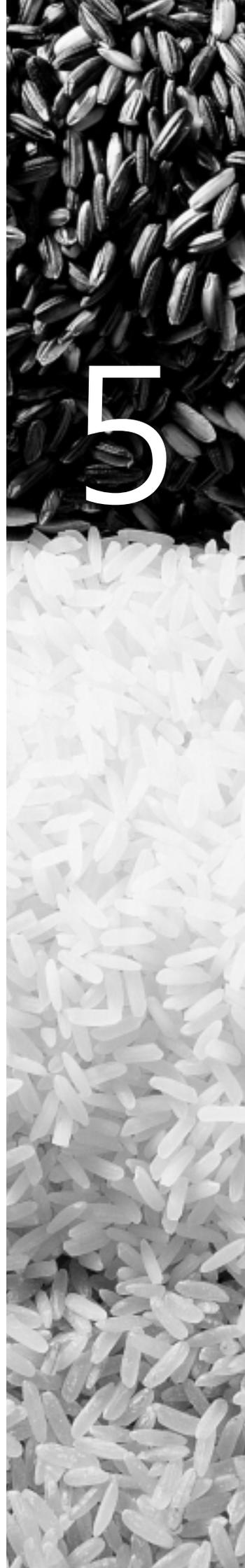


Chapter

Governance

5



Governance

- 5.1 Decisions regarding the development, planting and regulation of GM crops take place at many levels and are influenced by international regimes and national policies. They are also made by sub-national authorities, local communities and, ultimately, individual farmers and households. We have stressed that we cannot generalise about developing countries (see Box 1.1 and paragraphs 1.17-1.20). However, all such countries face the challenge of ensuring that policies towards GM crops make sense in the context of their own development needs, and also that they cohere with the complex system of international governance that is developing for GM crops.
- 5.2 In this chapter we:
- outline the system of governance that applies to GM crops, including issues of national administrative and technical capacity;
 - identify emerging ethical and regulatory issues within this system, particularly relating to the level of authority at which decisions should be made; and
 - highlight ethical and regulatory problems arising from the interdependence created through international trade.

Governance: international regulation

- 5.3 There are five main elements of international regulation relating to research into, and the trade and use of, GM crops:
- Agreements by the World Trade Organization (WTO) which aim to control barriers to international trade. It is within this framework that the US and a number of other states have most recently challenged the EU on the authorisation of GM crops.¹
 - The *Codex Alimentarius*, a set of international codes of practice, guidelines and recommendations pertaining to food safety. The WTO currently relies upon the *Codex* in making its adjudications.
 - The *Cartagena Protocol on Biosafety* under the *Convention on Biological Diversity* (CBD), a multilateral agreement covering the movement across national boundaries of living modified organisms (LMOs) that might have an adverse effect on biological diversity.
 - The *International Treaty on Plant Genetic Resources for Food and Agriculture* by the UN FAO, a multilateral agreement relating to any genetic material of plant origin of value for food and agriculture (not yet entered into force).
 - Directives and Regulations by the EU and its regional policies on agriculture, environment and genetically modified organisms (GMOs).

The World Trade Organization

- 5.4 The primary purpose of the WTO is to facilitate international free trade. It aims to achieve this by establishing trade rules, serving as a forum for trade negotiations and assisting in the settlement of disputes. There are two principal agreements that relate to GM crops. They concern the negotiation of free trade (the *Technical Barriers to Trade Agreement*, TBT), and the protection of public health and welfare standards in member states of the WTO (the *Sanitary and Phytosanitary Agreement*, SPS, see Box 5.1).

¹ de Jonquieres G, Alden E and Buck T (2003) Sowing discord: after Iraq, the US and Europe head for a showdown over genetically modified crops, *Financial Times* 14 May 2003, p21.

Box 5.1: **WTO agreements relating to the use of GM crops**

Sanitary and Phytosanitary Agreement (SPS)

- The SPS allows members of the WTO to temporarily block trade in the interest of protecting public health. However, such decisions must be based on scientific principles, internationally established guidelines and risk assessment procedures.
- When there is insufficient scientific evidence to determine the likely risk arising from the import of particular goods, members of the WTO may adopt measures on the basis of available information. Additional information which can support the initial decision must be submitted within a reasonable period of time.
- The SPS does not permit members to discriminate between different exporting countries where the same or similar conditions prevail, unless there is sufficient scientific justification for doing so.

Technical Barriers to Trade Agreement (TBT)

The TBT obliges members of the WTO to ensure that their national regulations do not unnecessarily restrict international trade. Three components make up the agreement.

- First, members are encouraged to accept 'standard equivalence' which means that the standards of other countries are mutually recognised through explicit contracts.
- Secondly, the TBT promotes the use of internationally established standards.
- Thirdly, the TBT requires members of the WTO to inform each other of relevant changes in policy. This means that members must establish centres that compile all available information on product standards and trade regulations. These centres must answer questions raised by other countries and consult with trading partners as requested, to discuss the relevant requirements for trade.

The Codex Alimentarius

5.5 The *Codex Alimentarius* was established by the Codex Alimentarius Commission, a subsidiary body of the FAO and the WHO. The Commission is the principal international body on food standards and represents more than 95% of the world's population. The primary aim of the *Codex* is 'to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonisation and in doing so to facilitate international trade.'² The *Codex* consists of a collection of food standards, guidelines and other recommendations (see Box 5.2).³ It also includes a Code of Ethics which aims to encourage food traders to adopt voluntarily ethical practices to protect human health and to ensure fair practices in food trade.

5.6 A conference organised jointly by the WHO and the FAO in 1999 addressed the question of how developing countries could participate more actively in the work of the Codex Commission. Delegates identified the need to make greater efforts to learn about and

² FAO (1999) Understanding the *Codex Alimentarius*: Codex and the international food trade. Available: <http://www.fao.org/docrep/w9114e/W9114e06.htm>. Accessed on: 17 May 2003.

³ The *Codex Alimentarius* standards, guidelines and other recommendations cover a wide range of issues and currently comprise 204 Food Standards, 43 Codes of Practice, 197 evaluated Pesticides, 2516 Limits for Pesticide Residues, 25 Guideline Levels for Contaminants, 1300 evaluated Food Additives, 54 evaluated Veterinary Drugs and 289 Limits for Veterinary Drug Residues. See FAO (1999) *Food Quality, Safety and International Trade: Codex Alimentarius and the SPS and TBT Agreements* Agricultural Trade Fact Sheet. Available: <http://www.fao.org/DOCREP/003/X6730E/X6730E05.HTM>. Accessed on: 17 May 2003.

