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Emerging Risks Related to the Environment and New Technologies

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1. Environmental risks related to conventional agriculture

Farming and nature exercise a profound influence over each other. Farming has contributed over the centuries to creating and maintaining a variety of valuable semi-natural habitats. They shaped an important part of landscapes worldwide and are home to many of the world's richest wildlife. Farming also supports a diverse rural community that is not only a fundamental asset of international culture, but also plays an essential role in maintaining the environment in a healthy state.

Farming is an activity whose significance goes beyond simple food production. Throughout the production chain processes occur that can have an impact on the natural environment and consequently, directly or indirectly, on human health and development. For example, heavy use of pesticides and fertilizers, incorrect drainage or irrigation practices, a high level of mechanization or unsuitable land use can produce environmental degradation. However, abandonment of farming activities can also endanger the environmental heritage through loss of semi-natural habitats as well as biodiversity and landscape associated with them. Likewise, the effect of agricultural production systems on human health directly (farmer's occupational health) or indirectly (consumer's health through food) are increasingly being recognized as an integrated element in the broader evaluation of environmental risks related to agriculture.

The links between the richness of the natural environment and farming practices are complex. While many valuable habitats are maintained by extensive farming, and a wide range of wild species rely on this for their survival, agricultural loss of wildlife can be the result of inappropriate agricultural practices and land use.

Discussions on possible future environmental effects of new technologies in food production will necessarily have to take outset in the present situation of agricultural effects on the environment, including derived effects on human health, recognizing that present trends of conventional agriculture are likely to be reflected in the objectives of modern food production.

1.1 Key aspects of environmental pollution and resource depletion[1]

Agriculture adds to greenhouse gas (GHG) problems. There are three main sources of GHG emissions from agriculture: N2O (nitrous oxide) emissions from soils, mainly due to nitrogen fertilization; CH4 (methane) emissions from intestinal fermentation, CH4 and

N2O emissions from manure management. Measures being considered include: encouragement of more efficient fertilizer applications to reduce overall use, composting and improvements in anaerobic digestion systems (e.g., for production of biogas), to deal with biodegradable by-products and waste; renewed emphasis on biomass production, conservation tillage and organic farming. Further development of renewable, agricultural biomass could contribute to reductions in emissions from energy and transport, while benefiting the agricultural sector.

Water pollution by nitrates from agricultural sources, where improved agricultural practices are thought to improve pollution.

Pesticides have been proven to have an effect on the environment and ecosystems by reducing biodiversity, especially by reducing weeds and insects which are often important elements of the food chain e.g. for birds. In addition, human health can be negatively affected through direct exposure and indirect exposure, e.g. via their residues in agricultural produce and drinking water. Systems to reduce the need for pesticide use, especially integrated pest management, organic farming or in some cases genetically modified crops are increasingly investigated at national and international level.[2]

Soil degradation processes such as desertification, erosion, decline in soil organic matter, soil contamination (e.g. by heavy metals), soil sealing, soil compaction, decline in soil biodiversity and salinization can cause soil to lose its capacity to carry out its main functions. Such degradation processes can result from inappropriate farming practices such as unbalanced fertilization, over abstraction of groundwater for irrigation, improper use of pesticides, use of heavy machinery, or overgrazing. Measures to prevent soil degradation include support to organic farming, conservation tillage, the protection and maintenance of terraces, safer pesticide use, integrated crop management, management of low-intensity pasture systems, lowering stock density and the use of certified compost.

Irrigation can also lead to environmental concerns, such as over-extraction of water from subterranean aquifers, irrigation driven erosion, soil salinization, alteration of pre-existing semi-natural habitats and, secondary impacts arising from the intensification of the agricultural production permitted by irrigation.

Bio diversity conservation: In recent decades, the rate of decline and even disappearance of species and related habitats, ecosystems and genes (i.e. biodiversity) has increased throughout the world. Declines in biodiversity are of direct consequence for food security when they affect food related organisms and relatives with relevance for breeding. Furthermore, intensified agriculture including modern breeding systems has resulted in significant reductions of landraces, adapted to local specificities as well as traditional knowledge.

Assessment of agricultural impacts on the environment requires the use of holistic models which are able to integrate multiple sources of information.[3]. Previous scientific discussions have concluded that solutions applied at farm level contributed environmental problems but they are not adequate to the task of realizing long-term environmental goals. This requires system innovations at higher levels of aggregation, involving, for example, looking for opportunities to negotiate recycling systems by linking sectors within agriculture and other areas affecting the environment, e.g. transport systems.[4]

As a consequence of public discussion, new concepts for policies of agriculture and environment interactions have been developed in many countries including an improved public monitoring and responsibility for sustainability. [5] [6]

