Regulating Biotechnology for the Poor?

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DEMOCRATISING BIOTECHNOLOGY

Are current systems for the regulation of biotechnology benefiting the poor? In designing regulations, governments are expected to balance the risks and benefits of GMOs in the public interest and determine whether biotechnology addresses the development needs of their country. However, increasingly, they are faced with global pressures upon the scope, depth and enforcement of their biosafety regulations. There is a real danger that in the push to accommodate trade concerns and the demands of exporters of GMOs, countries are losing an important opportunity to define for themselves whether and in what way biotechnology may assist their development.

Countries are faced with inconsistent and mixed messages from international organisations active in the biotechnology area, which place different emphasis on the balance between trade, environmental protection and food security in the design of regulations. These include the Cartagena Protocol on Biosafety and the WTO agreements on standards (e.g. Sanitary and Phytosanitary, and Technical Barriers to Trade), agriculture and intellectual property rights (see Briefing 6). Amid this confusion, however, there is a clear drive for countries to adopt standard approaches to risk assessment and regulations that are minimally disruptive to trade. This pressure is reinforced by the actions of GMO exporters lobbying weaker governments on a bilateral basis and using the leverage provided by aid and the threat of trade action against non-compliant countries (see Briefing 5).

Pressure to fashion a narrow system of biosafety regulation that prioritises market access also comes from the biotechnology industry itself, seeking minimal disruption to the international trade in GMOs, a speedy 'one-stop' approval process and strong forms of intellectual property protection for their products.

While more powerful governments may be in a position to accept commitments on their own terms, and defend their national interests, many developing countries are not. They find themselves torn between WTO pressures to open their markets to agricultural imports and resistance from farmers' groups whose livelihoods may suffer from sudden exposure to such global markets. They also find their ability to act upon concerns over the socio-economic impacts of GMOs on incomes, livelihoods and food security constrained by international instruments that focus on the environmental implications of the technology. Finally, global rules on intellectual property rights may sit uneasily with traditions of innovation and ethical concerns regarding the patenting of living organisms (see Briefing 4).

Will the effect of calls for common approaches to risk assessment and universalised approaches to standard-setting, aimed at keeping markets for biotechnology products open, be to close down spaces for developing countries to express their own priorities on biotechnology? Will they limit opportunities to respond to public demands, and identify appropriate biotechnology futures?

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Regulating for a different purpose

If, in designing an appropriate regime for the governance of modern biotechnology, we take as our starting-point the twin goals of promoting environmental protection and food security for the world's poor, a different set of global instruments and priorities may be envisaged. What is needed is an approach which accepts the need for risk assessments tailored to different agro-ecological contexts, and which upholds the rights of countries to decide which risks they consider most important. These may not be risks least restrictive of global trade and most compatible with the prevailing orthodoxies of scientific research. This is essentially what many African and other developing countries have appealed for in the international negotiations on biosafety. The amount of money invested in biotechnology, and the market potential for the technology, means that companies will be willing to meet the regulatory requirements set by different governments, just as they already do in most other areas of business activity.

A critical tension is coming to the fore in the regulation of GMOs. Participation in government decision-making on regulations is often encouraged at the same time as government autonomy and

responsiveness is limited by the demands of bodies such as the WTO. Such pressures for conformity may result in disillusionment with public consultation processes. Policies and measures that may be popularly desirable, such as labelling, comprehensive and precautionary forms of risk assessment, or even moratoria on the trade in GMOs, are increasingly difficult to enforce on the basis that they are incompatible with global trade accords.

KEY CHALLENGES FOR REGULATION

Speed of the approval process. Governments are under pressure to speed up their processes for approving biotech applications or face the cost of losing or deterring investors. The experience from the UK, India and elsewhere, however, suggests that a rushed process provokes public concern about inadequate consideration of possible social and environmental impacts, and perceptions of a technology being imposed from outside.

Scope of the process. The trade agreements mentioned above seek to restrict the nature of risk assessment procedures to narrow 'sound-science' criteria (see Briefing 8). While this makes sense for global commodity traders, it may not allow for adequate consideration of environmental uncertainties or the possible socio-economic implications of introducing the technology.

Participation in the process. While governments are obliged to engage the public in the design of their biosafety regulations, consultation is often limited to a small group of experts from the scientific community and private sector. Meaningful participation requires more ambitious and targeted strategies that create genuine spaces for people to question new technologies.

Implementation of policy. International agreements and national regulations mean nothing if they are not enforced on the ground. Yet, across the developed and developing world, there is now evidence of illegal growing of GM crops and of a seed trade that governments cannot adequately monitor, resulting in costly legal suits and loss of trust in regulatory systems. Building scientific and bureaucratic capacity, in advance of further releases, is therefore imperative.

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Are we then creating a democratic deficit in the global politics of biotechnology regulation, where the demands of international institutions and biotechnology corporations conflict with popular concerns about the technology? If we are, we can only expect the further breakdown of trust and loss of credibility of governments and international institutions set up to manage the technology in the public interest. Whatever your view of the technology, this is surely an undesirable outcome for all.

In designing regulatory systems, governments are inevitably faced with trade-offs between domestic priorities and international commitments, between a desire to promote biotechnology and a responsibility to mitigate risk. In responding to the mixed messages coming from international organisations, national governments, donors and the private sector, it seems the only way a country can regulate biotechnology in its own interests is to formulate a coherent national strategy on biotechnology where the technology and its potential is judged in relation to its ability to advance broader goals such as food security and poverty alleviation. Unless this happens, there is every danger that countries will be reacting to global agendas, rather than pursuing their own national development priorities.

This paper was written by Peter Newell (IDS). *It is based on papers 8, 10, 16, 36 and 37 (see publications list). These are available at:* **www.ids.ac.uk/biotech**

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