EUROPEAN PARLIAMENT

DIRECTORATE-GENERAL FOR RESEARCH
Directorate A: Medium- and long-term Research
Division for Industry, Research, Energy, Environment and STOA

BRIEFING

ENVI 504 EN

GENETICALLY MODIFIED ORGANISMS (GMOs)

Luxembourg, 28 October 2001 PE 309.707

This document is only available in English.

Summary

The field of genetic engineering has been both exciting and startling from the start. This paper tries to summarise current discussion concerning genetically modified organisms (GMOs) and describe the present legislation in this field.

Publisher European Parliament
L-2929 Luxembourg

Author: Ruth Espinosa García (former Robert Schuman scholar)

Editor: Peter Palinkas
Directorate General for Research
Division Industry, Research, Energy, Environment and STOA
Tel: (00352) 4300-22569
Fax: (00352) 4300-27718
E-Mail: DG4-Industrie@europarl.eu.int

PE 309.707

TABLE OF CONTENTS

1. INTRODUCTION

The field of genetic engineering has been both exciting and startling from the start. The scientific community first expressed fears in a moratorium on the use of this technology. When we "tweak" nature, we never have one hundred percent certainty of what the results will be; thus, it is why is advisable to adopt a prudent position. On the other hand, it is perfectly reasonable to exploit the possibilities that this new technology offers to improve nutrition and fight against disease.

1.1. GMOs

The basis of GMOs is the mixing of genes. Nature allows and practises a certain amount of genes mixing, but it imposes some limits that only man dares cross.

A GMO can be a micro-organism, an animal or a plant. At present, almost all commercialised GMOs are plants.

The great difference vis a vis traditional hybridation is that genetic manipulation is an imposed hybridation which can even transgress the species' barrier.

1.2. How to make a transgenic crop

The processes involved in making a transgenic crop are the following:

1. Identification of an organism containing the desired gene. This can be from a plant, animal or micro-organism.
2. Isolation of the desired gene from that organism.
3. The creation of a modified genetic sequence by the fusion of the desired gene, a promoter sequence which controls the functioning of the gene and a marker gene e.g. a fluorescent protein or an antibiotic resistance factor which allows the gene's presence to be detected even when the target gene is not being actively expressed.
4. Multiplication of the recombinant sequence, usually in bacteria, to produce multiple copies.
5. Insertion of the copies of the desired gene into the organism to be modified, using either a particle (gene) gun or a biological agent.
6. Selection of those organisms, which have successfully taken up the desired gene using a selection test that recognises only those organisms, which have adopted the marker gene.
7. Multiplication of the modified plants.

1.3. Scientific advice

GMOs are neither inherently risky nor inherently safe. Their degree of riskiness or safety depends on the characteristics of the inserted gene, the final organism that is produced and the application to which it is put. There is no scientific evidence that the use of this technology is itself inherently unsafe.

In Europe, the use of the technology in all organisms is strictly regulated, at all stage from research to production, in contained use and in deliberate release to the environment, or placing on the market.

EC research into the safety of GM crops and GM foods was initiated in 1986 and has not demonstrated any safety concerns for human health or the environment. However, there are some widely published reports that have suggested that there might be some harmful effects of specific GMOs in animals.

1.4. Potential risks

We know very little about GMOs impact on human health and environment. The following are *possible* scenarios.

- *On human health:*
- ***Allergic risk***: The introduction of a foreign gene in a plant might lead to the emergence of new allergens.
- ***Toxicity:*** Most transgenic plants are modified to make them resistant, by producing an insecticide that kills the attacking insect, or herbicide resistant, they survive while weeds die, but they absorb the herbicide. These insecticides and herbicides might be concentrated in the alimentary chain, producing disease
  On the other hand, the introduction of a strange gene into a plant can disturb its metabolism, leading to the appearance of toxic substances.
- ***Antibiotic resistance***: The use of GMOs might lead to the increase of bacterial antibiotic resistance. Most genetically modified plants contain antibiotic resistant genes that could be transmitted to bacteria dangerous to human beings. Since our choice of antibiotics to treat human diseases is restricted, the possible emergence of antibiotic resistant bacteria is rather worrying.

- *On the environment:*
- ***Neighbouring field contamination risk***: the growing of GMO's next to traditional crops might lead to cross-pollination, so that traditional products would no longer be considered as non-GMOs.
- ***Pesticide adaptation risk***: The possible transmission of a herbicide resistant gene from a GMO crop to a weed would result in the weed becoming resistant to the herbicide.

