BIOTECHNOLOGY AND THE POLICY PROCESS: CHALLENGES FOR DEVELOPING COUNTRIES

Final report
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Overview

This final report is in two parts. First, the report documents activities and outputs, including dissemination and policy networking efforts. Second, the report provides a summary of key findings across a number of different themes. This section is based on a series of briefing papers produced as part of this and related projects on biotechnology and policy. The appendices include some details of the final project workshop held at IDS in October 2003, and a full list of project written outputs.

More details on the project - and the broader programme of which it was part - can be found at www.ids.ac.uk/biotech

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I. Activities, outputs and dissemination

Since we first started working in this area with the development of the research proposal, subsequently funded by DFID-ESCOR in 2000, the overarching question for this work has been:

> *How can poor people's perspectives effectively influence the policy process in order that future developments in agricultural biotechnology meet their livelihood needs in a sustainable manner?*

The start of our work coincided with the publication in 1999 of the Nuffield Council on Bioethics' major report on biotechnology. One particular passage in report struck us:

> *As GM crop research is organised at present, the following worst case scenario is all too likely: slow progress in those GM crops that enable poor countries to be self-sufficient in food; advances directed at crop quality or management rather than drought tolerance or yield enhancement; emphasis on innovations that save labour costs (for example, herbicide tolerance), rather than those which create productive employment; major yield-enhancing progress in developed countries to produce, or substitute for GM crops now imported in conventional (non-GM) form from poor countries.*

We wanted to find out whether this 'worst case scenario' was in fact unfolding or whether a more optimistic conclusion about agricultural biotechnology in the developing world could be made. The focus of our work over the last 3-4 years has been on issues of politics and policy – or issues of 'governance'. It struck us that these were the areas which had been least addressed by research and analysis. While our concern was less on the economic-technical issues, these were also raised in our investigations, as section II of this report demonstrates.

Policy processes surrounding new biotechnology developments today involve a wide and growing range of actors, including scientists, government officials, international donors, transnational companies, farmers organisations among others. Policy processes occur at different levels, ranging from local level negotiations around agricultural technology priorities to global level debates surrounding property rights, biosafety regulation and biodiversity protection.

Through a series of country case studies in China, India, and Zimbabwe the research has traced a series of particular policy processes – some focused on local and national processes, others focused on links between such national debates and more international processes. Our aim has been to explore how different local and national contexts enable or constrain poor farmers' perspectives to be heard, and to assess who is involved and who is excluded and through what mechanisms.

In our view, too little effort had been invested in trying to understand how particular national and local contexts influence policy processes. Clearly, no single agricultural strategy or regulatory framework is universally applicable, and so particular contexts matter. Yet over the period since 1999, we have seen many attempts at the international level to suggest standard one-size-fits-all approaches to regulation and

policy. Such efforts have included the UNEP/GEF biosafety work, USAID research support to Africa, and various efforts by such agencies as OECD, UNIDO and others to encourage harmonised approaches to regulation.

The research has therefore:

- Examined existing policy processes (focussing on the link between science, policy and regulation in practice) surrounding biotechnology in three country case studies.

- Generated comparative lessons from three case study countries on ways forward for pro-poor biotechnology policy.

- Explored how alternative policy processes and regulatory approaches might be suited to different contexts, and, in turn, benefit poorer farmers.

In this work the challenge has been to explore what policy frameworks are realistic, given particular agricultural, environmental and livelihood priorities, scientific research capacities, regulatory frameworks and enforcement capacities, and broader economic and political contexts. In the biotechnology arena, given the range of actors, the uncertainties of the science, the commercial interests of companies, and the often highly contested nature of the debates, policy processes are highly complex. Encouraging a more pro-poor biotechnology policy process – whether at the local, national or global level – is far from an easy task.

By trying to understand the constraints of existing policy and regulatory systems in different developing country settings, the research offers a set of important lessons on the potentials and possible pitfalls of developing new approaches to encourage a pro-poor biotechnology policy process. We have attempted to distil the lessons of this work in a series of briefing papers, produced as a pack. This has been distributed widely to an international audience, and is reproduced here as Section II of this report.

A collaborative research effort

The outputs reported here have been very much part of a collaborative effort, involving participation by researchers in the three core case study countries (see below). However, in addition to this core group, we have developed a larger network of researchers working in this area by linking a number of projects together. Allied projects to this one have been:

- **Globalisation, food security and the international governance of food security**. This was coordinated by the Foundation for International Environmental Law, London and IDS and involving partners in India (National Law School) and Kenya (ACTS). The project was funded by DFID through the Globalisation and Poverty Programme.

- **Biotechnology policy processes in developing countries: meeting the challenge of inclusive participation**. This was coordinated by IDS, with partners in China (CORD/CIAD, Beijing), India (the Andhra Pradesh Coalition in Defence of

Diversity (PV Sateesh and colleagues), Dept of Communications, Centrla University of Hyderabad (Vinod Pavarala), the India National Biodiversity Strategy and Action Plan (Ashish Kothari), IIED, London (Michel Pimbert) and Zimbabwe (ITDG-Southern Africa) and was funded by the Rockefeller Foundation.

On two occasions - in Delhi in February 2002 and in the UK in October 2003 - the projects have come together to discuss outputs and to share dissemination and policy networking activities. The briefing series, funded by the Rockefeller Foundation, was a joint output of all three projects.

For the project reported here, the research collaborators have been:

China: Centre for Chinese Agricultural Policy, Beijing (Huang Jikun, Hu Ruifa, Wang Qinfang)

India: Centre for the Study of Developing Societies, New Delhi (Shiv Vishvanathan and Chandrika Parmar)

Zimbabwe: Independent consultants (Jennifer Mohamed Katerere, Munyaradzi Saruchera).

UK: Institute of Development Studies (James Keeley, Peter Newell and Ian Scoones)

Activity and outputs timeline

The following table presents an outline of the key activities and associated output over the period of the project. All project participants were part-time on the project. At IDS, IS and PN had 25% of their time funded by this project over three years and JK 66%. Project collaborators were not contracted on a time basis. IDS inputs, particularly by IS and PN were necessarily complemented by other funds.

Dates	Activity	Outputs
April 2000	Project initiated; discussions with partners and confirmation of collaborative arrangements made during visits to China, India and Zimbabwe	Partnership contracts developed and output/planning scheduled defined
End 2000	Background papers researched and prepared	From IDS: 2 Working Papers and one internal project paper prepared; From project partners: Background papers on country status/issues prepared
April 2001	First project workshop held at IDS to plan field work phase and discuss background papers	Field work plans developed
2001-2003	Field work phase: JK visits China (July 2000; Nov-Dec 2001; March-June 2001; March-May 2003); IS in India (August, 2000; Jan-April 2001 and Jan-March 2002 and February 2003); PN in India (August 2000; March-July 2001) and China (April 2003); JK and IS in Zimbabwe (July 2000; February 2001 and January 2003).	Fieldwork carried out in collaboration with local partners. Informal feedback workshops attended.
February 2002	Project workshop held in Delhi at RIS	Initial findings shared with project partners and Indian policy audience; dissemination and output plans defined.
2003	Working papers completed and published as dedicated IDS series	Working Papers produced and disseminated in paper and web formats
September 2003	Website updated; briefing paper pack launched; press lunch held	Briefing packs sent to mailing list of 2000; press briefing held in London
October 2003	International workshop	60 participants attended 2 day workshop from over a dozen countries. Conference report produced.

Fieldwork in China, India and Zimbabwe had the following emphases:

China

Key themes of James Keeley's work included:

*Investigating the degree to which China can be thought of as a biotechnology developmental state.*Biotechnology in China is different from other settings in that funding is overwhelmingly from the public sector and research is carried out by public sector scientists. Biotechnology has also been a key strategic high technology policy area, promoted by specially formed committees at high-levels of government. Interviews with policymakers explored to what extent this can be understood as a 'developmental state' at work, promoting biotechnology in a way that is more poverty-focussed than in other places, and in a way that avoids complete dominance by multinational corporations, allowing for more local control of the technology. To investigate this case studies were developed of Biocentury, the first Chinese biotech corporation, responsible for marketing Bt cotton, and the two joint-ventures set up by Monsanto, also targeting the Bt cotton market.

Analysis of debates and contests around the development of a regulatory system

Interviews explored the development of a progressively more sophisticated regulatory system. Key factors such as WTO entry, and the international trade in GMOs (particularly imports of GM soyabeans from the Americas) were considered in relation to processes of further elaboration of regulation, such as the introduction of labelling systems. A key theme in relation to regulation has been the competition for authority between different ministries (principally the Ministry of Agriculture and the State Environmental Protection Administration) with different remits and claims for responsibility in relation to biosafety. This line of research investigated the significance of these bureaucratic contests and suggested they lie at the heart of the biotech policy process in China. A key question was to what extent intra-bureaucratic debates are a site for a more fundamental questioning of the social purposes and consequences of the technology than has generally happened elsewhere in China, given the relative lack of civil society activism around biotechnology to date. The degree to which differences of perspective between ministries has resulted in an unexpected moratorium on further commercialisations of GM crops has been a key question.

Science-policy cultures around biotech, including practices of risk-assessment

Another key theme was the role of scientists in the policy process, and the nature of Chinese science-policy cultures. This line of research looked at how a network of biotech scientists with close links to bureaucracy have articulated biotechnology as an inevitable solution to various challenges facing Chinese policymakers (food security, agricultural productivity and industrial competitiveness). Research examined the extent to which this network has been able to maintain a tight grip of funding mechanisms and also the risk-assessment system, in the process excluding alternative scientific perspectives on the technology.

Understanding how the technology is debated and alternative perspectives are articulated, given challenges associated with the political culture, and the strong formal national policy commitment to biotech

This area of research looked at findings emerging from areas of biosafety research that raise questions about dominant narratives around Bt cotton as an unquestioned success, and the potential benefits associated with commercialisation of a GM food crop, such as GM maize, rice or soyabeans. Interviews with researchers and officials looked at the extent to which this research has been able to effectively find its way into policy debates, examining in particular controversies around the 'Greenpeace / Nanjing report' on Bt cotton.

The final element of the China work included a comparative piece written by Peter Newell looking at the ways in which India and China have been 'domesticating' their global commitments under agreements pertaining to biosafety, trade and intellectual property rights for example. The work sought to compare the role of bureaucratic politics and different negotiating styles, business groups and civil society and a range of other factors which help to explain why international commitments that both countries had signed up to have been interpreted in quite unique ways. The different role of each of these factors in the policy processes of the two countries was found to have a strong bearing on the scope and effectiveness of the biotech policies of India and China, as well as their implementation.

India

The India work had several strands. First, was the work by Peter Newell looking at the politics of business and biotechnology, and the implications for the policy and regulatory process. Second, was the work by Shiv Visvanathanan and Chandrika Parmar which looked at the way policy discourses around biotechnology have been framed, and particularly at the unfolding experience in Gujarat, where illegal Bt cotton had been planted. And, third, Ian Scoones' focused on a state level examination of policy processes, with an examination of the politics of policy in Bangalore, Karnataka.

