



# **Biotechnology regulations in EU**

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## **EU and Advanced Biotechnology**

- **Modern biotechnology has many applications in the pharmaceutical and agri-food industries. One example is the use of GMOs in the food production chain. GMOs are organisms such as plants, animals and micro-organisms (bacteria, viruses, etc.), the genetic characteristics of which have been modified artificially in order to give them a new property (a plant's resistance to a disease or insect, improvement of a food's quality or nutritional value, increased crop productivity, a plant's tolerance of a herbicide, etc.). In order to ensure that this development of modern biotechnology, and more specifically of GMOs, takes place in complete safety, the European Union has established a legal framework comprising various acts.**

## EU and Advanced Biotechnology

- 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, oilseed 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.

## EU and Advanced Biotechnology

- 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.

## **Conventional & GM Food & Feed**

- **Food and Feed are generally derived from plants and animals which have been grown and bred by humans for several thousand years. Over time, these plants and animals have undergone substantial genetic changes as those individuals with the most desirable characteristics for food and feed were chosen for breeding the next generation.**

**The desirable characteristics were caused by naturally occurring variations in the genetic make-up of those individuals. In recent times, it has become possible to modify the genetic material of living cells and organisms using techniques of modern gene technology. Organisms, such as plants and animals, whose genetic material (DNA) has been altered in such way are called genetically modified organisms (GMOs). The food and feed which contain or consist of such GMOs, or are produced from GMOs, are called genetically modified (GM) food or feed.**

## **The EU Commission point of view**

- **There are currently over 6.4 billion people living on the planet, a figure which is increasing by 77 million each year. By 2050, the United Nations estimates that total world population will be over 9.3 billion. The bulk of this population growth will occur in the developing world, where today over 1.2 billion people, mainly women and children, are living in extreme poverty. Coping with this future population increase will pose severe social and environment challenges for global leaders, not least of which will be providing enough food to go round.**

## **The EU Commission point of view**

- **Life sciences and biotechnology are likely to be important tools in the fight to feed the world's growing population. New biotechnology techniques have the potential to deliver improved food quality and environmental benefits through agronomically enhanced crops. Enhanced food and feed quality may be linked to disease prevention, and may result in the reduced use of chemical pesticides, fertilisers and drugs, leading to more sustainable agricultural practices in both the developed and developing world. Advances in biotechnology can also result in major health care benefits, allowing for the production of cheaper, safer drugs in large quantities. Personalised and preventative medicines based on genetic predisposition, targeted screening, and innovative drug treatments are among the possibilities on offer.**

## **The EU Commission point of view**

- **Despite these clear advantages, the subject of biotechnology, and genetically modified organisms (GMOs) in particular, has raised widespread public concern about the possible impact on human health and the environment. The sensitivity of this issue highlights the need for responsible policies at EU and international level to ensure these concerns are addressed and that the protection of the environment and human health remains a priority at all times. The EU has been legislating on GMOs since the early 1990s. These rules and regulations cover the use, traceability and labelling of GMOs or products and feeds containing GMOs and are designed to protect the health of both citizens and the environment.**

## The EU legislation, an overview

- 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.

## The EU legislation, an overview

- **Contained use of GMOs**
  - Council Directive of 23 April 1990 on the contained use of Genetically modified organisms ([90/219/EEC](#))
  - Council Directive of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms ([98/81/EC](#))
  - [Summary Report](#) from the Commission on the implementation by Member States of Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms and Commission staff working paper ([Annex](#) to the summary report from the Commission)

## Contained use of GMOs

- 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.

## The EU legislation, an overview

- **Deliberate release into the environment**
  - [Directive 2001/18/EC](#) of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing [Council Directive 90/220/EEC](#)
  - [Regulation \(EC\) No 1831/2003](#) of the European Parliament and of the Council of 22 September 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](#)

## The EU legislation, an overview

- **Deliberate release into the environment: other documents**
  - Report from the Commission to the Council and the European Parliament on the experience of member states with GMOs placed on the market under Directive 2001/18/EC and incorporating a specific report on the operation of parts B and C of the Directive ([COM\(2004\) 575 final](#))- Annexes to the Report [SEC \(2004\) 1063](#)
  - [Background Study Report](#) - 'Means to improve the consistency and efficiency of the legislative framework in the field of biotechnology art 31 (7a, 7b and 7d) of Directive 2001/18/EC'

## The deliberate release into the environment

- **Directive 2001/18/EC on the deliberate release into the environment of GMOs applies to two types of activities:**
  - the experimental (other than for placing on the market) 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 viable 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 deliberate 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.

## **The principles introduced by Directive 2001/18/EC**

- Directive 2001/18/EC introduces:
  - principles for environmental risk assessment;
  - 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 1831/2003 on traceability;
  - information to allow the identification and detection of GMOs to facilitate postmarket 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.

### **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 procedure for authorisation of the experimental release of GMOs into the environment**

- **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.**

## The EU legislation, an overview

- **Implementing measures under Directive 2001/18/EC**
- **Relating to Part B of the Directive:** "for purposes other than for placing on the market"
  - Council Decision of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market ([2002/813/EC](#))
  - Commission Decision of 29 September 2003 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market (*notified under document number C(2003) 3405*) ([2003/701/EC](#))

## 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 be 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 procedure for authorising the placing on the market of GMOs as such or as a component in products**

- 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.

