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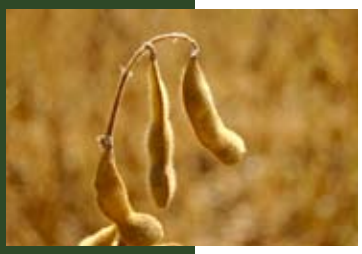

Biotechnology: Addressing Key Trade and Sustainability Issues

ICTSD

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The final product is the result of the collective efforts of the persons involved. However, the ICTSD team assumes sole responsibility for its contents.

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ACRONYMS

AIA	Advance Informed Agreement
APHIS	Animal and Plant Health Inspection Service
Bt	Bacillus thuringiensis
CBD	Convention on Biological Diversity
CEC	North American Commission for Environmental Cooperation
CGIAR	Consultative Group on International Agricultural Research
CIAT	International Centre for Tropical Agriculture
COP	Conference of the Parties
CPM	Commission on Phytosanitary Measures
DNA	Deoxyribonucleic acid
DSU	Dispute Settlement Understanding
EC	European Community
EFSA	European Food Safety Authority
ELISA	Enzymes-linked Immunosorbent Assay
ESA	European Seed Association
EU	European Union
FAO	Food and Agriculture Organization
FFDCA	Federal Food, Drug and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FSE	Farm Scale Evaluations
FTC	Federal Trade Commission
GATT	General Agreement on Tariffs and Trade
GEAC	Genetic Engineering Approval Committee
GEF	Global Environment Facility
GMA	Grocery Manufacturers Association
GMO	Genetically modified organism
GRHB	Golden Rice Humanitarian Board
GURT	Genetic Use Restriction Technology
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IPPC	International Plant Protection Convention
IPR	Intellectual property rights
IPS	Identity preservation system
ISO	International Organization for Standardization
ISPM	International Standards for Phytosanitary Measures
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IU	International Undertaking

KARI	Kenyan Agricultural Research Institute
LMO	Living modified organism
LMO-FFP	Living modified organism for food or feed, or for processing
MEA	Multilateral environmental agreement
MFN	Most favoured nation
MOP	Meeting of the Parties
NAAEC	North American Agreement on Environmental Cooperation
NAFTA	North American Free Trade Agreement
NBF	National Biosafety Framework
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
PCT	Patent Cooperation Treaty
PIC	Prior informed consent
PPM	Process and production method
PRA	Pest risk analysis
PVP	Plant variety protection
SCP	Standing Committee on the Law of Patents
SMTA	Standard Material Transfer Agreement
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT Agreement	Agreement on Technical Barriers to Trade
TPR	Technological property rights
TRIPS Agreement	Agreement on Trade-related Aspects of Intellectual Property Rights
TSCA	Toxic Substances Control Act
TUA	Technology Use Agreement
UPOV	International Union for the Protection of New Varieties of Plants
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

FOREWORD

Modern biotechnology offers promising advances in many fields. Its proponents point to biotechnology's potential to enhance food security, by enhancing both the productivity and quality of food crops, and to mitigate the environmental impacts of agricultural production by, for instance, reducing the use of pesticides. Medical biotechnology has also made important strides, offering new tools for the diagnosis and treatment of diseases. Industrial biotechnology, while still in its early stages, is promising to provide new industrial applications that use fewer resources and generate less waste.

On the other hand, the rise of modern biotechnology has brought with it vocal and passionate opponents who highlight environmental, health, ethical and equity concerns. They argue that biotechnology is yet another technological fix for alleviating hunger and poverty that neglects the fundamental causes of food insecurity, such as highly subsidised agricultural production in developed countries and inequitable distribution of food. Moreover, they argue that current biotech applications may pose potential long-term risks.

In responding to these opposing viewpoints, governments have taken a variety of different policy and regulatory approaches, with some enthusiastically embracing biotechnology while others seek to exclude it. International trade is now increasingly bringing these different approaches into conflict. Countries that have moved rapidly in applying the technology would like to see trade in biotech products flow as freely as possible to ensure returns on their investments and capitalise on the competitive advantage that the technology provides. Other countries, which have taken a more cautious approach to biotech use and development, have virtually closed off their markets through stringent import regulations and are opposed to trade liberalisation measures for these technologies and products.

The recent World Trade Organisation (WTO) ruling against the European Union's application of its approval procedures for biotech products has placed these tensions in the spotlight and sparked debate about countries' regulatory flexibilities in this area. As these conflicts are played out at the multilateral level, many countries, in particular less developed nations, continue to struggle with setting up the necessary policy, legal and institutional frameworks. At the same time, they need to respond to trade pressures from biotech exporters, meet export markets' import regulations, and comply with multilateral rules on trade and biosafety. As a result, these countries are often stuck in the middle of the biotech debate, while important sustainability issues surrounding these technologies are left largely unaddressed.

This publication aims to shed some light on key issues related to biotechnology, trade and sustainable development by providing a balanced overview that is accessible to a wide range of actors in the trade and biotechnology communities. It is intended to be a tool to enable the different stakeholders to identify and articulate their priorities related to biotechnology, and balance these objectives against the various trade interests and obligations. We hope that the document will help stimulate an informed debate that can go beyond entrenched and polarised positions towards a constructive exchange to support effective policy- and rule-making in this area.

Ricardo Meléndez-Ortiz
Chief Executive, ICTSD

NOTES TO READERS

This publication has been designed for readers who have an interest (though not necessarily a specialist one) in the intersection of trade, biotechnology and sustainable development. It does not assume any prior knowledge of these issues and includes explanations of the key technical terms and concepts introduced – both in the text and in the glossary at the end of the guide.

The document is structured in three sections:

Part A gives a brief introduction to biotechnology, focusing on agricultural, medical, industrial and animal biotechnology.

Part B provides a comprehensive overview of key issues related to biotechnology, trade and sustainable development.

Part C presents an overview of relevant international legal frameworks related to biosafety, trade, intellectual property rights and standard-setting.

As the core of the guide, Part B takes the form of frequently asked questions and concise answers. The answers are self-standing explanations and readers do not need to read them in any particular order. The questions and answers are grouped into five clusters, around the following themes:

- Environmental, health-related and socio-economic considerations;
- Multilateral trade rules;
- Cartagena Protocol on Biosafety;
- Intellectual property rights; and
- Implications for market access and competitiveness.

At the end of each cluster, readers are provided with sources of further information on these themes.

Part B also includes a series of boxes – 'Biotech headlines' – which provide brief summaries of events and developments that have attracted widespread attention, and often controversy, in the media and among the general public.

PART A: AN INTRODUCTION TO BIOTECHNOLOGY

A.1 What is biotechnology?

Biotechnology is any technology that uses biological systems or living organisms to make or modify products or processes for a specific use. Biotechnology in this broad sense has been in use for thousands of years, starting with the domestication and selection of plants and animals as early as 10,000 BC (see Table 1). More recently, however, the term has become associated with a scientific process that involves the manipulation of the DNA (deoxyribonucleic acid) of an organism. This so-called 'modern' biotechnology includes a variety of different scientific techniques, such as genomics, bioinformatics, cloning, embryo transfer and other technologies, which are widely used in the medical, industrial and agricultural sectors.

Biotechnology also includes the deliberate alteration of the genetic make-up of plants or animals by adding, altering or deleting one or more of the thousands of genes that control the characteristics of the plant or animal. This process, which is known as 'genetic modification' or 'genetic engineering', takes a useful gene from one plant or animal and inserts it into the genome of another plant or animal. The final altered plant or animal is known as 'transgenic' or genetically modified or engineered, and is often described as a 'genetically modified organism' (GMO) or 'living modified organism' (LMO).

A.2 Terminology

Different countries and organisations use different terminologies when referring to biotechnology processes and products (see Box 1). Some do not commonly distinguish between 'modern' and 'traditional' (or 'conventional') biotechnologies, assuming that one is simply a continuation of the other. Others prefer to distinguish between the different types of biotechnology, arguing that products of 'modern' biotechnology pose new and distinct challenges regarding potential risks, regulatory needs, ethics and consumer acceptance. Agricultural biotechnology that involves adding, altering or deleting genes, in particular, is defined and regulated separately by most countries and organisations, while medical biotechnology products are commonly included under the broader regulatory framework for pharmaceutical products.

Terminology also varies with regard to the products of biotechnology. The United States Food and Drug Administration (USFDA), for instance, uses the term 'bioengineered foods' rather than the more frequently used terms 'genetically modified foods' and 'genetically modified organisms', arguing that the use of these terms can be misleading because almost all foods have undergone some form of genetic modification (USGAO, 2002). The European Union (EU), on the other hand, refers specifically to GMOs in its regulations, defining them as organisms whose genetic characteristics have been modified artificially. Civil society activists have at times employed more ominous terms in their anti-GMO campaigns, such as 'frankenfoods', 'genetic pollution' or 'genetic monsters', highlighting deep emotional and ethical concerns surrounding the technology.

A.3 Types of biotechnology

Agricultural biotechnology

A brief history

Agricultural biotechnology is usually dated back to 10,000 BC when farmers began to select the most suitable plants and animals for breeding (see Table 1). Soon thereafter, Sumerians used yeast, a type of fungus, to make beer and wine in Mesopotamia. As the plant breeding process became better known,

BOX 1: Primary terms for biotechnology used by different organisations/countries

The Convention on Biological Diversity (CBD) defines biotechnology as "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use."

The Cartagena Protocol on Biosafety defines modern biotechnology as "the application of in vitro nucleic acid techniques, including rDNA and direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family." However, only living modified organisms (LMOs) are covered by the Protocol. LMOs are defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."

The UN Food and Agriculture Organization (FAO) adopts the definition of biotechnology in the Convention on Biological Diversity, but also provides a narrower interpretation "which considers only the new DNA techniques, molecular biology and reproductive technological applications [...] covering a range of different technologies such as gene manipulation and gene transfer, DNA typing and cloning of plants and animals."

The Organization for Economic Co-operation and Development (OECD) defines biotechnology as "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services." In addition, the OECD has a list-based definition that includes applications in DNA/RNA, proteins and other molecules; cell and tissue culture and engineering; process biotechnology techniques; gene and RNA vectors; bioinformatics; and nanobiotechnology.

The Codex Alimentarius Commission, a global food standards body, uses the Cartagena Protocol's definition of modern biotechnology in its Principles for Risk Assessment of Foods derived from modern biotechnology. Two standards have been adopted that refer to recombinant-DNA plants and micro-organisms (bacteria, yeasts or filamentous fungi) in which the genetic material has been changed through in vitro nucleic acid techniques, including rDNA and direct injection of nucleic acid into cells or organelles.

The World Trade Organization (WTO) dispute panel, which was initiated by the US with Canada and Argentina, uses the term 'biotech products'. In its original request for the establishment of a panel, the US defined the term as a short form of 'products of agricultural biotechnology'.

The United States Food and Drug Administration (USFDA) regulates 'bioengineered foods', which are defined in the Premarket Notice Concerning Bioengineered Foods (January 2001) as foods derived from a plant that is developed using the introduction into an organism of genetic material that has been manipulated in vitro.

The European Union (EU) recognises the broad definition of biotechnology, but regulations such as Directive 2001/18/EC and Regulation (EC) 1829/2003 are specifically aimed at GMOs, defined as "organisms, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."

Canada defines biotechnology as the manipulation of living organisms to produce goods and services, and divides it into health, environmental, agricultural and industrial biotechnology. In the field of agricultural biotechnology, the Canadian government has adopted the Cartagena Protocol's definition of LMOs.

farmers and early plant breeders would look for varieties with useful characteristics that could be crossed with other varieties to produce offspring that combined the characteristics of both. In the 1860s, Gregor Mendel methodically recorded the passing of traits from one generation to the next by crossing different pea plants to produce offspring with red or white flowers, and wrinkled or smooth peas. He identified the principles of inheritance and marked the beginning of conventional agricultural biotechnology. Major advances in plant breeding followed the revelation of Mendel's discovery. Breeders brought their new understanding of genetics to the traditional techniques of self-pollinating and cross-pollinating plants.

Recognising desirable traits and incorporating them into future generations is very important in plant breeding. A few of these traits can arise spontaneously through a process called mutation, but the natural rate of mutation is very slow and unreliable to produce all plants that breeders are looking for. In the late 1920s it was discovered that exposing plants to x-rays and chemicals could increase the rate of genetic variation, thereby increasing the pool of characteristics that breeders and farmers could choose from when looking for beneficial features for crop breeding. 'Mutation breeding' accelerated after World War II, when the nuclear age's techniques became widely available. Examples of plants that were produced via mutation breeding include varieties of wheat, barley, rice, potatoes, soybeans and onions.

However, the new varieties that result from conventional breeding have a number of limitations. The characteristics may not be consistent from generation to generation, as in the case of hybrid crops. Hybrid seeds are developed by crossing parent lines that are 'pure lines' produced through inbreeding. Pure lines are plants that produce sexual offspring that closely resemble their parents. By crossing pure lines, a uniform population of first generation hybrid seed can be produced with predictable characteristics. However, if the seeds of the first generation hybrids are used for growing the next crops, the resulting plants do not perform as well as the first generation material, resulting in inferior yields and vigour. Also, in conventional breeding, only varieties able to sexually reproduce with one another can share genes, thereby preventing for example the transfer of a useful characteristic of a variety of maize to cassava. Moreover, it can be difficult to select the characteristics that are of interest from two plants during the reproduction process. While the offspring that result will have characteristics from each parent, a key problem of hybrid breeding – and conventional biotechnology in general – is that genes are transferred randomly from the parents to the new variety.

Modern biotechnology is the latest stage in the development of plant breeding technology. Crick and Watson's discovery of DNA's double helix structure in the 1950s held the key to cracking the genetic code that determines the characteristics of all living organisms. As a result, techniques such as genetic modification enabled plant breeders to transfer solely the gene of interest and allowed them to choose genes not only from related varieties but from any organism. As a result, desired genes can be transferred more quickly than through the time-consuming variety-crossing process entailed in conventional biotechnology, while avoiding the uptake of unwanted characteristics.

The science behind genetic modification

The differences that distinguish one organism from another are encoded in its genetic material – its DNA. The DNA occurs in pairs of chromosomes, one coming from each parent. The genes, which control the organism's characteristics, are specific segments of each chromosome. All of the organism's genes together make up its genome. Some genes may be relatively unimportant while others may determine, for example, the length of time it takes for a crop

Table 1: An agricultural technology timeline

Technology	Era	Genetic interventions
Traditional	About 10 000 years BC	Early farmers domesticated crops and animals from available biodiversity, began to select plant materials for propagation and animals for breeding
	About 3 000 years BC	Beer brewing, cheese making and wine fermentation
Conventional	Late nineteenth century	Identification of principles of inheritance by Gregor Mendel, laying the foundation for classical breeding methods
	1930s	Development of commercial hybrid crops
	1940s to 1960s	Use of mutagenesis, tissue culture, plant regeneration. Discovery of transformation and transduction. Discovery by Watson and Crick of the structure of DNA. Identification by Barabara McClintock of genes that detach and move (transposons)
Modern	1970s	Advent of gene transfer through recombinant DNA techniques. Use of embryo rescue and protoplast fusion in plant breeding and artificial insemination in animal reproduction
	1980s	Insulin as first commercial product from gene transfer. Tissue culture for mass propagation in plants and embryo transfer in animal production
	1990s	Extensive genetic fingerprinting of a wide range of organisms. First field trials of genetically engineered plant varieties in 1985 followed by the first commercial release in 1994. Genetically engineered vaccines and hormones and cloning of animals, marker-assisted breeding
	2000s	Bioinformatics, genomics, proteomics, metabolomics, gene silencing (iRNA)

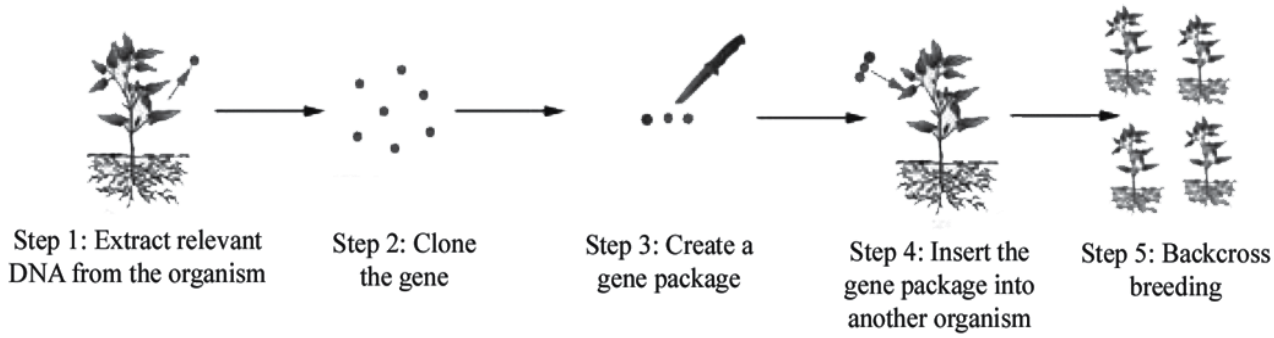
Source: Adapted from FAO (2004).

to come to harvest or the extent to which an animal is resistant to disease. As scientific understanding of DNA has increased through the development of the field of genetics, it has become possible to identify many of the genes that confer specific characteristics on an organism. It is also now possible to insert that gene into another organism.

Modern genetic modification involves five steps (Hain and Ehly, 2005; see also Figure 1):

1. **DNA extraction:** The relevant DNA is extracted from the desired organism by taking the organism containing the gene of interest through a series of steps.
2. **Gene cloning:** The gene has to be cloned or mass-produced to make thousands of copies.
3. **Gene design:** This step is particularly important. The gene has to be 'packaged' with two other pieces of DNA that control how the gene will work once it is inside its new organism. The first piece, called a 'promoter', is attached and controls whether the gene is switched 'on' or 'off' all the time, some of the time, or none of the time. The second piece, called a 'marker

Figure 1: The science of genetic modification



gene', is also attached to the gene of interest so that scientists can efficiently test whether the gene, and so the desired characteristic, has been transferred. Typically, this marker gene will confer resistance to a selectable agent, such as an antibiotic or a herbicide. Thus, only the cells containing the construct (i.e. the gene of interest and the marker gene) will survive or continue to grow after treatment with the selectable agent. Alternatively, a marker for screening can be used that will make the cell containing the gene look different, such as a colour marker.

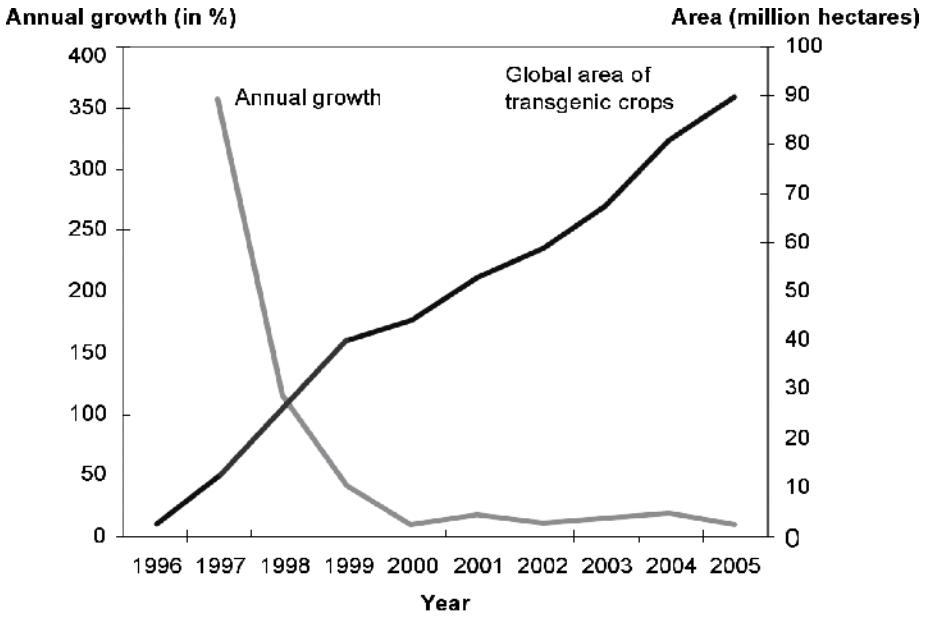
4. **Transformation:** The gene package is inserted into the cells of the organism being modified using either a gene gun or a bacteria called *Agrobacterium*.
5. **Backcross breeding:** The genetically modified organism is crossed with the best varieties of conventional crops in order to get a variety that has the best characteristics that conventional crops and genetic modification can deliver.

Transgenic crops were first commercialised in 1994. Since then, the global area of transgenic crops has increased from 2.8 million hectares to 90 million hectares (see Figure 2). The annual growth rate of the global area of approved biotech crops was very high in 1997 and 1998 at 357 percent and 117 percent respectively. In recent years, growth rates have fluctuated around 15 percent.

In 2005, 8.5 million farmers in 21 countries planted biotech crops, approximately 75 percent of which were grown in industrialised countries (see Figure 3). The countries include the US, Argentina, Brazil, Canada, China, Paraguay, India, South Africa, Uruguay, Australia, Mexico, Romania, the Philippines, Spain, Colombia, Iran, Honduras, Portugal, Germany, France and the Czech Republic. The global market value of biotech crops was US$ 5.25 billion. The value of the global biotech crop market is based on the sale price of biotech seed plus any technology fees that apply (James, 2006). Soybeans, maize, cotton and canola are the four main GM crops, with 54.4, 21.2, 9.8 and 4.6 million hectares respectively planted of each crop worldwide in 2005 (see Figure 4).

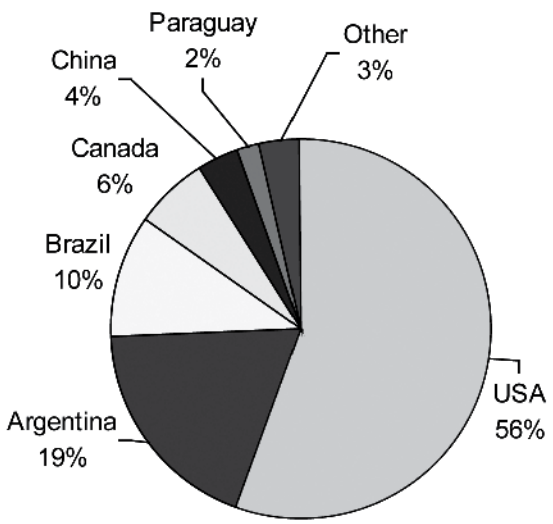
The two main biotechnology traits are herbicide tolerance (71 percent of total plantings) and pest resistance (18 percent). Herbicide-tolerant plants have been genetically modified to survive the spraying of a particular herbicide, usually by inserting a gene from the soil bacterium *Agrobacterium tumefaciens* that enables them to survive treatment from glyphosate, a pesticide that can eradicate most weeds in one application. By enabling farmers to apply a single treatment of glyphosate to control weeds, herbicide resistance aims to reduce the frequency of application and quantities of chemicals, and allow for the use of chemicals with lower toxicity and persistence in

Figure 2: Growth rates for the global area of transgenic crops (1996-2005)



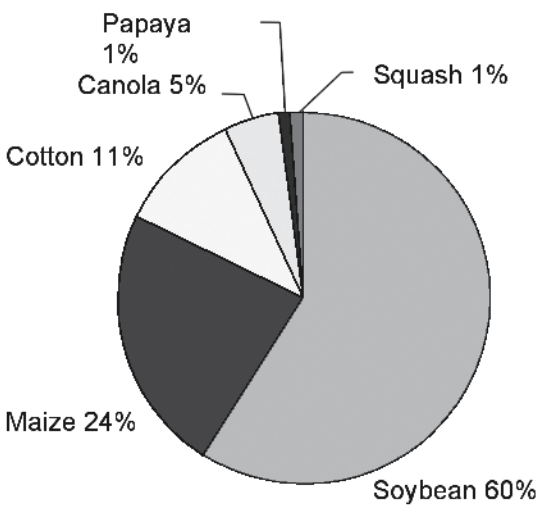
Source: Adapted from the International Service for the Acquisition of Agri-biotech Applications (ISAAA), www.isaaa.org

Figure 3: Location of legally planted GM crops in 2005 (percentage of global coverage)



Source: James (2006)

Figure 4: Global area of legally planted GM crops in 2005 by crops (percentage)



Source: James (2006)

the soil (FAO, 2004). Roundup Ready® soybeans, developed by Monsanto, are by far the most popular herbicide-tolerant crop. Grown in the US, Argentina, Brazil, Paraguay, Canada, Uruguay, Romania, South Africa and Mexico, they represent 60 percent of the global biotech crop area of 81 million hectares for all crops (James, 2006).

Commodity crops, such as maize, cotton, soybeans and canola, have also been genetically engineered for resistance to pests. When introduced into plants, a gene from the common soil bacterium *Bacillus thuringiensis* (known more simply as 'Bt') generates a protein that, when eaten by the target species, kills insect larvae and particularly caterpillar pests. Bt is harmless to humans, pets and most beneficial insects such as bees, and has been used for many years in insecticide sprays. Bt maize is the most popular insect-resistant crop, occupying 11.3 million hectares, equivalent to 14 percent of global biotech area in fields in nine countries: the US, Argentina, Canada, South Africa, the Philippines, Spain, Uruguay, Honduras, Portugal, Germany, France and the Czech Republic. Bt cotton is also widely used, covering 4.9 million hectares, equivalent to five percent of global biotech area, in China, India, Australia, the US, Mexico, Argentina, South Africa and Colombia (James, 2006).

Most of the GMOs commercialised in developing countries to date have been acquired from developed countries and focus on a limited number of traits (herbicide tolerance and insect pest resistance) and crops (commodities such as cotton, soybean, canola and maize). Efforts are also being made to develop GMOs with traits that address the needs of developing countries more specifically (see Q7). Several developing countries, headed by Argentina, Brazil, China, Cuba, Egypt, India, Mexico and South Africa, have been conducting research on a wider range of crops, such as banana, cassava, cowpea, plantain, rice and sorghum, and on traits such as abiotic stress tolerance that would allow crops to grow in salty soils or in dry areas. Research has also focused on developing crops that produce medicines or food supplements directly within the plants.

GM crops with improved agronomic traits have been categorised as 'first generation' biotech products. A shift in focus is expected with the transition from the first to the 'second generation' of GM crops, which in addition to new agronomic traits also incorporate enhanced quality traits, such as improved nutritional value of food and feed. Many of these new traits have already been developed by public, private and public-private partnership initiatives but have not yet been released on the market. Applications under development include soybeans with higher protein content; rice engineered to produce ß-carotene, and crops with modified oils, fats and starches to improve processing and digestibility. The success of the second generation of GM crops will ultimately depend on their profitability at the farm level and their acceptance by consumers (FAO, 2004).

Other forms of agricultural biotechnology

There are many kinds of biotechnology beyond genetic modification that find application in agriculture. For instance, *marker-assisted selection* uses genotypic information obtained through DNA testing (or 'genetic fingerprinting') to assist in the selection of suitable individuals to become parents in the next generation. Biotech critics (e.g. Rifkin, 2006) have hailed this technology as a viable alternative to genetic modification by allowing breeders to speed up natural plant and animal breeding programmes without the need for genetic modification. The International Centre for Tropical Agriculture (CIAT), for example, is using marker-assisted selection to develop a cassava variety with high contents of carotene, protein and dry matter as well as high resistance to cassava mosaic disease (CIAT, 2001). Molecular-assisted selection also provides a faster and more accurate tool for backcrossing – the final stage of genetic modification (see Figure 1).

Other techniques include *tissue culture* and *micropropagation*, which involves taking small sections of plant tissue, or entire structures such as buds, and growing them under sterile conditions on specially selected media containing substances essential for growth with the objective to regenerate complete plants. This technique is particularly useful for maintaining valuable plants, breeding otherwise difficult-to-breed species (such as many trees), speeding up plant breeding and providing abundant plant material for research. Micropropagation can also be used to generate disease-free planting material (FAO, 2004). The technique is relatively cheap and has been shown to increase general productivity.