2. CHRONOLOGY

- **1980:** Scientists are able to splice genes from one organism onto the DNA chain of another. US Supreme Court rules the patentability of genetically altered life forms.
- **1987:** First transgenic cultures in United States.
- **23 April 1990**: EU Directive 90/220 concerning the deliberate release of GMOs.

- **1991:** Introduction of pirale gene in maize and first widespread field-tests in Colmar, United States and Argentina.
- **1994:** USA approves the commercialisation of a tomato altered to ripen slowly and delay spoilage.
- **1995:** USA legalised the placing on the market of *Novartis* transgenic maize.
- **1 March 1995:** In France, the "genie biologique" Committee gives a favourable view to the placing on the market of Novartis transgenic maize.
- **1996**: United Kingdom authorises marketing of transgenic tomatoes. Japan authorises transgenic plant imports. Australia authorises the widespread field culture of three transgenic plants.
- **8 December 1996**: Adoption by the European Commission of a decision to authorise the placing in the market of BT maize containing three Novartis genes and soya.
- **January 1997**: Luxembourg prohibits transgenic maize import and culture.
- **27 January 1997:** Regulation 97/258 on Novel Foods which introduces requirements for safety assessment, environmental risk assessment and labelling of products.
- **February 1997**: Austria forbids transgenic maize culture and import.
- **4 March 1997**: Italy forbids transgenic maize culture and import.
- **19 September 1997**: Regulation 1813-97/EC concerning certain foods produced from GMOs, which completes Regulation 258-97, entered into force 15 May 1997.
- **1 November 1997:** Regulation 1813-97 entered into force.
- **5 February 1998**: France authorises the culture of Novartis maize.
- **26 May 1998**: Regulation 1139/98 /EC concerning transgenic soybeam and maize labelling.
- **25 June 1999**: France, Denmark, Italy, Greece and Luxembourg stop new authorisations for the culture and marketing of genetically modified plants. Old authorisations are not suspended: 18 GMOs approved between December 1992 and October 1998 continue to be on the market.
- **February 2001:** Directive 2001/18/EC on the deliberate release into the environment of GMOs repeals Council Directive 90/220/EEC.

3. EU LEGISLATION

3.1. Introduction

Genetic manipulation has been regulated from the beginning.

EU legislation on GMOs took account, first of all, of the concern to establish an EU safety assessment and authorisation procedure. No product consisting of, containing or derived from GMOs can be authorised for marketing without having undergone an appropriate safety assessment.

The United Kingdom was the first country in the world to pass legislation controlling genetic modification. Thereafter, similar regulations were introduced elsewhere in Europe and in the USA.

In the EU, three separate pieces of legislation are the basis for governing the use of GMOs in food: Directive 90/220/EC, the Novel Foods Regulation (97/258/EC) and Regulation 1139/98 about the labelling of certain foodstuffs. Directive 90/220/EC is the main instrument for consent to experimental releases and for placing on the market of GMOs. It is "horizontal" legislation, which

complements specialised vertical sectoral legislation such as the Regulation on novel foods and Regulation 1139/98. The new Directive 2001/18/EC has replaced this Directive.

3.2. Horizontal legislation: European Directives

3.2.1. Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms

This Directive lays down common measures for the contained use of genetically modified micro-organisms for the purposes of protecting human health and the environment.

The Directive classifies genetically modified micro-organisms into two groups according to the level of hazard.

For the purposes of this Directive:

1) **"micro-organism"** shall mean any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;
2) **"genetically modified micro-organism"** (GMM) shall mean a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
3) **"contained use"** shall mean any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment.

The basis of this Directive was the scientific knowledge of the early 1980's and the limited practical experience of that time with genetically modified micro-organisms especially in industrial applications. Within a short time of Directive 90/219/EEC entering into force, many Member States realised that developments in gene technology had overtaken this Directive and that the administrative procedures and notification requirements were not appropriately related to the risk of contained use. Therefore, this Directive was amended by Directive 94/51/EC and Directive 98/81/EC. The main amendments simplify the administrative procedures, introduce a link between the notification requirements and the risks posed by contained use, and add a list of genetically modified micro-organisms posing no risk to human health or the environment.

Directive 90/219/EEC stipulates that every three years, Member States must send a report of their experience with the Directive. A report based on the national reports is then presented by the Commission.

The latest report of 17 May 2001 covered the following aspects:

- installations and activities;
- classification and risk assessment;

- notification and approval system;
- accidents;
- enforcement;
- problems with interpreting the provisions of the Directive;
- public consultation and information;
- accidents and emergency plans;
- protection of confidential information;
- waste disposal.

