RESEARCH REPORT[1]

PROJECT R7626

Globalisation And The International Governance of Modern Biotechnology: Promoting Food Security In Developing Countries

Background and Objectives

This project sought to explore how the governance of modern biotechnology interacts with processes of globalisation. We focused on two main sets of actors: international law and institutions, as they set the framework for national policy making; and the biotechnology industry, as it drives the biotech research and development agenda and seeks to promote supportive regulatory and intellectual property frameworks at the international and national levels.

The increasing involvement of biotechnology companies in developing countries has presented both opportunities and challenges for poverty elimination. Few case studies highlight as clearly the intersection of globalisation with poverty as the role of biotechnology in the developing world. The absence of effective regulatory frameworks and safeguards for monitoring the handling and use of biotechnologies brings into sharp relief the limits of state capacity in this area. The globalisation of the biotechnology industry does not appear to have been matched by the internationalisation of effective regulation aimed at safeguarding the food security needs of the poor. This research sought to assess the ability of international institutions addressing biotechnology to promote food security in a context of globalisation. It identified existing and evolving activities of international institutions in the field of modern biotechnology, exploring issues of competing mandates and policy coherence. It also considered the ways in which the activities of these institutions and of multinational agribusiness enterprises impact upon developing countries. The overall goal of the research was to begin to identify ways in which a more coherent food security agenda might be developed amongst the international institutions dealing with crop biotechnologies.

[1] This report has been prepared by Ruth Mackenzie, FIELD and Peter Newell, IDS, with input from the other project researchers at FIELD and IDS (Dominic Glover, Fernando Latorre, Ian Scoones, and Farhana Yamin), the African Centre for Technology Studies (ACTS) (Patricia Kameri-Mbote and Hannington Odame), Research and Information Systems for the Non-Aligned and Other Developing Countries (RIS) (Biswajit Dhar) and the National Law School of India University (NLS) (T. Ramakrishna). This project was funded by the UK Department for International Development (DfID). DfID supports policies, programmes and projects to promote international development. DFID provided funds for this study as part of that objective but the views and opinions expressed are those of the authors alone.

In addressing these objectives, six questions formed the basis of our research:

1) In what ways do international arrangements relating to the trade and safe handling of agricultural genetically modified organisms (GMOs) impact upon the food security of the poor?

2) What are the objectives of the various relevant international institutions in relation to modern biotechnology, and what attempts have been made to promote policy coherence between them?

3) How do international institutions affect (in positive or negative ways) the ability of national governments to promote food security in the regulation of biotechnology? How do they enable or constrain particular policy options that might be desirable from a food security perspective?

4) How do the activities of multinational agribusiness companies affect (in positive or negative ways) the ability of national governments to promote food security in the regulation of biotechnology?

5) To what extent do moves towards international harmonisation of intellectual property rights relevant to modern biotechnology take into account food security concerns?

6) What reforms may be necessary to enhance the protection that the international institutions governing biotechnology can provide for the world's poor in the fields of biotechnology and food security?

Methods

These questions were addressed through a series of interlinked research papers and national case studies:

- Two national level case studies on India and Kenya that analyse the evolution of national policy and policy-making processes with a focus on (i) particular "events"/crops; and (ii) interactions between national policy-making and international institutions, and national policy-making and the biotechnology industry (Appendix I.6-I.8);.

- An analysis of the existing international legal framework on trade and safety aspects of biotechnology, focusing on the WTO, the Biosafety Protocol and certain FAO instruments, with an emphasis on the extent to which they reflect food security and related socio-economic concerns, and issues of participation and policy coherence (Appendix I.3);

- An analysis of the influence of the biotechnology industries upon biotechnology policy-making processes and regulation at national and international levels (Appendix I.2); and

- An analysis of impacts of intellectual property rights in relation to modern biotechnology and food security (Appendix I.4).

In the initial phase of the project, the UK-based collaborators, FIELD and IDS, initiated collaboration arrangements with research partners in India (Research and Information Systems for the Non-Aligned and Other Developing Countries (RIS); and the Centre for Intellectual Property Rights, National Law School of India University (NLS)) and Kenya (African Centre for Technology Studies (ACTS)). Researchers at FIELD and IDS also prepared three mapping papers (Appendix II.1-II.3) as a basis for discussions at the first project workshop to determine future research priorities.

