QUESTIONS AND ANSWERS ON THE REGULATION OF GMOS IN THE EUROPEAN UNION

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on the Regulation of GMOs in the European Union

What are GMOs?

Genetic modification, also known as "genetic engineering" or "recombinant-DNA technology" was first applied in the 1970's. It 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. A genetically modified organism (GMO) or a food product derived from a GMO can only be put on the market in the EU after it has been authorised on the basis of a detailed procedure. This procedure is based on a scientific assessment of the risks to health and the environment. The GM product is also checked to ensure it does not prejudice the interests of consumers.

Genetically modified organisms (GMOs) can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination. As an application of modern biotechnology, this technique allows selected individual genes to be transferred from one organism into another, also between non-related species.

The most common types of GMOs that have been developed and commercialised are genetically modified crop plant species, such as 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 total herbicides.

The development of insect resistant plants (such as cotton Bt) reduces the use of harmful insecticides 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 specific herbicides that only destroy a single or a few weed species.

There are other types of GMOs which have direct implications as regards the characteristics of the foodstuffs themselves. Hence, by introducing a particular gene into a plant, fruit with delayed ripening are currently being developed. In the years to come, these will have an enhanced nutritional quality. Animals such as fish (example: salmon) can be genetically modified to enhance their quality and accentuate certain characteristics (such as their resistance to cold). Genetically modified microorganisms, which are living microscopic entities, are used in the production of numerous vitamins, flavourings and additives.

Overview of EU legislation on GMOs

EU legislation on GMOs has been in place since the early 1990s. This specific legislation has two main objectives:

- to protect health and the environment and
- to ensure the free movement of safe and healthy genetically modified products in the European Union.

The entire corpus of GMO legislation has recently been amended, leading to the creation of a new legal framework. Its main legal instruments are as follows:

- Directive 90/219/EEC, as amended by Directive 98/81/EC, on the **contained use of genetically modified microorganisms** (GMMs). This Directive regulates

research and industrial work activities involving GMMs (such as genetically modified viruses or bacteria) under conditions of containment, i.e. in a closed environment in which contact with the population and the environment is avoided. This includes work activities in laboratories.

- Directive 2001/18/EC on the **deliberate release into the environment** of GMOs applies to two types of activities:

  - the experimental release of GMOs into the environment, i.e. the introduction of GMOs into the environment for experimental purposes (for example in connection with field tests) is regulated by Part B of the Directive;

  - the placing on the market of GMOs (GMOs from now on being defined as a product containing GMOs or consisting of such organisms), for example the cultivation, importation or transformation of GMOs into industrial products, is mainly regulated by Part C of the Directive;

- **The placing on the market of GMO food and feed or food and feed products containing or consisting of GMOs** is regulated by Regulation (EC) No 1829/2003 on genetically modified food and feed. In the presence of a food/feed product containing GMOs or consisting of such organisms, the applicant has in reality a choice: (1) either the application in its entirety is uniquely subject to Regulation (EC) No 1829/2003, applying the "one door, one key" principle, in order to obtain an authorisation for the deliberate release of GMOs into the environment in accordance with the criteria laid down by Directive 2001/18/EC, and the authorisation to use this GMO in food or feed in accordance with the criteria laid down by Regulation (EC) No 1829/2003, or (2) the application — or part of the application — is submitted both under Directive 2001/18/EC and Regulation (EC) No 1829/2003.

- **Intentional and unintentional movements of GMOs between Member States of the European Union and third countries** are regulated by Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms, with the exception of intentional movements within the Community.

All these instruments lay down the conditions which, for example, a company or university research department must satisfy before being allowed to develop, use or market a GMO or a food product derived from GMOs.

GMOs and food products derived from GMOs which are placed on the market must also satisfy **labelling and traceability** conditions. These conditions are laid down in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

Various other instruments have been adopted in connection with this legislation. These include:

- Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

- Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms

- Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003.