## **The procedure for authorising the placing on the market of GMOs as such or as a component in products**

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

- 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's in a safety dossier?



- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>• <b>Gene(s)</b> <ul style="list-style-type: none"> <li>– Source(s)</li> <li>– Molecular characterization</li> <li>– Insert / copy number / gene integrity</li> </ul> </li> <li>• <b>Protein(s)</b> <ul style="list-style-type: none"> <li>– History of safe consumption</li> <li>– Function / specificity / mode-of-action</li> <li>– Levels</li> <li>– Toxicology / allergenicity                             <ul style="list-style-type: none"> <li>• Amino acid homology</li> <li>• Digestibility</li> <li>• Acute oral toxicity</li> <li>• Clinical</li> </ul> </li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>u <b>Crop Characteristics</b> <ul style="list-style-type: none"> <li>– Morphology</li> <li>– Yield</li> </ul> </li> <li>u <b>Food / Feed Composition</b> <ul style="list-style-type: none"> <li>– Proximate analysis</li> <li>– Key nutrients</li> <li>– Key anti-nutrients</li> <li>– Feeding studies                             <ul style="list-style-type: none"> <li>» Wholesomeness</li> </ul> </li> </ul> </li> </ul> |
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## The EU legislation, an overview

- **Implementing measures under Directive 2001/18/EC**
- ***Relating to Part C of the Directive:*** “placing on the market”
  - Council Decision of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ([2002/811/EC](#))
  - Council Decision of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products ([2002/812/EC](#))
  - Commission Decision of 23 February 2004 laying down detailed arrangements for the operation of registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council ([2004/204/EC](#))

## The EU legislation, an overview

- **Implementing measures under Directive 2001/18/EC**
- ***Relating to Part B and Part C of the Directive***
  - Commission Decision of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ([2002/623/EC](#))

## **The Environmental Risk Assessment Procedure**

- **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).**

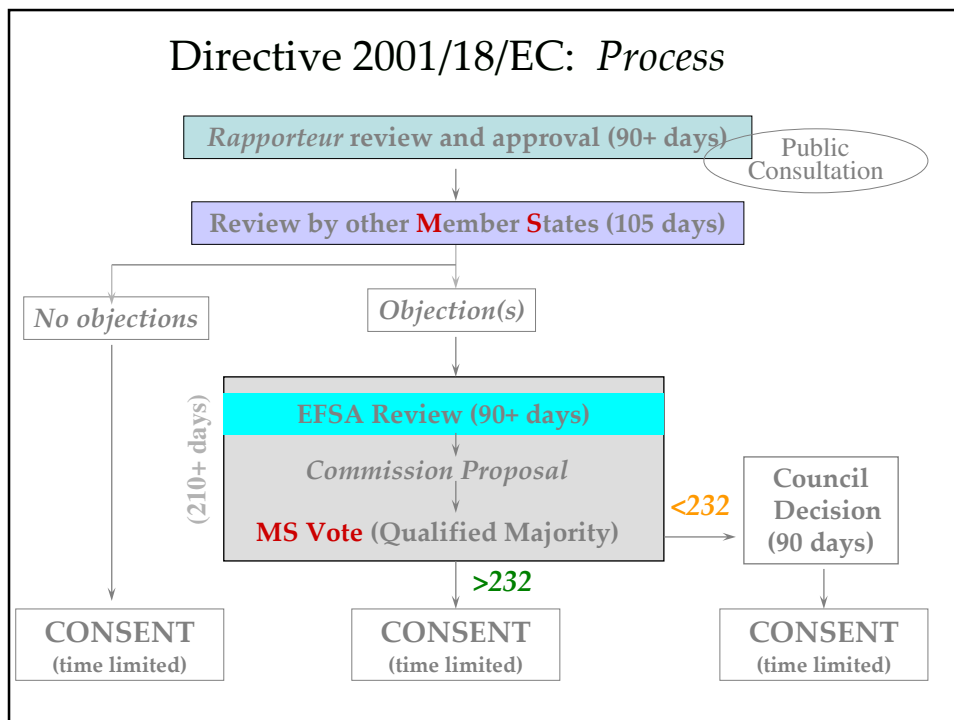
## **The Environmental Risk Assessment Procedure**

- **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).**

## GMOs 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.
- Several applications have a scope which is restricted to import and processing, while the remaining ones also include cultivation as a requested use.

