Agricultural Biotechnology in Developing Countries

A Briefing Paper for Sida

M.R. Bhagavan and I.Virgin

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Acknowledgements

Abbreviations and Acronyms

AATF	African Agricultural Technology Foundation
Bt	*Bacillus thuringiensis*
CBD	*Convention on Biological Diversity*
CGIAR	Consultative Group on International Agricultural Research, which comprises 16 International Agricultural Research Centres (IARCs)
CIMMYT	International Research Center for Maize and Wheat (part of the CGIAR group of IARCs)
CPB	Cartagena Protocol on Biosafety
CSO	Civil Society Organisation
DNA	Deoxyribonucleic acid
EU	European Union
FAO	UN Food and Agriculture Organization
GEF	Global Environment Facility
GM	Genetically modified
GMO	Genetically modified organism
GURT	Gene use restriction technology (the so called 'Terminator Technology')
IITA	International Institute for Tropical Agriculture (part of the CGIAR group)
ICCP	Intergovernmental Committee on the *Cartagena Protocol on Biosafety*
IFAD	International Fund for Agricultural Development
IFPRI	International Food Policy Research Institute (part of the CGIAR group)
IPR	Intellectual property rights
IRRI	International Rice Research Institute (part of the CGIAR group)
ISAAA	International Service for the Acquisition of Agri-biotech Applications
ISNAR	International Service for National Agricultural Research (part of the CGIAR group)
KARI	Kenya Agricultural Research Institute
KGI	Knowledge-generating and disseminating institution
LMO	Living modified organism
NGO	Non-governmental organisation
OECD	Organisation for Economic Co-operation and Development
PDP	Product Development Partnerships
PVP	Plant Variety Protection
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UPOV	International Union for the Protection of New Varieties of Plants
WTO	World Trade Organization

Executive Summary

BACKGROUND

Over the past two decades, the dramatic advances made in modern agricultural biotechnology (agro-biotechnology) have opened new frontiers in agricultural research. The use of advanced tools such as DNA-marker assisted breeding, genetic modification and new regimes for access to genetic resources is changing the conditions for agricultural development in many parts of the world. Large investments have been made into the research and development (R&D) of genetically modified crops (GM crops), in particular in the United States. Today, six transnational agro-chemical corporations (TNCs – Monsanto, Bayer, Syngenta, DuPont, Dow and BASF) dominate the global arena for GM crops, from R&D to marketing. However, a number of public-sector universities and research institutions in the West have also been deeply involved, often in close collaboration with the TNCs. This situation, in concert with the ability to protect the intellectual property rights (through patents, etc.) of their GM technologies and GM innovations, has to a large extent vested the ownership and control of globalised GM crops and GM technologies in the globalised private sector. The push by the TNCs has so far resulted not only in the commercial production of GM varieties of some global crops (such as cotton, maize, soya bean and oilseed rape) in the leading grain exporting countries (USA, Canada, Argentina and Australia), but also in GM cotton and GM maize being commercially grown in several developing countries (e.g. China, India, Indonesia, the Philippines and South Africa).

From the early 1990s onwards, a diverse range of developing countries have also entered the arena of agro-biotechnology by making significant public investments in R&D, e.g. Brazil, China, India, the Philippines, South Africa and Vietnam. In striking contrast to many OECD countries, the developing country R&D investments and activities are almost entirely in public sector universities and research institutions. These public sector R&D efforts are focused on local crops cultivated by small-scale farmers. In the short to medium term, some of this R&D work, and the subsequent commercialisation of the GM innovations, will be dependent on the GM technology of the private sector and thus on the intellectual property rights held by the private sector. But, in the longer term, and given the required resources and support, public sector institutions in many developing countries would be able to develop their own GM technology.

Intense debate is taking place in parts of the developing world about the potential benefits and risks associated with the introduction of GM crops. Broadly speaking, while many government departments, agro-biotechnology R&D institutions, and seed breeding and marketing companies are firmly in the protagonist camp, and environmental and consumer organisations make up the core of the antagonist grouping, other major 'stakeholders' such as farmers' associations and the media are split between the two sides. The principal issues of contention are the potential increases in yield, decreases in the use of pesticides and herbicides, impact on the physical environment (ecology and biodiversity), the health of human beings and animals, the livelihoods and socio-economic futures of small farmers, the ownership and control of genetic resources, and trade.

FUTURE FOOD SUPPLY AND DEMAND, AND CROP PRODUCTIVITY IN DEVELOPING COUNTRIES

According to the United Nations, world population is estimated to increase from the current 6.3 billion to 8.1 billion by 2030. Africa and Asia are expected to account for most of this increase. With accelerating urbanisation and increasing household incomes, not only will the *per capita* consumption of food increase, but also its content is expected to shift substantially towards more dairy products and meat, implying increased consumption of grains by livestock. Assuming that domestic production rather than imports from the OECD region will have to be the principal means for meeting the estimated increase in consumption, the productivity of farmers in the developing world has to keep pace with the rising demand. The wide variation of agro-ecological conditions in developing countries, low soil fertility, water stress and low use of agricultural inputs, means that improved planting materials constitute one of the most effective means by which developing country farmers' productivity could be enhanced. Agricultural biotechnology, including DNA Marker Assisted Breeding and GM technology, has the potential to contribute to more efficient and precise crop breeding systems in developing countries.

The 'Green Revolution' (1970-1990) led to dramatic increases in the yields of global staple cereals (maize, rice and wheat). But the growth rates began to level off in the late 1980s and have been falling since the early 1990s. Some GM protagonists argue that the next cycle of significant rises in crop productivity can only be ensured by largely resorting to genetically modified agriculture (now dubbed by some analysts as the 'Doubly Green Revolution'). This claim is contested by GM antagonists, who point to the success of several currently employed non-GM techniques in delivering productivity increases.

It is self-evident that farmers in developing countries face a host of problems that biotechnology will not be able to tackle, such as poor agricultural infrastructure, socio-economic obstacles, lack of farm management skills and the degradation of the natural resource base. The challenge of increasing farm-level production in a *sustainable* manner (environmentally, economically and socially) is a very complex one, requiring an integrated holistic approach, of which agro-biotechnology is but component. However, agro-biotechnology has the potential to make crop breeding and crop-management systems in developing countries more efficient in generating improved crop varieties and higher yields. Consequently, many breeders in developing countries are challenged with the task to find the right mixture of advanced and conventional technologies. *It is therefore important to focus on the conditions under which GM agriculture could benefit developing countries.*

POTENTIAL BENEFITS AND RISKS ASSOCIATED WITH GENETICALLY MODIFIED AGRICULTURE (GMA)

The potential benefits of genetically modified agriculture (GMA) and from GM crops comprise increases in crop yields and improvement in the nutritional content and storage characteristics of staple foods. In the case of some cash crops (like cotton) whose conventional cultivation is pesticide-intensive, the introduction of GM varieties may lead to substantial decreases in pesticide use. In contrast to 'Green Revolution' technology, GM technology will not directly lead to increases in the seed output of plants. The increases are attained *indirectly* through genetically engineered *resistance* in plants to certain pests and diseases (so called 'biotic stresses'), and greater tolerance to drought, salinity, frost, etc. (abiotic stresses). As these

stresses are indeed the major constraints on the growth of crop yields in developing countries, GM varieties designed to overcome them are potentially valuable to the developing world.

The potential risks to human and animal health would arise from unexpected consequences of introducing new genes, such as the appearance of allergens, toxins and carcinogens in GM food and GM feed. Ecological and other environmental risks could arise from cross-pollination between GM crops and their indigenous wild relatives, potentially leading to loss of biodiversity, and the emergence and spread of pests, diseases and weeds that could acquire the same resistances as are engineered into the GM crops. The socio-economic safety of small farmers may be put at risk by the potentially unfavourable impact on these classes of producers of the agronomic (i.e. farm-level economic) and trade consequences of GM crops.

ENABLING ENVIRONMENT FOR THE INTRODUCTION AND DEVELOPMENT OF GMA

Any developing country that is keen not to miss out on the potential benefits of GMA has to create an environment that is appropriate and conducive to the adoption and promotion of GMA. Such an environment comprises three major components:

1. R&D capacity in a number of specific and specialised subjects in science and technology, social sciences, legal disciplines and the policy arena;

2. Biosafety regulatory regimes with the capacity to assess, monitor and manage potential risks; and

3. GMA-specific policies and the instruments to implement them.

These components are briefly covered in the following paragraphs.

R&D CAPACITY BUILDING FOR THE INNOVATION OF GM-LOCAL CROPS

As indicated above, six TNCs dominate the global arena for GM crops, from R&D to marketing. Their primary interest is in developing GM crops (e.g. maize, wheat, soya bean, oilseed rape/canola, etc.) of importance to farmers in industrialised countries that have global-scale agricultural production and exports. A spin-off from this strategy is to market the same GM seeds in some key developing countries with large markets (actual and potential, domestic and export), e.g. Argentina, Brazil, China, India, Indonesia and South Africa. The TNCs have, however, a limited interested in the low profit, country-specific and local-specific crops of crucial importance to small-scale farmers and household food security in developing countries. Thus the development and commercialisation of genetically modified *local varieties* of crops such as maize, rice, wheat, cooking banana, cassava, yam, sweet potato, chickpea, beans, etc. will depend heavily on public sector based crop-breeding programmes. Such breeding programmes could benefit substantially if they were to use elite cultivars, with various preferred traits, including GM traits, to improve local varieties.

Indeed, public sector R&D institutions in some of the more technologically advanced developing countries have concentrated their efforts on developing these low-profit *GM-local crops*. While the public sector institutions have been able to take some of their innovations past the laboratory and greenhouse stages, they are experiencing severe difficulties and long delays in moving on to large-scale field trials as required by national biosafety regulations, owing to inadequate implementation capacity (in the institutions as well as in the regulatory

authorities), intra-governmental indecision; unclear policies and high compliance costs for biosafety regulatory approval. In several of the least developed countries too, public sector R&D institutions have begun to work on GM-local crops, undeterred by severe shortages in capacity and resources. These poor countries' GM efforts are underpinned by financial assistance from international donors and by the research and technical support provided by counterpart institutions in the donor countries. It is important to note that the successful application of GM technology depends not only on the existence of R&D capacity (scientific competence and infrastructure), but also of well-functioning conventional crop-breeding programmes within the country, into which the technology can be incorporated and used.

BIOSAFETY REGULATORY REGIMES

As mentioned earlier, the issues and concerns surrounding GM technology are complex, involving scientific, economic, social, trade and political aspects. Thus, countries interested in using the technology need to develop policies and regulatory systems that take account of these issues and concerns in a manner that is feasible in their specific contexts. Early on in the development of GM crops, leading industrialised countries realised the need to enact biosafety legislation and create the institutions that would regulate the introduction of GM crops after carefully assessing and balancing the potential risks and benefits involved. Several developing countries that have forged ahead in the R&D of agro-biotechnology have also enacted biosafety regulatory legislation and created institutional structures for implementing the legislation. In some cases, the biosafety regulations are modelled on those in force in leading OECD countries.

Many developing countries have tentatively begun the task of setting up biosafety regulatory frameworks under a global programme launched jointly, in 2001, by the United Nations Environmental Programme (UNEP) and the Global Environment Fund (GEF). The impetus for the UNEP/GEF programme was the adoption in January 2000 of the Cartagena International Protocol on Biosafety to the Convention on Biological Diversity. As of January 2004, 80 countries, including the EU, had ratified the Protocol. The central objective of the Protocol is to regulate the international (i.e. transboundary) movement of living genetically modified organisms (LMOs) in order 'to derive maximum benefits from biotechnology while at the same time protecting biodiversity and human health from potential risks posed by LMOs'. Its guiding principle is the *precautionary approach* and its central directive is that the import of LMOs into a signatory country for release requires the *advance informed agreement* of the country's authorities.

IMPLEMENTING BIOSAFETY REGIMES IS A MAJOR OBSTACLE

Even where a developing country has a biosafety regulatory system, the main difficulty arises in the implementation of the regulatory regime. Whereas the EU and the OECD countries limit the application of the concept of biosafety to the physical and ecological environment, and the health of humans and animals, many developing countries have extended it to include a review of the socio-economic impact on rural communities, in particular small-scale farmers. This makes biosafety assessment in many developing countries complex and demanding in terms of available resources.

The processes of carefully balancing and weighing the potential benefits against the potential risks of GM crops, and of arriving at a decision to approve or reject the application

for biosafety-clearance (say by an R&D institution or a commercial company), presumes the existence of relevant and adequate capacity in several specific areas of knowledge. In addition, countries require institutional capacity to implement and monitor biosafety regulations, to manage potential risks and to promote public participation and public trust in the workings of the biosafety regulatory authorities. Further, without access to biosafety capacity, the signatories to the Cartagena Protocol would be incapable of implementing its provisions, in particular the central measures triggered by requests to the national authorities for *advance informed agreement* between importers and exporters of GM crops.

The various required capacities cannot all be centralised but must necessarily be de-centralised to a variety of institutions matched to the nature of the capacities, e.g. knowledge-generating and knowledge-disseminating institutions, government entities and civil society organisations (non-governmental organisations). Only some of the relatively technologically and industrially advanced developing countries currently have the infrastructures and the resources that would enable them to build up and strengthen all these capacities on their own on a national basis. But it would be unrealistic for most developing countries, and in particular the least developed countries, to attempt to build these capacities exclusively on a national basis. Given the lacunae in their present R&D and institutional infrastructures, and the extreme scarcity of resources at their disposal, their efforts at building capacity are more likely to bear fruit if they were spread appropriately between the national and the sub-regional levels. In addition, these efforts are unlikely to make much headway without close collaboration with selected institutions in the industrialised world that would have the appropriate expertise and experience to offer, including the international agricultural research centres belonging to the CGIAR system.

BIOTECHNOLOGY POLICIES AND TRADE ISSUES AFFECT TECHNOLOGY TRANSFER

In addition to environmental safety and the safety of human and animal health, the biosafety regulatory authorities in a number of developing countries also evaluate the impact of GM crops on the socio-economic safety of the farming communities, as well as risks to domestic and foreign trade. Striking a balance between the various potential risks and benefits is ultimately governed by whether a government adopts a *promoting, permissive, precautionary or prohibitive policy approach* to GM crops. While the USA, Canada and Argentina have adopted a *permissive approach* and approved the commercial cultivation of several GM crops, the EU has taken a strictly *precautionary approach*.

Since 1998, the EU has imposed a moratorium on the commercial cultivation of GM crops, pending the outcome of experimental field trials to test their impact on the environment. In the autumn of 2003, the EU adopted stringent regulations on the labelling and tracing of GM products, even after they have passed the biosafety tests, as the necessary pre-condition for permitting their commercial production, import and sale. These regulations came into force in April 2004. In May 2004, the EU lifted its ban on the import and marketing of GM food, by approving the application by Syngenta to market its GM maize. Other pending applications (over thirty, as of mid 2004) will be considered on a case-by-case basis. However, the moratorium on the *commercial cultivation* of GM crops still remains in place, awaiting an agreement to that effect by all the member states, some of whom are still strongly opposed to ending the ban on commercial cultivation.