Release into the environment

The release of a GMO into the environment consists of an introduction of the GMO into the environment, without any precise confinement measure being taken to restrict the contact between this GMO and the population or the environment in general. Such a release may be carried out for experimental purposes or in connection with the placing on the market of a GMO.

Experimental releases of GMOs into the environment are mainly carried out for the purposes of study, research, demonstration and development of novel varieties. The behaviour of the GMO in an open environment and its interactions with other organisms and the environment are studied. The experimental releases are subject to the provisions of Part B of Directive 2001/18/EC.

If the results of the experimental release are positive, the company may decide to **place the GMO on the market**, i.e. make it available to third parties either free of charge or for a fee. This is a later stage in the development and use of the GMOs which consists, for example, in transferring a GMO free of charge between commercial partners or the marketing of the GMO. Hence, the GMO may be placed on the market for purposes of cultivation, importation, or transformation into different products. The placing on the market of a GMO is mainly governed by the provisions of Part C of Directive 2001/18/EC.

What are the principles introduced by Directive 2001/18/EC?

Directive 2001/18/EC introduces:

- principles for 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 (EC) No 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)/European Food Safety Authority (EFSA) to be obligatory;

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

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

What is the procedure for authorisation of the experimental release of GMOs into the environment?

A person or a company who wishes to introduce GMOs into the environment for experimental purposes must first obtain written authorisation to this end. This authorisation is issued by the competent national authority of the Member State within whose territory the experimental release is to take place, on the basis of an evaluation of the risks presented by the GMO – or GMOs – for the environment and human health.

To obtain this authorisation, the applicant (called "the notifier") must submit an application (called "the notification") containing the particulars set out in Article 6 of Directive 2001/18/EC. These particulars must include an evaluation of the environmental risks which the notifier has carried out.

The decision to authorise — or reject — the release of the GMO is exclusively incumbent on the competent national authority which has received the notification. Hence the authorisation procedure is a purely national one. This corresponds to a feature of the authorisation of release for experimental purposes: the authorisation to proceed with this release applies only in the Member State in which the notification has been submitted. However, the other Member States and the European Commission may make observations to be examined by the competent national authority. If the competent national authority considers that the notification complies with the requirements of Directive 2001/18/EC, it authorises the release. If the competent national authority considers that the notification does not meet the conditions laid down in Directive 2001/18/EC, it rejects the notification.

In the event of authorisation, the notifier may release the GMO in compliance with the conditions set out in this authorisation.

What is the procedure for authorising the placing on the market of GMOs as such or as a component in products?

Under Directive 2001/18/EC, a company intending to market a GMO — mainly with a view to commercialisation — must first obtain a written authorisation to this end. The GMO placed on the market will be defined as a "product consisting of a GMO" (such as GM carnations of modified colour) or a "product containing a GMO" (such as a batch containing a mixture of seeds).

As opposed to the release for experimental purposes, the authorisation procedure for placing the GMO on the market is not a purely national one, but it involves all Member States. This can explained by the fact that the authorisation of the placing on the market of a GMO implies the free movement of the authorised products throughout the territory of the European Union. Hence all Member States are concerned.

The application (called "notification") is first submitted to the competent national authority of the Member State which issues the final written authorisation permitting the placing on the market of the product in question within the Community. The notification must include the particulars listed in Article 13 of Directive 2001/18/EC, hence a full evaluation of the environmental risks. Having received the notification, the national authority must issue an opinion which will take the form of an "assessment report". This assessment report may be favourable or unfavourable. In the event of an unfavourable report, the company may submit a new notification for the same GMO to the competent national authority of another Member State. This authority may eventually issue a different report.

In the event of a favourable opinion for the placing on the market of the GMO concerned, the Member State, after having received the notification and produced the assessment report, informs the other Member States via the European Commission. The other

Member States and the Commission examine the assessment report and may issue observations and objections.

