

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 tracability 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 authorised 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 On this date, the Directive was repealed by the new, updated Directive 2001/18/EC of the European Parliament and Council on the deliberate release of genetically modified organisms.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

- 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 authorise the release of GMOs and
- the possibility for Council of Ministers to adopt or reject a Commission proposal for authorisation of a GMO by qualified majority.

How does the environmental risk assessment procedure work from 17 October 2002 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)
- 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 authorised 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. 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 twenty (20) notifications under Directive 2001/18/EC. These are listed in Annex 2. Seven (7) of these are products which were pending under Directive 90/220/EC at the time of its repeal.

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 authorisation and labelling of novel foods including food products containing, consisting or produced from GMOs.

The first step of an authorisation 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 authorise 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 authorisation 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?

Products from 16 GMOs can legally be marketed in the EU. These are

- One GM soy and one GM maize approved under Directive 90/220/EEC prior to the entering into force of the Novel Food Regulation
- Processed foods derived from *inter alia* 7 GM oilseed rape, 4 GM maize and oil from 2 GM cottonseeds (see Annex 4). These products have all been notified as substantially equivalent in accordance with the Novel Food Regulation.

Ten applications for GM foods are currently pending at different stages in the authorisation procedure, including products from GM maize, sugar beet and soy bean. (see Annex 3).

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

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 authorised 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 authorised 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 authorised in accordance with the Novel Foods Regulation.

Legislation on the marketing of forestry reproductive material also requires prior authorisation 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

Authorisation 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 authorisation 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 recognises the 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 equivalence¹.

Council Regulation (EC) 1139/98 lays down provisions for the labelling of foods and food ingredients derived from one maize and one soya² 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 authorisation 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.

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)

¹ 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 (i.e. genetic modification) by which the characteristic or property was obtained.

² 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

- 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.
- 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/EC³ 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.

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.

³ OJ L 106, 17.4.2001, p.1.

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);
- 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 authorisation 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 authorised under Directive 90/220/EEC will in future need to be labelled. See also Annex 5.

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 authorised?

Clear rules are already set out in the EU for the assessment and authorisation 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 authorisation 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 authorisation 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 authorised 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 authorisation.

The proposal will, as it is currently the case, be approved through qualified majority of the Member States within a Regulatory Committee.

Products authorised 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 authorised 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;
- 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 authorisation 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 authorisation 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;
- 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.

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

Product	Notifier	Date of Commission Decision⁴ / Member State Consent⁵
1. Vaccine against Aujeszky's disease	Vemie Veterinär Chemie GmbH	18.12.92
2. Vaccine against rabies	Rhône-Mérieux 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) ⁶	Vemie Veterinär Chemie GmbH C/D/92/I-1	18.07.94
5. Male sterile swede rape resistant to glufosinate ammonium (MS1, RF1) <u>Uses</u> : breeding activities	Plant Genetic Systems C/UK/94/M1/1	06.02.96
6. Soybeans tolerant to glyphosate <u>Uses</u> : import and processing	Monsanto C/UK/94/M3/1	03.04.96
7. Male sterile chicory tolerant to glufosinate ammonium <u>Uses</u> : 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) ⁷ <u>Uses</u> : import and processing	Plant Genetic Systems C/F/95/05/01/A	06.06.97 (not finally approved by F)

⁴ where objections were raised by Member State authorities

⁵ in the absence of objections by Member State authorities

⁶ linked to item 1 (same product, further uses)

⁷ linked to item 5 (same product, further uses)

Product	Notifier	Date of Commission Decision⁸ / Member State Consent⁹
10. Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF2) ¹⁰	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
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) <u>Uses</u> : 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 <i>cryIA(b)</i> gene (MON 810)	Monsanto C/F/95/12-02	22.04.98
16. Maize tolerant to glufosinate ammonium and expressing the Bt <i>cryIA(b)</i> gene (Bt-11) <u>Uses</u> : 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)

⁸ where objections were raised by Member State authorities

⁹ in the absence of objections by Member State authorities

¹⁰ this product is the result of a different transformation event to that of No. 9