Key themes of Peter Newell's work included:

The role of business in the policy process

This work sought to identify and explain the ways in which different firms affected by and involved in the debate about the role of biotechnology in Indian agriculture have sought to advance their interests. It found that the public positions of larger biotech and agro-chemical companies, seed enterprises and newer start-up firms and the associations they belong to relate to the differences in their underlying corporate strategies. The extent to which these firms are involved in primary research, export their products or require protection for their products helps to determine their political affiliations to the leading industry bodies that are active on biotechnology issues. In turn, each of these associations was found have distinct patterns of interaction with particular government agencies involved in the regulation of biotechnology products, as well as differing degrees of contact with global industry coalitions. Alongside this, individual firms, especially larger companies such as Monsanto have adopted their own unique and changing approach to policy engagement.

The influence of international regulation on domestic priority-setting and regulatory arrangements.

This work compared the way in which two leading developing countries in the global debate on biotechnology have sought to translate policy commitments contained in international agreements on trade and biosafety into workable national policy. It is a complex story of selective interpretation, conflict over priorities and politicking at the highest levels of government. It connects the micro-politics of inter-bureaucratic turf-wars with the diplomacy of inter-state negotiations and coalition-building. At the same time the role of business and civil society actors, media and scientific communities, were found to be key. We found that global commitments take on a fundamentally different shape once they have been refracted through domestic political processes. Competing policy networks that cut across the state and form part of global alliances seek to interpret international legal obligations in ways which help to consolidate their position within the bureaucracy. Working with allies in industry or among civil society groups, different government departments seek to domesticate loosely worded and often ambiguous obligations contained in trade and environmental agreements, such as the Cartagena Protocol, in ways which advance their political goals. This political manoeuvring takes on global dimensions when alliances are formed with international scientific, industry or activist communities to bolster positions adopted domestically. Likewise, domestic politics get played out in global fora as these agreements are being negotiated, where countries such as India and China have to adapt negotiating positions to a shifting sense of how the national interest is best served and navigating a course which is likely to be acceptable to key domestic constituencies when the agreement comes to be implemented. Likewise, each has a sufficiently clearly defined interest in biotechnology, that international processes are also regarded as an opportunity to 'internationalise' domestic policy preferences and secure scope for national discretion in policy-making.

Key themes of Shiv Visvanathan's and Chandrika Parmar's work included:

The importance of discourse in understanding the form of the contemporary biotech debate in India.

The debate has been imbued with politically charged and historically loaded terms and reference points that serve to privilege some understandings of the technology and its merits and potential hazards for India over others. This work not only provides an interesting historical perspective on biotech as part of a longer set of public debates about the future of agriculture in India, but the sociological tools that are used in this work are applied to the controversy around Bt cotton in India. The role of influential individuals in the debate, not within Delhi, Bangalore and Hyderabad, but in rural areas where controversies have been played out through citizen juries, are described and analyzed by this work.

The limits and alternatives to conventional approaches to 'regulation'

The work helped us to understand the limits of regulation as a set of legally bound practices that these papers argued translates poorly in setting such as India where corruption in seed markets is a problem and issues of capacity

and willingness conspire against local level enforcement. In a separate piece of work, the Green Revolution is the reference point for an enquiry into biotechnology and the politics that surround it. Again through reference to the cultural symbols and histories that accompany technological development, we come to understand the sources of risk perceptions, public concern and either enthusiasm or opposition to the technology.

Key themes of Ian Scoones' work included:

- *Scientific practice and cultures in biotechnology.* Interviews with scientists contrasted work in basic science institutes such as the Indian Institute of Science and the National Centre for Biological Sciences with applied agricultural science work at the University of Agricultural Sciences (Bangalore) and industry science, ranging from corporate companies such as Monsanto to small start-up firms.

- *Agricultural policy debates in Karnataka and India more broadly, and the role of biotechnology in these.* Interactions with officials in the Karnataka State Department of Agriculture, the University of Agricultural Sciences, politicians and industry players focused on the unravelling the economic, social and political implications of the 'farming crisis', particularly in the context of the new WTO regime following the removal of quantitative restrictions in 2001.

- *Policy networks, advisory groups and the politics of policy making*. By tracing the development of the recent Agricultural Commission reports and the new Biotechnology Policy of the state, and the formal and informal networks connecting scientists, bureaucrats, politicians and industry players, the research explored the contrasting 'discourse coalitions' emerging around the biotechnology debate in Karnataka.

- *Regulation and the management of risk.* The controversy around Bt cotton has been the focus for the analysis of regulatory dilemmas faced by agricultural biotechnology. Monsanto is undertaking field trials in the state under the aegis of Department of Biotechnology (Delhi) regulations. The perspectives of a range of different actors have been sought on this process, raising questions around the role of 'sound science', uncertainty, precaution, public accountability and transparency.

- *Commercial applications of biotechnology*. With biotechnology as being seen as a key engine of growth in the state, much interest is being focused on the development of new commercial initiatives in this area. Interviews with both established and new industry players have taken place, along with venture capital fund managers and regulators in government in order to gain a picture of how commercial applications of biotechnology are seen.

- *Dissent, opposition and the articulation of alternatives.* Biotechnology, particularly in agriculture, is being opposed by a number of different players. Interviews with scientists, NGOs, media people, farmers' group leaders and others unravelled the different dimensions of this debate, and how alternatives to a vision for agriculture based on biotechnology are being articulated.

Zimbabwe

The Zimbabwe work had four elements, led by different members of the team. These were:

Locating biotechnology within an understanding of the political economy of the seed industry (James Keeley/Ian Scoones).

Through a series of in-depth interviews with scientists, policymakers, industry personnel, farmer leaders and NGO workers the research explored the claims and counter-claims made about the potential contribution of GMOs to the future of agriculture looking at what biotechnology might mean for agricultural and food production systems in Zimbabwe. The research focused on two key crops: cotton and maize, and showed that choices about possible biotechnology futures have to be understood in relation to trends towards globalisation and liberalisation of the seed industry, and also shifts in the political economy of agriculture, both at home and overseas. Assuming that there is support for some role for agricultural biotechnology in Zimbabwe, and leaving aside questions of regulation, several key choices emerge, linked to four different future scenarios which were discussed with informants. Issues discussed included: is it best to rely on market-supply of technologies from multinational corporations? Or should Zimbabwe seek to develop technologies independently? Alternatively, if the latter is unrealistic, what scope is there for the pursuit of a middle position, striking bargains with big corporations and pushing for more locally appropriate forms of technology? Or, finally, are choices ultimately irrelevant with the most likely outcome being that transgenic biotechnology essentially passes Zimbabwe by? Several factors were identified that are key to these different scenarios, these include: technology choice; issues of technology access and ownership; the - as yet uncertain - role of new farmers emerging as a result of land reform and changes in the agrarian economy; the shifting dynamics of seed markets; changing industrial structure and ownership patterns; new economic conditions and trends in international trade relating to GMOs. The research concluded that these contexts and trade-offs need to be brought more specifically into debates about alternative GM or non-GM futures in Zimbabwe, and elsewhere in Africa, than has happened to date.

Understanding regulation in practice (Ian Scoones/James Keeley)

This element looked at the realities of the regulation of biotechnology in Zimbabwe. It showed that key uncertainties in biosafety debates are context specific and that locally-developed, flexible regulatory systems are more appropriate than the standardised, internationally harmonised, solely science-based forms of risk-assessment often advocated for developing countries. The research began with a brief examination of the development of regulatory institutions in Zimbabwe, building on the background work carried out earlier. It then looked at biosafety regulation in practice through two case studies: field testing of GM maize and cotton, and safety assessment of GM food aid imports. The research considered the limitations of the existing regulatory process and identifies challenges that exist for effective regulation in a small, agriculture-dependant country such as Zimbabwe.

Going beyond risk to rights (Jennifer Mohamed Katerere)

Human rights have become a key focus of law and development, yet they remain conspicuously absent from the regulatory and policy regimes for the use and development of modern agricultural biotechnology. In contrast to rights approaches biotechnology law and policy is concerned with individual property rights and global trade. In this context the only "acceptable" restriction on biotechnology development is safety and thus regulation has focussed almost exclusively on risk assessment. Drawing on the experience of Zimbabwe and other countries in southern Africa, this work has argued that a risk-based approach creates an artificial divide between civil and political rights and economic, social and cultural rights, desegregates society into a conglomerate of individual rights holders, effectively dis-empowers citizens and fails to create a viable and supportive legal framework for consensual agricultural biotechnology development that is responsive to local needs and perceptions about rights. The work has examined the legal underpinnings of a risk-based approach and asked why it has come to prominence. It has contrasted this with a rights approach and looked specifically at how rights framing and claiming has evolved since Zimbabwe's independence in 1980. Against this background it has examined demands for rights to participation, livelihood choice, farmer and community property and information in Zimbabwe and how these are manifested as challenges to the established regulatory regime. In particular it has looked at issues of problem framing, knowledge, culture, values, information and responsibility. Overall, the researach suggests that human rights law is a useful tool in creating more socially responsive law. This is so because it seeks to redress inequalities by establishing legal standards that allow for the restoration of human dignity by putting people back in control of their lives and limiting abuse and so creating substantial equality between people.

Investigating experiences of farmer participation in biotechnology (Munyaradzi Saruchera)

This work took a case study of Wedza district of Zimbabwe to examine the range ofchallenges that are adversely impacting on farming livelihoods. The aim was to see how biotechnology - and in what form - might fit into such a context. The study sought to understand the local Wedza resource-poor farmers' perspectives and participation in agricultural biotechnologies projects being implemented in the area by the Biotechnology Trust (BTZ) of Zimbabwe and its partners. Varied perceptions and attitudes towards biotechnology project activities were found to exist, depending on several factors, namely awareness and involvement in local development initiatives, management style of the different stakeholders, language and resource accessibility of the new technologies and policy / political environment.The problematic challenges of conceptualising and operationalizing the notion of 'participation' wasdemonstratedParticipation is warm, persuasive and attractive concept that is subscribed to by many, although very few, if at all, ever achieve it. Without a shared vision and meaning of participation, analytical tools, indicators and practical methods, participation remains an elusive pastime 'occupation' and endearing slogan of many development practitioners.

Dissemination and policy networking

Together with the two 'sister' projects, this project has produced over 45 written outputs. These are listed in full in Appendix 1, with those outputs specifically associated with this project highlighted. However, as indicated above, we were able to generate considerable synergies between the three projects, and therefore separating out outputs from one or other of the projects is somewhat artificial. For this reason, the full list of outputs from the wider agricultural biotechnology and policy programme at IDS are presented.

Early findings were presented to a one-day workshop in New Delhi in February 2002, attended by around 30 researchers, policymakers and activists. This provided an early opportunity to get feedback on initial results and share information with key users. This workshop also brought together all three linked projects adding to the integration of effort and output. This workshop was made possible by an additional supplementary grant provided by DFID. In September 2002 the 'International governance of biotechnology' project, led by FIELD / IDS held a workshop in Nairobi, Kenya which was attended by some participants from this project, again reinforcing links and cross-fertilisation.

