WORLD TRADE ORGANIZATION

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Committee on Sanitary and Phytosanitary Measures Original: English

RESPONSE TO THE COMMENTS FROM ARGENTINA (G/SPS/GEN/354)

to the replies by the European Commission to the comments provided by several WTO Members to the legislative proposals notified under either or both G/TBT/N/EEC/6 - G/SPS/N/EEC/149[1] and either or both G/TBT/N/EEC/7 - G/SPS/N/EEC/150[2]

Submission by the European Commission

[1] Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed – COM(2001) 425 FINAL.

[2] Proposal for a Regulation of the European Parliament and of the Council on Traceability and Labelling of Genetically Modified Organisms and Traceability of Genetically modified Food and Feed – COM(2001) 182 FINAL.

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Background

In Document G/SPS/GEN/337 (G/TBT/W/179) of 26 July 2002, the European Commission replied to comments made on the legal draft ("proposals") notified in either or both G/TBT/N/EEC/6 and G/SPS/N/EEC/149[3]. In document G/SPS/GEN/338 (G/TBT/W/180) of 26 July 2002, the European Commission replied to comments received on the legal draft notified in either or both G/TBT/N/EEC/7 and G/SPS/N/EEC/150[4]. Further to this, in document G/SPS/GEN/354 of 4 November 2002, Argentina provided further comments concerning the aforementioned EC responses. Moreover, in accordance with the co-decision procedure foreseen in Article 251 of the EC Treaty, both proposals were submitted to the European Parliament (EP) for a first reading. The EP changed both proposals and returned them to the Council. Now the Council, after examining the amendments contained in the EP's opinions, has adopted;

1. a "*Common position with a view to the adoption of Regulation of the European Parliament and of the Council on genetically modified food and feed*" which has been forwarded to the European Parliament (EP) for a second reading and notified to the WTO (G/SPS/N/EEC/149/Add.2, 11 April 2003); and
2. a "*Common position with a view to the adoption of a regulation of the European Parliament and of the Council concerning the labelling and traceability of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC*" which has been forwarded to the EP for a second reading and notified to the WTO (G/SPS/N/EEC/150/Add.2, 11 April 2003).

Preamble

In notices G/SPS/N/EEC/149/Add.2 and G/SPS/N/EEC/150/Add.2, the EC made it clear to all its trade partners that the progress of both proposals can be followed through an Internet site fully dedicated to the decision-making process between institutions (i.e. the Commission, the Council and the EP). This site is called "Inter-Lex"[5] and provides access to the original proposal as well as to further modifications and numerous informative notes. In order to achieve full transparency on this procedure, the Commission will also reply to further questions or requests for information that cannot be answered either by examining the information texts available through "Inter-Lex", or by this or previous replies.

In the following pages, the questions raised by Argentina in Document G/SPS/GEN/354 (4 November 2002) are responded to. The questions have been grouped into 20 clusters with a corresponding 20 replies. Some of these replies elaborate further or refer the reader to previous responses in documents G/SPS/GEN/337 and G/SPS/GEN/338.

Further to this, and in supplement to the responses to the questions by Argentina, an annex is attached to this reply that transcribes Commission document MEMO/03/160 (of 4 March 2003) "*Questions and answers on the regulation on GMOs in the EU*".

[3] Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed – COM(2001) 425 final.

[4] Proposal for a Regulation of the European Parliament and of the Council on Traceability and Labelling of Genetically Modified Organisms and Traceability of Genetically Modified Food and Feed – COM(2001) 182 final.

[5] http://europa.eu.int/prelex/rech_simple.cfm?CL=en.

1. COMMENTS BY ARGENTINA ON THE OBSERVANCE OF THE NOTIFICATION PROCEDURE

Argentina points out that the text notified was that drawn up by the European Council, which does not include the modifications subsequently introduced by the European Parliament. According to the notification procedure laid down in Decision G/SPS/7/Rev.2 " … a notification should be made when a draft with the complete text of a proposed regulation is available and when amendments can still be introduced and comments taken into account". Accordingly, Argentina requests the European Communities to notify the latest version of the draft regulation so that it can be examined in detail.

1.1. Response by the European Commission:

The European Commission has forwarded the latest text, which is the Common Position of the Council on the Proposal for a Regulation on GM food and feed and the Common Position of the Council on the Proposal for a Regulation on traceability and labelling of GMOs and traceability of GM food and feed to the SPS and TBT Committees for information.

2. COMMENTS BY ARGENTINA ON RISK ASSESSMENT AND RELATED ISSUES:

In its presentation, the European Communities recognize that, according to its risk assessment, genetically modified plants and products obtained therefrom authorized for marketing in the European Communities do not represent a higher risk than their conventional counterparts, in other words they have the same "level of safety".

In the light of this conclusion, what would be the justification for setting up a different regime for the approval, labelling and traceability of this type of product in comparison with its conventional counterparts?

Do the European Communities consider that the different treatment of GMO products and their conventional counterparts is consistent with the obligation laid down in Article 5.5 of the SPS Agreement?

Following the results obtained from the risk analysis of authorized events and foods, is the obligation to "communicate the risk" reflected in these results?

Could informing the customer that a food has been modified result in partial information that could have a negative impact on consumer decisions?

In this connection, should the information given not include a mention of the positive aspects of the type of food (lesser impact effect on the environment caused by pesticides, reduction in the type and quantities of certain pesticides in the final product, naturally fortified food, same risk as the conventional product, etc.)?

2.1. Response of the European Commission:

The European Commission would like to refer to the justifications already provided in documents G/SPS/GEN/337 and G/SPS/GEN/338 concerning its response to similar comments submitted by other WTO Members. The European Commission considers its proposals both SPS and TBT compatible.

The European Commission does not consider that labelling the fact that a food contains, consists or is produced from a GMO as partial information, but rather that it increases transparency in the market place. It facilitates consumer choice and ultimately, the market forces will determine whether products are purchased or not. Current European Community food law does not exclude the possibility of labelling "positive" aspects as proposed by Argentina provided that claims are truthful and not misleading. The European Commission is not, however, aware of business operators who have or are making use of this possibility.

3. COMMENT BY ARGENTINA ABOUT LABELLING

Why do the European Communities want labelling according to method of production rather than labelling showing the characteristics of the final product? In particular, what are the reasons for which the objectives pursued could not be reached on the basis of a declaration of the characteristics of the final product?

3.1. Response of the European Commission:

The European Community approach to labelling is not new. The general European Community law on labelling of foodstuffs (Directive 2000/13/EC), which was adopted for the first time in 1979, provides that "the labelling and methods used must not be such as could mislead the purchaser to a material degree, particularly as to the characteristics of the foodstuff and, in particular as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production".

Since 1997, Regulation (EC) 258/97 on novel foods and novel food ingredients has provided for mandatory labelling of food containing or consisting of GMOs. In 1998, this requirement was extended also to cover food produced from a GMO based on detectability of DNA and protein resulting from the genetic modification. Therefore, the fact that a food is genetically modified or produced from GMOs is already considered a characteristic of the final product with relevance for consumers. Enabling the consumer to make an individual choice would ensure that they are not liable to be misled, and thereby foster increased public confidence and acceptance of GM food.

4. COMMENT BY ARGENTINA ABOUT PARAMETERS CONSIDERED TO AUTHORIZE A FOOD

Argentina considers that, when authorizing the marketing of a food, whether or not genetically modified, the only parameters to be taken into account should be technical or scientific parameters concerning its safety. The "should not mislead the consumer" requirement/objective is observed if the labelling shows the specific characteristics of the final product.

4.1. Response of the European Commission:

The European Commission would reiterate its comments in documents G/SPS/GEN/337 and G/SPS/GEN/338, which were made in response to comments from other WTO Members that also raised the issue: "Whilst 'misleading the consumer' is indeed normally an aspect of labelling, advertising or presentation, there are instances in which the intrinsic characteristics of a food could be misleading for the consumer. For instance, the food could have been modified to suggest that it is fresh whilst it is not, or a food could have been modified to present the appearance of another food, more attractive to the consumer. Whilst such situations have not yet arisen in respect of genetically modified foods, this does not mean that the case may not arise in the future. The proposed Regulation is not meant to deal only with the type of products that went to the market over the last decade, it is also meant to deal with products that may be placed on the market in the coming decades, including products derived from genetically modified animals as the case may be."

The European Commission would like to point out that the "not mislead the consumer" criterion has been carried from Regulation (EC) No 258/97, where its application has never led to any difficulty.

5. COMMENT BY ARGENTINA ABOUT PROCESSING AIDS:

The European Communities have replied that processing aids (i.e. materials used during processing but not present in the finished product), including enzymes used as such, are not food ingredients, in other words they are not foods according to the European Communities' legislation.

Could the European Communities explain in practical terms what is the difference between a gene introduced into an event, which is not present in the final product, and processing aids (including enzymes) which are not present in the final product either?