The most common application of tissue culture in developing countries involves producing virus-free plantlets by heat-treating the tissue plant to kill any viruses present and then culturing cells from the plant's actively growing tissue. In Kenya, for instance, banana shoot tips have been heat-treated to destroy diseases and then reproduced in tissue cultures through micropropagation, creating as many as 1,500 new disease-free banana plants. In China's Shandong Province, micropropagation enabled the creation of virus-free sweet potatoes which led to an increase in yields of up to 30 percent. These productivity increases raised the agricultural income of the province's seven million sweet potato growers by three to four percent in one season (Fuglie *et al.*, 1999). In Uganda, a company uses tissue culture to produce pathogen- and pest-free plantlets which are being distributed through nurseries and demonstration gardens set up in different areas of the country (Nsubuga, 2006).

The use of *diagnostic tests* to fight plant diseases is another type of non-GM biotechnology. Molecular assays such as enzymes-linked immunosorbent assay (ELISA) can precisely identify viruses, bacteria and other disease-causing agents. ELISA has become an established tool in disease management in many farming systems and is now the most widely used commercial diagnostic technique in all regions of the developing world (Dhlamini, 2006).

Also, products based on *micro-organisms* play an increasing role in pest control and soil enrichment, including 'biopesticides' (i.e. pesticides derived from natural materials which are more selective, less toxic to humans and the environment and more effective at lower rates of application than conventional chemical pesticides), 'biofertilizers' and products that aid fermentation and food processing. While research in these products is in the early stages in Africa and Asia, developing countries such as China, India and the Philippines are already using advanced techniques. Studies on biofertilizers, mainly Rhizobium, are currently being carried out in many developing countries.

Industrial biotechnology

Industrial biotechnology (or 'white biotechnology') covers two areas, namely (1) the use of biological systems such as cells or enzymes (used as reagents or catalysts) to replace conventional, non-biological methods, and (2) the use of renewable raw materials (biomass) to replace raw materials derived form fossil fuels (Juma and Konde, 2005). Biotechnological processes are being widely applied in the chemicals industry (especially for fine chemicals and pharmaceuticals), pulp and paper production, textiles and leather, food processing (including animal feed), metals and minerals and the energy sector (OECD, 1998; OECD, 1999). They can be used to create new industrial supplies (biochemicals, enzymes and reagents for industrial and food processing); environmental elements (pollution diagnostics, products for pollution prevention and bioremediation); and energy.

Although industrial biotechnology is not 'clean' *per se*, it offers potential environmental benefits, such as reduced resource consumption and waste generation. Detergent enzymes, for example, such as protein-removing enzymes, can cut phosphate release into the environment and energy use during washing. Biotechnology is also used for processing pulp and paper to reduce energy use and extract more value from the resource. Driven largely

by market and environmental demands for less chlorinated products and by-products, the pulp and paper industry is cited as the fastest-growing market for industrial enzymes.

One interesting biotechnology application in the chemicals sector is the use of plants as finished products to produce plastics. Monsanto, for example, has experimented with a genetically modified cress variety to produce a biodegradable plastic using a gene extracted from a bacterium, *Ralstonia eutropha*. Other applications include the production of bio-based polymers. Cargill Dow LLC, for instance, has commercialised NatureWorks™ – polymers derived entirely from annually renewable resources, such as maize. The polymers, which are used to produce clothing, packaging materials and electronic goods, are claimed to require 25 to 55 percent less fossil resources to produce than comparable petroleum-based plastics (EuropaBio, 2003).

Biotechnology is also becoming increasingly important in the manufacture of textiles, for instance to produce fibres derived from natural substances such as lyocell, rayon and cellulose acetate (OECD, 1998). Other examples include fibres with improved or novel features, such as genetically engineered cotton containing a bacterial gene that makes a polyester-like substance, resulting in fibre that has the texture of cotton, but is much warmer. Companies such as Monsanto, Calgene, Agricetus, DuPont and Bayer are investigating possibilities of engineering cotton for increased strength, improved dye uptake and retention, enhanced absorbency and wrinkle- and shrink-resistance. Transgenic approaches could also increase the colour range of cotton. In the area of animal-derived fibres, genetic studies on sheep and goats are being carried out in Australia and elsewhere with the objective of producing fibres that are insect- and pest-resistant, softer, finer and more easily harvested.

Among food biotechnology applications, production of basic food ingredients (proteins, carbohydrates and fats) from non-traditional sources is theoretically possible using microbial fermentation or plant tissue culture. Also, consumer preferences for 'natural' food additives (including gums, emulsifiers, vitamins, minerals and preservatives) give biotechnology-derived products an advantage over chemically-synthesised ones, if their cost is competitive. The use for plant tissue culture for the production of natural flavours such as vanilla has also been suggested as a promising application (OECD, 1999).

Biotechnology has also been applied in the energy sector (OECD, 1998). It has improved the overall efficiency of processes, particularly in the area of pollution control. Processes and products currently under development, such as biodiesel, bioethanol and biodesulphurisation, aim to replace systems that are more energy-intensive and generate less benign by-products, for instance by replacing fossil fuels with renewable raw materials.

However, despite its potential, the widespread application of industrial biotechnology continues to face a number of challenges (OECD, 1999). Novel processes require capital expenditure and development costs, which can be higher than the costs of using traditional mechanical or chemical processes. As a result, significant investments in industrial biotechnology have been limited to industrialised countries and large developing countries. However, intermediate developing countries with existing industries and some scientific capacity could benefit from applying biotechnology to industrial processes, most notably in cleaner production processes. The Organisation for Economic Co-operation and Development (OECD), for example, has suggested that using industrial biotechnology for fuels and for creating more environmentally-friendly chemicals can reduce the environmental footprint of industrialisation while also reducing costs (OECD, 2001).

Medical biotechnology

The field of medical biotechnology continues to expand rapidly, offering new tools for the diagnosis and treatment of many diseases and inherited disorders. The Human Genome Project, which has mapped the approximately 20,000-25,000 genes in human DNA, has greatly contributed to advances in this field. The mapping has provided a framework to identify each human gene and the specific role(s) it performs. This map can then be used in a variety of ways, including diagnosis of genetic disease, preventative health care and gene therapy.

Biotechnology can contribute to diagnosis by looking at a patient's genes to assess the susceptibility to illnesses (Biotechnology Australia, 2006). Where a disease is known to be caused by one or a few genes (such as cystic fibrosis), or an extra chromosome (such as Down syndrome), genetic testing can help diagnose disorders before patients have developed symptoms. The technique can also be used to discover if a foetus has a genetic disorder. Moreover, reading the DNA of individual humans can help people who carry the genes linked to diseases such as breast cancer, diabetes or osteoporosis to undertake preventative measures, such as more frequent health checks or adapting their diet and lifestyle.

Another technique – gene therapy – involves the introduction of a healthy gene into a cell to replace a disease gene. Unlike conventional treatments which attempt to deal with the consequences of a defect, gene therapy aims to correct the defect itself. To this end, researchers isolate normal DNA and package it into a vector, such as a virus. Doctors then infect a target cell – usually from a tissue affected by the illness, such as the liver or the lungs – with the vector. The vector 'unloads' its DNA cargo, which then begins producing the missing protein and restores the cell to normal.

Medical biotechnology has also assisted in the development and production of new drugs, including antibiotics and specific compounds, such as interferon alpha to treat hepatitis C and cancer. By studying the genetics of viruses such as HIV/AIDS, fungi and bacteria that infect humans, scientists can understand how they cause disease and develop drugs that target them more specifically. Vaccines can also be developed using a fragment of the microbial DNA which will produce the antigenic protein directly in the body and may induce the immune system to produce antibodies.

Plant genetic modification can also serve medical purposes. For example, plants can be genetically modified to produce substances that can be refined into processed compounds used in pharmaceuticals. Plants can also be modified to produce vaccines that can be administered by eating the produce. However, both types of GM applications are relatively controversial and pose high regulatory demands.

Animal biotechnology

Biotechnology is also used for developing animal vaccines and medicines, cloning and the genetic modification of animals and insects. Other applications include improving animal health and performance, increasing livestock and poultry productivity, and using animals for the production of pharmaceuticals.

Biotechnology-based processes to produce animal vaccines are becoming more common and many regulators and animal breeders hope that they will provide more effective, safe and inexpensive vaccines to safeguard animal health. These new and improved medicines for animals help lower production costs and fight diseases caused by bacteria and parasites. Vaccines are used to prevent diseases, including foot and mouth disease, scours, brucellosis, shipping fever, feline leukaemia, rabies and infections affecting cultivated fish (Vines, 2002).

Animal biotechnology also includes techniques to enhance reproduction and breeding methods such as artificial insemination and multiple ovulation/ embryo transfer (MacKenzie, 2005). In addition, an animal can be directly genetically modified through the insertion of genes into the egg of the animal. This technique is used, for example, to increase the amount of casein in dairy cattle to increase milk protein and also to insert a growth hormone gene similar to insulin into swine to reduce fat and increase feed efficiency.

In addition, there are proposals to genetically modify animals to produce medicines or chemicals. For example, some have proposed to genetically engineer an animal to make milk that contains insulin. Companies are also performing research on using the mammary gland of sheep, goats and cows to produce proteins for drugs for humans. Moreover, genetically modified animals could provide organs and tissues for use in human transplant surgery. Organs from animals can be genetically modified so that they carry copies of the human genes that code for proteins inhibiting the immune response to foreign tissue. This might reduce the risk of rejection by the human immune system.

Since the 1980s, there has been a burst of biotechnology activity in research and development related to various fish species, in particular those used in aquaculture production (Pew Initiative, 2003). Traits that are being tested in fish species such as carp, trout, salmon and channel catfish include growth rates that are three to eleven times faster with more efficient feed utilisation, increased tolerance to cold water and improved disease resistance. Accelerated growth rates mean that fish reach marketable size sooner, thereby reducing overhead costs for fish farmers. In addition, researchers use the human interferon gene to improve disease resistance in carp, which could reduce the amount of antibiotics needed to keep fish healthy and reduce the costs incurred from losses due to disease. The first (and to date only) genetically engineered fish to be sold commercially is the fluorescent Glofish®, a zebra fish modified to glow red, which came onto the US market in 2004.

Animal cloning builds on pre-existing reproductive technologies in the hopes of creating animals with better characteristics, often through the cloning of GM animals. In 1997, a group of Scottish researchers announced the birth of Dolly the sheep – the world's first mammal cloned from an adult cell. Dolly has the same genes as the ewe from which an udder cell was taken and fused with an empty egg (whose nucleus was removed). The egg, with its new genome, was stimulated to begin developing into an embryo and was implanted into a surrogate sheep where it grew normally, resulting in the birth of Dolly.

GM insects are a new area of study in which the majority of the research is being carried out by government scientists, philanthropic organisations and publicly funded research institutions (Pew Initiative, 2004; Pew Initiative, 2005a). The focus of the research is currently on engineering insects to prevent them from spreading diseases such as malaria or to reduce populations of insect pests that destroy agricultural crops. One of the most advanced applications includes research to insert a marker gene into a male fruitfly that has been made sterile through conventional processes. The sterile fruitfly will then be released into the wild with the aim of decreasing fruitfly populations and thereby crop damage. The insertion of a marker gene would enable scientists and regulators to assess the extent to which the fruitflies have served their purpose of decreasing populations. Experts suggest that this relatively low-risk genetic modification could be the first to be discussed with the public and regulators regarding potential release, which is not estimated to happen until 2015 at the earliest.

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PART B: KEY ISSUES AND QUESTIONS

B.1 Environmental, health-related and socio-economic considerations

Concerns over the environmental and health impacts of biotechnology have fuelled the controversy on the approval and commercialisation of biotech products. The construction of a regulatory framework that addresses public concerns, yet at the same time considers the developmental potential offered by technology, requires policy-makers to carefully consider and balance the possible risks and benefits. Indeed, the many examples that different sides of the debate have pointed to as proof of the surplus of risks over benefits – or vice versa – have been landmark cases in the war of rhetoric and scientific proof that has been waged to capture the hearts and minds of the public, media and government. Whether GMOs will harm or enhance the environment; whether there are any threats to human health; and the potential for biotechnology to alleviate poverty are just some of the issues that are discussed by interest groups, biotechnology corporations, governments, scientists and the media. Making sense of the often contradictory stories can seem difficult, if not impossible. Varying interpretations of the impacts of biotechnology on health, the environment and poverty lead in turn to different regulatory approaches to the safety of biotechnology products. This section will attempt to provide a brief but comprehensive review of the environmental, health and socio-economic considerations that have been raised by biotechnology with the aim of making the issues, and their differing interpretations, more clear. The section will conclude by looking at the potential benefits of biotechnology for producers and consumers and the structure of research in the sector.

Q1 Are GMOs harmful to human health?

Although the impact of GMOs on human health is one of the most frequently cited reasons for opposition to biotechnology, existing studies have so far not yielded scientifically conclusive evidence indicating that GMOs have harmed human health. Proponents of the technology also point out that GMOs have been produced and consumed for over ten years without confirmed cases of harm. However, critics counter that not enough long-term studies have been conducted on the subject to provide a conclusive answer on the potential future health impacts of GMOs. Experts in risk assessment point out that no food, or for that matter any course of action, is without risk; the questions are therefore whether food containing GMOs presents unique risks to human health, what likelihood of harm these risks present, and how serious the impact of any such harm would be. Fears expressed regarding the health impacts of GMOs include the potential for allergens to be introduced into the diet, higher levels of toxicity, uptake of transgenic DNA by humans, increased resistance of bacteria to antibiotics and unintended side-effects.

The insertion of a gene from one plant into another has led to concern that consumers will buy and consume a food without being aware that it includes genes from another organism which they could be allergic to. For example, a gene from a peanut could be inserted into a maize variety, leading to allergic reactions in consumers with peanut allergies that were unaware that the maize contained peanut genes. Concerns over allergenicity have led to standard allergenicity testing being implemented before the commericalisation of GM crops around the world (see Section C.6).

In addition, adverse direct health impacts could stem from higher or lower levels of naturally occurring proteins, toxins or other harmful compounds in foods resulting from genetic modification. While conventional toxicity testing could address this,

BIOTECH HEADLINE 1: Pusztai's Rats

In April 1998, Arpad Pusztai, a researcher at the Rowett Research Institute in Aberdeen, UK, announced that a ten-day experiment he had performed had revealed that GM potatoes caused intestinal inflammation in rats. Controversy followed as civil society groups pointed to the research as scientific proof of the dangers posed by genetic modification. Problems with the conduct of the experiment soon surfaced, however, leading many in the scientific community to criticise his results and conclusions.

The experiment involved groups of rats who were fed parent (regular) potatoes, potatoes spiked with lectin and potatoes genetically modified to produce lectin. Lectin is a protein important in many plants' natural defences that could be used to improve their resistance to insects. Pustzai fed different groups of rats raw or boiled potatoes from each of the three groups. He examined the intestines of the rats after ten days and found that the length of a key part of the rats' intestinal system known as the jejunal crypt was longer if they had been fed with raw GM potatoes compared to rats fed with raw parent and parent+lectin lines. He also found that the walls of the caecal – a portion of the large bowel which receives faecal material from the small bowel – was thinner in the rats fed with boiled GM-potato than those fed with boiled parent and parent+lictin lines.

Pusztai presented preliminary findings, which had not yet been peer reviewed, on a popular UK TV show on 10 August 1998, making claims about the effects of GM potatoes in distorting rat digestive systems that his critics felt could not be substantiated by the data he had gathered. Shortly afterwards, he was suspended by the Rowett Institute and his research was subsequently subject to an audit. After over a year of speculative controversy in the press and scientific community, the scientific journal *The Lancet* decided to publish the research with the disclaimer that it was doing so in order to ensure the paper was in the public domain, but that many of the findings of the study, the process and the data were "flawed".

Various criticisms have been levelled at the experiment, including by the British Royal Society. Firstly, scientists have long known that many lectins are especially toxic and can cause intestinal damage. Pusztai had chosen the particular lectin ("snowdrop" GNA lectin) because his earlier studies had shown that such damage would be minimal. However, Brian Fenton from the Scottish Crop Research Institute, an institute that Pusztai co-operated with, described an experiment where the GNA lectin did in fact trigger adverse biological effects, and could thus be used to explain some of the results in the rats. In addition, there were several differences in composition of the different potato types, including macro and micronutrients, toxins, protein content (which was added separately, possibly causing other distortions in the results) and a lack of testing for various toxins. Reviewers also suggested that raw potatoes are not an ideal diet for any animal and could have caused data distortions.

Overall, many scientists found that there were too many other variables that could be responsible for the minor digestive differences viewed in the different groups of rats. Moreover, judging the safety of GM food products on the basis of experiments involving one species of animals, fed with one product modified by inserting one gene by one method was thought to be unjustifiable even for the best-designed research.

Sources: Ewen & Pusztai (1999); Royal Society (1998a); Storzek (1998).

methodological challenges in testing the toxicity of whole foods through animal tests – witnessed in the public controversy over Pusztai's rats (see Biotech Headline 1) – have led to the development of alternative ways of testing the safety of GM foods (WHO, 2005).

The potential for gene transfer from GMOs to humans has also been raised as an area of concern. Research has shown that DNA in food is not completely broken down by digestion and that small fragments of DNA from food can be found in different parts of the human gastrointestinal tract after eating, although the pieces are usually too small to be functional. However, even if sufficiently large pieces of DNA survived, the process of taking up the genes and functionally integrating them into human DNA would be extremely complex (Donaldson and May 1999; Royal Society 1998b). It has also been noted that DNA in food is consumed daily without any evidence that intact genes are transferred to humans.

In a related but separate scenario, the antibiotic resistance marker gene – which is included in the gene 'package' because it can survive the addition of antibiotics and thereby allow scientists to identify organisms that have been genetically modified – could be taken up by gut bacteria and lead to resistance of these bacteria to antibiotics. While gene transfer to micro-organisms is thought to be highly unlikely, the possibility cannot be ruled out and there is general agreement that the use of such marker genes should be restricted, in particular if the antibiotic is an important medication (FAO/WHO, 2001). Also, the widespread use of antibiotics as feed additives for animals and medicines for humans is thought to carry a far greater risk of creating antibiotic-resistant bacteria than the transfer of marker genes (Royal Society, 1998b).

As conventional breeding of plant varieties has been known to cause unexpected effects on the genetic structure, performance and characteristics of plants, it can also be expected that the insertion of one or more gene packages into a plant can cause similar effects. These effects can include changes in the DNA structure and the silencing or increased expression of genes. For example, the newly inserted gene and its accompanying elements might interact with the other genes in the organism and either create new characteristics, or stop the functioning of other characteristics (Wilson *et al.*, 2004). Methods to assess the potential of unintended effects in particular GMOs are being developed (WHO, 2005).

Q2 Are GMOs harmful to the environment?

Existing evidence on the environmental impacts of GMO production does not yield proof of systemic adverse effects of the technology; however, similarly to the above-mentioned health concerns, some argue that not enough long-term studies have been carried out to lay to rest the various concerns that have been highlighted. In particular, many suggest that there is a need for an appreciation and study of the distinct environmental conditions that prevail in different parts of the world, including the ecosystems and soils in tropical, biodiversity-rich developing countries. It has also been stressed that efforts to assess the adverse impacts of GM crops must use conventional agricultural crops as the frame of reference or counterfactual.

GM crops can have two types of environmental impacts, namely a direct impact that derives from the GMO itself and indirect impacts that stem from the different management choices that the new crop offers to the farmer.

Transfer of genes within species occurs naturally in the wild and in agricultural fields. In the context of GM crops, however, such gene transfer poses unique challenges because of the possible transfer of transgenic DNA to non-modified plants. Such transfer would decrease the ability to control or regulate the spread of modified crops, and could affect biodiversity or cultural and social values (see Biotech Headline 2). Environmental advocates

BIOTECH HEADLINE 2: Mexican Maize

In October 2000, Ignacio Chapela and David Quist, researchers from the University of California at Berkeley's College of Natural Resources, found transgenic DNA in maize grown in a remote area in the state of Oaxaca, Mexico. The Mexican government subsequently performed and in September 2001 released its own research confirming that, despite a moratorium on environmental release of GM maize in Mexico since 1998, transgenic DNA had in fact made its way into Mexican maize landraces. In November 2001, Chapela and Quist published their research findings in the scientific journal *Nature*. The discovery ignited a controversy fuelled by the fact that Oaxaca is the so-called 'centre of origin and diversity' of maize, where it was domesticated from a weed named teosinte hundreds of years ago.

Environmentalists, farmers and local communities from Mexico and around the world asked how the local races became contaminated and questioned what the potential implications could be for the local communities and genetic diversity. Greenpeace, the ETC Group and other international civil society groups suggested that permanent loss of biodiversity may result, and local communities made links between the contamination and systemic political problems in rural areas. As a result, in April 2002, twenty-one indigenous communities from Oaxaca and three Mexican environmental groups petitioned the North American Commission for Environmental Cooperation (CEC) to assess the impacts of transgenic contamination of Mexican maize races. The CEC was created under the North American Agreement on Environmental Cooperation (NAAEC), an environmental side agreement to the North American Free Trade Agreement (NAFTA) between Mexico, Canada and the US.

The final CEC report, which was released in November 2004, traced the arrival of the GMOs in Oaxaca back to imports of maize from the US, where GM maize makes up approximately one-third of the maize crop and is not segregated from non-modified maize. Although the maize was only intended for consumption, small-scale farmers planted the seeds. The report concludes that "there is no reason to expect that a transgene would have any greater or lesser effect on the genetic diversity of landraces or teosinte than other genes from similarly used modern cultivars", suggesting that, from a scientific point of view, transgenic maize does not threaten genetic diversity more than other methods of modern agriculture such as hybridisation. At the same time, the report stresses the cultural, symbolic and spiritual values of maize for many Mexicans, in particular the campesinos (or small-holder farmers) who "perceive GM maize as a direct threat to political autonomy, cultural identity, personal safety and biodiversity". The report adds "That sense of harm is independent of its scientifically studied potential or actual impact upon human health, genetic diversity, and the environment".

Based on these concerns, and using a precautionary approach, the CEC report recommends that the GM maize planting moratorium should be continued and strengthened "by minimising the import of living transgenic maize grain from countries that grow transgenic maize commercially". The US and Canada issued strong public statements criticising the report and, in particular, what they regard as a contradiction between the scientific key findings and the recommendations.

The publication of a new study in the *Proceedings of the National Academy of Sciences* in August 2005, showing no evidence of GMOs in more than 150,000 seeds taken from 870 plants in Oaxaca in 2003 and 2004 has, for now, calmed demands for measures to be taken.

Sources: CEC (2004); Ortiz-Garcia et al. (2005); Quist and Chapela (2001).

have cautioned that the transfer of genes from GM plants which have been genetically engineered to withstand herbicide applications could lead to the creation of 'superweeds' if the genes were taken up by related wild varieties of the same species. They warn that these 'superweeds' could be more difficult to kill, require more or stronger herbicides and could become invasive with adverse effects on agricultural biodiversity. A related concern is that GM plants themselves will become weeds, or could become invasive (Conner *et al.*, 2003) (see also Q3).

Gene flow from plants which have been genetically modified to produce pharmaceutical, chemical or industrial compounds could lead to the inadvertent spread of chemical compounds or medicines to soils, ecosystems and other plants. For example, in 2002, seeds from plants genetically modified to generate an animal vaccine germinated in the field from which they had earlier been harvested in the US, and mixed with soybeans that were subsequently grown on the land (Cohen, 2002). The soy was destroyed as the impacts of the vaccine on human health and the environment were unknown, and because ProdiGene – the Texas-based biotech company that had developed the GM maize – had not taken human consumption or environmental release into account in its risk assessment. However, given the unique nature of these plants, most regulators and actors in these industries agree that they need to be carefully segregated to prevent gene transfer to other crops and to the environment (Nuffield Council, 2004). Research on the environmental effects of these crops is in its infancy.

Genetic Use Restriction Technologies (GURTS) have been proposed by the biotech industry as a possible means to prevent unintended gene flow. GURTS can be used to genetically alter seeds to be sterile and thus prevent cross-fertilisation. The technology – dubbed 'terminator technology' by its critics – has attracted fierce criticism from environment, farmer and indigenous groups who warn that inhibiting a plant's ability to reproduce could have adverse effects on rural livelihoods by preventing reuse of the seeds by farmers and on biodiversity by risking to transfer the trait to wild varieties. As a result, a de facto moratorium on field trials of GURTS was instituted by the Parties to the CBD in 2000 when countries recommended that "products incorporating such technologies should not be approved by Parties for field testing […] and for commercial use" until potential environmental and socio-econoimc impacts have been assessed (CBD, 2000).

GM crops can also have direct impacts on non-target species that consume them or their pollen. Crops which use *Bacillus thuringiensis*, a soil bacterium that kills many of the worm-like insects that destroy crops, is a case in point. While Bt saves the crop from pests that destroy the crop, it could also hurt other harmless worm-like insects that are found in the fields (see Biotech Headline 3). There is also the possibility that insects will become immune to the Bt toxin since such resistance would provide them with an evolutionary advantage in the presence of widespread Bt use. This could have adverse long-term effects on the invasiveness of these insects in the environment and on farms, because use of Bt – including through sprays and non-GM methods – is one of the most effective, cheapest and least environmentally harmful ways to tackle the spread of pests. This problem has not emerged thus far – possibly owing to the requirement in many countries to have small areas of non-Bt plants ("refuges") near any Bt fields to minimise evolutionary advantages any Bt-resistant insects would have (IFATPC, 2004).

In addition, GM crops change the options that are available to farmers for pest and weed management. The use of the new crops can lead to farming practices that affect the agricultural environment, including different kinds and quantities of pesticides and herbicides, resulting in indirect effects of the new crops' characteristics on the surrounding environment.

BIOTECH HEADLINE 3: Monarch Butterflies

On 20 May 1999, the journal *Nature* published research by leading scientists at Cornell University showing that monarch butterfly larvae that ate milkweed leaves coated with pollen from GM maize ate less, grew more slowly and suffered a higher mortality rate than those that ate non-coated leaves. The larvae in question are small caterpillars that grow into the endangered and popular monarch butterflies, and the suggestion that they could be jeopardised by genetically modified Bt maize raised widespread concern.

Several studies released after the initial report have shown, however, that the actual risk posed to monarch butterflies by Bt maize was minimal. Bt is inserted into maize through genetic modification because it is selectively toxic to *lepidopteran* (larval or wormlike) insects. While the monarch butterfly larvae is such an insect, and was thus affected by consuming pollen from Bt maize in the lab, scientists concluded that under 'real world' conditions butterfly larvae are unlikely to encounter Bt maize pollen in nature. Butterfly larvae feed on milkweed, a weed which farmers keep out from the fields of agricultural crops such as maize. Monarch butterflies in particular prefer to eat milkweed near open meadows, ditches and pastures where they fly and deposit their larvae at a distance from the fields. Maize pollen cannot reach the milkweed plants in the ditches on which the larvae like to feed because it is too heavy. Field studies in Iowa and in agriculture departments of a number of US universities, along with a 2001 report from the US Environmental Protection Agency (USEPA), confirmed that the lack of milkweed in maize fields and the preference of butterflies for milkweed far from maize fields decrease the presence of Bt pollen in butterfly diets. They also pointed out that maize pollen is released in five to ten-day intervals when most butterfly larvae are not present because of migratory patterns, and that monarch butterflies do not like to eat pollen and tend to avoid pollen-tainted milkweed leaves, Bt or not. For all these reasons, during field trials scientists found that it was rare to have a combination of maize, pollen, milkweed and monarch butterfly larvae. Biotech supporters also stress that even if this combination were to occur, factors such as habitat destruction and the use of broad spectrum herbicides pose far greater threats to the Monarchs.

Sources: Losey et al. (1999); USDA (2004).

