PUBLIC PARTICIPATION AND THE CARTAGENA PROTOCOL ON BIOSAFETY

A REVIEW FOR DFID AND UNEP-GEF

PART II: THE CASE STUDIES

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Disclaimer: This guide is a summary of the IDS study and does not necessarily reflect the views of DFID and UNEP-GEF

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NOTE ON SAMPLING METHODS FOR THIS STUDY

In compiling the information for this study we have sought to solicit the views of key government officials, NGOs, business groups and other relevant civil society organisations. Meetings were conducted, telephone interviews took place and e-mail correspondence was used to collect as wide a range of views and experiences as possible within the allotted time frame. The study also builds on and draws from related research work in some of the case study countries including China, India, Kenya and Zimbabwe that has been conducted over the past two years. More details about this work can be found at http://www.ids.ac.uk/env/biotechpubs.

Nevertheless, within a short time frame, there is a danger that the views of key stakeholders from government, business and civil society get reproduced at the expense of those who have been left out of organised processes of consultation and participation and who may not have been reached by public education and awareness-raising efforts. It inevitably, therefore, over-represents the views of organised groups who are already active and have a position on biosafety rather than broader publics. This approach also inevitably draws attention to areas of concern when groups have strong interests at stake and have clear views on the process, rather than areas of satisfaction with the process. Nevertheless, with these qualifiers in mind, we believe that the analysis and reflection of country actions that follows is a fair representation of the experiences of different Parties to the Protocol about what works, when and why.

The selection of countries includes OECD members as well as developing and transitional countries. The selection is not intended to be a representative sample. Instead we have tried to select a range of countries that serves to illustrate a variety of approaches and a diversity of experiences. The countries selected here reflect a variety of different political cultures, regulatory structures and social attitudes towards technology and participation.

The UNEP-GEF biosafety capacity-building project for developing countries is premised on the recognition that such countries face particular and special challenges associated with the development and implementation of National Biosafety Frameworks. It is true that designing and elaborating effective, workable and transparent regulatory systems represents an enormous challenge for

all countries. However, the scale of these is magnified for developing countries for various reasons. For example, access to necessary scientific expertise may not be so easy, financial resources may be more scarce and government bureaucracies may be weaker. For many larger developing countries, such as India, China and Brazil, the challenge of administering and enforcing national biosafety regulatory regime presents an extra set of logistical and resource constraints.

It would also be naïve to neglect the question of economic power. Many developing countries find themselves in a position of weakness relative to western governments, international institutions and transnational enterprises, which makes them more vulnerable to various forms of pressure to bring their biosafety regulations in line with the demands of these actors. Debt, under-investment and reliance on donor money may make it difficult for many developing countries to set their own priorities in this area, whatever the demands made of them and presented to them by domestic constituencies whose participation in decision-making has been invited. Concerns about international trade relations, in particular, clearly leave a strong impression on the design of NBFs and have already exerted a large degree of influence over the regulatory model adopted by some developing countries. Pressures from investors, when backed by powerful governments, present a difficult force for poorer governments to resist.

There are also specific challenges associated with enabling popular participation in the policy arena in developing countries. Many signatories to the Cartagena Protocol have only recently undergone processes of democratization, or are still in the early stages of a transition to democracy. The creation of a political climate in which people feel they are able and entitled to participate in decision-making remains a distant aspiration for some and an unwelcome prospect for others. In donor-dependent countries, which have become used to policy decisions being heavily shaped by the conditions that creditor or donor agencies attach to development financing grants or loans, substantial and sustained effort will be needed to foster a political culture in which national ownership and broad-based participation are the norm.

The lack of robust and sustained interfaces between government and civil society is connected to a generally

lower degree of attention to issues of citizens' rights, both in terms of citizens having less knowledge of their entitlements, and in terms of the inevitable dominance of basic material rights over political and civil rights on the agendas of poor country governments. The growing importance of organised NGOs in many such countries, however, may help to foster a culture of political participation because of the skills many groups have in facilitation and working with local communities. Many of the cases below provide evidence of them performing this role in relation to biosafety issues.

We raise these comments in order to underscore the theme that runs throughout our report: that promoting consultation, participation and awareness-raising requires us to keep in mind the unique characteristics of each particular country's political, social and economic environment. These contextual factors will ultimately determine what is possible, realistic and desirable. In particular, this means it is vital to avoid the common mistake of assuming that particular policy prescriptions or 'models' that appear to work well in one context may be easily imported or adopted in another setting.

In the light of these comments we also wish to emphasise that, where we draw attention in the following case studies to the under-development of processes and procedures for participation and awareness-raising, our aim is to highlight future challenges for action, rather than imply criticism of government action or inaction, which may be constrained by the sorts of factors mentioned above.

BRAZIL

Brief Context

Brazil is one of most advanced countries in terms of agricultural biotechnology and has gained a good deal of experience in applications of the technology. Whereas Argentina, a major LMO exporting country, has performed 385 field tests, Brazil has already undertaken over a thousand, mostly in corn. Despite this, import and commercial production of LMOs are still illegal. At the same time, there is widespread concern about GM seeds entering Brazil because of seed smuggling, especially of GM soy beans, from Argentina via Paraguay.

Brazil has a Biosafety Law that covers research, production and commercialization of LMOs. This law created the National Biosafety Technical Commission (CTNBIO). The Commission holds all reports about the release of LMOs into the environment, as well technical reports about the registration, use, transportation, storage and commercialization of LMOs. Membership of the Commission is appointed by the Minister for Science and Technology. Of 18 members of the Commission, 8 are technical and scientific experts, 7 are representatives of the ministries, 1 representative comes from the private sector, 1 representative is from a consumer defense organisation and 1 representative is from the work health protection sector (appointed by the ministries of labour and health).

The policy process surrounding the regulation of LMOs has involved legal battles between some NGOs part of a nationwide campaign 'For a Brazil free of LMOs' and the government. In 1999, CTNBIO issued a technical decision in favor of several herbicide resistant varieties of soy, stating that there was no need for an environmental impact assessment (EIA). Greenpeace and the Consumer Defense Organisation (IDEC) questioned the legality of their subsequent release in terms of environmental safety when no EIA had been carried out. They also argued that CTNBIO did not hold the legal power to decide upon the necessity of carrying out an EIA.

The National Environmental Council (CONAMA) has been responsible for the definition of norms regarding environmental impact assessments and the licensing of any enterprise generating potential environmental risks since 1981 when the main Brazilian environmental law was launched and created the Council. CONAMA is a governmental body with representatives of environmental non-

governmental organisations among its members and, thus, is the ideal forum to decide about the EIA requirements, according to many NGOs. After the creation of the CTNBIO, the responsibility for the rules of the environmental impact assessment concerning LMOs was duplicated, and this has been discussed in the judicial action mentioned above.

The EIA in Brazil requires public discussion on the potential impacts of the LMO being assessed. Some representatives of the CTNBIO believe that public involvement is not necessary because biosafety issues are extremely technical. The NGO coalition 'For a Brazil free of LMOs', however, is struggling to make the EIA, with the consequent public involvement, mandatory.

In June 2000, in the course of the judicial action, a federal judge ordered the prohibition of any commercial application of LMOs until an EIA and other necessary precautions had been undertaken. The government, in turn, sought appeal with the federal court in order to annul the federal judge's decision. The Federal Court has not come to a final decision yet, though the federal judge has made recommendations on his decision concerning the need for the definition of norms on labeling and EIA requirements.

Last year, CONAMA created a working group made up by representatives of CTNBIO (apparently recognising the competence of CONAMA), Greenpeace, Monsanto and many others, to establish proceedings for the licensing of LMOs. Following the working group proposal, the Council decided on June 13th 2002 that in future the biotechnology industry will be responsible for securing a license from the environment agency, ensuring an environmental impact assessment and addressing public audiences more widely than has been the case in the past. In theory, the publishing of CONAMA's resolution in the official journal puts an end to the judicial case in which the government has found itself stuck between an environmental law that requires a license and the biosafety law that transferred responsibility for the authorization of use and commercialisation to the CTNBIO. Many look set to contest the decision, within the Ministry of Agriculture, for example. The status of the decision, in terms of what it means for CTNBIO, is unclear, as neither body is entitled to define responsibilities for the other.

Key Actions

Participation and Consultation

- Meetings of the CTNBIO are held behind closed doors and the public cannot access the complete reports of the discussions. The government justifies this approach through reference to commercial confidentiality requirements.

- Interested citizens have an opportunity to comment on proposed approvals for field trials. However, despite increased access to information, CONAMA has not received any contribution from the public to date.

- ActionAid Brazil, along with the Social Assistance and Education Federation (FASE), the Landless Movement (MST), Confederation of Labour Unions, and the Advisory and Research Centre (ESPLAR) have promoted citizen juries targeting small-scale farmers, landless people and poor urban consumers. The first one took place in Fortaleza, capital of the Northeast state of Ceará, in April 2001. The second happened in Belem do Para, capital of the Amazonian state of Para, in September 2001. The jury was selected randomly from lists provided by a representative range of community-based associations. Hundreds of small-scale farmers, landless people and poor urban consumers attended the events. Among the questions addressed by the jury was 'Is there enough evidence that LMOs do not threaten the environment?' and 'Is the process of testing and the commercial use of LMOs democratic, transparent and careful enough?' After hearing evidence from witnesses, the answer to both questions from the jury was 'no', in both events. The trial was undertaken over two days.

- Some months after the event in Ceará, students in a poor area of the state organised their own jury on LMOs in their school. A representative from ActionAid Brazil concluded that 'These people, always excluded from the process of policy-making on issues that affect them very much, had the opportunity to access all the information and to decide about it via members of the jury' (Campolina 2001:29). Another citizen jury will take place in Rio in August 2002. It will follow the same procedures of the previous ones, but will target urban consumers.

Information and Education

- Briefs of CTNBIO meeting agendas are placed on their website before the meetings and any decisions taken are posted on the internet afterwards. However, the public cannot access the complete reports of the discussions.

- The requirements for experimental plantations are published in the official government journal and on the internet one month in advance. Public comments are invited.

- The Biosafety National Association (ANBIO) was created in 1999 to disseminate information about biosafety in Brazil. Its Director is the former President of the CTNBIO. Companies such as Monsanto Brasil, Aventis Seeds Brasil, Azepack, Cargill, Novozimes and Syngenta Seeds are institutional members of the Association, which has been promoting several events to discuss biosafety such as the first Brazilian Congress on Biosafety (Sept. 1999); first Northern Meeting on Biosafety (Sept. 2000); and the second Brazilian Congress on Biosafety – Sept. 2001. Further, ANBIO has promoted seminars on biosafety targeting law and media professionals. For the year 2003, they are planning the third Brazilian Congress on Biosafety. The CTNBIO has supported events promoted by ANBIO, including the first Brazilian Congress on Biosafety. However, activists complained that in doing so, CTNBIO compromised its independence from the companies represented by ANBIO. The event also received sponsorship from biotechnology companies including Monsanto, Novartis, Agrevo and DuPont. As a result, according Pelaez and Schmidt (forthcoming) 'CTNBio faced a serious crisis of credibility in Brazilian society who suspected it was stimulating biotechnology to benefit the multinationals'.

- The Brazilian Council for Biotechnology Information (CIB) was created in 2000 to disseminate scientific information about biotechnology and its benefits. Among its members are the Brazilian Association of Food Industry, the Brazilian Association of Seeds Producers, Aventis Seeds Brasil, BASF, Cargill, Dow Agrosciences, DuPont Brasil, Monsanto Brasil and Syngenta Seeds. The CIB has a website with up to date scientific reports asserting the safety of LMOs and

supports events in partnership with ANBIO and other organisations.

- Representing a different perspective, 'Brazil Free of LMOs' is a NGO coalition made up by Greenpeace, IDEC, Services and Advice to Alternative Agriculture Projects, ActionAid Brazil, FASE, Socio-economic Studies Institute (INESC) and ESPLAR. Their main purpose is to promote public awareness concerning the environmental and health risks of the production and consumption of LMOs.

- Resistance to LMOs has traditionally come from urban-based environmental and consumer groups. However, the main peasants associations, such as the MST and the National Confederation of Agriculture Workers (CONTAG), have also stated their position against LMOs. CONTAG, for instance, has campaigned against the production and commercialization of LMOs, and for the labeling of LMOs that have been commercialised. A key issue in Brazil, as elsewhere, is for NGOs orchestrating various forms of public debate to maintain transparency in their operations to preserve credibility, often in the face of industry accusations that they are receiving funding from industrial interests threatened by the development of LMOs.

Reflections and Lessons

The conflictual and legal nature of the policy debate is seen by some as a result of grievances by groups that felt they were not consulted and continue to be left out of policy-making processes on these issues. In this regard it is worth citing a report of the Brazilian MP Ronaldo Vasconcellos, concerning the CTNBIO activities:

We believe it desirable that the CTNBIO make its procedures more open to the Brazilian society, breaking down myths and versions that have arisen, in many cases, because of the closed, untransparent procedures that marked its activities. We know that a forum of scientists cannot become a popular assembly but, also, it must not be characterized by an atmosphere of gods above the claims of the civil society. The authoritarian style that marked the CTNBIO, especially its presidency up until the year 2001, did not effectively contribute to the development of a biosafety policy in the best interests of the whole Brazilian society.

The MP ends his report recommending 'the definition of new criteria for the election of the members of CTNBIO and other measures to increase the transparency of its decisions, in order to bring it closer to civil society'.

Resort to the law to generate a public debate has been a conscious strategy for some groups, however. Referring to the case mentioned above, ActionAid note 'this fragile legal blockade against LMOs found today in the country has also given the Brazilian scientific community, consumers, parliamentarians, peasants and the media some time to start a vital debate about the advantages and disadvantages of the introduction of LMOs' (ActionAid 2001). This legal action, combined with continuing concern about seed smuggling, has undermined the credibility of governmental competence to manage biosafety issues.

Brief Context

Currently there are GM varieties of canola, corn, soybeans and potatoes that have been approved and are being produced in Canada which are considered to be LMOs as defined by the Protocol. Research on other LMO applications is well underway and there is the possibility of GM varieties of other grains and oilseeds, horticultural crops and nursery products being approved for commercial use in the near future (GoC 2002).

Contained use and deliberate release are regulated by the Plant and Novel Traits Regulations. For contained use, there are also voluntary guidelines. A procedure called 'safety-based decision-making' applies to deliberate release. There are attempts to consult the public when the regulations change, but consultation does not take place on a case-by-case basis. Details of regulatory decisions are publicly available in Canada.

Key Actions

Participation and Consultation

- The government of Canada has publicly committed itself to broad-based consultations to seek the views of Canadians in order to inform its decision on signing and ratification. These are meant to be 'transparent, accessible, accountable, supported by factual information and that take into account the broad diversity of Canada'. Since the conclusion of negotiations in January 2000, the government has engaged in consultations with the Provinces and Territories and stakeholders including environmental groups, exporters, producers and importers.

- Environment Canada, the government department responsible for handling these issues, has a mandate to consult the public widely on these issues, whereas agencies such as the Food Inspection Agency are only just starting to use consultative strategies of public engagement.

- The Canadian Biotechnology Advisory Committee (CBAC) includes representatives from provincial governments, non-government organisations, agricultural and industrial sectors and aboriginal peoples that meet prior to each of the negotiating sessions for the Protocol. The Committee is an independent advisory group to the government on all areas of biotechnology. The

committee is now two years old and has scientific and legal experts for the most part, with one NGO representative. One observer noted that of the 22 people on the committee only one individual could be considered to be a critic of biotechnology. The group posts papers on the web on all aspects of biotechnology (not just biosafety) such as IPR issues, ethical, moral and social issues. Often these are commissioned from academics. The Committees function is strictly advisory.

- In 2001, sixty Canadian environmental NGOs refused to participate in CBAC stakeholder consultations on the regulation of LMOs. They alleged that the stakeholder consultations were designed to prevent some group's statements becoming part of the public consultation record, as only positions on which consensus was found across the groups were reported publicly. The NGOs declared:

We believe the [CBAC process] is fundamentally and importantly flawed and that NGO participation in the consultation could legitimate CBAC's wholly inadequate mandate and process and undermine demands for true democratic processes and widespread public consultation.

- A federal interdepartmental working group has been established to develop and implement a plan to inform and gather the views of all interested parties on biosafety issues.

- Members of the public, via the web site, are invited to submit comments on a form or to submit them directly to the departments concerned. The submissions were to be summarized in a report to be distributed during a multi-stakeholder consultation on the Protocol in September 2002. The objective of the event is to obtain views on the implications of the Protocol that should be considered by the government and will involve national organisations and groups representing industry, NGOs, academia and civil society. The summary report will also be made available on the web (GoC 2002). Relevant documents and comments are to be posted on the site which is cited as a tool for correspondence with stakeholders on the issue.

- Agriculture and Agri-Food Canada (AAFC) is leading a consultation with the agriculture and agri-food sector on the practical implications of the Protocol for Canada (AAFC 2002). Towards this end, a discussion document has been produced to initiate discussion on how the Protocol may affect Canadian agriculture and the agri-food sector. The main aims of the paper are to 'help inform Canadian agriculture and agri-food sector stakeholders about the key provisions of the Protocol and their potential implications for the sector when implemented' and 'to solicit the views of industry stakeholders on the Protocol, including any concerns about the practical implications of implementing the Protocol' (AAFC 2000:2). The document ends with key questions to invite feedback on specific issues. However, the questions focus more on issues to do with documentation requirements and their associated financial and transaction costs, rather than broader issues of biosafety. This is justified partly because of the target audience of people working in the agri-food sector.
- Each government department has a responsibility to work with its particular constituency of stakeholders through correspondence, teleconferencing and existing channels of communication such as federal, provincial and territorial committees and to 'ensure the involvement of the broadest possible range of groups or individuals with an interest in or who may be affected by the Protocol' (GoC 2002).
- There has been no full parliamentary debate on biosafety per se, though one is being urged on the issue of labelling.
- There have been stakeholder consultations at federal and state level involving groups such as Environment Canada, Greenpeace, Sierra Club Canada, the Council of Canadians, the Canadian Environmental Network (the key contact point between government and NGO community on these issues), the Canadian Health Coalition, the Canadian Food Inspection Agency (CFIA), consumer organisations such as the Consumers Association of Canada, the industry-based Task Force on Foods from Biotechnology, the

Canadian Federation of Agriculture (CFA, a farmers' umbrella group). The CFA is pro-biotech and seeking to secure access for GM varieties, while farmers' groups in Quebec for example are much more opposed to GM. Indigenous peoples' groups have also sought to articulate their views on this subject.

- A Citizens' Panel was held in 1998, Calgary Alberta. This panel was framed around broader issues of food biotech than just biosafety. Critics allege that the questions posed to the expert panel were carefully chosen to encourage debate on how Canada could best proceed with biotechnology. The panel received a lot of industry support and a representative from Monsanto was on the panel. The timing of the event when biotech was a relatively low-key issue (prior to the 1999 European backlash) meant that the exercise is perceived to have had a relatively low overall impact.

Information and Education

- The Food Biotechnology Communications Network is an industry funded body that is also active in disseminating information on these issues, for example in the leaflet 'A growing appetite for information'. It also received matching funding from the CFIA and the agriculture ministry to set up a regional network of experts and to produce information materials directed at 'elementary school students and teachers, grocery clerks and dieticians' (Stewart 2002). It claims to provide 'credible, current, evidence-based information about biotechnology and food', yet the fact that half its budget comes from memberships taken out by biotech corporations, means that some regard its information as unbalanced.

- The CFIA produced a brochure titled 'Food safety and you' which was mailed to every household in Canada at a cost of Can$42.5 million (US$27.2 million). The CFIA is meant to be the regulator of the biotech industry but critics allege the brochure was very pro-biotech.

- Federal governments have spent at least Can$12 million (US$7.68 million) on a multi-faceted communications strategy on biotech funded through grants from the agriculture ministry, the CFIA, Industry Canada and Health Canada (Stewart 2002).

Reflections and Lessons

In Canada it is possible to find evidence both of formal institutional activity aimed at involving interested parties and conventional stakeholders in decision-making on biosafety issues and a great deal of NGO and industry activity aimed at circulating information supportive of their positions in the debate. But beyond a few isolated examples, more informal mechanisms for promoting public dialogue on biosafety issues are under-developed.

In 2000, the Canadian government asked the Royal Society of Canada to undertake an independent review of its regulatory system. Even government departments were not privy to the results until the moment the report was released publicly in February 2001. The report expressed reservations about the way crops and foods pass through the regulatory system, in particular the lack of public or peer-reviewed evaluations of the science. There is a recognised need in Canada, therefore, to further refine mechanisms of public consultation and participation.

Brief Context

Public deliberation of biosafety issues is important in China for several reasons. Chinese agro-ecosystems are extremely diverse and rich in biodiversity, with China a centre of origin and diversity for key crops such as rice and soyabeans. There is also strong national policy commitment to biotechnology as a key growth industry, and source of agricultural growth and transformation. These factors mean that careful reflection by different stakeholders on the risks associated with LMOs is a key challenge.

China has a significant biotechnology research capacity. US$112 million was invested in biotechnology research in 1999, spread between 150 laboratories in over 50 institutes. There is a plan to increase this to US$500m in 2004. Between 1997-2000 over 400 agricultural biosafety applications were processed, with 300 approved for field trial, environmental release or commercialisation. China has commercialised four transgenic crops (insect-resistant cotton; virus-resistant sweet peppers; colour-altered petunias; extended shelf-life tomatoes). It has the fourth largest sown area of GM crops in the world (Huang et al, 2002).

Several regulations dealing with LMOs have been produced in China, progressively becoming more detailed and wide-ranging, and reflecting experience gained over several years of biosafety evaluation. The first regulations were issued in 1993 ('Safety Administration Regulation on Genetic Engineering') by the Ministry of Science and Technology (MoST) (then the Science and Technology Commission). These were followed in 1996 by more detailed *Safety Administration Implementation Regulations* issued by the Ministry of Agriculture, which detailed four safety classes for LMOs and corresponding processes for biosafety evaluation. These regulations were superseded by further, more comprehensive regulations issued by the State Council in 2001. New procedures and areas of regulation included introduction of an additional production-trial stage prior to commercialisation, monitoring guidelines and labelling requirements. These guidelines were then clarified further in three 'Implementation Guidelines' issued by the Ministry of Agriculture (MoA) in May 2002 covering import and export procedures; biosafety assessment of LMOs; and labelling.