If there are no objections by other Member States or by the European Commission, the competent authority that carried out the original assessment authorises the placing on the market of the product. The authorised product may then be placed on the market throughout the European Union in conformity with any conditions set out in the authorisation. The authorisation has a maximum duration of ten years and may be renewed provided certain conditions are met (for example on the basis of the results of the post-market monitoring programme).

If objections are raised, the procedure provides for a conciliation phase among the Member States, the Commission and the notifier. The objective of this phase is to resolve the outstanding questions.

If at the end of the conciliation phase the objections are maintained, a decision must be taken at European level. The Commission first asks for the opinion of the European Food Safety Authority, composed of independent scientists, highly qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry and other similar disciplines.

The Commission then presents a draft decision to the Regulatory Committee composed of representatives of the Member States for an opinion. If the Committee gives a favourable opinion by qualified majority, 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 three 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 European Food Safety Authority (http://efsa.eu.int).

How does the environmental risk assessment procedure work?

The safety of GMOs in respect to health and the environment depends on the characteristics of the recipient organism (or parent organism), the inserted genetic material, the final organism that is produced, the recipient 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 result from the deliberate release or placing on the market of the 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 risk assessment methodology, reproduced in Annex II to Directive 2001/18/EC, 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 resulting from the deliberate release or placing on the market of GMO(s);

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

Have GMOs already been authorised for release into the environment?

Under the legislation governing the deliberate release of GMOs into the environment (Directive 2001/18/EC and, previously, Directive 90/220/EC) numerous GMOs have been approved for different uses, some for cultivation, some for import and processing, some as feed and food (see Annex 1 and Annex 1B). As regards varieties of agricultural products, these GMOs include maize, oil seed rape, soybean and chicory. Numerous applications for the placing on the market of GMOs for authorisation under Directive 2001/18/EC are pending, e.g. maize, oil seed rape, cotton, rice (see Annex 2). Several 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

During the late 1990s and in 2000, a number of Member States invoked the so called "safeguard clause" in eight separate cases under Article 16 of Directive 90/220/EEC to restrict provisionally or prohibit the use or the sale of certain GMOs on their territories.

With the entry into force of the new Community legislation on biotechnology, the Commission requested, in 2003, that the above-mentioned Member States re-consider their pending safeguard clauses in view of the new regulatory framework and, if necessary, re-submit them under Article 23 of Directive 2001/18/EC (which replaced Directive 90/220/EEC). Following this request, some of the Member States submitted further information in support of their bans in the first quarter of 2004.

This additional information potentially impacted on all eight cases and was submitted to the European Food Safety Authority (EFSA) for an opinion. In its opinion of July 2004, EFSA concluded, as for all previous arguments and information, that the additional information did not invalidate the original risk assessments for the products in question. Consequently, the Commission was required to submit draft decisions, initially to the Regulatory Committee, requesting the Member States concerned to lift their national safeguard measures. The Regulatory Committee, on 29 November 2004, failed to reach a qualified majority either in favour or against any of these proposals. Under these circumstances, and in accordance with the comitology procedures, the proposals were transmitted to the Council. On 24 June 2005 the Council rejected the proposals of the Commission to lift the national safeguard clauses.

In light of the Council's decision, the Commission has now to re-examine the proposals. According to the comitology procedure, it may submit amended proposals to the Council, re-submit its proposals or present a legislative proposal on the basis of the EC Treaty.

In addition, in January 2005, Hungary invoked the safeguard clause in order to prohibit the cultivation of MON 810 maize on its territory. The information provided was submitted to EFSA for an opinion. In its opinion of July 2005, EFSA concluded that the information provided did not invalidate the initial risk assessment of MON 810. The Commission is now working on a draft Decision to be submitted to the Regulatory Committee.

A list of pending safeguard clauses is available in Annex 5.

National safeguard measures chiefly concerning genetically modified foods

Only one Member State has invoked the safeguard clause (Article 12) under Regulation (EC) No 258/1997 on novel foods.

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.