3.2.2. Council Directive 90/220/EEC of 23 April 1990 on the deliberate releases into the environment of genetically modified organisms.

EU Directive 90/220/EEC regulates the deliberate release of GMOs (plants, micro-organisms and animals) into the environment. It is intended to approximate legislation in force in the Member States to ensure that there are uniform market conditions and uniform protection of human health and the environment throughout the EU with regard to "live" GMOs. It does not apply to processed or derived products but provides explicitly for the development of sectoral legislation to be adopted when new GMO types and new applications emerge.

There are two different types of release covered by this Directive: research and development purposes (Part B) and placing of products on the market (Part C).

As it appears in Article 2, for the purposes of this Directive:

1) **"organism"** is any biological entity capable of replication or of transferring genetic material;
2) **"genetically modified organism (GMO)"** means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
3) **"deliberate release"** means any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment

- Authorisation procedure

Under Directive 90/220/EEC, before undertaking a deliberate release into the environment of a GMO or placing it into the market for the first time, the national competent authority of the Member State must be notified. This notification will contain a technical dossier of information including a full risk assessment. The Member State will examine this dossier. In the case of a negative evaluation the notification is rejected. In the case of a favourable opinion, the dossier will be sent to the European Commission where all the competent authorities of the other Member States have the right to raise objections.

If there are no objections, the national authority concerned grants authorisation for marketing the product, which is valid throughout the European Union.

In case of objections, a decision must be taken at EU level. The Commission seeks the opinion of its Scientific Committees before drafting a Decision, which is submitted, to the Regulatory Committee composed of representatives of Member States. If the Committee cannot agree, qualified majority submits the proposal to the Council, which decides. If no Council decision is taken within three months the Commission takes the decision. In any case, in accordance with Directive 90/220/EEC, the Commission is ultimately obliged to adopt measures to authorise a GMO, if the application

fulfils current EU legislation and if it is not rejected by unanimity in the Council, or if the Council fails to act within the fixed deadline.

- *Risk assessment procedure*

GMOs must undergo a scientific assessment of risks to human health and the environment before receiving Community authorisation based on the following:

1. How the GMO was developed, including the source of the genes to be introduced and detailed molecular analysis of the modified organism. It is necessary to establish which genes are cut out of the donor organism and where they are pasted into the recipient organism.
2. Risk associated with the gene products in the plant, mainly proteins. It is necessary to test that the gene does not encode for a protein that is toxic to humans or does not produce an allergic response.
3. Investigation of the possibility that the inserted gene may be transferred to bacteria. This has particular relevance to the possible transfer of antibiotic resistance genes.

This Directive was amended by Directive 94/15/EC, Directive 97/35/EC and recently replaced by Commission Directive 2001/18/EC.

3.2.3. Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

This Directive replaces Directive 90/220/EEC. It establishes a procedure for granting consent to the experimental release of GMOs (for research and development purposes) as well as the placing of GMOs on the market. Its main aim is to make the procedure more efficient and transparent and to limit such consent to a period of ten years (renewable). In accordance with the precautionary principle, the new directive requires that an environment risk assessment be carried out before the authorisation procedure. Furthermore, the directive foresees the identification and elimination of GMOs, which contain genes resistant to antibiotics used in medical and in veterinary treatments. This elimination will take place before the end of 2004 in the case of GMOs on the market and before the end of 2008 in the case of GMOs authorised for experimental research.

The authorisation defines obligations relating to monitoring and labelling. Labelling is obligatory for all stages of the placing on the market and the label must indicate clearly that 'the product contains genetically modified organisms'. In addition to labelling requirements, provitions relating to the traceability of GMOs allow competent authorities to follow GMOs at all stages on the market.

Public consultation is made compulsory. Under the new Directive, the Commission is obliged to consult the competent scientific committees on any question, which may affect human health and /or the environment. It may also consult ethics committees. The Directive requires registers to be established recording information on genetic modifications in GMOs and on the location of GMOs. Every three years the Commission must publish a summary of the measures taken in the Member States to implement the Directive. In 2003, and every three years thereafter, the Commission must publish a report on experience with GMOs placed on the market. An annual report on ethical issues will also be published.

This Directive entered into force 17 April 2001 and must be transposed before 17 October 2001. EU member states' own legislative bodies must implement this legislation. Meanwhile, the moratorium on introducing new GM products will remain in place.