Box 5.2: Standards of the Codex Commission relating to the use of GM crops

- The standards set out by the Codex have been used widely as the benchmark in international trade disputes. They are explicitly referred to and adopted in the SPS agreement of the WTO, and the TBT agreement implicitly refers to them.
- Issues relating to the use of GM crops have recently been considered by the Codex Commission. At its meeting on 30 June – 7 July 2003 the Commission agreed three standards relating to GM crops:
 - *Principles for the Risk Analysis of Foods derived from Modern Biotechnology;*
 - *Guidelines for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants;* and
 - *Annex on the Assessment of Possible Allergenicity to the Guidelines for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants.**
- The principles include a science-based, pre-market risk assessment, performed on a case by case basis, and also an evaluation of both direct effects (from the inserted gene) and unintended effects (that may arise as a consequence of insertion of the new gene). Risk management should be based on the risk assessment and be proportionate to the risks identified. Effective post-market monitoring may in some cases require mechanisms of traceability and labelling to allow the withdrawal of products that pose risks to human health.

* Adopted at the Twenty-sixth Session held in Rome, 30 June – 7 July 2003. Report available: www.codexalimentarius.net/session_26.stm. Accessed on: 12 Nov 2003.

respond to concerns of consumers in these countries. Subsequently, National Codex Alimentarius Committees have been established with financial assistance from the FAO in most developing countries. These National Committees involve representatives of relevant government ministries, industry and consumer initiatives; each National Committee sends delegates to international Codex meetings.⁴

The Cartagena Protocol on Biosafety

5.7 At the time of publication of our 1999 Report, an international treaty which addressed possible risks posed by the introduction of GM crops was not in force. Negotiations on a protocol to the *Convention on Biological Diversity* (CBD), which focused on such matters, had been blocked by the US and a few other countries. However, agreement was reached in 2000 and the *Cartagena Protocol on Biosafety* was adopted by the parties of the CBD. It entered into force in September 2003. The Protocol was signed by 103 countries and has, to date, been ratified by 66 member states.⁵ Although the US participated in the negotiations of the Protocol, it is not a member of the CBD and hence the Protocol is not applicable to US trade relating to LMOs. The EU ratified the Protocol on 27 August 2002, when *The Regulation of the European Parliament and of the*

⁴ FAO (1999) *Food Quality, Safety and International Trade: Codex Alimentarius and the SPS and TBT Agreements* Agricultural Trade Fact Sheet. Available: <http://www.fao.org/DOCREP/003/X6730E/X6730E05.HTM>. Accessed on: 17 May 2003.

⁵ *Convention on Biological Diversity. Cartagena Protocol on Biosafety*. Available: <http://www.biodiv.org/biosafety/>. Accessed on: 2 June 2003.

Council on the Transboundary Movement of Genetically Modified Organisms implemented the provisions of the Protocol into Community Law. The Protocol is an important regulatory device which relates directly to the trade and use of GM crops.

5.8 Article One lists the objectives as follows:

‘to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.’

The Protocol contains procedural rather than substantive measures, relating to the provision of information and the carrying out of tests to assess the safety of LMOs such as GM crops. Some of the main procedures introduced by the Protocol are described in Box 5.3.

Box 5.3: **Main procedures of the Cartagena Protocol on Biosafety**

- **Advanced informed agreement procedure (AIA):** before exporting LMOs which are intended for release in the environment, the recipient country must be notified. The notification must include a detailed description of the LMO, including reference to existing risk assessment reports. Only upon consent of the recipient country may the export take place (Articles 7-10).
- **Risk assessment:** parties to the Protocol decide whether or not to accept LMOs primarily on the basis of scientific risk assessment procedures. Parties may decide to apply a precautionary approach and refuse the import of LMOs if the available scientific evidence is considered insufficient. Parties may also take into account socio-economic implications likely to result from the import of LMOs (Article 15). Article 15 enables a potential recipient to require the exporter to carry out a risk assessment. It may also charge the exporting country the full cost of the regulatory approval.
- **Capacity-building and involvement of the public:** Article 22 expects the parties to the Protocol to cooperate in the development and/or strengthening of human resources and institutional capacities. Article 23 requires the involvement of the public in the decision making process.
- **Biosafety Clearing House:** in order to assist parties of the Protocol in its implementation and in order to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs, the Protocol established the Biosafety Clearing House as a central source of reference (Article 20).
- **LMOs intended for direct use as food or feed:** parties in developing countries can declare through the Biosafety Clearing House that they wish to take a decision based on risk assessment information before agreeing to accept an import (Article 11).

- 5.9 The Protocol differs significantly from the WTO's SPS in terms of provisions for risk assessment. Under the SPS, import restrictions can only be established on a temporary or provisional basis. The Protocol, on the other hand, endorses a more open-ended approach, drawing on the precautionary approach (see paragraphs 4.35-4.42). We welcome the development and implementation of the Protocol as an important and essential device in the regulation of the transboundary movement of LMOs, such as GM crops. However, with regard to the implementation of the Protocol, we caution against overly narrow application of the precautionary approach (see paragraphs 4.37-4.41). Due to international controversies about the use of GM crops, and due to lack of facilities for safety assessment, policy makers in developing countries are under substantial pressure to opt for a conservative interpretation of this approach. However, there is a real risk that highly restrictive legislation could considerably delay research, development and use of potentially beneficial GM crops in developing countries.
- 5.10 It could be argued that in view of the alleged risks posed by GM crops, developing countries should first implement rigid regulation which could then be deregulated as appropriate. However, significant difficulties can be encountered in the deregulation of previously established regulations, as revisions can be delayed considerably by unrelated political and administrative disputes. It is therefore important that all developing countries which are currently involved in the implementation of the *Cartagena Protocol* consider carefully how to interpret the provisions of the precautionary approach, to allow for appropriate regulation before the need arises. **We draw attention to our view that a highly restrictive interpretation of the precautionary approach is likely to ignore the possibility that, in some cases, the use of a GM crop variety may pose fewer risks than are implied by current practices or by plausible non-GM alternatives. In applying the precautionary approach, risks implied by the option of inaction (or by alternative actions) must also be considered.**

