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# **MEMOIRE DE D.E.A**

## **THEME**

**GENETICALLY MODIFIED ORGANISMS IN  
EUROPE: USE, PRODUCTION, IMPACTS AND  
CHALLENGES IN THE UNITED KINGDOM**

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Dedication

## **Dedication**

☞ This work is dedicated to my dear parents, **Mahouchi Mama** and **Agoh Sowalo**. May they be greatly honoured by this achievement

# Acronyms

## **Acronyms**

**BFSA:** British Food Standards Agency

**Bt:** *Bacillus Thuringiensis*

**CAFO:** Confined Agricultural Feed- Operation

**CBD:** Convention on Biological Diversity

**CFACT:** Committee for a Constructive Tomorrow

**CGIARA:** Consultative Group of International Agricultural Research

**DNA:** Deoxyribo Nucleic Acid

**ECDGRI:** European Commission Directorate General for Research and  
Innovation

**EPA:** United States Environmental Protection Agency

**FAO:** Food and Agriculture Organization

**FDA:** Food and drug administration

**FFDCA:** Federal Food, Drug, and Cosmetic Act

**GE:** Genetically Engineered

**GMF:** Genetically Modified Foods

**GMOs:** Genetically Modified Organisms

**IFBC:** International Food Biotechnology Council

**ILSI:** International Life Sciences Institute

**IPCS:** International Program on Chemical Safety

**IPM:** Integrated Pest Management

**IPPC:** International Plant Protection Convention

**ISAAA:** International Service for the Acquisition of Agri-Biotech Applications

**NOAEL:** No Observed Adverse Effect Level,

**OECD:** Organization for Economic Cooperation and Development

**PG:** Polygalacturonase

**RTD:** Research, Technological development and demonstration activities

**CGIAR:** Consultative Group of International Agricultural Research

**TPA:** Tissue Plasminogen Activator

**U.K:** United Kingdom

**UNECA:** United Nations Economic Commission for Africa

**WHO:** World Health Organization

**IFBC:** International Food Biotechnology council

**CGIAR:** Consultative Group of International Agricultural Research

**IPPC:** International Plant Protection Convention

**APHIS:** Animal and Plant Health Inspection Service

**USDA:** United States Department of Agriculture

**EFSA:** European Food Safety Authority

**OGTR:** Office the Gene Technology Regulator

**OAGEBA:** Office of Agricultural Genetic Engineering Biosafety  
Administration

**COMESA:** Common Market for Eastern and South Africa

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# Introduction

## **Introduction**

Genetic engineering of food is the science which involves deliberate modification of the genetic material of plants or animals. It is an old agricultural practice carried on by farmers since early historical times, but recently it has been improved by technology. Many foods consumed today are either genetically modified whole foods, or contain ingredients derived from gene modification technology. Despite the potential benefits of genetic engineering of foods, the technology is surrounded by controversy. Critics of GM technology include consumers and health groups, grain importers from European Union countries, environmentalists, concerned scientists, ethicists, food advocacy groups, some politicians, protectionists etc. Some of the specific fears expressed by opponents of GM technology include alteration in nutrition quality of food, potential toxicity and possible antibiotic resistance from GM crops, from consuming GM foods. Benefits presented by proponents of GM technology include improvement in fruit and vegetable shelf life and organoleptic quality, improved nutritional quality and health benefits in foods, improved protein and carbohydrate content of foods, improved fat quality, improved quality and quantity of meat, milk and livestock. Other potential benefits are: the use of GM livestock to grow organs for transplant into humans, increased crop yield, improvement in agriculture through breeding insect, pest, disease, and weather resistant crops and herbicide tolerant crops, use of GM organism in drug manufacture, in recycling or removal of toxic industrial wastes. That means that the development of genetically modified organisms has followed a number of essential directives which are the improvement in the characteristics of plants, the improvement in the qualitative of the plants, the composition of the final product in one hand and the improvement in animal performance and rearing conditions and the improvement in the characteristics of foods derived from animals.

Therefore, genetically modified organisms have many potential beneficial uses, such as better and larger supplies of food and advances in health care. As with any technology, it is important to make sure that there are no significant risks to mankind and the environment. This experience has been done through the Environment protection Act 1990 and subsequent regulations. And the advice on all application to release or market GMOs has been provided by Britain statutory advisory committee. Britain also participated in drawing up draft in international guidelines on safety in biotechnology by supporting the development of a safety protocol to the convention on biological diversity, which would focus on transboundary movement of living modified organisms. But the potential risks and benefits of the new technology to man and the environment are reviewed. Ways of minimizing potential risks and maximizing the benefits of GM foods are suggested.

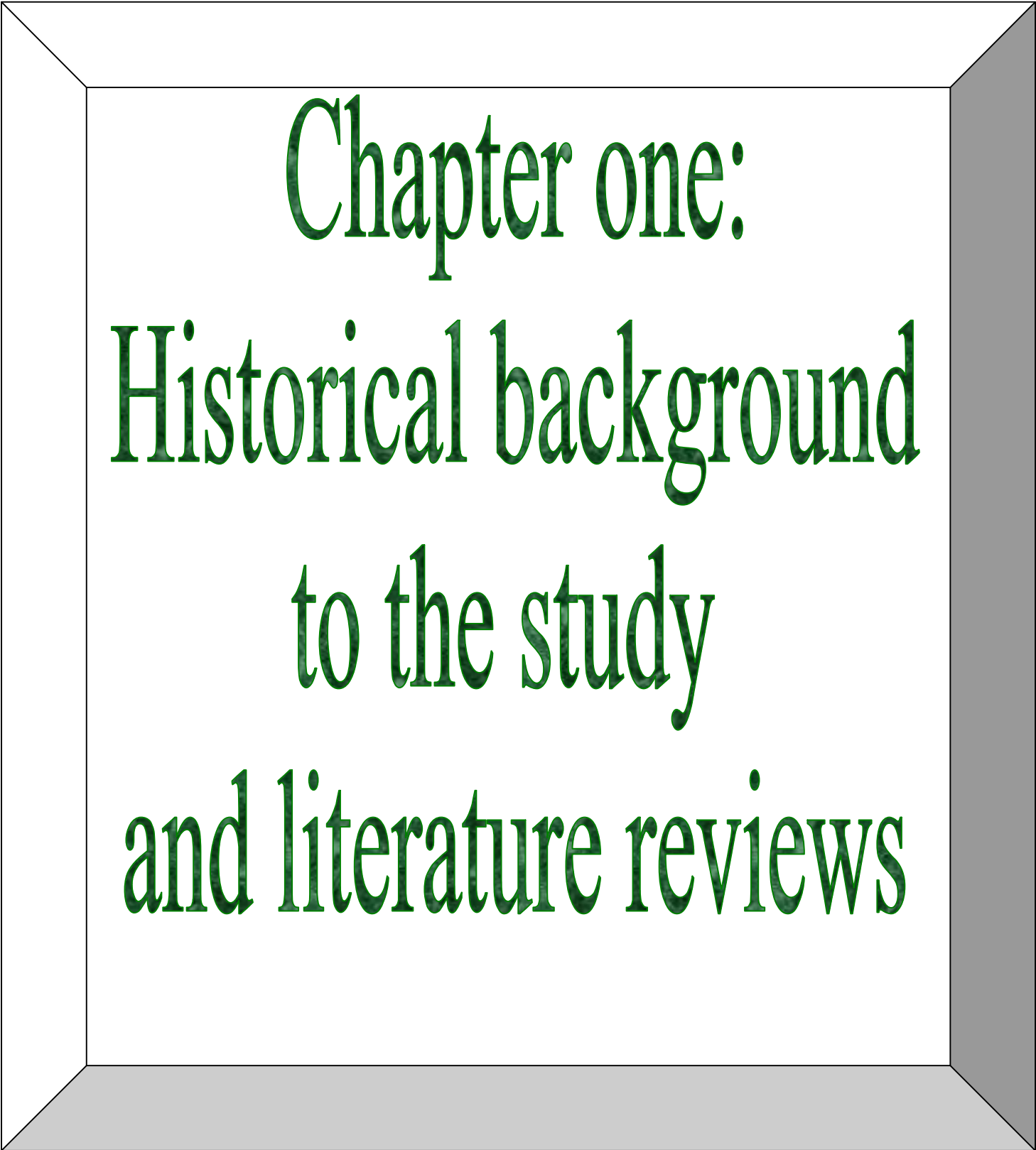
The quality of life and management of living resources", the improvement in the quality of life and health of European citizens are of stringent important. Accordingly, research efforts are thus directed at the improvement of the quality of food. In order to qualitatively improve human nutrition, the study of the genome becomes crucial and the social sciences can contribute to a better understanding of the changing consumer demands for better quality food. The key action of the Quality of life programme (Food, nutrition and health) has thus the following fundamental objectives: to satisfy the needs of consumers and to reinforce the competitiveness of the European food industry, to guarantee food security and integrity, to understand the role of nutrition for health and well-being (including the benefits of GM foods).

But these considerations were not the case in the early days of the European Community, when priorities were rather linked to market needs rather than societal needs.

In this light, a scientific study has been interested on: "**genetically modified organisms in Europe: use, production, impacts and challenges in the United Kingdom**" to see the top of their main policies, the measures and strategies implemented by the British government and the society to deal with genetically modified organisms.

This research work deals with a selected documentary research; second, a methodical documentary research added to websites visit will help collect an appropriate information and data structure on matters of genetically modified organisms in the United Kingdom.

The work is divided into four main chapters. Chapter one deals with the historical background of the study and literature review; chapter two focuses on institutional framework and strategies of genetically modified organisms; chapter three talks about GM safety evaluations and results and chapter four tackles the philosophical approach and dimensions; measures and suggestions on GMOs consequences.



Chapter one:  
Historical background  
to the study  
and literature reviews

## **HISTORICAL BACKGROUND TO THE STUDY AND LITERATURE REVIEWS**

### **1-1 HISTORICAL BACKGROUND TO THE STUDY AND TO THE PROBLEM**



#### **In 1974 Rudolf Jaenisch created the first GM animal**

The general principle of producing a GMO is to add new genetic material into an organism's genome. This is called genetic engineering and was made possible through the discovery of DNA and the creation of the first recombinant bacteria in 1973; an existing bacterium *E. coli* expressing an exogenic *Salmonella* gene. This led to concerns in the scientific community about potential risks from genetic engineering, which was first discussed in depth at the Asilomar Conference in 1975. One of the main recommendations from this meeting was that government oversight of recombinant DNA research should be established until the technology was deemed safe. Herbert Boyer then founded the first company to use recombinant DNA technology, Genentech, and in 1978 the company announced creation of an *E. coli* strain producing the human protein insulin. But in 1986, field tests of bacteria genetically engineered to protect plants from frost damage (ice-minus bacteria) at a small biotechnology company called Advanced Genetic Sciences of Oakland, California, were repeatedly delayed by opponents of biotechnology. In the same year, a proposed field test of a microbe genetically engineered for a pest resistance protein by Monsanto Company was dropped. In the late 1980s and early 1990s, guidance

on assessing the safety of genetically engineered plants and food emerged from organizations including the FAO and WHO.

In addition, small-scale experimental plantings of genetically modified (GM) plants began in Canada and the U.S. in the late 1980s. The first approvals for large-scale, commercial cultivation came in the mid 1990s. Since that time, adoption of GM plants by farmers has increased annually. GMOs are used in biological and medical research, production of pharmaceutical drugs, experimental medicine (e.g. gene therapy), and agriculture (e.g. golden rice). Furthermore, the term "genetically modified organism" does not always imply, but can include, targeted insertions of genes from one species into another.

To date, the most controversial but also the most widely adopted application of GMO technology is patent-protected food crops that are resistant to commercial herbicides or are able to produce pesticidal proteins from within the plant, or *stacked trait* seeds, which do both. The largest share of the GMO crops planted globally is owned by the United States firm Monsanto. In 2007, Monsanto's trait technologies were planted on 246 million acres (1,000,000 km<sup>2</sup>) throughout the world, a growth of 13 percent from 2006. However, patents on the first Monsanto products to enter the marketplace will begin to expire in 2014, democratizing Monsanto products. In addition, a 2007 report from the European Joint Research Commission predicts that by 2015, more than 40 percent of new GM plants entering the global market place will have been developed in Asia. On February 6, 2009, the U.S. Food and Drug Administration approved the first human biological drug produced from such an animal, a goat. The drug, ATryn, is an anticoagulant which reduces the probability of blood clots during surgery or childbirth. It is extracted from the goat's milk.

## 1-2- LITERARY VIEWS AVAILABLE

Many authors have devoted their writings on genetically modified organisms among which, Anne Ingeborg Mhyr and Terje Traavik who wrote the book titles *Sustainable Development and Norwegian Genetic engineering regulations: Applications, impacts, and challenges*. The main purpose of their writings is to enforce containment of genetically modified organisms and control of GMOs should take place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without detrimental effects to health and the environment. Hence it is obvious that, for the Norwegian authorities, sustainable development is a normative guideline when evaluating acceptable consequences of GMO use and production. In accordance with this, we have investigated the extent to which the sustainability criteria were decisive for the destiny of one approved and one declined application of genetically modified plant release. The present understanding of the ecological, socio-economical, and cultural consequences of GMO use and release is fragmentary and uncertain. We consider the Precautionary Principle and the notion of equitable distribution as key issues within the sustainable development framework, hence constituting important foundations for our analyses. The Act is legitimizing sustainable criteria, but does not seem to secure their conversion into concrete action. We envisage a more conscious implementation of the Norwegian Gene Technology Act. Sustainability concerns ecological, economical and social values can be ensured through longterm thinking, initiation of independent risk associated research, and broad involvement of all stakeholders in the evaluation of GMO issues and concerns. The adequacy of such measures is, however, to be judged against the background of calls at the highest level for an entrepreneurial community to participate more fully in the biotechnology revolution.

### **1-3- CRITICISM OF GENETICALLY MODIFIED ORGANISMS**

While it is evident that there is a food supply issue the question is whether GM can solve world hunger problems, or even if that would be the best way to address the issue.

Several scientists argue that in order to meet the demand for food in the developing world, a second Green Revolution with increased use of GM crops is needed. Others argue that there is more than enough food in the world and that the hunger crisis is caused by problems in food distribution and politics, not production. Recently some critics and environmentalists have changed their minds on the issue with respect to the need for additional food supplies. Further, it has been widely noted that there are those who consider over-population the real issue here, and that food production is adequate for any reasonable population size.

“Genetic modification is analogous to nuclear power: nobody loves it, but climate change has made its adoption imperative,” says economist Paul Collier of Oxford University. "Declining genetic modification makes a complicated issue more complex. Genetic modification offers both faster crop adaptation and a biological, rather than chemical, approach to yield increases."

On the other hand, many believe that GM food has not been a success and that we should devote our efforts and money into another solution. “We need biodiversity intensification that works with nature’s nutrient and water cycles, not against them,” says Vandana Shiva, the founder of Navdanya, the movement of 500,000 seed keepers and organic farmers in India, who argue that GMFs have not increased yields. Recently, Doug Gurian-Sherman, a member of the Union of Concerned Scientists, a nonprofit science advocacy group, published a report called “Failure to Yield”, in which he stated that in a nearly 20 years record, genetically engineered crops have not increased yields substantially of food and livestock feed crops in the United States.

Some claim that genetically modified food help farmers produce, despite the odds or any environmental barriers. “While new technology must be tested before it is commercially released, we should be mindful of the risks of not releasing it at all,” says Per Pinstrup-Andersen, professor of Food, Nutrition and Public Policy at Cornell University. Per Pinstrup-Andersen argues, “Misguided anti-science ideology and failure by governments to prioritize agricultural and rural development in developing countries brought us the food crisis.” He clearly states the challenge we face is not the challenge of whether we have enough resources to produce, but whether we will change our behavior.

The genetically modified foods controversy is a dispute over the relative advantages and disadvantages of genetically modified food crops and other uses of genetically-modified organisms in food production. The dispute involves biotechnology companies, governmental regulators, non-governmental organizations and scientists. The dispute is most intense in Japan and Europe, where public concern about GM food is higher than in other parts of the world such as the United States. In the United States, GM crops are more widely grown and the introduction of these products has been less controversial.