GM crops can change the way herbicides are applied to the crop (FAO, 2004). A single, broad-spectrum herbicide, such as glyphosate, is often sprayed on plants that have been genetically modified to be tolerant to herbicides in order to kill the weeds that surround the plants. Glyphosate has been advocated as a relatively benign herbicide since it rapidly degrades in the soil and has a low level of toxicity. Herbicide-tolerant crops are also claimed to require fewer applications of herbicides than conventional crops. However, whether the GM plants reduce overall herbicide use and persistence in the soil depends on a variety of factors, such as the suitability of the plant variety to the region, the extent of pre-GM investment in chemical herbicides and fertilizers, and the adaptation of pests and weeds to the treatment. Changes in herbicide application can also have impacts on non-target weed and plant life and the insects and animals that eat them. The effectiveness of the new herbicide in killing weeds (while allowing the crop itself to survive) can eliminate most weed cover and thereby reduce soil and agricultural biodiversity and harm non-target species that feed on these weeds. The largest agricultural biodiversity study to date, known as the UK Farm Scale Evaluations, concluded that while the use of GM crops does change the mix of weeds that survive herbicides, the impacts on agricultural biodiversity vary between crops and the particular herbicides used, and are within the normal scope of biodiversity impact variation within crops (see Biotech Headline 4).

BIOTECH HEADLINE 4: UK Farm Scale Evaluations

In 1999, the UK government asked an independent consortium of researchers to investigate how growing four types of herbicide-tolerant GM crops might affect the abundance and diversity of farmland wildlife compared with growing conventional varieties of the same crops. The resulting study, called the Farm Scale Evaluations (FSE), lasted five years, cost around GBP6 million and was the largest field experiment ever conducted on farmland ecology. The research pointed to differences in impacts on weed, insect and other farm wildlife populations between GM and non-GM crops. The report found that these differences could be attributed to the type and way herbicides were applied to the GM and non-modified crops rather than the genetic modification itself.

More specifically, it was found that GM beet and spring rape (canola) crops had fewer weeds, weed seeds, bees and butterflies, but more springtails (an insect that feeds on decaying plants). On the other hand, growing GM maize was better for many groups of wildlife than conventional maize because the GM crops had more weeds, seeds, bees and butterflies and springtails. Regarding winter rape, the GM and conventional crops had the same number of weeds overall. The GM crop was found to have more grass weeds and seeds but fewer broad-leaved weeds and seeds, resulting in fewer butterflies and bees, who feed predominantly on broad-leaved weed seeds, but more springtails.

Anti-GM campaigners, along with the UK and European media, hailed the study as proof that GM crops should be abandoned. "These results are another good reason to abandon all plans for growing GM oilseed rape in the UK," GeneWatch Director Sue Mayer said. Others suggested that the results showed that GM crops do not pose a threat in themselves to farm biodiversity; rather, GM-conventional comparisons test the relative impact of different herbicide uses given that GM crops offer new herbicide choices. They also pointed out that in all four cases there was only one herbicide spray for the GM crops, compared to multiple sprayings for conventional crops, delivering positive environmental impacts given that herbicides can also damage the environment in the long term. Also, they noted that differences in impacts on biodiversity were greater among the four types of crops than between GM and conventional varieties of one crop, implying that the choice of crop – along with the type of crop rotation, pesticide use and agricultural intensity – may have more significant impacts on farmland wildlife than the different herbicide uses resulting from GM crops.

Sources: AgBioWorld (2003); GeneWatch (2005); www.defra.gov.uk/environment/gm/fse/.

More broadly, there are fears that adoption of GM plant varieties could encourage a tendency towards monocropping, intensive farming and mechanisation of agriculture with adverse impacts on biodiversity. Supporters of GM crops argue that in fact it could do the opposite by reducing the need for chemical inputs and mechanised operations, with positive impacts on water supplies, pesticide use, pesticide residues, farmer health and food safety. For example, the fact that herbicide-tolerant plants need not be ploughed around for removal of weeds means that 'no-till' practices can be adopted, which in turn can preserve soil, prevent desertification and stripping of soil nutrients and reduce greenhouse gas emissions. However, it also needs to be borne in mind that, particularly in developing countries, GM crops and their accompanying herbicide or pesticide treatments might become a substitute for what has

so far been herbicide and pesticide-free production, rather than an alternative to herbicide and pesticide-intensive production as it is in developed countries.

The environmental implications of GM animals have also been raised. It is feared that the increased use of a few uniform GM animals could reduce animal biodiversity, and that the spread of genes from GM animals would be difficult to control, owing to the animals' mobility and reproductive patterns. Furthermore, there are concerns that unintended effects of genetic modification, similar to those described above for plants, could lead to novel changes to the animal physiology that could be difficult to predict, anticipate or address.

In this context, transgenic fish have raised particular concerns (Pew Initiative, 2003). It is feared that GM fish might escape from fish farms and spread novel traits into the ecosystem by breeding with wild relatives, thereby impacting on marine biodiversity. Transgenic fish that escape into natural ecosystems could also be an environmental nuisance by becoming an invasive species. Scientists are attempting to reduce these risks by sterilising transgenic fish (Pew Initiative, 2003).

Research is also under way to genetically modify insects in order to reduce invasive populations, such as fruit flies, through selective sterilisation. There are also more ambitious projects to change other characteristics of insects to make them less problematic – for example, to decrease their tendency to spread viruses. While such changes have been advocated by some as a means of ensuring human and in some cases animal health, the complicated relationship between insects, bacteria, animals and ecosystems, along with the difficulty in controlling the spread of insects, has raised concerns about the unintended spread of GM insects and the potential implications on their invasiveness and impacts. As such, no GM insects have been released to date (Pew Initiative, 2004).

At the same time, the most promising field of animal biotechnology – the use of biotechnology to develop vaccines and reproductive techniques – could in fact improve animal health and diversity (MacKenzie, 2005).

Q3 Can genetically modified, conventional and organic crops be grown in one country?

A range of different measures have been proposed to ensure that GM, conventional and organic crops that have been approved as safe for planting can be grown in the same country without intermingling. Such co-existence measures do not deal with the safety of GM crops *per se* because the seed must be approved for release by the relevant government body before being available for planting. Rather, co-existence measures have been called for in order to ensure farmers' and consumers' right to choose which type of agricultural crops to grow and eat. Supporters of strict co-existence measures have also pointed to contamination scares such as the case of "Starlink" – when GM maize not approved for human consumption entered the US food supply and exports (see Biotech Headline 5) – to back their call for stronger government regulations.

Economic impacts of the accidental (or "adventitious") presence of transgenes in conventional or organic crops may include the loss of price premiums for the crop; the possibility of litigation by the company holding the intellectual property rights over GM crops (see Biotech Headline 6), or – in cases where the accidental presence raises safety concerns – the costs of withdrawing a product from grocery shelves, destroying the harvest of a particular field and possible liability claims. Conversely, biotech farmers may wish to segregate certain value-added varieties (such as nutrient-enhanced crops) from conventional or organic crops to preserve their competitive edge.

BIOTECH HEADLINE 5: Starlink

In September 2000, the GM maize named "Starlink" was found in taco shells in the US. Starlink had been approved in 1998 only for animal feed but not for human consumption. Nonetheless, as a result of drifting pollen in fields and mishandling of the crop, Starlink maize made its way into food in the 1999 and 2000 crops. While Starlink made up only 0.4 percent of the total US maize acreage in 2000 (covering at least 350,000 acres), crops grown close to Starlink or stored in the same grain elevators became co-mingled (or contaminated as critics put it) with the GM crop. A massive food recall resulted, with Starlink manufacturer Aventis spending more than US$ 100 million buying back hundreds of millions of bushels and the US government recalling more than 300 kinds of maize tacos, chips and other products. Exports of maize from the US plummeted to as low as half their previous levels, in particular to South Korea and Japan, two of the largest importers of US maize, where Starlink had not been approved for animal or human consumption. US and world prices for maize also dropped, and public uncertainty and concern grew about regulators' ability to control their spread. About 37 US citizens claimed they became ill after eating Starlink, though in most cases the illness was later attributed to another cause. Several scientists and Aventis itself quietly assured the public that Cry9C, the GM protein in question, was not allergenic and was safe for human consumption.

In October 2000, Aventis cancelled its registration of the maize, thereby making any new planting of the seeds illegal. However, at the same time they asked the US government to approve Starlink for a four-year temporary human use permit which would have allowed the remaining maize to work its way through the food system and diminished Aventis' liability for removal. In addition, in April 2001 Aventis petitioned the USEPA to set a tolerance level that would allow trace amounts of Starlink to be present in food products rather than the zero-tolerance standard that led to the massive food recalls. The USEPA's Scientific Advisory Panel found on 5 December 2000 that there was a "medium likelihood" that the Cry9C protein was a potential allergen, although owing to the low amount of Starlink in the food supply, the low probability of exposure and the limited time that Starlink had been present, it was unlikely to pose an immediate allergenic threat. Nonetheless, the panel refused to set a permissible threshold for the presence of Starlink in food. As a result, the USEPA, the USFDA and the US Department of Agriculture (USDA) have continued to work to keep Starlink out of circulation domestically and in exports. A class-action suit brought by a group of maize growers against Starlink Logistics Inc. (a subsidiary of Aventis) and Advanta USA settled on a compensation of US$ 110 million to farmers who grew non-Starlink maize between 1998 and 2002.

Despite these measures, traces of Starlink maize were found in food aid and commercial imports sent from the US to Central America in February 2005. Following an analysis of almost 50 samples by a US laboratory, civil society criticised in particular the introduction of the unapproved maize by the World Food Programme, who distributed the food aid.

Sources: ACPB (2005); Centers for Disease Control and Prevention (2001); Pew Initiative (2003); University of Illinois (n.d.); www.non-starlinkfarmerssettlement.com.

BIOTECH HEADLINE 6: Schmeiser versus Monsanto

In August 1998, biotechnology firm Monsanto filed a lawsuit against Canadian farmer Percy Schmeiser alleging that Schmeiser had illegally bought Monsanto's Roundup Ready® GM canola (rape) seed and had planted it in his 1997 and 1998 crops. Monsanto sued for the CA$ 15-per-hectare technology use fee. Unlike many other farmers in a similar situation who settled out of court, Schmeiser decided to fight Monsanto, arguing that he did not intentionally plant the GM canola and did not profit from it. He suggested that the GM seed could easily have blown on to his soil from passing canola-laden trucks and that Monsanto investigators trespassed on his land to obtain samples. He challenged Monsanto tests that indicated that Schmeiser's fields were more than 90 percent Roundup Ready® canola, showing contradictory tests from the University of Manitoba. The latter found no evidence of modified genes in several samples, 2 and 8 percent GM content in two samples and 60 percent GM content in one sample.

Under patent law, Monsanto, as the patent owner, had exclusive rights to the GM canola. The company requires farmers purchasing its seeds to sign a technology use agreement (TUA) which usually prohibits farmers from selling the purchased seeds, saving a crop produced from the seed for replanting, or supplying saved seeds to anyone for replanting or research. Farmers also commit themselves to allowing Monsanto reasonable field access for sampling and testing during the year and following year of the TUA.

After failed mediation talks in August 1999, the case was heard in June 2000 in the Federal Court in Saskatoon, Saskatchewan. The judge ruled in Monsanto's favour, finding Schmeiser to have committed multiple infringements of Monsanto's patent. He noted that in light of the fact that Roundup Ready® canola constituted 95-98 percent of the crop in 1995, the levels of GM seeds on Schmeiser's property were so high that Schmeiser "knew or ought to have known" that his crop was planted with GM seeds. The judge instructed Schmeiser to pay a fine of CA$ 20,000 to Monsanto. Schmeiser launched an appeal soon thereafter which was rejected in May 2002.

The Canadian Supreme Court heard the case in January 2004 and a verdict was delivered in May 2004. The Court concluded that although the plant variety itself was not patentable, the gene that had been inserted in the plant was and the scope of protection of the patented gene extended to the plant variety. Under patent law, saving and planting seed containing the patented gene without authorisation from the patent holder infringes that patent and is therefore illegal, irrespective of whether or not the technology was actually used. However, since Schmeiser did not make a profit from the presence of Roundup Ready® canola in his fields (as he did not spray his fields with Roundup Ready® and therefore did not take advantage of the crop's resistance), the Court did not require Schmeiser to pay damages to Monsanto.

Sources: Bereano and Phillipson (2004); Louwaars and Minderhoud (2001); Supreme Court of Canada (2004); www.percyschmeiser.com.

At the farm level, seeds from one type of crop can make their way into another in several ways. Through cross-pollination, plant pollen can be transported in the air from one crop to another, bringing, for example, genes from a GMO to a conventional or organic field or vice versa. Plants left over in a field from a previous crop can sprout again in the same place later on where a different type of crop may be growing (so-called 'volunteer' seeds). Seed planting equipment, such as tractors or farm-level seed breeding tools, can also lead to the intermingling of GM, conventional or organic seeds, as can seeds sent to a local mill for cleaning as preparation for being replanted. Harvesting and storage facilities, along with local transport vehicles, also present opportunities for seeds to intermingle.

The likelihood of seeds and genes co-mingling in any of these fashions depends, among other factors, on the particular plant being grown. For example, GM canola seeds (a North American variety of rape) being transported by truck in the Canadian prairies have been shown to be particularly susceptible to being blown out of the vehicle by wind and into neighbouring fields growing conventional canola due to the low weight of the seeds and the proximity of the fields to the roads. Moreover, the open-pollinating nature of canola plants increases the likelihood that GM canola might cross with wild relatives.

Certain measures have been applied by government regulators and farmers at the farm level to facilitate the co-existence of GM, conventional and organic crops (see Q31 for segregation options at other stages of the production chain). The first, most obvious method is to physically separate different crops through the establishment of 'buffer zones' between fields, using different seed types to make sure that seeds or pollen from one field cannot reach the other. The distance necessary to isolate GM crops from non-GM crops depends on the plant in question, the risk of intermingling or cross-pollination, and the likely economic, social and environmental implications. These factors will also contribute to the 'threshold' that stakeholders decide is the maximum percentage of GM material that will be allowed in the non-GM variety, which varies from country to country. The EU, for instance, requires products with more than 0.9 percent GM content to be labelled as such, while Thailand and Japan have opted for a five percent labelling threshold. The threshold of GM content directly affects how many and to what extent measures must be taken to prevent intermingling, which in turn is likely to affect the costs of production.

Research in the US and Switzerland has suggested that establishing a 'buffer zone' of approximately 45 metres between GM and non-modified crops can reduce gene transfer to less than one percent (Norton, 2005). Similarly, the Farm Scale Evaluations in the UK (see Biotech Headline 4) used the guidelines of the Supply Chain Initiative on Modified Agricultural Crops, according to which GM crops should be separated from non-GM crops by 50 metres for oilseed rape, 6 metres for sugar beet and 200 metres for sweet corn (maize) (Brookes and Barfoot, 2003b). Farmers in Spain, one of the few European countries currently growing GM crops, have maintained a distance of 200 metres between GM and non-GM maize for several years, while others claim that 50 metres is sufficient because 99 percent of pollen can not travel farther than that distance (Brookes and Barfoot, 2003a). Research has suggested that such farm-level measures for soybean would add US$ 0.06 per metric ton to costs (Bullock *et al.*, 2000).

Other measures that can be taken to ensure co-existence of different types of crops and prevent co-mingling and cross-pollination include encouraging farmers adopting new types of seeds to: (i) take into consideration prevailing winds and the flowering times of different varieties; (ii) communicate with other farmers about their intentions and what measures they are taking; (iii) plant bands of non-GM crops between GM crops and other plants that are destined for markets where their non-GM identity is important; (iv) use different seed storage, transport

and processing facilities and technologies; and (v) generally practice good husbandry techniques. A number of post-harvest measures may also be necessary, including for transport vehicles, processing and marketing (see also Q31).

Co-existence may be encouraged through national or regional laws, or through GM crop stewardship guidelines created by GM seed distributors. Germany, Denmark, Portugal and six Austrian provinces have adopted co-existence legislation specifying the necessary separation distances. Austria, Denmark and Germany have also set up liability schemes for economic impacts of contamination. While efforts have been under way for some years to establish EU-wide co-existence procedures, it has been difficult to reach agreement, due to the diversity of farming practices across the EU, the limited area planted with GM crops and the fact that four countries have already adopted national co-existence rules and several others are in the process of developing them.

Very little research has been done on the practicalities of co-existence in developing countries. The same measures that work for developed countries, most notably separation of different types of crops, would help to minimise contamination elsewhere. The relatively smaller size of most landholdings in developing countries, however, suggests that setting aside a substantial amount of land as fallow might be relatively costly for the average developing country farmer. The social and economic dynamics of particular communities, regions and cultures will determine the extent to which measures to ensure co-existence are feasible, necessary and supported by rural peoples.

Q4 Can agricultural biotechnology contribute to food security, poverty alleviation and rural development in developing countries?

Food security was defined at the 1996 World Food Summit as a situation in which all people at all times have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life. This ability to access nutritious food directly determines people's ability to meet their basic material and social needs. As the inability to meet these needs is a symptom of poverty, it is clear that food security is closely linked to the reduction of poverty. While lack of food security can be driven by low income levels, which are in themselves indicators of poverty, the access of poor rural people to nutritious food is also strongly related to productivity, prices and distribution in the agriculture sector.

In this sense, the nature and extent of rural development will determine how much food is produced; the sustainability of the agriculture practiced; the type of technology and harvesting methods used; how the land is owned and shared; how food is distributed at the farm, region and country levels; and whether food is imported or exported. The determinants of food security and poverty vary greatly amongst regions and countries, depending on the nature of the rural area in all of these dimensions, while the institutional and political relationship between rural production and urban consumers will also play a key role in shaping local circumstances. Notwithstanding this diversity, the debate on the impact of biotechnology on food security, poverty alleviation and rural development has tended to focus on the rural poor in developing countries and the direct impacts that biotechnology could have on their food security through agricultural production, along with the indirect impacts on income.

Insofar as biotechnology allows scientists to insert genes with needed characteristics – such as drought resistance or the ability to thrive in salty soils – directly into plant varieties adapted to local conditions, it could lead to the development of plant varieties that address key long-standing problems of farmers in developing countries (FAO, 2004). If farmers as a result are able to reduce their vulnerability to plant viruses, climatic conditions and

other shocks, this can have direct impacts on their food security, by ensuring the continuity of their food supply. However, the trait that is introduced must be a trait that is locally needed, and it must be introduced into a locally-developed variety that also has the full package of other characteristics, such as taste, size or nitrogen-fixing abilities (Nuffield Council, 2004).

Moreover, genetic modification can be used to develop biotech crops that produce higher and more stable yields, which can give the people that produce it more food to eat or sell. Certain GM varieties, such as pest-resistant crops, can also improve working conditions in the fields by reducing the need for spreading particularly toxic chemicals or pulling out weeds for lengthy periods of time (FAO, 2004). However, it must be kept in mind that many small-scale farmers do not use chemicals, so the environmental benefits from reduced pesticide or insecticide use may not be forthcoming. It has also been argued that weed control provides an important source of employment in many developing countries while the weed is often used for food or fodder (Shiva, 2002).

Biotechnology can also be used to increase the nutritional quality of crops consumed in developing countries, including rice and cassava, and thereby address malnutrition, a key aspect of poverty. 'Golden rice' – genetically modified for higher beta-carotene content – is one such application which has attracted much praise and criticism from both sides of the biotech debate (see Biotech Headline 8).

There is also a range of potential indirect impacts. The use of GM crops can reduce pesticide costs, thereby increasing income. These cost savings, however, must be weighed up against other cost-related factors, such as the cost of the GM seeds *vis-à-vis* non-modified seeds, the cost of re-purchasing patent-protected seeds, the initial levels and costs of pesticides and other factors that impact on productivity and competitiveness (see Q29). Some technologies that are embodied in a seed, such as insect resistance, may be easier for small-scale, resource-poor farmers to use than more complicated crop technologies that require other inputs or complex management strategies.

Harnessing the technology for food security and poverty alleviation will also depend on the broader enabling environment for biotechnology development and application. The impact of the technology on agronomic practices and yields, for instance, is determined by a variety of non-technological factors, including soil biology, climate and socio-economic conditions. In addition, the producers of the crops as well as consumers must be willing to buy foods and other products derived from transgenic crops (Fransen *et al.*, 2005). Regulatory requirements and other costs will impact on the revenues that producers receive which in turn will affect their income and indirect benefits, as well as the price of biotech products on the market.

Perhaps most importantly, there must be sufficient national research capacity to identify where new research and products are needed, evaluate their feasibility, develop new seeds and processes, and adapt them to local conditions (Cohen, 2005). This will require greater investments in developing countries' public-sector agricultural research programmes in which biotech-related research and development would play one part (FAO, 2004). Other experts point out that the delivery of new seed technologies to farmers depends on working public or private delivery ('extension') systems (Delmer, 2005; Spillane, 2000). Balanced national intellectual property policies will be required to ensure that seeds are affordable while providing adequate incentives to encourage research and innovation (Kowalski *et al.*, 2002).

However, the reasoning and rhetoric of the arguments suggesting that biotechnology can alleviate poverty have been the subject of extensive criticism. The challenge to the linkages proposed above stems from

BIOTECH HEADLINE 7: Bt Cotton

In March 2002, the Indian government approved the commercial planting of three varieties of Bt cotton amidst widespread protests. The Bt cotton varieties (BT MECH 162, BT MECH 184, and BT MECH 12), known as 'Bollgard', are modified to be resistant to the bollworm, a pest known to devastate cotton crops, and were introduced to the subcontinent by a joint venture between Monsanto and the Indian firm Mahyco. The move to approve the varieties came after several years of controlled imports, small and then large environmental trials and subsequent farmer and popular protests, supreme court cases, open forums between Monsanto and Greenpeace and, in October 2001, the discovery of commercial Bt cotton farming in the state of Gujarat even though the Indian Genetic Engineering Approval Committee (GEAC) had not yet approved the crop. In April 2002, government-sanctioned commercial planting started in the states of Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh, Maharashtra and Tamil Nadu. In 2005, Bt cotton covered 1.26 million hectares in nine Indian states. However, the actual impacts of the GM variety on farmers' productivity and competitiveness remain unclear, as exemplified by the widely differing conclusions on the crop's success.

On the one side, several studies have concluded that farmers who adopted Bt cotton in a number of Indian states saw pest infestation rates drop and yields increase. In their widely-quoted study on the trial sites, Quaim and Zilberman reported a three-fold reduction in pesticide use for bollworm while sprays for sucking pests were found to be the same for GM and non-GM cotton. Bt cotton was also found to exceed the yields of non-modified counterparts by 80 to 87 percent. A subsequent assessment of commercial plantings also found yields from Bt cotton to have increased by 45 and 63 percent in 2002 and 2003 respectively *vis-à-vis* the non-GM varieties. However, while the study confirmed the significant reductions in pesticide use for bollworm, the additional costs of the GM seeds meant that average costs for Bt cultivation were higher compared to non-Bt cultivation (by 15 and 2 percent in 2002 and 2003 respectively).

On the other side, several non-governmental organisations, such as the Centre for Sustainable Agriculture and the Gene Campaign, have conducted research which they say shows that Bt cotton has led to lower profits and, in some cases, losses and suicides. They say that Monsanto-Mahyco should compensate farmers for their losses, and have urged the GEAC to cancel the permits for Bt cotton. Their findings suggest that higher costs of Bt seeds, which can be as much as three times the price of conventional seeds, along with higher spending on chemical pesticides to attack pests that are not affected by the Bt gene, result in net losses for many farmers. For example, a three-year study of Bt Cotton in the state of Andhra Pradesh by a coalition of organisations found that non-Bt cotton yields were 30 percent higher than Bt yields and had costs that were ten percent lower, and that changes in pesticide-related costs were minimal, owing to low pesticide use overall.

Sources: APCoAB, 2006; Bennett et al., 2004; Quaim and Zilberman, 2003; Qayum and Sakkhari, 2005.

a different understanding of the relative importance of *systemic* versus *technical* factors in the creation, perpetuation and alleviation of food insecurity and poverty. In a rift that has spread through the agriculture and sustainable development community, many southern civil society organisations, northern environmental groups and academics and governments alike have attacked the proposition that biotechnology can end hunger, saying that it cannot be a technological catch-all solution for what is a more systemic problem. While the supporters of biotechnology's potential to address hunger for the most part agree that it can not be a panacea, and should rather be an ingredient in the fight against poverty (FAO, 2004), some opponents suggest that the technology is at best incidental to the fight and at worst harmful (Orton, 2003).

Instead, systemic and structural problems are highlighted as the causes of hunger and poverty. These include skewed systems of land ownership, unfair commodity markets and fluctuating prices, poor access to capital, lack of a varied diet leading to malnutrition, displacement of the poor onto marginal lands and degradation of productive land through export-oriented monocropping practices (Rosset, 2005). Given that more than enough food is currently being produced to feed the world, the problem of food insecurity is seen as a problem of distribution and inequality that makes itself felt in rural areas through the mechanisms described above. It is argued that GMOs could in fact heighten food insecurity in cases where the GM crops are not tailored to local agricultural conditions or do not meet local economic and nutritional needs (as was allegedly the case for Bt cotton in India, see Biotech Headline 7). Critics suggest that resources should instead be used to support socio-economic changes and farmer-led participatory research networks (GRAIN *et al.*, 2004).

Q5 What are the benefits of biotech products to consumers?

Consumers can benefit from agricultural biotechnology through foods that have less pesticide residues, enhanced characteristics such as nutritional value, or are less expensive or better for the environment. However, there is a variety of farm-level practices, research and supply chain elements that determines whether these benefits actually come about.

A large part of the benefits that have accrued to consumers from the GM crops most widely commercialised today have resulted from decreased adverse health and environmental impacts where GM crops have led to reductions in pesticide and herbicide use. For instance, the reduction in pesticide use by Chinese farmers who grow GM crops has been shown to lead to relatively less crop-related health problems compared to those who grow conventional crops (Huang *et al.*, 2005). Changes in insecticide and pesticide use can also reduce adverse impacts on the environment, which consumers may value. Direct health benefits for those eating GM foods remain difficult to estimate empirically given that the average diet includes many non-GM items. The assumption that GM crops require fewer herbicides and pesticides, however, has been challenged by many biotech opponents and is clearly dependent on the nature of the crop, the local conditions and the agricultural system that was previously in use.

Consumers could also benefit from nutritionally enhanced GM products. Many consumers felt that they gained little from the 'first generation' of biotechnology, which focused on herbicide-tolerant and insect-resistant GM crops that were for the most part used for animal feed or processed into by-products such as oils, rather than being directly consumed by humans (Dibb and Mayer, 2000). In response, the biotech industry has been developing the so-called 'second generation' of GMOs which have been altered specifically to make them more appealing for consumers, for example, by increasing the beta-carotene content of rice or the protein content of sweet potatoes. Plants have also been modified to produce pharmaceuticals, such as bananas engineered to produce a Hepatitis B vaccine (Kumar *et al.*, 2005).

BIOTECH HEADLINE 8: Golden Rice

In 2000, scientists Ingo Potrykus and Peter Beyer from the Swiss Federal Institute of Technology ETH and the University of Freiburg in Germany announced that they had developed a new strain of rice that had been genetically modified to contain pro-Vitamin A (beta-carotene), which is used by the body to make Vitamin A. The new rice was dubbed "Golden Rice" because of the colour given by the beta-carotene. Vitamin A deficiency has devastating effects around the world – including up to 500,000 cases of childhood blindness, weakened immune systems and between two and three million deaths, largely in developing countries. It was hoped that Golden Rice, by providing substantial quantities of the beta-carotene could reduce the pervasiveness of the deficiency. The research that created the variety had been conducted within academia using public funds from the Rockefeller Foundation, Switzerland and the EU.

Shortly after developing the variety and applying for an international patent on it, Potrykus and Beyer went in search of a partner to assist them in transferring the technology to developing countries, securing the international patent and settling intellectual property rights (IPR) and technical property rights (TPR) issues. In May 2000, Potrykus and Beyer signed a deal with the biotech giant Syngenta (then known as Zeneca) according to which Syngenta bought the commercial rights to Golden Rice, granted non-commercial rights back to the inventors, promised to undertake research to improve the grain, and agreed to resolve outstanding patent restrictions on the tools used to create Golden Rice and assist with the testing and regulatory process.