Three meetings of project partners were held over the course of the project. The first meeting, held at IDS, reviewed the draft mapping papers and identified the areas of focus for future work. The second meeting, hosted by RIS in New Delhi, reviewed initial drafts of research papers/case studies and discussed dissemination options. The third meeting, hosted by ACTS in Nairobi, reviewed an outline for a synthesis paper prepared by FIELD and IDS, and discussed dissemination of final outputs. In conjunction with the second and third meetings, workshops for national level policy-makers were held to discuss interim findings of the project and to seek further inputs.

Detailed research outlines were prepared after the first workshop and reviewed by all project partners and by members of an informal advisory group.

An outline for a synthesis paper was prepared for discussion at the third workshop. After the workshop, a draft synthesis paper was prepared and circulated for review by all project partners. This paper draws upon all the papers produced during the course of the project and upon workshop discussions, and seeks to identify the main themes emerging from the research (Appendix I.1). It forms the basis of the "Findings" section of this report.

A range of research methods were utilised. Mapping papers were largely based upon desk-research, principally utilising materials available on websites of companies and non-governmental and intergovernmental organisations. Thematic papers on international regulation and intellectual property rights focused principally on competing legal obligations and policy priorities. These papers drew principally on reviews of international legal instruments and related national legislation, on negotiating texts and proposals, and on academic and grey literature. The thematic paper on the role of industry combined a series of interviews with key informants, including business representatives at the biosafety negotiations as well as firms in India in particular, with academic and grey literature on the influence of industry groups over national and international regulatory developments. Case studies were based upon review and analysis of national policy documents and legislation, interviews with national officials, and secondary

literature. Interviews with international and national officials, and industry and NGO representatives were conducted in India and Kenya, and at three meetings of the Intergovernmental Committee for the Cartagena Protocol in Montpellier and Nairobi between 2000 and 2002.

Throughout the project, FIELD, IDS and the other project partners drew on other relevant work in which we were involved. For example, the second project workshop was held jointly with an IDS project on *Biotechnology and the Policy Process in Developing Countries*, bringing in additional researchers from India, as well as from China and Zimbabwe. Researchers from China and Zimbabwe also joined our third workshop. FIELD also drew on its ongoing work with IUCN to produce an *Explanatory Guide to the Cartagena Protocol on Biosafety*, as part of which a series of review workshops were held involving government negotiators and national biosafety officials. IDS were also involved in some work for DfID and GEF on *Public Participation and the Cartagena Protocol* looking at a variety of country experiences with issues of consultation, participation and education and awareness-raising. That work benefited from insights from this project, with case studies on India and Kenya, but it also allowed us to learn more about the processes other countries have gone through in the design of regulations on biotechnology, providing interesting points of comparative reference.

Dissemination

A range of dissemination activities have been undertaken to date. One-day workshops for policy-makers have been held in New Delhi and in Nairobi in conjunction with the second and third project workshops (Appendix III.2 and IIII.3). These were organised and hosted by RIS and ACTS respectively. These workshops gave us an opportunity to share research from the project and explore policy priorities in case study countries. The workshops were useful in raising awareness of the projects, and generated useful information in their own right. Researchers from the IDS project on *Biotechnology and the Policy Process in Developing Countries* also participated in these workshops. At the end of the project, Ruth Mackenzie participated in a conference at NISTADS, in New Delhi, on issues of regulation, intellectual property rights and ethics in relation to biotechnology.

Researchers on the project have also engaged in a great deal of informal networking with policy-makers, sharing key findings from the work with them and learning from their insights. Meetings took place with staff at the Environmental Policy Department, DfID, and informal discussions with many government officials on delegations at the biosafety negotiations. IDS were also involved in discussions with the UK Cabinet Office Strategy Unit with regard to work on the impact of UK GM regulations on the developing world. A meeting was arranged at IDS with Halima Khan, and Peter Newell and Ian Scoones sent extensive comments on drafts of the paper that were shared with us. In-country DfID Kenya and DfID India staff were made aware of the work, and attended the one-day workshops in Nairobi and New Delhi respectively. Several meetings were held with DfID India representatives in advance of the New Delhi workshop.

A range of publications will emerge from the project. In July 2002, a special issue of the Indian journal *Economic and Political Weekly* was published with articles from a number of project researchers (Appendix III.4). In addition, researchers from the project have also contributed to a series of briefings to be issued by IDS in Spring 2003, funded by the Rockefeller Foundation (drafts in Appendix III.5).