Meanwhile, the USA, Canada and Argentina have jointly challenged the EU's policy by lodging a complaint with the World Trade Organisation. The EU's stand has also undoubtedly shaped the current 'wait and see' attitude of a number of developing country governments towards GM crops. While actively promoting indigenous R&D in local GM crops, some of the technologically advanced developing countries are nevertheless soft-pedalling on their commercialisation. Their caution is strongly motivated by the imperative of not jeopardising their current and potential future exports of food and feed crops and products to the EU.

Since countries have different conditions for agricultural production, export and import, it is not surprising that countries have adopted different biosafety policy approaches, However, it is important to understand that these approaches have implications. The passage of GM crops from the laboratory to the market is often a very long process, not least due to the rigorous and costly biosafety testing requirements. An excessively precautionary approach may severely impede the process, frustrating the ambition of some developing country R&D institutions to forge ahead with GM-local crops aimed at their own domestic markets. On the other hand, an overly permissive approach may lead to a neglect of potential risks, eroding public confidence. Steering a course between these two polar positions would be facilitated if governments and public sector R&D institutions were to develop adequate biosafety capacity, adopt explicit and clear goals and policies, and institute efficient and transparent procedures to guide the introduction and development of agro-biotechnology.

COLLABORATION BETWEEN PUBLIC AND PRIVATE SECTORS

In order to transfer, disseminate and commercialise appropriate agro-biotechnology, collaboration between the public and private sectors is essential. Such collaboration is also necessary in order for public research institutions to access proprietary technology. The intellectual property rights (IPR) to the GM technologies (gene constructs, transferred technologies, etc.) that are embedded in commercially cultivated GM crops, as well as in those that are still in the 'R&D pipeline', are to a large extent held by TNCs and public-sector universities and research institutions in leading OECD countries. Some of these technologies have been donated by the IPR holders to developing countries for R&D purposes and small-scale farmer use. If R&D institutions and seed breeding sectors in developing countries want to commercialise the locally developed GM crops in which IPR-protected technologies are incorporated, they are legally obliged to negotiate with the IPR holders the terms and conditions under which commercialisation can take place. In cases where the crops are targeted principally at small-scale, and not at agricultural export, it has been possible to persuade the IPR- holders to waive their IPR-rights. An example of such a waiver is the agreement reached by a research institution at the Swiss Federal Institute of Technology (ETH) in Zurich with Syngenta and other TNCs on the vitamin A-enriched rice (so-called 'golden rice') developed at the ETH. There is also the recent establishment of the African Agricultural Technology Foundation(AATF), funded by the Rockefeller Foundation, which will facilitate and fund the transfer of advanced agricultural technologies, including GM technologies from private sector to public institutions involved in improving crops for small-scale African farmers.

It is clear that the movement to stricter proprietary regimes on genetic resources and agro-biotechnologies will have an impact on national crop breeding activities. There is, as yet, little sign of developing country governments and R&D institutions devoting serious attention to the implications of IPR, let alone starting the process of negotiations and collaboration with the IPR holders on the commercialisation of local GM crops that contain IPR-protected

technologies. Hence, Product Development Partnerships, where various public, private and NGO actors collaborate on R&D work and technology-dissemination will probably be necessary for the successful transfer of GM technologies to small-scale farmers. These partnerships are specifically encouraged in the CBD's Agenda 21.

RECOMMENDATIONS FOR SIDA'S SUPPORT

Agricultural biotechnology has the potential to lead to significant increases in the yields of improved varieties of local crops that are of vital importance to the poor. For that to happen, governments in developing countries have to commit substantial resources over a long term to public sector efforts starting from R&D through biosafety assessment to commercialisation. Sustained support by international donors is indispensable to the success of efforts initiated by those least developed countries that are intent on embarking on agro-biotechnology. In responding to requests for assistance, Sida ought to ensure that the requesting country has either already begun the process of establishing a biosafety regulatory regime or demonstrated its willingness to do so. The best use of support, with sustainable outcomes in mind, would be in promoting effective combinations of national and sub-regional efforts at *institutional capacity development,* in four broad 'capacity areas':

1. R&D for understanding, absorbing and using GM technology for improvement of local crops. A prerequisite for R&D support ought to be the existence of a fairly strong crop-breeding programme in the country.

2. Functional biosafety regulatory regimes, including the capacity for assessing and compliance-monitoring potential risks and for implementing biosafety measures. This includes support to local institutions to forge and deploy the chain made up of R&D, large-scale field trials, biosafety testing, technology and innovation dissemination and commercialisation.

3. Biotechnology and biosafety policy regimes, and GMA-enabling environments, focused on the needs of the poor.

4. National and institutional structures and policies for handling IPR issues in relation to the trade-exchange of, and access to, genetic resources and technologies, and for promoting product development partnerships.

1 Agricultural Biotechnology: An Overview

1.1 INTRODUCTION

Over the past two decades, the many significant advances made in modern agricultural biotechnology (hereinafter 'agro-biotechnology') have opened up new frontiers in agricultural development. The use of advanced tools such as genetic modification will undoubtedly have a profound impact on agriculture in the 21st century. The new techniques for understanding and modifying the genetics of living organisms have led to rapid adoption and large investments in biotechnology research and development (R&D). Most of this development is taking place in North America, Western Europe and East Asia, with the United States far ahead of the others. However, a diverse range of developing countries, from the technologically advanced like Brazil, China, India, Malaysia and South Africa to the technologically less advanced like Egypt, the Philippines and Vietnam are also investing a significant part of their total R&D resources on agro-biotechnology. But the least developed countries are lagging far behind, with the very modest investments that have been made in countries like Kenya, Tanzania and Uganda originating mostly from a few donor agencies.

Recent advances in the technology of genetic modification (GM technology), and the rapid development and use of genetically modified crops (GM crops), have led to many questions, deep disquiet and intensive debate. Sharply polarised debates between GM protagonists and GM antagonists are continuing to take place on some issues, e.g. the impact of agro-biotechnology on the physical environment and the health of human beings and animals (biosafety), the ownership and control of genetic resources (intellectual property rights), and the livelihoods and socio-economic futures of small farmers. To a large extent, both sides in the debate overstate their case, with GM protagonists tending to exaggerate the near-term potential benefits of GM crops and the GM antagonists the potential risks. Genuine communication and discussion between the two camps have been rare.

Against this background, the Stockholm Environment Institute (SEI) was asked by Sida to write a briefing paper on modern, genetically modified, agriculture (GM agriculture, GMA) in developing countries. Our paper begins by describing and analysing the major issues concerning the use of GM technology in developing countries, followed by a presentation of the potential benefits and potential risks of GM agriculture in the areas of environment, health and socio-economics. The GM technology regulatory and policy structures that need to be in place are then briefly described. The last two sections deal, respectively, with the areas that we think merit consideration for donor support and the criteria that would be of relevance and importance to Sida and other international donor agencies in responding to requests for support for introducing, applying and developing agro-biotechnology in developing countries.

1.2 THE POTENTIAL OF AGRO-BIOTECHNOLOGY TO MEET FUTURE FOOD DEMAND

According to the United Nations, world population is estimated to increase from the current 6.3 billion to 7.5 billion by 2020 and 8.1 billion by 2030. Africa and Asia are expected to account for most of this increase, by factors of 1.3 and 1.7, respectively, over the next thirty years[1]. The demand for cereals in the developing world is expected to grow by about 560

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[1] *World Population Prospects: The 2002 Revision,* Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat (2003).

million metric tons over the 23-year period 1997-2020 (from 1120 to 1680 million metric tons), while the demand in the developed world is estimated to increase by about 100 million metric tons (from 720 to 820 million metric tons). Developing Asia will account for more than half the increase. The regional shares of increased cereal demand during the period 1997-2020 are estimated as follows [2]: developed countries 15 %, China 27 %, India 12 %, other Asian developing countries 14 %, sub-Saharan Africa 11 %, Latin America 11 %, and West Asia/ North Africa 10 %.

With accelerating urbanisation and increasing household incomes in both rural and urban areas, not only will the *per capita* consumption of food increase, but also its content is expected to shift substantially towards more dairy products, poultry products and meat, implying increased cereal consumption (most of it maize and soya) by livestock [3]. Therefore a corresponding increase in the animal feed share, and a decrease in human food share, of the developing world's total cereal demand is expected[4].

Assuming that domestic production within developing countries rather than imports from the OECD region will have to be the principal means of meeting this demand, the productivity of agriculture in the developing world has to keep pace with the growing demand. The views on how to meet this challenge vary greatly [5].

With the Green Revolution (1970-1990) growth rates in the yields of global staple cereals (maize, rice and wheat) levelling off in the late 1980s, and starting to decline in the 1990s, some GM protagonists argue that the next cycle of significant rises in crop productivity can only be ensured by resorting to agro-biotechnology. Some leading international organisations[6] and United Nations institutions[7] believe that one of the major constraints on increasing the crop yields in smallholder and subsistence cultivation is the non-availability of improved seeds, and that agro-biotechnology, including GM technology, can redress this disadvantage. This claim is contested by GM antagonists, who point to the success of several currently employed non-GM techniques in delivering productivity increases.

Box 1: Potential benefits of GM technology

GM technology can assist crop-breeders in improving the yields and quality of crops and their production under strenuous conditions. Through genetic engineering, desirable genes can be transferred to crops irrespective of species barriers. Plants can be made more tolerant of floods, drought, heat and frost. They can be made more resistant to diseases and insect pests, reducing the input of agrochemicals. Genetic engineering can also greatly facilitate the development of crops with improved storage properties and nutritional characteristics (e.g. proteins and vitamins). GM technology also makes it possible to develop thermo-stable and cost-effective vaccines to treat livestock diseases.

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[2] Rosegrant, M. W., Paisner, M.S., Meijer, S. and Witcover, J., *2020 Global Food Outlook: Trends, Alternatives and Choices*, International Food Policy Research Institute (IFPRI), Washington D C, August 2001.

[3] The shift to meat and poultry products will be pronounced in developing Asia, in particular in China, which partly explains why China is expected to account for more than a quarter of the cereal demand in the developing world, while India with a comparable population will be generating less than half the Chinese demand.

[4] The estimated breakdowns are: In 1997: food 67%, feed 21% and other use 12%; In 2020: food 62%, feed 26% and other use 12%; see Rosegrant *et al, op cit.*

[5] Some argue for fundamental reforms to agricultural and food systems, while others believe that significant growth in food and feed production can occur only if either new land is brought under cultivation or if agriculture becomes more intensive in its inputs, or both. Still others are convinced that appropriate location-specific combinations of economic, social and technical solutions are the answer.

[6] Rockefeller Foundation, World Bank, Asian Development Bank, Nuffield Council on Bioethics and the International Agricultural Research Centers (IARCs) of the CGIAR system.

[7] IFPRI, IFAD, FAO, UNDP.

1.3   AGRICULTURAL BIOTECHNOLOGY IS NOT A PANACEA, BUT AN IMPORTANT TECHNICAL TOOL

Needless to say, farmers in developing countries face many problems that technology cannot solve on its own[8]. Achieving sustainable growth in farm production is a very complex challenge, and needs an integrated holistic approach, where technology is only one component. In this context, it is clear that agro-biotechnology is not a panacea, but an additional tool to address agricultural problems and challenges. It is important to point out that agro-biotechnology, including GM technology, can never replace conventional plant-breeding, but it can be an important and successful tool in improving plant- breeding programmes. While GM technology is a powerful tool, it poses potential risks to the environment, the health of humans and animals and the socio-economy of some communities. Therefore, countries that adopt GM technology need to ensure that the technology is used within the framework of a biosafety regulatory and policy regime. The contours of such a proposed regime are described in Sections 2 and 3 below.

1.4   THE DIFFERENT CATEGORIES OF AGRICULTURAL BIOTECHNOLOGY

Agro-biotechnology, broadly defined, refers to any technique that uses living organisms, or substances from these organisms, to analyse and modify plants, animals and organic products, and make new organic products. It is not a separate science, but rather a mix of disciplines, e.g. molecular-, cell- and micro-biology, biochemistry, genetics and genomics. It consists of a gradient of technologies, ranging from the long-established and widely used techniques of traditional biotechnology (e.g. fermentation of foods and brewing of beverages), through to novel and continuously evolving techniques, such as genetic engineering. The present range of modern techniques in agro-biotechnology is summarised below in Box 2.

All of the modern biotechnology techniques (Box 2) can be used, and are being used, in the breeding of crops and livestock. Crop improvement through continual selection of better food-producing plants is an activity as ancient as agriculture itself. The breeding of crops and livestock has gone through several historical stages, beginning with the mass selection practised by the first pioneers, through the breeding revolution made possible by the discoveries of Mendelian genetics and the breakthrough of mutation genetics, to contemporary techniques in genetic engineering. Agro-biotechnology, including GM technology, can speed up the development of new improved crops in a more precise manner. However, it is important to note that the use of these new technologies depends on the existence of functioning conventional breeding programmes, where they can be used to enhance the crop breeding and plant propagation processes in local germplasm.

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[8] Such as political and socio-economic constraints on equity, lack of infrastructure, management and husbandry, and degradation of the natural resource base.

Box 2. The different categories of agro-biotechnology

Molecular diagnostics and serology to aid crop and livestock production and protection

The use nucleic acid based approaches (e.g. PCR based techniques or use of DNA probes) or use of antibodies to provide more accurate and quicker identification of pathogens and various diseases. The use of antibodies is a very mature and robust technology, which has been used since the 1960s.

Tissue culture

Tissue culture is based on the culture of cell-tissues in a nutrient medium under sterile conditions. It is a well-proven method and robust technology for mass propagation of improved and disease free planting material for economically important crops and recalcitrant trees species.

Marker aided selection (MAS)

Marker assisted selection (MAS) uses DNA-markers to select and identify particular traits (e. g. drought resistance and salt tolerance). The MAS technology makes traditional breeding of crops and livestock faster and more precise, and is highly relevant to developing countries.

Genetic modification/Genetic engineering

The modification or introduction of one or more genes within and transfer across species barriers conferring potentially useful traits on plants, livestock, fish and tree species. This results in a genetically modified organism (GMO), which signifies a living organism whose genes have been modified or into which genes conferring a new trait have been introduced.

Vaccine technology

Rapid advances in biotechnology and immunology over the last two decades have created new opportunities for developing thermo-stable recombinant DNA vaccines for improving control of livestock and fish diseases. This development is closely related to the development of edible vaccines for combating human diseases

Functional Genomics and Bioinformatics

The molecular characterisation of genes and the related assembly of data from genomic analysis into accessible forms, and studies of gene function and regulation in a species. Such studies pave the way towards a more precise engineering of desired physiological or structural properties in plants or other organisms using various biotechnological tools

1.5   CAPACITY BUILDING IN AGRICULTURAL BIOTECHNOLOGY

Understandably not all countries can be at the forefront of biotechnological innovations. But being a 'latecomer' can be advantageous, as institutions within the country can acquire tried and tested technologies at lower cost and with less risk. An attractive option for many developing countries could be to create R&D capacity in a stage-by-stage process, to meet short-, medium- and long-term goals. This would also mean a gradual consolidation of capacity (competence, resource and structure) at selected institutions, underpinned with corresponding higher education and research training in the mix of disciplines that comprise agro-biotechnology (see Section 3.1 below).