The International Treaty on Plant Genetic Resources for Food and Agriculture

- 5.11 The *International Treaty on Plant Genetic Resources for Food and Agriculture* (henceforth: the Treaty) was unanimously adopted by members of the FAO's Conference of November 2001.⁶ The objectives of the Treaty are the conservation and sustainable use of plant genetic resources, and the fair and equitable sharing of benefits derived from their use, so as to promote sustainable agriculture and food security. 'Plant genetic resources' are defined as 'any genetic material of plant origin of actual or potential value for food and agriculture'.
- 5.12 The exchange of plant genetic resources is indispensable for research and development of improved crops. Over recent decades, it has become increasingly common for the exchange of resources used for academic or commercial research to be covered by material transfer agreements (MTAs, see paragraphs 3.47 and 6.3-6.4). The new Treaty will establish a multilateral system for access and benefit-sharing for 33 important crops that are under the management and control of the Contracting Parties and in the public domain (Article 11.1 and Annex 1).
- 5.13 To facilitate access to these plant genetic resources, a standard MTA will be established, setting out the terms and conditions under which the resources can be used, for instance, 'solely for the purpose of utilisation and conservation for research, breeding and training for food and agriculture' (not, for example, for pharmaceutical use). The MTA will also require the sharing of benefits relating to information, technology, strengthening of

⁶ See Commission on Genetic Resources for Food and Agriculture *The International Treaty on Plant Genetic Resources for Food and Agriculture*. Available: <http://www.fao.org/ag/cgrfa/itpgr.htm>. Accessed on: 18 May 2003.

expertise and monetary benefits, arising from the use of the resources covered by the Treaty (Section 12.4 and 13.2.d). Article 13.2.d(ii) requires that a recipient who commercialises a product that involves material accessed through the multilateral system, shall pay 'an equitable share of the benefits arising from the commercialisation of that product' into a fund established by the Treaty unless access to the commercialised product is not restricted (for instance, by a patent), in which case payment is merely encouraged.

- 5.14 Article 13.2.d(ii) also provides that the Treaty's Governing Body, which consists of those countries which have ratified the Treaty, shall determine at its first meeting the level, form and manner of the payment, in line with commercial practice. The Governing Body may decide to establish different levels of payment for various categories of recipients who commercialise such products. It may also choose to exempt from such payments small-scale farmers in developing countries and in countries with economies in transition. Levels of payment are to be reviewed from time to time, as well as provisions which concern the question of whether benefit-sharing should also be mandatory where access to the product is not restricted. The Treaty has been signed by 78 members and non-members of the FAO. At the time of publication, fourteen countries have ratified the Treaty. It is due to enter into force 90 days after ratification by 40 governments.
- 5.15 **We welcome the recent decision by the UK Government to ratify the *International Treaty on Plant Genetic Resources for Food and Agriculture*. Access to resources falling under the Treaty is of crucial importance in the development of crops suited to developing countries. We recommend that in the negotiations regarding the standard Material Transfer Agreement (MTA), the UK Government aims for provisions that exempt users in developing countries from payments, where commercial applications arise from material covered by the MTA. Where exemptions are not appropriate, differentiation of payments should take into account the level of development of the country in question.**

The European Union

Directive 2001/18/EC and Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (GMOs)

- 5.16 The current EU legislation on GMOs is regarded as the strictest in the world. *Directive 90/220/EEC* relating to experimental releases and marketing of GMOs was entered into force in 1990. Eighteen applications, relating to varieties of GM soybean, maize and oilseed rape have received authorisation. However, shortly after implementation of the Directive, member states of the EU decided that it should be amended in the light of considerable advances in genetic modification in the 1990s. In the ensuing debate, five member states invoked the so-called safeguard clause of *Directive 90/220/EEC* in 1998. The clause allowed member states to temporarily ban a genetically modified product on its territory if there was substantial evidence that it implied risks to human health or to the environment.⁷ This resulted in a stalling of evaluations of further applications, and a declaration of a *de facto* moratorium at an EU Environment Ministers Council meeting in June 1999. While some viewed this as a reasonable application of the precautionary approach (see paragraphs 4.35-

⁷ Article 16, the so-called safeguard clause, stated 'Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.' (Council *Directive 90/220/EEC* Article 16.)

4.42), others perceived it to be primarily a barrier to trade, violating the WTO agreements. It has been claimed that the moratorium cost the US US\$250-300 million a year in lost exports.⁸

5.17 After substantial revisions, *Directive 90/220/EEC* was replaced by *Directive 2001/18/EC* in October 2001. It introduced the following measures to ensure that the regulation of GMOs would meet the demands of EU regulators and consumers:

- principles for environmental risk assessment (see Box 5.4);
- mandatory post-market monitoring requirements, including any long-term effects arising from the interaction with other GMOs and the environment;
- mandatory information for the public;
- a requirement for member states to ensure labelling and traceability at all stages of marketing (see paragraphs 5.20-5.21); and
- commercial approvals for the release of GMOs to be limited to a maximum of ten years.

5.18 *Directive 2001/18/EC* requires a step by step approval process for GMOs. The procedure is as follows: a company wishing to market a GMO must first submit an application to the relevant national authority of the EU member state where the product is to be marketed. This application must contain a full environmental risk assessment. The assessment needs to take into account direct or indirect effects on human health and the environment which may arise from the deliberate release or marketing of the GMO(s). The assessment must also consider whether these effects might be manifested immediately, cumulatively or on a long-term basis.⁹ Box 5.4 shows the methodology of the risk assessment process. If the national authority is satisfied with the application, the authority informs the other EU member states through the European Commission (EC). If, within a specified time limit, no objections from other states are received, approval is granted and the product can be placed on the market throughout the EU.

Box 5.4: Risk assessment methodology in *Directive 2001/18/EC*

- Identification of any characteristics of the GMO(s) which may cause adverse effects.
- Evaluation of the potential consequences of each adverse effect.
- Evaluation of the likelihood of the occurrence of each identified potential adverse effect.
- Estimation of the risk posed by each identified characteristic of the GMO(s).
- Application of management strategies for risks from the deliberate release or marketing of GMO(s).
- Determination of the overall risk of the GMO(s).

⁸ Mitchell P (2003) Europe angers US with strict GM labelling, *Nat Biotechnol* 21: 6.

⁹ Council *Directive 2001/18/EC* Annex II.

- 5.19 As noted above, *Directive 2001/18/EC* introduces basic provisions for a traceability system for GMOs. However, the Directive contains neither a definition of traceability, nor a complete approach for its implementation. These issues, and more detailed regulation concerning the labelling of GMOs and products derived from GMOs are addressed in two more recent regulations.