5.1. Response of the European Commission:

If an ingredient produced from a GMO is present in the final product, it is a basic fact that the ingredient is produced from a GMO irrespective of whether DNA or protein resulting from the genetic modification can be detected or not.

6. COMMENT BY ARGENTINA ABOUT INTEGRATION OF SCIENTIFIC ADVICE INTO MANAGEMENT

Argentina considers that risk assessment is a prior and separate procedure to risk management. Nevertheless, the latter should be based on the former so as to prevent discretionary practices and ensure that the final measure is based on science.

How do the European Communities interpret this obligation, in other words, how do the decision-making bodies (agencies) take into account the scientific assessment of risk?

6.1. Response of the European Commission:

The European Commission agrees that risk assessment is a separate "procedure" to that of risk management. The European Community has a long history of basing its decisions, relating to the safety of the environment and health, on risk assessment. Regulation (EC) 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down matters of food safety, provides for the separation of risk assessment and risk management.

7. COMMENT BY ARGENTINA ABOUT NATIONAL MEASURES:

In connection with the United States question on the procedures for granting or refusing an authorization, a modification, suspension or revocation of an authorization, or refusal to renew an authorization, the European Communities replied that these were the preserve of the European Communities and member States did not have authority to take national measures restricting the marketing of products for reasons of food or feed safety.

Argentina would like to know whether there are reasons other than "reasons of food or feed safety" that authorize member States to adopt national measures restricting the marketing of products covered by this draft text.

7.1. Response of the European Commission:

The Common Position on the Regulation on GM Food and Feed adopted on 17 March 2003 provides that member States may adopt emergency measures in very specific circumstances that relate to the protection of human health, animal health or the environment.

8. COMMENT BY ARGENTINA ABOUT LABELLING GMO MEDICINES :

In the case of medicines prepared on the basis of modern biotechnology methods, does the label also inform the consumer of the production method for the raw material used?

If this is not the case, how do the European Communities achieve the objective of "informing the consumer" in this case?

8.1. Response of the European Commission:

The European Commission does not agree with the suggestion that medicines are consumed as food. The European Commission does not consider medicines to be foods, but to be prescribed to cure diseases.

9. COMMENT BY ARGENTINA ABOUT A MODIFICATION TO THE ORIGINAL PROPOSAL :

In several parts of the draft text as notified it is mentioned, *inter alia*, that genetically modified food "should not present any risk to human health or the environment". As a result of the doubts expressed by several countries to the effect that such a level of security is absolutely unattainable for every type of food, the European Communities undertook to modify the text.

Could the European Communities explain how the text was adjusted to these requirements so that it does not constitute discrimination against genetically modified foods in comparison with conventional foods?

9.1. Response of the European Commission:

The European Commission has suggested modifying the text accordingly and the member States have agreed to change the original proposal to "should not present an unacceptable risk to human health or the environment". This is reflected in the Common Position on the proposed Regulation on GM Food and Feed.

10. COMMENT BY ARGENTINA ABOUT FACTORS CONSIDERED IN RISK ANALYSIS:

Article 2.2 of the SPS Agreement clearly establishes the obligation to base sanitary and phytosanitary measures on sufficient scientific evidence. In this connection, various reports of the Appellate Body have recognized the close relationship between this Article and the obligation to base measures on a risk assessment.

What are the reasons for which the adoption of decisions based on so-called "other factors" are not incompatible with the aforementioned articles of the SPS Agreement?

Could the European Communities identify what other factors are to be taken into account in risk analysis?

Do these factors differ in number and weight from those considered in the risk analysis for a conventional food?

Are the other legitimate factors taken into account by the European Communities at the risk analysis stage different from those considered for the authorization?

Could the European Communities state whether the "other legitimate factors" it is intended to take into account in the risk analysis are in conformity with Article 5.2 of the SPS Agreement?

10.1. Response of the European Commission:

In terms of "other legitimate factors", the European Commission would reiterate its response in document G/SPS/GEN/337 made to similar comments submitted by other WTO Members: "The European Commission contends that the proposed Regulation is entirely consistent with the General Principles for Risk Analysis recognized at the international level, which allows risk managers to take into account not only the results of a science-based risk assessment but also other legitimate factors relevant for the matter under consideration."

In Regulation (EC) 178/2002, it is indicated that other legitimate factors, relevant to the matter under consideration, include societal, economic, traditional, ethical and environmental factors and the feasibility of controls. Such factors relate to risk management decisions.

11. COMMENT BY ARGENTINA ABOUT CONSUMERS CONCERNS TO LABEL GMO FOOD:

On several occasions, the European Communities mention that there is "solid evidence" that the labelling requirements have been drawn up in response to the concern/needs of consumers.

What do the European Communities mean by solid evidence and on what studies is this based? How is the European Commission's action in response to such concerns regulated or implemented?

11.1. Response of the European Commission:

In the European Community, concerns and demands of citizens and interest groups are part of the political, democratic process.

The consumer demands are reflected in the positions of European consumer organisations, and the governments of the member States. The demands are also having effects on the situation in the market place. The fact that the European Parliament and the vast majority of member States have endorsed the proposed labelling requirements with the objective of ensuring transparency in the market place and facilitating consumer choice demonstrates that there is wide-spread democratic support of meeting the consumer demands in the European Community.

The most recent Eurobarometer survey (No 58) of March 2003 indicates that a majority of Europeans do not support GM food and consider that these are not useful for society. This further confirms the need to provide consumers with the choice to buy or not to buy GM foods.

12. COMMENT BY ARGENTINA ON LABELLING REQUIREMENTS AND TRADE RESTRICTION:

What are the reasons for which it is considered that the various labelling requirements for genetically modified foods and their conventional counterparts would not violate the principle of not being more trade-restrictive than required (Article 5.6 of the SPS Agreement)?

12.1. Response of the European Commission:

Labelling requirements to inform consumers about the presence of material that are known to cause a health problem to subsections of a population are fully justified by the SPS Agreement. Labelling requirements with the purpose of facilitating consumer choice is not regulated by the SPS Agreement.

13. COMMENT BY ARGENTINA ABOUT CROP SEGREGATION:

If it is the European Communities' view that it would not be necessary to implement a system of segregation and separate identity in order to comply with the draft regulations on labelling and traceability, what are the differences between the mechanisms proposed in the draft regulations and segregation and separate identity systems?

13.1. Response of the European Commission:

The proposals do not require GMOs or GM food to be separated from other crops.

14. COMMENT BY ARGENTINA ON TRACEABILITY ALTERNATIVES:

What alternatives to traceability were considered and why were they rejected?

14.1. Response of the European Commission:

The Commission would reiterate its comments made in document G/SPS/GEN/338 to similar questions submitted by other WTO Members: "In preparation of its Proposal, the European Commission examined the merits and disadvantages of a number of different labelling approaches, including the one that would complement the current mandatory labelling provisions (based on the presence of DNA or protein resulting from the genetic modification) with a Community-wide voluntary "GMO-free" (or similarly phrased) scheme.

The European Commission's preparatory work, including experiences in some member States, revealed that voluntary "GMO-free" (or similarly phrased) schemes were beset by a number of technical, commercial and other difficulties. It also became evident that consumers in the European Community were primarily interested in knowing whether their food was produced from GMOs or contained ingredients produced from GMOs. Consumers clearly prefer to be informed what is in products and not what is not in products. For instance irradiated food has to be labelled as such. European Community law allows for "free of" labelling claims provided the claim is truthful and not misleading. It would be considered misleading to label a food "GMO-free" or "non-GM" if there is no corresponding GM food on the market. "GMO-free" products are already supplied by the Organic Production scheme, which excludes the use of GMOs in the whole production chain on a very strict basis. A second "GMO-free" production scheme is therefore also considered to be confusing for consumers and potentially misleading."

In this context, traceability of GMOs and food and feed produced from GMOs would ensure that information concerning whether a food or a feed is consisting of, containing or produced from a

GMO is available at all stages of the placing on the market and should thereby facilitate accurate labelling of the final product, reduce the reliance on analytical methods as well as provide the means for inspection and control of labelling claims.

The European Commission would also like to reiterate that the two proposals facilitate consumer choice and a demand driven approach.

15. COMMENT BY ARGENTINA ON POST MARKETING MONITORING:

Bearing in mind that the European Communities have recognized that the genetically modified foods authorized have shown that they have the same level of safety as their conventional counterparts, on what basis has post-market monitoring been established?

What effect on human health is it expected to find when a food has been approved for consumption by the Community authorities?

If the objective pursued through post-market monitoring is to verify that the conclusions reached in the risk analysis are still valid, should the monitoring not then come within the mandatory scope of competence of community health authorities?