Two of the mapping papers from the initial phase have been updated and published (Appendix II.2 (as a refereed academic article) and Appendix II.1 (IDS Working Paper)). Information gathered for the mapping paper on international organisations was converted into a hyperlinked table and updated regularly throughout the project (Appendix III.1). It was made available on the FIELD and GAP Research websites throughout the project in order to provide a gateway to information for other researchers.

The thematic research papers and case studies will be disseminated in various formats. We are presently preparing some of the papers for publication in the IDS Working Paper series, as part of a set of papers in that series on biotechnology policy. These will be sent to international organisations, government departments, NGOs and business groups with whom we have worked over the course of the research. A book chapter is also forthcoming from the industry paper (Appendix I.2). In addition, we are exploring making the case studies available in the publications series of RIS and ACTS. All project papers will also be made available on the websites of IDS and FIELD, in addition to the GAP programme website. Further dissemination opportunities will be sought, including further links with the project on *Biotechnology and the Policy Process in Developing Countries*, as well as international conferences and intergovernmental meetings in 2003.

Findings

As described above, the papers produced for the second phase of the project focused on key thematic issues and national examples. Each generated its own specific conclusions and, where appropriate, recommendations. The papers produced during this phase are diverse, but each sought to contribute to an analysis of influences on national policy-making on biotechnology, and the extent to which those influences enable national governments to promote food security. In general, we concluded that present mechanisms of international governance relevant to modern biotechnology are not supportive of pro-food security policy-making at the national level. Food security is not central to the mandate of the most relevant international organisations. And international rules adopted to date relevant to trade in, property rights over, and use of GMOs do not fully accommodate the contexts in which they will be implemented at the national and local level.

Issues and conclusions emerging from the thematic studies, and informed by the case study analyses, include the following.

- *International regulation of biotechnology* International activity on biotechnology and biosafety appeared to have evolved in an *ad hoc* manner among agencies with distinct, sometimes conflicting, mandates, giving rise to different approaches and

emphasis, some duplication, and the need for coordination and operational linkages. But more serious substantive challenges lie ahead. While multiple international organisations now address aspects of biotechnology and biosafety, international instruments addressing regulatory frameworks presently provide limited, or ambiguous, scope for countries to factor food security and other socio-economic considerations into their policies and regulatory decisions on whether to permit the import and use of GMOs in agriculture. Countries that seek to build such considerations into their regulatory frameworks face bilateral pressure to adopt narrower approaches. They may also face potential challenge to their regulations through the WTO dispute settlement system, the procedures and remedies of which are less favourable to developing countries, and where outcomes may be unpredictable.

Efforts to address food security and distributive impacts of biotechnology, as elements of a regulatory framework, are tending to take place in less influential or non-binding fora. At the same time, the principles underlying the WTO are permeating other international agreements and guidelines, setting a baseline for compliance. This feature appears more pronounced in certain international standard-setting bodies, such as the Codex Alimentarius and the International Plant Protection Convention, but remains contested in multilateral environmental agreements (MEAs), such as the Biosafety Protocol. Nonetheless the influence of the WTO over the elaboration of MEAs is clearly illustrated by the Protocol negotiations.

The effectiveness of present approaches to the international regulation of biotechnology relies heavily on national implementation and capacity-building. It is questionable whether in the short to medium-term all developing countries will in fact be in a position to assess and manage effectively risks associated with GMOs in a manner that adequately takes into account national and local circumstances. National regulatory systems will need to be capable of dealing with applications for the import and use of GMOs, assessing risks associated with GMOs, policing "illegal" transboundary movements and unauthorised use of GMOs, managing risks identified, and monitoring the actual impact of authorised GMOs in the receiving environment.

- *Business and Biotechnology* The research from the industry paper showed that the activities of leading biotech companies impact on the food security agendas of national governments through a range of mechanisms. Directly, firms have been active in presenting their views to government about the desirability and enforceability of different approaches to the regulation of GMOs. The economic and strategic potential of biotechnology, about which there is considerable discussion in the Indian context for example, places firms in a strong position to assert their preferences regarding the scope of regulations, the speed of the process, and the nature of risks they address. This material power translates into high levels of institutional interaction with government through active consultations and membership of committees, for example. At a discursive level the firms have also been able to promote their work as key to broader governmental objectives regarding growth and in the case of biotechnology, poverty alleviation. Some of the

controversial claims made by companies about the merits and pro-poor nature of the technology have been readily internalised by leading policy-makers. This has often been at the expense of serious thinking about the potential of other technologies or approaches to agricultural rural development to contribute to the goal of food security.

