

EU policy on biotechnology



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Foreword



The European Union has been legislating on genetically modified organisms (GMOs) since the early 1990s. Its objective has always been to achieve a high degree of protection of public health and the environment in Europe, while simultaneously creating a unified market for biotechnology.

Over the last few years, this legislation has been modernised in the light of scientific developments and public concerns. The new EU legal framework fully entered into force in April 2004. It sets out clear, transparent and stringent rules on genetically modified food, feed and crops. It is possibly the strictest GMO legislation in the world.

Biotechnology has the potential, through agronomically improved crops, to deliver better quality food and environmental benefits. Indeed, life sciences and biotechnology offer opportunities to address many of the global needs relating to health, ageing, food, and the environment and sustainable development.

However, the use of GMOs also raises difficult policy issues and regulatory challenges, and of course ethical questions. Some applications of biotechnology are widely accepted but agri-biotechnology applications, in particular, have provoked broad public debate. Opinion on this issue is highly polarised in the EU.

Widespread public support is essential. Ethical and societal implications and concerns must be addressed. Having strengthened its legislative framework, the EU will continue to explore outstanding issues and take public concerns into consideration.

Stavros Dimas
European Commissioner for the Environment

1. EU strategic context

In January 2002, the Commission adopted a Communication outlining a Strategy for Europe on Life Sciences and Biotechnology¹, which establishes a strategic vision up to 2010. The Communication consisted of two parts, namely policy orientations and a plan to transform policy into action in order to exploit the development of biotechnologies in a responsible manner. In this context, it also detailed the action required from the Commission and other European institutions as well as recommending actions from other public and private stakeholders.

The Communication recognises that biotechnology offers potential to address global healthcare through innovative approaches, to deliver improved food and environmental quality through agronomically enhanced crops and to improve non-food uses of crops as sources of industrial feedstocks or new materials. At the same time, biotechnology raises particular policy and societal challenges.

Member States have been able to provide input into the Strategy via the Competitiveness Council. In addition, the European Commission has reported annually on progress with the Strategy and in June 2005 presented its third progress report and future orientations².

In line with the timetable set out in the action plan, the Commission has moved forward on the specific regulatory actions within its own jurisdiction in the field of GMOs. However, it is acknowledged in the progress report that the situation regarding European biotechnology and its competitiveness still needs to be improved.

2. Regulatory framework

The EU has legislated on the approval and use of GMOs since the early 1990s, with the adoption of the first directives on the contained use of genetically modified microorganisms (GMMs) and on the deliberate release of genetically modified organisms (GMOs).

The objective of the EU legislation on GMOs is to protect human health and the environment whilst ensuring the free movement of safe genetically modified (GM) products in the EU. Only GMOs and GM food or feed products that have been assessed as safe to health and the environment are authorised for use in the EU.

(¹) Life Sciences and Biotechnology – A strategy for Europe, COM (2002) 27.
(²) COM (2005) 286 final.

In order to address increasing public concerns and in the light of scientific developments, the European Commission started a full review of the entire corpus of GMO legislation in 1999. The aim of the revision was to make the Community legislative framework more stringent and transparent, as well as to develop traceability and labelling rules.

The revised legislative framework on GMOs, which is considered to be one of the strictest in the world, has been fully operational since April 2004. Its main legal instruments are as follows:

- **Directive 2001/18/EC on the deliberate release into the environment of GMOs applying to the intentional introduction of GMOs³** into the environment without specific containment measures. The Directive covers both releases of GMOs⁴ for experimental purposes (e.g. in connection with field trials) and for commercialisation (for example the cultivation, importation and processing or transformation of GMOs into industrial products).
- **Regulation (EC) No 1829/2003 on genetically modified food and feed⁵**, which regulates the placing on the market of GMOs for food and feed use, as well as food and feed containing, consisting of or produced from GMOs. If one of the uses of a GMO concerns food or feed, the applicant may file a single application for the GMO and all its uses (cultivation, processing into industrial products and feed use) under this regulation .
- **Regulation (EC) No 1946/2003 on transboundary movements of genetically modified organisms⁶** regulates unintentional transboundary movements of GMOs and exports of GMOs to third countries.
- **Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified microorganisms (GMMs)⁷**. 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 (e.g. a laboratory) in which contact with the environment and the population is avoided.
- **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

(³) OJ L106, 17.4.2001, p.1.
(⁴) GMOs from now on being defined as a product containing GMOs or consisting of such organisms
(⁵) OJ L268, 18.10.2003, p.1. This Regulation amended the 1997 Novel Foods Regulation (Regulation 258/97) which governed the placing on the market of novel food, including GM food.
(⁶) OJ L287, 5.11.2003, p.1.
(⁷) OJ L117, 8.5.90, p.1.

2001/18/EC⁸. As regards GM food and feed, Regulation 1829/2003 lays down specific labelling requirements.

A considerable number of implementing measures to support operation of this framework have also been adopted by Member States over the past few years. These include, amongst others, guidelines for risk assessment, monitoring, formats for submission of notifications, sampling and detection and co-existence measures.

2.1. Release into the environment: Directive 2001/18/EC in detail

In accordance with Directive 2001/18/EC, **the deliberate release of a GMO into the environment** means its intentional introduction 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 relation to 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. The GMO may be placed on the market for purposes of importation, cultivation or transformation into different products. The provisions of **Part C** of Directive 2001/18/EC govern the placing on the market of a GMO.

As compared to the previous legislation, Directive 2001/18/EC introduced the following **principles**:

During the authorisation procedure:

- Principles for environmental risk assessment to identify and evaluate potential adverse effects of the GMO;
- Mandatory information to the public;



Principles
underlying Directive
2001/18/EC

⁽⁸⁾ OJ L268, 18.10.2003, p.24.