An IPR audit showed that there were 70 IPRs and TPRs belonging to 32 different companies and universities that were associated with the experiments and final Golden Rice variety. Syngenta assisted in organising the free licensing of the patents, including from Monsanto, Syngenta itself and relevant universities, to enable the Golden Rice variety to receive its international patent and be distributed to commercial and humanitarian users.

A Golden Rice Humanitarian Board (GRHB) has been set up under the leadership of Potrykus and Beyer to ensure that the rice would be available for research and eventual free distribution in developing countries. Under the terms of the distribution plan, which has yet to be implemented due to lack of regulatory approval for planting and use of the crop, farmers in developing countries who are expected to earn less than US$10,000 from farming would be able to access the seed for free without paying royalties. Through the two-tier system created by the deal, Syngenta would control normal commercial release and prices for all other markets.

The inventors, along with the GRHB, have repeatedly stressed that Golden Rice can only be one part of a multi-faceted solution to malnutrition. However, Greenpeace and other critics have described the new technology as a "technical failure", saying that the average adult or child would have to eat many times their average intake of rice to get the daily recommended amount of Vitamin A. Its defenders respond that it would in fact be possible for women and children to get the recommended amount, and that Golden Rice's supplement would be complementary to other sources of Vitamin A in the diet. Also, in March 2005, the GRHB announced that a second strain of golden rice had been developed with a beta-carotene content 23-fold greater than the first strain, through which rice could deliver more than enough beta-carotene.

Another question concerns the extent to which the beta-carotene in the grain can be absorbed by the body and transformed into Vitamin A. For example, research shows that cooking and processing foods with beta-

carotene actually increases the extent to which it can be converted into Vitamin A in the body. However, the body's absorption of a single dose of beta-carotene as Vitamin A has been reported to vary from 4 to 55 percent. In addition to cooking and processing foods, other determining factors include the extent to which the person consuming the food is Vitamin-A-deficient (in which case higher absorption and bioconversion of beta-carotene is likely) and the presence of dietary oils and proteins which are necessary for the conversion. A recent study suggests that two-year-old children with Vitamin A deficiencies in developing countries would, through consumption of Golden Rice, be able to attain 58 percent of the recommended daily amount of Vitamin A. An economic analysis of Golden Rice furthermore concluded that the variety could provide substantial welfare gains by improving the health of workers in Asia and thereby increasing their productivity.

Greenpeace has argued that Golden Rice will not be able to address hunger, Vitamin A deficiency and malnutrition because it does not address systemic problems of access to and distribution of a range of healthy foods, and could in fact draw funding and attention away from more systemic solutions. In its statement announcing the release of the second variety of Golden Rice, the GRHB recognised that the GM variety is not a miracle solution, noting that "malnutrition is rooted in political, economic and cultural issues that cannot be magically resolved by a single agricultural technology. Golden Rice offers developing countries another choice in the broader campaign against malnutrition." Golden Rice-2 is currently undergoing field trials in India and the Philippines.

Sources: Anderson et al., 2004; Hess et al., 2005; Paine et al., 2005; Potrykus, 2001.

Consumers could also benefit from lower prices if producers of GM crops passed on the lower costs of production (Marra *et al.*, 2002; Bredahl and Kalaitzandonakes, n.d). The extent to which GM prices are lower will depend on the extent to which other actors at different stages of the agricultural supply chain, including the seed breeders, food processors and transporters, absorb price differentials resulting from lower production costs, as well as any additional costs that might accrue to GM varieties owing to segregation, labelling, regulation or related costs.

Medical biotechnology has delivered a wide range of health benefits to consumers, including the development of insulin and a variety of other drugs and diagnostic tools. In 2000, it was estimated that 100 biotech drugs and vaccines had been approved for use in the US, and that 270 million people have used these products for diseases such as Alzheimer's disease, cancer and heart disease (BIO, 2000). As a result, medical biotechnology has gained consumer support similar to that extended to other medical innovations and is regulated using, for the most part, the framework established for regular medical research.

Industrial biotechnology has revolutionised its field and facilitated the evolution of chemistry, biology and industrial practices; but the distance between such innovations and final consumers has meant that, beyond lower prices and better products, the direct benefits to consumers are not often analysed.

Q6 Should biotech products be subject to different rules than other technologies?

The approach to biotech products adopted by a government affects whether policy-makers decide to create a different set of rules for such products. There are broadly two types of approaches, namely a product-based approach guided by the 'substantial equivalence' principle and a process-based approach based on the precautionary principle. Each methodology, as described below, represents one end of a spectrum of possible approaches that a government can adopt; a combination of perspectives and practices is normal.

The product-based approach evaluates a novel product against an already approved counterpart by comparing the composition and characteristics of the two final products. This approach is based on the assumption that the process of genetic modification *per se* does not result in a different product. Countries adopting this principle often do not create a separate regulatory system for biotechnology, opting instead to regulate these products within the existing regulatory framework. The safety procedures tend to take the principle of 'substantial equivalence' as a starting point. Thus, the risk assessment begins by comparing the GMO to its conventional counterpart. If found to be substantially equivalent, the two products are subjected to the same safety considerations. If a food or food component is found to differ substantially from its counterpart, the safety evaluation focuses on the identified differences.

The concept of 'substantial equivalence' was developed by the OECD in 1993 as a guiding principle for safety assessment of genetically modified foods. Although there is no generally accepted definition of substantial equivalence, the concept is based on the assumption that the process of modern biotechnology "does not inherently lead to foods that are less safe than those developed by conventional techniques" (OECD, 1993:10). In other words, the substantial equivalence determination grants no significance to the fact that a product has been developed using modern biotechnology, but focuses solely on the compositional and other tangible characteristics of the GM product *vis-à-vis* its conventional counterpart (Kysar, 2004).

The substantial-equivalence approach, however, is controversial. It has been called "inherently anti-scientific" as it does not require biochemical and toxicological tests that would likely reflect critical differences (Millstone, 1999). It has also been criticised for not considering the unintended effects of genetic modification and the uncertainties regarding the effects of exposing humans, animals and other living organisms to the novel proteins generated by many GMOs that may not have physical manifestations in the GM product itself. Finally, it is considered inadequate for not taking into account significant, though non-scientific parameters such as consumer and ethical concerns (Stilwell, 1999).

The process-based approach, on the other hand, compares products by evaluating whether they were created using the same or different processes. Even if the final products are identical, a risk assessment is carried out if the production process was found to be different (such as genetic modification *vis-à-vis* traditional breeding), assuming that the process itself might impact on the final product. This approach is often based on the precautionary principle, which states that where there are threats of serious or irreversible damage to human health and the environment, lack of full scientific certainty should not be used as a reason for postponing measures to prevent possible harm. Thus, advocates of the principle argue that, given the lack of certainty regarding the long-term impacts of genetic modification, it is prudent to regulate GMOs in a way that presumes that they are different from conventional organisms.

The actual approach adopted by a government, and whether it decides to create a different set of rules, often reflects a mixture of the sentiments described above, motivated by the need to balance the risks and opportunities presented by biotech products. These risks and opportunities are discussed in Sections B.1 and B.5. In practice, many governments have chosen to develop separate rules to evaluate the safety and regulate the use of agricultural biotech products. Supporters of a distinct regulatory framework have also pointed to the Biosafety Protocol's existence as proof that the international community has recognised that biotech products require their own, distinct authorisation process.

Despite these differences in approaches, some forms of biotechnology have been widely recognised as posing unique regulatory challenges. For example, while medical biotechnology is largely regulated through existing legal frameworks for the pharmaceutical sector, some applications, such as human stem cell research or the cloning of animals, are generally seen as different from conventional animal and health research, not least due to the ethical concerns they have evoked. Similarly, most would agree that GM crops used to produce industrial or medical compounds should be grown under more restricted conditions than conventional crops (and GM food crops, some would argue) to avoid cross-pollination and intermingling with food crops.

Q7 What has been the role of the private and public sectors in biotechnology research?

While the public sector has provided some of the key innovations necessary for the development of biotechnology tools and products, the commercialisation of biotech products has been driven by the private sector, notably from pharmaceutical, industrial and chemicals companies (Charles, 2001; Graff *et al.*, 2003). The pioneers of agricultural biotechnology were scientists at the chemical firms that had developed, promoted and marketed pesticides and herbicides and were looking for new technologies with lower health and environmental impacts. As a result, companies like Monsanto poured money into the early years of biotechnology research, both doing work in-house and purchasing relevant work of university researchers (Winston, 2002).

In the process, some of the major breakthroughs in the field – the discovery of the *Agrobacterium*, *Bacillus thuringiensis* and the gene gun – either happened within the private sector or ended up under the protection of their intellectual property rights. After decades of financing basic and applied research, private sector actors began turning out biotech crops to cash in on lucrative markets in the US and other developed-country markets. At the same time, they created partnerships with plant breeding companies to incorporate their technologies into local varieties. These multinational companies continue a complex pattern of consolidation and mergers that has enabled them to finance cutting-edge research and safeguard the results through intellectual property rights. Today, the supply of GM seeds is dominated by a few large companies, including Aventis, Dow, Du Pont, Mitsui, Monsanto and Syngenta, which are estimated to control 98 percent of the global market for patented biotech crops (ActionAid, 2003).

The freedom of operation, salaries and flexibility offered by these companies led in the 1980s and 1990s to a movement of top researchers in the biological sciences to private companies, thereby shifting the locus of biological scientific research in the last half of the twentieth century from universities to the private sector (Charles, 2001). Some have argued that this has resulted in a shift in research away from farm-level technologies to increase agricultural productivity – traditionally the focus of the public sector – towards a greater emphasis on commercially important food products and agrochemicals by the private sector (see also Section B.4).

This shift towards private sector control is in marked contrast to what happened during the Green Revolution when new varieties of developing country crops created by research conducted in public sector research institutions and those of the Consultative Group on International Agricultural Research (CGIAR) led to an explosion in agricultural productivity in developing countries. The research environment was, in comparison to that of modern biotechnology, much more centred on the public sector, characterised by more sharing of genetic resources amongst research institutions, weaker intellectual property protection of the final results and greater (explicit and implicit) orientation towards addressing public policy objectives.

These differences in the research environment have – at least partly – been attributed to certain differences between biotechnology and conventional agricultural research (Trigo, 2005). Biotechnology research involves the use of basic sciences, such as biology, genetics, biochemistry, physiology and high-cost specialised research into new genes and how to insert them directly into seeds. In contrast, conventional research depended on the cross-breeding of crops and a direct link to how the technology could be applied. In the latter scenario, the direction of research is from specific problems to scientific inquiry, while for biotechnology crops the research into genetic constructs is more 'horizontal' and basic-science. As such, biotechnology research demands multi-disciplinary, high-level research with relatively more expensive tools, which increases the incentive to make the resulting technology proprietary. Others have argued that the additional cost of complying with biotech-specific safety regulations has also contributed to significant increases in the cost of bringing a biotech product to the market. Yet others point to cuts in funding to international agricultural research in the 1990s which has slowed down research in crops and traits of importance to small-scale farmers in developing countries but of limited commercial value.

Nevertheless, publicly-funded institutions have made strides in promoting research into GM varieties that meet the needs of developing countries (Cohen, 2005). Notably, all biotechnology research in China is conducted by the public sector and dates back to the 1980s. Crop biotechnology research networks also provide interesting examples of using biotechnology and entrepreneurship as tools of empowerment for rural communities (Aernie, 2006). The Cassava Biotechnology Network, for instance, brings together cassava researchers and end-users who apply biotechnological tools to cassava – one of the key staple crops in Africa – to address challenges facing small-scale agricultural producers in particular, such as pest and virus infestation or high cyanide content in some varieties.

In addition, several public-private partnerships have developed. Research, for example, has been conducted on virus-resistant sweet potatoes by the Kenyan Agricultural Research Institute (KARI) in Nairobi in partnership with Monsanto and with assistance from USAID and the World Bank, though some controversy surrounds the choice of the crop, trait and the results from the project (DeGrassi, 2003). Other examples include 'Golden Rice' which was developed by university scientists who subsequently signed a deal with Syngenta that allows for free dissemination of the variety to poor farmers (see Biotech Headline 8). Interestingly, dozens of private-sector owners of patents on the inputs used to create Golden Rice decided to waive their rights in this case because the GMO was targeted at poverty reduction in developing countries. However, most institutions find the regulatory requirements and availability of patented seeds to be particularly challenging.

Virtually all analyses of the impact of biotechnology on poverty alleviation and sustainable development agree that more public sector initiatives and public-private partnerships aimed at meeting the needs of the poor are necessary to make biotechnology deliver on its potential to address poverty reduction and enhance food security in developing countries (Sithole-Niang *et al.*, 2004).

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B.2 Multilateral trade rules

The relationship between multilateral trade rules established in the context of WTO and national regulations and measures related to biotechnology and biosafety is at the core of the trade and biotechnology debate and remains uncertain despite extensive analysis and discussion. This section will address some of the issues raised by the application of WTO rules to trade in biotechnology, including the applicable agreements, the interpretation of key terms in regard to genetically modified organisms, and the role of consumer concerns and standard-setting bodies. The section will focus on the text of WTO agreements and the varying interpretations submitted by countries, civil society groups and other commentators. In particular, the arguments presented in the European Communities – Measures Affecting the Approval and Marketing of Biotech Products (*EC-Biotech*) case will be used to exemplify the different positions on the linkages between trade rules and biotechnology, as well as the relevance of WTO rules to the adequate regulation of biotechnology. The findings of the final report on the case, issued by a WTO Dispute Settlement Panel on 29 September 2006, will also be referenced.

Q8 What WTO agreements apply to trade in biotechnology products?

Several WTO agreements are relevant to trade in biotechnology: (1) the General Agreement on Tariffs and Trade (GATT) which establishes the basic principles and rules for trade in goods; (2) the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) which deals with food safety and animal and plant health regulations; and (3) the Agreement on Technical Barriers to Trade (TBT Agreement), which addresses technical regulations and standards, including packaging, marking and labelling requirements. In addition, the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), which establishes minimum standards of protection for intellectual property, is also pertinent to biotechnology. Section B.4 will analyse in detail the relationship between intellectual property and biotechnology.

The extent to which and circumstances in which these agreements apply to biotechnology-related measures, however, are still uncertain.

- The GATT covers all international trade in goods between WTO Members, and would thus also apply to trade in biotechnology products. Nevertheless, the WTO Panels or Appellate Body generally only turn to the GATT in relation to issues not covered by more specific agreements. In certain cases, though, the GATT may apply concurrently with a more specialised agreement, such as the TBT or the SPS agreements. Moreover, these specific agreements would only prevail to the extent that there is a conflict between their provisions and those of the GATT; otherwise, both the general and the more specific agreements would continue to apply to the greatest extent possible (Zarrilli, 2005).

- The SPS Agreement applies to all sanitary and phytosanitary measures that may, directly or indirectly, affect international trade. Annex A (1) of the SPS Agreement defines SPS measures primarily on the basis of their purpose, including protecting animal or plant life or health from risks arising from pests and diseases, and from risks arising from additives and toxins in foods, beverages or feedstuffs. Annex A(1) also provides examples of the types of measures that are covered, such as laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; and quarantine treatments. To the extent that biotechnology-related measures address food safety concerns such as potential

toxicity, allergenicity, and antibiotic resistance, they would thus fall under the SPS Agreement. Measures with environmental objectives, insofar as they address pesticide resistance, genetic flow, and other animal and plant health issues, might also be considered to constitute SPS measures under WTO rules (Wolff, 2005). Indeed, in the EC-Biotech Report, the Panel developed a broad interpretation of the definition of an SPS measure and found the SPS Agreement was applicable to the EU approval procedures, as well as to the challenged measures – the general moratorium on approvals of biotech products, failure to provide final decisions on specific products and national safeguard measures (WTO, 2006).

- The TBT Agreement aims to ensure that technical regulations and standards do not create unnecessary obstacles to international trade. All products, including industrial and agricultural products, are subject to its provisions. However, Article 1.5 of the TBT Agreement states that its provisions do not apply to sanitary and phytosanitary measures. Measures such as packaging, marking and labelling requirements for biotechnology products – labelling to identify nutritional values, for example – would thus be considered under the TBT Agreement.

Q9 What issues are raised by the application of WTO rules in biotechnology?

The WTO rules that apply to a particular measure are significant given that the GATT, the SPS Agreement and the TBT Agreement each have different requirements that must be fulfilled for conformity. Moreover, the nature of biotechnology products raises particular challenges and opportunities in the context of each of these agreements.

In the GATT, several provisions are likely to be particularly relevant to trade in biotechnology. First, two of the core principles of the agreement – the national treatment and the 'most favoured nation' obligations – require countries to grant equal treatment (in terms of laws and regulations, for instance) to products of national and foreign origin, and products originating in or destined for the territories of different WTO Members, considered 'like products'. Whether genetically modified products and other non-modified products are 'like products' has been particularly controversial, as will be seen below.

Another important issue in the context of the GATT is whether biotechnology-related measures can be considered necessary "to protect public morals", " protect human, animal or plant life or health" or "relating to the conservation of exhaustible natural resources" and thus fall within the exceptions to GATT provisions established by Article XX. Moreover, even if Article XX is found to include such measures, they would still be subject to the requirement that they are not applied in a manner that would constitute "a means of arbitrarily or unjustifiable discrimination between countries where the same conditions prevail", or "a disguised restriction on international trade".

The SPS Agreement is perhaps the most relevant legal framework for biotechnology-related measures in the WTO context insofar these measures are generally aimed at safeguarding food safety or plant and animal health. Moreover, given its science-based approach to ensuring measures relating to human, animal, and plant health do not represent unnecessary, arbitrary, or disguised restrictions on international trade, it also poses the most difficult challenges for biotechnology-related measures. As will be further described below, the SPS Agreement encourages countries to base their measures on international standards, guidelines and recommendations, granting measures based on these standards the presumption of consistency with its provisions. However, where no standards exist or a country chooses to adopt a stricter standard

than the one established internationally, measures must be based on a risk assessment – thus the SPS Agreement aims to prevent the use of SPS measures for protectionist purposes.

Another significant element of the SPS Agreement is Article 5.7 of the SPS Agreement, which recognises the right of countries, in cases where relevant scientific evidence is insufficient, to provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information (see Section B.3).

The TBT Agreement could present a number of advantages from the perspective of countries implementing biotechnology-related measures. For instance, the TBT Agreement, while requiring these measures to be no more trade-restrictive than necessary to achieve a legitimate objective, does not require the same rigorous standard of scientific basis demanded in the SPS Agreement. Moreover, the open list of legitimate objectives in Article 2 includes the "protection of human health or safety, animal or plant life or health, or the environment". Another potentially important justification for GMO labelling that would also fall under the scope of the TBT Agreement is the right of consumers to information and choice. In addition, the TBT Agreement is open-ended as to the international standards on the basis of which WTO Members can prepare, adopt or apply a technical regulation that will be rebuttably presumed not to create an unnecessary obstacle to international trade. As a result, the provisions of the Cartagena Protocol on Biosafety, for instance, could be used as a basis for technical regulations. Nevertheless, because the TBT Agreement does not allow for discrimination between 'like products', similar problems as in the GATT context may arise given the lack of agreement on how this concept applies to biotechnology products. Finally, it is worth noting that technical regulations can include "terminology, symbols, packaging, marking or labelling requirements that apply to a product, process or production method", whose relevance in the context of biotechnology is discussed below.

Q10 What is the EC-Biotech case about?

In August 2003, a Panel was established under the WTO dispute settlement process to address claims by the US, Argentina and Canada that various measures allegedly taken by the EU and EU member states were inconsistent with WTO rules. These measures included:

- An alleged general de facto moratorium on the approval of biotechnology products in the EU since October 1998;
- The EU's failure to complete approval procedures for certain specific applications (so-called 'product-specific measures') – in total, 27 of these product-specific measures were challenged, and;
- Nine safeguard measures in the form of import and/or marketing bans applied to specific biotech products ('nation-level bans') adopted by six EU member states (Austria, France, Germany, Greece, Italy and Luxembourg).

The complaining parties and the panel stressed that it was not the WTO-consistency of the EU approval legislation as such that was being questioned, but rather the manner in which the legislation was being applied. EU approval legislation relevant for the case included Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, which repealed Directive 90/220/EEC; and Regulation 258/97 on novel foods and novel food ingredients.

On 29 September 2006, the Panel issued its final report, ruling in favour of the complainants. In particular, the Panel concluded that a general *de facto* moratorium did exist and resulted in an "undue delay" in the application of approval procedures, thus violating Article 8 and Annex C of the SPS Agreement. The Panel also found that there was "undue delay" in the completion of the approval procedure with respect to 24 of the 27 specific product applications. Finally, the Panel found that

the nine safeguard measures taken by some EU member states failed to meet the science-related requirements of the SPS Agreement. Nevertheless, the European Commission has depicted the results as "largely of historical interest" and highlighted they will not affect or alter European legislation on biotechnology products.

The situation in relation to the national safeguard measures seems to be the most complex. Under EU legislation, these measures are provisional and subject to an assessment at European level that either modifies the EU approval or terminates the measure. In June 2005, the EU Environmental Ministers had in fact rejected European Commission proposals that these national measures be lifted (ICTSD, 2005a). Nevertheless, the Panel's findings do not in themselves require a withdrawal of the safeguard measures. EU member states would be able to bring these measures in compliance with the ruling by conducting or putting forth risk assessments as defined by the SPS Agreement.

Q11 How should biotech regulations be notified?

Notification requirements are considered essential to achieving one of the fundamental aims of the WTO system: a greater degree of clarity, predictability and information about trade policies, rules and regulations of Members. In this regard, a direct link between notification requirements and transparency is often made in the WTO context. In the biotechnology context, the concept of 'transparency' is broader – including concerns regarding accurate information for an adequate scientific and public debate, and assessment of risks – but also incorporates the need to have access to information and to be able to influence biotechnology and biosafety-related decisions (van Dommelen, 2000). Under the SPS and TBT agreements, notification requirements are used to inform other WTO Members about new or changed regulations that affect trade, including through the obligation to respond to any specific questions other WTO Members may have. Notification requirements are complemented by rules regarding the publication of regulations. As will be seen below, both notification and publication rules came into play in the *EC-Biotech* case.

Article 2.9 of the TBT Agreement establishes that whenever a technical regulation is not based on international standards and "may have a significant effect on trade", countries are required to notify other WTO Members through the WTO Secretariat, allowing for comments and taking these comments into account. To provide the opportunity for meaningful participation, notification requirements must be fulfilled at "an early appropriate stage". Nevertheless, where urgent problems of safety, health, environmental protection or national security arise or threaten to arise, a country may omit the notification requirements as it finds necessary. It must, however, upon adoption of the technical regulation, fulfil several requirements including notifying other WTO Members through the WTO Secretariat and providing copies of the regulation upon request, allowing for comments and taking these comments into account.

Under the SPS Agreement WTO Members are obliged to notify other Members of changes and provide them with information on their sanitary or phytosanitary measures. In particular, and similarly to the TBT Agreement, when measures are not based on international standards and may have a significant effect on trade of other Members, countries must notify other Members through the Secretariat, allowing reasonable time for other Members to make comments in writing, discussing these comments upon request and taking the comments and the results of the discussions into account. However, where urgent problems of health protection arise or threaten to arise, a country may omit notification requirements. Nevertheless, once the measure is adopted, the country must, *inter alia*, immediately advise other Members of the regulations, allowing for comments and taking them into account.

The SPS Committee has adopted a number of recommendations in regard to notification procedures. In November 2000, the WTO Secretariat also prepared a handbook entitled *How to apply the Transparency Provisions of the SPS Agreement*. The handbook clarifies that the SPS Agreement does not require countries to notify the WTO of specific SPS decisions – for example, the marketing approval of a product containing GMOs – but rather of any proposed generally applicable SPS regulation such as a law, a decree or an ordinance, as well as proposed modifications to such regulations. Moreover, the obligation to notify only applies if there is no international standard, guideline or recommendation; or the proposed regulation is different to an existing international standard, guideline or recommendation; and if the regulation may have a significant effect on trade of other countries. When a regulation contains elements that fall under both the SPS and TBT agreements, it should be notified according to both.

Q12 Are mandatory traceability and labelling requirements unnecessarily trade-restrictive?

Labelling and traceability requirements are considered by many consumer groups to be an essential tool for implementing the right of consumers to receive information about the products they purchase. The Transatlantic Consumer Dialogue (TACD), for example, has repeatedly urged the EU and the US to recognise and advocate to other WTO Members that consumers have the right to know about the products they purchase, and that both voluntary and mandatory labelling programs that support the rights of consumers to know about the products they purchase are not *a priori* inconsistent with WTO rules.

In the biotechnology context, labelling and traceability requirements are also considered important due to concerns relating to food safety and the perceived need for public awareness and informed public debate, a broader precautionary approach and promoting economic efficiency by the internalisation of risks and costs (Stilwell, 1999a). On the other hand, the biotechnology industry and some civil society organisations consider that labelling and traceability requirements, particularly mandatory systems, could actually confuse or mislead consumers by suggesting that biotechnology products are inherently different or pose safety concerns when compared with traditional foods (e.g. BIO, 2000). In addition, these groups consider that mandatory traceability and labelling requirements for biotechnology products are fast becoming significant barriers to trade, often implemented in a way that violates key elements of WTO agreements. In particular, critics of mandatory traceability and labelling systems for biotechnology products argue that these systems often do not meet the requirement, established in both the SPS and TBT agreements, for measures to be "no more trade restrictive than necessary" (this is raised especially in relation to products derived from but no longer containing genetically modified organisms, as it is argued they are 'like' products under WTO rules – see discussion in Q13).

The SPS and TBT agreements require measures and technical regulations to be no more trade restrictive than necessary when those measures and regulations do not conform to international standards, guidelines or recommendations, and are thus not presumed to be consistent with WTO rules. Given that currently there are no international standards for labelling and traceability in regard to products of biotechnology (see Q14), determining the application and impact of this requirement is particularly important.

Under the SPS Agreement, countries must ensure that sanitary and phytosanitary measures are "not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility". A footnote clarifies that, for the purposes of that article of the SPS Agreement,

"a measure is not more trade-restrictive than required unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade". As a result, the United States, Canada, Australia, Argentina and other countries have argued that there are less trade-restrictive measures than a mandatory approach to biotechnology-related labelling. These less trade-restrictive measures might include labelling requirements to address particular health concerns such as allergenicity or toxicity, management strategies to deal with potential environmental risks, or voluntary labelling schemes for non-biotechnology foods to provide consumer information (Baumüller, 2003). Nevertheless, it is important to highlight that, under the SPS Agreement, WTO Members have the right to determine the level of protection deemed appropriate to safeguard human, animal or plant life or health within its territory, and may even find 'zero' to be the acceptable level of risk. Commentators point out, however, that because the level of protection only refers to human, animal or plant life or health, mandatory labelling and traceability systems that require labelling of all biotechnology products, regardless of their risks to health, may be considered more trade restrictive than required (Stilwell, 1999b).

Labelling and traceability systems seeking, for example, to provide consumers with information, facilitate monitoring of the effects of products of biotechnology on the environment and on health, and enable the rapid withdrawal of these products if an unexpected risk to human health or to the environment is detected, would thus likely be considered under the TBT Agreement (for more information on the scope of the TBT Agreement, see Q8). Article 2.2 of the TBT Agreement requires technical regulations established by WTO Members to "not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create". The meaning of "not more trade restrictive than necessary" has not been authoritatively determined in the context of the TBT Agreement. The word "necessary" has been interpreted in some dispute settlement cases as "least trade restrictive," but such an interpretation in the TBT context would place undue limits on governments' abilities to pursue their policy goals. In this regard, the definition of not more "trade-restrictive than required" in the SPS Agreement is seen as more adequate.