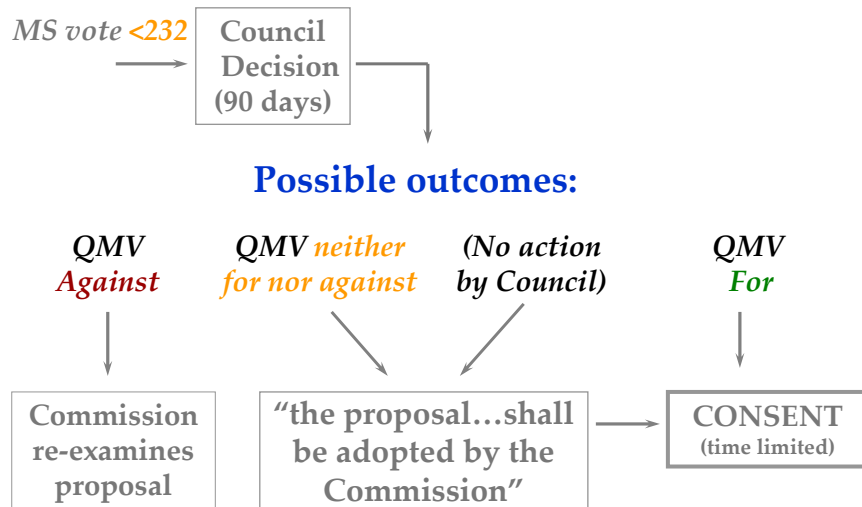
### Directive 2001/18/EC: *Process*



## Member State Votes

France	29	Denmark	7
Germany	29	Finland	7
UK	29	Ireland	7
Italy	29	Lithuania	7
Spain	27	Slovenia	7
Poland	27	Cyprus	4
Netherlands	13	Estonia	4
Belgium	12	Latvia	4
Czech	12	Luxemburg	4
Greece	12	Slovenia	4
Hungary	12	Malta	3
Portugal	12		
Austria	10	Total	321
Sweden	10	QMV	232

## Council Decision 1999/468/EC - Procedure



## **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.**

## **National safeguard measures**

- **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.**

## **National safeguard measures**

- **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.**

## **National safeguard measures 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.

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

- 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 and 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).

## The EU legislation, an overview

- **Authorisations**
  - [List of products authorised](#) under Directive 90/220/EEC
  - [List of products authorised](#) under Directive 2001/18/EC
  - List of [pending products](#) under Directive 2001/18/EC
  - List of [safeguard clauses](#)

## The EU legislation, an overview

- **Genetically modified food and feed :**
  - Regulation (EC) n° [1829/2003](#) of the European Parliament and of the Council of 22 September 2004 on genetically modified food and feed.
  - 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”).

## GM Food & Feed

- Since 18 April 2004, GM Food and Feed are regulated in the European Community under [Regulation \(EC\) No 1829/2003](#) on genetically modified food and feed. It provides for a single Community procedure for the new authorisation of all food and feed derived from a GMO and, as the case may be, of the GMO itself as a food or as a feed and of food or feed containing the GMO.
- Several applications for authorisation of genetically modified food and feed have been submitted under this Regulation. A few products have already been authorized in the meantime.
- [Genetically modified food and feed authorised](#)
- [Genetically modified food and feed pending authorisation](#)

## GM Food & Feed

- Until 18 April 2004, GM food was regulated as novel food, and food derived from eighteen GM events have been approved so far (essentially maize and soy derivatives, oilseed rape oil and cottonseed oil). There was no specific legislation covering GM feed, but nine GM events (five maize varieties, three rape varieties and one soy variety) have been approved under the EU environmental legislation so far, and these approvals include the use as or in feedingstuffs.
- Novel Food Regulation (EC) No 258/97 :[Genetically modified food authorised](#) Updated 17-01-2006
- Directive No 2001/18/EC on deliberate release of GMOs into the environment : [Genetically modified feed authorised](#) Updated 17-01-2006 and [pending authorisation](#) Updated 6-02-2006

## **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 principles of Regulation (EC) No 1829/2003**

- **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.**

## The principles of 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.

## The authorisation procedure under Regulation (EC) No 1829/2003

- In order to obtain this authorization, an application must be sent to the competent authority of a Member State. Detailed rules concerning applications have been laid down in [Regulation \(EC\) 641/2004](#). Further guidance to assist the applicants in the preparation and presentation of the application has been prepared by the European Food Safety Authority (EFSA).
- Where the application concerns food and feed containing or consisting of a GMO (rather than food and feed produced from a GMO) the applicant has the choice of either supplying an authorisation for the deliberate release into the environment already obtained under Part C of [Directive 2001/18/EC](#), or of applying for the environmental risk assessment to be carried out at the same time as the safety assessment of the food and the feed.

## **The authorisation procedure under Regulation (EC) No 1829/2003**

- 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](http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html)

## **The authorisation procedure under Regulation (EC) No 1829/2003**

- Applications for authorization are referred to EFSA, which makes a summary of the application dossier available to the public. EFSA carries a risk assessment and makes its opinion public (see [EFSA](#) website).
- The public may make comments on the EFSA opinion within 30 days of the publication of the opinion. Comments should be addressed to the Commission. When an opinion by EFSA is available the Commission will open a consultation on this site.

## **The authorisation procedure under Regulation (EC) No 1829/2003**

- 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](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.

## **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.
- 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.

## The authorisation procedure under Regulation (EC) No 1829/2003

- Maize 1507xNK603 EFSA opinion. An example about how to make comments
  - An [opinion](#) of EFSA has been published on the 12th of May 2006 . This opinion is related to an application for the placing on the market of food, feed and other products containing or consisting of genetically modified maize "1507xNK603" (e.g. maize grains) or food and feed produced from this maize (e.g. flour, oil). Comments on the EFSA opinion may be provided until the 11th of June by filling the provided [form](#) .
  - [12 May 2006 Link to Form 1507xNK603](#)

## The authorisation procedure under Regulation (EC) No 1829/2003

- On the basis of the opinion of EFSA, the Commission drafts a proposal for granting or refusing the authorization, which must be approved through qualified majority in the Section on GM food and feed of the [Standing Committee on the Food Chain and Animal Health](#).
- Standing Committee on the Food Chain and Animal Health Section : Genetically Modified Food and Feed and Environmental Risk
- Standing Committee on the Food Chain and Animal Health (SCFAH) was established following the adoption of [Regulation \(EC\) 178/2002](#). This Regulation set out the general principles and requirements of food law. It also established the European Food Safety Authority ([EFSA](#)) and laid down procedures for food safety issues which included the re-organisation of the regulatory committees system.

