Genetically Modified Organisms
A Summary of Potential Adverse Effects Relevant to Sustainable Development

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GenØk - Centre for Biosafety
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Acronyms and Abbreviations

AIA	Advance Informed Agreement
ARMG	Antibiotic resistant marker gene
BCH	Biosafety Clearing House of the Cartagena Protocol on Biosafety
Bt	*Bacillus thuringensis*
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
DNA	Deoxyribonucleic acid
EC	European Community
EU	European Union
FAO	Food and Agriculture Organization of United Nations
FFP	Food, feed and processing
GE	Genetic engineering
GHG	Green house gases
GM	Genetic modification / Genetically modified
GMO	Genetically modified organisms
HT	Herbicide tolerant
IFOAM	International Federation of Organic Agriculture Movements
IP	Intellectually protected
IPR	Intellectual Property Rights
IP-System	Identity preservation system
IPPC	International Plant Protection Convention
IT	Insect tolerant
LCA	Life Cycle Analysis
LM	Living modified
LMO	Living modified organisms
LMO-FFP	Living modified organisms for direct use as food, feed and processing
NEP	Nutritionally enhanced plants
NGTA	Norwegian Gene Technology Act
OIE	World Health Organization for Animal Health
RNA	Ribonucleic acid
RR	Roundup Ready
R&D	Research and development
SD	Sustainable development
STS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
TBT Agreement	Agreement on Technical Barriers to Trade
UNEP	United Nations Environment Programme
WCED	World Commission on Environment and Development
WTO	World Trade Organization

Summary

Genetically modified organisms (GMOs) are one of the most widespread and controversial products of modern biotechnology. The changes introduced in organisms and their secondary effects in complex natural and anthropogenic systems have raised a series of concerns and uncertainties with regard to their safety and the production packages that they rely on. These concerns are linked to the potential impacts of GMOs on the achievement of sustainable development.

This report emphasizes that the potential impacts of GMOs take place along their life cycle and value chain. In this sense, assessments only at specific stages (commonly at open field production or consumption) are incomplete, limiting the holistic understanding of impacts and their intertwined nature. This is consistent with findings in the literature review, carried out to identify potential effects along the value chain of GMOs, which show the potential multiple links and combinatorial effects of GMOs at different stages (e.g., from their research and development (R&D) to commercialization). Another feature of this report is that it focuses on potential adverse effects of GMOs (particularly GM crops) that may impact sustainable development.

At the R&D level, intellectual property rights (IRP) on GMOs impact the objectives, market organization and regulation, among others, of the modern biotechnology industry. IPR on GMOs, mainly GM seeds, have economic and social effects as well. This applies especially to farmers in relation to legal and economic liabilities arising from the unintentional presence of GMOs. Impacts at the production stage, mainly of GM crops, are related to the inherent characteristics of the GMOs and to the production packages that they rely on. Imbalance and contamination (both genetic and chemical) of the (agro) ecosystems are the most commonly reported adverse impacts at the ecological level. Changes in land use and production costs, dependency on a specific technological package, weakening of food sovereignty, inequity in access to the technology and benefits sharing, occupational health risks, and tensions among adopter and non-adopters of GMOs are some of the economic and social potential implications of GMOs at the production stage. During harvesting, storage, conditioning and processing of GMOs, the changes in yield, the economic implications of contamination, the limited options for differentiation and segregation for small-scale producers and enterprises are the main possible adverse impacts. Since GM-crops production is inserted into the industrial agricultural sector, particularly for the production of commodities, the transportation and commercialization of GMOs are linked to high carbon generation and energy consumption, market concentration and vertical integration, which relates to limited opportunities for fair trade. As for consumption of GMOs, the main issues are related to potential harm to animals (farm or wild) and human health, including an ethical issue on the right of informed consumption.

All these concerns have set the need for international agreements and national legal frameworks to contribute to the safe transport, handling and use of GMOs in order to minimize or prevent adverse effects. In this regard, relevant international agreements dealing with GMOs are the Convention on Biological Diversity (CDB), the Cartagena Protocol on Biosafety (CPB), the newly agreed upon Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the CPB, Codex Alimentarius, the International Plant Protection Convention (IPPC), standards, recommendations and guidelines of the World Organization for Animal Health (OIE), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Aarhus Convention specifically related to the right to public participation in biosafety decision-making. At the regional level, the EU probably has the most developed biosafety regulation, which deals with the deliberate release of GMOs into the environment, GM food and feed, traceability and labelling, transboundary movements and co-existence, among others. At the national level, the Norwegian Gene Technology Act is the most prominent example, with the inclusion of sustainable development, societal utility and the ethical aspects of biosafety regulation.

In the global context of biosafety, labelling and traceability are important since this will: i) provide means for monitoring long-term impacts on the environment and health, and ii) facilitate informed decisions among users and consumers. Besides initiatives on GMO labelling, GM-free certification provided by organic farming, sustainable development initiatives and fair trade represent other

approaches to addressing GMO labelling. In addition, the GMO-free regions movement also intends to create products and services with a differentiated identity by avoiding GMO production.

Preface

Scope and sources of information

Genetically modified organisms (GMOs) are arguably the most developed application of modern biotechnology in terms of research, commercialization, adoption and regulation. Genetically modified (GM) crops are the predominant GMOs introduced into the environment for food and feed production and to a lesser degree for industrial applications, and are controversial for this reason (Lee, 2009).

The available literature related to GMOs is significant. Much research has been conducted with accompanying debate around the science behind the potential applications, research methodologies, markets prospects, technological packages, potential impacts, regulations and many other aspects of GMOs. However, the existing information and knowledge on the safety of GMOs is not only far from being conclusive, it also continues to raise questions on potential adverse effects, risks and uncertainties related to: i) the new characteristics introduced and their expression, and ii) secondary effects of GMOs in relation to the complexity of the ecological and social systems to which they are introduced (Myhr, 2007).

This document focuses on reported information of potential adverse effects of GMOs motivated by the need to implement precautionary-based analysis in light of sustainable development, particularly in relation to long-term impacts on the welfare of natural and anthropogenic systems. Based on this, the potential adverse effects are described at ecological, economic, social and ethical levels along different stages of the value chain of GMOs (from research and development to consumption).

This review places particular emphasis on GM crops since they are: i) the GMO most introduced into the environment; ii) have several applications in the food, feed, industrial, energy and, probably the pharmaceutical sectors in the future; iii) have direct and indirect ecological, economic and social implications, and finally, iv) they represent the most researched and significant area of GMO literature.

The information contained in this report is based on a review of the available literature, mostly peer reviewed articles, as well as official documents and reports from relevant organizations (including the civil society). It also comprises review and personal communication with experts in specific fields of GMO biosafety.

Organization of the report

The report is organized in the following sections:

Introduction. Provides a briefing on crosscutting concepts (GMOs and SD) and on the global status of GMOs in terms of application and commercial adoption, as well as R&D.

Impacts of GMOs. Summarizes the potential adverse effects of GMOs, mostly GM crops, along the basic stages of their value chain according to the basic dimensions of sustainable development (ecological, economic, social and ethical). The value chain is used as an approximation to an analysis along the life cycle of GMOs. This is because little or nothing has been reported on certain GMO life cycle stages, such as disposal. The description of the impacts of GMOs, is complemented by a summary chart on the certainty of the effect analyzed, its relationship with sustainable development, potential temporal and spatial scale of occurrence and specificity of the impact. This summary chart is a modification of the criteria used in the analysis of information that was used in the International Assessment for Agricultural Knowledge, Science and Technology (IAASTD). The section on Impacts

of GMOs includes a brief case example analyzing potential adverse effects of the GM soybean-based agrofuel in Argentina.

Legislation and Regulatory Frameworks Related to GMOs. Provides an overview of the most relevant international agreements and EU regulations related to the safe production, transport, handling and use of GMOs in relation to environmental and human health. It also includes a revision of the Norwegian Gene Technology Act as the current example of a biosafety regulatory framework that considers sustainable development criteria. The review of these regulatory instruments is organized according to their objectives and main provisions.

Labelling and Traceability of GMOs and Products Containing GMOs. Provides complementary information on the current agreements and regulations on identification, traceability and labelling of GMOs, with special focus on EU regulations. This section also includes a brief review of GM-free certification and labelling.

I Introduction

1.1 Genetically Modified Organisms (GMOs)

1.1.1 What is a GMO?

A genetically modified organisms (GMO) is an organism (e.g., plant, animal or microorganism) whose genetic material has been altered using gene or cell techniques of modern biotechnology (IAASTD ed., 2009b).

Genetic material is any that transmits traits across generations or by infectious processes. In the middle of the 20th Century, genetic material became almost ubiquitously synonymous with the molecule DNA. This was an over-simplification that has become apparent in stages with the finding that: i) some genomes, namely in some viruses, were entirely made from RNA; ii) many significant traits are transmitted by material that is not DNA or RNA or not entirely those kinds of molecules (e.g., prions, methylation patterns) (Chong and Whitelaw, 2004; Egger et al., 2004; Heinemann and Roughan, 2000; Hernday et al., 2002; Klar, 1998; Mattick et al., 2009; Mikula, 1995; Petronis, 2001, Pillus and Rine, 1989; Toman et al., 1985; Wickner et al., 2004).

Of special note because of the scale at which it is being researched and tested in both commercial and pre-commercial developments is an epigene whose central component is a small RNA molecule in organisms with mainly DNA genomes because "in some organisms or circumstances [RNA molecules] demonstrate the ability to transfer traits and characteristics infectiously or across generations" (Heinemann, 2009a; p.129). In addition, different versions of RNA regulate the expression of several important genes (e.g., miRNA) (Zhang et al., 2006) and in general, RNA controls the activity of genes by defining which are active and how (Thakur, 2003; Buratowski and Moazed, 2005).

Despite the emergence of epigenetic approaches, so far all GM products on the market or that will appear on the market in the near future still technically depend on the use of some application of "recombinant DNA technology" (e.g., in the GM papaya or Flavr Savr tomato which use the production of small RNAs to achieve silencing) (Heinemann, 2009a). Therefore, the following outline of making a GMO generally remains true (Table 1).

Several of the uncertainties over the potential adverse impacts of GMOs on the environment and health (covered along Section II) are related to the recombinant DNA (or "transgene") and/or its expression. First, there remain scientific uncertainties about the regulation and activities of the DNA used in the transgene construct; several of them originate from pathogenic microorganisms and viruses (Quist et al., 2007). Second, the integration of the transgene into the genome of many kinds of organisms (particularly the commercially dominant GM plants, but also animals) occurs beyond the control of the engineer, meaning that the position of integration, number of integrations and final sequence of the transgene must always be retrospectively described rather than proactively designed leading to uncertainties about the direct and indirect effects of the activity and products of the recombinant DNA introduced (Traavik and Heinemann, 2007). Thirdly, a single DNA insert, just like any DNA gene, can be the source of many derivative RNAs as a result of normal processing within cells, and each RNA can be the source of many, up to thousands, of derivative polypeptides (chains of amino acids that proteins are made from) again due to normal processing within cells (Norregaard Jensen, 2004). Finally, considering that a single gene is part of a large network, its expression can affect either the synthesis or functionality of many other proteins, or because of its novel context it may demonstrate a different spectrum of functions (for extended discussion, see Heinemann, 2007). Thus, it is not known yet how transgenes may impact the synthesis, activity, stability and composition of proteins and the biological effects thereof (Quist et al., 2007).

Table 1. General steps in the process of making a GMO

Gene isolation and excision	The DNA or RNA of interest, after being identified, is isolated from the organism that contains the target gene (e.g., *Bt* toxin (*cry*) gene from *Bacillus thuringiensis*), This genetic material can be taken from plants, animals, viruses or bacteria.
Vector construction	Vectors have the role of transporting the isolated genetic material to the organism where it will replicate and, eventually, express. With the use of "biological scissors" (e.g., enzymes), a vector is prepared using a bacterial plasmid by inserting a promoter that secures the transcription of the transgene (often the 35S from the cauliflower mosaic virus, 35SCaMV), a terminator to stop the signals of transcription, and a marker gene (to identify the successful insertions), among other components. The most commonly used vector is a plasmid carried by *Agrobacterium tumefaciens:* a soil bacterium that contains a segment (Ti plasmid) that has a natural ability to transform cells and to induce the formation of crown gall tumours, an important agricultural disease occurring in certain plants. Because *A. tumefaciens* has limited ability to replicate, a selectable marker gene (usually an antibiotic resistant gene) is inserted in the Ti plasmid-based vector to identify the successful insertions of the transgene.
Transformation with the vector	In order to have enough Ti plasmids to transfer the DNA or RNA of interest into the genome of the organism to be genetically modified, the Ti plasmids are multiplied in the bacterium *Escherichia coli*.
Marker and target gene expression	*E. coli* cells that contain the Ti plasmid-based vector are determined by the inclusion of a selectable "marker" gene within the plasmid sequence. The marker gene confers resistance to a specific selectable agent that would otherwise inhibit or kill the *E. coli* cells in a growth medium. In the past, it was common to use an antibiotic resistant (AR) gene in the vector since only the cells containing the Ti plasmid will survive on media containing the antibiotic. However, due to health concerns related to the development of antibiotic resistance, new alternative methods are being developed and used for marking transformations (e.g. herbicide tolerance, nutrients selection and tolerance to toxic metals), although these are mainly in operation within Europe and developed countries.
Gene delivery	The successful Ti plasmids (those that effectively contain the transgene) are delivered into the genome of susceptible plant cells. The most common delivery methods are: i) *A. tumefaciens*-mediated gene transfer, effective to plant cells susceptible to this bacteria. ii) Microprojectile bombarding (or biobalistic) though which gold or tungsten spherical particles are coated with the Ti plasmids and accelerated to high speed to penetrate the cell where the transgene will be detached and integrated into the plant genome. This method is useful in plants not susceptible to *A. tumefaciens*.

Adapted from Traavik et al. *(*2007, p. 68).

1.1.2 Briefing on GMO applications and commercial adoption

Plants, animals, cellular microorganisms and viruses have all been genetically modified for several purposes with medicinal, agricultural, environmental (bioremediation) and more recently, industrial applications (Traavik et al., 2007; Lheureux et al., 2003). The Annex provides a glimpse of the variety of purposes of GMO development.

GM plants used in agriculture are the largest class of GMOs intentionally introduced into the environment. GM crops are grown in varying amounts in select countries, the largest producers being the United States, Canada, Brazil, Argentina and India. The main GM plants for agricultural and industrial processes are maize, soybean, cotton and rapeseed. The main traits introduced are herbicide tolerance (mainly tolerance to glyphosate and glyphosinate) and insecticide tolerance (mainly Bt or *Bacillus thuringiensis*). Lately there have also been introductions of double and triple-stacked traits (IAASTD ed., 2009b; Heinemann, 2009a; James, 2010).

GM crop production has been mostly concentrated in industrialized countries (mainly US and Canada). Although industry-based data shows the trend of GM crop production shifting to developing countries, the US still holds the majority of the the global GM crop production (45%) (GMO Compass, 2010). Industry-based data also shows a constant increase of areas under GM crop cultivation (James, 2010; GMO Compass, 2010); however, the percentage of global agricultural and arable land occupied with GM crops is still limited (IAASTD ed., 2009b; López-Villar et al., 2009; FoE, 2010). "The majority

of the top 20 GM-producing countries commit <1–5% of their agroecosystems to GM [cultivation] […]. Even the worlds largest producer, the US, commits no more than about a third of its cropping capacity to GM" (Heinemann, 2009a, p.124).

1.1.3 R&D and future applications

Current traits emphasized in GM plants may not be the focus, or sole focus, of future GM plants. Projecting into the near future based on current knowledge, we can foresee the following:

- Current R&D and application period. Focus on the improvement of herbicide (HT) and insect tolerant (HT) crops applying stacked gene technology to new crops, such as sugar beet, wheat, alfalfa, fruits and vegetables (Lheureux et al., 2003), and salinity and drought resistance (Stein and Rodríguez-Cerezo, 2009). (For examples see Table 2).

Table 2. Pending applications of GM crops in the EU

Crop	Number of applications	Introduced trait
Cotton	2	Herbicide tolerant Insect tolerant
Ornamental flowers	2	Altered colour Longer shelf-life
Maize	14	Herbicide tolerant Insect tolerant
Oilseed rape	2	Herbicide tolerant
Potato	2	Increased starch content
Soybean	1	Herbicide tolerant
Sugarbeet	2	Herbicide tolerant

Adapted from: FoE (2010)

- Imminent R&D (the next 5 to 10 years). Based on the R&D in the US and Japan, this period will emphasize changes in product quality and industrial applications. These include modifications such as altered nutritional characteristics of soybean and maize, production of decaffeinated coffee, altered levels of gluten in wheat, crops with different yield characteristics, coloured cotton, cotton with improved fibre (Lheureux et al., 2003), crops with higher content of industrial substances (e.g., oil and starch) (Stein and Rodriguez, 2009), and nutritionally enhanced plants (e.g., increased content of fatty acids and vitamin E) (Stein and Rodríguez-Cerezo, 2009; Schubert, 2008),), and the so called "nutritionally enhanced" plants (e.g., increased vitamin content) (Stein and Rodríguez-Cerezo, 2009; Schubert, 2008), among others.

- Medium term future (beyond 10 years). The future applications would focus on functional GM foods (e.g., hypoallergenic foods), industrial raw materials and plants better adapted to particular industrial fuel production methods (Lheureux et al., 2003). Some expect that the number of commercialized GM events will increase form the current 30 up to 120 — mainly stacked events — the majority of them developed by Asian providers. More introductions of soybean, maize, cotton, rice and potato have also been predicted (Stein and Rodríguez-Cerezo, 2009). Future gene transfer methodologies for this R&D might include chloroplast transgenesis, construction of artificial chromosomes, nanobiotechnology and synthetic biology (Traavik et al., 2007).

1.2 Sustainable Development (SD)

An analysis of changes in the natural environment resulted in the realization of: i) linkages between the deterioration of the environment and human activities, mainly those related to economic development; and ii) uncertainties around scientific knowledge and the possible economic costs of environmental remediation. In this context, two perspectives of policy making arise. One stating that prior to any change in policy which addresses environmental damage, scientific evidence needs to be improved. The other, maintaining that the level of environmental deterioration is such that we cannot afford to postpone remediation and preventive policy measures until there is full scientific certainty, that the existing knowledge is useful enough to take precautionary actions beyond economic utility (Jacob, 1994).

From these perspectives the concept of sustainable development (SD) was officially and broadly defined by the World Commission on Environment and Development (WCED) in 1987 as "the development that meets the needs of the present without compromising the ability of future generations to meet their own needs" (WCED, 1987, p 43).

The WCED concept on SD has been criticized for being too broad, unspecific in relation to policy implications, contradictory in the critical objectives stated in the WCED and anthropocentric in its framing (Lélé, 1991; Dovers and Handmer, 1993; Constanza and Patten, 1995; Small, 2007). Despite these weaknesses, the WCED definition of SD has contributed to acknowledging the close interrelation of environmental and development issues (Dovers and Handmer, 1993), the need for long-term considerations in relation to environmental and human welfare (Lélé, 1991) and the ethical responsibility in which it is rooted (Euston and Gibson, 1995). In this sense, SD is an interdisciplinary concept (Rao, 2000) and a moral value (Euston and Gibson, 1995).

Based on all this, in the context of this document SD is understood as the dynamic condition in which natural and human systems co-exist and co-evolve towards higher stages of health and resilience in the long-term (Small, 2007; Rao, 2000; Euston and Gibson, 1995; Norgaard, 1988).

Under this understanding of SD, natural systems, human health and long term-resilience are crucial elements, whose achievements rely on the following interrelated and mutually supported principles (Euston and Gibson, 1995; IUCN et al., 1991):

- Respect and care for the present and future communities of life, including both natural and human. It involves respect for ecological integrity and resilience by: i) conservation of natural vitality, equilibrium and diversity by conserving life-support systems (such as climate, air, water and soil), conserving biodiversity and using renewable resources according to their capacity of regeneration; ii) minimization of the depletion of non-renewable resources; iii) keeping human activities within a natural system's carrying capacity; and iv) recognizing that the natural ecosystem supports human and economic systems and not the other way around.

- Justice in reference to pursuing the common good by: i) changing personal attitudes and collective practices that are incompatible with respecting and caring for life and ecological integrity; ii) pursuing participation in the life and decision-making of communities and societies; iii) enabling communities to achieve sufficiency of sustenance while minimizing excess and wastefulness; iv) facilitating communities to care for their own environments by making empowered and informed decisions; and v) providing policy frameworks that put into place all of the above.

II Impacts of GMOs

2.1 Overview

Along with the broad potential applications of GMOs in the agricultural, environmental, medicinal and industrial fields there are a wide range of potential impacts both beneficial and adverse, short and long-term. Discussions and information on benefits and harms arising from GMOs are controversial for different reasons, including the difficulty of assessing the impacts of GMOs and conflict of interests in the research and analysis of the findings. This is particularly important in relation to impacts on health and the deliberate release of GMOs into the environment, where the difficulties of evaluation of impacts can be summarized as follows (based on IAASTD ed., 2009a; Nielsen and Myhr, 2007; Waltz, 2009a):

- The science and interdisciplinary analyses that can make reliable predictions of the impacts of GMOs when introduced to different kinds of intended and unintended receiving environments and used as food in different socioeconomic contexts, are still under development. To date, there is only limited experience of impact assessment in a small number of ecosystems, socioeconomic contexts and GMO applications. It is problematic to extrapolate these limited experiences and findings to other environments and socioeconomic contexts as evidence.

- Various types of uncertainty arise from the complexity of the biological systems and social processes involved in or resulting from the development, release and use of GMOs.

- Variation in research findings, which prevent the formulation of a scientific consensus on safety and proper regulation.

- A lack of uniform access to all material for testing leading to the accumulation of unreplicated studies or studies exclusively done by those with a vested interest in the outcome.

- Extremely polarized a priori positions in the analysis and communication of potential beneficial and adverse impacts of GMOs, particularly from the sectors with conflict of interest, making it difficult to have a non-speculative discussion on the science and safety issues related to GMOs.

In this scenario, positions on policy approaches to the potential impacts of GMOs differ significantly. On one hand, it can be argued that regulation or proprietary interests slow the spread of potential benefits. Some maintain that regulation of GMOs is unjustifiable and would jeopardize future developments of and further beneficial impacts from GMOs (Qaim, 2009; IAASTD ed., 2009a); while others note that the need to control intellectual property and proprietary advantage are probably more important than regulatory standards for inhibiting the availability of GMOs (McAfee, 2003; Pray and Naseem, 2007; Spielman, 2007; WHO, 2005). Conversely, in light of the potential adverse impacts, it is maintained that precautionary and participatory approaches should be central in biosafety research and policy-making to evaluate and communicate the certainties and uncertainties related to GMOs and comparatively assess other alternatives (Ammann et al., 2007; Stirling, 2008).

At the same time, these diverging policy positions result in different approaches to SD. The core distinction among them is the effective inclusion of uncertainty in the appraisal of impacts of GMOs in complex and dynamic ecological and human systems (Stirling, 1999). The consideration of uncertainty (resulting from incomplete knowledge or contradictory information) through precautionary approaches acquires a particular relevance in SD. This is of particular importance in the GMO debate because a significant amount of the information on their impacts on poverty is anecdotal (IAASTD ed., 2009a, Stirling, 1999).

The following sections relate to the impacts of GMOs. In these sections the most relevant reported potential beneficial impacts will be acknowledged, but the focus will be on the potential adverse effects of GMOs, particularly in the medium and long term and in light of a precautionary-based analysis.

This is justified because those with vested interests in developing GMOs have ample opportunity and motivation for emphasizing benefits, as well as exclusive access to research material on which to base their claims. For this purpose, the various impacts are described according to the ecological, economic, social and ethical considerations of SD along each stage of the value chain of GMOs. GM crops are used in this case study due to their predominance among current commercially available GMOs and the significant amount of information reported on them. A generic value chain of GM crops (Figure 1) is used as an approximation of their life cycle for the analysis of potential impacts.

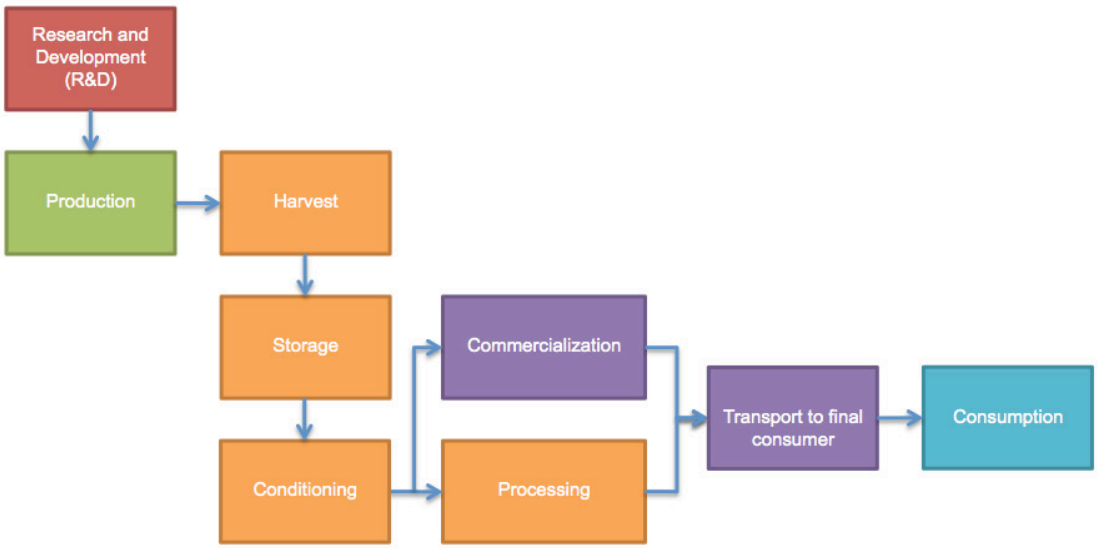

Figure 1. Value chain of generic agricultural products and derivatives
Based on: USSEC (2008); Soy20/20 (2008); López et al., (2008).

2.2 Research and Development (R&D)

2.2.1 General Context of GMO R&D

The analysis of the context in which goods and services are researched and developed (e.g., economic, social and political drivers) contributes to a broader understanding of the aims of the technologies introduced into societies. For this report, R&D is understood as the set of "[o]rganizational strategies and methods used by research and extension program[s] to conduct their work including scientific procedures, organizational modes, institutional strategies, interdisciplinary team research, etc." (IAASTD ed., 2009b, p.566).

Technical feasibility, economic profitability and social legitimacy are the main considerations when researching and developing GMOs (Kvakkestad, 2009). The level of relevance given to each of these considerations varies according to the institutional structures and hence incentives within the different organizations dedicated to R&D (Dasgupta and Davis, 1994). The strong trend has been that private R&D (e.g., that conducted by corporations) mostly focuses on the development of GMOs that are inexpensive to produce (for technical or other reasons) relative to the potential to generate profits when placed in the market. R&D of GMO products have historically had a strong focus on agriculture, mostly crops, and for large, monoculture cropping systems in agroecosytems where the main GM crops are subsidized (Heinemann 2009; IAASTD ed., 2009b). Although increasing, other commercial applications are still limited (IAASTD ed., 2009b; Stein and Rodriguez-Cerezo, 2009).

The global commercial GM plant-R&D context is characterized by the following features:

- GMO-R&D mainly carried out by the private sector, or in public-private consortia that adopt the profit incentive from the private sector, mostly from developed countries (IAASTD ed., 2009b). Approximately 90% of the global R&D of GMOs is carried out by six private companies: Monsanto, Syngenta, Bayer, BASF, DuPont and Dow (Kiers et al., 2008) and 70% of the worldwide approved field trials of GMOs are performed by the private sector from developed countries. In parallel, there is a tendency of transferring GMO-R&D programs to developing countries and also a trend towards growing public investment in GMO-related R&D in developing countries (e.g., Brazil, China, India, South Africa, Egypt and South Korea). However, as of 2007, all GM crops commercialized in the world, with the exception of those in China, were developed by the private sector (Pray and Naseem, 2007).

- Concentration of GMO-R&D in powerful modern biotechnology clusters composed by private and public actors. The concentration of modern biotechnology in a few stakeholders started with the merging of the major segments of the agricultural industry (agrochemicals, seeds and modern biotechnology) (IAASTD ed., 2009b; World Bank, 2007). This started in the 1990s, when large chemical companies began prospecting commercial opportunities in the modern biotechnology sector, including GMO-R&D, and applying patents and patent-like intellectual property instruments to germplasm for the first time (DeBeer, 2005). On one hand, these companies increased their commercial shares (e.g., by the mid 2000s the large modern biotech-industry held approximately 73% of the pesticides market) (Gepts, 2004; UNCTD, 2006). On the other hand, they increased their know-how by purchasing biotechnology and seed companies (Gepts, 2004, Pingali and Traxler, 2002; Pray and Naseem, 2007), and eventually invested in the public sectors (mainly research institutions and public universities) (Lotter, 2008).

- GMO-R&D supported by strong intellectual property rights (IPRs) instruments. Appropriability (either legal through IPR systems or biological from the private or public sector) is a precondition for securing profits on R&D of GMOs (Pray and Naseem, 2007; Heinemann, 2007) and a strong incentive to invest in modern biotechnology (Lesser, 1999; Keith, 2008). The result is monopolistic market behaviour characterized by the concentration of the vast majority of modern biotechnological IP into profit-oriented systems (either public or private), restricting the free and public access of modern biotechnology developments to non-profit purposes, such as safety research or traditional peasant seed saving (in the case of GM crops).

- Application of IPRs to genetic information and methods of GMO construction. IPRs applied to GMOs go beyond the modified organism itself (e.g., plant or animal). They include the genetic information of the GMO and the methods used to construct the GM trait and insert it into the genome of the host organism (See Box 1) (De Beer, 2005; UNCTD, 2006). The result of this is that just the presence of a transgene “triggers legal instruments that derive from intellectual property, liability or contract law” (Heinemann, 2009a, p.49), as described further.