Recently it has been announced in the Chinese press that the State Environmental Protection Authority (SEPA) will produce a Biosafety Law and further biosafety regulations. These will specify an overarching role for SEPA and coordinate the roles of other ministries and agencies with some remit in relation to biosafety (including the Ministry of Foreign Trade and Economic Cooperation, Ministry of Science and Technology, Ministry of Public Health, Ministry of Education, Ministry of Agriculture and the Forestry Administration).

SEPA is the national focal point for the Biosafety Protocol. The rationale for this is that SEPA houses the Steering Committee on Implementing the Convention on Biological Diversity. However, at present, SEPA lacks direct decision-making power in relation to biosafety, but participates in discussions because it has a responsibility for biodiversity protection. In 2000, SEPA published a 'Biosafety Framework of China' (funded by UNEP-GEF). This document summarises regulations and policies, but has no formal legal status.

Decisions on the biosafety approval of particular crops and traits are made by the Agricultural LMO Biosafety Office in the MoA, on the basis of recommendations from the National Biosafety Committee. This committee includes 56 experts and offers technical appraisal of LMO applications. It also has several subcommittees organised around different thematic areas such as key commodity crops, environmental impact, quality control and food safety. While approval formally rests with the MoA there is substantial consultation with other ministries before decisions are made. Given the key trade questions that are central to decisions about GM in China, final decisions about commercialization of GM crops involve discussion between several ministries and higher levels of government. Decisions about export and import of LMOs are dealt with by the Ministry of Foreign Trade and Economic Cooperation.

New biosafety institutions have been set up reflecting an on-going commitment to capacity building. At the central level, the Agricultural LMO Biosafety Office has been set up in the MoA to receive and process biosafety applications. Further to this, biosafety offices are being established at provincial level. They will inspect trials of GM crops, ensure that biosafety regulations are being observed, and handle provincial level import and export, and labelling of LMOs.

Key Actions

Participation and Consultation

- During the process of drafting the recent biosafety regulations, the Ministry of Agriculture convened a series of meetings and consultations. Primarily these involved scientists and policymakers; issues covered included trade and economic issues, food safety, and environmental impact.

- Industry stakeholders were invited to submit suggestions based on experience elsewhere, and also to organize fact-finding trips for officials.

- Draft regulations were put out for discussion. However, formulation was dominated by scientists and officials within, or linked to the MoA. Significantly, nearly a year elapsed between publication of the regulations and the more detailed set of three implementation guidelines. During this time a dispute with the US over soybean imports (some of which are LMOs) brought attention to questions around the future commercialisation of GM crops, and associated biosafety issues. This led to debates among policymakers, and to some extent in the media.

- To support the drafting of regulations, government officials went on fact finding trips to Europe, the US and elsewhere and examined different regulatory models. To understand the divergence of perspectives within OECD countries consultations were held with government agencies, and also in some instances with representatives of civil society organisations such as Greenpeace.

- Since the regulations and guidelines have been published, training programmes have been held for officials within different ministries, at provincial level and also for representatives from industry.

- Key research programmes have prioritised biosafety research. The MoST, through the 973 'Basic Research' and 863 'Applied Research' committees, has identified biosafety as a primary research focus. The 973-supported programme particularly looks at the safety of marker-assisted selection, gene flow, gene function in relation to insertion of genes in the genome, and food safety.

- SEPA also facilitated internet discussions between senior officials and the public on biodiversity (and biosafety), the first time such activities had happened in China.

Information and Education

- Significantly, new regulations emphasize the need for labelling of different seeds and crops (a precise list of 17 different crops is available from the MoA). This is explicitly framed in the regulations as a *response to the public right to information.*

- This year the MoA Agricultural LMO Biosafety Office is planning to produce an ABC guide to biosafety issues, written by scientists and aimed at the public.

- Studies are to be commissioned by the MoA on public attitudes towards, and understanding of, biotechnology and biosafety issues.

- SEPA uses its mandate in relation to biodiversity to promote public interest in biosafety issues. It recently sponsored a biosafety meeting where media were invited, co-organised with Greenpeace. This meeting brought together research suggesting that Bt cotton was having a negative environmental impact in China.

- SEPA uses Environment Day, Earth Day, and Biodiversity Days as links to publicise and do public education on biodiversity issues. These awareness days can have an important role in China in terms of news programming through the state media channels.

- SEPA plans to build biosafety awareness in schools through its environmental education activities in primary and middle schools. Some activities have been carried out already.

- Within each ministry there are well-organised and funded publicity sections and publishing houses. These liaise with *Xinhua (New China)* news agency, and with national, provincial, city and sectoral newspapers, and also other media organs such as radio and TV. Officials in SEPA expressed frustration that the media is often not as proactive as they would like in following biotechnology or biosafety stories.

Reflections and Lessons

Participation and consultation in the

Chinese case has happened predominantly within government, and there has been no broader public consultation and participation in the development of a biosafety regime. This is a reflection of the fact that consumer and producer stakeholders are not well articulated, that there is correspondingly not the level of 'demand' experienced elsewhere, and the tight control of biotechnology and biosafety policy by the state.

Nevertheless, biosafety issues are taken seriously given the pressures within the Chinese system (major technology development programmes and numerous state institutes) to push ahead with commercialising biotechnology applications. There has been a change of pace and tack to some extent in the way in which biotechnology is promoted, and no new crops have been commercialised in recent years. This is significant as according to scientists there are many new crops and traits 'ready' for commercialisation. This reflects growing awareness of the complexity of different facets of biosafety evaluation (including the range of environmental and health impacts to be considered, and social and economic impacts). Implicitly, within official reporting a range of different agricultural futures involving differing roles for biotechnology are being deliberated.

Further to this, it is important to note that biosafety in China happens in a very particular context. China faces pressures to open markets following its recent entry into the WTO, and to allow the import of GM seeds and commodities. At the same time caution is increasingly expressed within policy networks about the risks associated with a GM future for key commodity food crops, given recent experiences of losing access to certain 'GM-free' markets in Europe and Japan.

In relation to the details of regulation, some stakeholders make complaints about a lack of widely available biosafety information. In the Chinese context it is not always clear to what extent this is to do with policymakers experiencing overload, meaning that certain services or functions can only be offered in limited ways. Alternatively, certain information may be retained because an excess of publicly available information may weaken the government's position in relation to particular well-resourced and sophisticated stakeholders such as transnational corporations. Industry, for example, complains that the exact criteria for biosafety assessment are

sometimes unclear, and that when applications are turned down there is a lack of clear information as to why this has happened.

A related challenge is that at present there is no centralised, publicly accessible database of what biosafety applications have been made, what trials are underway, who is carrying them out and evaluating them, and on what basis particular applications have been rejected. Also there is not a clear publicly available record of what research is being funded by the MoST 863 and 973 committees (detailing, for instance, research institutes, projects, funding, and precise research focus). However, given these limitations there is keen awareness within ministries of the need for better practice in relation to informing and understanding the public. Policymakers express concerns that skills, time and other resources are lacking.

Interactions with stakeholders beyond core science-industry-policy networks are complicated. In the past there has tended to be an assumption that publics or farmers do not know or care about biotechnology or biosafety issues, and that these areas are too technical. There is also an assumption that farmers and consumers trust what scientists say. In relation to public participation, however, there is gradually more understanding of the importance of engaging with and understanding perceptions of different groups. Urban, middle-class awareness of environmental issues is perceived by government to have increased in recent years (around food safety issues in particular, such as pesticide residues), and a sense is expressed that in a similar way there could be opposition to genetically engineered foods on food safety grounds. Increasingly, influential and reflective newspapers such as *Southern Weekend* have discussed this.

The perspectives of farmers have not been explicitly sought out through formal consultation or learning exercises. Policymakers and researchers perhaps tend to expect that the market will reflect farmer priorities, and that if farmers like a technology they will adopt it. However, the Chinese system arguably also has some mechanisms and practices that allow for the articulation of rural interests. Technical extension services, agricultural research, state-owned seed companies and agricultural bureaus at the local level can be channels for consultation and expression of farmer opinions. These feedback systems may not however

provide scope for substantial deliberation about the nature of the farming system, and the range of issues that are implicit in a commitment to GM based agriculture.

There is a growing number of NGOs in China both international and nationally based. NGOs work most effectively in China when they work to demonstrate best practice at the local level, or to provide invited inputs to policy discussions. Being adversarial (particularly publicly) is unlikely to be effective at the national level. So far, NGOs appear not to have taken up LMOs as an issue in China. The exception is Greenpeace (Hong Kong) which has a cooperative project based in Beijing. They have been working with scientists based in Nanjing, and indirectly SEPA, to widen discussion about negative environmental impacts associated with widespread use of Bt cotton.

Finally, there is widespread recognition by policymakers and other stakeholders that however elaborate or deliberatively produced biosafety regulations are, it can be impossible to enforce aspects of them in a country as large and diverse as China, with such a vast smallholder agricultural sector, and diverse range of agro-ecosystems. Ensuring that seeds are not being used in provinces where there has been no biosafety approval is particularly hard to enforce. Given this, current biosafety work includes an emphasis on building capacity to check and monitor sources of marketed seed.

Brief Context

Denmark has ratified the Biosafety Protocol.

Biosafety regulations in Denmark are heavily influenced by EU legislation. Directive 90/220 on deliberate release was enacted into Danish law through the Environment and Genetic Engineering Act, no. 356 of 6th June 1991. A number of Statutory Orders have been made under this Act, including the Order on Transport and Import of Genetically Modified Organisms. Danish legislation is expected to be amended in time to implement the revised EU Directive 2001/18, which includes provisions on public access to information and notification and which comes into force in October 2002.

Denmark has also endorsed the EU Action Plan on LMOs, concerning purity and adventitious presence. Currently Danish inspection methods rely on documentary evidence rather than testing. Methods of genetic testing and analysis are currently being assessed (Lübeck, n.d.).

In 1999 the Ministry of Trade and Industry commissioned a group of experts in the natural sciences and philosophy to consider the ethical dimensions of genetic engineering. Their report contains proposals for the ethical guidelines that should inform biotechnology regulations (Danish Ministry of Trade and Industry 1999). The government has also created a Secretariat on Bio-ethics which is scheduled to start work soon. Its web site is in the process of being constructed. This is regarded by some in government as an opportunity to try some new ways of engaging the public in dialogue on these issues. In early 2000 the Danish Ministry of Environment and Energy commissioned a scientific literature review of the risks of genetic drift. The report was prepared by a group of biotechnologists (Johnsen et al. 2000).

Participatory technology assessment

Denmark has a number of years of experience with innovative participatory methods of technology assessment. The Danish Board of Technology was established by the Danish Parliament (the *Folketing*) in 1995 (successor to a body created in 1986). The Board is an independent advisory body established to evaluate the social and environmental impacts of new technologies and advise the *Folketing* and other governmental bodies. The

Board is responsible for disseminating knowledge and promoting ongoing discussions about technology issues. The Board is independent insofar as it is funded directly by a clause in the annual budget, is supervised by the Ministry of Research and reports to the Parliament's Research Committee. The 49-member Board includes representatives from business, journalism and academia and is assisted by a 24-member secretariat.

The Board employs a range of methods for technological assessment and public consultation including a variety of participatory methods. It takes a flexible approach to these methods and frequently experiments with new ones, which may be developed in-house or borrowed from elsewhere, or refine existing techniques. The Board uses a number of criteria to judge whether to launch a technology assessment. These include judgements about whether the subject has a technological content and is important to a large number of people, is controversial or likely to create conflict or require a decision to be made. The Board also considers whether it has a decisive role to play or a particular expertise or advantage to offer in contributing to the resolution of these questions. The Board publishes information about the aims, purposes and methods of the various participatory tools they use on their website (see also Andersen and Jaeger 1999; see Part I, Box 8 for more discussion on participatory methods).

Key actions

Participation and Consultation

- Act 356 on Environment and Genetic Engineering requires involvement by the public in decisions on the release of LMOs and contains provisions which lead to access to information for the public. Lasseur notes 'In practice this means that parts of the application are circulated to approximately 50 parties for comments. The decision is made on the basis of the comments received' (2000:13).

- Danish environmental NGOs are involved in the preparatory phase of plans, programmes, policies, laws and regulations through membership of advisory committees. This is in contrast to a country like Germany where environmental NGOs have the right to inspect and observe preparatory reports, but not to participate.

- Public hearings are organised by local authorities for all approvals. These are intended to garner peoples' views on the trials. For example, in 1999 there was a fodder beat trial and local organisations were given government money to bring together a range of stakeholders to debate issues surrounding the trial of the crop. A report from the consultation was subsequently published.

- There are also neighbourhood hearings and workplace meetings even where a proposed use of the technology is only in a contained environment. Companies are often expected to undertake these themselves in order to confront local public anxieties about the use of the technology in their locality.

- Since 1996 the Danish Board of Technology has used several consultation and participation techniques to address biosafety issues around biotechnology in food and agriculture. These include:

  ~ A 'consensus conference' – a three-day participatory dialogue between experts and lay people, open to the public (Genetically modified foods, March 1999). This conference is discussed in more detail in Box 8 of Part I of the report.

  ~ A formal hearing for the *Folketing* – a fairly traditional style of parliamentary scrutiny in which politicians are able to hear and question a range of experts identified by an initial working group of experts (Gene plants, February 1, 1996)

  ~ An 'interdisciplinary work group' – an interdisciplinary expert group (Biotechnological development and ecological research needs, 1989-90);

Information and Education

- The Minister of Environment and Energy has an obligation to inform parliament of receipt of applications for the deliberate release of LMOs into the environment. The applications are accessible through the web site of the Danish parliament

- Every new approval for contained use is published in national and local newspapers.

- Authorities, NGOs and companies holding public meetings relating to decisions about contained use or

deliberate release are encouraged by central government to disseminate information about the location and timing of the public meetings.

Reflections and Lessons

There seems, in general, to be high level of satisfaction with the hearings and consultations that have taken place in Denmark around biosafety issues. Key to this, according to most observers, is a willingness on the part of both government and industry to be transparent and open in terms of the types of information they make available to the public and a level of honesty about what trials are proposed and for what purpose.

Most also acknowledge the scope to further refine the application of participatory techniques to biosafety issues and there are currently discussions about the appropriate future role of focus groups and other means of engaging the public.

ESTONIA

Brief Context

Estonia has ratified the Convention on Biological Diversity and is expected to ratify the Cartagena Protocol in the near future. Estonia is also a party to the Aårhus Convention. In addition, as one of the ten 'accession countries' scheduled to join the European Union in 2004, EU legislation relating to biotechnology and public participation continues to be highly influential.

Estonia has a small domestic capacity in biotechnology, mainly in the public sector, although recent years have seen a growth in small start-up firms in the private sector. The most significant biotechnology project under way in the country is a large public-private human genomics project, involving significant foreign private capital. This is described in more detail below. The major transnational corporations apparently have no significant investment interests in agricultural biotechnology in Estonia, although some of these companies do have representatives in Estonia and interests in the chemicals or pharmaceuticals sectors.

The biosafety regulatory framework in Estonia is relatively well developed. The Estonian Act on the Release into the Environment of GMOs entered into force in January 1999. The Act aimed to implement the terms of European Directive 90/220/EEC. All applications for environmental release or commercialisation are required to be published in a national newspaper and shall be opened for public comment for thirty days. The Environment Ministry is required to provide written responses to all such comments within two weeks of the end of that period. However, the final decision on the application will not be published and there is no provision for public comment. The Act also contains provisions for confidential information[1]. To date, no applications under this law have been received by the government, and therefore it remains to be seen how effective these regulations may be in practice. However, there have already been two instances of environmental release of LMOs in Estonia, which apparently predated the entry into force of the Environmental Release Act. Neither instance concerns genetically-modified foods or crops: GM micro-organisms were used at two industrial sites to clean contaminated waste water.

1 See http://www.biosafety-cee.org

The Act on Contained Use of Genetically-Engineered Micro-organisms entered into force in December 2001. The Act aimed to implement European Directive 90/219/EEC as amended by Directive 98/187/EEC2. Estonia also has relevant regulations on novel foods and the protection of animals, as well as a provision of the Seed Act (1998) which requires labelling of GM seeds. Proposals for a new law on animal feed, including GM feed, are currently before the Estonian Parliament *(Riigikogu)*.[3]

There have been no official field trials of GM crops. Of the major GM crops that have been commercialised elsewhere in the world, only oilseed rape is suitable to the Estonian climate, but there appears to be little interest among Estonian rape farmers. However, there is widespread suspicion that GM seeds have already been imported and are being grown in Estonia, but since no testing is being conducted it is impossible to verify this. In recent months, random genetic tests have been carried out on grain imports from the world market, particularly shipments originating in the United States. These tests were simple 'yes/no' indicator tests, which cannot show the degree of contamination. The results showed that some of the tested shipments were contaminated, although the majority were 'surprisingly clean'. The enforcement action taken by the government was to alert the importers that their shipments had been contaminated, and that future imports would require a permit. In at least one case, concerning a shipment of maize for animal feed, the test results and enforcement action were too late to prevent onward sale and distribution of the affected shipments. The government notes that all of the consignments that tested positive were GM varieties that are accepted in EU countries.

There appears to be a universal perception that public awareness and concern about LMOs and biotechnology is rather low. A recent national survey carried out on behalf of the government showed two key insights into public perceptions. Firstly,

2 *See http://www.biosafety-cee.org*

3 *See http://www.biosafety-cee.org*

there is a strong public demand for more information about GM issues, especially in the Russian language4. Secondly, the survey showed small proportions of the population were strongly in favour (6%) or strongly against (3.4%) LMOs. The remaining, vast majority were largely ignorant about the issues and remained essentially undecided. The government has taken this survey as a clear indication of an urgent need for more information so that people can make a judgement.

Despite the apparent lack of awareness about GM foods and crops, there has been significant public concern and debate concerning the Estonian Genome Project[5]. This Project was initiated by the Estonian government in 2001. A non-profit foundation was established to manage the Project, which is intended to collect DNA samples from around one million people (approximately 75% of the population) in a national 'Gene Bank'. The Project is controversial partly because it is a public-private collaboration. Although the Estonian Genome Foundation will own the database, a private company is financing the Project and will be the exclusive licensee of the database. The initial public reaction was very negative, and the whole enterprise has raised important ethical and social questions which have stimulated public debate. Nevertheless, it seems that this debate has not stimulated a similarly broad or intense discussion of LMOs in agriculture and food.

The apparent lack of interest in the GM issue may be attributed to the fact that GM foods and crops have not officially been introduced to Estonia, and there has not yet been a public scandal relating to unauthorised imports, field trials or food contamination. Some respondents believed that the level of public knowledge and interest in the issues is rising as a consequence of the various information and awareness activities that have been undertaken in the country, as well as the publicity surrounding the Genome Project. However, the claim that the public will remain largely apathetic about the LMO issue is difficult to reconcile with

4 *Around 30% of the Estonian population are ethnically Russian (25%), Byelorussian or Ukrainian, many of whom speak Russian rather than Estonian as a first language.*

5 *http://www.genomics.ee/index.php?lang=eng&show=20/*

very clear evidence which shows that public agitation is quick to spring up when local or immediate environmental concerns are threatened. It is important to mention in passing the close connection between environmentalism and Estonian national identity in the political and social culture of post-Soviet Estonia. During the 1970s and 1980s, the emergence and growth of a popular environmental movement became a focus for a growing national consciousness which helped to bring about Estonian independence from the Soviet Union. For many Estonians, environmentalism lies close to the heart of Estonian national culture and identity, and environmental politics is intimately concerned with the accountability, transparency and responsiveness of government. Public demands for information and participation, particularly in environmental decision-making, need to be understood in this context.

In 1996, Estonia adopted an ambitious National Environmental Strategy and began to elaborate a National Environmental Action Plan, which encompassed the raising of public awareness and promotion of public participation as key priorities. The provision of information, education and training programmes and use of the media were highlighted as important elements of the strategy. A draft Action Plan on Public Environmental Awareness Raising was adopted, which includes 'fourteen actions to promote environmental education, eight actions to promote access to information, [and] eight activities to promote public participation (mainly to support NGOs)' (Ibid.:188).

The Estonian Constitution provides a supportive formal framework for public participation and information-sharing. Citizens have rights to information and the right to petition both local and national authorities. Estonia has also ratified a number of international conventions, besides Aårhus, which include provisions relating to access to environmental information, public participation and access to justice, such as the Basel Convention[6] (Merissaar and Roll 1998).

With respect to legislation, the picture is more complex because the rights to information or consultation are governed by different instruments in

6 The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes

different issue areas. A general Law on Protecting the Environment, which dates back as far as 1990, describes a public right to environmental information, but contains no provisions for operationalising this principle. Since then, a number of separate pieces of environmental legislation have been adopted or amended which include provisions for public access to information. In practice, '[t]here is no precedent for regular notification of an NGO or an interest group about lawmaking and policymaking' (Ibid.:190). Both notification and consultation seem to occur through informal networks between government and NGOs. Nevertheless, Estonia's experience of public participation is most extensive in the field of environmental governance.

There is no provision in any legal instrument which enables public participation in drafting of laws or policy documents. However, the government has commissioned ad hoc committees of paid advisors to draft documents on various issues such as the National Environmental Action Plan and the implementation of the Aårhus Convention. Increasingly, the membership of such committees includes a significant number of representatives from NGOs and environmental organisations and their involvement is said to have been influential. The process of including them seems to be governed by personal contacts and is essentially unregulated. Nevertheless, as this type of practice is repeated and becomes more common, there is an expectation that it will become normalised and assume a less *ad hoc* character. In particular it is felt that public participation will become more routine in national and local-level processes, rather than depending on the influence of foreign donors or international agencies. However, there is little sign that this process has been opened out to include the participation of members of the general public. Although a few pieces of environmental legislation have enshrined the right of the public to have their views taken into account, this 'is a right that has seldom been used in practice' (Merissaar and Roll 1998:190).

