DRAFT FOR COMMENT

JUNE 2003

The use of genetically modified crops in developing countries

A follow-up Discussion Paper to the 1999 Report 'Genetically modified crops: the ethical and social issues'

NUFFIELD COUNCIL ON BIOETHICS

DEADLINE FOR RESPONSES:

8 AUGUST 2003

Nuffield Council on Bioethics

The terms of reference are as follows:

1 to identify and define ethical questions raised by recent advances in biological and medical research in order to respond to, and to anticipate, public concern;

2 to make arrangements for examining and reporting on such questions with a view to promoting public understanding and discussion; this may lead, where needed, to the formulation of new guidelines by the appropriate regulatory or other body;

3 in the light of the outcome of its work, to publish reports; and to make representations, as the Council may judge appropriate.

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The use of genetically modified crops in developing countries: a follow-up

Terms of reference

1 To examine recent, current and prospective developments in the use of genetically modified crops in developing countries, in particular:

  i) to review recent progress of research in the use of genetically modified crops in developing countries

  ii) to identify current and possible applications of genetically modified crops that would be of particular benefit to developing countries;

2 to re-examine and assess arguments set forth for and against the use of GM genetically modified crops in developing countries;

3 to assess the consequences of a moratorium on the use of genetically modified crops in developing countries;

4 to produce a short publication.

The use of genetically modified crops in developing countries: a follow-up

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Invitation to comment

10 June 2003

The Nuffield Council on Bioethics provoked considerable discussion with the publication of its Report, **Genetically modified crops: ethical and social issues** in 1999. Now, three years on, the Council has decided to produce a follow-up Discussion Paper, focusing specifically on the role of genetically modified (GM) crops in developing countries. We should like to invite comments on this draft version of the Discussion Paper.

The Council hopes that the draft Discussion Paper will contribute to, and complement '***GM Nation?***', the public debate which has been organised by the UK Government and will take place in the UK during 2003. There are two main reasons for the focus on developing countries. First, the Council was concerned that in the current discussion disproportionate attention was being paid to the implications of the use of GM crops in developed countries at the expense of consideration of poorer countries. Secondly, in the 1999 Report, the Council concluded on the basis of the evidence available, that there was a moral imperative for making GM crops readily and economically available to those in developing countries who wanted them. The Council felt it was important not to neglect perspectives of developing countries and to examine whether the arguments for its conclusion are still valid today. The draft Discussion Paper reviews recent scientific evidence and developments in policy, regulation and trade. In light of this information, the current and potential use of GM crops is re-assessed, and ethical issues are identified and examined.

This Discussion Paper is published as a draft for comment and we invite comments from members of the public, stakeholders and experts by **8 August 2003**. All responses will be circulated to the members of the Working Group and will be considered carefully. The Working Group has held a number of fact-finding meetings during the past four months, and we hope that the period for comment will enable more people to contribute their views. We would also particularly welcome comments from those in developing countries. The final Discussion Paper will be published in early October 2003.

Comments on the draft discussion paper should be sent to:

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Closing date for comments: **8 August 2003**

Further copies of the Draft Discussion Paper can be downloaded from:
www.nuffieldbioethics.org

Acknowledgements

Work on this Discussion Paper is in progress. The Council wishes to thank the members of the Working Group for their contributions thus far. Their expertise has been invaluable.

The Working Group is very grateful to a number of individuals who have assisted its work: Dr Andrew Cockburn, Dr Joseph DeVries, Dr Geoffrey Hawtin, Dr Luis R. Herrera Estrella, Mr Antonio Hill, Professor John O'Neill, Professor Robert Paarlberg, Professor Jules Pretty and Dr Ana Sittenfeld all reviewed an earlier version of this paper. The Council would also like to thank the following individuals who have raised important issues in fact-finding meetings with the Working Group, which have been held between February and May 2003: Dr Andrew Bennett, Professor Gordon Conway, Professor Phil Dale, Professor Steve Jones, Professor Julian Kinderlerer, Professor Ingo Potrykus, Dr Richard Tapper and Mr Alex Wijeratna; and Dr Kerry ten Kate who has given valuable advice. The Council is also grateful to Kate Miller who assisted with research for this paper during an internship in January 2003.

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Executive Summary

Work on this Discussion Paper is still in progress. This version is a draft for comment. The executive summary below is therefore an interim summary, presenting our findings up to this stage of our work. A final Discussion Paper will be published in early October 2003.

Background

This draft Discussion Paper is a follow-up to our 1999 Report **Genetically modified crops: the ethical and social issues.** Its purpose is to assess the potential risks and benefits associated with the use of genetically modified (GM) crops in developing countries in relation to improving food security and economically valuable agriculture.

We are aware that in focusing on the contribution of GM crops we consider only part, albeit an important one, of a large and complex picture. Stable political environments, appropriate infrastructures and agricultural policies, access to land and water are all important. **However, we conclude that, in particular cases, GM crops can contribute to substantial progress in improving agriculture in parallel to the inevitably slow changes at the socio-political level. GM crops can also be used to prevent environmental degradation, and to address specific ecological and agricultural problems which have proved less responsive to the standard tools of plant breeding and organic or conventional agricultural practices.**

We conclude that possible costs, benefits and risks associated with particular GM crops can only be assessed on a case by case basis. Any assessment needs to take into account a variety of factors, such as the gene, or combination of genes, being inserted, the target crop, and the agro-ecology and economy of the developing country. **We recommend focusing on the specific situation in particular countries and to ask the question: 'How does the use of a GM crop compare to other alternatives?'**

Main findings

We consider a number of Case Studies which lead us to conclude that the **use of GM crops can, in some circumstances, have considerable potential to increase yields of crops, thereby improving agricultural practice and the livelihood of poor people in developing countries. Thus, we affirm our conclusion of the 1999 Report that there is an ethical obligation to explore these potential benefits responsibly, in order to contribute to the reduction of poverty, and to improve food security and economically valuable agriculture.**

We take the view that there is not enough evidence of actual or potential harm to justify a moratorium on either research, field trials, or the controlled release of GM crops into the environment at this stage. We recommend that research on the use of GM crops in developing countries be sustained. However, much of the current research on GM crops serves the interest of large-scale farmers in developed countries. There is also continuing concentration in the number of companies that control between them the provision of seeds, agrochemicals and important research technology. Consequently there is a serious risk that the needs of small-scale farmers in developing countries will be neglected. **We therefore affirm the recommendation made in our 1999 Report that genuinely additional resources be committed by governments, the European Commission and others, to fund a major expansion of public GM-related research into tropical and sub-tropical staple foods, suitable for the needs of small-scale farmers.**

We consider that particular care needs to be given to the way in which the *precautionary principle* is applied when making decisions about the use of GM crops. Highly restrictive interpretations invoke the fallacy of thinking that the option of 'doing nothing' is itself without risk. However, in some cases the use of a GM crop variety may well pose fewer risks than the agricultural system already in operation. **Therefore, in applying the precautionary principle, risks arising from the option of inaction must also be considered.**

Specific issues relating to international interdependence in the context of trade, regulation and food aid

The impact of European regulations on GM crops

The freedom of choice of farmers in developing countries is being severely challenged by the agricultural policy of the EU. Developing countries might be reluctant to use GM crops because of fears of jeopardising export markets. They may also not be able to provide the necessary infrastructure to comply with EU requirements for traceability and labelling.

If developing countries decide to use GM crops for domestic use only, problems may arise for exports if separation of GM crops and non-GM crops cannot be achieved readily. Small amounts of GM produce could mix with non-GM produce that are stored for export. Since EU regulators currently suggest a very low threshold for the labelling of produce as 'GM' (from 0.5 or 0.9 % presence of genetically modified material), non-GM produce might have to be labelled as GM. If current attitudes among EU policy makers and consumers prevails, this would result in a considerable disadvantage to exports from developing countries on the European market.

Further, scepticism by some NGOs from developed countries, who often exaggerate the risks associated with the use of GM crops, may complicate matters. Policy makers in developing countries are therefore faced with very difficult choices. If a national policy that allows the responsible use of GM crops for domestic use is adopted, it might well be perceived as promoting unsafe foods, and, in addition, could result in the loss of EU export markets.

Therefore, there is 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. Current and proposed regulatory provisions have not sufficiently considered the effect that these policy instruments are likely to have on those dependent upon the agricultural sector in developing countries. **We recommend that the EU, the Department for International Development (DFID) and appropriate non-governmental organisations who monitor agricultural policy of developing countries pay particular attention to the consequences of EU regulatory policies for GM crops. Developing countries may be reluctant to explore the possible benefits of using GM crops in particular instances because of the implications of EU policies. Potential adverse effects need to be examined and we recommend that the EC establish a procedure to report on the impact of its regulations accordingly.**

The case of food aid

The issues raised by food aid are complex. In view of the current evidence relating to assessments of safety of GM foods, we are not convinced that donations which have been derived from GM crops pose any significant risks to humans who eat them. **However, we take the view that the preferences of developing countries dependent on emergency food aid must be taken seriously. A genuine choice between GM and non-GM food must be offered, where this is possible. It is therefore necessary to provide full information about whether or not donated food is derived wholly or in part from GM crops.**

Where developing countries prefer to receive non-GM grain, the World Food Programme and other food aid organisations should purchase it. This is subject to such grain being available in sufficient amounts, with reasonable financial and logistical costs, and where it can be provided quickly enough to address the emergency situation. 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 food aid be provided in milled form. Grain from food aid donations is likely to be planted in developing countries. It would be unacceptable to introduce a GM crop into any country in this way.

Regulation of GM crops in developing countries

We suggest that the most appropriate approach for the regulation of GM crops would normally be a centralised and evidence-based safety assessment at the national or regional level. Possible risks for the health of consumers and for the environment should be assessed on a case by case basis. Wherever possible, such assessments should take into consideration information which is available from international sources. However, many developing countries lack the capacity to undertake such assessments. **We therefore welcome and endorse initiatives to promote the strengthening of capacity in relevant regulatory and scientific expertise, which have recently been launched jointly by the United Nations Environment Programme and the Global Environment Facility (UNEP/GEF).**

Micronutrient-enriched GM crops

Particular controversies surround the use of GM crops such as Golden Rice which can provide increased levels of crucially important micronutrients, in this case vitamin A. We consider that Golden Rice could make a valuable contribution where other means of obtaining sufficient levels of vitamin A are more difficult to provide. Since it is not yet clear how effective the approach is, **it is essential that reliable empirical data from nutritional and bioavailability studies be obtained as a priority. In addition, the cost-effectiveness, risks, and practicality of such approaches in comparison to other means of addressing deficiency of micronutrients need to be evaluated.**

Section 1
Introduction

Background

1 In May 1999, the Nuffield Council on Bioethics published a Report on **Genetically modified crops: the ethical and social issues.**[1] When we first began the work in 1997, issues raised by the use of genetically modified (GM) crops had received relatively little attention from the public. However, by the time the Report was published, plants and animals which had been produced by means of genetic modification had been likened in the media to Frankenstein's monsters, implying that reckless academic and commercial scientists were endangering the natural world. This view gained considerable support and GM crops were frequently referred to as 'Frankenfoods'. Our Report therefore entered a turbulent debate. In his foreword the Chairman of the Working Party, Professor Alan Ryan, wrote:

> 'As Reports of previous Working Parties have had occasion to observe, heat and light are not the same thing. We have been struck by the extent to which hard-to-allay fears are aroused by almost any discussion of genetic science, not only in this context, but also in the contexts of cloning and the genetic components of physical and mental illness.'

2 In June 1999, the Environment Ministers of the European Union (EU) declared a *de facto* moratorium on the use of GM crops which had not yet received regulatory approval. Since then, the controversy about their use has persisted and intensified. In many parts of Europe, experimental field trials on GM crops have been sabotaged. In the UK, some farmers, fearing repercussions, withdrew from such trials. Widespread discomfort about GM can also be gauged from the fact that many supermarkets and restaurants label produce as 'GM-free'. Some landowners have signs on their land which, in analogy to phrases used in the anti-nuclear power and weapons protests, declare a 'GM-free zone'.

3 Many view these developments with dismay and are unconvinced about the risks of GM crops. Most people believe that evidence-based rational assessment should take the place of scaremongering and highly vociferous debates. As one way of contributing to a more balanced and open discussion, the UK Government announced in 2002 a public debate on possible uses of genetic modification. It comprises three strands: a series of public meetings and discussions on issues arising from genetic modification;[2] an economic analysis of the costs and benefits of using GM crops;[3] and a review of the science underlying the genetic modification of plants.[4]

4 The Council decided to complement the various initiatives by producing a Discussion Paper to follow-up its 1999 Report. This Paper focuses in particular on the role of GM crops in developing countries (see Box 1). There were two main reasons for this decision. First, the Council was concerned that in the current debate, disproportionate attention was being paid to the implications of the use of GM crops in developed countries, at the expense of consideration of poorer countries. This narrow focus ignores the possibility that decisions made about the use of GM crops in developed countries may also have considerable consequences for those in developing countries. Furthermore since 1999, the total area planted with GM crops in developing countries has more than doubled, from 7.2 to 16.0 million hectares.[5] These

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1 The Executive Summary of that Report is at Appendix 1.

2 GM Nation? The Public Debate. Available: http://www.gmpublicdebate.org.uk/press/index.htm. Accessed on: 18 May 2003.

3 GM Crops - Strategy Unit Study. Available: http://www.strategy.gov.uk/2002/gm/summ.shtml. Accessed on: 18 May 2003.

4 GM Science Review. Available: http://www.gmsciencedebate.org.uk/. Accessed on: 18 May 2003.

points raise several important questions. How does the increased use of GM crops affect agricultural practice, malnutrition and food security in developing countries? What are the implications of the use of GM crops for employment and the reduction of poverty? Does the introduction of GM crops in developing countries raise issues with respect to health and the environment which differ from those examined in studies in developed countries? What are the implications of the use of GM crops for farmers in developing countries who are involved in domestic and international trade?

5 Secondly, in our 1999 Report, we concluded on the basis of the evidence available, that there was a moral imperative for making GM crops readily and economically available to those in

Box 1: **The use of the term 'developing countries'**

A useful approach to differentiate between countries at different levels of development is to consider the gross national income (GNP) per person. Unless otherwise stated, we therefore mean by *developing countries* those countries with a GNP in 2001 of less than US$9,206 *per capita* at official exchange rates.[*] However, a country's economic development, the well-being of its population, and its capacity to benefit from decisions and policies made in the developed world depend on much more than average GNP. For example, the purchasing-power of a country's currency; the composition and efficacy of its spending, especially on basic health and education; its income distribution; and its climatic and other risks are also influential. A succession of annual United Nations Human Development (UNHD) reports has endeavoured to allow for such matters. In practice, indicators of mean GNP (especially allowing for purchasing-power parity (PPP)) and of the proportion of people below the PPP dollar poverty line together provide a rough guide to levels and trends of welfare, and are closely correlated with human indicators such as life expectancy and access to education.[†]

Although, according to this classification, there is some homogeneity among the various countries that qualify as 'developing', it is important to consider the particular situation of each country when assessing the benefits and risks related to the introduction of a specific GM crop. Many factors relating to the agro-ecological and socio-economic context will influence this evaluation: for example, which specific climatic conditions prevail? Which other, or related types of crops occur naturally in the country? To what extent is water for irrigation available? What level of infrastructure is in place? Are farmers substantial users of purchased agrochemicals such as fertilisers or pesticides? Do they consume or sell most of the products from their farms? If the latter, is their production intended for domestic markets or for export? What access to markets does a country have, and how does the level of subsidies provided to competing agricultural products from developed countries affect its products? To what extent is the country governed by national or regional regulations relating to biotechnology? All these factors can greatly affect the deliberations about the benefits and risks related to the use of specific GM crops. Hence, generalised judgements about possible benefits and risks of 'GM crops' to 'developing countries' as such, are of limited use. Instead, it is much more helpful to focus on particular countries, or, where possible, on sufficiently similar types of countries, to assess the impact of a GM crop on the environment, agriculture and economy.

[*] World Bank (2003) World Development Report 2003. Washington, DC: Oxford University Press and World Bank. p. 233–5.

[†] World Bank (2003) World Development Report 2003. Washington, DC: Oxford University Press and World Bank. p. 234–7.

[5] Globally, the total area planted with GM crops has risen from 39.9 million hectares in 1999 to 58.7 million hectares in 2002. (James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.)

developing countries who wanted them (see paragraphs 4.1-4.82 of the 1999 Report). We wanted to ask whether the arguments for this conclusion were still valid today. To answer this question, and to assess the possible consequences of EU agricultural policy and the increasing use of GM crops in many parts of the developing world, the Council decided that it would be valuable and timely to re-examine the current and possible future role of GM crops in developing countries in the light of recent scientific evidence and developments in policy and regulation. This requires a careful analysis of the benefits and risks associated with their use. Below we briefly outline what these are commonly held to be.

Benefits and risks associated with the use of GM crops in developing countries

Possible benefits

6 GM crops (see Box 2) might offer advantages where other forms of plant breeding, agricultural practice or farm land management are not suitable to address specific problems prevalent in many developing countries. For example, some GM crops can provide improved resistance to disease and pests which occur primarily in the developing world. Genetic modification may enable the production of more nutritious crops. These could provide people in developing countries, who often lack important micronutrients, with sufficient amounts through consumption of their main staple food. There is also research to develop crops that are better suited to cope with stresses such as drought, or saline soils, which are found in many developing countries.[6]

7 GM crops might further prove to be an important tool in accelerating the increase of crop yields, especially of staple crops.[7] This might be particularly relevant for small-scale, resource-poor farmers in developing countries, two thirds of whom rely mainly on agriculture for their living.[8] Increased yields could also lead to higher demands for labour in agriculture. This could imply growth in employment income among the malnourished, and would have a positive effect on their ability to afford sufficient food. Such developments would be valuable, as it has become clearer that both the reduction of poverty and growth in crop yields have slowed down in most of the developing world since the 1970s. Moreover, poverty has persisted and yields of crops remained low in most of Africa, the poorest continent of the world.[9] We therefore examine which kinds of GM crops have been grown in particular developing countries, and assess whether there have been, or are likely to be, noteworthy improvements for farmers growing these crops.

Box 2: **Genetic modification**

Genetic modification allows selected individual genes to be transferred from one organism into another, including genes from unrelated species. The technology can be used to promote a desirable crop character or to suppress an undesirable trait (see paragraphs 34-47).

6 Thomson J (2002) Genes for Africa: Genetically Modified Crops in the Developing World. Cape Town: University of Cape Town Press; Conway G (2003) From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. Accessed on: 16 April 2003.

7 The term staple crops refers to crops which are mainly used for household consumption. By non-staple crops we mean crops which are grown predominantly for sale.

8 World Bank (2003) World Development Report 2003. Washington, DC: Oxford University Press and World Bank.

9 Between 1987 and 1998 the percentage of people living on less than US$1 a day in Sub-Saharan Africa remained unchanged at 46%. (World Bank (2001) World Development Report 2000/2001: Attacking Poverty. Washington, DC: The World Bank and Oxford University Pres.) See also Huang J, Pray C and Rozelle S (2002) Enhancing the crops to feed the poor, **Nature** 418: 678-84.

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Possible risks

8 However, any deliberation about the benefits of a technology clearly also needs to address likely risks. Some commentators take the view that possible implications of GM crops for the health of consumers have not yet been sufficiently examined even in the developed world. In a common, but controversial, interpretation of what is known as the *precautionary principle*, critics argue that GM crops should not be used anywhere unless there is a guarantee that no risk will arise (see paragraphs 118-121).[10] Similar demands are made with regard to the impact of GM crops on the environment. Critics point to the risk of potentially irreversible effects on *biodiversity*, which can be understood as the variety of plants, animals and other organisms that exist in nature. Genetic material from GM crops could be transferred to other plants and organisms. This could lead to unpredictable transformations. Critics therefore argue that unless there is certainty about the absence of such risks, neither field trials, nor commercial planting should take place.

9 With regard to the use of GM crops in developing countries, this concern is perceived to be of particular importance. Many regions are the *centre of origin* of modern crops, such as cotton or maize. These regions usually comprise a considerable variety of crops and wild relatives, which might be irreversibly altered by the transfer of genetic material from GM crops.[11] Critics also assert that encouraging the adoption of GM crops by developing countries demonstrates a lack of sensitivity to their vulnerable position. Many such countries urgently need to address issues of food security and may be tempted to adopt hastily a technology that could pose severe risks.[12]

10 There are also concerns about how and by whom GM crops are developed and delivered. The substantial benefits which accrued in developing countries from the Green Revolution (see Box 3) were largely the result of research undertaken in the public sector. But most research on GM crops is being undertaken by a relatively small number of private companies. Although there is significant work undertaken in the public sector, many of those who object to the use of GM crops fear that research will be directed primarily towards commercial users in developed countries.[13] Thus, it could be that only large-scale industrial farmers will benefit, while the needs of small-scale, resource-poor farmers in developing countries will be neglected.

Box 3: **The Green Revolution**

The Green Revolution is the popular term for the development and spread of high-yielding staple foods in developing countries. This began with maize hybrids in the 1950s, but the main component was the introduction of semi-dwarfed wheat and rice varieties, mainly to parts of Asia and Central America with well-functioning systems of irrigation, between 1962-1985.* The Green Revolution was brought about almost exclusively through research undertaken by institutions in the public sector. Apart from systematically spreading crop varieties that would flourish in a wide range of environments, it also involved a considerably increased use of fertilisers.

* Lipton M and Longhurst R (1989) New Seeds and Poor People. London: Routledge.

10 British Medical Association (1999) The Impact of Genetic Modification on Agriculture, Food and Health: An Interim Statement. London: BMA. Oxfam (1999) Genetically Modified Crops, World Trade and Food Security: Oxfam Great Britain position paper. Oxford: Oxfam.

11 FAO Electronic Forum on Biotechnology in Food and Agriculture (2002) Background paper to the 7th conference, 31 May -6 July 2002. FAO. Available: http://www.fao.org/biotech/C7doc.htm. Accessed on: 23 March 2003.

12 Independent Science Panel (2003) The Case for a GM-free Sustainable World. London: ISP.

13 Five Year Freeze (2002) Feeding or Fooling the World? London: Five Year Freeze.

11 Doubts have also been expressed about the technical and financial capacity of some developing countries to develop and apply regulation to ensure the safe use of GM crops.[14] Further, there is concern that a focus on GM-related applications may detract from efforts to explore other ways of enhancing agriculture, such as fostering more relevant national and international policies, improving systems of seed production and distribution, and promoting better development of markets and improved agricultural practices.[15] We consider these and other arguments in the sections that follow.

Structure and methodological approach

12 In this draft Discussion Paper, we review recent scientific, regulatory and policy-related developments with regard to the use of GM crops in developing countries. We assess the potential of the technology to improve the effectiveness of agriculture under challenging climatic conditions, and we identify important ethical issues arising in this context. We begin by outlining in Section 2 the economic and demographic observations which guided our deliberations on the use of GM crops in developing countries in the 1999 Report and contrast them with recent evidence. In Section 3 we explain the basic principles behind the genetic modification of plants, and we present seven Case Studies which illustrate some of the scientific evidence that has been gathered over the past three years on the current and potential use of GM crops in developing countries. This is followed by a discussion of socio-economic and ethical arguments about their use (Section 4). We then consider ethical issues raised by developments in governance, national and international regulation, and trade, in relation to GM crops (Section 5). Section 6 examines issues about the control of and access to technologies required for genetic modification, and Section 7 summarises our present findings.

13 The Paper does not provide an exhaustive account of how to improve food security and reduce poverty in developing countries. Focusing on the role of GM crops we consider only part, albeit an important one, of a large and complex picture. We are aware that, for example, the Food and Agriculture Organisation (FAO) of the United Nations (UN) has listed war and other forms of armed conflict as the exclusive cause of food emergencies in 10-15 developing countries during the last three years.[16] Problems also arise in some countries from worsening economic conditions for agriculture. These result from the failure of national agricultural policies and the absence of private organisations that could fill the void of state services. There are also instances of poor governance and corruption. Such problems urgently need to be resolved. However, it is likely that even if and when they are resolved, other substantial problems are likely to remain for agriculture such as difficult climatic conditions. In this context, GM crops could have a role to play, which we examine in more detail below. Restricting our examination to the specific question of what kind of technical contribution GM crops can make to improving agricultural practice in developing countries does not mean that we are indifferent to, or complacent about, the prevailing geo-political context in the majority of developing countries.[17]

14 We take a sceptical view about broad, often sweeping, generalisations of either the benefits or the risks associated with the use of GM crops in developing countries. As will be clear throughout this draft Discussion Paper, there are considerable differences in the way in which:

14 See, for example, the discussion at the most recent FAO Electronic Forum on Biotechnology in Food and Agriculture, 28 April – 25 May 2003, Available: http://www.fao.org/biotech/logs/c9logs.htm. Accessed on: 23 May 2003.

15 Oxfam (1999) Genetically Modified Crops, World Trade and Food Security: Oxfam Great Britain position paper. Oxford: Oxfam.

16 FAO (2003) Foodcrops and Shortages. Global Information and Early Warning System on Food and Agriculture. Available: http://www.fao.org/giews/english/fs/fstoc.htm. Accessed on: 13 May 2003.

17 This should also be clear from our discussion of issues arising in context of global food and trade policy in Section 5.

(a) socio-economic conditions, agricultural practices and national regulations bear upon decisions over GM crops in different developing countries (see Box 1);
(b) the impact of international and regional trade policies affect a variety of developing countries; and
(c) traits of particular GM crops pose risks and benefits to the health of consumers and to the environment.

15 The interplay of these factors makes generalisations about the use of GM crops in the developing world almost impossible. For example, increased yields resulting from the use of GM sweet potatoes that are resistant to particular pests will usually be to the advantage of small-scale, resource-poor farmers in rural Africa, who can thus make better use of their harvest. However, it may also be the case that the use of GM crops could be to the detriment of agricultural workers, as has recently been reported from Argentina. Here, the use of particular GM soybeans appears to have led to a considerable reduction in the demand for labour on large farms.[18] We also note that discussions about the benefits and risks of GM crops are as much about politics and economics as they are about technological issues. Thus, whether or not the use of a GM crop will be beneficial will depend on many factors. Even if the technology delivers its promises and poses negligible risks on the scientific level, political constraints arising from, for example, restrictive trade policies of specific markets, may lead to the conclusion that it is better not to use a GM crop in a particular context. We therefore take the view that it is important to focus on the specific situation in particular countries and to ask the question: ‘How does the use of a GM crop compare to other alternatives?’ This approach might lead to the conclusion that there may be other safer, more efficient or more economic options. It could also mean that GM crops might have attractive benefits in particular cases.

18 Branford S (2002) Why Argentine can’t feed itself – how GM soya is destroying livelihoods and the environment in Argentina. *The Ecologist* Vol 32 No 8. Farming Today Radio 4 (2003) Farming today this week: Saturday 17th May. BBC. Available: http://www.bbc.co.uk/radio4/news/farmingtoday/index.shtml. Accessed on: 20 May 2003.

Section 2
The socio-economic context: the role of agriculture in developing countries

16 In this section, we outline the economic and demographic observations which guided our deliberations in our 1999 Report in relation to the use of GM crops in developing countries. The focus of these observations was on possibilities for the improvement of agricultural practice, food security, and reduction of poverty. We summarize our findings from the 1999 Report in this area, and contrast them with recent evidence regarding the growth of populations in developing countries, focusing in particular on the growth of populations of working age. We then discuss the relation between the availability of food and the demand for labour. This leads to conclusions about the role of agriculture in developing countries with regard to the reduction of poverty.

The framework of the 1999 Report

17 In our 1999 Report, we approached the question of whether GM crops can offer benefits for poor people in developing countries through the following argument. Food production has kept ahead of growth in population in the past 60 years. This was the case not only globally, but, quite dramatically, also in most of Asia and much of Latin America, even where the area of available farmland could not be increased. Largely this was because a yield-enhancing Green Revolution (see Box 3) created considerable employment and greatly improved life for small-scale farmers and landless labourers. It also brought cheaper and more reliable staple foods to poor consumers. In consequence, yields of small-scale farmers and incomes for those in rural employment rose, and poverty and hunger fell dramatically in many countries between 1970-90.