15.1. Response of the European Commission:

The proposal provides that the need for post market monitoring requirements be assessed on a case by case basis during risk assessment. This is in line, for example, with the "Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology" at Step 8 of the Elaboration Procedure of the Codex Alimentarius Commission, which state (at paragraph 20) that "Post-market monitoring may be an appropriate risk management measure in specific circumstances".

16. COMMENT BY ARGENTINA ON POST MAKING MONITORING (2):

Could the European Communities give examples of cases in which it has been established that post-market monitoring of conventional foods that had been fortified had to be carried out? Who is responsible for such monitoring and what results that differed from those in the risk analysis of the product were reached?

16.1. Response of the European Commission:

The need for post market monitoring requirements is already evaluated during the risk assessments carried out under the Regulation (EC) 258/97 on novel foods and novel food ingredients. An example of such requirements can be found in Commission Decision of 24 July 2000 (2000/500/EC) on the authorization for the placing on the market of "yellow fat spreads with added phytosterol esters". It is the authorization holder who is responsible for carrying out the monitoring in accordance with above-mentioned Decision. Another example of monitoring requirements in European Community Food Law is Directive 94/35/EC, 94/36/EC and 95/2/EC on food additives, which provide that member States shall establish a monitoring system for the consumption of food additives.

17. COMMENT BY ARGENTINA ABOUT ENVIRONMENTAL MONITORING:

Has the environmental monitoring envisaged by the European Communities also been adopted in the case of events that have occurred using techniques for obtaining seeds other than recombinant DNA?

17.1. Response of the European Commission:

The European Community requirements for post market monitoring of GMOs is in fact not new and are laid down in Directive 2001/18/EC, which following adoption by the Council and the European Parliament entered into force in March 2001. The scope of that Directive covers GMOs exclusively.

18. COMMENT BY ARGENTINA ABOUT ETHICAL- RELIGIOUS CONSIDERATIONS:

The European Communities have indicated that the ethical and religious considerations to be taken into account in labelling are specially intended to cover, for example, a situation in which the gene of a bovine animal or a pig has been transferred to another animal species, because this could raise concerns on the part of those belonging to certain religions.

In the case of methods, which use animal albumin to clarify wines, is this information given to consumers on the labels?

18.1. Response of the European Commission:

Bovine albumin is not authorized for oenological practices in the EU. Article 43 and Annex IV and V of Council Regulation 1493/1999 forbids the use of this product. The general European Community labelling requirements provide for labelling of ingredients (Directive 2000/13/EEC), but not labelling of processing aids.

19. COMMENT BY ARGENTINA ABOUT CARTAGENA PROTOCOL:

In response to Argentina's question regarding the cost of the system which the European Communities intend to implement, it was stated that the requirements are the same as those in Article 18(2)(a) of the Cartagena Protocol.

Firstly, Argentina wishes to point out that this Protocol has not yet entered into force, and the labelling and traceability requirements in the European Communities' draft text greatly exceed the requirements laid down in the aforementioned Article of the Protocol.

How did the European Communities take into account the special needs of developing countries when drawing up this draft regulation (Article 10.1 of the SPS Agreement)?

19.1. Response of the European Commission:

The European Commission disagrees with Argentina that the proposal greatly exceeds the requirements of the protocol. The European Commission has noted the overwhelming support for the Biosafety protocol from developing countries and for specific information requirements concerning transboundary movements of living modified organisms. To date, 103 countries have signed the Protocol, many of them developing countries. Moreover, the European Commission believes that the proposals will foster social acceptability of the application of biotechnology in the agri-food sector and thereby promote trade in such products.

The European Commission would like to reiterate that it is ready to consider requests from developing countries for technical co-operation and assistance to address identified priorities and needs.

20. COMMENT BY ARGENTINA ABOUT THE UNIQUE CODE SYSTEM:

When do the European Communities think that the Unique Code system will be implemented?

20.1. Response of the European Commission:

The system for developing and assigning unique codes is to be adopted and implemented after final agreement on the Proposal on traceability and labelling of GMOs and traceability of food and feed produced from GMOs by the Council and the European Parliament.

MEMO/02/160[6]
Brussels, 4 March 2003

QUESTION AND ANSWERS ON THE REGULATION OF GMOS IN THE EU

This questions and answers fact sheet is divided into two sections; Part A covers legislation in force; Part B covers the legislative proposals on traceability and labelling put forward in July 2001

What are GMOs and GMMs?

Genetically modified organisms (GMOs) and genetically modified micro-organisms (GMMs) can be defined as organisms (and micro-organisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination. The technology is often called "modern biotechnology" or "gene technology", sometimes also "recombinant DNA technology" or "genetic engineering". It allows selected individual genes to be transferred from one organism into another, also between non-related species.

PART A: LEGISLATION IN FORCE

What is the current legislation in the EU on GMOs?

Community legislation on GMOs has been in place since the early 1990s and throughout the decade, this regulatory framework has been further extended and refined. The EU introduced specific legislation designed to protect its citizens' health and the environment while simultaneously creating a unified market for biotechnology.

The main legislation under which experimental releases and placing on the market of genetically modified organisms (GMOs) have been authorized in the Community was, up until 17 October 2002, Directive 90/220/EEC On this date, the Directive was repealed by the new, updated Directive 2001/18/EC of the European Parliament and Council on the deliberate release of genetically modified organisms.

Directive 2001/18/EC, as for Directive 90/220/EEC, puts in place a step-by-step approval process on a case by case assessment of the risks to human health and the environment before any GMO or product consisting of or containing GMOs, such as maize, tomatoes, or microorganisms can be released into the environment or placed on the market.

Products derived from GMOs, such as paste or ketchup from a GMO tomato are not covered by this horizontal Directive but by vertical, sectoral legislation, for example the Regulation on Novel Foods and Novel Food Ingredients of 27 January 1997 (Regulation (EC) 258/97). Directive 90/219/EEC, as amended by Council Directive 98/81/EC on the contained use of GMMs, regulates the contained use of GMMs for research and industrial purposes.

What has changed under the new Directive for the deliberate release of GMOs?

The revised Directive 2001/18/EC strengthens the existing rules on the release of GMOs into the environment. In particular, it introduces:

[6] In order to adapt the text of MEMO/02/160 to this document, its original formatting has been modified. The original page setting can be found in http://europa.eu.int/rapid/start/cgi/guesten.ksh (in English and French).

- principles for the environmental risk assessment (see below);

- mandatory post-market monitoring requirements, including on long-term effects associated with the interaction with other GMOs and the environment;

- mandatory information to the public;

- a requirement for member States to ensure labelling and traceability at all stages of the placing on the market;

- first approvals for the release of GMOs to be limited to a maximum of ten years;

- the consultation of the Scientific Committee(s) to be obligatory;

- an obligation to consult the European Parliament on decisions to authorize the release of GMOs; and

- the possibility for Council of Ministers to adopt or reject a Commission proposal for authorization of a GMO by qualified majority.

How does the environmental risk assessment procedure work from 17 October onwards?

The safety of GMOs depends on the characteristics of the inserted genetic material, the final organism that is produced, the receiving environment and the interaction between the GMO and the environment. The objective of the environmental risk assessment is to identify and evaluate potential adverse effects of the GMO(s). These include direct or indirect, immediate or delayed, effects taking into account any cumulative and long term effects on human health and the environment which may arise from the deliberate release or placing on the market of that GMO(s). The environmental risk assessment also requires evaluation in terms of how the GMO was developed and examines the potential risks associated with the new gene products produced by the GMO (for example toxic or allergenic proteins), and the possibility of gene-transfer (for example of antibiotic resistance genes).

The methodology of the risk assessment is as follows:

- Identification of any characteristics of the GMO(s) which may cause adverse effects;

- Evaluation of the potential consequences of each adverse effect;

- Evaluation of the likelihood of the occurrence of each identified potential adverse effect;

- Estimation of the risk posed by each identified characteristic of the GMO(s);

- Application of management strategies for risks from the deliberate release or placing on the market of GMO(s); and

- Determination of the overall risk of the GMO(s).

The Scientific Committee on Plants (SCP) issued opinions on applications for the placing on the market of 17 GM plant varieties under Directive 90/220/EEC. In one application, an unfavourable opinion was given due to an insufficient risk assessment in terms of the presence of a number of uncharacterised genes within the GM plant variety, in particular the gene which confers resistance to amikacin, a clinically important antibiotic. This application was withdrawn.

The Scientific Committee on Food is responsible for opinions relating to Novel Foods. This Committee has issued 3 favourable opinions on food of plant origin (tomato and maize) and 4 on products of microbial origin.

What is the procedure for approval of the release of GMOs into the environment?

Under Directive 2001/18/EC, a company intending to market a GMO must first submit an application to the competent national authority of the member State where the product is to be first placed on the market.

The application must include a full environmental risk assessment. If the national authority gives a favourable opinion on the placing on the market of the GMO concerned, this member State informs the other member States via the Commission. If there are no objections, the competent authority that carried out the original evaluation grants the consent for the placing on the market of the product. The product may then be placed on the market throughout the European Union in conformity with any conditions required in that consent.