Agro-biotechnology research programmes cannot be separated from the overall R&D budget, personnel development programmes and the organisational structure of the research system, but have to be considered as a component of them. And, as pointed out earlier, to be successful and sustainable, agro-biotechnology interventions must be based on, and linked to, well functioning breeding programmes[9]. Keeping this in mind, developing countries may well

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[9] It should be noted that, it is of course possible to make alterations, through gene technology, in local cultivars, without a strong breeding programme. This is especially true when the task is to add or modify a single trait, such as disease resistance or other single gene mediated (simply inherited) properties in well-adapted local variety. However, given the high degree of crop diversity in many developing countries and the need to continuously improve and produce locally adopted cultivars, it makes great sense for developing countries with an agro-based economy to have strong breeding programmes using a mix of conventional and modern breeding technologies.

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consider it to be within their list of priorities, and within the scope of resources available to them, to invest in agro-biotechnology. Investments in, and development of, biotechnological research capacity should be strategic and well planned. Thus, before a research programme is planned it is necessary to: (i) define research priorities; (ii) identify relevant biotech applications for priority products (iii) evaluate current capacities, and capacity building needs, etc.

There are three basic components of a biotechnology research programme that need to be developed and linked to on-gong crop-breeding efforts. It is important to develop these in parallel, if one wants to acquire the required capacity for absorbing and using the transferred technology and for embarking on local development. Generally speaking, in the context of most developing countries, quality control and the maintenance of a biotechnology R&D laboratory is constrained by untrained technicians, inadequate maintenance, unreliable power and water supplies, contamination sources and inadequate operational budgets. It is often the case that poor maintenance of equipment and the inability to make even relatively simple repairs to overcome small technical problems results in expensive equipment lying idle. Therefore, the training of technicians and other ancillary laboratory staff is an indispensable component of capacity building. If these constraints cannot be overcome, the reasons for considering further investments in biotechnology become rather tenuous.

The first component is *tissue culture and disease diagnostic capacity*. In addition to enabling countries to implement rapid mass propagation and production of vegetatively propagated crops such as cassava, sweet potato and cooking banana, tissue culture technology is an *essential* step towards implementing crop variety improvement programmes with downstream links to seed distribution and upstream links to more advanced agro-biotechnology research[10]. This area may also include the development of human capacity and infrastructure to use molecular markers for disease diagnostics and disease indexing[11].

A second, slightly more advanced area is the application of biotechnological tools in improving the efficiency of the crop-variety selection and development processes. This includes the use of *marker aided selection (MAS)* for the selection of desired traits and crops characteristics such as disease, pest and stress resistance. This technology is highly appropriate for developing countries. As said earlier, a functional breeding program is a precondition for moving to this stage, as well as the ability to utilise molecular maps and markers[12].

A third and even more advanced area is the development of capacity to transform and regenerate *genetically modified* plants, allowing for insertion of a specific gene construct into varieties with particular agronomic background. Such systems are seldom routine and significant research capacities are required to establish successful transformation, regeneration and characterisation systems. The regeneration capacity needed to produce GM plants will come from the first area, tissue culture. *Functional genomics and bioinformatics* will assist all the above applications, but require highly trained scientists and advanced laboratories.

Finally, the research programme will result in new agricultural planting materials that will only offer benefit if they can be released for use to the farming community. Getting GM

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[10] Such as Marker aided (MAS) breeding efforts and genetic modification of crops and livestock.

[11] This would be complementary to tissue culture since the development of disease free material is often connected to tissue culture of vegetatively propagated crops.

[12] These molecular markers will mostly be developed in highly advanced research laboratories such as the IARCs of the CGIAR system or other labs with similar capacity. Through networking and collaboration, developing country institutions will be able to access these markers for use in their own breeding programmes.

crops to the markets or to communities is a complex and time consuming process, which requires crop variety testing, biosafety field trails, risk assessment, compliance-monitoring and approval processes[13] (see Sections 2.2.1 and 3.4 below), farmer education and multiplication and provision of planting material.

In considering the third phase, i.e. GM technology capacity development, developing countries may want to compare the very substantial investment in monetary and other resources and time that it involves with the less burdensome and speedier option of acquiring the already developed GM techniques and GM inputs (e.g. gene constructs) from elsewhere through technology transfer agreements[14]. The technology so acquired could then be used directly in local crop breeding programmes, for instance through Marker Aided Selection (MAS)[15]. One would have to compare the costs of in-house development of specific techniques with costs involved in technology transfer arrangements. The biosafety approval process can also benefit from technology transfer where gene constructs already have regulatory approval in other countries. However, the environmental and socio-economic impacts will still need to be researched in the release environment and the costs of biosafety review and approval will still be accrued (see Sections 2.1 and 2.3).

1.6   THE NEED FOR PUBLIC-PRIVATE PARTNERSHIPS

Modern biotechnology is penetrating many parts of the developing world at an accelerating pace. However, the ownership of patents and the restrictions on access to technology have become critically important in the biotechnology transfer process. The *global scene* in GM crops is at present totally dominated by the six agro-chemical transnational corporations (TNCs) Monsanto, Bayer, Syngenta, DuPont, Dow and BASF, based in the USA and Western Europe[16]. Nearly all the GM crops on the *global market* today have been developed by these TNCs, who also control much of the technology, and the modalities of production and marketing. With the possible exception of China, public-sector R&D institutions in both industrialised and developing countries have been far less successful in *commercialising* the GM crops they have developed in their R&D institutions. (IFPRI, 2004)

The reason for the US-based private sector dominance and their huge investments in biotechnology R&D[17] and the subsequent development of GM crops are several. Firstly, the

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[13] The steps and procedures for placing GM crops on the market are today so demanding of resources that, at present, only the large seed companies can afford the process. However, as we argue in Section 3.3, developing countries can, with the support of the donor community, implement strategies that would enable their public-sector R&D institutions to take their GM innovations 'from the lab to the market'.

[14] Availability of transgenic crops depends heavily on who owns the particular crop, construct and associated technologies and the associated intellectual property rights (IPR).

[15] Through 'backcrossing' the particular GM trait by conventional breeding into a local crop variety. The resulting crops would, however, still be GM crops. Licences from the IPR-holders would be required for using such proprietary technology in any process or product.

[16] They are said to have already invested $10 billion in technology development and Monsanto alone has apparently spent $730 million on biotechnology research since 1997.

[17] The current global investment in medical, agricultural and industrial biotechnology sectors as a whole is of the order of 12 billion US dollars (about 60% in USA, 30% in Europe and 10% in Japan, with investments in developing countries amounting to less than a percent or two). As little as 20% of this total is invested by the public sector, the rest being in the private sector (principally in the TNCs). Of the private sector investment, 70 to 80% is invested in medical applications, 10-20% in agricultural applications and the rest in industrial applications.

United States already had a robust R&D component in commercial agriculture (i.e. hybrids, commercial plant breeding technologies, etc.). There was also a high market demand for timesaving and higher-yielding technological advancements in commercial agriculture[18], with plenty of venture capital to support these new agro-business innovations. Secondly, in the 1980s, it became possible to patent living organisms[19] in the United States. This affected patent regulations in many other OECD countries and enabled the patenting[20] of GM technologies. This patentability has spurred the private sector worldwide, but in particular in the United States, to invest in GM crop development. As a result of these investments, some of the leading private sector giant companies in the life sciences sector were able to fund cutting-edge science. Small biotechnology start-up companies in United States Netherlands and elsewhere, such as Calgene, MOGEN and Plant Genetic Systems (PGS), were also at the forefront of plant genetic engineering. To mention an example of this 'leading edge' technology, scientists at Monsanto in the USA and Plant Genetic Systems in the Netherlands were among the first to report the successful development of a GM crop (Charles, 2001).

The scientific breakthroughs resulting from the large private and public sector investments, and the ability to efficiently protect technologies used in GM crop varieties, have together led to the current situation, where the knowledge, the technologies (including modified DNA sequences), and output traits are largely proprietary and under commercial control. Patent protection is also increasingly popular in industrialised countries' public sector research institutions and publicly funded universities, because, among other things, it helps them to offset some of their research costs[21]. However, they tend to license their innovations to the private sector on an exclusive basis. As a consequence, a major part of all biotechnology products, including those funded by the public sector, are controlled by the private sector. Another factor further restricting access to technologies is that many of the breakthroughs in biotechnology that have occurred in, and were further developed by, the public sector are not freely available. The universities that developed them often licence them exclusively to private companies working on global crops such as maize, soya beans and cotton[22].

Developing countries may want to consider creating opportunities and mechanisms that would enable their crop-breeding institutions to access the technologies already innovated by the private and public sectors, in particular the TNCs. For this to happen, public-private partnerships have to be entered into, in which non-profit organisations (e.g. public sector national and international research institutions) should also be included. The main problem in accessing technologies may not be the unwillingness of the private and the public sectors to share their technology, but the lack of R&D capacity in countries to absorb and use these technologies, the absence of intellectual property rights (IPR) legislation and the institutional capacity to enforce it, and inadequate effort to attract foreign direct investment in GMA.

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[18] There has also been a growing environmental movement in the United States to move away from the intensive use of pesticides.

[19] The ruling in the decisive court case of Diamond *vs.* Chakrabarty in 1987 in the USA made multi-cellular living organisms eligible for patenting, thus opening the door for patenting a number of different GM organisms.

[20] Enabling stronger protection than the already existing Plant Variety Protection regimes.

[21] Many public R&D institutions are often licensing the technologies or inventions to private sector on an exclusive basis.

[22] The Boyle-Dole Act enables and encourages public sector universities in the United States to patent their scientific and technological discoveries and innovations and to licence them to the private sector.

1.7   THE CASE FOR PROMOTING PUBLIC-SECTOR R&D EFFORTS IN AGRO-BIOTECHNOLOGY

It important to note at the outset that several of the currently commercially available GM crops (e.g. cotton, maize, soya bean and potato), which have been developed by the TNCs and other private sector actors, are also of relevance to some sections of the farming community in developing countries. But the GM R&D efforts by the private sector are motivated by market value and not by the needs of small farmers in developing countries for whom the robustness, yield and re-sowing potential of their *local varieties of staple crops* are of critical importance. In general, commercial GM seed suppliers show little interest in crops where they cannot protect their proprietary rights or obtain a return on investment by offering sought after improved planting material. These include self-pollinating and vegetative crops, which are important to small subsistence and semi-subsistence farmers. It is however important to add that elite and hybrid varieties of non-GM crops (e.g. maize) *produced by the private sector* are being grown by small-scale farmers in many countries.

In the developing country context, one can talk about two market situations or systems. The first is a market-driven system for large- and medium-scale, cash crop-oriented farmers, who are catered to by commercial seed companies, including TNCs. *The second* is a system serving small-scale and subsistence-oriented farming communities. It is highly unlikely that the TNCs and other private sector actors will play a major role in the second type of market in the near future and thus in the development of crop varieties most relevant to the needs of subsistence and semi-subsistence farming communities (e.g. open-pollinated maize, sorghum and millets; vegetatively propagated cassava, sweet potato, yams, and cooking banana; beans, vegetables, etc)[23]. The dissemination of these GM-local crops will therefore depend heavily on public sector-based programmes. These will involve close collaboration between public-sector R&D institutions within the national agricultural research system (NARS), government seed-farms, NGOs, community-based organisations and national private seed companies. Opportunities exist, within the second market system, for small-and medium-scale seed-selling entrepreneurs[24].

Thus, strong public research efforts will be essential for harnessing the benefits of agro-biotechnology to the needs of small-scale and subsistence farmers in developing countries. Being close to the farmers and their problems, public-sector research institutions in developing countries have a key role to play. To be effective, institutions in the developing world need to collaborate broadly with one another, as well as with the IARCs of the CGIAR system, advanced research institutions in the industrialised countries and the private and public sector IPR-holders of GM technology.

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[23] However, some of the TNCs seem to have recognised this need and have made some of their gene constructs available for this kind of development in public sector institutions.

[24] To this end, Rockefeller Foundation is funding a development programme to support and develop seed producing entrepreneurs in developing countries.

1.8   CREATING AN ENABLING ENVIRONMENT FOR TECHNOLOGY TRANSFER AND DEVELOPMENT

Having recognised a role for agro-biotechnology, developing country policy-makers face a challenge. How can biotechnology be suitably integrated into the agricultural sector, so as to realise its potential benefits to society, while eliminating or minimising the potential risks? In order to meet this challenge, countries have to develop an 'enabling environment' for technology transfer and development, which comprises:

- Research and ancillary personnel with appropriate qualifications in relevant disciplines in the natural-, health- and social sciences (see Section 3.1 below) and adequately equipped and functional laboratories, libraries, databases and information technology.

- Biosafety[25] regulatory and compliance-compliance-monitoring structures, with risk assessment, risk compliance-monitoring and risk management capacity (see Section 2.2 below).

- A conducive policy environment, i.e. a willingness on the part of policy makers to promote agro-biotechnology and to institute policy-making and policy-implementing processes accordingly. This may include support to technology dissemination activities, incentives and clear guidelines for public-private partnerships, clear IPR polices, and structures at national and institutional levels that promote technology transfer and technology development.

The lack of effective research management, a shortage of trained scientists and poor R&D infrastructure are some of the major factors which limit the developing countries from taking advantage of the dynamic development in agro-biotechnology. A good deal of the technology is often accessible through collaboration with universities and research institutes in the more advanced industrialised countries[26] and the IARCs[27], with some international donor agencies being willing to fund the technology transfer involved. But the transfer of technology cannot occur without there being the capacity to absorb it. There is thus a significant cost to a developing country in lost opportunities if it does not have the basic scientific and other capacities indicated above.

Biosafety regulations and the capacity to implement them efficiently are critical to the safe application and development of GM technology. It may seem contradictory, at first sight, that regulatory oversight—with its accompanying cost for compliance and implementation—would promote biotechnology development, but there is growing agreement that this is the case. Private companies have frequently refused to transfer GM technology to countries that do not have effective biosafety systems. The adoption of biosafety regulations by a developing country is an indication of its willingness to adopt biotechnology and its ability to assess, monitor and manage potential risks. It should be stressed that regulations should be effective and appropriate to country needs and not form an insurmountable hurdle to local innovation.

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[25] The definition of 'biosafety' we adopt is that the application of biotechnology should ensure environmental, health and socio-economic safety (see Section 2.1 below).

[26] There are many such research institutions in Western Europe and North America, which are ready and eager to assist

[27] e. g. IRRI, CIMMYT, IITA etc.

Public sector R&D institutions have a crucial role to play in the development of appropriate agro-biotechnology applications for small-scale farmers. But public R&D institutions are often not the best agents for technology dissemination and commercialisation, which are activities more suitable for the private sector and other market actors[28]. An important role of the public sector is therefore to create conditions and an enabling environment for technology transfer and product development partnerships.