18 However, parts of Asia saw little gain; and in most of Africa, agricultural production grew no faster than population. In the 1990s, the improvement in yields, and the rate of decline of global poverty, were far less than in the previous two decades. Yield expansion had been curtailed by various factors, such as shortages of water, loss of soil, emergence of new types of pests and disease, and by the fact that important crops such as semi-dwarfed rice and wheat spread first into the best-suited lands, leaving less dynamic crops and areas for later use. These trends looked set to continue, as did a rise in the population, and even more significantly, in the number of persons of working age. Even in countries such as India, with aggregate surpluses of food, people remained unable to afford enough to eat, unless they were able to increase their incomes from employment.

19 Employment can be provided most readily in industry or agriculture. However, it is more expensive to create extra workplaces in industry, as this requires, amongst other things, reliable infrastructure and well functioning markets. The provision of employment in agriculture, on the other hand, can be achieved at lower costs. Growth in rural non-farm workplaces, which was the source of much reduction in rural poverty after the initial Green Revolution in China and elsewhere, depended mainly on demand from nearby small-scale farmers and their employees. Hence, we came to the following conclusions in our 1999 Report, which have been reinforced by evidence accumulating in 1999-2003:

To resume the rapid reduction in poverty and malnutrition of the 1970s and 1980s (despite continued expansion of the population and workforce) and to extend it to Africa, employment on farms and the growth of productivity in relation to staple crops had to be revived, either through the expansion of farmland, or the increase of yields.

The expansion of farmland was seldom feasible, environmentally and otherwise.

Conventional plant breeding was still making very substantial contributions in the growth of yield. But its effect was increasingly reduced by new types of pest, exhaustion of micronutrients, shortage of water, unsuitability of land (especially in Africa) for important semi-dwarfed varieties of rice and wheat, and overall exhaustion of the huge potential created by the early breakthroughs of the Green Revolution.

GM crops as a tool of, and addition to, conventional plant breeding, could revive, stabilise and spread the growth in yields of food staples, and of other crops grown by poor people.

This would be particularly relevant for areas so far untouched by the Green Revolution. Genetic modification could be used to develop crops that were better suited to environmental constraints, and yields could be increased considerably.

Growth in populations

20 Although growth in population has progressed somewhat more slowly than anticipated, it is expected that the present global population of approximately 6.3 billion people will increase to 8.1 billion people by 2030.[19] In Asia and Africa, growth in population between 2000-2030 is expected to be 0.95% and 1.76% respectively. Those regions and groups initially most subject to poverty and under-nutrition are expected to increase the most rapidly. Hence, requirements for food are likely to rise substantially.[20] More important is the even faster rise predicted in the workforce, and in particular of the numbers of people of working age. Unless this is at least matched by rising demand for people to take on workplaces, employment or wage-rates will fall and the hungry will have even more difficulty in affording enough food.

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19 Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat (2003) World Population Prospects: The 2002 Revision. New York: United Nations.

20 A major increase in production of food grain per head will further be required, as increasing urbanisation, growth of populations and rise in incomes will lead to a higher demand for meat and dairy products. Between now and 2020 this demand in developing countries is expected to double (Delgado C *et al*. (1999) Livestock to 2020: The Next Food Revolution (2020 Vision for Food, Agriculture and the Environment Discussion Paper 28). Washington, DC: IFPRI.) However, this means that the demand for cereals used for animal feed will increase substantially, as approximately three to seven times as much cereals are needed to provide the same amount of calories for people who consume animals as food.

21 In Asia and Africa, populations of working age (15-59) are projected to grow faster than populations of non-working age (respectively at 0.98 and 2.26% in 2000-2030 compared to 0.89 and 1.40%).[21] In 2030, therefore, Africa's population will be 1.76 times its level in comparison to 2000. However, the working-age population will be 1.97 times larger while the non-working-age population will only be 1.52 times larger. This higher ratio of workers in relation to the total population can be advantageous if it is complemented by improved working opportunities. These are most affordable where agriculture raises yields and demand for labour, but they are a burden if it does not.

Availability of food and demand for labour

22 Improvement in the diet of poor people depends on growth not only of the supply of food and nutrients, but also of demand for their labour, which provides them with income.[22] Yet it has become even clearer since our 1999 Report that the extent of undernourishment is substantial, and that the decline in undernourishment has stalled. According to the FAO, globally, 815 million people were undernourished in 1997-1999, of whom 777 million were living in developing countries. One third of the population of Sub-Saharan Africa is undernourished.[23]

23 The recent report on rural poverty produced by the International Fund for Agricultural Development (IFAD) provides some evidence about the role of agriculture, enhancement of yield within agriculture, and GM plants, as possible sources of greater or more stable yields in providing food and/or labour income to poor people.[24] Two thirds of the world's poor depend mainly on agriculture for their livelihood. The poorest are often in remote areas and depend on the production of local staple foods. Moreover, agricultural production and employment create the demand that allows nearby rural non-farm activity to flourish.

24 Seventy per cent of the world's poor live in rural areas. Despite urbanisation, over half will remain in these areas until 2035.[25] The role of agriculture is therefore crucial, as its rapid growth can lower and stabilise the cost of food to poor consumers living in rural and urban environments. Where, as in the Green Revolution, small-scale agriculture has been a major beneficiary, it has been associated with unprecedented reduction of poverty. This has been evident in the case of China in 1975-96, India in 1975-90 and Indonesia in 1970-95. Rapid agricultural growth, achieved labour-intensively and on smallholdings, remains the best hope for poor people to enhance their prospects to achieve sufficient availability of food, and sufficient access to work or land to afford it. But this will happen only if farming is more lucrative. In view of the fact that expansion of the agricultural area is uneconomic in most parts of the world, this will only be achieved by the enhancement of yields (see Appendix 2).

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21 This is because the steep fall in child mortality in 1950-70 initially raised the child/adult ratio but then reduced it, as the larger number of child survivors reached working age, while the subsequent decline in birth rates (even in Africa) after 1985 has steadily moderated, and in some developing countries even reversed, the growth in numbers of newly born children. (Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat (2003) World Population Prospects: The 2002 Revision. New York: United Nations.)

22 FAO Electronic Forum on Biotechnology in Food and Agriculture (2000) Background Paper to the 1st Conference, 20-26 May 2000. Available: http://www.fao.org/biotech/C1doc.htm. Accessed on: 18 Mar 2003; DFID (2002) Better Livelihoods for Poor People: The Role of Agriculture. London: DFID.

23 FAO (2002) The State of Food and Agriculture 2002. Rome: FAO.

24 IFAD (2001) Rural Poverty Report 2001 - The Challenge of Ending Rural Poverty. Rome: IFAD.

25 Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat (2003) World Population Prospects: The 2002 Revision. New York: United Nations.

25 Other factors can help, notably in two ways. First, by lowering barriers erected by developed countries to agricultural imports from poor countries. Secondly, by reducing subsidies to domestic farmers in developed countries. The latter induces them to glut world markets of agricultural products, and depresses both prices, and consequently the attractiveness, of agricultural production in developing countries. However, history suggests that these distortions will improve only slowly. Also, such improvements will do little to help the many very poor farmers in developing countries, especially in Africa, who are in substantial food deficit. Thus, the growth of farm yields of developing countries still remains central to better income and food security for the world's poor.

26 What has been learnt, since our 1999 Report, about the prospects of poor people achieving and benefiting from labour-intensive agriculture on small-scale farms? Over 90% of the world's poor live in Asia and Africa.[26] In the 1970s and 1980s, Asian agriculture has kept ahead of growth in population, and substantially improved availability of food per person. However, recent studies confirm that this improvement has subsequently faltered, and did not spread to more than a few countries in Africa. In many of these countries nutritional standards have actually declined.[27]

Climatic and ecological challenges for agriculture in developing countries

27 At the same time, physical conditions for agriculture appear to be becoming increasingly difficult. While there are distinguished dissenters, a large majority of agro-climatologists (as represented in the UN International Commission on Climate Change) believe that extreme weather conditions are becoming more frequent, especially in and near the inter-tropical convergence zone.[28] It is also assumed that even in normal years, water shortages are increasing in tropical areas, due to higher air temperatures, and therefore higher rates of evaporation and plant transpiration. Both trends are expected to accelerate. Even if the majority view on 'global warming' may be too pessimistic, the demand for water from expanding urban populations and industries adds to the problem. Work subsequent to our 1999 Report confirms an even sharper increase in the proportion of people and countries facing water shortages now and in the future than previously anticipated.[29] Thus, availability of water will increasingly pose problems for agriculture. At the same time in almost all of Asia, and in a growing majority of countries of Africa, agricultural progress has to depend on yield expansion, for it has become clear that expansion further into marginal lands is unprofitable and increases environmental hazards. Moreover, the quality of soil is in many places poor or actually decreasing, due to erosion, salination, loss of micronutrients, and accumulation of heavy metals.[30]

26 Earning less than one dollar a day at constant international purchasing-power of 1996.

27 There has also been a faltering in the yield growth in the long run for major staple foods in developing countries, between the 1960s and the 1990s, confirming the discussion in the 1999 Report (paragraphs 4.16-4.17). (See Lipton M (1999) Reviving Global Poverty Reduction: What Role for Genetically Modified Plants?, in *1999 Sir John Crawford Memorial Lecture*. 28 October 1999. CGIAR International Centers Week, Washington, DC.)

28 The inter-tropical convergence zone (ICTZ) is a region that encircles the Earth, near the equator, where the trade winds of the Northern and Southern Hemispheres come together, resulting in an almost perpetual series of thunderstorms. Examples of countries affected by the ICTZ include Zaire, Kenya and the People's Democratic Republic of the Congo.

29 Cosgrove WJ and Rijsberman FR (2000) World Water Vision. London: World Water Council.

30 AEBC (2002) Looking Ahead - An AEBC Horizon Scan. London: Department of Trade and Industry; Kendall H *et al*. (1997) The Bioengineering of Crops: Report of the World Bank Panel on Transgenic Crops. Washington, DC: World Bank. We consider in paragraphs 112-121 the possible effects of existing or likely GM crops on the environment, in developing countries and more widely.

28 In short, to safeguard the environment from degradation, it is increasingly important to achieve higher agricultural production and employment income, not by further expansion of cultivation into increasingly fragile land and by increased use of water, but by more productive and more conservative use of land and water already devoted to farming.[31] GM crops may well have a significant contribution to make towards such progress. For example, genetic modification could be used to express traits that allow crops to grow on less fertile, or saline soil. The technology could also be used to produce plants that are more resistant to moisture stress. Such crops could contribute considerably to agricultural practices that would be less harmful to the environment. However, hardly any commercial company that is involved in the development of GM crops will be interested in producing such varieties, primarily because farmers in developing countries would not be able to pay usual market prices for improved seeds. The virtual lack of incentive for commercial companies to produce GM crops to prevent damage to the environment means that such research will have to be supported, and perhaps also provided, primarily by the public sector.

The role of agriculture in relation to the reduction of poverty

29 As we have noted, agricultural growth is of crucial importance for the reduction of poverty in developing countries. It is important to be clear about two different aspects of this claim. First, most African countries are in substantial food deficit. This is so despite the fact that approximately 80% of the continent's population live in rural areas, and more than 70% of all workers are engaged primarily in agriculture.[32] Many poor and undernourished rural Africans, even those with land, operate with such poor quality seeds, and such recalcitrant soil-water environments, that their land and labour productivity are too low for them to feed themselves adequately. In such circumstances, higher productivity per unit of land and water is essential to permit basic availability of sufficient staple foods to poor people, especially in remote areas. Thus, crops with higher yields are clearly needed. While conventional plant breeding has achieved some improvements, especially for maize, similar advances are lacking with respect to the most important crops of the very poor, such as millet, sorghum, yams and cocoyams.[33]

30 Secondly, a different situation arises in regions of food surplus where serious poverty nevertheless causes undernourishment. For example, India frequently has 60 million tons of staple foods, over a third of its annual consumption and production, in public grain stores. Yet, access is limited. Despite slow and steady improvements over the last few decades, over half of all children under five years old are stunted, an even higher proportion than in Africa.[34] But this does not mean that extra food production, through for example, higher yields, is irrelevant to India's undernourished. They are poor, and therefore hungry, because they can neither produce enough food on their small farms, nor obtain enough employment by working on those of others. Enhancement of yields on small farms, which tends to increase the demand and hence rewards for poor labourers, addresses this problem. It does so much more affordably than do alternative and less employment-creating routes to economic growth. This approach also increases the availability of food for poor people by

31 Conway G (1997) The Doubly Green Revolution: Food for All in the 21st Century. London: Penguin.

32 2.8 billion people in developing countries live on less than US$2 a day. 1.2 billion people live on only US$1 a day. (World Bank (2003) World Development Report 2003. Washington, DC: Oxford University Press and World Bank.)

33 Partly this is because conventional plant breeding is limited by the characteristics of plant genomes that are adapted to robustness at the expense of yield.

34 ACC/SCN in collaboration with IFPRI (2000) Fourth Report on the World Nutrition Situation: Nutrition throughout the Life Cycle. Geneva: ACC/SCN.

reducing and stabilising the price of basic foodstuffs locally, which is of particular importance since food accounts for 60-80% of total expenditure by low-income groups.[35] However, we also note with concern that the majority of research on GM crops takes place in the private sector, neglecting those crops which provide employment, income and food for poor people in developing countries, especially rice, wheat, and white maize. We now outline the potential of contemporary plant breeding and examine recent developments in relation to GM crops that could be of use to developing countries, to determine whether this conclusion remains valid.

35 Gabre-Madhin EZ and Haggblade S (2001) Successes in African Agriculture: Results of an Expert Survey. Washington, DC: International Food Policy Research Institute.

Section 3
Current and potential uses of GM crops in developing countries

31 In the following section we provide a brief introduction to the use of genetic modification in the context of contemporary plant breeding.[36] We then outline which traits researchers are currently aiming to realise by means of genetic modification and give an overview of the types of GM crops that are currently grown in commercial agriculture worldwide. The section is completed by seven Case Studies, which describe the specific contributions that GM crops can make to commercial and subsistence agriculture in developing countries.

Research on GM crops in the context of conventional plant breeding

32 Following the rediscovery of Mendel's Laws in 1900, selective plant breeding has made dramatic progress. In combination with new agricultural methods, the application of this knowledge has contributed to a doubling of the production of food in the world over the past 50 years. In parallel, plant breeders have assimilated a variety of new technologies which have been used in both developed and developing countries. Many of these are aided by applications of biotechnology. Examples include: *double haploids*, where pure breeding lines can be made in a single step; *induced mutations*, where new variations can be generated by irradiation or by chemical treatments; and *F1 hybrids*, where farmers can benefit from the expression of *hybrid vigour*, which means that such plants grow faster, have higher yields and are more resistant to environmental stresses as a result of selecting parental varieties with specific genetic differences. A process which has been particularly beneficial to tens of thousands of small-scale farmers in developing countries is that of *tissue culture*, which allows whole plants to grow from a single cell in an artificial medium.[37]

33 *Marker-aided selection* enables plant breeders to select a piece of DNA that encodes a particular trait, thereby avoiding time-consuming and expensive tests in selecting the ideal parent or offspring. This technique allows significant savings in terms of time, as a new variety can be produced in approximately four to six generations, rather than in ten. Marker-aided selection is particularly useful for breeding crops with resistance to moisture-stress. This trait is useful where plants grow in environments with an irregular supply of water. However, to achieve increased resistance, a variety of different traits have to be selected. Marker-aided selection allows plants in which these different traits have been expressed to be identified rapidly. This is helpful, for example, for research which aims to interbreed maize varieties which are already resistant to moisture-stress with African varieties of the crop, which are otherwise well adapted.[38] Genetic modification is the latest technology which breeders hope to employ in their quest for ever-improved crops for commercial or subsistence agriculture.

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36 Further information can be found in Chapter 2 of the 1999 Report.

37 Successful applications of this technique include, for example, the production of improved and disease-free banana seedlings which have been made available to small-scale farmers in Kenya (Wambugu F and Kiome RM (2001) The benefits of biotechnology for small-scale banana producers in Kenya. ISAAA briefs; no. 22. Ithaca, NY: ISAAA) Another major application of tissue culture is the *embryo rescue* technique which allowed researchers to cross the particularly high-yielding Asian rice *Oryza sativa* with an African rice variety that was exceptionally competitive with weeds, resistant to moisture-stress and disease resistant (Jones MP (1999) Basic breeding strategies for high yield rice varieties at WARDA, **Japanese Journal of Crop Science** 67: 133-6.)

38 Ribaut JM and *et al.* (2002) Use of molecular markers in plant breeding: drought tolerance improvement in tropical maize, in *Quantitative Genetics, Genomics and Plant Breeding*, Kanage, Editor. CABI: Wallingford, UK. p. 85-99.

Genetic modification

34 Genetic modification allows selected individual genes to be transferred from one organism into another, including genes from unrelated species. Since the genetic code is universal, genes from one organism can generally work in any other organism. The transferred gene is called the *transgene*. Genetic modification can be used to promote a desirable crop character or to suppress an undesirable trait. The technology is also sometimes called gene technology, recombinant DNA technology or genetic engineering. Practical and functional methods have now been developed to modify most of our major crops.

35 Regulatory provisions require that the actual transfer of genes into the selected organism must always take place in a laboratory under carefully controlled conditions. GM plants will later be grown in a special glasshouse, and then in fields under regulated conditions, before being grown commercially. Once transferred, transgenes behave like any other gene and can be managed further in a conventional breeding programme.

36 However, the technique has also given rise to a considerable number of concerns. Some perceive the act of genetic modification as more ‘unnatural’ than processes applied in conventional plant breeding (see paragraphs 37-47).[39] In the case of GM plants which are grown in fields for experimental or commercial purposes, critics also fear the ‘escape’ of introduced genes into wild relatives of the plant, or to other organisms. There is concern that such events may be irreversible and uncontrollable.[40] Further, there are questions about the effect of GM crops on the health of consumers (see paragraphs 122-126).[41]

Naturalness

37 One of the most common objections to genetic modification is that it is unnatural. Intuitively, so it seems to some people, it cannot be right to change natural objects like plants in their ‘essence’. Arguments about naturalness are complex, and raise many difficult issues. We addressed some of these in our 1999 Report, where we examined concerns which were based on commonly held views, or on philosophical, sociological or theological grounds (see paragraphs 1.32-1.40 of the 1999 Report). However, we wish to re-consider two areas in more detail. The first is the question of the relation between conventional plant breeding and plant breeding that uses techniques of genetic modification: can it be said that the use of genetic modification is ‘unnatural’? The second concerns the question of what it means to transfer genes between species, which is possible through genetic modification: are such procedures unacceptable because they violate natural boundaries?

Conventional plant breeding and plant breeding using GM

38 Often, people take the view that conventional plant breeding only consists of selecting particular plants from a great variety of naturally occurring types of plants. This activity is seen as natural. Many would also view the systematic interbreeding of naturally occurring types of

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39 For a more abstract discussion of the issue of naturalness see Alan Holland’s submission to the New Zealand Royal Commission on Genetic Modification (Available: http://www.gmcommission.govt.nz/pronto_pdf/save_animals_from_exploitation_safe/(WB%20IP%200085-AI%20Holland).pdf. Accessed on: 20 May 2003). See also Food Standards Agency (2003) Public attitutes to GM: Debrief notes on qualitative research. Available: http://www.foodstandards.gov.uk/multimedia/pdfs/gmfocusgroupreport.pdf. Accessed on: 20 May 2003.

40 FAO Electronic Forum on Biotechnology in Food and Agriculture (2002) Background paper to the 7th conference, 31 May - 6 July 2002. FAO. Available: http://www.fao.org/biotech/C7doc.htm. Accessed on: 23 Mar 2003; Independent Science Panel (2003) The Case for a GM-free Sustainable World. London: ISP. See also paragraphs 112-121.

41 BMA (1999) The Impact of Genetic Modification on Agriculture, Food and Health: An Interim Statement. London: BMA.

plants in the same vein. However, as we have said, plant breeders also create plants which would not be achievable by judicious interbreeding, using techniques such as mutation breeding (see paragraph 33). This type of breeding involves the exposure of plants and seeds to radiation and/or to chemical substances. These procedure have been, and still are being used to produce many important staple crops, both in developed and also in developing countries.[42] Thus, it is important to note that the deliberate alteration of plants as they occur in nature has been practised and accepted for a considerable time. In this context, genetic modification can be seen as a new means to achieve the same end; it is certainly used in that way. It differs from conventional plant breeding in that it can allow for much faster and more precise ways of producing improved crops. For this reason, we concluded in our 1999 Report that it was not helpful to classify a genetic complement of a crop that has been arrived at by means of conventional plant breeding as 'natural', and to classify a crop with the same genetic complement as 'unnatural' if it has been produced through genetic modification.

39 However, there is some concern that the technique of genetic modification poses risks that differ from those implied by other forms of plant breeding. It may be the case that the intended effect of conferring a particular trait by insertion of specific gene sequences brings with it unintended effects, which could result from, for example, disruptions in existing genes in the modified material.[43] However, unintended effects are not specific to the use of genetic modification. They are often encountered in conventional breeding, and in particular in the case of mutation breeding.[44] From this it follows that the possible occurrence of unintended effects needs to be monitored strictly, both in the case of conventionally bred crops, as well as in the case of GM crops.

40 Other concerns relate to the fact that some forms of genetic modification involve genetic material that is foreign to the organism which is modified. Often, viral sequences are used to facilitate the insertion of a specific gene sequence. For example, the cauliflower mosaic plant virus is used as a *promoter*, which means that a short sequence of the genetic material of the virus is inserted together with a particular gene, to facilitate its expression (this function is also known as 'switching on' the gene).[45] Some people regard this as a threshold that should not be breached, because in their view, an organism has been created that has not previously existed in nature. Such concerns are even stronger where genes are inserted which come from another species, to which we now turn.

The transfer of genes between species

41 Genetic modification enables researchers to insert genes from unrelated species into crop plants. As we discuss in more detail below, this technique is applied widely in the case of *Bt* crops (see paragraphs 59-67) and also in the case of specific rice varieties (paragraphs 71-79).

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42 For example, radiation in the form of gamma rays was used to alter the genes of a successful rice variety which came to be known as Calrose 76. The radiation reduced the height of the plants which resulted in higher yields of grain. The same technique was also used to develop 'Golden Barley', the main variety grown in Scotland until the 1980s. Apart from radiation, chemical substances such as sodium azidide and ethyl methanesulphonate have been used, and are still being used, particularly in developing countries, to modify the genome of crops.

43 See FAO and WHO (2000) Safety aspects of genetically modified foods of plant origin Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology World Health Organization, Geneva, Switzerland 29 May – 2 June 2000. Geneva: WHO, Section 4.3 for a more extensive discussion of this issue. See also Royal Society (2002) Genetically modified plants for food use and human health - an update. London: Royal Society. p. 6.

44 The Royal Society notes two examples: celery and potatoes. (Royal Society (2002) Genetically modified plants for food use and human health - an update. London: Royal Society. p. 6.)

45 Royal Society (2002) Genetically modified plants for food use and human health - an update. London: Royal Society. p. 8; Independent Science Panel (2003) The Case for a GM-free Sustainable World. London: ISP. We discuss health issues raised by these and other techniques in paragraphs 122-126.

For many people, such possibilities raise the ethical question of whether it is acceptable to mix the genes of different species in this way. The notion underlying this often intuitive response is that there is a meaningful order in nature that needs to be respected (see paragraph 1.43 of the 1999 Report).

42 There are several aspects to this view. First, it can entail a claim about the status of species and their role in nature. The diversity of wild species of plants can be seen as a reflection of the process of natural selection of random mutations and other evolutionary mechanisms. This process is frequently interpreted as intrinsically valuable and 'off-limits'. Genetic modification is viewed critically because it is seen as aiming to direct the evolution of some plants. If such plants are released into the environment, then there is the possibility that GM crops would interbreed with wild relatives, thereby changing the process of natural selection in a way new to the natural world (see paragraphs 112-121). However exactly the same objection can also be made with respect to many other forms of plant breeding. In fact, crop varieties which are used in agriculture already frequently interbreed with their wild relatives. Given that the systematic cultivation of plants began at least 6,000 BC, man has been influencing natural selection for a long time.[46]

43 Secondly, the claim that the natural world order should be respected can also be understood as a reluctance to transgress boundaries between species, because these are given by nature. However, this view faces a number of objections. It does not follow automatically from the fact that something exists in nature, that it should exist, or that it is good in and of itself.[47] Furthermore, even within nature, boundaries between species are not irreversibly fixed. There is, for example, increasing evidence that throughout evolution, transfer of genes has occurred between lower and higher organisms, including humans.[48] Thus, *horizontal gene transfer*, as this phenomenon is called, appears in fact to be a natural phenomenon.

44 While it is difficult to maintain that nature as such should never be changed for the reasons outlined above, a third option may be to say that the order of nature needs to be respected because interferences may result in irreversible adverse consequences for biological systems, that may eventually endanger the natural world and our relation to it. It could be argued that natural biological and ecological systems are relatively robust and predictable, and pose few risks for humans. While it may be the case that horizontal gene transfer has occurred in nature, this has happened over a very long timescale. However, in the case of genetic modification, the transfer of genes between species introduces a sudden change. If such changes in the genetic complement of plants are released into the environment in the form of GM crops, it could be the case that biological and ecological systems are not sufficiently adapted to integrate the plant, which could result in unforeseeable and potentially irreversible changes in biodiversity. It could therefore be argued that 'nature knows best' how to integrate genetic changes, and that it would be irresponsible to interfere with this highly complex system that evolves slowly over time.

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46 Of course, from this it does not follow that all the ways in which humans have influenced natural selection so far would be unproblematic, see footnote 49. It does however mean that attention should be given primarily to the consequences of interfering with nature, rather than to the acts.

47 There is a substantial philosophical discussion on the question of how to derive values from facts. Seminal contributions have been made by David Hume in *A Treatise of Human Nature* (1739-40) and G.E. Moore's *Principia Ethica* (1903).

48 Syvanen M (2002) Recent emergence of the modern genetic code: a proposal, **Trends Genet** 18: 245-8; Capy P, Anxolabehere D and Langin T (1994) The strange phylogenies of transposable elements: are transfers the only explanation?, **Trends Genet** 10: 7-12.

45 The most obvious response to this argument would be to reject all forms of genetic modification that introduce foreign DNA into another organism, regardless of the possible benefits. Another response would be to claim that changes in nature should only be undertaken if there can be absolute certainty that no risks are implied. However, while the latter seems to differ from the former, it needs to be noted that the requirement of absolute certainty is unattainable. Neither do we apply such criteria consistently in other cases where our interventions affect biological and ecological systems.[49]

46 A third response is to challenge the assumption that 'nature knows best' with its corollary that altering nature requires proof of the exclusion of all conceivable risks. Proponents of this position would argue that it would be wrong to forego possible benefits in principle because of hypothetical and unspecified risks. They argue that it is more important to assess and balance risks in individual cases. In some instances, it may be clear that possible risks outweigh possible benefits. In other instances, it may be the case that the risks are not severe and that responsible use can be achieved by a step by step approach (see paragraph 118-121).

47 For now, we conclude that we are not convinced that arguments about 'naturalness' are sufficient to rule out the responsible exploration of the potential of genetic modification. We take the view that all forms of plant breeding have directly and indirectly changed biodiversity, and that risks and benefits of specific interferences need to be considered in individual cases. It is not helpful to forego likely benefits because of the possibility of unspecified and hypothetical adverse events. This is particularly relevant to the use of GM crops in developing countries. It may be the case that GM crops are effective tools for addressing specific agricultural problems prevailing in developing countries, and that associated risks for the health of consumers and the environment can be contained. To examine this question further, we now consider possible benefits and risks that may arise as a result of the use of GM crops in developing countries. The issue of how best to make decisions about the use of GM crops in conditions of uncertainty is taken up in more detail in paragraphs 118-121.