Regulation 1830/2003/EC on Traceability and Labelling

- 5.20 *Regulation 1830/2003/EC concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC* was formally adopted by the Council of Ministers in July 2003. It has the objective of controlling and verifying labelling claims; facilitating the monitoring of potential effects of GMOs on the environment; and enabling the withdrawal of products that contain or consist of GMOs that might prove to pose unforeseen risks to human health or the environment. The Regulation requires the labelling of all foods produced from GMOs. However, in November 2002, the European Council agreed that food and feed do not have to be labelled if the amount of genetically modified material is below a threshold of 0.9%, and if its presence could be shown to be unintentional and technically unavoidable. The threshold for the presence of GMOs which have not yet received approval in the EU was set at 0.5%. Although the primary criterion for labelling is detectability, processed foodstuffs such as highly refined oils derived from GM crops, which do not contain genetic material of the original GM crop, still have to be labelled as 'GM' according to the new Regulation.¹⁰
- 5.21 With regard to traceability, the Regulation requires that GMOs must be traceable throughout the entire production and distribution process. Thus, a company selling GM seed must inform any purchaser that the seed has been genetically modified, supplying specified information on the identity of the individual GMO(s). The company is required to keep a register of all recipients of the seed concerned for five years. Similarly, farmers who buy GM seed must transmit relevant information to those who buy their harvest, and keep a register of recipients. In the case of food and feed produced from GM crops, the process is repeated throughout the production and distribution chain.

Regulation 1829/2003/EC on GM Food and Feed

- 5.22 A second Regulation which was formally adopted by the Council of Ministers in July 2003, is *Regulation 1829/2003/EC on genetically modified food and feed*.¹¹ The new component which the Food and Feed Regulation introduces is a centralised authorisation procedure for GMOs used as food or animal feed. This means that those wishing to market GM crop in the EU need not request separate authorisations for the use of the crop as food or feed. A crop is either authorised for both uses, or for neither.¹² The use of GMOs in animal feed did not previously require a specific authorisation procedure. The Regulation will thus have an impact on imported GM crops, which are predominantly used as feed for animals. In view

¹⁰ However, food produced with the help of a GM enzyme, such as bakery products that involve amylase, do not need to be labelled.

¹¹ The Regulation replaces the authorisation for GM foods and food ingredients, which was previously covered by the *Novel Food Regulation (EC) 258/97*.

¹² One of the reasons for this approach is to prevent controversies such as those caused by the Bt maize variety StarLink™. StarLink™, produced by the company Aventis, received regulatory approval from the US Environmental Protection Agency (EPA) to be used as animal feed only. However, in 2000, traces of StarLink™ were found in taco shells which were sold in supermarkets in the US.

of the current stance of EU consumers, the Regulation is likely to give a considerable advantage to those producers who offer non-GM crops. The labelling requirements for GM crops which are used as feed follow the *Traceability and Labelling Regulation*, outlined above. However, the *Food and Feed Regulation* exempts products such as milk and meat, obtained from animals fed on GM crops, from mandatory labelling.

Regulatory and ethical issues

National administrative and technical capacity of regulating the use of GM crops in developing countries

- 5.23 We have noted that a number of the international agreements require the regulation of GM crops by administrative and technical measures at the national level. However, costs for provision of the relevant authorities which could undertake and verify risk assessment procedures are considerable, as is evident from the comprehensive European regulatory framework. It is not yet clear how different developing countries will respond to the requirement of establishing such regulations. We are likely to see considerable variation between developing countries. A recent document produced by the UK Prime Minister's Strategy Unit on the implications for developing countries of GM crops suggests that there is some pattern in this variability.¹³ Across eleven countries it assesses the capacity to undertake biotechnology assessments as ranging from advanced, in countries such as China, India and Brazil, to weak or non-existent in Kenya, Zambia and Mozambique.¹⁴ However, even this classification may be too general to be useful. The capacity of national agricultural research systems also varies widely. Weaknesses at the national level are often accompanied by weaknesses at the local level, particularly in agricultural extension systems.
- 5.24 At present, most developing countries do not have appropriate legal and administrative systems in place to regulate biotechnology-related activities as required by the *Cartagena Protocol*.¹⁵ However, initiatives such as the joint project by the United Nations Environment Programme and the Global Environment Facility (UNEP/GEF) on the *Development of National Biosafety Frameworks* (2002-2004) have recently been initiated. The aims of the project are to prepare parties of the *Cartagena Protocol* for entry into force of the treaty; to assist countries which are eligible under GEF to prepare frameworks for national biosafety; and to facilitate regional cooperation between countries.¹⁶ The project brings together more than 100 countries and has close working relations with other relevant organisations.¹⁷ It has received support from the UK Department for International Development (DFID), which seeks to devise guidelines for participation by the public in decision making processes for biosafety frameworks, and also from the EC. The EC recently

¹³ The UK Strategy Unit has published a working paper considering the potential economic impact of the commercialisation of GM crops in the UK on developing countries, see Strategy Unit (2003) *Developing Country Background Working Paper: Potential UK impact on developing countries*. Available: <http://www.number-10.gov.uk/su/gm/developing.pdf>. Accessed on: 30 Oct 2003.

¹⁴ Strategy Unit (2003) *Developing Country Background Working Paper: Potential UK impact on developing countries*, p35. Available: <http://www.number-10.gov.uk/su/gm/developing.pdf>. Accessed on: 30 Oct 2003.

¹⁵ United Nations Environment Programme (UNEP) – Global Environment Facility (GEF) *Project on the Development of National Biosafety Frameworks* Business Plan for 2002-2004 (Geneva, Switzerland: UNEP); Kinderlerer J (2002) Regulation on Biotechnology: needs and burdens for developing countries. Available: <http://www.unep.ch/biosafety/BTregulationJK.pdf>. Accessed on: 23 March 2003.

¹⁶ UNEP – GEF *Project on the Development of National Biosafety Frameworks* Business Plan for 2002-2004 (Geneva, Switzerland: UNEP), paragraph 1.2.

¹⁷ Such as the Bureau of the Intergovernmental Committee on the *Cartagena Protocol on Biosafety* (ICCP), the Secretariat of the CBD, the World Bank, the United Nations Development Programme (UNDP) and the International Centre for Genetic Engineering and Biotechnology (ICGEB).

offered to fund an initiative to help develop guidelines for establishing risk assessment and management systems for participating countries.¹⁸

- 5.25 It is of particular importance that developing countries improve their capacity to independently review and assess the use of GM crops in specific situations. As one respondent to our Consultation observed:

‘There is a very urgent requirement to empower developing countries to make their own risk/benefit assessments and decisions to implement technologies, based on their local needs. Otherwise they will remain the victims of others’ agendas. Key elements are capacity building in biosafety assessment and intellectual property management...’