The Estonian Green Movement (EGM) and other NGOs lack a strong foundation of grassroots support and receive most of their funding from the Estonian government (often using grants provided by foreign institutions such as the EU) or foreign donors. This financial dependence raises risk of undermining the rigour and critical

independence of the NGOs, encouraging them to avoid asking awkward questions. The NGOs also lack direct accountability to the public and, according to one interviewee, are generally considered to be just another species of politician – and treated with similar cynicism. Nevertheless, the strong international links which NGOs have been able to create place them in a strong position to tap into sources of information and knowledge which even the government struggles to access.

Key Actions

Participation and Consultation

As described above, LMO applications must be publicised and opened for public comment; government is obliged to respond formally to any such comments. Since this procedure has never been activated, it is impossible to judge how effectively it will be operationalised.

Although some of the events and activities described below are sometimes represented as examples of public participation, they generally fall a long way short of that.

Information and Education

In order to gather information about public awareness, the Environment Ministry recently commissioned a survey of public attitudes towards biotechnology and LMOs. The findings, which are discussed in the Context section (above) were used to inform the preparation of the recent public seminar on biotechnology and biosafety (see below).

With regard to information provision, a Law on Public Information[7], implementing the Aårhus Convention, came into force in January 2001. It stipulates that citizens may request information from any government office or private organisation providing public services, orally or in writing. The applicant must disclose their identity, but is not required to give a reason for wanting the information. The information should be made available free of charge and in the format requested by the applicant. The Act imposes time limits for government to respond to the requests, which may be extended for complex questions. There is some concern that the shortness of the time limits imposes unreasonable

7 http://www.envir.ee/arhus/docs/act_on_public_information.pdf

burdens on government officials. Decisions to withhold information must be notified and explained, and any such decision may be reviewed by the Data Protection Inspectorate (a kind of ombudsman). Estonia also has an Act on databases held by public authorities, which provides that regulations governing such databases must define a list of people who may have access to the information contained in them, including those people who may have access without charge, and lay out the methods for providing public access to the information (Merissaar and Roll 1998).

In terms of pro-active training, dissemination of information and promotion of public awareness, the Environment Ministry has under a few initiatives:

- The Ministry's Department of Training and Education is responsible for organising training courses and seminars for public bureaucrats and specialists. The Environment Ministry also funds radio and television programmes to inform the public about environmental matters. The state TV channel broadcasts a weekly schedule of environmental programmes. The Ministry's Information Centre disseminates information via its website[8]. Non-governmental sources of information include the EGM and the Estonian office of the Regional Environmental Centre for Central and Eastern Europe (REC Estonia)[9] (Ibid.).

- The Ministry of the Environment has published three targeted information leaflets on topics relating to biotechnology and biosafety. They were distributed by the Ministries of Environment and Agriculture, and to specific target organisations as appropriate, such as farmers' groups or the government's Consumer Protection Board. They covered:

  ~ ***Biosafety legislation***, targeted towards producers, importers, exporters and others who may have to be aware of or implement the requirements. Published in Estonian only.

8 *http://www.envir.ee/itk/eng/index.html*

9 *The headquarters of the REC are in Hungary.*

- ~ ***GM crops,*** targeted at the agricultural sector. Published in Estonian only.
- ~ ***GM food***, targeted at consumers and the general public. Separate Estonian and Russian-language versions.
- ~ A fourth leaflet, on ***the Biosafety Protocol,*** is planned for March 2003.

- The Environment Ministry also collaborated with the NGOs REC Estonia and the Open Estonia Foundation on the production of a separate leaflet in 'Question and Answer' format, entitled 'GMOs on the way to Estonia' (see below).

The Estonian government routinely uses the internet to make available a large amount of information and documentation. This information strategy is complemented by a government programme to extend access to information and communication technologies (ICTs) to every person in Estonia free of charge (in public libraries), with special programmes to target elderly people and school children.

The contact name of the national focal point for the CBD and CPB is contained on many of the government's biosafety websites and in information distributed by NGOs, but 'in three years, no-one [member of the public] has ever asked' her for information. The only people who have occasionally sought information have been journalists.

Awareness-raising activities that have taken place in Estonia include:

- ***An 'Information Day' on the pros and cons of LMOs,*** April 1999. The event was organised by the Estonian Society of Biology and Geography Teachers and involved speakers from Tallinn Technical University, Greenpeace-Estonia and Friends of the Earth-Denmark. The event was targeted at participants from schools, government ministries, NGOs, research institutes and the media. The event was also publicised in the popular magazine *Loodus (Nature)* and the weekly teachers' newspaper *Õpetajte Leht*.

- ***A three-day workshop on public participation,*** October 2000. The workshop was organised by REC-Estonia and brought together specialists from Estonia, Latvia and Lithuania to discuss the linkages between the implementation of the Aårhus Convention, EU Accession and decision-making processes on LMOs.

- ***Ongoing NGO activities for raising awareness about LMOs,*** co-ordinated by the EGM and other environmental NGOs since 2001. Specific events and activities have included awareness campaigns in the country's three largest towns and workshops in five counties; publication and dissemination of an information leaflet; and a workshop on LMOs in conjunction with the EGM's annual national bicycle tour.

- ***Publication and dissemination of an information leaflet on LMOs*** 'GMOs on the way to Estonia', as part of a public information campaign on the implications of the EU's environmental Directives, August 2001 – April 2002. The campaign was co-ordinated by REC Estonia with the support of the Environment Ministry and other NGOs, and the leaflets were distributed to schools and NGOs.

- ***A module as part of a schools-based course on 'Raising awareness among young consumers',*** February 2002 – January 2003. The course was targeted at students in Grade 9, organised by the Estonian Consumer Protection Union and funded by Consumers International.

- ***A pair of one-day seminars aimed at raising awareness of biosafety issues and regulations,*** November 2002. These were co-ordinated by REC-Estonia on behalf of the government. The workshops were advertised by direct invitation to organisations known to have an interest, in the national press, and by radio announcements on the days of the workshops. The format for both workshops was lectures by a panel of speakers, followed by a plenary discussion. The discussion in both workshops was described as 'not too lively'. Despite the participation of journalists, no media coverage had resulted at the time of our interviews for this report.

  ~ *'Stakeholders' workshop'* targeted at individuals and organisations whose activities would be implicated by biosafety issues and regulations. Part of the rationale for holding this workshop was that the Environment Ministry recognised that it had not received any applications for environmental release, and became concerned that this might be because those subject to regulation were unaware of

biosafety issues or their legal obligations. The stakeholders were identified by a steering group which included representatives from the Ministries of Environment and Agriculture, the science community and NGOs. Only around twenty people participated in the event. The participants included lawyers, the private sector and farmers. The stakeholders' workshop also included a questionnaire designed to assess the participants' awareness of biosafety issues and regulations before and after the event. The findings from the questionnaire were sent to the Environment Ministry.

~ *Workshop for the general public* including journalists and consumer protection groups. A recently-commissioned opinion poll survey on public attitudes and awareness of biotechnology and LMOs was used to help prepare the workshop.

Reflections and Lessons

One observer of the contemporary situation suggested that Estonia's laws on public access to information are rather progressive, but they are not matched by sufficient rights of access to justice and justiciability for private applicants. The progressiveness of the legal framework also seems to be undermined to some extent by the complexity and lack of coherence between the public information provisions of different pieces of environmental legislation. The Public Information Act may help to overcome this incoherence in due course.

The government and NGOs have made significant efforts to publicise biotechnology and biosafety issues in Estonia. These appear to be meeting with some success. However, we have not been able to find any significant area where there has been a genuine opportunity for dialogue or inclusive decision-making involving members of the general public. The lack of space for public dialogue may be due in part to a perception shared by both NGOs, scientists and the government that the general public is not really interested in or concerned about LMOs, or lacks the necessary scientific knowledge to understand their implications. The results of the recent opinion poll demonstrate that this is not the case, however.

One factor which distinguishes the Estonian case from many of the developing countries reviewed in this report is the strong degree of international integration and the strength of linkages with foreign and international institutions. In this respect, the prospective entry to the European Union is the most significant factor which unlocks both incentives and resources to support Estonia's efforts to implement EU and international norms. Close ties with the Baltic and Scandinavian countries also appear to be significant. In relation to public participation in environmental policy and the implementation of the Aårhus Convention, the role of Danish funds and technical support is especially important.

A particular challenge is the ethnic make-up of the Estonian population. Only just under seventy per cent of the population are ethnic Estonians, while most of the remaining thirty per cent of the population are ethnically Russian, many of whom speak Russian as a first language. In some parts of the country Estonian is a minority language. Language is a sensitive issue in post-Soviet Estonia. The Estonian language forms part of the national citizenship requirement for non-Estonians. Post-independence governments have adopted a firm orientation towards the West rather than Russia. This helps to explain why many official and NGO websites are bilingual in Estonian and English and have no Russian-language content. However, so long as there is such a significant proportion of the population which uses Estonian as a second language, it is questionable whether the current provision of biosafety information for the public is sufficiently well targeted. We found only one example of a leaflet on GM foods that was produced in Russian as well as Estonian.

Brief Context

Ethiopia has some capacity in non-transgenic forms of agricultural biotechnology such as tissue culture and marker-assisted selection. No transgenic research is being carried out, no GM crops are commercialised and there have been no GM trials to date. A twenty year vision for biotech in Ethiopia was developed by the Ethiopian Agricultural Research Organisation (EARO). To facilitate implementation of this a biotechnology policy has been developed under the auspices of the Ethiopian Science and Technology Commission (ESTC). This has been presented to the Council of Ministers for ratification. The country is now in the process of developing a biosafety framework supported by UNEP-GEF. A National Biosafety Committee will be set up in the Environmental Protection Authority (EPA), where there will also be a National Project Coordinator. A second phase project on capacity building and implementation will follow completion of the NBF. There are also plans to develop a Biotechnology Institute at EARO. A US$3.8 million loan for biotech strengthening has been agreed by the World Bank.

Biotechnology is an emotive subject for some in Ethiopia. The country's history of food insecurity, with 14 million facing starvation in 2002 according to some estimates, have led some to suggest that technological solutions such as biotechnology are essential. Others have emphasised that the rich agroecological, biological and cultural diversity of Ethiopia, and the uniqueness of the country's cropping systems make GE technologies particularly risky and inappropriate. Significantly, Ethiopia has played a key role in developing and promoting the African Model Laws on Biosafety and Community Rights. The General Manager of the EPA was also key negotiator for the Like Minded Group in discussions towards the Biosafety Protocol. Ethiopia has also been a member of the BIO-EARN programme on biotechnology and biosafety capacity building.

Ethiopia has experience of public participation in national policy processes through the development of the national PRSP. The PRSP process was led by the Ethiopian Government and involved *woreda* level consultations, and discussions with representatives from civil society such as NGOs at the national level from 2001-2002. Views on the PRSP experience were mixed. Some NGOs claim that the process was in some

respects effective, in terms of government allowing critique of its proposals and acknowledging that civil society had a contribution to make. Arguably consultation resulted in key changes in the draft document in some areas such as pastoralism and agricultural extension. However, other key areas of concern such as land tenure policy were not revised. The credibility of the process was also undermined because some government debt was written off before the PRSP process had been completed.

Key Actions

Participation and Consultation

- The National Steering Committee that will oversee the development of the NBF will include representatives from EARO, the Institute for Biodiversity Conservation and Research, Addis Ababa University, the Ministry of Agriculture, the ESTC and the Veterinary College. Civil society and business organisations will be invited to comment on a draft produced by the Steering Committee at a specially convened workshop. The expectation is that the Committee will then revise the draft in the light of comments received at the meeting.
- There have been consultative processes in relation to the development of the Biotechnology policy, following the status assessment, including a workshop in December 2001 to discuss the draft policy involving NGOs, representatives from industry and business associations, as well as parliamentarians.
- Other more intensive consultative processes may provide lessons for the conduct of biosafety framework consultations. These include the National Conservation Strategy (NCS) where consultations were carried out between 1993 and 1996. The NCS involved Federal, Regional and woreda (district) level participatory exercises to identify key natural resource challenges and potential solutions. The quality of these exercises seems to have been variable. While in places farmers and others at local levels were involved in a genuinely participatory manner, this was by no means true across the board, and the processes for compiling the subsequent reports were not always clear. In addition, there were not always opportunities to comment on and revise drafts. The process of translating the Federal strategy into

Regional documents and action plans has been criticised for reflecting bureaucratic priorities rather than wider stakeholder concerns.

Information and Education

- There has been little information sharing or awareness raising carried out so far in relation to biotechnology and biosafety. The BIO-EARN programme running from 2000-4 has trained policymakers in risk assessment and regulatory issues, and has also supported the compilation of an inventory of wild relatives for key crops. The programme has also supported six biotech PhDs and one on biosafety. There has been no work targeted directly at the public through this programme as yet.

- Although not on biosafety issues as such, ESTC does produce radio programmes on scientific issues. Some of the national programmes have been translated into local languages and used through local radio stations. But there is a sense that radio is also a very one way medium which may be strong on informational value but weak on promoting dialogue unless followed up with workshops and discussions. Using television is problematic in Ethiopia as only a very low percentage of the population has access to this medium. The same applies to internet. Use of written materials is also a problem where there are high levels of illiteracy.

- Hosting meetings where discussions about the merits and risks associated with biotechnology products can be discussed face to face with people represents another important channel for public awareness-raising.

- Related to this, ESTC organises field days at research stations around the country that are open to everyone. They host demonstration projects such as on highland maize varieties and discuss with people future plans for research and development. These are held once a year at each research station throughout the country.

Reflections and Lessons

Levels of awareness about biotechnology and biosafety are considered to be very low in Ethiopia, according to stakeholders interviewed for this report. This being the case, a programme of information sharing and awareness raising is essential prior to

consultative processes. They may also need to be some clear explanation of the nature and purposes of participatory exercises aimed at garnering peoples' views on biosafety issues and the uses to which their inputs will be put, in order to allay fears about the government's intentions.

There are some important lessons for the NBF process arising from the country's experience with its PRSP process. The key lesson is that the PRSP process lost some credibility because some government debt was written off before the process was complete, whereas completion of the process is meant to be a condition for debt forgiveness. This action generated suspicions that the debt would have been written off whatever the nature of the PRSP process, with the result that the value of engaging with the process was questioned. A second important lesson was the significance of building an enabling political culture in which people feel entitled to voice their concerns on issues and are helped to 'learn' to participate. Making participation work in a setting like Ethiopia, where rights to freedom of expression are still fairly new, takes time and people have to learn to trust government-led processes where previously they were viewed with suspicion and fear.

Achieving a balanced consideration of the risks and benefits associated with LMOs will not be easy in the Ethiopian context. There are strong differences of opinion about the technology between those in EARO, MoA and ESTC and parts of the seed industry who see a positive role for transgenics in Ethiopian agriculture and some in the EPA and key NGOs working on agriculture and natural resource management issues, who are either more sceptical or opposed to the technology. The role of external actors is not viewed as altogether benign either, amid concerns that BIO-EARN's work serves to promote biotechnology rather than biosafety assessment. Consequently it is seen by some as having made an assumption that there is a role for GE crops in Ethiopia. Against this background, there is concern that donors of food aid may use Ethiopia's current famine to introduce LMOs into the country. The experience of Zambia in this regard has clearly added to these fears.

Consultative processes in Ethiopia to date have tended to emphasise roles for different parts of the state, emphasising their bureaucratic

mandates or areas of technical expertise. This presents a particular challenge in thinking about wide-ranging stakeholder engagement in a biosafety framework design process. The status assessment prior to the biotechnology policy did not seek out the views of target groups for example. Even for the proposed NBF consultation, it appears that civil society stakeholders will not be engaged until later stages. This reflects a strong statist tendency in Ethiopian policy-making. Arguably the PRSP process diverged from this through engagement of civil society actors. However, as we have seen, the PRSP offers other lessons about maintaining the trust and confidence of civil society stakeholders in participatory processes.

Brief Context

In March 2002 the Indian government approved the commercial cultivation of three Bt cotton varieties developed by MAHYCO (Maharastra Hybrid Seeds Company) based in Mumbai. Contained field trials have also been taking place for tobacco, mustard, tomato and brinjal.

All experiments on GM crops are controlled under the Indian Environmental Protection Act of 1986. The 'Hazardous Micro-organisms Rules' for handling GM crops were announced in 1989. All institutions, public or private, working on GM crops have to obtain permission from the Institutional Biosafety Committee. The RCGM (Review Committee on Genetic Manipulation) prepared its latest guidelines in August 1998 and these were further amended in September 1999. RCGM has constituted the MEC (Monitoring-cum-Evaluation Committee) principally containing agricultural scientists, that conducts visits to field trial sites to ensure experiments are being conducted according to the rules and procedures. The GEAC (Genetic Engineering Approval Committee) in the Ministry of Environment and Forests is responsible for the approval of activities involving large-scale use of hazardous and genetically-engineered organisms including GM crops for further large-scale research or commercial production (Ghosh 2001). The State Biotechnology Coordination Committees have responsibility for monitoring large scale releases of genetically engineered products into the environment and overseeing field trials. Finally, the Environment Protection Act provides for the establishment of District Level Committees wherever necessary to monitor the safety regulations in installations engaged in the use of LMOs.

Like many regulatory systems, the Indian model has been criticised both for being too slow and cumbersome (AIBA 2001) and for being too hasty in its approval process (RFSTE 2002). While industry groups such as the All India Biotech Association (AIBA) and Confederation of Indian Industry (CII) have been calling for a streamlined 'one-stop' approval process requiring fewer regulatory hurdles before commercialisation, many scientists and NGOs have called for a more thorough, transparent and inclusive decision-making process. In this latter regard, allegations about improper use of regulatory mandates in the approval process for Bt cotton trials have formed

the basis of a Supreme Court case against the government of India launched by the Research Foundation for Science, Technology and the Environment (RFSTE). RFSTE claim that permission for trials of Bt cotton by Monsanto and MAHYCO was granted by RCGM instead of GEAC. They allege 'RCGM has not consulted the concerned departments of the state governments before granting permission even though 'agriculture' is a state subject and any such trials can have a direct impact on the agriculture of the particular state'. Revisions to the biosafety guidelines made in 1998, which allowed RCGM to grant approvals to cover this action, were made after the trials had started in open fields. This claim forms the basis of the group's public interest litigation against the Department of Biotechnology.

Critics allegations of flaws in the regulatory system have been fuelled by the recent exposure that a private seed company had been selling seeds that were planted on as much as 11,000 hectares of land in Gujarat state since 1998, only being detected four years later (Dhar 2002).

Key Actions

Participation and Consultation

- Opportunities are provided for public comment and there is scope for objection to government proposals concerning LMOs. Many NGOs active on this issue complain, however, about the lack of access to the reports of the trials undertaken that is necessary in order to meaningfully engage in discussion about the safety and effectiveness of trials taking place. Only members of GEAC and RCGM are entitled to see these.

- Citizens' Juries: A citizens' jury was organised by ActionAid India in the state of Karnataka on the issue of GM crops, though not specifically restricted to the issue of their biosafety. The jury was composed of 14 small and marginal farmers (6 men and 8 women) representing a variety of farming traditions, income levels and social groupings, to capture a spectrum of groups that would be affected by the introduction of LMOs. The jury spent 3-4 days hearing information from 'witnesses' on the merits and limitations of LMOs from a biosafety and other perspectives. The witnesses presented evidence

for and against LMOs and other participants and observers. Scientific institutes, biotech companies, development NGOs, farmers unions and NGOs were among those represented. All the deliberations were filmed and subsequently made publicly available to ensure transparency (Pimbert et al 2001). The jury, while rejecting LMOs under current conditions, specified actions that the government could take to gain acceptance of the seeds. These included only releasing seeds after extensive field trials of 5-10 years for safety and other aspects that farmers helped to define.

- A similar exercise was undertaken on the question of food futures in the state of Andhra Pradesh, whereby a scenario workshop was created to deliberate on the merits of different agricultural futures over a twenty year time frame, in which biotechnology played a smaller or larger part (depending on the scenario). The workshop found opposition among participants to vitamin A enhanced and Bt cotton GM crops (Pimbert and Wakeford 2002). Reflections about the merits and limitations of this approach have been summarised and are available on the web (<http://www.ids.ac.uk/env>)

- The biotech company Syngenta (India) was involved with one of the Indian citizens' juries and claims to have participated in other independently-facilitated stakeholder consultations with smallholder farmers in different parts of India. One company executive acknowledged that the responses of the participants represented important and challenging learning opportunities for the company. The data from the consultations has apparently been transmitted to the headquarters of Syngenta in Switzerland and the company is considering how it should respond.

Information and Education

- The Department of Biotechnology (DBT) funds *Biotechnology and Development Review*, hosted by Research and Information Systems for the Non-Aligned and Other Developing Countries. Some question the independence of the journal as a source of information on biosafety issues because of the government funding it relies upon. It is also serves more as an information dissemination tool for

policy-makers than for the public at large, given that is written by academics and policy researchers.

- National and state level media have been used to relay information about biotechnology and biosafety issues.

- Industries, through the use of video, presentations by representatives and various forms of literature have been disseminating information about LMOs to the public. While this provides an important outlet for information, its independence and reliability as a source of balanced opinion remains in question.

- Biotechnology Consortium India Limited (BCIL) is a public limited company set up in 1990 to provide linkages between research institutions, industry, government and funding institutions to facilitate the accelerated commercialisation of biotechnology. Promoted by the DBT and funded through venture capital funds and corporations such as Glaxo India, BCIL engages in extensive information dissemination work on biotechnology and biosafety issues alongside training and technology demonstration work. BCIL organises meetings between predominantly industry and government representatives ('Entrepreneurs Meets') whose aim, rather than public education as such, is 'to facilitate financial, regulatory and other support to the entrepreneurs for expeditious commercialisation' (BCIL 2002). It publishes materials such as *Vatis update-Biotechnology* and *Biotech bulletin*, again principally aimed at disseminating strategically relevant news to industry and policy-makers.

