MEMO/04/85

Brussels, 15 April 2004

Question and Answers on the regulation of GMOs in the EU

What are GMOs and GMMs?

Genetic modification, genetic engineering or recombinant-DNA technology, first applied in the 1970's is one of the newest methods to introduce novel traits to micro-organisms, plants and animals. Unlike other genetic improvement methods, the application of this technology is strictly regulated. Before any genetically modified organism (GMO) or product can be put on the market in the EU, it has to pass an approval system in which the safety for humans, animals and the environment is thoroughly assessed.

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.

The most common types of GMOs are genetically modified crop plant species and include genetically modified maize, soybean, oil-seed rape and cotton varieties. Such varieties have, in the main, been genetically modified to provide resistance to certain insect pests and tolerance to specific herbicides.

The development of insect resistant plants reduces the use of pesticides needed to control certain insect pests in the crop. Use of plants tolerant to a specific broad-spectrum herbicide allows this herbicide to be used to remove a range of weed species in the crop without destroying the genetically modified plants themselves. This type of herbicide reduces the need for a greater number of spray treatments with herbicides that only destroy a single or a few weed species.

Overview of EU legislation on GMOs

EU legislation on GMOs has been in place since the early 1990s. The EU introduced specific legislation on GMOs to protect its citizens' health and the environment while simultaneously creating a unified market for biotechnology.

- **Directive 2001/18 on the deliberate release into the environment of genetically modified organisms** is a 'horizontal' Directive, which regulates experimental releases and the placing on the market of genetically modified organisms.

- **Regulation 1829/2003 on GM food and feed** regulates the placing on the market of food and feed products containing or consisting of GMOs and also provides for the labelling of such products to the final consumer.
- **Regulation 1830/2003 on traceability and labelling of GMOs and the traceability of food and feed products from GMOs** introduces a harmonised EU system to trace and label GMOs and to trace food and feed products produced from GMOs.
- **Regulation 641/2004 on the detailed rules for the implementation of Regulation 1829/2003**
- **Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms (GMMs)**, regulates research and industrial work activities involving GMMs under conditions of containment. This includes work activities in laboratories.

Release into the environment

What are the main features of Directive 2001/18?

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, a Community system for which is provided for by Regulation 1830/2003 on traceability (see below);
- Information to allow the identification and detection of GMOs to facilitate post-market inspection and control;
- 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.

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 European Commission.

If there are no objections by other Member States or the European Commission, 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 EU level. The Commission first asks for the opinion of its Scientific Panels composed of independent scientists, highly qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry, or other similar disciplines. The European Food Safety Authority provides the relevant panels for this purpose.

If the scientific opinion is favourable, the Commission then proposes a draft legislative Decision to the Regulatory Committee composed of representatives of Member States for an 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 or rejection by qualified majority. If the Council does not act within 3 months, the Commission shall adopt the decision.

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

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 does the environmental risk assessment procedure work?

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).

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

Under the rules on the deliberate release of GMOs into the environment (Directive 2001/18/EC and previously Directive 90/220/EC) so far 18 GMOs have been approved for different uses, some for cultivation, some for import and processing, some as feed, some as food (see annex 1). In terms of crops species, these GMOs include maize, oil seed rape, soybean and chicory.

Twenty four applications for the placing on the market of GMOs have been submitted into the authorisation procedure under Directive 2001/18/EC (Annex 2), e.g. maize, oil seed rape, sugar beet, soy beans, cotton, rice, fodder beet. Eleven of these applications have a scope which is restricted to import and processing, while the remaining ones also include cultivation as a requested use.

National safeguard measures

A number of Member States have invoked the so-called 'safeguard clause' of the previous Directive 90/220/EEC. This clause provided that where a Member State has justifiable reasons to consider that a GMO, which has received written consent for placing on the market, constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory.

The safeguard clause has been invoked on nine separate occasions, three times by Austria, twice by France, and once each by Germany, Luxembourg, Greece and the United Kingdom (Annex 5). The scientific evidence provided by these Member States as justification for their measures, was submitted to the Scientific Committee(s) of the EU for opinion. In all of these cases, the Committee(s) deemed that there was no new evidence which would justify overturning the original authorisation decision.