The fact that we were able to generate a sufficient critical mass of activity and output during this period meant that there were a number of other spin-offs generated. These have all provided positive networking and dissemination opportunities. For example:

- Consultancy for GEF / UNEP on public participation in National Biosafety Frameworks, funded by DFID included presenting at training sessions in Malaysia, Dakar, and Vilnius.

- Invitation to provide support to developing country element of the Cabinet Office's 'economics report' on GM issues.

- Submission to the Nuffield Council on Bioethics' follow up report on developing countries

- Engagement with the discussions around the Zambia food aid issue

- Workshop presentation at Farmers' Link conference, Ely, UK

- Seminars at the University of Agricultural Sciences, Bangalore and Indian Institute of Management, Bangalore on science, regulation and biotechnology in the new economy.

- Workshop held at Habitat Centre in New Delhi with policy-makers, industry, donor and civil society representatives in attendance

- Workshop held in Nairobi Kenya with government officials, NGOs, business and donors organisations, hosted by ACTS.

Informal workshop held in Harare, Zimbabwe on participation and biotechnology policy.- Presentation at international conference on Biotechnology and the Poor, Cornell University, US.

- Paper presentation at British International Studies Association Global Environmental Change Group

- Presentations at CORD, China Agricultural University, Beijing, and at Institute for Biodiversity Sciences, Fudan University, Shanghai.

Working paper and the briefing pack have been distributed at a number of different conferences and events, including:

- London-based seminars organised by the UK Food Group, ITDG-UK, and the RIIA.
- Centres' week (CGIAR) Nairobi, Kenya
- Biotechnology working group, FAO, Rome
- Rockefeller Foundation, New York and international grantees
- Biotechnology and the poor international conference, Cornell, US
- Risk and the media briefing event, London

In addition to a general mailing of over 2000 to policy makers, researchers and activists internationally, the briefing packs have been distributed to 100 DFID staff, including all Chief Advisors, key members of new policy teams, and all Livelihood and Environment advisers internationally.

With such a large volume of outputs produced our strategy has been to focus dissemination around the briefing packs. These give highlights of key findings (see section II of this report) and direct readers to the working papers upon which these are based. All the working papers are available free of charge on the web, and have been extensively downloaded since they were posted. Paper copies of the working paper series have been distributed to key researchers, policy makers and libraries / resource centres, particularly in the 3 countries where we have worked. We have received many letters and emails of acknowledgement and thanks following these mailings.

A key focus for our dissemination activity in the final year of the project was the major international conference held in October 2003. This attracted a huge amount of interest, but we had to restrict numbers, although over 60 people attended including nearly all collaborators from each of the 3 linked projects. The two day event proved highly productive, and involved interchange between highly diverse perspectives. The conference was in part funded by this project, but additional funds had to be sought from elsewhere to make it happen. The highlights of the conference discussions, plus a list of participants and programme are presented in Section III of this report.

II. Key Findings

This section provides an overview of some of the key findings of the research. This is based on the briefing series produced as part of the project. See Appendix 2 for a full listing of all written outputs.

Overview

What are the key lessons emerging from the work as a whole? In the section that follows, the following challenges for the democratisation of biotechnology are listed:

- Understand the impact of trade choices for developing countries.
- Allow for alternatives to dominant intellectual property right models.
- Fashion regulatory systems that are responsive to local needs.
- Scrutinise the role of 'sound science' in decision-making.
- Think carefully about 'front end' technology priorities, not just 'back end' regulation.
- Allow the marginalised, as well as elites, to reflect on the different food and farming futures.

In essence the message is that debates about GM crops in the developing world should not just be viewed through a technical-economic lens: the politics of policy - whether around science, regulation, aid or trade - is key. As a result, contexts matter - choices look different in China, India, Kenya or Zimbabwe. Therefore general prescriptions - that GM is a good or bad thing for the developing world, for example - are inappropriate. Instead, a much more context-specific - and so political - analysis is required.

This may be a simple and rather obvious message. But it is one that is not often headed by those in the international community, driven as they often are by the need for universalising solutions and generic prescriptions, most often driven by a technical-economic set of views. When locale-specific politics of policy are brought into the picture, then things necessarily become more complex and uncertain. It is this complexity and uncertainty that must be addressed. In such contexts, we conclude, debates need reframing, including the recognition of wider issues of rights, and the participants involved need extending beyond a narrow expert elite to a more inclusive grouping that brings in lay perspectives.

The following sections offer some highlights of the project findings

1. Democratising biotechnology: an overview

Agricultural biotechnology has become one of the most intensely debated subjects of our time. In northern settings these encounters have been emotive and polarised, with consumers and civil society pitted against governments and corporations, and threats of major trade wars. The same vibrancy is unquestionably evident in the developing world. Indeed, in many ways, biotechnology becomes even more polarised when it takes on a 'development' angle. This is because, as many argue, it is precisely the poor in the developing world who stand to gain the most from biotechnological innovation, or, alternatively, who will be the most badly affected by

the introduction of genetically modified crops. These dilemmas are the subject of this briefing series. For a range of different issues, the briefings argue that a democratisation of biotechnology is needed if some of the worst case scenarios are to be avoided, and if imagined food and farming futures really are to be 'pro-poor'.

A bright GM future?
According to biotechnology advocates, transgenic crops will revolutionise agriculture in developing parts of the world - overcoming production constraints, achieving breakthroughs in crops where conventional breeding has reached its limits, and creating plentiful, cheap food. Others seriously question this techno-optimism and present a far more pessimistic picture of the future, where the poorest are actually the ones who lose, as biotechnology exacerbates trends towards industrialisation of agriculture, erosion of the diversity of agroecosystems and undermining of farmers' rights.

Neither course is inevitable. But as biotechnology is currently unfolding in developing world contexts there are good reasons to doubt the possibility of GM technology really facilitating agricultural change that benefits the poor. From a range of different perspectives, the scientific, legal and governance processes surrounding GMOs are weak at allowing the priorities of either poorer countries, or the poorer parts of their populations, to meaningfully contribute to policy framing and regulation. Agricultural biotechnology, and wider processes of planning for change in food and farming in which they are embedded need to be opened up, and made more responsive and accountable (see box). This kind of democratisation is vital if there is to be any possibility that agricultural and food systems respond to the concerns and priorities of marginalised farmers and consumers. The briefings draw out different aspects of this. They are based on a series of research projects that have investigated national and international biotechnology policy and regulation. This research has explored the particularities of processes in China, India, Kenya and Zimbabwe, and also their relation to changing global processes.

Food security, corporations and knowledge rights
'Can biotechnology feed the world?' is the apparently simple, but, in reality, complex question asked by the research. At the moment the results don't look too promising, with technologies geared primarily at wealthy farmers in affluent parts of the world, and many of the assumptions of pro-biotechnology advocates looking shaky. A key reason for this is the dominant role of the private sector in shaping research and development of GM crops , and particularly the associated IPR regimes, which frequently limit the options of both the national and international public sector .

Trade, regulation and science-policy
Trade and regulation are key themes with particular implications for developing countries. The choices a country makes about the role of GM technologies are fundamentally shaped by trade concerns, and by the choices of more powerful, northern states, as the research by the parallel 'Globalisation and biotechnology' project in particular explored explores. Equally, international regulatory regimes frequently constrain countries fashioning their own responses suited to their own circumstances, needs and priorities . The 'sound science' basis of many models of regulation and risk assessment is questioned. How science-based approaches can handle uncertainty more effectively, and balance different forms of knowledge in decision-making processes, are key questions.

Appropriate technology?
However, it is not only 'back-end' regulation that is important in relation to biotechnology debates. A key question is to what extent 'front-end' technology choices are relevant to the priorities of poor farmers. The Bt cotton experience is reflected on by a number of the case studies under this project. This technology was primarily developed with industrial agriculture in mind, but it is being taken up in many developing world settings. Nevertheless, concerns about long-term sustainability and biosafety remain. Drawing in particular on the Zimbabwe work - and parallel work in Kenya, section 10 belowexamines biotechnology in the African context, and explores some of the specific challenges of ensuring biotechnology is relevant to the needs of the continent's smallholders. Section 11 belowlooks at China, and asks to what extent the Chinese state, through its substantial investment in transgenic technologies, has been able to create a type of biotechnology development that offers an alternative to the dominant international agribusiness-led approach.

Ways forward? Citizen participation and rights
What types of changes are required for a democratisation of biotechnology? The final two sections below pick up this theme. Section 12 highlights the importance of a rights approach in allowing farmers and consumers to expand risk approaches to incorporate important socio-economic considerations, and to allow livelihood concerns to drive technology choice. These issues are echoed in Section 13 which looks at the need for new types of inclusionary practice in policy-making. This briefing explores the role that innovative techniques, such as citizens' juries, can play in giving a voice to marginalised groups, and allowing them to frame their priorities for food and farming futures.

Across the research findings what becomes clear is that fostering genuinely inclusionary biotechnology policy and regulation is a serious challenge. One key aspect of biotechnology is that it has many dimensions: it involves cutting edge science, and emergent fields of law, regulation and policy. Local realities, ecologies and livelihoods, in turn, are criss-crossed by global processes. These, too, are embedded in the politics of states, corporations, citizenship and development in a highly unequal world. However, despite this complexity, clear messages emerge. Decisions about biotechnology futures cannot be decided on the basis of simple cost-benefit analyses, law or 'sound science' alone. Finding ways of bringing together the different dimensions of GM debates, and the multiple perspectives they generate, is essential. Responsive and accountable biotechnology needs to be placed in the context of wider deliberations about values, livelihoods and the possibilities of different types of development. This is, the briefings suggest, the new agenda for policy and practice.

2. Can agricultural biotechnology be pro-poor?

The argument for agricultural biotechnology appears, at face value, simple. Well-harnessed new technologies can solve the problems of famine and hunger in the developing world, by increasing yields and overcoming challenges of disease, pests, drought and nutrient deficiencies. The reality, of course, is that things are not so simple. A more sceptical look at the assumptions of the 'feeding a hungry world' storyline suggests some important questions.

Growing populations and declines in yield growth of basic food crops in the post-Green Revolution era are, for many, the big contemporary problems. Biotechnological applications, and in particular transgenics, are an important part of the solution, it is argued. Production is the key, and redistribution / access issues, while important, are infeasible to implement. A focused biotech 'Gene Revolution' is the only realistic answer.

This ‘feeding a hungry world’ storyline is reflected in the justifications for the policy positions of most international organisations (and in much biotech industry PR material besides). How are these positions justified? Recent work by organisations such as the International Food Policy Research Institute and others, have rekindled a policy focus on food security issues, with scenario models, production gap predictions and Malthusian overtones surprisingly reminiscent of the debates in the 1970s. Debates about the implication of new trade regimes under the WTO have added fuel to the fire (see section 6 below). These discussions have firmly re-established the centrality of global food security issues in international policy discourse. Biotechnology is seen as a potentially neat, technical, science-based, apparently apolitical solution to this unfolding scenario.