If objections are raised and maintained, a decision has to be taken at Community level. The Commission first asks for the opinion of its Scientific Committees composed of independent scientists, highly qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry, or other similar disciplines.

If the scientific opinion is favourable, the Commission then proposes a draft Decision to the Regulatory Committee composed of representatives of member States for opinion. If the Regulatory Committee gives a favourable opinion, the Commission adopts the Decision.

If not, the draft Decision is submitted to the Council of Ministers for adoption by qualified majority or rejection. If the Council does not act within 3 months, the Commission can adopt the decision.

During the notification process, the public is also informed and has access to the publicly available data on the internet http://gmoinfo.jrc.it/, for example, the summary notification format, the assessment reports of the competent authorities or the opinion of the Scientific Committees.

For experimental releases, notifications are examined and consent is granted as appropriate by the authorities of the member State in which the release is to be conducted.

How many GMOs have been approved for release into the environment?

Since Directive 90/220/EEC entered into force in October 1991, the commercial release of 18 GMOs has been authorized in the EU, mostly by a Commission Decision following a qualified majority vote in the Regulatory Committee. In two cases the Commission Decision has not yet been implemented by the member State (see Annex 1).

Since October 1998, no further authorisations were granted under Directive 90/220/EEC although there were 13 applications pending at the time of its repeal (see Annex 2). Some member States also invoked Article 16, the so-called safeguard clause, of Directive 90/220/EEC to temporarily ban the placing on the market of genetically modified maize and oilseed rape products in their territories. There are currently nine outstanding Article 16 cases involving Austria, Luxembourg, France, Greece, Germany and United Kingdom. These cases have been examined by the Scientific Committee on Plants, which in all cases deemed that the information submitted by member States did not justify their bans.

Currently the Commission has received eighteen (18) notifications under Directive 2001/18/EC. These are listed in Annex 3. Seven (7) of these are products which were pending under Directive 90/220/EC at the time of its repeal (c.f. Annex 2).

What are the current rules on the marketing of GM foods?

Regulation (EC) 258/97 on Novel Foods and Novel Food Ingredients sets out rules for authorization and labelling of novel foods including food products containing, consisting or produced from GMOs.

The first step of an authorization procedure is an assessment of an application to market a GM food product by the member State where the food is to be first placed on the market. In case of a favourable opinion, this member State informs the other member States via the Commission. If there are no objections against the application, this member State can authorize the product for marketing in the entire EU.

If there are objections by other member States, a decision at Community level is required. The Commission consults the Scientific Committees on matters relating to public health and adopts a decision after receiving a favourable opinion from the Regulatory Committee composed of member State representatives.

As a derogation from the full authorization procedure, the Novel Foods Regulation provides for a simplified procedure for foods derived from GMOs but no longer containing GMOs which are "substantially equivalent" to existing foods with respect to composition, nutritional value, metabolism, intended use and the level of undesirable substances. In such cases, the companies only have to notify the Commission when placing a product on the market together with either scientific justification that the product is substantially equivalent or an opinion to the same effect, delivered by the competent authorities of a member State.

How many GMOs have been approved for use in food products?

Two genetically modified plants, a variety of soybean and a variety of maize have been authorized under Directive 90/220/EEC prior to the entry into force of the Novel Foods Regulation, to be on the European market for the use in food. Under the Novel Foods Regulation no products consisting of or containing live GMOs have so far been authorized under the full procedure. Ten applications concerning such products are pending at different stages in the procedure (Annex 4). Several products produced from GMOs have been notified to the Commission as being substantially equivalent (see Annex 5). Recently, two cotton seed oils for food use have been placed on the market in the EU in accordance with this procedure. The list of notifications is published in the Official Journal of the EU once a year.

What are the current rules on genetically modified feed and which ones have been authorized?

There is currently no Community legislation governing the use of material derived from GMOs in feed. This is provided for in the Proposal on GM food and feed, which was adopted by the Commission on 25 July 2001. However, eight GMOs are authorized in accordance with Directive 90/220/EEC for the purpose of use in feed; these are four maize varieties, three rape varieties and one soya variety (see Annex 1).

What are the current rules on genetically modified seeds?

Community legislation on seeds, notably Directive 98/95/EC, specifies that national authorities that have agreed to the use of a seed on their territory must notify this acceptance to the Commission. The Commission examines the information supplied by the member State concerned and its compliance with the provisions of Community seeds legislation. If such is the case, the Commission includes the variety concerned in the "Common Catalogue of varieties of Agricultural Plant Species" which means the seed can be marketed throughout the EU. The seed legislation furthermore requires that GMO seed varieties have to be authorized in accordance with Directive 90/220/EEC before they are included in the Common Catalogue and marketed in the EU. If the seed is intended for use in food, it also has to be authorized in accordance with the Novel Foods Regulation.

Legislation on the marketing of forestry reproductive material also requires prior authorization of GM material in line with the requirements of Directive 90/220. Community rules governing the marketing of vine material in line with Directive 90/220/EEC have also been adopted.

Further rules on growing conditions and other requirements for purity concerning the presence of GM seeds in seed lots of traditional varieties, as well as detailed labelling rules are to be proposed.

What are the rules for Medicines, Protection of workers and Transport

Authorization of medicinal products for human and veterinary use (including such derived from genetically modified organisms) is regulated under Regulation (EEC) 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use.

Council Directive 90/679/EEC on the protection of workers from the risks related to exposure to biological agents at work also regulates GMOs alongside other biological agents.

What are the current rules on labelling?

The EU recognizesthe consumers' right for information and labelling as a tool to make an informed choice.

Since 1997 labelling to indicate the presence of GMOs as such or in a product is mandatory. From 17 October 2002 onwards Directive 2001/18/EC foresees that member States shall take all necessary measures to ensure a labelling of GMOs as or in products at all stages of the placing on the market.

The Novel Foods Regulation provides for the mandatory labelling of foods and food ingredients which contain or consist of a GMO without prejudice to the other labelling requirements of Community law. The labelling requirements for foods produced from GMOs, but no longer containing GMO are based on the concept of equivalence[7].

Council Regulation (EC) 1139/98 lays down provisions for the labelling of foods and food ingredients derived from one maize and one soya[8] variety based on the presence of DNA or protein resulting from genetic modification. This criterion serves as a model providing the rules applicable to labelling of all foods and food ingredients derived from GMO.

In January 2000, the Commission adopted Regulation (EC) 50/2000 ensuring that also additives and flavourings have to be labelled if DNA or protein of GMO origin is present in the final product.

Regulation (EC) 49/2000 addresses the problem of adventitious presence of GM material in conventional food. It introduces a 1% *de minimis* threshold for the adventitious presence of DNA or protein resulting from genetic modification below which labelling is not required. Operators have to be in a position to demonstrate that they have used appropriate steps to avoid the presence of GM material.

Genetically modified seed varieties must be labelled, in accordance with Council Directive 98/95/EEC. The label has to show clearly that it is a GM variety.

Currently, there is no specific Community legislation on the labelling of feed produced from GMOs.

PART B: NEW LEGISLATIVE PROPOSALS

What are the contents of the latest proposals from European Commission concerning traceability and labelling of GMOs?

The European Commission adopted on 25 July 2001 two legislative proposals on GMOs. They set up a harmonised community system to trace GMOs, introduce the labelling of GM feed, reinforce the current labelling rules on GM food and establish a streamlined authorization procedure for GMOs in food and feed and their deliberate release into the environment.

The proposals aim to put into place a stringent regulatory framework and to close existing legal gaps. They address the legitimate concerns of citizens, consumer organisations and economic operators.

A strict safety assessment of GMOs will continue to assure a high level of health and environmental protection. The labelling of all GM food and feed products will allow consumers and farmers to decide if they want to buy food or feed produced from a GMO, or not.

[7] This means that if a characteristic or property (composition, nutritional value or nutritional effects, intended use) renders a food or food ingredient no longer equivalent to an existing counterpart, it has to be labelled indicating the method (ie. genetic modification) by which the characteristic or property was obtained.

[8] These varieties were approved before the entering into force of the Novel Foods Regulation under Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms

The package consists of:

- a proposal for a Regulation on traceability and labelling of GMOs and products produced from GMOs: COM 2001 - 1821 final, 25 July 2001, see http://europa.eu.int/comm/food/fs/biotech/biotech09_en.pdf; and

- a proposal for a Regulation on GM food and feed: COM 2001 - 425 final, 25 July 2001, see http://europa.eu.int/comm/food/fs/biotech/biotech08_en.pdf.

Why is the Commission proposing specific rules on traceability of GMOs?

Traceability provides the means to trace products containing or produced from GMOs through the production and distribution chains. The general objectives are to facilitate:

- control and verification of labelling claims;

- targeted monitoring of potential effects on the environment, where appropriate; and

- withdrawal of products that contain or consist of GMOs should an unforeseen risk to human health or the environment be established.