Dr Ray Mathias, John Innes Centre, UK

We share this view and emphasise that those involved in the use and regulation of GM crops in developing countries need to decide on suitable devices and procedures to govern the use of GM crops themselves. **Since means for the development of the required expertise are limited in most developing countries, we welcome and endorse the UNEP/GEF undertaking of promoting the building of capacity in relevant expertise.**

- 5.26 Similar projects have recently been announced by the FAO, to the same ends.¹⁹ Whilst the commitment of any international organisation to the improvement of administrative capacity in developing countries is to be welcomed, duplication of effort among international organisations can be counter-productive. Administrative resources are scarce in developing countries and it is important to ensure that international development efforts are coordinated.
- 5.27 It is clear that regulation needs to be established primarily at the national level. However, diverse regulations, requiring that every new GM crop is assessed for possible risks to human health and the environment in each country, can cause problems. For most developing countries, it will be a major financial and logistical challenge to provide the capacity and resources to undertake such evaluations. The absence of appropriate testing facilities could delay the granting of approval for much needed improved crops. **We therefore recommend that particular attention should be given to measures that will enable the sharing of methodologies and results. An example is environmental risk assessments for countries which have similar ecological environments. It should also be considered whether harmonised regional policies can be established, for example by the Southern African Development Community (SADC) and the Common Market for Eastern and Southern Africa (COMESA).**²⁰ In this context, we welcome the recent initiative by SADC to produce

¹⁸ UNEP - GEF Project on the *Development of National Biosafety Frameworks* Business Plan for 2002-2004 (Geneva, Switzerland: UNEP), paragraph A4.3.

¹⁹ Fresco L (2003) “Which Road Do We Take?” Harnessing Genetic Resources and Making Use of Life Sciences, a New Contract for Sustainable Agriculture, in *EU Discussion Forum Towards Sustainable Agriculture for Developing Countries: Options from Life Sciences and Biotechnologies* FAO, Brussels, 30-31 Jan 2003.

²⁰ COMESA is a regional grouping of 20 countries of Eastern and Southern Africa with a population exceeding 380 million. It was established in 1994 to replace the Preferential Trade Area for Eastern and Southern Africa (PTA) which had been in existence since 1981. COMESA aims to function ‘as an organisation of free independent sovereign states which have agreed to co-operate in developing their natural and human resources for the good of all their people.’ SADC comprises 14 Southern African nations and has the general aims of achieving development and economic growth, alleviating poverty, enhancing the standard and quality of life of the people of Southern Africa and supporting the socially disadvantaged through regional integration.

guidelines on food safety assessment and management of GM crops.²¹ We also recommend that developing countries should implement as far as possible standardised procedures for the assessment of environmental and health risks. Established international guidelines such as the *Cartagena Protocol on Biosafety* (see paragraphs 5.7-5.10) and the guidelines of the Codex Commission (see paragraphs 5.5-5.6) should be considered. Care must be taken to avoid an overly restrictive interpretation of the precautionary approach (see paragraphs 4.37-4.41 and 5.10).

- 5.28 The transfer of experience from advisory and regulatory bodies in developed countries to the developing world is urgently needed (see paragraphs 4.49-4.62 of our 1999 Report). Poor compliance of farmers with technical specifications, illegal planting of *Bt* cotton in India²² and the smuggling of GM soybean seeds from Argentina to Brazil are already raising concerns.²³ By ensuring appropriate public awareness, and by insisting on transparent arrangements for overview and enforcement, costs and any risks associated with GM crops can be minimised (see paragraphs 5.30-5.36).
- 5.29 What kind of regulatory systems are appropriate for the enforcement of biosafety regulations in developing countries? It is again difficult to generalise. For example, in China and Ghana, very different conditions prevail with regard to the capacity for policy enforcement, the number of farmers, and the type of agriculture. In particular, the very large number of small-scale farmers in developing countries poses great challenges for enforcement.²⁴ It seems unlikely that regulation can be achieved successfully by a compulsory 'command-and-control' approach. Such measures may be successful in developed countries, where licensing and monitoring is frequently a standard component of agricultural policy. However, in many developing countries it will be more likely that the intended effect of a particular policy will be achieved by incentives and well developed extension systems. An assessment of appropriate regulatory systems at the national level is beyond the scope of this Discussion Paper.

Local autonomy and choice

- 5.30 We now consider who, within a complex system of governance, should have the responsibility for deciding whether or not to use GM crops. In particular, the question arises whether it would be right to prevent farming communities in developing countries from adopting GM crops if they thought it was to their advantage. In this context, some might see an argument for the application of the principle of subsidiarity. The principle of subsidiarity says that, within a system of governance, decisions should be taken at the

²¹ Njoroge J (2002) Southern African nations to probe GM safety, *SciDev.Net*. Available: <http://www.scidev.net/News/index.cfm?fuseaction=readnews&itemid=273&language=1>. Accessed on: 2 June 2003; SADC (2003) Launching of the SADC Advisory Committee on Biotechnology and Biosafety. Available: http://www.sadc.int/index.php?lang=english&path=newscenter/mediareleases/&page=mr35_16042003. Accessed on: 20 May 2003.

²² Jayaraman KS (2002) Poor crop management plagues *Bt* cotton experiment in India, *Nat Biotechnol* 20: 1069, see Chapter 3, footnote 14.

²³ Bonalume Neto R (1999) Smugglers aim to circumvent GM court ban in Brazil, *Nature* 402: 344-5.

²⁴ It is estimated that there are about 817 million small-scale farmers in developing countries, see FAO (1988) *The Impact of Development Strategies on the Rural Poor: Second Analysis of Country Experiences in the Implementation of the WCARRD Programme of Action* (Rome: FAO).

lowest possible level, provided that goals such as safety and environmental protection are secured. Why might this principle be thought to apply?