GM crops of relevance to developing countries

48 Most commonly, the improvement of plants aims at increasing the yield or quality of crops. We have highlighted the importance of optimal yields in developing countries in paragraphs 17-30. Yield is influenced by many factors such as pests, diseases, abiotic stresses[50] which stem from unfavourable climatic conditions, or the quality of the soil. In many instances, significant improvements can be achieved by means of irrigation, the application of insecticides or pesticides and/or the addition of fertiliser. However, most of these interventions are expensive, particularly for small-scale farmers in developing countries.[51]

49 For example, it may be asked whether the rhododendron, which originated in Spain and Portugal, should ever have been introduced into the UK: it has been highly invasive and severely affected the environment, but it seems that this did not prevent its cultivation. Similar adverse effects have resulted from the introduction of other garden plants such as Japanese knotweed (*Fallopia japonica*) which has resulted in a significant loss of biodiversity in some areas of the UK, in particular along waterways (Royal Horticultural Society (2002) Invasive non-native species. The Science Departments, The Royal Horticultural Society's Garden, Wisley, UK. Available: http://www.rhs.org.uk/research/c_and_e_nonnative.pdf. Accessed on: 20 May 2003). These examples are not given to say that therefore one should not worry about the introduction of GM crops in particular environments. They are only mentioned to note that there is frequent inconsistency when it comes to taking risks with regard to decisions that may have an impact on natural environment. We take the view that a thorough assessment of the likely benefits and risks is required in all cases.

50 Stresses upon a crop may be either biotic or abiotic. Biotic stresses refer to the influence or impact which other living organisms have on a crop. Abiotic stresses usually refer to the physical and chemical components of a crop's environment.

51 With regard to fertilisers Gordon Conway notes that the price of urea in Western Kenya is US$400 per metric ton, whereas it is US$90 in Europe. (Conway G (2003) From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. Accessed on: 16 April 2003. p. 8.)

The application of genetic modification provides plant breeders with new opportunities to produce crops that are protected from environmental stresses and attacks from pathogens and insects. The following list gives examples of traits that researchers aim to produce by means of genetic modification. Some of these are still in early stages of development, others have been achieved more recently in the laboratory setting, some are in field trials, and a few can already be found in crops used in agricultural practice. Some of the traits that are of interest can be arrived at by means of conventional breeding. However, others are achievable only by means of genetic modification (see also Appendix 3).

- **Herbicide tolerance.** A transgene confers tolerance of a specific herbicide. This allows farmers to apply a herbicide which acts on a wide range of weeds while not affecting the modified crop. Herbicide tolerance is the most commonly used GM trait worldwide, for example in soybean, maize, cotton and oil seed rape. Herbicide tolerant crops are mainly grown in developed countries. The trait has also been achieved using other methods, particularly induced mutations and gene transfer from wild relatives.
- **Insect/pest resistance.** A transgene produces toxins to specific insects that feed on the crop. Such genes have been widely used and are already leading to large reductions in the use of pesticides and insecticides. Insect-resistant cotton, maize and potato varieties are being grown in both developed and developing countries (see Case Study 1 on *Bt* cotton).
- **Bacterial, fungal and viral resistance.** Here a transgene makes crops resistant to biotic stresses such as plant pathogens which often reduce yields substantially. Examples of crops in which these traits are being introduced include coffee, bananas, cassava, potato, sweet potato, beans, wheat, papaya, squash and melon (see Case Studies 5 and 6 on sweet potatoes and bananas). In some cases the transgenes used are genes which occur naturally in the same species.
- **Abiotic stress resistance.** The ability of some crop plants to survive in harsh climatic or soil conditions can sometimes be associated with specific groups of genes. These genes can be isolated and introduced into crops that are used for agriculture. Such applications promise to be particularly valuable for developing countries, where abiotic stresses such as drought, heat, frost and acid or saline soils are common. Research on crops such as cotton, coffee, rice, wheat, potato, brassica, tomato, and barley varieties is currently in different stages of completion (see Case Study 2 on rice that is resistant to moisture-stress).
- **Micronutrient enrichment.** In aiming to prevent malnutrition, transgenes could play a vital role in the provision of vitamins or minerals. GM crops could help to provide people with essential micronutrients through consumption of their main staple crop. Research in this area is currently being undertaken on rice, cassava, millet and potato (see Case Study 4 on Golden Rice).

49 Further applications of genetic modification include the controversial gene use restriction technology (GURT), also known as 'terminator technology', which was purported to effectively sterilise left over seed (see paragraphs 103-104 and paragraphs 2.26 and 4.75 of the 1999 Report).[52] Other applications of genetic modification which are either in advanced stages of development or already used in agricultural practice include improved shelf-life of fruit and vegetables, and the use of plants for the production of biopharmaceuticals, such as vaccines (see Case Study 7, paragraphs 86-87).[53] There is also a range of traits which are still in relatively

52 Companies developing this technology emphasise that its purpose is to allow the control of gene flow, whereas critics claim that the purpose is the control of seed markets, by making the saving of harvested seed for resowing in the next season unfeasible.

53 AEBC (2002) Looking Ahead - An AEBC Horizon Scan. London: Department of Trade and Industry; Genewatch (2003) Genetic Modification: The Need for Special Regulation. Briefing No. 21. Tideswell, Derbyshire: Genewatch.

early stages of development, but nonetheless are promising and potentially important. These include research to enable the transfer of genes conferring *apomixis*, which is the capacity to produce seed in the absence of normal sexual reproduction, to crops.[54] This application could enable outstanding traits to be perpetuated over generations without farmers needing to buy new seed (see paragraphs 2.23, 2.39 and 3.39 of our 1999 Report). Other research aims to produce GM crops that can be used most efficiently for the production of bioplastics or biofuels, which can be utilised as substitutes for fossil fuels and their products. It may also be possible to develop nitrogen-fixing cereals; gluten-producing sorghum for bread-making in Africa, which is currently dependent on imported wheat; or crops with such high tolerance to salinity that seawater can be used for irrigation.[55]

50 While many of these applications require considerable further research, some are already used widely in commercial agriculture in different countries. To examine whether, and if so to what extent, these crops are grown in developing countries, and to assess whether there has been a change in relation to the situation at the time of the publication of our 1999 Report, we provide in the next section a brief survey on the kinds of GM crops that are currently grown worldwide. This is followed by seven Case Studies which illustrate current and potential benefits and risks associated with the use of GM crops in developing countries.

Commercial use of GM crops

51 Three-quarters of GM crops which are grown worldwide are cultivated in developed countries, predominantly on large-scale industrial farms in the US and Canada. Traits which have been successfully introduced by means of genetic modification relate primarily to the needs of these farmers. However, it is also noteworthy that of the approximately six million farmers who grew GM crops in 2002 worldwide, more than three-quarters were resource-poor, small-scale cotton farmers in developing countries, mainly in China and South Africa.[56]

52 While the number of farmers using GM crops is thus the highest in developing countries, they only account for 27% of the global area of GM crops. The five main countries which grew 99% of the global GM crop are shown in Figure 1.

53 Both now and at the time of the publication of our 1999 Report, the principal GM crops cultivated in 2002 were non-staple crops. These were grown in developed countries, almost exclusively for commercial reasons. Traits achieved by means of genetic modification concerned primarily herbicide tolerance (75%) and pest resistance (15%). Varieties carrying two or more transgenes which conferred both pest resistance and herbicide tolerance accounted for 8% of all crops. Herbicide tolerant soybean was the most widely grown GM crop in 2002 (see Figure 2).

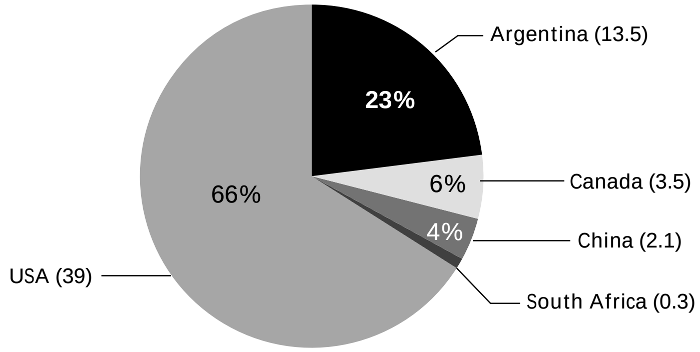
54 Nearly one-quarter of the total area of GM crops worldwide was grown in Argentina. Here, soybean and maize for export as animal feed was planted on large-scale industrial farms.

54 For a review see Chaudhury AM *et al*. (2001) Control of early seed development, **Annu Rev Cell Dev Biol** 17: 677-99.

55 See, for example, Mazur B, Krebbers E and Tingey S (1999) Gene discovery and product development for grain quality traits. **Science** 285(5426): 372-5; AEBC (2002) Looking Ahead - An AEBC Horizon Scan. London: Department of Trade and Industry; Fitzgerald F (2003) Salt-tolerant GM wheat. Grains Research & Development Centre. Available: http://www.grdc.com.au/growers/gc/gc44/gene_scene.htm. Accessed on: 2 Jun 2003; Hargrove T (2001) China announces seawater irrigation of GM crops. Available: http://www.mindfully.org/GE/GE2/China-Seawater-Irrigation.htm. Accessed on: 2 Jun 2003; James C (2000) Global review of commercialized transgenic crops: 1999. ISAAA briefs; no. 12. Ithaca, NY: ISAAA.

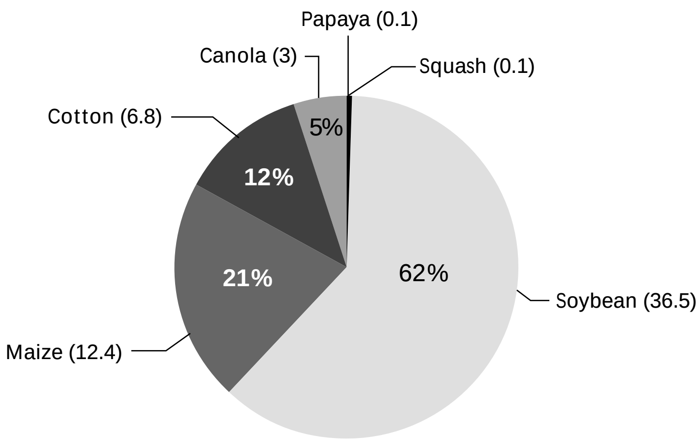
56 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA. It needs to be noted that this figure does not include farmers who grew GM crops illegally. There is anecdotal evidence of considerable illegal planting of GM crops in 2002 in Brazil, Pakistan and India. The discrepancy between the number of farmers growing GM crops in, respectively, developing and developed countries can be seen as a reflection of the fact that the size of farms in developed countries is on average considerably larger.

Figure 1: Global area of GM crops in 2002 by country (million hectares)



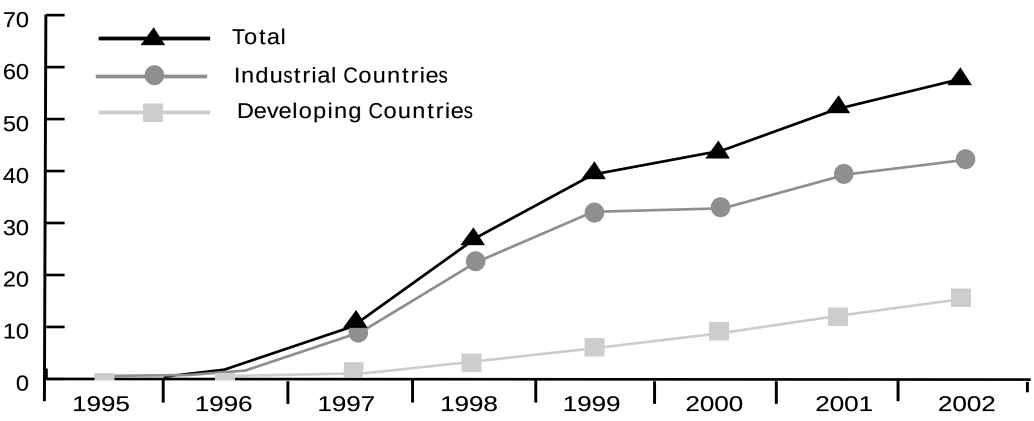
Source: James C (2002)
Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

Figure 2: Global area of GM crops in 2002 by crop (million hectares)



Source: James C (2002)
Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

Figure 3: Global area of GM crops, 1996-2002 (million hectares)



Source: James C (2002)
Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

Since our 1999 Report was published, the area of GM crops in developing countries has doubled. The growth in cultivation of GM non-staple crops in developing countries is expected to continue over the coming years (see Figure 3).

55 In China, GM varieties were grown on 51%, or two million hectares, of land used for growing cotton. In India, Columbia, and Honduras, GM crops were grown for the first time in 2002. In India, where the majority of cotton is grown, GM cotton received regulatory approval in April 2002. Subsequently 45,000 hectares were planted with GM cotton. Indonesia has also recently introduced GM crops, which means that the three most populous countries in Asia have taken up the technology.[57]

56 While the rapidly increasing spread of GM crops is noteworthy, it needs to be pointed out that beyond the Western hemisphere, almost all the GM crops planted are cotton. Most GM food and feed crops, such as soybean or rice, have not yet been approved for commercial planting in Africa, Asia, or the Middle East. The exceptions are South Africa and the Philippines, where GM maize has been approved, and Argentina, where GM maize and soybean are grown. One of the important reasons for this pattern is that regulators in developing countries often opt for a highly conservative precautionary approach when deciding about the use of a new GM crop. The reasons for this are manifold and are addressed in more detail below. Some reservations relate to unresolved concerns about the safety of GM crops in relation to human consumption and in relation to the environment (see paragraphs 112-126), others to restrictions resulting from international trade policies (see paragraphs 171-177).

Current and possible use of GM crops in developing countries

57 As we have said, concern has been expressed about the speed with which GM crops have been, or are intended to be, introduced in some developing countries (see paragraph 8).[58] With regard to food crops, critics point out that despite increasing populations, over the past 35 years, global food production has outstripped growth in population by 16%. It is argued therefore that current global food production is sufficient to provide food for the world's population, if only inequalities in access to food were eliminated.[59] GM crops are frequently perceived as a 'technological fix', proposed by those who fail to address the underlying causes of hunger and poverty, which really require economic, political and social change.

58 We are aware of these and further general objections and address them in more detail in Section 4 below. Here, we consider what kind of GM crops could offer benefits to farmers in developing countries, and what the likely risks might be. We also aim to assess the claim that GM technology may only benefit agrochemical companies and large-scale commercial farmers in developed countries, and may be of no use or even harmful for small-scale, resource-poor farmers in developing countries.[60] To examine this view, we first consider the use of GM cotton in China and Africa. We then discuss six further examples of research, where genetic modification is used to improve traits of crops which are important to many people in developing countries as food crops, but which are mostly neglected by plant breeders in developed countries: rice, sweet potatoes, and bananas.

57 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

58 Oxfam (1999) Genetically Modified Crops, World Trade and Food Security: Oxfam Great Britain position paper. Oxford: Oxfam; Five Year Freeze (2002) Feeding or Fooling the World? London: Five Year Freeze.

59 Five Year Freeze (2002) Feeding or Fooling the World? London: Five Year Freeze.

60 See, for example the study on possible benefits and disadvantages of GM coffee in Hawaii (Action Aid (2001) Robbing coffee's cradle - GM coffee and its threat to poor farmers. London: Action Aid).

Case Study 1: Non-staple crops – Bt cotton in China and South Africa

59 Cotton attracts a variety of insects and pests which farmers seek to control so as to prevent substantial losses in yield. A variety of compounds are used as insecticides or pesticides. One example is based on the naturally-occurring soil bacterium *Bacillus thuringiensis (Bt)*. There are a number of strains of *Bt*, each of which produces a slightly different protein, but all in turn cause a toxic reaction in the guts of insects or pests when they digest the protein. While such a reaction does not occur in humans, it strongly affects cotton bollworm, maize borers or potato beetles, that devastate many crops worldwide. The toxic effect of *Bt*-derived compounds is widely used by conventional and organic farmers.[61] Usually, farmers apply the toxin by spraying the crops. However, this method of application is relatively imprecise and means that repeated sprayings over an extended period of time are required to control pests effectively.

60 The attractiveness of using the protein produced by *Bt* is that it is, in many cases, not toxic to beneficial insects that are closely related to the target insect. This means that these insects, which would otherwise have been killed by the application of conventional chemical insecticides or pesticides, are left unaffected due to the selectivity of *Bt*. To preserve this useful quality, and to enable a more efficient application, researchers have produced *Bt* crop varieties, in which genetic modification has been used to insert a gene that enables the plant to produce the protein that is toxic to the relevant target insects. While the protein usually is produced throughout the crop, more recent developments also allow it to be expressed in specific parts of the plants, for example in the roots.[62]

61 The major advantage of *Bt* crops is the reduction in the levels of pesticides that are used. This has considerable ecological benefits, as excessive use of pesticides can be harmful to the environment. It also has economic benefits: in 2001, 20% of pesticides applied globally were used on cotton, at a total cost of US$1.7 billion.[63] Significant reductions can further have health-related benefits for farm workers who apply pesticides or insecticides, or who work in fields in which these have been applied (see also paragraph 84). Whether or not *Bt* crops lead to overall savings for farmers will depend on a variety of factors, such as the price of seed, licensing agreements with the producer of the seed, costs of insecticides and global cotton prices.

62 In China, researchers have successfully developed several *Bt* cotton varieties for national use.[64] By 2002, half the cotton grown was in the form of *Bt* varieties. The use of *Bt* had three main advantages:

- The average application of pesticides fell by as much as 50 kilograms per hectare, a reduction of between 60-80% in comparison to 2001.[65] This implied considerable financial savings for approximately 3.5 million farmers who managed small farms of an average size of between 0.5-2 hectares (see Table 1).[66]

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61 James C (2001) Global review of commercialized transgenic crops: 2001, Feature Bt cotton. ISAAA briefs ; no. 26. Ithaca, NY: ISAAA.

62 Kota M *et al*. (1999) The Next Generation of Bt Plants? Auburn University. Available: http://www.ag.auburn.edu/aaes/communications/highlights/spring99/btplants.html. Accessed on: 20 May 2003.

63 James C (2001) Global review of commercialized transgenic crops: 2001, Feature Bt cotton. ISAAA briefs ; no. 26. Ithaca, NY: ISAAA.

64 James C (2001) Global review of commercialized transgenic crops: 2001. ISAAA briefs ; no. 24. Ithaca, NY: ISAAA.

65 Huang J *et al*. (2002) Plant biotechnology in China, **Science** 295: 674-6.

66 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

- Further, *Bt* cotton yields were estimated to have increased by 10% in 2001, in comparison to farmers who grew non-*Bt* cotton.[67]
- As in many other developing countries, pesticides in China are often applied in the absence of protective clothing. The use of *Bt* cotton seems to have led to reductions of instances in which farmers suffered toxic effects related to the exposure to pesticides. Such events were reported to be reduced by 60% in comparison to farmers who grew non-*Bt* cotton.[68]

Table 1

Average costs and returns (US$) per hectare for farmers surveyed in China, 2001

Cost		*Bt*	Non-*Bt*
Output revenue		1277	1154
Non-labour costs			
	Seed	78	18
	Pesticides	78	186
	Chemical fertiliser	162	211
	Organic fertiliser	44	53
	Other costs	82	65
Labour		557	846
Total costs		1000	1379
Net revenue		277	-225

Source: Pray CE *et al*. (2002) Five years of Bt cotton in China - the benefits continue, Plant J 31: 423-30.

63 Similar improvements in yield were achieved in the Makhathini Flats area of KwaZulu-Natal, South Africa.[69] In 1999/2000, 12% of the 1376 cotton farmers who predominantly managed small farms of an average size of 1.7 hectares, adopted *Bt* cotton, rising to 60% the following year. Ninety five per cent are expected to have grown *Bt* cotton in 2001/2002. Due to increased yields, farmers were able to augment their gross margin by 11% in the first season, and 77% in the second season in comparison to farmers growing non-*Bt* cotton, despite *Bt* cotton seeds being twice as expensive.[70] The use of *Bt* cotton is also said to have led to savings of approximately 1500 litres of water per farm.[71]

64 Despite these benefits, the use of *Bt* cotton carries a number of risks. Concern has been expressed with regard to what some perceive as the undue influence of multinational agrochemical and seed companies. Corporate control of seed markets and ownership of technologies are important issues. For example, the company Monsanto has made 90% of the

67 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA; Pray CE *et al*. (2002) Five years of Bt cotton in China - the benefits continue, **Plant J** 31: 423-30.

68 Conway G (2003) From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. Accessed on: 16 April 2003; Pray CE *et al*. (2002) Five years of Bt cotton in China - the benefits continue, **Plant J** 31: 423-30.

69 Thirtle C, Piesse J and Jenkins L (2003) Can GM-Technologies Help the Poor? The Impact of Bt Cotton in Makhathini Flats, KwaZulu-Natal, **World Development** 31: 717-32.

70 Ismael Y, Bennett R and Morse S (2002) Benefits of Bt cotton use by smallholder farmers in South Africa, **AgBioForum** 5: 1-5.

71 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

patent applications for genes relating to the improvement of cotton.[72] Indeed, currently just 10 companies control approximately 85% of the global agrochemical market.[73] We consider issues relating to intellectual property rights in more detail in Section 6.

65 Critics of *Bt* crops note the possibility that pests may eventually acquire resistance to such crops.[74] The cotton bollworm has been monitored for *Bt* resistance in China since 1997, and resistant mutants have not yet been reported.[75] However, resistance is likely to develop if the first generation of plants remains in cultivation for long enough. The use of *refuges* is one way of addressing this issue. To slow down the emergence of resistance, many regulatory schemes require that sufficient acreages of non-*Bt* crops are grown close to the *Bt* crops, so as to allow refuges for insects which can mate with potentially *Bt*-resistant insects. We note that the establishment of refuges for *Bt* cotton farms in Australia is well regulated and has been successfully implemented.[76] However, while the monitoring of such refuges seems feasible in the case of large-scale commercial farmers, it may be considerably more difficult to assess whether the great number of small-scale farmers in developing countries are growing sufficient acreage of non-*Bt* crops. Other approaches to avoid pest resistance might be to use two or more *Bt* genes,[77] or to carry out research into new insecticidal genes that could eventually take the place of *Bt*.[78] However, so far *Bt* varieties have remained resistant for considerably longer timespans than had initially been anticipated.

66 Additional problems arise from the possibility of gene flow from *Bt* crops to wild relatives.[79] It is feared that the introduced *Bt* gene may 'escape' from the modified plant and change the genetic composition of other plants. This may be particularly relevant in the case of countries like India, which are centres of origin of cotton. Centres of origin often comprise considerable variety of specific types of crops and wild relatives, and possible outcrossing of *Bt* crops could irreversibly affect the local gene pool.[80] While some argue that these and related issues simply require stringent monitoring and assessment in field trials, others doubt whether such risks should be taken. We consider questions relating to the management of gene flow in paragraphs 112-117.

67 Further concerns have been expressed with respect to the possibility that *Bt* may lead to a decrease in biodiversity. For example, in 1999, researchers undertaking laboratory studies claimed that the pollen of *Bt* maize may negatively affect non-target species, such as

72 Genewatch (2001) Genetic Engineering: A Review of Developments in 2000. Briefing No. 13. Tideswell, Derbyshire: Genewatch.

73 AEBC (2002) Looking Ahead - An AEBC Horizon Scan. London: Department of Trade and Industry.

74 We note that this is a problem that is not unique to GM crops, it is equally applicable to conventionally applied pesticides or insecticides.

75 Wu K (2002) Agricultural and biological factors impacting on the long term effectiveness of Bt Cotton, in *Conference on Resistance Management for Bt crops in China: Economic and Biological Considerations*. April 28, 2002. Raleigh, NC: North Carolina State University.

76 Jim Peacock, (2003) in *Towards Sustainable Agriculture for developing countries: options from life sciences and biotechnologies*. 30-31 January 2003. Brussels.

77 Jim Peacock, (2003) in *Towards Sustainable Agriculture for developing countries: options from life sciences and biotechnologies*. 30-31 January 2003. Brussels; Gould F (1998) Sustainability of transgenic insecticidal cultivars: Integrating pest genetics and ecology, **Ann Rev Entomol** 43: 701-26.

78 Bowen *D et al*. (1998) Insecticidal toxins from the bacterium Photorhabdus luminescens, **Science** 280: 2129-32.

79 The transfer of genes via pollen to or from a cultivated crop to other crop plants, wild relatives, other plant species or other organisms.

80 Nester E *et al*. (2002) 100 years of Bacillus Thuringiensis: a critical scientific assessment, in *100 Years of Bacillis thuringiensis, a Paradigm for Producing Transgenic Organisms: A Critical Scientific Assessment*. November 16-18. American Academy of Microbiology: Ithaca, NY; Shiva V (27 Mar 2002) Soil Association's International Sir Albert Howard Memorial Lecture.

Monarch butterflies. However subsequent studies have shown that these results do not apply in the wild.[81] Evidence from *Bt* cotton field trials in KwaZulu-Natal even seems to suggest that the use of *Bt* can contribute to enhanced biodiversity, as increased numbers and varieties of insects and insectivorous birds were recorded in *Bt* fields.[82] This finding is supported by results from recent field trials in Denmark and in the UK, where sugar beet which has been genetically modified to express herbicide tolerance has been monitored.[83] Both studies showed a significant increase in spiders, beetles and other insects that are important food for skylarks, lapwings and partridges.

Examples of improved traits in staple crops

68 While the previous example related to a non-food crop that is used predominantly in international trade, we now discuss examples of food crops that are important for both subsistence and commercial farming. In many tropical developing areas, two or three crops a year can be harvested. Often, temperature and the length of days are more favourable to the growth of crops than in temperate developed countries. Best-case yield of important crops is, therefore, often higher in the tropics than in highly productive areas in temperate zones (for example, wheat in Amritsar and Ludhiana in the Indian Punjab, and in Sonora and Sinaloa, Mexico; rice in parts of Taiwan). However, average yield of almost all crops grown is significantly lower in developing countries compared to developed countries. This is so because poor farmers and governments are generally worse placed to deal with problems such as poor quality seed, saline or otherwise recalcitrant soil, environmental stresses such as drought and heat, pest and disease infestation, lack of fertilisers, short-term-orientated farm land management, and inadequate control of water.

69 Often, substantial improvements can be achieved cost-effectively in one or more of these areas without using new crop varieties, for example, by better irrigation, integrated pest management, or agricultural extension. However, these improvements also have limitations, and are unattractive to farmers if the seeds available are ill-adapted. With regard to improved seeds, there are a variety of cases where conventional, non-GM approaches have achieved little progress: sorghum and maize in Africa have produced scant improvement; maize hybrids, while high-yielding with adequate water and nutrient conditions, have proved very vulnerable to even small and brief delays in the rains during the time of flowering. Hence, as noted above (see paragraph 19) and in the 1999 Report (paragraphs 4.20-4.27), GM crops may be crucial for raising 'yield potential' (in other words, the maximum attainable crop yield from a given soil-water regime), and/or yield stability, of crops.[84]

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81 Losey JE, Rayor LS and Carter ME (1999) Transgenic pollen harms monarch larvae, **Nature** 399: 214; Sears MK *et al*. (2001) Impact of Bt corn pollen on monarch butterfly populations: a risk assessment, **Proc Natl Acad Sci U S A** 98: 11937-42; Hellmich RL *et al*. (2001) Monarch larvae sensitivity to Bacillus thuringiensis- purified proteins and pollen, **Proc Natl Acad Sci U S A** 98: 11925-30; Pleasants JM *et al*. (2001) Corn pollen deposition on milkweeds in and near cornfields, **Proc Natl Acad Sci U S A** 98: 11919-24; Stanley-Horn DE *et al*. (2001) Assessing the impact of Cry1Ab-expressing corn pollen on monarch butterfly larvae in field studies, **Proc Natl Acad Sci U S A** 98: 11931-6; Oberhauser KS *et al*. (2001) Temporal and spatial overlap between monarch larvae and corn pollen, **Proc Natl Acad Sci U S A** 98: 11913-8; Zangerl AR *et al*. (2001) Effects of exposure to event 176 Bacillus thuringiensis corn pollen on monarch and black swallowtail caterpillars under field conditions, **Proc Natl Acad Sci U S A** 98: 11908-12.