3.3. Sectoral legislation: European Regulations

3.3.1. Regulation 97/258/EC for Novel Foods and Novel Food Ingredients

This regulation concerns the placing of the market of novel foods and novel food ingredients where novel foods are:

"foods and food ingredients which have never been used for human consumption to a significant degree within the community."

The authorisation procedures for GMOs are slightly different from the procedure under Directive 90/220/EEC, but the basic rule is similar: in general, the authorisation of GMOs is a one-step process if all Member States agree to the initial assessment of a Member State, and a two-step process if one or more Member States object.

Before it can be placed on the market, the Novel Foods Regulation demands that a novel food or ingredient:

1. Is safe for the consumer when eaten at the foreseeable levels of use.
2. Is not presented in such a way as to mislead the consumer.
3. Does not differ from a food or ingredient that it replaces in such a way that its foreseeable consumption is nutritionally disadvantageous to the consumer.

The Novel Foods Regulation is the first that establishes specific labelling rules for products developed through biotechnology. It lays down mandatory labelling and requires that consumers be informed of differences between a new product and existing equivalent products. Labelling should be applied if:

1. The novel food differs from the equivalent familiar food due to a change in composition or nutritional value.
2. Consumption of the novel food has health implications.
3. The novel food creates ethical considerations.
4. The novel food is or contains a viable genetically modified organism.

3.3.2. EU Regulation 1139/98

Two different genetically modified crops, soya (developed by Monsanto) and maize (developed by Novartis) were launched on the EU market prior to the introduction of Regulation 258/97. While this Regulation provides for compulsory labelling, the legislation cannot be applied retrospectively and so did not apply to these two products. In order to bring the labelling of these two products in line with future GM products, EU Regulation 1139/98 was introduced in July 1998.
The Regulation applies to all foods and food ingredients produced in whole or in part from GM soya and maize, which are to be placed on the market for human consumption. The product must be

labelled when DNA and/or protein resulting from the process of genetic modification are detectable in these foodstuffs. For this purpose, it is vital that a laboratory be available to carry out the relevant tests.

The Regulation goes further and specifies what the label must say: "*produced from genetically modified soya*" or "*produced from genetically modified maize*"

EC Regulation 49/2000 amends Regulation 1139/98 by extending the requirements to foods delivered to the final consumer as well as to mass caterers. It also specifies that no additional specific labelling is required for foodstuffs when a GMO is present in a proportion no higher than 1% of the food ingredients individually considered*.

Regulation 50/2000 concerns specific labelling requirements for foods and food ingredients containing additives and flavourings from GM sources.

3.4. Comparative analysis of EU and US legislation on GMOs

EU and USA Legislation on GMOs have different approaches.

From the 1960s through the mid 1980s, the regulation of health, safety and environmental risks was generally stricter in the USA than in Europe. The precautionary principle, though never an explicit component of US law, also underlay much consumer and environmental policy - making in the United States during these years. Since the mid 1980s the situation has turned round: a wide array of European consumer and environmental regulations, including those governing GMOs, are now more restrictive than in the United States.

The US treats environmental and health hazards from GMOs no differently than any other food production technology. Europe, by contrast, has established a distinctive, and more rigorous set of regulatory requirements for GMOs. Despite this, public confidence is considerably higher in the USA than in Europe, probably because of European food scares such as mad-cow disease or dioxins.

The United States has in place a well-established set of national regulatory bodies, which appear to function relatively well:

Three federal agencies regulate different aspects of GMOs:

- US Department of Agriculture (USDA): Issues permits for field trials and commercial release for production;
- Pesticides used in or on foods and feed are regulated primarily by EPA;
- Safety of domestic and imported foods, except meat and poultry which is regulated by USDA.

After a nation-wide hearing, the Food and Drug Administration (FDA) has now proposed regulatory changes in the field of GMOs: mandatory notification and guidelines for voluntary labelling.

In Europe, EU biotechnology legislation has been in place since the early 1990s but is in the process now of being revised fundamentally.
The main instrument for giving consent to experimental releases and for placing on the market of GMOs in the EU is Directive 2001/18. This horizontal directive does not only cover GMOs (living organisms which can be reproduced) but also GMO-derived products. The Directive, which now covers food, feed and seeds, confirms the pre-marketing authorisation procedure and the risk assessment procedure for all GMOs, and strengthens the former Directive through the introduction of:

- mandatory traceability and labelling at all stages of the placing on the market;
- mandatory monitoring requirements after placing on the market;
- mandatory consultation of the public (as with the US Federal Register);
- mandatory consultation of the EU Scientific Committee;
- application of the Precautionary Principle when implementing the Directive;
- a time-limited consent of maximum ten years.