The debate on these issues has been particularly heated around the European traceability and labelling regulation for products of biotechnology. In the EU, GMOs and food products derived from GMOs placed on the market must comply with labelling and traceability requirements. These requirements are found in Regulation EC 1829/2003 and in Regulation EC 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. For instance, food products containing or consisting of GMOs, produced from GMOs or containing ingredients produced from GMOs must be labelled, regardless of whether or not the final product contains DNA or protein resulting from genetic modification. The traceability rules determine that anyone who places a biotechnology product on the market or receives a biotechnology product placed on the market in the EU must be able to identify their supplier and the companies to which the products have been supplied. There is an exemption from both labelling and traceability, however, for conventional products, i.e. those produced without genetic modification, which were contaminated unintentionally by GMOs during harvesting, storage, transport, or processing if they contain GMO traces below a 0.9 percent threshold level.

The United States, Canada and other countries and industry groups have argued that these regulations are unnecessarily trade-restrictive. The US Grocery Manufacturers Association (GMA), for instance, in a letter to the Office of the U.S. Trade Representative

in February 2003, stated that it considers the EU mandatory labelling and traceability system to be inconsistent with the TBT Agreement. In particular, the GMA highlighted the technical difficulties associated with compliance, including the lack of a single validated test for determining whether a food is derived from biotechnology and should be labelled, and what it considers are "exceedingly low" thresholds that would not accommodate accidental residues in grain handling and food systems. The European Commission, on the other hand, has stated that it expects the transmission and retention of the information required in the mandatory labelling and traceability systems to be largely incorporated into existing systems for transactions and would therefore not imply significant extra costs for operators (Baumüller, 2003). Moreover, civil society groups within Europe argue that such a strict system is necessary for clearer information to be passed on to the consumer and for governments to be able to remove GMOs from the food chain as soon as possible should new evidence of harm arise.

Q13 Are genetically modified and non-modified products 'like products'?

The most favoured nation treatment and national treatment obligations – two of the core principles of the GATT – prohibit discrimination between 'like products'. Article III.4 of the GATT – one of the references to 'like products' in relation to national treatment – states that "the products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use."

The concept of 'like products' is also fundamental to the TBT Agreement. Article 2.1 of the TBT Agreement stipulates that WTO Members are not allowed to treat imported products in a "less favourable" manner than "like products of national origin". As a result, whether import and other regulations for GMOs would be considered discriminatory vis-à-vis conventional products is a crucial issue in determining their consistency with WTO rules. The concept of 'like products', however, is not necessarily the same between the various agreements and their respective provisions (Bernasconi *et al.*, 2005).

No precise definition of 'like products' has thus far been developed in the WTO. In relation to the above-mentioned GATT provisions, the WTO Appellate Body has said that an assessment using individual and discretionary judgment must be made on a case-by-case basis (WTO, 2001). Nevertheless, four criteria have been suggested and used in WTO jurisprudence as a framework for analysing the 'likeness' of products. To determine if products are the same, the following four kinds of characteristics can be examined:

1. the physical properties of the products;
2. the extent to which the products are capable of serving the same or similar end-uses;
3. the extent to which consumers perceive and treat the products as alternative means of performing particular functions in order to satisfy a particular want or demand; and
4. the international classification of the products for tariff purposes.

In each case, a WTO Panel or Appellate Body must examine all of the evidence relevant to a determination of likeness, including the evidence relating to each of those four criteria, before deciding whether the products at issue could be characterised as 'like' (WTO, 2001). In the biotechnology context, two of the criteria are likely to be particularly challenging for WTO Panels. First, whether the physical properties and nature of GMOs are the same as those of conventional products is a heated ongoing debate (see Q6 on the concept of

'substantial equivalence'). Second, the perceptions and behaviour of consumers are remarkably polarised and intense in the context of biotechnology and exhibit considerable regional variations. In the *EC-biotech* case, the EU had argued that the international community had, through international agreement such as the Convention on Biological Diversity (CBD) and the Biosafety Protocol, accepted that GMOs are not to be treated as being the same as their conventional equivalents, and that special measures of protection, based on the precautionary principle, are justified (WTO, 2006).

Once 'likeness' has been established, the complainants would have to show that 'like' imported products are given less favourable treatment than 'like' domestic products (for the measures to be in violation of WTO rules). Various WTO panels, including in the *EC-biotech* case, have also stressed that complainants would need to prove that the *foreign origin* of the product had been the motivation for the alleged discrimination – rather than, for instance, the "perceived difference between biotech products and non-biotech products in terms of their safety" (para. 7.2514) and had resulted in any detrimental effects on an imported product (rather than other factors such as market share of the importer (WTO, 2001; WTO, 2006).

Other concepts that may arise in the determination of likeness in the biotechnology context are also quite challenging in the WTO, including 'substantial equivalence' and non-product-related processes and production methods or PPMs. In regard to the PPMs discussions, it must be noted that current interpretations of the GATT do not accept the manner in which a particular product is manufactured, if the production process is not detectable in the final product, as a basis on which to distinguish between products. Therefore, it is uncertain whether consumer concerns related to PPMs – for instance the use of animal testing or biotechnology in developing the product – would be able to support the WTO consistency of import bans or other such measures. In the context of the TBT Agreement, the extent to which PPM-based measures are allowed remains controversial. Some commentators believe that the 'like product' test in the TBT Agreement should be narrowly defined to differentiate on basis of processes, regardless of whether physical difference can be easily ascertained, thus allowing disparate measures for genetically modified and non-modified products.

Even if biotechnology and conventional products are found to be 'like', it should be noted that WTO Members may still justify regulations that distinguish between them under the exceptions of Article XX of the GATT, which also applies in the context of the TBT Agreement. Article XX of the GATT states that nothing in the GATT Agreement shall prevent WTO Members from adopting measures "necessary to protect human, animal or plant life or health" or "relating to the conservation of exhaustible natural resources" as long as "such measures are not applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade."

Q14 What is the role of international standard-setting bodies?

The harmonisation of measures and regulations based on international standards is one of the primary objectives of both the SPS and TBT agreements. Indeed, sanitary and phytosanitary measures and technical regulations based on international standards are presumed to be consistent with WTO rules. As a result, the standards and guidelines developed by international standard-setting bodies in the field of biotechnology will be critical in determining the measures and regulations that may be adopted by WTO Members in relation to genetically modified organisms and products.

The SPS Agreement establishes that sanitary or phytosanitary measures that conform to international standards, guidelines or recommendations of the following international standard-setting bodies are

presumed to be consistent with its provisions: (1) the Codex Alimentarius Commission (Codex) in relation to food safety; (2) the World Organization for Animal Health (OIE); (3) the Secretariat of the International Plant Protection Convention for plant health; and (4) other relevant international organisations open for membership to all Members, as identified by the SPS Committee, for matters not covered by the previous organisations, though no additional body has thus far been agreed upon. Of these international standard-setting bodies, both the Codex and the International Plant Protection Convention (IPPC) have already developed biotechnology-related standards and guidelines (see also C.6 and C.7).

An Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology was created by the Codex to develop standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology. These standards, guidelines, and recommendations are to be developed on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair trade practices. To date, the Codex has adopted three standards relevant to biotechnology, including the "Principles for the Risk Assessment of Foods Derived from Modern Biotechnology" and the "Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants." Efforts are also under way in the Codex towards developing labelling standards for biotechnology foods.

At the IPPC, the 2001 report of a working group on the phytosanitary aspects of genetically modified organisms and biosafety recommended "as a matter of urgency" that detailed standard specifications be drafted, in co-ordination with CBD experts, in the biotechnology context. A standard for the "Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms," for example, was adopted in 2004.

In 2005, the OIE adopted several resolutions on genetically engineered animals and the relationship between the implementation of the organisation's standards and international trade. OIE members stressed the importance of developing standards in this field. Although genetically engineered animals are subject to the organisation's overall risk assessment standards, some members raised concerns about the unique risks posed by this type of engineering and the lack of standards for regulations that aim to address them. OIE members thus created an Ad Hoc Group on Biotechnology and asked the Secretariat to develop and adopt standards and guidelines for: research and use of vaccines for animals produced through biotechnology, animal health risks linked to cloning, exclusion of unapproved animals and products from the livestock population and segregation from the feed and food supply, and animals that have been genetically engineered to produce medicines or chemicals (ICTSD, 2005b).

The TBT Agreement, unlike the SPS Agreement, does not limit the sources of international standards that WTO Members may use for their technical regulations for a presumption of not being unnecessarily trade-restrictive. As a result, other international standards on biotechnology become relevant, such as those developed by the International Organization for Standardization (ISO). The ISO is a non-governmental organisation that links the national standards institutes of 156 countries. In the ISO, the technical committee on food products, which addresses standardisation in the field of human and animal foodstuffs as well as animal and vegetable propagation materials, in particular terminology, sampling, methods of test and analysis, product specifications and requirements for packaging, storage and transportation, has a working group on GMOs and derived products. This technical committee has developed, for instance, standards on the methods of analysis for the detection of GMOs and derived products in foodstuffs.

In addition, it has been argued that the provisions of the Cartagena Protocol on Biosafety, as well as the work conducted by the Conference of the Parties (COP) acting as Meeting of the Parties (MOP) (see Section B.3), for instance, could play a significant role as international standards in the context of the TBT Agreement. For example, Article 18 of the Biosafety Protocol provides for handling, transport, packaging and identification of living modified organisms that are subject to intentional transboundary movement and requires the COP-MOP to consider the need for and modalities of developing standards with regard to identification, handling, packaging, and transport practices. It is interesting to note that the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol included a specific request to the Executive Secretary to establish co-operation with the World Customs Organization, the ISO, the United Nations Transport of Dangerous Goods Sub-Committee, the International Air Transport Association and other relevant customs and transport organisations, with a view to developing harmonised approach for the packaging and transport of living modified organisms (and the Secretariat eventually included the Codex in its consultations), highlighting the difficulties raised by the fragmentation of standards related to biotechnology.

References and further reading

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B.3 Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety (the 'Biosafety Protocol') is the only international agreement specially designed to address the challenges posed by the international trade of GMOs. In aiming to ensure an adequate level of protection in the transfer, handling and use of "living modified organisms", the Biosafety Protocol focuses on transboundary movements, which include trade. The relationship between the trade-related measures in the Biosafety Protocol and the WTO rules, which also govern biotechnology products (as described in Section B.2), has thus been the object of much speculation. This section will focus on some of the main issues for trade and biotechnology raised by the Biosafety Protocol and its relationship with multilateral trade rules.

Q15 Are living modified organisms different from genetically modified organisms?

The Biosafety Protocol uses the term 'living modified organism' (LMO) instead of the more commonly used 'genetically modified organism' (GMO), which has generated some confusion as to how these expressions relate to each other. According to Article 3 of the Biosafety Protocol, an LMO is "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology". The term 'GMO' which is used in the vernacular to refer to organisms produced by biotechnology, was avoided as more of a political than a scientific label (see Section A.2, and IUCN, 2003).

The reference to 'LMO' however, has raised concerns due to interpretations of the term that exclude products of biotechnology that are considered GMOs from the Protocol. Some commentators, for instance, have criticised the exclusion of "non-living" organisms (Li Ching, 2004). Under the Protocol, an LMO is "living" when it is a biological entity capable of "transferring or replicating genetic material". As a result, genetically modified seeds, cuttings and tissue cultures, for example, which are living parts of plants, are covered by the Protocol (FAO, 2004). On the other hand, non-living products derived from or containing GMOs, such as milled maize and soybean derivatives used in many foods and nonfoods, and yeast-based foods such as beer and bread, are not included (CBD, n.d.). Viruses and viroids, which are incapable of self-replication but can insert their genetic material into the cells of other organisms and thus reproduce, are nevertheless explicitly included (Mackenzie *et al.*, 2003). Sterile organisms, which can replicate their genetic material and may reproduce asexually, are also explicitly mentioned.

Since "organisms" are generally defined as living beings with the ability to function independently and/or reproduce, it is unclear, however, how qualifying them as "genetically modified" rather than "living modified" would have extended the scope of the Protocol. Moreover, the terms 'GMO', 'genetically engineered organism' and 'transgenic organism' are still widely used, including in legislation implementing the Protocol. Malaysia, for instance, is reported to have signed the CBD only with the written clarification that it interpreted 'LMO' as a term identical to 'GMO'. The EU directives on biotechnology also refer to 'GMO'.

Indeed, the restriction in the scope of the Protocol seems to have occurred, instead, in the exclusion – for the most part – of processed materials of LMO origin, also referred to as "products thereof" (MacKenzie, 2003). During extensive negotiations on the objective and scope of the Protocol, most developing countries favoured a broad and comprehensive approach, which incorporated products of LMOs. In the sixth meeting of the Open-ended Working Group on Biosafety, for example, Ethiopia, on behalf of the African Groups, argued for such an inclusion. Similarly, non-governmental organisations such as the Third World Network cited concerns posed by products of LMOs, including

cases of "considerable amount of recombinant DNA persisting in soy proteins", a product of transgenic soy beans, which "can be transferred to the microflora in the intestinal tracts of humans and animals, and thence to the environment, including soil and water systems".

Other countries and stakeholders, however, argued for a more limited scope for the Protocol. The US, for example, was "adamantly opposed" to subjecting products of LMOs to the Advance Informed Agreement (AIA) procedure. **Rafe Pomerance**, Deputy Assistant Secretary of State of the US at the time of negotiations, for example, noted: "products derived from GMOs are, to say the least, (of) extremely low risk to biodiversity".

The Protocol, ultimately, did not refer to products of LMOs in its objectives and scope, but they are addressed in Article 20(3)(c), Annex I(i) and Annex III(5), which refer to information required for the Biosafety Clearing House and for notifications and risk assessments under the AIA procedure. In this context, products of LMOs are defined as "processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology".

Q16 Is the Cartagena Protocol on Biosafety compatible with WTO rules?

As mentioned, several WTO agreements are relevant to the transboundary movement of GMOs (see Q8). All of these agreements may thus, to varying degrees, affect the implementation of the Biosafety Protocol.

The SPS Agreement seems to have raised the most concerns regarding the compatibility of the Protocol with WTO rules, for several reasons. First, the scope of the SPS Agreement would seem the most akin to that of the Protocol. National measures taken to implement the Protocol are likely to have a range of purposes. Nevertheless, because they will ultimately aim to prevent "adverse effects on the conservation and sustainable use of biological diversity", they are also likely to focus on a particular risk to plants or animals, and thus be considered SPS measures under the SPS Agreement. For example, a decision to ban a particular strain of Bt cotton under the AIA procedure, while essentially responding to overarching environmental concerns, may endeavour concretely to prevent the crop from promoting resistance to Bt in insects and contributing to a pest problem. Second, due to the Protocol also adopting a science-based approach, comparisons between the two regimes are inevitable. Indeed, the use of risk assessments in both instruments is remarkably similar, although it is not certain whether measures taken under the Protocol would fulfil the requirements of the SPS Agreement. Similar concerns arise in relation to the role of precaution in the Protocol *vis-à-vis* the SPS Agreement – these concerns are analysed in Q17.

In regard to risk assessment requirements, the Protocol obliges the decisions of importing countries in the context of the AIA procedure to be in accordance with risk assessments carried out in a scientifically sound manner and taking into account recognised risk assessment techniques. The SPS Agreement, on its part, requires Members to base their sanitary or phytosanitary measures on a risk assessment, as appropriate to the circumstances, and taking into account risk assessment techniques developed by the relevant international organisations. The question, however, is whether the SPS Agreement approach is wide enough to encompass that of the Protocol, which allows countries to consider, in addition to the risk assessment, a broader range of concerns, including "socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity." In this regard, many commentators point to the fairly expansive concept of risk assessment established by WTO jurisprudence, which would promote compatibility (Oliva, 2004). In one case, the Appellate Body affirmed that the fact that a risk assessment was a "scientific process"

did not mean that all matters not susceptible to quantitative analysis were excluded from its scope (WTO, 1998, para. 187). Nevertheless, other recent cases, including *EC-Biotech*, are seen as establishing a trend to restrict the scope of risk assessments under the SPS Agreement.

The GATT, which applies to all international trade in goods between WTO Members, should also be analysed. As mentioned in Q9, two of the core principles of the GATT – the national treatment and the most favoured nation obligations – require countries to grant equal treatment (in terms of laws and regulations, for instance) to products of national and foreign origin, and products originating in or destined for the territories of different WTO Members, considered 'like products'. These requirements may be relevant for measures implementing the Biosafety Protocol, for example, in the following two situations. First, the Biosafety Protocol does not require the domestic trade of LMOs to be regulated in the same way as international trade of LMOs. As a result, if a country were implementing the Biosafety Protocol but not regulating its national market in the same manner, it would arguably be violating the national treatment obligation of the GATT. Second, if a WTO Panel or Appellate Body were to consider LMOs 'like products' in relation to their conventional counterparts, then the different treatment given by Country A, implementing the Biosafety Protocol, to the LMO shipments from Country B with respect to the shipment of conventional products from Country C, could be argued to violate the most-favoured-nation obligation.

Of course, even if these measures implementing the Biosafety Protocol were found to violate the national treatment and most-favoured-nation requirements, they might nevertheless be justified under Article XX of the GATT. Article XX establishes a number of general exceptions to the GATT for measures that are, for example, necessary to protect human, animal or plant life or health or relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption. These measures, nevertheless, would have to not be applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade. No measure implementing an MEA has ever been challenged, and thus no defence on Article XX grounds has been attempted in this context. Nevertheless, given the emphasis by the Appellate Body in other cases on international co-operation as the best strategy to address environmental concerns, this line of argument has significant merit.

As mentioned above, the provisions of the TBT Agreement do not apply to sanitary and phytosanitary measures; it is thus unclear to what extent measures implementing the Biosafety Protocol would fall under the TBT Agreement. For example, Article 18 of the Biosafety Protocol, which deals with handling, transport, packaging and identification, clearly states that such measures are required "in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health".

If the TBT Agreement were found applicable to measures implementing the Biosafety Protocol, an important consideration for a WTO Panel would be whether the Biosafety Protocol could be considered an international standard. In the TBT Agreement, regulations in accordance with international standards are rebuttably presumed not to create an unnecessary obstacle to international trade. If the Biosafety Protocol were not found to be such a standard, then many of the issues raised by the GATT – explained above – would be relevant, including national treatment, most-favoured-nation, and general exceptions, as well as other TBT requirements relating to notifications.

Q17 How does the role of precaution differ under the Cartagena Biosafety Protocol and the SPS Agreement?

Elements of the precautionary approach find reflection in a number of the provisions of the Protocol, including the decision-making processes of the AIA mechanism and the procedure for living modified organism intended for direct use as food or feed, or for processing. The precautionary approach is also reflected in various provisions of the SPS Agreement, most importantly allowing countries to adopt provisional sanitary and phytosanitary measures in cases where scientific information is insufficient. Again, the question is nevertheless how a measure based on the provisions in the Protocol would fare under the SPS Agreement requirements.

The approach of both agreements appears to be quite similar. Article 10.6 and 11.8 of the Protocol state that

> *"lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on biodiversity, taking into account risks to human health, shall not prevent a party of import from taking a decision, as appropriate, with regard to the import of the LMO in question, in order to avoid or minimise such potential adverse effects."*

Measures allowed by Article 5.7 of the SPS Agreement constitute a qualified exemption to the risk assessment requirements. As such, they must comply with four cumulative requirements: (1) relevant scientific information must be insufficient; (2) the measure must be adopted on the basis of available pertinent information; (3) the country must obtain additional information necessary for a more objective assessment of risk; and (4) the measure must reviewed within a reasonable period of time.

Differences may arise, though, in some critical details. For example, both the Protocol and the SPS Agreement include "insufficient scientific evidence" as an element of their precautionary language. However, while in the Protocol it is the uncertainty caused by insufficient evidence that prompts the precautionary approach, the WTO Appellate Body has affirmed that Article 5.7 is *not* triggered by scientific uncertainty (WTO, 2003). Would a precautionary decision taken using the AIA procedure – where the amount of scientific studies on a particular GMO was considerable but did not prove conclusive – qualify under Article 5.7? It is likely. "Insufficient scientific evidence" under Article 5.7 has never been read to refer to the mere quantity of relevant scientific information. Since uncertainty generally will not allow, in qualitative terms, the performance of an adequate risk assessment, uncertainty by itself would not trigger Article 5.7 but would play a crucial role in determining whether scientific evidence was "insufficient" within the meaning of Article 5.7 (CIEL *et al.*, 2004).

Other differences that could result in conflict include the additional requirements in Article 5.7 of the SPS Agreement for Members to adopt precautionary measures. For instance, measures taken under Article 5.7 may only be provisional – a limitation that is not in the Protocol. However, under Article 12 of the Protocol, all importing decisions are in fact subject to review. An exporting party may request the importing party to review its decision if it considers that additional relevant scientific or technical information has become available. The importing party is obliged to respond in writing to such a request within ninety days and set out the reasons for its decision. Moreover, it should be noted that the Appellate Body has established certain flexibility in regard to the Article 5.7 review, having stated that the meaning of a "reasonable period of time" must be established on a case-by-case basis, because it depends on the specific circumstances of each case, including the difficulty of obtaining

the additional information necessary for the review and the particular characteristics of the provisional SPS measure (WTO, 1999). Another element of Article 5.7, though, the requirement that Members seek to obtain additional information in relation to the precautionary measures, is unparalleled in the Protocol.

Nevertheless, it is generally considered that the two approaches to precaution, while not identical, are complementary (Cosbey and Brugiel, 2000). In this regard, it has been argued that, while the Protocol is not one of the international standards recognised by the SPS Agreement, it may provide significant guidance in its application to measures relating to GMOs – particular those based on the precautionary approach. In the Report of the *EC-Biotech* case, the Panel found that the WTO dispute settlement process was not obliged to look at agreements that had not been ratified by all parties to the dispute (WTO, 2006). However, it did state that a Panel could consider other relevant rules of international law when interpreting the terms of WTO agreements if such rules were deemed to be informative.

Q18 In case of conflict, would WTO rules override the Cartagena Protocol on Biosafety?

Although the differences between WTO and MEA (multilateral environmental agreement) dispute settlement procedures are recognised, and while the WTO is seen by many as far from the appropriate forum to rule on conflicts between environmental and trade rules, it is likely that such conflicts would indeed be brought before the WTO by the complainants. Decision BS-I/7 of the Conference of the Parties (COP) acting as the Meeting of the Parties (MOP) established procedures and mechanisms to promote compliance and to address cases of non-compliance under the Protocol, which could address disputes arising between parties to the Protocol. Nevertheless, nothing in the Protocol would impede the complainant from challenging the measure at issue at the WTO – if of course both parties are also Members of the WTO – where the dispute settlement system is binding and includes the possibility of retaliation. Moreover, given that none of main producers or exporters of LMOs, including the United States, Canada, Argentina, China and Australia, have ratified the Protocol, disputes are more likely to arise between parties and non-parties to the Protocol. In these cases, it is certain that the complainants would bring the measures alleged to violate WTO rules before the WTO.

In disputes between parties, the text of the Preamble of the Biosafety Protocol, which addresses the relationship of the Protocol with other international agreements, would be relevant. The terms of the Preamble, however, are rather ambiguous. First, the Preamble recognises that trade and environment agreements should be mutually supportive with a view to achieving sustainable development. Second, it emphasises that the Protocol should not be interpreted as implying a change in the rights and obligations of a party under any existing international agreements. Third, it clarifies that the preceding statements are not intended to subordinate the Protocol to other international agreements. The clauses, particularly the last two, "cancel each other out" in some opinions (Rivera-Torres, 2003). Others, however, believe they establish a "savings clause" that preserves parties' rights and obligations under earlier agreements (Safrin, 2002).

The vagueness of the language responds to the controversy surrounding this issue in the negotiation of the Protocol. During negotiations, several countries, including the main exporters of GMOs assembled in the so-called Miami Group, insisted on a clear statement that the Protocol would not alter parties' existing international rights and obligations. The position responded to concerns that the new rules might be used to undermine existing trade rules because, under the rules of customary international law, in case of conflict between two agreements relating to the same subject matter, the

latter prevails. The "savings clause" requested was thus aimed at overcoming such a presumption. Other countries, however, including countries of the EU and several developing countries, considered that a "savings clause" would establish an inaccurate hierarchy, subordinating the Protocol to WTO rules. The compromise has been described as giving all sides what they wanted (Cosbey and Burgiel, 2000). It is unclear, however, how this compromise will play out in case of a dispute.

However, it should be noted that, in cases where a dispute is brought before the WTO (whether or not the countries concerned are all parties to the Protocol), the WTO dispute settlement system could only apply WTO law as it is contained in WTO agreements, and would thus resort to the trade rules (Dispute Settlement Understanding, at Articles 3.2 and 19.2). WTO rules, however, are not read in clinical isolation from public international law (WTO, 1996). Customary international law, recognised by the WTO dispute settlement system, requires that WTO agreements be considered as a part of the broader corpus of international law and principles, which would clearly include the Protocol. In the *EC-Biotech* case, however, the Panel noted it did not have an *obligation* to take the Biosafety Protocol into account since given that not all parties in the WTO dispute are also parties to the Cartagena Protocol and the CBD. Nevertheless, the panel noted that it certainly had the *option* of doing so, as had been done in previous dispute settlement cases. However, the panel did not feel that the provisions cited by the EU in its defence were relevant in this case.

Q19 Does the Biosafety Protocol adequately address the particular concerns of developing countries?

In the negotiations of the Biosafety Protocol most developing countries advocated for strong and wide-reaching provisions. Many developing countries find themselves both unable to reap the potential benefits of biotechnology and most vulnerable to its potential risks. A multilateral approach is seen as fundamental to effectively overcome the situation. The Biosafety Protocol contains a number of provisions that aim to address concerns raised by developing countries, but is also considered to have significant loopholes. Some essential development concerns regarding biotechnology, as well as the extent to which the Biosafety Protocol adequately takes them into account, will be described below. However, it should be noted that the interests and concerns of developing countries are not always homogenous in regard to trade and biotechnology. Developing countries vary in their commitment and investment in science and technology (Gopo and Kameri-Mbote, 2005). Various levels of public awareness and engagement also determine different approaches to biotechnology (Baumüller, 2005). The concerns of developing countries also differ in their diverse roles as exporters, importers and producers of GMOs (Kaushik, 2005).

Access to biotechnology is a concern of many developing countries. The lack of financial resources and the necessary legal, institutional, and policy framework, as well as increasing standards of intellectual property protection are seen as severe constraints towards accessing biotechnology. The lack of financial and technical resources also impacts the ability of developing countries to adequately monitor and assess the potential impacts of biotechnology products. It is in this context that an international framework to ensure the safe transfer, handling and use of LMOs and to adequately balance their potential benefits and risks is considered to have "immense implications" for developing countries (Egziabher, 2003). As a result, developing countries were, in many regards, the driving force behind the Protocol.

Many of the provisions of the Protocol address development concerns. For instance, the AIA mechanism, the backbone of the Protocol, responds to the need identified by developing countries for increased information and the opportunity to make informed decisions on imports of LMOs. First, the

Protocol requires the exporting country to notify, in writing, the proposed transboundary movement, providing a minimum amount of information. Then, the Protocol establishes the decision procedure of the importing country must follow to either approve the import, with or without conditions, prohibit it or request additional time or information. Notably, the importing country may require the exporter to carry out the risk assessment needed to come to a decision. Moreover, at no stage can a failure by the importing country to communicate its decision be considered implicit consent. Another important provision is Article 26, which empowers countries to consider potential socio-economic consequences of the impact of LMOs on biodiversity. The provision held particular interest for developing countries, many of which not only have a crop-based economy, but also are mega-diverse and home to indigenous and other local communities that are directly affected by the loss of biodiversity. The Protocol could be especially important to allow these countries to subject LMOs to a particular regulatory assessment given their unique biodiversity.

The Biosafety Protocol has been criticised, however, for not taking other important developing country concerns on board. For example, noting that the scope of the Protocol's provisions do not extend to the safe development, application and transfer of biotechnology products in both developed and developing countries, Gopo and Kameri-Mbote (2005) argue that the focus of the Protocol is not on biosafety but rather on "bio-trade" – and thus primarily benefits biotechnology exporters without giving adequate protection to people in the developing world. The need for balance between importers and exporters of biotechnology also continues to be the subject of discussions of the COP-MOP. Lengthy deliberations have taken place, for instance, on the identification and documentation requirements required by Article 18.2 for LMOs for food, feed or processing. Controversial issues included whether documentation should state that the shipment "contains" LMOs and that it "may contain" LMOs. Importing countries preferred the term "contains" to ensure they are provided accurate and actionable information regarding the content of shipments, while exporting countries are concerned about the feasibility of identifying every LMO that is contained in a shipment. The debate on developing international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of LMOs is another example, with importing countries pushing for binding provisions, while exporting countries favour a non-binding approach.