82 Thomson J (2002) Genes for Africa: Genetically Modified Crops in the Developing World. Cape Town: University of Cape Town Press. p. 169.

83 Aldhous P (2003) The world's forgotten crisis, **Nature** 422: 251; Coghlan A (2003) Altered beet is a haven for wildlife, **New Scientist** 177: 6.

84 But why should further rises in yield potential be important for developing countries? Because it is beneficial for farmers to attain only a given fraction of the yield potential 'ceiling', in other words, of the maximum attainable crop yield. Once this fraction is attained, the only way that field yields can rise further is for the ceiling itself to rise.

70 We now discuss several examples which may contribute to increasing yield and quality of food crops. The first three concern research on genetically improved traits in rice, a staple food for over three billion people, in other words, half the world's population.[85]

Case Study 2: Abiotic stress resistant rice

71 In November 2002, researchers at Cornell University successfully produced and tested in greenhouses a variety of GM rice that maintained yields under abiotic stress such as cold, drought and high salt levels in the soil. Such research is important since, for example, one third of the 1.5 billion hectares of the world's arable land is affected by drought.[86] To improve rice for such conditions, the researchers transferred a set of genes which control the expression of a sugar called trehalose into a variety of *Indica* rice, which represents 80% of rice grown worldwide. Trehalose occurs naturally in many so-called 'resurrection' plants, which can survive prolonged droughts in desert conditions. Under stress, these plants appear to have died; however, the sugar helps stabilise biological molecules and protects tissue damage during dehydration. It is estimated that the GM crop variety could potentially increase yields under poor conditions by as much as 20%, although field trials are only expected to take place in several years time.[87] The researchers plan to seek patent protection and will assure availability of the modified crop in the public domain, particularly for farmers in developing countries. It is also hoped to introduce the trait in other crops, such as maize, wheat or millet.[88]

Case Study 3: Increasing yield in rice by dwarfing

72 Another method of increasing yield is by producing dwarfed varieties of crops, as shorter plants can make more nutrients available for the production of grains. Selecting crops of a shorter height that produced higher yields was one of the primary advances of the Green Revolution in the 1960s and 1970s, contributing to the doubling of yields of wheat worldwide. The introduction of the dwarfed rice variety IR-8 in 1963 was of similar importance.[89]

73 The development of such dwarfed crops by means of conventional plant breeding is time-consuming and costly. In addition, in the case of IR-8, increased yields were achieved mostly because the plants could be treated with higher amounts of fertiliser. However, fertilisers are often unavailable or unaffordable for farmers in developing countries. For this reason, it would be desirable to maximise the benefits arising from dwarfing in the absence of fertilisers. In 1999, a team at the John Innes Centre (JIC) analysed normal and dwarfed forms of a common weed (*Arabidopsis thaliana*) and isolated a gene that controls the dwarfing character. This gene is closely related to the gene that was important in the production of

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85 Lantin R. Compendium on Post-harvest Operations. FAO. Available: http://www.fao.org/inpho/compend/text/ch10.htm. Accessed on: 18 Mar 2003.

86 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA. p.19.

87 Garg AK *et al*. (2002) Trehalose accumulation in rice plants confers high tolerance levels to different abiotic stresses, **Proc Natl Acad Sci U S A** 99: 15898-903.

88 At the International Maize and Wheat Improvement Centre (CIMMYT) in Mexico trials on moisture-stress resistant wheat plants are currently taking place in biosafety greenhouses. (Pellegrineschi A (2003) Drought-resistant GM crops: a promising future. SciDev.Net. Available: http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierReadItem&type=3&itemid=5&language=1&dossier=6. Accessed on: 2 Jun 2003.) Other research projects on abiotic stress resistance which are currently in the stage of field trials include, for example: frost tolerant potatoes in Bolivia, cold tolerant tomatoes in China, salt tolerant wheat in Egypt, moisture-stress resistant brassica in India, and salt and moisture-stress resistant rice in Thailand. (FAO Electronic Forum on Biotechnology in Food and Agriculture (2002) Background paper to the 8th conference, 13 November -11 December 2002. FAO. Available: http://www.fao.org/biotech/C8doc.htm. Accessed on: 23 Mar 2003.)

89 Dalrymple D (1976) Development and spread of high yielding wheat and rice in the less developed nations. US Dept of Agriculture, Foreign Development Division, Economic Research Service: Foreign Economic Agricultural Report No. 95. p. 120.

dwarfed varieties of wheat in the Green Revolution. When the gene was introduced into rice, dwarfed plants were obtained.[90]

74 At present, collaborators with the JIC in India have introduced the *Arabidopsis* gene into a variety of basmati rice and produced dwarfed basmati rice. This rice is commonly grown on the Indian subcontinent. Usually, the plants are tall, have weak stems and are highly susceptible to damage by wind and rain, which frequently leads to considerable losses of yield. Previous attempts to reduce the height of the basmati variety while retaining its desirable qualities using conventional breeding methods resulted in the loss of the characteristics for which it is valued. Field trials will eventually reveal whether the basmati dwarfed rice varieties have higher yields. An important feature of this application of genetic modification is that it contributes to both the improvement of traits and the preservation of biodiversity at the same time. The single gene can be inserted with minimal disturbance to the rest of the genetic complement and a multitude of locally well-adapted varieties can simultaneously be preserved and improved.[91]

Case Study 4: Improved micronutrients in rice

75 There are a variety of research projects which aim to produce enhanced levels of ß-carotene in food crops.[92] ß-carotene is an important micronutrient which is converted to vitamin A in the body. In the case of rice, ß-carotene is contained in the leaves, but not in the rice endosperm (the edible part). However, ß-carotene can be produced in the endosperm by means of genetic modification. In 2000 this was achieved by Professor Ingo Potrykus and Dr Peter Beyer at the Swiss Federal Institute of Technology, who transferred one bacterial gene and two daffodil genes into an edible strain of rice and thereby developed a ß-carotene enriched strain of rice which they called *Golden Rice*.[93] The primary aim of the researchers was to help prevent vitamin A deficiency (VAD) which is a frequent phenomenon in developing countries. In 1995, clinical VAD affected some 14 million children under five, of whom some three million suffered xerophthalmia, which is the primary cause of childhood blindness. 250 million children had sub-clinical deficiency, greatly increasing their risk of contracting ordinary infectious diseases such as measles, which in many developing countries lead to high mortality rates.[94] At least one third of the sufferers are found among poor people, who are unable to afford costly sources of vitamin A and live in Asian areas where rice is the main staple crop.

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90 Peng J *et al*. (1999) 'Green revolution' genes encode mutant gibberellin response modulators, **Nature** 400: 256-61.

91 Peng J *et al*. (1999) 'Green revolution' genes encode mutant gibberellin response modulators, **Nature** 400: 256-61.

92 Research is currently being undertaken in India, where researchers aim to produce mustard seeds to contain ß-carotene. The seeds are used to produce oil and preliminary findings suggest that fairly high levels of ß-carotene can be provided. The project is a joint enterprise between Tata Energy Research Institute (TERI) and the company Monsanto, with support of the US Agency for International Development (US AID). (Monsanto (2002) Growing Partnerships for food and health. St. Louis: Monsanto.) Also, researchers at the International Crops Research Institute for Semi Arid Tropics (ICRISAT) have produced a millet strain that contains high levels of ß-carotene, similar to those found in Golden Rice. However, unlike in the case of Golden Rice, the Golden Millet strain was produced by conventional breeding techniques. Using genetic marker techniques, it is intended to transfer the trait to other millet crops. (Jayaraman K (2002) Natural 'golden millet' rivals 'golden rice'. SciDev.Net. Available: http://www.cdrive.co.za/ge_info/34.htm. Accessed on: 2 Jun 2003.) Further research relating to micronutrient enriched crops involves potatoes. Researchers at the Jawharal Nehru University in New Delhi are currently working on the 'Protato'. Adding the *AmA1* gene to conventional potatoes, the plants produced three times more protein than conventional potatoes, including significant amounts of the essential amino acids lysine and methionine. Deficiencies of these nutrients in the diets of children are common. Lack of lysine, for example, affects brain development. (Coghlan A (2003) 'Protato' to feed India's poor, **New Scientist** 177: 7.)

93 Golden Rice technology was developed with funding from the Rockefeller Foundation (1991-2002), the Swiss Federal Institute of Technology (1993-1996), the European Union under a European Biotech Programme (1996-2000) and the Swiss Federal Office for Education and Science (1996-2000).

94 Personal communication, Professor Potrykus, 21 March 2003; ACC/SCN in collaboration with IFPRI (2000) Fourth Report on the World Nutrition Situation: Nutrition throughout the Life Cycle. Geneva: ACC/SCN.

76 The development of Golden Rice was significantly complicated by issues relating to intellectual property rights (IPRs) and material transfer agreements (MTAs), which are discussed in more detail in Section 6. However, these issues were resolved after a public-private partnership with the company Syngenta was established, which provided assistance in the negotiation of legal matters. The terms of the partnership are such that the company retains the rights for the commercialisation of Golden Rice, but allows Golden Rice to be made available free of charge to all those whose profit is below US$10,000 per year per farmer or trader. Research on Golden Rice is currently undertaken in 14 public sector research institutes which form the Golden Rice Network, an international cooperative, bringing together researchers from India, China, Indonesia, Vietnam, Bangladesh, the Philippines and South Africa.

77 Although a successful laboratory strain of Golden Rice has been available since 2000, field trials which are needed before the rice can be made available to farmers in developing countries have been delayed considerably. In particular, deregulation for trials in the countries participating in the Golden Rice Network has proved to be onerous. Influenced by the European debates about the risks associated with the use of GM crops, regulatory agencies in developing countries have been hesitant to grant licences for field trials.

78 Proponents of Golden Rice point out that this is a particularly undesirable consequence of the regulatory approach currently favoured by the EU with regard to GM crops. They emphasise that the genome of Golden Rice as well as that of other GM crops is modified in a much more precise way than that of varieties produced by means of conventional plant breeding, which often leads to unpredictable and major rearrangements of the parental genomes. They argue that the regulatory requirements for Golden Rice are therefore unreasonably high. Under the current regulatory regime, field trials of Golden Rice are not expected to take place until 2007/8.[95] Proponents of the technology are therefore frustrated by these setbacks, and note that Golden Rice could be tested in field trials as soon as the coming season in many developing countries.[96]

79 Opponents, on the other hand, have questioned whether the amount of ß-carotene in Golden Rice would actually be sufficient to make a significant contribution to improved vitamin uptake.[97] Also, the bio-availability of ß-carotene from Golden Rice is unknown, which means that it is not yet clear to what extent the human body can make use of ß-carotene when it is eaten in Golden Rice. Some point out that to make use of the vitamin, an adequate intake of fat is needed. Others claim that the yellow colour of the rice may not be compatible with cultural preferences, and that Golden Rice will be rejected accordingly.[98] We consider these questions in more detail in paragraphs 106-110.

95 Personal communication, Professor Potrykus, 21 March 2003; Potrykus I (2000) The golden rice tale. Available: http://www.mindfully.org/GE/Golden-Rice-Ingo-Potrykus.htm. Accessed on: 3 Apr 2003.

96 Other areas of research on micronutrient-enriched plants concern crops with enhanced levels of iron, vitamin E, or protein. Experiments to produce these traits independently and simultaneously in rice have already been completed successfully. However, it has been reported that regulatory authorities might be hesitant to give approval for field trials of crops which involved multiple transgenic events. If that would be the case, it would seem unlikely that such crops will be available to people in developed or developing countries in the near future. Personal communication Prof Ingo Potrykus 21 March 2003; Potrykus I (2000) The golden rice tale. Available: http://www.mindfully.org/GE/Golden-Rice-Ingo-Potrykus.htm. Accessed on: 3 Apr 2003.

97 Greenpeace (2001) Vitamin A: Natural Sources vs 'Golden Rice'. Available: http://archive.greenpeace.org/~geneng/reports/food/VitaAvs.PDF. Accessed on: 20 May 2003.

98 Five Year Freeze (2002) Feeding or Fooling the World? London: Five Year Freeze; Koechlin F (2000) The 'Golden Rice' - a big illusion? Third World Network. Available: http://www.twnside.org.sg/title/rice.htm. Accessed on: 20 May 2003.

Case Study 5: Improved resistance to viruses in sweet potato

80 In Kenya, as in many other African developing countries, sweet potato is an important subsistence crop, typically grown by small-scale farmers. About 40% of the harvest is usually kept for household consumption. Yields are low. The common African yield of six tons per hectare is less than half of the global average.[99] Viruses and weevils frequently reduce yields by as much as 80%.[100] Effective controls of these pathogens are not available, and the crop has generally been neglected in international agricultural research.[101]

81 Since 1991 the Kenya Agricultural Research Institute (KARI) in cooperation with the company Monsanto and universities in the US has produced GM sweet potato strains that are resistant to the feathery mottle virus. Royalty-free licensing agreements have been signed that allow KARI and research institutes in other African countries to use the technology in the future. The crops are currently being tested in field trials and it is expected that yields will increase by approximately 18-25%. Where farmers sell part of their crops, the increased income has been estimated to be between 28-39%.[102]

Case Study 6: Improved resistance to diseases in bananas

82 Bananas make important contributions to food security in many developing countries. Leaves and fibres are used for a multitude of household and industrial purposes. Bananas also provide income to the farming community through local and international trade. World production of bananas is estimated to be approximately 70 million tons per year, of which around 85% are grown for local consumption by tropical small-scale farmers.[103] Approximately half a billion people in Asia and Africa depend directly on farming bananas. In Uganda, the crop is cultivated on one third of the arable land, and per capita consumption is 50 times higher than in the UK.[104]

83 Like all plants, bananas attract a range of different and highly adapted pests. However, the potential impact of these pests can have a particularly harmful effect on the crop. Unlike many plants, bananas reproduce asexually. The variety of different fruit grown today around the world have been cultivated from cuttings of a small number of naturally occurring mutants. Each 'variety' is therefore a clone, and the crop species is characterised by a very low level of genetic diversity. Cultivated bananas are actively sterile triploids, which means that there is little hope that conventional plant breeding will produce crops that are resistant to active bacterial or viral infections.[105] Genetic modification offers possibilities of increasing

99 Qaim M (1999) The Economic Effects of Genetically Modified Orphan Commodities: Projections for Sweetpotato in Kenya. ISAAA briefs: no. 13. Ithaca, NY: ISAAA.

100 Monsanto (2003) Our committments: Technology cooperation. Available: http://www.monsanto.com/monsanto/layout/our_pledge/techcoop.asp. Accessed on: 20 May 2003.

101 However, considerable work is undertaken by the International Potato Centre (CIP), one of the centres of the Consultative Group on International Agricultural Research (CGIAR). CIP's aim is to reduce poverty and achieve food security on a sustained basis in developing countries through scientific research and related activities on potato, sweet potato, and other root and tuber crops. Their research program comprises 13 projects, several of which involve the use of genetic modification: the improvement of sweet potato varieties, virus control, and improving post-harvest quality and nutrition (see CIP. Projects. Available: http://www.cipotato.org/projects/projects.htm. Accessed on: 20 May 2003).

102 Odame H, Kameri-Mbote P and Wafula D (2002) Innovation and policy process: case of transgenic sweet potato in Kenya. Economic and Political Weekly, Vol XXXVII, No 27. Qaim M (1999) The Economic Effects of Genetically Modified Orphan Commodities: Projections for Sweetpotato in Kenya. ISAAA briefs: no. 13. Ithaca, NY: ISAAA; Pew Initiative on Food and Biotechnology (2001) Harvest on the Horizon: Future Uses of Biotechnology. Washington, DC: Pew Initiative on Food and Biotechnology.

103 FAO (2002) FAOSTAT. Available: http://apps.fao.org/. Accessed on: 20 May 2003.

104 Pearce F (2003) Going bananas, **New Scientist** 177: 26-9.

105 Conway G (2003) From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. Accessed on: 16 April 2003. p. 19.

resistance to pest and disease. The technology may also help increase the diversity of banana varieties, which in turn can contribute to slowing down the impact of pests.

84 Common infestations of bananas include nematodes, viruses, and fungal diseases. The most harmful fungal disease is Black Sigatoka which can reduce fruit yields by as much as 50-70%. It can cut the productive lifetime of a plant from approximately 30 years to two or three years. The Cavendish banana is the most frequently grown commercial banana variety. To protect it from the fungus, on average up to 40 sprayings of fungicide are applied per year. These sprayings represent up to a quarter of the production costs, are environmentally problematic, and have considerable negative health implications for farm workers. According to a recent Pan American Health Organisation (PAHO) study, one fifth of the male workers on banana farms in Costa Rica are sterile, and it is reported that female workers have a 50% increased chance of developing leukaemia and passing on birth defects to their children.[106]

85 One of the goals of a public, global biotechnology consortium led by the International Network for the Improvement of Banana and Plantain (INIBAP), a programme of the International Plant Genetic Resources Institute (IPGRI), is to sequence the genome of inedible wild bananas from South East Asia, as these are resistant to Black Sigatoka. It is hoped that the project will help in the identification of genes which are relevant for resistance, and that these genes could then be introduced in leading varieties of edible bananas.[107] Other research is being undertaken to produce bananas that are resistant to nematodes,[108] or to viral diseases such as the banana bunchy top virus or banana bract mosaic virus.[109]

Case Study 7: Biopharmaceuticals

86 An application of genetic modification of crops that differs considerably from the previous examples is the possibility of producing biopharmaceuticals, such as vaccines, in crops. Two distinct procedures can be identified. One option is to modify plants in such a way that they produce substances which are extracted from the harvested plant and then processed into refined compounds. The other option is to modify plants in such a way that they produce vaccines which can be administered by ingesting the crop. This is achieved by modifying the crop to produce DNA fragments from a specific pathogen. These fragments code for proteins which provoke an immune response in the human body. The advantages of edible vaccines are manifold: injected vaccines are expensive, require trained medical staff for their administration, and usually necessitate constant cooling during transport and storage, which creates difficulties in many developing countries. The use of needles also brings with it the risks of spreading infections.

87 Development of GM crops which can produce biopharmaceuticals is at a very early stage. Scientists at Cornell University are currently working on tomatoes modified to be used as a vaccine against the Norwalk virus, which causes severe diarrhoea. Studies on mice have already

106 Pearce F (2003) Going bananas, **New Scientist** 177: 26-9.

107 Pearce F (2003) Going bananas, **New Scientist** 177: 26-9. AstraZeneca is also developing cultivars with resistance to Black Sigatoka Biotechnology Information Organisation Agricultural Biotech Products on the Market. Available: http://www.bio.org/food&ag/approvedag98.html. Accessed on: 20 Mar 2003.

108 Researchers at the Catholic University of Leuven are developing banana cultivars with resistance to nematodes, which can lead to an average 20% loss in banana plantations, and fungi resistance. KU Leuven Laboratory of Tropical Crop Improvement. Available: http://www.agr.kuleuven.ac.be/dtp/tro/home.htm. Accessed on: 20 May 2003.

109 Research at the Catholic University of Leuven and at Queensland University of Technology, in Australia has focused on developing bananas which are resistant to these viruses, which are among the major viral diseases relevant for bananas worldwide. KU Leuven Laboratory of Tropical Crop Improvement. Available: http://www.agr.kuleuven.ac.be/dtp/tro/home.htm. Accessed on: 20 May 2003; Demegen (2001) International Plant Biotech Groups Colloborate. Available: http://www.demegen.com/prs/pr011213.htm. Accessed on: 20 May 2003.

shown an increased immune response. In another study, bananas have been genetically modified to produce a vaccine against hepatitis, although it has not yet been possible to accumulate robust levels of antigens in the fruit.[110] There have also been experiments with GM potatoes aiming to develop a vaccine against rotavirus and against the bacterium *E. coli* which causes diarrhoea. Feeding studies involving mice have shown valid responses.[111] However, a number of questions remain to be addressed. One of these is how the appropriate dose could be controlled. Another has to do with the effect of such crops on insects and other animals which might feed on the crop. For example, with respect to proteins which are produced commercially for use in research and diagnostics it has been reported that avindin, which is produced by the company Prodigene, is toxic for certain insects.[112] There are also environmental issues relating to gene flow from GM crops to non-GM crops, and it has been reported that left-over grains from GM maize which has been manipulated to express biopharmaceutical compounds have inadvertently germinated amidst soybeans which have been grown on the same field in the season following the trial.[113]

Summary of Case Studies

88 We briefly summarize the possible benefits and risks which have been illustrated by the Case Studies above. Current evidence suggests the following advantages of specific GM crops:

- *Bt* cotton has the potential for more efficient and selective pest control, reduced applications of pesticides, reduction of environmental degradation, increased health benefits for farm workers and increased profits for farmers (Case Study 1);
- improved resistance to environmental stresses such as cold, moisture-stress and high salt levels in the soil can be achieved in GM rice (Case Study 2); the yield in rice can be increased more efficiently by means of ‘dwarfing’, (Case Study 3), while maintaining the benefits of locally well adapted varieties;
- there is potential for the production of micronutrient-enriched rice which could make a significant contribution to prevent health problems such as VAD (Case Study 4);
- Case Study 5 showed that the use of GM virus-resistant sweet potatoes could prevent dramatic and frequent reductions in yield of one of the major food crops of many poor people in Africa, which is of essential importance for subsistence farmers and those selling parts of their harvest;
- Case Study 6 on GM bananas illustrated the possibility of achieving protection against devastating fungal diseases and reductions in applied pesticides, with direct financial and health-related consequences for farmers and farm workers. Since bananas produce sterile pollen and only reproduce asexually, genetic modification can also help to produce a more diverse range of varieties, which would allow for additional protection against the impact of pest infestation;
- although somewhat more distant in terms of practical application, GM crops may also offer cheap and far-reaching provision of vaccines against diseases such as severe diarrhoea and possibly hepatitis (Case Study 7).

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110 AEBC (2002) Looking Ahead - An AEBC Horizon Scan. London: Department of Trade and Industry.

111 Wong K (2001) Souped-Up Spuds Show Promise for Edible Vaccines. Scientific American. Available: http://www.sciam.com/article.cfm?chanID=sa003&articleID=00019658-ED97-1C5E-B882809EC588ED9F. Accessed on: 20 May 2003.

112 Genewatch (2003) Genetic Modification: The Need for Special Regulation. Briefing No. 21. Tideswell, Derbyshire: Genewatch.

113 Cohen P (2002) Stray genes spark anger, **New Scientist** 176: 7.

89 We also noted the following possible risks associated with these benefits:

- The possibility of gene flow, and the potential impact of this event on other plants and organisms needs to be considered in the case of all GM crops which have been discussed, with the exception of bananas (Case Study 6). Transgenes that come from another organism or species may require particular attention, as has become clear from the examples of *Bt* cotton and of those crops used for the production of biopharmaceuticals (Case Studies 1 and 7). The possibility of gene flow might also need to be considered carefully where a GM crop is planted in an area in which there is a high level of genetic diversity of the crop;
- Case Studies 1 and 7 illustrated that the effect of genetic modification on insects and animals that may feed on the GM crop requires consideration, in particular where crops have been modified to contain substances which wild relatives of the respective crops would not normally contain.
- There were also questions related to the setting of priorities: should approaches such as Golden Rice (Case Study 3) or the production of biopharmaceuticals (Case Study 7) be pursued, if there could be other ways to achieve the same end? Would investments in such approaches distract attention and resources from other approaches?
- Commercial agrochemical companies and those who own IPRs over technologies necessary for the development of GM crops have considerable influence over the availability of GM crops, as was clear from the Case Study on Golden Rice (Case Study 3) and on *Bt* cotton (Case Study 1).

90 We now consider arguments in relation to these potential risks and benefits, and possible ways to balance them.

Section 4
Questions relating to the use of GM crops in developing countries

In view of the amount of food available worldwide, are GM crops really necessary?

91 Some argue that GM food crops are superfluous because enough food is already produced globally. Instead, it is recommended that more effort should be put into better distribution of food.[114] It is true that the world's current population of six billion could get more than enough calories and most, though by no means all, of its other essential nutrients from the current world production of staple crops alone, as there would be 3,600 calories per person per day available.[115] However there are two critical objections to this argument.

- Most cattle and poultry consume staple crops in the form of maize or soybean. The conversion of grain and fodder into meat and milk requires three to six-fold more staple crops than would be needed if people ate the crops directly. Therefore, to obtain 3,600 calories (or even only the recommended 2,000-2,500 calories), for everyone daily from existing production of staple crops, the consumption of meat, dairy products, eggs and poultry would have to be abandoned.
- Staple crops, the land on which to grow them, and/or cash to buy staple crops, would need to be distributed equally to all in the world, entailing considerable logistical and political challenges.

92 Progress towards such ends has been, and will probably remain, slow, as we pointed out in our 1999 Report (paragraph 4.8). The growing demand for meat, milk and eggs has meant that a rapidly rising proportion of the world's staple crops are used for their production and this rise is set to continue.[116] As for redistribution, political difficulties within, let alone between, countries would be considerable. In addition there are onerous logistical problems to be taken into account: costs for local and international distribution of food are high, and it may not always be possible to consider cultural preferences for certain types of food. All in all, while striving for a fairer distribution of land, food and purchasing power, we take the view that it would be unethical to rely entirely on these means to address food security. Given the limits of what redistribution can reasonably be expected to achieve, we take the view that there is a duty to explore and enhance the possible contributions which GM crops can make in relation to reducing world hunger, malnutrition, unemployment and poverty.

93 Providing farmers with, for example, pest-resistant crops, appears to be a more appropriate solution than the alternative of leaving them to rely on replacement crops by the World Food Programme (WFP) or other organisations in the event of their harvest being destroyed by pests or viruses. This is of particular importance as the production of food is not just a necessity of life, but is an integral part of social and cultural practice. As we have said, a

114 Five Year Freeze (2002) Feeding or Fooling the World? London: Five Year Freeze.

115 Prof Mazoyer in FAO Electronic Forum on Biotechnology in Food and Agriculture (2000) Can agricultural biotechnology help to reduce hunger and increase food security in developing countries? FAO. Available: http://www.fao.org/biotech/C5doc.htm. Accessed on: 23 Mar 2003.

116 Delgado C *et al*. (1999) Livestock to 2020: The Next Food Revolution (2020 Vision for Food, Agriculture and the Environment Discussion Paper 28). Washington, DC: IFPRI. In addition, it has been noted that a further increase in the use of staple crops for animal feed can be expected because animal feed that has been derived from meat has been abandoned due to the controversies about BSE.

substantial part of people's livelihood in developing countries depends on agriculture, where, for example, in Africa more than 70% of the population are farmers or work on farms.[117] We conclude therefore that genetic modification has the potential to make a substantial contribution to improving agricultural practice of farmers whose crops are affected by pests or viruses, as the examples of GM sweet potato (see Case Study 5) and banana (see Case Study 6) have shown. If such crops can be made freely available in developing countries they could contribute to preserving the independence and livelihood of farmers, who could avoid being reliant on redistribution or food aid.

Why should alternative forms of agriculture, such as organic farming, not be sufficient to provide crops for household consumption and sale?