The Millennium Ecosystem Assessment (MA), launched by U.N. Secretary-General Kofi Annan in June 2001, is an international work programme designed to meet the needs of decision makers and the public for scientific information concerning the consequences of ecosystem change for human well-being and options for responding to those changes. The MA focuses on ecosystem services (the benefits people obtain from ecosystems), how changes in ecosystem services have affected human well-being, how ecosystem changes may affect people in future decades, and response options that might be adopted at local, national, or global scales to improve ecosystem management and thereby contribute to human well-being and poverty alleviation.[7]

Work on agro-environmental indicators provided information on the current state and changes in the conditions of the environment in agriculture. It also resulted in a better understanding of linkages between the causes and impacts of agriculture on the environment, looking at agricultural policy reform, trade liberalization and environmental measures. This all contributes to monitoring and evaluating the effectiveness of policies addressing agri-environmental concerns.[8] A review of empirical work in OECD countries on effects of agricultural policies and practices on the environment is given by OECD.[9] Work on environmental health indicators suggests that various agricultural practices have direct or indirect effects on human health via environmental effects. Hazards can take many forms, wholly natural in origin or derived from human activities and interventions.[10]

1.2 Approaches for environmental protection and values to be protected

In 1992 the Convention on Biological Diversity (CBD, ratified by 188 countries) defined a legally binding instrument for biodiversity protection and sustainable use of biological resources.[11] According to the CBD, biodiversity means "the variability among living organisms from all sources including, *inter alia,* terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part" (CBD, 1992 [12]). The goal of the Convention on Biological Diversity is "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefit arising out of the utilization of genetic resources." The treaty recognized the great value of genetic and biological diversity.

Biological diversity is closely linked to human interests. Biodiversity is highly important for several quite different reasons: the value of species in the wild, the many varieties of plants, animals and microorganisms used for farming and other human activities worldwide, as a genetic resource in healthcare, agriculture and food production. It provides a source of significant economic, aesthetic and cultural benefits. The well-being and prosperity of earth's ecological balance as well as human society depend directly on the extent and status of biological diversity.[13]

Naturalism and nature protection: Some difficulties for environmental protection derive from different interpretations and understanding of the idea of nature. Especially in the consumer's debate on the creation of genetically modified organisms, the idea of the need to protect nature was often not well defined, mainly because of differences in the understanding of the concept of nature, ranging between concepts of wilderness, human environment, flexibility of natural systems[14] and ideas of naturalism.[15] Ethicists try to improve this situation by using clear definitions, whichever school they might come from (Nuffield report).[16]

Levels of protection may vary as goals range from sustaining ecosystem services to fully preserving endangered species or fragile protected areas. Biotic homogenization that decreases regional biotas and functional diversity would reduce resilience by reducing the available range of species-specific responses to such environmental changes as droughts, contaminants, or invasive species.[17] Therefore, different criteria for protection will be needed for different management goals and socio- ecological contexts. The links between environmental protection and human health through the control of direct and indirect health effects of environmental deterioration needs to be factored into these equations, notably with food safety as one of the direct indicators.

2. Emerging new technologies in food production

Following adoption of hybrid breeding technologies further breeding objectives included methods for the introduction of increased genetic variability using several methods for **mutagenesis** such as chemical mutagenesis or irradiation as well as various ways of tissue cultures. The further development resulted in the presently most advanced methods of modern biotechnologies, the production of organism by **genetic modification** using introduction of defined new or recombinant genetic material by vectors and transformation methods. These organisms are typically named Genetically Modified organisms or GM organisms. Improved methodology for the development of GM organisms (GMOs) by homologous recombination may ultimately reduce the potential for unintended effects, including health effects, of the inclusion of new genes randomly in the genome, stemming from present technology. Likewise improved methods for a molecular containment of recombinant genes may reduce problems of unintended gene dispersal.

Conflicting assessments and incomplete substantiation of the benefits, risks and limitations of GM food by various scientific, commercial, consumer and public organizations have resulted in national and international controversy regarding their safe use as food and safe release into the environment. An example is the recent debate on food aid that contained GM material offered to countries in southern Africa in 2002. This international debate has often been focused on human health and environmental safety of these new products.

At present, only a few food crops are permitted for food use and traded on the international food and feed markets. These include herbicide- and insect-resistant maize (*Bt* maize), herbicide-resistant soybeans, rape (canola) oilseed and insect- and herbicide-resistant cotton (primarily a fibre crop, though refined cottonseed oil is used as food). In addition, several government authorities have approved varieties of papaya, potato, rice, squash, sugar beet and tomato for food use and environmental release. Further development of GM crops is likely to produce a range of GM crops with enhanced nutritional profiles[18]. Various novel traits are currently being tested in laboratories and field tests in a number of countries, but are unlikely to enter the market for several years. A significant proportion of these traits relates directly to human health, the beta-carotene (Vitamin-A precursor) rich "golden rice" as the most well-known example. Other examples with health implications are removing allergens and anti-nutrients, altering fatty-acid profiles and increasing the anti-oxidant content. All new products related to such potential health benefits will naturally need to be scrutinized through thorough environmental and food safety risk assessments.