In spite of the repeal of Directive 90/220/EEC, the bans remain in place and have now to be considered under safeguard provision (Article 23) of Directive 2001/18/EC. In view of the new regulatory framework, the Commission informed Member States that they should withdraw their measures under Directive 90/220/EEC and lift the prohibitions. The Commission is currently in the process of finalising decisions to lift the bans taking account of the information provided by the above Member States.

National safeguard measures on GM foods

Only one Member State has invoked the safeguard clause (Article 12) under the Novel Food Regulation. This took place in August 2000, when Italy suspended the trade in and use of products derived from four GM maize varieties (MON 810 from Monsanto; T25 from Bayer Crop Science; Bt11 from Syngenta and MON 809 from Pioneer) which had been notified under the simplified procedure for products considered as “substantially equivalent”.

The Commission immediately sought an opinion from the Scientific Committee for Food (SCF) which concluded, in September 2000, that the information provided by the Italian Authorities did not provide detailed scientific grounds for considering that the use of the GM foods in question endangered human health. The Commission has written to the Italian Government asking it to repeal the Decree of August 2000.

GM Food and Feed

What are the main features of Regulation 1829/2003 – GM Food and Feed?

Regulation 1829/2003 on genetically modified food and feed covers GMOs for food/feed use and includes all rules concerning food/feed containing or consisting of GMOs; food/feed produced from GMOs and food containing ingredients produced from GMOs referred to as GM food/feed. The Regulation stipulates that GM food/feed must not:

- Have adverse effects on human health, animal health, or the environment;
- Mislead the consumer;
- Differ from the food/feed it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer/animals.

The Regulation puts in place a streamlined, uniform and transparent EU 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. The Regulation also ensures that experiences such as with Starlink maize in the US (a GM maize which was only authorised for feed but turned up in food) are avoided because GMOs likely to be used as food and feed can only be authorised for both uses, or not at all.

What is the approval procedure?

The Regulation is based on the “one door-one key” principle. Thus, it is possible to file a single application for obtaining both the authorisation for the deliberate release of a GMO into the environment, under the criteria laid down in Directive 2001/18/EC and the authorisation for use of this GMO in food and/or feed under the criteria laid down in Regulation 1829/2003. This authorisation, valid throughout the Community, is granted subject to a single risk assessment process under the responsibility of the European Food Safety Authority and a single risk management process involving the Commission and the Member States through a regulatory committee procedure.

Applications are submitted first to the competent authority of the Member State where the product is first to be marketed. The application must clearly define the scope of the application, indicate which parts are confidential and must include a monitoring plan, a labelling proposal and a detection method for the new GM food or feed. The national authority must acknowledge receipt in writing within 14 days and inform the European Food Safety Authority. The application and any supplementary information supplied by the applicant must be made available to EFSA which is responsible for the scientific risk assessment 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.

In general a time limit of 6 months for the EFSA opinion will be respected. This time limit can be extended if EFSA has to request further information from the applicant. A draft guidance document for the risk assessment of GM plants and derived food and feed is available from EFSA.

(http://www.efsa.eu.int/consultation/372/consultation_guidance_gmo_01_en1.pdf)

Within 3 months of receiving the opinion of EFSA and on the basis of that opinion, the Commission will draft a proposal for granting or refusing authorisation. The proposal will, be approved through qualified majority of the Member States within the Standing Committee on the Food chain and Animal Health, composed of representatives of the Member States.

If the Committee gives a favourable opinion, the Commission adopts the Decision. If not, the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council does not act within 3 months, the Commission shall adopt the decision.

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.

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

Products from 16 GMOs can legally be marketed in the EU (see Annex 3). These are:

- One GM soy and 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.

These products have all been notified as substantially equivalent in accordance with the Novel Food Regulation. Nine GM foods are currently pending at different stages in the authorisation procedure, including products from GM maize, sugar beat and soy bean. These can be found in Annex 4.

Which genetically modified feeds have been authorised?