It has also been argued, however, that the negotiation and implementation of the Protocol has been a significant contribution to increased awareness and regulation of biosafety issues. The Protocol provides particular attention to enabling developing countries to adequately implement its provisions. First, the Biosafety Clearing House facilitates the exchange of scientific technical, environmental and legal information on LMOs, while also actively assisting countries in implementing the Protocol. Second, the Protocol requires co-operation in the development and strengthening of human resources and institutional capacities in biosafety in developing countries. No specific commitments in this regard, however, are included. Third, following the adoption of the Protocol, the Council of the Global Environment Facility (GEF) adopted the GEF Initial Strategy on Biosafety, which is aimed at assisting countries establish national biosafety frameworks (NBFs) to implement the Protocol. Currently, besides running the Biosafety Clearing House, UNEP-GEF is managing a development project assisting 123 countries to develop a draft National Biosafety Framework (NBF) and eight implementation projects with the goal of establishing operational NBFs.

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B.4 Intellectual property rights

Intellectual property rights are one of the primary tools used to promote research and development in agricultural biotechnology. The application of intellectual property rights to agriculture, however, has long been contentious. Traditionally, inventiveness in the sector was based on the sharing of genetic resources and related knowledge. In this context, exceptions to intellectual property protection, allowing farmers to freely use, exchange and sell seeds they grow and providing breeders the scope for research and breeding, are critical. It has been argued that intellectual property protection of biotechnology products is essential to stimulate research and to allow recovery of the investment capital. As international rules increasingly raise the level of intellectual property protection, however, there is rising concern about the potential negative impacts on the dissemination of knowledge and important products, further research and development, food security, and the conservation of biodiversity, among other fundamental areas of public policy. This section will examine the relevance of intellectual property rules to agricultural biotechnology and discuss some of the concerns raised by increasing levels of intellectual property protection.

Q20 What intellectual property rights apply to agricultural biotechnology?

Patents and plant variety certificates are the main types of intellectual property rights used in relation to agricultural biotechnology. Patents were created as a tool to promote innovation and the dissemination of knowledge. They are privileges granted by a government that allow an inventor to exclude other persons from exploiting a patented product or process. Essentially, patents create a fence around the claim of a new contribution to technological knowledge for a limited period of time. Originally, this was meant to provide an incentive for intellectual creativity, but increasingly, the balance between protecting private and public policy interests is being lost.

It should be noted that the very legitimacy and characteristics of patent protection for biotechnology products remain controversial. While such concerns will not be analysed here, they cannot be ignored by the patent system whose basic principles require governments to avoid its misuse (CIEL, n.d.). Patents on biotechnology products, moreover, may also impact the integrity of the patent system undermining the very purpose of patent protection. For instance, the increasingly broad understanding of an 'invention', which is fundamental to accommodate many biotechnology-related patents, could have serious consequences for the functioning of the patent system. The level of patenting activity and the low quality of many patents on biotechnology products has also induced widespread concern (OECD, 2002). Patents granted on products and processes that do not involve an inventive step, for instance, or patents "fencing in" an overly broad portion of knowledge are increasingly common in regard to biotechnology products.

Plant variety protection (PVP) is also relevant to agricultural biotechnology. Indeed, biotechnology is increasingly becoming an important tool for plant variety breeders. Given the particular nature and characteristics of agricultural innovation and its significance for livelihoods, efforts to use intellectual property to protect agricultural innovations originally did not resort to the patent system, but rather to a distinct form of protection. PVP thus developed separately from patent protection, generally focusing on traditional plant breeding methods (APEC, 2001). The protection only applies to new plant varieties (including new varieties that result from genetic engineering) that are distinct variations within a given species (Jördens, 2002).

The benefits of PVP from a sustainable development perspective have been noted by various organisations,

including the Commission on Intellectual Property Rights. With PVP, countries are able to elaborate a regime that promotes innovation while, for instance, controlling the impact of intellectual property protection on seed prices, safeguarding farmers' traditional practices of saving, exchanging and planting seeds, supporting public agricultural research institutions, and maintaining and developing varieties tailored to local conditions. The choice granted by the TRIPS Agreement, which requires WTO Members to provide some sort of protection for plant varieties, but allows an option for *sui generis* plant variety protection systems, is significant in this regard. While countries are free to design their own *sui generis* system, the most widely used PVP system is the International Convention for the Protection of New Varieties of Plants (the UPOV Convention), which was adopted in 1961 and revised in 1972, 1978 and 1991 (see Section C.2).

Q21 Which biotech products are patentable?

At the international level, the minimum standards of patent protection, including the cases in which patents must be granted, are established by the TRIPS Agreement. Article 27.1 of the TRIPS Agreement states that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." While international rules in place before the TRIPS Agreement allowed countries to exclude certain areas from patentability, or to establish special rules for them, the TRIPS Agreement means that governments can no longer distinguish between different fields of technology, including biotechnology (UNCTAD-ICTSD, 2005). As will be explained below, however, countries may choose not to grant patents in certain cases, including patents on plants and animals other than micro-organisms.

By allowing the granting of patents on genetic material, the TRIPS Agreement thus adhered to the reasoning famously established by the US Supreme Court in *Diamond v. Chakrabarty*. Ananda Chakrabarty, a biochemist, applied for a patent in the US on a bacterium bioengineered to break down crude oil. The US Patent Office denied him the patent, arguing that the bacterium, as a living organism, was a product of nature. In 1980, however, the Supreme Court, by a slim margin, held that the fact that the invention was alive was irrelevant since it had been created by man and thus deserved a patent. In 1998, the European Union Biotechnology Directive also established that the fact that an invention concerns either a product or process related to biological material does not place it outside the scope of patenting.

To qualify for patent protection, patent applications related to biotechnology must nevertheless demonstrate compliance with all the other criteria for patentability, as well as prove they are not contained in an exception to patentability established by national legislation. The TRIPS Agreement establishes three minimum criteria for patentability: An invention must be new, inventive and industrially applicable. However, the Agreement does not harmonise the way in which patents have to be implemented, leaving countries considerable leeway (UNCTAD-ICTSD, 2005). In general terms, however, an invention must be new in that it must not have been available to the public before – patents cannot be put on material that is already in the public domain. It must also be inventive, that is it must involve a development over the state of the art, though the degree of inventiveness required by different countries varies significantly. Finally, the invention is considered 'industrially applicable' by some national laws if "it can be made or used in any kind of industry, including agriculture" and by others if it can be "made or used in economic activities". It should be noted, however, that countries may decide that, even if an invention is technically eligible for a patent, it should not be granted such protection on the basis of broader policy reasons.

Q22 Is the identification or isolation of genes an invention?

Patent protection is based on the premise that protection should only be given to the result of a creative idea. Since the identification of the relative positions of genes on a DNA molecule, or even their isolation, is a discovery rather than an invention, it is thus argued that patents should not be granted as a result of this gene mapping. However, it is also argued that genes, in isolation, can be utilised in new manners and yield useful results. US patent guidelines, for example, state that the discovery of a gene can be the basis for a patent "on the genetic composition isolated from its natural state and separated from other molecules naturally associated with it", as long as there is a "specific, substantial, and credible utility for the claimed isolated and purified gene" (DoC, 2001). The EU Biotechnology Directive also establishes that biological material isolated from its natural environment or produced by a technical process is patentable, even if it is identical to a natural element, although "a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention."

Patents on genes may have unforeseen consequences. For instance, major similarities in the genetic make-up of biological organisms may determine that patents on specific gene sequences also extend to other species, genera and classes. The patent application related to the mapping of the rice genome, for example, extends to the genes that regulate flower formation in other major cereals and plants in general (Oldham, 2004).

Q23 Are countries allowed to exclude life forms from being patented?

Articles 27.2 and 27.3 of the TRIPS Agreement contain the exceptions to patentability which countries are allowed, but not obliged, to implement in their national laws.

Article 27.2, for instance, establishes that countries may exclude products and processes from patentability in cases where the prevention of their commercial exploitation is necessary "to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment." Exceptions on these bases follow the need to balance the protection of patents with the broader public interest. Exactly what is excluded differs from country to country, as morality depends, for the purposes of the TRIPS Agreement, on the particular culture of a country or region (UNCTAD-ICTSD, 2005). Given the concerns raised by biotechnology, the exclusion of at least certain biotechnology products on the basis of ethical and moral considerations is fairly common. For instance, in an OECD survey of the intellectual property practices of a number of its member states, most answers reported exclusions of biotechnology products from patentability on the basis of ethical or moral concerns, particularly relating to human beings (OECD, 1999). For example, the German Biotechnology Law of 1990 foresees the protection of the environment and human life and health "against the potential dangers of biotechnology". In addition, the EU Biotechnology Directive considers the following not patentable on the basis of ethical or moral concerns: processes for cloning human beings; processes for modifying the genetic identity of human beings; uses of embryos for industrial or commercial purposes; processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal, and also animals resulting from such processes (EC, 1998 at Article 6). The Australian Patents Act establishes that "human beings, and the biological processes for their generation, are not patentable inventions".

Article 27.3 establishes specific products and processes that Members may exclude from patentability, including "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes". As a result, the TRIPS Agreement allows

the exclusion of certain products and processes while obliging countries to protect others. Micro-organisms, for example, must be protected. Although the concept remains controversial, it is clear it does not require the patenting of cells, genes or other sub-cellular components (UNCTAD-ICTSD, 2005). Moreover, it does not require WTO Members to grant patents on micro-organisms if they are not an invention or if they fail to meet all the relevant patentability criteria. Non-biological processes, which include the methods used in modern biotechnology, must also be protected (as opposed to conventional plant breeding methods, which are considered essentially biological processes).

The different elements of Article 27.3(b) reflect the compromise reached between the strong interests of some developed countries in the protection of biotechnology, other developed countries that granted such protection but in different degrees, and developing countries that questioned whether patents were at all appropriate in the biotechnology context (UNCTAD-ICTSD, 2005). Article 27.3, moreover, included an early review provision. The review, which started in 1999, has still not been achieved, with differences remaining between countries as to whether the "review" is one of implementation or of the provision itself (UNCTAD-ICTSD, 2005).

Increasingly, however, limitations on the use of these facultative exceptions come from outside the WTO. Recent intellectual property provisions agreed through bilateral trade negotiations such as US-Chile and US-DR-CAFTA, for example, oblige parties to undertake best efforts to introduce legislation making available patent protection for plants.

Q24 Are scientists allowed to use patented GM seeds for research purposes?

As noted, since innovation in agriculture has traditionally been a collective process, its incorporation into intellectual property regimes has been controversial. In particular, as new plant varieties are often the product of generations of breeding, plant breeders and researchers have emphasised the need to freely access genetic material, including that which is protected by intellectual property (QMIPRI, 2004). PVP systems, therefore, have tended to provide exceptions for acts conducted with experimental purposes or with the objective of breeding and commercialising other varieties. Nevertheless, the tendency towards increasing levels of intellectual property protection is also evident in these systems, at the expense of experimental and research exceptions.

UPOV, for instance, provides for a breeder's exemption, implementing the basic principle of the international PVP regime that the right holders cannot prevent other breeders from using the protected plant varieties in research and development. If the use of protected varieties for the purposes of developing new varieties were an infringement, the ability to develop new varieties would be restricted, which would run counter to the objective of granting rights to the breeders of new plant varieties. The 1978 UPOV Convention thus stated that the authorisation of the breeder of a plant variety was not required for its use as an initial source for the purpose of creating other varieties or for the marketing of such varieties.

In the 1991 UPOV Convention, however, although the breeder's right still does not extend to acts done for the purpose of breeding other varieties, it excludes situations relating to "essentially derived varieties" which may significantly limit the research exception. The notion of "essentially derived varieties" is vague and includes, for example, varieties that derive from others while retaining the expression of the essential characteristics that result from the genotype of the initial variety, even if it is clearly distinguishable. Moreover, in the 1991 UPOV Convention, the acts that require the authorisation of the breeder increase to include any production or reproduction of propagating material;

its conditioning for the purpose of propagation; its selling, exporting and importing; and its stocking for any of these purposes. Finally, UPOV 1991 allows the double protection of plant varieties, that is, both by specific systems and by patents. In countries that grant this double protection, the patent protection of a gene or other biological material would extend to all derived biological material, and thus trump the breeders' exemption provided by the PVP system (Le Buanec, 2003). The EU Directive on Biotechnology, for example, has tried to overcome this situation by the possibility, under certain conditions, of compulsory licenses in cases where a plant variety right cannot be exploited without infringing a prior patent (Moufang, 2003).

Patent law, indeed, tends to have much narrower research exceptions. Although research *as such* is not enumerated as an exclusive right of the patent owner, it is normally necessary to make or use the patented product or process to conduct research, which is why a research exception may be necessary (Correa, 2004). As a result, patents can significantly limit access to GM seed for research purposes. For instance, in *Monsanto v Stauffer*, courts in the UK interpreted the research exception in regard to biotechnology narrowly, considering the size, scale, recipient and methodology of the experiments (QMIPRI, 2004). Another example is the case of Golden Rice (see Biotech Headline 8), in which a complex legal arrangement was necessary to overcome patent restrictions on the tools used to create Golden Rice and conduct the necessary further research.

International patent rules recognise that the information protected by patents is an essential input to the knowledge production process, and should be available for further experimentation and research for the sake of scientific and technological progress (Correa, 2004). Article 7 of the TRIPS Agreement states: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." In addition, Article 30 of the TRIPS Agreement allows countries to establish "limited exceptions" to the rights conferred by a patent, as long as such exceptions "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." Research exceptions, which were analysed by the WTO dispute settlement panel on Canada's patent protection of pharmaceutical products, can easily fulfil this "three-step" test (Canada – Patent Protection of Pharmaceutical Products, 2000). For instance, research exceptions are limited because they involve using the patented products or processes on a laboratory scale and are relatively short in duration. Moreover, research exceptions do not conflict with the "normal" exploitation of the patent because they do not deprive the patent owner of the benefits generated by the market exclusivity s/he enjoys.

Research exceptions are particularly important in biotechnology, given the increasing number and scope of related patent claims. Nevertheless, the OECD recently noted concerns that "the present patchwork of national research exemptions is both ill defined and may be breaking down due to legal challenges" (OECD, 2002:23). In this regard, the OECD recommended that countries clarify and enhance research exceptions. Breeders' associations agree. The European Seed Association (ESA), for instance, has stated that the research exception is frequently unclear or far too narrow. In particular, it proposes that acts done for the purposes of breeding and developing other plant varieties should be excluded from the scope of patent protection of biotechnological inventions, and consequently, the commercial use of new plant varieties no longer expressing the function of patented elements should

be allowed (ESA, 2004). Biotechnology companies, however, consider that such changes would be undesirable and ineffective on several grounds, including: (1) inventors in the area of plant breeding and development should be rewarded to the same extent as inventors in other fields; (2) US law does not provide or support a research exception under patents; and (3) any support for a research exception would appear to support research exceptions in general, as well as other exemptions, such as farm-saved seed (Donnenwirth *et al.*, 2004).

Q25 Are farmers allowed to save, re-use and re-sell GM seeds?

Another consequence of the particular way that plant genetic resources for agriculture have developed is the need to recognise and preserve the traditional activities conducted by farmers, including saving, exchanging, and selling seeds. The issue of farmers' rights is closely linked with the potential impact of biotechnology patents on food security, which will be analysed below.

In the context of PVP, the 1978 UPOV Convention, by limiting the scope of breeders' rights, allowed farmers to continue these practices. In the 1991 revision, the acts that require the authorisation of the breeder were amplified to include any production, reproduction, sale or stocking of propagating material, though an optional exception was introduced to allow farmers to, "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder", save seeds from their own harvests for use in their own holdings.

In international patent rules, there are no specific exceptions for farmers. Under the TRIPS rules, patented seeds cannot in principle be saved, re-used and re-sold. However, as has been noted, the TRIPS Agreement allows countries to introduce exceptions to patent rights subject to the "three-step" test. For instance, the European Directive on the Protection of Biotechnological Inventions establishes that "the sale or other form of commercialisation of plant propagating material to a farmer by the holder of patent… implies authorisation for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm" under certain conditions.

There is increasing recognition, however, that the contribution of farmers to the conservation and development of plant genetic resources cannot be fully acknowledged and preserved through exceptions to patents or plant variety protection. Indeed, many believe that referring to the traditional activities of farmers as a "privilege", "exception" or "exemption" is a misnomer because, in the same way that plant breeders and biotechnology companies have their rights recognised because of their innovations, farmers' rights should be equally recognised based upon their ongoing and past conservation and enhancement of genetic material (GRAIN, n.d.).

The concept of "farmers' rights" was thus developed as a way to achieve an improved balance and to allow farmers to benefit from the value they have contributed (Correa, 2000). The African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, for instance, is based on the notion that the rights of local communities over their biological resources, knowledge and technologies are *a priori* rights which take precedence over rights based on private interests.

Farmers' rights in this context include the right to the protection of their traditional knowledge relevant to plant and animal genetic resources; to obtain an equitable share of benefits arising from the use of these resources; to participate in making relevant decisions; to use a new breeders' variety protected under this law to develop farmers' varieties, including material obtained from genebanks or plant genetic resource centres; and to collectively save, use, multiply and process farm-saved seed of protected varieties.

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which was negotiated under the auspices of the UN Food and Agriculture Organisation (FAO) and entered into force on 29 June 2004, was created to explicitly incorporate the concept of farmers' rights. In Article 9 of the ITPGRFA, countries recognise "the enormous contribution that the local and indigenous communities and farmers of all regions of the world… have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world." Countries should take measures to protect and promote farmers' rights, including the protection of traditional knowledge, the right to an equitable share of the benefits arising from the use of plant genetic resources and the right to participate in national decision-making related to these resources. Article 9 also states "nothing in this Article shall be interpreted to limit any right that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate." Because these measures are subject to each country's legislation, however, their adequate implementation will also require changes to patent rules to accommodate farmers' rights.

One of the challenges to a full realisation of farmers' rights, however, comes not from patent law itself but from related contracts. Most seed companies require farmers to sign a "technology agreement" when purchasing patented seeds. These agreements often limit the ability of farmers to save seed and control their production practices (NALC, n.d.). Some biotechnology companies have aggressively monitored and prosecuted potential breaches of these agreements (Grain, 2004). In one case, for example, Monsanto sued a farmer, Homan McFarling, for saving Monsanto's Roundup Ready® soybean seeds although the technology agreement required him to use the seed for planting a commercial crop in a single season. While McFarling argued that the agreement violated farmers' rights as recognised in the US plant variety protection laws and that Monsanto had impermissibly broadened the scope of the patent by "tying" an unpatented product to a patented product, the courts found in favour of Monsanto. The courts affirmed that the protection of plant varieties and patents was complementary and that the right to save seeds under the first does not impart the right to do so when the seeds are patented. Moreover, the courts stated that since the licensed and patented product (the first generation seeds) and the good made by the licensed product (the second generation seeds) are nearly identical copies, Monsanto's patent equally extends to both.

Q26 Is a strong intellectual property regime necessary to stimulate research and development in biotechnology?

Strong intellectual property rights, and patents in particular, are considered important to safeguarding investment in biotechnology because of the high costs of research (EuropaBio, n.d.). As the number and scope of patents on biotechnology products and processes continue to increase, however, so does the concern that, even if patents do play an important role in business strategies, they may be hindering rather than promoting innovation in the field. Moreover, the characteristics of patents on biotechnology may also be affecting the focus of research and development, with potentially negative consequences for food security and biodiversity.

Patents have been a foundational element of the biotechnology industry, driving the march of commercial investment as well as the practices of public research institutions (Cornish and Llewelyn, 2003). Patents are thus sought for a number of reasons, including to obtain income from licensing, increase share prices, and keep other companies out of potentially commercially rewarding fields. The rising intellectual property protection of biotechnology products and processes can be considered successful

in this regard, as private sector investment in plant breeding has increased substantially since the 1980s. In particular, patent protection has been critical as a means by which large biotechnology companies can protect and strengthen their positions in the industry. Taking into account firm acquisitions and splits, the top ten patent assignees in agricultural biotechnology patents in the United States controlled over half of such patents issued through 2000 (King and Heisey, 2003). Barton, for instance, notes that in the case of agricultural biotechnology there is a greater "incentive to sue outsiders seeking to enter the industry than to sue other major participants" (Barton, 1998). As a result, while the upward trend in agricultural biotechnology patents may reflect the strategic importance of intellectual property protection, it does not necessarily indicate that they are promoting innovation or increasing research and development in the field.

On the contrary, patents may be hindering research in biotechnology and other fields. For example, given the particular nature of genetic material, transferring traditional patent notions to biotechnology may provide patents with excessive scope, which limits further innovation. The gene that regulates flower formation in rice, for example, on which patent claims have been made, is the same one that fulfils this function in other major cereals and plants in general.

In addition, biotechnology, as an enabling or general-purpose technology, has the ability to open up important avenues of research (Hirschhorn, 2001). Nobel laureate John Sulston, for instance, notes: "to the extent that the data are fundamental and important, they should be available to all on equal terms, not to the wealthy few" (Sulston and Ferry, 2002). However, if the novel methods of investigation are subject to patent protection, as is the case for biotechnology patents, access by researchers is subject to significant limitations. Research exceptions are available only for research on the patented subject matter itself, not for its use as a research tool. Moreover, the patenting of research tools also raises the problem of 'reach-through' patent claims, which seek protection for any processes or products that are prospectively obtained using these tools. While patent offices and courts seem to be disfavouring claims that endeavour to reach beyond their investigations, biotechnology patent holders are now resorting to reach-through license royalties, which tie the value of the research tool to the revenue stream generated by the product (Brodowski, n.d.).

The complexities and costs of licensing may be another obstacle to research created by biotechnology patents. Research on genetic material tends to follow a limited number of pathways which are increasingly clustered with patents, through which researchers must search with significant uncertainty and few resources (Cornish and Llewelyn, 2003). These "patent thickets" will become more and more complex, creating disincentives for innovation drawing on patented inventions and ultimately undermining the goals for which the patents were originally granted (Kesan, 2001). Other analysts, however, such as the International Food and Policy Research Institute, minimise the negative impact of licensing, as long as costs are reasonable.

Finally, even if patents do not pose challenges for continuing research in biotechnology, they may significantly affect the type of research that is undertaken both in the private and public sector. Research and development by industries, for example, naturally focuses on the major grains and industrial crops, which have the largest world markets (Tansey, 2002). As patents are increasingly used as incentives, the programs and activities of public research institutions also orient themselves towards enterprise and market needs (Washburn, 2005). The State of Food and Agriculture 2003-2004, a report prepared by the FAO notes, for instance, that agricultural biotechnology research and almost all of the commercialisation is being carried out by private firms based in industrialised countries, which

"has important implications for the kind of research that is performed, the types of technologies that are developed and the way these technologies are disseminated" (FAO, 2004). These trends fuel concerns on the impact of patents on biotechnology for food security and biodiversity conservation, which will be analysed below. Nevertheless, given the fundamental role of public research and science in agricultural biotechnology and some of the challenges of management of intellectual property in the field, the relevance of public-private partnerships is likely to increase. The majority of collaborations in agricultural biotechnology are, in fact, cross-sectoral public-private arrangements (Graff *et al.*, 2003).

Q27 How does intellectual property protection for biotech products impact biodiversity conservation?

A recent study by a UK research institute on the relationship between intellectual property and food security identified several concerns regarding the impact of the former on biodiversity conservation, including by: encouraging a system of agriculture based on a limited variety of crops; promoting the use of a relatively small pool of genetic material; and supporting the combined commercialisation of GM seeds and the pesticides and herbicides for which they have built-in resistance (QMIPRI, 2004). The study concludes that biotechnology patents and other intellectual property protection cannot be identified as the sole factor driving these trends, but that they may be contributing to differing degrees. Similar conclusions have been reached by other studies (Kothari and Anuradha, 1997). These concerns are also relevant in the context of food security, which will be analysed in Q28. The impact of biotechnology patents on research, for instance, plays a role in this context. By promoting the development of commonly utilised crops that can be cultivated as widely as possible, patent-led research may result in a limited range of GM products with the capacity of adapting to particular environmental conditions, rather than those tailored to particular conditions in precise areas. Ultimately, this would lead to decreased agricultural biodiversity. On the other hand, the QMIPRI study highlights that monocultural agricultural systems are not inherently biodiversity-erosive: if a monocultural system produces higher yields per harvest, pressure to open up biologically-diverse ecosystems to cultivation may be reduced as a consequence.

The most debated question regarding the linkages between patents and the conservation of biodiversity, however, is whether the patent system is indeed "supportive" and does not "run counter" to the objectives and principles of the CBD. The CBD, which came into force in 1993, recognised from early on the relevance of intellectual property to its objectives, in particular the "multifaceted and complex" correlation with the TRIPS Agreement, stressing the need to exchange information and increase synergies.

In the WTO, on the other hand, the Doha Ministerial Conference mandated countries to examine the relationship between the TRIPS Agreement and the CBD in the context of the review of Article 27.3(b), analysed above. Many developing countries, particularly those rich in biodiversity, had previously raised the issue, considering that the TRIPS Agreement, by allowing patents over life forms, inherently contradicts the national sovereignty over the genetic resources in their territory that is recognised by the CBD. Developed countries, including the US, the EU and Japan, have generally taken the position that there is no inherent conflict, and that both agreements can be implemented in a supportive manner. Current discussions, however, have focused on the concern that the TRIPS Agreement allows the granting of patents for inventions that use genetic material and associated knowledge without requiring compliance with the provisions of the CBD, primarily prior informed consent (PIC) and fair and equitable benefit sharing, and thus result

in misappropriation of these resources. Cases of misappropriation that have been highlighted include the Neem tree, Basmati rice lines, the Ayahuasca vine, the Hoodia cactus and the Enola bean, among others.

Discussions are taking place on the basis of a proposal by Brazil, Bolivia, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela, which attempted to facilitate a more result-oriented discussion by putting forth a checklist of elements that need to be addressed, including the disclosure of source and country of origin of biological resources and traditional knowledge in patent applications, as well as of evidence of PIC and benefit sharing under relevant national regimes. These disclosure requirements would arguably ensure the objectives and principles of the CBD are supported by the international intellectual property system, and would significantly enhance patent examination and quality by assisting in the establishment of prior art, thus avoiding the granting of patents over claims that lack novelty or inventive step. In addition, they would ensure the effectiveness of disclosure requirements established at the national level by a number of developing countries when the misappropriation occurs in countries outside their territory. Nevertheless, other countries, most vocally the US, Switzerland and the EU, reject the need for an amendment to the TRIPS Agreement. While the EU and Switzerland, for example, recognise the usefulness of disclosure requirements in patent applications, they favour addressing these issues outside of the WTO and maintaining any consequence of non-compliance outside of the patent system. The US has also expressed concern about adding uncertainty to the patent system and believes that other approaches, such as contracts and databases, would provide more effective alternatives.

In the World Intellectual Property Organization (WIPO), an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was created in 2000 to discuss this relationship and advance internationally acceptable and equitable solutions for the challenges it raises. The issues have also been discussed in the WIPO Standing Committee on the Law of Patents (SCP) in the context of a potential treaty on substantive patent law, and in the Working Group for the Reform of the Patent Cooperation Treaty (PCT).

Q28 How does intellectual property protection for biotech products impact food security?

The State of Food and Agriculture 2003-2004 noted the unprecedented challenges facing agriculture, with more than 842 million people chronically hungry in the world, and concluded that biotechnology can contribute to meeting these challenges (FAO, 2004). Insofar as intellectual property protection continues to enable the development of biotechnology products and processes, it could be said to have a positive impact on food security. In this regard, the report encourages governments to provide incentives, institutions and an enabling environment for public and private sector agricultural biotechnology research, development and deployment.