An analysis of risks and effects of food production practices using modern methods of biotechnology needs to reflect on all developments in the area, based on knowledge of modern biology and keeping in mind that the definition of modern biotechnology is often not very standardized.

Integrated pest management (IPM) needs to be seen in the light of modern biotechnology because of the use of advanced bio-technological methods: Definitions of IPM cover a range of approaches: from safe use of pesticides, to elimination of virtually all pesticide use. Suitable pest control methods should be used in an integrated manner and pesticides should be used on an “as needed basis” only, and as a last resort component of an IPM strategy. In such a strategy, the effects of pesticides on human health, the environment, sustainability of the agricultural system and the economy should be carefully considered. According to FAO, IPM programmes are designed to generate independence and increased profits for farmers, and savings on foreign imports for governments. IPM enables farmers to make informed decisions to manage their crops. [19]

Sometimes also **organic farming** is discussed as a modern technology for food production, where farmers adhering to this idea are aiming for similar objectives like IPM but more clearly pronounce the ideas of integrity, self determination and co evolution.[20] Although organic farming will inherently affect the use of agricultural chemicals, the safety considerations related to food derived from these practices do not only contribute positively in the broader health equation.

2.1 Environmental risks related to food production using GM technologies

Principles of the environmental risk assessment, ERA: In many national regulations the elements of the ERA for GM food organisms include the biological and molecular characterizations of the genetic insert, the nature and environmental context of the recipient organism, the significance of new traits of the GMO for the environment, and information on the geographical and ecological characteristics of the environment in which the introduction will take place. The risk assessment focuses especially on potential consequences on the stability and diversity of ecosystems, including putative invasiveness, vertical or horizontal gene flow, other ecological impacts, effects on biodiversity and the impact of presence of GM material in other products. [21]

Internationally the concept of familiarity was developed also in the concept of environmental safety of transgenic plants. The concept facilitates risk/safety assessments, because to be familiar, means having enough information to be able to make a judgment of safety or risk (U.S. NAS, 1989). Familiarity can also be used to indicate appropriate management practices including whether standard agricultural practices are adequate or whether other management practices are needed to manage the risk (OECD, 1993). Work of international organizations on biosafety in summarized chronologically by ICGEP. [22]

Currently the Cartagena Protocol on Biosafety to the Convention on Biological Diversity is the only international regulatory instrument which deals specifically with the potential adverse effects of genetically modified organisms (known as Living Modified Organisms (LMOs) under the Protocol) on the environment. The Biosafety Protocol covers transboundary movements of any genetically modified foods that meet the definition of LMO. Annex III of the Protocol specifies general principles and methodology for risk assessment of LMOs. The Protocol establishes a harmonized set of international rules and procedures designed to ensure that countries are provided with the relevant information, through the information exchange system called "Biosafety Clearing-House". This Internet-based information system enables countries to make informed decisions before agreeing to the import of LMOs. It also ensures that LMO shipments are accompanied by appropriate identification documentation. While the Protocol is the key basis for international regulation of LMOs, it does not deal specifically with GM foods and its scope does not consider GM foods that don't meet the definition of an LMO. Furthermore, the scope of its consideration of human health issues is limited, given that its primary focus is biodiversity, in line with the scope of the Convention itself.

Potential unintended effects of GMOs on non target organisms, ecosystems and Biodiversity: Potential risks for the environment include unintended effects on non target organisms, ecosystems and biodiversity. Insect resistant GM crops have been developed by expression of a variety of insecticidal toxins from the bacterium *Bacillus thuringiensis* (Bt). Detrimental effect on beneficial insects or a faster induction of resistant insects (depending on the specific characteristics of the Bt proteins, expression in pollen and areas of cultivation) have been considered in the environmental risk assessment (ERA) of a number of insect protected GM crops. These questions are considered an issue for monitoring strategies and improved pest resistance management, which inherently can affect food safety in the longer term. WHO/ANPA, 2000 [23] increased doses of herbicide can be applied post emergence to herbicide tolerant crops, thus avoiding routine pre-emergence applications and reducing the number of herbicide applications needed. Under certain agro-ecological situations, such as a high weed pressure, the use of herbicide tolerant crops has resulted in a reduction in quantity of the herbicides used, in other cases no herbicide reductions or even the need of increased herbicide uses have been reported [24].

Out-crossing: Out-crossing of transgenes has been reported from fields of commercially grown GM plants including oilseed rape and sugar beet, and has been demonstrated in experimental releases for a number of crops including rice and maize. Out-crossing could result in an undesired transfer of genes such as herbicide resistance genes to non-target crops or weeds creating new weed management problems. The consequences of out-crossing can be expected in regions where a GM crop has a sympatric distribution and synchronized flowering period, that is highly compatible with a weedy or wild relative species as demonstrated e.g. for rice[25]. In view of the possible consequences of gene flow from GMOs the use of molecular techniques to inhibit gene flow has been considered and is under development.