- 5.31 First, in many cases the beneficiaries of GM crops may be poor communities in developing countries for whom improved agriculture is crucial. If members of such communities believe that a particular technology can be an important means of improving their livelihoods, then it may be argued that it would be wrong to prevent them from pursuing that option. Secondly, there is evidence of illegal plantings of GM crops in some developing countries, most notably of soybean in Brazil and cotton in India. This indicates that irrespective of decisions made at the national level, promising technologies will be taken up regardless. It might therefore be better to allow communities to adopt the technology within a framework of regulation, despite its inevitable inadequacies, than to have them try it outside such a framework. Thirdly, there is evidence that it is institutions at the level of the local community, rather than the state, in which members of poor farming communities have most confidence.²⁵ Small-scale farmers are some of the most vulnerable people in the world. If they are enabled to make their own decisions within their own communities, then they can exercise some influence over their own future.
- 5.32 In principle, we sympathise with this approach, but we also anticipate problems. First, would local communities be given real or merely nominal control, if the decision to grow GM crops were left to them? In view of the increasing concentration of biotechnology, seed and agrochemical companies, many decisions are taken by powerful corporations. It seems unlikely that local communities would be given an equal role in negotiations. We therefore see a real risk of exploitation if the principle of subsidiarity were rigidly applied. Secondly, important issues are raised in the context of international trade. It could be the case that a particular community decides to grow GM crops, but in doing so affects the ability of others in the country to export crops of the same kind to external markets that have a restrictive policy towards GM crops. Thirdly, we have noted that the administrative and technical capacity of developing countries to monitor and regulate health and environmental effects, even at the national level, is often very limited. It seems unlikely that local communities would be able to undertake individual environmental and health risk assessments.
- 5.33 Nevertheless, local communities should be included as far as possible in decision making processes, for example by means of consultations with stakeholders. In this context, formal and non-formal programmes that promote the dissemination of balanced information, communication, education and training of those involved are essential. In particular, farmers need to be informed about the technological potential and management requirements of GM crops. Expectations are sometimes inappropriately high, and knowledge about specialised farm management practices may be absent. **We recommend that companies marketing GM crops in developing countries share, with governments, the costs of:**
- locally appropriate schemes to elicit small-scale farmers' preferences regarding traits sought by GM-based breeding;
 - their participation, where appropriate, in plant breeding; and
 - subsequent mechanisms to improve dissemination of balanced information, education and training about the use of GM crops.

²⁵ Pimbert M and Wakeford T (2002) Prajateerpu: Food and Farming Futures for Andhra Pradesh: A Citizens' Jury / Scenario Workshop, *Economic and Political Weekly [India]* 37: 2778–87 (Review of Science Studies), 6–12 July 2002.

5.34 Such measures can help to ensure that the views of farmers and other stakeholders are considered in the decision making processes about the possible use of GM crops. **We conclude that the most appropriate approach would normally be a centralised and evidence-based safety assessment at the national or regional level. Environmental and health risks should be assessed on a case by case basis. Wherever possible, such assessments should consider information which is available from international sources, particularly with respect to data about food safety assessments, which are more transferable than environmental risk assessments.**

5.35 While such arrangements could enable an appropriate means of balancing benefits and risks of GM crops, we need to consider one additional element that is crucial for an efficient and effective regulatory framework. This is the provision of a system of remediation in the case of crop failures. As one respondent to our Consultation observed:

'Regulations must include provisions for correcting mistakes. Multinational companies cannot be allowed to use small-scale farmers as guinea-pigs to try out whether new crop varieties are really successful. When the cotton balls fell off prematurely in the US,²⁶ farmers were able to get compensation. Would the same be true of crop failures in developing countries?'

Tracey McCowen, MBE, Canada

5.36 **We agree that the same standards of liability need to apply in both developing countries and developed countries. Where there is clear evidence of damage attributable to the seed producer, compensation will need to be provided, regardless of whether the seed is GM or non-GM. We note that in previous instances of crop failures in developed countries compensation has been negotiated successfully. We recommend that possible scenarios, which include the principle of compensation, be considered by policymakers and the seed industry. Agreed standards should be published widely, taking into account in particular the situation of small-scale farmers in developing countries. Illiteracy and lack of adequate infrastructure for effective communication can present additional obstacles that need to be considered. Wherever possible, agreements should be established, to facilitate compensation of small-scale farmers who, in the event of loss or damage, are unlikely to be able to afford appropriate legal action.**

Interdependence: the case of food aid

5.37 The nature of international economic interdependence means that the freedom of developing countries to choose technologies that they judge to be to their own advantage is influenced by decisions of policy makers and consumers in developed countries. For example, the agricultural policies of the US and the EU have been of particular significance in the case of food aid to three East African countries in 2002 (see Box 5.5).

²⁶ This refers to problems encountered by some cotton farmers in a specific area of the Mississippi Delta in the US, see Memphis Commercial Appeal (1997) Mississippi Investigates Monsanto's Cotton, 18 Aug 1997. Available at: <http://newgomemphis.com/newgo/core/archives.htm>. Accessed on: 10 Nov 2003.

Box 5.5: Food Aid

In the summer of 2002, several African governments rejected donations of food aid from the US through the World Food Programme (WFP). Zimbabwe, Mozambique and Zambia faced dramatic food shortages which threatened more than ten million people with starvation.* Their governments decided to refuse maize donations from the US on the grounds that the cereal was genetically modified.

In the autumn of 2002, Zimbabwe and Mozambique agreed to accept milled GM maize but the Zambian government remained unconvinced and rejected 63,000 tons of maize from the US, despite the threat of more than two million Zambians facing starvation.† The decision was based on an appeal to the precautionary approach (see paragraphs 4.35-4.42) as well as on advice from a team of Zambian scientists who undertook a fact-finding mission to the US, Europe and South Africa.

First, it was argued that circulation of GM maize in Zambia might lead to its uncontrolled spread, if kernels were used for planting rather than for consumption. There were fears that the unauthorised planting of GM maize could have unpredictable consequences in terms of gene flow and in particular, that pollen could eventually spread to fields on which non-GM maize might be grown for export. Given the *de facto* moratorium in the EU and its reluctance to accept imports of GM foods, there were concerns that a major future export market might be lost.‡

Secondly, although the governments of Zimbabwe and Mozambique had eventually decided to accept milled food aid, the Zambian government was sceptical about whether GM food was safe to eat. While acknowledging that GM maize may be safe for consumption by the US population where the crop forms a relatively small proportion of the diet, it was noted that maize accounted for as much as 90% of the typical Zambian diet. It was also feared that the high prevalence of HIV/AIDS in Zambia could bias the transferability of studies on food safety undertaken in developed countries. Thus, it was argued that GM maize might be unsafe for consumption by Zambians.

In response to the controversy, agricultural ministers of 20 African countries decided at a meeting of the COMESA in the autumn of 2002 to establish a regional policy on the trade and use of GMOs. A similar agreement was reached between delegates of the SADC who decided to establish an Advisory Committee on GMOs 'to develop guidelines to assist member states guard against potential risks in food safety, contamination of genetic resources, ethical issues, trade related issues and consumer concerns'.‡

In view of the number of people faced with starvation in Zambia, international critics took issue with the decision to refuse food that was considered safe by US regulatory authorities and was consumed by the US population on a regular basis.** Others expressed support for the Zambian position and referred to the notification procedure enshrined in the *Cartagena Protocol*, arguing for respect for the decision to reject GM food aid.†† Various donor countries agreed with the Norwegian Minister for International Development who, in February 2003, offered to finance GM-free donations where a recipient country made the explicit demand, and urged that all international donors should respect the principle of freedom of choice of recipient countries, which should be 'real and not illusive'.‡‡

* World Food Programme (2002) WFP launches massive regional appeal as starvation threatens millions. 26 Sept 2002. Available: <http://www.wfp.org>. Accessed on: 23 March 2003.