Another, more indirect, channel of industry influence has been through attempts to shape and promote particular international approaches to risk assessment, trade and biosafety regulation. Commodity traders and biotech firms became increasingly involved in the biosafety negotiations in trying to narrow the range of risks being discussed and ensuring that detailed provisions on socio-economic considerations as justifications for restricting the trade in GMOs were not included in the Protocol. The preference of these groups has been for the predominance of the trade rules contained within WTO agreements such as the SPS and TBT Agreements.

Biotech and large seed enterprises are not only important shapers of regulations, they are also key to the effective implementation of biotechnology regulations. They are the 'street-level bureaucrats' of biotechnology regulation, with expertise about crops and traits in the pipeline, often acting as *de facto* self-regulators making their own biosafety assessments, and being the ultimate subjects of government regulation. Understanding corporate strategy is key then to assessing the nature of the governance problem associated with biotechnology. The concentration of power in the hands of a few global biotech companies, consolidated through mergers and acquisitions and extending this control through tie-ins with local seed firms allows the degree of global reach that many firms now have. The pace of technological change they are able to generate as a result creates a problem for regulators who are often several steps behind.

- *IPRs and biotechnology* Biotechnology companies have been at the forefront of campaigning for stronger IPRs arguing this is necessary to recoup their R&D investments. To date, key institutions such as patent offices, courts and other national and international bodies which are directly concerned with IPR policy and enforcement, such as the WTO, have been receptive to industry arguments. As a result of industry pressure, harmonised standards of IPRs have been agreed at the global level but this has generated intense controversy. The most recent studies indicate that for low-income developing countries, the costs of strengthening IPRs may well outweigh the gains. Such studies were unavailable to most developing countries at the time of the negotiation of the TRIPs Agreement. Overall, developing countries' initial resistance to TRIPs appears justified by the lack of clear developmental gains. Rather than providing justification for an extension of the time-frame for TRIPs implementation, or relaxing the minimum standards, such studies are being virtually ignored in the WTO policy process. Ironically, there is now increased political and economic pressure for developing countries to accelerate their implementation of TRIPs. These only serve to highlight the lack of negotiating power and policy expertise of developing countries within the WTO and the strategic forum-shifting policies of the US and EU on trade/IPR related matters.

In Europe, where rules on legal standing allow NGOs to oppose patents, legal challenges have been lodged against decisions made by patent offices and courts. Such challenges have served to highlight the crucial role of patent offices and judicial bodies in making IPR policy. The ten year legislative process that resulted in the adoption of the 1998 EU Biotechnology Directive also provided an opportunity for the European public to comment on all aspects of the emerging IPR legislation for biotechnology. By contrast, the patent and legislative process in developed countries such as the US, Japan and the EU, patent offices and courts has not been as controversial and, in general, their resulting policy is more conducive to industry needs than in the case in the EU.

In general, opportunities for public comment on prospective IPR legislation have not been readily available in developing countries. For many developing countries, bilateral trade or aid related agreements signed with developed countries have foreclosed opportunities for public comment as well as foreclosing options for such countries to develop *sui generis* IPR policies appropriate to their developmental circumstances.

Although TRIPs implementation by developing countries is at an early stage, many developing countries have "imported" the IPR legislation of developed countries. Others, such as India, have taken a more creative approach but it remains to be seen whether their tailor-made solutions survive judicial scrutiny – at the domestic and international level.

The findings from the thematic papers and case studies led us to identify a number of over-arching themes or problems that characterise the present "system" of international governance of modern biotechnology. These are explored in more depth in the synthesis paper appended to this report (Mackenzie and Newell, 2003; Appendix I.1). They include:

- The "shadow" of WTO over national and international biotechnology policy-making;
- The limits of multilateralism;
- Problems of participation in international processes;
- The limits of international governance through law; and
- The gap between food security concerns at national level and the content and orientation of international mechanisms governing GMOs.

Throughout these themes, a number of factors arise repeatedly: issues of capacity and participation; gaps and ambiguities in legal frameworks, giving rise to a lack of certainty and predictability; and issues of autonomy and of creating a secure policy space for food security in the face of international commitments relating to trade liberalisation.

