Science, Policy and Biotechnology Regulation 8

DEMOCRATISING BIOTECHNOLOGY

'Sound science' is often presumed to be the basis of effective decision-making and regulatory policy. But how are debates framed? How are risks and uncertainties dealt with? What is the relationship between 'facts' and values? How sound is 'sound science' in practice? If biotechnology regulatory policies are to gain broad-based support – and so be implementable – a rethinking of the ways risk and uncertainty are handled is needed.

Science and policy

Science enters biotechnology regulatory policy debates in a number of ways, often providing authority for particular terms, models and methods and ways of framing risk assessments. As accredited 'experts', scientists are invited into the regulatory policy arena through membership of approval/release committees, advisory boards and commissions of enquiry. In the biotechnology policy debate there is much reliance on the principles of so-called 'sound science', as both the arbiter and legitimator of decisions.

But questions about how sound such principles really are have been raised. Concerns about food safety and environmental risks of biotechnology, fuelled by an apparent growing distrust of expert-driven decision-making, have questioned a purely science-led regulatory policy process. Distrust of expert institutions has resulted, in many places, in a sceptical public, alongside a growing array of activist organisations committed to an anti-biotechnology stance. Clearly leaving it all to the experts is not enough. So what new relationships between science, policy and regulation might work better?

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Risks and uncertainties

As in any new area of science and technology, uncertainty and, to some degree, ignorance dominate. This is inevitable. Conventional risk assessment, where the probabilities of outcomes are known, is not generally possible. Uncertainty – where we don't know the odds – and ignorance – where we don't know what we don't know – are central. Yet bureaucratic decision-making is poor at dealing with such complexity. Legal frameworks for regulations tend to require strict, unambiguous protocols, and international initiatives tend to push for standardisation and harmonisation of regulations (see Briefing 6).

The very nature of genetic engineering – involving complex genomic responses arising from transgenic work – or crop trials and environmental release of genetically modified organisms – involving interactions with the dynamics of existing agro-ecosystems – suggest many more uncertainties than are commonly assumed (see box).

SCIENTIFIC UNCERTAINTIES

Precision engineering or complex genomic responses?
Agricultural biotechnology science is dominated by a particular type of molecular genetics, one that argues – at least in regulatory and policy contexts – that the processes employed in genetic engineering are precise and controlled, resulting in predictable and manageable effects. Complex, interactive and longer-term genomic responses, are effectively ignored. Scientists of course recognise such complexities, but a convenient silence is often maintained. This means long-term or multi-causal issues such allergenicity and resistance often get left out of the regulatory remit.

Scales, boundaries and the design of field trials
Field trials are seen as a key step in the regulatory approval process. Specialists from different disciplines argue for different types of design. Agronomists, for example, favour simple plot-based experiments, while ecosystems ecologists, on the other hand, argue for more elaborate and long-term designs. Still others argue that field trials are probably not necessary at all, as likely impacts can be predicted from models and the extrapolation of *in vitro* or greenhouse responses. Such contrasting perspectives present dilemmas for regulators. What spatial scale is appropriate for field trials? Over what time period should tests be carried out? What boundaries are appropriate to prevent cross-pollination?

Policy principles and risk assessment

Yet, when science enters the regulatory arena, such uncertainties are often ignored. In the place of a considered assessment of complexity, a number of simplified policy principles are applied (see box). These carry with them problematic assumptions, despite being presented as based on 'sound science'.

QUESTIONING POLICY PRINCIPLES

Food safety: substantial equivalence
Are GMOs novel biological entities that require special risk assessments? Or are they not substantially different from other equivalent crops? Process-based regulation emphasises the special qualities of the genetic engineering processes by which new products arise, particularly the potentials for unknown and indeed unknowable effects. By contrast, product-based regulation focuses exclusively on the final product, emphasising chemical, toxicological and immunological testing on the same basis as other new food products. The contested notion of 'substantial equivalence' has been central to this debate. Proponents of biotechnology promote the concept, while others argue it is fundamentally unscientific, given the inevitably special characteristics that arise from genetic engineering processes.

Ecological impacts: familiarity
Issues of biodiversity loss, gene flow, and pest resistance all raise complex questions about the functioning of ecosystems following new introductions. How can regulators handle such unknown impacts? As familiarity increases, it is argued, deregulation – or streamlined harmonisation – can occur, allowing larger-scale releases. But diverse environments do not permit such extrapolations, others say. Cotton-farming in the US is not the same as in India or China; different pest complexes, field patterns and soil conditions prevail, requiring ecosystem specific assessments.

With limited budgets, staff, skills and time, regulatory decisions often focus on the obvious and apparently tractable elements of a decision problem. Policy principles such as familiarity or substantial equivalence help streamline and standardise a regulatory process, making approvals for new products easier and quicker. But they also 'black box' key uncertainties – around ecological and genomic contexts for introductions, for example, making their claim to be based on 'sound science' highly questionable.

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A more precautionary approach would argue for a case-by-case assessment, taking into account the particularities of any situation. Yet the narrow, technical perspective, with scientists dominating the regulatory committees, remains firmly entrenched in many settings. With such a focus on 'technical' issues, risk assessments have tended to shy away from broader socio-economic criteria, let alone moral, ethical and other questions (see Briefings 7 and 12).

Rethinking risk assessment

If biotechnology regulatory policy is to have credibility and legitimacy in the eyes of a sceptical and distrustful public and well-organised, globally-connected activist movements, risk assessment processes need to be fundamentally rethought. Broader contexts and framings of decision issues need to be examined, and areas of uncertainty and ignorance made explicit in the development of policy and regulatory solutions. By opening up the debate, a range of criteria can be included, and uncertainties accepted as an inevitable consequence of real-life complexity.

A number of challenges arise:

- the scope of assessment has necessarily to be expanded beyond narrow technical concerns to a range of strategic economic, socio-cultural, political, ethical and moral issues associated with choices about new technologies.
- methods need to go beyond narrow risk assessment tools to include systematic assessment and inclusive deliberation techniques that deal explicitly with multiple criteria and uncertainty.
- the range of expertise involved in risk assessment and regulatory policy decision-making needs to be expanded to include other disciplinary scientific perspectives, and often marginalised lay knowledges or 'citizen sciences'.
- context-specific assessments mean there will be a divergence in emerging assessments and regulatory choices in different locations, rather than uniformity and harmonisation.
- to generate trust in decisions, the institutional contexts for the development of regulatory policy need to become more open and transparent.

This briefing was written by Ian Scoones (IDS). It is based on papers 6, 8, 11 and 13 (see publications list). These are available at: **www.ids.ac.uk/biotech**

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