Italy replied that the new provisions concerning the placing on the market and labelling of GM products as provided by Regulation (EC) No. 1829/2003 are regarded by Italy sufficient to overrule their suspension of trade. Thus the Italian safeguard measures no longer apply.

National safeguard measures concerning genetically modified seed varieties inscribed in the common catalogue of varieties

On 31 March 2005, a Member State (Poland) requested to be allowed to prohibit on the basis of Article 16(2) of Directive 2002/53/EC the use of seeds from the seventeen MON 810 maize varieties inscribed in the common catalogue of varieties of agricultural plant species in September 2004. Subsequently a modified request, accurately based on Article 16(2)(b) (varieties well known not to be suitable for cultivation in Poland) was sent, specifying that the demand was now limited to sixteen varieties only and that it was requested for an indefinite period of time. Poland has complemented end of June 2005 the request by extending it to non-genetically modified varieties, on the basis of the same Article and for the same grounds. In addition, Poland sent in December 2005 and January 2006 a list of the varieties concerned. The Commission is examining these new elements and will present appropriate measures to the Member States.

On 7 April 2005, another Member State (Greece) invoked the safeguard clause (Article 18) under Directive 2002/53/EC for the seventeen MON 810 maize varieties inscribed in the common catalogue in September 2004 which provides that where there is imminent danger of spread of harmful organisms or imminent danger for human health an the environment a Member State may impose the prohibition of the marketing of the seeds of the varieties concerned. A draft Commission Decision providing that this Member State is not authorised to prohibit the marketing of these seeds reached no qualified majority in the Standing Committee on Seeds and Plant Propagating Material for Agriculture, Horticulture and Forestry in July 2005 and was referred end of August to the Council which has neither adopted the proposed measure nor indicated its opposition to it. The Commission has consequently adopted the measure on 10 January 2006 (Commission Decision 2006/10/EC).

GMOs for food and feed use and genetically modified food and feed

Regulation (EC) No 1829/2003 applies to applications for the placing on the market – in the territory of the European Union – of the following products:

- GMOs for food and feed use

- food and feed containing GMOs, consisting of such organisms or produced from GMOs (in the Regulation these are called: "genetically modified food" and "genetically modified feed").

What are the principles of Regulation (EC) No 1829/2003?

The Regulation stipulates that the products to which it applies must not:

- have adverse effects on human health, animal health, or the environment;
- mislead the consumer or user;
- differ from the food/feed they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for human beings (and for animals in the case of genetically modified feed).
- in the case of genetically modified food and feed, harm or mislead the consumer by impairing the distinctive features of the animal products.

The Regulation puts in place a centralised, uniform and transparent EU procedure for all applications for placing on the market, whether they concern the GMO itself or the food and feed products derived therefrom.

This means that business operators may file a single application for the GMO and all its uses: a single risk assessment is performed and a single authorisation is granted for a GMO and all its uses (cultivation, importation, processing into food/feed or industrial products). If one of these uses concerns food, all the uses (cultivation, processing into industrial products, etc.) may be treated under Regulation (EC) No 1829/2003.

In the presence of a food product containing GMOs or consisting of such organisms, the applicant has a choice: Either his application as a whole is filed exclusively under Regulation (EC) No 1829/2003 pursuant to the "one door, one key" principle in order to obtain an authorisation for the deliberate release of a GMO into the environment — in accordance with the criteria established by Directive 2001/18/EC — and the authorisation to use this GMO in food and feed — in accordance with the criteria established by Regulation (EC) No 1829/2003. Or the application is split and submitted both under Directive 2001/18/EC and Regulation (EC) No 1829/2003.

The Regulation also ensures that experiences such as with Starlink maize in the US (a GM maize which was only authorised for feed but was found in food) are avoided because GMOs likely to be used as food and feed can only be authorised for both uses.

What is the authorisation procedure under Regulation (EC) No 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.