This scenario of GMO-R&D has resulted in a broad array of impacts, with both potential adverse and beneficial effects in relation to opportunities for SD. Probably the main benefit is related to the growth of this specific field of knowledge (modern biotechnology). The R&D of GMOs, either by the private or public sector, has been a driver to accelerate the generation of knowledge in molecular biology (Pray and Naseem, 2007). This has been accompanied by investment in infrastructure and the generation of capacities for molecular biology research. The potential application of this knowledge may not only be related to commercially-oriented research of GMOs but also to biosafety. As for the adverse implications, they are described in Section 2.2.2 in relation to the IPR systems since they are a central and crosscutting issue in the market-oriented development of GMOs. This analysis is made using the case of GM crops.

BOX 1 Patents on GMOs

"A genetically engineered seed or plant cultivar may contain three different kinds of components that can be protected as intellectual property, namely:

1. [G]ene sequences and genetically coded traits and enhancements that code for specific physical or behavioral traits of an organism (often referred to as "software");

2. [T]he research tools needed to transfer the new genetic trait into plant cells and to regenerate from these engineered cells genetically modified plants with the new genetic trait stably integrated and properly expressed ("enabling" technologies, such as transformation vectors and systems, gene transfer promoters, and transformation marker systems); and

3. [T]he germplasm of the plant variety, that is, the seed or plant cultivar itself, genetically transformed to create enhanced varieties ("hardware").

That means, given the cumulative and complex nature of varietal development:

1. [E]ither the transgenic variety is developed by a large company backed by a broad portfolio of patents; or

2. [A] number of owners have valid patent entitlements on the technologies and genetic contests included in the cultivar, or on particular aspects of each technology. In the first case, the barrier to accede innovative contents and technologies is the single owner who may refuse to license; in the latter case, the accumulated transaction costs that would accrue from tracking down "who owns what" and negotiating with all the single patent assignees" (UNCTAD, 2006, p. 23).

"Because of […] increasing number of patents, patents being increasingly issued on fundamental technologies, multiple claims over various aspects of a technology […], companies often find it difficult to avoid infringing patents when conducting product development research. In practice, each company's patent portfolios have become so substantial that every firm is likely to infringe patents held by each of its competitor. Monsanto and DuPont, DuPont and Syngenta, Monsanto and Syngenta, Syngenta and Dow have all filed suits against one another involving claims of patent infringement" (UNCTAD, 2006, p. 25).

2.2.2 Implications of the Current R&D of GMOs

2.2.2.1 Implications for Ecological Sustainability of R&D of GMOs

Deterioration of local knowledge and in situ conservation systems

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecologic	Competing arguments	Indirect	Medium and long term	Regional	Applicable especially in regions with predominance of peasant agriculture

The current dynamic of GMO-R&D and related IPR systems are associated with restrictions on the free access and use of genetic resources (e.g., seeds), limiting the access of seeds for local adaptation and knowledge generation (IAASTD ed., 2009b; Heinemann, 2009a). This together with

the potential genetic contamination of local varieties (detailed in Section 2.3.2.1 under the subtitle "Gene flow and persistence of GMOs in the environment"), impacts negatively on the capacity for in situ conservation of agricultural varieties.

Reduction of agrobiodiversity

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecologic	Competing arguments	Indirect	Medium and long term	National and global	Widely applicable

The market concentration of the GM seed industry and the R&D of GMOs focused on a few profitable crops has led to a narrowing of the total number of crops and varieties, decreasing the diversity of agricultural crops and sources of food, and also leading to agricultural homogeneity in large agricultural regions (Mascarenhas and Busch, 2006).

2.2.2.2 Implications for Economic Sustainability of R&D of GMOs

Potential of new economic damage arising from presence of GMOs

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Well established	Direct	Short and long term	National	Wide applicability in countries with strong IPR systems on GMOs

In countries with strong IPR systems on GMOs, the accidental or unintentional presence of GMOs results in costs related to the reduction or avoidance of potential contamination, and financial liabilities for illegal holding of intellectually-protected GMOs. For instance, unlicensed presence of GM seeds in agricultural plots are considered an infringement of the patent held by the companies that develop GMOs, regardless of how this presence was caused, (See Box 2) since the majority of the IPRs applied to the recombinant DNA contained in the GMO (Heinemann, 2009a; Heinemann, 2007). This is a case of a restriction on usage due to legal excludability, which in most developing countries (for now) does not apply due to the nature of their IPR systems or failure to join the World Trade Organization (WTO). These are reasons why the modern biotechnology sector exerts pressure to put IPR systems in place or to change the current ones in developing countries (Heinemann, 2009a).

BOX 2 The Case of Monsanto versus Percy Schmeiser

In 1998, the Canadian farmer Percy Schmeiser was sued by Monsanto Canada, for allegedly growing GM canola without a licensing agreement. Although it was recognized by the court that the presence of GM canola was the result of wind-based seed contamination, the court decided that it was the responsibility of P. Schmeiser to know what he was growing in his field and he was disqualified of "innocent bystander" status. This case shows the irrelevance of the sources of contamination and the burden put on farmers to increase vigilance, monitoring and legal advice to avoid patent infringement lawsuits regardless of whether they choose to plant GM plants or not (Heinemann, 2009a).

Potential to increase in production costs

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Well established	Direct	Short and long term	National	Applicable in countries with IPR systems on GMOs

GM seeds usually have higher costs in countries with strong IPR systems due to costs related to enforcing commercial exclusivity. In fact, the high price of GM seeds is one of the factors that limits the spread of GM technology in agriculture. Studies show that farmers are only willing to pay less than half the actual price for GM seeds (Qaim and DeJanvry, 2004). This is one of the reasons that GM crops are mainly adopted on a large scale in subsidized agricultural systems.

Weakening of the market competitiveness within the seed market

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Well established	Direct	Medium and long term	Global	Wide applicability

Market concentration of the GM seed market, as in any other market segment, leads to a weakening of market competitiveness. According to the World Bank, when the top-four-companies' concentration ratio (known as CR4) within a given commercial sector is more than 40%, the market competitiveness declines (World Bank, 2007; Heinemann, 2009a). As previously mentioned, the R&D of GMOs is highly concentrated in six companies and supported by strong IPR systems; just one company, Monsanto, "has provided the seed technology for at least 90 percent of the world's genetically engineered crop" (CFS, 2005, p. 10). In general, two mutually supportive factors (R&D and IPRs) set the context for market concentration of GM seeds and non-GM seeds, resulting in low market competitiveness. The impacts of this low market competitiveness are the decrease and eventual disappearance of small seed companies that do not have the financial or technical means to survive (Gepts, 2004), a decreasing pool of seed options (pushing farmers to choose GM seeds) (Heinemann, 2009a) and a higher spread between what consumers pay and what producers receive for their produce (World Bank, 2007).

2.2.2.3 Implications for Social Sustainability of R&D of GMOs

GMO R&D mostly focused on market-oriented products rather than in societal benefits

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Competing explanations	Direct	Short and long term	National	Wide applicability

This applies particularly to GM crops, the majority of which are intended to strengthen agroindustrial systems and which have limited sustained benefits to the broad society in terms of: i) favouring vulnerable or marginalized groups in developing countries (e.g., subsistence farmers) (Altieri, 2008) and ii) generation of public knowledge and goods (Shorett et al., 2003). This situation leads to a reduction in production opportunities for farmers already in disadvantageous positions, adding to poverty in the rural sector (Pray and Naseem, 2007).

Deterioration of farmers´ rights related to seed saving

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Well established	Direct	Short and long term	National	Applicable in countries with patents on GMOs

Farmers' rights are understood as the "legal recognition for the innovative work that farmers are engaged in, and calls for reserving to farmers the traditional ability to select, save, use and exchange seed stock grown in their own field" (UNCTAD, 2006, p.18). Seed saving and exchange is one of the most fundamental farmers' right, together with experimentation and development of local varieties (IAASTD ed., 2009b). Seed saving allows farmers to have control over their production knowledge and supply (Mascarenhas and Bush, 2006) and is also an important component of agroecosystem resilience (Heinemann, 2009a). Farmers from developing and developed countries rely on seed saving (e.g., the origin of up to 90% of planted crops in the developing world according to WHO, 2005). Accordingly, patented seeds in general and specifically GM seeds weaken significantly the realization of farmers' rights by shifting their status from "seed owners" to "licensees" (UNCTAD, 2006, 19). Women are socially and economically more vulnerable to the consequences of this, mainly in societies where they are the main developers and custodians of locally adapted varieties (IAASTD ed., 2009b).

Destabilization of the local food systems, food security and sovereignty

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Contested arguments	Direct and indirect	Short and long term	National	Applicable in countries with patents on GMOs

Seed saving, exchange and improvement contribute to self-reliance in food production by securing access to a key production input (Mascarenhas and Busch, 2006; Heinemann, 2009a). When farmers have limited access to and use of seeds their production self-reliance is jeopardized together with the opportunities to build local knowledge, secure food supply and food sovereignty (Heinemann, 2009a). In this context, 'food sovereignty' is understood according to the definition of Via Campesina (the world´s largest farmers' union) adopted by IAASTD and acknowledged by various countries (e.g., Bolivia, Ecuador, Mali, Nepal, Senegal and Venezuela) (Beauregard, 2009), as the right of peoples to healthy and culturally appropriate food produced through ecologically sound and sustainable methods, and their right to define their own food and agricultural systems (Via Campesina, 1996).

Increase of inequities in access to technology

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Competing arguments	Indirect	Medium and long term	National and global	Wide applicability

The market concentration of the GMO-R&D sector facilitated by current patent law which strongly favours large companies, the nature of the majority of GM products which mainly target profitable sectors (e.g., industrialized agriculture) and the profile of the biggest majority of users of GMOs

(e.g., large-scale agricultural producers) results in increasing inequities in the R&D of GMOs. These inequities occur at several stages: i) at the technological level between developing and developed countries, as well as in both the private and the public sector dedicated to GMO-R&D; ii) at the financial level between large and medium / small-size biotechnology companies and research institutions; iii) at the economic level between users (e.g., farmers) accused of patent infringement and those with no financial or legal liability; and iv) at the social level between farmers capable of saving and reproducing their seed and those who cannot (Heinemann, 2009a; Kvakkestad, 2009; UNCTAD, 2006; Mascarenhas and Busch, 2006).

2.2.2.4 Ethical Considerations for Sustainability on R&D of GMOs

Legal and financial barriers to the exercise of fundamental farmers' rights

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Well established	Direct	Short and long term	National	Applicable in countries with patents on GMOs

In the current regulatory framework governing GMOs, particularly GM seeds, farmers' rights are contested by of the plant breeders and GM seed developers (Borowiak, 2004). The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) recognizes a number of farmers' rights in relation to the protection of traditional knowledge and the right to save, use, exchange and sell farm-saved seeds and propagating material particularly in centres of origin and genetic diversification (Article 9) (FAO, 2009). However, farmers' rights and, specifically those in this treaty, are weakly implemented. While the institutionalized implementation of farmers' rights remains weak, strong and well-defined IPR systems are put in place to protect R&D of GM seeds (Borowiak, 2004) contradicting the traditional notion of improvement of agricultural varieties as a public service and improved seeds as a public good (Mascarenhas and Busch, 2006). As mentioned previously, this imposes restrictions on the realization of farmers' rights, but also undervalues the historical and current contribution of farmers to societies in the conservation of biodiversity, domestication of agricultural species and production of agricultural seed varieties (IAASTD ed., 2009b; Borowiak, 2004). These arguments are contested by some sectors which argue that IPRs are instruments to create social benefits by encouraging the recovery of the investment costs of R&D of GM goods (O'Driscoll and Hoskins, 2003). Although this argument has merit to some degree; the economic benefits that IPRs may generate, particularly in economies geared to profit making, do not justify — in social and ethical terms — limitations imposed on long-standing farmers' rights on which local food systems depend.

Influence of modern biotechnology industry in shaping IPR regulatory frameworks

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Competing arguments	Direct	Short and long term	National and global	Wide applicability

The consolidation of the modern biotechnology industry as a very powerful economic sector was a result of but also a driver towards strict IPR systems (Fernández-Cornejo and Caswell, 2006; IAASTD ed., 2009b). As a consequence, R&D and IPR regulatory frameworks favour ownership and profits on investments in GMOs. As a result: i) there is a significant advantage to the private sector since it is better prepared to assume ownership positions, and ii) there is a lack of protection and promotion of other sources of technological innovation adequate for developing locally-adapted technological alternatives (Heinemann, 2009a).

Restrictions to independent biosafety research and contested transparency

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Competing arguments	Direct	Short and long term	Global	Wide applicability

Patents on GMOs cover recombinant DNA and the "technologies behind, and applications of, this information" (Heinemann, 2009a, p.113). This restricts the access and use of intellectually protected GMOs for activities different from their licensed purposes, imposing restrictions on activities such us independent safety research (Shorett et al., 2003). At the same time, this may lead to situations where independent researchers are pushed to: i) withdraw their research ideas due to the impossibility of accessing research material; ii) carry out their research under conditions imposed by GMO developers seeking to oversee the research process and the results; or iii) to access GMO material without declaring that it is for research purposes and therefore to carry out independent research in violation of IP protection (Waltz, 2009a).

Companies developing GMOs argue, among other justifications given, that restrictions on GM material for research are needed to ensure that studies are carried out under "good stewardship practices" since "adverse events with a pre-commercial product, [GMO] makers could be liable, even if the event occurred under the watch of a public sector scientists" (Waltz, 2009a, 881). However, access restrictions do not apply exclusively to pre-commercial material but also to material placed on the market.

At the same time, restricted access to GM material for research purposes has resulted in: i) a strong trend to market modern biotechnology and biosafety research among corporations to secure and attract research grants (Shorett et al., 2003); consequently ii) a conflict of interest since corporate-funded research is more likely to produce information that supports the corporate interest (Shorett et al., 2003; Cho et al., 2000; DeAngelis et al., 2001; Myhr and Rosendal, 2009; Kvakkestad, 2009); and iii) a strong focus on business-oriented research. The context of secrecy limits the generation and disclosure of information relevant to the public (Sagar et al., 2000), mainly research that warns of the potential adverse effects of GM products (Waltz, 2009b; Scientific American, 2009). Paradoxically, it can be argued that economic growth enhances knowledge generation through R&D (O'Driscoll and Hoskins, 2003). However, IPR on GMO-R&D shows that economic forces also play a role in limiting the disclosure of information and knowledge because there is a cost-benefit relationship in R&D secrecy (Dasgupta and David, 1994, 500).

2.3 Production of GMOs

2.3.1 General Context of the Production of GMOs

The vast majority of the GMOs introduced into the environment are crops for agricultural and industrial purposes, although GMOs for medicinal, environmental and industrial applications are also available or in the R&D pipeline. The largest proportion of the R&D on GM crops has focused on the inclusion of traits profitable to industrial agriculture (Pray and Naseem, 2007), specifically soybean, corn, cotton and canola for herbicide (HT) and insect tolerance (IT) (Figure 2) (Brooks and Barfort, 2010). Consequently, most of the GMOs under open field production are suited to large-scale monocultures that characterize industrialized agriculture, adding in several cases to the current adverse impacts of this type of production (IAASTD ed., 2009b).

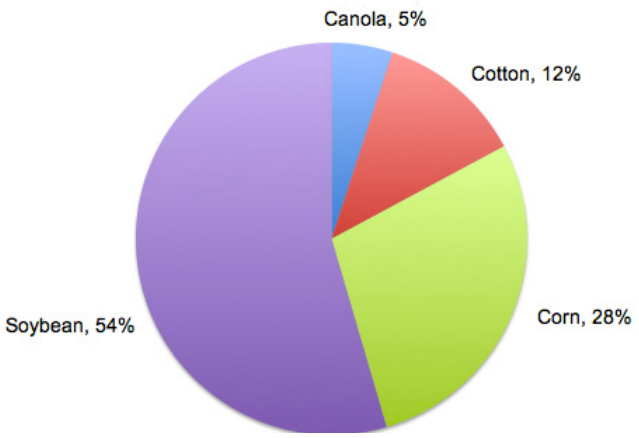

Figure 2. GM crops planted in 2008
Adapted from: Brooks and Barfoot (2010)

GM crops are promoted by their developers as important technologies that protect the environment by, for instance, reducing the use of pesticides (in the case of HT and IT), increasing profits by reducing inputs (e.g., less expense for inputs and labour for pest control), mitigating climate change by using improved plant-based energy sources (in the case of crops modified for more efficient agrofuels production) and increasing the nutritional value of food (in the case of nutritionally 'enhanced' plants). Developers of GM crops maintain that all of these potential benefits have as their ultimate goal the protection of the environment, the achievement of food self-sufficiency and the eradication of poverty, particularly in developing countries (Shapiro, 1999; Monsanto, 2006; Syngenta, 2009; Qaim, 2009). However, a main criticism of these goals has been focused on the intention to solve non-technical problems (e.g., hunger and poverty) by applying technological solutions (Lee, 2009). In addition, the reported beneficial impacts of GMOs are mostly seen in the short term, shifting to combinatorial and accumulative negative impacts in the medium and long term (detailed in the proceeding sections) (IAASTD ed., 2009b).

Research on the potential beneficial impacts of GMOs focuses on environmental effects during the first years of adoption. Most of this research is on HT and IT crops in relation to the decrease in the use of herbicides and insecticides, respectively. Other potential benefits such as increase in agrobiodiversity in production plots, decrease in greenhouse gas (GHG) emissions deriving from the reduction in the use of herbicides and heavy machinery (related to the technological production package of GM crops); and accordingly, better preservation of the soils, have also been reported. In parallel, economic research focuses on the decrease in production costs due to the reduction of input expenses (chemical inputs, machinery and labour) and the consequent increase in profits. Changes in yield, reduction of exposure to pesticides, and the advantages of simple agricultural management are also common topics (Brooks and Barfort, 2010; Qaim, 2009; Qaim and Trexler, 2005; Nuffield Council on Bioethics, 2004; Carpenter et al., 2002).

However, there remain important gaps in knowledge related to the potential benefits of GMOs (Wolfenbarger and Phifer, 2000). The reported beneficial impacts of GM crop production have not been uniform due to environmental, socioeconomic and institutional variations at the local level (Brooks and Barfort, 2008; Glover, 2010). This since the potential benefits of GMOs are context specific and in the case of agricultural GMOs, are more likely to take place in situations where farmers have particularly good access to production resources and assets (Glover, 2010). In addition, most of the beneficial impacts shown have not been sustainable over time or have been shown to intensify previously existing negative impacts. This is the case in agricultural systems where GMOs are introduced (mainly industrial and subsidized agriculture). This has raised environmental, health and socio-economic concerns about unforeseen adverse effects in the long term, which have not been fully evaluated, yet are relevant from the SD perspective (IAASTD ed., 2009b; Then, 2010; Lu et al., 2010; Pengue, 2004; Heinemann, 2009a; Glover, 2010).

As mentioned previously, the evaluation of potential negative impacts arising from GMOs becomes difficult due to the conflicting findings from research carried out by different sectors. These variations are rooted in the different methodological approaches applied (e.g., hypothesis framing, sample size and timeframe) (Dona and Arvanitoyannis, 2009; Doming, 2008), different levels of independence or conflicts of interest, and limited disclosure of the information generated (Pavone et al., 2010; Myhr and Rosendal, 2009).

Due to their relevance to SD, the following are potential or likely adverse effects of GM crop production from a long-term perspective.

2.3.2 Implications of the Production of GMOs/GM Crops

2.3.2.1 Implications for Ecological Sustainability of the Production of GMOs/GM Crops

A Related to the GMOs

Increased potential for weeds in agricultural lands

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecologic	Well established	Direct	Medium and long term	Regional	Applicable in areas with cultivation of HT crops

Two main factors increase the problem of weeds in agricultural fields planted with GM crops: i) mismanagement of herbicides in HT crops (basically excessive use of the herbicide that the crop is tolerant to); and ii) gene flow resulting in the development of HT wild plants and HT volunteer crops germinating even several years after harvesting. These two are particularly important under no-tillage direct-seeding systems (Martínez-Ghersa, 2003; Clark, 2006, Heinemann, 2007). For instance, in 2000, four years after the commercial introduction of the transgenic Roundup Ready (RR) soybean (which is tolerant to the herbicide glyphosate), eight different glyphosate-tolerant weeds had already been identified (Papa, 2000). By 2010, the major producers countries of glyphosate tolerant crops have reported different glyphosate tolerant weeds: 11 tolerant biotypes in the US, 5 in Brazil, 5 in Argentina and 3 in South Africa, among others (Weed Science, 2010). The increase in the frequency of tolerant weeds leads to the use of complementary herbicides to control them (Martínez-Ghersa, 2003; Van Acker et al., 2004); however, in some cases this measure prompts "multiple resistant" volunteer crops resulting from gene flow among varieties tolerant to different herbicides (Hall et al., 2000; Heinemann, 2007; Heinemann and Kurenbach, 2008). These mechanisms and further complexities due to the increased ability of plants to become weeds from the cultivation of HT crops affect adopters and non-adopters of the GM technology to varying degrees (Clark, 2006).

Potential adverse effects of IT crops on non-target organisms

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecological	Competing arguments	Direct and indirect	Medium and long term	Local with potential to regional	Applicable in areas under intense use of GM crops

'Non-target organisms of IT crops' refers to populations of insects impacted by insecticide properties but which are not the population the IT crop was designed to impact. Non-target organisms susceptible

to negative effects from IT crops can be grouped in the following overlapping categories according to Snow et al. (2008): i) beneficial species, including natural enemies of pests (lacewings, ladybird beetles, parasitic wasps, and microbial parasites) and pollinators (bees, flies, beetles, butterflies and moths, birds and bats); ii) non- target herbivores; iii) soil organisms; iv) species of conservation concern, including endangered species and popular, charismatic species (e.g., the monarch butterfly); and v) species that contribute to local biodiversity.

While some researchers found that the abundance and diversity of non-target organisms in GM crops (e.g., invertebrates in HT-crops fields) had remained constant or had increased (Snow et al., 2004; Ammann, 2005), others have reported a decrease in plant and insect diversity. For instance, the following effects on non-target organisms from Bt-plants have been reported: i) increased mortality of natural insect predators at early stages of development (e.g., green lacewings *Chrysoperla cornea*, and ladybird *Adalia bipunctata*) (Hilbeck, 2002; Schmidt et al., 2008); ii) altered consumption or learning processes of pollinators, affecting pollination efficiency (e.g., honey bees *Apis mellifera*) (Ramírez-Romero et al., 2007); and iii) altered population composition and dynamics of beneficial soil microorganism (Stotzky, 2002; Castaldini et al., 2005; Stotzky, 2004) important for soil fertility (e.g., mycorrhizal fungi) (Turrini et al., 2008).

One explanation of this wide range of effects on non-target organisms is the larger persistence and capacity of spatial distribution of Bt-toxins from Bt-plants in comparison to their natural counterparts (Heinemann, 2009a). This implies an increased exposure of non-target organisms to Bt-toxins resulting in potential inter-related implications, such as new challenges in agricultural pest and fertility management (Hilbeck, 2002) due to the emergence of new pests (Then, 2010). The permanent presence of an insecticide in the GM plant (e.g., Bt-toxin) breaks the population equilibrium between natural predators and competitors opening up new ecological niches where populations previously considered occasional or minor pest emerge as economically important pests (See Table 3) (Then, 2010). However, this goes beyond agricultural considerations and may have broader implications in the agro-ecosystem and stability of several trophic levels (Lu et al., 2010).

Table 3. The problem of pest replacement. New pest management problems in Bt crops.

Source (Year)	Species	Crop / Region	Effect
O'Rourke & Hutchison (2000)	Western bean cutworm	Corn / USA (Minnesota)	Pest replacement
Dorhaut & Rice (2004)	Western bean cutworm	Corn / USA (Illinois, Missouri)	Pest replacement
Catangui & Berg (2006)	Western bean cutworm	Corn / USA (South Dakota)	Pest replacement
Li et al (2007)	Cotton bollworm	Cotton/ China	Higher tolerance (Cry1Ac)
Wang et al (2008)	Mirid bug	Cotton / China	Secondary pests
Di Fonzo & Hammond, (2008)	Western bean cutworm	Corn / USA (Michigan, Ohio)	Pest replacement
Tabashnik et al (2009)	Fall armyworm	Corn / Puerto Rico	Resistance (Cry1F)
Tabashnik et al (2009)	Maize stalk borer	Corn/ South Africa	Resistance (Cry1Ab)
Tabashnik et al (2009)	Cotton bollworm	Cotton/ USA	Resistance (Cry1Ac, Cry2Ab)
Zhao et al, (2010)	Aphids, spider mites, lygus bugs	Cotton/ China	Secondary pests
Lu et al, (2010)	Mirid bug	Cotton/ China	Secondary pests
Monsanto (2010)	Pink bollworm	Cotton/ India	Resistance (Cry1Ac)

Source: Then (2010, p. 95).

Potential recombination of animal and plant pathogens

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecological	Undetermined / long-term impacts not available yet	Direct	Medium and long term	Local	Applicable in areas under intense use of GMOs

In transgenic virus-resistant organisms, recombination between viral transgenes and invading viruses could lead to increased virulence and undesirable effects on wild hosts existing in natural habitats (Snow et al., 2005). Little is known yet on the regulation and activities of the pathogenic microorganisms and viruses inserted in the transgene construct (e.g., CaMV) (Quist et al., 2007), which increases the uncertainty about how they could impact wild fauna and farm animals.

Gene flow and persistence of GMOs in the environment

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecological	Competing arguments / Long-term impacts not available yet	Direct and indirect	Medium and long term	Local Regional Global	Wide applicability

"Gene flow refers to the movement of genes into a new genome or environment" (Heinemann, 2007, p.69) that occurs with or without human intervention. Gene flow is particularly relevant in relation to conservation of biodiversity and genetic resources from the biological and ecological point of view. However, it is also important from the agricultural, social and cultural perspective (Heinemann, 2007).

Gene flow of GMOs can occur vertically (called vertical gene transfer when transgenes flow through the normal reproductive processes), or horizontally (called horizontal gene transfer when transgenes flow by infectious processes). Transgenes also move across different environments through seeds or propagules (Heinemann, 2007).

All of these different channels of gene flow contribute to the persistence of GMOs in the environment and food chain after their release because it is very difficult to contain or prevent their spread (Clark, 2006; Marvier, 2004). This is the case of StarLink (a Bt maize) that was found in food samples at various concentrations in the US even three years after it was banned and recalled from the market shelves (Marvier, 2004). Even confined production of GMOs does not guarantee containment. For instance, the unapproved GM rice LLRice601 under R&D in the US was found in the European food market (Vermij, 2006).

The impacts of gene flow and the persistence of GMOs are diverse since they depend on the characteristics of the GMO and the ecological and social context where they are introduced. Some of these impacts are:

- Agricultural: Potential development of new or more aggressive weeds and loss of valuable agronomic and commercial varieties (Heinemann, 2007).

- Conservation of biological diversity (including agrobiodiversity): Gene flow may cause genetic contamination resulting in the loss of genetic purity of some species and varieties, and the consequent reduction in the number of species at the local and global scale. Gene flow may result in the transfer of GM traits to organisms that could become super-competitive

species. This is particularly important for GMOs with complex traits, such as GM crops tolerant to stress (e.g., drought, salinity and temperature). The transfer of these traits will increase competitiveness and the invasiveness of certain species in habitats where they would previously not have succeeded, changing the biological composition of ecosystems. (Heinemann, 2009a; Andow and Zwahlen, 2006; Tilman, 1999). This is of special concern in the case of agricultural biodiversity and landraces in centres of origin and genetic diversification (Heinemann, 2007; Ellstrand, 2003). Current examples of drivers of genetic erosion linked to gene flow of GMOs are: i) development of weed characteristics among wild and cultivated plants; ii) development of tolerance to insects; and iii) replacement of ecological niches (Bohan et al., 2005; Clark, 2006; IAASTD ed., 2009b; Viljoen C. and Chetty L., 2010; Dale et al. 2002; Benzler, 2004; Marvier, 2004; Quist & Chapela, 2001; Van Acker et al., 2004). In relation to animal biodiversity, wild and farm animals could also be affected when gene flow causes the expression of toxic, allergenic or anti-nutrient compounds in plants that are important to the animal's diet. Animal diversity could also decrease due to the disappearance of sources of food, such as small animals or insects important in the animal food chain.

- Human and animal health: May be affected by spread of plant-based pharmaceutical, industrial compounds, or altered nutritional substances that may become a source of potential negative health impacts when entering the food web.

B Related to the production systems associated with GM crops

GM crops and their production systems are inseparable (IAASTD ed., 2009a). The GM technologies introduced in agricultural systems define either the continuation or the introduction of specific production approaches, each one with different impacts. As mentioned previously, most of the R&D of GMOs is focused on highly commercial crops and, consequently, their adoption has occurred mostly in industrial agricultural systems (Pray and Naseem, 2007). As a result, in several cases, the inherent impacts of industrial agriculture are reinforced by the production systems related to GM crops. The following impacts are associated to these in respect to the consideration of ecological sustainability of the production system of GM crops.

Increased pesticides residues in the environment

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecological	Competing arguments	Indirect	Medium and long term	Local and regional	Applicable in areas with widespread cultivation of HT and IT crops

There are divergent reports on pesticide use in GM crop cultivation. Part of the peer-reviewed literature reports decreased use of pesticides (e.g., Subramanian and Qaim, 2009; Fernández-Cornejo and McBride, 2002). This reduction of pesticides is particularly important in highly industrialized farming systems. However, the reported decreases mostly relate to the specific pesticide that the GM crop is tolerant to, excluding an analysis of the overall farm pesticide applications in the medium and long term. These reports have been criticized for their focus on early adopters, successful farmers and fields with particular extra care (Stone, 2011; Glover, 2010).