The key areas of political controversy related to genetically engineered food are food safety, the effect on natural ecosystems, gene flow into non GE crops and corporate control of the food supply. While it is not possible to make general statements on the safety of all GM foods, to date, no adverse health effects caused by products approved for sale have been documented, although two products failed initial safety testing and were discontinued, due to allergic reactions. Most feeding trials have observed no toxic effects and saw that GM foods were equivalent in nutrition to unmodified foods, although a few non-peer-reviewed reports speculate physiological changes to GM food. Although there is now broad scientific consensus that GE crops on the market are safe to eat, some scientists and advocacy groups such as Greenpeace and World

Wildlife Fund call for additional and more rigorous testing before marketing genetically engineered food.

#### **1-4- "TERMINATOR" AND "TRAITOR"**

An often-cited controversy is a "Technology Protection" technology dubbed 'Terminator'. This uncommercialized technology would allow the production of first-generation crops that would not generate seeds in the second generation because the plants yield sterile seeds. The patent for this so-called "terminator" gene technology is owned by *Delta and Pine Land Company* and the United States Department of Agriculture. Delta and Pine Land was bought by Monsanto Company in August 2006. Similarly, the hypothetical trait-specific Genetic Use Restriction Technology, also known as 'Traitor' or 'T-GURT', requires application of a chemical to genetically modified crops to reactivate engineered traits. This technology is intended both to limit the spread of genetically engineered plants, and to require farmers to pay yearly to reactivate the genetically engineered traits of their crops. Genetic Use-Restriction Technology is under development by companies including Monsanto and AstraZeneca. In addition to the commercial protection of proprietary technology in self-pollinating crops such as soybean (a generally contentious issue), another purpose of the terminator gene is to prevent the escape of genetically modified traits from cross-pollinating crops into wild-type species by sterilizing any resultant hybrids. Some environmentalist groups, while considering outcrossing of GM plants dangerous, feel the technology would prevent re-use of seed by farmers growing such terminator varieties in the developing world and is ostensibly a means to exercise patent claims. However, other environmental groups welcome the terminator gene as a means of preventing GM crops from mixing with natural crops.

Hybrid seeds were commonly used in developed countries long before the introduction of GM crops. Some hybrid crop seeds cannot be saved, so

purchasing new seed every year is already a standard agricultural practice for a majority of farms.

## **1-5- CONCEPTUAL CLARIFICATION**

Food Security has become a key issue for governments the world over with growing fears that there will be mass starvation due to an increasing world population and crop losses attributed to climate change.

Over 850 million people are suffering from chronic hunger due to extreme poverty and 2 billion people lack food intermittently due to varying degrees of poverty as published by the Food and Agriculture Organization of the United Nations. This makes the issue of food security a reality for most governments on earth. Finding a solution is thus a priority for any government that wishes to stay in power or who cares about the welfare of their people.

The first and most obvious solution would be to reduce population growth and thus also the demand for food. This would require extensive education and a shift in cultural norms which are entrenched in our society, this approach is long term and would require ongoing reinforcement across all cultures to have a significant impact. Governments simply do not have the time to invest in such long term programmes, regardless of the end result.

It is human nature to find the easy way out and the issue of food security is no different. Through advances in science and technology the problem seemed to be solved by genetically modified foods. Genetically modified organisms are created by altering the DNA of an organism, in this case a food producing plant; this is done in order to change the characteristics of the plant. Through this process of genetic engineering a plant can be made to produce a higher yield, be more resistant to pesticides, require less water and still be fast growing etc. The problem of food security seemed to be solved by producing plants which produce more food and are resistant to pests, so with very little testing and no

real case studies and field trials, genetically engineered seeds began to be produced to grow Genetically modified crops.

An American company called Monsanto took the lead and became the largest producer of GM seeds as well as their famous herbicide called 'Roundup'. Monsanto made the winning combination; a very successful weed killer and their GM seeds, which are tolerant to their herbicide. However, the one question that had yet to be answered was, "what are the long term effects of GMO foods and the extensive use of pesticides?" There are several issues that have come to light as potential hazards to people and the environment due to the production of GMO foods: GMO foods are harmful to the Human body, not only is there concern that they will create an environment where bacteria themselves can become drug resistant, thus the creation of super bacteria and viruses, they also increase the risk of cancer and precancerous growths. But here again scientific testing is lacking as the whole GMO process was fast tracked.

GM crops are a threat to wildlife: due to the fact that GM plants are made to be resistant to chemical weed and pest controls, farmers tend to use high doses of these chemicals to control pests, thus increasing the impact on non-target wildlife. Furthermore, the increased use of these chemicals will eventually produce super weeds and pests as they naturally adapt and these life forms become more resistant to the chemical. In addition, the wide spread application of these chemicals kills naturally occurring insects which are a crucial part of the pollination process for indigenous plant species. Already farmers are noticing a drastic decrease in natural pollinators which is endangering entire ecosystems. Herbicide resistant crops could accumulate more toxic substance as the absorption of these chemicals does not necessarily kill the plant. In other words GM plants can remain alive and grow with much higher levels of chemicals present. There has been no study to determine the seriousness of this issue. Bioaccumulation could also occur in animals fed on GM feed, this includes people.

The most serious of these issues is the fact that farmers cannot harvest seeds from their GM crops, these crops have to be replanted every year.

Monoculture farming (intensive single crop farming) as a whole creates some environmental effects that are worth mentioning. In general, farming practice applies artificial fertilizer to increase yields. These fertilizers contain nutrients for the crops, namely nitrogen and phosphate, through over application and run off, some of these nutrients are washed with rain and ground water into rivers and eventually the ocean. In an effort to solve some of the global environmental issues, environmentalists and scientists sometimes create long term problems while solving short term pressures. In the haste to solve very public, social, ethical issues; potential solutions are fast tracked and are often not fully investigated. A couple of examples are energy efficient light bulbs (Compact Florescent Lights) and bio-fuel. This brings us back to GM foods; with very little testing and with the tests that were conducted showing evidence that GMO's could be harmful to human health, have we created another "quick fix" solution that could come back to haunt mankind?

As mentioned previously, one of the most serious issues other than the potential health risk is the fact that farmers cannot harvest seeds from their GM crops. These crops have to be replanted every year using new GM seeds. Now this really violates the concept of food security. How secure is our food source if most of it is engineered and can't be regrown year after year. New seeds have to be bought each season and these seeds are by no means inexpensive. This means that farmers, both large scale agriculture and small subsistence farmers, become utterly reliant on companies, such as Monsanto, whose primary motive is profit. These companies have cleverly engineered a solution which ensures a continued demand for their product, all under the guise of food security. Enabling them to establish a monopoly and dictate the price of their GM seeds leaving farmers and the population at large at their mercy.

When we look at a cross section of those who are most affected by reckless and greedy corporations it is more often than not the poor. When this is viewed globally the same applies, it is the third world countries that are the most exposed. The Earth Organization has chapters all over Africa and therefore we often see the results of unethical business practise on the African continent. One thing that has become clear in our work is that Africa is very exposed to corporate exploitation. Many of the poorer countries do not have an international voice. Ghana is the focus of logging companies, Zambia and Namibia have been mined relentlessly often with little regard for the environmental impact of the mining process.

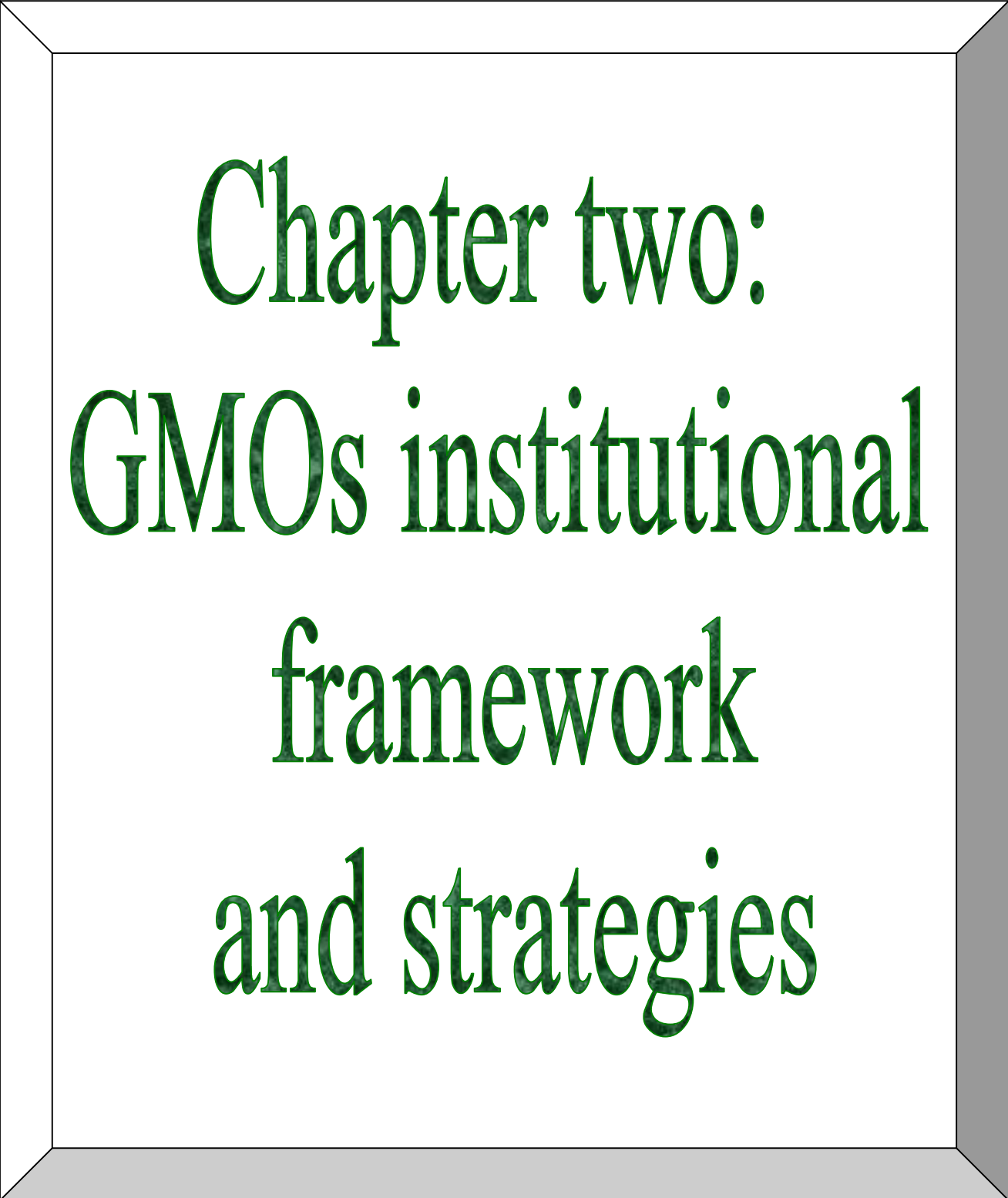
These are just a few examples of what occurs on our continent. The question is, "how do we handle this?" As environmentalists it is their job to find ways to solve these challenges, but how do we take on big corporations all over

Africa and force them to conduct their business in an ethical manner. Well perhaps it is time to change this from a position of enforcement to a position of empowerment. How easy would it be to violate the environment of an educated public? In solving the challenge we have to discover a method that is sustainable and simply to implement.

## **1-6- IMPOWERISHED NATIONS**

Some groups believe that impoverished nations will not reap the benefits of biotechnology because they do not have easy access to these developments, cannot afford modern agricultural equipment, and certain aspects of the system revolving around intellectual property rights are unfair to "undeveloped countries". For example, The Consultative Group of International Agricultural Research is an aid and research organization that has been working to achieve sustainable food security and decrease poverty in undeveloped countries since its formation in 1971. In an evaluation of CGIAR, the World Bank praised its

efforts but suggested a shift to genetics research and productivity enhancement. This plan has several obstacles such as patents, commercial licenses, and the difficulty that third world countries have in accessing the international collection of genetic resources and other intellectual property rights that would educate them about modern technology. The International Treaty on Plant Genetic Resources for Food and Agriculture has attempted to remedy this problem, but results have been inconsistent. As a result, "orphan crops", such as teff, millets, cowpeas, and indigenous plants, are important in the countries where they are grown, but receive little investment.



Chapter two:  
GMOs institutional  
framework  
and strategies

## **GMOS INSTITUTIONAL FRAMEWORK AND STRATEGIES**

### **2-1- INSTITUTIONAL BODIES INVOLVED IN THE FIELD: FAO/WHO**

FAO and WHO have been organizing workshops and consultations on the safety of GMOs since 1990. At the Joint FAO/WHO Consultation in 1996 (FAO/WHO, 1996) it was recommended that the safety evaluation should be based on the concept of substantial equivalence, which is ‘a dynamic, analytical exercise in the assessment of the safety of a new food relative to an existing food’. The following parameters should be considered to determine the substantial equivalence of a genetically modified plant: molecular characterization; phenotypic characteristics; key nutrients; toxicants; and allergens. The distinction between three levels of substantial equivalence (complete, partial, non-) of the novel food to its counterpart, and the subsequent decisions for further testing based upon substantial equivalence, are similar to those defined by OECD. The Codex Alimentarius Commission of FAO/WHO is committed to the international harmonization of food standards. Food standards developed by Codex Alimentarius should be adopted by the participating national governments. The Codex *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology has the task to develop standards, guidelines and other recommendations for genetically modified foods. During its first session in Chiba (Japan) in March 2000 (FAO/WHO, 2000a), definitions were agreed concerning the ‘risk assessment’ and ‘risk analysis’ of genetically modified foods. Risk assessment covers issues such as food safety, substantial equivalence and long-term health effects, while risk analysis may include decision-making and post-market monitoring.

An Expert Consultation held in Geneva, Switzerland in May/June 2000 evaluated experiences gathered since the 1996 Consultation. Topics considered included substantial equivalence, unintended effects of genetic modification,

food safety, nutritional effects, antibiotic resistance marker genes, and allergenicity.

The Consultation endorsed the concept of substantial equivalence as a pragmatic approach for the safety assessment of genetically modified foods, and concluded that at present no suitable alternative strategies are available. Application of the concept is a starting point for safety assessment, rather than an end-point. It identifies similarities and possible differences between the genetically modified food and its appropriate counterpart, which should then be assessed further (FAO/WHO, 2000b).

The issue of the potential occurrence of unintended effects due to the genetic modification process, such as the loss of existing traits or the acquisition of new ones, was examined. The occurrence of unintended effects is not unique for the application of recDNA techniques, but also occurs frequently in conventional breeding. Present approaches to detecting such effects focus on chemical analysis of known nutrients and toxicants (targeted approach). In order to increase the possibility of detecting unintended effects, profiling/fingerprinting methods are considered useful alternatives (non-targeted approach). This is of particular interest for plants with extensive modifications of the genome (second generation of genetically modified foods) where chances of the occurrence of unintended effects may increase.

The Expert Consultation noted that, in general, very little is known about the potential long-term effects of any foods, and that identification of such effects may be very difficult, if not impossible, due to the many confounding factors and the great genetic variability in food-related effects among the population. Thus the identification of long-term effects specifically attributable to genetically modified foods is highly unlikely. Epidemiological studies are not likely to identify such effects given the high background of undesirable effects of conventional foods. The Consultation was of the opinion that pre-market

safety assessment already gives an assurance that genetically modified foods are as safe as their conventional counterparts.

Experimental studies, such as randomized controlled human trials, if properly performed, might provide additional evidence for human safety in the medium to long term.



**A consultation of experts convened at FAO in January 2005 has recommended that any responsible deployment of Genetically Modified crops needs to comprise the whole technology development process, from the pre-release risk assessment, to biosafety considerations and post release monitoring.**

Genetically modified organisms are here to stay. Scientists in both public and private sectors clearly regard genetic modification as a major new set of tools, while industry sees GMOs as an opportunity for increased profits. Yet the public in many countries distrusts GMOs, often seeing them as part of globalization and privatization, as being "anti-democratic" or "meddling with evolution". In turn, governments often lack coherent policies on GMOs, and have not yet developed and implemented adequate regulatory instruments and infrastructures. As a result, there is no consensus in most countries on how biotechnology and GM crops in particular, can address key challenges in the food and agricultural sector. FAO recognizes both the great potential, and the complications, of these new technologies.