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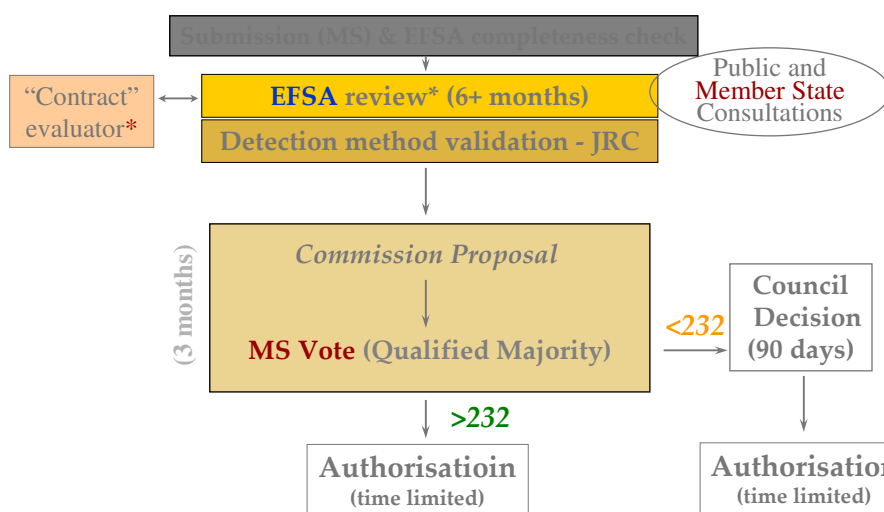
## The authorisation procedure under Regulation (EC) No 1829/2003

- The Committee's mandate covers the entire food supply chain, ranging from animal health issues on the farm to the product that arrives on the consumer's table, therefore significantly enhancing its ability to target risks to health wherever they arise in the production of our food. It is chaired by a European Commission representative.
- SCFAH has eight sections :
- [General Food Law](#);
- [Biological Safety of the Food Chain](#);
- [Toxicological Safety of the Food Chain](#);
- [Controls and Import Conditions](#);
- [Animal Nutrition](#);
- [Genetically modified Food and Feed and Environmental Risk \(2004\)](#);
- [Animal Health and Animal Welfare](#);
- [Phytopharmaceuticals](#).

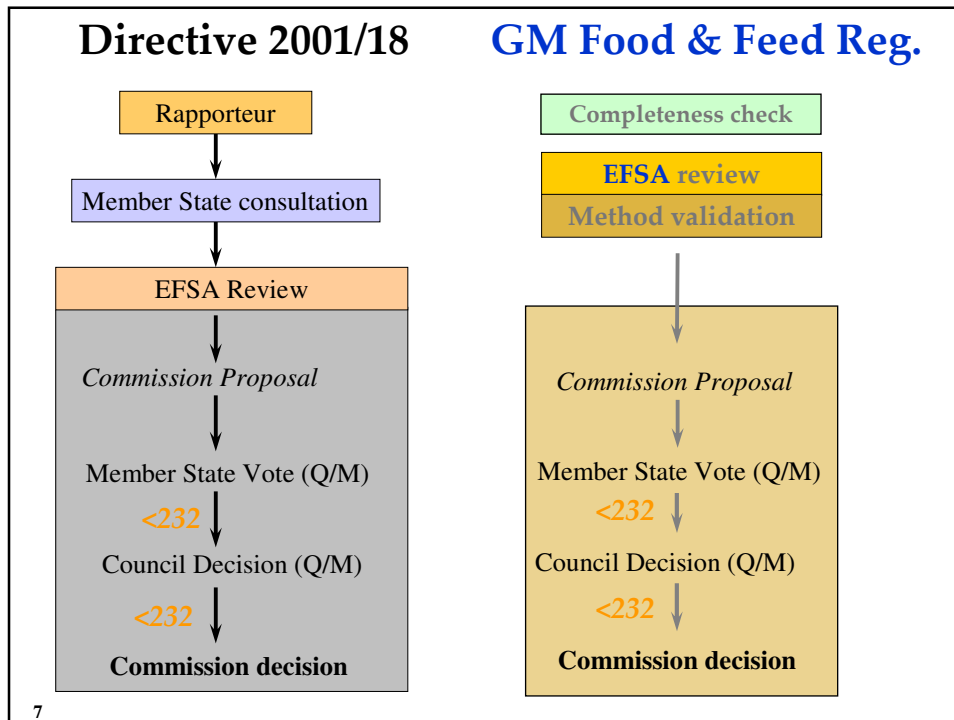
## The authorisation procedure under Regulation (EC) No 1829/2003

- There are also several other current Regulatory Committees:
- [Standing Committee on Plant Health \(SCPH\)](#)
- [Standing Committee on Propagating Material and Ornamental Plants \(SCPOP\)](#)
- [Standing Committee on Fruit Plants \(SCFP\)](#)
- [Standing Committee on Agricultural, Horticultural and Forestry Seeds and Plants \(SCPS\)](#)
- [Standing Committee on Community Plant Variety Rights \(SCPVR\)](#)
- [Standing Committee on Zootechnics \(SCZ\)](#)

### Reg 1829/2003 – Procedure for new applications



\* Obligatory MS ERA for cultivation files



## GMOs approved for use in food products

- **Products from numerous GMOs can legally be marketed in the EU. 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.
  - 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.**

## **Genetically modified feeds 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.**

## **Genetically modified feeds authorised**

- 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.
- A series of other authorisations of GMOs, including their use as feed, are pending.