GM animals: The possibility that certain genetically engineered fish and other animals may escape, reproduce in the natural environment and introduce recombinant genes into wild populations is a concern of a report of a recent US Academy of Science study[26]. Genetically engineered insects, shellfish, fish and other animals that can easily escape, are highly mobile and form feral populations easily, are of concern, especially if they are more successful at reproduction than their natural counterparts. For example, it is possible that transgenic salmon with genes engineered to accelerate growth released into the natural environment could compete more successfully for food and mates than wild salmon, thus endangering wild populations. The use of sterile all-female genetically engineered fish could reduce interbreeding between native populations and farmed populations, a current problem with the use of non-engineered fish in ocean net-pen farming. Sterility eliminates the potential for spread of transgenes in the environment, but does not eliminate all potential for ecological harm. Monosex triploidy is the best existing method for sterilizing fish and shellfish, although robust triploidy verification procedures are essential.[27]

GM microorganisms: Gene transfer between bacteria belonging to different species, genera or even families has been demonstrated in soil and other systems. Such gene transfer goes on between ordinary microorganisms in all ecosystems, and has also been demonstrated from GM microorganisms to other microorganisms, e.g. for antibiotic resistance genes. The transfer of antibiotic genes to microorganisms present in foods and of clinical importance is an unwanted event relative to food safety, while the very low frequency of such transfer most probably leads to very low levels of concern. Only a limited number of releases of GM microorganisms (e.g. *Pseudomonas* and *Rhizobia*) have been permitted mainly to explore the spread and the fate of microorganisms in nature. In some cases released GM bacterial populations have been found to persist in the soil for years. The possible consequences of such on natural communities of soil microorganisms are under investigation Risk assessment in such fields is impeded by a number of factors, such as the limited knowledge of indigenous microorganisms in the environment (only approximately 1 % of soil bacteria are currently taxonomically described), the existence of natural transfer mechanisms between microorganisms, and the difficulties in controlling their spread. (FAO/WHO expert consultation, GMM, 2001)[28]

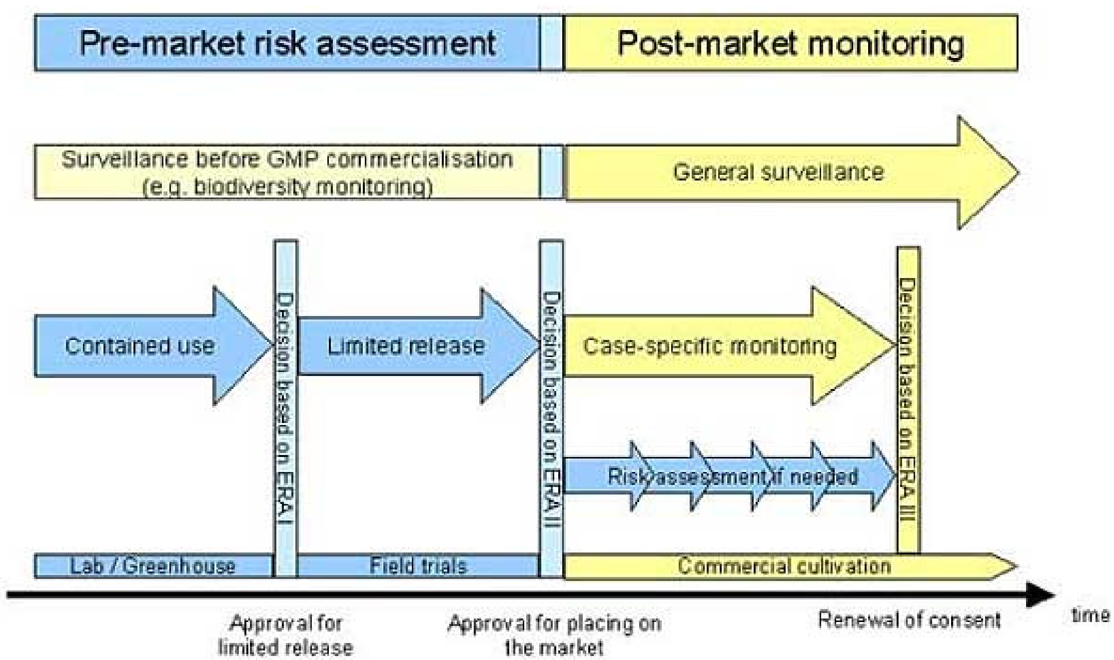
Regional specificity in safety assessments: Contradictory findings as relates benefits or disadvantages for the same GM crop may reflect different agro-ecological conditions in different regions. For example, the use of herbicide resistant crops and the consequent herbicide use could potentially be detrimental in a small sized agricultural area, which has extensive crop rotation and low levels of pest pressure. However, the moderate herbicide use related to these GM plants could be beneficial in other agricultural situations where it might represent a decrease in herbicide use. Presently, no conclusive evidence on environmental advantages or costs can be generalized from the use of GM crops. Consequences may vary significantly between different GM traits, crop types and different local conditions including ecological and agro-ecological characteristics.