However, whilst Directive 2001/18 includes general provisions on which a traceability system for GMOs could be based, it neither contains a definition of traceability for GMOs, nor does it include the objectives of traceability or a complete approach for its implementation.

Differences and overlap between national laws, regulations and administrative provisions concerning traceability of GMOs and food and feed products produced from GMOs may hinder the free movement of products and create conditions of unfair competition. A Community Regulation based on the requirements of Directive 2001/18/EC and laying down a harmonised framework for traceability of such products would provide legal certainty and a coherent approach, and thus contribute to the effective functioning of the internal market.

Does traceability apply to GMOs and GM products only, or also to other food products?

Traceability for certain products has existed for many years. The proposed regulation sets specific traceability requirements for GM products. Traceability specifically for GMOs was introduced in general terms into Community legislation with Directive 2001/18/EC[9] which requires that member States ensure traceability at all stages of the placing on the market for GMOs. General traceability provisions have already been laid down in Community legislation concerning food, feed and seed. Legislation for specific traceability scheme for beef products has been put into place as in response to the BSE crisis (Regulation 1760/2000/EC). Council and Parliament Regulation (Regulation EC/178/2002) laying down the general principles and requirements of food law, establishes also the principle of traceability at all stages of the production and distribution chain in the food and feed sectors.

[9] OJ L 106, 17.4.2001, p.1.

What are the new rules on traceability of GMOs?

Under the rules of the proposed Regulation on traceability business operators must transmit and retain information about products that contain or are produced from GMOs at each stage of the placing on the market.

In particular, the requirements are that:

- operators shall have systems and procedures in place to identify to whom and from whom products are made available;

- for GMOs intended for deliberate release into the environment, operators must transmit specified information on the identity of the individual GMO(s) a product contains;

- for GMOs intended for food, feed or for processing, business operators may either transmit the specified information mentioned above or transmit a declaration that the product shall only be used as food or feed or for processing, together with the identity of the GMO(s) that the product may contain;

- for food and feed produced from GMO(s) operators shall inform the next operator in the chain that the product is produced from GMO(s); and

- operators shall retain the information for a period of 5 years and make it available to competent authorities on demand.

Transmission and keeping records of this information will reduce the need for sampling and testing of products. To facilitate a co-ordinated approach for inspection and control by the member States, the Commission will develop technical guidance on sampling and testing methods prior to the application of this proposed regulation.

How does traceability work in practice?

Traceability can be defined as the ability to trace products through the production and distribution line. For example, where production starts with a genetically modified seed , the company selling the seed would have to inform any purchaser that it is genetically modified, together with more specified information allowing the specific GMO to be precisely identified. The company is also obliged to keep a register of business operators who have bought the seed.

Equally the farmer would have to inform any purchaser of the harvest that it is genetically modified and keep a register of operators to whom he has made the harvest available.

The proposal covers all GMOs that have received Community authorization for the placing on the market, that is all products, including food and feed, containing or consisting of GMOs.

Examples are seeds, which have been genetically modified and bulk quantities or shipments of whole GM grain eg. soybean and maize.

The proposal also covers food and feed which are derived from a GMO. This includes tomato paste and ketchup produced from a GM tomato or starch, oil or flour produced from a GM maize.

What are the cost implications for operators of the traceability proposal?

It is difficult to estimate the exact costs of introducing traceability specifically for GMOs and products derived from GMOs.

Information with respect to the supplier, customer, price and transaction date as well as the nature, source, contents and amount of the product already accompanies the majority of transactions. This information has also to be retained by operators under national administrative systems, for example for filling in VAT returns. Transmission and retention of the information specified in the proposal could largely be incorporated into existing systems for transactions and as such, should not imply significant extra costs for operators.

What are the new proposed labelling rules and what is the difference with the existing rules?

The proposal extends the current labelling provisions to all genetically modified food or feed, irrespective of the detectability of genetically modified DNA or protein. All food and feed which consist of, contain or are produced from GMOs would have to be labelled as such. The purpose is to inform consumers and farmers about the exact nature and characteristics of the food or feed, so that they can make informed choices.

The current GM labelling system is based on the detectability of genetically modified DNA or protein in the final food product. In practice this means that highly processed foodstuffs produced from GM material, such as highly refined oils, do not need to be labelled. The proposed labelling rules extend the labelling requirements to all food and ingredients produced from GMOs to allow consumers to exercise their freedom of choice.

Genetically modified feed will need to be labelled along the same principles to give livestock farmers accurate information on the composition and properties of feed. This will mean that a large number of feedstuffs currently not subject to GM labelling requirements, such as GM soy meal in feed or compound feedstuffs and the four genetically modified feed plants authorized under Directive 90/220/EEC will in future need to be labelled. See also Annex 6.

Will the meat or milk of an animal fed with GM feed also be labelled as GM?

In line with the general EU rules on labelling, the proposal does not require labelling of products that are not food ingredients such as processing aids. It does not require labelling of products such as meat, milk or eggs obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products.

How will GM food and feed in future be authorized?

Clear rules are already set out in the EU for the assessment and authorization of GMOs and GM-food, but the responsibilities are currently divided between the member States and the Community. The Commission has proposed to replace this with a "one door – one key" procedure for the scientific assessment and authorization of GMOs and GM food and feed It puts in place a streamlined, uniform and transparent Community procedure for all marketing applications, whether they concern the GMO itself or the food and feed products derived thereof. This means that business operators need not request separate authorisations for use of the GMO, and for its use in feed or in food, but that a single risk assessment and a single authorization are given for a GMO and its possible uses. This will ensure that experiences

such as with Starlink maize in the US are avoided because GMOs likely to be used as food and feed can only be authorized for both uses, or not at all.

The scientific risk assessment will be carried out by the European Food Safety Authority covering both the environmental risk and human and animal health safety assessment. Its opinion will be made available to the public and the public will have the possibility to make comments. On the basis of the opinion of the European Food Authority, the Commission will draft a proposal for granting or refusing authorization. The proposal will, as it is currently the case, be approved through qualified majority of the member States within a Regulatory Committee.

Products authorized shall be entered into a public register of GM-food and feed. Authorisations will be granted for a period of 10 years, subject where appropriate to a post-market monitoring plan. Authorisations are renewable for 10-year periods.

The simplified procedure for putting on the market GM-foods which are considered to be substantially equivalent to existing foods will be abandoned.

Will there be new rules on GM seed?

Two further proposals relating to GM seeds in seeds of conventional varieties are to be adopted in the near future. The first one is a Commission Directive amending the annexes of the different seed Directives, setting additional conditions and requirements concerning the adventitious or technically unavoidable presence of GM seeds in seed lots of non-GM varieties and specifying the labelling requirements of seeds of genetically modified varieties.

At the same time a Commission Regulation on a protocol for sampling and testing of seed lots of non-GM varieties for the presence of GM seed will define how seed testing has to be carried out when applying the requirements set out in the previously mentioned Commission Directive will be put forward.

Why is the Commission proposing to allow the presence of traces of GMOs which have received a favourable scientific assessment, but which are not yet formally approved?

The adventitious or unintended presence of GMOs in products placed on the market in the European Union is largely unavoidable and can occur during cultivation, handling, storage and transport. This situation already exists and affects products originating both in the Community and third countries.

This is not a problem which is not unique to GMOs. In the production of food, feed and seed, it is practically impossible to achieve products that are 100% pure.

The proposal acknowledges this fact and defines the specific conditions under which a technically unavoidable presence of GMOs not yet formally authorized could be permitted.

A number of GMOs have already been assessed by the Scientific Committees advising the European Commission as not posing a danger to environment and health, but their final approval is still pending. The proposal allows the presence of these GMOs in a food or feed up to a maximum of 1% below which labelling and traceability will not be enforced. This is on the basis that the presence of such material is adventitious or technically unavoidable and has been subject to a scientific risk assessment by the relevant Scientific Committees or European Food Authority, which has concluded that the material does not present a risk for human health and the environment.

This exemption aims to solve the problem faced by operators who have tried to avoid GMOs, but find that their products contain a low percentage of GM material due to accidental or technically unavoidable contamination. Current legislation on GM foods (Regulation 1139/98, see above) already sets a threshold of 1% for the labelling of approved GM material.

Are the new labelling rules in line with the international trade rules?

The proposals take account of the Community's international trade commitments and of the requirements of the Cartagena Protocol on Biosafety with respect to obligations of importers. A further legislative proposal setting rules concerning the obligations of exporters and other elements of the Cartagena Protocol is being prepared.