**GM products 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.

**GM products already legally on the market at the time Regulation 1829/2003 on GM food and feed entered into force**

- 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](http://europa.eu.int/comm/food/food/biotechnology/authorisation/register_notification/index.htm)

## Current rules on genetically modified plant 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.

## The EU legislation, an overview

- **Implementing measures under Regulation 1830/2003 on traceability and labelling**
  - Commission Regulation (EC) of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms ([65/2004](#))
  - Commission Recommendation 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) N° 1830/2003 ([2004/787/EC](#))

## The EU legislation, an overview

- **Other documents for information:**
  - Commission Decision of 21 June 2005 establishing a network group for the exchange and coordination of information concerning coexistence of genetically modified, conventional and organic crops ([2005/463/EC](#))
  - Commission Common Catalogue of Agricultural plant species: sixth supplement to the 23rd [complete edition](#) (O.J.C 334 A/01 of 30.12.2005), [Legend](#), [List of agricultural species](#).
  - [EU policy on biotechnology](#)

## GM Food & Feed - Community Register of GM Food and Feed

- The authorizations granted after the entry into force of [Regulation \(EC\) No 1829/2003](#) on genetically modified food and feed shall be entered in the Community Register of GM Food and Feed. It provides useful product information such as the name of the authorisation holder, the exact scope of the authorisation, the designation of the authorised product, links to relevant risk assessments and the date of entry on the EU market. Thereby, the authorizations become accessible and transparent to everybody. Besides, the Community Register of GM Food and Feed contains products which were lawfully placed on the market in the Community prior to 18 April 2004 and were notified to the European Commission before 18 October 2004. The notifications received by the European Commission have been subject to the verifications and the procedures in application of Article 8 and 20 of Regulation (EC) No 1829/2003.

## **Traceability and Labelling**

- **Products consisting of or containing GMOs and food products obtained from GMOs which have been authorised on the basis of the procedure under Directive 2001/18/EC (Part C) or Regulation (EC) No 1829/2003 are subject to traceability and labelling requirements pursuant to Regulations (EC) Nos 1829/2003 and 1830/2003.**
- **Labelling provides information for consumers and users of the product and allows them to make an informed choice.**
- **Generally speaking, in the case of pre-packaged products consisting of or containing GMOs, Regulation (EC) No 1830/2003 requires operators to state on a label that "This product contains genetically modified organisms". In the case of non-pre-packaged products offered to the final consumer, these words must appear on, or in connection with, the display of the product.**

## **Rules on Traceability**

- **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 , in addition to labelling requirements, subject to traceability requirements in application of Regulation (EC) No 1830/2003.**
- **Traceability is the ability to track GMOs and food products obtained from GMOs at all stages of their placing on the market, throughout the production and distribution chain. Traceability makes it easier to label products precisely, to closely monitor the potential effects on the environment and on health and, where necessary, to withdraw products if an unexpected risk to human health or to the environment is detected**
- **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.**

## **Traceability - General Objectives**

- **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.**

## **Traceability**

- **The traceability rules mean that all of the operators involved, in other words anyone who places a product on the market or receives a product placed on the market in the Community, must be able to identify their supplier and the companies to which the products have been supplied.**
- **Operators must provide the following, in writing, to the operator receiving the product:**
  - **an indication that the product - or certain ingredients - contains GMOs or consists of GMOs or is obtained from GMOs, and**
  - **the unique identifier(s) for these GMOs, if the products contain or consist of GMOs.**
- **In case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, this information 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.**

# Traceability

- Operators must ensure that the information received is passed on in writing to the next operators to receive the products.

For a period of five years after every transaction, every operator must retain this information and be able to identify the operator from whom he or she obtained the products and the one to whom he or she supplied them.

- In order to help prevent contamination of conventional crops by transgenic crops, the European Commission has drawn up guidelines on the [co-existence](#) of genetically modified, conventional and organic crops (Commission [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 - OJ L 189, 29 July 2003).
- The Commission has left the Member States the possibility of adopting measures to avoid the unintended presence of GMOs in conventional products. However, the primary responsibility for avoiding contamination lies with operators.

# Rules on Traceability

- 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.

## Rules on Traceability

- **(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.

## Traceability 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.

## 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.

## Labelling Obligations

- Food products (containing or consisting of GMOs, produced from GMOs or containing ingredients produced from GMOs) delivered as such to the final consumer or to mass caterers (restaurants, hospitals, canteens and similar establishments) must be labelled in accordance with Regulation (EC) No 1829/2003, regardless of whether or not the final product contains DNA or protein resulting from genetic modification.
- The labelling obligation also applies to highly refined products, such as oil obtained from genetically modified soybean or maize.

## **Labelling Obligations**

- **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).**

## **Adventitious or Technically Unavoidable Presence**

- **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.**
- **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.**

**Presence of traces of GM  
materials with a favourable scientific  
assessment, not yet formally approved**

- 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.