**GMO PRODUCTS – NOTIFICATIONS RECEIVED BY THE COMMISSION
UNDER DIRECTIVE 2001/18/EC
As of 26 June 2003**

Product notification details	Company
<p>1. Oil seed rape – herbicide resistant GT 73</p> <p>Received by the Netherlands (C/NL/98/11) under Dir 90/220/EC. Received by the Commission under Dir 2001/18 : 16/1/03</p> <p><u>Uses:</u> import and uses in feed and industrial processing, not for cultivation.</p>	Monsanto
<p>2. Maize Roundup Ready NK603, tolerant to glyphosate herbicide</p> <p>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</p> <p><u>Uses:</u> import and use in feed and industrial processing, not for cultivation.</p>	Monsanto
<p>3. Maize hybrid MON810 x NK603 (glyphosate-tolerant and containing Bt toxin)</p> <p>Received by UK under Dir 90/220/EC. (C/GB/02/M3/03) Received by the Commission under Dir 2001/18 : 15/01/03</p> <p><u>Uses:</u> import and use in feed and industrial processing, not for cultivation.</p>	Monsanto
<p>4. Potato with altered starch composition from Sweden (C/SE/96/3501)</p> <p>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</p> <p><u>Uses:</u> for cultivation and production of starch, not for use as human food.</p>	AMYLOGENE HB
<p>5. Oilseed rape (Ms8, Rf3) from Belgium (C/BE/96/01)</p> <p>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</p> <p><u>Uses:</u> import and cultivation in the EU, uses in feed and industrial processing.</p>	Bayer CropScience

Product notification details	Company
<p>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</p> <p><u>Uses:</u> import only</p>	<p>Bayer CropScience</p>
<p>7. Roundup Ready sugar beet (event T9100152), glyphosate tolerant from Belgium C/BE/99/01</p> <p>Received by the Commission under Dir 2001/18: 5/02/03</p> <p><u>Uses:</u> for cultivation and use in animal feed, processing of sugar and other products.</p>	<p>Monsanto/ Syngenta</p>
<p>8. Oilseed rape tolerant for glufosinate-ammonium herbicides. (FALCON GS40/90pHoe6/Ac) from Germany (C/DE/96/5)</p> <p>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</p> <p><u>Uses:</u> for import and cultivation</p>	<p>Bayer CropScience</p>
<p>9. Oilseed rape tolerant for glufosinate-ammonium (Liberator pHoe6/Ac) from Germany (C/DE/98/6)</p> <p>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</p> <p><u>Uses:</u> for import and cultivation</p>	<p>Bayer CropScience</p>
<p>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</p> <p><u>Uses:</u> for cultivation and use in processing of sugar and other processed products.</p>	<p>KWS SAAT AG/Monsanto</p>

Product notification details	Company
<p>11. Maize MON 863 X MON 810 (protection against certain insect pests)</p> <p>from Germany C/DE/02/9 (6788-01-09) Received by the Commission under Dir 2001/18: 7/02/03</p> <p><u>Uses:</u> for import and use of grain and grain products.</p>	<p>Monsanto</p>
<p>12. Oilseed rape (event T45) tolerant for glufosinate-ammonium herbicide</p> <p>from UK C/GB/99/M5/2</p> <p>Received by the Commission under Dir 2001/18: 10/02/03</p> <p><u>Uses:</u> import and use in feed and industrial processing.</p>	<p>Bayer CropScience</p>
<p>13. Maize herbicide and insect resistant (line 1507 -- CRY1F)</p> <p>received by the Netherlands (C/NL/00/10) under Dir 90/220/EC. Received by the Commission under Dir 2001/18 : 12/02/03</p> <p><u>Uses:</u> import and processing, not for cultivation</p>	<p>Pioneer/ Mycogen Seeds</p>
<p>14. Insect-protected Cotton expressing the Bt <i>cryIA(c)</i> gene (line 531)</p> <p>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</p> <p><u>Uses:</u> for import, processing and cultivation</p>	<p>Monsanto</p>
<p>15. Roundup Ready Cotton tolerant to herbicide (line 1445)</p> <p>from Spain (C/ES/97/01)</p> <p>(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</p> <p><u>Uses:</u> for import, processing and cultivation</p>	<p>Monsanto</p>
<p>16. Roundup Ready Maize tolerant to glyphosate (GA21)</p> <p>from Spain (C/ES/98/01)</p> <p>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</p> <p><u>Uses:</u> use in feed and industrial processing</p>	<p>Monsanto</p>