Louise. O. Fresco Assistant-Director General, FAO Agriculture Department and Professor at the University of Amsterdam, focusing on sustainability and international development says: ‘ we need to move carefully, with a full understanding of all factors involved. In particular, we need to assess GMOs in terms of their impact on food security, poverty, biosafety and the sustainability of agriculture. GMOs cannot be seen in isolation, simply as technical achievements’’. For this reason, FAO has been conducting a worldwide inventory of agricultural biotechnology applications and products, with special reference to developing countries. Preliminary findings indicate that the total area cultivated with GMO crops stands at about 44.2 million hectares, up from 11 million hectares just three years ago. About 75% of this area is in industrialized countries. Substantial plantings largely concern four crops: soybean, maize, cotton and canola. About 16% of the total area planted to these crops is now under GM varieties, and two traits - insect resistance and herbicide tolerance - dominate. There are also small areas of potato and papaya, with inserted genes for delayed ripening and virus-resistance.

Only seven developing countries cultivate GMO crops commercially, with most of the areas involved (except in Argentina and China) being smaller than 100,000 hectares. Here again, the dominant crops are soybean and cotton, and the traits are herbicide tolerance and insect resistance. Only China is using a locally developed and commercialized GM crop (cotton). Throughout the world, several thousand GMO field tests have been conducted or are under way, again mostly in industrialized countries. Some 200 crops are currently under field testing in developing countries, the vast majority (152) in Latin America, followed by Africa (33) and Asia (19). Many more countries are involved than the seven that have already released GMOs, and many more crop-trait combinations are being investigated, with greater focus on virus resistance, quality and, in some cases, tolerance to abiotic stresses.

It can therefore be expected that the number of GMOs ready for commercial release in these countries will expand considerably in the next few years. However, many important crops - such as pulses, vegetables, and fodder and industrial crops and certain traits - such as drought- and aluminum-tolerance - are still almost entirely neglected.

As the portfolio of GM applications increases, the international community needs to ensure that GM crops make an optimal contribution to world food security, to food safety and food quality, and to sustainability, and that they remain available to the public at large. However, despite some hopeful signs, FAO's inventory suggests that genomics and related research are not being directed to meeting these key challenges. Indeed, the perceived profit potential of GMOs has already changed the direction of investment in research and development, in both the public and private sectors, away from systems-based approaches to pest management, and towards a greater reliance on monocultures. The possible long-term environmental costs of such strategies should not be overlooked. Developing transgenic crops implies massive investments, and the need for massive returns. The small number of GM technologies currently in use suggests that there is a real danger that the scale of the investment may lead to selective concentration on species and problems of global importance, and concomitant capital inertia. At the same time, there is a growing use of "hard" intellectual property rights over seeds and planting material and the tools of genetic engineering. This changes the relationship between the public and private sectors, to the detriment of the former. But a policy question that governments must take up, in both the national and international contexts, is how to ensure that public research does not become a "poor relation". In developing countries in particular, it is important for the public sector to retain enough capacity, resources and freedom of action to provide the services on which their national private sectors can build.

They will also need to build their policy and regulatory capacities with regard to transgenic crops that originate elsewhere. In this area, the International Plant Protection Convention is establishing practical cooperation with the Convention on Biological Diversity and its Biosafety Protocol. It is also developing a detailed standard specification for an International Standard for Phytosanitary Measures that identifies the plant pest risks associated with Living Modified Organisms, and ways of assessing these risks. Another issue of concern to FAO is access to research and new technologies for developing countries, poor producers and consumers. Biotechnology in agriculture is applied to genetic resources that are the fruit of selection and development by farmers throughout the world since the Neolithic age. This poses the immediate question of how to guarantee continued access by farmers and breeders. A major step forward is the International Undertaking on Plant Genetic Resources, which aims at creating a multilateral system of facilitated access and benefit-sharing for the world's key crops. Multilateral access provides multilateral benefit-sharing, which includes the sharing of the benefits arising from the commercialization of materials from the multilateral system through a mandatory payment. The access of breeders to genetic material for further breeding - which becomes ever more difficult with GM crops under patents - is a public good that needs to be protected. On this issue, FAO is involved in discussions on food and agriculture and IPRs in association with the World Intellectual Property Organization.

While genetic modification has increased production in some crops, the evidence suggests that the technology has so far addressed too few challenges, in few crops of relevance to production systems in developing countries. Even in developed countries, a lack of perceived benefits for consumers, and uncertainty about their safety, have limited their adoption.

The scale of investment involved, and the attraction of advanced science, may distort research priorities and investment. But Genetic modification is not a good in itself, but a tool integrated into a wider research agenda, where public and private science can balance each other. Steering research in the right direction and developing adequate, international agreements on safety and access is a difficult and responsible task. While we are more aware than ever of the need to manage international public goods responsibly, the political tools to do so are weak, and, in a globalized economy, the voices of small countries and poor producers and consumers often go unheard. If research is to address the challenges in agriculture, we need to put genetic modification in context, and realize that it is but one of the many elements of agricultural change. Scientists must not be blinded by the glamour of cutting-edge molecular science for its own sake. Governments must not let this glamour, or private industry's perception of major profit opportunities, draw investment away from research in other, more traditional fields, such as water and soil management or ecology, and from public sector research. At the same time, the best science is developed in a climate of intellectual freedom without much direct government interference. It will be a difficult balance to strike!

International consensus has been reached on the principles regarding evaluation of the food safety of genetically modified plants. 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 end point of the assessment.

Consensus on practical application of the principle should be further elaborated. Experiences with the safety testing of newly inserted proteins and of whole genetically modified foods are reviewed, and limitations of current test methodologies are discussed. The development and validation of new profiling methods such as DNA microarray technology, proteomics, and metabolomics for the identification and characterization of unintended effects, which may occur as a result of the genetic modification, is recommended. The assessment of the allergenicity of newly inserted proteins and of marker genes is discussed. An issue that will gain importance in the near future is that of post-marketing surveillance of the foods derived from genetically modified crops. It is concluded, among others that, that application of the principle of substantial equivalence has proven adequate, and that no alternative adequate safety assessment strategies are available.

## **2-2- REGULATIONS AND STRATEGIES**

The USA is the largest commercial grower of genetically modified crops in the world. For a genetically modified organism to be approved for release it is assessed by the Animal and Plant Health Inspection Service agency within the United States Department of Agriculture , the Food and Drug Administration and the Environmental Protection Agency . The USDA evaluated the plants potential to become weeds, the FDA reviewed plants that could enter or alter the food supply and the EPA regulated the genetically modified plants with pesticide properties. Most developed genetically modified plants are reviewed by at least two of the agencies, with many subject to all three. Final approval can still be denied by individual counties within each state. In 2004, Mendocino County, California became the first and only county to impose a ban on the "Propagation, Cultivation, Raising, and Growing of Genetically Modified Organisms", the measure passing with a 57% majority.

The European Union has possibly the most stringent GMO regulations in the world. All GMOs, along with irradiated food, are considered "new food" and subject to extensive, case-by-case, science based food evaluation by the European Food Safety Authority. The EFSA reports to the European Commission who then draft a proposal which if accepted will be adopted by the EC or passed on to the Council of Agricultural Ministers. There is also a safeguard clause that Member States can invoke to restrict or prohibit the use and/or sale of a GMO within their territory if they have a justifiable reason to consider that the approved GMO constitutes a risk to human health or the environment. In February 2008 the French government used the safeguard clause to ban the cultivation of MON810 after Senator Jean-François Le Grand, chairman of a committee set up to evaluate biotechnology, said there were "serious doubts" about the safety of the product (although this ban was declared illegal in 2011 by the European Court of Justice and the French Conseil d'État. In April 2009 German Federal Minister Ilse Aigner announced an immediate halt to cultivation and marketing of MON810 maize under the safeguard clause. Currently (2010) the only GMO food crop with approval for cultivation in Europe is the GM maize MON810, which gained approval in 1998. On 2 March 2010 a second GMO, a potato called Amflora, was approved for cultivation for industrial applications in the EU by the European Commission and was grown in Germany, Sweden and the Czech Republic that year. Co-existence of GM and non-GM crops is regulated by the use of buffer zones and isolation distances between the GM and non-GM crops. The regulations concerning the import and sale of GMOs for human and animal consumption grown outside the EU involve providing freedom of choice to the farmers and consumers. Twice GMOs unapproved by the EC have arrived in the EU and been forced to return to their port of origin. The first was in 2006 when a shipment of rice from America containing an experimental GMO variety (LLRice601) not meant for commercialisation arrived at Rotterdam. The second in 2009 when trace

amounts of a GMO maize approved in the US were found in a "non-GM" soy flour cargo.

Genetic engineering in Australia is overseen by the Office of the Gene Technology Regulator, a Commonwealth Government Authority within the Department of Health and Ageing. The OGTR reports directly to Parliament through a Ministerial Council on Gene Technology and has legislative powers. The OGTR decides on license applications for the release of all genetically modified organisms and Food Standards Australia New Zealand regulates any GM food. Individual state governments are able to assess the impact of release on markets and trade and apply further legislation to control approved genetically modified products. In 2007 the New South Wales government extended a blanket moratorium on GM food crops until 2011, but approved GM Canola for commercial cultivation in 2008. GM canola is grown in Western Australia, while South Australia and Tasmania have extended their moratoriums on all genetically modified crops.

Health Canada, under the Food and Drugs Act, and the Canadian Food Inspection Agency are responsible for evaluating the safety and nutritional value of genetically modified foods. The committee that reviewed the regulations in 2003 was accused by environmental and citizen groups of not representing the full spectrum of public interests and for being too closely aligned to industry groups. In central and South America Mexico, Honduras, Costa Rico, Colombia, Bolivia, Paraguay, Chile, Argentina, Uruguay and Brazil all grow GM crops.

In Argentina the National Agricultural Biotechnology Advisory Committee (environmental impact), the National Service of Health and Agrifood Quality (food safety) and the National Agribusiness Direction (effect on trade) assess GM products for release, with the final decision made by the Secretariat of Agriculture, Livestock, Fishery and Food. In Brazil the National Bio safety

Technical Commission is responsible for assessing environmental and food safety and prepares guidelines for transport, importation and field experiments involving GM products. The Council of Ministers evaluates the commercial and economical issues with release. Mexico's senate passed a law allowing planting and selling of genetically modified cotton and soybean in Mexico in 2005 and in 2009 the government enacted statutory provisions for the regulation of genetically modified maize. Mexico is the center of diversity for maize and concerns have been raised about the impact genetically modified maize could have on local strains.

GM crops in China go through three phases of field trials (pilot field testing, environmental release testing, and preproduction testing) before they are submitted to the Office of Agricultural Genetic Engineering Bio safety Administration for assessment. Producers must apply to OAGEBA at each stage of the field tests. The Chinese Ministry of Science and Technology developed the first bio safety regulations for GM products in 1993 and they were updated in 2001. Most of the National Bio safety Committee are involved in biotechnology leading to criticisms that they do not represent a wide enough range of public concerns. India regulators cleared the Bt brinjal, a genetically modified eggplant, for commercialisation in October 2009. Following opposition from some scientists, farmers and environmental groups a moratorium was imposed on its release in February 2010. The only other Asian country to currently grow GM crops is the Philippines.

In 2010, the Common Market for Eastern and Southern Africa proposed a policy where new GM crops would be scientifically assessed by COMESA. If it was deemed safe for the environmental and human health permission would be granted for the crop to be grown in all 19 member countries, although the final decision would be left to each individual country. In 2010 South Africa was the major grower of genetically modified crops in Africa, with smaller areas planted

in Burkina Faso and Egypt. Burkina Faso has established a National Bio safety Agency that regulates GM products with advice from various governmental and non-governmental advisory committees. Kenya passed laws in 2011 which allowed the production and importation of GM crops. The Zambian government rejected a consignment of GMO maize supplied by donors during a famine in 2002 on the basis of the Cartagena Protocol.

One of the key issues concerning regulators is whether GM products should be labelled. Labelling can be mandatory up to a threshold GM content level (which varies between countries) or voluntary. A study investigating voluntary labelling in South Africa found that 31% of products labelled as GMO-free had a GM content above 1.0%. In Canada and the USA labelling of GM food is voluntary, while in Europe it all food (including processed food) or feed which contains greater than 0.9% of approved GMOs must be labelled.

A legislative framework has been set up in order to accompany the developments of techniques in genetic engineering. This was partly due to the concerns associated with possible hazards linked to the development of new genetic manipulation techniques and to avoid trade distortions. The introduction of GMO has been felt as introducing new risks for human health and the Environment which had to be evaluated according to certain standards. These directives are process-oriented focusing on the genetic manipulation rather than the product being genetically manipulations.

The European Commission's revised proposal (COM (99)139final) has not included the banning of the use of antibiotic marker genes and has rejected the proposals of the European Parliament to include the precautionary principle explicitly in the Directive. It also ignored the proposal made by the Parliament to introduce a liability regime and does not provide for sanctions in case of damages caused by unintentional GMO releases. The idea of introducing a certification system for GMO products, which would aim to detect the GMO at

all stages of the production process (going further than labelling, since it has not only the aim of informing the public, but also the traceability of the GMOs) has not been included in the revised proposal. The safeguard clause was modified taking into account the Parliament's proposal: "new" information has been modified by "additional" information.

The Parliamentary Assembly of the Council of Europe also issued declarations on GMOs in June and September 1999. It mentioned the fact that "...a balance between private and public interests... [...]... is nearly impossible to find" and yet the necessity for researchers in the field of biotechnology of conforming to the Convention on Biological Diversity of 1992 and the WTO to comply with it.

As a result of the declarations issued by the EU Member countries at the - 2149th Ministerial Meeting of the Environmental Council of the EU on 24/25 June 1999, the granting of new GMO licences has been blocked until a new revised directive is adopted. Future policy statements might however be influenced by the WTO conference in Seattle due to start on November 30th 1999. The current situation in the EU has been assimilated to a *quasi* or *de facto* moratorium. NGOs such as Friends of the Earth demand a global moratorium on GMOs while a new directive is defined and the innocuity of GMOs for health and the environment is clearly established.

## **2-3- UTILISATION OF ANTIBIOTICS RESISTANCE FACTORS**

Today, at least half of GM plants which are cultivated, tested or awaiting authorisation in the world contain antibiotic marker genes. The risks associated with these genes concern the spread of human and animal resistance to antibiotics. This is because the inserted genes could integrate bacteria present in the digestive tract and the guts or bacteria in the soil, with effects on humans and animals. In addition, bacterial resistance to antibiotics is a phenomenon induced by the fact that antibiotics are widely used in sectors ranging from human medicine to animal breeding and crop production. Resistance is not only dependent upon individual consumption but also global use, for all sectors and countries. For some companies, the need to use antibiotics resistance factors as marker genes in gene transfer is no longer technically necessary, since other systems have been introduced. For others, they are still widely used in transgenic plants commercialized for food purposes precisely since no viable alternatives are available yet. The current transgenic plants contain one or two antibiotic resistance genes. TPS technology, well known as "Terminator", uses the antibiotic tetracyclin.

NGOs such as Friends of the Earth believe that it is irresponsible to take a risk, even if minimal, of contributing to the build up of antibiotic resistance and affecting the main tool for fighting against bacterial infections.

## **2-4- HUMAN NUTRITION**

Due to the fact that discoveries in the field of GMO are relatively recent, insufficient knowledge on the possible chronic toxicity due to the consumption of food containing GMO is available today. Tests of chronic toxicity would have to last over a period of 20-40 years. More research is needed on the possible negative long-term impact on health of the consumption of GM food.

There are tens of thousands of allergenic substances and only about 300 are known. Current research is yet to assess whether genetic changes may result in allergenic reactions. But, toxicological studies on GM plants resistant to herbicides do not take into account the long term impact of agro-chemicals which have been introduced into the plant. Furthermore, up-to date studies are not always considered in the evaluation of imported products.

No official tests exist today which are able to prove whether the proteins coded by the modified DNA can be transmitted, in their entirety or partially, to GM plants and animals or animals fed with GMOs. As far as the detection of GMO in food is concerned, a valid and universally recognized detection method is still to be developed.