Before the entry into force of the Regulation on GM Food and Feed, there was been no EU legislation governing the specific use of material derived from GMOs in feed. Eight GMOs are authorised in accordance with Directive 90/220/EEC for use in feed; these are four maize varieties, three rape varieties and one soya variety.

What are the current rules on genetically modified seeds?

EU 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 EU 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 2001/18/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 GM Food and Feed Regulation

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.Legislation on the marketing of forestry reproductive material also requires prior authorisation of GM material in line with the requirements of Directive 2001/18. EU rules governing the marketing of vine material in line with Directive 2001/18 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 shortly.

Labelling and traceability of GMOs

Why does the EU have 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.

What are the rules on traceability of GMOs?

Under the rules of Regulation 1830/2003 on labelling and 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 'have been used' to constitute the original mixture from which the product arose;
- 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.

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 Regulation covers all GMOs that have received EU 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 Regulation also covers food and feed that 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 rules on labelling of GMO products?

Regulation 1830/2003 on labelling and traceability provides for comprehensive information by labelling all food and feed containing, consisting of or produced from a GMO. All food, including soya or maize oil produced from GM soya and maize, and food ingredients, such as biscuits with maize oil produced from GM maize must be labelled. The label has to indicate “This product contains genetically modified organisms” or “produced form genetically modified (name of organism)”.

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 same rules apply to animal feed including any compound feed that contains GM soya. Corn gluten feed produced form GM maize must also be labelled. This is to give livestock farmers accurate information on the composition and properties of feed.

Thresholds for labelling: Minute traces of GMOs in conventional food and feed could arise during cultivation, harvest, transport and processing. Whether we like it or not this has become a reality. This is something that is not particular to GMOs. In the production of food, feed and seed, it is practically impossible to achieve products that are 100% pure. With this background, in order to ensure legal certainty thresholds have been established above which conventional food and feed have to be labelled as consisting of or containing or being produced from a GMO. The presence of GM material in conventional food does not have to be labelled if it is below 0.9% and if it can be shown to be adventitious and technically unavoidable.

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 Regulation 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.

Why do the new Regulations allow the presence of traces of GM material which have received a favourable scientific assessment, but which are not yet formally approved?

The adventitious or unintended presence of GM material 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 EU 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 Regulation 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 Regulations allow the presence of these GMOs in a food or feed up to a maximum of 0.5% below which labelling and traceability will not be enforced. Above 0,5% it is prohibited to put the product on the market.

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 Safety Authority, which has concluded that the material does not present a risk for human health and the environment. The Regulation limits the application of this threshold to three years and provides that a detection method must be publicly available.

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.

Co-existence

What are the rules on co-existence of various farming practices?

The cultivation of GM crops will logically have implications for the organisation of agricultural productions. Pollen flow between adjacent fields is a natural phenomenon and there will be some pollen flow from GM crops to conventional crops and vice versa. Because of the labelling requirements for GM food and feed, this may have economic implications for farmers who want to produce non-labelled food or feed products. Coexistence is about giving farmers the practical choice between conventional, organic and GM crop production in compliance with the legal obligations for labelling and purity standards.

On 5 March 2003, the Commission agreed that it should be up to the Member States to develop and implement management measures concerning co-existence, in accordance with the subsidiarity principle. On 27 July 2003 the Commission adopted a Commission recommendation (2003/556/EC) on co-existence setting out guidelines for the development of national strategies and best practices to ensure co-existence.

The guidelines state that approaches to co-existence need to be developed in a transparent way, based on scientific evidence and in co-operation with all stakeholders concerned. The guidelines are based on experiences with existing segregation practices (e.g. in certified seed production); at the same time they ensure an equitable balance between the interests of farmers of all production types.

Further, they state that management measures to ensure co-existence should be efficient and cost-effective, without going beyond what is necessary to comply with EU threshold levels for GMO labelling. They should be specific to different types of crop, since the probability of admixture varies greatly from one crop to another; while for some crops the probability is high (e.g. oil seed rape) for others the probability is fairly low (e.g. potatoes). In addition, local and regional aspects should be fully taken into account.