The European legislator — i.e. the Council and the European Parliament — has adopted Regulation (EC) No 1829/2003 which lays down a procedure for issuing authorisations for placing on the market of genetically modified food and feed. In this procedure, the Commission has an important role. Notably, it is up to the Commission to adopt the final decision and grant or reject the authorisation if the Committee, composed of representatives of the Member States, and the Council have not managed to adopt the decision by qualified majority within the time limit in question. Hence the adoption of the final decision by the Commission constitutes the democratic exercise of a responsibility

which was vested in it by the Council and the European Parliament, which directly represents the European citizens.

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. The national authority must acknowledge receipt in writing within 14 days and inform EFSA. 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 opportunity to make comments.

In general a time limit of six 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 guidance document for the risk assessment of GM plants and derived food and feed has been adopted by EFSA on the 24 of September and is available at the following URL:

http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html

Within three months of receiving the opinion of EFSA, the Commission will draft a proposal for granting or refusing authorisation. The Commission may diverge from EFSA's opinion, but it must then justify its position. The Commission's proposal will be approved through qualified majority by 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, or in the event of rejection of the Commission's proposal by qualified majority of the Committee, the draft Decision is submitted to the Council of Ministers for adoption or rejection by qualified majority. If the Council does not act within three months or does not obtain a qualified majority for the adoption or rejection of the Commission's proposal, the Commission shall adopt the decision.

Products authorised shall be entered into a public register of GM food and feed (http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm). 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.

Have GMOs already been approved for use in food products?

Products from numerous GMOs can legally be marketed in the EU (see annex 3). These are in particular:

- one GM soy and one GM maize approved under Directive 90/220/EEC prior to the entering into force of Regulation (EC) No 258/1997 on novel foods.
- processed foods derived inter alia from seven GM oilseed rape varieties, four GM maize varieties and oil from two GM cottonseed varieties, which have all been notified as substantially equivalent in accordance with Article 5 of Regulation (EC) No 258/1997 on novel foods.
- these GM food products which could be legally placed on the market in the EU according to the rules in place before Regulation 1829/2003 and other food products that did not require special approval at the time they were placed on the market were gathered in the Community register of GM food and feed. A separate chapter in this document is dedicated to these products.
- in addition, Bt 11 sweet corn and NK603 maize have been approved under Regulation (EC) No 97/258 on novel foods on 19 May and 26 October 2004

respectively. More recently, GA21 and MON863 maize were approved under the same Regulation with date of 13 January 2006. Also these products have been included in the Community register of GM food and feed.

Further applications for the placing on the market of food products have been introduced in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. These GM foods (and feeds) are currently pending at different stages in the authorisation procedure. This mainly concerns products derived from GM maize, sugar beet, cotton and soybean. They are indicated in Annex 4.

Which genetically modified feeds have been authorised?

Before the entry into force of the Regulation on genetically modified food and feed, there was no Community legislation governing feed derived from GMOs. Feed containing GMOs or consisting of such organisms was subject to Directive 90/220/EEC. Hence, several GMOs have been authorised as products containing GMOs or consisting of such organisms for use in feed, in accordance with Directive 90/220/EEC; these are chiefly maize varieties, rape varieties and one soya variety.

These GM feed products which could be legally placed on the market in the EU according to the rules in place before Regulation 1829/2003 and other feed products that did not require special approval at the time they were placed on the market were gathered in the Community register of GM food and feed. A separate chapter in this document is dedicated to these products.

On 19 July 2004, the import and processing of NK 603 has been authorised under Directive 2001/18 on the deliberate release of GMOs into the environment. This authorisation covers the use of NK 603 as feed. In August 2005, two more authorisation decisions were taken under this Directive concerning MON 863 maize and GT 73 oilseed rape, followed by an authorisation decision on 1507 maize taken in November (see Annex 1B).

A series of other authorisations of GMOs, including their use as feed, are pending. They are listed in annex 3.

What are the current rules on genetically modified varieties and seeds?