## **2-5- CONTENTS- METHODS-PRODUCTION- USES**

### **A - CONTENTS OF GENETICALLY MODIFIED ORGANISMS**



#### **GloFish, the first genetically modified animal to be sold as a pet**

A genetically modified organism or genetically engineered organism is an organism whose genetic material has been altered using genetic engineering techniques. These techniques, generally known as recombinant DNA technology, use DNA molecules from different sources, which are combined into one molecule to create a new set of genes. This DNA is then transferred into an organism, giving it modified or novel genes. Transgenic organisms, a subset

of GMOs, are organisms that have inserted DNA from a different species. GMOs are the constituents of genetically modified foods. They are also foods derived from genetically modified organisms (GMOs). Genetically modified organisms have had specific changes introduced into their DNA by genetic engineering techniques. These techniques are much more precise than mutagenesis (mutation breeding) where an organism is exposed to radiation or chemicals to create a non-specific but stable change. Other techniques by which humans modify food organisms include selective breeding; plant breeding, and animal breeding etc.

Genetically Modified foods were first put on the market in 1996. Typically, genetically modified foods are transgenic plant products: soybean, corn, canola, rice, and cotton seed oil. Animal products have also been developed, although as of July 2010 none are currently on the market. In 2006 a pig was engineered to produce omega-3 fatty acids through the expression of a roundworm gene. Researchers have also developed a genetically-modified breed of pigs that are able to absorb plant phosphorus more efficiently, and as a consequence the phosphorus content of their manure is reduced by as much as 60%. Critics have objected to GM foods on several grounds, including safety issues, ecological concerns, and economic concerns raised by the fact these organisms are subject to intellectual property law.

## **B- METHOD**

Genetic modification involves the insertion or deletion of genes. In the process of cisgenesis, genes are artificially transferred between organisms that could be conventionally bred. In the process of transgenesis, genes from a Different species are inserted, which is a form of horizontal gene transfer. In nature this can occur when exogenous DNA penetrates the cell membrane for any reason.

To do this artificially may require transferring genes as part of an attenuated virus genome or physically inserting the extra DNA into the nucleus of the intended host using a microsyringe, or as a coating on gold nanoparticles fired from a gene gun. However, other methods exploit natural forms of gene transfer, such as the ability of *Agrobacterium* to transfer genetic material to plants, and the ability of lentiviruses to transfer genes to animal cells.

The method to introduce new genes into plants requires several important factors such as specific promoter, codon usage of the gene and how to deactivate the gene. The specific promoter must relate to area that we want the gene to express. For instance, if we want the gene to express only in the rice instead of the leaf then we would only use an endosperm specific promoter. The reason is because we only want our transgenic genes to express only in the rice and not the leaves.

The codon usage of the gene must also be more optimized for the rice since there are several different codons for each of the 20 amino acid. The transgenic genes should also be able to be denatured by heat in order for human consumption.

### **C- DEVELOPMENT AND PRODUCTION**

The first commercially grown genetically modified whole food crop was a tomato (called FlavrSavr), which was modified to ripen without softening, by Calgene, later a subsidiary of Monsanto. Calgene took the initiative to obtain FDA approval for its release in 1994 without any special labeling, although legally no such approval was required. It was welcomed by consumers who purchased them at a substantial premium over the price of regular tomatoes. However, production problems and competition from a conventionally bred, longer shelf-life variety prevented the product from becoming profitable.

A tomato produced using similar technology to the Flavr Savr was used by Zeneca to produce tomato paste which was sold in Europe during the summer of 1996. The labeling and pricing were designed as a marketing experiment, which proved, at the time, that European consumers would accept genetically engineered foods. Currently, there are a number of food species in which a genetically modified version exists like rice, tomatoes, maize, cotton, sugar cane, sugar beet, peppers etc.

#### **D- USES**

GMOs are used in biological and medical research, production of pharmaceutical drugs, experimental medicine (e.g. gene therapy), and agriculture (e.g. golden rice). The term "genetically modified organism" does not always imply, but can include, targeted insertions of genes from one species into another. For example, a gene from a jellyfish, encoding a fluorescent protein called GFP, can be physically linked and thus co-expressed with mammalian genes to identify the location of the protein encoded by the GFP-tagged gene in the mammalian cell. Such methods are useful tools for biologists in many areas of research, including those who study the mechanisms of human and other diseases or fundamental biological processes in eukaryotic or prokaryotic cells.

To date the most controversial but also the most widely adopted application of GMO technology is patent-protected food crops that are resistant to commercial herbicides or are able to produce pesticidal proteins from within the plant, or *stacked trait* seeds, which do both. The largest share of the GMO crops planted globally are owned by the United States firm Monsanto. In 2007, Monsanto's trait technologies were planted on 246 million acres (1,000,000 km<sup>2</sup>) throughout the world, a growth of 13 percent from 2006.

However, patents on the first Monsanto products to enter the marketplace will begin to expire in 2014, democratizing Monsanto products. In addition, a 2007 report from the European Joint Research Commission predicts that by 2015, more than 40 per cent of new GM plants entering the global marketplace will have been developed in Asia. In the corn market, Monsanto's triple-stack corn—which combines Roundup Ready 2-weed control technology with YieldGard Corn Borer and YieldGard Rootworm insect control—is the market leader in the United States. U.S. corn farmers planted more than 32 million acres (130,000 km<sup>2</sup>) of triple-stack corn in 2008, and it is estimated the product could be planted on 56 million acres (230,000 km<sup>2</sup>) in 2014–2015. In the cotton market, Bollgard II with Roundup Ready Flex was planted on approximately 5 million acres (20,000 km<sup>2</sup>) of U.S. cotton in 2008.

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), in 2010 approximately 15 million farmers grew biotech crops in 29 countries. Over 90% of the farmers were resource-poor in developing countries. 6.5 million farmers in China and 6.3 million small farmers in India grew biotech crops (mostly *Bacillus thuringiensis* cotton). The Philippines, South Africa (biotech cotton, maize, and soybeans often grown by subsistence women farmers) and another twelve developing countries also grew biotech crops in 2009. 10 million more small and resource-poor farmers may have been secondary beneficiaries of Bt cotton in China.

The global commercial value of biotech crops grown in 2008 was estimated to be US\$130 billion. In the United States, the United States Department of Agriculture (USDA) reports on the total area of GMO varieties planted. According to National Agricultural Statistics Service, the states published in these tables represent 81–86 percent of all corn planted area, 88–90 percent of all soybean planted area,

and 81–93 percent of all upland cotton planted area (depending on the year). USDA does not collect data for global area. Estimates are produced by the International Service for the Acquisition of Agri-biotech Applications (ISAAA) and can be found in the report, "Global Status of Commercialized Transgenic Crops: 2007". Transgenic animals are also becoming useful commercially. On February 6, 2009, the U.S. Food and Drug Administration approved the first human biological drug produced from such an animal, a goat. The drug, ATryn, is an anticoagulant which reduces the probability of blood clots during surgery or childbirth. It is extracted from the goat's milk.

## **E- TRADE IN EUROPE AND AFRICA**

In response to negative public opinion, Monsanto announced its decision to remove their seed cereal business from Europe, and environmentalists crashed a World Trade Organization conference in Cancun that promoted GM foods and was sponsored by Committee for a Constructive Tomorrow (CFACT). Some African nations have refused emergency food aid from developed countries, fearing that the food is unsafe. During a conference in the Ethiopian capital of Addis Ababa, Kingsley Amoako, Executive Secretary of the United Nations Economic Commission for Africa (UNECA), encouraged African nations to accept genetically modified food and expressed dissatisfaction in the public's negative opinion of biotechnology.

Patrick Mulvany, Chairman of the UK Food Group, accused some governments, especially the Bush administration, of using GM food aid as a way to dispose of unwanted agricultural surpluses. The UN blamed food companies and accused them of violating human rights, calling on governments to regulate these profit-driven firms. It is widely believed that the acceptance of biotechnology and genetically modified foods will also benefit rich research

companies and could possibly benefit them more than consumers in underdeveloped nations.

## **G- ISSUES OF WORLD COMPETITION**

According to the International Service for the Acquisition of Agri-biotechnology Applications, the area devoted to growing GM crops reached 27.8 million hectares in 1998 (against 1.7 million in 1997). 85% of transgenic plants are cultivated in industrialised countries. The USA covers 75% of the area followed by Argentina (15%), Canada (10%) and only a few European countries (less than 1%).

In 1999, 40% of the area planted to maize and 50% of the area planted to soya was GM in the US. In Argentina, 70% of soya was planted in Roundup Ready. In Europe, there were only about 200 ha in France, 500 ha in Germany and between 20.000 and 30.000 ha in Spain.

Around 60 GM plant species are cultivated in the United States and 10 species in Europe represent 80-90% of field trials. These include tobacco (the first transgenic plant created) and tomato (the first transgenic plant to be marketed) and other economically important crops such as maize and potato and, more specifically, soybeans in the United States and sugar beet in Europe. Major advances have been made in soya beans and maize, which are also the main US export crops. Wheat (a major European export crop) only represents about 1% of field trials due to the difficulties encountered in the identification of its DNA. The development of GMO in agriculture has followed three directions:

- The improvement of the agronomic characteristics of plants (input traits). This concerns herbicide resistance (to Roundup Ready for Monsanto, a technology used on soya, oil seed rape, cotton, maize and sugar beet), insect resistance (for potatoes, cotton, and maize), fight against diseases and viruses (potato).

- The improvement in the qualitative characteristics of plants and the composition of the final product (output traits). The aim is to alter the plant's composition in order to improve its nutritional qualities. The plant produces elements which it did not produce before and is made more appetising to animals.

## **2-6- STRENGTHS AND WEAKNESSES OF GENETICALLY MODIFIED FOODS**

### **A- Transgenic maize**

Genetically modified maize (corn) has been deliberately genetically modified to have agronomically desirable traits. Traits that have been engineered into corn include resistance to herbicides and resistance to insect pests, the latter being achieved by incorporation of a gene that codes for the *Bacillus thuringiensis* (Bt) Immunoglobulin E (IgE). Hybrids with both herbicide and pest resistance have also been produced. In 2009, transgenic maize was grown commercially in 11 countries, including the United States (where 85% of the maize crop was genetically modified), Brazil (36% GM), Argentina (83% GM), South Africa (57% GM), Canada (84% GM), the Philippines (19% GM) and Spain (20% GM).

Herbicide-resistant GM corn is grown in the United States. A variation of herbicide-resistant GM corn was approved for import into the European Union in 2004, but such imports remain highly controversial.



### **Bt corn**

The European corn borer, *Ostrinia nubilalis*, destroys corn crops by burrowing into the stem, causing the plant to fall over. Bt corn is a variant of maize, genetically altered to express the bacterial Bt toxin, which is poisonous to insect pests. In the case of corn, the pest is the European corn borer.

Over the past couple years they have added traits against Corn ear worm, and Root worm. In 2001, Bt176 varieties were voluntarily withdrawn from the list of approved varieties by the United States Environmental Protection Agency when it was found to have little or no Bt expression in the ears and was not found to be effective against second generation corn borers.

In order to assess the advantages of Bt maize compared to the use of pesticides, their potential impact on ecosystems must be studied. One negative impact is the persistence in time and the dissemination in the environment. For the Bt toxin, produced by GM maize, persistence is rather long and dissemination wide-ranging, compared to all other modern pesticides. From an ecological point of view, it corresponds to the utilisation of a conventional pesticide with high persistence on large areas. In order to ensure the continuity of the economic interest due to savings in plant protection applications, there is a need to control the development of resistance in target insects. A fundamental rule in the fight against plagues states that relying on more than one arm is capital. The more an insect is exposed to Bt, the greater the selection pressure which is exerted on it, favouring the development of resistance to Bt.

The utilisation of Bt as biopesticide is to be differentiated from the expression of the toxin by the plant. Spraying biopesticide based on Bt delivers a given amount over a limited period of time, then the toxin is inactivated by UVs. The selection pressure is thus greatly reduced compared to a plant producing the Bt toxin over an entire growth period. Further studies have shown that some Bt maize cultivars do not secrete a sufficient amount of Bt toxin to fight against the European Corn Borer all through the season and particularly in Southern Europe.

Field observations have highlighted that the quantity of Bt secreted by transgenic plants is not so high nor constant as the theory suggests and might have a negative impact on minor pests.

The possible adverse effects of Bt crops on the environment, such as non target insect fauna feeding on Bt plants, reduces the range of benefits which can be achieved from their use.

## **B- Genetically modified rice**



### **GM rice**

Genetically modified rice is types of rice that have been genetically modified for agricultural purposes. The rice genome is usually modified using particle bombardment via the use of a gene gun or more commonly, a process known as Agrobacterium mediated transformation. Rice plants can be modified to be herbicide resistant, resist pests, increase grain size, generate nutrients,

flavours or even produce human proteins. The natural movement of genes across species, often called horizontal gene transfer or lateral gene transfer, can also occur with rice through gene transfer mediated by natural vectors. Some examples of such natural transgenic events in plants through movement of natural mobile DNAs called MULEs between rice and *Setaria* millet have been identified. The cultivation and use of genetically modified varieties of rice is however controversial and not legal in some countries.

### **C- Genetically modified tomatoes**



#### **A plant physiologist with examples of bioengineered tomatoes**

A genetically modified tomato, or transgenic tomato is a tomato that has had its genes modified, using genetic engineering. The first commercially available genetically modified food was a tomato engineered to have a longer shelf life (the Flavr Savr). Currently there are no genetically modified tomatoes available commercially, but scientists are developing tomatoes with new traits like increased resistance to pests or environmental stresses. Other projects aim to enrich tomatoes with substances that may offer health benefits or be more nutritious. As well as aiming to produce novel crops, scientists produce

genetically modified tomatoes to understand the function on genes naturally present in tomatoes.

On the whole, a GM tomato contains more solids and less water than its conventional relatives, which means that there is less waste at harvesting and processing costs are lower, resulting in a slightly cheaper product for the consumer. The FlavrSavr Tomato has been developed in 1992 for the trait of "delayed ripening", the fruit being able to ripen on the plant, achieving thus a better taste while remaining firm up to the shelves.

However, the effects of transport were badly evaluated and the ripe tomato did not arrive in the shops in the conditions expected. The organoleptic characteristics of parent plants were insufficient and the application of genetic engineering techniques could not result in a satisfactory taste. Consumers disliked the product due to the high price compared to quality. Yields and disease resistance were not up to expectations either. Calgene conducted eight field trials on FlavrSavr between 1989 and 1992. Furthermore, traditional breeding methods have the advantage of obliging the breeder to seek genes of interest in wild varieties, contributing to the conservation of the diversity of the genetic make-up and will as such remain one of the basic tools for genetic improvement. Transgenic tomatoes can produce tomato purees and sauces which are viscous without the need for a process of inactivation of PG through heat ("hot-break"). The result is a reduction in the costs of energy, avoiding additives and, through the reduction in time needed for processing, a better taste can be achieved. Tomato purees have been successfully marketed by Zeneca in the UK in 1996. A communication campaign in partnership with two retailers (Sainsbury's and Safeway Stores) included product labelling, a 4-page prospectus on the advantages of the product, and an attractive sales price (-20%), proving that transparency could be a major asset in the development of a

new product. Current developments have however shown that influences from NGOs conducting anti-GMO campaigns and adverse consumer reactions, particularly in the UK, changed the 1996 situation. The Zeneca tomato represented a major advantage for the processor who made energy savings linked to a reduced processing time.

#### **D- GMOs and Transgenic animals**



#### **GM ANIMALS**

Transgenic animals are used as experimental models to perform phenotypic and for testing in biomedical research. Genetically-Modified (Genetically Engineered) animals are becoming more vital to the discovery and development of cures and treatments for many serious diseases. By altering the DNA or transferring DNA to an animal, we can develop certain proteins that may be used in medical treatment. Stable expressions of human proteins have been developed in many animals, including sheep, pigs, and rats. Some examples are: Human-alpha-1-antitrypsin, which has been developed in sheep and is used in treating humans with this deficiency and transgenic pigs with human-histo-compatibility have been studied in the hopes that the organs will be suitable for transplant with less chances of rejection.

Transgenic livestock have been used as bioreactors since the 1990s. Many medicines, including insulin and many immunizations are developed in transgenic animals.