But what is the likelihood that agricultural biotechnology will respond to the needs of poor farmers in the developing world? Will technological solutions really eliminate hunger and famine? Is the science up to it? Are the political and economic conditions right? Are there enough public resources available? Will the private sector play ball? Are there other solutions that might deliver similar - or even better - returns to the undeniably important issue of raising agricultural production? So what are the advocates of a pro-poor biotechnology assuming when they argue for the importance of seeing agricultural biotechnology as the solution to global food security problems? Box 1 identifies ten key assumptions.

Ten key (sometimes hidden) assumptions of the pro-poor biotech advocates

1. The priority for tackling poverty and food insecurity needs to be focused technological transfer to support agricultural development.

2. Declining yield growth in the major food crops is the key factor affecting food insecurity and both chronic and acute famine.

3. Biotechnology can deliver elusive solutions to key agricultural constraints affecting poor people, including resistance to pests and diseases, salt and drought tolerance and yield improvements in crops.

4. The resulting products will be acceptable to farmers because they will provide improved returns, both reducing costs and providing tangible benefits.

5. Biotechnology options offer more cost- effective and sustainable solutions to key agricultural problems than more conventional, lower tech solutions.

6. Major increases in international public research funds will be available for both basic and applied research in high-end biotechnology.

7. Intellectual property issues will be dealt with through 'public-private partnerships' modelled on the Vitamin-A rice brokered deal.

8. The private sector will deliver solutions to developing countries suited to local needs in areas where there are high returns: high-value or cash crops, or well-established hybrids such as maize.

9. Food and biosafety issues will not be a major issue in the promotion of biotechnology. Transgenic products are essentially 'substantially equivalent', and appropriate refuge strategies for new introductions will prevent major risks to biodiversity. Problems of antibiotic marker resistance will be ironed out through scientific developments.

10. Regulatory issues will be dealt with throughout the world by international 'capacity building' along standardised lines.

Critics sceptical about the future of agricultural biotechnologies regard meeting all (or even some) of these assumptions as highly unlikely. They question the likelihood of biotechnology science delivering the type of products that would make a big difference in the medium or even long term. Even if the science was up to it, a variety of other factors make a pro-poor biotech unlikely. Among these are: the limited availability of public funds; the complications of intellectual property arrangements, and the aggressive insistence of the private sector majors on holding on to their proprietary rights; and constraints associated with the way the agri-food industry is increasingly organised around a limited number of multinational companies (see sections 3 and 4 below). The most likely scenario is a 'worst case' where multinationals dominate the agricultural sector, promoting biotech products only of interest to better off farmers in higher resource endowment areas.

But a non-biotechnology future may not be so rosy either. The critics, in turn, must assume that the development of alternative technologies can result in the necessary returns (in terms of production, risk reduction etc.) to increase food security, over areas far larger than the relatively isolated case examples documented to date. They must also assume that policies for local, national and international redistribution of food will take place. This is unlikely where governments lack capacity or are constrained from intervening in the economy.

So far, the answers are not clear. The emerging mainstream consensus position on 'pro-poor biotechnology' is far from established. With the current cosy talk of win-win solutions, couched in a swathe of problematic assumptions, a major redefinition of the parameters of – and, crucially, participants in – the debate is essential.

Issues of ownership, control and involvement are central to guiding the directions of innovation, the form of risk assessment and the broader structure of the agri-food business. The technical questions at the centre of policy debates are thus inevitably political. The future is not just about the need for more scientific effort and technical breakthroughs generated by both more public funding and private sector interventions, but centrally about the political economy of agriculture and food in the developing world. With the policy debate cast in these wider terms, there may be more chance of seeing under what conditions biotechnology can indeed benefit the poor.

3. Corporate dominance and agricultural biotechnology: implications for development

The development and commercialisation of agricultural biotechnology has profound implications for developing countries and poor farmers, whether or not they have access to it. Contrary to the enthusiastic claims of some of biotechnology's cheerleaders, these are likely to include adverse as well as beneficial consequences for those who depend on farming. But biotechnology's evolution will be driven largely by the decisions of company directors and research scientists in the private sector, who are preoccupied with corporate profitability and competitiveness, rather than the problems of poverty, food security and economic development in poor countries.

A genetically-modified crop which requires less labour for its cultivation might benefit the land-owning poor, but would undermine the livelihoods of landless people who rely on income from agricultural labour. Similarly, genetic engineering may be used to develop novel crop varieties which could undermine developing countries' export markets. An example is the attempt by an American company to engineer a new variety of rice, based on a Thai variety, that will grow in Florida. In this fashion, the application of agricultural biotechnology can have positive and negative developmental impacts. However, these consequences are not intrinsic to biotechnology. The actual effects will be determined by the way the technology is applied in practice.

Private sector dominance

The private sector is currently in a better position than the public sector to mobilise the major resources necessary to carry out sophisticated biotechnology research.

Consequently, the decisions of private companies will largely determine what R&D takes place and which products are commercialised, even though in most developing countries most biotechnology research happens in the public sector. In this respect, private sector decision-makers probably have more influence over the developmental impact of agricultural biotechnology than their counterparts in the public sector, whether they be in government, agricultural research institutes or even the major multilateral, bilateral and philanthropic donor agencies.

Budgets in the public agricultural research sector are under great pressure. At the same time, public sector researchers' 'freedom to operate' is undermined by a battery of legal instruments (intellectual property rights, research contracts, material transfer agreements and so on), that impose extra transaction costs. For the private sector, these costs represent important investments to safeguard future income and preserve key commercial assets, but for the public sector they are a burden on their financial and technical resources, and inhibit their traditional strengths in working collaboratively to generate public goods.

Private companies' commercialisation strategies prioritise transgenic crops over other potential biotechnological applications. Genetic engineering is attractive to firms because the ability to register exclusive ownership over new varieties makes it more feasible for them to recoup the high costs of biotech R&D. In principle, GM crops have the potential to address key problems relevant to food security and poverty in developing countries. However, in practice the GM seeds commercialised to date by private companies are more expensive than conventional seeds, tend to be marketed along with a package of other inputs such as proprietary chemicals, and have complex management requirements that are often impracticable on small plots of land. Most seriously, they threaten to increase poor farmers' dependence because they restrict their rights to save and exchange seeds.

The crops and traits commercialised so far have been targeted at the needs of large-scale commercial farmers, particularly in North America. Even observers who are favourable towards genetic engineering universally agree that the crops, traits and challenges of interest to poor farmers in developing countries are being neglected. Critics point out that the tendency of both private and public sectors to focus on GM distracts attention from research into alternative technologies – including advanced non-transgenic biotechnologies – that are more likely to be appropriate to the capacity of both science institutes and farmers in developing countries.

The private sector and public 'developmental' goods

There is a shortfall in R&D directed at the production of 'public goods' for development. The public sector is poorly positioned to address this gap. For their part, the major biotech firms have embarked on a few projects designed to demonstrate the capacity of biotechnology to contribute to development. The private sector's willingness to engage with projects like vitamin-A rice, virus-resistant sweet-potato and the Insect-Resistant Maize for Africa (IRMA) project should perhaps be welcomed. But the rarity and small scale of such projects only serves to highlight the yawning gap between them and the array of crops and traits already commercialised for developed-country markets.

Projects like vitamin A rice and IRMA seem to happen against the odds, in the particular circumstances when public or philanthropic organisations can agree terms

with the private sector. Although company executives are often willing in principle to engage with such initiatives, in practice they will only do so under very particular conditions, which include strict safeguards for their intellectual property rights. Ultimately, the decision to get involved hinges on a hard-headed business assessment about whether the philanthropic or public endeavour may undermine the company's commercial interests. For example, Monsanto's willingness to share its rice data certainly helped public researchers to complete the sequencing of the rice genome more quickly. However, the agreement came with strict conditions on who could use the information, and how. Significantly, it happened when the company had decided to direct its R&D efforts away from rice to concentrate on four other crops.

Much more profound and far-reaching than any philanthropic project or public-private partnership, the impact of corporate strategies in the developing world will be felt through their core business activities. As things stand, the public sector is poorly-equipped to address the needs of poor farmers, and companies will continue to concentrate on high-value proprietary GM technologies, attuned to the needs of wealthy markets in developed countries. There is a risk that smallholders in developing countries will be left to apply spin-off technologies, in the hope that crops developed with the agronomic and economic conditions of developed countries in mind, will nevertheless perform acceptably well under their own conditions.

Corporate voluntarism can only achieve a small amount of good in terms of harnessing appropriate and socially desirable biotechnology for development. Therefore, an effective, coherent regime of public policy and regulation is urgently needed. This should include:

- Public funding for R&D to address the need of developing country farmers for affordable, appropriate technologies.
- A regulatory framework to ensure that the core business activities of companies will contribute to development rather than undermine it. This may entail:
    - providing incentives for companies to develop products for which large markets do not exist;
    - re-examining the scope of IPRs to ensure that undesirable monopolies are not created and public-good research is not inhibited (see section 4 below);
    - the effective enforcement of competition and anti-trust laws in order to tackle the negative consequences of concentration in the biotech and seed sectors; and
    - a careful evaluation of the potential for policy and regulatory frameworks to create incentives and institutionalise the best practices of corporate social responsibility and corporate citizenship, in order to harness the capacity of the private sector to deliver public as well as private goods more effectively and more often.

4. Intellectual Property Rights, Biotechnology and Development

Developing countries are being urged to implement strong intellectual property rights (IPRs) in order to enable poor farmers to take advantage of genetically modified crops. IPRs are claimed to provide a vital stimulus for trade, investment, innovation and technology transfer for development. However, for many developing countries, the costs of implementing IPR regimes outweigh the benefits and may even undermine development in the long term. IPRs do little to stimulate private research into crops and traits of importance to food security in poor countries, and tend to hamper public research that could address these needs.

Biotechnology companies argue that IPRs provide a vital incentive for investment in expensive biotechnological research and development, and provide the necessary safeguards to encourage them to commercialise their genetically engineered products in developing countries. Largely in response to industry pressure, harmonised standards of IPR protection have been agreed at the global level, chiefly through the World Trade Organisation's (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPs), which requires developing countries to implement strong domestic IPR regimes.

Influential voices in international agricultural research and policy networks have also urged developing countries to implement TRIPs as part of a suite of enabling policies to promote agricultural biotechnology. However, claims that IPRs are essential prerequisites for innovation in, and technology transfer to developing countries do not stand up to close scrutiny.

A recent study, by the independent UK Commission on Intellectual Property Rights (CIPR), confirms that IPRs may benefit those developing countries that already possess a fairly high level of manufacturing and innovation capacity, but bring few benefits for the poor. For the poorest countries, the costs of strong IPRs outweigh the benefits in the short term, and potentially in the long term as well.