**Presence of traces of GM  
materials with a favourable scientific  
assessment, not yet formally approved**

- 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/vents\\_en.pdf](http://www.europa.eu.int/comm/food/food/biotechnology/gmfood/vents_en.pdf)

## International Regulations

- European policy and legislation in this field also takes account of international regulations. Accordingly, the European legal framework applicable to GMOs and the way in which it is implemented are consistent with rules laid down within
  - the [WTO](#),
  - the provisions of the [Cartagena Protocol on Biosafety](#)
  - and the work carried out in the context of the [Codex Alimentarius](#) and [EU position papers for Codex - ad hoc Intergovernmental Task Force on Food Biotechnology \(TFFBT\)](#).

## Labelling Rules in the International Environment

- 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.

## **The EU legislation, an overview**

- **Transboundary movements of GMOs**
  - Regulation (EC) n° [1946/2003](#) of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms

## **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/eurlex/prl/en/oj/dat/2003/l\\_287/l\\_28720031105en00010010.pdf](http://europa.eu.int/eurlex/prl/en/oj/dat/2003/l_287/l_28720031105en00010010.pdf)

## **Rules Governing the Transboundary Movements of GMOs**

- **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.

## **The European Commission's Joint Research Centre (JRC)**

- **[The European Commission's Joint Research Centre \(JRC\)](#), acting via its [Institute of Health and Consumer Protection \(IHCP\)](#), and more particularly the "Biotechnology and GMOs Unit" has the mandate to provide scientific support for the development and implementation of the EU biotechnology regulations and is playing a leading role in the harmonisation of technical GM-issues.**

## the European Network of GMO Laboratories

- Setting up and coordinating the European Network of GMO Laboratories ([ENGL](#)) is considered as one of the major achievements of the JRC in recent years. ENGL constitutes a unique platform for experts from EU Member States, EEA countries and Accession Countries to discuss technical issues related to sampling, detection, identification and quantification of GMOs.  
The Commission that has adopted on July 25th 2001 a proposal in which the JRC, assisted by ENGL, is designated as [Community Reference Laboratory](#) for the GMO food and feed regulation has recognized the importance and value of ENGL.

## JRC Biotechnology and GMOs Unit

- In support of the Commission policy, the Biotechnology and GMOs Unit provides specific services to various Commission Services, such as:
- The reception of all summary notifications of deliberate field trials (SNIFs), notified under the deliberate release [Directive 2001/18/EEC](#);
- The weekly updates of the [SNIF](#) database, providing information to the general public of all field trials carried out in the EU;
- Participation as nominated expert in the development of an operational [Biosafety Clearing House](#).

## JRC Biotechnology and GMOs Unit

- In support of ENGL, the Unit has built up an outstanding [molecular biology expertise and facilities](#), mainly devoted to the development and the validation of methods for GMO detection and quantification. Significant efforts have been devoted to the understanding of [sampling](#) problems related to GM detection and quantification in food and raw materials. It shares its expertise and facilities for the purpose of training as it is jointly organising a number of [training courses](#) with the [World Health Organisation](#). Results obtained are not only transferred to ENGL, but also to international standardisation bodies such as CEN.

## JRC Biotechnology and GMOs Unit

- As horizontal support, a core informatics activity has been built up to:
- Set up a confidential Intranet in support of the ENGL activity;
- Set up and maintain a [database](#) that gives an overview of analytical methods for DNA and protein detection and quantification;
- Develop a [molecular register](#) to house all DNA sequences of authorised GMOs as well as the tools for analysis;
- Harmonise efforts for the development of a unique allergen database.
- Many of these activities are carried out in collaboration with or in support to the other JRC Institutes [IRMM](#) (for the production of Reference Material) and [IPTS](#) (for evaluation of GMOs perspectives).

## Deliberate releases and placing on the EU market of Genetically Modified Organisms (GMOs)

The purpose of this web site, managed by the [Joint Research Centre](#) of the [European Commission](#) on behalf of the [Directorate General for the Environment](#) is to publish information and to receive comments from the public regarding notifications about deliberate field trials and placing on the market of genetically modified organisms, as defined in [Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001](#).

Deliberate release into the environment of GMOs for any other purposes than placing on the market		Placing on the market of GMOs as or in products
<b>Plants</b>	<b>Organisms other than plants</b>	<b>All products</b>
<a href="#">Browse notifications</a>	<a href="#">Browse notifications</a>	<a href="#">Browse and comment</a>
Download the SNIF application form in <a href="#">Word</a> or <a href="#">RTF</a> format	Download the SNIF application form in <a href="#">Word</a> or <a href="#">RTF</a> format	
<a href="#">List of Main Traits</a>	<a href="#">List of Main Traits</a>	

## EFSA Role

- **The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks.**
- **EFSA's "raison d'être" and core activity is that of providing independent scientific advice on food safety issues throughout the food chain. Through its own scientific expertise and the work of its Scientific Committee and Expert Panels, EFSA provides risk assessments on all matters linked to food and feed safety, including animal health and welfare and plant protection. In addition, the Authority provides scientific advice on nutrition in relation to Community legislation.**