Conversely, other reports mention that reduction in pesticides is less likely to occur in the long run (Pengue, 2004; Wolfenbarge and Phifer, 2000). The reported causes of increase in pesticide use in GM crops are: i) appearance of tolerant weeds and volunteer crops; ii) emergence of new (insect) pests; and iii) expansion of the surface under HT and IT crop cultivation (Van Acker et al., 2004; Pengue,

2005; Powles and Preston, 2006; Vila-Aiub et al., 2008; Heinemann and Kurenbach, 2008). The first two causes are linked to the use of pesticides with higher toxicity than those replaced (such as 2,4-D and atrazine in GM cultivation in Argentina) (Pengue, 2004; Tuesca et al., 2007), and applications at higher concentrations or at higher frequency (Graef et al., 2007). For instance, Qaim and Traxler (2005) report that from 1996 to 2001, growers of RR soybeans in Argentina have experienced an increase in the number of herbicides applications at the farm level by almost 17% and a total increase in volume of herbicides used by more than 100%, with a parallel increase in the level of toxicity of the complementary herbicides. The introduction of RR soybean in Argentina has resulted in the increase of glyphosate use from 14 million to 175 million litres from 1996/97 to 2007 (SAyDS, 2008).

In terms of ecological impacts, the rise in pesticide use is accompanied by an increase in the accumulation of toxic residues in soils, surface and groundwater (Dale et al., 2002; Benzler, 2004).

Changes in land use and agricultural production systems

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecological	Well established	Indirect	Short and long term	Local, regional and global	Applicable in countries with large cultivation of HT and IT crops

The cultivation of GM commodities has intensified and increased monocrop production, which has resulted in: i) expansion of the agricultural frontier at the expense of wild habitats (Benzler, 2004); and ii) displacement of local production systems (Pengue, 2005).

In Argentina, Brazil and Paraguay, the expansion of GMO cultivation has contributed to deforestation, pushing the agricultural frontier into wild ecosystems (Pengue, 2004). For example, in Argentina from 2003 to 2008, there has been an estimated increase in soybean production (98% GM according to Tomei and Upham, 2009) of 4 million hectares, mostly into areas that were previously forest habitats. Since agriculture is carried out within a mosaic of land uses (forest, semi-natural habitats, peri-urban, etc.,) there are many interactions and functional exchanges amongst these different types of habitats. Therefore, some expect that GMOs and their production systems will affect the ecology of the surrounding areas (Benzler, 2004).

The displacement of local production is described bellow in Section 2.3.2.2 under the subtitle "Impacts on food security".

2.3.2.1 Implications for Economic Sustainability of Production of GMOs

Increased production costs

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Competing arguments	Direct and indirect	Short and long term	Local and national	Applicable to cultivation of GM crops

An increase in the production costs of GM crops may result in the short term due to the higher costs of GM seeds (particularly those with intellectual protection), which are sold at premium price because of the technology fee for the novel traits they carry (e.g., in the US the GM seed premium price including the technology fee may vary from $20.00/ha, in the case of RR soybean, to $50.00/ha, in the GM cotton varieties) (Benbrook, 2003). In the medium and long run, additional expenses to manage the increase in weeds or the emergence of new pests may add to production costs (e.g., additional costs for managing RR volunteer canola in Canada may vary from approximately $5.00 to $50.00/ha) (Van

Acker et al., 2004).

Restricted economic benefits

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Competing arguments	Direct	Short and long term	Local and national	Applicable to cultivation of GM crops

Economic benefits from GM crop cultivation is another controversial field of inquiry. While some authors report significant increase of income at farm level (e.g., Subramanian and Qaim, 2009: Stone, 2011) others report minimal variations (Fernandez-Cornejo and McBride, 2002; Benbrook, 2001). The economic benefits of GM crops have mostly resulted from the stability of the major commodity markets (e.g., soybean, corn, canola and cotton), competitive pressure, price changes and/or the reduction of labour, rather than higher yields or the economic efficiency of the technology (Gurian-Sherman, 2009). In fact, some studies have shown that yields in non-GM crops are higher in comparison to GM cultivation, concluding that profitability of GM crops does not necessarily result from higher yields (Jost et al., 2008).

In addition, gene flow of transgenes also has the potential to negatively impact the economy of farmers regardless of whether or not they are adopters of GM crops. This may occur under the following conditions: i) when gene flow results in financial and legal liabilities for infringement of patents on GM seeds (see above "Potential of new economic damage arising from presence of GMOs" in Section 2.2.2.2); ii) when non-GM fields, either conventional or organic, are contaminated by GM plants or experience an increase in the frequency of HT weeds; and iii) depletion and degradation of natural resources (e.g., soils) since the replacement of their function in agricultural production (e.g., soil fertility) adds to production costs (e.g., replacement of soil fertility with synthetic fertilizers). However, natural resource rehabilitation costs are usually not included in the economic analysis of GM crop production, making their economic evaluation inaccurate and even overly optimistic (Glover, 2010). The adverse economic impacts of genetic contamination are particularly relevant for non-GM crops in differentiated GM-free markets (IAASTD ed., 2009b; Vijoen and Chetty, 2010; IFOAM, 2002).

2.3.2.2 Implications for Social Sustainability of Production of GMOs/GM Crops

Technology dependence

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Contested arguments	Direct	Medium and long term	Local and national	Applicable in countries with widespread GM crops cultivation

Technology dependence results from the excessive reliance of farm, local and even national agricultural activities on a few GM agricultural technologies (e.g., glyphosate-tolerant crops). Technological dependence results in the lack of efficacy of the technology itself (e.g., weeds and volunteer crops tolerant to glyphosate in HT crop cultivation (Waltz, 2010), and the emergence of new pests in Bt-crop fields (Stone, 2011). This leads to additional technological solutions to the unforeseen problems arising from the GM technology introduction (Stone, 2011), whose implementation results in higher costs to the farmers, fewer options for local adaptation of technologies, agricultural homogeneity in

extensive agricultural regions and weakened self-reliance (Heinemann, 2009a; IAASTD ed., 2009b; Mascarenhas and Busch, 2006).

Weakening of farmers' right to choose

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Well established	Direct	Medium and long term	Local and national	Applicable in countries with widespread GM crops cultivation

Adopters of GMOs have few technological options in terms of on-farm and locally adapted technological innovation when producing GM crops, mainly in relation to seed varieties and phytosanitary measures. On the other hand, genetic pollution resulting from persistence and gene flow makes it unfeasible to carry out GM-free production for non-adopters of GM technology in proximity to GM crop fields (Binimelis, 2008; Clark, 2004).

Impacts on food security

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Contested arguments	Direct	Medium and long term	Local and national	Applicable in countries with widespread GM crops cultivation

As mentioned previously (Section 2.3.2.1 under "Changes in land use and agricultural production systems"), an increase in the area under production using GM crops is related to changes in land use and agricultural production. Countries with high pressure to plant GM crops or expanding GM crop production are facing the replacement of local food production systems, raising food security concerns. This is the case in Argentina, where from 1996/97 (the year of introduction of GM soybean) to 2002/03 a decrease in rice (-44.1%), corn (-26.2%), sunflower (-34.2%) and wheat (-3.5%) has been reported, while GM soybean has experienced an increase of 74.5% in relation to other crops, and an increase of 126% in terms of area under cultivation since the year of its introduction (Pengue, 2004). In Argentina, from 2000 to 2005 the GM soybean production has replaced 4.6 million hectares of local food production (Pengue, 2005).

In general, developing countries with a significant percentage of GM crops in production (particularly as commodities), such as Argentina, Brazil, Paraguay and Uruguay have decreased their local food supply since 1996 (when the introduction of commercial GM crops occurred). Since that time, there has been an increase in undernourishment, according to FAO statistics, in some of the most important GM crop producing countries such as Argentina and Paraguay (Heinemann, 2009a). This is because "the industrial model of agriculture is also correlated with the oversimplification of diets" (Heinemann, 2009a, p.125). Certainly, food security and undernourishment are multidimensional issues where the agricultural specialization of some GM commodities plays only a partial role. Precisely because of this, and based on the existing information, the introduction of GM crops is not synonymous with the improvement of food security or a decrease in hunger.

Tensions between GM and non-GM adopters

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Established	Direct	Medium and long term	Local and national	Applicable in countries with differentiated production systems and markets

Illegal introductions, undisclosed farming of GMOs and proximity of GM and non-GM production systems have created tensions between adopters and non-adopters of GM crops. Other tensions arise when gene flow occurs in non-GM fields (either organic or conventional) entailing economic and non-monetary damage. Moreover, in this situation, farmers seeking compensation are obliged to identify the entity responsible for the damage, creating further tension among the different actors in the agricultural sector, usually located in the same community (Binimelis, 2009).

Increase in inequities due to the restricted access and benefits sharing from technology adoption

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Contested arguments	Indirect	Medium and long term	Local and national	Applicable in countries with widespread use of GM crops and peasant/ subsistence farming

Information on the contribution of GM crops to farmer welfare is contested. While some authors report benefits and welfare increase arising from GM crop production (mainly an increase in income) (Qaim and Traxler, 2005; Pray et. al., 2002; Marshal, 2009; NRC, 2010;), others report increased inequities among GMO adopters and non-adopters (Morse et al., 2007: Palau et al., 2007). This situation leads to a reduction in production opportunities for farmers already in disadvantageous positions, adding to poverty in the rural sector. Most of the reports examining GM crops as drivers of economic welfare cover the first period of introduction of GM crops or on farmers with access to key production (e.g., irrigation) and financial resources (Glover, 2010).

In light of the long-term perspective of SD, the following is a summary of reported causes of inequities among adopters and non-adopters of GM crop production:

- "[T]raits that have been introduced in GM crops to date tend to largely favour the existing farming practices of industrial agriculture, rather than meet the needs of the poor" (Pray and Naseem, 2007, p.193). Hence, the adoption of GM crops and their potential economic benefits remain with agroindustrial or subsidized farmers.

- The costs for implementing the GM crop package becomes economically feasible only at certain acreage (e.g., in Bolivia the GM soy production becomes economically profitable only in plots larger than 50 hectares) (Catacora, 2007). Hence, small-scale farmers surrounded by GM crops, lacking enough land and financial resources to join GM production, usually rent or sell their land to larger GM producers (Palau et al., 2007; Pengue, 2004; Lehmann and Pengue, 2000). This results in interrelated impacts: i) land concentration (e.g., in Argentina, the average surface of GM soybean production plots has increased from 243 to 538 hectares

in 2003) (Pengue, 2005); ii) exclusion of medium and small-scale farmers; and iii) exodus to urban areas by displaced farmers or peasants without land (Palau et al., 2007). At the same time, the rural exodus, particularly of displaced farmers and landless people, results in loss of traditional culture, overall change in livelihood and high probability of an increase in peri-urban poverty and social problems (Palau et al., 2007; Tomei and Upham, 2009).

- Since GM crop cultivation is mostly mechanized, it creates or exacerbates problems related to job opportunities in rural areas. "Whereas small farms may create 1 job per 8 ha, mechanised plantations may employ as few as 1 person per 200 ha" (Tomei and Upham, 2009, p.3896).

Occupational and public health risk

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Contested arguments	Direct	Acute, medium and long term	Local and regional	Applicable to areas of GM crops production mainly HT and IT

HT and IT crop production field workers are exposed to toxins from the transgenes and the pesticides inherent to the GMO production system (e.g., herbicides) with potential immune responses and other health impacts.

It has been reported that workers exposed to Bt-crops experienced skin sensitization (Bernstein et al., 1999; Bernstein et al., 2003). This raises the question of potential occupational risks at farm level but also to people working in processing factories who are in constant contact with material derived from GMOs (e.g., breathing GM-corn flour dust) since there is no evidence indicating that it is possible to "avoid ingestion of DNA, protein or other substances that might be unique to a GM plant or its method of cultivation and processing" (Heinemann, 2009b; p.5).

As for pesticides used in the production of GMOs, simple exposure during field application is in itself an issue of human and public health. Workers in fields where a decrease in the use of pesticides has been experienced by the introduction of HT or IT crops have less exposure. However, this might not be the case in the long term. In Argentina, for instance, eight years after the introduction of GM soybean, the overall increase of pesticide use is a general public health issue. For instance, up to 160 million of litres of glyphosate plus an additional 25 million litres of complementary herbicides to combat only one weed tolerant to glyphosate was applied in the 2004/2005 cultivation season (Pengue, 2004; Tomei and Upham, 2009). These levels of pesticide use increase the concentration of airborne toxins in the environment, putting people, wildlife and water sources at risk (Tomei and Upham, 2009). Civil society groups and inhabitants of communities close to GM crop plots have also reported (and even filed law suits in regards to) increases in cases of chronic intoxication, cancer, incidences of allergies, skin irritation, fetal malformations, respiratory disorders and neurological illnesses (e.g., communities in Argentina and Paraguay close to RR soybean fields) (GRR, 2009; Semino, 2008; BASE-IS, 2008; Palau et al., 2007).

Studies on the combinatorial health impacts of toxins from the transgenes and pesticides used in GMO production are still missing, particularly in relation to populations with chronic diseases and undernourishment.

Possible erosion of local knowledge systems related to local (agro)biodiversity

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Expected	Indirect	Medium and long term	Local and national	Applicable in countries where (agro) biodiversity is relevant to indigenous or local communities

Changes in the dynamics of local species and their ecosystems resulting from GM crops may bring a series of new elements into play so that local knowledge on (agro)biodiversity (e.g., local practices on pest management, in situ conservation of native varieties, traditional crop rotations, etc.) may become obsolete. This could lead to erosion of local knowledge and lack of means to cope with changes in the local (agro)biodiversity. This is particularly important in the centres of origin since the sustainability of rural and indigenous livelihoods depend to a great extent on local knowledge of local biodiversity (IAASTD ed., 2009b). Erosion of local knowledge is also related to land use and land ownership changes. Replacement of diversified production systems by large-scale monocrops and disappearance of small-scale properties either by sale or lease to large-scale producers (both situations related to GM crop production particularly in developing countries) lead to the loss of knowledge related to local foods and agricultural practices (Tomei and Upham, 2009).

2.3.2.3 Ethical Considerations for Sustainability of Production of GMOs/GM Crops

Individual decisions with collective impacts

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Competing arguments	Direct	Medium and long term	Local and national	Applicable in regions with differentiated production systems and markets for GM and non-GM crops

The notion of containment and co-existence of GM and non-GM crops is inconsistent with the biological dynamic of living organisms (Clark, 2004) and the socioeconomic systems where they are introduced (Dyer et al., 2009). Based on this, unilateral decisions by individual farmers on the introduction and production of GMOs have collective impacts, particularly on non-GM crops adopters (e.g., organic farmers, concerned consumers, and others).

The balance between harm and benefits

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Competing arguments	Direct	Short and long term	Global	Wide applicability

How to establish a comprehensive analysis of adverse and beneficial impacts when there are gaps in our knowledge and uncertainty about the safety of GMOs? How to assess potential damage to socio-economic dynamics that are either non-marketable or have non-monetary value? Should the damage on biodiversity and the environment be measured in terms of utilitarian or intrinsic value? These are some of the difficult questions when trying to set a balance between potential negative and beneficial impacts of GMOs, especially when current regulatory frameworks focus on liability and compensation of isolated economic aspects leaving aside collective social and environmental concerns, according to Binimelis (2009) and Clark (2006).

2.4 Harvesting, Storage, Conditioning and Processing of GMOs

2.4.1 Implications for Ecological Sustainability of Harvesting, Storage, Conditioning and Processing of GMOs

Potential contamination of surrounding wildlife

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecological	Long-term impacts not available yet	Direct	Long term	Local and regional	Applicable in areas of storage, processing or transport of GMOs

GM pollen, harvest residues of GM crop and GMO-processing by-products have been found in the environment, particularly in soil and aquatic ecosystems (Kratz et al., 2010; Turrini, 2008; Castaldini et al., 2005; Bøhn et al., 2008; Rosi-Marshall et al., 2007) and feed (Heinemann, 2009b). Although there is no conclusive information on the potential effects of these residues, their presence in fragile biological ecosystems raises concerns. Small particle fractions resulting from harvesting or processing activities (e.g., milling of GM grains) are of special importance since deposition rates at large distances have been reported; these smaller particles have a greater surface area to volume ratio, increasing their biodegradability but also their biological availability for small non-target organisms along the food chain (Kratz et al., 2010).

2.4.2 Implications for Economic Sustainability of Harvesting, Storage, Conditioning and Processing of GMOs

Changes in yield

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Contested arguments	Indirect	Short term	Local	Applicable to GM crops

Impacts of GMOs on yield are subtle. Qaim and Trexler (2005) reported an increase in productivity of GM soybean production in Argentina up to 10% from 1996 to 2001, Gurian-Sherman (2009) mentioned that only sporadic or minimal yield increases have been registered with the use of GMOs in the US, and Jost et al., (2008) assessed a field trial in the US where non-GM cotton yields more

than GM varieties. Others also reported a reduction in yield when comparing GM crops with their non-GM counterparts (Altieri and Rosset, 1999). The issue is still to be resolved since several factors affect yield and current information does not allow generalization.

Economic and market loss due to contamination

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Well established	Direct	Short and long term	Local, national and global	Wide applicability

Genetic contamination of harvest, bulk or processed products is likely to happen due to biological and socioeconomic factors, such as: i) lack of means for biological containment of GMOs once released into the environment (Clark, 2004); ii) gene flow enhanced by human activities such as transport or exchange of seeds (Dyer et al., 2009); and iii) sharing or rental of harvesting machinery, transport vehicles and storage facilities particularly among small and medium-scale farmers (Catacora, 2007). Reported examples of genetic contamination along the value chain of agricultural products causing significant economic damage are:

- Starlink, a GM corn containing Bt-toxins approved only for animal feed, banned and recalled from the market shelves in 2000 due to potential acute allergic reactions among US consumers, is still found in maize exports and food aid sent to developing countries (Breckling, 2010).

- LLRice-601, a rice resistant to the herbicide glufosinate, in field-trial stage from 1991–2001 and unapproved in the US, was found in US rice exports to Europe in 2006. This resulted in decreased rice prices and export volumes, and prompted lawsuits from farmers against the responsible company, (Bayer) (Vermij, 2006).

- Triffid flax, a modified flax to tolerate high levels of agrochemical residues in the soil; it was not permitted in Europe during the late 1990s, and was de-registered in Canada in 2001. In 2009 Triffid flax was found in Europe as an impurity in food samples. When the contamination became public, the flax market in Canada dropped by 32%. The product was recalled and all products containing flax in Europe were tested to assess the level of contamination (Schmidt and Breckling, 2010; Breckling, 2010).

- Cases of genetic contamination amongst plots neighbouring organic farms have been reported since 1999. The majority of the cases of genetic contamination of organic produce have been reported in soybean (e.g., US, Korea, UK, Brazil), maize (e.g., Us and Spain), papaya (e.g., US and Hong Kong), cotton (e.g., India) and canola (US and Canada). The economic damage affecting organic farmers and companies has been related to the loss of markets, decrease in sales, lower prices, negative publicity, withdrawal of organic certification and product recall (Hewlet and Azeez, 2008).

Limited differentiation/segregation alternatives for small-scale farmers and enterprises

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Well established	Direct	Short and long term	Local, national and global	Applicable in countries lacking segregation of GM crops

Potential contamination of the value chain of agricultural crops imposes restrictions on small-scale producers and small-scale enterprises that wish to differentiate/segregate their production. The potential contamination could be reduced or delayed by having different or segregated channels (infrastructure) for harvesting, storing, conditioning and processing. However, in developing countries, where small-scale farmers depend on rented infrastructure, the possibility for segregation becomes quite limited an even unfeasible (Catacora, 2007).

2.4.3 Ethical considerations for Sustainability in Harvesting, Storage, Conditioning and Processing of GMOs

Technological fixes to solve complex issues related to agricultural productivity

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Competing explanations	Direct	Short and medium term	Global	Wide applicability

When an increase-in-yield variety is promised as a mean to enhance agricultural productivity, the social, economic and political roots of the low yield are ignored. This is especially sensitive in the context of small-scale farming where agricultural and social problems result from a complex interaction of factors unlikely to be solved only through technological means (Pavone et al., 2010).

Technology promotion strategies: GM crops promoted as yield-enhancing and poverty-reduction technologies

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Competing explanations	Direct	Short and long term	Global	Wide applicability

The biotechnological sector has been effective in disseminating two messages: i) GM crops yield more (Spielman, 2007) and ii) with increased yields from using GM crops it will be possible to eradicate world hunger and poverty (Monsanto, 2006). Although the GM crops placed in the market have the potential to control different factors that may result in decrease in production costs during the first years of production, none of the current GM crops have yield-enhancing characteristics per se (Heinemann, 2009a). Moreover, productivity and poverty are multi-dimensional challenges (IAASTD ed., 2009b), so they are unlikely to be resolved with the introduction of a single technology (Pavone et al., 2010). Further discussions are needed on the ethics of promoting technologies under arguments that go beyond the capacity of the technology.

2.5 Transport and Commercialization

The impacts related to the transport and commercialization of GMOs result from the fact that most of the GMOs, specifically GM crops, are produced as commodities for external markets. Several impacts discussed in this section are closely linked to industrial farming, to which GMOs are integral,reinforcing the commercial dynamic on which industrial agriculture relies.

2.5.1 Implications for Ecological Sustainability of Transport and Commercialization of GMOs

High carbon generation and energy consumption GM commodities

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecological	Competing explanations	Direct	Short and long term	Global	Wide applicability

GM commodities, as is the case with non-GM commodities, travel in large quantities over long-distances from area of production (U.S. Argentina, Brazil, Canada, Paraguay among others) to main markets (e.g., EU, Japan, China) (Toomey, 2004). Although GM commodities are usually transported by ship, the most efficient mean of transportation in terms of volume per fossil fuel (Heinberg and Bomford, 2009), the emissions of GHGs is still high due to the long-distance transport. However, the impacts of GM commodities in relation to GHG emissions and climate change go much beyond that caused by the distance they are transported to reach their markets (Sounders et al., 2006; Desrochers and Shimizu, 2008; Carlsson-Kanyama, 1997). Based on reports from main producing countries GM commodities are related to deforestation for GM-crop expansion (Pengue 2004; 2005), which is a high carbon emission activity (Panichelli et al., 2008). Other sources of carbon emission and high-energy consumption are the production system, conditioning, means of transportation and modes of consumption of GMOs (Desrochers and Shimizu, 2008; NRDC, 2007), which are important to consider as the parts of their life cycle. The contribution of GMOs to GHG emissions in terms of energy demand is both direct and indirect: fuels and electricity needed for production are a direct energy demand, while the production of synthetic fertilizers, pesticides, food supplements for animal production, etc., are indirect energy demands. In addition, capital goods (energy used for the construction of assets used during the production cycle such as equipment, vehicles, machinery, buildings, fences, etc.) also represent another indirect energy requirement from GM commodities production (Sounders et al., 2006). A full energy consumption analysis of GMOs under these criteria is still lacking.

2.5.2 Implications for Economic Sustainability of Transport and Commercialization of GMOs

Market concentration and vertical integration of the GM commodities supply

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Well established	Indirect	Medium and long term	Global	Wide applicability

The international trade of GM crops (specifically GM soybean, maize and canola) is inserted in the commodity system, which works under the rationale that harvests of the same crop from different farms are sufficiently similar to trade them as bulk under a common price and grading specification. With this, transport and handling costs are reduced while a continuing supply of raw material to the processing and industrial sectors is secured (CEC, n.d.). Currently, the practice of bulking up of GM and non-GM commodities (particularly grains) is concentrated in five companies: Archer Daniel Midland (ADM) (US), Cargill (US), Bunge (US/The Netherlands), Dreyfuss (France) and ConAgra (US). Besides providing collection services, these companies also undertake processing and trade of the agricultural commodities that they collect (UNCTAD, 2006). In relation to GM commodities, these companies work under a vertical integration approach resulting in alliances between modern biotechnology, food industry, seed and agrochemical sectors establishing clusters of stakeholders from the different stages of the value chain (from the R&D of the GM traits to their commercialization). For instance, Cargill and Monsanto have established joint ventures and strategic alliances for these purposes, as have Syngenta/Novartis with ADM and DuPont with ConAgra. The

vertical integration facilitates cooperation with upstream partners and easy access to farmers and raw material. The concerns over vertical integration are that it operates in a "closed" market dynamic, with participation of the same stake- and shareholders making the decisions along the whole production and value chain. In this way, the same actors influence the R&D, production and marketing (including price determination) of GMO-based commodities (UNCTAD, 2006).

Weakening of economic opportunities for differentiated production

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Well established	Direct	Medium and long term	National and global	Applicable in countries with sectors with differentiated non-GM markets

Just as in the production stage, genetic contamination during transport and commercialization is possible, leading to market losses and weakening of economic opportunities especially in the GM-free differentiated markets. A study carried out in Germany on the economic effects of different scenarios of large-scale farming showed that processed products manufactured with or containing up to 1% of GM ingredients could lead to a utility loss of 38% of retail price (based on consumers' willingness to pay), resulting in losses varying from €403 million to €574 million/year (Barkmann et al., 2010). Examples of economic damage resulting from genetic contamination are in Section 2.4.2 ("Economic and market loss due to contamination").

2.5.3 Implications for Social Sustainability of Transport and Commercialization of GMOs

Limitations for fair trade

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Economic	Contested arguments	Indirect	Medium and long term	Local and national	Applicable in countries with sectors with differentiated non-GM markets

The overall commercialization system of GMOs, particularly related to long-distance commodity markets and vertical integration, significantly reduces opportunities for farmers to access fair trade prices, mainly for small-scale producers (Desrochers and Shimizu, 2008). On the other hand, the vertical integration of GM commodities means that farmers lose bargaining power particularly due to a lack of information disclosure, a characteristic of vertical integration. Hence, prices of agricultural commodities remain advantageous to traders (Ongwen and Wright, 2007). These limitations in accessing fair trade prices also affect non-adopters of GM-crops when they face problems of contamination and lose access to differentiated markets.

2.5.4 Ethical Considerations for Sustainability of Transport and Commercialization of GMOs

Weakened right to know and right to choose

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Contested arguments	Indirect	Short and long term	National and global	Wide applicability

Restrictions in the right to know and to choose between GM and non-GM products apply to farmers and consumers. For farmers, the current dynamic of vertical integration of the food industry restricts alternatives through which farmers not adopting GM crops may access and choose GM-free markets. As mentioned earlier, small and medium size farmers usually depend on rented infrastructure provided by the vertically integrated companies to harvest, store and transport their produce. This situation leads to few or no options to control or avoid potential sources of contamination of GM-free produce. In cases of uncontrolled or undesired contamination of GM-free produce targeting differentiated markets, the immediate impacts are the reduction in price and restrictions to access those markets (Catacora, 2007). In the same vein, consumers, particularly long-distance ones, have limited options to access products transported and commercialized outside the vertical integration. A difference between these two scenarios is that usually non-GM farmers have more restricted alternatives and more recognized needs than consumers; while long-distance consumers might not be aware that they are part of a trade dynamic with few options to choose from.

2.6 Consumption of GMOs

There is no conclusive information on the safety of GMOs as food. The literature reports no significant negative effects on health nor conclusive evidence of potential adverse effects associated with the novel proteins, toxins resulting from the GM construct or its expression (Weaver and Morris, 2005) mainly due to the lack of long-term studies (Doming, 2007; Dona and Arvanitoyannis, 2009). In addition, opposing findings are reported in the literature in relation to herbicide residues in GMO–based food and feed (mainly HT) (Gasnier et al., 2009). The literature also reports contentious discussions on the different methodologies applied in the research of GMO-based food safety. The conclusion of several researchers is that the current methodologies applied are leading to underestimation of the potential adverse effects on health from the consumption of GMO-based foods, and that long-term studies are required before continuing the introduction of GMO-based products into the market (Dona and Arvonitoyannis, 2009; Domingo, 2007). The following sections summarize the potential adverse effects on the safety of GMO-based foods.

2.6.1 Implications for Ecological Sustainability of Consumption of GMOs

Potential adverse health effects on farm and wild animals

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecological	Contested arguments / Long term impacts not available yet	Direct	Long term	Regional and global	Wide applicability

Studies in small mammals show that novel proteins and toxins derived from the consumption of GMO-based foods could lead to variations in growth, characteristics of internal organs (e.g., stomach, intestines, liver, pancreas, kidney) and biochemical (e.g., glucose, cholesterol, triglyceride), hematological, reproductive and immunological parameters (Dona and Arvonitoyannis, 2009;

Domingo, 2007; Malatesta et al., 2008). These variations observed at the laboratory level point to potential changes in fitness affecting survival and population dynamics of both farm and wild animals.

Potential for bioaccumulation of toxins in the food chain

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ecological	Contested arguments	Direct	Medium and long term	Regional and national	Wide applicability

Transfer of recombinant DNA and residues of agrochemicals (particularly in the case of HT and IT crops) may result in accumulation of toxins in the food web with unknown potential effects. Research on animals shows that recombinant DNA can persist along the gastrointestinal tract (Heinemann, 2009b) and reach internal organs through the bloodstream (Schubbert et al., 1997). Consequently, it could: i) be transferred to fetuses and newborn animals through transplacental routes (Doerfler and Schubbert, 1998; Schubert et al., 1998); or ii) persist in animal products (e.g., milk) (Agodi et al., 2006). Long-term studies on potential bioaccumulation of toxins related to GMO-based foods are still missing.

2.6.2 Implications for Social Sustainability of Consumption of GMOs

Potential negative effects on human health

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Social	Contested arguments	Direct	Medium and long term	National and global	Wide applicability

Based on findings in animal research, potential hazards to human health from GMO-based foods are related to the genetic construct, the expression of this genetic construct, and chemical residues associated with GM plants, mainly from IT and HT crops.

In relation to the genetic construct and its expression, potential health impacts are (based on Schubert, 2008; Dona and Arvanitoyannis, 2009):

- Unexpected gene expression influencing the production and interaction of enzymes and metabolites, especially in the new generation of GMOs (e.g., GM plants designed to produce plant-based pharmaceuticals and nutritional substances), which might result in the production of biologically active compounds in host plants that could result in unpredictable potential adverse health effects.