Reflections and Lessons

At this stage the process of ensuring the biosafety of biotechnology products in India is essentially a government-led process. Guidelines and revisions are drafted in Delhi and then sent for comment from government bureaucrats at state level where competence for agricultural issues lies. It is perceived by central government that the responsibility for public consultation and education around these issues lies with state governments, particularly of course when field trials are to be conducted in those states. That said, there are mechanisms of consultation at the national level among key stakeholders and many key scientists and some NGOs are, in theory, entitled to access

to key decision-making bodies such as the RCGM and GEAC. While proposed changes to rules and guidelines in this area are put out for public comment, some view this process as jumping through bureaucratic hoops rather than a more substantive effort to engage the public. Critics allege that the circle of consultation that is invited to comment on guidelines through a questionnaire format is both fairly closed and 'safe', in terms of bodies and institutions that DBT can broadly rely upon for support, partly because some of them receive funding from DBT for their work.

Others claim 'the present guidelines have no provisions for the democratic participation of the public in biosafety decisions which reveal its loopholes and inadequacies both from a democratic as well as ecological perspective' (RFSTE 2002). RFSTE, for example, argues that approval for the trial or release of LMOs should be notified to the public as part of the citizens right to information. The group has called for public hearings to be organised in villages, districts and states where introductions and trials of LMOs are planned. They argue that participation should extend to local communities, *gram sabhas and panchayats* (local government bodies) whose permissions should be obligatory for the trial and release of GM crops and plants (RFSTE 2002). Though they concede that 'all environmentally destructive activity is supposed to be notified and cleared only after a public hearing', they allege 'Public participation in decisions about whether trials can be carried out has not even been considered'.

Some observers of the process also suggest, that without having to consult the public, the government knows already that the public are sceptical about the safety and benefits of GM crops, but it is government's role to persuade the public that the products are safe. Despite the activities described above, therefore, the emphasis appears to be on public education and informing the public of decisions already made, than on public participation and consultation. This is the concern of activists too, that DBT views it role as promotional rather than consultative in terms of garnering popular views about the safety and suitability of LMOs for release into the environment. At state level too, some commentators have suggested that permissions have been granted to grow LMOs without the active consent of farmers whose land the crops will be grown on. This makes a farce of public participation on biosafety issues if

decisions have already been made to proceed with testing.

As with many countries, the battle over the safety or otherwise of LMOs tends to be fought out in the media. While the media retains an important role in public education, others have highlighted the need for other public education strategies, including, for example, pamphlets in regional Indian languages that convey in a balanced way the risks and opportunities associated with LMOs.

NGOs such as the Centre for Science and Environment, Greenpeace and others have held public dialogues on issues of biosafety, sometimes working with scientists from government-funded scientific institutions such as the Indian Council for Agricultural Research, to amplify their concerns about the biosafety of crops proposed for commercialisation (such as Bt cotton). Some have claimed that it was NGOs ability to raise these concerns that led to delays in the commercialisation of Bt cotton for further testing.

The experience of India suggests that the appropriate role of more informal DIPs such as citizen juries (see Part I, section 4.3.2), in promoting public participation in the assessment of biosafety, is contested. While some view them as important vehicles for opening up debate about LMOs to a greater plurality of voices, others view them as one-off events that fail to bring about a change in policy even where they generate controversy in the media. Whether they bring about a more sustained process of change is in many ways a prerogative of the government rather than a function of the technique itself.

In so far as they do facilitate public participation in decision-making on these issues, however, creating the right conditions for their success is important. These conditions include: putting the perceptions, priorities and judgements of ordinary farmers centre stage, conducting the event in a rural setting, getting government, scientific and other witnesses to travel to the farmers to present the evidence, using TV and video technology to ensure transparency and the free circulation of information on the process and the outcomes (Pimbert et al. 2001). According to those involved, 'the jury process demonstrated the competence with which farmers, many of whom had not finished basic schooling, or were even illiterate, could discuss often highly technical issues to which they had no previous exposure, such as

genetically engineered crops' (Pimbert et al. 2001:29).

The key to this was not judging LMOs in isolation, but as part of a broader agricultural and developmental system. For proponents, therefore, citizens' juries and scenario workshops provide useful methodologies for addressing information deficits in the area of biotechnology and for garnering views on closely interconnected issues. A further key lesson was that once citizens' juries reach their conclusions it is essential that intermediary organisations act between the jury and those with the power to change. NGOs, farmer organisations and consumer organisations have an important role to play in this regard. (For more on the juries see http://www.actionaid.org/resources/resources.shtml and http://www.ids.ac.uk/env/envnew.html).

Brief Context

Kenya has ratified the Biosafety Protocol.

A Biosafety Committee was appointed in Kenya in 1996. The National Biosafety Committee comprises representatives from government ministries and departments, public universities, research institutions such as the Kenya Agricultural Research Institute (KARI) and ILRI (International Livestock Research Institute), the National Council for Science and Technology (NCST) and stakeholders such as the Kenya National Farmers Union and the Kenya Agricultural Biotechnology Platform (KABP).

The national policy and legal framework for biosafety in Kenya is contained in the 'Regulations and Guidelines for Biosafety in Biotechnology for Kenya'. The guidelines are promulgated under the auspices of the National Biosafety Committee of the National Council for Science and Technology. The guidelines cover areas of research and development involving the release of genetically modified organisms, as well as aspects of recombinant DNA technology and the use of biotechnology products derived through genetic modification. These guidelines have not, however, been promulgated into law and as such, there are no clear guidelines for large-scale enforcement.

In Kenya, open field testing of transgenic sweet potato is being carried out in at least five different agro-ecological zones in Kenya. These began in August 2000. Bioassays have been conducted in the lab for Bt maize, but have not yet progressed to field trials. Mock trials have been conducted to provide opportunities for staff training on the management of Bt maize growing in open quarantine sites. There is also some discussion about the introduction of Bt cotton. As yet, however, no crops have been commercialised.

On farm evaluations will be done with the involvement of farmers to establish protection, agronomic performance, consumer valuation and acceptance of the technology. The monitoring and assessment of the evaluation process is the responsibility of KARI's Institutional Biosafety Committee, the Kenya Plant Health Inspection Service (KEPHIS) and the National Biosafety Committee. In addition to the organisations already mentioned, KEBS (Kenya Bureau of Standards), in consultation with other stakeholders, is dealing with issues of

labeling under the Kenya Standard Labelling of Pre-Packaged Foods Act.

There remains scope for broader consultations with farmers and other stakeholders and increased efforts in the area of public information on both the positive and negative impacts of the technology (Odame et al. 2002). A workshop organised last year by the East African Regional Programme and Research Network for Biotechnology (BIO-EARN) noted that 'Public awareness and ability to participate in discussions on biotechnology should be developed to improve the quality of debates and the making of informed choices' (2001). This is based on a recognition that there has been an 'over-emphasis on policy-makers and scientists without paying similar attention to civil society' (ibid). It has been acknowledged that this means going beyond traditional stakeholders such as consumer organisations, as individual consumers 'should be made aware of their rights and involved in all stages of biotechnology' (BIO-EARN 2001).

Key Actions

Participation and Consultation

- Kenya developed its biosafety framework under the Pilot Biosafety Enabling Activity Project in September 1999, before the Cartagena Protocol was put in place. This was implemented by the National Council for Science and Technology and funded by Biotechnology Trust Africa and GEF
- There have been efforts to involve key stakeholders in decision-making on the biosafety guidelines in Kenya. The NCST, together with BTA, formed a task force representing different stakeholders to help draft the biosafety guidelines. The people initially represented were largely scientists from agriculture, environment, health and industry sectors as well as policy makers and lawyers. The guidelines produced were discussed in a national workshop where farmers, members of the private and NGO sector and extension agencies participated.
- The NCST organised a national workshop to develop mechanisms for implementing the biosafety guidelines which were published in 1998. The meeting recommended the establishment of the National Biosafety Committee (NBC).
- After the Cartagena Protocol was signed, a stakeholder meeting was

convened by the African Biotechnology Stakeholders Forum (ABSF) to review the biosafety framework in light of the Protocol.

- While awaiting parliamentary approval of the biosafety framework, the NCST, BTA and ABSF have continued consultations with the public, parliamentarians and stakeholders on biosafety.

- Alongside the principal government actors such as departments of agriculture and the National Council for Science and Technology, the key stakeholders in this context are considered to be KARI, scientists from the university sector, ActionAid, the Kenyan Association of Consumers, the Kenya Seed Company, Kenya Tea Development Authority, the Coffee Board of Kenya, various farmers organisations (such as the Kenyan National Farmers Union), the African Biotechnology Stakeholders Forum, the African Agency of Biotechnology, National Council of NGOs, the Environment Liaision Centre International) and the Kenya Institute of Organic Farming.

- There has also been some attempt to reach out to those at the front-line of using biotechnology products (hospitals, laboratories, research institutes etc). While the purpose of these visits was to hear from people what their concerns were about the safe use and application of biotechnologies, in practice government representatives found themselves explaining issues of containment, safety and handling to these organisations because of a lack of understanding of basic issues.

- The Dutch government programme (Special Programme on Biotechnology and Development) has provided funding and help with capacity-building since 1992. The programme brought the first elements of biotechnology planning to Kenya through a 'priority-setting exercise' in 1993 including farmers, researchers, extensionists and policy-makers. This resulted in the creation of the Kenya Agricultural Biotechnology Platform (KABP). The Platform advises the NCST and the government on the development of agricultural biotechnology in Kenya and has played a lead role in the development of national biosafety guidelines. KABP has also organised regular participatory consultations and 'stakeholder workshops' on various issues. In 2001 the KABP

was incorporated into the new Biotechnology Trust Africa (BTA) which is meant to serve a similar purpose of 'bridging the gap between research scientists and African farmers' (Biotechnology News 2001).

- While funding has been available for public participation in priority setting in relation to biotechnology in general, this has not been the case for biosafety specifically. There have been few opportunities for public feedback on how the guidelines have been used in practice and the sorts of change people might want to see. The NBC has no resources of its own for public education and awareness.

- A related problem in this regard is that the NBC has a weak secretariat. Members of the Committee hold other full-time jobs in the university and other sectors and are not in a position to commit fully to the process as a result.

- Most observers agree that consultations that have taken place have been largely restricted to the national level and outreach to the local level has been fairly limited.

- Nevertheless, BTA is based in Nairobi. The trust provides assistance to carry out needs assessment and priority-setting for biotech development in targeted countries in Africa and, among other things, promotes participatory research in biotechnology projects. BTA claims to support the active participation of stakeholders in all stages of project development and implementation. Specific activities have included: awareness-raising workshops for farmers in Machakos and greater Kakamega pilot districts, research and extension workshops for the implementation of participatory research in pilot districts, documentaries about farm-level activities, production of the *BioNews* newsletter, media articles and information-sharing through the web.

Information and Education

- ABSF and BTA have been targeting farmers specifically with awareness-raising efforts on issues relating to the biosafety of LMOs.

- There is also an Interlink Rural Information Service (IRIS) disseminating information relating to issues of biosafety and adoption of biotechnologies, in particular the

status of applications and policy on biotech.

- Organisations such as KARI have sought to raise awareness through press releases, workshops, seminars and meetings, KARI bulletins and field demonstrations. There has been discussion about preparing radio programmes in local languages, or at least in Swahili, on issues relating to biotech and Bt Maize specifically.

- The government has also worked closely with organisations such as the African Centre for Technology Studies (ACTS) in hosting workshops on specific issues associated with biotechnologies in order to raise awareness and engage stakeholders. ACTS, IDS and FIELD (the Foundation for International Environmental Law and Development) organised a meeting with stakeholders in Nairobi November 2002 to share lessons on issues of regulation and participation in relation to biosafety issues emerging from their work in other countries.

- In addition, the following types of public education and awareness-raising activity have been undertaken: On Bt and insect-resistant maize, 'stakeholder meetings' (with farmers, consumers, religious groups, environmental groups, media etc) have been held and print, audio and electronic materials been made available. There has also been some discussion about extending biotechnology into the formal education structure in Kenya as well as hosting seminars for policy-makers.

- The media, notably national papers such as 'Nation' and TV (Kenyan Television Network) has played a key role in disseminating awareness. In this latter regard, KTN has hosted public debates on biotech issues between proponents and opponents of the technology where a public audience is encouraged to cross-examine the speakers. Given the importance of the media to targeting at least some sections of the population, the ABSF has been active in providing media training on biosafety issues to make journalists more aware of the issues. The ABSF was registered and launched in Kenya in February 2000 to aim 'To improve public understanding on all aspects of biotechnology to enhance informed participation that

adequately articulates Africa's agenda in the global biotechnology arena' (IRMA 2001). It does this through stakeholder workshops, participation in media debates, publication of newsletters such as *Biotek Afrika*, public lectures and training for journalists (<www.absfafrica.org>).

- Picasso productions in Nairobi also produce the newspaper *Biosafety News.*

Reflections and Lessons

Reflecting on the work of the Dutch special programme on biotechnology and development, the KABP and the BTA, Wafula claims that 'National priorities for biotechnology have been set up through participatory bottom-up approaches bringing together all stakeholders to make collective decisions. Such priorities are thus based on the felt-need of the country' (Wafula 1998:3). Most forms of capacity building measures around agricultural biotechnology in Kenya have focussed on training for 'experts' and 'professionals', however. It has also been observed that these sessions have not allowed for much participation beyond the terms of reference for the workshops themselves. Some observers have felt that the agenda has been more or less set and there has been little scope for interrogating agricultural policy more generally and whether agbiotech development represents the best and safest way forward (Frempong 1999).

Others also note the extent to which attempts to involve the public in decision-making on biosafety issues have tended to be externally-driven by actors such as the Dutch government, UNEP-GEF and the Stockholm Environment Institute (SEI) in the form of BIO-EARN. One report notes 'the debate on what is good or bad for Africa has been driven by people and groups outside the continent, some without adequate knowledge of the situation and needs of the continent' (IRMA 2001:10).

People within government that we spoke to expressed the view that the development of regulations in this area is inevitably top-down and government-led. The regulations have to come first before the public can be meaningfully engaged on these issues. Many also reflect that this has also been the case in many European and other western countries, despite more recent attempts to engage the public in dialogue on biosafety issues. Given this, some people have suggested that public hearings and some of the other

participatory techniques discussed in this report may follow in time as agricultural biotechnology takes off and awareness of the technology increases. Experience elsewhere, however, would underscore the importance of consulting people prior to major developments rather than informing them after the event. One potential channel for this outreach to smaller farmers in particular could be through the Ministry of Agriculture and Rural Development which not only has the capacity to create awareness among small-holder farmers through its extensive network of frontline agricultural extension staff, but could reverse the communication flow so that it becomes simultaneously a mechanism for soliciting and 'drawing up' the views of smaller farmers on biosafety issues.

A difficult problem to date has been the link between the scientific, social and ethical dimensions of biosafety. Trying to manage the links between these issues in a way that invites useful and constructive inputs from the public has proved to be a key challenge. To confront it NCST has been working through the BIO-EARN programme to raise critical awareness on issues such as food safety which are slowly coming into the current framework. Nevertheless, there is an acknowledged need to strengthen capacity for risk assessment and management, currently perceived to be inadequate, in a way that involves key stakeholders at different levels.

On the side of public education and awareness-raising, there is an identified need to harmonize information and avoid duplication which can only be done through improved coordination between the key agencies in this area (BIO-EARN 2001). This could indeed be the function of the ABSF as a coordinator of activities and information flows. This will be key to closing the 'knowledge gaps' which are acknowledged by all sides to exist in the public arena. Others have noted the importance of workshops and field days, as well as using audio, radio and user-friendly print materials to package and disseminate biotechnology information which could be done through the Agricultural Information Resources Centre (IRMA 2001). Multiple communication and dissemination strategies will be necessary given that, for example, print media generally still reaches a small percentage of the population and mainly those living in urban areas. The majority of the population still relies on state run radio or public broadcasting and communication through extension workers of the ministries of agriculture.

Brief Context

Malaysia is expected to ratify the Biosafety Protocol in the first quarter of 2003 through the adoption of a national biosafety law.

Biotechnology has been identified as one of the five core technologies that is expected to accelerate Malaysia's transformation into a highly industrialised nation by 2020. A high-level National Biodiversity-Biotechnology Council (NBBC) was established in May 2001, chaired by the Deputy Prime Minister. The Secretary-General of the Ministry of Science, Technology and the Environment (MOSTE) serves as the Secretary of the Council, at the head of a Secretariat of the Conservation and Environmental Management Division (CEMD) of MOSTE. The Council's functions are to determine national policy direction and strategy, and co-ordinate and make recommendations to the Government on issues national biodiversity conservation and the development of biotechnology.

Under the 8th Malaysia Plan (2001-2006), the Government has proposed the setting up of three National Biotechnology Institutes. These Institutes will be the hubs for biotechnology development and biotechnology companies, in a planned BioValley (a geographical area within the existing Multimedia Super Corridor). The launching pad for the BioValley was the BioMalaysia 2002 conference in October 2002, which brought together the scientific community and industry, to foster biotechnology partnerships and investments in the country.

In the 3rd National Agricultural Policy (1998-2010), biotechnology was identified as one of the new sources of growth. The Policy stresses human resource development in order to "generate highly skilled and innovative manpower in new and emerging sciences such as food, genetic engineering and biotechnology". Despite this, Malaysia has not yet commercialised any modern biotechnology (GE) applications nor has it been sowing or harvesting genetically engineered crops. There are currently no exports of LMOs from Malaysia. However, a number of GE trials are in the pipeline, including GE oil palm and papaya. These applications are being developed by local research and development institutes, some with the collaboration of foreign companies and institutes. GE herbicide-tolerant soya was the subject of a formal application by Monsanto. Field trials on GE rubber

trees have also been conducted and it is widely acknowledged that LMOs are likely being imported and consumed in the country.

MOSTE, as the national focal point for the CBD and the Protocol, is the lead agency for providing policy guidance and coordinating conservation and environmental management in the country. Other line Ministries and government agencies involved and which have an interest in issues relating to biosafety, include the Ministries of Health, Agriculture, Primary Industries, International Trade and Industry, Domestic Trade and Consumer Affairs; and public research agencies such as the Malaysian Agricultural Research and Development Institute, the Malaysian Palm Oil Board, the Malaysian Rubber Board and the Institute for Medical Research. Public universities also have research programmes that relate to biosafety.

The National Biotechnology Directorate (NBD) of MOSTE is responsible for strengthening and developing the commercial potential of biotechnology, through eight Biotechnology Cooperative Centres (BCCs). No direct work on biosafety-specific issues is scheduled to be carried out by the BCCs. The CEMD is the division of MOSTE that is responsible for biosafety and the CPB.

The Genetic Modification Advisory Committee (GMAC) has been established under MOSTE's National Steering Committee on Biological Diversity, and is the sole forum dealing with issues relating to genetic engineering (GE). Like the NBBC, the GMAC is supported by a Secretariat provided by the CEMD. As the national advisory forum on genetic modification, GMAC provides scientific and technical advice to MOSTE as well as to private bodies. GMAC comprises scientists from different universities, research institutions, relevant government Ministries and agencies, and an NGO representative.

At present, the GMAC is only an administrative entity, and any applications for field trials and commercialisation of LMOs are purely voluntary. The National Guidelines for the Release of GMOs into the Environment (1996) formulated by GMAC, are also not legally binding but serve to provide scientific and technical guidelines for releases of LMOs. NGO experts participated actively in developing the Guidelines. When the national biosafety law is enacted, GMAC will become a legally

constituted body. In the absence of legally binding national legislation, GE research and development in the country has also proceeded with little regulation or oversight. The pace and scope of biotechnology research and development has outstripped the development of the national biosafety framework.

A task force, convened by MOSTE and comprising relevant Ministries, agencies, scientists, academics and an NGO, began work on drafting the Biosafety Bill before the Protocol was concluded. The Bill is now undergoing the final stages of inter-agency consultation. The draft law is basically premised on the regulation by approval or notification of all activities relating to LMOs. Under the proposed law, a National Biosafety Board (NBB) will be established to be the competent authority to decide on applications for LMO activities. Chaired by the Secretary-General of MOSTE, the NBB will comprise representatives from relevant Ministries and four other persons from various fields and disciplines, including one representative from an NGO and one from industry. The GMAC will be legally established, and the current voluntary Guidelines will be updated and incorporated as legally binding regulations. It is anticipated that several additional regulations, schedules and administrative guidelines, such as manuals for standard operating procedures, will also be drawn up to complement and facilitate the implementation of the Biosafety Law.

The NBB will receive scientific and technical advice from GMAC, which will be made up primarily of government scientific and technical experts, as well as from technical advisors from the Ministry or Department responsible for the particular product or application that is being assessed. The role and participation of civil society groups and NGOs is envisaged to be in an auditing function to keep the system transparent without crippling the procedures of the biosafety regime. Dialogues or workshops for different States and Ministries to share and exchange experiences in implementing the biosafety framework and law are also planned.

LMO regulation cuts across the jurisdiction of different line Ministries. As such, the Biosafety Bill will be an 'umbrella act', under which various pieces of sectoral legislation will deal with specific or sectoral issues. Other legislation or regulations which are

implicated by biosafety considerations include the amendments to the Food Regulations 1985 (which relate to the Food Act 1983), and a new Feed Act, both currently being developed. These two pieces of legislation come under the purview of the Ministries of Health and Agriculture, respectively. The proposed amendments to the Food Regulations 1985 will require mandatory labelling of GM foods. The new Feed Act will refer the issue of GM feed to the Biosafety Bill.

Key Actions

Participation and Consultation

- A national public consultation was held on 20th September 2001, where other line Ministries, agencies, institutions, NGOs, academics, scientists, experts and representatives from industry and the media were invited to deliberate and provide their comments and feedback on the Biosafety Bill. A draft 'scheme of the law' was used as the basis for discussions. The purpose of the consultation was also to inform and sensitise the public and stakeholders to the issue, particularly to the difficulties of 'striking a balance' on a polarised and contentious issue. Around 150 people participated in the consultation.

- Such a wide-ranging and 'open' consultation is unprecedented in the formulation of a national law. Usually, if consultations are held on the development of a national law, it is only among the relevant government ministries, agencies and institutes, and non-government actors are restricted to a small group of people with demonstrated expertise on the issue, and interest groups who may be most directly affected by the proposed legislation.