The political agreement in Council on the Proposals

In its political agreements in 2002, the Council endorses the main features of the original Commission Proposals. However, the political agreement includes two significant changes:

- a 0.9 % threshold for the labelling of GM food and feed. The Commission originally proposed that the threshold be fixed in comitology procedure; and

- a 0.5 % threshold instead of 1 % as suggested by the Commission for presence of GM material in food or feed, or for processing, which has received a favourable scientific risk assessment by the Scientific Committees or the European Food Safety Authority, but which has not yet been finally approved to be placed on the market. The political agreement also limits the application of this threshold to three years and provides that a detection method must be publicly available.

Concerns and questions raised by third countries

A detailed response to the concerns and questions raised by third countries in the WTO context can be found on web-site:
http://europa.eu.int/comm/food/fs/gmo/resp_ec_com182_en.pdf

concerning the traceability Proposal, and on web-site:

http://europa.eu.int/comm/food/fs/gmo/resp_ec_com425_en.pdf

concerning the GM food and feed Proposal.

Will the Commission resume the authorization process of GMOs?

The revised rules on the deliberate release of genetically modified organisms in Directive 2001/18/EC set out effective, efficient and transparent measures to ensure a high level of protection for human health and the environment. The two legislative proposals put forward in July 2001 build on the principles of this Directive and provide a regulatory framework for labelling and traceability. Together, this package of measures aims to address the concerns of member States and to build consumer confidence in the authorization of GM products. The revised Directive and the two proposals for Regulations are expected to pave the way for a resumption of GM authorisations in the European Union.

How is the issue of exchange of GMOs regulated with Countries outside of the EU?

The UNEP Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted on 29 January 2000. The overall purpose of this United Nations agreement is to establish common rules to be followed in transboundary movements of GMOs in order to ensure, on a global scale, the protection of biodiversity and of human health. The Commission Proposal on the transboundary movements of GMOs, dated from 18 February 2002, is linked to the recent ratification by the European Community of the Cartagena Protocol on Biosafety.

The European Union has to fulfil its international obligations and therefore we transpose into our own legal order the provisions of the Biosafety Protocol. The Commission's Proposal complements the existing Community regulatory framework, in particular for exports of GMOs, in order to align it with the provisions of the Biosafety Protocol.

The main elements of the proposal are the following:

- Firstly, the obligation to notify exports of GMOs intended for deliberate release into the environment;

- Secondly, the obligation to provide information to our international partners on Community practices, legislation and decisions on GMOs, as well as on accidental releases of GMOs; and

- Thirdly, a set of rules for identifying GMOs for exports. These rules are in line with latest developments in Community legislation on GMOs, and in particular with the provisions of the Draft Regulation on Traceability and Labelling.

The current Proposal does not foresee new specific Community provisions for imports or for movements of GMOs between member States. These operations will continue to be covered by existing Community legislation.

Annex 1

GMO PRODUCTS – APPROVED UNDER DIRECTIVE 90/220/EEC
as of March 2001

Product		*Notifier*	*Date of Commission Decision[10] / Member State Consent[11]*
1.	*Vaccine against Aujeszky's disease*	Vemie Veterinär Chemie GmbH	18.12.92
2.	*Vaccine against rabies*	Rhône-Mêrieux C/B/92/B28 & C/F/93/03-02	19.10.93
3.	*Tobacco tolerant to bromoxynil*	SEITA C/F/93/08-02	08.06.94
4.	*Vaccine against Aujeszky's disease (further uses)[12]*	Vemie Veterinär Chemie GmbH C/D/92/I-1	18.07.94
5.	*Male sterile swede rape resistant to glufosinate ammonium (MS1, RF1)* *Uses : breeding activities*	Plant Genetic Systems C/UK/94/M1/1	06.02.96
6.	*Soybeans tolerant to glyphosate* *Uses : import and processing*	Monsanto C/UK/94/M3/1	03.04.96
7.	*Male sterile chicory tolerant to glufosinate ammonium* *Uses : breeding activities*	Bejo-Zaden BV C/NL/94/25	20.05.96
8.	*Bt-maize tolerant to glufosinate ammonium (Bt-176)*	Ciba-Geigy C/F/94/11-03	23.01.97
9.	*Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF1)[13]* *Uses : import and processing*	Plant Genetic Systems C/F/95/05/01/A	06.06.97 (not finally approved by FR)
10.	*Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF2)[14]*	Plant Genetic Systems C/F/95/05/01/B	06.06.97 (not finally approved by F)
11.	*Test kit to detect antibiotic residues in milk*	Valio Oy C/F1/96-1NA	14.07.97

[10] Where objections were raised by member State authorities.
[11] In the absence of objections by member State authorities.
[12] Linked to item 1 (same product, further uses).
[13] Linked to item 5 (same product, further uses).
[14] This product is the result of a different transformation event to that of No. 9.

Product		***Notifier***	***Date of Commission Decision[10] / Member State Consent[11]***
12.	*Carnation lines with modified flower colour*	Florigene C/NL/96/14	01.12.97 (MS consent)
13.	*Swede rape tolerant to glufosinate ammonium (Topas 19/2)* *Uses : import and processing*	AgrEvo C/UK/95/M5/1	22.04.98
14.	*Maize tolerant to glufosinate ammonium (T25)*	AgrEvo C/F/95/12/07	22.04.98
15.	*Maize expressing the Bt cryIA(b) gene (MON 810)*	Monsanto C/F/95/12-02	22.04.98
16.	*Maize tolerant to glufosinate ammonium and expressing the Bt cryIA(b) gene (Bt-11)* *Uses : import and processing*	Novartis (formerly Northrup King) C/UK/96/M4/1	22.04.98
17.	*Carnation lines with improved vase life*	Florigene C/NL/97/12	20.10.98 (MS consent)
18.	*Carnation lines with modified flower colour*	Florigene C/NL/97/13	20.10.98 (MS consent)

Annex 2

GMO PRODUCTS - PENDING APPROVAL UNDER DIRECTIVE 90/220/EEC
As of October 2002

Product notification details	*Company*
1. *Maize expressing the Bt cryIA(b) gene (MON 809)* *from France (C/F/95/12-01/B)* *Received by the Commission: 06.08.96* *Favourable opinion of EU Scientific Committee 19.05.98* *Uses: as any other maize*	Pioneer
2. *Male sterile chicory*[15] *from the Netherlands (C/NL/94/25/A)* *Received by the Commission: 20.09.96* *Favourable opinion of EU Scientific Committee 18.12.98* *Uses: food and feed*	Bejo-Zaden BV
3. *Swede rape tolerant to glufosinate ammonium (FALCON GS40/90)* *from Germany (C/DE/96/5)* *Received by the Commission: 25.11.96* *Uses: as any other swede rape*	AgrEvo GmbH
4. *Male sterile swede rape tolerant to glufosinate ammonium (MS8, RF3)* *from Belgium (C/BE/96/01)* *Received by the Commission: 16.01.97* *Favourable opinion of EU Scientific Committee 19.05.98* *Uses: as any other swede rape*	Plant Genetic Systems
5. *Fodder beet tolerant to glyphosate* *from Denmark (C/DK/97/01)* *Received by the Commission: 09.10.97* *Favourable opinion of EU Scientific Committee 23.06.98* *Uses: production of seeds and roots, animal feed*	DLF-Trifolium, Monsanto and Danisco Seed

[15] This is the same product as No. 7 on the list of approved GMOs, which was restricted to breeding activities.

Product notification details		***Company***
6.	*Tomato with reduced activity of the expression of the endogenous tomato fruit PG genefrom Spain (C/ES/96/01)* *received by the Commission: 24.11.97* *Favourable opinion of EU Scientific Committee 23.06.98* *<u>Uses</u>: as any other processing tomato*	Zeneca
7.	*Cotton expressing the Bt cryIA(c) gene (line 531)* *from Spain (C/ES/96/02)* *Received by the Commission: 24.11.97* *Favourable opinion of EU Scientific Committee 14.07.98* *<u>Uses</u>: as any other cotton*	Monsanto
8.	*Cotton tolerant to herbicide (line 1445)* *from Spain (C/ES/97/01)* *Received by the Commission: 24.11.97* *Favourable opinion of EU Scientific Committee 14.07.98* *<u>Uses</u>: as any other cotton*	Monsanto
9.	*Potato with altered starch composition* *from Sweden (C/SE/96/3501)* *Received by the Commission: 20.05.98* *Favourable opinion of EU Scientific Committee 18.07.02* *Uses: as any other starch potato*	AMYLOGENE
10.	*Swede rape tolerant to glufosinate ammonium (Liberator)* *from Germany (C/DE/98/6)* *Received by the Commission: 29.10.98* *Favourable opinion of EU Scientific Committee 30.11.00* *<u>Uses</u>: as any other swede rape*	AgrEvo GmbH
11.	*Maize tolerant to glufosinate ammonium and expressing the Bt cryIA(b) gene (Bt-11)*[16] *from France (C/F/96/05-10) and Spain (C/ES/98/02)* *Received by the Commission: 12.04.99 and 03.05.99 respectively* *Favourable opinion of EU Scientific Committee 30.11.00* *<u>Uses</u> : cultivation*	Novartis

[16] This is the same product as No. 16 on the list of approved GMOs, which was restricted to import and processing.