Product notification details	Company
<p>17. Maize MaisGard/Roundup Ready (derived from MON 810 and GA21). Tolerance to glyphosate and Cry1Ab protein derived from Bt.</p> <p>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</p> <p><u>Uses:</u> import and use in feed and industrial processing, not for cultivation.</p>	<p>Monsanto</p>
<p>18. Maize 1507 (or Bt Cry1F 1507)</p> <p>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</p> <p><u>Uses:</u> import, feed and industrial processing, and cultivation</p> <p>19. Roundup Ready Fodder beet (line A5/15) from Denmark (C/DK/97/01)</p> <p>Received by the Commission under Dir 90/220: 09.10.97 Favourable opinion of EU Scientific Committee 23.06.98 Received by the Commission under Dir 2001/18/EC: 26/02/03</p> <p><u>Uses:</u> for <i>cultivation</i> and animal feed</p> <p>20. Maize tolerant to glufosinate ammonium and expressing the Bt cryIA(b) gene (Bt-11) from France (C/F/96/05-10)</p> <p>Received by the Commission under Dir 90/220: 12.04.99 and 03.05.99 respectively Favourable opinion of EU Scientific Committee 30.11.00 Received by the Commission under Dir 2001/18/EC: 16.6.2003</p> <p><u>Uses :</u> for <i>cultivation</i>, feed and industrial processing</p>	<p>Pioneer Hi-Bred /Mycogen Seeds</p> <p>DLF-Trifolium, Monsanto and Danisco Seed</p> <p>Syngenta Seeds SAS</p>

Annex 3

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 <i>Radicchio rosso</i> 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 Plateastraat 22 B - 9000 Gent	Liberty Link Soybean by AgrEvo	Bioveiligheidsraad (B)	2 February 1999	Initial assessment report pending.
5	Novartis Seeds AG Basel 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 <i>B.t.</i> CRY1F Maize line 1507	Gezondheidsraad (NL)	26 February 2001	Initial assessment report pending
9	Monsanto Services International S.A. Avenue de 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 4

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
2 a	Plant Genetic Systems N.V. Jozef Plateaustraart 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
2 b	Plant Genetic Systems N.V. Jozef Plateaustraart 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

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

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
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 Schwarzwalddallee 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 genetically 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
10	Plant Genetic Systems N.V. Jozef Plateastraat 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 <i>Bacillus subtilis</i> as nutrient	ACNFP* Report on Riboflavin from fermentation using genetically modified (GM) <i>Bacillus subtilis</i>	20 March 2000	26 April 2000

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

1	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
2					
1	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
3					

* **ACNFP** Advisory Committee on Novel Foods and Processes (UK)
 *** **AFSA** Agence française de sécurité sanitaire des aliments

Labelling of GM-Food and GM-Feed – Examples ¹¹

GMO-type	EXAMPLE	Labelling Required at present	Labelling required in future
GM plant	Chicory ¹²	Yes	Yes
GM seed	Maize seeds	Yes	Yes
GM food	Maize, Soybean sprouts, Tomato	Yes	Yes
Food produced from GMOs	Maize flour ¹³	Yes	Yes
	Highly refined maize oil, soybean oil, rape seed oil ¹⁴	No	Yes
	Glucose syrup produced from maize starch ¹⁴	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 ¹⁴	No	Yes
GM Feed	Maize ¹⁵	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

¹¹ The examples include foods which have not been authorised for marketing in the EU. See Annex II for a list of products which can legally be marketed in the EU.

¹² One chicory has been approved for breeding purposes under Directive 90/220/EC, but not for food use

¹³ DNA or protein of GM origin detectable in the final product.

¹⁴ DNA or protein of GM origin not detectable in the final product.

¹⁵ The current labelling rules entered into force in 1997, and do not include four GMOs approved prior to that date.