EU legislation on seeds, notably Directive 2002/53/EC and 2002/55/EC concerning the common catalogue of varieties of agricultural plant species and the marketing of vegetable seed, specifies that national authorities that have agreed to the marketing of seed of a certain variety on their territory must notify the acceptance of the variety to the Commission. Varieties may be included in national catalogues only if they meet defined Community criteria as regards distinctness, uniformity, stability and in the case of agricultural species value for cultivation and use. The seed legislation furthermore requires that GM varieties have to be authorised in accordance with EU GMO legislation, in particular 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 or feed, it can also be authorised in accordance with the GM food and feed Regulation.

The Commission examines whether the information supplied by the Member State as regards inclusion in a national list is in compliance with Community legislation and includes the variety concerned in the Common Catalogue of Varieties which means the seed of such a variety can be marketed throughout the EU.

Currently, 31 varieties of genetically modified maize MON 810 are registered in the Common Catalogue (17 in were inscribed on 17 September 2004 and 14 on 30 December 2005). Three additional MON 810 derived varieties have been notified recently to the Commission by Germany with a view of their inscription into the common catalogue.

What happens to GM products that were already legally on the market at the time Regulation 1829/2003 on GM food and feed entered into force?

Articles 8 and 20 of Regulation 1829/2003 provide for a specific notification procedure for GM products that were already legally on the market at the time Regulation 1829/2003 entered into force.

There is a series of GM food and feed products which could be legally placed on the market in the EU according to the rules in place before Regulation 1829/2003. Such "existing products" were either approved under former EU legislation, or did not require specific approval at the time that they were placed on the market.

For the sake of transparency the new legislative framework seeks to take stock of these existing products and to have full information on them. To this end Article 8 and 20 of Regulation 1829/2003 introduce a notification procedure according to which operators who wished to continue marketing existing products had to notify these to the Commission before 18 October 2004.

The Commission, in co-operation with the Joint Research Centre, has examined the validity of the notifications received and has entered 26 GM products into the Community register of genetically modified food and feed on 18 April 2005. The existing products contained in this register can continue to be legally placed on the market in the EU for a period of between 3-9 years, after which a renewal of the authorisation is necessary. The GM food and feed products entered in the register consist of, contain and/or are produced from 12 varieties of maize, 6 of oilseed rape, 5 of cotton and one of soybean, as well as of one bacterial biomass and one yeast cream.

Existing products falling within the scope of the legislation that were not entered in the register can no longer be legally placed on the EU market.

For the register of GM existing products, see:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/register_notification/index.htm

Labelling and traceability of GMOs

Why does the EU have specific rules on traceability of GMOs?

Traceability provides the means to trace products through the production and distribution chains. The general objectives are to facilitate:

- control and verification of labelling claims;
- targeted monitoring of potential effects on health and the environment, where appropriate;
- withdrawal of products that contain or consist of GMOs where an unforeseen risk to human health or the environment is established.

What are the rules on traceability of GMOs?

Products which consist of GMOs or which contain GMOs and food products derived from GMOs, which have been authorised under the procedure referred to in Directive 90/220/EEC replaced by Directive 2001/18/EC (Part C) or under Regulation (EC) No 1829/2003, are subject to traceability requirements in application of Regulation (EC) No 1830/2003.

The traceability rules make it mandatory on the operators concerned, i.e. all persons who place a product on the market or receive a product placed on the market within the Community, to be able to identify their supplier and the companies to which the products have been supplied.

The traceability requirement varies depending on whether the product consists of or contains GMOs (Article 4 of Regulation (EC) No 1830/2003) or has been produced from GMOs (Article 5 of Regulation (EC) No 1830/2003). Hence, two hypotheses must be distinguished:

(1) In the case of a product consisting of or containing GMOs:

Operators must ensure that the following two particulars are transmitted in writing to the operator receiving the product:

- an indication that the product – or some of its ingredients – contains or consists of GMOs
- the unique identifier(s) assigned to those GMOs, in the case of products containing or consisting of GMOs.