94 Farmers in many developing countries currently practice a form of organic farming as they cannot afford artificial fertilisers, insecticides and pesticides. Some people in developed countries view this situation with envy and think that it is a particularly 'natural' and desirable form of agriculture.[118] Often, they are unaware of the intensive inputs which are supplied by organic farmers in developed countries. But organic farmers in developing countries are usually not able to provide the continuous enrichment of the soil without fertiliser. On closer inspection 'organic farming' in developing countries takes on a different meaning. Most crop yields are too low to provide leftover material to replenish the land. Livestock produce poor quality manure which is mostly burned as fuel. Infestations of pests can often not be countered effectively.[119] As a consequence, yields of almost all crops grown in developing countries are significantly lower than in developed countries. For example, on average, yields of maize and rice are approximately half of that in developed countries.[120] In addition, we have noted the devastating effect which, for example, viruses and weevils have on sweet potatoes (see Case Study 5), and the consequences of the Black Sigatoka fungus for bananas (see Case Study 6). In view of the fact that populations in developing countries are expected to increase considerably over the coming generation (see paragraphs 20-21), it is unlikely that organic farming alone can cope with these challenges and provide for sustainable agriculture.

95 We emphasise that this view does not imply that other important strategies in agricultural research and practice should be neglected. For example, integrated pest management can be a useful way to combat *Striga*, which is a weed that attacks maize seeds. Research has shown that planting maize together with the legume *Desmodium unicatum* can substantially help to control *Striga*. With respect to combating the cassava mealy bug, the introduction of a South American wasp, which is a natural enemy of the pest, helped to reduce its impact.[121] Thus,

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117 World Bank (2000) Can Africa Claim the 21st Century? Washington, DC: World Bank.

118 With regard to achieving reductions in the application of agrochemical compounds such as pesticides or insecticides, we note that the use of GM crops is indeed complementary to the interests of those promoting organic farming. For example, considerable reductions in the use of pesticides have already been reported in the case of *Bt* cotton (see Case Study 1) and similar reductions in the use of fungicide seem likely for GM bananas (Case Study 6).

119 Conway G (2003) From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. Accessed on: 16 April 2003.

120 FAO (2002) FAOSTAT. Available: http://apps.fao.org/. Accessed on: 20 May 2003.

121 Herren HR (1995) Cassava and Cowpea in Africa, *in Biotechnology and Integrated Pest Management*, Persley, Editor. CABI: Wallingford, UK; Khan Z and *et al* (2002) Control of *Witchweed Striga hermonthica* by intercropping with Desmodium spp. and the mechanism defined as allelopathic, **J. of Chemical Ecology** 28: 1871-85. However, we note that, just as with the introduction of any new crop variety, whether GM or non-GM, all such measures have to be carefully considered with regard to their impact on biodiversity (see paragraphs 112-117). In all cases, a reasonable application of the precautionary principle needs to take place.

many factors can contribute to improving agriculture, and the development of better adapted crops is as important as the development of alternatives to inorganic fertilisers and pesticides, or the improvement of soil and water management.

96 As Gordon Conway, President of the Rockefeller Foundation, has recently observed, the question of whether it is wiser to draw on biotechnological advances in the context of contemporary plant breeding to improve agriculture, rather than achieve this aim by way of more effective use of resources and alternative methods, is hardly ever a question of 'either/or'. It is mostly a situation of 'both/and': 'the best technology is the one that will safely get the job done in the simplest and least expensive way possible'.[122] Thus, while in some cases, organic farming has the potential to improve substantially agricultural practices of small-scale, resource-poor farmers, it seems highly unlikely that it can solve all the problems.[123] For example, growing rice in areas with frequent lack of water (see Case Study 2) and protecting crops from viral or fungal diseases (see Case Studies 5 and 6) may require other solutions. In these cases, the application of GM crops may be the more promising solution. We therefore take the view that sustainable agriculture can be achieved most effectively when the relevant approaches and practices are combined, as appropriate.

Will GM crops be of benefit only to large-scale farmers and what would their role be in relation to the reduction of poverty?

97 We concluded in our 1999 Report that agriculture has a crucial role in developing countries in relation to both the reduction of poverty and enhancement of the local food supply. We noted that GM crops could have substantial potential to contribute to improving agriculture (see paragraphs 4.4-4.12). In re-examining the arguments we find our views confirmed in light of subsequent developments (see paragraphs 16-30).[124]

98 While it is clear that poverty has many causes (see paragraph 13), it is also clear that the efficiency of agriculture has considerable impact on the standard of living of people involved in work on small-scale farms in developing countries. This is most notable in Africa, where the majority of the population live and work on small farms in rural areas (see paragraph 24). Moreover, it is particularly true with respect to improving the situation of women, since the majority of the world's resource-poor farmers are women. While it is estimated that world-wide, women produce more than 50% of all the food that is grown, this percentage is considerably higher in many developing countries.[125] For example, it is estimated that 80% of the food grown in sub-Saharan Africa, and 50-60% in Asia, is grown by women. In many instances, the improvements which can be achieved through GM crops may reduce much of the effort required in subsistence agriculture.[126]

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122 Conway G (2003) From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. Accessed on: 16 April 2003.

123 Pretty *et al*. found improvements in food production occurring through one or more of four mechanisms: intensification of a single component of a farm system; addition of a new productive element to a farm system; better use of water and land; improvements in per hectare yields of staples through introduction of new regenerative elements into farm systems and new locally appropriate crop varieties and animal breeds. (Pretty J, Morison JIL and Hine RE. 2003. Reducing food poverty by increasing agricultural sustainability in developing countries. **Agric. Ecosys. Environ.** 95(1), 217-234.)

124 Similarly, a recent report by DFID points out that agriculture is critical for the reduction of poverty in developing countries as it contributes to economic growth; is a key basis of livelihood strategies of poor people; provides locally available staple foods for poor people, and enables a sustainable management of resources. DFID (2002) Better Livelihoods for Poor People: The Role of Agriculture. London: DFID.

125 DFID (2002) Better Livelihoods for Poor People: The Role of Agriculture. London: DFID.

126 Background documentation prepared for the *International Technical Conference on Plant Genetic Resources*, Leipzig, Germany, 17-23 June 1996.

99 With respect to crops grown primarily for commercial reasons, as in the case of *Bt* cotton in China and South Africa (see Case Study 1), we conclude that the case for the use of GM crops remains compelling. Beneficiaries of the crop have predominantly been small-scale farmers who manage farms of between one and two hectares. We have noted the considerable financial gains (see Table 1) and highlighted benefits for the health of those working on farms, and for the environment, which have resulted from significant reductions in the amounts of pesticides that need to be applied to GM varieties (paragraphs 61-62, see also Case Study 6 on GM bananas, paragraph 84).

100 We also observed in our 1999 Report that it is important to consider the implications of GM crops for international trade (paragraphs 1.21, 4.31-4.32). The main exports from developing countries are tea, coffee, cocoa, cotton and sugar. In the case of cotton, products from developing countries will have to compete with those produced in developed countries. The use of *Bt* cotton and other GM crops is likely to become more widespread in developed countries. This may lead to an increase in supply and lower costs of inputs such as pesticides, which can be expected to lead to depressed prices for the crops. Those farmers who use non-GM varieties are likely to face financial disadvantages. It is therefore of crucial importance that developing countries have the opportunity to use high-yielding crops to allow their exports to compete on the world markets. Failure to develop the capacity to screen, breed and test the safety of GM crops and to manage their release and use, may result in increasing the gap between rich and poor even further.[127]

Can GM crops be introduced in such a way that local customs and practices are respected?

101 It is sometimes argued that GM crops will transform agricultural practices in developing countries in such a way that local traditions are not respected. So-called ‘informal seed systems’ may be broken down, which means that it may become impossible for farmers to keep, or exchange with other farmers some of their harvested grains as seed for the next season.[128] In the 1990s, more than 80% of crops sown in developing countries were sown from farm-saved seeds.[129]

102 While it is clearly important to respect such traditions, we question whether, in contemporary agricultural practice, informal seed systems are equally important in all developing countries, and throughout individual countries. In many cases, farmers are well aware that, for open-pollinated crops such as maize, saved seed produces lower yields than F1 hybrids (see paragraph 32). Many farmers in Zambia, Kenya and South Africa have been buying hybrid seed from local or multinational companies for some years.[130] For self-

127 However, the uptake of GM crops in developing countries is, for a variety of reasons, not likely to be straightforward. In particular, due to the lack of appropriate systems for the administration and monitoring of the use of GM crops, and also because of the restrictive policy currently adopted by the EU. These and further issues relating to international trade and policy will be considered in more detail in Section 5.

128 Action Aid (1999) AstraZeneca and its genetic research. Feeding the world or fuelling hunger? London: Action Aid; Christian Aid (1999) Selling suicide. Farming, false promises and genetic engineering in developing countries. London: Christian Aid; Corner House (1998) Food? Health? Hope? Genetic Engineering and World Hunger. Sturminster Newton: The Corner House.

129 Jaffee S and Srivastava J (1992) Seed System Development: The Appropriate Roles of the Private and Public Sectors. World Bank Discussion Papers 167. Washington, DC: The World Bank; Srivastava JP and Jaffee S (1993) Best Practices for Moving Seed Technology. New Approaches to Doing Business. World Bank Technical Paper No. 213. Washington, DC: The World Bank; Tripp R (1997) New Seed and Old Laws: Regulatory Reform and the Diversification of National Seed Systems. London: Intermediate Technology Development Group Publishing.

130 Thomson J (2002) Genes for Africa: Genetically Modified Crops in the Developing World. Cape Town: University of Cape Town Press; Ismael Y, Bennett R and Morse S (2002) Benefits of *Bt* cotton use by smallholder farmers in South Africa, **AgBioForum** 5: 1-5; deVries J and Toenniessen G (2001) Securing the Harvest: Biotechnology, Breeding and Seed Systems for African Crops. New York: CABI Publishing.

pollinated crops such as rice and wheat, where hybrids are unavailable, there is nothing to prevent farmers from retaining seed from the harvest for several years with only minor reductions in yield, as they have been doing for decades with leading varieties developed during the Green Revolution.[131]

103 Seed re-use can be prevented by technologies such as GURT which effectively sterilises saved seed (see paragraph 49). Such technologies continue to be patented and may be problematic, as we observed in our 1999 Report (see paragraphs 2.26, 4.75).[132] However, this development need not prevent farmers from continuing to save seed from non-terminated varieties. Nor do we take the view that it is objectionable in principle when farmers in developing countries decide to buy seed rather than sow saved seed.

104 Finally, we note that the use of GURT in developed countries has also been suggested as an effective way of preventing the spread of pollen from GM crops to neighbouring organic or conventional crops, a cause of great concern to many farmers. If new varieties of crops, whether GM or not, for technical or economic reasons compel the use of this technology, there could be problems of affordability (though seeds are seldom a high proportion of total farm costs), and of dependence on credits to purchase more expensive seed (especially if the rains fail) or on a single monopolistic seed supplier. Possible remedies would appear to lie in public sector support for research into appropriate seeds (whether GM or not) that can be retained by farmers with minimal losses of yield, and in policies to keep the private supply of seeds reasonably competitive.

105 Although it is possible that some applications of GM crops may have detrimental effects on traditional farming practices, as has been suggested in the case of coffee,[133] we are not persuaded by the argument that the use of GM crops in all cases entails and disseminates Western farm practices which will displace the use of locally-adapted crops. As we have noted, researchers are attempting to create improved sweet potatoes (see Case Study 5) and bananas (see Case Study 6) by means of genetic modification. These traditional crops are used almost exclusively in the context of subsistence farming, or for domestic consumption and trade. Much of this research is, moreover, being undertaken by researchers from developing countries.

Can GM crops make a relevant contribution to solving health problems in developing countries?

106 The development of Golden Rice (see Case Study 4) has become particularly controversial. For a considerable time, strong claims with regard to its usefulness have been made by both proponents as well as opponents in the absence of validated empirical evidence. Some see Golden Rice as a prime example of an ineffective ‘technological fix’ and a waste of public and private funding. They argue that instead of focusing on biotechnology-based solutions, an analysis of political, economic and social structures that influence the access to food should be undertaken. Others claim that provision of a greater variety of food is the best solution to improving health.[134]

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131 Although this does not apply to the still infrequent F1 hybrids of such crops.

132 Also, it has been reported that despite its pledge in 1999 not to commercialise GURT, the company Monsanto has recently reconsidered its position. See Collins HB and Krueger RW (2003) Potential Impact of GURTs on Smallholder Farmers, Indigenous & Local Communities and Farmers Rights: The Benefits of GURTs. Paper made available to the CBD's Ad Hoc Technical Expert Group on the Impact of GURTs on Smallholder Farmers, Indigenous People and Local Communities, February 19-21, 2003. The paper is presented as the official position paper of the International Seed Federation.

133 Action Aid (2001) Robbing coffee's cradle - GM coffee and its threat to poor farmers. London: Action Aid.

134 Five Year Freeze (2002) Feeding or Fooling the World? London: Five Year Freeze. p. 20-26; Ho M-W 'Golden Rice' - An Exercise in How Not to Do Science. ISIS. Available: http://www.i-sis.org.uk/rice.php. Accessed on: 20 Mar 2003.

107 Most of the proponents of Golden Rice do not deny that consideration of adequate political, economic and social frameworks is essential. Golden Rice is also not seen as a long-term substitute for a properly balanced diet. However, it is well known that green leafy vegetables, which are often cited as an appropriate alternative for the provision of vitamin A are seldom cheap, or easily prepared (especially for small children), or available year-round to people in developing countries. In addition, if and when they are available and affordable, considerable numbers of servings of green leafy vegetables are required to provide the desirable level of vitamin A.[135] Therefore, since vitamin A cannot be derived from rice without genetic modification, it is argued that there is every reason to use the potential of Golden Rice, and in addition, that even small increases in the level of vitamin A are desirable.

108 With regard to the question of whether or not the levels of ß-carotene which Golden Rice could produce are of nutritional relevance to people living in developing countries, we make the following observation. According to the environmental group Greenpeace, a child would need to consume approximately 3 kilograms of uncooked Golden Rice per day to cover the recommended daily allowance (RDA) of vitamin A.[136] This is based on the assumption that a child between one and three years would require 400 micrograms of vitamin A per day. Professor Potrykus and Dr Beyer, on the other hand, report that an RDA of 300 micrograms of vitamin A is appropriate, and that 100 grams of Golden Rice produces approximately 160 micrograms. Thus, a daily portion of 200 grams of Golden Rice yielding 320 micrograms of ß-carotene could technically cover the RDA if ß-carotene were converted into vitamin A at a 1:1 ratio.[137]

109 However, the researchers also note that it is not yet clear whether these figures equal the amount of vitamin A that is actually available to the body. A standard conversion rate for the production of vitamin A from ß-carotene in man has not yet been agreed. Researchers for Golden Rice work on the basis of a conversion rate of 2:1. Thus, Golden Rice only seems to provide an amount of 80 micrograms of ß-carotene per 100 grams. However, this level is still thought to be significant, as the amount of ß-carotene required to prevent VAD-related diseases in the average child is half of the RDA. 200 grams of Golden Rice per day, providing 160 micrograms of ß-carotene which would be directly available to the body, would therefore be sufficient to prevent these diseases.[138]

110 In the case of conversion rates, we consider that it is too soon to come to any conclusions. We understand that experiments to assess more precisely the levels of vitamin A uptake are currently in progress at the United States Department of Agriculture (USDA) Laboratory for Human Nutrition, Boston, and are expected to be completed by the end of 2004. **Since it is not yet clear how effective the approach is, it is essential that reliable empirical data from nutritional and bioavailability studies be obtained as a priority. However, in endorsing continuing research of approaches such as Golden Rice, we emphasise that it is also**

135 Conway G (2003) From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. Accessed on: 16 April 2003.

136 Greenpeace (2001) Vitamin A: Natural Sources vs 'Golden Rice'. Available: http://archive.greenpeace.org/~geneng/reports/food/VitaAvs.PDF. Accessed on: 20 May 2003.

137 Beyer P and Potrykus I How Much Vitamin A Rice Must One Eat? AgBioWorld.org. Available: http://www.agbioworld.org/biotech_info/topics/goldenrice/how_much.html. Accessed on: 20 May 2003.

138 Beyer P and Potrykus I How Much Vitamin A Rice Must One Eat? AgBioWorld.org. Available: http://www.agbioworld.org/biotech_info/topics/goldenrice/how_much.html. Accessed on: 20 May 2003.

important to continue to evaluate the cost effectiveness, risk, and practicality of the approach in comparison to other means of addressing micronutrient deficiency.[139]

Will GM technology be controlled in ways that are compatible with self governance and economic security?

111 Case studies 2 and 5 have shown that some lessons about access to new varieties have been learned: in particular issues relating to access of poor farmers to beneficial varieties of seed should be considered early in the development phase. However, there have also been reports of difficulties with IPRs in the case of Golden Rice. We further note that the increasing concentration of seed companies and their control over germplasm raise particular issues. We consider these matters in more detail in Section 6 (see paragraphs 178-191).

Is the introduction of GM crops in developing countries consistent with the precautionary principle with regard to safeguarding biodiversity and human health?

Gene flow and biodiversity

112 The possibility that genes from GM crops may be transferred by pollen to other cultivars or wild-types of the same kind of crop has caused concern. This possibility is called *gene flow*. Gene flow is a common phenomenon and frequently occurs in nature, where many species of plants cross in this way with related species to produce new kinds of plants.[140] Gene flow is therefore in part responsible for the wide variety of plants which have evolved over many thousands of years. It may, however, be undesirable where it leads to the transfer of specific unwanted traits, or to the permanent and irreversible transformation of a species or variety. While this possibility exists both for gene flow from conventional crops, as well as for gene flow from GM crops, some fear that gene flow from GM crops could endanger biodiversity in a new way. In particular, this would occur where a GM crop has been modified to include a gene from another plant variety or species, as in the case of *Bt* cotton (see Case Study 1) or GM crops used for the production of biopharmaceuticals (see Case Study 7).

113 Negative consequences of gene flow are, in principle, less problematic with applications such as maize which has been genetically modified to express tolerance to herbicides when used in the UK, because there are no close relatives of maize which are susceptible to gene flow. However, there could be a problem in a country like Mexico, which is home to many different kinds of maize, and as such, a centre of diversity for the crop. The great variety of maize to be found in Mexico is important as raw material for farmers and plant breeders to improve the quality of crops in Mexico and worldwide. It is feared that these crops may be negatively affected by the introduction of genetic material from GM maize varieties.

114 In 2001, considerable interest was therefore aroused when researchers at the University of California at Berkeley published findings claiming that gene flow had occurred from GM maize to native Mexican maize.[141] A number of non-governmental organisations (NGOs) interpreted this as an instance of 'genetic pollution'[142] claiming that the 'well had been

139 Such comparisons would need to consider that, for example, according to the World Health Organisation (WHO), the annual cost of a known and proven solution for combating VAD (as a temporary alternative to an appropriate diet) is estimated to be in the area of US$75 million. (WHO (2002) Vaccines, Immunization and Biologicals: Vitamin A deficiency. Available: http://www.who.int/vaccines-diseases/diseases/vitamin_a.shtml. Accessed on: 20 May 2003.)

140 Ellstrand NC, Prentice HC and Hancock J (1999) Gene flow and introgression from domesticated plants into their wild relatives, **Annual Review of Ecology and Systematics** 30: 539-63.

141 (2002) Editorial note, **Nature** 416: 600.

142 ETC group (2002) Genetic Pollution in Mexico's Center of Maize Diversity, in *Backgrounder (Food First/Institute for Food and Development)*. Spring 2002.

poisoned'.[143] While it was not clear how the GM maize might have been introduced in Mexico, where a ban on GM crops is in place, subsequent debate about the scientific validity of the research led the journal *Nature* to disavow the published paper.[144]

115 The possibility of gene flow from GM crops may indeed require special attention, particularly in areas that comprise a high degree of natural variety of crops that are wild relatives of the GM crop. However, it is necessary to be clear about the precise characteristics of gene flow. First, the fact that a crop has been genetically modified to express a particular trait does not automatically mean that this trait confers a selective advantage in the wild. A specific trait may be present for a generation or two in wild plants, but it may disappear after the next generation, because other plants are more suited to the specific environment.[145] Nonetheless, in some instances, selective advantages have been reported, for example, in the case of GM insect-resistant rape seed.[146] Possible risks would therefore depend largely on the particular crop and trait, and research to assess such risks is vital.

116 Secondly, research is being undertaken to prevent pollen-mediated transmission of transgenes by ensuring that transgenic DNA is not incorporated in the pollen.[147] Such research would be crucial in particular with regard to GM crops used for the production of biopharmaceuticals. Thirdly, although pollen can travel over considerable distances, pollination, and therefore the successful transfer of genetic material, does not always occur.[148] Fourthly, appropriate separation distances can be established between fields containing GM and non-GM crops. Research to examine these and other issues is currently being undertaken on a large scale in the UK and other countries.[149] Where results of such research are not transferable to developing countries, additional research should be undertaken as necessary, to assess the impact of gene flow, particularly in sensitive areas that are centres of diversity. Fifthly, we note that many GM crops are male sterile varieties, which means that pollination cannot occur, although pollen may spread.[150] While these points make it clear that the risks of gene flow need to be assessed on a case by case basis, we note again that gene flow occurs widely throughout nature. Whether or not it is acceptable depends primarily on its consequences.

117 The question to be asked must therefore be: what kinds of risks are posed by the transfer of the genetic material X? Are these risks substantial? A necessary condition for answering these questions depends upon whether gene flow has occurred at a measurable level. We note that these two sets of issues are often confused. We accept that the introduction of GM crops in developing countries which are centres of diversity of specific crops may in some

143 GRAIN (2003) Poisoning the well: the genetic pollution of maize, in *Seedling*. 20 January 2003.

144 (2002) Editorial note, **Nature** 416: 600.

145 Brookes M (1998) Running wild, **New Scientist** 2158: 38-41; Masood E (1999) UK gets the green light on modified crops, **Nature** 397: 286.

146 Stewart C *et al*. (1997) Increased fitness of transgenic insecticidal rapeseed under insect selection pressure, **Molecular Ecology** 6: 773-9.

147 Daniell H *et al*. (1998) Containment of herbicide resistance through genetic engineering of the chloroplast genome, **Nat Biotechnol** 16: 345-8; Gray A and Raybould A (1998) Reducing transgene escape routes, **Nature** 392: 653-4.

148 ACRE (2000) Gene flow from genetically modified crops. Unpublished report, Advisory Committee on Releases to the Environment and the ACRE Secretariat. London: Department of the Environment, Transport and the Regions; Young J et al. (1999) The risks associated with the introduction of GM forage grasses and forage legumes. Report for MAFF (RG0219) research project. Aberystwyth: Institute of Grassland & Environmental Research.

149 Department for Environment Food and Rural Affairs Farm scale evaluations. Available: http://www.defra.gov.uk/. Accessed on: 20 May 2003.

150 Pretty J (2001) The rapid emergence of genetic modification in world agriculture: contested risks and benefits, **Environmental Conservation** 28: 248-62.

cases be problematic. **However, we are not persuaded that the possibility of gene flow should be sufficient to rule out the planting of GM crops in such areas. Specific risks need to be assessed in particular contexts, and possibilities of safeguarding biodiversity must be considered carefully. We note that the establishment and maintenance of comprehensive seed banks to conserve genetic resources of crop plants and their relatives is crucial.**

The precautionary principle

118 Even if it is agreed that an assessment of the safety of GM crops should focus primarily on the severity of the consequences of gene flow, it remains possible to conclude that GM crops should never be introduced in a particular environment or used for human consumption because there may be a very low, but significant possibility that some unpredictable, very substantial negative consequence will ensue. There are some who understand this possibility as the appropriate basis for the interpretation of the precautionary principle (see Box 4). They therefore argue that, irrespective of possible benefits, a new technology should never be introduced unless there is a guarantee that no risk will arise. Since no one can guarantee an absolute absence of risk arising from the use of GM crops, it follows that there should be a delay in the use of the technology until complete assurances of absence of hazard are available.

119 An alternative interpretation of the principle with regard to the use of GM crops is that it enjoins us to 'proceed with care', when we have no well-grounded reason to think that a hazard will arise and when there is a valuable goal to be achieved. By this interpretation, each release of a GM crop into the environment needs to be considered on a case by case basis. Each application would require an iterative approach in which contained use of GM crops preceded several smaller field trials, which might then be followed by larger trials and possibly a provisional and time limited commercial release.

120 In view of these observations, we favour the latter interpretation which we view as a reasonable application of the precautionary principle. To hold to the most cautious interpretation invokes the fallacy of thinking that the option of doing nothing is itself without risk. Yet, as we said in our 1999 Report (Chapter 4, see also paragraphs 17-28 above),

Box 4: **The precautionary principle**

The precautionary approach is invoked in order to address the absence of reliable scientific data, as stated in Principle 15 of the Rio Declaration on Environment and Development:

> 'In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.'*

The non-binding Declaration was agreed by 178 governments in Rio de Janeiro in 1992.

Similarly, Annex III of the Cartagena Protocol (see paragraphs 137-141) states that: '[l]ack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk'.

* Rio Declaration on Environment and Development (1992) The United Nations Conference on Environment and Development, Rio de Janeiro, 3-14 June 1992. Available: http://habitat.igc.org/agenda21/rio-dec.htm. Accessed on: 18 May 2003.

food security and environmental conditions are deteriorating in many developing countries. This is not to say that we should be imprudent in the assessment of risks. It is to say, however, that restrictive interpretations of the precautionary principle, that imply a general prohibition on the use of GM technology, require very strong justification.

121 The precautionary principle is also relevant in relation to the effectiveness of conventional and 'organic' agriculture in developing countries. As we have noted (paragraphs 27-28), expansion into marginal lands is generally unprofitable and increases environmental hazards. Nonetheless, it is widely practiced throughout much of Africa, and leaves an unmistakable and undesirable *farming footprint*, destroying forests and other areas of wildlife. We have also shown (Case Studies 1 and 6) that much of the current agricultural practice in relation to the farming of cotton and bananas requires the application of considerable amounts of pesticides and fungicides, with negative consequences for the environment, and for the health of farm workers. Thus, questions about the use of GM crops need to be posed in the light of a realistic comparator system: how does the use of a GM crop compare to other alternatives? What are the risks of the non-GM approach, that would constitute the option of 'doing nothing'? In what respect are the risks posed by the introduction of a GM crop greater or less than those of the alternative system? It seems likely that GM crops could have an active role to play in the safeguarding of environments, if they can grow under more demanding conditions such as aridity, or on soils which would not be suitable for most conventionally bred crops.[151] We also observe that the precautionary principle should be invoked in cases such as the deliberate introduction of wasps that are exported from one continent to another to act as the natural enemy of a domestic pest (see paragraph 95). While we take the view that such solutions can indeed make valuable contributions to improving agriculture in developing countries, we emphasise that the *naturalness* of the approach should not distract from careful analysis of possible impacts on the environment. Here, too, the potential for the irreversible alteration of eco-systems needs to be considered.[152]

Food safety

122 We take the view that a reasonable interpretation of the precautionary principle should also be applied when assessing the safety of GM crops that are intended for human consumption. In this context, we welcome the use of the concept of 'substantial equivalence' as an essential part of safety assessments of GM crops. This concept, which has been endorsed by the World Health Organisation (WHO), involves comparing the GM crop in question to its closest conventional counterpart.[153] The purpose of the procedure is to identify similarities and differences between a GM crop and a comparator which has a history of safe use. The approach does not aim to establish absolute safety, which is impossible to attain for any type of food. Rather, it aims to assure that a new type of food, such as a GM crop, is as safe to eat as its closest traditional counterpart. This procedure is very useful for identifying intended or unintended differences between a GM crop and its comparator which might require further safety assessments (see Box 5).

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151 We have also pointed out that GM crops can in specific instances have the potential of improving biodiversity (paragraph 67) as increased numbers and varieties of spiders, beetles and other insects that are important food for a number of birds have been reported in the case of *Bt* crops.

152 See also footnote 49.

153 FAO and WHO (2000) Safety aspects of genetically modified foods of plant origin. Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology World Health Organization, Geneva, Switzerland 29 May – 2 June 2000. Geneva: WHO. paragraph 4.4.