The "shadow" of the WTO: international trade rules and biotechnology policy

A major theme throughout our research is the pivotal role of the WTO in framing the context within which both national and international institutions are addressing the governance of modern biotechnology, both in terms of regulation and property rights. This emerged in a number of different contexts, and could be said to include both direct and indirect impacts on national and international policy-making. Areas of influence include, the impact of WTO rules on national law and policy, through requiring adaptation of national level regulations to comply with WTO disciplines, such as under TRIPs; the influence of WTO rules on the negotiation of international agreements, for example the Biosafety Protocol; the bilateralisation or regionalisation of WTO disciplines in free trade agreements; and the impact of the potential for challenge to national health and environmental standards through the WTO dispute settlement system. In particular, we questioned the suitability of trade liberalisation and harmonisation policies in the context of the differing capacities and priorities of countries at different stages of development. While this is by no means a novel observation, it would seem to be of particular concern in relation to the emergence of a new technology, where information gaps exist as to potential environmental, agricultural, human health and socio-economic impacts in different situations, and where many countries lack capacity to assess and manage risks of such impacts within their national and local contexts.

The limits of multilateralism

Despite the great faith that is placed in multilateral institutions to deliver effective accords able to tackle pressing environmental problems, from climate change and ozone depletion to managing the environmental impact of the trade in GMOs, our work has underscored the need to keep in mind the limits of multilateralism in producing effective outcomes and in overseeing a process that is beneficial to developing countries. This is illustrated by numerous examples of bilateral pressure brought to bear on developing countries to structure their IPR or biosafety laws in a particular way, in the context of trade, aid and investment negotiations. It is also revealed in the continuing problems of participation of developing countries in international processes; the difficulty of accommodating national differences within internationally harmonised approaches to risk regulation; and in the difficulties inherent in regulating a sector such as the seed industry, which is characterised by informal transfer and exchange in circumstances where there is limited regulatory capacity.

Participation in international and national policy processes

Our work highlighted the continuing problem of fostering effective participation of developing countries in international processes, and of creating genuine feedback mechanisms between national and international policy processes involving all relevant stakeholders. Among the difficulties here are imbalances in the relative depth and timing of the private sector participation as against the participation of communities and non-governmental organisations. While emphasising problems of participation for developing countries in institutions such as the WTO, however, we do not suggest that an answer to

these difficulties lies solely in "forum-shifting" debates around regulation and property rights to international institutions that, while potentially more responsive to developing country concerns, are likely to prove less influential.

The limits of international governance through law

A number of the papers highlighted more generally the limits of law in regulating a rapidly-evolving technology and in addressing the specific features of agricultural biotechnology. Among the problems identified here include an over-reliance in the short-term on national implementation and related capacity-building. But the papers called into question whether, at the national or international level, it can presently be said that there is a clear, predictable and enforceable legal framework governing modern biotechnology both in terms of regulation and property rights. This may give rise to both opportunities and risks to countries seeking to develop national frameworks, in a context where new biotech products and technologies are rapidly being developed. The biotech sector raises particular challenges for effective regulation. Since it is a knowledge intensive sector, industry plays a key role in brokering knowledge: through ownership of property rights; generating risk assessment and monitoring data and so on; and in defining the scope of effective and feasible regulation. By contrast, lack of understanding and awareness among the public and among some regulators creates serious impediments to implementation.

Bridging the gap: food security and international governance

It is apparent that there is an inconsistency between the content and orientation of the international mechanisms that have been developed to 'govern' biotechnology and the nature of the policy mechanisms that governments have traditionally, and in some cases continue to, deploy in order to enhance food security, including domestic protection from exposure to foreign markets. These tensions have emerged in a number of contexts, in particular in the disjuncture between socio-economic concerns around biotechnology at the national and local levels, and the failure to analyse and integrate those concerns into international regulatory and property rights frameworks.

The research generated a range of specific and overarching policy relevant recommendations. The specific recommendations are set out in the thematic papers and case studies, as relevant. Below, we seek to summarise some of these recommendations and to outline a set of broader considerations that need to be taken into account in efforts to improve international governance of modern biotechnology in a way that might better promote food security considerations.