The formulation and implementation of national biotechnology policies, and biosafety regulatory and compliance-compliance-monitoring structures, are the responsibility of the government (see Section 2.2 below). A coherent biotechnology policy would, *ideally*:

• define priority areas for biotechnology research;

• lead to public investment in biotechnology research in public-sector institutions;

• provide, where appropriate, incentives to the forging of public-private sector partnerships in the development and dissemination of biotechnology;

• lead to investment, technology transfer and product development;

• provide a clear and legally mandatory biosafety regulatory and compliance-compliance-monitoring framework, and ensure that the regulations are applied, monitored and reviewed;

• establish a national legal framework for IPR (including plant variety protection regimes) and enact access- and benefits-sharing legislation to regulate the transfer of genetic resources, knowledge and information.

While this is an ideal 'wish-list' indicating the direction in which to advance, its translation into practice would be piecemeal and proceed by degrees and stages, depending on the specific circumstances in any given country at any given time. The critical challenge that the regulatory and policy authorities face, and where clear policies are needed, is the weighing of potential risks against potential benefits associated with GM technology.

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[28] Including NGOs, cooperatives etc.

2 Potential risks, concerns and issues associated with GM agriculture (GMA)

2.1 BIOSAFETY CONCERNS

As pointed out previously, GMA offers the prospect of important potential benefits to developing countries. At the same time, the introduction of GMA carries with it some potential risks. Strong debates about the potential benefits and risks have been going on between the protagonists and antagonists of GMA for nearly a decade, with varied and mixed outcomes depending on the developing country concerned. It is therefore very important to be aware of the issues raised in the debate, not least to compare and contrast, weigh and balance, the benefits and risks. This is particularly so for the governments of developing countries and the donor community, as they collaborate in the development of agriculture and food supply in the developing world.

The issues involved can be grouped under the broad concept of 'biosafety'. While the definition of 'biosafety' in the industrialised countries is limited to food, health and environmental safety, in some developing countries it has been broadened to include socio-economic impact as well. We sketch all these issues briefly in the following three sub-sections. It should be stressed that biosafety assessments are carried out on a *case-by-case basis* in most of the countries that review activities concerned with GM crops.

2.1.1 Food, animal feed and health safety issues

Genetic modification has the potential to confer health benefits through, for example:

- increasing the nutritional content in some crops (e.g. protein-potato being developed in India and vitamin A 'golden rice' in Switzerland , though both these are currently subjects of considerable controversy);

- decreasing the levels of natural toxic compounds in some foodstuffs; and

- reducing the use of pesticides and herbicides in agriculture, with corresponding reductions of their residues in crops.

On the other hand, there is concern that genetic modification could affect the safety of food and animal feed and thus pose potential risks to human and animal health. The GM-introduced proteins and other resulting molecules[29] may cause allergic reactions or act as toxins or carcinogens[30]. In addition, inserting new genes may change the nutrition of crops or their digestibility.

Allergenicity could increase either by raising the levels of naturally occurring allergens or through the introduction of new allergens. The great majority of *natural allergens* that affect human beings occur in certain food groups, which have been part of our food system for a long time (e.g. soya bean, plant nuts, tree nuts, wheat, eggs, fish and shellfish). In the development of GM food crops, close attention is being paid to the issue of allergenicity. An example of this is the case where a protein from brazil nut that was introduced into a variety of soya bean in

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[29] There may be unintended insertion effects causing the production of new substances in the plants.

[30] Cancer-causing agents.

order to improve its protein content. This effort was halted when food safety tests revealed that the transgene coded for a potential allergen that could have been added to the soya bean.

Pesticide toxins introduced into plants through genetic engineering (e.g. Bt-protein) may generate proteins, which may be safe for other animals but carry unexpected allergenic potential for humans. 'StarLink' maize is a case in point: the heat tolerant Bt-protein introduced into this GM crop was thought to have allergenic potential in humans and was therefore initially approved for animal consumption only, by the United States Food and Drugs Agency (USFDA) [31] Conversely, while a GM crop may be safe for humans, its residue used as feed may pose a risk to animals. For example, Bt-cotton is grown commercially in China, India and Indonesia and has passed thorough safety testing. Even so, it is uncertain what long-term impact the widespread use of GM cotton seeds as feed could have on the health of livestock. The techniques for testing the presence of allergens, toxins and carcinogens in food and feed are well established and are used to test all GM food crops before they are approved for use. Developing countries need to acquire and use these techniques an integral part of any effort they may make in the field of GM crops. They should also to the extent possible use available data since it is food and feed safety issues of GMOs are universal. This means that GM food and GM feed found to be safe for human and domestic animal consumption in one country are likely to be equally safe for consumption in other parts of the world[32].

Another area of concern is antibiotic resistance. The technique of using antibiotic resistant genes as selectable markers in GM plants could result in these genes being transferred to micro-organisms that are human pathogens, rendering them antibiotic-resistant. Recognition of this risk is resulting in the phasing out of antibiotic markers or their replacement by others that can be removed from the plants before commercial approval is given.

GM labelling of foods, feeds and other consumer products is being considered in several developing countries[33]. The recently issued EU directive on GM tracing and labelling and the draft guidelines on GM labelling by the UN/FAO Codex Alimentarius Commission will have a strong influence on the decisions that developing countries will make not only on GM labelling but also on the introduction of GM crops.

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[31] Notwithstanding the conditions laid down by the US Environment Protection Agency (USEPA), traces of StarLink were found in food products on sale in supermarkets in the USA. The StarLink incident has led to some serious rethinking about the biosafety regulatory regime in the USA. Addressing the Advisory Committee on Biotechnology in Washington, DC, the US Department of Agriculture (USDA) Secretary Ann M. Veneman stressed that the USA 'needed to really understand, better define the appropriate role of government regulatory systems to make sure that we didn't undermine the consumer confidence in our food supply.' Secretary Veneman went on to say that the USDA had taken the lead in bringing an inter-agency process to determine the appropriate regulatory responsibility necessary for 'the diverse nature of biotech that we're dealing with today.' See http://www.usda.gov/Newsroom/0220.04.html. Incidentally, an attempt by a US-based non-governmental international charity organisation to distribute imported StarLink maize as food aid to some of the poorest sections of the population in India was halted by the Indian authorities, after an intervention by Indian GM-concerned NGOs.

[32] In the area of food safety, information exchange between regulatory authorities is crucial, a measure that is also fairly straightforward. Thus, for instance, a specific GM product that has been approved for consumption in the USA by the US authorities ought in principle be safe in Tanzania. However, the Tanzanian authorities indeed to *locally* validate the US data and assessments, and decide whether additional country and regional specific food safety assessments needs to be undertaken, e.g. different allergenic profiles within locally specific parts of the Tanzanian population with respect to specific proteins or metabolites.

[33] It has been made mandatory in China, but reports say that it is not yet being practised.

2.1.2 Environmental safety issues

As indicated earlier, the potential reductions in the use of some chemical pesticides and herbicides that the cultivation of GM crops may allow would have a positive impact on the environment, as would the ability to grow more food on less land. Nevertheless, concern persists about the potential risks posed by GM agriculture to ecology and environment. Harm could potentially arise, directly or indirectly, through six routes:

- geneflow and transfer of genetically engineered traits to other species;
- invasiveness, weediness and resistance;
- impact on subsoil and other 'non-targeted' organisms, including soil micro-organisms;
- unexpected characteristics through genetic variability;
- mixed virus infections;
- new pests and diseases.

Geneflow and transfer of genetically engineered traits to other species
A critical issue arises when GM crops are grown in areas close to their native wild relatives (such as in the so called 'centres of origin' or centres of high biodiversity). Cross-pollination can lead to the transfer of the GM trait to the native wild relative[34]. If the transgene is foreign[35] then the trait transferred would be foreign to the wild relative as well. These recipient plants may[36] have a competitive advantage over other vegetation and displace weaker, but equally important species. This may have potentially[37] negative consequences for the biodiversity of the centre of origin and diversity[38] of the wild relatives and domesticated farmer varieties[39]. Most of the major food crops grown in the world today have their centres of origin in the developing world[40] making it important to consider the impact of gene flow in GM decision making. It should be pointed out that it is not cross pollination itself that is harmful, but rather the effect the new trait could potentially have on the new recipient.

Invasiveness, weediness and resistance
There is a possibility that a GM crop may establish self-sustaining populations of itself outside the area of cultivation and may become a 'weed' that out-competes not only the cultivated crops, but also wild species, including native wild relatives if this happens in a centre of origin. The consequence again would be a loss of both agricultural and natural biodiversity.

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[34] There are ongoing studies on the prospect of limiting or completely stopping gene flow through various types of mechanisms, including novel scientific approaches for achieving male sterility. However, these approaches (e.g. Gene Use Restriction Technology/GURT, also termed 'Terminator Technology' by GM opponents) are extremely controversial in developing countries where the saving of seeds for replanting by small-scale farmers is an age-old tradition.

[35] In principle, genetic engineering makes it possible to introduce any gene from any organism into any other organism, irrespective of species boundaries (irrespective of whether the species are from the plant, animal or other kingdoms).

[36] This very much depends on the type of trait and the type of selection pressure in the various habitats.

[37] It has been argued that most of these types of traits (e.g. disease resistance, etc.) are already present in the wild populations and that the risks posed by GM crops are not dramatically different form those associated with the introduction of traditionally bred cultivars.

[38] Places in the world where crops have the greatest genetic diversity in the form of traditional crop varieties/and or wild relatives. Centres of diversity are typically, but not always, the same locations as the centres of origin, or of the oldest cultivation, of the crops.

[39] A scientific and political controversy is going on about whether or not GM maize (corn) from the USA has 'contaminated' wild maize in Mexico, of which Mexico is the centre of origin.

[40] Western Europe, in contrast, is the centre of origin of only one of the globally grown major crops, oilseed rape.

Herbicide-tolerant genetically modified crops may accelerate the establishment of herbicide-tolerant weeds[41] and pesticide-resistant insects. This could also lead to a situation where specific naturally occurring pesticides and insecticides, which are considered to be environmentally benign, will be less useful[42]. In any given agro-ecological zone, various species of insects that form vital links in the food chains of the zone feed and flourish on traditionally-cultivated non-GM crops and native wild plants. A number of insect species are entirely dependent on single plant species. If cross-pollination from GM crops leads to spread of insect-resistant hybrid plants, insect populations could potentially decline, which may cause disruptions in the food chains. Thus, consideration of food webs and interdependence is an important part of any biosafety review.

Impact on non-target organisms
A trait that is genetically engineered into a crop to attack a specific organism could end up harming others that were not targeted by the GM product. For instance, Bt-maize[43] (corn), which is designed to produce a toxin that is fatal to the stemborer insect (a lepidopteron, i.e. butterflies and moths) may affect some non-pest lepidoptera as well. Trait effects therefore need to be carefully studied and monitored, as part of the process of GM crop development.

Unexpected characteristics through genetic variability
In addition to expected characteristics, plants tend to display unexpected ones. This is well known in conventional crop-breeding. In GM crops, this genetic variability including unintended insertion effects could lead to unexpected hazards like increased weediness.

Mixed virus infections
A GM crop may be given ('express' is the technical term) a virus gene that produces a protein as a protection from specific plant virus infections. This virus gene in the plant, or in any naturally infected plant may recombine with another virus infecting the plant, and result in a new plant virus, which may pose a new hazard[44].

2.2   INSTITUTIONAL STRUCTURES FOR REGULATING AND MANAGING BIOSAFETY RISKS

Developing countries that wish to promote GMA have to find ways of dealing with the potential risks outlined above. In practical terms, this involves assessing in depth the potential benefits and risks associated with each GM crop, deciding which risks are acceptable and ensuring that the country has mechanisms in place for compliance-monitoring and managing the risks. Such assessments and measures call for the establishment of government institutions with

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[41] Reports are emerging of the appearance of broad-spectrum herbicide-resistant weeds in the GM soya bean producing areas of Argentina, where Monsanto's Roundup Ready soya bean is extensively grown in combination with Monsanto's broad-spectrum glyphosate herbicide marketed under the trademark 'Roundup'. See the New Scientist, April 2004, and Paul Brown's article in The Guardian Weekly (the global edition of The Guardian) London, April 22-28 2004, entitled *'Superweed warning as GM soya 'miracle' in Argentina turns sour'*, www..guardianweekly.co.uk and www.guardian.co.uk/international/story.

[42] An issue has been the resistance to Bacillus Thuringiensis toxin (Bt), a naturally occurring toxin used by organic farmers, but also a widely used toxin in GM insect resistant plants. If the widespread use GM plants expressing Bt cause resistance to Bt, organic farmers may loose an important tool. However, the conventional Bt-spraying of non-GM crops to combat pests is as likely to cause resistance build-up as the genetically engineered resistance in Bt-crops.

[43] A GM maize created by the introduction of genes from a naturally occurring *Bacillus thuringiensis* (Bt), which produces proteins fatal to a narrow range of insects.

[44] This happens to all plants infected by viruses, but the point being debated is whether GM plants pose new and different kinds of risks in this context.

the mandate to formulate, legislate and implement biosafety regulations and biotechnology policies (biopolicies).

So far, only a few of the relatively advanced developing countries have managed to establish somewhat optimal national structures for dealing with biosafety regulation and biopolicies. Although a fairly substantial number of developing countries (including some of the least developed countries) have begun the process, they have a long way to go before arriving at adequate and functional structures. Our recent research reveals that while a few of the advanced developing countries may have put fairly differentiated structures in place, including comprehensive biosafety legislation and obligatory policies, their capacities to *implement* the biosafety regimes remain very unsatisfactory.

Many developing countries have tentatively begun the task of setting up biosafety regulatory frameworks under a global programme launched jointly, in 2001, by the United Nations Environmental Programme (UNEP) and the Global Environment Fund (GEF). The impetus for the UNEP/GEF programme was the adoption in January 2000 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. As of January 2004, eighty countries, including the EU, had ratified the Protocol. The central objective of the Protocol is to regulate the international (i.e. transboundary) movement of living genetically modified organisms (LMOs) in order 'to derive maximum benefits from biotechnology while at the same time protecting biodiversity and human health from potential risks posed by LMOs'. The Protocol is based firmly on the *precautionary principle*[45]. Its main directives are that the import of LMOs into a signatory country requires the *advance informed* agreement of the country's authorities, and the LMOs should be assessed using a *case-by case*[46] approach.

We provide below a brief template sketch of the institutional structures and functional-competences that biosafety and biopolicy regimes need to incorporate, not only for formulating the regimes but also for implementing them. It was arrived at by analysing the components, characteristics, strengths and shortcomings of the biosafety regulatory structures that are in place in several developing countries (e.g. India, the Philippines, etc.).

2.2.1 National biosafety regulatory and compliance-monitoring structure

In an ideal situation, this would comprise four government-appointed national bodies: a biosafety decision-making body, a biosafety scientific advisory body, a biosafety compliance-monitoring body and an administrative and implementing body set up for servicing the first three[47]. Hereinafter, we will refer to these four bodies, respectively, as the '*Regulator*', the '*Advisor*', the '*Monitor*' and the '*Secretariat*'. In addition to these, several government ministries and departments may be closely involved in the biosafety arena.