In 1999, the UK government asked an independent consortium of researchers to investigate how growing genetically modified (GM) crops might affect the abundance and diversity of farmland wildlife compared with growing conventional varieties of the same crops.[29] The team found that there *were* differences in the abundance of wildlife between GM crop fields and conventional crop fields depending from GM crop specificity and site of analysis, but no general trend for or against GM crops. The researchers stress that the differences they found do not arise just because the crops have been genetically modified. They arise because these GM crops give farmers new options for weed control where they use different herbicides and apply them differently.

Monitoring of human health and environmental safety: In the future specific GM organisms may gain approvals for widespread production where the approval may not always include the possibility to enter them also in the human food supply. Examples could be plants or animals used for drug production. In such situations, it will be important to consider whether or not to apply post-market monitoring for unexpected environmental spread of the GM animals or animals and their transgenes in the event that these would pose food safety hazards.

A prerequisite for any kind of monitoring are tools to identity or trace GMOs or products derived from GMOs in the environment or food-chain. Detection techniques (such as PCR) are in place in a number of countries to monitor the presence of GMOs in foodstuffs, to enable the enforcement of GM labelling requirements and for the monitoring of effects on the environment. Attempts to standardize analytical methods for tracing GMOs have been initiated e.g. for use in ISO norms.

The WHO/FAO Expert Consultation on GM Animals, 2003, identified a need for Post Market Surveillance and therefore for product tracing systems in specific cases.

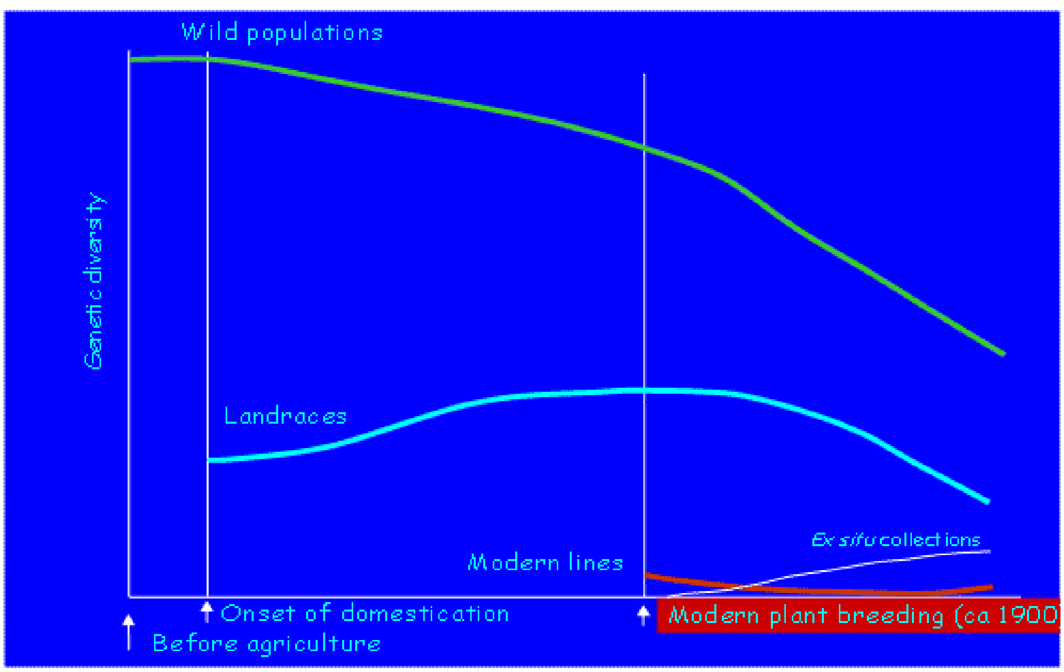


2.3 Potential effect of GMOs on human health mediated through environmental impact

The need to assess indirect effects of the use of GMOs in food production has been emphasized by many countries. Potential environmental health hazards of releases of GMOs in the environment have been discussed in a report by WHO/ANPA where health effects have been suggested as "an integrating index of ecological and social sustainability"[30]. For example, the production of chemicals or enzymes from contained GM micro-organisms (e.g. chemicals, pharmaceutics or food additives), have contributed significantly to decreases in the amount of energy use, toxic and solid wastes in the environment, thereby significantly enhancing human health and development. A further example of beneficial human environmental outcomes of the use of GM crops is the reduction in the use, environmental contamination and human exposure to pesticides demonstrated in some areas. This has been demonstrated especially through the use of pesticide resistant Bt cotton, which has been shown to decrease pesticide poisoning in farm workers[31]. Out-crossing of GM plants with conventional crops or wild relatives, as well as the contamination of conventional crops with GM material, can have an indirect effect on food safety and food security by contamination of genetic resources. [32] The Codex guidelines for the safety assessment of GM foods include the analysis of potential unintended effects, where effects on the environment may result in unintended, indirect effects on human health.[33]