- Increased content of anti-nutrients in GMO-based foods.

- Potential serious health disorders (e.g., carcinogenesis, mutagenesis, etc.) resulting from the use (and inclusion in GM foods) of highly infectious viral DNA in plants.

- Antibiotic resistance.

- Exposure to novel proteins with the capacity of generating allergic reactions.

In addition, dietary recombinant DNA is not fully degraded in the gut (Schubbert et al., 1997). Moreover, it can survive high levels of processing (e.g., pasteurization) (Agodi et al., 2006).

In relation to pesticide crops, IT crops (specifically Bt-plants) produce substances (e.g., Cry proteins) toxic to human cells and other mammals, and have the potential to result in immune response such as allergies (Ito et al., 2004; Heinemann, 2009a; Bernstein et al., 1999; Bernstein 2003). In relation to HT crops, they contain residues classified as carcinogens, mutagens and reprotoxin agents (substances with long-term and systematic effects on the reproductive systems in humans), which originate from the herbicide formulations that they are resistant to (e.g., glyphosate-based herbicides) (Benachour and Seralini, 2009; Gasnier et al., 2009). Recent research detected the presence of pesticide residues associated with GM crops circulating in the organs of pregnant and non-pregnant women, raising important questions on reproductive toxicology (Aris and Leblanc, 2011).

2.6.3 Ethical Considerations for Sustainable Consumption of GMOs

Enhanced foods to improve nutrition versus uncertain health impacts derived from enhanced foods

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Contested arguments	Direct	Medium and long term	Regional and national	Applicable to future areas of production and consumption of NEP

Plant-based pharmaceuticals and 'nutritionally' enhanced plants (NEP) are developed with the aim of reducing certain diseases or nutritional deficiencies (e.g., vitamin deficiencies) (Zimmermann and Qaim, 2004; Monsanto, 2006). These are a new generation of GM plants with the potential to complement current health and nutritional strategies to decrease undernourishment (Enserink, 2008). Under this view, GM plant-based pharmaceuticals and NEP are an approach to producing efficient pharmaceuticals and micronutrient synthesis. However, this approach is marred by potential adverse health effects. Slight changes in biologically active compounds potentially related to GM pharmaceuticals and foods may trigger serious effects on the biological system. For instance, Golden Rice, a GM-rice that produces higher quantities of ß-carotene than its conventional counterparts, was developed to decrease vitamin A deficiency, a cause of blindness and other diseases especially among pregnant woman and children from developing countries (Zimmermann and Qaim, 2004). The assimilation of ß-carotene results in compounds crucial for the development of the nervous system; however, a slight overproduction of some of the ß-carotene by-products might have too great a toxicity effect and produce teratogenic agents. This example shows that the increase of certain compounds to overcome nutritional deficiency is only one type of potential impact of NEP. This also applies to NEP-derived fatty acids and NEPs overproducing vitamin E, among others (Schubert, 2008). Questions remains: To what extent are these GMOs safe or capable of solving (or worsening) the health and nutritional problems that they were intended to solve? How can the promotion of health be counter-balanced with technologies that might have adverse effects on health itself? Are there better understood and safer alternatives?

Introduction of novel foods into the market place with no comprehensive or long-term studies

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Contested arguments	Direct	Short and long term	National and global	Wide applicability

In some countries, novel foods such as GMO-based foods do not require mandatory safety testing in

spite of the numerous findings about their potential health effects. This is the case in the US, where plant-based pharmaceuticals and NEP are "generally recognized as safe" (GRAS) (Schubert, 2008). Short-term pre-market assessments have been the regular practice to grant marketing permissions for GMO-based foods (Domingo, 2007). This contradicts the regular long-term pre-marketing safety testing that other products, such as pharmaceuticals and cosmetics, require before entering the market place. This contributes to the difficulty of assessing the wide range of potential long-term effects of GMO-based foods (Domingo, 2007). In addition, a significant amount of the research done, mainly sponsored by the modern biotechnlogy industry, has been subject to methodological and analytical criticism which increases the uncertainty about the safety of GMO-based foods (Domingo, 2007; Dona and Arvanitoyannis, 2009; Heinemann, 2008). Several researchers have questioned the ethics of marketing products for daily consumption that lack solid evidence of their safety (Dona and Arvanitoyannis, 2009).

Right to informed consumption

SD goal impacted	Certainty on the implication	Relationship with the SD goal	Temporal scale of impacts	Spatial scale of impacts	Specificity of the impact
Ethical	Contested arguments	Direct	Medium and long term	National and global	Wide applicability

Informed consumption of GMOs is particularly relevant due to the inconclusive knowledge about their safety, yet identification of GMO-based foods and products is generally scarce, resulting in uninformed use and ingestion, especially in the developing world. Traceability and labelling of GMOs are options for facilitating informed consumption; however those measures are considered unnecessarily trade-restrictive by the WTO, particularly for products derived from GMOs and GMO-based feed (Baumüller, 2003). Lack of labelling of GMO-based products results in: i) limitations on the consumer's rights to make informed decisions according to their environmental, social and ethical values (Uusitalo, 2008) and ii) lack of means to monitor any adverse effect from the consumption of GMO-based products by post-market safety monitoring (Schubert, 2008).

2.7 Sustainable Development Considerations Along the Value Chain of GM Soybean-Based Agrofuel Production: An Example from Argentina

Argentina is the third-largest of the major global GMO producers (James, 2010) whose main GM crop is soybean (RR technology, meaning a soybean tolerant to the herbicide glyphosate), which accounts for more than 98% of total soybean production in the country. Soybean in general represents 50% of Argentine cultivated grains and a significant portion of the nation's exports (Tomei and Upham, 2009).

By 2008, Argentina produced more than 10% of global agrofuel. The importance of the production of GM soybean-based agrofuel in the Argentine economy has resulted in its prioritization and expansion for economic development purposes (rather than as a measure to reduce GHG emissions). Between 2007 and 2008, the installed capacity for agrofuel processing increased by 150%, and similar increases have been estimated for the coming years. During the same period, the production of (GM) soybean-based agrofuel has increased almost 2.4 times (Tomei and Upham, 2009).

Although soybean has the lowest oil content, the lowest agrofuel yield and requires the largest area per unit of agrofuel produced in comparison to other crops (e.g., sunflower, jatropha and rapeseed) soybean for agrofuel production is widely common (Schvarzer and Tovosnanska, 2007). Some factors contributing to this are: i) intense promotion of soybean production; ii) RR seeds are not patented in Argentina, allowing farmers to save RR soybean seeds; iii) the lack of licensing fees makes RR

soybeans particularly attractive and affordable for large-scale producers and foreign oil refiners for the export market; and iv) the technological package of RR soybean includes a no-tillage system and chemical fallow that facilitate the mechanized management of large-scale areas, significantly decreasing labour costs (Tomei and Upham, 2009).

Although GM soybean-based agrofuel production is economically attractive, it does not result in ecological and social sustainability in the long term. A LCA of (GM) soybean-based agrofuel in Argentina showed a greater global warming potential, as well as aquatic and human toxicity, when compared with fossil energy sources due to extensive deforestation and intensive agrochemical applications related to the current GM soybean production systems (Panichelli et al., 2008). Moreover, the high level of deforestation is leading to habitat and biodiversity loss, and reduction in soil and biomass (an important driver of carbon concentration in the atmosphere). Some reports mention that since the introduction of GM soybean in Argentina, more than "2.5 million hectares of native forests have been lost, especially in northern Argentina, due to the expansion of soybean, an equivalent in 2007, of an average 821 hectares of forest lost per day" (Altieri, 2009, p. 238). This expansion into what had been forest land has been motivated by the decrease in production costs of GM soy (Altieri, 2009).

In Argentina, the expansion on GM-soybean over small-scale production systems is also related to the decrease in traditional and diversified agriculture, and agrobiodiversity (Tomei and Upham, 2009). From 1996/97 to the 2002/03 agricultural season, the area cultivated with GM soybean has increased 126% (Figure 3). In relation to other agricultural crops, this expansion equals 74.5%. Conversely, other crops have experienced a decrease in surface planted, such as rice (-44.1%), corn (-26.2%), sunflower (-34.2%) and wheat (-3.5%) (Pengue, 2004; 2009), among other crops (Figure 4).

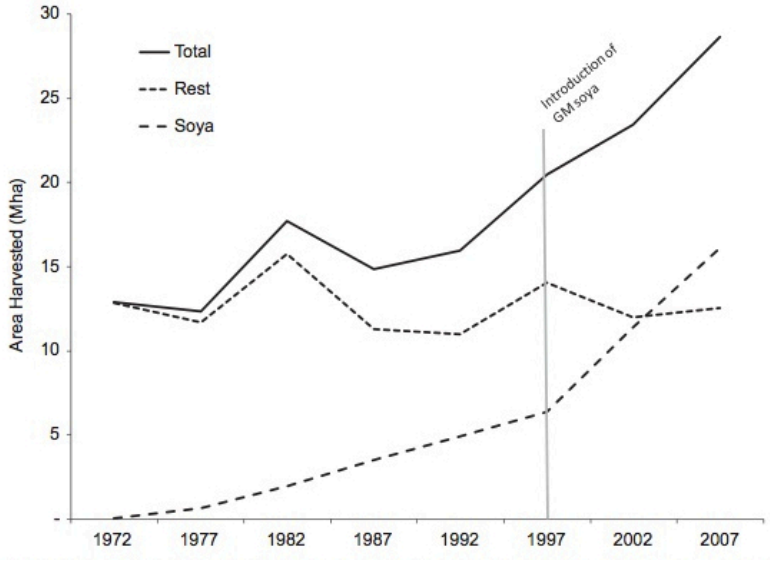

Figure 3. Evolution of the cultivation of soybean in Argentina
Source: Tomei and Upham (2009, p. 3892)

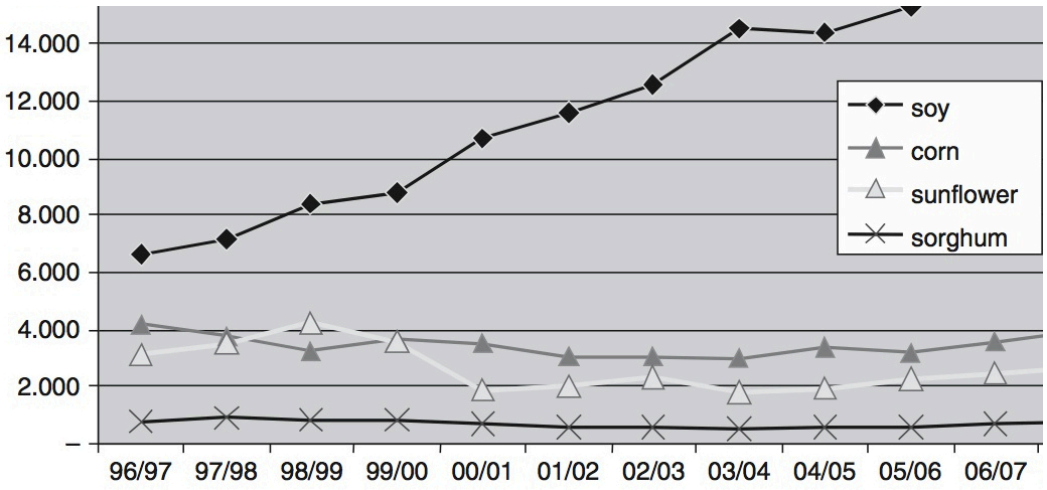

Figure 4. Comparative evolution (hectares x 1000) of (GM) soy in Argentina in relation to other crops
Source: Pengue (2009, p.168)

Another important environmental impact takes place in the soils. Although no-tillage systems contribute to reduced soil erosion, in Argentina GM soybean in general and for agrofuel production specifically is also linked to soil loss that ranges from 19 to 30 tons/hectare depending on management, local weather conditions and topography (Altieri and Bravo, 2009). No-tillage systems applied to GM soybean production in Argentina are also a driver for increased application of agrochemicals. For instance, the application of glyphosate in 2004 was approximately 160 million litres (Pengue, 2004) accounting for 70% of the pesticides used in Argentina (Tuesca et al., 2007). However, pesticides are not only used during the production of GM soybean, but also in the so-called chemical fallow. "Chemical fallow" refers to the application of herbicides to the plot surface as a soil preparation activity before planting. No-tillage systems and chemical fallow are components of the same production package, and it is estimated that 70% of the GM soybean is cultivated under this system (Dalgaard et al., 2008). In the Argentine GM soybean the chemical follow consists of the applications of different chemicals complementary to glyphosate (e.g., atrazine, 2,4-D, dicamba, paraquat and metsulfuron), all of them highly toxic (Tuesca et al., 2007) (Figure 5).

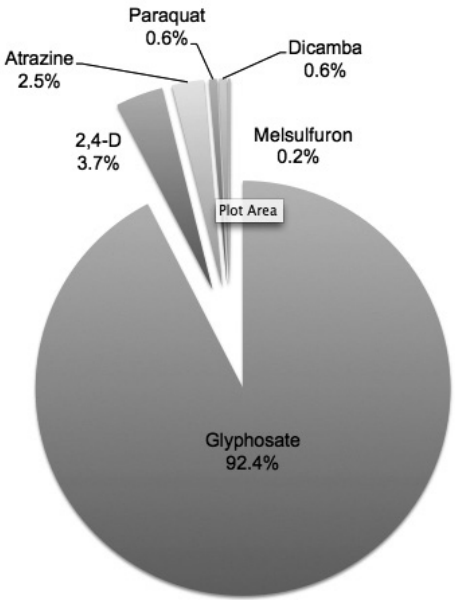

Figure 5. Market share of the herbicides used in chemical fallow in GM soybean production in Argentina (2005)
Adapted from: Tuesca et al. (2007)

The intensive production of GM soybean is also related to the depletion of soils minerals, mainly nitrogen and phosphorus (Dalgaard et al., 2008; Pengue, 2005; 2004). "In Argentina, intensive soybean cultivation has led to massive soil nutrient depletion. It is estimated that the continuous soybean production has resulted in the loss of 1 million metric tons of nitrogen and 227,000 metric tons of phosphorous from soils nationwide. The cost of replenishing this nutrient loss with fertilizers is estimated US$910 million." (Altieri, 2009, p. 239, based on Pengue, 2005) (Figure 6).

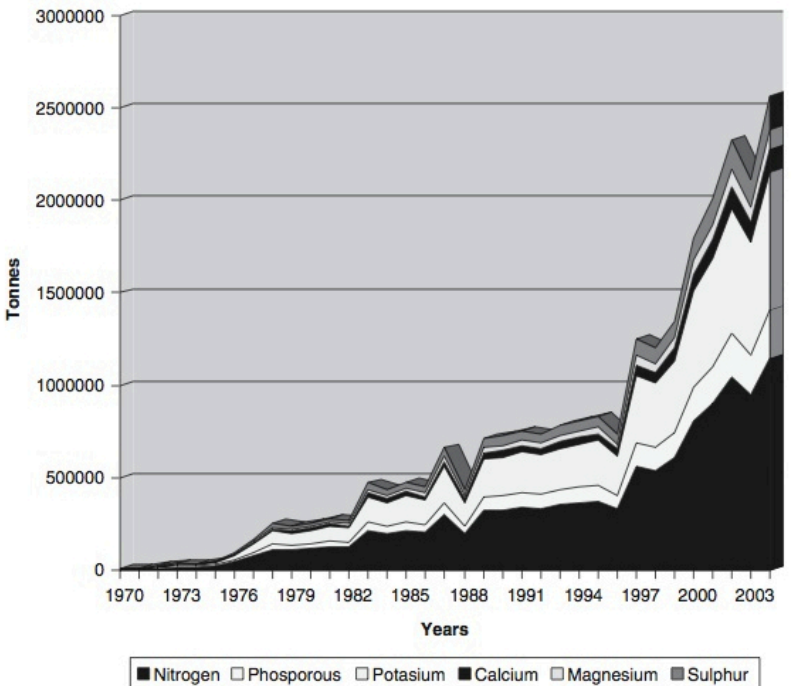

Figure 6. Cumulative depletion of soil nutrients related to soybean production in Argentina
Source: Pengue (2009, p.175)

The intensive application of agrochemicals in GM soybean production is leading to serious health issues and cases of severe public health disorders. For instance, civil society groups have reported that in the community of Ituzaingó (close to Cordova Province where 25% of the GM soybean for export is produced) (Giancola et al., 2009), 4% of the inhabitants face different health disorders due to chronic contamination by pesticides (e.g., cancer, allergies, skin irritation, fetal malformations, neurological and respiratory illnesses) (GRR, 2009).
The concentration of GM soybean production in large-scale producers has excluded approximately 60 thousand small-scale farmers for various reasons: i) impossibility to compete with the surrounding large-scale production of GM soybean, ii) pressure to sell or rent their property to surrounding GM soybean producers; and / or iii) lack of job opportunities resulting from the mechanized production that decreases agricultural labour demand and replacement of local agricultural systems. From 1998 to 2002, the number of farms in Argentina has decreased approximately 25%. Taking into account the increase in the area planted by (GM) soybean, these numbers reflect the concentration of land tenure (Pengue, 2005).

All of these socioeconomic factors result in the general impoverishment of Argentine rural families who have been excluded from the agricultural dynamic. Other factors are migration, decrease in the availability of local and diverse food, deterioration of public health due to chemical contamination and weakening of food security (Tomei and Upham, 2009; Pengue, 2004).

Table 4 makes an approximation of the potential adverse effects of GM soybean production for agrofuel production in Argentina in the short and long term. This is done in light of SD dimensions and based on the potential impacts described in the previous sections.

Table 4. Potential adverse effects of GM soybean-based agrofuel in Argentina in light of SD

Value chain stage / Potential impacts	Considerations for sustainable development							
	Ecologic		Economic		Social		Ethical	
	Short term	*Long term*	*Short term*	*Long term*	*Short term*	*Long term*	*Short term*	*Long term*
R&D								
Local knowledge and *in situ* conservation	+/-	-						
Conservation of agrobiodiversity	+/-	-						
Potential for new economic damage			NA	?				
Impacts in production costs			+/-	?				
Seed market competitiveness			-	-				
Societal benefits considerations in GMO R&D					+/-	-		
Farmers'rights related to seed saving					NA	?		
Local food systems and food security / sovereignty					NA	?		
Equity in access to technology					+/-	?		
Local knowledge and in situ conservation					NA	?		
Agrobiodiversity					NA	?		
Exercise of farmers'rights							NA	?
Influence in sharing IPR regulatory frameworks							NR	?
Independent biosafety research and transparency							NR	?
Production								
Weeds in agricultural lands	+/-	-						
Effects on non-target organisms	+/-	-						
Recombination of pathogens	+/-	-						
Gene flow and persistence	+/-	-						
Pesticide residues in the environment	-	-						
Changes in land use and agricultural production	-	-						
Production costs			+/-	-				
Economic benefits			+/-	-				
Technology dependence					+/-	-		
Farmers'right to choose					+/-	-		
Food security					-	-		
Relationship between GM and non-GM adopters					+/-	-		
Equity in access and benefit sharing					+/-	-		
Occupational and public health risks					+/-	-		
Local knowledge related to (agro)biodiversity					?	-		
Impact of individual decisions							+/-	-
Balance between harms and benefits							+/-	-
Harvesting / Storage / Conditioning / Processing								
Contamination of surrounding wildlife	NR	?						
Changes in yield			+/-	?				
Economic and market impacts due to contamination			NR	?				
Differentiation and segregation for small-scale producers			-	-				
Technological fixes							-	-
Technology promotion strategies							-	-
Commercialization / Transport								
Carbon generation and energy consumption	-	-						
Market concentration and vertical integration			-	-				
Opportunities for differentiation			+/-	-				
Fair trade					+/-	-		
Right to know and right to choose							-	-
Consumption								
Effects on farm and wild animals	+/-	-						
Potential bioaccumulation of toxins	?	?						
Effects on human health					?	?		
Safety of enhanced foods							?	?
Introduction of novel food lacking long-term studies							-	-
Right to informed consumption							-	-

(+) = Beneficial impacts; (-) = Negative impact; (?) = Uncertain impacts; (NA) = Not applicable; (NR) = Not reported

III Legislations and Regulatory Frameworks Related to GMOs

3.1 International Agreements Related to GMOs

3.1.1 Convention on Biological Diversity (CBD)

The CBD is a legally binding agreement under the United Nations Environment Programme (UNEP) that entered into force in 1993. As of March 2011, there are 193 Parties to the Convention (CBD, n.d.).

3.1.1.1 Objective of the CBD

The objectives of the CBD are: i) conservation of biological diversity; ii) sustainable use of its components; and iii) fair and equitable sharing of benefits arising out of the utilization of genetic resources (UNEP, 1992).

3.1.1.2 Provisions of the CBD on GMOs

Although not defined in its text, the CBD uses the term "living modified organisms" (LMOs) to refer to live organisms that result from traditional and modern biotechnology. The implications of this term have resulted in opposing opinions and controversial discussions. Some are of the view that LMO in the context of the CPB is a much broader notion than "genetically modified organisms" (GMOs) in the sense that the LMO concept includes adverse effects to biodiversity from organisms developed by traditional and modern means (MacKenzie et al., 2003). Others maintain that LMO is a restrictive term that in the context of biosafety legal instruments, tends to exclude the potential adverse effects resulting from the use of component parts and products that are of GMO-origin (Council for Responsible Genetics, 1998; TWN, 1998). Nevertheless, different interpretations of modern biotechnology and LMOs vary at the national level and the actual implementation of biosafety measures depends on how these terms are defined in the national legislation.

Since the Cartagena Protocol on Biosafety (covered in section 3.1.2) has been derived from the CBD, it restricts its scope to LMOs resulting from modern biotechnology based on the Decision II/5 of the Conference of the Parties to the CBD (Decision II/5 mandates the Protocol text negotiations according to Article 19(3) of the CBD) (Husby, 2007a).

The CBD contains three specific provisions related to LMOs that apply to all Parties of the CBD whether they are Parties or not to the Cartagena Protocol:

- Article 8 (g), related to domestic measures: "Each Party shall […] [e]stablish or maintain means to regulate, manage or control risks associated with LMOs resulting from biotechnology that are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health".

- Article 19 (3) provides instructions for the elaboration of a protocol to agree on "appropriate procedures, including in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity". In other words, the CPB is rooted in this article.

- Article 19 (4), related to the transfer of LMOs among Parties, specifically in relation to provision of information: "Each Contracting Party shall […] provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms,

as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced".

3.1.2 Cartagena Protocol on Biosafety (CPB)

The Cartagena Protocol on Biosafety (CPB) is a legally binding agreement under the United Nations´ Convention on Biological Diversity (CDB) of UNEP. The CPB derives from Article 19(3) of the CBD, which calls for possible elements and modalities of a protocol on biosafety (Secretariat of the CBD, 2003) (Section 3.1.1.2). The CPB entered into force on September 11, 2003 (Lim L.L., 2007) and as of March 2011 there are 160 Parties to the Protocol (Secretariat on the Convention on Biological Diversity, 2011a).

3.1.2.1 Objective and Scope of the CPB

The objective of the CPB is to "contribute to ensuring an adequate level of protection in the field of 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 risk to human health, and specifically focusing on transboundary movements" (Article 1) (Secretariat of the Convention on Biological Diversity, 2000, p.3). Accordingly, the main rationale behind the CPB is to guarantee an appropriate level of protection of biodiversity and human health[1] from risks that may arise from activities associated with LMOs.

Although the CPB has a particular focus on the movement of LMOs across national borders (transboundary movement and transit), it is also related to other activities linked to it (handling and use) and that may have adverse effects on national territories as indicated in the CPB scope (Article 4): "This Protocol shall apply to the transboundary movement, transit, handling and use of living modified organism that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risk to human health" (Secretariat of the Convention on Biological Diversity, 2000, p.5).

LMOs that are intended to be used as pharmaceuticals for humans are excluded from the scope of the CPB (Lim L.L., 2007; MacKenzie, 2004; Husby, 2007b), although this is only so if these are already addressed by other relevant international agreements or organizations.

3.1.2.2 Main Provisions of the CPB

- Precautionary approach. The CPB, as environmental law in general, is rooted in the precautionary approach as stated in Principle 15 of the Rio Declaration on Environment and Development. However, the CPB is not based on a cost-effectiveness precaution rationale (as is Principle 15 of the Rio Declaration). This implies a stronger implementation of precaution in the context of the CPB. The precautionary approach is included in the CPB preamble and in Article 1 (Objective). During the negotiations of the CPB, it was also agreed that the CPB should operationalise the precautionary approach, as it is reflected in Article 10.6 (Decision procedure), Article 11.8 (Procedure for living modified organisms intended for direct use as food, feed or for processing), and Annex III paragraph 4 (Risk assessment) (Meyer, 2007a; Secretariat on the Convention on Biological Diversity, 2000).

- Advance informed agreement (AIA) procedure. This is related to the prior notification from Parties of export to Parties of import about the intention to export a LMO by providing information (according to Annex 1 of the CPB) relevant for a risk assessment to the Party of import. Under the AIA procedure, risk assessment is mandatory and no export can take place

1 To which extent human health issues are considered under the CPB is open to interpretation by Parties. The CPB text allows two different interpretations. One, where human health considerations are subject to damage to biological diversity, and the other separated from potential adverse effects of LMO on biological diversity (MacKenzie et al., 2003).

until the importing Party gives its consent. LMOs in transit, for contained use and direct use as food, feed or processing are excluded from the AIA procedure. Hence, the AIA procedure applies only to LMOs intended for deliberate release into the environment and this is further restricted to the first transboundary movement of the LMO in question.

- LMOs for direct use as food, feed or processing (LMO-FFPs). The information related to domestic approval and transboundary movement of LMO-FFPs should be shared via the Biosafety Clearing House (BCH, a website administrated by the CBD Secretariat, www.bch.cbd.int/protocol/). With this provision on LMO-FFPs, the burden on accessing information for monitoring is placed on the importing country.

- Risk assessment and risk management (RA/RM). The CPB requires that LMOs undergo these procedures, which are scientifically-based, but with consideration to precautionary approaches. RA procedures are the responsibility of the country importing LMOs; yet, the importing country may also require the exporting country to assume this task or its costs. The RA must be undertaken in accordance with Annex III of the CPB. For this purpose, specific guidelines are been developed[2]. RM under the CPB is based on a preventive logic of intentional and unintentional release of both imported and locally produced LMOs.

- Socioeconomic considerations. When making a decision on import of LMOs, the CPB gives the option to Parties to consider socioeconomic impacts that may arise from potential adverse effects of LMOs on the sustainable use and conservation of biological diversity, giving special importance to indigenous and local communities (Article 26). This is a rather general provision since the CPB does not give specific guidance on how socioeconomic considerations can be effectively put in place in biosafety decisions, leaving this to domestic law.

- Public participation. This is a cross-cutting and mandatory provision of the CPB. Under domestic laws, Parties must promote public awareness, education and participation ”concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health” (Article 23.1). Access to information and justice is relevant to this provision. Parties must also consult the public in the decision-making process regarding LMOs.

- Unintentional and illegal transboundary movements. Parties have an obligation to notify potential affected Parties about any unintentional transboundary movement of LMOs. At the same time, Parties have the right to prevent and penalize illegal transboundary movements of LMOs.

- Other relevant issues under the CPB are handling, transport, packing and identification (detailed in section 4.1), liability and redress (detailed in section 3.1.3), capacity building, obligation of consistency with the objectives of the CPB between Parties and non-Parties when a transboundary movement occurs, and the relationship with other international agreements.

3.1.3 Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

Article 27 of the CPB mandates to Parties to elaborate “international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms”. The result is the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety. The process of negotiation of the Nagoya-Kuala Lumpur Supplementary Protocol was held from 2004 to 2010 and adopted on the 15th of October 2010. The Supplementary Protocol is open to signature from March 7, 2011 to March 6, 2012.

2 Since 2009, a “Guidance on Risk Assessment of Living Modified Organisms” is been under development and discussion. It includes a LMO risk assessment road map and specific guidance for risk assessment of LM with stacked genes or traits, LM crops with tolerance to abiotic stress and LM mosquitoes.

3.1.3.1 Objective and scope of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress

The objective of the Nagoya-Kuala Lumpur Supplementary Protocol is "to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to living modified organisms" (Article 1). In this sense, the Nagoya-Kuala Lumpur Supplementary Protocol applies to damage occurring within the jurisdiction of a Party and resulting from LMOs that find their origin in transboundary movement, whether intentional, unintentional or illegal. LMOs that have undergone intentional transboundary movement are those for direct use as LMO-FFPs, for contained use or intended for deliberate introduction into the environment. Damage arising from transboundary movement of LMOs from non-Parties is also covered in the scope, through domestic law implementing the Supplementary Protocol (Article 3) (Secretariat of the Convention on Biological Diversity, 2011).

The Nagoya-Kuala Lumpur Supplementary Protocol, as in other environmental instruments on liability and redress, is rooted in the "polluter pays principle". In environmental law, the polluter pays principle means that the cost of environmental damage must be covered by those responsible for the damage in question (Wikipedia, 2010). The practical application of the polluter pays principle calls for identification of the liable persons or entities responsible for damage, and promoting prevention measures. However, effective implementation of the polluter pays principle is difficult at the domestic level, usually — among other reasons — due to the resistance within countries to bear the changes in economic benefits and environmental/social cost between different groups resulting from the implementation of technologies or processes (ten Brick et al., 2009). Based on this, the Supplementary Protocol also aims to fill, to some extent, the national and international gaps in regulation on liability and redress for damage arising from the transboundary movement, transit, use and handling of LMOs.

