DEMOCRATISING BIOTECHNOLOGY

Harmonisation, Diversity and Uncertainty in International Biosafety Regulation

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The Cartagena Protocol provides countries with an opportunity to assess the risks associated with a GMO before authorising it to be imported for the first time. Some aspects of the new regime still remain to be worked out, including more detailed requirements for the identification of shipments of GM commodities, and issues of liability and redress. Developing countries face particular challenges in the implementation of the Protocol, not least because their capacity to implement, monitor and enforce national biosafety laws remains weak. In addition, they need to decide how to address a number of issues left to national discretion in the Protocol, and how to balance their rights and obligations under the Protocol with their commitments under the WTO.

In developing and implementing national biosafety frameworks, countries must decide how to deal with proposed imports of GMOs and GM commodities; and how to take the precautionary principle and socio-economic considerations into account in decision-making on GMO imports. For the time being, the precise contours of the international regime for the governance of GMOs remain somewhat uncertain. The resolution of these issues at the national level creates the possibility of divergent national approaches, and opens up scope for dispute.

Harmonisation and diversity

Regulatory harmonisation is often considered to be a positive end in itself, largely because it provides greater predictability in international trade. It is promoted and underpinned by international agreements such as the Biosafety Protocol and the WTO Agreements. Pressure for harmonisation also comes from other sources. For example, developing and transition countries, including Bolivia, China, Croatia, Ethiopia and Sri Lanka, have been subjected to bilateral pressure by more powerful states not to implement stringent regulations on GMOs and GM foods. Developing countries are likely to be susceptible to pressure applied via diplomatic channels, through bilateral trade, investment, and aid negotiations, and backed up by the threat of WTO litigation. The relationship between WTO rules and the Biosafety Protocol has become particularly pertinent in the international governance of GMOs.

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Pressure for international harmonisation also comes from domestic constituencies within developing countries. In some cases, interest groups have criticised their own governments for the slow implementation of regulations or for the lengthy assessment and approval process. Sometimes, demands for speedy progress of biotechnology research and development have led to *ad hoc* responses which, though they may be pragmatic in the short term, may obscure the need for clear and comprehensive regulation based on a thorough appraisal of national needs, priorities and capacity.

International harmonisation of regulatory procedures for GMOs risks ignoring a broader and more pressing set of questions to do with accommodating diverse national and local priorities and realities that go beyond ecological differences. This is an especially important consideration for developing countries, bearing in mind the diversity of agricultural practices, as well as the significant diversity in developing-country capacities in biotechnology, in the degree to which they have

REAL WORLD REGULATION

The Biosafety Protocol and other international instruments in this field, such as the *Codex Alimentarius*, focus primarily on environmental and human health risks. But concerns over the use of biotechnology in agriculture are more far-reaching, encompassing – alongside health and environmental concerns – ethical and socio-economic issues which demand analysis, public consultation and debate at the national level. Regulatory policy needs to look to the real world conditions under which GMOs will be used:

How are any approved GMOs to be monitored and assessed? Will necessary risk management measures work in the field? What sections of the community might benefit or lose out from the use of GMOs in place of traditional crop varieties? How will any unforeseen health, environmental or socio-economic impacts be addressed?

RESOLVING POTENTIAL CONFLICTS WITH WTO AGREEMENTS

Analysts have paid a great deal of attention to how the WTO might deal with a dispute between WTO-members involving trade restrictions on GMOs. While the Protocol and the WTO are both relevant to such measures, their objectives differ, and in some respects may conflict. A measure intended to implement the Protocol could be assessed under the General Agreement on Tariffs and Trade (GATT), the Agreement on Sanitary and Phytosanitary Measures (SPS), or the Technical Barriers to Trade (TBT) Agreement. Essentially, these agreements share the common purpose of ensuring that measures that affect trade are no more trade restrictive than is necessary to achieve the purpose for which they were designed.

Countries regulating GMOs may well reach different conclusions about:

- the appropriate level of protection of the environment or of human health to be achieved;
- acceptable levels and types of risk;
- interpretations of what constitutes risk and of available scientific evidence;
- the workability and effectiveness of risk management measures; and
- the significance of socio-economic factors in reaching decisions on the import and use of GMOs.

The WTO Agreements are backed by a compulsory and binding dispute settlement system that can authorise trade sanctions against any WTO member found to have violated WTO rules. This has provoked concern that implementing legislation under the Protocol could be overturned by the WTO if deemed inconsistent with any of the WTO Agreements. Ambiguities in both regimes make the precise outcome of any dispute unpredictable. While the WTO Appellate Body has strongly upheld the SPS Agreement's requirements of risk assessment and scientific justification for domestic regulatory measures, it has also affirmed the sovereign right of countries to set their own level of protection of human, animal and plant life and health, provided that measures adopted to achieve that level of protection otherwise conform to WTO requirements. Also it has recognised that risk may be evaluated in qualitative as well as quantitative terms, using risk assessments based not only on risk ascertainable in laboratory conditions but also 'risk in human societies as they actually exist'.

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adopted GM crops to date, and in the socio-economic conditions that prevail in different countries and among different communities within them.

The elaboration of national biosafety frameworks, which many countries have recently initiated, represents an important opportunity to consider and address many of these issues. Public consultation is required under the Biosafety Protocol, but few countries (including developed countries) have yet undertaken the type of consultations which are necessary in order to determine what levels of risk are considered acceptable by the public, and consequently what measures are appropriate to achieve the desired level of protection.

Given this diversity of conditions, interests, experience and capacity, some additional flexibility in the application of international trade disciplines would appear to be desirable in any assessment of biosafety measures applied by developing countries. Accommodating national diversity in the face of a relatively new technology represents a challenge not only for the Protocol and for national biosafety authorities, but also for the international trade regime.

This briefing was written by Ruth Mackenzie (FIELD), with input from Dominic Glover (IDS). It is based on papers 18 and 19 (see publications list).These are available at: **www.ids.ac.uk/biotech**

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IDS

Institute of Development Studies
University of Sussex
Brighton BN1 9RE, UK.
Tel: +44 (0) 1273 606261
Fax: +44 (0) 1273 621202/691647