IPRs do little to stimulate investment where there is no likely lucrative market for the end product. Thus, while IPRs may succeed in generating private investor interest in cash crops produced in developing countries, they are not effective in stimulating investment in subsistence crops and traits relevant to poor farmers or food security. In addition, patents may restrict farmers' conventional rights to save and exchange seeds. The experiences of some North American farmers, who have been sued by biotech firms for breaching their contracts and infringing company patents, vividly testifies to this likelihood.

The CIPR recommends that developing countries should tailor their IPRs regimes to their national circumstances and developmental priorities, taking full advantage of the flexibility the TRIPs Agreement allows. Among other recommendations, they are advised to

- exclude plants and animals from patent protection;

- explicitly allow farmers to save, re-use and possibly even sell and exchange harvested seeds;
- allow access to protected varieties for further research and breeding;
- resist further attempts in international fora to entrench a global, 'one-size-fits-all' IPRs standard.

However, few developing countries appear to be following this approach. For some, the reasons may be associated with a lack of expertise, leading to a lack of awareness about the available options and the possible advantages of using them. Such countries tend to be the ones most reliant on multilateral, bilateral and even private 'capacity-building' support, which generally promotes strong IPRs models. In addition, many developing countries have foregone TRIPs flexibilities in order to preserve key bilateral trade, aid and investment relationships with wealthy countries, which support stronger IPRs.

Larger and economically more powerful developing countries like India have been more creative in developing IPRs legislation that is tailored to their needs, including provisions allowing farmers to save, use, resow, exchange, share and even sell their seeds. However, such '*sui generis*' solutions are likely to be challenged by industry and it remains to be seen whether they will survive judicial scrutiny. In developed countries, courts and patent offices have generally interpreted intellectual property laws in a manner that supports the biotechnology industry's demands for strong IPRs. At the international level, *sui generis* IPRs regimes may be vulnerable to legal challenges through the WTO, which is ill-equipped to reconcile trade objectives with socio-economic and environmental considerations (see below, section7).

Thickets of Patents

Scientific innovations build on existing knowledge that has accrued over generations. IPRs allow innovators to claim exclusive rewards for each incremental step they have contributed. When genetic engineering is applied to plants, successive layers of IPRs accumulate over the plant material itself, as novel varieties with desirable traits are used as the basis for further R&D. The rapid accumulation of IPRs over germplasm and enabling technologies has caused a rapid increase in transaction costs, as IP owners have to be identified, licenses negotiated or disputes litigated.

This has led to a number of consequences for the biotechnology sector, with implications for the conduct of agricultural research of relevance to developing countries, including:

- Dramatic consolidation among biotech firms, keen to avoid lengthy negotiations for technology licences and / or patent litigation.
- Hampering the exchange of data, plant material and enabling technologies among researchers in both public and private sectors.
- Increasing the costs of administering the IPR system, as patent offices have been inundated with applications from firms and universities seeking to build a 'defensive' patent portfolio.

The private sector has responded to the 'IPR thicket problem' by buying access to as wide a portfolio of patents as possible. Solutions for public sector researchers, in both developed and developing countries, are more difficult to find. The idea of a common pool or clearing-house of publicly-owned IP is being seriously considered in influential policy circles, aimed at facilitating the protection, transfer and even commercial exploitation of public IP. This apparently pragmatic approach brings its own legal, administrative and political difficulties, with cost implications. In particular, it requires public-sector research institutions to expend their scarce resources on developing their IPR-management capacity.

Policy responses

The policy consensus, that strong IPRs are good for development, seems to be entrenched. Nevertheless, it is coming under increasing scrutiny, and perhaps the criticisms and recommendations for reform will be heeded. However, the political willingness to acknowledge its flaws, and to take on its champions, is conspicuously absent. So long as this situation continues, the result is likely to be the further entrenchment of technological inequality and the undermining of development in the long term. In order to avoid this undesirable outcome, the following policy responses need to be considered urgently:

- Greater scrutiny of the developmental effects of IPRs, particularly the linkages with poverty and food security.
- In particular, attention needs to be paid to the impacts of strong IPRs on public good research, especially the tendency for patent rights to inhibit the exchange of knowledge and technology and divert scarce resources away from front-line research.
- Proposals for reform of the TRIPs regime, currently under consideration, should preserve the rights of WTO members to tailor their IPRs regimes according to

their particular circumstances, especially with regard to the special needs of poor farmers.

- Multilateral and bilateral donors, international and philanthropic organisations should provide effective support to developing countries to design and implement IPRs laws that support their developmental priorities.

5. GMOs and the politics of international trade

The politics of biotechnology are often played out through the politics of international trade. Ever since it was announced in 1999, the most prominent nexus linking these two fields has been the European Union's *de facto* moratorium on new approvals for the production and import of GMOs. The moratorium continues to fuel a heated trade dispute between the United States and the EU. The dispute has major implications not only for these two trading partners, but also for the global politics of biotechnology in agriculture and trade.

The US and the EU are major trading partners, aid donors and providers of foreign direct investment for many developing countries. The size of the European and North American markets means that they strongly affect global food and feed production and commodity prices. For these reasons, among others, their policies and decisions on biotechnology and agricultural trade affect the policies of many other countries. Among the immediate impacts of the EU moratorium have been:

- A rapid switch by European buyers of commodities like soya-beans and maize, from North American suppliers to those in countries that are formally GM-free such as Brazil. This has contributed to a dramatic change in the flows of transatlantic trade.
- A significant slow-down in the Chinese commercialisation of GM food crops. China appeared poised to commercialise GM varieties of food crops such as rice and maize. Quite suddenly, the commercialisation of GM food crops was – unofficially – put on hold, although China continued to commercialise varieties of transgenic insect-resistant cotton. India has behaved in a similar way.
- A new fragmentation in the politics of biotechnology among farmers and industry groups in North America. Whereas transgenic crops such as soya-bean, maize, cotton and canola had been commercialised with remarkably little fuss, wheat growers and food processors in the US have called for biotech firms to delay commercialising transgenic wheat until consumer acceptance in export markets has been secured.

Risks and opportunities for developing countries

Some developing countries are vulnerable to the risks of losing markets in the EU through GM contamination. In **Namibia**, for example, where approximately 80% of the country's meat exports go to the EU, livestock farmers are concerned that GM animal feed entering the country unofficially could undermine the confidence of European consumers. Similarly, the recent controversy over GM food aid shipments to famine-affected southern African countries was heightened by fears among the recipient countries that GM grain, if planted, could threaten exports to the EU. Such fears contributed to **Zambia**'s decision to refuse the food aid altogether, while **Malawi**, **Mozambique** and **Zimbabwe** agreed to accept the shipments on condition that they were milled to prevent planting.

Other developing countries, such as **Brazil**, may feel that they can take advantage of the difficulties faced by American producers and shippers in meeting the European demand for non-GM supplies of crops such as soya beans. Ironically, it is widely acknowledged that GM seeds are being grown in parts of Brazil, which presents a risk to the country's exporters because European processors and supermarkets have the power to impose stringent standards of purity on suppliers, and can reject shipments.

Some developing countries may be relatively insulated from the effects of the EU-US tussle. For example, **China** and **India** both have large domestic markets which may enable them to commercialise certain GM crops without threatening exports. A recent analysis of GM commercialisation scenarios in China argues that the country could realise significant gains domestically from commercialising some GM crops, regardless of the policies adopted by potential export markets.

Achieving acceptance by the back door?

The United States, backed by other countries and transnational corporations, argues that restrictions on trade in GMOs amount to an unwarranted restriction on trade that contravenes WTO rules, distorts world markets, and prevents consumers from having the opportunity to choose GM foods. Nevertheless, European consumers continue to exhibit serious misgivings about GMOs. Biotechnology industry representatives acknowledge that an attempt by the US to use the WTO to force open European markets to GMOs would be resented by many people and could be disastrous for consumer acceptance in Europe.

The export of American GM food aid to famine-affected countries in southern Africa has also provoked suspicion that the US government is attempting to achieve acceptance of GMOs by the back door. In a series of extraordinary public diatribes, senior US officials have used the controversy to attack both African and European leaders, arguing that it is more important to feed starving people than worry about the 'irrational' concerns of well-fed Europeans. However, African governments have justifiable concerns about both biosafety and protecting their future trading relations with important export markets in Europe. This episode has provoked increased suspicion that the US is willing to use its diplomatic and economic weight to make the international spread of GMOs a *fait accompli*.

The Biosafety Protocol, governing the transboundary movement of GMOs, will shortly enter into force. The Protocol recognises that GMOs may pose different risks in different environments, and requires the implementation of effective mechanisms for risk assessment of GMOs at the national level before they may be imported (see sections 6 and 7, below). Many

developing countries are at an early stage of elaborating their legal frameworks and face a difficult challenge in building their capacity to enforce them. They need time and the support of richer countries to complete this task. However, although 103 countries have signed the Protocol, the US is not a Party. American exports of GM food aid to countries which have not yet implemented their biosafety management regimes seems calculated to pre-empt and undermine the Protocol. Its willingness to use the threat of a WTO dispute to gain entry to European markets suggests that it is determined to subordinate the Protocol to international 'free trade' rules.

Closing down options for diversification?

Many producers in the developed and developing world are examining the potential of diversifying production in order to exploit multiple markets, which may include GM, organic and 'GM-free' products. However, there is significant uncertainty on the question of whether GM and non-GM crops can be effectively segregated to a level that will be acceptable to consumers. Existing organic producers and consumers are angry about the potential threat posed to their markets and freedom of choice by the risk of gene flow between GM and other crops. Advocates of biotechnology, such as the American Soybean Association, argue vociferously that segregation will be prohibitively expensive, if not technically impossible to achieve under all but the most liberal thresholds. Research suggests that coexistence of GM and non-GM agriculture may be possible, at a regional level, for particular crops and particular farm-types. However, it would demand significant changes in farming practices for some crops and could impose significant additional costs. A very low level of contamination (0.1%) will be extremely difficult, if not practically impossible, to achieve for all the crops and farm types considered. Segregation is particularly unlikely in smallholder farming systems in developing countries.

6. Harmonisation, diversity and uncertainty in international biosafety regulation

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

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? And how will any unforeseen health, environmental or socio-economic impacts be addressed?

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.

7. Regulating biotechnology for the poor?

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. SPS and TBT, Sanitary and Phytosanitary, and Technical Barriers to Trade), agriculture and intellectual property rights (see section 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 section 5). Pressure to fashion a narrow system of biosafety regulation that prioritises market access also comes from the biotech 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 section 4).

We have to ask ourselves whether the effect of calls for common approaches to risk assessment and universalised approaches to standard-setting aimed at keeping markets for biotechnology products open, will be to close down the very spaces in which developing countries can express their own priorities on biotechnology, respond to the pressing needs of their own publics and identify for themselves which biotechnology future they want.

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.

Are we then creating a democratic deficit in the global politics of biotechnology regulation, where the demands of international institutions and biotech 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.