2.4 Modern methods in plant breeding and effects on diversity

Crop breeding strategies are highly dependent upon preservation of diversity of crops and wild relatives. Many methods of conventional and modern biotechnology can interfere with diversity of organisms which have relevance for further breeding. In crops these methods can often concentrate on the further improvement of few elite lines only. The majority of locally adapted land races e.g. will not be propagated further. Also the system for the protection of intellectual property rights interferes with crop diversity. There is growing scientific and public concern about a rapid decline of diversity, e.g. of land races. On the other hand modern methods of biotechnology can be beneficial for enabling diversity in scenarios where possibilities of conventional breeding are difficult because of sterility and pests , e.g. as discussed for bananas. [34]



Historically, plant genetic resources were freely provided by developing countries to gene-banks world-wide. Now international policy attaches importance to national ownership of such resources. An important aspect for the future potential of agricultural research is access to genetic resources for researchers on terms that recognize the contributions made by farmers to the conservation and sustainable utilization of these resources.

The International Treaty on Plant Genetic Resources adopted at a conference by the Food and Agriculture Organization in November 2001, provides the legal framework for dealing with the resources on which food security and sustainable agriculture depend. The Treaty gives a directive on the conservation and sustainable use of plant genetic resources for food and agriculture making provision for the fair and equitable sharing of the benefits arising out of their use, in harmony with the United Nations Convention on Biological Diversity (CBD). The Treaty also addresses farmers' rights.

The Treaty establishes a Multilateral System of Facilitated Access and Benefit-sharing (MLS) for key crops, emphasizing the interdependency of countries in terms of plant genetic resources for food and agriculture. The developing countries rich in genetic resources are encouraged to place germplasm in the MLS. The users of the material will sign a Material Transfer Agreement, incorporating the conditions for access and benefit sharing through a fund established under the Treaty. In return, the owners of the genetic resources would get a share of the benefits arising from their use and development in the way of information, technology transfer and capacity building

3. Interaction between environmental risks, food risks and socioeconomic aspects

The U.S. Agency for International Development reported that between 1975 and the year 2000 the world lost 22 percent of its high-potential agricultural land. That's 600,000 square miles, an area equal in size to Alaska. The loss is alarming because, as population pressures mount, agricultural production will have to expand onto medium- and low-potential lands that are not only less productive but also more fragile and susceptible to degradation. Soil is degraded mainly through deforestation, agricultural activities, overgrazing, and overexploitation. Biophysical manifestations include erosion and loss of moisture-holding capacity. But more important, and more complex, are the social and economic aspects. Indeed, some view land degradation as a socioeconomic rather than biophysical problem. For example, population growth increases demand for land on which to grow crops, which often leads to deforestation, shorter fallow periods, and continuous cropping. Short-sighted economic policies often make the problem worse by encouraging farmers to clear new land for cultivation rather than to protect land already under cultivation. Insecure land tenure arrangements discourage farmers from making long-term investments needed for resource conservation.[35]

The Impacts of trade liberalization: The implementation or reform of agricultural and trade policy creates a complicated set of environmental effects - some negative, some positive, and in some cases linked to food safety issues. The effect of freer agricultural trade on environmental quality depends on a number of factors, such as the mix of post-reform commodities, level of output, changes in production inputs, land use, technical change, and the capacity of the natural resource base to assimilate production impacts. The additional effect of such changes related to food safety will in many cases relate to the existence of food safety systems and experience related to the new or increase food commodity production.

Freer trade improves market access for goods previously governed by quantity restrictions (such as quotas and other non-tariff barriers) and aligns domestic prices closer to world prices. Resource reallocation occurs as prices adjust to market conditions and reflect the availability of resources such as arable land, labour, and other farming inputs. As prices change, farmers respond by altering their crop mix and their input use, buying or selling land, and investing in new machinery. In countries where reform leads to an increase in producer prices, farmers will respond by increasing output, placing more pressure on land use, and/or increasing chemical input uses.[36]

In addition, trade and health considerations are intimately connected. The use of international standards for traded food, focusing on food safety, but in the future also most likely on environmental issues, will have the potential to improve not only internationally traded food but also local food, and thereby the health of local consumers. This in turn would then favour both health and social and economic development - a true win-win situation. The cooperation between international agencies to focus development in these areas is exemplified by the creation of the STDF (Standards in Trade and Development Facility)[37] in a joint effort between WHO, FAO, World Trade Organization, World Animal Health Organization and World Bank. This Facility will hopefully provide the means for developing countries to strengthen their systems to comply with international standards to the benefit of both exported and locally consumed food.