3.1.3.2 Main provisions of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress

Some of the particularly relevant provisions of the Nagoya-Kuala Lumpur Supplementary Protocol are:

- Scope. The scope is broad, in that the Supplementary Protocol applies to damage from LMOs that find their origin in a transboundary movement, regardless of whether those LMOs are intended for direct use as FFP, contained use, intentional introduction into the environment, or subjects of unintentional and illegal transboundary movements. In addition, although the scope of the Supplementary Protocol does not mention products thereof, during the negotiations of its text it was recognized that there would be the possibility of broad interpretation of the application of the Supplementary Protocol. This emerged from the different understandings of the application of Article 27 of the CPB in relation to processed materials that are of LMO-origin (CBD, 2010). Accordingly, the Supplementary Protocol may also apply to damage caused by processed materials from LMOs (meaning by products thereof) subject to the establishment of the causal link between the damage and the LMO in question and originated in a transboundary movement.

- Definition of operator. The definition of operator is also broad. It includes potential persons in direct or indirect control of the LMO causing the damage, leaving a wide range of options for more detailed definitions in the Parties' domestic law.

- Causation. The causal link between the damage and the LMO in question should be established in accordance with domestic law. In this sense, as mentioned previously in relation to the broad interpretation of the scope of the Supplementary Protocol, damage resulting from the processed material of a LMO that finds its origin in a transboundary movement may be the subject of liability and redress when the causal link is established.

- Preventive measures. The Supplementary Protocol makes operational the precautionary approach by mandating preventive measures to avoid damage on the conservation and sustainable use of biological diversity, taking into account human health, when there is sufficient likelihood of damage.

- Response measures. They are the operational component of the Supplementary Protocol and understood to be the actions which prevent, minimize, contain, mitigate or avoid damage, and restore biodiversity. However, response measures are not restricted only to: i) biodiversity, but should also take into account risks to human health; or ii) damage that has occurred, since they should also be implemented when there is sufficient likelihood of damage if timely preventive measures are not taken. The establishment of the sufficient likelihood of damage is not limited to scientific information, but all sorts of information available in light of the precautionary approach. Operators are responsible for addressing damage and sufficient likelihood of damage, and have the duty to implement and cover the cost of response measures under the supervision of the competent authorities and according to domestic law.

- Financial security. By making explicit that Parties have the right to provide for a financial security mechanism in their domestic law to cover the expenses related to redress of damage, the Supplementary Protocol provides an approximation to the "polluter-pays-principle".

- Civil liability. A legally binding article in relation to civil liability is included in the Supplementary Protocol. This clause allows Parties to apply or develop, as appropriate, domestic civil liability rules and procedures to address damage to the conservation and sustainable use of biodiversity and taking also into account human health. The implementation of this article may occur through different approaches: i) by applying existing domestic law; ii) applying or developing specific civil liability rules or procedures; or iii) applying or developing a combination of both. In addition, the civil liability provision also applies to material or personal damage, allowing Parties three options to set their civil liability law: i) continue to apply existing general civil liability law; ii) develop and apply or continue to apply specific civil liability; and iii) a combination of the previous options. With these three alternatives, the civil liability provision takes into consideration the different levels of regulation in the field of civil liability among countries. An additional article mandates the review and improvement of the legally binding civil liability provisions based on the experience gained five years after the Supplementary Protocol enters into force.

- Consistency with international agreements. The Nagoya-Kuala Lumpur Supplementary Protocol calls for consistency with other international agreements.

- Human health has limited coverage in the Nagoya-Kuala Lumpur Supplementary Protocol.

3.1.4 Codex Alimentarius

Codex Alimentarius is a set of internationally recognized standards, codes of practice, guidelines and other recommendations on: i) food or groups of foods; ii) operation and management of food production processes; and iii) operation of government regulatory systems for food safety and consumer protection. Codex Alimentarius is developed by the Codex Alimentarius Commission, which is an intergovernmental body that operates under the Joint Food and Agriculture Organization (FAO)/ World Health Organization (WHO) Food Standards Programme (Codex Alimentarius Commission, 2009; Lim L.C., 2007). As of March 2011, 185 governments are members of the Commission (Codex Alimentarius, 2010).

3.1.4.1 Objective of the Codex Alimentarius

The objective of the Codex Alimentarius is to provide international standards relevant to the regulation of food with the aim of protecting consumer health, ensuring fair trade practices, and promoting coordination among existing food standards. The Codex Alimentarius is not legally binding; however,

it is recognized by regulatory bodies and other international agreements as a set of international standards, codes of practice, guidelines and recommendations for safety (Codex Alimentarius Commission, 2006a).

3.1.4.2 Main provisions of Codex Alimentarius on GMOs

In 2008, the second version of the Codex Alimentarius on Foods Derived from Modern Biotechnology was approved. The main purpose of these principles and guidelines is to assess the safety of foods derived from modern biotechnology, particularly GMOs. The Codex Alimentarius adopts the definition of modern biotechnology as defined by the CPB (Codex Alimentarius Commission, 2009). The adoption of this definition reasserts and reinforces the importance of the CPB in setting standards for biosafety regulation at the international level (Lim L.C, personal communication, March 30, 2011).

The documents adopted under the Codex Alimentarius related to GMOs are:

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (2003)

- Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (2006), with the following Annexes: Assessment of Possible Allergenicity (Annex 1); Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits (Annex 2 of the Guidelines); and Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food (Annex 3 of the Guidelines).

- Guidelines for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms (2003)

- Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (2008)

The main issues addressed in these documents are the following based on Codex Alimentarius Commission (2009); Codex Alimentarius, (2006b) and Lim L.C. (2007):

- Pre-market safety assessment. According to the Codex Alimentarius, the safety of GMO-based foods need to be assessed before being placed on the market. This pre-market safety assessment is considered part of a risk assessment to identify potential nutritional hazards, which should be undertaken on a case-by-case basis for GM foods.

- Unintended effects of GM foods. It is acknowledged that the process of insertion of DNA sequences, environmental factors and genetic background could influence the expression of transgenes and have unintended adverse impacts on health, which need to be assessed.

- Antibiotic resistant marker genes (ARMGs). Under Codex Alimentarius, ARMGs are not recommended due to the possibility of horizontal gene transfer from microorganisms to human cells.

- Food safety assessment. Codex Alimentarius provides a general framework to assess GMO-based foods, which includes the description of the genetic modification and the key components of the transgene construct, description of the host organisms and a safety assessment per se. This safety assessment comprises the characterization of possible toxicity and allergenicity (proteins) arising from GM food consumption, as well as compositional analysis of key substances, evaluation of metabolites, potential effects of food processing of GMO-based foods (including home preparation) and potential nutritional modifications. Additional considerations to safety assessment of ARMGs and potential accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances relevant to human health. A relevant feature of the Codex Alimentarius safety assessment is that substantial equivalence is not considered to be a safety assessment

itself but only a preliminary study to identify similarities and differences between GM foods and conventional counterparts.

- Additional nutritional assessment of GM-plant-based foods. Foods derived from GM plants or GM microorganism-mediated processes to intentionally modify the nutritional content or functionality of foods require additional nutritional assessment since the nutrient profile may change due to unexpected alterations of nutrients, leading to potential adverse effects in the nutritional status of people consuming those foods.

- Consideration of uncertainties. Risk management needs to take into consideration uncertainties identified during risk assessment procedures.

- Labelling as a food safety measure. Labelling is considered as a possible food safety condition for marketing approvals and post-market monitoring. Currently (as of March 2011) the Commission is elaborating standards for "Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering". The process has encountered difficulties setting mandatory international labelling standards due to opposition from the major GMO producing countries such as the US, Canada and Argentina.

3.1.5 International Plant Protection Convention (IPPC)

The IPPC is an international agreement under the FAO. As of March 2011, there are 177 Parties to the IPPC (IPPC, 2010).

3.1.5.1 Objective of the IPPC

The general objective of the IPPC is to provide guidance on an integrated process of risk assessment and risk management options to protect the health of cultivated and wild plants by preventing the introduction and spread of pests (IPPC, 2010).

3.1.5.2 Main Provisions of the IPPC on GMOs

In 2004, the IPPC endorsed the integrated standard "ISPM No.11: Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms", which is a guidance document for evaluating potential phytosanitary risks to plants and plant products posed by living modified organisms (LMOs) (Secretariat of the IPPC, 2006).

The IPPC adopts the definition of LMO and modern biotechnology given by the CPB (Secretariat of the IPPC, 2008). Under the IPPC, LMOs are considered a potential phytosanitary risk until decided otherwise.

In relation to the risk assessment, important issues considered under ISPM No.11 are the following (Secretariat of the IPPC, 2006; Lim L.C., 2007):

- Broad application of the risk assessment. Living modified (LM) plants, insects, fungi and bacteria that may pose direct and indirect sanitary risks to other plants and plant products should be risk assessed independent of their intended use. With this provision, unintended pathways of risk are recognized in a broader sense than in the CPB given that the CPB includes a distinction between LMOs for intentional introduction into the environment and LMOs for direct use as food, feed or processing (which may unintentionally end up in the environment).

- Economic evaluation. Economic factors resulting from potential damage or costs of control

or eradication need to be appraised, as well as the cost-effectiveness of alternative approaches to limiting risks.

- Potential phytosanitary risks from LMOs. They may result from the characteristics or properties related to the genetic modification, which need to be considered in the risk assessment and include:

    - Changes in adaptive characteristics that may increase the potential for introduction or spread of alterations, such as tolerance to adverse environmental conditions, reproductive biology, dispersal ability, growth rate or vigour and pest resistance and pesticide tolerance, among others.

    - Adverse effects of gene flow or gene transfer including pesticide or pest resistance genes, potential to overcome reproductive and recombination barriers and hybridization that results in higher phytogenicity, among others.

    - Adverse effects on non-target organisms.

    - Genotypic and phenotypic instability.

    - Other adverse effects such as phytosanitary risks from new traits in organisms that naturally do not pose that risk, novel or enhanced capacity for virus recombination, synergy events related to the presence of virus sequences, phytosanitary risks resulting from nucleic acid sequences (markers, promoters, terminators, etc.) present in the insert.

Other important provisions of the IPPC are:

- Inspection, testing, and restriction of end use, distribution, and periods of entry should be undertaken;

- Procedures to provide information on the phytosanitary integrity of consignments (e.g., tracing, documentation and identity preservation systems) need to be developed; and

- Prohibition of LMOs should be a last resort to avoid phytosanitary risks, subject to monitoring, review and modification of decisions, if needed.

3.1.6 World Organization for Animal Health (OIE)

The OIE is the intergovernmental organization responsible for improving animal health worldwide. As of March 2011, 178 member countries are part of the OIE (OIE, 2011).

3.1.6.1 Objective of the OIE

The main purposes of the OIE are: i) to generate and disseminate information (through national reports and scientific research) on global animal disease status, including diseases transmissible to humans and the intentional introduction of pathogens in order to take preventive measures; ii) strengthen the capacities of countries (mainly developing) in the prevention and control of animal diseases by improving national frameworks and technical capacities; iii) protect world trade of animals and animal products by setting standards for the prevention of transboundary introduction of diseases and pathogens in accordance with WTO rules; and iv) improve general safety and animal welfare in collaboration with other international organizations (primarily with the Codex Alimentarius Commission and WTO SPS Agreement) (OIE, 2010).

3.1.6.2 Main provisions of the OIE on GMOs

The work of the OIE on GMO issues is relatively new. Since 2005, through the Ad Hoc Group on Biotechnology, which was established by Resolution No. XXVIII: Applications of Genetic Engineering for Livestock and Biotechnology (Lim L.C., 2007), the OIE has been working on developing standards, recommendations and guidelines, as well as research on the following (OIE, 2007; OIE, 2008a; OIE, 2008b):

- Best technologies applied to the development of biotechnology-derived animals. This includes transgenic animals, taking into account existing work by relevant organizations. Special focus is given to information generation and sharing of experiences related to the application of transgenesis in farm animals including therapeutic methods (RNA-based technologies) and development of specific traits (e.g., disease-resistant traits, nutritionally enhanced products such as milk, meat, etc., development of products for pharmaceutical use, etc.).

- Safety and nutrition. Safety and nutritional aspects of foods derived from animals produced by assisted reproductive technologies, including transgenics.

- Risks assessment. Applied to transgenic and cloned animals (e.g., fish), and to animals produced for xenotransplantation or as organ donors.

- Identification and tracing. Related to the development of suitable procedures for the identification and tracing of animals and animal products that have resulted from biotechnological interventions.

- Development of Guidelines on: i) Animal health guidelines for transgenic animals, ii) risk analysis of new reproductive biotechnologies, and iii) new vaccine technologies (e.g., DNA vaccines, plant-expressed antigens).

- Other priority topics for OIE's future work are: diagnosis, vaccinology and reproductive biotechnologies (including traceability, welfare, health, food safety and risks of pathogens associated with transgenic and cloned animals), and research on transgenic animals that failed to express the introduced traits.

These OIE areas of work complement a number of provisions under the CPB, particularly in common areas such as risk assessment and risk management, information-sharing, documentation and handling requirements, unintentional transboundary movements and emergency measures (Sendashonga, et al. 2005), as well as in relation to identification and traceability, capacity building and illegal transboundary movements.

3.1.7 World Trade Organization (WTO) and Biosafety

Under the WTO there are two agreements that are most specifically related to biosafety and regulation of GMOs (while GATT 1994 and the Dispute Settlement Agreement also apply generally) (Chee and Lim L. C., 2007):

- Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which "applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade" (Article 1).

- Agreement on Technical Barriers to Trade (TBT Agreement), that regulates technical measures and standards (e.g., packing, making, labelling requirements and others) affecting trade of all products, including industrial and agricultural products. Sanitary or phytosanitary measures are excluded from this agreement (Article 1).

3.1.7.1 Main Provisions of the WTO SPS Applicable to GMOs

The SPS Agreement recognizes or includes (Chee and Lim L.C., 2007):

- Recognition of biosafety standards set by international bodies. The standards set by the Codex Alimentarius Commission for food safety, IPPC for phytosantary measures and the OIE for animal health and zoonoses are considered WTO-consistent.

- Adoption of higher biosafety standards in accordance with specific criteria. The SPS Agreement is not restricted to already existing standards. Article 3.3 allows adherence to a higher level of sanitary or phytosanitary protection to protect human, animal or plant life or health when there is scientific justification or when appropriate in accordance with the following criteria: i) the measure is based on scientific evidence through a risk assessment; ii) measures are not discriminatory between foreign and domestic products; and iii) measures are not more trade-restrictive than necessary.

- Risk assessment during pre-marketing approval procedures. Mandatory pre-marketing approval procedures arguably comply with the SPS Agreement if they are based on a case-by-case scientific risk assessment, are not discriminatory and are not more trade-restrictive than necessary. If this process results in a provisional ban on certain products, this should be justified with scientific evidence. In addition, the WTO Member should demonstrate that the provisional ban is made on a rational basis, supports a legitimate policy objective, is no more trade-restrictive than necessary and is not applied in an arbitrary or discriminatory manner.

- Preventive measures. When assessing risks, the SPS Agreement also acknowledges preventive measures in the case of insufficient scientific evidence. Article 5.7 states that in cases where scientific evidence is insufficient, a Member may adopt provisional sanitary or phytosanitary measures on the basis of available relevant information. Relevant information, in this case, would not be restricted to scientific information, but also to pertinent information from international organizations and sanitary or phytosanitary measures applied by other Members (WTO, n.d., a).

- Prohibition of discriminatory measures among counterpart products. The SPS Agreement states that similar products should not be the subject of arbitrary or unjustifiable distinctions. This is in order to achieve consistency in the application of the concept of appropriate levels of sanitary and phytosanitary protection against risks to human, animal or plant life or health. These sanitary and phytosanitary measures should be based on scientific principles and evidence. However, it is also recognized as a basic right of a Member that preventive measures can be taken in the case of insufficient scientific information (as stated in Article 5.7). This may apply to GMOs and GMO-based processed products when there is insufficient or inconclusive information that they are like their conventional counterparts (WTO, n.d., a).

3.1.7.2 Main Provisions of the WTO TBT Agreements Applicable to GMOs

The main issues addressed in the TBT Agreement with biosafety relevance are (Chee and Lim L.C., 2007; WTO, n.d., b):

- Labelling. Labelling of products should be WTO-compatible, meaning that imported products should receive no less favourable treatment than their counterparts of national origin or among similar products originating in any other country (denominated as “like products” according to the TBT Agreement terminology) (Article 2.1). “Like products” are defined in line with the following criteria: i) physical properties of the product; ii) extent to which the product is able to serve the same or similar uses; and iii) international classifications of products for tariff purposes.

- Recognition of legitimate national objectives. For the TBT Agreement, technical regulations should not be more trade-restrictive than necessary to fulfil a legitimate objective. "Legitimate objectives" are national security requirements, prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or the environment, among others (Article 2.2.). In relation to the objective of prevention of deceptive practices, labelling of GMO products with the aim of providing consumer information is arguably considered consistent with the TBT Agreement.

3.1.8 Aarhus Convention

The Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (known as Aarhus Convention) is a treaty under the United Nations Economic Commission for Europe (UNECE). The Convention entered into force in 2001 and as of August 2010, there are 44 Parties to the Convention and 26 Parties to the amendment on "Public participation in decisions on the deliberate release into the environment and placing on the market of genetically modified organisms (GMOs)" (UNECE, n.d.)

Currently (as of April 2011), Parties to the Aarhus Convention are discussing the procedural steps for approval of accession by non-UNECE States, which is allowed for under the Convention (C. von Weizsäcker, personal communication, April 5, 2011).

3.1.8.1 Objective of the Aarhus Convention

The objective of the Aarhus Convention is to "contribute to the protection of the right of every person of present and future generations to live in a environment adequate to his or her health and well-being" by securing "the rights of access to information, public participation in decision-making, and access to justice in environmental matters" (Article 1) (Aarhus Convention, 1998). Accordingly, the Aarhus Convention is related to human rights (mainly from the procedural point of view) on access to information, decision-making and justice. The Convention also sets some legal obligations towards sustainable development when making the linkage of protection of the environment with human rights for the benefit of present and future generations (Stec and Casey-Lefkowitz, 2000).

3.1.8.2 Main Provisions of the Aarhus Convention on GMOs

In 2005, the Aarhus Convention adopted an amendment to the Convention entitled "Public participation in decisions on the deliberate release into the environment and placing on the market of genetically modified organisms (GMOs)". This Amendment sets forth (ECE, 2005):

- Public information and participation prior to decision-making. Parties have the legal obligation to "provide for early and effective information and public participation prior to making decisions on whether to permit the deliberate release into the environment and placing on the market of genetically modified organisms" (Article 6bis.1).

- Consistency with national and international biosafety frameworks. Public participation should be carried out by Parties in a complementary and mutually supportive fashion "to the provisions of their national biosafety framework, consistent with the objectives of the Cartagena Protocol on Biosafety" (Article 6bis.2).

- Confidentiality. The following cannot be kept confidential: i) the general description of the genetically modified organism or organisms concerned, the name and address of the applicant for the authorization of the deliberate release, the intended uses and, if appropriate, the location of the release; ii) the methods and plans for monitoring the GMOs or organisms concerned and for emergency response; and iii) the environmental risk assessment (Annex

1bis paragraph 4)[3].

- Transparency in decision-making. Transparency should be ensured along the decision-making procedure. Paragraph 4 of Annex 1bis is related to access to the relevant procedural information to the public. This information could include: i) the nature of possible decisions; ii) the public authority responsible for making the decision; iii) public participation arrangements; iv) an indication of the public authority from which relevant information can be obtained" (Annex 1bis paragraph 4).

3.2 EU Regulation

3.2.1 Directive 2001/18/EC (EC 2001) on Deliberate Release into the Environment of GMOs

3.2.1.1 Objective

The EU's Directive 2001/18/EC sets minimal standards to be transposed into national law, which could be more restrictive, and a common procedure for granting consent for the deliberate release and placing on the market of GMOs based on the precautionary principle: "Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs." (Article 1, Objective) (EC 2001). Accordingly, its aim is to provide the basis for assessing environmental and human health risks associated with the release and placing on the market of GMOs, and common objectives for the monitoring of GMOs. In 2004 Regulation (EC) No. 1829/2003 dealing with GM food and feed entered into force. This regulation supplements and partly replaces Directive 2001/18/EC and restricts Member States in their right to set national regulations beyond the Directive (Husby, 2007).

3.2.1.2 Main Provisions of Directive 2001/18/EC

- Mandatory pre-release authorization procedure is based on a case-by-case risk assessment and a step-by-step procedure; the latter implies building on the results of the evaluation of earlier stages of release. No commercial release should be made without field-testing.

- Risk assessments should consider direct, indirect, immediate and accumulative (long-term) effects of GMOs on the environment and human health. Guidance on the objectives, elements, general principles and methodologies of environmental risk assessments are provided by Commission Decision 2002/623 (Annex II of the Directive 2001/18/EC).

- In the case of objections raised by the competent authority of one or more Member States on risks to the environment or human health, relevant Scientific Committees(s) should be consulted by the Commission. Moreover, the Commission and Member States can request opinions to Ethical Committee(s) on ethical implications of GMOs. This ethical consultation should be transparent and include public participation.

- The establishment of public registers of the releases and public participation to allow the public the opportunity to comment on the local legislation and application/notification submitted by the GMO applicants is mandatory.

- Presence of GMOs in products containing or consisting of GMOs should be identified on the label or accompanying documents with the phrase "This product contains GMOs".

3 Confidentiality in Aarhus Convention and CPB have similar elements, as Art. 21.6 of CPB also states that the following shall not be considered confidential: "a) The name and address of the notifier; (b) A general description of the living modified organism or organisms; (c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; (d) Any methods and plans for emergency response."

- Authorizations are for a 10-year period with the possibility of renewal based on updated scientific information and monitoring data obtained after GMOs have been placed on the market.

- Unauthorized releases remain illegal and are terminated immediately.

- Phase-out of antibiotic resistance marker genes (ARMGs) in GMOs by 2008, due to the risks associated with horizontal gene transfer, for antibiotics used in commercial products and in GMOs for experimental purposes.

- Medicinal products for human and veterinary use consisting of or containing GMOs are not included in Directive 2001/18/EC.

- GMOs that fulfil the requirements under this Directive are subject to free circulation, meaning that "Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products" (Article 22) (EC 2001). However, in light of new or additional scientific knowledge available after the approval of the GMO in question, showing risks to the environment and human health, "Member States may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on their territory" (Article 23) (EC 2001). In this case, i.e., if such safeguard clauses are invoked (such as suspension or termination of the placing on the market of the GMOs), the Member States shall inform the public and the European Commission of the measures taken, providing reasons for the decision, supplying a review of the environmental risk assessment, and indicating whether and how the conditions of the consent should be amended or terminated. In this regard, currently (April 2011) there are discussions and a proposal to amend Directive 2001/18/EC aiming to give the possibility to the Member States to restrict or prohibit the cultivation of GMOs in their territory. If this proposal is adopted, it is likely that justifications for measures taken by the Member States may include their specific environmental conditions (particularly related to biodiversity), since the current European legislative framework does not allow the freedom of Member States to decide on the cultivation of GMOs (European Parliament 2011; EC, 2010b).

- International trade commitments should be in line with the CPB (provision that led to the adoption of Regulation (EC) No. 1946/2003 on transboundary movements of GMOs) and exercise them without prejudice of Member States to set national legislation on environmental liability.

- The Commission should regularly account for the activities related to this Directive by submitting reports on: i) the measures taken by Member States in the implementation of Directive 2001/18/EC, ii) experience with GMOs placed on the market, including a separate chapter on the socio-economic impacts (considering farmers' and consumers' interests) of each type of GMO authorised to be placed on the market, and iii) ethical issues.

3.2.2 Regulation (EC) No. 1829/2003 on GM Food and Feed

3.2.2.1 Objective

The objectives of Regulation (EC) No. 1829/2003 on GM food and feed are: i) to protect human and animal life, health and welfare, the environment, and consumer interest in relation to GM food and feed while ensuring appropriate functioning of the internal market; and ii) lay down procedures for the authorization, supervision and labelling of GM food and feed (Article 1, Objectives) (EC, 2003a). Regulation (EC) No. 1829/2003 provides a legal framework for and is directly applicable to all Member States, i.e., it does not need to be transposed into national legislation.

3.2.2.2 Main provisions of Regulation (EC) No. 1829/2003

- Regulation (EC) No. 1829/2003 applies to: i) GMOs used for food or feed; ii) food and feed containing or consisting of GMOs; and iii) food or feed produced from or containing ingredients produced from GMOs. These categories of food or feed must not have adverse effects on the environment or human and animal health, mislead consumers or lead to nutritional disadvantages when normally consumed in order to conform with the mandatory pre-marketing authorization procedure.

- The mandatory pre-marketing authorization procedure relies on risk assessment of GM food and feed. The risk assessment procedure is conducted according to Directive 2001/18/EC and its annexes complemented by Regulation (EC) No. 1829/2003 at EU level via the European Food Safety Authority (EFSA), which has a maximum period of 6 months to carry out the risk assessment after communication with the respective authority.

- Food or feed manufactured with processing aids of GMO origin, obtained from animals fed with GM feed or treated with GM medicinal products fall outside the scope of Regulation (EC) No. 1829/2003. In this context "processing aid" is any substance intentionally added to treat or process raw material, food or their ingredients, and is not consumed as a food by itself (Europa, 2008).

- In the case a GMO is likely to have dual purposes (as food and feed) it should get approval for both purposes since experience has shown that separation of food and feed chains is difficult to achieve.

- All products containing, consisting of, or produced from GMOs and products thereof should compulsorily be labelled regardless of whether transgenic DNA or proteins are expressed in the final product. The words "genetically modified" or "produced from genetically modified [name of organism]" must be clearly displayed on the labels.

- Presence up to a maximum of 0.9% per GM ingredient in final products is considered adventitious or technically unavoidable; hence does not require labelling as GMO. In this case, operators must demonstrate that this level of contamination is adventitious or technically unavoidable to the respective authorities.

- Marketing approvals are granted for a 10-year period and renewable at the finalization of it.

- Regulation of GM food and feed should also fulfil the provisions of Regulation (EC) No. 1830/2003 concerning the traceability and labelling of GMOs.

3.2.3 Regulation (EC) No. 1830/2003 on Traceability and Labelling of GMOs

3.2.3.1 Objective

The objective of Regulation (EC) No. 1830/2003 is to facilitate: i) the labelling and monitoring of the effects of products consisting of or containing GMOs in the environment and health along the marketing chain, and ii) implement appropriate risk management measures including withdrawal of products (Article 1, Objective) (EC, 2003b).

3.2.3.2 Main provisions of Regulation (EC) No. 1830/2003

- Documentation system to track the origin and flow of the product is required. This includes keeping records for five years using the unique identifier codes (specific to GMOs), established

by the OECD and taken up in the European legislation. Withdrawal of products is possible if the documentation requirements are not fulfilled.

- Shipments of GMOs for food, feed or processing imported to the EU should be accompanied by specific relevant documentation.

- Labelling of GM food, GM feed or products thereof should follow Regulation (EC) No. 1829/2003 on traceability and labelling of GMOs, Directive 2000/13/EC on labelling of foodstuffs and Directive 96/25/EC on the circulation of feed materials.

- In relation to traceability, when placing in the market a product consisting of or containing GMOs, operators along all stages of the supply chain should provide a written report to the receiving operator containing the following information: i) an indication of each food ingredient produced from GMOs; ii) an indication of each raw material or additive for feeding stuffs produced from GMOs; iii) if there is no list of ingredients, the product must nevertheless bear an indication that it is produced from GMOs, and iv) the unique identifier(s) assigned to the GMOs in question. "Unique identifier" refers to the "simple numeric or alphanumeric code which serves to identify a GMO" on the basis of the authorized transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO (EC, 2003b). The Commission Regulation (EC) No. 65/2004 establishes a system for the development and assignment of unique identifiers for genetically modified organisms, authorized for the placing on the market for cultivation and for FFP. Medicinal products for human and veterinary use are excluded from this Regulation.

- Products containing less than 0.9% per GM ingredient do not need to follow the traceability regulation.

Section 4.2 provides complementary information on traceability and labelling of GMOs in the EU.

3.2.4 Regulation (EC) No. 1946/2003 Transboundary Movements

3.2.4.1 Objective

Regulation (EC) No. 1946/2003 governs the export and import of GMOs in relation to the obligations under the CPB on the deliberate release of GMOs into the environment of the importing country, and the procedure for GMOs intended for direct use as FFP. Article 1 (Objective) states that "the objectives of this Regulation are to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) and to ensure coherent implementation of the provisions of the Protocol on behalf of the Community in order to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health" (EC 2003c).

3.2.4.2 Main Provisions of Regulation (EC) No. 1946/2003

- Regulation (EC) No. 1946/2003 differentiates GMOs intended for deliberate release into the environment and GMOs intended for use as FFP and contained use. In the case of GMOs intended for deliberate release into the environment exporters must notify the competent national authority of the country on the intention to import prior to the transboundary movement. The notification must be in writing and according to the information contained in the Annex I of Regulation (EC) No. 1946/2003. Exporters of GMOs-FFP must sign a declaration that the GMOs in question will not be deliberately released into the environment. In the case that these GMO-FFPs do not receive an authorization to move within the European

Union, then may not be moved across boundaries. GMOs intended for contained use must be accompanied by a detailed description of the safety measures for their storage, transport and use. Exporters should ensure that GMOs subject to transboundary movement are clearly identified.

- All decisions related to GMOs and products consisting of or containing GMOs should be reported to the BCH of the CPB. The notification must contain the information specified in Annex II to the Regulation (EC) No. 1946/2003.

- Member States are responsible for taking the necessary measures to avoid unintentional transboundary movements of GMOs. In the case of foreseeable unintended transboundary movement of GMOs with potential adverse effects on the environment or human health, Member State must inform the public and notify the European Commission, other Member States, the BCH and other relevant organizations. This information is particularly important to potentially affected Member States to enable them to take the necessary action measures.

3.2.5 Co-existence

Co-existence was introduced by the European Commission in 2002 for the purpose of allowing agricultural producers to choose among different agricultural systems according to "individual preferences and economic opportunities, in compliance with the legal obligations regarding the labelling of GMOs" (CEC, 2009, p.2).