1. Food security should be central to biotechnology policy making. We have noted already how food security has been marginalised on the agendas of key international organisations in this debate. This has produced a gap between international agendas on biotechnology and priorities at the national level, which needs to be bridged. The impacts of policies of multilateral financial institutions, such as the World Bank and the IMF, on the capacity of developing countries regulate biotechnology in a "pro-food

security" manner should be considered. This is key to the possibility of a coherent pro-poor biotechnology policy. These institutions have an impact on levels of public resources committed to particular types of agricultural research, on the effectiveness of intermediary channels between farmers and government decision-makers (through extension services and the like), and on the acceptability of controls on foreign investors. These are examples of areas where pro-poor intervention can be made.

A serious discussion on food security futures should not be constrained by prevailing trade disciplines. We have seen many recent examples where developing countries such as Zambia, Zimbabwe, and China have been condemned either for allegedly restricting access for GM products to their markets or for refusing GM food aid. There are sound social and economic reasons why controls on imports are sometimes necessary to protect fragile markets and vulnerable groups from the consequences of full market exposure, especially where environmental, health and socio-economic impacts are uncertain and potentially damaging. Forcing countries to accept GM products through resort to trade and aid pressures runs counter to the need for countries to consider whether they want biotechnology, having assessed its implications, and if so, under what conditions and with what safeguards in place. At the moment, the democratic space in which to make that assessment is being closed down. Ironically, the net effect may be to generate resentment towards an imposed technology, without adequately considering its potential advantages.

2. Funding for basic research into staple food crops should be increased. Our work on the corporate strategies of the leading biotech firms suggests that while they may have an important contribution to make, there remains an enormously important role for state-led agricultural research into crops and traits that will benefit smallholder farmers in particular. Biotechnology may well feature in such programmes, but it should not be at the expense of due consideration to other technologies and production processes. The neglect of lower-tech biotechnological innovations in tissue-culture etc, as well as other non-GM techniques, highlights the need not to overlook existing technologies in the rush to embrace the potential of high-tech biotech as a solution to complex food security issues. Investment is currently flowing into projects aimed at attracting the biotechnology industry. 'Biotech Parks' part funded by the World Bank, that have sprung up around India would be an example of this. But if food security is the priority, it makes sense for funds to be directed towards those forms of agricultural innovation that governments (and others) best feel meet their national food security needs. This requires agencies such as USAID not making the receipt of funds conditional on the development and use of biotechnology, but rather allowing this to be one option among many. Where countries do opt to explore biotech options, access to basic research technologies should be facilitated, for example, by allowing licensing for research without payments.

3. Building capacity for participation in national and international policy making on these issues is essential. This means using a wider range of tools for participation and consultation at the national level (for example, see Glover *et al*, 2003) but also strengthening legal literacy and understanding of the operations of key international institutions. This needs to happen alongside efforts to improve levels of resources

available to developing countries to attend and participate meaningfully in international negotiations. Of itself, of course, boosting capacity and profile in these ways does not ensure that food security issues will be more adequately addressed. Combined, however, with more substantial reforms in the mandates of international organisations active in this area, such changes could make a difference to the ability of smaller developing countries in particular to use international policy processes to their advantage.

4. Scientific and institutional capacity for developing, and some developed, countries needs to be greatly enhanced to meet the challenge of effectively regulating biotechnology products. This means building indigenous scientific capacity within countries to undertake their own testing of products for environmental and health safety, as well as socio-economic impacts, and reinforcing the capacities of government regulators at national and sub-national level to ensure that regulations are implemented on the ground. We also recommend a more 'bottom-up' approach to defining capacity needs rather than assuming either that needs are similar or that differences will not exist between capacity that exporters of GMOs might like to see improved and capacities that governments or farmers groups would prefer to be strengthened. International organisations should cooperate to ensure that capacity-building for biosafety and biotechnology is better integrated. Although some coordination and cooperation occurs, present approaches suggest that capacity-building initiatives flow from the mandates of particular international organisations, which risks entrenching the marginalisation of food security concerns in biotechnology policy development.

If we are serious about putting food security first, we should also ensure that the capacity of countries *not* willing or able to engage in the trade in GMOs is also strengthened, so that choices over agricultural futures are not reduced. There may be a danger at present that funding goes to those countries that are willing to accept biotechnology products, a commitment which they demonstrate by setting up a National Biosafety Framework or creating a scientific platform to receive and test biotechnology products.