However, the new Directive provides an exception for pharmaceutical products.

If one compares the US and EU regulatory approaches, the first is industry-driven and the second, consumer-driven.

4. DISCUSSION

4.1. Environmental organisations

Environmental groups emphasise that risks associated with GMOs cannot be evaluated in probability terms given the current state of knowledge. They claim that genetic modification can introduce (into the food supply) genes from unrelated species with no history of use as part of the human diet. Although all will readily agree that there has been no demonstration of risk to human health, they are effectively spreading the message that the food industry is failing to protect consumer interests by not conducting long-term studies on the effects of genetically modified foods before selling them.

These groups are the same proponents of GMO labelling and they've gained a stronghold in the European Union (EU) by carefully fomenting consumer anxiety about such products.

They call for more in-depth studies and a strict application of the "Precautionary Principle". They also point out that with GM crops there is an inherent risk of reducing biodiversity.

4.2. Biotechnological industries

Companies and institutions involved in developing GM food say that benefits far outweigh risks, with assurances that detailed tests are carried out before GMOs are released commercially. They say that GMOs will revolutionise food production, making agriculture more efficient and thereby

helping to solve the world's food crisis. Modified to withstand disease and pests, the new crops are a dream come true for farmers in constant battle with natural enemies. Stronger crops need less chemicals like pesticides and herbicides - themselves a significant environmental problem. Less chemicals on food would also be a plus for consumers.

Biotech companies, such as Monsanto Canada, have recently stepped up their campaign to promote the safety of their products.

4.3. Farmers

Farmers are excited about the prospects these new technologies present for reducing costs and increasing production yields. However, they wish to have the choice of whether or not to use GMO seeded crops on their farms. They are also concerned about intellectual property rights belonging to a few multinational companies which could lead to the exercise of monopolistic power worldwide.

Farmers also wish to know the international trading rules on GM foods before cultivating crops that may not be saleable abroad.

4.4. Scientists

The scientific community recognises that all science, all progress, carries risks or hazards and this has always been the case. But progress on science has been possible because science makes a distinction between the concept of hazard (danger) and that of risk (the probability that the danger will be realised). The scientific approach can systematically identify hazards, as well as the critical control points and monitoring methods that will help us avoid the risks associated with those hazards.

4.5. Consumers

Consumers question outright the benefits of genetically engineered foods as opposed to traditional foodstuffs, and are concerned by the possibility of transfer of known and unknown allergens and toxins via novel foods and feeds. For consumers, genetically engineered foods don't offer added benefits. The first generation of biotech crops that are programmed to withstand pests and certain herbicides may benefit producers, but offer no obvious benefits to consumers. Consumers won't change their food supply unless they get something that tastes better, looks better, or costs less.

Consumers also feel that they are not fully informed about the risks associated with genetically modified foods. They want more control over the risks they assume and better information about what those risks are.

Consumer organisations feel that labelling is essential for ascertaining the origin of foods, and in particular for separating GM from non-GM foods, for monitoring possible adverse effects of ingredients and for security of the public in the long-term. These organisations are of the view that

GM food safety should not be left to companies but that the governments have a clear role in developing risk management tools such as mandatory labelling, transparent approval processes for novel foods and regular, systematic environmental impact analyses as part of risk assessment. Some suggest that GMO food should be subjected to the same requirements as pharmaceutical products.

4.6. Legal situation and Member States position

GMOs have been the issue of many comments in the press. We include here some of the views that appeared in the French newspaper "Liberation" concerning GMOs which reflect the legal and social situation on this matter during the last two years:

- *Harmonisation:* The suppression of EU inner border controls and the free circulation of goods have aided the spread of various food crises, which lead the European population to distrust what they eat. It must be a priority to harmonise European food safety standards in order not to make the Single Market synonymous with distrust. Clear and strict regulations are required.
  The creation of an independent "*European food agency*" like the Food and Drug Administration in the US has also been proposed. If an European FDA were created, it would be responsible for approving new production procedures and new foods. It should dispose of the necessary means to function efficiently and be able to supervise national controls.