While the *Regulator* would have the mandate to take decisions on the applications by GM-active institutions for biosafety clearance for (i) conducting R&D projects, including greenhouse and limited contained testing, (ii) conducting large-scale field trials, (iii) commercial release of GM crops and (iv) imports of living GMOs, it would be the *Monitor's* responsibility to

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[45] Annex III of the Cartagena Protocol defines the Precautionary Principle as follows: 'Lack 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'.

[46] This means that since the knowledge of potential risks is bound to be limited, each GM crop has to be assessed individually.

[47] In some of the developing countries that have actually established operational regulatory systems, these three bodies have been merged into one or two.

ensure that GM-active institutions comply with the biosafety regulations, and the conditions of approval of activities. The *Advisor* would conduct the risk assessments, determine the risk management conditions under which the activities should be allowed to proceed and indicate specific areas that need inspection for compliance.

It is important to be aware of, and ensure, the distinction between the responsibilities of the Regulator and the Advisor. The Regulator takes the actual decisions about the applications submitted by GM-active institutions, on the basis of the risk assessment recommendations submitted by the Advisor and the much broader inputs (socio-economic, civil society and 'national imperatives') by other organisations. The Advisor assesses the risks involved in the proposed GM activities on the basis of the principles, criteria and methods prevalent in the natural-, health- and social sciences. Since the scientific expertise required for assessing risks depends on the specificities of the GMOs, the GM crops and GM activities being examined, it would be logical to make the membership of the Advisory body contingent on the application being considered.

Approval for commercial release of GM crops would be subject to satisfactory demonstration of (i) environmental biosafety through large-scale and multi-location field trials, (ii) health safety through established channels for food and feed safety testing, and (iii) socio-economic safety through assessment studies. On the basis of the results of the trials, tests and studies, the Regulator would have to weigh the potential risks against potential benefits of a GM crop, and take into consideration alternative solutions or technologies, before taking a decision about whether or not to approve its commercial release.

The exercise of balancing risks against benefits poses a serious challenge to the Regulator. The central questions to be faced are who would be exposed to the risks and who would reap the benefits. Regulators cannot bypass social values and cultural practices in arriving at their decisions[48]. These considerations require that the Regulator will shoulder the responsibility of implementing and enforcing the risk management conditions.

The Regulator and the Monitor are statutory bodies composed in accordance with national legal precedence. In order to ensure the participation of the representatives of all the main stakeholders and the public in decision making, the Regulator and the Monitor should be broadly constituted, comprising nominees from (i) the ministries (government departments) of environment, agriculture, forestry, health, science and technology, industry, commerce (trade), and legal affairs (law and justice), (ii) the government-funded public sector national research councils dealing with the natural and social sciences, technology, policy research, agriculture, health and industry, (iii) the knowledge-generating and knowledge-disseminating institutions in the public and private sectors, dealing with both the fundamental and applied areas of knowledge in the biotechnology and biosafety arenas, (iv) GM-concerned civil society organisations (CSOs, which include NGOs, in particular environmental and consumers' organisations) and iv) farmers' and industry organisations.

It is of crucial importance that the Regulator and the Monitor should include representatives of CSOs that articulate public concern over GM agriculture and actively campaign for public participation in the biosafety regulatory regime. In other words, 'public-concern expertise' from the ranks of the CSOs ought to involved in the assessment and compliance-monitoring of potential risks and benefits of GM activities in a country.

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[48] Although socio-economic impact and ethical concerns are often not part of biosafety evaluations in OECD countries.

Regulating the processes and the products of GM agriculture involves the regulation of imports of living GMOs, GM R&D and contained use, field testing, general release and marketing (commercialisation) of GMOs, including GM crops. In addition to the work of the Regulator, the Monitor and the Secretariat, this calls for the close involvement of the government ministries, departments and agencies responsible for agriculture, environment, health, rural development, industry, trade, legal affairs, and the funding of GM related research (including the social sciences, legal disciplines and policy arena). To this end, government entities have to establish mechanisms for inter-departmental governance of GM issues or create specific units or 'desks' dedicated to agro-biotechnology issues. Additional institutionalised mechanisms may be needed for regular consultation and effective coordination between the biopolicy units and 'desks'. This may be the responsibility of the biosafety Secretariat.

Developing countries are unlikely to have the full complement of capacities and resources to generate all the requisite biosafety data themselves. Therefore, Regulators and the Advisor in developing countries have to acquire the capacity to absorb and validate biosafety data generated elsewhere, and adapt these to their own local and national conditions, where this is feasible.

2.2.2 Feasible regulatory structures in developing countries

In view of the economic and institutional constraints operating in developing countries, the modalities of the implementation of biosafety regulations must be such as to be financially and institutionally feasible within the limits set by the constraints. They must be scientifically based and be amenable to the appropriate use of scientific information, knowledge and expertise. Risk assessment relies on expertise covering a wide range of scientific disciplines. A number of industrialized countries have set up complex systems of institutions, committees and expert panels to formulate and implement biosafety regulations. The replication of this model in the developing world would require institutions and resources (professional competence and skills, finance and infrastructure) that are far beyond the means of the majority of developing countries. Developing countries also need to make sure that they are not setting up biosafety systems that impose prohibitive costs on local innovation. They therefore have to use an approach that is feasible in terms of the resources at their disposal, which involves some trade-off between the costs and benefits of regulation, without sacrificing protection from potential risks. Developing countries could build on assessments and experiences[49] made in more developed countries. Having said that, it is also clear that developing countries have to acquire the capacity to assess biosafety issues specific to their local conditions.

2.2.3 Implementing biosafety regimes still a major obstacle

Even where a developing country has a biosafety regulatory system, the main difficulty arises in the implementation of the regulatory regime. Whereas the EU and the OECD countries limit the application of the concept of biosafety to the physical and ecological environment, and the health of humans and animals, many developing countries have extended it to include the socio-economic impact on rural communities, in particular small-scale farmers. This makes biosafety assessment in many developing countries more complex and time consuming[50].

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[49] For instance through accessing the regulatory reviews made in leading OECD countries.

[50] A recent study shows that regulatory approval rates of GM crops are much lower in developing countries compared than in industrialised countries. Of about 210 GM–crops and GM transformation events in various stages of testing, only 20% may have some opportunity for regulatory approval and commercialisation. Such high rates of 'non-realisation' may result in potentially useful crops and technologies not being developed and marketed. (IFPRI briefing paper, 2004)

Human resources both enable and limit biosafety implementation. Biosafety implementation is shaped by the scope and the quality of available competence in the disciplines of biological and environmental sciences, plus the aptitude for inter-ministerial regulation and government-scientist collaboration. In the opinion of some analysts 'a thin, weak, or limited knowledge and skills base tends to produce regulations that are highly protective (at the expense of innovation), poorly defined or inconsistent, comparatively rigid, and /or narrowly interpreted. A deep and broader knowledge, skills and capacity base will foster more latitude in the regulatory development and more flexibility in regulatory implementation'[51].

The processes of carefully balancing and weighing the potential benefits against the potential risks of GM crops, and of arriving at a decision to approve or reject the application for biosafety-clearance (say by an R&D institution or a commercial company), presumes the existence of relevant and adequate capacity in several specific areas of knowledge. In addition, countries require institutional capacity to implement and monitor biosafety regulations, to manage potential risks and to promote public participation and public trust in the workings of the biosafety regulatory authorities, and financial capacity to effectively implement biosafety regulatory programmes. Further, without access to biosafety capacity, the signatories to the Cartagena Protocol would be incapable of implementing its provisions[52], in particular the measures triggered by requests to the national authorities for their *advance informed agreement* by importers and exporters of GM crops.

The various required capacities cannot all be centralised but must necessarily be decentralised to a variety of institutions matched to the nature of the capacities, e.g. knowledge-generating and knowledge-disseminating institutions, government entities and civil society organisations (non-governmental organisations).

Only some of the relatively technologically and industrially advanced developing countries currently have the infrastructures and the resources that would enable them to build up and strengthen all these capacities on their own on a national basis. But it would be unrealistic for most developing countries, and in particular the least developed countries, to attempt to build these capacities exclusively on a national basis. Given the lacunae in their present R&D and institutional infrastructures, and the extreme scarcity of resources at their disposal, their efforts at building capacity are more likely to bear fruit if they were spread appropriately between the national and the sub-regional levels. In addition, these efforts are unlikely to make much headway without close collaboration with selected institutions in the industrialised world that would have the appropriate expertise and experience to offer, including the international agricultural research centres (IARCs) belonging to the CGIAR system[53].

2.3   SOCIO-ECONOMIC ISSUES

It is clear that mastering GM technology and its potential environmental and health impact is not enough. It is also necessary to understand the society into which the new GM products will

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[51] McClean, M, Frederick, R.J, Traynor, P. L., Cohen, J.I and Komen, J (2002), A Conceptual Framework fro Implementing Biosafety: Linking Policy, Capacity and Regulation, ISNAR Briefing paper 47.

[52] To this end the GEF has approved funding to extend the Implementation Phase for biosafety frameworks to other countries as they complete development and move towards implementation. The project has a specific requirement to investigate sub-regional cooperation to assist in effective capacity development and use for biosafety.

[53] While some selected IARCs have excellent capacity to assist in the science and technology of agro-biotechnology, they are unlikely to be able to provide in-depth assistance in the area of biosafety, as their experience in this area is quite limited.

be introduced. GM technology has raised a number of important issues, which relate to how this technology is developed, by whom, for whom and with what consequences. Historically speaking, few technologies have been as scrutinized, assessed and debated as GM technology, with the exceptions perhaps of immunisation and nuclear technology. The critique is often focused on who is setting the R&D agenda and who is delivering the technology or products, rather than on the safety issues and the impact of the technology, *per se.* Socio-economic issues proved very controversial during the drawn out negotiations that resulted in the Cartagena Protocol on Biosafety[54].

2.3.1 Limits of the Green Revolution

As is well researched and documented, the Green Revolution (use of high-yielding varieties in combination with inorganic fertilisers, pesticides and herbicides, and intensive irrigation) had a mixed impact on small-scale farmers in Asia and Latin America, with a majority managing to benefit, while a minority have become marginalized. Decades of continuous use of agro-chemicals and irrigation have led to serious and persistent environmental damage of soils and water bodies. The Green Revolution in the developing world has in many cases reached its limits, with examples of yields either levelling off or declining. It could well be that the currently experienced limits in yields are an outcome of restricted input-intensification (e.g. the application of fertilisers), rather than a result of the properties bred into the high yielding cultivars[55]. In addition, while the Green Revolution increased the production of the main staple cereals (maize, rice and wheat) by several factors in Asia and Latin America, it was unable to establish itself in sub-Saharan Africa[56] (for a variety of reasons), where agricultural productivity has remained very low.

The proponents[57] of GM technology believe that it heralds a new 'Doubly Green Revolution'[58], arguing that the use of GM crops will dramatically revive the now stagnant levels of yield, while simultaneously having a beneficial impact on the environment because of the decrease in the use of pesticides and herbicides. This claim is hotly disputed by GM opponents[59]. Socio-economic issues are in the forefront of the debate, together with environmental and health safety issues.

2.3.2 Differential impact of technological change on farmers in the developing world

More than two-thirds of the population of Africa and Asia live in rural areas. The great majority of them are small farming households with land-access to between one and two

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[54] Most of the countries in the North favoured an exclusion of socio-economic issues from the Protocol, whereas many countries in the South wanted these issues included. (e.g. liability). In the final Protocol, socio-economic issues were largely left out.

[55] An example is the yield of winter wheat in Sweden. According to Lars Ohlander of the Swedish University of Agricultural Sciences, if the cultivation of winter wheat in Sweden were made more intensive, the yield could be raised to 13 to 14 metric tons per hectare from the current average of 6 to 7 metric tons. But, apparently, under the present EU policies, it is not profitable for Swedish farmers to do so.

[56] With the exception of South Africa and Zimbabwe. Unless otherwise mentioned, this exception applies throughout this paper when we refer to the economies of sub-Saharan Africa.

[57] Governments, agribusiness companies, R&D establishments and parts of the farming community and the media

[58] The phrase 'Doubly Green Revolution' was coined by Gordon Conway, Head of the Rockefeller Foundation, to denote the possibility of harnessing agro-biotechnology to the challenge of achieving environmentally sustainable increases in crop productivity

[59] Parts of civil society (civil society organisations/NGOs), and parts of the farming community and the media

hectares. A sizeable minority are landless people, who earn their living as agricultural wage labourers or farm on communal land governed by traditional leaders. Latin America presents a somewhat different picture, with more than half the population urbanised, and the southern cone dominated by immense individual landholdings, while the Andean region and Central America display a mix of large, medium and small landholdings, with the last category by far the most common. As with the technological changes introduced over the last thirty years by the 'Green Revolution', the medium- and large-scale farmers can be expected to face no difficulty in turning GM technology to their own advantage. But it is highly debatable whether the same applies to small-scale and subsistence farmers.

2.3.3 Potential impact on rural incomes and livelihoods: Transnational GM technology versus developing countries' domestic R&D

One of the questions under close scrutiny is how GM technology is going to affect the incomes and livelihoods of small farmers and landless rural households, who are not only the majority population of the developing world but also its predominant suppliers of food and cash crops to domestic and export trade. The answer differs depending on the appropriateness, origin, ownership and control of the GM crops in question. On the one hand, there are half a dozen TNCs[60], which have so far put several lucrative GM crops on the global market (cotton, soya bean, maize, oil-seed rape/canola, sugar beet, tomato and potato) and are on their way to introducing some more in the near future (mustard and tobacco).

On the other hand, there are public-sector research institutions in a few developing countries, which are in the process of innovating genetically modified versions of *local varieties* of subsistence and cash crops (GM-local crops), that small farmers grow for their own use and the local market, which are vital not only for their daily subsistence income but also for basic consumption by the poor majority (e.g. local varieties of maize, rice, wheat, cooking banana, cassava, yam, potato, sweet potato, chickpea, tomato, papaya, cabbage, cauliflower, etc.) These will be crops, developed either by local seed companies or public breeding institutions registered under national plant variety protection (PVP) regimes, or community developed farmer varieties. The ownership and control of the improvements to the latter type of crops, and the rules for sharing the economic benefits resulting from them, will not be easy to establish, since PVP regimes in most cases[61] fail to acknowledge established farmer varieties. However, new plant genetic resource regulations may fill this gap[62].

The potential *benefit* of current commercial GM crops arises from the transgenes that either confer resistance to certain globally occurring plant pests and diseases[63], or immunity from certain chemical herbicides that wipe out all other vegetation in the areas sprayed[64]. In the former case, potential monetary savings accrue to the farmer by obviating the need to use certain pest-specific pesticides and there is a net safety gain for workers by minimising the use and exposure to toxic agrochemicals. In the latter case, the potential gain is from the

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[60] Monsanto, Bayer (now incorporating Aventis), Syngenta (now incorporating Novartis and Zeneca), DuPont (now incorporating Pioneer), Dow and BASF.

[61] *Sui generis* PVP regimes to protect local farmer varieties have so far been developed in only a few countries and are yet to be operationalised.