8. Science, policy and biotechnology regulation

'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 in expert institutions has resulted, in many places, in a skeptical public, alongside a growing array of activist organisations committed to an anti-biotech stance. Clearly leaving it all to the experts is not enough. So what new relationships between science, policy and regulation might work better?

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 agroecosystems - 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. Biotech proponents 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.

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

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 with multiple criteria and uncertainty explicitly.

- 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.

- The institutional contexts for the development of regulatory policy need to become more open and transparent, to generate trust in decisions.

9. Bt cotton: benefits for poor farmers?

Cotton genetically engineered to express the insecticidal toxin *Bacillus thuringiensis* (*Bt* cotton) has been celebrated as a success story for poor farmers in developing countries. *Bt* cotton varieties have been adopted by commercial and smallholder

farmers in several developing countries, including China, South Africa and India. In 2002, *Bt* cotton varieties occupied 20% of the global cotton area and more than half of the national cotton acreage in China. An estimated 90% of smallholder cotton farmers in the Makhatini Flats area of KwaZulu-Natal, South Africa planted *Bt* cotton.

Transgenic *Bt* technology is popular with farmers because it appears to provide effective control of important cotton pests, principally bollworms. Consequently it has been adopted very rapidly and it is now possible to review the experiences of *Bt* cotton farmers over several growing seasons. A number of recent studies have claimed there are clear benefits for cotton farmers (see box).

Bt *cotton in three developing countries*

China: Cotton is an important export crop for the Chinese economy. A high proportion of it is produced by the country's vast population of smallholders, for whom, in some provinces, cotton is an important source of income. Separate *Bt* cotton events developed by the American company Monsanto and the Chinese Academy of Agricultural Sciences have been commercialised in China, beginning in 1997. By 2002 the area planted to GM cotton varieties had grown to 2.1 million hectares (mha) out of a total cotton area 4.1 mha. *Bt* cotton is reported to have contributed to increased yields, financial and labour savings, and a reduction in poisonings linked to pesticide use. The total benefits were calculated at US$334 million nationally, most of which was captured by farmers.

South Africa: *Bt* cotton varieties developed by the US firm Delta and Pine, using a *Bt* gene owned by Monsanto, have been planted since 1997 by smallholder farmers in the Makhatini Flats with apparent success. The trials have become an important demonstration project for the potential of GM crops for smallholder farmers in Africa as a whole. Reportedly, the higher cost of *Bt* cotton seed was offset by lower chemical use and yield increases in the order of 20-40%.

India: Varieties of *Bt* cotton developed by the Indian seed company MAHYCO using Monsanto genes, only received formal approval for commercialisation in 2002. However, in the same year it was discovered that an unauthorised variety had been marketed and planted during two growing seasons on an estimated 10,000 hectares in Gujarat and elsewhere, without being detected. The rapid adoption of this illegal *Bt* variety indicates a high level of demand for GM cotton among some farmers.

An open-and-shut case?

On the face of it, *Bt* cotton appears to be a success story and a powerful advert for the benefits of GM technology for poor farmers in developing countries. Yet, questions remain. It is not possible to conclude, on the basis of a few favourable studies and a few years' experience, that *Bt* cotton can be relied upon to produce benefits for poor farmers.

- The positive results shown by *Bt* cotton in the first few years are likely to be highly contingent. The experience of India serves as a reminder that the *Bt* event cannot protect cotton against diseases or non-target pests, which can wipe out profit margins. Paying the higher price for GM seeds remains a risky choice, especially for cash-poor farmers.
- The performance of transgenic crops depends heavily on the local suitability of the varieties into which the GM events are inserted. In Zimbabwe, *Bt* cotton was

originally introduced into varieties to which Monsanto had access, rather than the locally-adapted hairy cotton varieties, which are resistant to other pests. Similarly, North American *Bt* varieties commercialised by Monsanto in China are arguably ill-suited for hand-picking or long, humid Chinese summers.

- Ecosystems are dynamic and the cotton pest complex is constantly coevolving. Research in China has indicated that success in controlling bollworm as the primary pest led to their place being taken by an increase in the number of secondary pests such as aphids and red spider mites. The particular ecological dynamics of cotton pests requires dynamic, ongoing management.
- There is concern in both China and India that pest resistance to the *Bt* toxin may already be emerging. Pest refuges are recommended as a way of controlling this problem, but these may be unworkable or ineffective on the tiny plots of land farmed by smallholders.
- Most seed varieties only remain competitive for a few seasons, before giving way to newer and better ones. The length of time required to negotiate intellectual property rights, carry out biosafety testing and bring GM varieties to the market can mean that the background variety into which the transgene is bred may be 'out of date' by the time it is available. This may mean that they do not perform as well as some conventional varieties, despite having the advantage of inserted genes.

Transgenic technology has been criticised for reflecting a simplistic view that one gene can be responsible for one trait, and that one or two traits can guarantee an extensive range of benefits . A closer examination of the cases demonstrates that a range of factors, besides the *Bt* gene, are important. It is especially important not to assume that the *Bt* cotton experience can be taken to indicate that other GM crops will bring benefits to poor farmers.

- In India and South Africa, the smallholders adopting *Bt* varieties tend to be the richer and better-established farmers who have access to productive land and credit, and can afford the higher up-front costs of GM cotton-seed. In many countries, cotton is an important export crop which is supported by an infrastructure of input supply and marketing support. In this respect it is not a typical smallholder or subsistence crop.
- As a non-food crop, transgenic cotton has been insulated from consumer resistance to GM food crops in some export markets. The adoption of transgenic food crops for export would expose smallholders to the risk of exclusion from some markets, such as the EU (see section5).
- Cotton prices have fallen to historic lows on world markets, with agricultural subsidies and protectionism in rich countries helping to keep commodity prices down. In these circumstances, can cotton continue to be a key crop for smallholders or developing countries? Diversification could be a less risky strategy for smallholder livelihoods.

Adopting *Bt* cotton varieties may be beneficial for some cotton farmers in some places, provided the economic conditions are right and a supportive infrastructure is in place. It remains to be seen whether, and for how long, *Bt* cotton's benefits can be

sustained against the emergence of pest resistance and in the face of unfavourable world markets. The extra costs of GM seed mean that the potential benefits for smallholders have to be weighed against substantial risks, especially debt. GM seeds are often marketed with an obligation that fresh seeds must be purchased each year; this undermines an important source of insurance – seed-saving and informal exchange – which in the past has served to protect poor farmers against such risks. The early evidence on *Bt* cotton serves as a timely reminder that GM crops can never be a 'magic bullet' against poverty and hunger.

10. Biotechnology for Africa?

Africa 'missed out' on the Green Revolution. In many parts of the continent, agriculture faces complex agronomic challenges that have proved difficult to address using conventional breeding techniques. In some regions and crops, yields are declining. Many African countries suffer from chronic hunger and recurrent food crises, and rely on regular shipments of food aid. Against this background, some argue that Africa needs to embrace the biotechnology revolution, especially GM crops. Can biotechnology succeed where previous efforts have fallen short?

Arguments in favour of biotechnology imply that GM crops can resolve the problems facing poor farmers without addressing the complex and intractable issues of poverty, land rights, lack of access to credit and weak extension services. Kenyan scientist Florence Wambugu has asserted that GM crops are ideally suited to poor farmers because 'the technology is in the seed'. In fact, however, the transgenic crops that are actually on the market all require a package of expensive inputs and special management practices, which pose special challenges and risks for poor farmers. They also tend to be crops and traits designed for industrialised, capital-intensive, temperate farming. This is primarily because they have been developed by private firms for wealthy northern markets (see section 3).

Some, mainly large-scale commercial farmers, in countries such as Argentina, Brazil, India and South Africa have adopted GM varieties of maize, cotton and soya, even though GM traits have sometimes been available only in imported, rather than locally-adapted, varieties (see section 9). However, so-called 'orphan' crops and traits, which could be relevant to subsistence and smallholder farmers, are being neglected. These include food crops such as cassava, millet and sorghum, and traits such as drought resistance, salt tolerance, and nutrient use efficiency.

So what has been the experience of GM crops in Africa to date? Experience to date illustrates the importance of integrating GM solutions with other options. *Bt* maize can only address one production constraint and does not prevent other serious problems, such as plant diseases and the striga weed. Many are also concerned about the food safety of *Bt* maize. Virus-resistant sweet potato is projected to boost yields by up to 18%, but this can only be achieved if there is an efficient system of extension and distribution to provide clean planting material to farmers. At present this is lacking. In this respect, the obstacles to the potential biotechnology revolution are the same as those that stalled the Green Revolution in Africa.

There is also concern that the futuristic possibilities of genetic engineering are diverting attention - and resources - from other promising technologies (including

modern biotechnological techniques such as marker-assisted selection) that could prove more affordable and appropriate for developing countries. These technologies attract little attention from the private sector because, unlike transgenic technologies, it is hard to capture exclusive benefits from them.

Biotechnology for smallholders

Making biotechnology work for African agriculture means harnessing the technology to address the socio-economic and agronomic constraints faced by African smallholders, rather than relying on technologies developed for other contexts. Unfortunately, the public research systems of many African countries lack the independent capacity to supplement the shortcomings of private sector-driven biotechnology. Although countries such as Kenya and Zimbabwe have experienced rapid increases in qualified microbiologists, most African countries lack experienced scientists, laboratories and equipment to carry out biotechnology research or biosafety testing. It is no surprise that in a country like Kenya, virtually all the meaningful biotechnology research depends on donor funding or public-private partnerships.

Technologies are more likely to be successfully adopted if laboratory researchers and the end-users are linked together. This requires participatory methods to help define research priorities, and effective extension to apply new technologies. This approach has been applied to developing-country biotechnology programmes in the past. For example, the Dutch-sponsored Special Programme on Biotechnology operated in four countries, including Kenya and Zimbabwe. Poor farmers were involved in the priority-setting process for the country programmes, and identified technologies such as biopesticides and biofertilisers, as well as transgenic traits.

In general, biotechnologies that are appropriate for smallholder farming in Africa will be those which:

- are affordable and do not restrict the freedom of farmers to save and exchange seeds;
- are manageable and appropriate for small plots of land in marginal areas;
- are responsive to local livelihood contexts, including patterns of labour availability
- are suitable for use with a varied cropping system, including a number of different crops;
- prioritise traits such as drought tolerance, nutrient-use efficiency and disease resistance, rather than traits like herbicide tolerance, which require expensive inputs;
- are suitable and acceptably safe for introduction into the local ecosystem;
- are backed up by appropriate support, such as access to credit, markets and extension services.

11. A biotech developmental state? The Chinese experience

The biotechnology revolution has almost overwhelmingly been a private sector phenomenon. This alarms many who, aside from other concerns, fear the consolidation of the agri-food industry in the hands of a few multinationals. Two scenarios for the developing world are often imagined: either genetically modified crops will intensify the industrialisation of agriculture in a way that is particularly harmful for poor farmers, with corporations getting the benefits while processes of marginalisation intensify. Or, they will be largely an irrelevance, with transgenic product portfolios way out of the price range of the world's poorest farmers, beyond a few high-profile goodwill projects. China's experience with biotechnology has been very different from other countries. The state has determined the objectives and led the process. Does this Chinese 'developmental state' model suggest that alternative more pro-poor biotechnology futures are possible?