Box 5: **Safety issues relating to GM crops**

Following identification of the differences between a GM crop and its nearest conventional counterpart, it may be important to consider the following issues:

- process of genetic modification;
- safety of new proteins;
- occurrence and implications of unintended effects;
- gene transfer to gut microflora;
- allergenicity of new proteins;
- role of the new food in the diet; and
- influence of food processing.

123 This approach has been used successfully in the case of crops which have been produced by other forms of contemporary plant breeding, such as mutation breeding (see paragraph 38). With regard to assessing risks that are specific to GM crops, we have already seen that the technique often involves the introduction of genetic material from other species. Risks may also arise from the use of genes from some plant viruses to facilitate the expression of a gene (see paragraph 40).

124 Fears have been expressed that viral promoters could produce new viruses that would affect humans. However, there are a number of difficulties with this speculation: first, only a small part of such viruses are used (usually the 35S promoter from the cauliflower mosaic virus). Secondly, viruses usually infect only a very narrowly defined range of species. It is therefore unlikely that viruses that are adapted to infect cauliflower would infect humans.[154] Another possibility is that plant viruses may produce new viruses in humans by recombination with remnants of viral DNA sequences which exist in human DNA. However, research has shown that there are considerable natural barriers to such a process.[155] Indeed humans have eaten virally infected plants for millennia and there is no evidence that new viruses have been created as a consequence.[156]

125 There are also questions with regard to how other foreign genetic material that has been introduced in a GM crop will be taken up by the body. When humans eat plants or animals, they also eat the DNA of these organisms. Similarly this is the case with GM crops. However, the fact that such crops have been genetically altered does not mean that this necessarily creates new health risks. According to a recent FAO/WHO document, the amount of DNA which is ingested varies widely, but it is estimated to be in the area of 0.1 to 1.0 grams per day. Novel DNA from a GM crop would represent less than 1/250,000 of the total amount

154 Royal Society (2002) Genetically modified plants for food use and human health - an update. London: Royal Society. p. 8.

155 Worobey M and Holmes E (1999) Evolutionary aspects of recombination in RNA viruses, **Journal of General Virology** 80: 2535-44; Aaziz R and Tepfer M (1999) Recombination in RNA viruses and in virus-resistant transgenic plants, **Journal of General Virology** 80: 1339-46.

156 Royal Society (2002) Genetically modified plants for food use and human health - an update. London: Royal Society. p. 9. This Report also discusses other implications of the use of viral DNA in plants, relating to the use of the CaMV 35S promoter, which functions in a wide variety of species, and the possibility that viral DNA may activate so called transposable elements which are already present in the human genome. However, the Report concludes that risks to human health associated with the use of specific viral DNA sequences in GM crops are negligible.

consumed.[157] This means that the possibility of the transfer of genes that have been introduced through genetic modification is extremely low. In fact, it would require that all of the following events would occur:

- the relevant gene(s) in the plant DNA would have to be released, probably as linear fragments;
- the gene(s) would have to survive harvesting, preparation and cooking, and also nucleases in the plant;
- the gene(s) would have to compete for uptake with other dietary DNA;
- the recipient bacteria or mammalian cells would have to be able to take up the DNA and the gene(s) would have to survive enzymic digestion; and
- the gene(s) would have to be inserted into the person's DNA by very rare recombination events.[158]

Thus, the DNA of the modified crop will usually be processed and broken down by the digestive system in the same way as that of conventionally bred, or otherwise modified crops.[159]

126 Finally, while we are not aware of any studies documenting proven health damage arising from the consumption of GM crop products, we point out that the use of some conventional varieties of crops can have grave health consequences. For example, most varieties of *Lathyrus sativus*, a lentil formerly grown widely in North India and now spreading in Ethiopia, are known to cause the crippling disease of lathyrism. Plant scientists have bred varieties that do not cause this disease. They have also produced cassava varieties which, following processing into food, do not endanger the consumer with high levels of hydrocyanic acid as do many traditional cassava varieties in Nigeria. Research on GM crops could well aim to create safer varieties of these crops which could replace harmful traditional varieties. In our judgement, there is no empirical or theoretical evidence that GM crops pose greater hazards to health than plants resulting from conventional plant breeding. However, we welcome the fact that concerns about GM have focused attention on issues of safety with regard to new crops and varieties. **We recommend that the same standards should be applied to the assessment of risks from GM and from non-GM plants and foods, and that the risks of inaction be given the same careful analysis as risks of action, in a responsible application of the precautionary principle.**

Summary of Sections 2-4

127 In the short timespan between the publication of our 1999 Report and the present, there has been a substantial increase in evidence, both quantitative as well as qualitative, on GM crops and their use in developing countries, as outlined in Section 3 (see also Appendix 3). However, the debate about the use of GM crops remains characterised by highly polarised views (see paragraphs 1-3). Proponents often claim that all forms of GM crops will

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157 FAO and WHO (2000) Safety aspects of genetically modified foods of plant origin Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology World Health Organization, Geneva, Switzerland 29 May – 2 June 2000. Geneva: WHO. p. 11.

158 FAO and WHO (2000) Safety aspects of genetically modified foods of plant origin Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology World Health Organization, Geneva, Switzerland 29 May – 2 June 2000. Geneva: WHO. p. 11.

159 FAO and WHO (2000) Safety aspects of genetically modified foods of plant origin Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology World Health Organization, 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.

automatically be to the benefit of developing countries, while opponents frequently argue that no application of GM crops can be of use to farmers in developing countries. The examples in Section 3 amply demonstrate the potential advantages offered by some GM crops. The discussion of important arguments outlined in Section 4 shows that possible costs, benefits and risks resulting from the introduction of a particular GM crop in a particular developing country depend on a variety of factors and can only be assessed on a case by case basis (see also paragraphs 13-15).[160] **We conclude that the potential benefits of contemporary plant breeding, including those arising from the use of genetic modification of crops, can, in particular instances, have considerable potential to improve agricultural practice and the livelihood of poor people in developing countries while reducing environmental degredation. There is an ethical obligation to explore these potential benefits responsibly, in order to improve food security, economically valuable agriculture and the protection of the environment in developing countries** (see also paragraphs 1.20-1.31 of the 1999 Report). **We do not take the view that there is enough evidence of actual or potential harm to justify a moratorium on either research, field trials, or the controlled release of GM crops into the environment at this stage. We therefore recommend that research into GM crops be sustained, governed by a reasonable application of the precautionary principle. Discussions about the use of GM crops must be informed continuously by the accumulating evidence from new scientific developments. The views of farmers and consumers must be taken into account, as well as studies of environmental and health impacts. Such research needs to be governed by appropriate regulation.** We consider the current regulatory context, relevant recent developments in the area, and ethical issues arising from these, in the next section.

160 This approach may provoke the objection that most of the GM food crops which are promising for developing countries have not yet been planted in field trials, and that therefore a robust assessment of their usefulness and the associated risks is currently unavailable. However, this objection also applies to promising new developments in conventional plant breeding. With regard to both cases we take the view that it is too early to dismiss ongoing research in its entirety.

Section 5
Governance

128 Decisions regarding the development, planting and regulation of GM crops take place at many levels and influence international regimes and national policies. Decisions are also made by sub-national authorities, local communities and, ultimately, households and individual farmers. We have stressed in this draft Discussion Paper the extent to which we cannot generalise about developing countries (see Box 1, paragraphs 13-15). However, all such countries face the challenge of ensuring not only that their policies towards GM crops make sense in the context of their own development needs, but also that they cohere with the complex system of multi-level governance that is emerging in the case of GM crops.

129 In this section we:

- outline the system of multi-level governance that applies to GM crops, including issues of national administrative and technical capacity to which this system of governance gives rise;
- identify emerging ethical and regulatory issues within this system, in particular with regard 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.

Multi-level governance: international regulation

130 At the international level there are five main elements of regulation relating to research into, and the trade and use of, GM crops:

- Agreements by the World Trade Organisation (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.[162]
- The *Codex Alimentarius* which is 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), which is a multi-lateral agreement covering the transboundary movement of living modified organisations (LMOs) that might have an adverse effect on biological diversity (not yet entered into force).
- The *International Treaty on Plant Genetic Resources for Food and Agriculture* by the UN FAO, which is a multi-lateral 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 organisations (GMOs) (at different stages of legal implementation).

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161 A system of multi-level governance is one in which important policy decisions are made at different tiers of political authority. This type of vertical complexity is a continuing feature of decision making in such systems.

162 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, in *Financial Times.* 14 May 2003: London. p. 21.

World Trade Organisation

131 The primary purpose of the WTO is to facilitate international free trade. In order to achieve this, the WTO establishes trade rules, serves as a forum for trade negotiations, and aims to assist in the settlement of disputes. With regard to the use of GM crops, there are two principal agreements that concern the negotiation of free trade, and the protection of public health and welfare standards in member states of the WTO: the *Technical Barriers to Trade Agreement* (TBT) and the *Sanitary and Phytosanitary Agreement* (SPS).

132 The SPS allows members of the WTO to block trade in the interest of protecting public health.[163] 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 related to the import of a particular good, 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.

133 The TBT obliges members of the WTO to ensure that their adopted 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, TBT promotes the use of internationally established standards. Thirdly, it requires members of the WTO to inform each other of relevant changes in policy. This entails that members must establish centres that compile all available information in the respective country 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.

Codex Alimentarius

134 The *Codex Alimentarius* was established by the Codex Alimentarius Commission which is a subsidiary body of the FAO and the WHO. The Commission is the highest 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.'[164] The Codex consists of a collection of food standards, guidelines and other recommendations.[165] It also includes a Code of Ethics which aims to encourage food traders to adopt voluntarily ethical practices to protect the health of consumers and to ensure fair practices in food trade.

135 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 application of GM

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163 In addition, the SPS covers trade measures designed to protect animal and plant health.

164 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.

165 The Codex Alimentarius is made up of 204 Food Standards, 43 Codes of Practice, 197 Pesticides evaluated, 2516 Limits for Pesticide Residues, 25 Guideline Levels for Contaminants, 1300 Food Additives evaluated, 54 Veterinary Drugs evaluated and 289 Limits for Veterinary Drug Residues. (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.)

crops have been considered by the Codex Commission, but no separate standards have been elaborated as yet. However, principles for the analysis of risks to human health as posed by GM foods are currently being developed.[166] The principles would dictate a pre-market assessment, performed on a case by case basis, and include 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). The principles are at an advanced stage of development and are expected to be adopted in July 2003.[167]

136 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, and identified the need to make greater efforts to learn about and respond to concerns of consumers in these countries. Subsequently, National Codex Alimentarius Committees have been established with financial assistance from the FAO in a great number of developing countries. These National Committees involve representatives of relevant government ministries, industry and consumer initiatives, and each National Committee now sends delegates to international Codex meetings.[168]

The Cartagena Protocol

137 To date, there is no international treaty in force which addresses possible risks posed by the introduction of GM crops. At the time of publication of our 1999 Report, negotiations on a protocol to the *Convention of Biological Diversity* (CBD), which focused on such matters, had been blocked by the US and a few other countries. Agreement was reached later in 2000 and the *Cartagena Protocol on Biosafety* was adopted by the parties of the CBD. This Protocol is an important device which relates directly to the use and trade of GM crops.

138 Article One of the Protocol 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 6.

139 The Protocol was signed by 103 countries and has, to date, been ratified by 49 member states.[169] 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

166 At the 3rd session of the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology (4-8 March 2002) the following documents were proposed: 'Draft Principles for the Risk Analysis of Foods derived from Modern Biotechnology', 'Draft Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Plants' and 'Proposed Draft Annex on the Assessment of Possible Allegenicity'. (Codex Alimentarius Commission (2003) Report of the Third Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. Yokohama, Japan 4-8 March 2002. Available: ftp://ftp.fao.org/codex/alinorm03/Al03_34e.pdf. Accessed on: 18 May 2003.)

167 WHO (2002) 20 Questions on Genetically Modified (GM) Foods. Available: http://www.who.int/fsf/Documents/20_Questions/q&a.pdf. Accessed on: 18 May 2003.

168 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.

169 Convention on Biological Diversity. Cartagena Protocol on Biosafety. Available: http://www.biodiv.org/biosafety/. Accessed on: 2 Jun 2003.

Box 6: **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 needs to 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 further take into account socio-economic implications likely to result from the import of LMOs (Article 15). Article 15 also 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).

Protocol will enter into force 90 days after the 50th ratification. The EU ratified the Protocol on 27 August 2002, when the *The Regulation of the European Parliament and of the Council on the Transboundary Movement of Genetically Modified Organisms* implemented the provisions of the Protocol into Community Law.

140 In terms of risk assessment, the Protocol differs significantly from the WTO's SPS. Under 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 principle (see paragraphs 118-122). We welcome the development and implementation of the *Cartagena Protocol* as an important and essential device in the regulation of the transboundary movement of LMOs, such as GM crops. However, we caution against overly narrow application of the precautionary principle in its implementation in individual countries (see paragraphs 120-121, 126). Due to the international controversies about the use of GM crops, and due to the lack of safety assessment facilities, policy makers in developing countries are under substantial pressure to opt for a conservative interpretation of this principle. However if this results in highly restrictive legislation, there is a real risk that such devices could considerably delay research, development and use of GM crops in developing countries.

141 It may be argued that in view of the alleged risks posed by GM crops it is appropriate for developing countries to implement initially more rigid governance which could then be deregulated. However, significant difficulties can be encountered in the deregulation of

previously established regulations, as the revision 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 principle, to allow for appropriate regulation. **We draw attention to our view that a highly restrictive interpretation of the precautionary principle 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 the currently practised agricultural system. Therefore, in applying the precautionary principle, risks implied by the option of inaction also need to be considered.**

The International Treaty on Plant Genetic Resources for Food and Agriculture

142 The *International Treaty on Plant Genetic Resources for Food and Agriculture* (henceforth: the Treaty) was unanimously adopted by members of the FAO's Conference in November 2001.[170] 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.'

143 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). The new Treaty will establish a multilateral system for access and benefit-sharing, in relation to 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).

144 To facilitate access to those plant genetic resources, a standard MTA will be used, setting out the terms and conditions under which the material can be used, for instance, 'solely for the purpose of utilization 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 in relation to information, technology, strengthening of 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) provides 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 simply encouraged.

145 Article 13.2.d (ii) also provides that the Treaty's Governing Body, which consists of those countries who 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; to exempt from such payments small farmers in developing countries and in countries with economies in transition; and to review the levels of payment from time to time, as well as whether benefit-sharing should also be mandatory where access to the product is not restricted. The Treaty has been signed by 78 member and non-members of the FAO and is expected to enter into force late in 2003 or early 2004.

170 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.

146 **We welcome the recent decision by the UK Government to ratify the *International Treaty on Plant Genetic Resources for Food and Agriculture*. Since access to resources falling under the Treaty is of crucial importance in the development of crops suited to the needs of farmers in developing countries, we recommend that in the negotiations about specifications of the standard Material Transfer Agreement (MTA), the UK Government aims for provisions that exempt users in developing countries from payments in cases of commercial applications arising from material covered by the MTA. Where exemptions are not possible, differentiation of payments should take into account the level of development of the country in question.**

147 **We take the view 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 also welcome and endorse the initiative of promoting the building of capacity in relevant expertise.**

The European Union

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

148 The current and proposed EU legislation on GMOs is regarded as the strictest in the world. The first main legislation relating to experimental releases and the placing on the market of GMOs was *Directive 90/220/EEC*. The Directive entered into force in 1991, and 18 applications falling under the Directive have received authorisation, including applications for varieties of GM soybean, maize and oilseed rape. However, soon after its implementation, member states of the EU decided that the Directive needed amendment in the light of the considerable advances achieved in the area of 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 allows member states to temporarily ban a genetically modified product on its territory if there is substantial evidence that it implies risks to human health or to the environment.[171] This resulted in a stalling of evaluations of further applications, and in the declaration of a *de facto* moratorium at an EU Environment Ministers Council meeting in June 1999. While some viewed this approach as a reasonable application of the precautionary principle (see paragraphs 118-121), others perceived it to be a barrier to trade, violating the WTO agreements. It is claimed, that it cost the US US$250-300 million a year in lost exports.[172]

149 After substantial revisions, *Directive 90/220/EEC* was replaced by *Directive 2001/18/EC* in October 2002, which introduced the following measures to ensure regulation of GMOs that would meet the demands of EU regulators and consumers:

- principles for environmental risk assessment (see Box 7);
- mandatory post-market monitoring requirements, including of long-term effects associated with the interaction with other GMOs and the environment;
- mandatory information for the public;

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171 Article 16, the so-called safeguard clause, states '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.)

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

- a requirement for member states to ensure labelling and traceability at all stages of placing on the market (see paragraphs 152-153); and
- first approvals for the release of GMOs to be limited to a maximum of ten years.

150 *Directive 2001/18/EC* requires a step by step approval process of 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 placed on the market. 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 placing on the market of the GMO(s) concerned. The assessment must also consider whether these effects might manifest immediately, cumulatively or on a long-term basis.[173] Box 7 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 noted, approval is granted and the product may be placed on the market throughout the EU.

Box 7: **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 placing on the market of GMO(s).
- Determination of the overall risk of the GMO(s).

151 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 legislative proposals which have been adopted by the European Council on 25 July 2001 and are expected to enter into force in late 2003.

Regulation on Traceability and Labelling

152 The *Proposal for a Regulation on Traceability and Labelling of GMOs and Products Produced from GMOs (COM(2001) 182 final, 25 July 2001)* 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 the health of consumers or the environment. To achieve this, the proposed regulation requires the labelling of all foods produced from GMOs, irrespective of whether the final product contains DNA or protein of GM origin. However, in November 2002, the European Council agreed that food and feed would not have to be labelled if the amount of genetically modified material was 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

173 Council Directive 2001/18/EC Annex II.

GMOs which have not yet received approval in the EU was set at 0.5%. Although the criterion for labelling is detectibility, processed foodstuffs such as highly refined oils derived from GM crops, which do not contain genetic material of the original GM crop, would still have to be labelled according to the proposal.[174]

153 With regard to traceability, the proposed Regulation requires that GMOs can be traced throughout the entire production and distribution process. Thus, a company selling GM seed needs to 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, the farmers who bought the seed need to transmit the relevant information to those who buy the harvest. Farmers, too, are required to keep a register of recipients. In the case of food and feed produced from GM crops, this process is then repeated throughout the production and distribution chain.

Regulation on GM Food and Feed

154 The other Proposal which is expected to enter into force in late 2003 is a *Regulation on GM food and feed (COM(2001) 425 final, 25 July 2001)*.[175] 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 place a GM crop on the EU market would not need to request separate authorisations for the use of the crop as food or feed. A crop is either authorised for both uses, or for none.[176] Currently, the use of GMOs in animal feed is unregulated by the EU. GM feed requires no specific authorisation procedure. The proposed Regulation would thus have an impact on imported GM crops, which, at present, are predominantely used as feed for animals. In view of the current stance of EU consumers on GM crops, 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 would follow the proposal of the *Traceability and Labelling Regulation*, outlined above. However, the proposed *Food and Feed Regulation* exempts products such as milk and meat which have been 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

155 As we have seen, a number of the international agreements require that the regulation of GM crops be implemented through 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 and extensions. Hence, 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

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

175 The Regulation would replace the authorisation for GM foods and food ingredients, which is at present covered by the Novel Food Regulation (EC) 258/97.

176 One of the reasons for this approach is to prevent controversies such as those caused by the *Bt* maize variety StarLink. StarLink, which has been 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.

countries of GM crops advances the view that there is some pattern in this variability.[177] Across eleven countries it sees the capacity to undertake biotechnology assessments as ranging from advanced in countries such as China, India and Brazil, to weak or non-existent in countries such as Kenya, Zambia and Mozambique.[178] However, even this classification may be too general to be useful. There is a similar wide range in the capacity of national agricultural research systems. Moreover, weaknesses at the national level are often accompanied by weaknesses at the local level, particularly agricultural extension systems.

156 At present, most developing countries do not have appropriate legal and administrative systems in place to handle modern biotechnology as required by the *Cartagena Protocol*.[179] 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 started. The aims of the project are to prepare parties of the *Cartagena Protocol* for entry into force of the treaty; to assist countries who are eligible under GEF to prepare frameworks for national biosafety; and to facilitate regional cooperation between countries.[180] The project brings together more than 100 countries and has close working relations with other relevant organisations.[181] 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 offered to fund an initiative to help develop guidelines for establishing risk assessment and management systems for participating countries.[182]

157 We welcome the UNEP/GEF undertaking. Similar projects have recently been announced by the FAO, to the same ends.[183] Whilst the commitment of any international organisation to the improvement of administrative capacity in developing countries is to be welcomed, we express some concern lest there be a counter-productive duplication of effort among international organisations. In a situation of scarce administrative resources, such as prevails in developing countries, it is important to ensure co-ordination of international development efforts.

158 While it is clear that regulations need to be established primarily at the national level, diverse regulations, requiring that every new GM crop undergo environmental and health risk assessments in each country, can cause problems. For most developing countries, it will

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177 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 (Strategy Unit (2003) Developing country background working paper: Potential UK impact on developing countries. Available: http://www.strategy.gov.uk/2002/gm/downloads/developing.pdf. Accessed on: 18 May 2003.) It is currently envisaged that the Strategy Unit's final report will be available for comment at the end of June 2003, with the final report published in the autumn.

178 Strategy Unit (2003) Developing country background working paper: Potential UK impact on developing countries. Available: http://www.strategy.gov.uk/2002/gm/downloads/developing.pdf. Accessed on: 18 May 2003. p.35.

179 See UNEP UNEP/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 Mar 2003.

180 UNEP UNEP/GEF Project on the Development of National Biosafety Frameworks. Business Plan for 2002-2004. Geneva, Switzerland: UNEP. paragraph 1.2.

181 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).

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

183 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 January 2003.

be a considerable financial and logistical challenge to provide the capacity and resources to undertake such evaluations. The absence of appropriate testing facilities could result in considerable delays in granting 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).**[184] **In this context, we welcome the recent initiative by SADC to produce guidelines on food safety assessment and regulation.**[185] **We also recommend that developing countries should implement as far as possible standardised procedures for the assessment of risks in relation to the environment and the health of consumers, drawing on established international guidelines like the *Cartagena Protocol on Biosafety*** (see paragraphs 137-141) **or the forthcoming guidelines of the Codex Commission** (see paragraphs 134-136), **and avoiding an overly restrictive interpretation of the precautionery principle** (see paragraphs 120-121, 126).

159 The transfer of experience from advisory and regulatory bodies in developed countries to the developing world, with suitable adaptation to its socio-political as well as physical environments, is urgently needed (see paragraphs 4.49-4.62 of our 1999 Report). This has been most recently illustrated by controversies arising from poor compliance of farmers with technical specifications and illegal planting of *Bt* cotton in India,[186] as well as by GM soybean seeds smuggled from Argentina to Brazil.[187] By ensuring appropriate public awareness, and by insisting on transparent arrangements for overview and enforcement, costs and any risks associated with GM crops can almost certainly be significantly reduced.

160 This raises the question of what kind of regulatory systems are appropriate for the enforcement of biosafety regulations in developing countries. We note again that it is difficult to generalise on this subject. Very different conditions prevail with regard to factors such as capacities for policy enforcement, the number of farmers, and the type of agriculture in countries like, for example, China and Mali. In particular, the great number of small-scale farmers in developing countries (estimated to be about 817 million) poses great challenges.[188] In many cases it will seem unlikely that regulation can be achieved successfully by a compulsory 'command-and-control' approach. Such measures may have success in developed

184 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.

185 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 Jun 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.

186 An article in Nature Biotechnology in November 2002 reported poor crop management of *Bt* cotton in India. Farmers were said to have failed to provide refuges of non-*Bt* cotton. It has also been suggested that the crops were introduced too hastily and that farmers paid four times the price of traditional varieties for Bt crops, and were not made aware that they required more intense irrigation than previously used varieties. In addition, several thousand acres had been sown with illegal second and third generation seeds, which had very low yields. (Jayaraman KS (2002) Poor crop management plagues *Bt* cotton experiment in India, **Nat Biotechnol** 20: 1069.)

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

188 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, Italy: FAO.

countries, where licensing and monitoring is frequently a well implemented component of agricultural policy. However, in the case of many developing countries it will be more likely that the intended effect of a particular policy can be achieved by measures such as incentives and well developed extension systems, because there are too many small distributors of seeds, and far too many small-scale farmers to supervise. An assessment of appropriate regulatory systems at the national level is beyond the scope of this draft Discussion Paper.

Local autonomy and choice

161 We have seen that there are many unanswered questions about GM crops. On the one hand, they promise benefits in terms of increased and more stable yields, lower input costs, health-related improvements and reduction of environmental degradation. On the other, the extent and nature of these benefits are contested and it is alleged that there are health and environmental risks associated with their use. We have suggested that these doubts are not sufficient to support a ban or moratorium on the planting of GM crops in developing countries. Indeed, we see the potential for great benefit in specific cases. However, realising the benefits will take experience and the need to learn from that experience. We have also seen that the planting of GM crops in developing countries, whilst still on a small-scale, is increasing, and in some countries is increasing rapidly. Their use is also extending to small-scale farmers, some of whom have already benefited considerably (see paragraphs 61-63).

162 This raises the question: who, within a system of multi-level governance, should have the responsibility for deciding how to balance the potential risks against the benefits? In particular, the question arises as to whether it would be right to prevent farming communities in developing countries from adopting GM crops if the members of those communities thought it was to their advantage to do so. 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 lowest possible level, provided that goals such as safety and environmental protection are secured. Why might this principle be thought to apply?

163 First, in many cases the beneficiaries of GM crops may be poor communities in developing countries for whom development through improved agriculture is a crucial component of their well-being. If members of such communities believe that a particular technology can be an important means for them to improve their livelihoods, then it may be argued that it would be wrong to prevent them from trying 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.[189] 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.

164 In principle, we sympathise with this approach, but we also see problems. First, would local communities be given real or merely nominal control, if the decision to grow GM crops were

189 World Bank Study, Institute of Development Studies, University of Sussex (2001).

left to them? In view of the increasing concentration of the biotechnology, seed and agrochemical industries, 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 is applied in this area. Secondly, important issues are raised in the context of international trade. It could be the case that a particular community decides for themselves 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 sub-national communities would be able to undertake individual environmental and health risk assessments. **We therefore take the view that the most appropriate approach would normally be a centralised and evidence-based safety assessment at the national or regional level. Possible risks which are posed by specific GM crops with regard to the health of consumers and to the environment should be assessed on a case by case basis. Wherever possible, such assessments should take into consideration information which is available from international sources, in particular with respect to data about food safety assessments, which can be more easily transferred than risk assessments relating to impacts on the environment.**

Interdependence: the case of food aid

165 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 has implications for the behaviour of developed countries. This is especially the case in the EU, where agricultural protectionism already poses considerable barriers to the economic growth of poor countries. The complexities to which this interdependence can give rise were illustrated in the case of food aid to three East African countries in 2002 (see Box 8).

166 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

Box 8: **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 principle (see paragraphs 118-121) as well as on advice from a team of Zambian scientists who undertook a fact-finding mission to the US, Europe and South Africa.

Continued next page

Box 8: *Continued from previous page*

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. It was pointed out that planting GM maize may have unpredictable consequences in terms of gene flow and in particular that genetic material might 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, it was feared 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 government of Zambia did not wish to take any risks and was sceptical about whether GM food was safe to eat. While acknowledging that GM maize may be safe to eat for 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 autumn 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 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'.[‡‡]

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

**The same stance was taken by India in January 2003, when it rejected a large shipment of GM maize and soybean. (Luce E (2003) India rejects gene-modified food aid, in *Financial Times*. 3 January 2003: London.)

††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 February 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.