5. Additional capacity is also required for policy analysis of IPR options, including impacts of IPR policies on prices paid by small-scale farmers and impacts on current farming practices (such as seed exchange). Capacity-building efforts should also seek to ensure patent offices and judicial bodies in developing countries understand flexibilities available under TRIPs and implications of different interpretations of key terms, including how such terms were interpreted by developed country patent offices and courts. Developing countries require both time and resources to craft *sui generis* options for IPRs relating to plant varieties and biotechnological innovations, and there are strong arguments to support increased time-frames for TRIPs implementation for all developing countries, not just least developed countries;

6. While there has to be some respect for questions of commercial confidentiality, priority-setting and policy making should be more transparent with clear lines of accountability between regulators and those subject to the regulations and the intended beneficiaries of those regulations. This means, from a food security perspective, actively reaching out to consult marginalised and resource-poor farmers prior to decisions being

made. In turn, this requires international institutions and the programmes they oversee to be more flexible in the time-frames within which they allow countries to set up biosafety frameworks, for example, to allow more time for fuller forms of consultation and public participation. Particularly in order to anticipate negative impacts and positive potential of particular biotechnology developments for the food security of the poor, engaging such groups early on in a process will avoid costly mistakes later on. This applies to both national institutions, and international institutions involved in agricultural research, such as the CGIAR bodies.

As noted above, however, for such processes to be legitimate and for groups to consider engaging in them worthwhile, they have to make a difference. If governments' hands are to some extent tied by their existing international treaty obligations and certain policy options are already off the agenda, it will be difficult to persuade citizen groups to engage in exercises in public consultation and participation if they feel the government cannot, ultimately, act on their demands. Harmonised approaches to regulation and risk assessment run the danger of closing down public spaces for citizens to debate which biotechnology future they want and why and certainly reduce the scope for countries and groups within countries to prioritise the role of biotechnology in tackling food insecurity in their own (different) ways.

7. Socio-economic analysis of potential impacts of GMOs should encompass not only macroeconomic gains, but also distributive aspects. Additional research is needed on the potential impacts of new technologies on traditional knowledge and diversity. This analysis is required to underpin international and national level policy-making in this area. The difficulties associated with *ex post* analysis are well illustrated by controversies around the impacts of IPRs on biodiversity since the adoption of the CBD and the TRIPs Agreement. In this respect, calls from international institutions, such as the CBD Conference of the Parties, for analysis of socio-economic impacts of GURTS, coupled with a precautionary approach, ahead of field testing, may represent a useful precedent.[2]

8. New mechanisms to enhance accountability of the private sector are required. These may include enhancing understanding and application of competition law to prevent monopolistic practices in the agricultural biotechnology and seed sectors; restricting the scope of claims for commercial confidentiality where these limit public access to information and participation in decision-making; and clarifying the allocation of risk and liability for any damage arising out of the use of GMOs. Broader links exist here, of course, to current debates about corporate governance including the need for more clear and comprehensive understandings of corporate responsibilities. This recommendation flows from the observation above that while most international governance mechanisms in the area of biotechnology apply to states, the shapers and enforcers of regulations pertaining to the development and release of biotechnology products, are often in reality the companies themselves. This requires us to consider the need to place issues of business regulation much more centrally in the global debate about how to manage biotechnology in a way which benefits the poor.

[2] CBD Conference of the Parties Decision V/5, section III.

9. Communication strategies are key components of any effort to enhance food security. Information exchange should be addressed in capacity-building initiatives to enable interaction and coordination between proponents, critics and potential users and consumers of GM products. Policy-makers need to be kept aware of ongoing developments in biotechnology in order to be able to respond effectively and adequately to new developments as they come on-stream. And citizens need to be consulted in an effective manner before products are near or on the market, requiring more interactive dialogue about science and technology policy. This, in turn, requires greater transparency on the part of the private sector, in making information available about new products and in engaging potential users to inform the technology development process to respond to societal needs including food security. Social scientists can play a useful role in promoting such dialogues, as the work of POST (Parliamentary Office on Science and Technology) in the UK demonstrates.

10. More broadly, as discussed in more detail above, our research has questioned the suitability of universal harmonised approaches to assessing risks associated with modern biotechnology. In this respect, ways need to be found to take into account in decision-making, local differences that extend beyond ecological differences, without legitimising unjustified discriminatory or protectionist barriers to market access. Given that obligations under the WTO multilateral agreements are binding on all Members, under the single undertaking principle, and notwithstanding existing special and differential treatment provisions, in formulating negotiating positions in the WTO and elsewhere, developing countries are forced into difficult trade-offs to protect their interests. Clearer accommodation of developing country priorities, and of diversity among Members, within the WTO is required, whether through enhanced provisions on special and differential treatment or in some other manner.

