenth Report: the Release of Genetically Engineered Organisms to the Environment.* HMSO, London. The case for path-dependent, product based regulation was made in Organisation for Economic Co-operation and Development, 1986, *Recombinant DNA Safety Considerations*. Paris OECD.

Note 5. Williams, R. (2006) Compressed Foresight and Narrative Bias: Pitfalls in Assessing High Technology Futures. *Science as Culture, 15(4),* 327-348.

This policy brief it based on the following paper:

Tait, J. (2007). Risk Governance of Genetically Modified Crops: European and American Perspectives. In eds. O. Renn and K. Walker, Global Risk Governance: Concept and Practice Using the IRGC Framework. Dordrecht, NL: Springer Science and Business Media; pp 134-153.

Social science research in the ESRC Genomics Network (EGN) interprets the field of genomics broadly, including plant, animal and health related innovations in life sciences. The Network ranges across five of the UK's leading universities, and involves over a hundred researchers, administrative and support staff, and international visiting research fellows. It is one of the largest social science investments in the ESRC's current portfolio, and is becoming the largest concentration of social scientific research on life sciences in the world.

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