[62] Such as the new Indian Plant Variety Protection Act and provisions in the International Treaty on Plant Genetic Resources for Food and Agriculture.

[63] For example, Monsanto's Bt-cotton and Bt-maize, which are resistant respectively to the bollworm and the stemborer.

[64] For example, as mentioned earlier above, Monsanto's Roundup-Ready soybean, which tolerates the broad-spectrum herbicide glyphosate marketed by Monsanto as Roundup.

yield rescued from the weeds. These broad-spectrum herbicides were developed with the industrialised countries' commercial farmers in mind, for whom the decisive issue is the saving of labour costs prevalent in their high-wage economies.

The current commercial GM crops are designed primarily with the high-income markets of the industrialised world in mind and may turn out not to be appropriate to the very different socio-economic contexts of rural Africa, Asia and Latin America[65]. The potential *risks* faced by the rural communities in developing countries that may adopt the current commercial crops are related to the:

(i)   monopoly control that the TNCs' developing country agents/subsidiaries/joint-ventures exercise on the price of the GM seeds;

(ii)   need to buy GM seeds for every new planting season to maintain high-yield levels and fulfil farmer's agreements with the seed-selling companies;

(iii) dependency on new generation of GM seeds or a reversion to old technology to address resistance that plant pests and diseases are likely to develop;

(iv)   profitability margins being squeezed between increasing seed prices and declining harvest selling prices; and

(v)   possible loss of existing robust crop varieties and technologies, thereby reducing the diversity, flexibility and resilience of farming systems, and increasing vulnerability to events that could lead to famine.

Most of these concerns are not unique to GM crops. To some extent, they are the same as the concerns raised when hybrid seeds and elite cultivars were introduced some decades ago. One new component, however, is the stronger IPR protection accorded to GM technologies and crops. Additional concerns have to do with the ongoing globalisation and liberalisation of markets, and the changes in agricultural systems and how this is impacting on rural societies. Turning these arguments around, it could be said that developing country farmers can benefit from improved commercial seeds, even if they cost more[66] *provided* they are able to produce more and *find* a market for their products at *reasonably profitable prices*.

Turning now to the public-sector R&D institutions in developing countries, they have a greater possibility of responding seriously to *specific local* requirements than the TNCs with their globalised and globalizing approach. National and provincial agricultural universities and other GM-related R&D institutions are aware of the local farming and agronomic practices, the economic, infrastructural and social constraints facing the local farming community, seed producers and traders, and local consumer preferences. Were they to let this awareness

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[65] There is considerable debate in a few countries in Asia and Latin America about whether small farmers have actually experienced the benefits expected of TNCs' GM crops. For instance, a bitter controversy is currently raging in India about the supposedly increased yields, and the ensuing apparent monetary benefits to small farmers, from Monsanto's Bt-cotton, following the first harvesting in late 2002 of this first legally commercialised GM crop in India. The parties ranged in the conflict are, on the one side, Monsanto-Mahyco (a USA-India joint venture company) and the central government authorities in New Delhi, and, on the other side, GM-concerned CSOs and some state-level government authorities in the five states where Monsanto-Mahyco's Bt-cotton was sowed. It should be noted that a year prior to the commercialisation of the Monsanto-Mahyco Bt-cotton, another Indian company had marketed 'its own' Bt-cotton but with the same transgene as the Monsanto one, *without* central government approval, i.e. illegally. This illegal harvest reached the domestic market in the autumn of 2001, producing an outcry by various actors in the GM arena. (Illegal recourse to GM seeds has also been reported from other parts of the world, for instance the cultivation of Monsanto's Roundup Ready GM soya beans brought over the border from Argentina.) In collaboration with our Indian colleague Dr A Indira, we have conducted an in-depth review of the Bt-cotton case in India as part of our ongoing Sida-funded study entitled ' Comparative Asian Biosafety Project', which covers India, the Philippines and Thailand.

[66] Farmers will buy GM seed only if the cost is justified by the returns. GM seed prices may vary from area to area, so that they are priced to be competitive and reflect the potential benefit for that area.

determine their R&D work, they would avoid the risks associated with the monopoly and global approach of the TNCs, and be able to deliver benefits identified by the local people themselves.

2.3.4 Impact on agricultural practices: seed saving, biodiversity and inputs into agriculture

For the sake of maximising their profitability, medium- and large-scale farmers in some parts of the developing world have tended to concentrate on monoculture[67] of certain varieties of staple cereals and industrial crops. Like their counterparts in the industrialised countries, they have become practitioners of industrialised agriculture, buying new seeds and agrochemicals from agribusiness companies every planting season. They have paid scant attention to preserving agricultural biodiversity[68].

The situation is quite different with regard to the small farmers. Tradition has taught them that in order to ensure their own food security, *within the severe limits set by semi-subsistence cultivation*, they have to preserve genetic diversity in the crops they cultivate, so that an epidemic caused by a pest or a disease or a climatic stress cannot wipe out their entire production. For this, as well as other economic, social and cultural reasons, small farmers have saved seeds from one harvest to the next to replant and exchange. Fortunately, while they may accept the cultivation of some GM crops, they are most unlikely to give up their seed saving and intercropping cultivation practices that ensure the conservation of genetic diversity on their plots. These practices find support in the International Treaty on Plant Genetic Resources for Food and Agriculture[69].

From the standpoint of the developing countries, a potential risk factor associated with commercial GM technology is the attempt by some TNCs to incorporate the gene use restriction technology (GURT, or the so-called 'terminator technology') into their GM seeds. GURT systems make seeds sterile and therefore useless for replanting, obliging farmers to buy new seeds every planting season. The US Department of Agriculture and Pioneer (now part of DuPont) were the first public-private partnership to announce work on GURT. But following an international outcry, they backtracked and agreed that GURT could compromise small-scale farming practices. However, a report emerged in mid-2003 indicating that the GURT option was being revived as it offers a viable mechanism to stem gene flow from GM crops. However, it would be safe to predict that TNCs will face tremendous opposition if they tried to impose GURT on developing countries. In fact, a number of developing country biosafety frameworks have stated that they will not approve GM technologies that could impact negatively on a farmer's right to save seed.

Even if the cultivation of some GM crops becomes established and widespread among farmers in the developing world, the cultivators' present dependence on fertilisers, pesticides, and herbicides, and on pump-fed and canal irrigation, will not cease[70]. What the GM technology

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[67] By 'monoculture' we mean the repeated growing of the same distinct and uniform crop variety, as a sole crop, in contrast to growing several 'morphologically not well-defined' varieties of the same crop on the same field.

[68] Relying on breeders to provide new diversity as and when it is available.

[69] The Treaty provides for sharing the benefits of using plant genetic resources for food and agriculture through information-exchange, access to and the transfer of technology, and capacity building. It also foresees a funding strategy to mobilize funds for activities, plans and programmes the help, above all, small farmers in developing countries. This funding strategy also includes the share of the monetary benefits paid under the Multilateral System.

[70] If yields are to be maintained at a given level, or raised to a higher level, the nutrients removed by the crop (non-GM or GM) from the soil have to be replenished or increased, which means that the soil has to be appropriately fertilised one way or another. Yields do not come 'free'.

allows them to do is to dispense with only those inputs that the transgenes make redundant. In other words, GM technology is *not* a magic wand that does away with the current dependence on inputs. What it could lead to is some increase in monetary and safety benefits through savings on some chemical inputs, irrigation and increased shelf-life (for vegetables and fruits).

2.3.5 Role of public-sector R&D institutions in developing countries

Historically, a necessary condition for the successful dissemination and use of the public-sector R&D innovations was that the innovated technologies were transferred *free of charge* to the local and national entrepreneurs and companies, and were backed up by *free and reasonably prompt* technical advice[71]. However, the resources required forgoing 'from the lab to the market' are too heavy to be borne by the R&D institutions themselves and it may be time to consider another model that might include selling the innovations to the domestic public and private sector agricultural companies to recover the costs. Alternatively, the full costs will have to be met by the national governments (through, for instance, national research councils) and by foreign donors in the case of the poorest countries.

A review of the GM crops developed so far in developing country public research organisations shows that the major constraint to final release of the new, improved and tested varieties is the cost of the biosafety process. This cost now equals the cost of development and was not included in project budgets initiated ten years ago.

There is always the risk of the public-sector R&D institutions not being able to deliver the innovations expected of them by government authorities, the farming community and other GM stakeholders. One indispensable element in any strategy designed to improve the institutions' ability to 'deliver' is to develop their institutional capacity (functional-competence, resources and structure). The 'capacity issue' is covered in Section 4 below, not only with respect to R&D institutions, but also in relation to government entities and CSOs (including NGOs). Our brief examination there will include the capacity to conduct studies on socio-economic impact, as well as other agro-biotechnology issues.

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[71] This was one of the necessary conditions, among others, that led to the 'taking off ' of the Green Revolution in Asia.

3 Biotechnology Policy Issues

3.1 TRADE ISSUES

The vivid debate about the safety of GM products has created significant consumer resistance to GM products in developed and developing countries. This is particularly true in the EU, but consumer resistance is also emerging in many other regions of the worlds, including South Asia, Southeast Asia and Latin America. The scepticism in the EU towards GM crops led to the imposition in 1998 of a moratorium on the import, marketing and commercial cultivation of GM crops and the development and enforcement of the strictest biosafety regulations in the world[72]. Apart from a precautionary approach, the EU regulations require member states to ensure labelling and traceability of GMO products at all stages of placing a product on the market[73]. These regulations came into force in April 2004. In May 2004, the EU lifted its ban on the import and marketing of GM food, by approving the application by Syngenta to market its GM maize. Other pending applications (over 30, as of mid 2004) will be considered on a case-by-case basis. However, the moratorium on the *commercial cultivation* of GM crops still remains in place, awaiting an agreement to that effect by all the member states, some of whom are still strongly opposed to commercial cultivation[74].

The demand for labelling and traceability of GMO products has created trade conflicts, in particular between EU and the United States. The US is challenging the EU regulations on the grounds that they constitute a 'pure trade barrier'[75] under the World Trade Organisation rules. The EU regulations mean that practically all maize, soya beans and other crop products (including processed food) exported from the United States to EU have to be labelled[76]. Since European consumer opinion is, for the time being, negative to GM crops and GM products, the labelling is likely to have a negative impact on the marketing of US crop and food exports in the EU[77].

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[72] However, through this period the EU has remained one of the biggest producers of GMOs for the food-processing and animal feed industry (enzymes, additives, supplements) and one of the biggest importers of approved GM commodities for use in the food- processing and animal feed industry. Interestingly, the labelling and traceability rules will not extend to the GM products used in the EU in food- processing and food-supplementation.

[73] The labelling threshold is at 0,9% for approved GM products and 0,5% for unapproved GM products. This means that if a product contains less than 0.9% or 0.5% of GM material, and its presence is shown to be unintentional and technically unavoidable, it does not have to be labelled.

[74] An indication of the impact of the resistance to GM crops is the decision by Monsanto in May 2004 to abandon its plans to introduce its GM wheat in the USA and elsewhere, in the face of the opposition by a large section of wheat farmers in the USA and wheat importers in the EU and East Asia., who together account for over 45 percent of the annual wheat exports of the USA. Similarly, although approved by the British government, Bayer has given up attempts to grow its GM maize (meant for animal feed) commercially in Britain, citing the adverse conditions facing the growing and marketing of GM crops in the UK. See Paul Brown's articles 'Monsanto abandons global GM wheat plan' and 'Despairing GM firms halt crop trials' in the Guardian Weekly (the global edition of The Guardian) London, May 13-19 and April 22-28, 2004, respectively, www.guardianweekly.com. See also Paul Geitner's dispatch in the Associated Press, May 18, 2004 and the BBC report in http://news.bbc.co.uk/2/low/europe/3727827.stm.

[75] The European stand is that the regulations constitute a reasonable application of the precautionary principle, but the US rejects this argument. See Paul Brown's article in The Guardian Weekly (the global edition of The Guardian) London, 'US seeks $1.8bn compensation from Europe over GM ban', www.guardianweekly.com.

[76] There is no mandatory labelling of GM products in the United States, where GM and non-GM products are not segregated. Since more than half of all maize and soya bean planted in the US is genetically modified, and these two crops go into a number of food products, many of the agricultural crop products exported by the US to EU will have to be labelled.

[77] The US authorities claim that the USA has lost $300 million a year in lost maize exports to the EU over the last six years. See Paul Brown, *op. cit* .

The trade conflict between the US and the EU, in combination with the EU's strict labelling and traceability regulations, has also greatly influenced the debate and the decisions in many developing countries on whether or not to approve the introduction and commercialisation of GM crops. As a result, the GM development process has slowed down in many developing countries, as they have adopted a 'wait and see' approach. It is fair to say that unless European consumers become far less sceptical towards GM crops, few developing countries will wish to take the risk of being construed as GM crop producing country with negative knock-on effect on their current and future agricultural exports to the EU. Consequently, regulatory authorities in several developing countries are wary of permitting the TNCs to conduct in-country field trials of some GM crops, as a prelude to marketing them, even though these may be of interest to small-scale farmers (e.g. GM maize and cotton). This attitude has also negatively affected ongoing public sector development of GM-local crops, intended primarily for small-scale and subsistence farmers and local markets. All this will undoubtedly delay the introduction of GM crops in a number of developing countries for several years to come. It may also lead to a widening of the 'crop productivity gap' between the GM crops producing countries and the others.

3.2   FOOD AID

The controversy and conflict sketched above has also spilled over to the arena of food aid. The United States, which is one of the largest donors of food aid, tends to donate the grain grown by its farmers, whereas the EU and other major donors donate in cash either bilaterally or multilaterally through the United Nations World Food Programme. This cash is then used to buy the aid food on the world market, which in the case of maize means that a high proportion would be GM produce from the USA The US donations of maize and other crops include GM varieties, confronting recipient countries with the difficult dilemma of approving or not approving the entry of GM commodities into their territories[78]. This is a challenge to many developing countries, in particular in sub-Saharan Africa, as they lack biosafety regulatory structures and capacities to assess and manage potential risks from GM food. This problem came to a head during the recent food crisis in Southern Africa, when Zambia and a few other countries in the region rejected maize donations from the US on the grounds that it they contained genetically modified grain. Apart from the food safety issue as such, another major issue was the consequence for potential future exports of agricultural products to the EU and other markets[79]. In the light of the controversies that raged around GM food aid to Southern Africa, we agree with the approach suggested by the Nuffield Council on Bioethics[80] 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 it 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. ---- Where only donations of GM varieties are available and developing countries object to*

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[78] In fact, a number of countries in Southern Africa have been net trade- importers of food grains for many years from both the regional (e.g. .South Africa) and international producers, which are likely to have contained GM varieties.

[79] It was pointed out that, besides consumption, if some of the maize were used for planting (which was likely to happen), the prospect of geneflow from GM to non GM maize may endanger future exports of maize from the region to the EU.

[80] Nuffield Council on Bioethics, London: *The use of genetically modified crops in developing countries: A follow- up Discussion Paper*, January 2004. www.nuffieldbioethics.org/gmcrops

their import solely on the basis of environmental risks, we recommend that food aid be provide in milled form.'