- However, the consultation was primarily used to gather the different views of the different sectors, without really engaging in a debate on the issues, or the specifics of the Biosafety Bill. Ultimately, policy decisions are regarded to be within the purview of the government, and MOSTE, which is responsible for driving this process, sees its role as balancing between the different interests and concerns among the relevant stakeholders and other government Ministries and agencies.

- There were strong views represented at the consultation,

and some of these were followed up with written submissions. However, there is no mechanism to continue this type of public participation. Responses to oral and written submissions have not been adequately provided, and those who participated in the consultation have no means of knowing how their views will be reflected in the Biosafety Bill, or if their concerns will be taken into account at all. Those consulted have no means of knowing how the final decisions are taken.

- Despite the large number of participants at the consultation, the public at large was not consulted, for instance in the form of an open call for views or an organized media effort to inform the public. Participation was by invitation only, and selected by MOSTE. Factors such as physical space, financial constraints, and the value of throwing open to the public a relatively unknown issue, were cited as reasons for not opening up the consultation to the larger public.

Information and Education

- To date the government has undertaken no significant public awareness and education activities. However, this is likely to change once policy regarding biosafety and the Biosafety Bill are more firmly established, and funds are available. NGOs and privately funded institutes have been undertaking some of this work, though the main challenge is to ensure that biosafety awareness is the primary objective, rather than the promotion of biotechnology *per se*.

- One example is the Malaysian Biotechnology Information Centre (MABIC). MABIC is the country node for the International Service for the Acquisition of Agri-biotech Applications (ISAAA) Global Knowledge Centre. MABIC has organized a number of seminars and public forums on biotechnology, and published briefings and pamphlets aimed at the public. MABIC also has a website. The former Executive-Director of MABIC also had a regular column in the largest English readership daily newspaper, 'The Star', entitled 'Biotech Fortnightly'. However, concerns from readers including some scientists led to some lively letters to the editor criticising information supplied by MABIC, which although promoted as 'science-based' and

'neutral', leaned heavily towards pro-biotechnology views and the viewpoint of industry. The fortnightly column in the newspaper was eventually terminated reportedly due to the critical response received from the public.

- A number of NGOs in Malaysia have been active on biosafety and GE issues, particularly the Pesticides Action Network-Asia Pacific, the Consumers' Association of Penang (CAP), and the Third World Network (TWN). Of these groups, however, only CAP has a national public focus, and specifically targets public education and awareness. A vast quantity of literature has been produced by these groups specifically on GE and biosafety, and also carried in the regular publications of these organizations (in the case of CAP, in local languages, too), and considerable biosafety information and analyses are distributed primarily through the internet and via email. But public distribution channels, especially mainstream media, have not yet been effectively utilised for the dissemination of biosafety information.
- From time to time, the print and broadcast media (radio and television) have carried articles and programmes on GE. However, these have tended to be articles and programmes expressing views at either end of the spectrum, and no real initiative has been made to foster a genuine public debate.
- Various seminars and fora have also been organized by bodies such as the National Academy of Sciences, the Malaysian Institute of Islamic Studies, and local universities. However, awareness meetings targeted to the public at large have been few and far between.
- In terms of access to information, the law provides that:

"Subject to the discretion of the National Biosafety Board, the public may have access to the information relating to any application made to the Board at the office of the Board and they may make comments within such period as may be specified by the Board. However, the Board shall protect information which it determines to be confidential upon the application made by the applicant and/or the approved person."

The details and implementation of this provision will be developed further in regulations or administrative guidelines.

- As part of Malaysia's capacity building for implementing the national biosafety framework, some plans for public awareness activities in relation to the transboundary movement of LMOs have been laid out, as well as for the participation of stakeholders. There are plans for biosafety public awareness programmes in every State, and this includes the production and dissemination of materials such as education kits, flyers and posters targeted at different groups. A website will also be set up, to provide information to the public, and also as an avenue for the public to voice their opinions and concerns.

Reflections and Lessons

Although the government has taken unprecedented steps in public participation on the issue of GE and biosafety, and has been consistent about allowing and inviting NGO representation in developing and implementing its national biosafety framework, comprehensive and effective public participation is still lacking.

Public participation is seen more as a one-way flow of information, where views and concerns are gathered, but dialogue and discussion is still minimal. As such, there is little transparency and genuine participation in decision-making and policy formulation. When the government takes the final decisions, the process and rationale for decisions taken are not openly known.

The views and opinions of the public at large, have not, on the whole, been taken into account. While it is recognized that NGO views may not represent the public's views, there are few mechanisms for real public participation. While it is recognised that for meaningful public participation, the public must be made aware of the issues, this has not been properly addressed. The role of the government in public education and awareness is seen as a balancing act, to supply 'balanced' and 'neutral' information to the public. Encouraging a public debate, and even a scientific debate, has not been a priority. There is then substantial room and need for improvement of the decision making process through better and more effective public participation.

Brief Context

Mexico has ratified the Biosafety Protocol.

Mexico is home to two important research centres for biotechnology: CIMMYT and CINVESTAV. CIMMYT receives support from the CGIAR and CINVESTAV is a National Polytechnic Institute department. But while Mexico exports agricultural products to North America and Europe, the country also imports LMO crops (Gálvez 2001). Being a mega-diverse country in biological resources and ecosystems, with more than 10% of the global biological diversity in plant species, biosafety is of primary ecological significance in Mexico. Mexico is the centre of origin of important globally commercialised crops such as tomatoes, beans, potatoes, chillies, cacao, agave and maize; and other regionally important crops such as avocado, papaya, and amaranth (UNDP 2002). It is considered the "custodian of maize germplasm", which is the commercial crop most subject to genetically engineering (Gálvez 2001).

Since 1988, the Government of Mexico has implemented several measures on biosafety. The key federal agencies involved in this process are: CONABIO, SEMARNAT and its decentralized agency the INE, the Health Secretariat which determines potential health effects, and SAGARPA. Also, agencies such as the Education Secretariat have been incorporated to design training programs and incorporate biosafety into higher education curricula, and most recently CIBIOGEM, which is the national focal point for biosafety.

Before the creation of CIBIOGEM in 1999, regulations on biosafety were basically focused on health and agriculture legislation. Health regulations require informing and obtaining special authorization for trade in a list of pharmaceutical products, drugs, insecticides, food or raw material created by biotechnology. In 1997 Congress modified the General Health Law, which regulates products for human consumption or use either directly or in processed form, specifically to include the creation of a biosafety commission to oversee genetic engineering research. With regard to agricultural legislation, in the context of the negotiation of NAFTA among the USA, Canada and Mexico, the Federal Law for Production, Certification and Commerce of Seeds was modified in 1991 in order to restrict the certification of transgenic plants. The National Law on Plant Health and the Mexican Standard 056-

FITO-1995 require phytosanitary certification for the inter-state movement, importation and conduct of field trials of LMOs. The General Directorate for Plant Health of SAGARPA was responsible for giving these authorizations. In 1988 a multi-disciplinary group of experts began to handle requests for the trans-boundary introduction of LMOs. This group was formalized in 1989 with the CNBA. Following the creation of the CNBA, close to 190 requested permissions were evaluated (from 1988-2000); most of them were approved for experimental release, and just cotton and soybean on a semi-commercial scale. However, since 1998 the certifications issued for the experimental release of transgenic maize have been suspended in order to address the possible risks associated with GM maize in a country which is centre of origin. There are five proposals for a National Biosafety Law which are being discussed in the Congress.

To comply with the Protocol, the Government of Mexico created CIBIOGEM in November 1999. CIBIOGEM's task is to coordinate the official actions related to biosafety and production, importation, exportation, movement, release, consumption and use of LMOs. CIBIOGEM is made up of the Secretaries of: SAGARPA, SEMARNAT, Economy, Treasury, Education, Health and CONACYT; its presidency is rotated every six month among SEMARNAT, SAGARPA and Health, since these are the agencies with core responsibilities for LMO release and for risk evaluation and management. CONABIO is a member of the consultative body and provides recommendations and carries out the risk evaluations. However, authorizations are given by CIBIOGEM after a revision by the Specialized Sub-committees for Agriculture and for the Environment. CIBIOGEM is described as a 'virtual' agency that takes form when these Secretaries meet to discuss biosafety and LMOs issues. Nevertheless, CIBIOGEM has an Executive Secretary who, according to its Rules of Operation, has the task of raising awareness among the public, social and private sectors of the country, of its policies, guidelines and agreements (Article 9 section 5).

CIBIOGEM´s Technical Committee is formed by officials of the Secretariats that are part of this body. This Committee is currently designing a long-term capacity building program to comply with the Cartagena Protocol. The issue of public participation is one

of the general subjects which is meant to be tackled by each member of the Technical Committee from their respective responsibilities. CIBIOGEM has a BCC made up of fourteen Mexican scientists that are supposed to act in an independent manner. BCC has the task of carrying out consultative processes with NGO and private organizations related to the matters that CIBIOGEM covers. However, the BCC quit in August 2002, after its members declared that CIBIOGEM had not taken their views into account. BCC experts also claimed that they had little incentive to work on the CIBIOGEM requests since they did not receive any payment for their work. To overcome this problem, a new work "scheme" was created where experts would be represented within CONACYT, which has a Scientific and Technological Consultative Forum. On the positive side, the creation of CIBIOGEM did serve to broaden discussions on biosafety issues and the way in which the Protocol would be implemented in Mexico to a more diverse audience.

Key Actions

Participation and Consultation

- Within government, CIBIOGEM has set up a communication process between ministries and high level officials involved in biosafety matters. For instance, all these agencies are consulted before giving the AIA. CIBIOGEM also rotates its presidency every six months among the ministries with core responsibilities for LMOs. The BCC was intended to be the body within CIBIOGEM which would undertake public consultation. However, as we saw above, BCC disbanded itself in August 2002.

- The CCDS of SEMARNAT conducts consultations and seeks to inform civil society groups about contemporary environmental issues through workshops and by drawing up policy recommendations for SEMARNAT. The CCDS is made up of elected representatives; there are a total of five CCDS councils in the country. During the last administration (1994-2000) the CCDS organised three workshops on biosafety, which took place in different regions of the country. The current CCDS has yet to carry out any consultations or information campaigns because of changes within the new administration. However, a biodiversity and biosafety technical commission has just been created. The first

consultation of SEMARNAT with the members of the CCDS took place at the end of October 2002, along with a number of information meetings and workshops.

- The Commission for Technology and Science of the Senate has initiated a Public Consultative Forum through the internet in order to gather views and suggestions on the proposals for a Biosafety National Law, based on the four previous initiatives on Biosafety. This was presented on November the 12th, 2002 (www.senado.gob.mx/comisiones/directorio/cyt/foro).

- The Natural Resources Commission of the Congress has invited some organisations from the NGO coalition, such as UNORCA, to participate in its round tables discussing biosafety related issues.

NGOs have also been active in encouraging public participation activities on biosafety and broader biotechnology issues:

- A NGO coalition was recently formed for promoting public awareness concerning the environmental and health risks associated with the production and consumption of LMOs. It is made up of Greenpeace, GEA, CECCAM, ETC (formerly RAFI), *Guerreros Verdes*, and UNORCA. This coalition has handed the Government an emergency plan regarding the presence of GM maize in Oaxaca and Puebla. Members of the coalition have tried to engage the public on biotechnology issues by using a range of public forums, workshops and conferences. For instance, in April 2002 CECAM, CASIFOP and ETC organised a public conference on LMOs. This followed the coalition's presentation, in December 2001, of a public demand to PROFEPA with regards the GM maize contamination in Oaxaca and Puebla. In May 2002, it presented a public petition to CEC (derived from NAFTA) to investigate the issue and produce a series of recommendations for the Mexican Government. At present, no response has been forthcoming from CEC or PROFEPA.

- *The Citizen Movement for Democracy,* has organised preparatory meetings for the new round of WTO talks. These have included discussion of the Biosafety Protocol and its relationship to the WTO.

Information and Education

- In terms of informing legislators, in 1999 the Environment and Natural Resources Commission of the Senate organised a workshop where experts and officials from CONABIO and SEMARNAT provided information on LMO and biosafety issues. After the signing of the Protocol, the new SEMARNAT administration gave two presentations to Senators and Representatives, mainly focussing on LMOs and the importance of ratifying the protocol.

- CONACYT, SAGARPA and the industrial sector have organised forums to facilitate information exchange. The forum "Successes and Perspectives on Biotechnology in Mexico" took place in Mexico City and was organised by CONACYT, with assistance from the Mexican Academy of Sciences, the National Chamber for Industrial Change and the Mexican Society of Biotechnology. After the news that GM maize had been found in Oaxaca and Puebla, SEMARNAT ran a series of workshops to inform local communities about what an LMO is, the associated risks, and the recommended actions to help protect biodiversity.

- Under the UNDP project "Basic Capacity Building for the Implementation of the Cartagena Protocol" there is a public awareness campaign and a communication program. Under this strategy, CIBIOGEM has the task of designing a website that serves as an information network to store data (abstracts of each risk evaluation, norms and guidelines, final decisions and reports of the AIA) and to provide links to other, related databases. This information will be connected to the BCH and the focal points of the 26 countries with which Mexico has trade agreements. Also, as part of this strategy, a targeted information campaign, on the potential risks and benefits of LMOs for small-holders in rural communities who participate in government agricultural outreach and subsidy programs, will be undertaken. In general, the UNDP-GEF project plans to have the following outputs: public information forums; preparation of basic information on LMO risks for the potential recipients of official agriculture programs; stakeholder consultations on specific issues and information campaigns on media and targeted material. The project is planned to

last three years and it already underway (UNDP 2002).

NGOs have also played an important part in raising public awareness around biosafety and biotechnology issues:

- UNORCA is promoting a national debate on the need to have legal instruments to guarantee the implementation of the Cartagena Protocol. It has been lobbying the Congress for a National Law on Biosafety. UNORCA, which represents 280 organisations of 26 Mexican states, has a Committee for Biodiversity and Natural Resources. This Committee plans and executes work proposals for the 26 Mexican states on subjects such as biosafety, LMOs, intellectual property rights, indigenous rights etc. It is particularly oriented towards the protection of peasants' and indigenous peoples' rights and it has conducted research to inform and support a number of environmental groups. (www.unorca.org.mx).

- ERA, a group that works primarily with peasant communities in Oaxaca, co-ordinated a virtual discussion of GM maize, with the participation of many NGOs and academics. The Protocol and its implementation in Mexico was also discussed.

- On January 24th 2002, the 1st 'Forum for the Defence of Maize' took place with the participation of 138 civil and non-governmental organisations (including environmental, peasant, indigenous groups, womens' groups and academics etc.) to discuss the GM maize problem. The main objective was to develop proposals and strategies to tackle the "emergency situation". The outcome was an agreement to form citizen vigilance and monitoring committees.

- Greenpeace and GEA have played an important role in informing the public about LMOs, the Protocol and other biosafety related issues. Both Greenpeace and GEA have been invited to participate in public information workshops and publish bulletins and essays in different magazines, principally with a rural focus. In order to reach rural communities, where many people cannot read, Greenpeace and GEA developed a video on GM maize, which has been distributed to other social organisations. WWF has a project under the UNDP/GEF program, mentioned above, aimed

at strengthening CIBIOGEM's institutional capacity to design and implement widespread public awareness strategies. In particular, it will provide assistance for the development of public awareness campaigns, ensuring that a broader set of stakeholders have access to reliable information (UNDP 2002)

Reflections and Lessons

A number of issues emerge from this case study. Firstly, efforts around both public consultation and participation and information-sharing and awareness-raising are at an early stage since biosafety is a relatively new issue on the political agenda. Secondly, officials and academics both agree that there is a lack of public information on LMOs, and the little that there is generally comes from NGOs, who are, on the whole, opposed to transgenics, or from the media who often report the issues inaccurately (Aerni, Chauvet and Hernández 2001). Thirdly, there is the issue of representation. Because of the lack of governments' own attempts to involve the public in decision-making on biosafety issues, governments have to rely on NGO accounts of the nature and depth of popular concern about biotechnology. Yet concerns have been raised about who these NGOs represent in making claims about levels and types of popular concern about biosafety.

The government is faced with a real challenge of providing balanced information regarding LMOs and biosafety issues. As such, the National Biosafety Law needs a broad-based national dialogue and according to UNDP, "information needs to be more science-based in order to balance industry lobbying currently underway in Congress" (UNDP 2002). At the same time, there is a clear need to look beyond these narrow scientific and commercial aspects of the technology, if the public is to be meaningfully engaged on broader issues of biosafety and biotechnology development. For example, NGOs have pointed out that CIBIOGEM does not include in its technical committee representatives from either peasant groups or environmental organisations and Greenpeace is the only NGO recognised by CIBIOGEM as being involved in biosafety issues. CIBIOGEM involves government representatives at the federal level, but not the different civil society stakeholders. Although CIBIOGEM is given the responsibility of providing information on biosafety, this agency has yet to carry out any activity itself and tends instead to piggy-back

on the events of other actors. Clearly CIBIOGEM is at an early stage of development, but the fact that the BCC quit the process suggests there are important lessons to be learnt about incorporating non-governmental and scientific communities and about how to facilitate public consultations. The same is to some extent true of the SEMARNAT strategy to inform society through the CCDS, where participants have complained that their views and suggestions have not really been taken into account.

Most information-oriented events, such as conferences and workshops, have been arranged by local governments, universities and academics, NGOs or the media. When the federal government has organised a LMO-awareness function, invitations to participate have been limited to certain groups, typically those in favour of transgenics. The Forums organised by SAGARPA have invited only a handful of groups. For instance, only Greenpeace was invited to the forum "Successes and Perspectives on Biotechnology in Mexico" which took place in Mexico City. Others that tried to attend were denied access. In the face of a lack of cooperation from the government to inform and consult the public on LMO and Biosafety issues, NGOs have been left to inform society according to their own views.

Brief Context

Namibia has a population of just 1.8 million and is considered unlikely ever to have a large domestic biotechnology industry, nor in the near future to have a high demand for the most advanced biotechnology applications. However, Namibia's position in the southern African region presents particular challenges for the management of the risk assessment of and trade in LMOs. Namibia has close historical ties with South Africa, where research on and commercialisation of GM crops is proceeding rapidly. Consequently there is significant concern about unauthorised transboundary movements of unapproved GM seeds across the relatively porous border with South Africa, for example by informal sale and exchange between family-members and friends living on either side of the border. This problem is exacerbated by weaknesses in the supervision of the border and the enforcement of customs regulations, due largely to resource and training constraints. In early 2001, a shipment of modified maize intended for animal feed was detected at the South African border, but was returned unopened.

Namibia is also a member of the Southern African Development Community (SADC), some of whose other members are also moving forward with or contemplating the adoption of GM crops in agriculture. Since 2000, SADC members have been involved in the Southern African Regional Biosafety (SARB) programme, which is funded by USAID and coordinated by the Agricultural Research Council in South Africa. The objectives of the SARB programme are to build policy and technical capacity in the southern African region to support science-based regulation of the development, commercial application, and trade in agricultural products derived from LMOs.

Approximately 80% of the country's meat exports are sent to the EU, and consequently the EU's regulations and standards for meat production and import are very influential. In the light of the current EU moratorium on LMO production and import, as well as consumer hostility, livestock farmers in Namibia tend to have a fairly conservative stance on LMOs. However, some feel that GM seed could benefit cotton producers.

The Namibian National Biodiversity Programme (NNBP) was established In September 1994 to co-ordinate and stimulate national activities relating to biodiversity conservation and the sustainable use of biological resources. The major aims of the Programme include improving the quality, quantity, focus and accessibility of biodiversity information, which would include computerising and making the country's biodiversity data available for environmental planning and management purposes. The NNBP receives funding from the Namibian government, UNEP-GEF and the German government. It is co-ordinated within the Directorate of Environmental Affairs (DEA) of the Ministry of Environment and Tourism, but run by a National Biodiversity Task Force consisting of technical and management representatives from different agencies.

During the second phase of the Programme (1998-2000 – the 'biodiversity strategy' phase), the Task Force, while still retaining decision-making power, became an umbrella body overseeing twelve working groups that were mandated to develop different sections of the National Biodiversity Strategic Plan. The working groups were conceived as flexible, informal, and interdisciplinary, and focused on developing solutions to

specific problems. In order to limit the burden of regular and time-consuming committee meetings, much of their work is conducted by e-mail, phone and fax; however, face-to-face meetings are also convened when thought necessary. According to the issue in question, the working groups include representatives from relevant partner institutions and stakeholder organisations, including other government ministries, NGOs, community organisations, tertiary education institutions and the private sector. In practice they retain a strong technical focus.

Of the twelve working groups established, only seven are fully operational. These include the Namibian Biotechnology Alliance (NABA), established in 1996 as a non-profit, interdisciplinary interest group on biotechnology and biosafety issues, operating as an interim technical review and advisory group. It is mandated to co-ordinate, plan, support and regulate the development of biotechnology in Namibia, through an effective biosafety framework, policy and guidelines. The NABA is regarded as one of the most productive among the NNBP working groups. Its members are specialists in biological, agricultural, conservation and legal fields and are drawn from government, universities, NGOs and the private sector. The initiative is coordinated by the Science Faculty at the University of Namibia (UNAM). Its main activities include:

- driving the development of the Namibian National Biosafety Framework;
- implementing cabinet-approved national policy on, and codes of conduct for, biotechnology research and related activities in Namibia;
- assessing the national status of biotechnology and biosafety activities, plans, and institutional capacities;
- developing appropriate technical safety guidelines for the practice of biotechnology in agriculture, industry, health, mining and other fields.

Biosafety technical guidelines were created in 1999, together with a biotechnology policy (1999) and a draft Act and Regulations (2001) (see below).

Although the NNBP and NABA have made some attempts to increase public participation in biotechnology and biosafety matters, grassroots involvement has been quite low. This

has been attributed variously to public apathy and the generally low level of civil society activism in Namibia; high levels of passive trust in the government; and a lack of interest in the aims of the respective programmes. In addition, the media is accused of creating confusion around the issue through inaccurate reporting.