Under the notion of co-existence, admixture problems (mixture of genetic material among different types of agriculture, e.g., GMO, conventional and organic) could be solved by allowing 'adventitious' or 'low-level, technically-unavoidable and unintended presence' of genetic material from GMOs in non-GMO production systems and products when reasonable efforts to prevent admixture are put in place (Levidow and Boschert 2007; Binimelis and Strand, 2009). Accordingly, in the cases of adventitious presence of GM material, the operator must demonstrate that the contamination was truly unavoidable (Levidow and Boschert, 2007).

In response to this concept, two opposite trends of opinion arise. On one hand, there are concerns about cumulative effects of gene flow, environmental and health uncertainties and a weakening of GM-free production systems, mainly organic farming. On the other hand, there are opinions that certain agricultural practices (e.g., separation distance between crops, buffer zones, management of crop rotation and pollination times, use of differentiated machinery for GM and non-GM crops, etc.,) would be sufficient to reduce admixture, and co-existence was necessary to diversify agricultural production (Levidow and Boschert 2007; Lee 2009). Yet under the latter rationale, admixture becomes mainly an economic problem seeking feasible solutions (although not all proposed management practices may, in real terms, be feasible from the socioeconomic point of view, particularly to small-scale producers).

In 2003, the European Commission issued non-binding recommendations for the development and establishment of co-existence procedures: "Guidelines for the development of National Strategies and Best Practices to Ensure the Co-existence of Genetically Modified Crops with Conventional and Organic Farming". Among others, these Guidelines are based on the following principles: "(1) No form of agriculture, be it conventional, organic, or agriculture using GMOs, should be excluded in the European Union. (2) The ability to maintain different agricultural production systems is a prerequisite for providing a high degree of consumer choice. (3) Co-existence refers to the ability of farmers to make a practical choice between conventional, organic and GM-crop production, in compliance with the legal obligations for labelling and/or purity standards" (EC 2003d, p. 2). Under this rationale, the Guidelines also set a threshold for adventitious or technically unavoidable presence of GMOs in products as 0.9% GM ingredients. In addition to these guidelines, the EC has issued recommendations for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (EC 2010c), also allowing the justified ban of GMO cultivation in large areas. These recommendations need to be implemented in national co-

existence measures to avoid the unintended presence of GMOs in conventional and organic crops (EC, 2010c).

Since the release of these Guidelines, several EU countries have put into place specific national regulations on co-existence. By 2009, fifteen Member States developed and adopted specific legislation on co-existence (CEC, 2009)

Co-existence is considered to be the way to settle the contested ecological, economic and human health issues arising from GM crop production. Co-existence regulation intends to set ”good practices” to avoid unintended contamination by e.g., registering the type of cultivation, capacity building, reporting information to the authorities and the public, distance rules for planting, liability for contamination of crops and compensation, among others (Stoppe-Ramadan and Winter, 2010; Gylling, 2010). Hence, from a regulatory perspective, meeting the threshold of 0.9% is the result of the adequate implementation of co-existence measures. Problems with these co-existence regulations include the failure to acknowledge the systemic characteristic of the problem related to the impossibility of containing gene flow (see Section 2.3.1.2 on “Gene flow and persistence of GMOs in the environment”). It may also add socioeconomic and legal pressure to farmers (mainly small-scale) since co-existence, by being a factor for genetic contamination, may contribute to reducing alternatives for GM-free production and place the burden on the operators to prove that adventitious contamination was unavoidable (usually those producers who have or aim at GM-free production). However, the extent of the impacts of co-existence regulations depend on national legislations and the level of implementation of the co-existence guidelines.

3.3 Norwegian Gene Technology Act

3.3.1 Objective

The purpose of the Norwegian Gene Technology Act (NGTA) is to “ensure that the production and use of GMOs takes place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects on health and the environment” (Ch. 1-1). Accordingly, biosafety decision-making in the context of the NGTA is rooted in sustainability, societal utility and ethical responsibility (Rosendal, 2008).

3.3.2 Main Provisions

The impact assessment is a central element and it is based on the following:

- Precautionary approach and sustainable development. The precautionary approach and sustainable development are crucial in the process of evaluating the deliberate release of GMOs. The procedure of evaluation includes not only the characteristics of the GMO or the substances and products consisting of the GMO in question; but also the production process and use. The main issues considered by this assessment are: i) risks of adverse effects on human and animal health and the environment, and ii) impacts on sustainable development.

- Potential adverse effects. Risks of adverse effects on human and animal health and the environment are analyzed under the precautionary approach mainly in terms of: i) the existence of sufficient documentation and knowledge; and ii) assessment of the levels of uncertainty (referred to as a reasonable degree of doubt, especially in relation to unforeseen or long-term adverse effects), and the mitigation measures in the case of negative impacts.

- Sustainable development. Assessed in relation to:

    - Sustainable development per se as: i) global effects in terms of impacts on biodiversity

and ecosystem functions; ii) ecological limits and impacts related to the efficiency of energy and natural resources use, emissions of global and transboundary pollutants, GHG emissions, etc.; iii) basic human needs; iv) distribution between generations of benefits and negative impacts that may arise; v) distribution of benefits and negative effects between rich and poor countries; and iv) economic growth in relation to how it is affected when energy and natural resources are used, the global and regional environment and how the distribution of growth is impacted (IV of Appendix 4 of the NGTA).

- Societal utility as how favourable or unfavourable the outcomes would be to society. The societal utility is analyzed in relation to the demand or need of the GMO (including its production and use processes), potential to solve or create social problems, impacts on industrial development and wealth (including job creation in rural areas and countries of production), among others. It also includes a comparative analysis with conventional products already existing in the market and other alternatives (V of Appendix 4 of the NGTA).

- Ethical considerations analyzed in terms of: i) ethical norms and values relating to people, including conflicts with ideals of solidarity and equity, adverse effects on indigenous people, traditional cultures and vulnerable groups; and ii) eco-ethical considerations, referring to potential conflicts with any intrinsic value and unnecessary suffering of animal species, and crossing natural species barriers that are incompatible with the integrity of species (VI of Appendix 4 of the NGTA).

- The NGTA also contemplates: public consultation in the process of approval, right of inspection of the place of production and use of the GMO, duty to provide information to the competent authority when necessary, regardless of the duty of secrecy, liability and compensation for any "damage, inconvenience or loss [caused] by deliberate release or emission of genetically modified organism into the environment" (Ch.4-23), among other provisions (MD, 1993).

IV Briefing on the Labelling and Traceability of GMOs and Products Containing GMOs

In general, two different types of labelling may apply to GMOs and products containing GMOs: risk/hazard warning labelling and consumer information labelling. Risk/hazard warning labels aim to provide information or instruction for safe handling on products that are risky or hazardous. Voluntary risk/hazards labelling is unlikely to take place since it carries more costs than benefits to firms. Conversely, mandatory risk/hazard warning labelling is efficient when the social benefits of its implementation are higher than its costs (e.g., in relation to public health). Risk/hazard warning labelling is not meant to enable consumers to choose to avoid certain products, although it would play some role in giving the public the right to know about risks and hazards (Hilson, 2005). Within a regulatory system, products approved after a proof of no or negligible risk, risk/hazard warning labels are of no real importance. However, they make sense in systems that allow products to market although they carry risks, which could have been shown (H. Meyer, personal communication, 18 March 2011).

As for consumer information labelling, it is related to information disclosure to facilitate consumers in ascertaining risk or a precautionary consumption decisions (Hilton, 2005). Consumer information labelling may be positive ("does contain") or negative ("does not contain"), may be applied to products with different characteristics, and may convey different information and generate different consumers attitudes (Crespi and Marete, 2003).

In relation to GMOs and GMO-based products, labelling is relevant in the biosafety context for two main reasons: i) to provide a means to monitor indirect and long-term impacts of GMOs on the environment and health; and ii) to facilitate informed decisions among potential users and consumers of GMOs.

Effective traceability and labelling systems require segregation of the value chain lines. At the same time, segregation requires Identity Preservation (IP, a designation given to bulk commodities to be managed in a differentiated manner due to their unique characteristics). IP-systems have special relevance in the commercialization of GMOs to differentiate them from other products according to their content of GM material or how they have been produced (either with the application of GM technologies or not) (Wong, 2007; CEC, n.d.).

4.1 Identification of GMOs in the Context of the CPB

The CPB provisions in relation to the identification of LMOs (according the Secretariat of the Convention on Biological Diversity, 2004) are:

- LMOs for food, feed and processing (LMOs-FFP). In the case that the identity of the LMO is known (e.g., by identity preservation systems), the shipment should be identified as "contains LMOs intended for direct use as food, feed or processing". In the case that the identity is not known then the shipment can be identified as "may contain one or more LMOs intended for direct use as food, feed or processing". In both cases, the shipments should be accompanied by the following information:
    - Clear statement that the LMOs are not intended for intentional introduction into the environment.
    - Denomination of the LMO (common, scientific and commercial name).
    - Transformation event code of the LMO or — if available — its unique identifier code for accessing this information through the CPB-Biosafety Clearing House (http://bch.cbd.int/).

- LMOs for contained used. Must be clearly identified as "LMOs destined for contained use" and be accompanied by documentation on:

    - Denomination of the LMO (common, scientific and commercial name).

    - Contact information of the consignee and exporter/importer.

    - Requirements for the LMOs safe handling, storage, transport and use under applicable existing international instruments e.g., UN Recommendations on the Transport of Dangerous Goods, the IPPC, OIE, domestic regulatory frameworks or others.

    - Characteristics of the LMO in terms of new or modified traits, characteristics of the transformation event, risk class, use and unique identification, which are made available at the BCH.

- LMOs intended for intentional introduction into the environment and any other LMO within the scope of the CPB (e.g., deliberate release into the environment or as transit). They must be identified as LMOs. They should be accompanied by similar information as for LMOs-FFP and contained use. In the case of LMOs for introduction into the environment, the exporter should add to this documentation a declaration that the movement of the LMO for deliberate release is in conformity with the requirements of the CPB.

The CPB welcomes the development and adoption of the OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants and encourages the development of a unique identification system for LMOs towards the development of a harmonized system of unique identifiers for GM microorganisms and animals (Secretariat of the CPB, 2004).

Finally, since 2006 within the CPB there have been discussions on the need for a "stand–alone" document in relation to identification of LMOs-FFP (Secretariat of the CBD, 2007). The relevance of a "stand-alone" document is that it will provide easy access to the biosafety competent authorities to relevant information needed to monitor the introduction of LMOs-FFP. This information is not necessarily available when information on the LMO-FFP is restricted to the commercial invoice considering that trade and biosafety authorities are usually not the same (Lim L.,L. and Lim L.,C., 2007).

4.2 Traceability and Labelling in the EU Context

The 2010 research on perceptions and opinions of Europeans on different fields of modern biotechnology showed that there is a generalized decline in support for GM foods among European citizens (Eurobarometer Survey on the Life Sciences and Biotechnology) (EC, 2010). The survey reports that 61% of the respondents disagree to different extents that GM foods should be encouraged (33% disagree and 28% tend to disagree). 76% of respondents think that GM foods are fundamentally not natural and there is a significant tendency to consider them non-beneficial and unsafe. The majority of respondents mentioned the desire to be informed to different levels on issues related to GMOs (58% of respondents have heard of and have researched GMOs and 26% were aware although did not search for additional information). This glimpse of opinions on GMOs (specifically on GM foods) reiterates the need for proper traceability and identification systems, as well as more comprehensive assessment of their indirect and long-term impacts.

The European Commission has issued the following regulations on GM traceability and labelling, the implementation of which is the responsibility of each individual Member State.

4.2.1 Traceability requirements

According to Regulation (EC) No. 1830/2003 (see Section 3.2.3), EU Member States are obliged to trace GM products (mainly food) along their value chains (from production to distribution channels).

Implementation of traceability systems is intended to: i) control and verify labelling claims; ii) monitor potential adverse effects on the environment and health; and iii) enable authorities to withdraw products that contain or consist of GMOs demonstrated after their placing on the market to have adverse effects to the environment or on animal and human health (Wong, 2007).

The traceability requirements for products containing, consisting of, or produced from GMOs are related to the provision of written documentation at each stage of transaction of the GM-product, which has to be kept by the operators for a period of five years. In this way, information on the GM product is available and identification of operators involved is possible. The written records should be available to the authorities.

The information that the operator who places the GM product on the market should provide to the operator who receives it, is:

- For products containing or consisting of GMOs: i) indication that the product, or some of its ingredients, contains or consists of GMOs; and ii) the unique identifiers assigned to those GMOs.

- For products produced from GMOs: i) indication of each of the GMO-based food ingredients; ii) indication of each of the feed materials or additives that are produced from GMOs; and iii) in the case of a product for which no list of ingredients exists, an indication that the product is produced from GMOs.

4.2.2 Labelling

Two regulations apply in the case of GM products in the EU (Wong 2007):

- Regulation (EC) No. 1830/2003 (Section 3.2.3), applicable to all products containing or consisting of GMOs. For pre-packed products, it requires that the operator include in the label “This product contains genetically modified organisms” or “This product contains genetically modified [name of the organism(s)]”. In the case of non pre-packaged products offered directly to the final consumers or to mass caterers, the same words should appear in connection with or in the display of the GM products.

- Regulation (EC) No. 1829/2003 (Section 3.2.2), states that labelling is required regardless of whether the GM DNA or proteins derived from genetic modification are contained or identifiable in the final product. This implies that even highly refined products (e.g., oils) should be labelled if obtained from a GMO. The labelling requirements are the same as in regulation (EC) No. 1829/2003 as described in previously.

The exceptions to these regulations apply to products contaminated with authorized GMOs, which contain up to 0.9% per GM material if this is considered adventitious or technically unavoidable. It is under debate whether products with a contamination below 0.9%, which is not adventitious or technically unavoidable, need to be labelled also, and how to prove this (H.Meyer, personal communication, 18 March 2011).

4.3 GM-free Certification and Labelling

GM-free labelling and certification may include products containing, consisting of, or processed from produce originating in conventional and organic systems. This is referred to as negative labelling in the sense that it suggests that products with this label “do not” contain GMOs or products thereof. Usually GM-free labelling is voluntary; however, under organic certification systems, it is mandatory to verify the absence of GMOs or derivatives in the final organically certified product.

GM-free certification and labelling involves a differentiated management (in time and space) of non-GM materials and products along all stages of the production and value-added chain. This means from the selection of the raw material (or from seed selection in the case of agricultural GMOs) to production, transport, handling, processing and storage of the final product. This differentiated management has particular importance in organic certification.

While GM-free or negative labelling has been the subject of criticism for placing the burden of proof and additional expenses for "GM-free certification" on the non-GMO producers, users and consumers, GMO producers maintain that mandatory positive labelling (e.g., "This product contains GMOs") is a "threat to the continued development of biotechnology products and processes […] [since] [l]abelling goes to the heart of private sector, biotechnologically-based research and development in the agri-food business" (Phillip and Isaac, 1998, p.30).

4.3.1 GMO-free zones

"GMO-Free zones" is a global citizens´ movement initiated in the early '70s after the first publications on potential risks related to GMOs were published (Meyer, 2007b). The GMO-free zones movement is rooted in: i) the environmental and health concerns arising from GMOs, ii) the limitations of risk assessment procedures to properly address the risks and uncertainties related to genetic engineering; iii) the lack of consideration of socioeconomic and ethical issues in risk assessment procedures; iv) economic concerns deriving from markets with restrictions on GMOs; and v) the need to develop different paths in technology and sustainable development (Schermer and Hoppichler, 2004; Meyer, 2007b).

Generally speaking, GMO-free zones is a civil society movement and faces regulatory difficulties for actual implementation and recognition. Despite this, several examples of GMO-free zones exist worldwide, particularly in regions where there is high public awareness due to significant dissemination of information on GMOs and accumulated experience with industrialized agriculture. Moreover there are a growing number of local governments endorsing GMO-free zones (Meyer, 2007b). This is the case in Europe where by September 2010, in 37 different countries[4] there were 169 regions, 4,713 local governments[5] and 31,357 individuals[6] declared GMO-free (GMO-free Europe, 2010). A detailed list and map of GMO-free zones in Europe is available at http://www.gmo-free-regions.org/gmo-free-regions.html

Based on current experiences, key drivers of GMO-free zones are (according to Meyer, 2007b):

- At regulatory level: i) Municipalities with strong legislative power; ii) lack of regulation on GMOs; iii) non-transparent procedures for decision making on GMO risk assessment and approval of field trials; iv) political will; and v) initiatives by decision-makers.

- At social level: i) Organized or empowered rural communities that value indigenous and traditional lifestyles; ii) tradition of social and environmental awareness and activism; iii) awareness of the controversial GMO R&D and safety assessments, strong and radical movements against globalization and corporate dominance; iv) long history of civil society debate on genetic engineering; v) strong farmers´ movements; and vi) concerns or lack of acceptance of co-existence.

- At institutional level: i) Strong environmental movement; strong culture and legal provisions for public participation; ii) organizations raising awareness on access and use of genetic resources, farmers' rights and organic farming; iii) coalitions between environmental, consumer, church, organic farming, and (organic) food business groups; and iv) no national industry working on GMOs.

4 Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxemburg, Netherlands, Macedonia, Malta, Montenegro, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovenia, Spain, Sweden, Switzerland, UK

5 Including communities, towns, cities, municipalities, districts and councils.

6 Including landowners, farms, schools and initiatives.

At present, the impacts on the establishment of GMO-free zones are: i) bans of specific GMOs with crucial environmental or socioeconomic relevance to the respective GMO-free zone; ii) strengthening of regulatory frameworks related to GMOs; iii) increased public awareness: iv) implementation of initiatives on environmental conservation of specific ecosystems and local biodiversity; and v) initiatives on sustainable development with strong components of nature conservation and market differentiation (as GMO-free products or services) (Schermer and Hoppichler, 2004; Meyer, 2007b).

4.3.2 Organic certification

Generally speaking, organic labelling is synonymous with GM-free; however, this varies among different standards. For instance:

- The EU Council Regulation (EC) No. 834/2007 of 28 June 2007 on "Organic production and labelling of organic products and repealing Regulation (EEC) No. 2092/91" states that GMOs are banned in EU organic production, and labelling and tracing follows the Regulation (EC) No. 1829/2003 (EC 2007) (Article 9). However, while GMOs and products thereof are prohibited in EU organic production, unintentional and technically unavoidable proportions of GMOs up to 0.9% are allowed and will still qualify for the EU organic label. This is according to the EU co-existence guidelines (Section 3.2.5).

- The Japanese Agricultural Standards (JAS) bans the use of GM seeds or seedlings, as well as additives and cleaning substances that are of GMO origin. In addition, management concerning transportation, selection, processing, cleaning, storage, packaging, and other processes must avoid contact and mixing with GM material (Ministry of Agriculture, Forestry and Fisheries, 2005).

- The Norms for Organic Production and Processing of the International Federation of Organic Agriculture Movements (IFOAM) prohibits the use of GMOs and derivatives. Moreover, "contamination of organic products by GMOs resulting from circumstances beyond the control of the operator may alter the organic status of the operation and/or product" (Norm 2.3.6) and parallel production using GMOs "is not permitted in any production activity on the farm" (Norm 2.3.7) (IFOAM, 2006). According to IFOAM, organic certification shall not imply "GM-free" certification given the multiple sources of potential involuntary genetic contamination. Instead, organic certification should mean and guarantee "production without GMOs" (IFOAM, 2002).

4.3.3 Other voluntary certification and labelling schemes dealing with GMOs

- Fairtrade (FLO). Fairtrade standards and certification intend to enable producers to receive prices that cover their sustainable production costs and to have access to additional income to support projects for their own social, economic and environmental development (FLO, 2011). FLO deals with GMOs under two sets of standards: Generic Fair Trade Standards for Small Producers' Organizations (Standards 3.6) and Generic Fair Trade Standards for Contract Production (Standard B3.1.9). These standards state that Fairtrade certified producers "do not use GMOs in either the production or processing of products" (FLO, 2009, p.22) regardless whether the products are destined or not "for sale under Fairtrade conditions." (FLO, 2010, p.25). In this sense, organizations applying to FLO label, need to set guidelines for monitoring (as minimum requirements to ensure that their members do not grow any GMO products) and precautionary measures to avoid contamination from neighbouring fields mainly to avoid outcrossing (making distinctions between wind-, insect- and self-pollinated crops). Fairtrade standards do not provide a definition for GMOs.

- FSC (Forest Stewardship Council). FSC standards and certification aim at promoting responsible production and consumption of the world's forests by encouraging environmentally appropriate, socially beneficial and economically viable forest management (FSC, n.d.). FSC standard 6.8 of the FSC International Standard/FSC Principles and Criteria for Forest Stewardship mentions that "Use of biological control agents shall be documented, minimized, monitored and strictly controlled in accordance with national laws and internationally

accepted scientific protocols. Use of genetically modified organisms shall be prohibited." (FSC, 1996, p.7). FSC does not specify if presence of GMOs in forest management implies any restriction on accessing FSC label. Finally, FSC standards provide a rather imprecise definition of GMOs: "Genetically modified organisms: Biological organisms which have been induced by various means to consist of genetic structural changes" (FSC, 1996, p.11)

- RSB (Roundtable on Sustainable Biofuels). As its name indicates, RSB standards intend to ensure sustainability of biofuels production (McClellan, 2010). RSB standards deal with GMOs under Principle 11 of RSB Principles & Criteria for Sustainable Biofuel Production. Under this principle, Criterium 11.b mentions that "biofuel operations including genetically modified: plants, micro-organisms, and algae, shall minimize the risk of damages to environment and people, and improve environmental and/or social performance over the long term." (RSB, 2010, p.26). It also defines minimum requirements for operators to comply with "relevant national or international guidelines, laws and agreements, crop-specific stewardship systems, and local and community coexistence agreements or understandings" (RSB, 2010, p. 26), and to implement monitoring and preventative measures, as well as crop-specific and technology-specific mitigation strategies. Criterion 11.b also mentions the use and consultation of the Biosafety Clearing House established under the Cartagena Protocol on Biosafety, or any other such clearinghouse established by law to access information about GMOs (e.g., risks, regulatory frameworks, etc.). In addition, Criterion 11.c related to micro-organisms used in biofuel operations states that "In no case shall genetically modified micro-organisms or any micro-organisms that pose a risk (pathogenic, mutagenic, contaminant, etc.) to human health or the environment be released outside the processing/production unit. Any such organism used for processing shall be destroyed or adequately neutralised (i.e., loss of any potentially hazardous character) before being disposed of". (RSB, 2010, p.27). Accordingly, RSB does not restrict the use of GMOs in biofuel production but recommends management that minimizes or prevents environmental or social damage. RSB does not provide a definition of GMOs. Finally, in 2010 the RSB established a GMO Expert Group on liability related issues. The purpose of this group is to "ensure that the RSB standard, in going beyond regulatory requirements, does not create unreasonable liability burdens on participating operators based solely on management decisions and without regard to the environmental, social and economic impacts of those management decisions." (McClellan, 2010, 1). The work of this group will give special emphasis to co-existence.

- RTRS (Round Table on Responsible Soy). RTRS intends to promote responsible soy production to foster economical, social and environmental sustainability through joint cooperation among the sectors involved in the soy value chain (RTRS, 2010a). The RTRS Standards for Responsible Soy deals with GMOs in its scope of application and a specific criterion guidance (Criterion Guidance 5.10). The scope of application mentions that RTRS "standard applies to all kinds of soybeans, including conventionally grown, organic, and genetically modified (GM). It has been designed to be used for all scales of soy production and all the countries where soy is produced." (RTRS, 2010b, p.i). Criterion Guidance 5.10 states that "When a change in soybean production practices is introduced which could impact on neighbouring production systems, it is the responsibility of the producer making the change to implement a buffer strip of 30 m (e.g. in areas where production is generally GM, it is the responsibility of an organic or non-GM farmer to maintain the buffer around his own production in areas where production is mainly non-GM or organic, a farmer planting GM or using" (RTRS, 2010b, p.15). Accordingly, RTRS does not restrict the use of GMOs and recommends producers put contention measures into place to prevent contamination of non-GM soy, placing the burden on non-GMO producers. RTRS standards do not provide a definition of a GM soybean.

Certification systems are used as tools to communicate with consumers on compliance with specific standards (e.g., sustainability and environmental and socially responsible management of production systems) (Dankers, 2003). However, it is arguably common that voluntary environmental and social sustainability certification schemes do not address the negative impacts associated with an intensive production system, including social consequences. This is the case of GMOs due to: i) the complexity

of and controversy of their ecological and socioeconomic impacts, and ii) the lack of strong regulatory institutions in the producing countries which oversee the adequacy of environmental and social protection and monitoring standards. Finally, the involvement of actors with conflict of interest in the development of sustainability standards has cast doubt on the true intentions behind some sustainability seals with their seeming prioritization on market and economic growth rather than sustainable development (See Box 3) (Tomei et al., 2010).

BOX 3 Critics of the Responsible Soy Certification of the RTRS

In 2009, the principles and criteria of the RTRS Association were approved in order to promote and increase the use of responsible soy, understood to be economically feasible, socially beneficial and environmentally appropriate (RTRS, 2010a). The core intention of the RTRS certification is — in the face of increasing demand for soybeans — to ensure that expansion of cultivated areas and increase in volume of production occurs sustainably (ICTSD, 2008).

By 2010, The RTRS Association was composed of large-scale soybean producers (30 members), industry, trade and finance companies (73 members), civil society organizations (16 members) and observers (26 members) (RTRS, 2010c).

The major criticisms around the RTRS certification are:

- Set of standards with strong conflict of interest. The major stakeholders of the global soybean value chain have developed the RTRS principles and criteria (CEO, 2009). This includes companies such as Monsanto, Syngenta, Bayer CropScience, Cargill, ADM, Bunge, Shell, PB International, UNILEVER, among others (RTRS, 2010c).

- "Green washing" of the expansion of soybean production, particularly GM. Important international civil society organizations have qualified the responsible business management criteria included in the RTRS certification as weak and called it instrumental to the interest of the global soybean cluster of NGOs participating in the RTRS Association (ICTSD, 2008). Large-scale producers, industry, trade and finance companies represent 70% of the RTRS members, while civil society organizations (mostly conservationist NGOs) correspond to 11%.

- Exclusion of small-scale producers and continuation of social and environmental damage. The major international civil society organizations have denounced the RTRS Association for not including small-scale farmers or indigenous organizations. Also, it has been stated that RTRS certification does not prevent forest and ecosystem destruction, which is linked to cases of human rights violations of peasant and indigenous communities affected by the (GM) soybean expansion (according to CEO, 2009; Holland et al., 2008; Bebb, 2008).

V Conclusions

GMO development and commercial introduction are in constant growth and the introduction of GMOs into natural and social systems results in a series of intertwined impacts.

Although there is significant information about different GMOs, and life cycle assessments are starting to be published (mainly of GM soybean for industrial applications), life cycle assessment and value chain analysis of most GMOs are still missing. There are important gaps of information with regard to long-term health effects and social impacts in relation to vulnerable groups considered in the international agreements, such as indigenous people. Information on the different stages of the life cycles of GMOs are also missing (e.g., disposal of GMO material residues). The lack of information limits the comprehensiveness of the impact analysis. Moreover, the identification and analysis of impacts become difficult due to the inconclusive information and contested findings related to the safety of GMOs. Accordingly, a precautionary approach was applied in the review of literature related to impacts of GMOs, with special focus on GM crops due to the availability of information.

A comprehensive assessment of GMO impacts requires an analysis of both direct and indirect impacts along the life cycle or value chain of the GMOs in question in light of sustainable development. In this report it is suggested that an assessment of GMO impacts needs to include:

- Application of a precautionary approach to the ecological, economic, social and ethical implications.
- Consideration of the impacts along all the states of the value chain of GMOs (such as R&D, production, harvesting, handling, processing, transport, commercialization and consumption of GMOs).
- Life cycle analysis of GMOs introduced to the environment.

This is necessary since different related, accumulative and combinatorial adverse effects may occur along the life cycle and value chain stages. Hence, any analysis of the impacts of GMOs restricted to specific stages or fields of study, although very useful, would be far from been holistic according to the concept of sustainable development.

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VI Glossary

Antibiotic resistant marker gene (ARMG)
A gene that confers resistance to specific antibiotics to cells that have successfully integrated the transformed genetic material (transgene) into their genomes, allowing them to survive and facilitating their identification (BAT, 2011; GMO Compass, 2006; GMO Compass, 2011).

Biosafety
Refers to approaches and measures taken to evaluate, avoid or mitigate the potential ecological and socioeconomic risks and adverse effects from products of biotechnology (BAT, n.d.).

Biotechnology
"Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." (UN, 1992, p.3)

Bt crops
"Plants engineered to produce protein insect toxins (pesticides) sourced from the chromosome or infectious agents within the soil bacterium Bacillus thuringiensis." (Heinemann, 2007, p.69).

DNA
"Deoxyribonucleic acid, found mostly in the nucleus in eukaryotic organisms. A molecular form of the gene, the basis of inheritance of characteristics." (BAT, n.d.)

Epigenetics
"Basis of inheritance of traits that are not directly determined by DNA sequences" (BAT, n.d.).

Gene flow
"Movement of genes into a new genome or environment" (Heinemann, 2007, p.69).

Genetic engineering
"A variety of techniques used to intentionally change the genes in a living cell or organism." (BAT, n.d.)

Genetic material
Refers to whole hereditary information of an organism encoded in the DNA or RNA (Heinemann, 2009a; IAASTD ed., 2009).

Genetically modified organism (GMO)
Organism (e.g., plant, animal or microorganism) whose genetic material has been altered artificially by the application of gene or cell techniques of modern biotechnology (IAASTD ed., 2009).

Genome
A collection of genetic material contained in each cell of an organism (BAT, n.d.).

Herbicide tolerance (HT)
"Plants made herbicide tolerant (or resistant) using genetic engineering. Note that it is also referred to as herbicide resistance. The commercially predominant resistances are to glyphosate and glufosinate ammonium" (Heinemann, 2007, p.69).