3.3   PUBLIC-PRIVATE PARTNERSHIPS ARE INCREASINGLY IMPORTANT

As pointed out previously, GM technologies (including DNA sequences), research tools and output traits are today largely proprietary and under commercial control. An outcome of this situation is that the public sector R&D institutions, including the IARCs of the CGIAR system, are to some extent using the technologies controlled by the private sector. This may not pose a serious problem as long as the institutions limit their use of proprietary technology to research, but should they want to disseminate and commercialise their research results and output, they will have to negotiate with the private sector and public sector holders of IPR-protected technology. An instructive example of the challenges is the negotiations on the use of the vitamin A-enriched GM rice variety[81].

For public sector institutions involved in the breeding of crops for poor farmers, the privatisation of biotechnology research is likely to result in higher transaction-costs in the technology transfer process and it may also potentially block valuable R&D pathways. The impact on developing country seed saving practices is very difficult to predict. Our guess is that as long as farming communities in developing countries, which are outside the IPR-agreement systems, use IPR-protected GM varieties for local markets only, the practice of seed saving for replanting will not become contentious. However, if traders and companies in developing countries want to export the GM crops to countries with IPR systems, the IPR-holders are bound likely to impose royalties on those exports and also possibly impose restrictions on seed saving for replanting[82].

On the other hand, it can also be argued that proprietary regimes are effectively propelling the development of new attractive technology for developing country breeding systems. These regimes may also create increased incentives for owners of technologies to market their technologies to developing countries at a reasonable price[83]. After all, crop and livestock breeding institutions in many developing countries may not be in a weak position to negotiate favourable conditions for technology access[84]. There are examples of GM technologies being transferred to developing countries for use by poor farmers at either no cost or at low cost, the 'golden rice' cited above being one[85] and insect-resistant maize for Africa being another[86]. There is also the recent establishment of the African Agricultural Technology Foundation (AATF) which will facilitate and fund the transfer of advanced agricultural technologies, including

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[81] An instructive example is the vitamin-A enriched GM rice variety (the so-called 'golden rice') developed by the Federal Institute of Technology (ETH) in Zurich, Switzerland, which was based on nearly 70 patented technologies held by about 30 private sector companies and public institutions. In order to handle the complicated IPR negotiations, the ETH-team entered into a so-called 'public-private partnership' with the TNC Syngenta, which provided assistance in negotiating the deals successfully. In return, the ETH-team handed over to Syngenta the rights to the commercialisation of 'Golden Rice', under the *quid pro quo* that the GM-local cultivars incorporating the 'Golden Rice' technology would be available free of charge to farmers and traders in developing countries whose profits from the sale of the crops were less than US$ 10,000 per year per farmer or trader. See Nuffield Council on Bioethics, 2004, *op cit.*

[82] This may run counter to the provisions in The International Treaty on Plant Genetic Resources for Food and Agriculture. However current IPR protected GM crops fall outside the scope of this agreement.

[83] Prior to the stricter patent regimes, the main incentives for sharing technology were humanitarian, but now the actors have also financial incentives.

[84] Since the crops they work on are, by and large, intended for small-scale farmers and local non-export markets, they are not likely to be of interest to IPR-holding TNCs from a commercial point of view..

[85] ETH and Syngenta

[86] Involving KARI, CIMMYT and the Novartis Foundation for Sustainable Development.

GM technologies from the private sector to institutions involved in improving crops[87] for small scale African farmers. AATF is funded by the Rockefeller Foundation and has secured support from four main agro-chemical TNCs, which have agreed to share patent rights, seed varieties and expertise with African researchers. The AATF will also negotiate with other IPR holders for support and licences allowing for efficient R&D efforts benefiting African farmers. Hence, product development partnerships (PDP), where various public, private and NGO actors collaborate on R&D and technology dissemination will probably become increasingly important for the successful transfer of GM technologies to small-scale farmers

There is, as yet, little sign[88] of developing country governments and R&D institutions devoting serious attention to the implications of IPR, let alone starting the process of negotiations and collaboration with the IPR holders on the commercialisation of local GM crops that contain IPR-protected technologies.

It is clear that the movement towards stricter proprietary regimes on genetic resources and agro-biotechnologies will have an impact on national crop breeding activities. The new regimes for access to, and exchange of, genetic resources have created both threats and opportunities for countries in the South, which must acquire a clear understanding of the regimes and their implications. To be able to capture benefits, while protecting indigenous knowledge and genetic resources, developing countries must formulate appropriate national policies and regulations and also engage in international debates and negotiations.

3.4   BALANCING BENEFITS AND RISKS: THE NEED FOR CLEAR BIOTECHNOLOGY POLICY FORMULATION

Assessing the environmental (ecological and biodiversity) safety of a GM crop is a science-based process and one would therefore expect it to be relatively free of controversy. But, in practice, one is unlikely to arrive at a full consensus on the identification, characterisation and quantification of environmental risks, because the different scientific disciplines and sub-disciplines involved in the process could lead to conflicting conclusions. The best one can hope for is a majority opinion, i.e. a limited consensus.

As said previously, many OECD countries limit their regulatory review to environmental and health issues. In many developing countries, the regulatory review of GM crops are broader. In addition to environmental safety, and the impact of GM crops on the safety of human and animal health, regulatory authorities also evaluate impacts on the socio-economic safety of the farming communities, as well as risks to domestic and foreign trade. Striking a balance between the various potential risks and benefits is ultimately governed by the policy approach (explicit or implicit) that a government adopts, i.e. a promoting or permissive or precautionary or prohibitive approach to agro-biotechnology and GM crops.

The assessment of potential biosafety risks (environmental, health) and socio-economic impact is crucially dependent on the information and knowledge available to the assessors. National- and site-specific knowledge is as vital as internationally validated knowledge. Biosafety research (environmental, health) and research on socio-economic impact of GM

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[87] E.g. Cowpea, chickpea, cassava, sweet potatoes, maize and cooking bananas
[88] One exception is the recent negotiation of private sector technology for the potato breeding unit at South Africa's Agricultural Research Council. This unit will be developing GM potatoes for small scale farmers over the next four years using technology from Europe and the Michigan State University in the USA.

crops is therefore indispensable to the process of ensuring biosafety and sustainable use of GM crops. Depending on which component of GM impact research one is considering, it could be undertaken at a national or sub-regional or regional level, whichever is the most optimal from the point of view of resource-efficiency and feasibility.

There is nothing unusual in the fact that different countries have adopted different biopolicies, given their different conditions for agricultural production, import and export. It may, for example, be natural for a country rich in agro-biodiversity and genetic resources, but with little agricultural export, to take a precautionary approach towards GMA. On the other hand, it may be commercially logical for a country depending on agricultural exports and competing on the world grain markets to take a promoting approach. It may be appropriate for a country that is dependent on cheap imports of food and animal feed to have a permissive approach[89]. All of these approaches are understandable, but they all have implications.

The process of taking a GM crop from the R&D phase to the market stage is a long one, not least due to the rigorous biosafety testing requirements[90]. An excessively precautionary approach may block research and the field trials, severely delaying the introduction of GM crops[91]. This does not pose a serious problem for TNCs, which have the necessary resources to fulfil the field trials and other requirements of the regulatory process within a period of a few years, and also because they are not critically dependent on any one country or market, having simultaneous access to many countries and markets. It is, however, likely to be a serious problem for the public sector R&D institutions in developing countries[92]. On the other hand, an overly permissive approach may lead to a neglect of potential risks (environmental, health and socio-economic), resulting, among other things, in an erosion of public confidence in the working of the regulatory regime and undermining public acceptance of GM crops. These problems become noticeably aggravated if the biosafety regulatory and policy regimes lack clarity. Countries would therefore need to work out clear biotechnology and biosafety strategies, prior to establishing biosafety regulatory systems and instituting decision-making processes and procedures, with the strategies providing a set of principles, objectives and goals to guide the introduction and development of agro-biotechnology. Such strategies ought, ideally, to integrate environmental, health, economic, social, and legal considerations. But that is hardly the case in current practice, whether it be in industrialised or developing countries.

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[89] For instance, a large proportion of maize and soya bean available on the world market are genetically modified.

[90] Under the existing regulatory conditions in some GM-active developing countries, it would take approximately ten years for a GM crop to make the transition from the lab to the market, which involves laboratory testing, greenhouse trials and large-scale, multi-seasonal and multi-locational field trials.

[91] In several developing countries, public sector agricultural research institutions have a number of GM crops on hold because of the high cost of obtaining biosafety approval for commercial release.. When faced with having to choose GM technologies for testing, the budget constraints on these developing country institutions often force them towards choice of GM technologies that have already been approved in the context of other GM crops, to help reduce the costs of biosafety package development. Until mechanisms can be found to carry out biosafety testing affordably, many public sector innovations will not get into the field for further assessment.

[92] Experience shows that it is only after several years of tests and trials by the R&D institutions, and dialogue between the R&D community and the regulatory agencies, that enough knowledge, understanding, practice and confidence have been gained to be able to take considered decisions on permitting large-scale field trials and subsequent commercialisation of GM crops.

4   Areas that merit consideration for support by Sida and other donor agencies

As sketched above, a fairly strong case can be made for promoting the innovation of *GM-local crops*, which could be of considerable benefit to the small farmers and the poor majority of consumers in developing countries

Over a number of years now, public-sector biotechnology R&D institutions in several developing countries have devoted themselves to the task of developing GM-local crops. Although the least developed countries, in particular in sub-Saharan Africa, are still very weak in agro-biotechnology, some among them have nevertheless started taking the first steps in the direction of GM-local crops.

To a large extent, the support that developing countries will be looking for from Sida and other donor agencies will be for *institutional capacity development*, complemented in some cases with 'project assistance, enabling countries to develop agro-biotechnology applications according to their own needs.'. The concept of 'institutional capacity ' (or 'capacity' in short) that we employ comprises three distinct components: On the one hand, the *functional-competence* (or functional-ability) of the institution's personnel to perform the institution's mandated functions (tasks), and on the other hand, the *resources* (technical, infrastructural and financial) and the *structures* they need for performing the functions [93].

As we would like to keep this paper short and focused, we will discuss only the functional-competence component of capacity explicitly. In the context of any given initiative to develop institutional capacity, the required structures and resources can be derived from the functional-competences addressed. With this understanding, we will use the terms 'capacity' and 'competence' interchangeably.

In addition to R&D in the science and technology of agro-biotechnology, the development and use of GM-local crops calls for the involvement of social scientists, in particular economists, sociologists, legal experts and policy analysts. Further, it necessitates strong regulation by governments to ensure biosafety*,* as well as public participation in the regulatory regime through representatives of GM-concerned civil society organisations (CSOs, the concept includes NGOs). *Therefore, capacity development initiatives need to cover three types of institutions: knowledge-generating and knowledge-disseminating institutions (R&D units, university departments, etc.), government entities and CSOs.*

Although, in the main, capacity would have to be developed at the national level, there are several areas where capacity development at the regional or sub-regional level would be the most appropriate to undertake in terms of some of the functions that institutions have to perform, as well as being more rational and effective in the use of scarce resources. Whether capacity development is addressed at the national, sub-regional or regional levels, institutions ought to avoid duplication, aiming instead firmly at complementing one another's capacities, utilising synergies and dismantling barriers to inter-institutional capacity sharing and cooperation.

We do not intend to provide a comprehensive account of the 'capacity-areas' that need to be addressed by developing country governments. Rather, we will indicate below those capacity-areas where donor support is likely to make a difference and produce an impact.

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[93] Bhagavan, M. R. and Virgin, I., 2004, Generic Aspects of Institutional Capacity Development in Developing Countries, Stockholm Environment Institute.

4.1 CAPACITY IN KNOWLEDGE-GENERATING AND -DISSEMINATING INSTITUTIONS (KGIS)

In the specific context of agro-biotechnology and biosafety, the knowledge-generating and knowledge-disseminating institutions (KGIs) fall into the following five broad categories:

- Agricultural universities
- Agricultural research institutes outside the university system
- General (i.e. non-specialist) universities
- Laboratories and institutes, either within or outside the university system, which concentrate on the fundamental knowledge components rather than on the applications of the technology
- Private sector companies dealing in agricultural commodities, inputs and technologies

The acquisition, retention and upgrading of competence obliges KGIs to get involved in R&D projects, research training leading to research degrees and postgraduate teaching of specialist courses. The capacity required for accessing, using, adapting and further developing agro-biotechnology spans a number of disciplines, which we list below.

In science and technology:
- Modern biology (molecular, cell and micro biology), biochemistry, recombinant-DNA techniques
- Biodiversity (agricultural and natural), ecology (of plants, soils and water bodies)
- Crop-breeding, plant evolution, plant diseases, entomology and invasiveness (i.e. impact on wild communities and non-target organisms through pollen drift and gene transfer)
- Crop production science (agronomy)

In the health sciences:
- Pathogens and phytosanitary measures
- Toxicity and allergenicity
- Digestibility and nutrition

In the social sciences, legal disciplines and policy arena:
- Local farming and cropping systems, and farm-level economy
- Rural and agricultural economics; rural sociology; rural livelihoods and incomes
- Food security
- Consumer choice
- Intellectual property rights (IPR) and patents
- Trade economics, trade laws, and trade related IPR (TRIPS)
- International legal issues concerning access to genetic resources and biological materials
- Expertise in business development, market analysis and management of R&D products in a business development cycle

4.2 CAPACITY FOR IMPLEMENTATION OF R&D RESULTS

Agro-biotechnology R&D projects and research degree programmes seldom proceed beyond the laboratory and greenhouse stages in the development of crops. But three 'implementation stages' have to be traversed before the innovation-process can hope to deliver the expected products. We outline them below.

4.2.1 Demonstrating the technical feasibility and the socio-economic viability of GM innovations

Having completed the greenhouse stage, R&D units in KGIs are confronted by the task of demonstrating the *technical feasibility* of their GM innovations to the *local* seed companies, entrepreneurs and farming community. Such a task calls for an integration of the same range of field cultivation activities that arise in conventional crop-breeding with activities that are specific to the GM nature of the demonstrated crops, including environmental safety testing, i.e. (i) multi-location and large-scale field trials, conducted over several planting seasons, for investigating the stability, productivity and economics of the GM crop over several generations, (ii) the dependence of the crop yields on the specificities of soil types, soil preparation, irrigation, (iii) pollen drift into the local ecological environment, and (iv) geneflow from the GM to the non-GM plants.

The capacity required for the assessment of *socio-economic viability* ought to be capable of analysing the economic expectations of market actors, as well as small farmers. Individual entrepreneurs would be on the look out for low risk and quick return ventures that can be initiated with very modest investment, while local seed companies may be able to tolerate higher risks, longer periods of return and high investment demand. Small farmers have very low operational margins[94] and their tolerance of risk is virtually zero.

Economic factors display considerable variations that reflect the specificities of local market-actors and the small farmer communities. These specificities are shaped by local social and institutional factors. In order to be economically viable, GM innovations have to be robust enough to adjust to this diversity of factors. In order to design such flexible innovations, GM-active institutions have to be able to tap readily into a range of experienced expertise in rural economics and sociology, which no single institution in a given country is likely to be able to cover. Help will be required to mobilise the expertise through inter-institutional cooperation and coordination.