Key Actions

Participation and Consultation

- During 1998 and 1999, the NABA convened four national participatory workshops involving government agencies, parastatals, research institutes, farmers' unions, NGOs, the private sector and consumer representatives. The workshops had three main objectives:
  - ~ raising awareness about biotechnology and biosafety issues, as well as providing a forum for raising people's concerns about these issues;
  - ~ involving different stakeholders on the preparation of a national framework; and
  - ~ drafting a national policy on biotechnology and biosafety.
- The initiative for these workshops originated from the NABA itself, which was also the agency responsible for identifying and selecting the participants. Participants were selected by formal direct invitations to potential stakeholders (for example, specific NGOs, academics, scientists and farmers' unions), as well as general announcements through the radio and newspapers. The invitation encouraged participants to extend the invitation to other potential stakeholders known to them. Participants from neighbouring countries, including South Africa, Zimbabwe, Botswana and Zambia were also present. The outcomes of the deliberations at these workshops were passed on to the National Biodiversity Task Force, which in turn communicated them to official policy-makers.
- The draft Act and Regulations of 2001 were initially developed with the assistance of a private consulting firm (Biotech Consult), in co-operation with representatives from academic, agronomic, health and consumer's rights institutions and organisations. The draft is currently being amended in response to a concern of the

governing board that there should be more active participation from other actors, including farmers and citizens. The final draft is hoped to be finished by early 2003.

- Since early 2002, consultative workshops targeted at farmers have been carried out by members of the NABA working in conjunction with regional staff from the Ministry of Agriculture, Water and Rural Development's (MAWRD) Directorate of Extension and Engineering Services (DEES).

Information and Education

Namibia benefits from a history of scientific enquiry, which puts it in a relatively strong position with regard to information gathering on biodiversity. However, much of the information held was initially poorly accessible, as little was computerised, and even less analysed for policy-makers.

According to a UNEP-GEF report, NABA gives a medium priority to implementing Article 23 of the Protocol, making use of media, educational and public awareness programmes to a limited extent. Public education and awareness needs are addressed in the national strategy and action plan, but implementation of these goals is hindered by insufficient resources.

The NNBP has an internet site[10], which is constantly updated with news on biotechnology and biosafety. The site is also used by biotechnology researchers to publish their studies, and also provides a space for participants to discuss changes in the draft legislation.

To date, activities aimed at raising public awareness have included:

- A series of national and regional workshops convened by the NABA during 1998-99 to raise awareness about biosafety issues. Groups identified by the NABA as stakeholders were invited to take part and encouraged to invite others to participate as well. In addition to raising awareness, these workshops were designed to enable participatory deliberation on the national biosafety framework (see below).

- A national workshop on 'Biotechnology and the media' was convened by the NABA in September 2002. Journalists and

10 *http://www.dea.met.gov.na/programmes/biodiversity/biodiversity.htm*

editors from all the country's newspapers and broadcasters were invited to attend. The workshop was used to publicise the NABA's work to date, answer journalists' questions about biotechnology and biosafety, and to help prepare reporters to cover biotechnology news.

- Publication of a brochure on biotechnology and biosafety.
- A series of articles in two national newspapers *(Republikein (Afrikaans)* and *Allgemeine Zeitung (German))*.
- A thirty-minute televised public debate on national broadcaster NBC's flagship talk show Talk of the Nation. As this debate lasted only 30 minutes, it was decided to have four more debates on biotechnology issues on the same programme during 2002.

Partly in response to the participatory workshops of 1998-99, it was agreed that the Namibian Government, together with UNAM and the Polytechnic of Namibia, would develop a cost-effective training strategy to educate relevant stakeholders in biotechnology procedures, biosafety guidelines, risk assessment and risk management. To date, the following training activities have taken place:

- Training targeted towards the registrar, support units and members of the National Biosafety Inspectorate (NBI), on *biosafety management procedures and handling permit applications* (9 participants);
- Three training courses on risk assessments to be carried out by permit applicants, the *Advance Informed Agreement procedures* and issuing of *import permits* (36 participants);
- Two training courses on *decision-making* related to biosafety issues (6 participants);
- Two courses for personnel at ports of entry, customs officials and police officers, on *identification of products and certification* (organised in conjunction with the NBI) (70 participants);
- One training course for laboratory technicians, on *laboratory biosafety* and the implementation of the Protocol (10 participants);
- Two training courses for Information Management Officers on the *Biosafety Clearing House Mechanism* (4 participants);

- Two training workshops for farmers and representatives of consumers' groups, on *biosafety issues* (25 participants);
- *Exchange programmes* for technicians, including training, with a view to their professional and academic advancement.
- In addition to these activities, members of the NABA have since early 2002 been cooperating with regional staff from the MAWRD, especially the Directorate of Extension and Engineering Services (DEES), to organise meetings and workshops with both commercial and communal farmers, for the purposes of education and awareness as well as participation and consultation (see below). These workshops are intended to acknowledge farmers' needs and concerns as producers and potential users of biotechnology products.

Reflections and Lessons

The Namibian case is a good illustration of a country which is faced with a need to upgrade its scientific and regulatory capacity largely in response to developments under way elsewhere. Namibia has a negligible domestic capacity in biotechnology research, and at the same time LMOs present a possible threat to Namibian meat exports and are not strongly desired by livestock farmers. However, the existence of GM grains on the international market, and the decision of Namibia's immediate neighbour, South Africa, to move forward with the testing and commercialisation of GM crops, creates an urgent need for strengthening the country's capacity to monitor and regulate the food and feed trades.

Most participants and observers praise the openness of the consultative process to date and welcome its results, although some express frustration at the slow pace of the process. So far, there has been no significant public controversy on biotechnology or biosafety issues in Namibia. Some attribute this to a low level of civic activism on these issues in Namibian civil society. The apparent lack of controversy may also be attributed to the existence of a significant degree of consensus which unites much of the Namibian public, commercial farmers, academics and researchers against the import of LMOs. This may owe in part to the fact that public attitudes towards biotechnology and biosafety issues emerged from a broader set of concerns, shared by all levels of

Namibian society, relating to the traditional use of natural resources in Namibia's fragile environment. It was this set of issues that led to the formation of the NNBP and of regulations on natural resource management. The creation of a working group concerned with biotechnology and biosafety needs to be seen in this context.

Formally speaking, the NABA's role is primarily an advisory one, and therefore its impact depends strongly on the effectiveness of its working relationships with government departments and individuals. The NABA has worked closely with officials from Ministry of Higher Education, MAWRD (especially with the Permanent Secretary), and the Ministry of Environment and Tourism. Informants mentioned that through these channels the Namibian government has been very receptive to the NABA's work, enabling the Alliance to draft the country's policy on biotechnology and biosafety. This degree of devolved decision-making to a stakeholder advisory body is remarkable, although the extent to which the NABA can be said to have tapped into the concerns of ordinary citizens should not be overstated. In part, the successful outcome of public participation and consultation processes may be linked to the personal agency of individuals. In this regard, the leadership and effective facilitation of the whole process by the NABA's chairperson, Dr. Martha Kandawa-Schulz from UNAM, has been widely acknowledged.

Clearly, Namibia's authorities have undertaken a significant amount of work to prepare and deliver targeted information and training to particular groups, especially the bureaucrats, officials and practitioners who are responsible for implementing the national biosafety guidelines. Meanwhile, the recent series of televised debates may help to raise broad public awareness and thus indirectly facilitate public participation. In relation to consultation and participatory deliberation, the workshops undertaken in 1998 and 1999 seem to have set a good example in terms of reaching out to stakeholders and the public. However, it has been recognised that public participation (as distinct from 'stakeholder' participation) has happened only at a low level. Therefore more work may need to be done in order to take advantage of the full potential of citizen participation in designing and implementing regulatory systems that reflect public concerns and interests.

Brief Context

In New Zealand the Hazardous Substances and New Organisms (HSNO) Act of 1996 and the Biosecurity Act of 1993 are the two key pieces of legislation that cover issues to do with LMOs. Since no LMO has been approved for release in New Zealand, all LMOs are considered to be new organisms and are therefore not permitted for release into the environment (though several LMOs have been approved for laboratory development and lab testing). The HSNO Act establishes the Environmental Risk Management Authority (ERMA) and provides a decision-making framework and criteria for applications for new organisms to be developed or field tested in containment, imported into containment or released in New Zealand. ERMA is the body responsible for using this decision-making framework to approve or decline a new organism. Food products derived from LMOs are regulated under the Food Act of 1981 and a joint Australia-New Zealand Food Standard overseen by the Ministry of Health.

A voluntary moratorium on all applications for the release of LMOs has been negotiated between the government and relevant industry and research groups. With some exemptions, the moratorium also applies to the field-testing of LMOs. The moratorium was set up to allow time for the government's Royal Commission[11] on Genetic Modification (see below) to complete its report, and for the government to consider the options and issues surrounding genetic modification. The demand for a Commission came from environmentalists and became an election issue in 1999 for the Green Party of Aotearoa New Zealand. Embarrassingly for the government, genetically modified corn was found being grown in three areas in New Zealand. These releases were contrary to the law described above and politically untimely because the accident was revealed while the Royal Commission was still sitting. The government has announced that it will hold a select committee enquiry into the sweet corn scandal.

11 A Royal Commission is kind of ad hoc public enquiry in which a panel of advisers is appointed by the government to examine a specific policy issue. The Commission invites and receives submissions from experts and interested parties and prepares a report for the government.

Key Actions

Participation and Consultation

- A Royal Commission on Genetic Modification (RCGM) was established on May 8th 2000. The Commission was given a broad mandate which gave it the authority to consider ethical, social, cultural, environmental and economic risks and benefits. The RCGM was an independent body, composed of non-expert individuals, that produced recommendations for the government. The government is free to decide whether to accept or reject the recommendations. The aim of creating the commission was to stimulate a broad-ranging discussion on genetic modification and consideration of strategic options open to New Zealand. The Commission came to an end on July 27th 2001. Specifically its objectives were to identify strategic options available to New Zealand regarding genetic modification and secondly to identify changes considered desirable to current legislative, regulatory, policy and institutional arrangements. Towards this end, the Commission looked at matters including uncertainty, risks and benefits of the technology, 'public interest' issues (including human health and the environment) and the adequacy of statutory and regulatory processes.

- The Commission undertook a widespread public consultation process over 12 months holding 15 public meetings, convening 10 regional assemblies *(hui)*, one three-day national *hui* and a youth forum. The hui were intended to provide a formal channel for Maoris to present oral and/or written submissions concerning their views on genetic modification. People were able to register to make a 15-minute presentation in the meeting, which was also recorded. The purpose of the public meetings was to create an informal setting to complement the formal sitting, hui and written submissions, whereby the Commission could access the views and opinions of a cross-section of the country on issues of genetic modification. Issues raised by participants were recorded on 'Summary cards' and can be accessed through the GM commission web site[12]. In addition,

12 http://www.gmcommission.govt.nz/media/publicmeetings.html

the body received over 10,000 public submissions. 107 people with a particular interest in the issue from a research, health or business perspective for example were granted 'interested person status'. The Commission also conducted a public opinion survey of 1,153 New Zealanders by telephone.

- Interested parties, that could identify themselves, were invited to present evidence and cross-examine other interested parties in an opportunity for open debate. Although the sixteen questions on the template for submissions to the Commission allowed space for discussion of various 'non-physical' aspects of LMOs (such as ethical, social or religious issues), the Commission ruled that submissions received on each question were to be considered separately. This made it difficult to discuss the links between the different issues that were being discussed (Genus and Rogers-Hayden 2002).

- The Royal Commission proposed a precautionary approach that would allow the co-existence of all forms of agriculture in New Zealand, a new category of conditional release of LMOs and the establishment of a Bioethics Council on the socio-economic, cultural and ethical aspects of the release of LMOs. There was also a recommendation to establish a Parliamentary Commissioner on Biotechnology. There were also calls to improve communication, transparency and accountability for the public, especially on cultural and ethical issues.

Information and Education

- The Ministry for the Environment is responsible for informing the general public of the government's decisions, how they will be implemented and what they mean in terms of everyday life (particularly consumer choices). In order to better understand the 'communication environment' in which the government is launching its public information campaign, a benchmark survey of a representative cross-section of the population was undertaken to assist the Ministry for the Environment with the development of a public information campaign on genetic modification. The survey found that most people wanted to know more about the possible risks of genetic

modification, the level of use of genetic modification in New Zealand and the use of genetic modification in food or products for human consumption. In terms of peoples' awareness of the bodies created to encourage public consultation, a third of respondents were not aware of the existence of the Royal Commission and no respondents mentioned the Royal Commission or government departments as one of the main ways in which they had learnt about genetic modification (For the exact figures see Harsant and Kalafatelis 2001).

Reflections and Lessons

A key challenge in the New Zealand context, but with a resonance for many other countries, is how to integrate the perspectives of indigenous peoples in biosafety frameworks. An important lesson from New Zealand approach is the way that targeted strategies were adopted for soliciting the views of particular groups. For example, special efforts were made by the Royal Commission to access the views of the Maori community (involving ten regional *hui* and one national *hui*) rather than relying heavily on the internet and written materials to tap into the NGO community. The workshops that were conducted alongside this process are aimed at providing information to the Maori people on the role of the Commission and the submission process, rather than educating or debating opinions on LMOs specifically. This strategic approach to targeting particular groups for consultation and awareness-raising has also been applied in the 'youth forum' to collect the views of young New Zealanders on the risks and benefits of genetic modification.

With regard to targeting the public with information on biosafety issues, an important finding from the surveys undertaken in New Zealand is that most people prefer household mailings to newspapers or television as a medium to receive information about LMOs, though these channels remain crucially important. The results of these surveys suggest that radio, magazines, web sites and meetings should be used as secondary mediums.

There has been some attempt to evaluate the impact of public awareness-raising efforts around biosafety issues. A survey was conducted to discover whether changes in awareness, knowledge and perceptions had occurred as a result of

the work of the Royal Commission, and as a result of the Ministry for the Environment's public information campaign on GM issues. Surprisingly perhaps, 88% of respondents reported that they had not changed their views at all as a result of the Commission's work (Harsant and Kalafatelis 2001).

Another interesting lesson that emerges from the experience of New Zealand is the importance of providing bodies whose mandate it is to engage the public on issues of biosafety, with a sufficiently broad and flexible mandate that it is genuinely open and responsive to what the public consider to be the key issues. The RCGM was entitled to hear evidence on 'the key strategic issues drawing on ethical, cultural, environmental, social and economic risks and benefits arising from the use of genetic modification, genetically modified organisms and products' (RCGM 2001) The approach of the Royal Commission on Genetic Modification has been compared favourably with the more restrictive approach adopted by the Australian federal government's House of Representatives 1992 inquiry where the terms of reference for the inquiry were premised on the benefits of LMOs. As a result, a significant proportion of the submissions made, which were critical of the safety of LMOs, were not reported when the inquiry's findings were tabled in parliament (Genus and Rogers-Hayden 2002).

Brief Context

Biotechnology 'has been identified as a major field of research in Norway', but at present work involving LMOs remains mainly on a small scale and at the level of research (Myhr 1999).

Norway was one of the earliest countries to ratify the Biosafety Protocol. Norway is a member of the European Economic Area but not of the European Union. Therefore the EU Directives have some influence but are not definitive in shaping the Norwegian regulatory framework. Norway's treaty with the EU contains a special provision relating to LMOs which gives Norway the legal freedom to depart from EU regulatory norms.

The Gene Technology Act (GTA, 1993) governs both contained use and releases of LMOs into the environment. It lays down a framework for subsidiary regulations relating to notification, approvals, and when an impact assessment is or may be required. Implementing regulations for transport and import entered into force in 1999. The Act includes liability provisions by which the user of an LMO is liable for any damage the activity may cause. Criminal penalties of a fine or imprisonment may be applied personally to individuals for intentional or negligent breaches of the GTA (Myhr 1999).

The GTA established the Norwegian Biotechnology Advisory Board (NBAB) 'to evaluate the social and ethical consequences of modern biotechnology and to discuss usage which promotes sustainable development'. The legislative framework also requires the Board to pay attention to the long-term implications for developing countries. The NBAB is an independent body consisting of 24 members appointed by the government for limited terms. Sixteen are appointed on a personal basis and eight are nominated by organisations. The current membership encompasses a range of expertise and perspectives, including representatives from the public, private and voluntary/NGO sectors; the fields of biology, medicine, law and ethics; and interest groups including farmers and fisheries, environmentalists, consumers and patients. The NBAB meets about ten times a year and its opinions are public (GTA s.26). Observers from six government ministries also participate in its meetings. The Board is assisted by a small Secretariat.

The NBAB sits under the Ministry of Health, but expends about 50% of its

effort on environmental issues. It is mandated to express its opinions to the government on request or *ex officio* (GTA s.26). All applications for environmental release or import of LMOs are first assessed by the Directorates for Food Safety and Nature. These scientific reports are then passed to the NBAB which evaluates the health, environmental, ethical and social benefits and risks of the proposed release and prepares advice for the Environment Ministry. The final decision rests with the Ministry. To date, the procedure is said to have worked effectively, although there have been few applications for environmental release and none for import under the Cartagena Protocol. In 1999 it was reported that there had been only 28 applications for use or production of LMOs under the GTA; four applications for deliberate release and one for contained use had been approved, whereas five applications for European commercialisation had been refused. The low level of applications has been attributed to the fact that Norway's regulatory regime is quite restrictive.

The government has appointed a Commission to conduct a broad survey of Norway's laws and regulations relating to biodiversity, including biosafety. The Commission's report is due to be delivered in the Autumn of 2003. Biosafety risk assessment and risk management is considered to pose a particularly difficult challenge in Norway because its long, narrow geography encompasses around forty different different agro-ecological zones; any particular LMO might pose a different level of risk in different locations.

A significant sum of money has been allocated to the Norwegian Research Council to conduct broad-ranging scientific and social-scientific investigations into the dynamics of complex ecosystems. The Council has invited universities and research institutes to submit proposals for both research and educational programmes.

Key Actions

Participation and Consultation

- As long ago as 1989, the Norwegian government appointed a public group to examine biosafety and ethical issues associated with biotechnology. The parliamentary standing committee on local government and the Ministry of the Environment concluded that 'further development of biotechnology should be based on

ethical considerations and that Norwegian biotechnology policy should promote development following basic Christian-humanistic values and ecological knowledge' (Myhr 1999:9).

- In October 1991, the government published a consultation document on biotechnology policy and sought comments from approximately one hundred different organisations, including government agencies, NGOs, the private sector, academics and trades unions. According to one observer, the Ministry of the Environment was concerned to balance the needs of research, trade and industry, health and the environment with ethical and social considerations (Myhr 1999:9). The GTA followed this consultation period and clearly reflects some of the outcomes of this consultative process.

- In October 1996 the NBAB, in conjunction with the national committees for research ethics in medicine, science and technology and social science, organised a 'consensus conference' (also referred to as a 'citizens' jury') on GM food. The aim of the conference was to assess public perception of GM food and to give advice to politicians, authorities and the food industry in Norway. The sixteen-person panel reached the remarkable conclusion that 'there is no need for genetically modified food in Norway' (Myhr 1999). The consensus conference was an elaborate and expensive process that cost around NOK 1m (US$140,000), which is a relatively large sum for a population of around 4.5 million people.

- Where approval is required under the GTA for contained use or environmental release, the competent authority may decide that a public consultation exercise will be carried out. Such consultation must be announced publicly and be carried out in good time before a decision is made (GTA s.13). It is expected that such consultations will be influential on individual release applications, for example by applying conditions to permits for environmental release or use of a particular LMO.

Information and Education

- The Norwegian Freedom of Information Act applies to all cases dealt with under the GTA. The GTA provides that, in all but exceptional

circumstances, the following information must be made public: a description of the LMO; the identity of the user; the purpose and location of use; methods and plans for monitoring and emergency response; and assessment of foreseeable consequences (GTA s.12).

- The NBAB has taken a number of steps to raise public awareness and initiate public debate:
  - ~ NBAB meetings are generally open to the public and its opinions are published. In addition, the Board has organised a number of special open meetings with invited speakers. According to their website[13], the Board organises two to three such public conferences annually.
  - ~ The Board publishes a free, quarterly journal, *Genialt,* aimed at the general public and also used as a source by journalists. About 10,000 copies are produced and circulated directly to a mailing list of 6,500 individuals and organisations, including schools.
  - ~ The NBAB has also published reports and information pamphlets on various topics regarding modern biotechnology, which have been used widely in schools.
  - ~ The Board provides contact details for scientists and bureaucrats and encourages journalists to contact them. It also promotes itself as a resource for schools and teachers.
- The NBAB has endeavoured to open up the issues covered by its mandate as widely as possible, to include, for example, issues relating to LMOs in both 'developed' and 'developing' countries.

Reflections and Lessons

The Norwegian case is one of the few cases we have examined in which it can be said that a significant amount has been done to promote and facilitate both awareness and participation. The case is a rare example of a government taking the bold step of allowing citizens a significant space to frame the social agenda for bioethics, biosafety, and the

13 http://www.bion.no

future development of a major new technology in the country. In doing so, it made creative use of innovative public consultation mechanisms, notably the 1996 consensus conference on GM food. The contents of the GTA and the establishment of the NBAB demonstrate that the government was willing not only to consult people but also to listen to and be guided by their concerns. The official policy and regulatory framework that emerged from this process is embedded principally in a set of cultural and religious values, and incorporates consideration of ethical and social as well as scientific and economic benefits and costs. It is relatively restrictive towards biotechnology, particularly in food and agriculture. It remains to be seen whether this regulatory regime may be subjected to challenge under the provisions of the WTO, and if so whether it will prove to be robust against such a challenge.

Although the membership of the NBAB provides a mechanism to incorporate 'non-science' perspectives in its considerations and advice, it remains a small and exclusive expert panel which falls short of providing an avenue for participation by 'non-expert' ordinary citizens. However, the NBAB demonstrates a reflective and sophisticated approach to its public awareness and participation activities. It recognises that it tends to reach the most 'active' and interested citizens with its open meetings, and therefore it complements these meetings with a range of printed materials targeted at different audiences and distributed widely through a mailing list, schools and the media.