Many of the conclusions and recommendations we have set out above relate to an overarching need to clarify rights and responsibilities in relation to the governance of modern biotechnology. International organisations can clearly play a central role, providing a forum for analysis, discussion and negotiation, and the elaboration or better implementation of relevant principles and norms. But the respective responsibilities of government, business and civil society need to be further clarified. Businesses are key actors in this debate as we have highlighted strongly. Their rights are well understood but the boundaries of their corresponding responsibilities that they assume as investors in developing countries, in particular, are less well developed. Civil society has rights to participate in these debates, but again should also assume responsibilities to engage responsibly and report and represent biotechnology issues accurately and honestly. In many respects the "rights" side of the equation takes issues of governance into the realm of human rights, including the right to adequate food but also encompassing rights of participation, access to information and access to justice and appropriate remedies (where liability issues arise), as well as respect for traditional knowledge. This suggests a broader framing of the biotechnology and food security debate to address governance not only within institutions addressing regulatory harmonisation, agricultural R&D and capacity-building, but as they relate to each of the key stakeholders in these debates.

We have discussed a great deal the reciprocal balance between the rights and responsibilities of governments and international institutions and the importance of maintaining a democratic space for governments, in consultation with their citizens, to consider whether and how they might use biotechnology in meeting their food security needs. But a major theme that comes through strongly is the need to revisit the issue of the appropriate relationship between international institutions active on the question of biotechnology. Putting food security, rather than standards harmonisation or more pertinently trade liberalisation, as the driver of policy change means redefining, in some potentially fundamental ways, the relationship between the WTO and the Cartagena Protocol, for example, as well as the relationship between the WTO and its Members around issues of food sovereignty. It would mean, for example, viewing trade liberalisation as a means to achieve food security rather than as an end itself. Ultimately if the purpose of trade is make welfare gains, it becomes nonsensical to insist on trade liberalisation even if there is no anticipated improvement in the livelihoods or incomes of the poorest. A more selective approach to the dismantling of trade barriers may be key to ensuring that the food security needs of vulnerable groups are adequately provided for, and the food sovereignty of nations fully respected.

LIST OF APPENDICES

Appendix I: Project papers

1) *Globalisation and the International Governance of Modern Biotechnology: Promoting Food Security? (synthesis paper)*
   Ruth Mackenzie, FIELD, and Peter Newell, IDS

2) *Business and Biotechnology: Regulation and Politics of Influence*
   Peter Newell and Dominic Glover, IDS

3) *The International Regulation of Biotechnology*
   Ruth Mackenzie, FIELD

4) *Intellectual Property Rights, Biotechnology and Food Security*
   Farhana Yamin, FIELD

5) *Tracing Policy Connections: The Politics of Knowledge in the Green Revolution and Biotechnology Eras in India*
   Shaila Seshia and Ian Scoones, IDS

6) *Globalisation and the International Governance of Modern Biotechnology: Implications for Food Security in Kenya*
   Hannington Odame, Patricia Kameri-Mbote, and David Wafula, ACTS

7) *Regulating Biotechnology in India*
   Biswajit Dhar, RIS

8) *Development of the IPR Regime in India with reference to Agricultural Biotechnology*
   T. Ramakrishna, NLS

Appendix II: Mapping Papers

1) *Agricultural Biotechnology and Food Security: Exploring the Debate*
   Ian Scoones, IDS, Working Paper No. 145 (bound separately).

2) *Globalisation, and the Governance of Biotechnology*
   Peter Newell, IDS, Global Environmental Politics (forthcoming, 2003).

3) *International Organisations and GMOs,*
   Ruth Mackenzie, FIELD, Draft paper produced for first project partners' workshop, January 2001.

Appendix III: Other Materials

1) Table of activities of international organisations relevant to the international governance of biotechnology

2) *Report on the Biotechnology Policy Workshop,* 7 February 2002, Habitat Centre, New Delhi, India

3) *Report from Policy Workshop on Globalisation and Governance of Biotechnology, with special reference to Kenya,* 28 November 2002, Hotel Intercontinental, Nairobi, Kenya

4) *Economic and Political Weekly*, July 6-12 2002, Vol. XXXVII, No 27 (bound separately)

5) Draft IDS policy briefings

Appendix IV: List of Additional Publications