In March 2011, the bioactive recombinant Human Lysozyme was expressed in the milk of cloned transgenic cattle. This field is growing rapidly and new pharming uses are being discovered and developed.

The extent that transgenic animals will be useful in the medical field as well as other fields is very promising based on results thus far.

The objectives pursued in the modification of the animal genome are essentially the improvement in animal performance and rearing conditions and the improvement in the characteristics of food derived from animals. Modifications of the animal genome are less frequent compared to plant modifications due to a number of technical difficulties involved.

Examples of current research include changing milk composition such as increasing its protein content for the optimisation of cheese production or the production of milk without lactose (some consumers being allergic to lactose).

Improving the nutritional value of milk in order to produce medicines or food supplements has been done, for instance, through an increase in the amount of phosphorous-rich proteins. These modifications are however well mastered only in mice. Another aim of the modification of the animal genome is to achieve leaner animal carcasses (e.g. 5 to 7% fat instead of 26 to 33% in sheep in an Australian experiment). The consequences of the latter tests have nevertheless shown that animals often had physiological anomalies (such as diabetes) due to an uncontrolled expression of the transgene involved.

Other experiments on animals involving transgenes having an impact on food production have been aimed at seeking resistance to frost in salmon, raising fertility in sheep (Booroola gene), improving the digestion of cellulose (enzyme secretions) to improve food intake, pigs and chickens capable of

synthetising essential amino-acids (which would no longer be brought by the food ration), chickens genetically programmed for their leanness (Bonny, 1998). While most often regarded as a crop or plant issue, “Genetically modified organisms” or GMOs also includes genetically modified animals that are frequently a part of biomedical research.

Like other forms of genetic modification, animals can be genetically modified in several ways, for example by removing genes from its DNA structure or by adding new. Gene knockouts allow researchers to delete individual genes from animals, giving us valuable clues as to what those genes do. In others modifications, researchers introduce new genetic material into suitable hosts (typically rodents), from other species, often human. Commonly referred to as transgenic, these animals have been genetically engineered/modified to create new or isolate existing characteristics. In many cases this has no noticeable effect, while in some cases the alteration leads the animal to develop the equivalent of a human disease being studied. These transgenic animals have proven to be an important way to not only study a disease, but also to treat or even cure a disease. As an example, to get specific human antibodies for use in drug development, mice have been developed that are capable of making fully human antibodies, in place of the normal mouse antibodies that are normally generated. Such mice can be injected with cells or material from a human tumor or an infectious agent.

The mice respond with a human antibody response instead of a mouse antibody response. Researchers then immortalize the antibody-producing cells from the mice into special nutrients so they multiply, producing therapeutic quantities of monoclonal antibodies. As a result of such research, at least 33 fully human antibodies have been tested in human clinical trials to date. These antibodies are analogous to approved antibody therapeutics such as Erbitux for colorectal cancer; Remicade and Humira for rheumatoid arthritis; three drugs for preventing organ transplant rejection and Xolair for asthma. While almost all of

the aforementioned antibodies are originally mice in origin, the transgenic mice that produce fully human antibodies are a potential advantage over these therapeutics as their antibodies are fully tolerated in humans; mouse-derived antibodies can be quickly rejected.

None of these advances would have been possible without research using genetically modified organisms.

Other examples of GMOs or transgenic animals being used in medical research include transgenic goats to produce TPA or tissue plasminogen activator, and Antithrombin 3 for the treatment of blood clots; Factor 8 and factor 9 being produced in sheep for the treatment of blood clotting disorders such as hemophilia; and human protein C in pigs for use as an anticoagulant; the development of CFTR for the treatment of cystic fibrosis; and the production of MSP-1 antigen in transgenic mice. MSP-1 produces a human antibody response to malaria, and could be the basis for an eventual malaria vaccine. Researchers are developing techniques for gastrointestinal disturbances, rheumatoid arthritis, Alzheimer's disease, and cures and vaccines for hepatitis and herpes infections. Researchers are working with dairy cattle to produce milk with an inactive b-lacto globulin milk protein so that people with lactose-intolerance can eat dairy products. Another role genetically modified or transgenic animals play in research is xenotransplantation – the production of tissues and organs in animals for human use. New heart valves from pigs are an important example.

Pharmaceutical products derived from genetically modified organisms are also developed for veterinary use. An example is the use of a recombinant vaccine-rabies virus for vaccinating foxes against rabies, which is more efficacious and safer than the conventional attenuated SAD B19 strain. This strain, which is still used sometimes, is pathogenic for some non-target

mammals. Another is the recombinant Merial canarypox DNA vaccine (for West Nile Disease) that incorporates WNV membrane and envelope proteins into the canarypox DNA and expresses these proteins following administration. Research is also currently underway using forms of GMOs to address Bovine Spongiform Encephalopathy (BSE - mad-cow), various influenzas, feline HIV and leukemia, among many others.

### **G- Transgenic plants**



### **Kenyans examining insect-resistant transgenic Bt corn**

Transgenic plants have been engineered to possess several desirable traits, such as resistance to pests, herbicides, or harsh environmental conditions, improved product shelf life, and increased nutritional value. Since the first commercial cultivation of genetically modified plants in 1996, they have been modified to be tolerant to the herbicides glufosinate and glyphosate, to be resistant to virus damage as in Ringspot virus-resistant GM papaya, grown in Hawaii, and to produce the Bt toxin, an insecticide that is allegedly non-toxic to mammals.

Most GM crops grown today have been modified with "input traits", which provide benefits mainly to farmers. The GM oil seed crops on the market today offer improved oil profiles for processing or healthier edible oils. The GM crops in development offer a wider array of environmental and consumer benefits such

as nutritional enhancement and drought and stress tolerance. GM plants are being developed by both private companies and public research institutions such as CIMMYT, the International Maize and Wheat Improvement Centre. Other examples include a genetically modified sweet potato, enhanced with protein and other nutrients, while golden rice, developed by the International Rice Research Institute (IRRI), has been discussed as a possible cure for Vitamin A deficiency.

Scientists at the University of York developed a weed (*Arabidopsis thaliana*) that contains genes from bacteria that can clean up TNT and RDX-explosive contaminants from the soil; it was hoped that this weed would eliminate this pollution.

The coexistence of GM plants with conventional and organic crops has raised significant concern in many European countries. Due to high demand from European consumers for freedom of choice between GM and non-GM foods, EU regulations require measures to avoid mixing of foods and feed produced from GM crops and conventional or organic crops. (Unlike the US, European countries require labelling of GM food.) European research programs such as Co-Extra, Transcontainer, and SIGMEA are investigating appropriate tools and rules. At the field level, biological-containment methods include isolation distance and pollen barriers. Such measures are generally not used in North America because they are very costly and the industry admits of no safety-related reasons to employ them.

## **2-7- CAUSES AND CONSEQUENCES OF GMOS**

### **A-CAUSES**

Food Security has become a key issue for governments the world over with growing fears that there will be mass starvation due to an increasing world population and crop losses attributed to climate change. **Over 850 million people**

are suffering from chronic hunger due to extreme poverty and 2 billion people lack food intermittently due to varying degrees of poverty as published by the Food and Agriculture Organization of the United Nations. This makes the issue of food security a reality for most governments on earth.

Finding a solution is thus a priority for any government that wishes to stay in power or who cares about the welfare of their people.

The first and most obvious solution would be to reduce population growth and thus also the demand for food. This would require extensive education and a shift in cultural norms which are entrenched in our society, this approach is long term and would require ongoing reinforcement across all cultures to have a significant impact. Governments simply do not have the time to invest in such long term programmes, regardless of the end result.

## **B-CONSEQUENCES**

### **1- For the environment**

The new genetic combinations arising from modern genetic engineering have never been tested as part of an evolutionary process (Hindar, 1998). The unpredictable stability of the introduction of new genes in a genome imply that the performance of GMO in the long-term is equally difficult to predict. The phenotype in particular may vary according to the events occurring in the environment of the GM organism. As a result, reaching a clear understanding of the potential ecological hazards is difficult.

A useful example to illustrate these difficulties is the application of genetic engineering to aquaculture, with the aim of producing animal proteins. Confined fish breeding cannot ensure that no accidental disseminations occur. Apart from direct effects on the performance of the fish itself, ecological and/or population imbalances occurs. It seems therefore that there are potential hazards for biodiversity associated with the (uncontrolled) dissemination of GMO in the

environment, sometimes compared to the introduction of a species in a new area in the past. Other arguments are in favour of an increase in biological diversity precisely through the creation of "genetically new" living organisms. The difficulty is that *a priori* estimates on the effects of these disseminations cannot be made.

## **2- For human health**

The importance of taking into account health aspects of the introduction of GM food has been reflected by the creation of specific national agencies aimed at issuing recommendations concerning possible risks for human health. In the UK, for instance, a Food Standards Agency has recently been created and a similar body has been set up in France (Agence Française de Sécurité Sanitaire des Aliments) (Philipon, 1999). Several consequences resulting from the introduction of foreign genes in a genome are unpredictable, as well as the effects on the composition of the food concerned. Besides desirable (primary) effects, the introduction of foreign genes may thus produce undesirable (secondary) effects.

The risks for human health are two fold: toxic and allergic. One potential danger is the intake of new, unknown pathogens together with modified plants, which may have appeared due to the modification which has made plant species resistant to viral infections. It has been shown that inactivated viruses, inserted in GM plants, are capable of recombining with the host genome and be « reactivated » (Martinez, 1997). Inserted genes may activate on cogenes and cause certain cancers (Pimbert, 1997). In addition, toxicological risks can be associated with the addition of one new gene in a plant. Secondary metabolic changes may cause undesirable effects, such as the production of new toxic substances or stimulating the production of toxins normally present in the plant, even if only at very low level. But, the evaluation of allergenic risks is complicated by the uncertainties linked to the prediction and future of the

behaviour of transferred genes. The effect of a gene's genetic and cellular environment on the characteristics of amino-acids produced may have been underestimated.

The behaviour of proteins is thus not fully known and it is currently impossible to say whether these changes will bring about an increased sensitivity to allergenic substances.

If we consider that a GM plant only produces an expected protein, the exact sequence of its amino-acids can be known. This can be compared to the sequences of known allergens contained in gene banks and look for homologies in order to predict the risk of allergenicity. However, the proteins expressed by transgenes and derived from bacteria often contain no recognized allergene and historical, clinical and comparisons are difficult epidemiological.

Furthermore, allergenicity in food is rarely due to one single component, but to a large number of proteins (glycoproteins). Experiments on animals (90-day feeding tests on rats) do not currently provide a valid extrapolation to humans. But, animal products derived from the application of new technologies are related to the European Novel Food regulation. The safety of their use in food destined to humans is based on a preliminary evaluation of the toxicological risks and nutritional qualities. For a more reliable and complete risk assessment, the concept of "substantial equivalence" should be extended to cover knowledge of: the transgenes used (analysis of genetic constructions), the products expressed (new proteins, metabolic derivatives, expression sites, residual levels in processed products, toxicity, allergenicity), "non intentional" effects resulting from the action of genetic modification (pleiotropic effects).

Case by case answers are needed given the various objectives pursued with the application of genetic engineering techniques to animals. Quality improvement (animal carcass improvement, nutraceuticals) demands a nutritional evaluation. Stimulating the production of the growth hormone (GH)

in pigs, sheep, bovines and fish results in muscular growth through the reduction of body fat.

The production of GH could interfere with the animal's metabolism, which would tend to store a higher amount of chemical residues in its organs. The fat/muscle relationship being higher, these animals could accumulate more dioxine and pollutants depending on the chemical sanitary quality of their feed. Hormonal residues in meat and meat products can have endocrinous, immunological and immunotoxic, neurobiological and cancerigenous effects for humans. Development can also be affected. Exposure to even small quantities of these residues implies risks, in particular for children, but no threshold has been determined to date.

### 3 -A scientific analysis of the rat study conducted by Gilles-Eric Séralini et al.



On Wednesday, 19 September 2012, the scientific journal *Food and Chemical Toxicology* published online a study by Gilles-Eric Séralini and his team about the alleged effects of genetically modified maize and the herbicide, Roundup, on the health of rats.

In Séralini's opinion, the study showed alarming results. He sent shocking

images around the world of rats with large tumors, images eagerly reproduced by the media. Sharp criticism of the study soon followed. Various scientists pointed to the significant shortcomings in the research and raised several questions. Among other things, a petition was launched requesting Séralini to release the data underpinning the study.

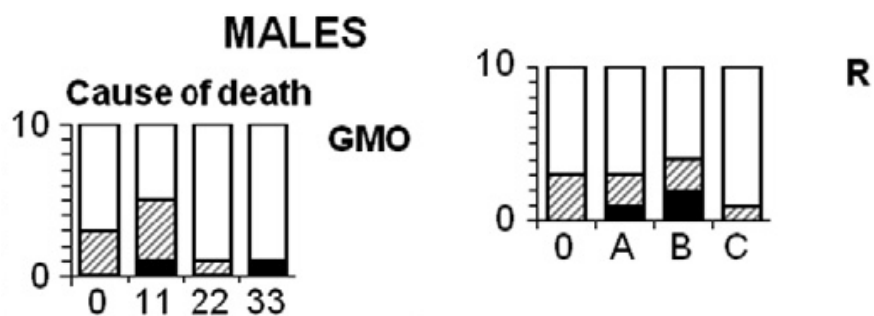
The Flemish Interuniversity for Biotechnology [*Vlaams Interuniversitair Instituut voor Biotechnologie* (VIB)] was also shocked at the images and the messages that the study provoked in the media. Let it be clear that VIB is in no way involved in the development of NK603<sup>2</sup> maize that the study used, and that they have no stake whatsoever in the herbicide Roundup. However, VIB is a world authority in plant research that uses genetically modified plants as a research resource. New knowledge that VIB garners in this way can, in some cases, contribute to the development of genetically modified crops. For this reason, VIB considers it their social duty to thoroughly examine new information about the possible health effects of genetically modified plants.

- **The results of the experiment**

The results of Séralini et al.'s experiment show that there were fewer deaths among the male animals whose diet comprised food with 22 or 33% genetically modified maize (= negative control) (the left hand side of the figure below). This is remarkable given that the genetically modified maize was herbicide tolerant, and no new properties that may have had health advantages for the rats. We see the same result after Roundup was added to the drinking water. There were fewer deaths among the male rats that had drunk the highest concentration of Roundup than among those who had drunk pure water (the right hand side of the figure below).

And this while Roundup certainly does not contain any known life-

extending properties. The researchers should have taken these observations as a warning that there was something wrong with the experiment, because if these results were correct it would mean that consuming large amounts of genetically modified NK603 maize or Roundup would be a way to live longer. These strange findings are not interpretable because as noted previously there is something fundamentally wrong with the research design.



11 = 11 % NK603 in the food A =  $1.1 \times 10^{-8}$  % Roundup in the drinking water

22 = 22 % NK603 in the food B = 0,09 % Roundup in the drinking water

33 = 33 % NK603 in the food C = 0,5 % Roundup in the drinking water

The number of animals that died during the experiment is lower in the groups that ate genetically modified NK603 maize (left hand figure) and drank Roundup (right hand figure).

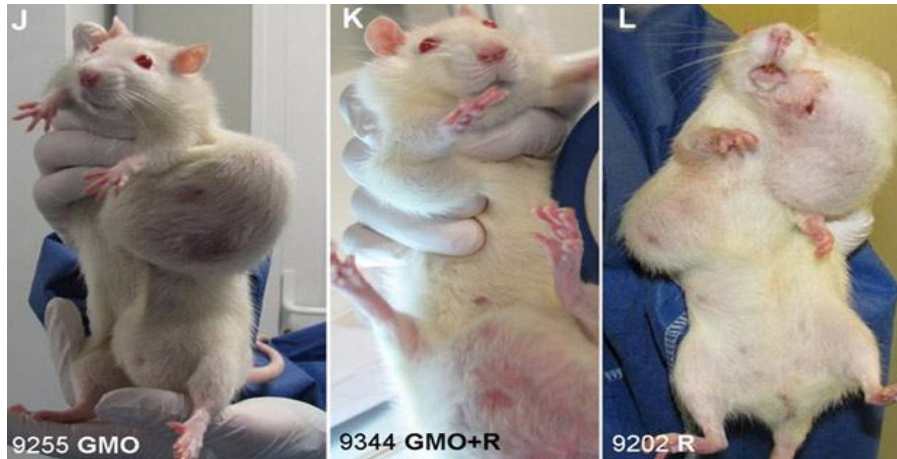
The shaded area illustrates how many animals died during the experiment, and the black area within this indicates the number of animals that needed to be put down to end their suffering.