4. Ethical aspects in the assessment of environmental risks

International agreements related to nature and food production are summarized in a report from FAO on ethical issues in food and agriculture. They include the value of food, the value of enhanced well-being, the value of human health, the value of natural resources, and the value of nature, whereas the Convention on Biological Diversity recognizes that nature itself is to be valued for what it is. The summary of these objectives shows that all principle arguments usually discussed in a risk–benefit evaluation of food biotechnology, especially enhanced productivity for increased food production, equity, health and nature protection, interfere with each other, thus requiring a high level of ethical consideration.[38,39]

There is international agreement that risk assessment, risk management and risk communication are central elements in the management of possibly emerging risks of new technologies for food production where risk assessment needs to be done based on "sound science". But discussions on the use of precaution (by some countries referred to as the precautionary principle) and the need to respect legitimate factors other than the scientific assessment of risk have turned out to be controversial[40].

Scientific progress on these issues was made in the FAO Expert Consultation on Food Safety: Science and Ethics Rome, 2002: The experts agreed that risk assessment is based on science, but scientific evidence and analysis cannot always provide immediate answers to questions posed. Much scientific evidence is tentative, as the established processes of science include checking and re checking outcomes in order to obtain the required level of confidence. Decisions usually are defended as based on "science," and sometimes on economic costs and benefits as well, which offer seemingly objective, verifiable evidence that the policy choice is "correct." Decisions explicitly based on ethical principles and value preferences can be just as defensible, if the society agrees broadly on the ethical assumptions used to make policy. The emphasis on science and the exclusion of ethical argument as the basis for decisions may polarize the scientific debate.

A cross sectoral group of scientists, NGOs and industry formulated the safety first approach asking for interactive negotiation between research, industry, government and consumers to formulate safety standards. These standards would make safety a criterion in discussions on developments from the beginning and not at the end before product notification and include post market monitoring, training and stewardship.[41]

The dependence of factors directly relevant for the risk assessment of products of new technologies with socio-economic or ethical factors will be addressed in attempts of an integrated/holistic assessment of possible consequences in an ongoing WHO project.[42] In the FAO/WHO expert consultation on GM animals, Rome 2003, furthermore, an analysis including ethical criteria was proposed using an ethical matrix [43] and recently the principles of beneficence and non-maleficience, justice and fairness as well as choice and self determination were proposed for a structured methodological evaluation. [44]

5. The role of international organizations, capacity building and coordination

Products produced with different methods of modern biotechnology are already produced for local or international markets. Crops, animals or microorganism have been improved according to agricultural objectives where these organisms may display specific characteristics in regard to safety or usefulness in different agro- ecological, socio-economic or cultural areas. A globalized market for food production will most likely trade products of these organisms internationally and the safety measures of the Biosafety Protocol will be of importance in risk prevention. However, possibilities of the protocol are restricted to transboundary movements of LMOs and direct effects on diversity. Furthermore, sufficient technical capacities for coherent analysis may be difficult to achieve in many developing countries and the need for coordinated local as well as international information exchange on complex parameters will require sophisticated technical and scientific capacities. The capacity of the Codex Alimentarius Commission to continue its work on internationally agreed principles and guidelines for a food safety risk analysis framework will be key to a truly global development in this area of integrating the different areas of assessment of new agricultural technologies and ensuring that human health considerations will remain at the core. This will ultimately need measures for capacity building in some countries as well as the intensive engagement of international bodies in coordinated monitoring activities, data collection and data analysis. An engaged cooperation of international organizations, especially UN-bodies will be essential for a successful and equitable development in this direction.