## **EFSA Role**

- The principles for the future creation of the European Food Safety Authority were laid down in the White Paper on Food Safety which called for the creation of an independent source of advice on food safety issues in order to: "... contribute to a high level of consumer health protection in the area of food safety, through which consumer confidence can be restored and maintained."
- The European Food Safety Authority was legally established by a European Parliament and Council Regulation No178/2002. Adopted on 28 January 2002, the Regulation laid down the basic principles and requirements of food law. It also stipulated that EFSA should be an independent scientific source of advice, information and risk communication in the areas of food and feed safety. A further requirement is to set up a network enabling close collaboration with similar bodies in the European Union Member States.
- In the Regulation, the responsibility for risk assessment is clearly separated from that of risk management. While EFSA advises on possible risk related to food safety, the responsibility for risk management lies with the EU institutions (European Commission, European Parliament and the Council, ie EU Member States). It is the role of the EU institutions, taking into account EFSA's advice as well as other considerations, to propose and adopt legislation as well as regulatory and control measures when and where required.

## **EFSA Role**

- EFSA is a Community body with its own legal personality, funded from the Community budget but operating independently of the Community Institutions. It is not therefore managed by the Commission but by an Executive Director, who in turn is answerable to a Management Board.
- Since its creation, EFSA has established key operating principles and rules which have been adopted by its Management Board. They include a commitment to openness and transparency in all of the Authority's work. For example, EFSA undertakes to open up its meetings, to organise consultations with stakeholders and the public, and to ensure full access to all documents.
- Communicating on risks associated with the food chain is a key part of the European Food Safety Authority's (EFSA) mandate. By communicating on risks in an open and transparent way based on the independent scientific advice of its scientific expert panels, EFSA contributes to improving food safety in Europe and to building public confidence in the way risk is assessed.
- The Panel on genetically modified organisms deals with questions on genetically modified organisms as defined in Directive 2001/18/EC, such as micro-organisms, plants and animals, relating to deliberate release into the environment and genetically modified food and feed including their derived products.

# EFSA Evaluation: an Example

- **Summary**

- This document provides an opinion of the Scientific Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) on genetically modified maize NK603 x MON810 (Unique Identifier MON-ØØ6Ø3-6 x MON-ØØ81Ø-6), developed to provide protection against specific lepidopteran pests and tolerance to glyphosate.
- In delivering its opinion the GMO Panel considered the application (Reference EFSA/GMO/UK/2004/01) and the specific comments submitted by the Member States as well as the notification C/GB/02/M3/3 for NK603 x MON810 maize as submitted under Directive 2001/18/EC. Further information from placing MON810 and NK603 maize on the market was taken into account where appropriate. Although an overall single risk assessment of all uses, excluding cultivation, has been made, for regulatory reasons, opinions for the application under Regulation (EC) No 1829/2003 and the notification under Directive 2001/18/EC are issued separately.
- NK603 x MON810 maize was assessed with reference to its intended uses and the appropriate principles described in the 'Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed'. The scientific assessment included examination of the transgenic DNA present in NK603 x MON810 maize and the nature and safety of the new proteins produced by the transgenic plants with respect to toxicology and allergenicity. Furthermore, a comparative analysis of agronomic traits and composition was undertaken and the safety of the whole food/feed was evaluated. A nutritional and an environmental assessment, including monitoring plan, were both undertaken.

# EFSA Evaluation: an Example

- The single events MON810 and NK603 have been the subjects of earlier assessments. MON810 maize has been previously evaluated and approved under Directive 90/220/EEC. NK603 maize has been previously evaluated and approved under Directive 2001/18/EC. The use of food ingredients from MON810 maize and from NK603 maize were both notified under Regulation (EC) No 258/97.
- Molecular analysis of the individual inserts in NK603 and MON810 parents included information on the complete sequence of inserts and flanking regions. The GMO Panel is of the opinion that bioinformatic analysis of the DNA insert and flanking regions indicates no cause for concern. As traditional breeding methods were used in the production of NK603 x MON810 maize, no genetic modification was involved and thus the molecular structures of the DNA inserts in NK603 and MON810 were expected to remain unchanged in NK603 x MON810. This was indicated by the preservation of the phenotypes and was further confirmed using Southern blots which demonstrated that insert structures were indeed retained in NK603 x MON810 maize.
- The mean levels of Cry1Ab and CP4 EPSPS proteins in forage and grain of NK603 x MON810 were not significantly different from MON810 and NK603 maize, which were previously considered safe and approved. There were large but similar ranges in the expression of these proteins in NK603 x MON810 and in NK603 and MON810, respectively. The GMO Panel concludes that these data do not raise safety concerns.
- The Panel found no evidence of any interactions between the newly expressed proteins Cry1Ab and CP4 EPSPS and there were no indications of altered allergenic potency of NK603 x MON810 as compared to non-modified maize. In addition, a compositional comparison of NK603 x MON810 maize with non-transgenic comparators revealed no relevant differences. The GMO Panel is therefore of the opinion that this hybrid between MON810 and NK603 maize is as safe for human and animal health as conventional maize. The GMO Panel further concludes that experimental studies have shown NK603 x MON810 maize to be nutritionally equivalent to conventional maize.
- The application EFSA-GMO-UK-2004-01 concerns food and feed uses. There is therefore no requirement for scientific information on possible environmental effects associated with the cultivation of the GM maize. The GMO Panel agrees that unintended environmental effects due to the adventitious establishment and spread of NK603 x MON810 maize will not be different from that of traditionally bred maize. The GMO Panel also concludes that the amounts of Cry1Ab protein being distributed onto land in animal and food waste would be very low, minimizing the possibility for exposure of potentially sensitive non-target organisms. The monitoring plan provided by the applicant is in line with the intended uses for the NK603 x MON810 maize.