### **Gilles-Eric Séralini's background**

Gilles-Eric Séralini works at the University of Caen in France. He works there in the Oestrogen and Reproduction Laboratory of the Biology Institute and is co-director of the Risks Pole-Quality and Sustainable Environment – MRSH-CNRS [Pôle Risques, Qualité et Environnement Durable - MRSH-CNRS]. Séralini is co-founder of CRIIGEN, the ‘Committee for Research & Independent Information on Genetic Engineering’ ([www.criigen.org](http://www.criigen.org)). This is an organization that has an extremely negative opinion when it comes to genetically modified crops and is undertaking an active campaign against them.

This is not the first time that Séralini and his team have presented research findings that, according to them, indicate the potentially harmful effects of genetically modified organisms. Scientists and official advisory organizations, such as EFSA (European Food Safety Authority), consigned all these earlier studies to the bin because there was no scientific underpinning for the conclusions that they presented.



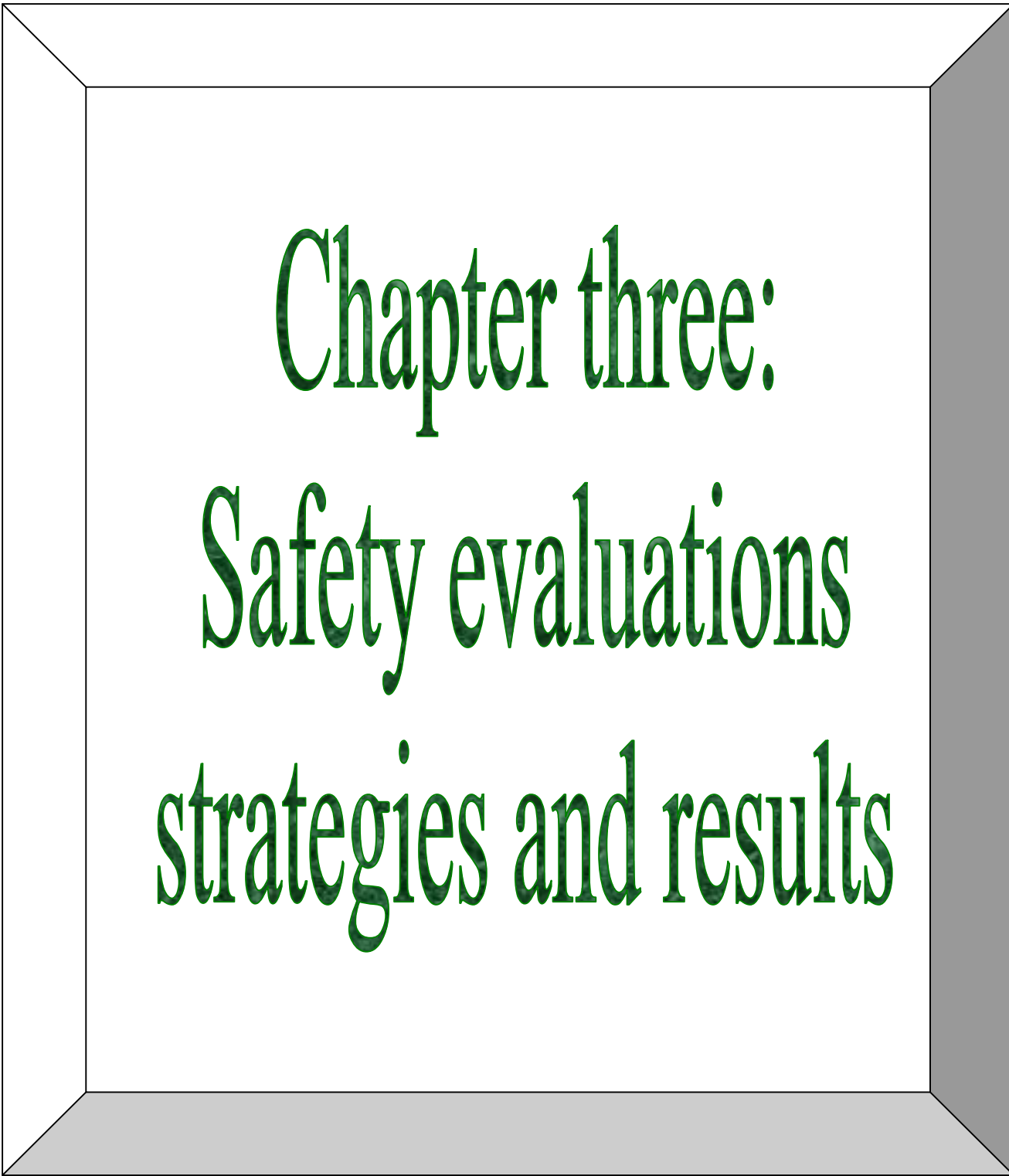
One must look at the speed with which tumours are triggered. In all three treatment groups of rats, tumours or diseases of the kidneys and liver begin in the 4th month and explode in the 11th and 12th months. Which corresponds to the age of 35 to 40 years in a human. In the control group, tumours occurred mostly at the end of life, in the 23rd and 24th months, which seems to be normal in these rats. The study already cost 3.2 million Euro.

#### **4-Contamination issues**

In the 1990s genetically modified Flax tolerant to herbicide residues in soil was developed by the Crop Development Centre (CDC) at the University of Saskatchewan in Canada. Named Flax variety FP967, but commonly called *CDC Triffid*, research was controversially halted following protests from Canadian farmers who stood to lose up to 70% of their traditional export markets if it was introduced. GM Flax was deregistered, its sale was criminalized and in 2001 all modified seeds were destroyed. No modified crops had been planted and no seed had been sold but GM industry proponent Alan McHughen controversially passed out sample packets of seeds at presentations. In early September 2009, Flax imported into Germany was found to be contaminated with *CDC Triffid* causing the price of Canadian Flax to fall 32 percent. By mid November 35 countries reported contamination of imported

Canadian Flax which has now been banned by the European Union. Canadian farmers are expected to be responsible for the cost of the cleanup and testing of future crops.

In 2000, AventisStarLink corn, which had been approved only as animal feed due to concerns about possible allergic reactions in humans, was found contaminating corn products in U.S. supermarkets. An episode involving Taco Belltaco shells was particularly well publicized which resulted in sales of StarLink seed being discontinued. The registration for the Starlink varieties was voluntarily withdrawn by Aventis in October 2000. Aid sent by the UN and the US to Central African nations was also found to be contaminated with StarLink corn and the aid was rejected. The US corn supply has been monitored for Starlink Bt proteins since 2001 and no positive samples have been found since 2004. GeneWatch UK and Greepeace International set up the GM Contamination Register in 2005.



Chapter three:  
Safety evaluations  
strategies and results

## **EVALUATIONS STRATEGIES AND RESULTS**

### **3-1- Safety evaluation strategies**

At an early stage in the introduction of recombinant-DNA technology in modern plant breeding and biotechnological food production systems, efforts began to define internationally harmonized evaluation strategies for the safety of foods derived from genetically modified organisms. Two years after the first successful transformation experiment in plants (tobacco) in 1988, the International Food Biotechnology Council published the first report on the issue of safety assessment of these new varieties (IFBC, 1990). The comparative approach described in this report has laid the basis for later safety evaluation strategies. Other organizations, such as the Organization for Economic Cooperation and United Nations and the World Health Organization and the International Life Sciences Institute have developed further guidelines for safety assessment which have obtained broad international consensus among experts on Development , the Food and Agriculture Organization of the food safety evaluation.

The British Food Standards Agency began a feasibility study in 1999 to determine whether long-term monitoring of novel foods is possible (Baynton, 1999). The study aims to obtain data on household consumption patterns and supermarket sales in the 239 local authority districts in Great Britain. The idea is that if variation at district level regarding food purchasing and consumption can be detected, it may be possible to link this variation to health outcomes at district level. The results of the study will lead to recommendations with respect to the future surveillance of novel foods.

A number of genetically modified plants and foods obtained through extensive genetic modification(s) with the purpose of improving agronomic or

food-quality traits will soon enter the commercial market. These developments are reviewed in more detail elsewhere.

With respect to safety assessment, these new (second-generation) products should, in principle, also be assessed applying the concept of substantial equivalence.

The assessment of genetically modified plants/foods with enhanced nutritional properties should focus on the simultaneous characterization of inherent toxicological risks and nutritional benefits. This requires an integrated, multidisciplinary approach, incorporating molecular biology, toxicology, nutrition and genetics. Issues to be addressed are: (i) evidence for nutritional/health claims and target population(s); (ii) toxicological and beneficial dose ranges of selected compounds; (iii) impact on overall dietary intake and associated effects on consumers; (iv) interactions between food constituents and food matrix effects; and (v) possibilities for effective post-market surveillance, if necessary. Assessment of the safety of this type of foods is the crucial part of the evaluation, regardless of the potential benign effects of certain food constituents.

Our understanding of the relationship between dietary intake of specific foods/food components and human safety and health increases rapidly, even at the level of individual responses through the development of modern genomic and proteomic techniques. This will, in the near future, guide plant breeders more precisely in developing crops with improved safety and wholesomeness. In addition, safety assessment of genetically modified foods should be carried out on a case-by-case basis, comparing the properties of the new food with those of a conventional counterpart. This approach, the concept of substantial equivalence, identifies potential differences between the genetically modified food and its counterpart, which should then be further assessed with respect to their safety and nutritional implications for the consumer. The concept as developed by OECD has been endorsed by FAO/WHO, and contributes to an

adequate safety assessment strategy. No alternative, equally robust strategy is available.

Testing of whole (genetically modified) foods in laboratory animals has its problems. The specificity and sensitivity of the normally applied methods is usually poor. There is a need for improvement of the test methodology using *in vivo* and *in vitro* models. Moreover, there is a need for standardization and harmonization of methods to test the long-term safety of whole foods. But present approaches to detecting expected and unexpected changes in the composition of genetically modified food crops are primarily based on measurements of single compounds. In order to increase the possibility of detecting secondary effects due to the genetic modification in plants that have been extensively modified, new profiling methods are of interest and should be further developed and validated . Application of these techniques is of particular interest for genetically modified foods with extensive genetic modifications (gene stacking) meant to improve agronomical and/or nutritional characteristics of the food plant.

Pre-market safety assessment of genetically modified foods must provide sufficient safety assurance. The use of post-marketing surveillance as an instrument to gain additional information on long-term effects of foods or food ingredients, either GMO-derived or traditional, should be further explored, but the requirement of routine application will entail large costs for limited amounts of information, and does therefore not seem desirable. Only in specific cases where, for example, allergenicity of newly introduced proteins cannot be excluded, or when exposure assessment is hampered by insufficient insight into the diets of specific consumer groups, post-marketing surveillance strategies may be employed.

### 3-2- Results

The starting point for the safety assessment of genetically engineered food products is to assess if the food is "substantially equivalent" to its natural counterpart. The issue of GM food safety was first discussed at a meeting of the Food and Agriculture Organization (FAO), the World Health Organization (WHO) and biotech representatives in 1990.

A 2003 review in *Trends in Biotechnology* identified seven main parts of a standard safety test:

1. Study of the introduced DNA and the new proteins or metabolites that it produces;
2. Analysis of the chemical composition of the relevant plant parts, measuring nutrients, anti-nutrients as well as any natural toxins or known allergens;
3. Assess the risk of gene transfer from the food to microorganisms in the human gut;
4. Study the possibility that any new components in the food might be allergens;
5. Estimate how much of a normal diet the food will make up;
6. Estimate any toxicological or nutritional problems revealed by this data;
7. Additional animal toxicity tests if there is the possibility that the food might pose a risk.

This process was examined further in a review published by Kuiper *et al.* 2002 in the journal *Toxicology*, which stated that substantial equivalence does not itself measure risks, but instead identifies differences between existing products and new foods, which might pose dangers to health. If differences do exist, identifying these differences is a starting point for a full safety assessment, rather than an end point.

The authors concluded that "The concept of substantial equivalence is an adequate tool in order to identify safety issues related to genetically modified

products that have a traditional counterpart". However, the review also noted difficulties in applying this standard in practice, including the fact that traditional foods contain many chemicals that have toxic or carcinogenic effects and that our existing diets therefore have not been proven to be safe. This lack of knowledge on unmodified food poses a problem, as GM foods may have differences in anti-nutrients and natural toxins that have never been identified in the original plant, raising the possibility that harmful changes could be missed.

The application of substantial equivalence has also been more strongly criticized. For example, in a speech in 1999, Andrew Chesson of the University of Aberdeen, stated that substantial equivalence testing "could be flawed in some cases" and that some current safety tests could allow harmful substances to enter the human food chain. In a commentary in *Nature*, Millstone *et al.* argued that all GM foods should have extensive biological, toxicological and immunological tests and that the concept of substantial equivalence based solely on chemical analyzes of the components of a food should be abandoned. They stated that this is necessary since it is currently impossible to predict the biological properties of a substance only from knowledge of its chemistry. This commentary was controversial and was criticized for misleading presentation of data and presenting an over-simplified version of safety assessments. For example, Kuiper *et al.* responded to this criticism by noting that equivalence testing does involve more than chemical tests and may include toxicity testing.

The large scale growth of GM plants may have both positive and negative effects on the environment. These may be both direct effects, on organisms that feed on or interact with the crops, and wider effects on food chains produced by increases or decreases in the numbers of other organisms.

As an example of benefits, insect-resistant Bt-expressing crops will reduce the number of pest insects feeding on these plants, but as there are fewer pests, farmers do not have to apply as much insecticide, which in turn tends to increase the number of non-pest insects in these fields. As an example of a concern about

environmental risk, a lab at Cornell University published an article which caused worry in the US that Bt-corn pollen might affect the monarch butterfly. Other possible effects might come from the spread of genes from modified plants to unmodified relatives, which might produce species of weeds resistant to herbicides. There has been controversy over the results of a farm-scale trial in the United Kingdom comparing the impact of GM crops and conventional crops on farmland biodiversity. Some claimed that the results showed that GM crops had a significant negative impact on wildlife. They pointed out that the studies showed that using herbicide resistant GM crops allowed better weed control and that under such conditions there were fewer weeds and fewer weed seeds. This result was then extrapolated to suggest that GM crops would have significant impact on the wildlife that might rely on farm weeds. The President of the Royal Society, the body that had carried out the trials, stated that "To generalize and declare 'all GM is bad' or 'all GM is good' for the environment as a result of these experiments is a gross over-simplification", arguing that although the trials showed that the combination of some GM crops with long-lasting herbicides were bad for biodiversity, using other GM crops without these herbicides increased biodiversity. In July 2005 British scientists showed that transfer of a herbicide-resistance gene from GM oilseed rape to a wild cousin, charlock, and wild turnips was possible. Many agricultural scientists and food policy specialists view GM crops as an important element in sustainable food security and environmental management. This point of view is summarized in the ABIC Manifesto: On our planet, 18% of the land mass is used for agricultural production.

This fraction cannot be increased substantially. It is absolutely essential that the yield per unit of land increases beyond current levels given that: The human population is still growing, and will reach about nine billion by 2040; 70,000 km<sup>2</sup> of agricultural land (equivalent to 60% of the German agricultural area) are lost annually to growth of cities and other non-agricultural uses;

Consumer diets in developing countries are increasingly changing from plant-based proteins to animal protein, a trend that requires a greater amount of crop-based feeds. Other scientists, such as Dr. Charles Benbrook, argue that improvement of global food security is hardly being addressed by genetic research and that a lack of yield is often not caused by insufficient genetic resources. Regarding the issues of intellectual property and patent law, an international report from the year 2000 states: If the rights to these tools are strongly and universally enforced - and not extensively licensed or provided pro bono in the developing world - then the potential applications of GM technologies described previously are unlikely to benefit the less developed nations of the world for a long time.

