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Questions and Answers 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 æmicro-organisms, plants and animals. Unlike other genetic improvement methods, the application of this technology is strictly regulated. A genetically modified organism (GMO) or a GM food or feed product 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.

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 on the characteristics of foodstuffs. For example, by introducing a particular gene into a plant, fruit with delayed ripening is currently being developed. 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 human health and the environment and
- to ensure the free movement of safe 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 2001/18/EC on the **deliberate release into the environment** of GMOs[1] 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);
- the placing on the market of GMOs, for example the cultivation, importation or transformation of GMOs into industrial products.

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.

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.

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.

Labelling and traceability requirements 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.

Release into the environment

The release of a GMO into the environment means 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.

1 GMOs from now on being defined as a product containing GMOs or consisting of such organisms

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. 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 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 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 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).

The authorisation procedure for placing the GMO on the market 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 an EU Member State. The notification must include 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 (EFSA), 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/).

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 from the competent national authority of the Member State within whose territory the experimental release is to take place. It is given on the basis of an evaluation of the risks presented by the GMO – or GMOs – for the environment and human health. Hence, the authorisation procedure is simpler than the one referred to above. It is a purely national procedure as it is only applicable in the Member state where the notification was submitted. However, the other Member States and the European Commission may make observations to be examined by the competent national authority.

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 'deliberate release' legislation (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). Varieties of agricultural products 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 some 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 is also included in Directive 2001/18/EC, which replaces Directive 90/220/EEC. This clause provides 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 was invoked on nine separate occasions under Directive 90/220/EEC, three times by Austria, twice by France, and once each by Germany, Luxembourg, Greece and the United Kingdom. The scientific evidence provided by these Member States as justification for their measures was submitted to the Scientific Committee(s) of the European Union 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, eight (8) of the nine (9) bans remain in place (UK has withdrawn its ban) and have now to be considered under the safeguard provision (Article 23) of Directive 2001/18/EC. In view of the new regulatory framework, the Commission has examined the additional information provided by certain Member States which have invoked the safeguard clause. This additional information has also been reviewed by EFSA. The Commission is currently preparing decisions asking Member States to lift their bans.

In addition, in January 2005, Hungary invoked the safeguard clause in order to prohibit the cultivation of MON 810 maize in its territory. The Commission is currently examining this case.

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

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”).

The new Regulation replaces the 1997 Novel Foods Regulation (Regulation 258/97) which governed the placing on the market of novel food, including GM food.

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

The Regulation says 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 1829/2003.

For a food product containing GMOs or consisting of such organisms, the applicant has a choice: he can either file his application exclusively under Regulation 1829/2003 pursuant to the "one door, one key" principle.

This would be 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 1829/2003. Or he can choose to split the application, and submit both under Directive 2001/18/EC and Regulation 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 EU, 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.

Regulation 1829/2003 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.

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 must 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/food/biotechnology/authorisation/commun_register_en.htm) 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 the Novel Foods Regulation.
- more recently, Bt 11 sweet corn and NK603 maize were approved under the Novel Foods Regulation on 19 May and 26 October 2004 respectively.

Further applications for the placing on the market of GM food products have been introduced under the Novel Foods Regulation and the new GM Food and Feed Regulation 1829/2003. They are currently pending at different stages in the authorisation procedure. This mainly concerns products derived from GM maize, sugar beet and soybean. See 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. Such feeds were subject to Directive 90/220/EEC, and several GM feeds were authorised under this Directive. These are chiefly maize varieties, rape varieties and one soya variety.

On 19 July 2004, the import and processing of NK 603 maize was authorised under Directive 2001/18 on the deliberate release of GMOs into the environment. This authorisation covers the use of NK 603 as feed. See Annex 1B.

A series of other authorisations of GMOs, including their use as feed, are pending. See Annex 3.

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

EU legislation on seeds, notably Directives 2002/53/EC and 2002/55/EC concern the marketing of seed of varieties of agricultural plant and vegetable species. They specify that national authorities that have agreed to use 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, it also has to 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. If so, it includes the variety concerned in the Common Catalogue of Varieties which means the seed of such a variety can be marketed throughout the EU. So far, 17 GM varieties derived from MON 810 maize are inscribed in the common catalogue.

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.

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.

What are the rules on traceability of GMOs?

The Labelling and Traceability Regulation (Regulation 1830/2003) 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 for instance tomato paste and ketchup produced from a genetically modified tomato or flour produced from a genetically modified maize.

The traceability rules oblige the operators concerned, i.e. all persons who place a product on the market or receive a product placed on the market within the EU, 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) or has been produced from GMOs (Article 5).

1) In the case of a product consisting of or containing GMOs: Operators must transmit in writing to the operator receiving the product:
   - an indication that the product – or some of its ingredients – contains or consists of GMOs or is produced from GMOs and
   - the unique identifier(s) assigned to those GMOs, in the case of products containing or consisting of GMOs.
2) In the case of products produced from GMOs: Operators must transmit 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 both cases 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. Each operator must keep records and make the information available to the public authorities on demand.

Transmission and record-keeping of this information will reduce the need for sampling and testing of products.

What are the rules on labelling of GMO products?

Besides traceability requirements, Regulation 1830/2003 also sets out labelling requirements for GM products. 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 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)]”. For 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 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, 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, 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[2].

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 set 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 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.

Regulation (EC) No 1829/2003 acknowledges this 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%, below which labelling and traceability will not be enforced. Above 0.5% it is prohibited to put the product on the market.

The Regulation limits the application of this threshold to three years (until 2007) and provides that a detection method must be publicly available.

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[2] 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

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.

What scientific support does the EU provide relating to the use of GMOs?

The Commission's in-house research centre (Joint Research Centre - JRC) provides scientific support for EU legislation on traceability and cultivation & consumption of GMOs. It is responsible for collating all summary notification of deliberate field crop trials in the EU, updating the database and providing public access to this information. JRC is undertaking research on underlying mechanisms for integrating foreign genes into host plants, and evaluating their long-term stability. It also undertakes research to better understand the composition of foods with minimal amounts of GMOs, and to develop methods to detect and quantify the presence of GMOs in raw materials, ingredients and final products. The JRC also coordinates the European Network of GMO Laboratories, which brings together more than 45 EU control laboratories to discuss important issues and share information and methods for sampling, detection, identification, and quantification of GMOs.

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 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 Cartagena Protocol on Biosafety is incorporated into EU legislation through a wide range of legislation governing the use of GMOs within the European Union. 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.

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

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

- **GMO products authorised under Directive 2001/18/EC as of 15 March 2005**

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

- **GMO products – pending notifications under Directive 2001/18/EC as of 15 March 2005**

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

- **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

For applications for authorisation of genetically modified (GM) foods submitted under the Novel Food Regulation (EC) No. 258/97 see:
http://europa.eu.int/comm/food/food/biotechnology/authorisation/258-97-ec_pending_authos_en.pdf

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

- **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