- † Mitchell P (2003) Europe angers US with strict GM labelling, *Nat Biotechnol* 21: 6.
- ‡ Zambia exported 254 metric tonnes of maize to the UK in 1999, and 88 metric tonnes in 2000. See FAO (2000) FAOSTAT. Available: <http://apps.fao.org/>. Accessed on: 20 May 2003.
- § GENET (2002) COMESA to have regional GM policy. Available: <http://www.gene.ch/genet/2002/Nov/msg00065.html>. Accessed on: 2 June 2003.
- ** The same stance was taken by India in January 2003, when it rejected a large shipment of GM maize and soybean. See Luce E (2003) India rejects gene-modified food aid, *Financial Times*, 3 Jan 2003.
- †† As noted, the US is not party to the CBD and hence neither to the *Cartagena Protocol*. In addition, the Protocol has not yet entered into force.
- ‡‡ Johnson HF (2003) Globalisation, Food and Freedom. *International Conference on GM Food*, Oslo, 5 Feb 2003. Available: http://odin.dep.no/ud/norsk/aktuelt/taler/statsraad_b/032171-090111/index-dok000-b-n-a.html. Accessed on: 20 May 2003.

- 5.38 The issues raised by food aid are complex. For example, it is noteworthy that the US donates food aid in kind, whereas the three other major donors worldwide, the WFP, the EU and the UK, donate in cash. The latter group argues that financial assistance allows for the quickest and most effective form of aid, which also supports local economies of countries close to the recipient country. The US, on the other hand, has provided aid to southern African countries entirely in the form of shipments of US maize. Indeed, the US Agency for International Development (USAID) emphasises on its website that in buying cereals from US farmers rather than from the world market or markets in developing countries, it actively seeks to subsidise US farmers and the US economy.²⁷ Furthermore, the US did not offer to provide milled maize, once it had become apparent that several African countries would prefer the donation in that form. This has led some to allege that USAID is seeking to play a role in a US-led marketing campaign designed to introduce GM food in developing countries.²⁸ There have also been reports that donations through the WFP have previously included GMOs, and that the recipient countries had not been informed accordingly.²⁹
- 5.39 While these events are quoted as evidence that food aid is being used to promote the marketing of GM crops, there are also reports that pressure has been put on developing countries from the opposite end of the spectrum. For example, it has been alleged that African leaders were advised by EU officials not to accept GM maize, as this would jeopardise current and future trade relations. However, this claim has been refuted vehemently by, amongst others, EU Development Commissioner Poul Nielsen.³⁰ With regard to discussions organised in Zambia, proponents of the use of GM crops reported that major workshops had been organised by national, regional and international consumer organisations. These had been attended by Zambian government officials, but apparently failed to provide balanced panels of speakers. It has also been alleged that inaccurate

27 'The principal beneficiary of America's foreign assistance programs has always been the US. Close to 80% of the USAID contracts and grants go directly to American firms. Foreign assistance programs have helped create major markets for agricultural goods, created new markets for American industrial exports and meant hundreds of thousands of jobs for Americans.' USAID (2002) Direct economic benefits of US assistance by State. USAID. Available: http://www.usaid.gov/procurement_bus_opp/states/. Accessed on: 30 Sept 2002.

28 Greenpeace (2002) USAID and GM Food Aid. Available: <http://www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/5243.pdf>. Accessed on: 18 May 2003; Friends of the Earth International (2003) *Playing with Hunger: The Reality Behind the Shipment of GMOs as Food Aid* (Amsterdam: Friends of the Earth International).

29 Pearce F (2002) UN is slipping modified food into aid, *New Scientist* 175 (2361): 5; Friends of the Earth International (2003) *Playing with Hunger: The Reality Behind the Shipment of GMOs as Food Aid* (Amsterdam: Friends of the Earth International).

30 Verbal statement at the conference *Towards Sustainable Agriculture for Developing Countries: Options from Life Sciences and Biotechnologies*, 30-31 Jan 2003, Brussels.

evidence had been presented which supported claims that GM crops posed dangers to human health and the environment.³¹

- 5.40 However, a number of recent authoritative reviews have concluded that, on current evidence neither GM crops, nor food produced from GM crops, pose a significant risk to humans who consume them.³² During the course of our investigation, we have been repeatedly impressed by the extent to which complex issues are over-simplified in public and policy debates. In a highly charged political atmosphere, the impact of public statements by influential bodies needs to be carefully considered, including the way in which those statements may be misinterpreted. In our view, there is a pressing obligation on all those who seek to be influential in the making of policy to weigh carefully all the current and relevant evidence and to consider the characteristics of specific uses of GM technology by comparison with other feasible systems. This obligation to base statements on an impartial consideration of the evidence applies as much to campaigning organisations as it does to any other public or professional body. We have therefore come to a sceptical view of claims from individuals or organisations who found their arguments on political convictions rather than scientific evidence.
- 5.41 We recognise that long-term reliance on food aid, whether provided in the form of GM or non-GM cereals, is highly undesirable. Clearly, assistance to developing countries should, where possible, be directed towards self sufficiency in food production. This is a complex task and GM crops could play a substantial role in improving agriculture. However, the question remains as to how developed countries can comply with their ethical obligations when emergencies arise. With regard to donations of GM crops as food aid **we note that the preferences of developing countries dependent on emergency food aid must be taken seriously. A genuine choice between GM and non-GM food should be offered, where this is possible. It will therefore be necessary to provide full information about whether or not donated food is derived wholly or in part from GM crops.**
- 5.42 **Where developing countries prefer to receive non-GM food, the World Food Programme and other aid organisations should consider purchasing it. This is subject to its availability at reasonable financial and logistical costs. Where only donations of GM varieties are available and developing countries object to their import solely on the basis of environmental risks, we recommend that it be provided in milled form.** This is because seeds from food aid donations are likely to be planted in developing countries, and it would be unacceptable to introduce a GM crop into any country in this way against its will. We further note that although milling increases the costs of providing food aid, it does allow for the fortification of the milled produce with micronutrients.