### **3-3- CONCLUSIONS AND OTHER DIFFICULTIES**

The conclusions of joint FAO and WHO conference in 2000 are the following:

1. The Consultation agreed that the safety assessment of foods derived from biotechnology requires an integrated and stepwise, case-by-case approach, and that this method also be applied to the evaluation of the allergenicity of food derived from biotechnology.

2. The Consultation emphasized that all foods derived from biotechnology must be assessed for allergenic potential.

3. The original decision tree from the FAO/WHO 2000 Consultation served as a basis for this consultation. The Consultation concurred that this decision tree be modified as a consequence of more recent research and which is reflected in the FAO/WHO 2001 decision tree.

4. When the expressed protein is derived from a source with known allergenicity, the FAO/WHO 2001 decision tree proposes that the initial investigation be analysis of sequence homology to known allergens in the source. If this is negative, the next step will be investigations on possible IgE

binding using immunoassays and may also include investigations in vivo in patients allergic to the source food.

5. When the expressed protein is derived from a source with no known allergenicity, the FAO/WHO 2001 decision tree proposes that the initial investigation would also be analysis of sequence homology to known allergens from food and environmental sources. If positive matches are found with known allergens, then the protein is considered likely allergenic. If no significant sequence homology is identified, then targeted serum screening is conducted with serum samples that contain high levels of IgE antibodies with a specificity that is broadly related to the gene source. If the targeted serum screening is positive, then the protein is considered likely allergenic. If the targeted serum screening is negative, then pepsin resistance of the expressed protein and the immunogenicity of the expressed protein in suitable animal models are to be assessed to determine the likelihood that the protein will be allergenic.

6. The Consultation agreed that the FAO/WHO 2001 decision tree is not applicable to the evaluation of foods where hypo-allergenicity has been induced by down-regulation of genes.

7. The Consultation was of the opinion that an evaluation of proteins for sequence homology with sufficient sensitivity and specificity to detect potential cross-reactivity is an important part of the process for the assessment of the allergenicity of the expressed protein.

8. The Consultation agreed that further studies would be required to determine the amount of allergen that sensitises and elicits allergic events.

9. The Consultation recognized the need to constantly update allergen databases.

10. The Consultation concluded that animal models have not been evaluated for all food allergens but there is sufficient scientific evidence that using these models will contribute valuable information regarding the allergenicity of foods derived from biotechnology.

11. The Consultation agreed that pepsin susceptibility is a relevant parameter for the identification of potential allergens and that the protocol described is not intended to mimic the physiologic conditions of gastric digestion.

12. The use of human in vivo methods to evaluate the allergenicity of foods derived from biotechnology may in many circumstances raise ethical issues and their use will have to be considered on a case-by-case basis.

13. Post-market surveillance is a valuable tool in the monitoring of adverse effects and longterm sequelae of foods derived from biotechnology and the Consultation recognized that the feasibility of certain aspects of its implementation would need further investigation.

14. The Consultation accepted that the FAO/WHO 2001 decision tree and its accompanying clarifying text will require modification in the future as a result of the rapidly expanding scientific base in the allergy and biotechnology fields but that this decision tree is appropriate based on our present knowledge.

One of the most common fears about GMOS in the plant world is the possibility of plant-based GMOs mixing with food supplies, or the potential of transgenic animals breeding with native population.

To prevent this, biomedical researchers have turned to producing the pharmaceutical products in non-food, or feed crops such as tobacco (*Nicotiana tabacum*), duckweed, and others to produce a wide range of human proteins to treat illness, including anticoagulants, growth hormone, Hepatitis C and B treatments, human interferon, liver cirrhosis, human serum, and cystic fibrosis. Regulation of transgenic organisms, including genetically modified or transgenic plants, is shared by three agencies: the Environmental Protection Agency, the Food and Drug Administration, and the USDA – and at the local level, the California Department of Fish and Game oversees transgenic aquatic species. Research facilities are secure, research animals carefully housed and cared for, and no transgenic animal is allowed to breed with wild populations. In

addition, the United Nations, World Health Organization, American Medical Association, and the National Academy of Sciences have examined the health and safety issues of GMOs. The UN recently reported that genetically modified crops "pose no more risk than conventionally grown crops" and "there have been no verifiable reports of their causing any significant health or environmental harm."

There are also concerns about the use of transgenic animals in research. In particular that these animals suffer more abnormalities, are more likely to be destroyed and that they could have a negative impact on wild populations if they are accidentally released. All animal-based research is subject to rigorous government regulation and inspection.

In addition to profoundly benefiting biomedical research and by association offering dramatic developments in medical treatment and improvements in human and animal health, using genetically modified animals can be good for animal welfare because: Fewer animals can be used for each experiment because researchers get more accurate results; the use of transgenic mice is helping to reduce the number of other animals needed for medical research.

For example one pharmaceutical company has helped develop a new safety test for the polio vaccine that uses transgenic mice, rather than monkeys; researchers can use simpler animals like fruit flies and earthworms, or rats and mice instead of using complex animals like primates; and in many cases, researchers don't even need to take blood samples from animals to test for proteins because they can get them to produce those proteins in their milk.

### **3-4- RECOMMENDATIONS**

New methods for the evaluation of risks associated with GMO in food should be developed in the future and should be integrated in the official evaluation procedure. Meanwhile, the precautionary principle<sup>26</sup>, whose introduction has been prompted by increased scientific uncertainties in the evaluation of risks for the environment ("irreversible damage")<sup>27</sup> – and which states what should be done in a situation of uncertainty, without waiting for scientific proofs to take the necessary measures to reduce a potential risk - should be applied. This principle remains, however, largely ill-defined and its application is not universal nor compulsory. Is the standardisation of risk assessment possible? In order to be used as a management and regulatory tool, risk assessment should result in precise measures. The reliability of expert judgement and the definition of scientific knowledge are often questioned. This might be due to the fact that scientific and technical knowledge is today in the hands of the main industrial actors worldwide and, amongst the researchers of public research institutes, only a few do not work in partnership with industry.

As a result, the credibility of control procedures, as some experts might find themselves in a situation of judge and party is questioned.

Nevertheless, most warnings on GMOs today are mainly issued by experts which are fully independent from the interest groups involved in the debate.

At European level, the Commission has proposed to rely on the European Group on Ethics in Science and Technology, created in 1997, for ethical advice, which should become the "Ethical committee" (12 members in 1998). The recommendations of joint FAO/WHO are sited on the following steps.

1. The Consultation recommends that the FAO/WHO 2001 decision tree be used for determining allergenicity of foods derived from biotechnology.

2. The Consultation recommends that FAO and WHO should endeavour to update the decision tree as and when required.

3. The identification of food allergens and the characteristics of these allergens that define their immunogenicity are encouraged.

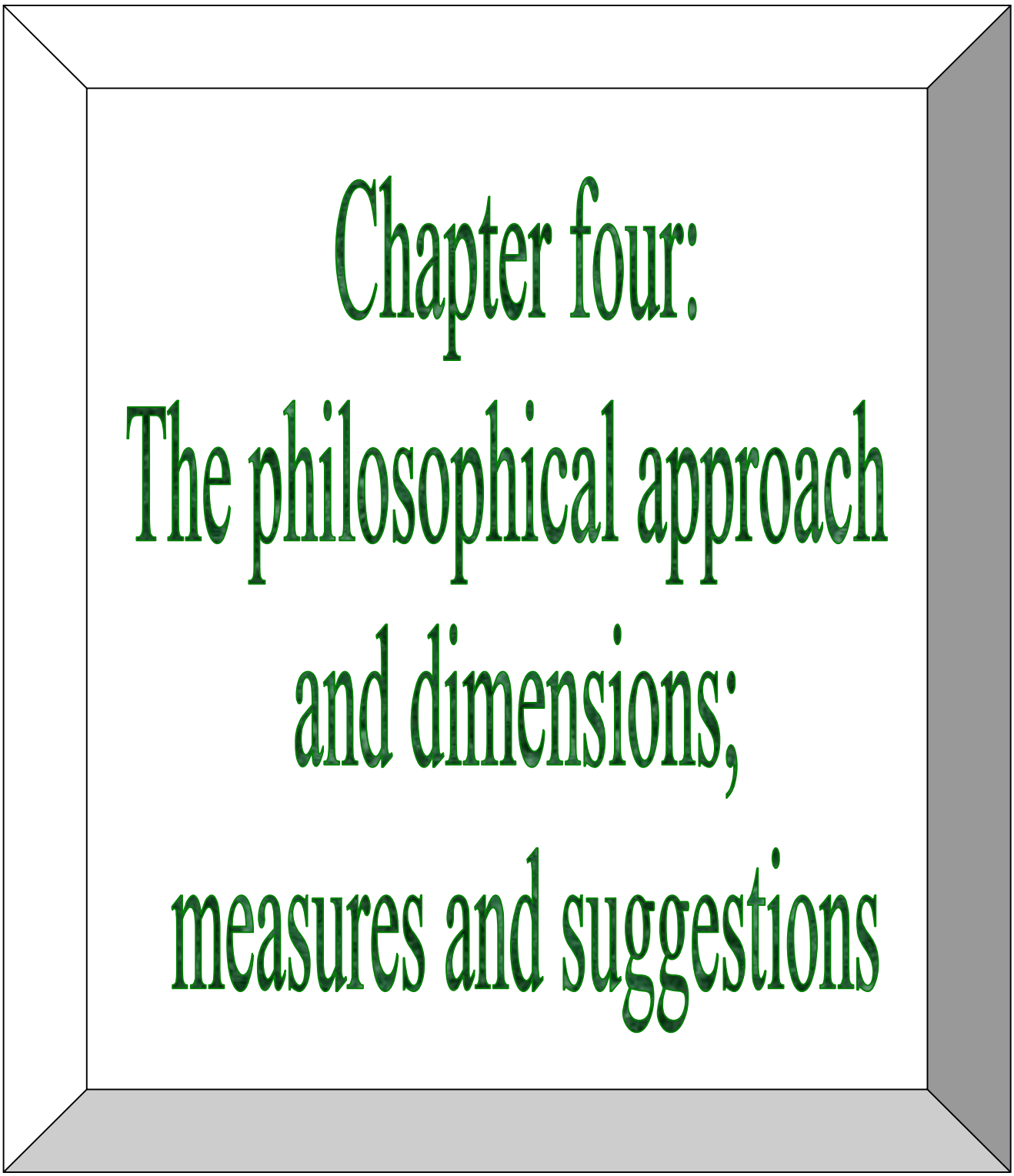
4. Protein and gene databases required for the assessment of allergenicity of foods derived from biotechnology should be frequently updated and maintained.

5. Further research is needed on the development and validation of suitable animal models and procedures for the assessment of allergenicity of foods derived from biotechnology.

6. The Consultation recommends that the possibility of implementing post-marketing surveillance should be further studied.

7. The Consultation recommends that FAO and WHO provide technical support to member countries to strengthen their capacity and infrastructure to enable those countries to undertake the evaluation of the allergenicity of foods derived from biotechnology.

8. The Consultation recommends to FAO and WHO the establishment of a coordination network to promote and strengthen the interaction between experts to improve standard operating procedures, good laboratory practices and good clinical practice to facilitate the evaluation of the allergenicity of foods.



Chapter four:  
The philosophical approach  
and dimensions;  
measures and suggestions

## **THE PHILOSOPHICAL APPROACH AND DIMENSIONS; MEASURES AND SUGGESTIONS OF MODIFIED ORGANISMS**

### **4-1- THE PHILOSOPHICAL APPROACH AND DIMENSIONS**

With the development of biotechnology, Nature has become a resource with a high commercial value for its genetic components, the basis of new products, above all for the pharmaceutical and agro-chemical industry. Patents giving intellectual property rights have extended to live organisms and its genetic material. Nature has thus become an object of private property and the Convention on Biodiversity has mentioned the need for compensation for countries giving access to their natural resources.

Due to the very nature of the subject studied (genes, their variation, transmission and organisation in the genome); research on GMOs concentrates many questions on human values and the relationship between science and ethics. The genetic modification of living organisms raises philosophical and ethical questions, the definition of "species", their appropriation by man through patents and also the status of animals and plants compared to man.

The introduction of GMOs can have a negative impact for developing countries if the production of molecules previously derived from local plant varieties becomes possible in laboratories or other plants grown in the North. Moral values should have priority above commercial considerations, especially if it is claimed that development and solidarity between poor and wealthy countries are fundamental. To this end, financial means should be allocated to research into the applications of biotechnology which are interesting for developing countries, adapting to their traditions and taking into consideration their way of life (FAO Seminar, Paris 1999). Given that the prevailing model today is intensive agriculture, the debate on biotechnology has concentrated on a

restricted definition of risk : global risk (social, economic, environmental) deriving from an industrial type of agriculture has not been taken into account, as well as other methods which can respond to the real problems encountered in the field. Further issues raised include the impact on the environment: on the loss of biodiversity and the ecosystem's equilibrium, with the fear that new plants and animals are created, crossing the species barrier, simply in response to the socio-economic plans of man.

### **A- Growing GM Engineered Organs in Animals to Replace Human Parts**

There are too many heavily funded, highly praised scientists who think they can outwit nature and play God. A recent medical science development in Japan is leading the way to using animals for creating organs to be transplanted into humans. Though hailed as a solution for many who await organ transplants, this actually extends medical science's departure from natural healing further with more rationale for animal suffering. (NaturalNews).



**GM ANIMALS**

Professor Hiromitsu Nakauchi of Tokyo University declared at the European Society of Human Genetics: “Our ultimate goal is to generate human organs from induced pluripotent stem cells. The technique, called blastocyst complementation, provides us with a novel approach for organ supply.

We have successfully tried it between mice and rats. We are now rather confident in generating functional human organs using this approach.” This is to say that pluripotent stem cells are able to reproduce as other types of cells rather than repeat themselves or replicate embryonic cells. Blastocyst refers to early mammalian embryonic development. Since inducing pigs to generate human blood has already been established with this procedure, the switch from rats and mice to pigs and humans is the next logical step. The pigs could be injected with human stem cells to produce a replicate organ for a human who requires a transplant.

### **B- What about the Animals?**

The experiments involved mice that couldn't grow a pancreas. Why? *They were genetically engineered that way.* That made newborn mice diabetic because they couldn't produce insulin. The mice were injected with stem cells from rats with healthy pancreases and as the mice matured they grew pancreases and were no longer diabetic. So a pig would have to be missing a pig organ for it to grow a human organ that would be taken out for placing into a human.

This is double suffering and subsequent often gruesome death for many pigs. Sure, this farm animal suffering and death for greedy human consumption is rampant with factory farming and large slaughter houses. But that should also be stopped. To paraphrase Ghandi: “A society's morality can be determined by its treatment of animals.” If you've seen any covertly filmed footage of CAFOs (confined agricultural feed operations) or factory farms, or demonic slaughter house activity, you'd be shocked or grief stricken if you have any compassion.

### **C- Current Transplant Activity**

The list for people in need of a liver, kidney and heart is long. Many at the bottom of a list engage in “organ tourism” in which someone pays big bucks for some poor sap to give up an organ to a black market surgeon.

Black market organ transplanting also leads to snatching body parts from cadavers, temporarily kidnapping and operating to remove a desired organ, and even killing someone to get a good organ for the highest bidder.

In addition, people who receive successful transplants commonly feel they're "fixed" now. But they're put on a protocol of meds that often make life a little uncomfortable. Some feel they can go back to their old lifestyles, which often include drinking and smoking, consuming lots of sugar and processed foods. In a few years, it's not uncommon for some of these folks to need another transplant or simply perish. Then there are transplants that fail. One cause is the body's excessive immune reaction to a foreign substance. Another reason is that the transplanted organ is faulty or diseased to begin with. There was a rash of fatty livers transplanted in the UK over the last few years. The possibility of undetected infectious disease looms as well, especially with organs groomed in animals. So is organ roulette a wise move toward improved health and longevity? Of course not. The right ways for prevention and healing have been the most ignored ways. Embracing real knowledge of proper nutrition, healthy lifestyle, and traditional healing should be where modern medicine looks and what the main stream media.

#### **D-Public perception**

Only 2 % of Britons were said to be "happy to eat GM foods", and more than half of Britons were against GM foods being available to the public, according to a 2003 study. However a 2009 review article of European consumer polls concluded that opposition to GMOs in Europe has been gradually decreasing. Approximately half of European consumers accepted gene technology, particularly when benefits for consumers and for the environment could be linked to GMO products. 80 % of respondents did not cite the application of GMOs in agriculture as a significant environmental problem.