Horizontal gene transfer (HGT)
"Introduction of genes into organisms by processes which are independent of organism reproduction" (Heinemann, 2007, p. 69). HGT can occur between members of the same or different species, through processes mediated by biological vectors, such as infectious microorganisms or parasitic plants and fungi (BAT, n.d.).

Insect tolerant (IT)
Characteristic conferred to plants through genetic engineering to resist the toxins of pathogenic insects, usually by the insertion of an insecticide characteristic.

Intellectual Property Rights (IPR)
"Rights granted to persons or entities over intellectual [inventions] which they can claim is unique to them. Patents are legal instruments establishing certain intellectual property rights." (Heinemann, 2007, p. 70).

Living organisms
"Any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids" (Secretariat of the CBD, 2000, p. 4).

Living modified organism (LMO)
"Any living organisms that possesses a novel combination of genetic material obtained through the use of modern biotechnology" (Secretariat of the CBD, 2000, p. 4.)

Modern biotechnology
"Application of: a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection" (Secretariat of the CBD, 2000, p 4.)

Patent
Patent is a government grant of a temporary monopoly over a particular invention, usually for a period of up to 20 years. During that time the patent holder may exclude all others from making, using or selling the invention (CFS, 2005).

Phytosanitary measure
"A piece of legislation, regulation, or procedure with the purpose of preventing the introduction or spread of pests. Phytosanitary procedures often include the performance of inspections, tests, surveillance, or other treatments" (Global EDGE, 2011)

Plasmid
"Natural infectious elements similar to a virus and normally found in bacteria. Plasmids have been modified for use in recombinant DNA experiments as carriers of rDNA." (BAT, n.d.).

Research and development (R&D)
"Organizational strategies and methods used by research and extension program[s] to conduct their work including scientific procedures, organizational modes, institutional strategies, interdisciplinary team research, etc." (IAASTD ed., 2009b, p. 566).

RNA
"Ribonucleic acid, a molecule similar to DNA" (BAT, n.d.). RNA "is one of the three major macromilecules (along with DNA and proteins) that are essential for all known forms of life […]. [S]ome RNA molecules play an active role in cells by catalyzing biological reactions, controlling gene expression, or sensing and communicating responses to cellular signals" (Wikipedia, 2011a).

Substantial equivalence
Concept that "maintains that a novel food (for example, genetically modified foods) should be considered the same as and as safe as a conventional food if it demonstrates the same characteristics and composition as the conventional food" (Wikipedia, 2011b). "The concept of substantial equivalence has been developed as part of a safety evaluation framework, based on the idea that existing foods can serve as a basis for comparing the properties of genetically modified foods with the appropriate counterpart. Application of the concept is not a safety assessment per se, but helps to identify similarities and differences between the existing food and the new product, which are then

subject to further toxicological investigation. Substantial equivalence is a starting point in the safety evaluation, rather than an endpoint of the assessment. (Kuiper et al., 2001, p. 503)

Traceability
"Records and testing to track products through the supply chain" (Heinemann, 2007, p 72).

Transgene
"[A] reference to the recombinant DNA used in a GMO" (Heinemann, 2007, p. vi).

Vertical gene transfer
"Transmission of genetic material from mother cell to daughter cell during cell division" (Lawrence, 2005; p. 255).

Volunteer plants
"Crop plant which persist for several seasons without being deliberately replanted" (Heinemann, 2007, p. 72).

References

Aarhus Convention (Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters) (1998). www.unece.org/env/pp/documents/cep43e.pdf Access date: December 10, 2010.

Agodi, A.; Barchitta, M.; Grillo, A.; Sciacca. A. (2006). Detection of genetically modified DNA sequences in milk from The Italian market. Int. J. Hyg. Environ. Health 209: 81–88.

Altieri, M.A. (2008). El Papel Estratégico de la Sociedad Latinoamericana de Agroecología (SOCLA). Agroecología 3:87-93.

Altieri, M.A. (2009). The Ecological Impacts of Large-Scale Agrofuel Monoculture Production Systems in the Americas. Bulletin of Science Technology Society 29:236-244.

Altieri, M. A.; Bravo, E. (2007). The ecological and social tragedy of crop-based biofuel production in the Americas In Agrofuels in the Americas, R. Jonasses, ed. (Oakland, FoodFirst/Institute for Food and Development Policy), pp. 15-24.

Ammann K. (2005). Effects of biotechnology on biodiversity: herbicide-tolerant and insect-resistant GM crops. Trends in Biotechnology 23(8):388-394.

Ammann, D.; Hilbeck, A.; Lanzrein, B.; Hübner, P.; Oehen, B. (2007) Procedure for the Implementation of the Precautionary Principle in Biosafety Commissions. Journal of Risk Research 10(4):487-501.

Andow, D. A.; Zwahlen, C. (2006). Assessing environmental risks of transgenic plants. Ecol. Lett. 9:196-214.

Aris, A.; Leblanc, S (2011). Maternal and fetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec, Canada. Reproductive Toxicology doi:10.1016/j.reprotox.2011.02.004

Barkman J.; Thiel M.; Theuvsen L.; Eschenbach C.; Windhorst W.; Marggraf R. (2010). GM maize and oil seed rape in Germany: Economic welfare losses from large-scale adoption scenarios In Large-area Effects of GM-Crop Cultivation. Thoerie in der Ökologie 16, B, Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 21-27.

BASE-IS (Investigaciones Sociales) (2008). Rural communities in Paraguay endangered by soya pesticides. Pesticide News 81:12-15.

BAT (Biosafety Assessment Tool) (n.d.). GenØk - Centre for Biosafety. http://bat.genok.org/bat/. Access date: February 22, 2011.

Baumüller, H. (2003). Domestic Import Regulations for Genetically Modified Organisms and their Compatibility with WTO Rules. Some Key Issues (Manitoba, Trade Knowledge Network), p. 40.

Beauregard, S. (2009) Food Policy for People: Incorporating food sovereignty principles into State governance Case studies of Venezuela, Mali, Ecuador, and Bolivia. (Los Angeles, Urban and Environmental Policy Institute, Occidental College), p. 94.

Bebb, A. (2008). Sustainability as a smokescreen: The inadequacy of certifying fuels and feeds. An assessment of the expected effectiveness of applying sustainability criteria to agrofuel and animal feedstock production in the Mercosur region. (Brussels, FoE), p. 42.

Benachour N.; Séralini G.E. (2009). Glyphosate formulations induce apoptosis and necrosis in human umbilical, embryonic and placental cells. Chem Res Toxicol 22:97-105.

Benbrook C. (2001). The Farm-Level Economic Impacts of Bt Corn from 1996 through 2001: An Independent National Assessment. Commissioned by the Institute for Agriculture and Trade Policy. http://www.biotech- info.net/Bt_premium_IATP2002.html Access date: November 17, 2010.

Benbrook, C. (2003). GMOs, Pesticide Use, and Alternatives Lessons from the U.S. Experience. http://www.biotech-info.net/lessons_learned.pdf Access date: November 17, 2010.

Bernstein, J.A.; Bernstein, L.; Bucchini, L.; Goldman, L. R.; Hamilton, R.G.; Lehrer, S.; Rubin, C.; Sampson, H.A. (2003). Clinical and Laboratory Investigation of Allergy to Genetically Modified Foods. Environmental Health Perspective 111:1114-1121.

Bernstein,L.; Bernstein J. A.; Miller, M.; Tierzieva, S.; Bernstein, D.; Lummus, S.; Selgrade, M.J.K.; Doerfler, D.; Seligy, V.L. (1999). Immune Responses in Farm Workers after Exposure to Bacillus thuringiensis Pesticides. Environmental Health Perspective 107:575-582.

Binimelis, R. (2008). Coexistence of Plants and Coexistence of Farmers: Is an Individual Choice Possible? Journal of Agricultural and Environmental Ethics 21:437-457.

Binimelis, R.; Strand, R. (2009). Spain and the European Debate on GM Moratoria vs. Coexistence In Science for Policy. New Challenges, New Opportunities. Ecological Economics and Human Well-Being Series, Guimãraes Pereira, Â.; Funtowicz, S. ed. (New Delhi, Oxford University Press), pp. 120-134.

Bohan, D.A.; Boffey, C.W.H.; Brooks, D.R.; Clark, S.J.; Dewar, A.M.; Firbank, L.G.; Haughton, A.J.; Hawes, C.; Heard, M.S.; May, M.J.; Osborne, J.L.; Perry, J.N.; Rothery, P.; Roy, D.B.; Scott, R.J.; Squire, G.R.; Woiwod, I.P.; Champion, G.T. (2005). Effects on weed and invertebrate abundance and diversity of herbicide management in genetically modified herbicide-tolerant winter-sown oilseed rape. Proceedings of the Royal Society of London, Series B 272, 463-474.

Borowiak, C. (2004). Farmers' Rights: Intellectual Property Regimes and the Struggle over Seeds. Politics & Society 32(4):511-543.

Bøhn, T.; Primicerio, R.; Hessen, D.O.; Traavik, T. (2008) Reduced Fitness of Daphnia magna Fed a Bt-Transgenic Maize Variety. Arch. Environ. Contam. Toxicol. 55:584-592.

Breckling, B. (2010). Dead end developments – lessons learned from unsuccessful GMO In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B, Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 129-137.

Brooks, G.; Barfort, P. (2010). GM crops: global socio-economic and environmental impacts 1996-2008 (Dorchester, PG Economics Ltd.), p. 165.

Buratowski, S.; Moazed, D. (2005). Gene Regulation: Expression and silencing coupled. Nature 435:1174-1175.

Carlsson-Kanyama A. (1997) Weighted average source points and distances for consumption origin-tools for environmental impact analysis? Ecological Economics 23:15–23

Castaldini, M.; Turrini, A.; Sbrana, C.; Benedetti, A.; Marchionni, M.; Mocali, S.; Fabiani, A.; Landi, S.; Santomassimo, F.; Pietrangeli, B.; Nuti, M. P.; Miclaus, N.; Giovannetti, M. (2005). Impact of Bt corn on rhizospheric and soil eubacterial communities and on beneficial symbiosis in experimental microcosms. Appl. Environ. Microbiol. 71: 6719-29.

Carpenter, J.; Felsot, A.; Goode, T.; Hammig, M.; Onstad, D.; Sankula, S. (2002). Comparative Environmental Impacts of Biotechnology-derived and Traditional Soybean, Corn, and Cotton Crops (Iowa, Council for Agricultural Science and Technology for the United Soybean Board), pp. 189.

Catacora G. (2007). Soya en Bolivia: Producción de oleaginosas y dependencia. In Repúblicas unidas de la soja. Realidades sobre la producción de soja en América del Sur, J. Rulli, ed. (Asunción, BASE-IS), pp. 235-251.

CBD (Convention on Biological Diversity) (n.d.). List of Parties. http://www.cbd.int/convention/parties/list/ Access date: March 12, 2011.

CBD (Convention on Biological Diversity) (2010). Report of the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety. UNEP/CBD/BS/COP-MOP/5/17. http://www.cbd.int/mop5/documents/ Access date: February 10, 2010.

CEC (Commission of the European Communities) (n.d.). Economic Impacts of Genetically Modified Crops on the Agri-Food Sector. A First Review. Working Document Rev. 2. ec.europa.eu/agriculture/publi/gmo/full_en.pdf Access date: February 15, 2011.

CEC (Commission of the European Communities) (2009). Report from the Commission to the Council and the European Parliament on the coexistence of genetically modified crops with conventional and organic farming http://ecob.jrc.ec.europa.eu/documents/2009Coexreport.pdf Access date: February 15, 2011.

CEO (Corporate Europe Observatory) (2009). 'Responsible Soy' in Paraguay: Group DAP and the advancement of soy monocultures in San Pedro. http://www.corporateeurope.org/agrofuels/content/2009/05/responsible-soy-paraguay-grupo-dap Access date: February 15, 2011.

Chee, Y.L.; Lim, L.C. (2007). The WTO Agreements: An Introduction to the Obligations and Opportunities for Biosafety In Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, T. Traavik, Lim L.C., ed. (Tromsø, Tapir Academic Press), pp. 427-441.

Cho, M.K., Shohara, R., Schissel, A., Rennie, D. (2000). Policies on Faculty Conflicts of Interests at US Universities. JAMA 284(17):2203-2208.

Chong, S.; Whitelaw, E. (2004). Epigenetic germline inheritance. Curr. Opin. Genet. Dev. 14:692-696.

CFS (Center for Food Safety) (2005). Monsanto vs. U.S. Farmers. (San Francisco, CFS), pp. 79.

Clark, A. 2004. GM crops are not containable In Risk Hazard Damage. Specification of Criteria to Assess Environmental Impact of Genetically Modified Organisms, B. Breckling and R. Verhoeven, ed. (Bonn, Federal Agency of Nature Conservation), pp. 91-108.

Clark, A. (2006). Environmental risk of genetic engineering. Euphytica 148:47–60.

Codex Alimentarius Commission (2006a). Codex Alimentarius. Understanding the Codex Alimentarius (Rome, FAO/WHO), p. 39.

Codex Alimentarius Commission (2006b). Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants. CAC/GL 45-2003. http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10021 Access date: November 13, 2011.

Codex Alimentarius Commission (2009). Codex Alimentarius. Foods Derived from Modern Biotechnology (Rome, FAO/WHO), p. 76.

Codex Alimentarius (2010). Membership of the Commission. http://www.codexalimentarius.net/web/members.jsp?lang=EN Access date: March 12, 2011.

Costanza, R.; Patten, B.C. (1995). Defining and predicting sustainability. Ecological Economics 15(3):193-196.

Crespi, J.; Marete, S. (2003). "Does Contain" vs. "Does Not Contain": Does it Matter which GMO Label is Used? European Journal of Law and Economics 16:327-344.

Dale, P.J, Clarke, B., Fontes, E.M.G. (2002). Potential for the environmental impact of transgenic crops. Nat. Biotechnol. 20:567-574.

Dalgaard, R.; Schmidt, J.; Halberg, N.; Christensen, P.; Thrane, M.; Pengue, W.A. (2008). LCA of Soybean Meal. Int J LCA 13(3):240-254

Dankers, C. (2003). Environmental and Social Standards, Certification and Labelling for Cash Crops (Rome, FAO), pp 103.

Dasgupta P.; David P.A. (1994). Toward a new economics of science. Research Policy 23(5):487-521.

DeAngelis, C.D.; Fontanarosa F.B.; Flanagin A. (2001). Reporting Financial Conflicts of Interest and Relationships Between Investigators and Research Sponsors. JAMA 286(1):89-91.

DeBeer, J. (2005). Reconciling Property Rights in Plants. The Journal of World Intellectual Property 8:5-31.

Desrochers P.; Shimizu H. (2008). Yes We Have No Bananas: A Critique of the Food Miles Perspective. Mercatus Policy Series Policy Primer, No.8 (Arlington, Mercatus Center at George Mason University) http://mercatus.org/publication/yes-we-have-no-bananas-critique-food-miles-perspective?id=24612 Access date: November 13, 2010.

Doerfler, W.; Schubbert, R. (1998). Uptake of Foreign DNA from the Environment: The Gastrointestinal Tract and the Placenta as Portals of Entry, Wein Klin. Wochenschr 110(2):40-44.

Domingo, J.L. (2007). Toxicity Studies if Genetically Modified Plants: A Review of the Published Literature. Critical Reviews in Food Science and Nutrition 47(8):721-733.

Dona, A.; Arvanitoyannis, I. (2009). Health Risks of Genetically Modified Foods. Critical Reviews in Food Science and Nutrition 49:164-175.

Dovers, S.; Handmer, J.W. (1993). Contradictions in Sustainability. Environmental Conservation 20:217-222.

Dovers, S.; Handmer, J.W. (1995). Ignorance, the Precautionary Principle, and Sustainability. Ambio 24(2):92-97

Dyer, G.A.; Serratos-Hernández, J.A.; Perales, H.R; Gepts, P., Pineyro-Nelson, A.; Chávez, A.; Salinas-Arreortua, N.; Yu´nez-Naude, A.; Taylor, J.E.; Alvarez- Buylla, E.R. (2009). Dispersal of Transgenes through Maize Seed Systems in Mexico. PLoS ONE 4(5): e5734. doi:10.1371/journal.pone.0005734

EC (2001). Directive 2001/18/EC in the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Official Journal of the European Communities OJ L 106 of 17/4/2001.

EC (2003a). Regulation (EC) No 1829/2003 of the European Parliament and of the Council of the 22 September 2003 on genetically modified food and feed. Official Journal of the European Communities OJ L 268 of 18/10/2003.

EC (2003b). Regulation (EC) No 1830/2003 of the European Parliament and of the Council of the 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Official Journal of the European Communities OJ L 268 of 22/10/2003.

EC (2003c). Regulation (EC) No 1946/2003 of the European Parliament and of the Council of the 15 July 2003 on transboundary movements of genetically modified organisms. Official Journal of the European Union OJL 287 of 5/7/2003.

EC (2003e). Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (notified under document number C (2003) 2624). 2003/556/EC. Official Journal of the European Union OJL 189 of 29/7/2003.

EC (2003d). Commission Recommendation of 23 July 2003on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming. ecob.jrc.ec.europa.eu/documents/Recommendation_2003_556.pdf Access date: February 15, 2011.

EC (2004). Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms. Official Journal of the European Union OJL 10 of 16/01/2004.

EC (2007). Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91. Official Journal of the European Union OJL 189 of 27/7/2007.

EC (2010a). Europeans and Biotechnology in 2010. Winds of change? (Brussels, European Commission/European Research Area), p. 170.

EC (2010b). Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory. COD/2010/0208. ec.europa.eu/food/food/biotechnology/docs/proposal_en.pdf Access date: February 15, 2011.

EC (2010c). Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops (2010/C 200/01). Official Journal of the European Union OJL 200 of 22/7/2010.

ECE (Economic Commission for Europe) (2005). Report of the Second Meeting of the Parties ECE/MP.PP/2005/2/Add.2. www.unece.org/env/documents/2005/pp/ece/ece.mp.pp.2005.2.add.2.e.pdf Access date: February 20, 2011.

Egger, G.; Liang, G.; Aparicio, A.; Jones, P. A. (2004). Epigenetics in human disease and prospects for epigenetic therapy. Nature 429:457-463.

European Parliament (2011). Draft Report on the proposal for a regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory. 2010/0208 (COD). http://www.europarl.europa.eu/sides/getDoc.do?type=COMPARL&mode=XML&language=EN&reference=PE456.911 Access date: March 1, 2011.

Ellstrand, N. (2003). Current knowledge of gene flow in plants: implications for transgene flow. Phil. Trans.R. Soc. Lond. B 358:1163-1170.

Europa (2008). GM Food and Feed. http://europa.eu/legislation_summaries/environment/nature_and_biodiversity/l21154_en.htm#KEY Access date: February 22, 2011.

Euston, S.R.; Gibson, W.E. (1991). Ethics of sustainability. Earth Ethics 6:5-7.

FAO (Food and Agriculture Organization of United Nations) (2009). International Treaty on Plant Genetic Resources for Food and Agriculture (Rome, FAO), p. 56.

Fernández-Cornejo, J.; Caswell, M. (2006). The First Decade of Genetically Modified Crops in the United States (Washington D.C., Economic Research Service USDA), p 30.

Fernández-Cornejo, J.; McBride, W.D. (2002). Adoption of Bioengineered Crops. Agricultural Economic Report No. 810 (Washington D.C., Economic Research Service USDA), p 61.

FLO (Fair Trade Organization) (2009). Generic Fair Trade Standards for Small Producers' Organizations. http://www.fairtrade.net/654.0.html Access date: February 22, 2009.

FLO (Fair Trade Organization) (2010). Generic Fair Trade Standards for Contract Production. http://www.fairtrade.net/712.0.html Access date: February 22, 2011.

FLO (Fair Trade Organization) (2011). Aims of the Fairtrade Standards. http://www.fairtrade.net/aims_of_fairtrade_standards.0.html Access date: February 22, 2011.

FoE (Friends of Earth) (2000). The Starlink Scandal. FOEE Biotech Mailout 6 (7). http://www.foeeurope.org/GMO/publications/vol6no7.pdf Access date: November 15, 2010.

FoE (Friends of Earth) (2010). Who benefits from GM crops? http://www.foeeurope.org/GMOs/Who_Benefits/who_benefits_full_report_2010.pdf Access date: November 1, 2010.

FSC (Forest Stewardship Council) (n.d.). Our vision and mission. http://www.fsc.org/vision_mission.html Access date: February 22, 2011.

FSC (Forest Stewardship Council) (1996). FSC International Standard. FSC Principles and Criteria for Forest Stewardship FSC-STD-01-001 V4 EN. http://www.fsc.org/standards.html Access date: February 22, 2011.

Gasnier, C.; Dumont, C.; Benachour, N.; Clair, E.; Chagnon, M.C.; Séralini, G.E. (2009). Glyphosate-based herbicides are toxic and endocrine disruptors in human cell lines. Toxicology 262:184-191.

Gepts, P. (2004). Who Owns Biodiversity, and How Should the Owners Be Compensated? Plant Physiology 134:1295-1307.

Gioncola, S.I.; Salvador, M.L.; Covacevich, M.; Iturrioz, G. (2009). Análisis de la Cadena de la Soya en Argentina. Estudios Económicos de los Sistemas Agroalimentarios y Agroeindustriales. No.3. (Buenos Aires, INTA), p. 117.

Global EDGE (2011). Phytosanitary measure. globaledge.msu.edu/resourceDesk/glossary.asp Access date: February 24, 2011.

Glover, D. (2010). Is Bt Cotton a Pro-Poor Technology? A Review and Critique of the Empirical Record. Journal of Agrarian Change 10(4):482–509.

GMO Compass (2006). Food Safety Evaluation. Why Antibiotic Resistance Genes?http://www.gmo-compass.org/eng/safety/human_health/45.antibiotic_resistance_genes_transgenic_plants.html Access date: February 22, 2011.

GMO Compass (2009). Field areas 2009. Genetically modified plants: Global cultivation in 134 million of hectares. http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/257.global_gm_planting_2009.html Access date: January 10, 2011.

GMO Compass (2011). Marker genes. http://www.gmo-compass.org/eng/glossary/87.marker_gene.html Access date: February 22, 2011.

Graef, F.; Stachow, U.; Werner, A.; Schütte, G. (2007). Agricultural practice changes with cultivating genetically modified herbicide-tolerant oilseed rape. Agricultural Systems 94:111-118.

GRR (Grupo de Reflexión Rural) (2009). Pueblos Fumigados: Informe sobre la problemática del uso de plaguicidas en las principales provincias sojeras de la Argentina. /http://www.grr.org.ar/trabajos/Pueblos_Fumigados__GRR_.pdf Access date: December 2, 2010.

Gurian-Sherman, D. (2010). Failure to Yield. Evaluating the Performance of Genetically Engineered Crops (Cambridge, UCS), p. 43.

Gylling, M. (2010). The Danish coexistence regulation and the Danish farmers attitude towards GMO. In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B. Breckling and R. Verhoeven, eds. (Frankfurt, Peter Lang), pp. 101-104.

Hall, L.M.; Topinka, A.K.C.; Huffman, J.; Davis, L.; Good, A. (2000). Pollen flow between herbicide-resistant Brassica napus is the cause of multiple-resistant B. napus volunteers. Weed Sci 48:688-694.

Hewlett, K.L.; Azeez, G.S.E. (2008). The Economic Impacts of GM Contamination Incidents on the Organic Sector. http://orgprints.org/view/projects/conference.html Access date: March 2, 2011.

Heinberg R.; Bomford M. (2009) The Food and Farming Transition: Toward a Post-Carbon Food System (Sebastopol, Post Carbon Institute), p. 39.

Heinemann, J.A. (2007). A Typology of the Effects of (Trans)Gene Flow on the Conservation and Sustainable Use of Genetic Resources. Background Paper Study No. 35 (Rome, FAO), p. 94. ftp://ftp.fao.org/ag/cgrfa/bsp/bsp35r1e.pdf Access date: November 2, 2010.

Heinemann, J.A. (2009a). Hope not Hype. The future of agriculture as guided by the International Assessment of Agricultural Knowledge, Science and Technology for Development (Penang, TWN), p. 160.

Heinemann, J.A. (2009b). Report on animals exposed to GM ingredients in animal feed. Prepared for New Zealand Commerce Commission investigation. http://www.comcom.govt.nz/FairTrading/inghamswarnedovergmfreechickenclai.aspx. Access date: December 13, 2010.

Heinemann, J.A.; Kurenbach, B. (2008). Special threats to the agroecosystem from the combination of genetically modified crops and glyphosate. TWN Biosafety Briefing. August 2008. www.biosafety-info.net/file_dir/4634860148bfa74152746.pdf Access date: January 23, 2011.

Heinemann, J. A.; Roughan, P. D. (2000). New hypotheses on the material nature of horizontally transferred genes. Ann. New York Acad. Sci. 906:169-186.

Hernday, A.; Krabbe, M.; Braaten, B.; Low, D. (2002). Self-perpetuating epigenetic pili switches in bacteria. Proc. Natl. Acad. Sci. USA 99:16470-16476.

Hilbeck A. (2002). Transgenic host plant resistance and non-target effects In Genetically Engineered Organisms. Assessing Environmental and Human Health Effects. D.K. Letourneau, B.E. Burrows, ed. (Boca Raton, CRC Press), pp. 167-185.

Hilson, C. (2005). Information Disclosure and Regulation of Traded Product Risks. Journal of Environmental Law 17(3):305-322

Holland, N.; Joensen, L.; Maeyens, A.; Samulon, A.; Semino, S.; Sonderegger, R.; Rulli, J. (2008). The Round Table on Ir-Responsible Soy. Certifying Soy Expansion, GM soy and Agrofuels. www.grr.org.ar Access date: March 5, 2011.

Husby, J. (2007a). A General Introduction to the Regulation of GMOs and Gene Technology In Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, T. Traavik, Lim L.C., ed. (Tromsø, Tapir Academic Press), pp. 352-364.

Husby, J. (2007b). Definitions of GMO/LMO and Modern Biotechnology. In Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, T. Traavik, Lim L.C., ed. (Tromsø, Tapir Academic Press), pp. 366-373.

IAASTD (International Assessment of Agricultural Knowledge Science and Technology for Development), ed. (2009a). Agriculture at Crossroad. Synthesis Report (Washington D.C., Island Press), p. 94.

IAASTD (International Assessment of Agricultural Knowledge Science and Technology for Development), ed. (2009b). Agriculture at Crossroad. Global Report (Washington D.C., Island Press), p. 590.

ICTSD (International Centre for Trade and Sustainable Development) (2008). 'Responsible' Soy Stirs Controversy. Bridges Trade BioRes 8(8):2-5.

IFOAM (2002). Position on Genetic Engineering and Genetically Modified Organisms. www.ifoam.org/press/positions/ge-position.html Access date: December 10, 2010.

IFOAM (2006). The IFOAM Norms for Organic Production and Processing. Version 2005. www.ifoam.org

IPPC (International Plant Protection Convention) (2010). https://www.ippc.int/ Access date: March 12, 2011.

IUCN; UNEP; WWF (1991). Caring for the Earth: A Strategy for Sustainable Living. (Gland, Switzerland and Cambridge, UK, IUCN).

Jacob, M. (1994). Towards a Methodological Critique of Sustainable Development. Dev. Areas 28(2):238-52.

James, C. (2010). Executive Summary of Global Status of Commercialized Biotech/GM crops: 2010. ISAAA Brief No. 42. (Metro Manila; ISAAA), p. 23.

Jost, P.; Shurley, D.; Culpepper, S.; Roberts, P.; Nichols, R.; Reeves, J.; Anthony, S. (2008). Economic comparison of transgenic and nontransgenic cotton production systems in Georgia. Agron. J. 100:42-51.

Keith, D. (2008). Why I had to walk out of farming talks. New Sci. 17-18.

Kiers, E.T.; Leakey, R.R.B.; Izacs, A.-M.; Heinemann, J.A.; Rosenthal, E.; Nathan, D.; Jiggins, J. (2008). Agriculture at a crossroads. Science 320:320-321.

Klar, A. J. S. (1998). Propagating epigenetic states through meiosis: where Mendel's gene is more than a DNA moiety. Trends Genet. 14:299-301.

Kratz A.; Mante C.; Hofman F.; Schlechtriemen U.; Kuhn U.; Ober S.; Vögel R. (2010). Exposure of maize harvest by-products to aquatic ecosystems and protected nature reserves in Branderburg, Germany In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B. Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 21-27.

Kuiper, H.A.; Kleter, G.A.; Noteborn, H.P.J.M.; Kok, E.J. (2001). Assessment of the food safety issues related to genetically modified foods. The Plant Journal 27(6):503-528.

Kvakkestad, V. (2009). Institutions and the R&D of GM-crops. Ecol. Econ. 69:2688-2695.

Lawrence, J.G. (2005). Horizontal and Vertical Gene Transfer: The Life History of Pathogens In Concepts in Bacterial Virulence. W. Russell and H. Herwald, ed. Contrib. Microbiol. Basel, Karger, Vol. 12, pp. 255-271.

Lee, M. (2009). EU Regulation of GMOs. Law and Decision Making for a New Technology. Biotechnology Regulation Series (Massachusetts, Edward Elgar Publishing, Inc.), p. 274.

Lehmann, V.; Pengue, W.A. (2000). Herbicide tolerant soybean: Just another step in a technology treadmill? Biotechnology and Development Monitor 43:11-14.

Lélé, S. M. (1991). Sustainable Development: A Critical Review. World Development 19(6):607-21.

Lesser, W. (1999). Intellectual Property Rights and Concentration in Agricultural Biotechnology. AgBioForum 1(2):56-61.

Levidow, L., Boschert, K. (2008). Coexistence or contradiction? GM crops versus alternative agricultures in Europe. Geoforum, 39(1):174-190.

Lheureux, K.; Libeau-Dulos, M.; Nilsagård, H.; Rodriguez-Cerezo, E.; Menrad, K.; Menrad, M.; Vorgrimler, D. (2003). Review of GMOs under Research and Development and in the pipeline in Europe. Technical Report Series EU 20680 EN (EC, JRC), p. 122.