4.3 CAPACITY FOR MOVING THE INNOVATIONS 'FROM THE LAB TO THE LOCAL MARKET'

We will now look very briefly at the three main capacity-challenges facing the principal stakeholders, as they attempt to transfer the innovations to the small farmers.

4.3.1 Local technology transfer: enabling market actors to absorb the GM innovations

Diffusion of innovations to market actors is a very complex process, involving several different types of actors. In some cases, R&D institutions that have the infrastructure for, and experience in, agricultural extension work, may undertake this effort. However, the multiplication and propagation of the crop planting material are often done more efficiently by other types of institutions (e.g. public and private sector seed companies, public sector commodity boards, small- and medium-scale entrepreneurs and NGOs), with whom therefore R&D institutions need to link up.

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[94] The production costs they can afford are determined almost entirely by what the local retail traders are prepared to pay for each harvest, which can vary from harvest to harvest.

To begin with, a given R&D institution would need assistance to innovate and implement intra-institutional policies aimed at establishing and strengthening such linkages. This would have to be followed with the setting up of a unit within the institution dedicated specifically to the tasks of (i) linking the local market actors with the appropriate technical personnel within the institution, (ii) administering and managing the technology transfer process and the associated back-up service and (iii) ensuring that the technical personnel seriously address the ideas and suggestions presented by the market actors. With a few exceptions, public sector R&D institutions in most developing countries would be total strangers to such ventures, and would therefore need capacity development from the beginning in this area.

4.3.2 Coping with intellectual property rights (IPR)

As mentioned earlier, access to the state-of-the-art agro-biotechnology is severely restricted[95], which has profound implications for public sector R&D institutions in developing countries that are attempting to develop and disseminate GM-local crops to local farming communities. It will be almost impossible for developing countries' R&D institutions to conduct their GM work without recourse to some of the techniques patented by the private and public sector. Thus, developing countries' R&D institutions and governments must acquire the capacity to negotiate with the IPR-owning organisations for the use of specific patented technologies and products at affordable terms and conditions, including the conditions that will govern the institutions' own IPRs *vis à vis* the indigenous market sector (so-called 'freedom to operate' clauses). It ought to be in the interests of patent holders to negotiate favourable terms if they hope to obtain returns on the invention within the lifespan of the patent. In this context, it is worth noting that the lifespan of the patents for many of the GM techniques developed in the West have either expired or are about to expire.

4.3.3 Government policies for promoting linkages between institutions and market actors

With some exceptions, research in public sector institutions in *developing* countries has tended to confine itself to problems of mainly academic and scientific interest. Only occasionally has it moved beyond basic and applied research to technological innovation of interest to market actors. Governments may have formally put in place some policies and instruments to steer R&D institutions towards establishing linkages with, and working on problems of practical importance to, market actors, e.g. tax breaks, reduced customs duties on imports of R&D inputs and ready access to training and service infrastructure. What is universally lacking though is the capacity to implement the policies and instruments, and to monitor their impact.

4.4 CAPACITY IN THE REALMS OF BIOSAFETY REGULATION AND BIOTECHNOLOGY POLICY

It is important for developing countries to acquire capacity to develop a biosafety regulatory framework and biotechnology policies appropriate for their own needs. In Section 2, we have outlined the kinds of biosafety and biopolicy institutions/and or functions that developing

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[95] Six agro-chemical TNCs own most of the technology: Monsanto, Bayer, Syngenta, DuPont, Dow and BASF.

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countries need to set up. It involves the establishment of a biosafety Regulator, Advisor, Monitor and Secretariat, and biopolicy units or 'desks' in several government entities. We provide below a sketch of the capacity that needs to be developed in these institutions.

4.4.1 Capacity requirements of the Regulator and the Advisor

Under a biosafety regulatory regime, it would be obligatory for R&D institutions and agro-biotechnology companies to submit applications to the Regulator for permission to conduct their GM activities. The principal function of the Regulator is to assess (review) the applications, and on that basis to approve or reject the applications, or postpone a decision pending the applicant's compliance with certain requirements and conditions. The purpose of the review is to examine the potential risks and benefits of the applicants' proposed GM activities and the applicants' capability to manage the potential risks. The expertise needed for the review would have to tackle the myriad aspects involved in environmental, health and socio-economic safety, *on a case-by-case basis*. It is just not feasible to incorporate into the Regulator all the *specialist* competence that the review calls for. Realistically speaking, the most one can aspire to is that the Regulators' members have some *generalist* understanding of the relevant areas of knowledge (e.g. the biological, biochemical and ecological sciences, health sciences, economics and sociology, legal and policy issues, etc.).

The specialist competence required should be sought within the advisory body. The *specialists* who can provide expert assessments of specific aspects of the applicants' submissions should be drafted into the Advisor, on a case-by-case basis. Where a required specialist competence is not available within the country, it would have to be sourced either regionally or internationally.

With the active assistance of the specialists drafted into the advisory body, the Regulator ought to be in a position to undertake the following functions:

- formulating the national biosafety guidelines, regulations and legislation, and refining and revising them as and when necessary;

- harmonising the biosafety regulations with other existing regulations on seeds, crop pest control, environmental protection, food and feed safety, import and export of seeds and crops, etc;

- establishing the processes and procedures for weighing risks and benefits;

- obtaining and handling of information under crisis situations;

- on the basis of the Monitor's report (see below), imposing sanctions on institutions that have not complied with the biosafety regulations and procedures in implementing their GM activities.

4.4.2 Capacity requirements of the Monitor

Our remarks above concerning the generalist and specialist competences that the Regulator should be able to call upon apply equally to the Monitor.

It is the central responsibility of the Monitor to check how far the applicant institutions are abiding by the biosafety procedures and measures laid down in the 'decision-document' issued by the Regulator to the institutions, as well as in the generally applicable national biosafety regulations. In particular, the report of the Monitor should be specific and detailed in alerting the Regulator to those biosafety conditions that the institutions have not complied with.

To be able to carry out its tasks, the Monitor needs enough capacity (staff and infrastructure) to carry out unannounced and frequent inspections of the applicant institutions, in particular the institutions' field trials. To be credible, the experts commissioned by the Monitor to conduct the inspections and report their findings must be independent of the applying institutions.

In general, the compliance-monitoring body of a biosafety regulatory framework is an established inspectorate (such as the national phytosanitary bodies) with the training and authority for inspections and the additional training to understand biosafety and compliance associated with GM activities. Many developing countries are training existing agricultural, health and environmental inspectors to fill this biosafety function.

It is important to note that although the Monitor can verify whether or not the applicant institution has complied with the biosafety regulations, procedures, etc. stipulated by the Regulator in conducting the field trials, it can in no way 'police' the multitude of small-scale farmers to ensure that they abide by the proscribed methodology for GM crop cultivation, i.e. the need to plant buffer rows to limit the possibility of insect resistance from developing. In fact, such 'policing' is simply impossible. *That is why it is crucial to take into account the local context and conditions under which small-scale farming takes place, when developing GM crops aimed at small-scale farmers.*

4.4.3 Capacity requirements of the Secretariat

The principal functions of the Secretariat will be to service the Regulator, the Advisor and the Monitor, and to implement the biosafety regime. The capacity it needs to perform these dual functions is fairly wide ranging in terms of competence, structure and resources. The nature of this capacity can be inferred from the following breakdown of the principal functions into specific tasks:

- administering applications for GM activities;
- handling enquiries about GMOs and biosafety;
- producing guidance and application procedures for stakeholders;
- training of biopolicy and biosafety regulatory personnel within and outside the government;
- facilitating assessment of applications through administration and formation of review committees;
- coordinating intergovernmental decision making on GM activities;
- coordinating inspections;
- facilitating the work of the Monitor to inspect and report on GM activities;
- following up on non-compliance;
- creating and updating the national biosafety database, ensuring its reliability and on-line-accessibility;
- promoting the regional sharing of biosafety information; and
- providing information to, accessing information from and interacting with the computerised and hard copy requirements of the Biosafety Clearing House established at the CPB secretariat in Montreal.

4.4.4 Capacity requirements of biopolicy units and 'desks' in government entities

These units and desks have to acquire competence for performing the following policy-related functions:

- Formulation and implementation of policies and legislation in subject-areas affected by the development and practice of GMA, e.g. biodiversity, plant genetic resources, food and animal feed safety, human and animal health and nutrition, movement of GMOs within the country,. transboundary movement LMOs[96], transfer of technology, domestic and foreign trade, patents and IPR, R&D funding, etc.

- Development of the inter- and intra-ministerial institutions appropriate to the implementation and compliance-monitoring of policy, legislation and the biosafety regulatory regime.

- Conducting negotiations in regional and international fora in the above-mentioned subject-areas, including potential liabilities arising from transboundary movements of GMOs and LMOs.

- Harmonising national policy and legislation with the provisions of the Cartagena Biosafety Protocol and other relevant international agreements to which the country is signatory.

- Accessing the benefits of GMA-technology that the public and the private sector GM stakeholders in other countries may be willing to share.

4. 5   CAPACITY REQUIREMENTS OF CIVIL SOCIETY ORGANISATIONS (CSOs, INCLUDING NGOs)

The GM-concerned CSOs have two primary goals: first, to ensure that the concerns of the general public and the non-governmental GM stakeholders are taken into account in the formulation and implementation of the biosafety regulations and legislation; second, to enforce their right to participate fully in decision-making by the biosafety regulatory regime.

In pursuit of these two goals, the GM-concerned CSOs would have to acquire the required *generalist* competence by partly creating it in-house and partly accessing it from the KGIs in the country and the region. Besides the generalist expertise that at least partly corresponds to the one that the Regulator has, CSOs have to ensure that they have the specific skills to undertake the following tasks:

- Access information, data and knowledge, locally, nationally and internationally

- 'Outsourcing', i.e. the commissioning of specialist studies and biosafety tests by independent experts and institutions

- Improving the quality of their intellectual inputs into public debates and campaigns

- Participating and negotiating in national, regional and international fora

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[96] According to the provisions of the Cartagena International Biosafety Protocol, which defines LMOs as ' any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology'

5   Important criteria for Sida's support to agro-biotechnology in developing countries

There are great differences in the stages of development that developing countries have reached, in the sectors of agriculture, industry, infrastructure, trade, higher education, and R&D (in the natural-, health- and social sciences, and technology). This diversity has obviously determined, and is reflected in, the different levels of agro-biotechnology development that developing countries display today. One can therefore expect developing countries to focus on different aspects and features of agro-biotechnology in their approach to the donor community for support. These could range, at one end of the 'development spectrum', from 'the lab to the market' transition process, which is currently of chief interest to the more technologically advanced developing countries, to the other end of the spectrum (i.e. the least developed countries), where basic capacity building in public sector R&D and biosafety regulation are the pressing needs.

Since poverty alleviation is the overriding priority of Sida, its support ought to concentrate on promoting activities that, directly or indirectly, have the potential to lead to increased yields of local crops of importance to small-scale farmers and the poor.

The development and cultivation of GM-local crops involves several stages: GM technology transfer from external sources to local public sector R&D institutions (requiring in some cases the handling of IPR and patents), local R&D work, field trials and studies to ensure appropriateness and biosafety (environmental, health and socio-economy), technology dissemination to local farmers, entrepreneurs and companies, agricultural extension work, and finally the commercialisation of the crop (which triggers issues of farmers' rights, patents, IPR, TRIPS, etc.). Each of these stages merits Sida support, provided that the activity is demonstrably aimed at sustainable improvement of crop yields at the level of small-scale farming. Each stage usually involves proceeding by steps and phases, calling for flexibility, pragmatism and perseverance in providing support. For instance, the introduction and application of GM techniques in agriculture presume that a country has acquired some capacity in the pre-GM areas of conventional crop-breeding, molecular marker assisted crop-breeding, tissue culture, etc. Least developed countries would need support in these pre-GM areas as well as in GM techniques.

Biosafety ought to be the leading concern in providing support. UNEP/GEF have an ongoing programme of assistance to developing countries for establishing biosafety regulatory frameworks. A number of least developed countries are participating in this programme and have taken the first steps towards building up their biosafety regulatory structures. A demonstrated political willingness to embark on the task of acquiring biosafety capacity, and of implementing a biosafety regulatory regime ought to be a decisive criterion for making Sida support available to a developing country in the area of agro-biotechnology.

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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 *protein*s.

Biodiversity: The number and variety of plants, animals and other organisms that exist in nature genetic data.

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.

Centre of diversity: A centre of diversity would often contain a variety of *cultivars* and their wild relatives. Such areas often harbour a wide range of natural genetic variation for a particular crop.

Chromosomes: The thread-like structures in *cells* that carry *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.

Disease resistance: The capacity of a plant, usually determined by one or a few *gene*s, 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 *chromosome*s, each of which contains many *gene*s.

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

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.

Genetic engineering: The manipulation of genes through the use of recombinant DNA techniques for the purpose of modifying the function of a gene or genes for a specific purpose

Genetics: The study of the process by which traits are transmitted from parent to offspring; the study of inheritance.

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.

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.

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.

Living modified organism (LMO, as defined in the Cartagena Protocol on Biosafety): Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

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.

Pathogen: Any microorganism that causes disease or produces a pathological condition.

Precautionary principle/precautionary approach: 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.

Precautionary Principle (as defined in the Cartagena Biosafety Protocol): Lack 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

Recombinant DNA: A DNA that has become joined to another unrelated or foreign segment of DNA

Tissue culture: The growth of *cell*s, 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.

Transformation: The process by which foreign *DNA* is transferred and incorporated into a living *cell*.

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

The Stockholm Environment Institute (SEI)

SEI is an independent, international research institute specializing in sustainable development and environment issues. It works at local, national, regional and global policy levels. The SEI research programmes aim to clarify the requirements, strategies and policies for a transition to sustainability. These goals are linked to the principles advocated in Agenda 21 and the Conventions such as Climate Change, Ozone Layer Protection and Biological Diversity. SEI along with its predecessor, the Beijer Institute, has been engaged in major environment and development issues for a quarter of a century.

Mission

SEI's mission is to support decision-making and induce change towards sustainable development around the world by providing integrative knowledge that bridges science and policy in the field of environment and development.

The SEI mission developed from the insights gained at the 1972 UN Conference on the Human Environment in Stockholm (after which the Institute derives its name), the work of the (Brundtland) World Commission for Environment and Development and the 1992 UN Conference on Environment and Development. The Institute was established in 1989 following an initiative by the Swedish Government to develop an international environment/development research organisation.

Risk and Vulnerability Programme

This programme conducts research on environmental and technological hazards and global environmental change. Expanding on ongoing and previous work on risk analysis, risk perception, and risk management, research now also focuses on the differential vulnerability of people, places, and ecosystems. The hallmark of this programme is integrated analyses that seek to bridge the best of the social and ecological sciences. A major priority is the development of policies and initiatives that hold promise for enhancing human security, adaptive capacities, social equity, and resilient societies.

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