However, patents on biotechnology products, as has been noted above, may limit the availability of research tools, affect the focus of further innovation and developments and impede the traditional practices of farmers. As a result, they may also have negative impacts on food security. Private sector research naturally focuses on the crops and traits of commercial interest to farmers in higher income countries, raising the concern that farmers in developing countries, particularly poor farmers, may not benefit because appropriate innovations are either not available or are too expensive.

The restrictions on the saving, reusing and exchanging of seed are also of concern to farmers in developing countries, where saving seed from harvests for replanting and exchange are common practices and thus essential to meeting basic nutritional needs

(QMIPRI, 2004). While seed companies affirm that farmers are not obliged to purchase protected seed, it should be noted that government support for farmers, including credit, is sometimes conditional on the sowing of particular crops and types of seed, and that often external aid is used by providers as a way to promote the use of particular crops and seeds (QMIPRI, 2004). The UN World Food Programme, for example, recognised in 2002 that it had made no attempt to distinguish between GM and conventional cereals since 1996, when GM crops first became part of US grain stocks destined for aid. Half of world food aid comes from the US, and a quarter of that nation's maize is genetically modified. In addition to the problems posed by the very limited possibility for exceptions for farmers in international patent rules, seed companies are also calling for a new amendment to the UPOV Convention to further restrict farmers' rights, for example, by requiring compensation for the breeders (ASTA, 2004).

The traditional knowledge related to the conservation and sustainable use of biological resources is another important factor for global food security that may be impacted by patent protection for biotechnology. Traditional knowledge has developed as a direct response to people's essential needs and is therefore critical for the welfare of numerous indigenous and other local communities, as well as potentially beneficial to society more broadly. Examples include the use of the Hoodia cactus by the San people to stave off hunger and the use of the Ayahuasca vine by communities in the Amazon for medicinal purposes. Patents on genetic resources and associated knowledge, however, may negatively impact the protection, preservation and promotion of traditional knowledge. For instance, the potential for such patents to be used to allow the misappropriation of traditional knowledge without adequate consent or an equitable sharing of benefits is currently being addressed in a number of international fora.

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B.5 Implications for market access and competitiveness

While countries are generally free to pursue their own biotech development strategy, international trade is increasingly bringing the different approaches into contact – and at times conflict – with resulting impacts on policy and regulatory flexibilities. The recent WTO dispute between the US, Canada and Argentina on the one side and the EU on the other over the EU's application of its approval procedures for biotech products has placed the resulting tensions under the spotlight (see Q10). When considering policy approaches to biotechnology development, countries will therefore need to consider the impacts of their choices on their industries' and farmers' competitiveness in the international market place, their capacity (and costs) to comply with export market requirements and how these factors affect their domestic public policy priorities.

Q29 How could agricultural biotechnology impact competitiveness?

The impact of biotechnology on competitiveness – including *vis-à-vis* other biotech industries or farmers, or producers of conventional counterparts at the national and multilateral levels – is of particular interest in the context of international trade. Competitiveness impacts can be assessed at different levels. Most commonly, analysts refer to improved productivity *vis-à-vis* relevant competitors, which, simply put, refers to generating more output with less input. This approach is particularly relevant, for instance, to the most commonly used commercial GM crops, such as herbicide-tolerant or insect-resistant varieties, where claims have often been made regarding their ability to improve agricultural productivity. Another dimension relates to the additional attributes that biotechnology can add to varieties and which therefore might give the sellers an edge over their competitors.

Productivity is generally related to three factors: land, labour and capital goods. Higher yields of biotech crops could reduce the crop area needed to achieve the same yield. Insect-resistant varieties could potentially lower the number of applications and levels of pesticides needed, which could save both on labour and capital goods costs. Environmental benefits, such as reduced soil erosion or lower soil contamination levels from pesticides or herbicides, could increase the long-term productivity of the land, while health benefits, for instance resulting from fewer pesticide applications or the use of more benign pesticides, could improve labour productivity. Equally, however, environmental risks, such as soil compaction or the emergence of herbicide-resistant weeds, could increase costs in the long term. Moreover, the cost of accessing the patent-protected technology in the first place and repurchasing IPR-protected seeds every year can add significantly to the cost of production. The development of Golden Rice, for instance, required no fewer than 70 intellectual and technical property rights belonging to 32 different companies and universities (see Biotech Headline 8).

If promises regarding the next generation of biotech crops hold true, the use of varieties and products with additional attributes, related, for instance, to nutritional content or better processing characteristics, could become increasingly important in providing a competitive advantage for biotech producers. This advantage would stem from higher revenues received at sale for these products, which would have to offset input costs that would likely be relatively high compared to competitors' products. Examples include the Flavr Savr tomato, genetically engineered for longer shelf life, or beta-carotene-enhanced Golden Rice. The producer would either need to obtain a sufficiently high price premium or sell in sufficiently greater quantities in order to out-compete other sellers and achieve greater returns in the end. This approach will largely depend on consumer demand and the substitutability of the GM product with non-enhanced GM or non-modified counterpart(s).

These examples mask a significant level of complexity when assessing the actual contribution of genetic modification to enhancing competitiveness or predicting changes in productivity that could be attained through GM crops. Indeed, such changes will vary significantly by the crop, region and technology, and are dependent on a range of external factors, such as crop prices, the cost of alternative pest control, weather conditions, weed pressures and management capacities. Moreover, biotech products are becoming increasingly complex as different traits are being incorporated in one product. As a result, economic models that show GM crops can enhance competitiveness or reduce poverty have to rely on a variety of assumptions that are frequently questioned by real-world conditions. As such, claims over the efficiency of GM crops tend to vary widely. Differing estimates over the success of Bt cotton in India are a case in point (see Biotech Headline 7). On pesticide use, the US National Center for Food and Agricultural Policy, for instance, concluded that the use of biotech crops in the US led to a reduction in pesticide use by approximately 21,000 tonnes in 2003 (Sankula and Blumenthal, 2004). Benbrook (2003) in contrast, concluded that herbicide-tolerant GM crops had in fact increased herbicide use by approximately 32,000 tonnes between 1996 and 2003, while Bt varieties had reduced pesticide use by 9,000 tonnes, leading to an overall increase of 23,000 tonnes.

A myriad of other factors will also impact on the competitiveness of the GM producer. One important factor is the cost of regulation, such as requirements for risk assessment, market approval, segregation, labelling and traceability, as well as the risk and possible cost of liability. If GM producers have to comply with additional requirements, they might be placed at a competitive disadvantage *vis-à-vis* producers of conventional counterparts that are subject to less stringent regulations. At the international level, differing levels of regulatory stringency in different countries (such as the US and the EU, see Q30) could impact on the cost of getting a product to the market. In particular the cost of identity preservation systems that are necessary to segregate GM from non-modified crops and products for markets with strict labelling and traceability requirements have often been cited as imposing a high financial burden on biotech producers. In addition, other domestic policies will impact on competitiveness, such as investments in research and development, training opportunities or currency rate variations.

In the case of competition with non-modified counterparts, consumer attitudes and demand will also impact the GM producers' ability to sell their products competitively, including consumers' willingness to purchase the GM product in the first place, substitutability with other products and the quantities and the premium that they are willing to pay. Supermarkets and large food companies also play a significant role in this regard as they might decide (and some have already decided) to ban GM products and ingredients from the shelves and their products or impose special product standards. Even if agricultural biotechnology enhances the competitiveness of GM producers, the additional gains can be expected to decrease over time if more competitors adopt the technology and the early adopters lose their initial competitive advantage.

Q30 What are the requirements for exports of biotech products to the US and EU markets?

The US and EU continue to provide key export markets for developing countries. The trading blocs have taken very different approaches to regulating imports of biotech products, making them useful case studies for the types of requirements to which agricultural exports might be subject.

The US is perhaps the most lenient of regulators, covering biotech products through existing legislation, approval procedures and institutions. Their product-based approval process assumes that the process of genetic modification does not result in a different product *per se*. Rather, safety

evaluations compare the biotech product with its conventional counterpart and – if necessary – assess the identified differences. Labelling would then only be required if specific health risks or nutritional issues have been identified. Relevant legislation includes the Plant Protection Act (PPA), the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act (TSCA).

In the US, food and feed safety are under the responsibility of the USFDA. Imports and field releases of GMOs that may pose a plant pest risk are regulated by the USDA's Animal and Plant Health Inspection Service (APHIS). Finally, development and release of GM plants with pest control properties are regulated by the USEPA. Depending on its intended use, a biotech product may be reviewed by one or several of these agencies. For instance, a food crop genetically modified to produce a pesticide in its own tissue (e.g. Bt maize) might be reviewed by all three organisations.

If the GM plant poses a potential plant pest risk, the USDA will oversee the transportation (including importation), field-testing and disposal of the GMO. Most GM plants will simply be required to be notified as long as they meet a number of requirements to ensure that they do not pose a significant plant pest risk. For GM plants that could have elevated risks (such as plants that produce pharmaceutical or industrial compounds) and GMOs other than plants, a field-testing permit will be required that sets out certain permit conditions that applicants must meet in order to receive approval to field test or transport their GMO.

For its part, the USEPA regulates the distribution, sale, use and testing of the pesticidal substance, e.g. the Bt in Bt maize. In order to field test, sell or distribute the pesticide in commerce, the pesticide needs to be registered with the USEPA. The Agency can then establish the conditions of commercial use and set the amounts or levels of pesticide residue that may safely be allowed in food or feed. Developers can also voluntarily consult with the USFDA about possible other, unintended, changes to the food or feed, for example possible changes in nutritional composition or levels of native toxicants.

The US does not require labelling for biotech products, although *Draft Guidance for Industry Voluntary Labelling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering* has existed since 2001 to assist manufacturers who wish to voluntarily label their biotech foods.

The US has not ratified the Cartagena Protocol on Biosafety and has consequently not implemented its provisions. Nevertheless, the US might decide to implement related rules under bilateral or regional economic integration agreements. For instance, in a trilateral agreement struck with its NAFTA (North American Free trade Agreement) partners Canada (not a party to the Biosafety Protocol) and Mexico (a party), the US agreed to a five percent threshold above which shipments must be labelled as "may contain" LMOs. The unintentional presence of LMOs does not trigger any labelling requirements. The information should be provided on the invoice accompanying the shipment and no other documentation is required.

In contrast to the US, the EU has implemented a process-based regulatory system that distinguishes between and consequently regulates products on the basis of whether they have been genetically modified or not. Environmental release and 'placing on the market' (e.g. for cultivation, import or processing) of GMOs are regulated by EU Directive 2001/18/EC. Under the Directive, GMOs are subject to a single risk assessment and a single application to obtain approval for the deliberate release of GMOs into the environment and for use in food or feed (the so-called 'one door, one key' procedure). Scientific risk assessments are conducted by the European Food Safety Authority (EFSA). The European Commission will then draft a proposal for granting or refusing authorisation, which will be submitted for approval by member states. Should member states be unable to reach a decision

either in favour or against an application, the European Commission is authorised to take the decision. However, individual member states under Article 23 of the EU Directive may provisionally restrict or prohibit the use and/or sale of an EU-approved biotech product on its territory if they believe that the product constitutes a risk to human health or the environment (based on new or additional scientific knowledge obtained after the EU-level risk assessment was completed).

To complement the Directive, extensive labelling and traceability regulations were adopted in 2003 and entered into force in 2004. The traceability regulations require all GMOs and food products obtained from GMOs to be tracked throughout all stages of the production and distribution chain. To this end, operators have to provide information to the next operator that the product or certain ingredients contains GMOs or consists of GMOs or is obtained from GMOs, together with the unique identifier(s) for these GMOs. Moreover, all GM foods or feed are subject to labelling, irrespective of whether the GM material can still be detected (e.g. soy oil made from GM soy). The labelling threshold is 0.9 percent, above which GM products have to be labelled. The threshold for the accidental presence of unauthorised GM material is 0.5 percent, provided that the GMOs have been judged as safe for human health and the environment by the European Food Authority.

The EU has ratified the Cartagena Protocol on Biosafety and in 2003 adopted specific regulations for the transboundary movement of GMOs that cover exports of GMOs to third countries. The EU did not amend its import and approval procedures which they felt already contained rules that are in line with the objectives of the Protocol.

Q31 Will the cost of labelling and traceability requirements make GM products more expensive?

Some countries have put in place stringent labelling and traceability requirements for domestically produced and imported GM products. The EU leads this group with a labelling threshold of 0.9 percent – the most stringent in the world – and extensive traceability rules that require producers to keep a record of the presence and type of GMOs throughout the production chain. Many GM producers, especially in the US, have long complained that such requirements are unnecessarily cumbersome and in fact pose an unfair barrier to international trade. Often cited in this context are the costs of product differentiation – to keep the modified and non-modified crops and products separate – and record keeping – to collect and maintain information about the products' attributes through production and distribution channels. The US, for instance, estimates that compliance with the EU regulations could cost US companies up to US$ 4 billion a year in export earnings (Paarlberg, 2002).

Additional costs of complying with labelling and traceability requirements are likely to occur at all stages of production, including seeds, cultivation, harvest, storage, transportation, sale from the producer to wholesaler/retailer and processing. In the case of grains and oilseeds, where the greatest costs are likely to arise in the immediate future, a number of steps are involved where traceability systems would need to be implemented (Golan *et al.*, 2004, European Commission, 2000):

- Throughout the production chain, storage and transportation systems will need to be modified to keep the grains and oilseeds separated, possibly requiring testing and certification at the various stages, including by third-party certifiers.
- Farmers will be required to obtain seeds with verified crop traits (GM or non-GM) and purity levels, maintain sufficient distances between modified and non-modified crops to avoid cross-pollination, avoid crop mixing with volunteer GM plants that are already present in the soil when a non-modified crop is sown, and employ harvesting systems that avoid co-mingling (see also Q3).

- Elevator operators will either need to dedicate their entire facility to GM or non-modified crops, use multiple bins or clean their bins and equipment after each crop.
- Processors may need to dedicate entire plants or establish distinct production lines to ensure continued separation of the grains and oilseeds, and reflect the GMO content on the label and/or shipment documentation.

In the case of fresh produce, such as fresh fruits and vegetables, boxing and identification of quality attributes are often done early on in the production process, thereby facilitating traceability (Golan *et al*. 2004). Similarly, traceability systems for livestock and meat products are already fairly well established to control animal diseases and quality.

The additional costs of implementing traceability and labelling systems are difficult to estimate as they vary considerably with a range of factors. Estimates tend to rely on a number of assumptions that make them difficult to compare. It also remains unclear who would – or indeed should – bear the cost of implementing these systems (primary producers, processors or consumers? the GM or the non-GM producers?). Furthermore, the magnitude of additional costs is not fixed and is likely to change as the industry adapts to the traceability requirements and as the volume of material involved increases (Buckwell *et al*. 1998).

One estimate puts the costs at US$ 5-25/tonne depending on the types of grains and identity preservation systems (European Commission, 2000). The USDA's Economic Research Services calculated additional segregation costs of US$ 0.22 per bushel (ca. US$ 8.7/tonne) for maize and US$ 0.54 per bushel (ca. US$ 19.8/tonne) for soy, in both cases excluding possible additional costs at farm level (Lin *at al.*, 2000). A European study estimates additional costs of EUR 9.3/tonne (ca. US$ 11.3) for intensive cultivation of maize and EUR 5.5/tonne (ca. US$ 6.7) for non-intensive with a threshold of one percent. Production costs for organic production would increase by EUR 14.2/tonne (ca. US$ 17.2) (Bock *et al.*, 2002). Other research suggests that if the threshold for GM content was lowered from one to 0.5 percent in the EU, the cost of production for grain elevator businesses in the Midwest of the US would increase between 34 and 50 percent (Barnes *et al.*, 2005). Another study concludes that most of the additional costs would likely arise at the grain handling level rather than adapting agricultural practices or testing for GM content (Bullock *et al.*, 2000).

Perhaps the most extensive study on the cost of segregation has been carried out by the Argentinean Secretariat of Agriculture, Livestock, Fishing and Food and the UN Food and Agriculture Organization (SAGPyA and FAO, 2004). In the case of Argentina, the study estimates upfront costs of establishing the necessary segregation systems at US$ 40 million in the case of soy and slightly less in the case of maize in order to comply with the European 0.9 percent threshold, while compliance with a 5 percent threshold would cost US$ 10.2 million for soy and US$ 7.4 million for maize. The annual segregation costs for maize are thought to amount to US$ 2.8/tonne with a 5 percent threshold and US$ 7.8/tonne with a 0.9 percent threshold. For soy, average costs are estimated at US$ 8/tonne with a 5 percent threshold and US$ 13.9/tonne with a 0.9 percent threshold.

In general, costs will vary with the desired level of precision and consequently the type of traceability system. Two systems are commonly used. *Segregation systems* separate crops or food ingredients from each other and usually do not involve a very high level of precision. *Identity preservation systems* (IPS) identify the source and/or nature of the crop or food ingredient. The level of precision would be determined by requirements of domestic legislation or the export market, notably the threshold set for the accidental presence of GMOs, which commonly range between 0.9 and 5 percent. The rigour of the traceability system will also impact on the cost of testing at the various stages of production.

Variations in costs are also associated with different crops, for instance due to differing agronomic traits, such as the genetic disposition for cross-pollination. Another important determinant of cost is the complexity of the production and distribution system, such as the number of handlers and manufacturers, with costs likely to increase with increasing complexity. These costs could be reduced with greater vertical integration of the supply chain where a company might handle several stages of the chain and could streamline record keeping systems. In addition, the volume of production – partly as a result of greater demand – will influence costs by allowing for economies of scale and the minimisation of unused capacity.

It is important to note that most studies on the cost of implementing segregation systems have focused on developed countries, notably the US and EU, which already have well-established quality control and processing systems in place that can be adapted to fulfil the new requirements. Concerns have been raised that production and distribution systems in many developing countries differ significantly from those in developed countries, making it more difficult – and some claim impossible – to implement effective segregation systems. Plot sizes tend to be significantly smaller and close together; the harvest is transported in loosely closed containers with potential for spillage; the produce is often sold directly on the market rather than passing through a handling system and farmers exchange and reuse seeds for the next growing season.

Q32 How might the approach to agricultural biotechnology in one country impact the policy- and decision-making in another?

Approaches to agricultural biotechnology vary widely around the world. As a result, countries wishing to export to certain markets find themselves confronted with different regulatory frameworks and levels of consumer acceptance. At the same time, countries face pressures from their trading partners to open their markets to GM imports. At the global level, competitiveness considerations will also play a role in countries' biotech strategies. These constraints and opportunities will invariably contribute to shaping domestic policy approaches.

When deciding on whether and how to engage in biotechnology, countries will need to bear in mind the requirements and sales opportunities in the export markets. In this context, a number of scenarios could be considered:

- *Status quo:* Implications of commercialising and exporting existing biotech products (e.g. existing GM soy or maize varieties) under current trade flows to current markets
- *New applications:* Implications of commercialising and exporting possible future biotech products (e.g. GM rice) under current trade flows to current markets
- *New markets:* Implications of commercialising and exporting existing or future biotech products to new markets.

Relevant import requirements can include mandatory risk assessments, specific documentation for biotech commodities, and traceability and labelling regulations with varying degrees of stringency. While some efforts have been made to harmonise some of these requirements at the multilateral level, notably through the Cartagena Protocol on Biosafety and the Codex Alimentarius Commission, significant differences remain, in particular with regard to domestic labelling requirements, where thresholds vary from 0.9 to 5 percent between countries. Faced with this diversity, countries may choose to either segregate production so as to cater for different markets or adapt their domestic regulatory frameworks to the requirements of the most stringent export market to ensure compliance. Alternatively, they might opt for either 100 percent GM or GM-free production, depending on their key export interests.

Moreover, the choice of products to commercialise and export will likely be influenced by the products that have already been approved in the export market and would therefore face lower import hurdles. Some countries, for instance, have been reluctant to give the green light to certain maize and soy varieties for commercial production that have not yet been approved in the EU. Consumer acceptance in the export market – and the likelihood of obtaining a price premium or at least sufficient returns to make the use of biotech worthwhile – would also need to be borne in mind.

Export interests will also need to be balanced with import considerations. For instance, a country may wish to export to a market with stringent requirements and would consequently need to comply with the import regulations for its biotech products by setting up an equivalent domestic regulatory framework. The domestic regulations, however, might come under pressure from other biotech exporters who seek easy market access for their products. Anecdotal evidence of such pressures abound, for instance in the case of Bolivia, Sri Lanka and China.

In the global trading environment, policy choices will also be influenced by changes in competitive relationship resulting from the adoption of biotechnology. Improved productivity through the adoption of biotechnology in one country, for instance, may encourage adoption in another (competing) country that would seek to maintain its market position. Alternatively, anti-biotech attitudes among consumers might open possibilities for GM-free markets, thereby providing an incentive to maintain conventional crops and reap any potential price premiums. It has been argued, for example, that European farmer groups – who due to the comparatively small size of their farms are unlikely to reap the same benefits from using biotech crops as their large-scale counterparts in the US – have lobbied for stringent biotech regulations to keep the more efficient producers out of the market (Anderson *et al.*, 2004).

These factors will need to be carefully weighed up against national public policy objectives, such as food security, environmental sustainability or rural development, to evaluate the costs and benefits of embarking on the biotech path.

References and further reading

For further information on the US regulatory system, see:

- http://usbiotechreg.nbii.gov/
- http://www.aphis.usda.gov/brs/
- http://www.cfsan.fda.gov/~lrd/biotechm.html
- http://www.epa.gov/biotech_rule/index.htm

For further information on the EU regulatory system, see:

- http://europa.eu.int/comm/food/food/biotechnology/index_en.htm
- http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf

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PART C: INTERNATIONAL LEGAL FRAMEWORKS

Several international agreements and institutions establish the framework within which domestic regulation of GMOs is developed and implemented (see Table 2 for a summary). Some of these agreements do not address biotechnology in an explicit manner. Nevertheless, they contain provisions that compel, guide or affect domestic biotechnology policies and rules. For example, although WTO agreements do not make specific references to biotechnology, the requirements several of them establish in fact define the scope WTO Members have to develop domestic regulation on GMOs that affects international trade. Other agreements, such as the CBD and the Cartagena Protocol on Biosafety, address biotechnology and trade in biotechnology directly, while others deal with issues related to intellectual property.

In all cases, however, international rules in the context of trade, biotechnology and sustainability must deal with the tension between the need to regulate biotechnology – for example, to protect public health and biodiversity – and the need to minimise unnecessary or non-transparent barriers to international trade. In addition, because this tension may be resolved in different ways by each international agreement, there is also the challenge of ensuring mutual supportiveness among the broad international framework for biotechnology. The section will introduce some of the most relevant international agreements to trade in biotechnology, briefly noting their objectives and main provisions, as well as their links with each other.

C.1 World Trade Organization (WTO)

The WTO is the international organisation dealing with the rules of trade between nations. It was created by the Uruguay Round of negotiations and entered into force in 1995. Although the General Agreement on Tariffs and Trade (GATT) had provided the rules for the trade in goods since 1948, the WTO revised this agreement and expanded the scope of the multilateral system. Indeed, WTO agreements, several of which are analysed below, address agricultural and services trade, standards, intellectual property rights and a variety of other issues. In particular, WTO rules specify what kinds of policies governments can use to regulate trade, including tariffs, subsidies and trade remedy measures (which include anti-dumping duties, countervailing duties against subsidised imports and safeguards). These rules are legally binding on WTO Members and enforceable through a Dispute Settlement system. The WTO currently has 149 Members.

The WTO attempts to set out a framework for the liberalisation of international trade that enables its Members to move collectively towards free trade that is supportive of national commercial interests and sustainable development more broadly. To this end, WTO rules include a number of key principles that aim to ensure fair treatment of all Members:

- The '*most favoured nation*' (MFN) treatment, as described in Article I of the GATT, requires WTO Members to impose the same duties, charges, regulations, favours and methods of regulation on all goods imported from or exported to all Members. For example, an importing country could not put a higher tariff on imported apples from Australia than those placed on apples from New Zealand. Instead, any advantage or privilege granted to one Member must be extended to other Members. The GATT includes some exemptions to this article – the most notable being that allowing for regional trade agreements in article XXIV and for the Generalised System of Preferences in the 'enabling clause' decision taken in 1979.

Table 2: Overview of international legal frameworks relevant to biotechnology

MULTILATERAL TRADE AGREEMENTS UNDER THE WTO	
WTO General Agreement on Tariffs and Trade (GATT)	• Lays down the basic rules for trade in goods. • Articles of particular relevance: - Art. I (most-favoured-nation treatment) - Art. III (national treatment, including non-discrimination for like-products in Art. III 4) - Art. XX (general exceptions, including to protect public morals, human, animal or plant life or health and to conserve exhaustible natural resources in Art. XX(a), (b) and (g))
WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)	• Recognises the sovereign right of Members to provide the level of protection of human, animal or plant life or health they deem appropriate • Aims to ensure that SPS measures do not represent unnecessary, arbitrary, scientifically unjustifiable, or disguised restrictions on international trade. • Articles of particular relevance: - Art. 3 (harmonisation of SPS measures, including through the use of international standards, guidelines or recommendations, or of risk assessment) - Art. 5.7 (precautionary approach)
WTO Agreement on Technical Barriers to Trade (TBT)	• Aims to ensure that technical regulations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade. • Articles of particular relevance: - Art. 2.1 (non-discrimination for like-products) - Art. 2.2 (legitimate objectives)
Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)	• Establishes the minimum standards of intellectual property protection to be provided by each WTO Member, including the subject matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. • Sets out domestic procedures and remedies for the enforcement of intellectual property rights • Articles of particular relevance: - Art. 27.1 (criteria of patentability) - Art. 27.2 (exclusion from patentability to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment) - Art. 27.3(b) (patentability of life forms)

OTHER MULTILATERAL AGREEMENTS	
Convention on Biological Diversity (CBD) 1992	• Aims to ensure the 'conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies' • Articles of particular relevance: - Art. 8(j) (traditional knowledge, prior informed consent, benefit-sharing) - Art. 16 (access to and transfer of technology, including biotechnology) - Art. 19 (handling of biotechnology and distribution of its benefits)
Cartagena Protocol on Biosafety 2000	• Protocol to the CBD (pursuant to Art.19) • Aims to ensure "an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements" • Deals with living modified organisms intended for environmental release, and for use as food, feed or for processing • Seen by many as the first operationalisation of the precautionary principle (Art 1, 10.6 and 10.8) • In force since 11 September 2003.
International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA) 2001	• Objectives: conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the CBD, for sustainable agriculture and food security. • Instructs governments to protect farmers' rights • Establishes a multilateral system that aims to facilitate access and benefit-sharing for PGRFA • Articles of particular relevance: - Art. 6 (sustainable use) - Art. 9 (farmers' rights) - Art. 13.2(b) (access to and transfer of technology, including technologies for the use of PGRFA which are under the Multilateral System) - Part IV (benefit-sharing) • In force since 29 June 2004.
International Union for the Protection of New Varieties of Plants (UPOV) 1961	• Provides a framework for intellectual property protection of plant varieties (plant variety or plant breeders' rights) • Revised in 1972, 1978 and 1991 • Protection for plant varieties is granted independently of the technology used (traditional breeding or transgenic)

INTERNATIONAL STANDARD-SETTING BODIES	
Secretariat of the International Plant Protection Convention (IPPC)	• IPPC (1952): - legally-binding - aims to secure common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote measures for their control - Amended in 1979 (entered into force in 1991); revised in 1997 (but not yet in force) to reflect contemporary phytosanitary concepts and the role of the IPPC in relation to WTO Agreements, esp. the SPS Agreement • Standard ISPM No. 11 (2004) Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms
Codex Alimentarius Commission (created jointly by the FAO and WHO in 1963)	• Adopted by the Commission in July 2003: - Principles for the Risk Analysis of Foods Derived from Modern Biotechnology - Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants - Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Micro-organisms • Committee on General Principles: - Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius (adopted in July 2003) - Proposed Draft Working Principles for Risk Analysis for Food Safety • Committee on Food Labelling: - Draft Recommendations for the Labelling of Foods obtained through Certain Techniques of Genetic Modification / Genetic Engineering
World Organisation for Animal Health (OIE)	• Manual of Standards for Diagnostic Tests and Vaccines

- Article III of the GATT lays down the principle of ***national treatment***, which requires WTO Members to treat imported products the same as domestically-produced products. This means that any regulations – including border duties, internal taxes and any rules that impact on domestic conditions of sale, transportation or distribution – that affect imported goods must also be extended to domestic goods. As such, duties and rules on imports of GM goods must be the same as domestic regulations on GM goods.