Farmers should be able to choose the production type they prefer, without imposing the necessity to change already-established patterns in the neighbourhood. As a general principle, during the phase of introduction of a new production type in a region, farmers who introduce the new production type should bare the responsibility of implementing the actions necessary to limit admixture.

Continuous monitoring and evaluation and the timely sharing of best practices are indicated as imperatives for improving measures over time.

Priority should be given to farm-level management measures and to measures aimed at co-ordination between neighbouring farms. If it can be demonstrated that these measures can not ensure co-existence, regional measures could be considered (e.g. restriction on the cultivation of a certain type of GMO in a region). Such measures should apply only to specific crops whose cultivation would be incompatible with ensuring co-existence in the region, and their geographical scale should be limited as possible. Region-wide measures should be justified for each crop and type (e.g. seed and crop production separately).

International environment

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

The new Regulations take account of the EU's international trade commitments and of the requirements of the Cartagena Protocol on Biosafety with respect to obligations of importers.The EU's regulatory system for GMO's authorisation is in line with WTO rules: it is clear, transparent and non-discriminatory.

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

The EU is a party to the UNEP Cartagena Protocol on Biosafety to the Convention on Biological Diversity. It entered into force on 11 September 2003. 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 implementation of the Cartagena Protocol on Biosafety into EU legislation relies on a wide range of biotechnology legislation applying to the use of GMOs within the European Union, including imports. The centre part of this legal framework is the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. It is completed by the Regulation on the transboundary movements of GMOs, which was adopted in June 2003.

The main elements of the Regulation are:

- The obligation to notify exports of GMOs intended for deliberate release into the environment and secure express consent prior to a first transboundary movement;
- The obligation to provide information to the public and to our international partners on EU practices, legislation and decisions on GMOs, as well as on accidental releases of GMOs;
- A set of rules for the export of GMOs intended to be used as food, feed or for processing;
- Provisions for identifying GMOs for export.

GMO products

Approved under directive 90/220/eec as of march 2001

Product	Notifier	Date of Commission Decision[1] / Member State Consent[2]
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)[3]	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)[4] Uses : import and processing	Plant Genetic Systems C/F/95/05/01/A	06.06.97 (not finally approved by F)

[1] where objections were raised by Member State authorities
[2] in the absence of objections by Member State authorities
[3] linked to item 1 (same product, further uses)
[4] linked to item 5 (same product, further uses)

Product	Notifier	Date of Commission Decision[5] / Member State Consent[6]
10. Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF2)[7]	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) 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)

[5] where objections were raised by Member State authorities
[6] in the absence of objections by Member State authorities
[7] 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

Product notification details	Company
1. 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
2. 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
3. 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
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 & A 5547-127) from Belgium (C/BE/98/01) Received by the Commission under Dir 2001/18: 5/02/03 Uses: import only, *not for cultivation*	Bayer CropScience
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 (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, *not for cultivation*.	Monsanto

12. Oilseed rape (event T45) tolerant for glufosinate-ammonium herbicide from UK C/GB/99/M5/4 (Replacing C/GB/99/M5/2 received by the Commission on 10/2/03 and withdrawn on 26/3/04). Received by the Commission under Dir 2001/18: 30/03/04 Uses: import and use in feed and industrial processing, *not for cultivation*.	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
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. 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*	
17. Roundup Ready Fodder beet (line A5/15) from Denmark (C/DK/97/01) 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 Uses: for *cultivation* and animal feed.	DLF-Trifolium, Monsanto and Danisco Seed