African countries entirely in the form of shipments of US maize. Indeed, the US Agency for International Development (USAID) website even stresses 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.[190] Further, the question may be asked why 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. Many therefore suspect that USAID is seeking to play a role in a US-led marketing campaign designed to introduce GM food in developing countries.[191] There have also been reports that donations through the WFP have previously included GMOs, and that the recipient countries have not been informed accordingly.[192]

167 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 jeopardize current and future trade relations. However, this claim has been refuted vehemently by, among others, EU Development Commissioner Poul Nielsen.[193] It has also been reported that some NGOs were very active in persuading the Zambian government to refuse GM maize.

168 We recognise that long-term reliance on food aid, whether provided in the form of GM or non-GM cereals, is highly undesirable. It is therefore necessary to assist developing countries in becoming self sufficient in food production. This is a complex process and we have noted that GM crops could play a substantial role in it. However, the question remains as to how developed countries can comply with their ethical obligations in the case of food aid in emergencies that may continue to arise in a number of developing countries.

169 In view of the current evidence relating to assessments of food safety of GM crops, or products produced from GM crops, we are not convinced that these pose significant risks to humans who eat them.[194] We therefore take a critical stance towards activities of some NGOs which fail to provide a rational assessment of the risks and benefits which GM crops may have in the context of agriculture in developing countries. **At the same time, we take the view that the preferences of developing countries dependent on emergency food aid must be taken seriously. A genuine choice between GM and non-GM food must be offered, where this is possible. It is therefore necessary to provide full information about whether or not donated food is derived wholly or in part from GM crops.**

170 **Where developing countries prefer to receive non-GM grain, the World Food Programme and other food aid organisations should purchase it. This is subject to such grain being available in sufficient amounts, with reasonable financial and logistical costs, and where it**

190 'The principal beneficiary of America's foreign assistance programs has always been the United States. 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 Sep 2002.

191 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: FoEI

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

193 Verbal statement during *Towards Sustainable Agriculture for developing countries: options from life sciences and biotechnologies* conference, 30-31 January 2003, Brussels.

194 Royal Society (2002) Genetically modified plants for food use and human health – an update. London: Royal Society.

can be provided quickly enough to address the emergency situation. 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 food aid be provided in milled form. Grain from food aid donations is likely to be planted in developing countries. It would not be acceptable to introduce a GM crop into any country in this way. We further note that although milling increases the costs of providing food aid, it allows for fortification of the milled grain with micronutrients.

Interdependence: the impact of European and international trade policy

171 The case of food aid clearly illustrates that debates about the use of GM crops in developed countries, and direct and indirect agricultural subsidies in the developed world have a major impact on agriculture in developing countries. Further, the nature of UK and EU agricultural policy is of considerable significance for developing countries that are growing or may grow GM crops. The precise impact will depend on a variety of factors.

172 EU regulations are likely to have relatively little effect on the growth of non-traded GM food crops for domestic use, such as sweet potato or cassava. However, with regard to GM food crops intended for export, decisions of developing countries regarding the choice of crops are likely to be influenced by the type of crops approved by European regulations. As noted, the revised *Directive 2001/18/EC* in conjunction with the proposed *Regulations on Traceability and Labelling* and on *Food and Feed* determine the types of GMOs that may be imported into the EU. If the current perception of the majority of the European consumers that such materials are 'contaminated' prevails, it is very likely that GM food and feed, and products derived from GM crops, will be less competitive on the European market.

173 There are also issues with regard to ensuring the traceability requirements specified in the proposed Regulation. Most developing countries may find it difficult and costly to provide for adequate institutions and systems to assure appropriate monitoring. Further, even in the case where a developing country decides not to use GM crops for export, but only for domestic use, EU regulations may have a considerable financial effect. As the labelling threshold is at a very low level of 0.9% for an approved GMO, and 0.5% for an unapproved GMO, care would have to be taken to prevent the mixing of grain and flour from GM crops intended for domestic use with non-GM grain and flour intended for export. The separation is likely to be costly for many developing countries. It would be undesirable if developing countries chose not to use safe and higher yielding GM crop varieties for domestic use because of concern about 'contamination' of non-GM crops for export.

174 Within any country, regulations similar to those in the EU would also strongly discriminate against small and poor farmers, for two reasons. First, the verification of grades and standards for, say, 1000 hectares of crop is more costly if those hectares are divided between 1000 farmers, than if they comprise one very large (and almost certainly labour-displacing) farm.[195] Secondly, where the food chain comprises millions of small-scale farmers connected through thousands of small-scale retailers, the verification of GM content and processing methods is much more expensive than for a few large farmers linked mainly to supermarkets or multinational exporters. Where traceability is required, the effect is especially harmful to poorer farmers. Under the proposed EU regulations the determination of the level and type of genetically modified DNA in the end-product will not suffice. Instead, production and processing throughout the whole food chain

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195 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).

from producer to final user needs to be observed and verified. Just as overly stringent regulation, and exclusive focus on the possible risks of GM crops discriminates against poor countries, so it discriminates against smaller and poorer producers and retailers, in all countries, especially poor ones. In the case of several export crops from developing countries, such as sugar, coffee, tea, rubber and cotton, both plantations and small-scale farmers are heavily involved; small-scale farms are run by much poorer people, and employ considerably more workers per hectare. It is therefore especially important that developed and developing countries avoid measures that discriminate against these small-scale growers.

175 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 in many parts of the world has taken place (paragraphs 52-56). This assertion needs to be qualified by the fact that scarcely any GM food and feed crops have been approved for commercial planting in the developing countries of Asia, Africa or the Middle East. Partly this situation appears to derive from fears that a highly restrictive interpretation of the precautionary principle in Europe and Japan will close off export sales.

176 The freedom of choice of farmers in developing countries is restricted severely 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 negative effects on the health of consumers.[196] There have been reports about gene flow from GM crops to other cultivars or wild relatives. However, as we have said (see paragraph 115) this phenomenon is not specific to GM crops. It also frequently occurs 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. The possibility of gene flow as such cannot justify the prohibition of the planting of a crop, but only specific possible adverse consequences which result from it (see paragraphs 119-120). However, while measurable gene flow from GM crops has been reported, it is not clear that this has posed environmental hazards.

177 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, if these were not impeded as a result of the EU regulations (see also paragraphs 4.1-4.2 of the 1999 Report). We conclude that the current provisions of the revised *Directive 2001/18/EC*, and of the proposed provisions of the *Regulation on Traceability and Labelling* and of the *Regulation on Food and Feed* have not taken into account sufficiently the effect that these policy instruments are likely to have on those dependent upon the agricultural sector in developing countries. It seems unlikely that the current and proposed European regulations will be revised substantially in the near future to prevent the raising of artificial trade barriers for products from developing countries. **However, we recommend that the EU, the Department for International Development (DFID) and appropriate non-governmental organisations who monitor agricultural policy of developing countries pay particular attention to the consequences of EU regulatory policies for GM crops. Developing countries may be reluctant to explore the possible benefits of using GM crops in particular instances because of the implications of EU policies. Potential adverse effects need to be examined and we recommend that the EC establish a procedure to report on the impact of its regulations accordingly.**

196 Royal Society (2002) Genetically modified plants for food use and human health - an update. London: Royal Society.

Section 6
Control and access to genetic modification technologies

178 Intellectual property rights (IPRs) mainly in the form of patents, are crucial to the development of GM crops. In our 1999 Report, we observed the growing importance of IPRs in agricultural biotechnology. Over the past 15 years, the expansion of the interests of the private sector in agriculture, particularly in the areas of GM crops and seed production, has resulted in much of the technology and germplasm being under commercial control. Universities in developed countries, encouraged by governments, have also increasingly sought patents to protect their inventions in this area.[197] As a consequence, many discoveries and important technologies in plant biotechnology are no longer treated as *public goods*.[198] Rather, they tend to be patented and licensed, often exclusively, to private companies working on major crops such as maize, soybean and cotton. The development of GM crops relevant to agriculture in the developing world will also require the negotiation of IPRs.

179 In making our recommendations in the 1999 Report, we recognised the potential of IPRs to constrain the development and commercial growing of crops important in developing countries. In particular we recommended that owners of patented technology should be encouraged to license their technology non-exclusively, that patent offices should avoid the granting of overly broad patents, and that the impact of patents on access to germplasm should be monitored (see paragraphs 3.47, 3.56 and 3.61 of the 1999 Report). In this section, we consider whether recent developments in IPRs demonstrate that the concerns underlying these recommendations were well-founded. We give particular attention to three aspects of IPRs which are crucial to the development of GM crops: use of MTAs, licensing of patented technology, and access to germplasm.

Material Transfer Agreements

180 MTAs are widely used as a means of transferring tangible property such as isolated DNA sequences and plasmids. An MTA is a binding private contract between the provider of the technology and the recipient. In essence, it allows the recipient the right to work with the materials under terms agreed by both parties. Commercialisation usually requires a licence agreement. An MTA can be a powerful tool in controlling novel technologies and germplasm. For example, it can be used to exercise a right of refusal to negotiate a non-exclusive licence for patents arising from materials or data provided under the MTA. MTAs may also impose *reach through* rights to products developed by others. The development of the majority of new crop varieties will involve MTAs.

181 The perception that the recent proliferation of MTAs is not necessarily in the public interest is widespread. Researchers in the public sector often view the use of MTAs in research as burdensome in that they tend to make heavy demands on their time and resources. The fact that many research materials can no longer be shared freely but must be the subject of a private contract irrespective of their potential value is a trend which

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197 In the US, the Bayh-Dole Act (1998) gave universities and other public research institutions the rights to patented inventions funded by government research grants. Similar legislation is being applied in most other industrialised countries.

198 Toenniessen G and Herdt R (2001) Intellectual property rights and food security. Available: http://www.genomics.cornell.edu/gmo/toenniessenpaper.html. Accessed on: 18 May 2003.

runs counter to the ethos of scientific research in the public sector. Nor is the use of MTAs confined to transfers between researchers in the public and private sectors. Researchers in the public sector now routinely exchange materials using MTAs. Despite concerns, there are as yet few documented examples of MTAs having a negative impact on the development and application of research. We note however that in the case of Golden Rice, difficulties over access to an MTA owned by a private company delayed progress for about twelve months.[199]

Licensing of patented GM technologies

182 Five major industrial groups of large agricultural biotechnology companies control between them most of the technology which is needed to undertake commercial research in the area of GM crops.[200] They have achieved this position by licensing, and strategic mergers and acquisitions. Several of these companies have used their proprietary technologies effectively to develop new varieties of major crops that enhance farm productivity and reduce agricultural impacts on the environment both in the US and elsewhere.[201] However, work on crops of less commercial interest has progressed slowly, highlighting the need for greater involvement of the public sector in these cases of market failure. The power and advantage that these companies may choose to exercise in respect of licensing patent rights has attracted much negative comment. We concluded in our 1999 Report that the development of GM crops relevant to the developing world would depend upon the low cost availability or waiving of licences for the patented technology. The recent example of the development of Golden Rice (case Study 4) is illustrative in this respect. It shows that while patented technologies may delay the development of new crops, they are not necessarily a barrier.

183 Golden Rice is intended for use by farmers whose profit is below US$10,000 per year. These farmers are predominantly subsistence farmers and therefore the crops need to be supplied free of cost and without restrictions. It became apparent once the research was complete that commercial applications would require licences covering 70 patents belonging to 32 different owners.[202] After complex negotiations with the owners, which involved discussions about the public interest in humanitarian licensing, free licences for all of the intellectual and technical property were eventually secured. This example suggests that requests for waivers of licence fees to allow the use of patented technologies for the development of crops suitable for subsistence farmers may be received sympathetically in the future. However, the existence of a significant number of patents in the case of Golden Rice suggests that a more systematic mechanism is needed if delays are to be avoided and if seed is to be made available to farmers at the low prices that they can afford.

184 The shift towards exclusive control of agricultural technologies by the private sector has been aided by organisations in the public sector. Universities, especially those in the US, have licensed most of their innovations, including important technologies in plant biotechnology, exclusively to companies. Consequently, three quarters of the new agricultural biotechnology products, including those funded by the public sector, are controlled by the

199 Personal communication, Professor Potrykus, 21 March 2003.

200 Syngenta, Bayer CropScience, Monsanto, DuPont and Dow AgroSciences. (ETC group (2002) Ag Biotech Countdown: vital statistics and GM crops. Available: http://www.etcgroup.org/documents/biotech_countdown_2002.pdf. Accessed on: 2 Jun 2003)

201 Huang J *et al*. (2002) Plant biotechnology in China, **Science** 295: 674-6; Phipps RH and Park JR (2002) Environmental benefits of genetically modified crops: Global and European perspectives on their ability to reduce pesticide use, **Journal of Animal and Feed Sciences** 11: 1-18.

202 Potrykus I (2001) Golden rice and beyond, **Plant Physiol** 125: 1157-61.

private sector. One effect of this academic-industry collaboration is that the direction of university research is increasingly influenced by corporate interests.[203]

185 The growth of IPRs has been attributed to the intense competition and low profit margins which exist in the seed industry. These conditions, it is suggested, encourage companies to accumulate intellectual property to render technologies inaccessible to competitors despite the fact that they may have low market potential. The increasing number and complexity of IPRs which need to be licensed tends to limit their availability to researchers from the public sector. Indeed it has been suggested that only large companies have the capacity to assemble the complex mix of IPRs to enable the freedom to operate.[204]

Germplasm

186 As well as having proprietary control over critical technologies for GM crops, plant breeding companies hold large collections of germplasm, which they use for breeding and improvement of the crop varieties in which they specialise. They may seek access to national collections and to those of the CGIAR, to improve their own elite strains of germplasm that have resulted from their breeding programmes. The 16 International Agricultural Research Centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR, see Box 9) hold over 500,000 accessions of landraces and improved varieties of the world's major crops. These *ex situ* collections are held in trust on behalf of the international community by the IARCs, and the Governing Body of the Treaty will seek to enter into agreements with the IARCs to allow access to these materials under another standard MTA, respecting the access and benefit-sharing conditions of the Treaty. We welcome *The International Treaty on Plant Genetic Resources for Food and Agriculture* by the UN FAO which, once ratified, will regulate the fair exchange of germplasm for 33 important crops (see paragraphs 142-147). The Treaty will require a standardised MTA to be used by institutions holding these collections. Although the collections cannot be patented 'in the form received', once a modification has been introduced, it may then be eligible for patenting. Patent protection

Box 9: Consultative Group on International Agricultural Research (CGIAR)

The CGIAR, created in 1971, is an association of public and private members supporting research in a system of 16 centres that work in more than 100 countries. The CGIAR aims to contribute to food security and the reduction of poverty in developing countries through research, strengthening of local expertise, and support for policy through environmentally sound practices. The CGIAR's research agenda has five main priorities: increasing agricultural productivity, protecting the environment, conserving biodiversity, improving policies which influence the spread of new technologies and the management and use of natural resources, and strengthening networks for national research. The CGIAR holds one of the world's largest *ex situ* collections of plant genetic resources in trust for the world community. It contains over 500,000 accessions of more than 3,000 crop, forage, and agroforestry species. The germplasm within the collections is made available without restriction to researchers around the world, on the understanding that no intellectual property protection is to be applied to the material.

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203 For a discussion of how the increasing trend to acquire IPRs may also affect the direction of academic research see Royal Society (2003) Keeping science open: the effects of intellectual property policy on the conduct of science. London: Royal Society.

204 Conway G (2003) From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. p10. Accessed on: 16 April 2003.

for plants or seeds is frequently obtained by securing a broad patent which claims rights over the gene or carrier, and may cover a number of varieties or even crops incorporating the gene. In effect, this may have the same outcome as patenting the whole plant because the patent extends to 'all material ... in which the product is incorporated'.[205] Further, the holder of a patented variety can prevent others from using it for breeding purposes.

Conclusion

187 We observed in the 1999 Report that the agrochemical and seed industry was tightly consolidated around a small number of multinational companies. We noted that further consolidation might not be in the public interest and we recommended that the relevant competition authorities keep the sector under close review. Since then, AstraZeneca and Novartis have merged to form Syngenta and Aventis CropScience merged with Bayer to form Bayer CropScience. With regard to markets in developing countries, Monsanto has, for example, increased its share of the Brazilian maize market from 0% to 60% in just two years. Only one Brazilian company remains, with a 5% market share.[206] In anticipation of such developments, we emphasised in our 1999 Report that farmers in developing countries should retain the capacity to choose between growing either new improved seed from the companies or improved seed from national breeding programmes or the CGIAR centres.

188 It has been argued that the growth of patent claims in both the public and private sectors could have an inhibiting effect on research. The challenge for the public sector, especially where research is directed at agriculture in developing countries, is how to access GM technologies without infringing IPRs. In addition, they must decide on the way in which their own technologies will be made available.

189 New initiatives which recognise the potential of these constraints to inhibit research into crops relevant to developing countries are therefore particularly welcome. Several US universities are now finding that the exclusive licensing of their technologies has deprived them of access to their own inventions. The recently established Public Sector Intellectual Property Resource for Agriculture (PSIPRA) initiative aims to promote licensing strategies in US universities that encourage retention of rights to their own technologies. These rights can be exercised for non-profit purposes or for the development of crops especially suited to the needs of developing countries.

190 The recent establishment of the African Agricultural Technology Foundation (AATF) also seeks to address IP issues in agriculture, particularly in relation to the needs of developing countries.[207] The AATF will create partnerships with existing organisations by transferring materials and knowledge associated with advanced agricultural technologies, that are privately owned by companies and other research institutions, on a royalty-free basis.[208] The AATF will focus on improvements that can be achieved by means of genetic modification of crops which are relevant to small-scale African farmers, such as cowpeas, chickpeas, cassava, sweet potatoes, bananas and maize. It has secured support from four of the main global agrochemical companies which have agreed to share patent rights, seed varieties and

205 *Directive 98/44/EC* Article 9.

206 Commission on Intellectual Property Rights (2002) Integrating Intellectual Property Rights and Development Policy. London: CIPR.

207 The AATF website is at: http://www.aftechfound.org/index.php.

208 Conway G (2003) From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. Accessed on: 16 April 2003.

expertise with African researchers.[209] The AATF also intends to negotiate with other companies from developed countries for support as well as for appropriate patent licences which allow for efficient research.[210]

191 As we noted, the majority of successful applications of GM crops have been developed by industry and relate to plants used in commercial agriculture in developed countries (see paragraphs 51-53 and 184). In contrast, most research on GM crops that may have potential for developing countries continues to be undertaken by publicly-funded organisations. A major concern which we expressed in our 1999 report was the neglect of a serious issue in the 'GM debate': the risk that the gains from GM crops will not be brought to bear on the needs of poor people in developing countries. We concluded in our 1999 Report that GM crop technology was unduly concentrated on the crops and farm systems of industrialised countries. Although the CGIAR spends about US$360 million per year, only a small fraction of this, currently less than 10% of the total, funds research on the genetic modification of crops. The role of the CGIAR in research is strategically important. But funding for the CGIAR has fallen in real terms since 1990. **We therefore affirm the recommendation made in our 1999 Report that genuinely additional resources be committed by governments, the European Commission and others, to fund a major expansion of GM-related research into tropical and sub-tropical staple foods.**

209 Monsanto, DuPont, Syngenta and Dow AgroSciences.

210 Gillis J (2003) To feed hungry Africans, firms plant seeds of science, in *Washington Post*. 11 March 2003: Washington, DC.

Section 7
Summary

192 In our 1999 Report, we concluded that GM crops had considerable potential to improve food security and the effectiveness of the agricultural sector in developing countries. Since then, a vociferous debate has taken place with regard to the risks and benefits associated with the use of GM crops. This debate has focused predominantly on the needs of developed countries. In this draft Discussion Paper, we have concentrated on the role of GM crops for developing countries. We have reviewed some of the recent scientific and regulatory developments. In doing so, we have aimed to reassess the potential contribution that GM crops could make towards improving the effectiveness of agriculture in developing countries. We also aimed to identify ethical issues arising in the area.

193 We began our work aware that this is a complex task. Developing countries differ in their ecological, socio-economic and political conditions (paragraphs 13-15 and Box 1). Factors such as armed conflict or political instability, inappropriate national agricultural policies and lack of infrastructure all affect agricultural productivity. Thus, the realisation of possible benefits arising from new technologies such as the genetic modification of crops depends on a complex interplay of these factors.

194 Improved crop varieties are nonetheless crucially important. They have considerable potential to reduce poverty because they can contribute significantly to the improvement of agricultural productivity. This can sometimes allow for substantial progress in the reduction of poverty in parallel to the inevitably slow changes at the socio-political level. Furthermore, some GM crops may be used in a highly effective way to address specific ecological and agricultural problems which have proved less responsive to the standard tools of plant breeding and organic or conventional agricultural practices. Similar significant contributions are also being made by a variety of other applications of biotechnology including tissue culture, and marker-aided selection (see paragraphs 32-33).

195 We have reviewed in Section 2 the crucial role of agriculture in relation to the reduction of poverty in developing countries. It is in dramatic need of improvement. Effective agriculture is essential for sustainable food security and for ensuring the livelihood of approximately 817 million small-scale farmers in developing countries, of which 190 million live in Africa alone. Furthermore, it can allow poor people, with little else but their labour to participate in growing prosperity. The Case Studies in Section 3 have illustrated that, in particular instances, GM crops have the potential to alleviate significantly the problems of low yields and pest or insect infestation, which dramatically affect the productivity of agriculture in developing countries. GM crops can also contribute to reducing environmental degredation. We concluded in Section 4 that the possible costs, benefits and risks resulting from the introduction of a particular GM crop in a developing country depend on a variety of factors, such as the gene, or combination of genes, being inserted, the target crop, and the agro-ecology and economy of that country. Each possible use should be assessed on a case by case basis. We are not persuaded that there are valid arguments to rule out the use of GM crops in principle, or to call for a moratorium on their use. (paragraphs 120 and 126-127).

196 In a reasonable application of the precautionery principle (see paragraphs 118-121), the primary question must always be: 'How does the use of a GM crop compare to other

alternatives?' There may, for example, be no environmental or other advantages from *Bt* maize for small-scale farmers in Mexico, if they already practice integrated pest management, hand weeding, and dense mixed cropping of maize, squash and beans.[211] On the other hand, the use of GM crops may have considerable benefits where the comparator is industrialised agriculture, which usually involves the application of large amounts of pesticides. Here, significant financial, ecological and health-related advantages can be achieved. We have noted that these benefits are real for both small-scale and large-scale farmers growing *Bt* cotton in China (see Case Study 1). Also, GM crops could greatly help small-scale farmers in countries such as Kenya, who rely on the sweet potato as the main staple crop and who regularly face reductions in yield by as much as 80% due to poor control of viruses and weevils. **In view of these and other examples, we have no hesitation in affirming the conclusion drawn in our 1999 Report that there is an ethical obligation to explore the potential of GM crops to improve food security and economically valuable agriculture in developing countries** (see paragraphs 1.20-1.31 of the 1999 Report)**.**

197 Careful thought and planning are required to answer the question of whether or not a farmer should use a GM rather than a non-GM crop, and the means by which a country should screen such choices before they are offered to farmers. Appropriate devices need to be in place for the governance and monitoring of the use of all agricultural technology that is new to its environment and users, including new crop varieties, whether GM or non-GM. Also, systems that enable the views of farmers and consumers to be taken into account by policy makers need to be in place. Evidence from studies concerning the impact of a particular GM crop on the environment and on the health of consumers needs to be available. Crops which are appropriate for the specific needs of farmers in poor countries need to be developed.

198 At least two further major factors complicate decisions about the use and regulation of GM crops in developing countries. The first is the adverse impact of controversies about the introduction of GM crops in developed countries (paragraphs 1-3). These controversies together with the limited facilities for safety assessment in developing countries, have resulted in substantial pressure being placed on their policy makers to opt for a highly restrictive interpretation of the precautionary principle. This is of considerable concern, in particular where such interpretations are incorporated in new national legislation. Conservative regulation could considerably delay research, development and use of GM crops.

199 Secondly, restrictive international and regional trade policies relating to GM crops, established in particular by the EU, have an adverse impact on the policy options open to developing countries. Policy makers in poor countries are faced with very difficult choices. A national policy that allows the responsible use of GM crops may entail the loss of export markets (paragraph 179). **There is a considerable imbalance between the benefits afforded by the European Union (EU) policies to European consumers, and the benefits that could be afforded to developing countries. EU regulators have not paid sufficient attention to the effect of EU policies on those involved in agriculture in developing countries.**

200 We have also presented a number of further conclusions and recommendations, relating to the exploration of promising applications of GM crops such as Golden Rice (paragraph 110); the introduction of GM crops into centres of diversity (paragraph 117); the application of the precautionary principle (paragraphs 120, 126); the general approach towards using GM crops

211 Miguel Altieri from the University of California, quoted in Pearce F (2001) An ordinary miracle, **New Scientist** 169: 16.

(paragraphs 127, 158, 164); the provision of capacity-building and training (paragraphs 147, 158); the negotiation of MTAs for plant genetic resources (paragraph 146); issues surrounding food aid (paragraphs 161-170) and funding for public sector research (paragraph 191).

201 Our review of these issues was in part undertaken with a view towards contributing to the current public debate 'GM Nation?' which has been initiated by the UK Government. We hope that the Discussion Paper will make a contribution to this series of events. The present draft of this Discussion Paper is for comment. The Council would therefore welcome your comments on issues that we have raised. Please also tell us if you think that we have not covered other important issues. All responses received by the Council before **8 August 2003** will be carefully considered in the revision for the final version of this Discussion Paper, which will be published in early October 2003.

Appendix 1

Executive Summary of the Council's 1999 Report *Genetically modified crops: the ethical and social issues*

The introduction of genetically modified (GM) crops has become highly controversial in the UK and some other parts of the world. The principal objections concern possible harm to human health, damage to the environment and unease about the 'unnatural' status of the technology. The Working Party has therefore examined the ethical issues which are raised by the development and application of GM plant technology in world agriculture and food security. Its perspective on GM crops has been guided by consideration of three main ethical principles: the principle of general human welfare, the maintenance of people's rights and the principle of justice. Some of these considerations, such as the need to ensure food security for present and future generations, safety for consumers and care of the environment have been straightforward and broadly utilitarian. Others, stemming from the concern that GM crops are 'unnatural', have been more complex.

The Working Party accepts that some genetic modifications are truly novel but concludes that there is no clear dividing line which could prescribe what types of genetic modification are unacceptable because they are considered by some to be 'unnatural'. It takes the view that the genetic modification of plants does not differ to such an extent from conventional breeding that it is in itself morally objectionable. GM technology does, however, have the potential to lead to significant changes in farming practices in food production and in the environment. **The Working Party concludes that it is now necessary to maintain and develop further a powerful public policy framework to guide and regulate the way GM technology is applied in the UK. It recommends that an over-arching, independent biotechnology advisory committee is established to consider within a broad remit, the scientific and ethical issues together with the public values associated with GM crops.**

Recommendations about the needs for improved risk assessment methods, post-release monitoring and the evaluation of cumulative and indirect environmental impacts are made. **The Working Party does not believe that there is enough evidence of actual or potential harm to justify a moratorium on either GM crop research, field trials or limited release into the environment at this stage.** Public concern about the introduction of GM crops has led to calls for bans on GM food and moratoria on plantings. **The Working Party concludes that all the GM food so far on the market in this country is safe for human consumption**. A genuine choice of non-GM foods should remain available, with foods which contain identifiable GM material being appropriately labelled. The Working Party urges the Government and the scientific community to share their responsibilities in disseminating reliable information about the underlying science and to respond to public concerns.

The application of genetic modification to crops has the potential to bring about significant benefits, such as improved nutrition, enhanced pest resistance, increased yields and new products such as vaccines. **The moral imperative for making GM crops readily and economically available to developing countries who want them is compelling. The Working Party recommends a major increase in financial support for GM crop research directed at the employment-intensive production of staple foods together with the implementation of international safeguards**.

Appendix 2

The importance of labour intensive agriculture

In parts of rural Africa, the incomes of small-scale farmers and farm workers are constrained by lack of labour. This can be a result of mortality due to HIV/AIDS, or because many young people have abandoned farming. However, even in these areas, higher demand for labour pushes up wages, which improves the well-being of poor people. In addition, few areas remain in Africa, or even Latin America, where farm land can be expanded without:

- significantly lower returns than are obtained on existing land, or
- intensification of fragile lands (for example, converting grazing to maize in parts of Southern Africa; shortening fallows in shifting cultivation in parts of West Africa).