In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information relating to the unique identifiers may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

Operators must ensure that the information received is transmitted in writing to the operator receiving the product.

(2) In the case of products produced from GMOs:

Operators must ensure that the following particulars are transmitted in writing to the operator receiving the product:

- an indication of each of the food ingredients which are produced from GMOs;
- an indication of each of the feed materials or additives which are produced from GMOs;
- in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

In these two hypotheses (products consisting of or containing GMOs; products produced from GMOs), operators must hold the information for a period of five years from each transaction and be able to identify the operator by whom and to whom the products have been made available. In order to respect these traceability requirements, it is important that each operator has in place a system to allow the information to be kept and to make it available to the public authorities on demand.

Transmission and record-keeping 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, if a genetically modified seed constitutes the raw material of a food product, the company selling the seed would have to inform any purchaser that it is genetically modified, together with more specific 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 their placing on the market, that is all products, including food and feed, containing or consisting of GMOs. Examples include seeds which have been genetically modified and bulk quantities or shipments of whole GM grain, e.g. 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 genetically modified tomato or flour produced from a genetically modified maize.

What are the rules on labelling of GMO products?

Besides traceability requirements, products consisting of or containing GMOs and food products produced from GMOs which are authorised under the procedure set out in Directive 2001/18/EC (Part C) or under Regulation (EC) No 1829/2003 are subject to the labelling requirements laid down in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003.

Labelling informs the consumer and user of the product, hence allowing them to make an informed choice.

Generally speaking, for all pre-packaged products consisting of or containing GMOs, Regulation (EC) No 1830/2003 requires that operators indicate on a label: "This product contains genetically modified organisms" or "This product contains genetically modified [(name of organism(s)]". In the case of non pre-packaged products offered to the final consumer or to mass caterers (restaurants, hospitals, canteens and similar caterers) these words must appear on, or in connection with, the display of the product.

In particular as regards **genetically modified food and feed,** Regulation (EC) N° 1829/2003 lays down specific labelling requirements.

Genetically modified foods which are delivered as such to the final consumer or mass caterers (restaurants, hospitals, canteens and similar caterers) must be labelled in accordance with Article 12 of Regulation (EC) No 1829/2003, regardless of whether DNA or proteins derived from genetic modification are contained in the final product or not. The labelling requirement also includes highly refined products, such as oil obtained from genetically modified maize.

The same rules apply to animal feed, including any compound feed that contains transgenic soya. Corn gluten feed produced from transgenic maize must also be labelled, in compliance with Article 25 of Regulation (EC) No 1829/2003, so as to provide livestock farmers with accurate information on the composition and properties of feed.

Therefore, genetically modified food and feed are subject to the specific labelling requirements imposed by the GMO legislation. However, besides these specific labelling requirements, genetically modified food is subject to the labelling requirements of the general legislation in this area (cf. in particular Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs; see also Directive 96/25/EC on the circulation of feed materials, amending Directives 70/524/EEC, 74/63/EEC, 82/471/EEC and 93/74/EEC and repealing Directive 77/101/EEC).

Exemption from the traceability and labelling requirements

Conventional products, i.e. products created without recourse to genetic modification, may be accidentally contaminated by GMOs during harvesting, storage, transport or processing. This does not only apply to GMOs. In the production of food, feed and seed, it is practically impossible to achieve products that are 100% pure. Taking this into account, the legislation has laid down limits above which conventional food and feed must be labelled as products consisting of GMOs, containing GMOs or produced from GMOs.

These conventional products "contaminated" by authorised GMOs are not however subject to traceability and labelling requirements if they contain traces of these (authorised) GMOs below a limit of 0.9%, provided the presence of this material is adventitious or technically unavoidable. This is the case when operators demonstrate to the competent authorities that they have taken adequate measures to avoid the presence of this material.

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

In line with the general EU rules on labelling, Regulation (EC) No 1829/2003 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. Nor are these products subject to traceability requirements.