It is interesting to note the emphasis placed by the NBAB on providing information and resources to schools, which by definition represent only a particular section of society, and one which is not necessarily equipped to influence the political process. However, in the long-term this approach seems likely to support a new generation of citizens to understand and grapple with issues of biotechnology and their implications.

It is also important to note a few limitations on the Norwegian practice of consultation. For example, the decision to initiate a local public consultation on an application for contained use or environmental release remains in the discretion of the competent authorities and is not an automatic right of citizens.

Brief Context

The United Kingdom has experienced a high level of public concern about genetically modified organisms in food and the environment, manifested in intense and polarised media coverage, public protests, trespassing and property damage in field trial sites and consumer activism including supermarket letter campaigns and boycotts. The recent history of 'mad cow disease'[14] and the related emergence of 'new-variant' Creutzfeld-Jacob Disease (nvCJD) in humans, and the recent outbreak of foot-and-mouth disease in pigs, cattle and sheep, have provoked profound unease about the intensification of farming and the food trade, and its consequences for human health and the environment. The government's management of these crises has also led to an atmosphere of distrust and suspicion about the capacity of government ministers, scientists and inspectors to protect the public. At the same time, senior members of the government, including the Prime Minister, have strongly endorsed the importance of biotechnology for Britain's commercial and technological competitiveness (Levy and Newell 2000).

The UK has been affected by the *de facto* moratorium on LMOs in the EU, although the government's official policy is to oppose the moratorium on the grounds that it is an unscientific way of proceeding. Instead, in an effort to address the concerns of groups such as English Nature, the UK government commissioned university researchers to undertake a three-year programme of 'farm-scale evaluations' (FSEs) to assess the performance and environmental impact of GM crops. The FSEs are a voluntary arrangement and do not form part of the formal regulatory process governing the release of GM crops. There are up to eighty sites for testing maize, oil seed rape and beet up to ten hectares in size. The FSEs have been criticised for focusing on the performance of the crops rather than their environmental impact.

The third year of crop trials has been completed (Autumn 2002). Interim results have been published during the FSE programme, and the overall findings are due to be published in scientific journals in the summer of 2003, with a further set of results scheduled to be completed later in the year or early in 2004. The review of the EU moratorium at European level, and the impending release of the FSE data,

14 Bovine spongiform encephalopathy (BSE).

mean that the government must in the near future make decisions about the future of LMOs in British agriculture and food.

UK policy with regard to participation and biosafety is to a large extent determined at EU level. In this regard, Directive 2001/18 demands high levels of consultation with the public on applications for approval.[15] However, the revised EU directive on deliberate release does not allow European governments to halt developments in agricultural GM on the grounds of lack of public support. In the absence of evidence of risk of adverse effects on human health or the environment, the applicant is entitled to be granted the consent. Although the Directive makes provision for periodic reporting on the socio-economic implications of deliberate releases and on the placing of LMOs on the market, 'it provides no obvious machinery for giving effect to any adverse conclusions' (AEBC 2001:51). The decision-making process will also continue to be 'evidence-based', which makes it unclear how public consultation can be integrated into the decision-making process. The government has sought views from the public on how consultation arrangements under the new Directive might work (AEBC 2002a). The government has also been encouraged to consult widely on its proposals for the post-commercialisation monitoring and on action to be taken if adverse effects are discovered.

In 2000, in response to public concerns, the government established the Agriculture and Environment Biotechnology Commission (AEBC) to look at the social and ethical issues relating to developments in biotechnology which have implications for agriculture and the environment and to provide strategic advice to government in this area. The Commission includes a range of interests from all sides in the GM debate and heard evidence during 2001 from the public, politicians, farming and industry groups, non-governmental organisations and technical experts (AEBC 2002a). The

15 For example, the new directive (2001/8) accepts that ethical considerations may be taken into consideration when LMOs are placed on the market so there is an opportunity to debate the ethics of technologies like 'terminator'. The Directive also explicitly requires consultation with the public on proposed experimental releases and on notifications for commercialisation consents (AEBC 2001).

short term need to understand and explain evident public concern is accounted for by the intensity of public opposition to the FSEs, which became the focus of 'local resentments and of wider national concerns about possible GM crops and foods' (AEBC 2001:7). According to the Commission, 'local citizens' reaction to the rationales for, and processes surrounding, particular FSEs at local level may now itself be contributing actively to growing disrespect for the Government's policy' (AEBC 2001:12).

Important context is also the fact that the UK is a signatory to the Aårhus Convention of 1998 on *Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters.*

Key Actions

Participation and Consultation

- For permits for the release of LMOs, all proposed releases are advertised and placed on a public register providing the opportunity for the public to comment. Following this period of consultation a permit will be granted or refused.
- Government web sites contain information on biotechnology, on meetings, agendas and reports related to decisions in the area of the deliberate release of LMOs. AEBC use their web site and a mixture of advertising, direct mail and other approaches to promote their meetings locally and nationally (AEBC 2000-2001). Feedback is gained from people that attend the meetings through questionnaires.
- In consultations about their Work Plan, AEBC received inputs from over 400 organisations. The proposed future work plan will be published on the internet and 'the Commission plans to invite comments on the study and contributions to it from the public and outside bodies' (AEBC 2000-2001:9). They have used a range of techniques to involve people in their work. For example, a technique called 'horizontal scanning', in which several possible scenarios for the future of genetic modification in agriculture were considered, was used for deliberative and public meetings with stakeholders; public meetings were held to hear evidence about the FSEs (see below); panel discussions on specific themes and informal meetings with different stakeholders were also held.

- The Government hosted a meeting for stakeholders to discuss the FSEs in July 1999, prior to the first round of plantings. Farm-scale evaluations were to assess what impact approved GM crops such as maize, oil seed rape and beet might have on the environment and biodiversity. The AEBC has recommended that 'the objectives and limitations of the trials [be] clearly stated and communicated to the public' and be subject to 'effective local consultation taking place on the selection of plots' with local stakeholders. AEBC's expectation is not that the data generated by the FSEs will be sufficient to reach a decision about whether crops should be commercialised. The AEBC asserts that 'Additional information and consideration of a wide range of viewpoints must be factors in the eventual decisions' (2001:13).

- The Government has also engaged in discussions with interested groups about how their interests might be better considered when compiling the preliminary pool of locations from which the researchers select the proposed sites. For example, they have sought information from organic growers so as to avoid the most obvious conflicts between local interests and the evaluations.

- An independent Scientific Steering Committee, including NGOs as members, was established to monitor the FSEs.

- Alongside this, there are public meetings about the field trials and visits by the public. Details of the meetings and visits are advertised in local newspapers. At the meetings people hear presentations and are allowed to put questions to a panel consisting of a government official, a scientist, a representative from an environmental NGO and industry. In addition, all information about the project is published on the UK government's web site and leaflets and fact sheets are disseminated.

- There have been proposals to extend the notice period from four to six weeks before sowing to allow more time for people to make their views known.

In 2001, the AEBC produced a report, *Crops on Trial* (AEBC 2001), in which it recommended that the government should initiate a broad public debate on GM foods and crops. Proposals to promote the public debate include:

- Hiring an independent professional organisation to recruit and brief 'lay groups' (defined as those with no vested interest in the outcome and not conventional 'stakeholders') to discuss and define what the issues are around the commercialisation of GM crops that need to be debated.

- Contracting out responsibility for overseeing the process to facilitators, assessors and evaluators, backed up by an independent steering board that would give strategic guidance to the contractors (AEBC 2001:51). The purpose of this would be to generate confidence that the framing of the issues for debate are not being dictated to people by government or other vested interests.

- Making an informative broadcast film to illustrate the issues selected by the group drawing on information and evidence selected by the groups. The film (distributed on CD-rom and DVD or video) and other materials related to the groups' discussions would be distributed to schools, universities, rural and urban community groups, women's institutes, as well as the traditional stakeholders, to invite their reactions to the issues raised in it.

- Working with local, regional and national media, with a view to initiating interactive TV events on the issues being debated

- Backing this process up with a web-based discussion forum.

It has also been acknowledged that, in order to explore the subtleties of peoples' concerns, deliberative events such as focus groups, citizens' juries, consensus conferences and multi-attribute analyses, could be used to follow up the discussions. However, it remains to be seen whether such activities will be included in the proposed public debate.

The government accepted the AEBC's proposal regarding the public debate in a high-profile announcement by the Secretary of State for Environment, Food and Rural Affairs in July 2002. The public debate would be initiated in the Autumn of 2002. It would be overseen by an independent steering committee chaired by the chairman of the AEBC and including a variety of stakeholder representatives. The debate would proceed alongside two other strands, a review of the scientific issues relating to GM (the 'science review')

and a review of the 'overall costs and benefits of GM crops' (the 'economic review'), to be prepared by the Prime Minister's Strategy Unit. Only GBP£250,000 (USD$400,300) has been allocated to the public debate and the government has requested a report from the steering committee by June 2003 (DEFRA 2002).

Two statutory research bodies, the Biotechnology and Biological Sciences Research Council (BBSRC) and the Natural Environment Research Council (NERC), have sought public input into the development of a research programme to examine the transfer of genetically-modified plants into wild species, as part of the government's trials of genetically-modified crops. The internet site they have set up does not really provide a place for deliberative debate, but it does allow people to post their views and read comments by others.

Information and Education

- Public authorities are obliged to publish LMO release consents in a public register
- The Scientific Steering Committee overseeing the FSEs has produced a paper setting out the science involved and its limitations, published on the DEFRA web site (www.defra.gov.uk)
- The Government has also produced a leaflet on the FSEs explaining the processes behind the approval of a LMO release ('LMOs: The Regulatory Process'). Copies of the leaflet are distributed at public meetings and can be obtained free of charge as well as being available on the DEFRA web site.
- The Scottish executive has also prepared factual booklets about GM crops. The Minister for Environment and Rural Development in Scotland also participated in a radio phone-in answering questions from a cross-section of the population.
- In terms of public access to information on LMOs, much of the evidence considered by the advisory committees and their advice to Ministers is publicly available and open to independent review.

Reflections and Lessons

The impact of the many attempts at promoting public information by the UK government has been mixed. While there was a large amount of public attention and all public meetings were

well attended, contributing to improvements in peoples' understanding of the scientific issues and enhanced transparency, the publicity that the field studies attracted made them attractive targets for direct action groups that destroyed some sites in protest (Lasseur 2000:23). In addition, the AEBC (2001) notes that people involved in the public meetings complained that they were not attempts to consult, but rather top-down announcements of a *fait accompli*. Groups such as GeneWatch UK and Friends of the Earth were among those making this complaint. Others also suggested that although the meetings were well-attended, many of those present were not local, drawing a distinction between 'the public' and 'activists' in this regard.

A key lesson has been that 'the absence of consultation, the very short notification, and the particularly unfortunate location of some of the chosen sites, have made it seem that the trials have been conceived and designed in a secretive way with key players not fully engaged. Some people have felt excluded from decisions which they perceive as affecting their environment and compromising their local socio-economic objectives' (AEBC 2001:14). Because of this, and the fact that FSEs have become a 'lightning rod' for peoples' concerns about GM technology in general, in the AEBC's own words 'it will be important to ensure that future decision-making is based on the fullest information, is transparent and inclusive'(ibid:15). At the moment one problem appears to be the lack of any agreed procedures for legitimising the choices of particular trial sites which has given rise to 'bad feeling and mistrust within some communities' (AEBC 2001:50). Recognised criteria for making these judgements and fuller consultation at local level may help to avoid this situation.

Given the constraints imposed by EC legislation in this area, as well the nature of rules contained within the WTO agreements on risk assessment, it will be difficult to broaden the scope of risk assessments to include the broader social and economic impacts that flow from the commercialisation of LMOs such as effects on non-GM farming and on the rights of choice for consumers and farmers, which are currently not taken into account. Yet these are among the issues that appear to concern people most.

The AEBC found that 'The risk assessment approach does not address

many people's wide philosophical or ethical concerns. Nor does it tackle genuine concerns about some of the unknown impacts of GM technology'. This underlines the need for policy-makers to be honest about areas of uncertainty. But it is also a question of institutional flexibility and responsiveness. For example, comments on the safety of gene flow would not be taken as relevant to the decision, because the issue is felt to have been already adequately considered by ACRE.

The Scientific Steering Committee also felt that the large degree of media exposure that the trials attracted, while useful in raising awareness, was often imbalanced and misinformed with disproportionate attention to the risks associated with the trial which compromised public understanding of the issues.

There is an expressed concern to ensure that the process itself is evaluated, lessons learned about its effectiveness in stimulating debate and consideration given to what other areas of policy these techniques might be applied to. A new Code of Practice for Scientific Advisory Committees is to be published that all such committees will be expected to follow. The aim is to strengthen good practice based on lessons that have been learnt so far.

The UK has been keen not to embark on a process that raises false expectations about how peoples' contributions, made in the course of debate, will be used. There is fear that this will give rise to cynicism about the exercise and make people doubtful about the value of taking part in it. A key lesson then is about being clear why and for what purpose, a public debate is being stimulated. The government group in the UK has been anxious to avoid a 'quasi-referendum' to ask people participating in focus groups to act as proxies for ministers. It has been made clear that it is ministers that will make the decisions. Nevertheless, public debate can help set the context of public interests and concerns which may help to influence decision-making indirectly.

The AEBC contends at the moment 'there seem to be no avenues for a genuine, open, influential debate with inclusive procedures, which does not marginalise the reasonable scepticism and wide body of intelligent opinion outside specialist circles. We need to harness new deliberative mechanisms, to develop participatory methods of public engagement, together with new

capacities within government and industry for digesting and responding to the implications' (2001:24).

The current public debate process initiated by the government has the advantage of strong, high profile backing from a Cabinet-level minister, while being overseen by an independent steering committee at arms' length from the government. The UK tradition of Cabinet government and collective responsibility means that the process is insulated against a change of minister (though not necessarily a change of government). However, since it was announced, preparatory work has begun behind the scenes but there has been very little public sign of the debate getting under way. It remains unclear how the debate is to be activated.

The process has already attracted criticism on a number of grounds. The small budget and the tight deadline for completion of the report mean that the steering group must be highly selective and small-scale in the methods it uses. This makes it difficult to take full advantage of the opportunity to combine a range of potentially useful complementary mechanisms and processes that could be targeted at different audiences or focused on specific issues. The resource constraints also mean that the public debate is heavily dependent on the goodwill of media organisations to enter into a partnership in order to diffuse the public debate beyond the small groups which may be reached directly by stakeholder forums etc. It is still unclear how such a 'partnership' with the media may occur.

The government has also been criticised for initiating the debate and demanding the report too soon for the findings of the FSEs to be incorporated as background material for the public deliberations. Because of this, there is suspicion that a purely technocratic assessment of the FSEs may be used to undermine or supercede the outcome of the public debate after it is over. In this regard, the government has not made clear how the three strands of the process will come together. There is concern that the science review and economic review may be used to frame the public debate in a way that will undermine the possibility for citizens to bring their own concerns to the table. There is particular suspicion of the role of the Prime Minister's Strategy Unit in the process, since the Prime Minister and other prominent ministers have strongly allied themselves with a pro-GM position in the debate.

It is not clear how the outcomes of the public debate will be fed into policy and decision-making. It has been suggested that in order to demonstrate the government's commitment to taking public attitudes into account, contributions made by people in the debate could be collated and assessed, possibly by a team of social scientists, and presented to government as a report or series of reports. However, throughout the process, it has been made clear that Ministers will determine how the analysis of public interests should inform the decision-making process. The UK does not have a strong tradition of participatory decision-making and there is a tension within the government between, on one hand, fear about the consequences of opening up decisions to public deliberation, and on the other hand a recognition that participation can be a strategic opportunity.

Brief Context

Though the US is not a party to the Biodiversity Convention and therefore cannot become a party to the Biosafety Protocol, it maintains a strong interest in the negotiations because the Protocol regulates the trade in LMOs, a market in which the US takes the lead (Pomerance 2000). US officials acknowledge that widespread adherence to the Protocol by other countries has significant implications for US interests and therefore recognise the need to engage with the process.

Under the US Coordinated Framework for the Regulation of Biotechnology, federal authority for reviewing the safety of new genetically modified products is shared among three agencies: the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the US Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) (Dunn 2000). In practice the three agencies collaborate quite closely and coordinate their activities through a White House committee.

The FDA currently operates a policy under which companies wishing to bring a GM product to the market may voluntarily notify the FDA of its intention, thus giving the Agency an opportunity to scrutinise the product if it feels there may be issues to be looked at. To facilitate this process, the Agency has developed a series of flow-chart 'decision-tree diagrams' which enable applicants to 'walk themselves through' the regulatory decision process. The flow-charts show applicants what questions they should ask themselves and indicates the circumstances in which the FDA would recommend that it should be notified and asked for guidance. The Agency acknowledges that, in principle, this makes it possible for a novel food product to reach the supermarket shelves without any FDA scrutiny. However, the Agency carries out market surveillance which should alert it if any novel food product unexpectedly arrives on supermarket shelves without the FDA having been aware. FDA officials are confident that, in practice, companies tend to take a cautious approach and generally consult the Agency even when their internal regulatory assessment using the FDA flow-chart indicates that a reference to the Agency is not necessary. FDA officials and company executives acknowledge that the importance of defending corporate 'brands', as well as America's litigious legal culture, provide strong incentives

for companies to take a cautious approach, in order to be able to demonstrate if necessary that they had prudently fulfilled their legal obligations and responsibilities.

Partly in response to public comments on the voluntary notification policy, the FDA has recently published a proposal to move to a policy of compulsory notification (see below).

Within USDA, a Biotechnology Coordinating Committee has been established, comprised of representatives from all of the USDA agencies that deal with biotech issues. The committee is intended to serve as an information clearing house and review and planning body for the department.

APHIS regulates the development and field testing of certain GE organisms, primarily new plants and plant products, to ensure that they are as safe to use in agriculture as traditional varieties. APHIS oversight of LMOs currently provides three possible routes to commercialisation for transgenic plants: notification by the user/developer; permission; and petitioning for non-regulated status.

- At present almost all field-testing of new transgenic varieties occurs under the notification procedure. The applicant notifies APHIS before planting the new variety. APHIS has 30 days to determine that the notification process is sufficient for the plant in question. Applicants are required to follow general guidelines to ensure that there are no environmental effects from planting the transgenic variety. There is no public or external scientific input into this process.
- In the permitting process the applicant is required to submit more information to APHIS. Details of the application will only be published (in the Federal Register) if APHIS decides that an environmental assessment is required. Federal Register notices are open to public comment.
- Petitioning for non-regulated status is the typical route to commercialisation for transgenic plants. Under this mode, a formal environmental assessment is always required and is published in the Federal Register. The public has 60 days to comment. APHIS is required to respond to each comment received (NAS 2002:9-10). 'Deregulation' is considered absolute and therefore no post-commercialisation monitoring takes place.

In January 2000, the USDA commissioned the National Academy of Science (NAS) to carry out a review of APHIS's regulatory oversight of GM crops. The study was carried out by a committee of scientists (mainly biologists, plant geneticists, entomologists and agronomists). The committee's report was published in 2002 (NAS 2002). The report noted that risk assessment needs not only to support specific regulatory decisions but also to maintain the public legitimacy of the regulatory system or authority. The authors wrote that 'democracy is best served when people affected by regulatory decision making can be significantly involved in the decision making, and that inclusion of diverse interests in the risk analysis process can be a powerful force to garner legitimacy of a decision. This is especially true because the significance of environmental effects of novel genetic material depends on societal values' (NAS 2002:6).

The NAS report made a number of critical comments about the regulatory system including recommendations relevant to public awareness and participation. These are outlined among the bullet-points below. The committee's recommendations are currently being considered by the government. According to regulatory officials, the speed and content of the response may be affected by the fact that the NAS report was commissioned by the outgoing Secretary of Agriculture at the end of the Clinton presidency, but the report was submitted after the new Bush administration took office.

The EPA is a relatively small Agency which is regarded by some as having very limited influence within the Bush Administration. It gets involved with the regulation of GM crops only in so far as they are analogous to, for example, chemical pesticides (in the case of insect-resistant crops), and assesses them on a similar basis.

Key Actions

Participation and Consultation

The government claims that 'all of the regulatory processes that are now in place were developed after extensive scientific review and solicitation of public opinion' (Dunn 2000). Public involvement is seen to be important because 'As the public's understanding and trust in these processes grows and educational efforts increase, consumer acceptance should follow'.

- The FDA uses advisory committees

on biotechnology in food and agriculture. Their composition depends on the specific issue or product in question and their meetings are open to the public. The committees are generally made up of scientists and often include stakeholder representatives from industry. Committee-members are required to state any conflict of interest but may still participate in discussions. On some issues, such as labelling, other representatives such as consumer groups may be invited to join a committee, as (in the words of one interviewee) 'you don't need to be a scientist to discuss it'.

- In February 2002 USDA invited nominations for a new body, the Advisory Committee on Biotechnology and 21st Century Agriculture (ACBTCA). This body will replace the Advisory Committee on Agricultural Biotechnology (ACAB), whose charter and membership expired on 4 February. The invitation to nominate members for the ACBTCA was published in the Federal Register and advertised on the USDA website. It is unclear whether the new body is yet operating. Nominations were to close on 28 February 2002 but the notice was still shown as a 'New' item on the USDA website in June 2002. Personal enquiries among US regulatory officials in May 2002 suggested that few people were aware of the existence, mandate or activities of such a committee. One former member of the ACAB told me that she had re-applied for the new committee, but had not had any response and concluded that 'nothing is happening'.

- The old ACAB[16] was comprised of 38 members drawn from academia, industry, environmental and consumer interest groups. The Committee was expected to provide essential input on USDA policies related to the social, scientific and economic issues pertaining to biotechnology.

- The NAS review of APHIS' regulatory oversight noted the importance of including external scientific expertise because a 'consensus of multiple external scientific experts is likely to be more rigorous than regulatory

16 www.usda.gov/agencies/biotech/acab.html

judgements because disagreements among external experts are likely to lead to more robust risk assessments' (NAS 2002:7). The report recommended that APHIS should solicit broad external scientific review and advice when considering changes in regulatory policy or before making 'specific, precedent-setting decisions' (NAS 2002:10).