In China, biotechnology research and development has been the preserve of the public sector. This is not unusual in itself, as private sector research is small in many developing countries. What is significant in the Chinese case is the scale and intensity of state commitment. This means that the profile of biotechnology products emerging from research is very different from most other developed and developing country settings (see box). China has not so far, for example, concentrated on the herbicide-resistant crops that have been a priority of multinational corporations. The emphasis has been more on producing new seeds that lower input costs for farmers, rather than tie them into particular proprietary chemicals. In the case of *Bt* cotton some farmers have already made significant savings (see Briefing 10). Also, there has been more emphasis on non-transgenic techniques of less interest to the private sector, because they are less likely to result in patentable products: marker-assisted selection, for example. Meanwhile, crops are being developed with a 'pro-poor focus', including stress tolerant crops suited for dry, low-fertility or saline settings.

China's biotechnology achievements

China will spend $500m per annum on biotechnology research by 2004, on over one hundred labs and research institutes. In 2002 one of these institutes decoded the rice genome. Field trials have been carried out for all key crops and research is underway on an extremely wide range of traits. Four crops have so far been commercialised: peppers, tomatoes, petunias and cotton. Bt cotton is the most important of these and now accounts for as much as 35% of the cotton grown in China. Around half of this area is planted with varieties developed at the Chinese Academy of Agricultural Sciences. Biocentury, the company spun off from CAAS is now looking to commercialise its products in India, Vietnam and parts of Africa. One advantage of Chinese seed in this respect is that it is cheaper than that of its rival Monsanto. The other side of Chinese investment in biotechnology has been a policy of controlling corporations: forcing them to operate through joint ventures with Chinese seed companies; restricting their access to local germplasm; demanding comprehensive biosafety assessments; and controlling their expansion.

Despite the achievements there are dilemmas when the Chinese example is used to either present biotechnology as problem-free for poor farmers, or as an example of an alternative model for the GM revolution. Key questions that need to be thought about include:

- Do the huge state investments in research lead to pressure to commercialise new crops and override biosafety concerns, as some Chinese ecologists would claim in relation to Bt cotton?

- What are the opportunity costs in relation to other non-transgenic forms of agricultural research? The vast resources committed to biotechnology laboratories inevitably mean a diversion from conventional research programmes, some of which might offer more to poor farmers and might be more ecologically appropriate.

- Over the longer-term will state research institutes and their spin-off companies increasingly behave like corporations and focus on creating income-earning products, rather than technologies for marginalised farmers?

- Are farmers really able to influence types of new GM technologies being developed on their behalf?

- Do farmers and consumers have enough information to be aware of the risks associated with transgenics?

The Chinese developmental state can, it seems, promote a different type of biotechnology. However, there are dilemmas associated with the Chinese model of biotechnology development. Chinese policy-makers are now more circumspect about GM crops than popular media images often suggest. No new GM crops have been commercialised for several years. In the face of a set of competing pressures and interests pulling them in different directions, Chinese officials appear to be taking a 'wait and see' position (see box).

Competing pressures on Chinese policy-makers

Trade and livelihood concerns:
A decision to commercialise transgenic varieties of major food crops could have implications for exports to EU markets (see Briefing 5). It might also restrict scope for excluding imports of more competitive US GM soya and maize, following entry into the WTO. This could have implications for the livelihoods of farmers in China's economically troubled north-eastern provinces.

Don't get left behind:
China has invested heavily in biotechnology. Starting with Deng Xiaoping, senior leaders have viewed biotechnology as a key area of the knowledge economy, one where China must not be left behind. However, some policy-makers complain that they are now under pressure from influential scientists who argue that China must not be over-cautious, and should begin to capture the returns from its substantial investments in GM crop research.

Biosafety management:
Officials are also aware that, with China's diverse smallholder farming systems, implementing biosafety regimes is very difficult. This is an argument against the commercialisation of Bt maize in the Chinese north-east, for example. Non-Bt maize is a key refuge crop in China's Bt cotton growing areas. Policy-makers fear, that if maize were commercialised in north-eastern provinces, seed would quickly travel south and be used in the cotton zones. Further to this, for crops where China is a centre of origin - rice and soya beans, for example - biodiversity concerns cannot be taken lightly.

Sceptical Chinese consumers:
The growing Chinese urban middle-class is increasingly informed about food safety issues. Some recent opinion polls suggest that substantial opposition to genetically modified foods is a real possibility.

Under some circumstances, a 'developmental state' can challenge the major biotechnology multinationals, as the Chinese case suggests. This could mean that technology is more relevant to a greater range of farmers, with less emphasis on proprietary products, where profits can be captured for corporations, and with greater emphasis on exploration of a range of non-transgenic biotechnology tools. However, questions still need to be asked. One dilemma for the developmental state is that rapidly developing technological capacity may not always allow sufficient space for careful deliberation of the risks associated with new innovations, or what forms of development are most appropriate for poor farmers. Added to this, China is clearly different from many other states in terms of its size, its political and organisational culture, and the scale of resources it can put behind its biotechnology programme. Not all developing countries can guide the path of technology development in quite this way.

12. From Risks to Rights: Challenges for Biotechnology Policy

In the new biotech era, scientists and industry have been instrumental in shaping biotechnology policy and law. They have emphasised the protection of individual interests - both human and corporate - through tight property laws, globalised trade rules and narrow regulatory regimes. Within this framework the only 'acceptable'

restriction on biotechnology development is safety. Regulation focuses on the containment of risk through science-based assessments. Little attention has been given to broader social, cultural or development concerns, and *critically*, to rights. But gradually this is changing, with consumers and farmers challenging dominant problem framings. Such a rights approach, this briefing argues, is key to rethinking biotechnology policy development.

Rights approaches

Rights approaches draw on well-established human rights and international law principles and have become prominent in development debates.The human rights movement promoted the development of legal provisions for civil and political participation, alongside wider cultural, economic and social rights. The original aim was the restoration of dignity by putting people back in control of their lives. However, legalistic interpretations that focus on civil and political rights have shaped most national law systems. Consequently, although human rights have brought significant political and civil gains, there have been few social, cultural and economic benefits for the poor. A rights approach seeks to address this by acknowledging the inter-relatedness and indivisibility of rights.

Rights, whether enshrined in national constitutions, legislation or global agreements, only become real when they are exercised or adhered to. The ability of poorer, marginal farmers to claim them is dependent both on organisational capacity and power dynamics. Rights approaches recognise the political dimensions of policy, and the consequences of unequal power relations.

The following sections, drawing on experience in Zimbabwe, show how an emphasis on rights has influenced thinking about property, consumer, livelihoods and development rights.

Property rights: assuring the rights of farmers

Intellectual property rights (IPRs) are often argued to be central to innovation and technology development. But current IPR approaches, reinforced by international agreements such as WTO and TRIPS, favour those with access to resources and the ability to patent genes and processes- generally northern-based multinational companies (see section 4). In many instances, these approaches have meant that farmers' rights to seed have been effectively downgraded.

Acknowledging the links between farmers' rights, genetic and biological diversity, internationally-recognised rights to an adequate standard of living and of local communities to the maintenance of their cultural identity calls into question this narrow definition of ownership and control (see box).

Farmers' rights in Zimbabwe

Together with others in Africa, Zimbabwean activists have been at the forefront of the struggle to protect the rights of local communities and farmers. The motivation is to protect and ensure access to the genetic resources that form the basis of local livelihoods, culture and knowledge. After many years of active lobbying they succeeded in getting the OAU (now the African Union) to adopt a model law as a guide to help African countries develop national legislation to protect these rights. This model acknowledges the connection between livelihoods, property and social-cultural rights. The rights of farmers, breeders and local communities to their biological resources, traditional knowledge and technologies are protected over individual and corporate rights. Now efforts to develop national legislation based on the model are afoot, with a Zimbabwean NGO recently bringing together a range of stakeholders to discuss a 'white paper' on appropriate law for Zimbabwe.

Consumer rights: allowing for informed choice

Consumer groups have drawn attention to their right to evaluate the risk posed by new agricultural biotechnologies and to make an informed choice. Here, rights to information, labelling and issues of liability have emerged as key.

In Zimbabwe, consumer organisations have effectively lobbied for labelling regulations to be adopted, not only on the grounds of safety, but also to ensure that food choices remain consistent with cultural and other belief systems. This marks an important deviation from narrow risk approaches, where safety is the only consideration. They have, however, maintained a cautious respect for the 'right' of companies to market their products. Voluntary standards are currently been developed, through a multi-stakeholder process led by the Standards Association of Zimbabwe. The dilemma over importation of GM food aid sharply illustrates this difference between risk and rights approaches (see box).

Zambia Rejects GM Food Aid

In August 2002, in the midst of a drought, Zambia rejected GM food aid. This followed a national debate incorporating NGOs, farmers, women's groups, church leaders, traditional leaders and politicians, and advice from Zambian scientists and economists. Zambia, asserting its national sovereign right, argued for a wider consideration of risks, including future trade and agriculture options. Concerns included:

- The speculative nature of safety reassurances
- Suspicion that the promoters of GM – like those of hybrid seed before them– provided skewed information highlighting only the positive and failing to warn of associated costs
- Concerns about economic impacts and marketing of agri-products to the EU
- Uncertainty about environmental impacts

Rights to livelihoods and development

Recognising the rights of citizens as custodians of germplasm or as consumers of food, although important, is not enough. These rights are essentially protective and are designed to offset potential risks associated with new technologies. They do not address the well-demonstrated need for people to have control over development. A rights approach requires a focus on local understandings of 'development' and 'technology'.

Today technology development is no longer solely the domain of the public sector, where the 'public good' is assured. In contrast to the Green Revolution era, private sector technology R and D now has a dominant role . A rights approach emphasises the right of citizens, together with governments, to choose technology futures that support locally-defined livelihood needs and do not undermine or foreclose livelihood and development options. This validates issues of humanity, culture, society and economy as legitimate and so creates space for a wider range of voices and issues.

Several initiatives in Zimbabwe focus on local rights. Spanning several decades, community- and farmer-focussed organisations have developed projects that are based on farmers' self-defined needs. These include biotechnology projects focussing on fermentation or tissue culture, for example. Recently an NGO-led grouping has begun a deliberative process where farmers and other community members actively engage with scientists, corporations, government officials and others in defining technological futures consistent with their livelihood vision .