Many consumers seem unafraid of health risks from GMO products and most European consumers did not actively avoid GMO products while shopping.

However, multiple surveys have shown that while 45% of the public will accept GM foods, some 93% demand all genetically modified foods be labelled as such. A 2007 survey by the Food Standards Australia and New Zealand found that 27% of Australians looked at the label to see if it contained GM material when purchasing a grocery product for the first time. Labelling legislation has been introduced and rejected several times since 1996 on the grounds of "restraint of trade" due to the cost of labelling. The controversy erupted again in 2009 when Graincorp, the nations largest grain handler, announced it would mix GM Canola with its unmodified grain. Traditional growers, who largely rely on GM-free markets, had been told they would need to pay to have their produce certified GM free. Graincorp reversed its decision the same year. Critics such as Greenpeace and the Gene Ethics Network have renewed calls for more labelling.

Since 1991, large surveys on the opinions of Europeans on biotechnology and genetic engineering have been carried out (Eurobarometer surveys). In general, the results have predominantly shown a reticence towards these technologies, for both the principle of genetic modification of foods, plants and animals, and the mechanisms with which they are regulated (POST, 1998). These reactions vary according to country: in 1996, favourable reactions towards biotechnology were found in Portugal, Spain, Italy and Ireland, while there was little confidence in the Netherlands, Germany, Luxembourg and Denmark. France, the UK, Belgium and Greece were in an intermediary position (Bonny, 1996). There have been several factors contributing to the negative reactions by consumers in Europe to the introduction of the first transgenic plants: the presence of marker genes causing antibiotic resistance, the production of products without direct benefits for the consumers, developed by multinational agro-chemical companies and concerning mainly animal feed.

GMO have been assimilated to the results of productivism associated with public health accidents.

Initially, a clear labelling of GMO foods such as tomato paste in the UK did not cause *much fuss* (POST, 1998) since consumers had a choice to buy GM foods or not. What has fuelled adverse reactions is however the incorporation of GM soya, maize and other bulk crops into many processed foods. Furthermore, GM products are felt as something inevitable and at the same time consumers are unable to see the direct benefits which they could derive from GMOs and their widespread usage, which is felt as being more often spurred by the expected profits which the industry might derive from it (IFN, 1998).

#### **4-6- Measures and suggestions**

In spite of stricter provisions in the new EU directive on deliberate release of genetically modified organisms (GMOs), critics still advocate a moratorium on permits for cultivation of GMOs. However, in an attempt to meet concerns raised by the public, the directive explicitly gives Member States the possibility to take into consideration ethical aspects of GMOs in the decision-making. This works investigates the potential effects of such formulation by means of an empirical analysis of experiences gained the last years from similar Swedish regulations for GMOs, aiming at promoting sustainable development. The faulty implementation shown in the Swedish case indicates that legal stipulations for ethics as such have limited importance. It is suggested that public participation is an important factor for successful implementation of the ethics of sustainable development. The research was needed, however, and should be welcomed, because food security is one of the biggest challenges we face, and we must find ways in which to produce more food while continuing to reduce the impact our agricultural practices have on the environment.

Britain has a key role to play in helping to deliver this solution; however, as widely acknowledged, our current methods of production will not be sufficient to meet the increasing demand. In fact, GM technology has done much to empower small farmers – over 90% of those who choose to use GM crops are small-scale farmers living in developing countries. They grow them because they work, contributing to exactly the kind of "sustainable intensification" which the Royal Society called for – producing more food from a lighter environmental footprint. Additionally, it's worth noting that GM technology is highly accessible to small as well as large companies, and to university and public sector researchers, who have already developed GM crops of great potential value, such as virus-resistant papaya, insect-resistant vegetables for India, and vitamin-enriched "golden" rice.

If we are serious about allowing UK farmers to produce more food at a fair price to consumers while safeguarding our natural resources, they must be given the freedom to choose modern, efficient farming methods based on tried and tested science. We need science-based decision-making, something our politicians clearly understand. The world has moved on, and it's time the anti-science activists did too. Testing on GMOs in food and feed is routinely done using molecular techniques like DNA microarrays or qPCR. These tests can be based on screening genetic elements or event-specific markers for the official GMOs. The array-based method combines multiplex PCR and array technology to screen samples for different potential GMOs, combining different approaches (screening elements, plant-specific markers, and event-specific markers). The PCR is used to detect specific GMO events by usage of specific primers for screening elements or event-specific markers. Controls are necessary to avoid false positive or false negative results.

Detection methods mainly concern proteins and DNA. Those concerning proteins cover products which are only slightly processed or not processed at all and are based on immunochemical reactions.

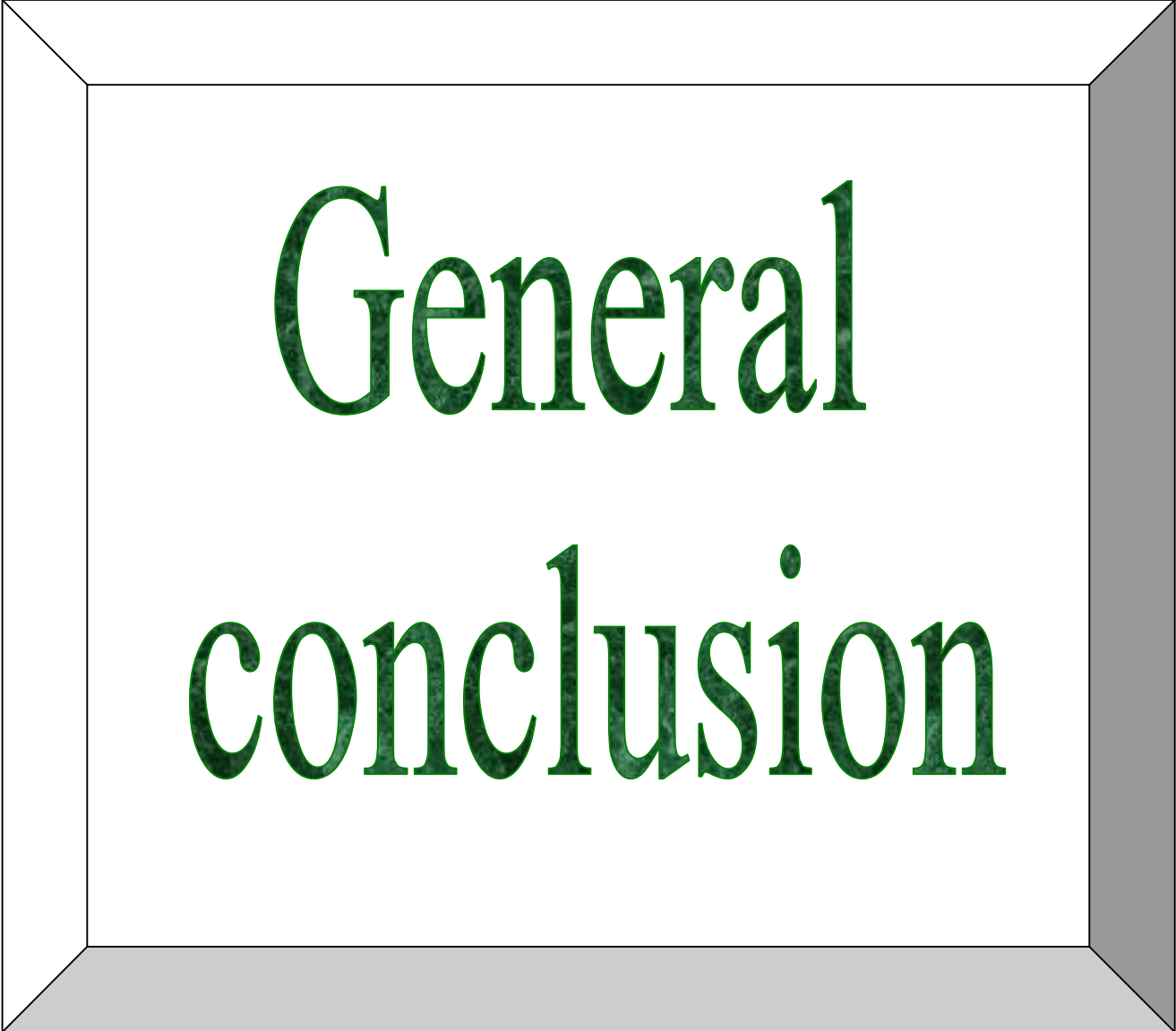
Proteins derived from the expression of a gene of interest introduced in the plant are specifically recognized by antibodies ("Elisa" method). The detection of DNA is done through a method called polymerase chain reaction (PCR) (Campaniol, 1999). This method can be applied on processed products since DNA is degraded at a lower rate than proteins. It enables the multiplication of a large number of copies of the DNA fragment which is of interest and thus detects even very small quantities of DNA. In general, a genetic modification can be detected because of the existence of common DNA fragments between GM plants. A weak point of this method is however the impossibility of asserting the absence of foreign DNA if it is not detected. The identification of a particular genetic modification requires the knowledge of a specific fragment, linking part of the transgene and part of the chromosome on which the transgene itself is inserted. However, this information remains inaccessible to the general public and there is no centralized database for these fragments, which would be a useful reference for the traceability of GMOs throughout the food chain, from the field to the consumer.

GMO labelling was introduced to give consumers the freedom to choose between GMOs and conventional products. Essentially, if a foodstuff is produced using genetic engineering, this must be indicated on its label. Actual labelling practice, however, is far more complicated - and must be planned and regulated with issues such as feasibility, legal responsibilities, coherence and standardisation in mind. Labelling is also required for foods which are offered by restaurants, canteens and takeaways - although there are exceptions.

By law, the use of genetical engineering is prohibited for products defined as 'organic'. Nevertheless, these products are permitted in certain cases to contain

slight traces of genetically modified organisms. New, strict labelling regulations took effect in April 2004. Many people expected that they would soon find products with GMO labels in grocery stores. With the notable exception of the Netherlands, GMO labelled products never really appeared. All food, and any ingredients, directly produced from a GMO must be labelled, even if this GMO is undetectable in the final product.

Detection methods for specific GMOs have improved in recent years - but, unlike most chemical measurements, may vary in reliability, precision and accuracy. Whether or not to require labeling of genetically engineered (GE) foods is a key issue in the ongoing debate over the risks and benefits of food crops produced using biotechnology. Consumers have a right to know what's in their food, especially concerning products for which health and environmental concerns have been raised. Mandatory labeling will allow consumers to identify and steer clear of food products that cause them problems. Labels on GE food imply a warning about health effects, whereas no significant differences between GE and conventional foods have been detected. If a nutritional or allergenic difference were found in a GE food, current FDA regulations require a label to that effect.



General  
conclusion

## GENERAL CONCLUSION

The use of genetically modified organisms represents an *enormous* advance in the science of biological and medical research, and GMOs are playing an *increasingly* important role in the discovery and development of new medicines to treat and cure: to create and produce vaccines to prevent diseases, to develop new and more efficient ways to create antibodies for the treatment of diseases, and to develop and manufacture pharmaceuticals. Likewise, genetic modification in bacteria has resulted in the production and marketing of human growth hormone etc.

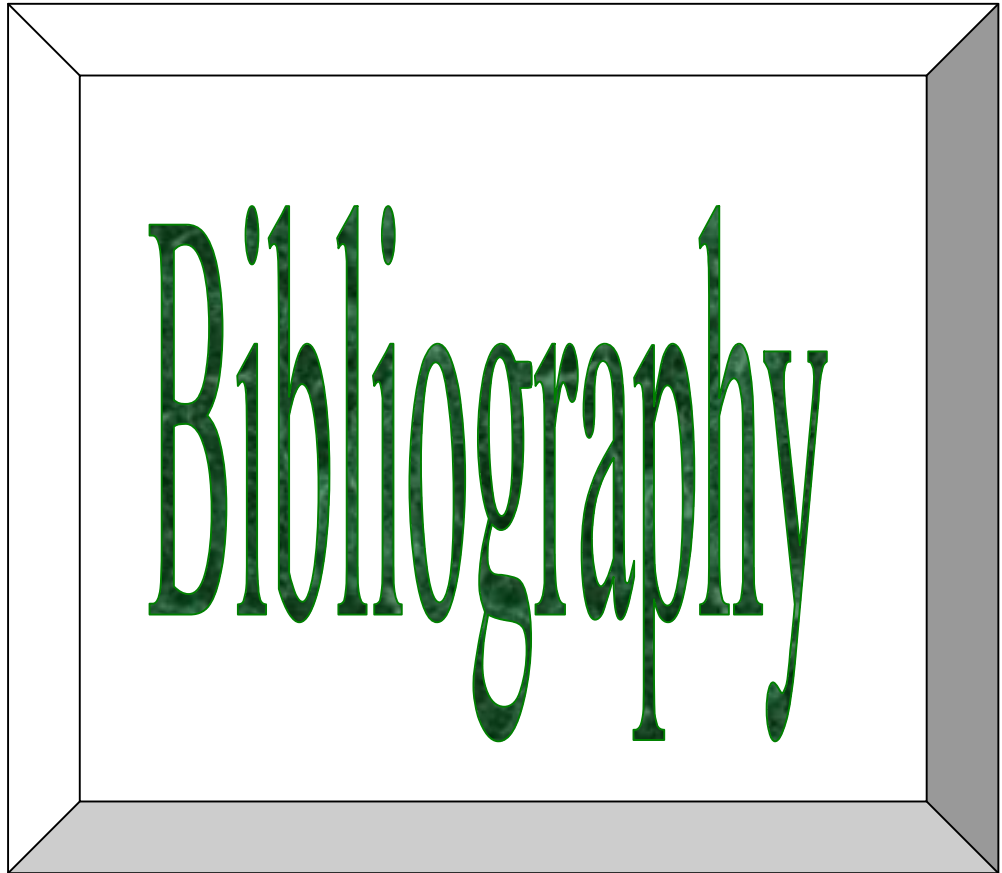
Genes change continuously by natural mutation and recombination enabling man to select and breed crops having the most desirable traits such as yield or flavour. Genetic modification is a recent development which allows specific genes to be identified, isolated, copied and inserted into other plants with a high level of specificity. The food safety considerations for GM crops are basically the same as those arising from conventionally bred crops, very few of which have been subject to any testing yet are generally regarded as being safe to eat. In contrast a rigorous safety testing paradigm has been developed for GM crops, which uses a systematic, stepwise and holistic approach. The lack of any adverse effects resulting from the production and consumption of GM crops grown on more than 300 million cumulative acres over the last 5 years supports these safety conclusions.

As far as GMO and the environment are concerned, projects in key action should focus on the development of methods and strategies for a risk-free introduction, utilisation, monitoring and detection of GMO in food and the environment. Possible orientations and priorities concerning the quality of life will be given on the basis of additional information gathering and assessment of the current situation of research in Europe, with the views expressed from professionals in this field.

What seems to be already desirable is to take a closer look at the development of research in food biotechnology. This is because research has all too often been dictated by short-term commercial interests, which did not take into account the importance of the long-term usefulness and profitability of research to society, several areas for the improvement of the quality of life through better food quality remaining under-researched. This is where the member States and the European Union could intervene, ensuring also a better coordination of European research in order to create added value also favorable to others communities.

The two-year long rat study conducted by Séralini and his colleagues displays, from a scientific point of view, considerable shortcomings. The most serious of these can be found in the fact that the study used far too few rats per treated group and that there were too few control groups. In one fell swoop this entirely removes the basis for the conclusions that Séralini et al. draw. In addition to this, for every conclusion that they draw there is sufficient evidence in their own text to undermine them completely. There are also other shortcomings and numerous other questions that remain unanswered. One thing is clear: Séralini et al. have not been able to substantiate in any way whether genetically modified NK603 maize or Roundup is harmful or not. The only thing that the study confirms is that Sprague-Dawley rats, like many other laboratory rats, develop relatively speaking many pathologies and that, as a consequence of this, many of the animals do not reach two years of age.

Genetic modification is analogous to nuclear power: nobody loves it, but climate change has made its adoption imperative. Declining genetic modification makes a complicated issue more complex in all over the world.



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