Lim L.,C. (2007). International Standards Setting on Biosafety: An Introduction to Some other International Agreements and Forums In Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, T. Traavik, Lim L.C., ed. (Tromsø, Tapir Academic Press), pp. 444-455.

Lim L.,L. (2007) Cartagena Protocol on Biosafety. In Biosafety First – Holistic Approaches to Risk and Uncertainty In Genetic Engineering and Genetically Modified Organisms. T. Traavik, Lim L. C., ed. (Tromsø, Tapir Academic Press), pp. 408-425.

Lim L.,L.; Lim L.,C. (2007). Identification requirements for Shipment of genetically engineered commodities: Analysis of the decision adopted under the Cartagena Protocol on Biosafety (Penang, TWN).

López, A.; Ramos, D.; Simkievich, C. (2008). A Study of the Impact of China's Global Expansion on Argentina. Soybean Value Chain analysis: Final Report. DEV/ODG, ESRC. www.uea.ac.uk/polopoly_fs/1.113468!SOYBEAN%20VALUE%20CHAIN.pdf Access date: November 8, 2010.

López-Villar, J.; Freese, B.; Holder, H.; Chandrasekaran, K.; Rodriguez, L. (2009). Who benefits from GMO crops. Feeding the biotech giants not he world's poor (Amsterdam, FoE), p. 48.

Lotter, D. (2008). The Genetic Engineering of Food and the Failure of Science – Part 2: Academic Capitalism and the Loss of Scientific Integrity. Int. Jrnl. of Soc. of Agr. & Food 16(1):50-68.

Lu, Y.; Wu, K.; Jiang, Y.; Xia, B.; Li, P.; Feng, H.; Wyckhuys, K.A.G.; Guo Y. (2010). Mirid Bug Outbreaks in Multiple Crops Correlated with Wide-Scale Adoption of Bt Cotton in China. Science 328:1151-1153.

MacKenzie R.; Burhenne-Guilmin F.; La Viña A.G.M.; Werksman J.D. (2003). An explanatory guide to the Cartagena Protocol on Biosafety. Environmental Policy and Law Paper No. 46 (Cambridge, IUCN), p 295.

Malatesta, M.; Boraldi, F.; Annovi, G.; Baldelli, B.; Battistelli, S.; Biggiogera, M.; Quaglino D. (2008). A long-term study on female mice fed on a genetically modified soybean: effects on liver ageing. Histochem Cell Biol. 130:967-977

Martinez-Ghersa, M.A.; Worster, C.A.; Radosevich, S.R. (2003). Concerns a weed scientist might have about herbicide-tolerant crops: A revisitation. Weed Technol. 17:202-210.

Marshal, A. (2010). 13.3 million farmers cultivate GM crops. Nature Biotechnology 27(3):221.

Marvier, A. (2004). Risk assessment of GM crops warrants higher rigor and reduced risk tolerance than traditional agrochemicals In Risk Hazard Damage. Specification of Criteria to Assess Environmental Impact of Genetically Modified Organisms, B. Breckling and R. Verhoeven, ed. (Bonn, Federal Agency of Nature Conservation), pp.119-129.

Mascarenhas, M.; Busch, L. (2006). Seeds of Change: Intellectual Property Rights, Genetically Modified Soybeans and Seed Saving in the United States. Soc. Ruralis 46:122-138.

Mattick, J. S.; Amaral, P. P.; Dinger, M. E.; Mercer, T. R.; Mehler, M. F. (2009). RNA regulation of epigenetic processes. BioEssays 31:51-59.

McAfee, K. (2003). Neoliberalism on the molecular scale. Economic and genetic reductionism in biotechnology battles. Geoforum 34:203-219.

McClellan, J. (2010). Draft Terms of Reference of the Roundtable on Sustainable Biofuels GMO Expert Group. Available at: http://rsb.epfl.ch/page-53274.html Access date: February 22, 2011.

MD (Miljøverndepartementet) (1993). Gene Technology Act. http://www.regjeringen.no/en/doc/Laws/Acts/gene-technology-act.html?id=173031 Access date: January 7, 2011.

Mesnage R.; Clair E.; Séralini G.-E. (2010). Roundup® in genetically modified plants: Regulation and toxicity in mammals In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B. Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 31-33.

Meyer, H. (2007a). The Precautionary Principle and the Cartagena Protocol on Biosafety: Development of a Concept. In Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, T. Traavik, Lim L.C., ed. (Tromsø, Tapir Academic Press), pp. 470-482.

Meyer, H. (2007b). GMO-Free Regions Manual: Case Studies from Around the World. (Germany, IFOAM), p. 89.

Mikula, B. C. (1995). Environmental programming of heritable epigenetic changes in paramutant r-gene expression using temperature and light at a specific stage of early development in maize seedlings. Genetics 140(4):1379-1387.
Ministry of Agriculture, Forestry and Fisheries (2005). Japanese Agricultural Standards for Organic Plants. Notification No. 1605, 27 October 2005.

Monsanto (2006). The sum of our commitments. '06 Pledge Report (Missouri, Monsanto Company), p. 48.

Monsanto (2010). 2010 Monsanto Technology/ Stewardship Agreement (TSA) form.

Morse, S.; Bennett, R.; Ismael, Y. (2007). Inequality and GM Crops: A Case-Study of Bt Cotton in India. AgBioForum 10(1): 44-50.

Myhr, A.I. (2007). The role of precautionary motivated science in addressing scientific uncertainties related to GMOs In Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, T. Traavik, Lim L.C., ed. (Tromsø, Tapir Academic Press), pp. 279-286.

Myhr, A.I.; Rosendal, G.K. (2009). GMO Assessment in Norway as Compared to EU Procedures: Societal Utility and Sustainable Development (Trondheim, Direktoratet for naturforvaltning), p. 49.

Nielsen, K.M.; Myhr A.I. (2007). Understanding the Uncertainties Arising from Technological Interventions in Complex Biological Systems: The Case of GMOs In Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, T. Traavik, Lim L.C., ed. (Tromsø, Tapir Academic Press), pp. 107-122.

Norgaard, R B. (1988). Sustainable Development: A Co-Evolutionary View. Futures December: 606-620.

Norregaard Jensen, O. (2004). Modification-specific proteomics: characterization of post-translational modifications by mass spectrometry. Curr. Opin. Chem. Biol. 8:33-41.

NRC (National Research Council) (2010). Impact of Genetically Engineered Crops on Farm Sustainability in the United States (The National Academy Press; Washington), p. 240.

NRDC (2007). Food miles: How far your food travels has serious consequences for your health and the climate. www.nrdc.org/health/effects/camiles/foodmiles.pdf

Nuffield Council on Bioethics (2004). The use of genetically modified crops in developing countries. A follow-up Discussion Paper (London, Nuffield Council on Bioethics), p. 122.

O'Driscoll, G.Jr.; Hoskins, L. (2003). Property Rights The Key to Economic Development. Policy Analysis No 482 (Washington D.C., Cato Institute), p. 17.

OIE (World Organization for Animal Health) (2007). Report of the Meeting of the OIE Biological Standard Commission. 75 SG/12/CS2 B. www.oie.int/downld/SC/2007/A_BSC_Jan2007.pdf Access date: January 17, 2011.

OIE (World Organization for Animal Health) (2008a). Report of the Meeting of the OIE Biological Standard Commission. 76 SG/12/CS2 B. www.oie.int/downld/SC/2008/A_BSC_Jan2008.pdf Access date: January 17, 2011.

OIE (World Organization for Animal Health) (2008b). Report of the Meeting of the OIE Biological Standard Commission. http://www.oie.int/downld/SC/2008/A_BSC_sept2008.pdf Access date: January 17, 2011.

OIE (World Organization for Animal Health) (2010). The OIE. Objectives. http://www.oie.int/eng/OIE/en_objectifs.htm#1 Access

date: January 17, 2011.
OIE (World Organization for Animal Health) (2011). http://www.oie.int/en/ Access date: March 12, 2011.
Ongwen O.; Wright S. (2007). Small farmers and the Future of Sustainable Agriculture. ECOFAIR Trade Dialogue. Discussion Paper No. 7 (Berlin), p. 64.
Palau, T.; Cabello, D.; Maeyens, A.; Rulli, J.; Segovia, D. (2007). Los refugiados del modelo agroexportador. Impactos del monocultivo de la soya en comunidades campesinas de Paraguay (Asunción, BASE-Is), p. 363.
Panichelli, L.; Dauriat, A.; Gnansounou, E. (2008). Life cycle assessment of soybean-based biodiesel in Argentina for export. Int J Life Cycle Assess. doi 10.1007/s11367-008-0050-8
Papa, J. (2000). Malezas tolerantes que pueden afectar el cultivo de soja (Santa Fe, National Institute of Agricultural Research INTA).
Pavone, V.; Goven, J.; Guarino, R. (2010). From risk assessment to in-context trajectory evaluation: GMOs and their social implications In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B. Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 105-108.
Pengue, W. (2004). Environmental and socio economic impacts of transgenic crops in Argentina and South America: An ecological economics approach In Risk Hazard Damage. Specification of Criteria to Assess Environmental Impact of Genetically Modified Organisms, B. Breckling and R. Verhoeven, ed. (Bonn, Federal Agency of Nature Conservation), pp. 49-59.
Pengue, W. (2005). Transgenic Crops in Argentina: The Ecological and Social Debt. Bulletin of Science Technology & Society 25:314-322.
Pengue, W. (2009). Agrofuels and Agrifoods: Counting the Externalities at the Major Crossroads of the 21st Century. Bulletin of Science Technology Society 29:167-179.
Petronis, A. (2001). Human morbid genetics revisited: relevance of epigenetics. Trends Genet. 17:142-146.
Phillips P.W.B.; Isaac G. (1998). GMO Labelling: Threat or Opportunity? AgBioForum 1(1):25-30.
Pillus, L.; Rine, J. (1989). Epigenetic inheritance of transcriptional states in S. cerevisiae. Cell 59: 637-647.
Pingali, L.P.; Traxler, G. (2002). Changing locus of agricultural research: will the poor benefit from biotechnology and privatization trends? Food Policy 27:223-238.
Powles, S.; Preston, C. (2006). Evolved Glyphosate Resistance in Plants: Biochemical and Genetic Basis of Resistance. Weed Technology 20:282-289
Pray, C.E.; Huang, J.; Hu, R.; Rozelle, S. (2002). Five years of Bt cotton in China - the benefits continue. The Plant Journal 31(4):423-430.
Pray C.; Naseem A. (2007). Supplying Crop Biotechnology to the Poor: Opportunities and Constraints. Journal of Development Studies 43(1):192-217.
Primavesi, A. (1984). Manejo ecológico del suelo. La agricultura en regiones tropicales. 5th Edición (Rio de Janeiro, El Ateneo), p. 499.
RSB (Roundtable on Sustainable Biofuels) (2010). RSB Principles & Criteria for Sustainable Biofuel Production. RSB-STD-01-001 (Version 2.0). http://rsb.epfl.ch/. Access date: February 22, 2011.
RTRS (Round Table on Responsible Soy) (2010a). Round Table on Responsible Soy Association http://www.responsiblesoy.org/ Access date: February 22, 2011.
RTRS (Round Table on Responsible Soy) (2010b). RTRS Standards for Responsible Soy Version 1.0. RTRS_STD_001_V1-0_ENG_for responsible soy http://www.responsiblesoy.org/index.php?option=com_docman&task=cat_view&gid=142&Itemid=19&lang=en Access date: February 22, 2011.
RTRS (Round Table on Responsible Soy) (2010c). Members. http://www.responsiblesoy.org/# Access date: March 11, 2011.
Qaim, M. (2009). The Economics of Genetically Modified Crops. Annu. Rev. Resour. Econ. 1:665-93.
Qaim, M.; De Janvry, A. (2003) Genetically Modified Crops, Corporate Pricing Strategies, and Farmers' Adoption: The Case of Bt Cotton in Argentina. American Journal of Agricultural Economics 85:814-828.
Qaim, M.; De Janvry, A. (2004). Cheaper GM Seeds Could Boost Adoption, Farm Benefits and Company Profits: The Case of Bt Cotton in Argentina. Crop Biotech Brief 4(1):1-4
Qaim, M.; Traxler, G. (2005). Roundup Ready soybeans in Argentina: farm level and aggregate welfare effects. Agricultural Economics 32:73-86.
Quist, D., Chapela, I. (2001). Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico. Nature 414:541-543.
Quist, D.; Kaare, M.N.; Traavik, T. (2007). The Complex and Interactive Pathway from (Trans)Genes to Proteins In Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, T. Traavik, Lim L.C., ed. (Tromsø, Tapir Academic Press), pp. 49-64.
Ramirez-Romero R.; Desneux N.; Decourtye A.; Chaffiol A.; Pham-Delègue M.H. (2008). Does Cry1Ab protein affect learning performances of the honey bee Apis mellifera L. (Hymenoptera, Apidae)? Ecotoxicol Environ Saf. 70:327-33.
Rao, P.K. (2000). Sustainable Development: Economics and Policy (Oxford, Blackwell Publishing), pp. 393.
Rosendal, G.K. (2008). Interpreting Sustainable Development and Societal Utility in Norwegian GMO Assessments. Eur. Env. 18:243-256.
Rosi-Marshall, E.J.; Tank. J. L.; Royer, T. V.; Whiles, M. R.; Evans-White, M.; Chambers, C.; Griffiths, N. A.; Pokelsek, J.; Stephen, M. L. (2007) Toxins in transgenic crop byproducts may affect headwater stream ecosystems. Proc Natl Acad Sci USA 104:16204-16208.
Sagar, A.; Daemmrich, A.; Shiya, M. (2000). The Tragedy of the Commoners: biotechnology and its publics. Nat. Biotechnol.

18:2-4.
SAyDS (Secretaría de Ambiente y Desarrollo Sostenible) (2008). El avance de la frontera agropecuaria y sus consecuencias (Buenos Aires, Secretaría de Ambiente y Desarrollo Sustentable).
Schubbert, R.; Renz, D.; Schmitz B.; Doerfler, W. (1997). Foreign (M13) DNA ingested by mice reaches peripheral leukocytes, spleen, and liver via the intestinal wall mucosa and can be covalently linked to mouse DNA. Proc. Natl. Acad. Sci. 94:961-966.
Schubert, D. (2008). The Problem with Nutritionally Enhanced Plants. J. Med Food 11(4):601-605.
Schmidt, J.E.; Braun C.U.; Whitehouse L.P.; Hilbeck A. (2009). Effects of Activated Bt Transgene Products (Cry1Ab, Cry3Bb) on Immature Stages of the Ladybird Adalia bipunctata in Laboratory Ecotoxicity Testing. Arch Environ Contam Toxicol 56:221-228.
Schmidt, G., Breckling, B. (2010). The Triffid case: A short résumé on the re-discovery of a de-registered GMO In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B. Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 79-81.
Schvarzer, J.; Tovosnanska, A. (2007). Biocombustibles: Expansión de una industria naciente y posibilidades para Argentina. Documento de Trabajo N0 13. (Buenos Aires, CESPA-UBA), p. 65.
Scientific American ed. (2010). A seedy practice. Scientific American p. 22.
Secretariat of the Convention on Biological Diversity (n.d.). Cartagena Protocol Biosafety: From Negotiation to Implementation. Historical and New Perspectives as the World marks the Entry-into-force of the Protocol (Montreal, Secretariat of the Convention on Biological Diversity), p. 40.
Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety: Text and Annexes (Montreal, Secretariat of the CBD), p. 30.
Secretariat of the Convention on Biological Diversity (2003). The Cartagena Protocol on Biosafety: A Record of the Negotiations (Montreal, Secretariat of the Convention on Biological Diversity), p. 140.
Secretariat of the Convention on Biological Diversity (2004). Global Biosafety: From concepts to Action. Decisions from the First Meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety. Kuala Lumpur, Malaysia 23-27 February, 2004 (Montreal, Secretariat CBD), p. 127.
Secretariat of the Convention on Biological Diversity (2004). Biosafety: Building Further Consensus for Action. Decisions from the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety. Curitiba, Brazil 13-17 March, 2006 (Montreal, Secretariat CBD), p. 72.
Secretariat of the Convention on Biological Diversity (2011a). Parties to the Protocol. http://bch.cbd.int/protocol/parties/ Access date: March 12, 2011.
Secretariat of the Convention on Biological Diversity (2011b). The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (Montreal, CBD), p. 10.
Secretariat of the Convention on Biological Diversity; UNEP (2003). Biosafety and the Environment. An Introduction to the Cartagena Protocol on Biosafety (Geneve, Secretariat of the CBD/UNEP), p. 16.
Secretariat of the IPPC (International Plant Protection Convention) (2006). International Standards for Phytosanitary Measures. ISPM No. 11. Pest Risk Analysis for quarantine pests including analysis of environmental risks and living modified organisms (2004) (Rome, FAO), p. 32.
Secretariat of the IPPC (International Plant Protection Convention) (2008). International Standards for Phytosanitary Measures. ISPM No.5. Glossary of Phytosanitary Terms (Rome, FAO), p. 21.
Semino, S. (2008). Can certification stop high soy pesticide use? Pesticide News 82:9-11.
Sendashonga C.; Hill R.; Petrini A. (2005). The Cartagena Protocol on Biosafety: interaction between the Convention on Biological Diversity and the World Organization for Animal Health. Rev. Sci. Tech. Off. Int. Epiz 24(1):19-30.
Séralini G.-E.; Spiroux de Vendomois J.; Cellier D.; Mesnage R.; Clair E. (2010). Genetically modified consumption at large scale: Possible negative health impacts due to holes in assessment. Overview of the safety studies of GMOs performed in mammals In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B. Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 28-30.
Small, B. (2007). Sustainable development and technology: genetic engineering, social sustainability and empirical ethics. Int. J. Sustainable Development 10(4): 402-435.
Sharipo, R.B. (1999). How genetic engineering will save our planet. The Futurist 33/34:28-29.
Shorett, P., Rabinow, P., Billing, P.R. (2003). The changing norms of the life sciences. Nat. Biotech. 21:123-125.
Snow A.; Andow D.; Gepts P.; Hallerman E.M.; Power A.; Tiedje J.M.; Wolfenbarger L.L (2008) Genetically Engineered Organisms and the Environment: Current status and recommendations. Ecological Applications 15(2):377-404
Sounders C.; Barber A.; Taylor G. (2006). Food Miles – Comparative. Energy/Emissions. Performance of New Zealand's Agriculture Industry. AERU Research Report 285. Lincoln University. www.lincoln.ac.nz/story_images/2328_RR285_s13389.pdf Access date: October 12, 2010.
Soy20/20 (2008). Canada's Soybean Value Chain. http://soy2020.ca/reports.php Access date: November 8, 2010.
Spielman, D. J. (2007). Pro-poor agricultural biotechnology: Can the international research system deliver the goods? Food Policy 32:189-204.
Stec S.; Casey- Lefkowitz S (2000). The Aarhus Convention: An Implementation Guide. (Geneve, UN/ECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters), p. 186.

Stein, A.; Rodríguez-Cerezo, E. (2009). The global pipeline of new GM crops. Implications of asynchronous approval for international trade. EUR 23846 EN. (Spain, JRC), p. 114.

Stirling, A. (1999). The appraisal of sustainability: Some problems and possible responses. Local Environment 4(2):111-134.

Stirling, A. (2008). Science, Precaution, and the Politics of Technological Risk Converging Implications in Evolutionary and Social Scientific Perspectives. Ann. N.Y. Acad. Sci. 1128:95-110.

Stone, G.D. (2011). Field versus Farm in Warangal: Bt Cotton, Higher Yields, and Larger Questions. World Development 39:387-398.

Stoppe-Ramadan S.; Winter G. 2010. EU and German law on coexistence: Individual and systematic solutions and their compatibility with property rights In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B. Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 121-124.

Stotzky G. (2004). Persistence and biological activity in soil of the insecticidal proteins from Bacillus thuringiensis, especially from transgenic plants. Plant Soil 266:77-89.

Subramanian, A.; Qaim, M. (2009). Village-wide Effects of Agricultural Biotechnology: The Case of Bt Cotton in India. World Development 37:256-267.

ten Brink, P.; Berghöfer, A.; Schröter-Schlaack, C; Sukhdev, P.; Vakrou, A.; White, S.; Wittmer, H. (2009). TEEB – The Economics of Ecosystems and Biodiversity for National and International Policy Makers. Executive Summary: Responding to the Value of Nature. http://www.teebweb.org/ForPolicymakers/tabid/1019/Default.aspx Access date: January 23, 2011.

Thakur, A. (2003) RNA interface revolution. Electronic Journal of Biotechnology http://www.ejb.org/content/vol6/issue1/full/1 Access date: November 1, 2010.

Then, C. (2010). New pest in crop caused by large scale cultivation of Bt corn In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B. Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 94-97.

Tilman, D. (1999). Global environmental impacts of agricultural expansion: The need for sustainable and efficient practices. Proc. Natl. Acad. Sci. USA 96:5995-6000.

Toman, Z.; Dambly-Chaudière, C.; Tenenbaum, L.; Radman, M. (1985). A system for detection of genetic and epigenetic alterations in Escherichia coli induced by DNA-damaging agents. J. Mol. Biol. 186:97-105.

Tomei, J.; Upham, P. (2009). Argentinean soy-based biodiesel: An introduction to production and impacts. Energy Policy 37:3890-3898.

Toomey P. (2004). Bringing home the apples: examining the impacts, causes, and potential policy solutions to long-distance agricultural transport. Thesis. Teksam/International Master of Science. Roskilde University. rudar.ruc.dk/bitstream/1800/837/1/Bringing_home_the.pdf Access date: October 12, 2010.

Traavik, T.; Heinemann, J. (2007). Genetic Engineering and Omitted Health Research: Still no Answers to Ageing Questions In Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, T. Traavik, Lim L.C., ed. (Tromsø, Tapir Academic Press), pp. 153-167.

Traavik, T.; Neilsen K.M.; Quist, D. (2007). Genetic Engineering of Living Cells and Organism In Biosafety First – Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms, T. Traavik, Lim L.C., ed. (Tromsø, Tapir Academic Press), pp. 65-93.

Tsui M.T.; Chu L.M. (2003). Aquatic toxicity of glyphosate-based formulations: comparison between different organisms and the effects on environmental factors. Chemosphere 52:1189-1197.

Tuesca, D.; Niesemsohn, L.; Papa, J. (2007). Para estar alerta: el sorgo de alepo resistente al glifosato In Soja para mejorar la producción 36, INTA/ EEA, pp. 72-75.

Turrini, A.; Sbrana, C.; Giovannetti, M. (2008). Experimental Systems to Monitor the Impact of Transgenic Corn on Keystone Soil Microorganisms www.bch.org.co/bioseguridad/admon/archivos/noticias/turrini.pdf Access date: October 24, 2010.

UN (United Nations) (1992). Convention on Biological Diversity (Montreal, Secretariat of the Convention on Biological Diversity), p. 28.

UNCTAD (2006). Tracking the Trend Towards Market Concentrations: The Case of the Agricultural Input Industry UNCTAD/DITC/COM/2005/16. www.unctad.org/en/docs/ditccom200516_en.pdf Access date: October 5, 2010.

UNECE (United Nations Economic Commission for Europe) (n.d.).Introducing the Aarhus Convention. http://www.unece.org/env/pp/ Access date: March 12, 2011.

UNEP (1992). Convention on Biological Diversity. http://www.cbd.int/convention/text/ Access date: November 13, 2010.

USSEC (U.S. Soybean Export Council) (2008). Life cycle of a bean http://www.ussoyexports.org/resources/lifecycle.html Access date: November 8, 2010.

Uusitalo, S. (2008) Affective Implications of GM Food on Social and Individual Integrity: An Ethical Approach In Women in Biotechnology: Creating Interface, F. Molfino and F. Zucco F ed. (Rome, Springer Science and Business Media), pp. 257-262.

Van Acker, P. C.; Brule-Babel, A.L.; Friesen, L.F. (2004). Intraspecific gene movement can create environmental risk: The example of Roundup Ready wheat in Western Canada In Risk Hazard Damage. Specification of Criteria to Assess Environmental Impact of Genetically Modified Organisms, B. Breckling and R. Verhoeven, ed. (Bonn, Federal Agency of Nature Conservation), pp. 37-47.

Vermij, P. (2006). Liberty Link rice raises specter of tightened regulations. Nature Biotechnology 24:1301-1302.

Vía Campesina (1996). Declaración sobre la soberanía alimentaria de los pueblos. Cumbre Mundial de Alimentación de la FAO.

Viljoen C.; Chetty L. (2010). An African perspective of GM maize gene flow In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B. Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 60-61.

Vila-Aiub M.; Vidal, R.; Balbi M.; Gundel P.; Trucco F.; Ghersa, C. (2008). Glyphosate - resistant weeds of South American cropping systems: an overview. Pest Management Science 64:366–371.

Wagner, P. (2010). Influence of GM-crop cultivation on local apiculture and floral environment In Large-area Effects of GM-Crop Cultivation. Theorie in der Ökologie 16, B. Breckling and R. Verhoeven, ed. (Frankfurt, Peter Lang), pp. 65-67.

Waltz, E. (2009a). Under wraps. Nature Biotechnology 27(10):880-882.

Waltz, E. (2009b). Battfield. Nature 461:27-32.

Waltz, E. (2010). Glyphosate resistance threatens Roundup hegemony. Nature Biotechnology 28(6):537-538.

WCED (World Commission on Environment and Development) (1987). Our Common Future http://www.un-documents.net/wced-ocf.htm

Weaver, S.; Morris, M. (2005). Risks associated with genetic modification: An annotated bibliography of peer reviewed natural science publication. Journal of Agricultural and Environmental Ethics 18:157-189.

Weed Science (2010). Glyphosate-Resistant Weeds Globally – 2010. http://www.weedscience.org/Maps/GlyphosateMap.htm Access date: April 18, 2011.

WHO (World Health Organization) (2005). Modern food biotechnology, human health and development: an evidence-based study (Geneva, WHO), p. 79.

Wickner, R. B.; Edskes, H. K.; Roberts, B. T.; Baxa, U.; Pierce, M. M.; Ross, E. D.; Brachmann, A. (2004). Prions: proteins as genes and infectious entities. Genes & Develop. 18:470-485.

Wikipedia (2010). Polluter Pays Principle. http://en.wikipedia.org/wiki/Polluter_pays_principle Access date: March 26, 2011.

Wikipedia (2011a). RNA. http://en.wikipedia.org/wiki/RNA#Types_of_RNA Access date: April 15, 2011.

Wikipedia (2011b), Substantial equivalence. http://en.wikipedia.org/wiki/Substantial_equivalence Access date: February 24, 2011.

Wolfenbarger, LL.; Phifer, P.R. (2000). The Ecological Risks and Benefits of Genetically Engineered Plants. Science 290:2088-2093.

Wong, D. (2007). Genetically modified food labelling in the European Union and selected places (Research and Library Services Division/ Legislative Council Secretariat), p. 50.

World Bank (2007). World Development Report 2008: Agriculture for Development. Overview (Washington D.C.,World Bank), p. 320.

WTO (World Trade Organization) (n.d., a). Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm Access date: December 10, 2010

WTO (World Trade Organization) (n.d., b). Agreement on Technical Barriers to Trade (TBT Agreement) http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm Access date: December 10, 2010.

Zhang, B.; Pan, X.; Cobb, G.P.; Anderson, T.A. (2006). Plant microRNA: A small regulatory molecule with big impact. Developmental Biology 289:3-16.

Annex

Examples of applications of genetic modification

Organism	Some purposes of the genetic modification	Examples of traits
Plants	Herbicide tolerance	Tolerance to glyphosate, glufosinate, bromoxynil, sulfonamide, etc.
	Pest tolerance	Insecticidal activity (e.g., Bt crops and trees) Tolerance to fungi, bacteria and viral infection (e.g., papaya resistant to ringspot virus) Resistance to nematodes
	Environmental stress tolerance	Tolerance to drought, frost and salinity Tolerance to cyanamide Increased fitness Suppression of shade avoidance
	Modified yield-influencing factors	Alteration of phosphate metabolisms Dwarf phenotype introduction Improved rooting ability Stimulation of growth rate
	Reproduction control	Male sterility Seed sterility
	Modified nutrients and ingredients	Decrease of antinutritive ingredients Enhancement of nutritional value Fatty acid, protein, oligosaccharides and starch metabolism
	Improved industrial and commercial value	Better food processing qualities (e.g., improved baking and malting quality) Modification of ripening (e.g., controlled cell division, inhibition of flowering) Delay of senescence Increased postharvest/storage shelf life Modification of colours and forms (e.g., altered flower pigmentation) Higher production of industrial substances (e.g., alteration of lignin biosynthesis, high laurate content, etc.) Enzyme production
	Production of health-related compounds	Production of plant-based pharmaceuticals Synthesis of viral antigenic determinants (edible vaccines) Synthesis of health-related compounds (e.g., albumin, antibody, collagen, lactoferrin, etc.)
	Environmental remediation	Update of heavy metals
	Study the action of genes during development and other biological processes	Marker development Other trait development (e.g., gene expression and stability testing, gene tagging)

Animals	Tolerance to animal diseases	Tolerance to viral, bacterial and coccidial diseases (e.g., livestock tolerant to mastitis)
	Modified nutrients/ingredients	Lower fat and cholesterol levels in animal products
	Improved industrial and commercial value	Increased production of animal products e.g., milk and white eggs Increased growth
	Production of health-related compounds	Production of pharmaceuticals (e.g., transgenic chicken producing eggs with high content of pharmaceutical proteins) Production of biologically active compounds (e.g., transgenic chicken that synthesize antibodies, growth hormones, insulin, human serum albumin) Xenotransplantation
	Environmental remediation	Reduction of environmental pollutants in animal manure
	Genetic engineering and medical research	
Microorganism	Improved industrial value	Enzyme production for industrial processes
	Production of health-related compounds	Production of probiotics
	Environmental remediation	Degradation of xenobiotic pollutants

Source: Traavik et al. (2007); Lheureux et al. (2003)