Challenges for the future

Making local participatory rights real requires supportive legislative provisions. These may include administrative justice provisions such as rights of access to information and rights to be given reasons for public decisions. Other reforms may include rights to deliberate over potential socio-economic impacts of GM crops prior to commercialisation, priority-setting exercises, both by public and private sector agencies, and the development of codes of conduct, protocols and laws. Such provisions may be included in biosafety regulations. To date these kinds of mechanisms for assuring wider rights have not been fully incorporated into legal or other provisions in Zimbabwe, as in many other countries. Addressing this is a key challenge for future livelihood and technology policy.

Appendix 1: International Conference: Can Biotechnology be Pro-Poor? Examining the Politics of Policy in the Developing World

An outline programme for the conference is presented below. For the full conference report, including list of participants, web discussion comments and summary of discussions at the conference, see the website at www.ids.ac.uk/biotech

Day 1 (Wednesday 1 October)

MORNING

Overview of the research programme, its outputs and key findings.
Country panel presentations

Presentations by IDS project collaborators, on the status of biotech policy and regulation in **China, India, Kenya, Zimbabwe** and the **international level**, highlighting key policy issues arising from the work.

AFTERNOON

Overview of the web discussion forum.
Parallel thematic working groups

Parallel working groups (WGs) on four themes. Each working group was used to generate a comparative reflection on the project outcomes, drawing on WG-members' own experiences and views. Each group was asked to produce a 1–2 page summary of their deliberations for circulation at the beginning of Day 2.

- WG1: **Biotechnology for smallholder farmers: implications for agriculture and food security**
- WG2: **Science, uncertainty and the politics of biosafety regulation**
- WG3: **Access, control and ownership: public and private dilemmas**
- WG 4: **Trade, aid and the politics of dependency**

End of session
Workshop dinner

Day 2 (Thursday 2 October)

MORNING

Plenary: Report back and discussion session on working group themes

One rapporteur from each group presented the key findings of their discussions, including points of agreement and disagreement.

AFTERNOON

Plenary: Eminent panel commentary and discussion

An invited panel of discussants each delivered a short commentary on the workshop discussions, drawing, from their perspective, some of the key conclusions. This opened into a general discussion.

The panel-members were **Professor Michael Lipton, Devinder Sharma, Linda Brown** and **Sue Mayer**.

Closing comments from participants and organisers.
End of workshop

Appendix 2: Outputs from the Agricultural Biotechnology and Policy Programme at IDS

Below is a full alphabetical list of all outputs emerging from the IDS programme. Those outputs directly emerging from this project are marked (*). Further outputs are planned, focused on academic publication, including a book on the India work (IS), a DPhil thesis building on the China work (JK) and a series of journal articles (PN). These outputs will be carried out with other funding.

Dhar, B. 2003
Regulating biotechnology in India
[Background paper, Globalisation and the international governance of modern biotechnology project]

Glover, D. 2001
Modern Biotechnology and Developing-World Agriculture
[IDS Internet briefing]

Glover, D. 2002
Transnational Corporate Science and the Regulation of Biotechnology
Economic and Political Weekly [India] 37 (27) (Review of Science Studies), 6-12 July: 2734-40

Glover, D. 2003
Biotechnology for Africa?
Democratising Biotechnology: Genetically Modified Crops in Developing Countries Briefing Series, Briefing 10. Brighton, UK: IDS

Glover, D. 2003
Bt cotton: benefits for poor farmers?
Democratising Biotechnology: Genetically Modified Crops in Developing Countries Briefing Series, Briefing 9. Brighton, UK: IDS

Glover, D. 2003
Corporate dominance and agricultural biotechnology: implications for development
Democratising Biotechnology: Genetically Modified Crops in Developing Countries Briefing Series, Briefing 3. Brighton, UK: IDS

Glover, D. 2003
GMOs and the politics of international trade
Democratising Biotechnology: Genetically Modified Crops in Developing Countries Briefing Series, Briefing 5. Brighton, UK: IDS

Glover, D. 2003
Public participation in national biotechnology policy and biosafety regulation: comparisons and lessons from sixteen countries
IDS Working Paper 198, Biotechnology Policy Series 23. Brighton, UK: IDS

Glover, D. Keeley, J. Newell, P., McGee, R. et al. 2003
Public participation and the Biosafety Protocol: a review for UNEP-GEF and DFID
Brighton: IDS

Glover, D. and Newell, P. 2003
Business and Biotechnology: Regulation and the Politics of Influence
IDS Working Paper 192, Biotechnology Policy Series 17. Brighton, UK: IDS

Glover, D. and Newell, P. 2004
Business and Biotechnology: Regulation of GM Crops and the Politics of Influence
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Intellectual property rights, biotechnology and development
Democratising Biotechnology: Genetically Modified Crops in Developing Countries Briefing Series, Briefing 4. Brighton, UK: IDS

* Huang, J. Wang, Q. and Keeley, J. 2001
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[Background paper, Biotechnology and the policy process in developing countries project]

* Huang, J. and Wang, Q. 2003
Biotechnology policy and regulation in China
IDS Working Paper 195, Biotechnology Policy Series 4. Brighton, UK: IDS

* Huang, J., Hu, R., Fan, C., Pray, C., and Rozelle, S. 2003
Bt cotton benefits, costs and impacts in China
IDS Working Paper 202, Biotechnology Policy Series 5. Brighton, UK: IDS

* Huang, J., Hu, R., Wang, Q., Keeley, J., and Falck-Zepeda, J. 2002
Agricultural Biotechnology Policy and Impact in China
Economic and Political Weekly [India] 37 (27) (Review of Science Studies), 6-12 July: 2756-61

* Keeley, J. 2003
A biotech developmental state? The Chinese experience
Democratising Biotechnology: Genetically Modified Crops in Developing Countries Briefing Series, Briefing 11. Brighton, UK: IDS

Keeley, J. 2003
Democratising biotechnology: an overview
Democratising Biotechnology: Genetically Modified Crops in Developing Countries Briefing Series, Briefing 1. Brighton, UK: IDS

* Keeley, J. 2003
The biotech developmental state? Investigating the Chinese gene revolution
IDS Working Paper 207, Biotechnology Policy Series 6. Brighton, UK: IDS

* Keeley, J. 2003
Regulating biotechnology in China: the politics of biosafety
IDS Working Paper 208, Biotechnology Policy Series 7. Brighton, UK: IDS

* Keeley, J. 2003
Contexts for biotechnology: discourses of agricultural development in China, India and Zimbabwe: 1947 to the present
[Background paper, Biotechnology and the policy process in developing countries project]

* Keeley, J. and Scoones, I. 2003
Seeds in a Globalised World: Agricultural Biotechnology in Zimbabwe
IDS Working Paper 189, Biotechnology Policy Series 8. Brighton, UK: IDS

* Keeley, J. and Scoones, I. 2003
Contexts for Regulations: GMOs in Zimbabwe
IDS Working Paper 190, Biotechnology Policy Series 9. Brighton, UK: IDS

Mackenzie, R. 2003
The international regulation of modern biotechnology: finding space for food security?
IDS Working Paper, Biotechnology Policy Series 18. Brighton, UK: IDS

Mackenzie, R. with Glover, D. 2003
Harmonisation, diversity and uncertainty in international biosafety regulation
Democratising Biotechnology: Genetically Modified Crops in Developing Countries Briefing Series, Briefing 6. Brighton, UK: IDS

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Globalisation and the international governance of modern biotechnology: promoting food security?
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Biotechnology and the policy process: Zimbabwe
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Risk and rights: challenging biotechnology policy in Zimbabwe
IDS Working Paper 204, Biotechnology Policy Series 10. Brighton, UK: IDS

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Biotechnology and the politics of regulation
IDS Working Paper 146, Biotechnology Policy Series 2. Brighton, UK: IDS

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IDS Working Paper 201, Biotechnology Policy Series 11. Brighton, UK: IDS

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Innovation and Policy Process: Case of Transgenic Sweet Potato in Kenya
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Pimbert, M. and Wakeford, T. 2003
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Making policy in the 'New Economy': the case of Karnataka's biotechnology policy
IDS Working Paper 196, Biotechnology Policy Series 13. Brighton, UK: IDS

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PLA Notes 46, 2003

Appendix 3. Highlights summary

AGRICULTURAL BIOTECHNOLOGY AND THE POLICY PROCESS: CHALLENGES FOR DEVELOPING COUNTRIES

How do different local, national and international contexts enable or constrain poor farmers' perspectives to be heard, and to assess who is involved and who is excluded and through what mechanisms? What are the politics of this policy process? These are just some of the questions asked in a three year comparative assessment of the experiences of agricultural biotechnology policy in China, India and Zimbabwe.

The research has asked: How can poor people's perspectives effectively influence the policy process in order that future developments in agricultural biotechnology meet their livelihood needs in a sustainable manner? A number of general conclusions emerge. These include the need to:

- Understand the impact of trade choices for developing countries.
- Allow for alternatives to dominant intellectual property right models.
- Fashion regulatory systems that are responsive to local needs.
- Scrutinise the role of 'sound science' in decision-making.
- Think carefully about 'front end' technology priorities, not just 'back end' regulation.
- Allow the marginalised, as well as elites, to reflect on the different food and farming futures.

In essence the message is that debates about genetically modified (GM) crops in the developing world should not just be viewed through a technical-economic lens: the politics of policy - whether around science, regulation, aid or trade - is key. As a result, contexts matter - choices look different in China, India or Zimbabwe. Therefore general prescriptions - that GM is a good or bad thing for the developing world, for example - are inappropriate. Instead, a much more context-specific - and so political - analysis is required.

This may be a simple and rather obvious message. But it is one that is not often heeded by those in the international community, driven as they often are by the need for universalising solutions and generic prescriptions, most often driven by a technical-economic set of views. This research has shown how, when locale-specific politics of policy are brought into the picture, then things necessarily become more complex and uncertain. It is this complexity and uncertainty that must be addressed.

In such contexts, we conclude, debates need reframing, going beyond the narrow definition of technical / scientific / risk issues to a recognition of wider issues of framed in different ways around issues of rights and justice, access and control. With current policy processes dominated by a scientific-technical elite - both 'local' and international, it is critical that the participants involved in discussions about technology options - including GM - be broadened to include farmers, consumers and others in the developing world. By extending the deliberation beyond a narrow expert elite to a more inclusive grouping that brings in lay perspectives there is

potential for a different perspective on technology choice and regulatory priorities for food and farming.

Research collaborators: **China:** Centre for Chinese Agricultural Policy, Beijing (Huang Jikun, Hu Ruifa, Wang Qinfang); **India:** Centre for the Study of Developing Societies, New Delhi (Shiv Vishvanathan and Chandrika Parmar); **Zimbabwe:** Independent consultants (Jennifer Mohamed Katerere, Munyaradzi Saruchera); and **UK:** Institute of Development Studies (James Keeley, Peter Newell and Ian Scoones)

Further information: see www.ids.ac.uk/biotech and in particular the series of briefings summarising key findings from the research. More information on this and other related work is available from Oliver Burch, Environment Group, IDS, University of Sussex.

Key words: Biotechnology, agriculture, GM crops, regulation, science, policy

Regions: Asia, sub-Saharan Africa, China, India, Zimbabwe

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