18. Maize tolerant to glufosinate ammonium and expressing the Bt *cryIA(b)* gene (Bt-11) from France (C/F/96/05-10) 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 Uses : for *cultivation*, feed and industrial processing	Syngenta Seeds SAS
19. Brombxnnil-tolerant cotton lines 10215 and 10222 from Spain (C/ES/99/01) Received by the Commission under Dir 2001/18/EC: 18.07.2003 Uses : for importation and processing to non-viable products	Stoneville Pedigreed Seed Company
20. NK603 Roundup Ready® maize from Spain (C/ES/03/01) Received by the Commission under Dir 2001/18/EC : 22/07/2003 Uses: Cultivation	Monsanto
21. Rice tolerant to glufosinate-ammonium, event LLRICE62 from UK (C/GB/03/M5/3) Received by the Commission under Dir 2001/18/EC : 3/9/2003 Uses: import and use in feed and industrial processing, *not for cultivation.*	Bayer CropScience Ltd.
22. NK603 X MON 810 maize from Spain (C/ES/04/01) Received by the Commission under Dir 2001/18/EC : 12/1/2004 Uses: import and use in feed and industrial processing, and *for cultivation.*	Monsanto
23. Cotton, insect resistant (281-24-236/3006-210-23) from the Netherlands (C/NL/04/01) Received by the Commission under Dir 2001/18/EC : 18/2/2004 Uses: import and use in feed and industrial processing, *not for cultivation*	Agrigenetics Inc. d/b/a Mycogen Seeds, c/o Dow AgroSciences
24. Cotton (LLCotton25) glufosinate tolerant from Spain (C/ES/04/02) Received by the Commission under Dir 2001/18/EC : 26/3/2004 Uses: import and use in feed and industrial processing, *not for cultivation*	Bayer CropScience

Annex 3

Genetically modified (gm) foods authorised in the european union

‘	EVENT	CROP	APPLICANT	TRAIT	POTENTIAL FOOD USES	DATE	LEGAL BASIS
1	GTS 40/3/2	Soybean	Monsanto	Insect protection and herbicide tolerance	Soy foods. Soy foods include soy beverages, tofu, soy oil, soy flour, lecithin.	03.04.1996	Dir. 90/220/EEC – Art. 13
2	Bt 176	Maize	Ciba-Geigy	Insect protection and herbicide tolerance	Maize foods. Maize foods include kernels, oil, maize flour, sugar, syrup.	23.01.1997	Dir. 90/220/EEC – Art. 13
3	TOPAS 19/2	Oilseed rape	AgrEvo	Herbicide tolerance	‘	24.06.1997	Reg. (EC) 258/97 – Art. 5
4	MS1 / RF2	Oilseed rape	Plant Genetic Systems	Herbicide tolerance	Rapeseed oil. Products made with rapeseed oil may	24.06.1997	Reg. (EC) 258/97 – Art. 5
5	MS1 / RF1	Oilseed rape	Plant Genetic Systems	Herbicide tolerance	include fried foods, baked products and snack foods.	24.06.1997	Reg. (EC) 258/97 – Art. 5
6	GT 73	Oilseed rape	Monsanto	Herbicide tolerance	‘	21.11.1997	Reg. (EC) 258/97 – Art. 5
7	MON 810	Maize	Monsanto	Insect protection	‘	06.02.1998	Reg. (EC) 258/97 – Art. 5
8	T 25	Maize	AgrEvo	Herbicide tolerance	Maize derivatives. These may include maize oil, maize flour, sugar and syrup. Products made with maize	06.02.1998	Reg. (EC) 258/97 – Art. 5
9	Bt 11	Maize	Novartis	Insect protection	derivatives may include snack foods, baked foods, fried foods, confectionary and soft drinks.	06.02.1998	Reg. (EC) 258/97 – Art. 5
10	MON 809	Maize	Pioneer	Insect protection	‘	23.10.1998	Reg. (EC) 258/97 – Art. 5
11	Falcon GS 40/90	Oilseed rape	Hoechst / AgrEvo	Herbicide tolerance	‘	08.11.1999	Reg. (EC) 258/97 – Art. 5

12	Liberator L62	Oilseed rape	Hoechst / AgrEvo	Herbicide tolerance	Rapeseed oil. Products made with rapeseed oil may include fried foods, baked foods and snack foods. ‘	08.11.1999	Reg. (EC) 258/97 – Art. 5
13	MS8/RF3	Oilseed rape	Plant Genetic Systems	Herbicide tolerance		26.04.2000	Reg. (EC) 258/97 – Art. 5
14	1445	Cotton	Monsanto	Herbicide tolerance	Cottonseed oil. Products made with cottonseed oil may include fried foods, baked foods and snack foods. Vitamin B2	19.12.2002	Reg. (EC) 258/97 – Art. 5
15	531	Cotton	Monsanto	Insect protection		19.12.2002	Reg. (EC) 258/97 – Art. 5
16	pRF69/pRF93	Bacillus subtilis	F. Hoffmann - La Roche	Riboflavin		23.03.2000	Reg. (EC) 258/97 - Art. 5