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[1] EC, Agriculture and the Environment, 2003
[2] EC, Agriculture and the environment, 2003
[3] Levitan, L., Merwin, I. and Kovach, J., 1995. Assessing the relative environmental impacts of agricultural pesticides: the quest for a holistic method. *Agriculture, Ecosystems and Environment*. 55 (1995).p 153-158
[4] *National Council for Agricultural Research, The Netherlands,* http://www.agro.nl/nrlo/english/pdf/9804e.pdf
[5] Ervin et al., Environment 1998. http://www.findarticles.com/p/articles/mi_m1076/is_n6_v40/ai_20979662
[6] Baldock et al., environmental integration and the CAP, a report of the E.C.
[7] http://www.millenniumassessment.org/en/about.overview.aspx
[8] OECD Agro- Environmental indicators, http://www.oecd.org/document/6/0,2340,en_2649_33791_1842886_1_1_1_1,00.html
[9] OECD 2002, COM/AGR/CA/ENV/EPOC(2001)60/FINAL
[10] von Schirnding YE. Health-and-environment indicators in the context of sustainable development. World Health OrganizationCan J Public Health. 2002 Sep-Oct; 93 Suppl 1: S9-15
[11] http://www.biodiv.org/world/parties.asp
[12] www.biodiv.org/convention/articles.asp
[13] EFB: Biodiversity: The impact of Biotechnology, briefing paper 2001
[14] http://www.nature.com/nature/journal/v405/n6783/pdf/405228.pdf
[15] http://debate.uvm.edu/NFL/rostrumlib/policy200305bauschard.pdf
[16] http://www.nuffieldbioethics.org/go/browseablepublications/gmcrops/report_238.htr
[17] Olden, J.D. and al., 2004. Ecological and evolutionary consequences of biotic homogenization. Trends in Ecology and Evolution 19:18-24.
[18] The Pew Initiative on Food and Biotechnology, 'Harvest on the horizon: Future uses of agricultural biotechnology', September 2001: http://pewagbiotech.org/research/harvest/harvest.pdf
[19] FAO, integrated pest management : http://www.fao.org/ag/AGP/AGPP/IPM/gipmf/index.htm
[20] Organic: is it the future of farming? Nature, 2004: 428; http://www.nature.com/cgi-taf/DynaPage.taf?file=/nature/journal/v428/n6985/full/428792a_fs.html
[21] Anthony J. Conner, Travis R. Glare, Jan-Peter Nap . The release of genetically modified crops into the environment. Part II. Overview of ecological risk assessment. The Plant Journal (2003) 33, 19–46
[22] http://www.icgeb.org/~bsafesrv/bsflib.htm
[23] WHO, ANPA, 2000 http://www.euro.who.int/foodsafety/Otherissues/20020402_5
[24] 9 Duke SO. Weed Management: Implications of Herbicide Resistant Crops . 2001.
[25] LI JUAN CHEN and BAO-RONG LU*,3 Gene Flow from Cultivated Rice (Oryza sativa) to its Weedy and Wild Relatives *Annals of Botany* 93: 67-73, 2004
[26] National Academy, Animal Biotechnology: Science based concerns, 2002; The Royal Society, 2000. http://www.nap.edu/catalog/10418.html?onpi_topnews082002
[27] WHO/FAO Expert Consultation, GM Animals, 2003
[28] http://www.who.int/foodsafety/publications/biotech/ec_sept2001/en/
[29] UK, Acre; www.defra.gov.uk/environment/gm/fse/results/fse-summary.pdf
[30] World Health Organization/National Agency for the Protection of the Environment. Release of Genetically Modified Organisms in the Environment: Is it a Health Hazard? Report of Joint WHO/EURO-ANPA Seminar (WHO, Rome, Italy) http://www.euro.who.int/document/fos/Fin_rep.pdf (7-9 September 2000).
[31] Prey CE, Huang J, Hu R, and Rozelle S. 2002. Five years of BT cotton in China- the benefits continue. *Plant J.31* 31:423-430.

[32] Alvarez-Morales, A. Transgenes in maize landraces in Oaxaca: official report on the extent and implications. Presented at the 7th International Symposium on the Biosafety of Genetically Modified Organisms http:// www.worldbiosafety.net/paper
[33] Haslberger A., 2003 Nature Biotechnology , 21:739, http://www.alexander-haslberger.at/pdf/CODEX,%20NB.pdf
[34] http://cooltech.iafrica.com/technews/201934.htm
[35] USAID Program and Operations, Assessment Report No. 18
[36] USDA, Agricultural outlook, Dec. 1996
[37] http://www.standardsfacility.org/techdb.htm
[38] FAO, http://www.fao.org/DOCREP/003/X9601E/X9601E00.htm
[39] Center for agriculture, bio- and environmental ethics, http://www.kuleuven.ac.be/cabme/index.php?LAN=E
[40] http://www.consumersinternational.org/document_store/Doc604.pdf
[41] Kapuscinski AR, Goodman RM, Hann SD, Jacobs LR, Pullins EE, Johnson CS, Kinsey JD, Krall RL, La Vina AG, Mellon MG, Ruttan VW., Minnesota Nat Biotechnol. 2003 Jun;21(6):599-601.
[42] WHO, description of WHO study on modern food biotechnology, human health and development http://www.who.int/foodsafety/biotech/who_study/en/
[43] Kaiser, M., http://www.ccels.cardiff.ac.uk/pubs/kaiserpaper.pdf
[44] Gesche A. et al., towards a global code of ethics for modern foods and agricultural biotechnology. In: Tavernier, J. and Aerts S., 2004. Eurosafe, 2004, Science ethics and society, p 125-128. http://www.alexander-haslberger.at/pdf/Food%20ethics.PDF