- The NAS report also noted that '[p]ublic confidence in biotechnology will require that socio-economic impacts are evaluated along with environmental risks and that people representing diverse values have an opportunity to participate in judgements about the impact of the technology' (NAS 2002:15). The committee recommended that 'the APHIS process should be made significantly more transparent and rigorous by … solicitation of public input, and development of determination documents with more explicit presentation of data, methods, analyses, and interpretations' (NAS 2002:10).

- 'The committee finds that there is a need for APHIS to actively involve more groups of interested and affected parties in the risk analysis process' (NAS 2002:12). Accordingly, the report recommended that an independent body should be established to develop a post-commercialisation 'indicator-monitoring program… This monitoring program / database should allow participation by agencies, independent scientists, industry, and public-interest groups. The database depository should be available to researchers and the interested public… Finally, there should be an open and deliberative process involving stakeholders for establishing criteria for this environmental monitoring program (NAS 2002:14). In order to ensure that the feedback provided by the proposed participatory monitoring mechanism should effectively influence the regulatory process, the NAS committee recommended 'that a process be developed that allows clear regulatory responses to findings from environmental monitoring' (NAS 2002:14).

- Starting in 2000, the FDA commenced a series of three public meetings in San Francisco, Chicago and Washington DC to raise awareness about the FDA's policies and regulations and discuss issues

relating to GM foods. Stakeholders were invited to attend. The format of the meetings was in the form of panel discussions with questions and statements from the audience. The meetings were reportedly well-attended. In response to the concerns raised in these meetings, the FDA recently invited public comments on a proposal to change from the current policy of voluntary notification to a system of compulsory notification. The Agency received around 100,000 comments. By law it is required to give a reasoned response to every issue raised by the comments (though it is not required to respond to comments individually), and must take them into consideration.

Information and Education

- The FDA also adopts the practice of publishing 'guidance notes' which are intended to clarify the Agency's views on what is required by formal regulations. These guidance notes have no legal weight, as it would be for a court to determine what the law requires in specific cases. However, the guidance is intended to inform those subject to regulation how the Agency proposes to implement and enforce its executive mandate. These guidance notes are published in the Federal Register.

- The institution of the Federal Register enables announcements, notices and new regulations to be published as a matter of routine practice. The Federal Register is easily accessible via the internet, and web access is widespread. However, the sheer volume of information published daily for all departments and agencies of government makes monitoring the Register 'a full-time job in itself'. Consequently, sharing information often relies on informal networks between government officials and NGOs, and among NGOs. Government officials will sometimes circulate new information to NGOs and groups known to have an interest in the topic, and NGOs often share information with one another. However, there does not seem to be a standard approach across all departments and agencies of government in the way they deal with information. Much seems to depend on the willingness of individual officials to network with NGOs and interest groups.

- The period for public comment

varies and seems to be set at the discretion of the Agency concerned; often the deadline for comments can be rather short, putting pressure on the capacity of NGOs and other interested parties to submit a considered and effective response. It makes it especially difficult to carry out effective outreach to stimulate comments from grassroots networks. This factor highlights once again the importance of being 'plugged in' to information networks, in order to receive prompt notification about such comment periods. In some cases, public and NGO lobbying has succeeded in getting a comment deadline extended.

- The NAS review of APHIS procedures also recommended that the style of public announcements should be improved to make the APHIS process 'significantly more transparent and rigorous' with 'more explicit presentation of data, methods, analyses, and interpretations' (NAS 2002:10). The NAS report also remarked that 'the extent of confidential business information (CBI) in registrant documents sent to APHIS hampers external review and transparency of the decision-making process... [R]egulatory agencies of other countries receive documents with less CBI than does APHIS' (NAS 2002:11-12). One observer remarked that the extent of CBI sometimes leads to absurd Federal Register notices stating that an 'undisclosed' company has submitted an application relating to an 'undisclosed' product to be used for an 'undisclosed' purpose, thus making it impossible to submit any meaningful response.

- Some NGOs have become frustrated by the sometimes superficial responses given by government agencies to public comments, and have essentially given up trying to read and respond to a mass of policy announcements in favour of alternative, more manageable strategies. The NAS review of APHIS regulatory procedures noted that 'the number of comments on Federal Register notices has declined almost to zero… this decline in responses … is at least in part due to a perception that APHIS is only superficially responsive to comments' (NAS 2002:12). One interviewee complained that there is no sign that critical comments have been taken into account.

- An initiative by the private philanthropic Pew Foundation, the Pew Initiative on Food and Biotechnology[17], includes a 'Stakeholder Forum'. The Stakeholder Forum has held a small number of public events in different cities of the US to raise awareness and air views on GM issues. Reportedly these events have taken the form of panel discussions involving presentations by panel members followed by question-and-answer sessions from the audience. Some of these, such as one on transgenic food and pharmaceutical crops, were co-sponsored by the FDA.

- The Forum is described on the website as ' a consensus building effort among key stakeholders in the agricultural biotechnology debate' intended to 'help stakeholders get past conflict'. The Forum consists of nineteen individuals representing a range of perspectives but dominated by representatives from major biotech and seed companies such as Cargill and Monsanto (6 people) and agricultural industry organisations such as the National Corn Growers Association and National Cotton Council (5 people). The remaining 8 spaces are shared between science, technology and 'public interest' groups such as the Center for Science in the Public Interest and the Union of Concerned Scientists (4 people); academics (2 people), and one person each from a consumers' organisation (Consumer Federation of America) and an environmental NGO (Environmental Defense).

- The Forum, and the Pew Initiative as a whole, have been criticised by some observers for being biased and loaded in favour of biotechnology, with insufficient space for public concerns to be aired. Meetings have been described as 'manufactured'. The Pew organisation has also been criticised for seeking to control the membership of the Forum. The environmental NGO Greenpeace claims that it was invited to take part and nominated its senior staff scientist as a representative, but the individual concerned was refused by Pew. However, others have argued that the Forum contains a balanced range of views and

17 http://pewagbiotech.org/

perspectives, to the extent that it will be surprising if it succeeds in achieving a consensus. It was noted that the Forum has now been going for a year without anybody walking away from the process. The real challenge for the Forum is that there is no formal linkage into the official policy process and it will be difficult to mobilise the Congress or an executive Agency to take up proposals from such a source. However, one interviewee noted that the Pew Foundation has sufficient stature, credibility and resources to enable it to influence the government.

- Another non-governmental initiative which contributes to public awareness and facilitates participation is the National Agricultural Biotechnology Council (NABC)[18]. The NABC is a 'not-for-profit consortium' involving 36 academic institutions and government agencies involved with agricultural research and education. According to its website, the NABC 'strives to provide an open forum for persons with different interests and concerns to come together to speak, to listen, and to learn from meaningful dialogue on the potential impacts of agricultural biotechnology'. The NABC uses its annual meetings, newsletters and other publications to provide information and a forum for discussion of bioethical, biosafety, policy and regulatory issues associated with modern biotechnology. It is difficult to assess how successful the NABC is in achieving these goals, or how influential its reports and meetings are on public policy and regulation. Its work does not appear to have a high profile among government bureaucrats or NGOs.

Reflections and Lessons

Although it is claimed that the Coordinated Framework for biotechnology regulation establishes a coherent and streamlined structure for managing the risks posed by biotechnology, it has been criticised for being incoherent, ill-defined and excessively complex, making it difficult for ordinary citizens to engage with. It is difficult to reach any conclusion other than that there are very few opportunities for ordinary citizens to participate meaningfully in discussions

18 http://www.cals.cornell.edu/extension/nabc/

about biosafety regulation. Even the Pew Forum appears to fall a long way short of a genuinely inclusive, participatory and open-ended arena for citizens to learn about scientific biotechnological issues and air their concerns about biosafety.

Critics of the US regulatory system believe that it is 'culturally hostile to' or 'not particularly interested in' public participation. The recent NAS report on the regulatory system was welcomed in these quarters but reportedly there has been a 'deafening silence' from the government about possible steps to incorporate or implement its recommendations for strengthening the regulatory system or opening it up to public participation. In response, government officials and policy-makers tend to claim that there simply is not significant public concern about LMOs in food and agriculture, and therefore major efforts to promote public participation are unnecessary. Such a position sits uneasily with evidence from public opinion surveys, for example those by the International Food Information Council (IFIC)[19], from which the clearest conclusion is that there are dramatic levels of ignorance and / or misapprehension among American consumers about the fact that genetically-engineered crops and foods are widespread in the US food chain. These levels of ignorance are themselves attributed, by critics of the US regulatory system, in part to the fact that GM food products do not have to be labelled.

One respondent noted that the possibility of stimulating a meaningful public debate at the national level is a major challenge for such a large and diverse country. Many citizens focus their attention on local or regional issues and get their news from local or regional news sources. Paradoxically, the large variety of news and information sources that are widely available in the United States makes it difficult to reach more than a small fraction of the population using any particular communication channel. For example, there is no such thing as a 'national newspaper' in the US. This makes it especially important to have a targeted and multi-pronged communication strategy.

19 http://ific.org/

Brief Context

Biotechnology research capacity in Zimbabwe is limited compared to larger developing countries. The key research centre is the state Biotechnology Research Institute, but biotechnology research is also carried out in the Tobacco Research Institute and in several laboratories in the University of Zimbabwe. Most of this work is not transgenic biotechnology. No LMOs have been commercialised yet in Zimbabwe. However, last year permission was granted for field trials of Bt cotton[20] and Bt maize[21]. Within the southern Africa region the only country where commercial production of Bt cotton is taking place is South Africa, with Bt maize to follow. Illegal trials of Bt cotton by Monsanto took place in 1997. When discovered these were destroyed. Through 2002 Zimbabwe has been facing severe drought, and has needed food aid from the international community. As with other neighbouring countries, Zimbabwe has been pressured by the US and WFP (World Food Programme) to accept GM maize as food aid. Zimbabwe has accepted this providing it is milled before distribution, so that it cannot be saved and planted, and potentially contaminate maize production. Neighbouring Zambia has refused GM food aid in any form.

The first attempts at regulation of biotechnology in Zimbabwe included a voluntary code of conduct agreed by scientists in 1992 (ITDG, 2000:26). In order to develop a more comprehensive regulatory system, a Biosafety Board was established in 1998 under the Research Council of Zimbabwe in the President's Office. It has the responsibility of setting out clear procedures for biosafety application, field trials and environmental release. Guidelines were set out for consultation in 1998, and given formal statutory endorsement in 2000.

According to policymakers, the Biosafety Board was located in the President's Office to ensure it was properly effective. It has the responsibility for advising on all aspects of the development, production, use and release of LMOs. Initially it was composed entirely of scientists. However, more recently there have

20 *Zimbabwean varieties owned by local company Cottco with a Monsanto Bt gene*

21 *Varieties from the Zimbabwean firm Seed Co and Monsanto, both with Monsanto Bt genes*

been discussions about the expansion of the board to include more non-scientific stakeholders, including NGO representatives and those from other Ministries concerned with social and environmental issues, such as Ministry of Mines Environment and Tourism (MMET).

Zimbabwe has strong traditions of civil society engagement in policy processes. Civil society can be seen as multi-faceted and reasonably well-mobilised, including farmers unions, commodity producer groups, NGOs with significant experience and capacity, alongside local farmer and community groups, and groups formed around traditional institutions. There is considerable experience within Zimbabwe of organising consultative processes around environmental issues (examples include the Environmental Management Bill and also legislation governing water and wildlife management). In addition to policy development, participatory processes have been institutionalised to some extent in key bureaucracies such as the Department of Research and Agricultural Services and the Department of Natural Resources, in MMET (Keeley and Scoones, 2000).

For communal farmers maize is the staple crop and the most common cash crop (Miedema 2001), hence GM maize is highly emotive, as media coverage and policy debates around the food aid issue illustrate. Particular stakeholders have strong interests in this area, such as Zimbabwean livestock exporters who have lobbied against the introduction of GM maize from a fear of losing key European export markets.

Key Actions

Participation and Consultation

- The government put the biosafety regulations out for stakeholder discussion in 2000-1, and has encouraged debate about biosafety issues. Much of this government consultative activity in relation to biosafety has been facilitated by the NGO BTZ (discussed below). Parliamentarian days have been held, with representations made by experts and other stakeholders encouraging discussion of biosafety among MPs.

- An initiative by ITDG (Intermediate Technology and Development Group) sought to engage farmers in Zimbabwe in a discussion about the comparative merits of LMOs and IPM/IPPM (Integrated pest

management and integrated production and pest management). Drawings were used to explain genetic engineering to farmers in ways that could be easily understood. Farmers raised concerns about the impacts of particular traits on non-target organisms (other insects for example), cross-contamination, resistance build-up and broader environmental impacts such as on soil structure. These concerns were expressed alongside anxieties about social, economic and human health impacts associated with the use of LMOs (ITDG 2000). (See Appendix 2 in Part I of the report for more details on this initiative).

- The Biotechnology Trust of Zimbabwe (BTZ) was set up in 1996 by DGIS (the Dutch aid agency) as part of the Dutch Biotechnology Support Programme (formerly it was the Zimbabwe Biotechnology Advisory Committee, ZIMBAC). The aim of this organisation is to educate, facilitate debate, and raise awareness, alongside supporting the development of pro-poor farmer demand-led agricultural biotechnology in Zimbabwe. Stakeholder feedback suggests it is perceived as not having been captured by any particular interest group, is well-respected and has convened discussion effectively.

- There were two well publicised public debates on LMOs in 2001 convened by the Biotechnology Association of Zimbabwe (BAZ). BAZ is a membership association facilitating discussion of biotechnology and linked to BTZ (see below). The first was entitled 'GM foods and products- which way forward for Zimbabwe', and the second, 'The implications of international conventions for farmers rights'. BTZ has had a particular role in asserting stakeholder rights to information (including details of current contained trials). It has also encouraged discussion of the implications of LMOs and the role of MNCs, of labelling and liability issues, and also raised awareness of the right of stakeholders to judge if potential gains overwhelm the risks.

- There is also a Regional Biosafety Programme funded by DGIS. This aims to look at the status of implementation of policies and legislation in southern and eastern Africa, and to facilitate consultative processes around biotechnology

and biosafety priority setting. A regional biosafety stakeholder workshop was held in Zimbabwe in July 2001. It focussed on national gaps in capacity and regional harmonisation of biosafety legislation.

Information and Education

- BTZ has several farmer participatory research projects in Buhera and Wedza districts. These aim to show the potential effectiveness of 'pro-poor need driven biotechnology'. These projects attempt to meaningfully link technology generation to the needs of farmers, and to encourage stakeholder reflection on the need for biotechnology that is responsive to farmer needs and conditions. Tours of the two districts have been organised for media, NGOs, and farmer organisations. ZBC TV coverage generated substantial interest in end-user led biotechnology. Projects focus on marker assisted selection for maize production and micropropogation of sweet potatoes, among other things. None of these projects, it should be noted, involve transgenic techniques.
- In terms of raising awareness and promoting education, ITDG developed a 'communications package' to communicate information and issues to local-level participants. The project team in Zimbabwe reported that small-holder farmers could only absorb about 30% of the information that was imparted through the communications package, partly because, for many, the community level workshops were the first time many of them had confronted these technical issues. The danger of information overload was also raised. Some participants in these workshops felt frustrated at the presentation of so many apparently conflicting opinions and wanted instead more proscription about the technologies and their potential risks and benefits.
- 'Farmer exposure visits' have been another way of encouraging reflection on the potential costs and benefits of LMOs. BTZ took farmers from Buhera and Hwedza to Makathini in South Africa to learn about the experiences of South African farmers growing Bt cotton. Concerns were raised about agronomic problems, licensing issues and questions of

environmental impact, which were fed back to local communities.

- BTZ publishes the 'Biotechnology' newsletter, which aims to present a balanced range of articles on potential costs and benefits of biotechnology, on biosafety issues, and on the latest biotechnology developments in Zimbabwe. BTZ have also produced a documentary video for educational purposes.
- DGIS/BTZ run a Capacity Building Programme. This includes a Biotechnology Policy and Management Training workshop, and an IPR training workshop. They have also organized biosafety training for policymakers and technical personnel.
- The Biotechnology Association of Zimbabwe (BAZ) is a membership organization for schools, companies, NGOs and churches. It has a secretariat based at BTZ. It was established with the aim of spreading public awareness about GM issues. BAZ was set-up as a response to concerns expressed at a symposium on biotechnology research in Zimbabwe that the public was woefully unaware and poorly engaged on biotech issues.
- Awareness raising workshops organised by BTZ have brought together consumer groups, health, education and extension sectors and the media. Discussions have focussed on how to develop appropriate information packages for dissemination through society.
- BAZ publishes 'Biotechnews'. This publication gives regular updates on biotechnology issues in a popular style, and covers a wide range of viewpoints.
- The Commercial Farmers Union has also produced materials for its members on biotechnology issues.

Reflections and Lessons

Discussions of the role of biotechnology in Zimbabwean agriculture sought to engage as wide a range of stakeholders as possible. There has been careful consideration of how to develop a biosafety system appropriate for Zimbabwe, and of the importance of going through a clear regulatory process before decisions are taken. Zimbabwe has maintained a GM-free position, and has decided to go for thorough and inclusive consideration of the issues. Clearly LMOs have not been rejected out of hand, as trials are proceeding at

present and biotechnology research capacity is also growing, although it is still small. This cautious and rigorous approach so far has meant that debates around LMOs have not become polarized in the way they have in other places.

Consensus building has been a feature of how biotechnology development and biosafety management is handled in Zimbabwe. The regulations took some time to be finalised, and while the degree of detail is alienating for some stakeholders, spaces were created for debate, and for stakeholders to feedback on draft regulations. The government has worked closely with the NGOs to encourage this kind of debate and deliberation. According to regulators, the process of drafting also involved careful consideration of the experiences of EU countries and materials provided by the ICGEB.

This view of the process is not shared by everyone, however. Some commentators such as Mohammed-Katerere (2000) have expressed reservations about the degree of participation, suggesting that key stakeholders such as the MMET were not involved in early stages. While formulation of the regulations was consultative and lengthy, the complexity of the subject matter has meant that engagement of some stakeholders was difficult. Both unions and companies have complained about the very technical way in which information is framed (whether draft regulations or application form procedures). ZFU in particular, have complained there was a lack of time to respond to draft regulations. They have also expressed concern at not being formally involved in the monitoring of trials, and that farmers are not involved in trial evaluation.

Engagement with civil society and NGOs has helped with consensus building. Initially, the Biosafety Board was accused of being dominated by a small number of scientists, and constrained by being based in the Research Council given its explicit research mandate. These issues and the need to think more carefully about social and economic issues are recognised by regulators. Accordingly, membership of the board may soon be expanded, bringing in representatives of NGOs articulating farmers' rights perspectives such as Commutech. Discussions with NGO officials suggest they appreciate this, and that it reflects a genuine desire to incorporate them and make use of their expertise. It

should be noted that while NGO engagement is a positive development, engaging NGOs is not the same thing as consulting with farmers and other rural stakeholders.

The ITDG participatory biotechnology assessment is another example of there being an environment in Zimbabwe conducive to reflection and debate on LMO issues. A key lesson emerging from this work has been the importance of developing biosafety capacity, and widening the availability of information and access to inventories on existing biotechnology research and applications (ITDG 2000). Updating the information used to inform people also emerged as a key challenge, especially in an area as fast-moving as biotechnology where the basis of information is so subject to scientific dispute and public debate. The Biosafety Clearing House may help in this regard. Also, generating new in-country information as a means of raising awareness could be done through the expanded Biosafety Board (ITDG 2000). Alongside this, many suggest there is scope to build local capacity for awareness raising among extension agents, consumer and farmer organisations. Greater use might be of existing channels of communication where local-level specialists such as extension workers can be mobilised to help solicit the views of different groups of farmers in particular. The ITDG work included a specific recommendation that a public forum on GM crops be established to discuss and exchange views on the technology.

Given that the Protocol (Article 26) allows countries to take socio-economic considerations into account ('arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities'), tools developed by groups such as ITDG represent an important vehicle for assessing such impacts in a way which involves those groups and communities most likely to be affected by the release of LMOs. An ITDG report on the subject notes: 'The methodology developed and tested in this project shows that assessment of socio-economic implications of modern agricultural technologies on sustainable livelihoods can be undertaken using existing participatory research techniques that are widely used in agricultural extension activities' (2000:7).

As with other countries and processes we have looked at, an important lesson is ensuring that relevant parallels and points of comparison are made with the risks associated with existing and alternative technologies,in order to allow people to meaningfully evaluate risks for themselves. The importance of this is heightened in the case of modern biotechnology where the newness of the technology and the low capacity for assessment of issues related to transgenics in agriculture make it difficult for 'lay' stakeholders in particular to make informed judgements about the safety of LMOs. Using proxy examples of conventional crop varieties to demonstrate some of the characteristics of transgenic crops that might be introduced provides one way of drawing parallels that people may be more familiar with. Often space will have to be created for broader issues than narrow biosafety concerns alone to be considered when stakeholders are often more concerned with issues of price, access and control than environmental impacts of the technology in isolation. This is particularly so in countries such as Zimbabwe, without much direct experience of the technology, where the discussion is necessarily more abstract and speculative. An ITDG report notes 'in the community-level workshops, farmers focussed on their more immediate interests related to their current situation than on the implications that could arise for them from the future introduction of a new type of technology or crop variety' (2000:24).

Limited capacity is clearly an issue in a small country like Zimbabwe. There are a small number of scientists who are both engaged in research, and carrying out regulatory responsibilities. This could present a danger of conflict of interest, though other consensus-building mechanisms mitigate this. There is also limited capacity to inspect trials. A need has been expressed to train more staff to MSc level to engage in inspection and monitoring work.

The current political instability in Zimbabwe and particularly in rural areas clearly impinges on biosafety processes. Management and inspection of trials may be difficult in the context of farm invasions. Furthermore, biosafety monitoring approaches such as implementing a refuge strategy to delay insect resistance to Bt may become less feasible as the structure of landholdings changes in the commercial farming sector. As and when large farms are broken up, it will

be more difficult to check and limit what is being grown. Also, confidence in biosafety procedures is undermined to some extent by the perception that GM maize may already be entering the country by way of food imports, or through illegal cross-border trade.