Interdependence: the impact of European and international trade policy

- 5.43 The issues associated with the provision of food aid derived from GM crops clearly illustrate the powerful influence that external factors can have on decision making regarding the use of GM crops in developing countries. As we have observed, the attitudes of consumers in Europe and the US and the provision of direct and indirect agricultural subsidies by

³¹ Institute of Science in Society (2002) African Consumer Leaders Support Zambia. <http://www.i-sis.org.uk/ACLSZ.php>. Accessed on: 31 Oct 2003. Consumers International organised a three day conference 18-21 Nov 2002 in Lusaka, Zambia. Delegates agreed the *Lusaka Declaration* which concluded that GM technology was not suitable to address problems of food security. See <http://www.consumersinternational.org/search/newssearch.asp?newsID=175®ionid=135&langid=1>. Accessed on: 31 Oct 2003.

³² GM Science Review (2003) First Report (London); The European Network on Safety Assessment of Genetically Modified Food Crops (ENTRANSFOOD) Forthcoming report; International Council for Science (ICSU) (2003) *New Genetics, Food and Agriculture: Scientific Discoveries – Societal Dilemmas* (France: ICSU); Royal Society (2002) *Genetically Modified Plants for Food Use and Human Health – an update* (London: Royal Society).

developed countries have been significant. However, the impact of EU regulatory policy for the management of GM crops and GM food may have an even greater impact.

- 5.44 In the case of GM food crops intended for export, decisions made by developing countries about the choice of crops are likely to be influenced by the selection of crops approved by European regulations. The revised *Directive 2001/18/EC* in conjunction with *Regulations 1830/2003/EC* and *1829/2003/EC on Traceability and Labelling* and on *Food and Feed* determine the types of GMOs that may be imported into the EU. Furthermore, if the current perception of the majority of European consumers that such imported materials are 'contaminated' prevails, it is very likely that GM food and feed, and products derived from GM crops, will be less competitive on European markets.
- 5.45 There are also issues with regard to ensuring the traceability requirements specified in the EU regulations. As we have said, most developing countries may find it difficult and costly to put in place adequate institutions and systems to assure required standards of monitoring. EU regulations may also have a significant financial impact when a developing country decides to use GM crops for domestic use only. As the thresholds for labelling are very low (0.9% for an approved GMO, and 0.5% for an unapproved GMO), care would have to be taken to prevent mixing of grain and flour from GM crops intended for domestic use with non-GM grain and flour intended for export. Ensuring adequate separation of the two is likely to be costly. It would be highly undesirable for developing countries to choose not to use higher yielding GM crop varieties for domestic use because of concerns about 'contamination' of non-GM crops for export.
- 5.46 Within any country, regulations similar to those in the EU would tend to discriminate strongly against poor small-scale farmers, for two reasons. First, the grades and standards of verification for, say, 1,000 hectares of a crop is more costly if those hectares are divided between 1,000 farmers, than if they comprise one very large (and almost certainly labour-displacing) farm.³³ Secondly, where the food supply chain comprises a great number of small-scale farmers connected through many small-scale retailers, the verification of GM content and processing methods will be much more expensive than for a few large farmers linked mainly to supermarkets or multinational exporters. Where traceability is required, the effect will be especially harmful to poor farmers. Under the newly approved EU regulations, the determination of the level and type of genetically modified DNA in the end-product will not suffice. Instead, verification will be required for all stages of the production and processing, throughout the whole food chain, from producer to final user.
- 5.47 Just as overly stringent regulation which focuses almost exclusively on the possible risks of GM crops discriminates against poor countries, so it also discriminates against smaller and poorer producers and retailers. Many small-scale farmers in developing countries grow crops for export such as sugar, coffee, tea, rubber and cotton. Small-scale farms are run by much poorer people, and employ considerably more workers per hectare than large plantation-based farms. It is therefore especially important that developed and developing countries avoid measures that discriminate against these small-scale growers.
- 5.48 Unless European consumers become far less sceptical towards GM crops, few developing countries will wish to grow them. We have observed that a rapid spread of GM crops has already occurred in several parts of the world (paragraph 3.21). However, scarcely any GM food and feed crops have been approved for commercial planting in the developing countries of Asia, Africa or the Middle East. This situation appears to derive in part from

³³ Reardon T *et al.* (2001) Global change in agrifood grades and standards: agribusiness strategic responses in developing countries, *International Food and Agribusiness Management Review* 2(3).

fears that a highly restrictive interpretation of the precautionary approach in Europe and Japan will close off export sales.

- 5.49 The freedom of choice that farmers in developing countries can exercise is severely restricted by the agricultural policy of the EU. This policy has been developed primarily to protect European consumers and the environment from potential dangers. But after almost a decade of use of GM crops, there is no robust scientific evidence that their consumption has adverse effects on human health.³⁴ There have been reports of gene flow from GM crops to other cultivars or wild relatives. However, as we have said (see paragraphs 4.28-4.34) this phenomenon is not specific to GM crops. It also occurs frequently in the case of organic and conventionally bred crops, and from improved crops, which have been changed in their genetic structure by exposure to radiation or chemical substances. In our view, the possibility of gene flow as such cannot justify the prohibition of the planting of a crop; only specific adverse consequences which result from it should provide the basis for such a decision (see paragraphs 4.28-4.34).
- 5.50 There is thus a considerable imbalance between the hypothetical benefits afforded by the EU policy for its own citizens, and the probable and substantial benefits that could be afforded to developing countries (see also paragraphs 4.1-4.2 of the 1999 Report). We conclude that the current provisions of the revised *Directive 2001/18/EC, Regulation 1830/2003/EC on Traceability and Labelling* and *Regulation 1829/2003/EC on Food and Feed* have not taken sufficiently into account the negative effect that these policy instruments are likely to have on those working in the agricultural sector in developing countries. It seems unlikely that the current and proposed European regulations will be substantially revised in the near future to prevent the raising of artificial trade barriers for GM products from developing countries. **However, we recommend that the European Union (EU), the UK Department for International Development (DFID) and appropriate non-governmental organisations which monitor the agricultural policy of developing countries examine the consequences of EU regulatory policies for the use of GM crops in developing countries. We recommend that the European Commission (EC) establish a procedure to report on the impact of its regulations accordingly.**

³⁴ FAO and WHO (2002) *Safety Aspects of Genetically Modified Foods of Plant Origin* Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, WHO, Geneva, Switzerland, 29 May – 2 June 2000 (Geneva: WHO); Royal Society (2002) *Genetically Modified Plants for Food Use and Human Health – an update* (London: Royal Society).