Four WTO agreements are considered particularly relevant in the context of trade and biotechnology: the General Agreement on Tariffs and Trade, the Agreement on the Application of Sanitary and Phytosanitary Measures, the Agreement on Technical Barriers to Trade, and the Agreements on Trade-related Aspects of Intellectual Property Rights. The specific issues raised by these agreements with regard to biotechnology are analysed in Section B.2. Below, however, is a brief overview of the more general characteristics of these agreements.

The General Agreement on Tariffs and Trade (GATT)

The GATT, which came into force in 1948, continues to act as the main governance mechanism for the multilateral trading system. In 1994, the WTO adopted a revised version of the GATT (GATT 1994), but it is largely the same as GATT 1947, including only some minor changes. GATT 1994 applies to all trade in goods in the context of the WTO.

The GATT stipulates that the non-discrimination provisions of Articles I and III apply to 'like' products, leaving what constitutes 'like' undefined. In the context of biotechnology, this has raised the question whether genetically modified products should be considered 'like' their conventional counterparts (see Q13).

At the same time, the rules recognise that policies with trade-distorting effects are sometimes necessary for domestic public policy objectives. In particular, Article XX exempts from the GATT measures necessary to address a range of public policy concerns so long as the measures do not "constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail" or are "a disguised restriction on international trade". Included in the list of legitimate exempted measures are those necessary to protect public morals, human, animal or plant life or health, and to conserve exhaustible natural resources.

Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)

The SPS Agreement sets out the rules applicable to measures taken by WTO Members on food safety and animal and plant health that may, directly or indirectly, affect international trade. These measures may only be developed and applied in accordance with its provisions. As a result, although the SPS Agreement stipulates that WTO Members have the sovereign right to provide the level of protection they deem appropriate to safeguard human, animal or plant life or health, its main objective is to ensure that measures to achieve such protection are not misused for protectionist purposes and do not result in unnecessary barriers to international trade.

The SPS Agreement encourages countries to use international standards, guidelines and recommendations where they exist, noting that measures based on such standards are "presumed to be consistent" with the SPS Agreement and the GATT 1994. Three standard-setting bodies are explicitly recognised in the Agreement: the Codex Alimentarius Commission for food safety, the International Plant Protection Convention for Plant Health and the World Organisation for Animal Health (OIE). As such, the biosafety-related standards developed by these organisations, while not binding, become of key interest to those investigating the relationship between biosafety regulations and the WTO (see below).

Members are also allowed to implement measures in the absence of international standards, or that result in a higher level of protection than existing standards, with adequate scientific justification (Article 3) based on a risk assessment as set out in Article 5 of the Agreement. In cases where relevant scientific evidence is insufficient, Members may temporarily adopt measures on the basis of available pertinent information, as long as they "seek to obtain the additional information for a more objective assessment of risk and review the sanitary and phytosanitary measure accordingly within a reasonable period of time" (Article 5.7). The WTO Appellate Body has recognised that this provision reflects the precautionary approach, although the SPS Agreement does not make explicit reference to the precautionary principle (see glossary).

In all cases, to make sure that SPS regulations are not disguised restrictions on international trade, the SPS Agreement requires regulations to be based on science, to be applied only to the extent necessary to protect human, animal or plant life or health, and to not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.

Agreement on Technical Barriers to Trade (TBT)

The TBT Agreement aims to ensure that technical regulations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade. Such technical regulations and standards include packaging, marking and labelling requirements, terminology, symbols, process or production methods and procedures for assessment of conformity with technical regulations and standards. According to the Agreement, technical regulations must be no more trade restrictive than necessary to fulfil a legitimate objective, which in Article 2.2 are described as "national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment." In addition, Article 2.1 requires that Members ensure that products imported from any Member are treated no less favourably than 'like' products produced domestically or by any other WTO Member. Measures relating to the labelling of GM foods or changes in nutritional content of GM foods that do not relate to food safety could fall under the jurisdiction of the TBT Agreement. Central to any such discussion would likely be the definition of 'like' products in Article 2.1 and whether the measure in question could be described as no more trade restrictive than necessary.

Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement requires WTO Members to adopt minimum standards of protection for a wide range of intellectual property rights, including patents, copyright, trademarks geographical indications and trade secrets, establishing subject matter that must be protected, certain rights that must be conferred, and the duration and permissible exceptions to those rights. For patents, for example, which are perhaps the most relevant intellectual property right in relation to biotechnology, it requires patents be granted for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. As such, biotechnology inventions can not *per se* be treated any differently than other sectors under the TRIPS Agreement, although the facultative exceptions provided by the Agreement have in fact resulted in a variety of approaches among WTO Members in the context of intellectual property and biotechnology.

Article 27 sets out the inventions that Members may exclude from patentability. Under Article 27.2, exclusion is possible "to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment". Under Article 27.3, Members may include "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" as well as "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes". The Article stipulates, however, that Members are required to provide protection for plant varieties, either through patents, a *sui generis* system or a combination of both.

Article 7 of the TRIPS Agreement affirms that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer

and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. However, there are a number of concerns about the negative effects of the increasing levels of intellectual property protection, including in relation to biotechnology.

C.2 International Union for the Protection of New Varieties of Plants (UPOV)

The International Union for the Protection of New Varieties of Plants, known as UPOV from its French acronym, was established by the International Convention for the Protection of New Varieties of Plants (the 'UPOV Convention'). The Convention came into force in 1968 and was revised in 1972, 1978 and 1991. Parties who signed up to one of the older versions were free to decide whether to adopt the revised versions, while new parties are obliged to sign up to UPOV 1991. The UPOV Convention provides a specific system of intellectual property protection for plant varieties. In particular, the UPOV Convention contains a system of protection for the rights of plant breeders – with the objective of encouraging the development of new varieties of plants. As a result, the UPOV Convention also includes breeders' exemptions to allow to some extent the use of protected varieties for additional breeding.

UPOV 1991 has strengthened breeders' rights in several ways compared to the 1978 version. For instance, while UPOV 1978 allowed farmers to save seeds for re-use without paying or requesting the approval of the breeder who originally bred the seed and sold it to him, UPOV 1991 made this provision optional in Article 15(2) and specified that this exemption was only to be applied "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder". In addition, farmers are not allowed to sell protected seeds.

Another difference between UPOV 1978 and 1991 relates to "essentially derived varieties". Under UPOV 1978, very similar varieties could be registered as different strains and therefore qualify for protection for breeders' rights, even if one variety was just a slight alteration of the other. Under Article 14.5(b) of UPOV 1991, a variety that is "essentially derived" from a protected plant variety – that is, it is predominantly derived from, has the same essential characteristics as and yet is clearly distinguishable from the original variety – falls under the intellectual property protection of the protected variety. This change was partly motivated by the desire to prevent different plant breeders and in particular developers of GMOs from securing protection for varieties that were merely slightly changed versions of already protected varieties.

C.3 International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

The ITPGRFA was agreed upon at the 2001 FAO Conference and entered into force in June 2004. It builds on the 1983 International Undertaking (IU) on PGRFA but, unlike the IU, contains binding obligations with respect to access to plant genetic resources and benefit-sharing in the area of food and agriculture. Its objective is the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the CBD, for sustainable agriculture and food security.

In particular, the ITPGRFA sets up a 'Multilateral System' containing certain PGRFA that countries agreed should be freely accessible to plant breeders, farmers and research institutions for "use and conservation in research, breeding and training for food and agriculture, provided that such purposes do not include chemical, pharmaceutical and/or other

non-food/feed industrial uses" (Art. 12.3(a)). To date, the Multilateral System contains 64 important crops and forages from around the world. In order to ensure that access to these crops remains as open as possible, Article 12.3(d) says that recipients of the crops can not impose intellectual property or other rights that limit access to the resources covered by the Treaty, or their genetic parts or components, in the form received from the Multilateral System.

The Treaty also sets up a system of benefit-sharing for the resources covered, which in Article 13 is described as including exchange of information; access to and transfer of technology; capacity building; and sharing of the benefits arising from commercialisation. Article 13.2(b) calls for countries to provide access to and transfer of technologies for the conservation, characterisation, evaluation and use of the resources covered. Article 13.2(d)(ii) obliges recipients who commercialise a PGRFA that incorporates material received from the Multilateral System to equitably share the benefits arising from the commercialisation in cases where availability of the product is restricted for further research and breeding. If availability is not restricted, benefit-sharing is "encouraged". Benefits will be paid to a trust fund set up under the ITPGRFA. Article 18.5 specifies that priority use of these funds is to go to farmers in developing countries who conserve and sustainably utilise plant genetic resources for food and agriculture.

Access to genetic resources in the Multilateral System is provided under a "standard material transfer agreement" (SMTA). The SMTA adopted at the first meeting of the Governing Body of the ITPGRFA in June 2006 sets out two possible benefit-sharing arrangements from which the recipients can choose. One option requires the recipient to pay 1.1 percent of the revenues (minus thirty percent to cover cost of transport, marketing and other related costs) derived from the commercialisation of a product that incorporates material from the Multilateral System, in cases where availability of the product is restricted. An alternative option requires the recipient to pay 0.5 percent of commercial revenues for all products incorporating PGRFA belonging to the crops covered by the Multilateral System, regardless of whether the use of the product has been restricted or whether the products contain material provided by the Multilateral System.

Article 9, for the first time in international law, explicitly recognises 'Farmers' Rights', saying that countries are responsible for taking measures to protect and promote Farmers' Rights including the protection of traditional knowledge; the right to equitably participate in sharing benefits from the use of plant genetic resources for food and agriculture; and the right to participate in making decisions on issues relating to the conservation and sustainable use of plant genetic resources. In Article 9.1, the Treaty recognises the "enormous contribution" that local and indigenous communities and farmers "have made and will continue to make for the conservation and development of plant genetic resources". In addition, in Article 9.3 it notes that "nothing in this Article should be interpreted to limit any right that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate."

C.4 Convention on Biological Diversity (CBD)

The CBD was signed at the 1992 Rio Earth Summit and has since been ratified by over 175 countries. As one of the MEAs, the Convention aims to ensure the "conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies". It stipulates that ratifying governments will, according to their capacity and conditions, develop national strategies for the conservation and sustainable use

of biological diversity and integrate the conservation and sustainable use of biological diversity into their domestic policies.

Under Article 19, the CBD mandates parties to "consider the need for and modalities of a protocol […] in the field of the safe transfer, handling and use of any LMO resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity". This clause led to the negotiations that culminated in the adoption of the Cartagena Protocol on Biosafety (see below).

Other relevant issues addressed by the CBD include traditional knowledge, the sharing of benefits arising from the use of biodiversity and the transfer of technology. The CBD instructs its parties to help respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities which embody traditional lifestyles relevant for the conservation and sustainable use of biological diversity. Parties are to promote the sustainable use of such traditional knowledge with the approval and involvement of the original holders, including by encouraging the equitable sharing of any resulting benefits.

Article 15 deals with access to genetic resources. It calls on parties to create conditions that facilitate such access which should be provided on "mutually agreed terms" and subject to "prior informed consent" of the party providing the resources. Measures should also be put in place to enable the fair and equitable sharing of benefits that arise from the use of the genetic resources with the provider of the resources.

Article 16 states that parties will provide and facilitate other parties' access to technologies (including biotechnology) that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment. Measures will be taken in order to ensure that parties that provide access to genetic resources, and particularly developing countries which do so, get access to and transfer of technology which makes use of those resources "on mutually agreed terms, including technology protected by patents and other intellectual property rights". Parties will co-operate to make sure that intellectual property rights do not run counter to the objectives of the Convention including the conservation of biological diversity.

C.5 Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety to the CBD (also referred to as the 'Biosafety Protocol') was adopted by the Conference of the Parties to the CBD on 29 January 2000 and entered into force on 11 September 2003. The Protocol aims to ensure "an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements".

The Protocol covers both LMOs for intentional introduction into the environment and LMOs for use as food, feed or for processing (LMO-FFP). LMOs for introduction into the environment are subject to an Advance Informed Agreement (AIA) procedure to ensure that countries are provided with the information necessary to make informed decisions before agreeing to import the LMOs. A less stringent approval process is set up for LMO-FFPs, which are often traded as bulk commodity shipments. LMOs for pharmaceutical use are explicitly excluded from the scope of the Protocol, while LMOs for contained use and in transit are exempt from certain provisions related to approval procedures.

The Protocol reaffirms the precautionary language in Principle 15 of the Rio Declaration on Environment

and Development in its Preamble and Articles 1 and 10 and allows for precautionary decision-making on the imports of LMOs if cases where there is a "lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of the LMO on the conservation and sustainable use of biological diversity in the party of import, taking also into account risks to human health". The Protocol also establishes a Biosafety Clearing House to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol.

Article 18 on handling, transport, packaging and identification calls on parties to ensure that LMOs are handled and moved safely across borders to avoid adverse effects on biodiversity and human health. It sets out requirements for the documentation that should accompany the transboundary movement of LMOs for environmental release, FFP and contained use. The requirements have been further elaborated by subsequent decisions of the Protocol's Meeting of the Parties, detailing the type of information that should be included in the documentation. Thus, in cases where the identity of the LMO is known "through means such as identity preservation systems", the shipment should be labelled as containing LMO-FFPs. In cases where the identity is not known, the shipment should be labelled as "may contain" LMOs. In both cases, exporters would be required to provide the common scientific or where available commercial names of the LMOs as well as the transformation event or unique identified code.

Article 22 on capacity building commits parties to co-operate to strengthen human resources and institutional capacities on biosafety in developing country parties and parties with economies in transition in order to ensure the effective implementation of the Protocol. Article 26 on socio-economic considerations notes that when making decisions on importing LMOs under the Protocol, parties may take into account socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity.

C.6 Standards of the Codex Alimentarius Commission

The Codex Alimentarius Commission is the international body charged with the development of food standards. Since its establishment in 1963, the Commission has brought together government experts to negotiate internationally-supported standards that can guide national laws and regulations regarding food and consumer protection. These standards are recognised by the WTO in the context of the SPS Agreement, as mentioned above.

Three documents specifically dealing with biotech foods were adopted by the Commission in 2003. These are: *Principles for the risk analysis of foods derived from modern biotechnology*; *Guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA plants*; and *Guidelines for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms*. These documents were the result of extensive negotiations within the Codex Intergovernmental Task Force on Foods Derived from Biotechnology between 2000 and 2002. The Principles state that a safety assessment comparing the GM product to its conventional counterpart to see if the two products are 'substantially equivalent' should only act as the beginning of a risk analysis of a GM product. While the safety assessment should look at intended and unintended effects, new or altered hazards and changes in key nutrients, the risk assessment should also take into account other relevant factors suggested by science-based multidisciplinary data. In addition, risk analysis should also include the imposition of risk management measures that are proportional to the risk, which could include 'the tracing of products' and labelling as risk management tools. Moreover,

the principles stipulate that authorities should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties. Furthermore, the standards state that "in the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts".

The Guidelines for the conduct of food safety assessment of foods derived using GM plants and GM micro-organisms are quite similar in their description of the necessity of food safety tests not only for the new gene itself but also for the food in which it is embedded. The guidelines include safety assessment requirements for foods produced with GM micro-organisms and an annex setting out standards for the assessment of possible allergic reactions.

Also of relevance to biotechnology, the Codex Committee on General Principles in 2003 adopted *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius Commission* and is currently negotiating similar principles to apply to governments. Furthermore, the Codex Committee on Food Labelling is currently considering *Draft Recommendations for the Labelling of Foods obtained through Certain Techniques of Genetic Modification/Genetic Engineering* which have been the subject of heated negotiations for over twelve years. In September 2005, the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology decided to create guidelines for the conduct of food safety assessments of food derived from GM animals and from plants modified for nutritional and health benefits, and the process of drafting the guidelines began in early 2006.

C.7 International Plant Protection Convention (IPPC)

The IPPC is an international treaty that aims to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control. It was adopted by the Conference of the FAO in 1951 and has been recognised as an official standard-setting body in the SPS Agreement. The IPPC is governed by the Commission on Phytosanitary Measures (CPM), which adopts International Standards for Phytosanitary Measures (ISPMs). Amendments made in 1979 entered into force in 1991, and revisions made in 1997 entered into force in 2005. The most recent revisions aim to reflect contemporary phytosanitary concepts and the role of the IPPC in relation to WTO agreements, in particular the SPS Agreement. For example, the new IPPC strengthens the mechanisms for co-operation and exchange of information between its parties through the creation of a Secretariat for the Convention, with the express goals of developing new ISPMs and facilitating the exchange of information and technical assistance necessary for implementation. As such, the revisions ensure that more countries will be able to meet the plant protection requirements of the standards in a way that enables regulatory harmonisation and does not lead to the creation of unjustified barriers to international trade.

Based on a decision by the ICPM, the Standards Committee of the IPPC at their 4th meeting in April 2004 added a supplement on pest risk analysis for LMOs to ISPM (International Standards for Phytosanitary Measures) No. 11 Revision 1 entitled *Pest risk analysis for quarantine pests including analysis of environmental risks*. The revised version includes two Annexes outlining the IPPC's LMO standards. The first, Annex 2 on "Comments on the scope of the IPPC in regard to pest risk analysis for LMOs", says that phytosanitary risks associated with a LMO are within the scope of the IPPC and that, while some LMOs present a phytosanitary risk and therefore warrant a pest risk analysis (PRA), others will not pose such risks and thus will not warrant a PRA. The extent of the pest risk is dependent, according to the standard, on a combination of factors including the characteristics of the donor

and recipient organisms, the genetic alteration, and the specific new traits, and may result from certain traits introduced into the organism such as those that increase the potential for establishment or spread, or from gene sequences that might "act independently of the organism or have unintended consequences". In recognising the possibility of phytosanitary risks related to gene flow, the standard clarifies that the LMO itself is not a pest, but rather there is a risk that the LMO could increase pest potential.

Annex 3 on "Determining the potential for a living modified organism to be a pest" outlines the following potential phytosanitary risks for LMOs: changes in adaptive characteristics which may increase the potential for introduction or spread; adverse effects of gene flow or gene transfer; and adverse effects on non-target organisms. It recognises, in addition, that an LMO may need to be subject to a pest risk analysis if there is a lack of knowledge about a particular modification; the credibility of the information; field experience, research trials, or laboratory data; the expression of pest-related characteristics by the LMOs; and experiences in other countries.

The rest of Standard 11 outlines the PRA process that countries can take up to analyse the pest risks posed by LMOs and other organisms in safeguarding plant health.

C.8 Standards of the World Organisation for Animal Health (OIE)

The OIE was created in 1924 and has been recognised in the WTO SPS Agreement as the organisation responsible for setting international standards to safeguard animal health. Overall guidelines for risk assessment and management are included in the organisation's Terrestrial and Aquatic Animal Health Codes, under which genetically modified animals could be considered. Current OIE standards referring specifically to biotechnology are limited to vaccines created through biotechnological processes. In the Manual of Standards for Diagnostic Tests and Vaccines, a specific procedure for testing vaccines created through genetic modification is described. In addition, at their 73rd General Session in Paris in May 2005, OIE members asked the Secretariat to give priority to the creation of additional standards for vaccines and medicines produced through biotechnological methods, given the high potential that such vaccines and medicines could have in improving animal health and the relatively minimal public concern about their impact.

At the same meeting, delegates discussed the creation of cloned animals and animals that have been genetically engineered to produce chemicals or medicines (for example, an animal that is genetically engineered to make milk that contains insulin). Members raised some concerns about the unique risks posed by these two types of genetic engineering and asked the Secretariat to become more involved with risk assessment in this field through the convening of a group of scientists to discuss the issues, draft a business plan, and produce a document that the OIE's elected Commissions could then consider in coming years as a draft standard.

GLOSSARY

Agrobacterium tumefaciens: A naturally occurring bacteria that can insert its own DNA into other plants, thereby changing their genetic structure, through a process known as crown gall. Used by scientists to transfer new, foreign genes into plants such as tobacco and soybean.

Antibiotic resistance marker (ABRM) genes: A gene that can disable antibiotics that is inserted, along with the new gene of interest, into the organism that is being modified in order to test that the ABRM gene and gene of interest are present in the organism. After the two genes are inserted into the organism, the organism is treated with normally toxic antibiotic substances. If the organism survives, that means that the ABRM gene and the gene of interest are in the organism and that the organism has been successfully genetically modified.

Biological Diversity: The variability among living organisms from all sources including, among others, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

Biosafety: The safeguarding of biodiversity from potential risks including biotechnology and its products.

Biotechnology: Any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for a specific use.

Bacillus thuringiensis (Bt): A so-called 'natural pesticide' bacteria that produces a protein that is lethal when eaten by certain insects. Crops that have been genetically modified to contain the Bt gene are able to produce this toxin, thereby providing protection throughout the plant.

Contained use: Any operation in which GMOs or their products are produced, grown, stored, destroyed or used in a closed system in which physical barriers are employed, either alone or together with chemical and /or biological barriers, to effectively limit their contact with, and their impact on, the general population, biological diversity and the external environment.

Conventional: Agricultural goods produced through methods that do not include modern biotechnology.

Co-existence: The need to ensure that both conventional and GM agricultural practices can exist in a given geographical area without compromising the environment or the production and/or economic interests of either group of producers.

Dispute settlement understanding (DSU): Under WTO rules, one or more WTO Members can file a complaint under the WTO Dispute Settlement Understanding against another Member if they feel that this Member has acted contrary to the rules of the WTO. The set of documents that make up the WTO Agreements (including the GATT, Agreement on Sanitary and Phytosanitary Standards and the Agreement on Technical Barriers to Trade) are all enforced through the DSU. Following a short mandatory consultation period, the complaint goes to a Panel that is created expressly for the case, which rules on the WTO-compatibility of the measures in question. Should one of the parties to the Dispute disagree on the ruling, they can appeal the case, in which case the permanent WTO Appellate Body can rule on the Panel's interpretation of WTO rules but not on the substantive facts of the case that have been determined by the Panel. The rulings of the Panel and Appellate Body are adopted, and are made legally binding, by the WTO General Council unless all Members of the WTO say it shouldn't be adopted. If a Member who has been ruled against refuses to change the policies/measures that have been disallowed, then the complaining Member is entitled to take punitive measures by hurting the trade interests of the refusing Member.

DNA (Deoxyribonucleic acid): a long chain of molecules that encodes genetic material in cells and controls all cellular

functions in most forms of life. It is usually found as two complementary chains known as the double helix. The chain is arranged in subunits repeated many times.

Doha declaration: The name given to the Declaration adopted by World Trade Organization Members at their Ministerial Conference in Doha, Qatar in 2001. The Declaration gave birth to ("mandated") the set of multilateral trade negotiations in several issue-areas, including the environment, that have been conducted since 2001.

Food security: Defined by the FAO as a situation in which all people at all times have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life.

Genetically modified organism (GMO): An organism whose genetic makeup has been changed through the processes of modern biotechnology.

Genetic use restriction technologies (GURTs): Also known as "terminator" technologies, GURTS are a tool of modern biotechnology that either makes the organism sterile, i.e., unable to replicate itself, or makes a certain gene sterile, so that a beneficial characteristic added to an organism by a gene would not appear in the seeds of subsequent generations. The technology makes unauthorised re-planting and use of genetically modified seed impossible without paying its inventor or distributor, and prevents undesired escape of genes because modified genes cannot be passed on through seeds or amongst different species.

Intellectual property rights (IPRs): A system of entitlements granted by national, regional or international laws that aims to enable owners of inventions to appropriate the full market value of the subject matter that the system recognises they own. IPRs may serve as an incentive for the creation, use and exploitation of inventions, works, marks and designs, and may enhance competition in some circumstances, but may also constrain the number of entities entitled to produce a product.

'Like' products: A number of different WTO provisions forbid Members from putting different regulations and tariffs on products that are the same as one another ('like') but are from different places. If a WTO Member can show that two products from two different Members, or from itself and another Member, are not 'like', then it can treat the two differently including by putting extra regulations, tariffs, etc. on one of the products. It is unclear whether GM and non-GM products are 'like' one another under WTO rules.

Living modified organism (LMO): Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Living organism: Any biological entity capable of transferring or replicating genetic material, including sterile organisms and viruses.

Modern biotechnology: Generally, a process that involves the manipulation of the DNA of an organism. This can include nucleic acid techniques such as the direct injection of DNA into cells or organelle, or fusion of cells between different unrelated organisms that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. (CBD)

Multilateral environmental agreement: A document that sets out environmental goals and practices that has been signed and/or ratified by many countries and has, according to its own rule, come into force as a result of a certain number of countries' ratification.

Non-discrimination: A WTO Principle that WTO Members cannot treat different products differently just because they are from different places. This includes equal treatment of products from foreign countries and one's own territory

('national treatment' principle) and from two different countries ('most favoured nation' principle).

Patent: A document issued by a state that confers an exclusive right to an inventor for a certain period of time (20 years under the Agreement on Trade-Related Intellectual Property Rights (TRIPS) at the WTO) in return for disclosure of his or her invention in a document known as the patent specification. The extent of these rights varies from country to country.

Precautionary principle: As presented in Principle 15 of the Rio Declaration on Environment and Development (1992): "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Incorporated into the Cartagena Protocol explicitly in Article 10.6.

Products derived from GMOs: A substance in which the presence of GMOs can no longer be detected by tests but that includes as one or its only ingredient a substance that results from the processing of a GMO. While a GMO has gone into its production process, and so some might say it "contains" GMOs, no GMOs are present in the final product as a result of processing. Subject to different regulatory treatment in different countries.

Plant variety protection (PVP): A system of intellectual property rights for the creators of new plant varieties that grants them a set of rights that, while recognising their ownership and providing for, at a minimum, right of sale, generally provides a weaker set of rights than a patent does. For example, others may be allowed to use the plant variety for research and breeding practices.

Risk assessment: The evaluation of the direct and indirect, short, medium and long-term risks to the environment, biological diversity, human health, socio-economic conditions or values arising from the contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism.

Risk management: Measures and strategies to regulate, manage and control risks identified in risk assessment procedures.

Sanitary and phytosanitary (SPS) measures: National regulations and practices that aim to support food safety and animal and plant health.

Segregation: The practice of creating and monitoring separate production, marketing and trade channels for GM and non-GM products.

Substantial equivalence: Principle that presumes that food crops that use biotechnology are the same as conventional foods unless shown otherwise. Countries adopting this principle often do not create a separate regulatory system for biotechnology, opting instead to regulate these products within the main regulatory stream unless they exhibit different characteristics from conventional crops.

Threshold: A percentage of GMO-content above which a product is defined as a "GM product" for the purpose of a regulation including labelling rules.

Traceability: The ability to follow the trail of GMOs from the field to the final product so as to ensure that adequate procedures are in place to withdraw feed and food from the market should a risk to biodiversity, plants, animals or the health of the consumer become apparent.

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- Biotechnology: Addressing Key Trade and Sustainability Issues. By ICTSD, 2006.
- Trading in Genes: Development Perspectives on Biotechnology, Trade and Sustainability. Edited by Ricardo Meléndez-Ortiz and Vicente Sánchez. ICTSD and Earthscan, November 2005.

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Founded in 1996, the International Centre for Trade and Sustainable Development (ICTSD) is an independent non-profit and non-governmental organization based in Geneva. By empowering stakeholders in trade policy through information, networking, dialogue, well-targeted research and capacity building, the Centre aims to influence the international trade system such that it advances the goal of sustainable development.