Annex 4

Genetically modified (gm) foods pending authorisation in the european union

‘	EVENT	CROP	APPLICANT	TRAIT	FOOD USES	INITIAL ASSESSMENT	SCIENTIFIC OPINION	LEGAL BASIS
1	Bt 11	Maize	Syngenta	Insect resistance	Processed sweet maize.	NL – 27/04/2000	SCF – 13.03.2002	Reg. (EC) 258/97 – Art. 7
2	GA 21	Maize	Monsanto	Herbicide tolerance	Maize and maize derivatives	NL – 21/12/1999	SCF – 02.02.1999	Reg. (EC) 258/97 – Art. 7
3	NK 603	Maize	Monsanto	Herbicide tolerance	Maize and maize derivatives	NL – 13/08/2002	EFSA – 04.12.2003	Reg. (EC) 258/97 – Art. 7
4	MON 863	Maize	Monsanto	Insect protection	Maize and maize derivatives	DE – 08/04/2003	EFSA - pending	Reg. (EC) 258/97 – Art. 7
5	MON 863 x MON 810	Maize	Monsanto	Insect protection	Maize and maize derivatives	DE – 08/04/2003	EFSA - pending	Reg. (EC) 258/97 – Art. 7
6	1507	Maize	Pioneer	Insect protection	Maize and maize derivatives	NL – 04/11/2003	EFSA - pending	Reg. (EC) 258/97 – Art. 7
7	MaisGard/ RoundupReady	Maize	Monsanto	Insect protection and herbicide tolerance	Maize and maize derivatives	NL - pending	‘	Reg. (EC) 258/97 – Art. 4
8	RoundupReady Sugar Beat	Sugar Beat	Monsanto	Herbicide tolerance	Sugar Beat derivatives	NL - pending	‘	Reg. (EC) 258/97 – Art. 4
9	Liberty Link Soybean	Soybean	AgrEvo	Herbicide tolerance	Soybean derivatives	B - pending	‘	Reg. (EC) 258/97 – Art. 4

Gmo products

Invocation of article 16 under directive 90/220/eec

Member State and date of invocation	Product details and date of Scientific Opinion
1. France (20.11.98)	Male sterile swede rape resistant to glufosinate MS1/RF1 **Uses:** Cultivation for breeding activities (seed production) **Product approval:** 1996 **Scientific Committee Opinion:** 18.05.99
2. Austria (14.02.97) 3. Luxembourg (17.03.97) 4. Germany (04.04.00)	Bt-maize tolerant to glufosinate ammonium (Bt-176) **Uses:** All uses (cultivation, food and feed, processing) **Product approval:** 1997 **Scientific Committee Opinion**: 21.03.97 (2 and 3 opposite) 10.04.97 (2 and 3 opposite) 12.05.97 (2 and 3 opposite) 09.11.00 (4 opposite)
5. Greece (03.11.98) 6. France (20.11.98)	Swede rape tolerant to glufosinate (Topas 19/2) **Uses:** Import, storage and processing (no cultivation) **Product approval:** 1998 **Scientific Committee Opinion:** 18.05.99
7. Austria (01.06.99	Maize expressing the Bt *cryIA(b)* gene (MON 810) **Uses:** All uses (cultivation, food and feed, processing) **Product approval:** 1998 **Scientific Committee Opinion:** 24.09.99
8. Austria (08.05.00) 9. United Kingdom (13.07.01)	Maize tolerant to glufosinate (T25) **Uses:** All uses (cultivation, food and feed, processing) **Product approval:** 1998 **Scientific Committee Opinion:** 30.11.00 (8 opposite) 08.11.01 (9 opposite)