Sustainable methods of enhancing yields on farmed land, in ways that increase the demand for labour, by use of GM crops or otherwise, therefore remain a crucial priority of research for the reduction of poverty in almost all developing rural areas, since income from agriculture is the best way to enable the poor in rural areas of developing countries to afford food. Agricultural research should therefore seek outcomes that are labour-intensive.

Yet, to stimulate farmers to employ more labour, and workers to supply it, farm labour-productivity (in other words, the output per unit of labour) also has to rise. With land and/or water for farming increasingly in constrained supply, how can both conditions be met? In relation to assessing, for example, new varieties in the field, it is important to examine their effect on raising:

i) labour productivity (at least enough to offset any fall in output prices and rise in input costs), but also

ii) land and water productivity (in other words, output per hectare and per litre), normally at a faster rate.

Total employment on farms can then continue to rise despite constraints of land and water, and rising labour productivity.

Modern plant breeding in the Green Revolution generally met both conditions (i) and (ii). The same can be expected in many cases where genetic modification is introduced, as long as there is a careful choice of crop, trait, and user. However, care is needed. For example, if land is scarce, the introduction of GM or other varieties with herbicide tolerance might merely lead farmers to replace farm labour by herbicides without raising yield. This would reduce the demand for labour, and hence the wages and/or employment.

Appendix 3

Examples of GM crops with relevance to developing countries

The following table gives examples of GM crops which are either currently used in developing countries or are the subject of ongoing research. The table does not provide an exhaustive list of all applications or research projects. Rather, it aims to give an overview of the kinds of projects which are being undertaken and it aims to detail the stage of research or use.

Stage of Research

L Laboratory studies
F Field studies
G Greenhouse studies
C Commercialised
N Not specified

Crop	Country	Improved trait	Comments	Stage
Banana	■ Egypt[1]	■ Viral resistance	■ Resistance to banana bunchy top virus and banana-cucumber mosaic virus ■ Research undertaken by the Agricultural Genetic Engineering Research Institute (AGERI), Egypt	L
	■ Uganda, South Africa, Belgium and France[2]	■ Pest resistance (eg. nematodes and weevils) ■ Fungal resistance	■ Aims to enhance the resistance of the local East African Highland bananas to the wide range of pests and diseases currently affecting the crop ■ Project undertaken by the International Network for the Improvement of Banana and Plantain (INIBAP) ■ Project began in 2001 with an expected duration of 5 years ■ See Case Study 6	L
	■ US[3]	■ Biopharma-ceutical	■ Vaccine for hepatitis ■ Research undertaken at Cornell University, US ■ See Case Study 7	L

1 AGERI. Production of Transgenic Banana Plants Resistant to Banana Bunchy Top Virus (BBTV) and/or Banana-Cucumber Mosaic *Cucumovirus* (Banana-CMV). Available: http://www.ageri.sci.eg/topic6/banana.htm. Accessed on: 9 Jan 2003.

2 INIBAP (2001) Novel approaches to the improvement of banana production in Eastern Africa the application of biotechnological methodologies. Available: http://www.inibap.org/presentation/biotechnology_eng.htm. Accessed on: 17 January 2003.

3 Demegen (2001) International Plant Biotech Groups Colloborate. Available: http://www.demegen.com/prs/pr011213.htm. Accessed on: 20 May 2003.

Crop	Country	Improved trait	Comments	Stage
	■ Australia[4]	■ Fungal resistance	■ Resistance to Black Sigatoka ■ Project undertaken by the Queensland University of Technology and the companies Demegen and Farmacule BioIndustries ■ See Case Study 6	L/F[5]
Barley[6]	■ Egypt	■ Abiotic stresses	■ Development of varieties tolerant of salt, drought and heat shock ■ Partnership between AGERI and the International Centre for Agricultural Research in the Dry Areas (ICARDA)	L
Cassava[7]	■ Various developed and developing countries	■ Pest and disease resistance ■ Enhanced protein and nutrient levels	■ Project undertaken by the Global Partnership for Cassava Genetic Improvement, a partnership of institutions including the FAO and the Swiss Federal Institute of Technology	N[8]
Coffee[9]	■ Hawaii, Brazil and Central America	■ Controlled ripening ■ Caffeine-free	■ Research by the company Integrated Coffee Technologies, Hawaii	L
Cotton	■ Egypt[10]	■ Abiotic Stresses ■ Biotic stresses	■ Development of varieties which have tolerance to salt, heat and drought as well as pests ■ Project undertaken by AGERI and the Cotton Research Institute	
	■ Columbia[11]	■ Pest resistance (*Bt*)	■ Commercialised planting expected in 2003	F

4 Demegen (2001) International plant group collaborate. Available: http://www.demegen.com/prs/pr011213.htm. Accessed on: 29 May 2003

5 AEBC (2002) Looking Ahead - An AEBC Horizon Scan. London: Department of Trade and Industry. p. 50.

6 ICARDA (2001) ICARDA Annual Report 2001. Available: http://www.icarda.cgiar.org/Publications/AnnualReport/2001/cooperat/nile.htm. Accessed on: 20 May 2003; AGERI. Development of Transgenic Barley with Improved Tolerance to Abiotic Stresses. Available: http://www.ageri.sci.eg/topic6/barley.htm. Accessed on: 9 Jan 2003.

7 FAO (2002) Partnership formed to improve cassava, staple food of 600 million people. News Release 5 November. Available: http://www.fao.org/english/newsroom/news/2002/10541-en.html. Accessed on: 9 January 2003.

8 The Global Partnership for Cassava Genetic Improvement was launched on the 5 November 2002. The Partnership next aims to raise funds for specific research projects.

9 Action Aid (2001) Robbing Coffee's Cradle: GM Coffee and its Threat to Poor Farmers. London: Action Aid.

10 Momtaz OA (2002) Current Status and Prospects of Transgenic Egyptian Cotton. Available: http://www.icac.org/icac/Meetings/Plenary/61cairo/documents/tis/momtaz.pdf. Accessed on: 9 Jan 2003.

11 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

Crop	Country	Improved trait	Comments	Stage
	■ India[12]	■ Pest resistance (*Bt*)	■ Approval to grow *Bt* cotton produced by the company Monsanto granted in March 2002	C
	■ South Africa[13]	■ Pest resistance (*Bt*)	■ See Case Study 1	C
	■ Indonesia[14]	■ Pest resistance (*Bt*)	■ 2,700 farmers grow Bt cotton in South Sulawesi	C
	■ China[15]	■ Pest resistance (*Bt*)	■ Both locally developed varieties and varieties by the company Monsanto are grown ■ *Bt* cotton is grown on over 50% of the cotton farming area in China ■ See Case Study 1	C
Faba bean[16]	■ Egypt	■ Viral resistance	■ Resistance to the faba bean necrotic yellows virus	L
Maize	■ Egypt[17]	■ Pest resistance (*Bt*)	■ Resistance to maize stem borers ■ Project being undertaken by AGERI and the company Pioneer	L
	■ Philippines[18]	■ Pest resistance (*Bt*)	■ Fields trials to evaluate the resistance of *Bt* maize to the Asiatic corn borer began in 2000 ■ Multi-site trials began in 2001	F
	■ Honduras[19]	■ Pest resistance (*Bt*)	■ Commercialisation expected in 2003	F
	■ Argentina[20]	■ Pest resistance (*Bt*)	■ Four varieties are grown commercially[21]	C

12 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

13 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

14 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

15 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

16 AGERI. Development of Improved Strategies for the Control of Faba Bean Necrotic Yellows Virus (FBNYV) in Food Legume Crops of West Asia and North Africa. Available: http://www.ageri.sci.eg/topic6/fbnyv.htm. Accessed on: 9 January 2003.

17 Agricultural Biotechnology Support Project (2002) Biotechnology Research and Policy Activities of ABSP in Egypt: 1991-2002. Available: http://www.iia.msu.edu/absp/egypt-absp.pdf. Accessed on: 29 May 2003.

18 ISAAA. Introduction and Field Testing of Insect Resistant Corn in the Philippines. Current Asian project portfolio. Available: www.isaaa.org. Accessed on: 9 January 2003.

19 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

20 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

21 Agbios. Essential Biosafety. Available: http://www.essentialbiosafety.info/dbase.php. Accessed on: 20 May 2003.

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Crop	Country	Improved trait	Comments	Stage
	■ South Africa[22]	■ Pest resistance (*Bt*)	■ Varieties produced by the companies Monsanto and Pioneer	C
	■ Bulgaria[23]	■ Herbicide tolerance	■ Less than 100,000 hectares were grown in 2002	C
Melon[24]	■ Egypt	■ Viral resistance	■ Resistant to the zucchini yellow mosaic virus	G
Papaya[25]	■ Malaysia, Thailand, Philippines, Vietnam and Indonesia	■ Viral resistance	■ Resistance to the papaya ringspot virus ■ Project undertaken by the Papaya Biotechnology Network of Southeast Asia with support from the company Monsanto and the ISAAA ■ Project aims to benefit small-scale farmers in southeast Asia	C
Potato	■ Mexico[26]	■ Viral resistance	■ Cooperative project between the Centre for Advanced Studies (CINVESTAV), the ISAAA and the Rockefeller Foundation. ■ The company Monsanto provided funding in earlier stages of research	F
	■ Egypt[27]	■ Pest resistance	■ Resistance to potato tuber moth ■ Project undertaken by AGERI (Egypt), Michigan State University (US), Central Research Institute for Food Crops (Indonesia), Vegetable and Ornamental Plant Institute (South Africa), and International Potato Center (Peru	F

22 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

23 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

24 Agricultural Biotechnology Support Project (2002) Biotechnology Research and Policy Activities of ABSP in Egypt: 1991-2002. Available: http://www.iia.msu.edu/absp/egypt-absp.pdf. Accessed on: 29 May 2003.

25 Chiang C-H *et al*. (2001) Comparative reactions of recombinant papaya ringspot viruses with chimeric coat protein (CP) genes and wild-type viruses on CP-transgenic papaya, **Journal of General Virology** 82: 2827–36; Monsanto (2001) Monsanto Welcomes U.N. Report on Biotech's Benefits for Developing World. News Release July 9. Available: http://www.monsanto.com/monsanto/layout/media/01/07-09-01.asp. Accessed on: 16 January 2003; Flasinski S *et al*. (2001) Value of Engineered Virus Resistance in Crop Plants and Technology Cooperation with Developing Countries. The International Consortium on Agricultural Biotechnology Research (non-technical abstract). Available: http://www.economia.uniroma2.it/conferenze/icabr01/nontechabsrtact2001/Falsinski.htmAccessed on: 15 January 2003.

26 Monsanto (2001) Monsanto Welcomes U.N. Report on Biotech's Benefits for Developing World. News Release July 9. Available: http://www.monsanto.com/monsanto/layout/media/01/07-09-01.asp. Accessed on: 16 January 2003.

27 Agricultural Biotechnology Support Project (2002) Biotechnology Research and Policy Activities of ABSP in Egypt: 1991-2002. Available: http://www.iia.msu.edu/absp/egypt-absp.pdf. Accessed on: 29 May 2003.

Crop	Country	Improved trait	Comments	Stage
			■ Four years of field trials have been completed	
	■ US[28]	■ Biopharma-ceutical	■ Development of vaccine against rotavirus and *E. coli*, prevalent in many developing countries ■ Project being undertaken at Loma Linda University	L
	■ India[29]	■ Protein enhanced	■ Varieties are in the final stage of testing	L
Rice	■ US and India[30]	■ Dwarfing	■ Gene from *Arabidopsis* transferred into Basmati Rice ■ See Case Study 3	L
	■ Philippines[31]	■ Micronutrient enrichment	■ Vitamin A (ß-carotene and other carotenoids) ■ Project undertaken by the Golden Rice Network (India, China, Indonesia, Vietnam, Bangladesh, the Philippines and South Africa). Collaborators includes the International Rice Research Institute (IRRI), the Rockefeller Foundation and the company Syngenta ■ Case Study 4	L
	■ India[32]	■ Pest resistance (*Bt*)	■ Research undertaken at the International Centre for Genetic Engineering and Biotechnology, New Delhi	L

28 Wong K (2001) Souped-Up Spuds Show Promise for Edible Vaccines. Scientific American. Available: http://www.sciam.com/article.cfm?chanID=sa003&articleID=00019658-ED97-1C5E-B882809EC588ED9F. Accessed on: 20 May 2003.

29 Coghlan A (2003) 'Protato' to feed India's poor, **New Scientist** 177: 7.

30 Peng J *et al*. (1999) 'Green revolution' genes encode mutant gibberellin response modulators, **Nature** 400: 256-61.

31 Pearce F (2001) Protesters Take the Shine off Golden Rice, **New Scientist** 169: 15; IRRI (2001) Greenpeace Visits IRRI. News release. Available: http://www.irri.org/vis/line2001.htm. Accessed on: 14 Jan 2003; Syngenta (2000) 'Golden Rice' Collaboration Brings Health Benefits Nearer. Available: http://www.syngenta.com/en/media/zeneca.asp. Accessed on: 15 January 2003; Rockefeller Foundation (2001) International Rice Research Institute Begins Testing 'Golden Rice'. Available: http://www.rockfound.org. Accessed on: 15 January 2003.

32 Bhatangar RK (2000) ICGEB Activity Report. Available: http://www.icgeb.org/RESEARCH/ND/Bhatnagar.htm. Accessed on: 9 January 2003.

Crop	Country	Improved trait	Comments	Stage
	■ US and South Korea[33]	■ Abiotic stresses	■ Salt, drought and cold tolerance ■ Research undertaken by Cornell University and researchers in South Korea with funding from the Rockefeller Foundation ■ Technology to be placed in public domain to benefit farmers from developing countries ■ See Case Study 2	L
	■ Philippines[34]	■ Micronutrient enrichment	■ Increased iron and zinc content ■ Research undertaken by the Institute of Human Nutrition, at the University of the Philippines, in cooperation with IRRI ■ Trials involving humans are about to commence to establish whether the micronutrients are bioavailable	F
	■ US and Philippines[35]	■ Bacterial resistance	■ Resistance to bacterial leaf blight ■ Gene patented by the University of California, Davis. The technology has been made available to developing countries free of charge ■ Field trials conducted in the Philippines by the IRRI	F
Soybean[36]	■ Argentina ■ Uruguay ■ South Africa ■ Mexico ■ Romania	■ Herbicide tolerance	■ The majority of herbicide tolerant soybeans grown worldwide are Monsanto varieties	C

33 Coghlan A (2002) Sweet genes help rice in a drought, **New Scientist** 176: 10; Garg AK *et al*. (2002) Trehalose accumulation in rice plants confers high tolerance levels to different abiotic stresses, **Proc Natl Acad Sci U S A** 99: 15898-903; (2002) GM Rice Can Tough it Out. BBC News Online. 26 November. Available: http://news.bbc.co.uk/1/hi/sci/tech/2512195.stm. Accessed on: 15 January 2003.

34 Future Harvest (1999) New Rices May Improve Human Health: Iron and Zinc Enriched Rice Undergoing Trial in Convent; Vitamin A-Enhanced and Iron-Enriched Rice Varieties to Be Tested. Available: http://www.futureharvest.org/news/rice.bckgrnd.shtml. Accessed on 17 Jan 2003.

35 GRAIN (2000) BB rice: IRRI's first transgenic field test. Available: http://www.grain.org/publications/bbrice-en.cfm. Accessed on 9 May 2003.

36 James C (2002) Preview: Global review of commercialized transgenic crops: 2002. ISAAA briefs; no. 27. Ithaca, NY: ISAAA.

Crop	Country	Improved trait	Comments	Stage
Squash[37]	■ Egypt	■ Viral resistance	■ Egyptian cultivar transformed using a construct with the Zucchini Yellow Mosaic Virus coat protein gene ■ Collaboration between AGERI, Cornell University and Michigan State University ■ Preliminary field trials in 1999 and 2000	F
Sweet potato	■ Vietnam[38]	■ Pest resistance (*Bt*)	■ Resistance to the sweet potato weevil ■ Research undertaken by the Institute of Biotechnology in Hanoi, Vietnam ■ *Bt* strains were donated free of charge by the company Novartis	L
	■ Kenya[39]	■ Viral resistant	■ Resistance to Sweet Potato Feathery Mottle Virus ■ Research undertaken by the Kenya Agricultural Research Institute (KARI), ISAAA and Monsanto ■ See Case Study 5	F
Wheat[40]	■ Egypt	■ Abiotic stresses	■ Development of varieties with tolarance to salt and drought ■ Collaborative research undertaken by AGERI and Ohio State University	L

37 Agricultural Biotechnology Support Project (2002) Biotechnology Research and Policy Activities of ABSP in Egypt: 1991-2002. Available: http://www.iia.msu.edu/absp/egypt-absp.pdf. Accessed on: 29 May 2003.

38 Syngenta (2000) Novartis Agribusiness: New agricultural technologies for developing countries. Available: http://www.syngenta.com/en/media/article.asp?article_id=63. Accessed on: 15 January 2003.

39 Monsanto (2001) Monsanto Welcomes U.N. Report on Biotech's Benefits for Developing World. Available: http://www.monsanto.com/monsanto/layout/media/01/07-09-01.asp. Accessed on: 16 January 2003.

40 Agricultural Biotechnology Support Project (2002) Biotechnology Research and Policy Activities of ABSP in Egypt: 1991-2002. Available: http://www.iia.msu.edu/absp/egypt-absp.pdf. Accessed on: 29 May 2003.

Glossary

Abiotic stress: Environmental stresses which can reduce the productivity of a crop. These include weather conditions such as excessive or untimely frosts, and extended droughts and adverse soil conditions such as high levels of salt or aluminium.

Agrochemical: A chemical, such as a fertiliser, a *herbicide* or an insecticide, that improves the productivity of crops.

Amino acids: Molecules which, when linked together, form *proteins*.

Biopharmaceuticals: Compounds which are used for the development of medicines, that are produced by living organisms rather than by chemical synthesis.

Biotic stress: Stress resulting from attack by organisms capable of causing disease.

Bt: The bacterium *Bacillus thuringiensis* which produces *proteins* that are toxic to some insects.

Carrier: *DNA* of undefined sequence which is used to 'carry' genes which are inserted into cells. A *plasmid* is a type of carrier.

Cell: The smallest component of a living organism that is able to grow and reproduce independently.

Centre of origin: The geographic location from where a domesticated plant species originated. Such areas often harbour a wide range of natural genetic variation.

Chromosomes: The thread-like structure in *cells* that carries *DNA*, on which genetic information is arranged.

Crossing: Cross breeding different varieties of a crop species or, occasionally, varieties of closely related species.

Cultivar: A genetically defined plant variety which has been selected to be adapted for agricultural use.

Developed countries: Those countries with an average *per capita gross national income* in 2001 of more than US$9,205 at official exchange rates (see Box 2).

Developing countries: Those countries with an average *per capita gross national income* in 2001 of less than US$9,205 at official exchange rates (see Box 2).

Disease resistance: The capacity of a plant, usually determined by one or a few *genes*, to suppress or retard the activities of a disease-causing organism.

DNA: The biochemical substance from which the genetic material of cells is made. DNA has a thread-like structure. The DNA in a plant or animal cell is in several long lengths called *chromosomes*, each of which contains many *genes*.

Double haploid: A crop variety in which each pair of *chromosomes* is identical. This can also be achieved by several generations of inbreeding although the resultant line never has identical copies of every gene. With double haploid techniques, a pure line is achieved in one generation.

Dwarfed crops: Crop varieties that are bred to be relatively short. Dwarfed cereals are higher yielding and will accept more fertiliser before they collapse in the field.

F1 hybrid crop: The initial *hybrid* generation resulting from a cross between two parents. F1 hybrids are favoured by farmers because they display *hybrid vigour.* They are favoured by industry because *hybrid vigour* is suppressed in subsequent generations. This means that farmers need to purchase new seed every year, rather than use saved seed.

Food security: According to the FAO, a state in which all people at all times have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for a healthy life.

Gene: A linear fragment of *DNA* which contains the information needed to make a *protein*.

Gene flow: The transfer of *genes* via pollen to or from a cultivated crop to other crop plants, wild relatives, other plant species or other organisms.

Genetic modification: A technology which allows selected individual *genes* to be transferred from one organism into another, including *genes* from unrelated species. The technology can be used to promote a desirable crop characteristic or to suppress an undesirable trait.

Gene use restriction technology (GURT): A technology which genetically compromises the fertility or the performance of a *cultivar* so that harvested grains cannot germinate without agrochemical treatment. The technology is intended to prevent undesired *gene flow* and/or to protect the market of the seed producer.

Genome: The entire complement of *DNA* (*genes* plus non-coding sequences) present in each *cell* of an organism.

Germplasm: Tissue from which new plants can be grown, for example, seeds, pollen or leaves. Even a few cells may be sufficient to culture into a new plant.

Golden Rice: A type of *genetically modified* rice, which contains increased amounts of ß-carotene (a precursor of vitamin A). It was achieved by genetically modifying rice with two genes from daffodils and one from a bacterium.

Green Revolution: The Green Revolution is the popular term for the development and spread of high-yielding staple foods in developing countries from the 1950s (see also Box 3).

Gross national income: The dollar value of all goods and services produced by a nation's economy, including goods and services produced abroad.

Herbicide: A substance that kills plants and is used to control weeds. *Herbicides* vary in their specificity. Some kill a broad spectrum of plant species, while others kill only specific species or groups of species.

Herbicide tolerance: This allows a plant to tolerate a *herbicide* that would otherwise kill it. This can be achieved by means of either *genetic modification* or conventional plant breeding.

Hybrid: See *F1 hybrids*.

Hybrid vigour: The extent to which a *hybrid* crop performs better relative to the parents with respect to specific traits, particularly yield.

Informal seed system: Seed production and exchange activities by farmers and grassroots organisations. The informal seed system is a semi-structured system which primarily deals with small quantities of farm-saved seed, farmer to farmer exchange and informal markets.

in situ/ex situ: Generally used in the context of conservation of *germplasm*. *In situ* describes the conserving of *germplasm* in its natural environment. This can include conservation by continued farming of crop varieties. *Ex situ* refers to conserving *germplasm* in long term storage such as seed banks and by growing it, for example, in botanical gardens.

Intellectual property: An intangible form of personal property. Copyrights, patents, and trademarks are examples of intellectual property. Intellectual property rights enable owners to select who may access and use their property, to protect it from unauthorised use and to recover income.

Marker-aided selection: The use of *DNA* markers to select a particular trait. Selection of a DNA sequence near the *gene* on a *chromosome* avoids time-consuming and expensive tests to select the ideal parent or offspring.

Material transfer agreement (MTA): A widely used means to govern the property rights in relation to the exchange of materials used in plant breeding research such as isolated *DNA* sequences and *plasmids*. A MTA is a binding private contract between the provider of the material and the recipient. In essence, it allows the recipient the right to work with the materials under terms agreed by both parties.

Micronutrient enrichment: The production of crops with increased levels of essential micronutrients. This process aims to address the problem of micronutrient malnutrition which occurs primarily as the result of diets poor in vitamins and minerals.

Moisture stress: A condition of abiotic physiological stress in a plant caused by lack of water.

Mutations: The modification of a *DNA* sequence that can potentially result in a change in the function of a *gene*. Mutations can be harmful, beneficial or as is most often the case, have no effect at all.

Open-pollination: Pollination by wind, insects or other natural mechanisms. See also *self-pollinated*.

Plasmid: A type of small *DNA* molecule that can be used to deliver a *DNA* sequence or gene into a cell.

Precautionary principle: A rule that permits governments to impose restrictions on otherwise legitimate commercial activities, if there is a perceived risk of damage to the environment or to human health. Its interpretation is disputed (see Box 4).

Promoter: A short *DNA* sequence that regulates the expression of a *gene*. Each *gene* has its own promoter, to which specialised *proteins* bind in order to activate it.

Proteins: Biological molecules that are essential for all life processes and are encoded by an organism's *genome*. A protein consists of chains of *amino acid* subunits and its function depends on its three-dimensional structure, which is determined by its *amino acid* sequence.

Purchasing power parity (PPP): A method of measuring the relative purchasing power of different countries' currencies over the same types of goods and services. Because goods and services may cost more in one country than in another, PPP aims to make more accurate comparisons of standards of living across countries. However, since not all items can be matched exactly across countries and time, the estimates are not always robust.

Refuges: Areas of crops which are susceptible to weeds or, more usually, insects, and thus provide a safe haven for them. These are maintained near fields of *herbicide tolerant* or insect resistant crops with the aim of providing a supply of insects and weeds that remain susceptible to the respective toxin. The strategy is designed to greatly decrease the odds that a resistant insect can emerge from the *herbicide tolerant* or insect resistant field and choose another resistant insect as a mate. By preventing the pairing of *genes* conferring resistance, these refuges help ensure that susceptibility is passed on to offspring.

Resistance: The ability to withstand *abiotic* or *biotic* stress, or a toxic substance. Resistance, relative to susceptibility, is genetically determined. Forms of biotic resistance are pest resistance, insect resistance, bacterial resistance and fungal resistance.

Rotavirus: A virus which causes acute gastroenteritis. Symptoms include vomiting and diarrhoea.

Self-pollination: Plants that pollinate their own flowers. See also *open-pollination*.

Subsidiarity: The principle of subsidiarity says that within a system of governance decisions should be taken at the lowest possible level, provided that goals such as safety and environmental protection are secured.

Substantial equivalence: A concept that allows a novel food to be compared with a similar existing food.

Tissue culture: The culture of *cells*, tissues or organs in a nutrient medium under sterile conditions.

Traceability: The ability to trace and follow a food or feed through all stages of production, processing and distribution.

Transgene: An isolated *gene* sequence used to transform an organism. The transgene may have been derived from a different species than that of the recipient.

Glossary of abbreviations and acronyms

ACC/SCN	United Nations Administrative Committee on Coordination, Sub-Committee on Nutrition
AGERI	Agricultural Genetic Engineering Research Institute
AIA	Cartegena Protocol's advanced informed agreement procedure
AATF	African Agricultural Technology Foundation
BMA	British Medical Association
Bt	*Bacillus thuringiensis*
CBD	Convention of Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CIP	International Potato Centre
COMESA	Common Market for Southern and Eastern Africa
DFID	UK Department for International Development
DNA	Deoxyribonucleic acid
EC	European Commission
EU	European Union
FAO	UN Food and Agriculture Organisation
GEF	Global Environment Facility
GM	Genetically modified
GMO	Genetically modified organism
GNP	Gross national income
GURT	Gene use restriction technology
ICCP	Intergovernmental Committee on the Cartagena Protocol on Biosafety
ICGEB	International Centre for Genetic Engineering and Biotechnology
ICRISAT	International Crops Research Institute for Semi Arid Tropics
ICTZ	Inter-tropical convergence zone
IFAD	International Fund for Agricultural Development
INIBAP	International Network for the Improvement of Banana and Plantain
IPGRI	International Plant Genetic Resources Institute
IPR	Intellectual property rights
ISAAA	International Service for the Acquisition of Agri-biotech Applications
JIC	John Innes Centre
KARI	Kenya Agricultural Research Institute
LMO	Living modified organism
MTA	Material transfer agreement
NGO	Non-governmental organisation
PAHO	Pan American Health Organisation
PPP	Purchasing-power parity
PSIPRA	Public Sector Intellectual Property Resource for Agriculture
RDA	Recommended daily allowance
SADC	South African Development Community
SPS	WTO's Sanitary and Phytosanitary Agreement
TERI	Tata Energy Research Institute
TBT	WTO's Technical Barriers to Trade Agreement
UN	United Nations
UNEP	United Nations Environment Programme
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
VAD	Vitamin A deficiency
WFP	World Food Programme
WHO	World Health Organisation
WTO	World Trade Organisation

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