Product notification details	***Company***
12. Maize tolerant to glufosinate ammonium and expressing the Bt cryIA(b) gene (T25 + MON810)[17] *from the Netherlands (C/NL/98/08)* *Received by the Commission: 29.04.99* *Favourable opinion of EU Scientific Committee 06.06.00* *Uses: as any other maize*	Pioneer
13. Maize tolerant to glyphosate (GA21) *from Spain (C/ES/98/01)* *Received by the Commission: 20.05.99* *Favourable opinion of EU Scientific Committee 22.09.00* *Uses: as any other maize*	Monsanto

[17] This product is obtained from conventionally derived crosses between Nos. 14 and 15 on the list of approved GMOs.

Annex 3

GMO PRODUCTS – NOTIFICATIONS RECEIVED BY THE COMMISSION UNDER DIRECTIVE 2001/18/EC
As of 20 February 2003

Product notification details		*Company*
1.	*Oil seed rape – herbicide resistant GT 73* *Received by the Netherlands (C/NL/98/11) under Dir 90/220/EC.* *Received by the Commission under Dir 2001/18 : 16/1/03* *Uses: import and uses in feed and industrial processing, not for cultivation.*	Monsanto
2.	*Maize Roundup Ready NK603, tolerant to glyphosate herbicide* *Received by Spain (C/ES/00/01) under Dir 90/220 : 21/12/2000* *Received by the Commission under Dir 2001/18 : 17/01/03* *Uses: import and use in feed and industrial processing, not for cultivation.*	Monsanto
3.	*Maize hybrid MON810 x NK603 (glyphosate-tolerant and containing Bt toxin)* *Received by UK under Dir 90/220/EC. (C/GB/02/M3/03)* *Received by the Commission under Dir 2001/18 : 15/01/03* *Uses: import and use in feed and industrial processing, not for cultivation.*	Monsanto
4.	*Potato with altered starch composition* *from Sweden (C/SE/96/3501)* *Received by the Commission under Dir 90/220: 20.05.98* *Favourable opinion of EU Scientific Committee 18.07.02* *Received by the Commission under Dir 2001/18/EC: 24/01/03* *Uses: for cultivation and production of starch, not for use as human food.*	AMYLOGENE HB
5.	*Oilseed rape (Ms8, Rf3)* *from Belgium (C/BE/96/01)* *Received by the Commission: under Dir 90/220 16.01.97* *Favourable opinion of EU Scientific Committee 19.05.98* *Received by the Commission under Dir 2001/18: 5/02/03* *Uses: import and cultivation in the EU, uses in feed and industrial processing.*	Bayer CropScience
6.	*Soybeans Glufosinate tolerant (Events A 2704-12 and A 5547-127)* *from Belgium (C/BE/98/01)* *Received by the Commission under Dir 2001/18: 5/02/03* *Uses: import only*	Bayer CropScience

Product notification details		***Company***
7.	*Roundup Ready sugar beet (event T9100152), glyphosate tolerant* *from Belgium C/BE/99/01* *Received by the Commission under Dir 2001/18: 5/02/03* *Uses: for cultivation and use in animal feed, processing of sugar and other products.*	Monsanto/ Syngenta
8.	*Oilseed rape tolerant for glufosinate-ammonium herbicides.* *(FALCON GS40/90pHoe6/Ac)* *from Germany (C/DE/96/5)* *Received by the Commission under Dir 90/220: 25.11.96* *Opinion of EU Scientific Committee 27.07.98* *Received by the Commission under Dir 2001/18: 7/02/03* *Uses: for import and cultivation*	Bayer CropScience
9.	*Oilseed rape tolerant for glufosinate-ammonium (Liberator pHoe6/Ac)* *from Germany (C/DE/98/6)* *Received by the Commission under Dir 90/220: 29.10.98* *Favourable opinion of EU Scientific Committee 30.11.00* *Received by the Commission under Dir 2001/18: 7/02/03* *Uses: for import and cultivation*	Bayer CropScience
10.	*Roundup Ready Sugar Beet event H7-1 (tolerant to glyphosate)* *from Germany C/DE/00/8* *Received by the Commission under Dir 2001/18: 7/02/03* *Uses: for cultivation and use in processing of sugar and other processed products.*	KWS SAAT AG/Monsanto
11.	*Maize MON 863 X MON 810 (protection against certain insect pests)* *from Germany C/DE/02/9 (6788-01-09)* *Received by the Commission under Dir 2001/18: 7/02/03* *Uses:, for import and use of grain and grain products.*	Monsanto
12.	*Oilseed rape (event T45) tolerant for glufosinate-ammonium herbicide* *from UK C/GB/99/M5/2* *Received by the Commission under Dir 2001/18: 10/02/03* *Uses: import and use in feed and industrial processing.*	Bayer CropScience
13.	*Maize herbicide and insect resistant (line 1507 -- CRY1F)* *received by the Netherlands (C/NL/00/10) under Dir 90/220/EC.* *Received by the Commission under Dir 2001/18 : 12/02/03* *Uses: import and processing, not for cultivation*	Pioneer/ Mycogen Seeds

Product notification details		*Company*
14.	*Insect-protected Cotton expressing the Bt cryIA(c) gene (line 531) from Spain (C/ES/96/02)* *(Received by the Commission under Dir 90/220: 24.11.97* *Favourable opinion of EU Scientific Committee 14.07.98)* *Received by the Commission under Dir 2001/18: 12/2/03* *Uses: for import, processing and cultivation*	Monsanto
15.	*Roundup Ready Cotton tolerant to herbicide (line 1445) from Spain (C/ES/97/01)* *(Received by the Commission under Dir 90/220: 24.11.97* *Favourable opinion of EU Scientific Committee 14.07.98)* *Received by the Commission under Dir 2001/18: 12/2/03* *Uses: for import, processing and cultivation*	Monsanto
16.	*Roundup Ready Maize tolerant to glyphosate (GA21) from Spain (C/ES/98/01)* *Received by the Commission under Dir 90/220: 20.05.99* *Favourable opinion of EU Scientific Committee 22.09.00* *Received by the Commission under Dir 2001/18: 13/2/03* *Uses: use in feed and industrial processing*	Monsanto
17.	*Maize MaisGard/Roundup Ready (derived from MON 810 and GA21). Tolerance to glyphosate and Cry1Ab protein derived from Bt.* *Received by Spain (C/ES/99/02) 3/9/1999 under Dir 90/220/EC.* *Received by the Commission under Dir 2001/18: 13/2/03* *Uses: import and use in feed and industrial processing, not for cultivation.*	Monsanto
18.	*Maize 1507 (or Bt Cry1F 1507)* *Received by Spain (C/ES/01/01) 11/7/2001 under Dir 90/220/EC.* *Received by the Commission under Dir 2001/18: 13/2/03* *Uses: import, feed and industrial processing, and cultivation*	Pioneer Hi-Bred /Mycogen Seeds

Annex 4

Pending applications under Regulation (EC) N° 258/97 of the European Parliament and of the Council

	Applicant	*Description of Food or Food Ingredient*	*Initial Assessment Carried out by*	*Application Date*	*Status By June 2002*
1	Bejo-Zaden P.O.Box 50 NL - 1749 Warmenhuizen	Transgenic Radicchio rosso with male sterility	The Provisional Committee for the safety evaluation of novel foods (VcVnv) (NL)	8 April 1998	Under assessment by the Scientific Committee on Food (SCF).
2	Bejo-Zaden P.O.Box 50 NL - 1749 Warmenhuizen	Transgenic Green hearted Chicoree with male sterility	The Provisional Committee for the safety evaluation of novel foods (VcVnv) (NL)	8 April 1998	Under assessment by the SCF
3	Monsanto Services International S.A. Avenue de Tervueren 270-272 B - 1150 Bruxelles	Roundup Ready Maize line GA21	The Provisional Committee for the safety evaluation of novel foods (VcVnv)	24 July 1998	SCF opinion of 27 February 2002
4	Plant Genetic Systems N.V. Jozef Plateaustraat 22 B - 9000 Gent	Liberty Link Soybean by AgrEvo	Bioveiligheidsraad (B)	2 February 1999	Initial assessment report pending.
5	Novartis Seeds AG CH - 4002 Basel	Bt11 sweet maize	Gezondheidsraad (NL)	11 February 1999	SCF opinion of 13 March 2002
6	Monsanto Services International S.A. Avenue de Tervueren 270-272 B - 1150 Belgium	MaisGard®/RoundupReady®	Gezondheidsraad (NL)	16 March 2000	Initial assessment report pending
7	Monsanto Europe S.A. Avenue de Tervueren 270-272 B - 1150 Brussels and; Novartis Seeds AB, Box 302 S - 261 23 Landskrona	Foods and food ingredients derived from Roundup Ready® Sugar Beet	Gezondheidsraad (NL)		Initial assessment report pending
8	Pioneer Overseas Corporation Avenue Tedesco 7 B - 1160 Brussels	Food products of genetically modified B.t. CRY1F Maize line 1507	Gezondheidsraad (NL)	26 February 2001	Initial assessment report pending