## EFSA Evaluation: an Example

- In conclusion, the GMO Panel considers that the information available for NK603 x MON810 maize addresses the outstanding questions raised by the Member States and considers it unlikely that NK603 x MON810 maize will have any adverse effect on human and animal health or the environment in the context of its proposed uses.
- This scientific opinion corresponds to the risk assessment report requested under Article 6(6) of Regulation (EC) No 1829/2003 and will be part of the overall opinion as required by Regulation (EC) No 1829/2003.

## EFSA Organization

- EFSA is made up of four distinct bodies. They are the Management Board, the Executive Director and staff, the Advisory Forum and the Scientific Committee and Panels.
- [The EFSA Management Board](#) comprises 14 members, appointed from across the European Union, and in addition a representative of the European Commission. Its main role is to ensure that EFSA functions well and efficiently. It therefore adopts, on proposals from the Executive Director, the draft budget and work programmes, monitors their implementation, and approves internal rules and regulations. It also appoints the Executive Director and members of the Scientific Committee and Panels.
- [The Acting Executive Director](#) is the legal representative of the Authority. He is in charge of day-to-day management and is responsible for all staff matters. The post is for five years, renewable, and is answerable to the Management Board. It was filled on the basis of a list of candidates proposed by the European Commission after an open competition and confirmed following a hearing in the European Parliament. Assisting the Executive Director is [the EFSA Management Team](#) that includes the Acting Deputy Executive Director, Antoine Cuvillier and the functional directors of Accounts; Communications; Facilities; Finance; Human Resources; Information Technology; Institutional and International Affairs; Legal Affairs, Quality Management, Science. When fully operational, the Authority is expected to have more than 300 staff.

# EFSA Organization

- EFSA staff are responsible for:
  - supporting the Scientific Committee and Scientific Expert Panels and their working groups, and the investment in cutting edge science;
  - providing scientific expertise on food and feed safety matters including emerging risks;
  - gathering scientific data and information;
  - defining and implementing the Authority's communications programme;
  - supporting the Board and Advisory Board;
  - ensuring liaison and collaboration with stakeholders, national and European institutions and international bodies;
  - assisting the EU institutions in crisis management;
  - providing appropriate administrative and specialist support in the area of finance, legal affairs, quality management, information technology and human resources.

# EFSA Organization

- EFSA's risk assessments and other scientific work are undertaken by its [Scientific Committee and eight scientific Panels](#), each responsible for a different aspect of food and feed safety. The scientific work is also supported by external Scientific Expert Working Groups, each specialising in a specific subject.
- EFSA provides the scientific secretariat for each of the Scientific Panels, the Scientific Committee and the Scientific Expert Working Groups. In addition, EFSA is currently recruiting scientists for the Scientific Expert Services that provide further scientific and technical assistance. EFSA aims to recruit scientists with experience in the following areas of expertise: Data Collection, Networking; Environmental Effects; Hazard Characterization & Animal Welfare; Epidemiology and Exposure; Toxicology; Assessment Modelling; Analytical Chemistry; Pesticide Risk Assessment; BSE/TSE Assessment; Monitoring of Zoonoses.
- EFSA's risk assessments are carried out by its Scientific Committee and eight Scientific Panels specialized in the following areas:
  - Panel on food additives, flavourings, processing aids and materials in contact with food (AFC)
  - Panel on additives and products or substances used in animal feed (FEEDAP)
  - Panel on plant protection products and their residues (PPR)
  - Panel on plant health (PLH)
  - Panel on genetically modified organisms (GMO)
  - Panel on dietetic products, nutrition and allergies (NDA)
  - Panel on biological hazards (BIOHAZ)
  - Panel on contaminants in the food chain (CONTAM)
  - Panel on animal health and welfare (AHAW)

## **EFSA Organization**

- **The Panels are made up of leading independent scientists coming from all over Europe and even in a few cases from beyond Europe, and were appointed following an open call for expression of interest. The Scientific Committee co-ordinates the work of the Panels, proposes common methodology and guidance in carrying out risk assessments, and addresses transversal issues common to all Panels (for instance, exposure assessment).**
- **The Scientific Committee and Expert Panels are supported by EFSA's own scientific staff. In addition, the Authority expects to reinforce its Science department by creating a series of expert service "teams" each dedicated to a specific area of risk assessment (eg data collection, epidemiology and exposure...). In total EFSA's team of highly qualified scientists, experts in their respective fields, and support staff is expected to represent approximately 50% of total headcount.**

## **Co-existence**

- **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.**

## Co-existence

- 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](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.

## Co-existence

- 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.

## **Co-existence**

- **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 coexistence 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).**

## **CONCLUSIONS**

- **EU shows a broad and almost complete set of rules, consistent with international ones.**
- **The rules undergo a continuous review and updating process.**
- **Transposition and implementation at Member State level largely varies among the countries.**
- **As a consequence, the adoption of GM crops is largely different in Member States**

**GRAZIE!**

**THANK YOU FOR THE  
ATTENTION**