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

The adventitious or technically unavoidable presence of GM material in products placed on the market in the European Union 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 unique to GMOs. In the production of food, feed and seed, it is practically impossible to achieve products that are 100% pure.

Regulation (EC) No 1829/2003 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. These committees have indicated that the GMOs do not pose a danger to the environment and health, but their final approval is still pending. The rules allow the presence of these GMOs in a food or feed up to a maximum of 0.5%, above which it is prohibited to put the product on the market.

This threshold is applied on the basis of the following conditions: 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 (until 2007) and provides that a detection method must be publicly available.

The Commission has published a list of GM material which has not been authorised but which has had a favourable scientific assessment. This list may be consulted at the following address:

http://www.europa.eu.int/comm/food/food/biotechnology/gmfood/events_en.pdf

This exemption aims to solve the problem faced by operators who have tried to avoid using 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 between transgenic crops and traditional or organic crops?

The cultivation of GM crops will have implications for the organisation of agricultural productions. Pollen flow between adjacent fields is a natural phenomenon. Because of the labelling requirements for GM food and feed, this may have economic implications for farmers who want to produce traditional plants intended for food. Co-existence 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 23 July 2003 the Commission adopted a Recommendation (2003/556/EC) on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming (http://europa.eu.int/comm/agriculture/publi/reports/coexistence2/guide_en.pdf)

The guidelines state that approaches to co-existence need to be developed in a transparent way, based on technical guidelines 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. oilseed 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 forcing them to change patterns already established in the area. 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 bear 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 the measures adopted.

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).

The international environment

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

The new rules take account of the EU's international trade commitments and of the requirements of the Cartagena Protocol on Biosafety, specifically as regards the obligations on importers of products in the EU and the obligations on exporters of products to third countries. The EU's regulatory system for authorizing GMOs is in line with WTO rules: it is clear, transparent and non-discriminatory.

What are the rules governing the movement and international trade of GMOs?

The EU is a party to the Cartagena Protocol on Biosafety annexed to the UNEP's 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 incorporation of the Cartagena Protocol on Biosafety into EU legislation relies on a wide range of biotechnology legislation governing the use of GMOs within the European Union, including imports. The cornerstone of this legal framework is Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. It is supplemented by the Regulation on the transboundary movements of GMOs, which was adopted in June 2003: http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf

The main features 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.

Annex 1

GMO Products approved under Directive 90/220/EEC as of March 2001

See:

http://europa.eu.int/comm/environment/biotechnology/authorised_prod_1.htm

Annex 1B

GMO Products authorised under Directive 2001/18/EC

See:

http://europa.eu.int/comm/environment/biotechnology/authorised_prod_2.htm

Annex 2

GMO Products – Pending notification under Directive 2001/18/EC

See:

http://europa.eu.int/comm/environment/biotechnology/pending_products.htm

Annex 3

Genetically modified (GM) Foods and Feeds authorised in the European Union

For genetically modified (GM) food authorised in the EU under the Novel Food Regulation (EC) No. 258/97 see:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/258-97-ec_authorised_en.pdf

For GMOs authorised for feed use in the EU in accordance with Directives 90/220/EEC and 2001/18/EC see:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/2001-18-ec_authorised_en.pdf

Annex 4

Genetically modified (GM) Foods and Feeds pending authorisation in the European Union

For feed consisting of or containing GMOs notified under Directive 2001/18/EEC pending authorisation in the EU see:

http://europa.eu.int/comm/food/food/biotechnology/authorisation/2001-18-ec_pending_authos_en.pdf

For applications for authorisation of genetically modified food and feed submitted under Regulation (EC) No 1829/2003 on genetically modified food and feed see:

http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html

Annex 5

GMO Products invocation of Article 16 under Directive 90/220/EEC and Article 23 of Directive 2001/18/EC

See:

http://europa.eu.int/comm/environment/biotechnology/safeguard_clauses.htm