	Applicant	*Description of Food or Food Ingredient*	*Initial Assessment Carried out by*	*Application Date*	*Status By June 2002*
9	Monsanto Services International S.A. Avenue Tervueren 270–272 B - 1150 Bruxelles	Roundup Ready maize line NK603	Gezondheidsraad (NL)	June 2001	Initial assessment report
10	Monsanto Services International S.A. Avenue de Tervueren 270-272 B - 1150 Bruxelles	Insect protected maize line MON 863 and maize hybrid MON 863 X MON 810	Robert Koch Institut (D)	28 August 2002	Initial assessment report pending

Annex 5

Notifications Pursuant to Article 5 of Regulation (EC) N° 258/97 of the European Parliament and of the Council

	Applicant	*Description of Food or Food Ingredient*	*Scientific Evidence*	*Notification*	*Transmission to Member States*
1	AgrEvo UK Limited Chesterford Park Saffron Walden UK - Essex CB10 1XL	Processed oil from genetically modified canola seed, transformation event TOPAS 19/2 and all conventional crossed	"Report on oil from a genetically modified (GM) glufosinate ammonium tolerant oilseed rape" (ACNFP)*	9 June 1997	24 June 1997
2a	Plant Genetic Systems N.V. Jozef Plateaustraat 22 B - 9000 Gent	Processed oil from genetically modified oilseed rape seed derived from: i) male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses; ii) fertility restorer RF2Bn (B94-2) oilseed rape line and all conventional crosses; iii) hybrid combination MS1XRF2	"Report on oil from a fertility restorer line for use in a hybrid breeding programme for genetically modified (GM) oilseed rape" (ACNFP)*	10 June 1997	24 June 1997 again 28 July 1998
2b	Plant Genetic Systems N.V. Jozef Plateaustraat 22 B - 9000 Gent	Processed oil from genetically modified oilseed rape seed derived from: i) male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses; ii) fertility restorer RF1Bn (B93-101) oilseed rape line and all conventional crosses; iii) hybrid combination MS1XRF1	"Report on oil from a fertility restorer line for use in a hybrid breeding programme for genetically modified (GM) oilseed rape" (ACNFP)*; and "Report on oil from genetically modified oilseed rape" (ACNFP)*	10 June 1997	24 June 1997 again 28 July 1998
3	Monsanto Services International S.A Avenue de Tervueren 270-272 B - 1150 Brussels	Refined oil from glyphosate tolerant oilseed rape line GT73	"Report on oil from genetically modified (GM) glyphosate tolerant oilseed rape" (ACNFP)*	10 November 1997	21 November 1997
4	Monsanto Services International S.A Avenue de Tervueren 270-272 B - 1150 Brussels	Food and food ingredients produced from maize flour, maize gluten, maize semolina, maize starch, maize glucose and maize oil derived from the progeny of maize line MON 810	"Report on processed products from genetically modified (GM) insect protected maize" (ACNFP)*	10 December 1997	6 February 1998

* ACNFP: Advisory Committee on Novel Foods and Processes (UK).

	Applicant	*Description of Food or Food Ingredient*	*Scientific Evidence*	*Notification*	*Transmission to Member States*
5	AgrEvo France S.A. Les Algorithmes Bâtiment Thalès Saint Aubin F - 91197 Gif-sur-Yvette Cedex	i) Starch and all its derivatives; ii) crude and refined oil; iii) all heat-processed or fermented products obtained from hominys, grits and flour (dry milled fragments) obtained from the genetically modified maize, tolerant to glufosinate ammonium, transformation event T25 and all the varieties derived from	"Report on processed products from genetically modified (GM) glufosinate ammonium tolerant maize" (ACNFP)*	12 January 1998	6 February 1998
6	Novartis Seeds AG Schwarzwaldallee 215 CH - 4058 Basel	Food and food ingredient products derived from the original transformant Bt11 crossed with the Northrup King Company inbred line #2044 (maize), as well as from any inbred and hybrid lines derived from it and containing the introduced genes	ACNFP* Report on grain from maize genetically modified for insect resistance	30 January 1998	6 February 1998
7	Pioneer Overseas Corporation Avenue Tedesco, 7 B - 1160 Brussels	Novel foods and novel food ingredients produced from gentically modified maize line MON 809	ACNFP* Report on genetically modified (GM) insect protected maize Pioneer Hi-bred International – line MON 809	14 October 1998	23 October 1998
8	Hoechst Schering, AgrEvo GmbH Industriepark Hoechst AgrEvo-Haus K 607 D - 65926 Frankfurt am Main	Processed oil from genetically modified oilseed rape derived from Falcon GS 40/90	BgVV** Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte Falcon GS/40/90 gewonnenen raffinierten Speiseöls	21 October 1999	8/9 November 1999
9	Hoechst Schering, AgrEvo GmbH Industriepark Hoechst AgrEvo-Haus K 607 D - 65926 Frankfurt am Main	Processed oil from genetically modified oilseed rape derived from Liberator L62	BgVV** Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte Liberator pHoe6/Ac gewonnenen raffinierten Speiseöls	21 October 1999	8/9 November 1999

** BgVV: Bundesamt für gesundheitlichen Verbraucherschutz und Veterinärmedizin (D).

	Applicant	*Description of Food or Food Ingredient*	*Scientific Evidence*	*Notification*	*Transmission to Member States*
10	Plant Genetic Systems N.V. Jozef Plateaustraat 22 B - 9000 Gent	Processed oil from genetically modified oilseed rape derived from: the male sterile MS8 (DBN 230-0028) oilseed rape line and all conventional crosses; the fertility restorer RF (DBN212-0005) oilseed rape line and all conventional crosses; the hybrid combination MS8 x RF3	BgVV** Stellungnahme zur wesentlichen Gleichwertigkeit des aus der transgenen, Glufosinat-toleranten Rapssorte MS8/RF3 gewonnenen, raffinierten Speiseöls	21 October 1999	8/9 November 1999
11	F. Hoffman – La Roche Ltd. Vitamins & Fine Chemicals Regulatory Affairs Bldg 241/283 CH - 4070 Basel	Riboflavin from Bacillus subtilis as nutrient	ACNFP* Report on Riboflavin from fermentation using genetically modified (GM) Bacillus subtilis	20 March 2000	26 April 2000
12	Monsanto Services International Avenue de Tervueren 270-272 B - 1150 Brussels	Cottonseed oil from genetically modified cotton line 1445 (herbicide resistant)	ACNFP* Request for an Article 5 opinion on the substantial equivalence of cotton seed oil and food ingredients derived from Roundup® Ready cotton	24 July 2002	19 December 2002
13	Monsanto Services International Avenue de Tervueren 270-272 B -1150 Brussels	Cottonseed oil from genetically modified cotton line 531 (insect protected)	ACNFP* Request for an Article 5 opinion on the substantial equivalence of cottonseed oil and food ingredients derived from insect protected cottonseed	24 July 2002	19 December 2002

Annex 6

Labelling of GM-Food and GM-Feed – Examples [18]

GMO-type	*EXAMPLE*	*Labelling Required at present*	*Labelling required in future*
GM plant	Chicory[19]	Yes	Yes
GM seed	Maize seeds	Yes	Yes
GM food	Maize, Soybean sprouts, Tomato	Yes	Yes
Food produced from GMOs	Maize flour[20]	Yes	Yes
	Highly refined maize oil, soybean oil, rape seed oil[21]	No	Yes
	Glucose syrup produced from maize starch[21]	No	Yes
Food from animals fed on GM feed	Eggs, meat, milk	No	No
Food produced with the help of a GM enzyme	bakery products produced with the help of amylase	No	No
Food additive/flavouring produced from GMOs	Highly filtered lecithin extracted from GM soybeans used in chocolate[21]	No	Yes
GM Feed	Maize[22]	Yes	Yes
Feed produced from a GMO	Corn gluten feed, Soybean meal	No	Yes
Feed additive produced from a GMO	Vitamin B2 (riboflavin)	No	Yes

[18] The examples include foods which have not been authorized for marketing in the EU. See Annex II for a list of products which can legally be marketed in the EU.

[19] One chicory has been approved for breeding purposes under Directive 90/220/EC, but not for food use.

[20] DNA or protein of GM origin detectable in the final product.

[21] DNA or protein of GM origin not detectable in the final product.

[22] The current labelling rules entered into force in 1997, and do not include four GMOs approved prior to that date.