  (Libération, 18 June 1999)

- *GMOs undesirable in Europe:* France, Greece, Denmark, Italy and Luxembourg have proposed a moratorium for the entry of GMOs to the European Union until a regulation exists guaranteeing the labelling and traceability of GMOs and its derived products.
  Germany, Austria, Belgium, Finland, Netherlands and Sweden, rather than support such a radical measure, agreed another text which doesn't require the adoption of new legislation but just no authorisation of GMOs until there is certainty that they don't have any effect on human health or the environment.
  Great Britain, Spain, Portugal and Ireland have not agreed to either of the texts.
  Most Member States, the Commission and the European Parliament think that GMOs are the object of an irrational fear, since there has been no proof of any danger. Brussels already authorised the placing on the market of 18 GMOs between December 1992 and October 1998. Another 12 GMOs are waiting for permission. Many people don't understand why no one is proposing the removal of the 18 GMOs already on the market, whereas twelve, many of which have the same properties, remain suspended.
  Even if opponents of GMOs are a minority in the EU, they are able to block the placing on the market of GMOs.

  (Libération, 27 April 1999)

- *GMOs: Compulsory labelling:* Two regulations entered into force 10 April 2000 in the EU imposing the labelling of "foods and food ingredients" containing more than 1% GMOs, as well as all "genetically modified additives and flavourings."
  The objective is to advise consumers about GMOs in their food; and give them the choice to consume it or not. But sometimes the labelling is hardly visible.
  Many producers, faced with the need to label, have decided not to use GMOs. In 1999, Nestlé and Danone announced that they would exclude ingredients from maize and soybeans, two of the most susceptible plants for genetic modification.

The project for compulsory labelling began in 1996, when the EU approved the import of transgenic maize. However, at that time, we didn't dispose of the necessary methods to detect the presence of GMOs. From 1998 on, worldwide public opinion hardened against GMOs influenced by environmental campaigns. In April 2001, Japan made public its decision to label products containing more than 5% GMOs.
Nowadays, compulsory labelling is becoming a reality in European countries. The 1% limit in GMOs has reached a consensus. Under this limit, the detection of GMOs can be caused by accidental contamination in the fields or while transporting the plants.

(Libération, 10 April 2000)

5. CONCLUSION

Genetic engineering could turn out to be the greatest gift science has to offer the next century. It is vastly more precise than crossbreeding, which has been used for centuries to alter the genetic make-up of plants and animals. The resistance of consumers, however, based on their lack of knowledge in this field, is at present developing faster than the science itself. Not until governments demonstrate that regulation on approvals and on labelling is as adequate as it is for other areas, will these fears disappear.

Recently EU biotechnology legislation is being revised for this purpose. The new Directive 2001/18, replacing Directive 90/220/EEC, establishes new and higher safety standards to protect the environment and human health, is based on a broader risk assessment approach and introduces new concepts of traceability and monitoring which might help to identify and remedy adverse effects of GMOs at an earlier stage.

BIBLIOGRAPHY

OECD consultation with non-governmental organisations on biotechnology and other aspects of food safety, C(2000)86/ADD4, 20 November 1999

Peter, G., "Genetically Modified Crops", *Magazine of the European Union*, No 407, June 2001, p.22-25

Facts on GMOs in the EU
http://www.europa.eu.int/comm/environment/index_en.htm

Belgian Biosafety Server: EU legislation.
http://www. biosafety.ihe.be/Menu/BiosEur3.html

EU: GMO releases and legislation.
http://www.groundup.org/eugene.htm

SCADPlus: Genetically Modified Organisms.
http://europa.eu.int/scadplus/scad_en.htm

Food Law: EU Background Papers
http://www.fst.rdg.ac.uk/foodlaw/eu/doc-8.htm

Food safety and Genetically Modified foods.
http://www.fsai.ie/Gm_site/chap3.html

EU and UK regulation of GMOs
http://www.ncbe.reading.ac.uk/NCBE/GMFOOD/euregs.html

Libération: Les OGM mis en examen.
http://www.liberation.fr/ogm

SAC: Genetically Modified Organisms.
http://www.sac.ac.uk/info/External/About/publicns/gmos2.htm

OGM Santé
http://www.amisdelaterre.org/OGM/sante/page_sante.htm

What the EU wants the US to understand about European biotech imports.
http://www.eurunion.org/news/speeches/2001/010315tvdh.htm

RECENT ENVIRONMENT BRIEFINGS

These documents are all available in printed form.

Environment and Energy: Challenges of Enlargement
(ENVI 501, January 2001, En)

The Environmental Situation in Albania and the Federal Republic of Yugoslavia: A Short Overview
(ENVI 502, July 2001, En)

EU Chemicals Policy
(ENVI 503, September 2001, En)