- Information to allow the identification and detection of GMOs to facilitate post-market inspection and control;
- The consultation of the European Food Safety Authority (EFSA) to be obligatory;
- An obligation to inform the European Parliament on decisions to authorise the release of GMOs and
- The possibility for the Council of the EU to adopt or reject a Commission proposal for authorisation of a GMO by qualified majority.

Once the product is authorised and placed on the market:

- Mandatory post-market monitoring requirements, including on long-term effects associated with the interaction with other GMOs and the environment;
- A requirement for Member States to ensure labelling and traceability at all stages of the placing on the market, according to a Community system provided for by Regulation 1830/2003 on traceability;
- First approvals for the release of GMOs to be limited to a maximum of ten years.

Under Directive 2001/18/EC, a person or a company who wishes to introduce a GMO 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.

Authorisation
for experimental
purposes

Following a national procedure, authorisation is granted on the basis of an evaluation of potential risks of the GMO for the environment and human health. Even though the authorisation would only be applicable in the Member State where the notification was submitted, the other Member States and the European Commission may make observations to be examined by the competent national authority.

In the case of a company intending to **market a GMO**, it must also 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 appropriate.

Authorisation for
placing on the
market

In this case, the authorisation procedure involves all Member States, due to the fact that once authorised, the product will be allowed to move throughout the territory of the EU. 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.

The **environmental risk assessment** will identify and evaluate potential adverse effects of the GMO according to a methodology described in Annex II to the Directive 2001/18/EC, and including the consideration of direct, indirect, immediate or delayed effects, as well as cumulative and long term effects.

Environmental risk assessment

The assessment also requires an evaluation of how the GMO was developed and examines the potential risks associated with the new gene products produced by the GMO (e.g. toxic or allergenic proteins) and the possibility of gene transfer (e.g. of antibiotic resistance genes).

The national authority must issue an opinion on the notification, in the form of an "assessment report", which 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 informs the other Member States via the European Commission, which 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 in conformity with any conditions set out in the authorisation, which has a maximum duration of ten years. The authorisation may be renewed provided certain conditions are met, for instance on the basis of the results of the post-market monitoring programme.

Standard procedure

When 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 EU level. The Commission first asks for the opinion of the European Food Safety Authority (EFSA), composed of independent scientists. The Commission then presents a draft decision to the Regulatory Committee⁹ composed of representatives of the Member States for an opinion.

Community procedure

⁽⁹⁾In accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission. OJ L184, 17.7.1999, p.23.

In the event of the Committee giving 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. In the case of the Council failing to reach qualified majority or not acting within three months, the decision would go back to the European Commission for adoption.

Following the adoption of the decision, the notifier may proceed with the placing on the market once the written content of the competent authority has been received.

During the notification process, the public is informed and has access to the publicly available data on the Internet at: <http://gmoinfo.jrc.it>, including the summary notification, the assessment reports of the competent authorities, or the opinion of the European Food Safety Authority (<http://efsa.eu.int>). The public has the possibility of providing comments on the summary notification and the assessment report.

Information to the public

2.2. Traceability and labelling



Traceability provides the means to trace products through the production and distribution lines. The general objectives of traceability are to facilitate control and verification of labelling claims; targeted monitoring of potential effects on health and the environment, where appropriate; and withdrawal of products that contain or consist of GMOs where an unforeseen risk to human health or the environment is established.

The Labelling and Traceability Regulation (Regulation 1830/2003) covers all GMOs that have received EU authorisation for their placing on the market, namely all products containing or consisting of GMOs, including food and feed. Examples include GM seeds and bulk quantities or shipments of whole GM grain, such as soybean and maize. The regulation also covers food and feed derived from a GMO, as flour produced from 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.

Traceability requirements

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**: according to Article 4 of Regulation 1830/2003, operators must transmit in writing together with the product:
 - an indication that the product – or some of its ingredients – contains or consists of 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**, and according to Article 5 of Regulation 1830/2003, operators must transmit in writing accompanying 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. This practice will reduce the need for sampling and testing of products containing a mixture of seeds.

In addition to these traceability provisions, 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.

Labelling rules

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**¹⁰. Genetically modified foods which are delivered as such to the final consumer or mass

Specific labelling requirements for GM food and feed

⁽¹⁰⁾ See http://www.europa.eu.int/comm/food/food/biotechnology/etiquetage/index_en.htm for more information

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.

In the production of seeds, food and feed, it is practically impossible to achieve products that are 100% pure. Similarly, conventional products may be accidentally contaminated by GMOs during cultivation, harvesting, storage, transport or processing. Therefore, 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.

Exemption from the traceability and labelling requirements

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.

0.9% threshold for adventitious presence of authorised GMOs

In addition, Regulation (EC) No 1829/2003 defines specific conditions for GMOs that have received a positive assessment by EFSA in terms of safety for health and the environment, but not yet formally authorised. The regulation allows the presence of these non-authorised 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.

0.5% tolerance level for non authorised GMOs under specific conditions

The Regulation limits the application of this threshold to three years (until 2007) and provides that a detection method must be publicly available. The Commission has published a list of GM material which has not been authorised but which has had a favourable scientific assessment. This list may be consulted at the following address: http://www.europa.eu.int/comm/food/food/biotechnology/gmfood/events_en.pdf

2.3. International trade of GMOs

The EU regulatory framework on GMOs takes account 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 regulatory system for authorising GMOs is consistent with the EU's international trade commitments and with WTO rules: it is clear, transparent and non-discriminatory.

The EU is party to the Cartagena Protocol on Biosafety, which entered into force on 11 September 2003. This Protocol to UNEP's Convention on Biological Diversity aims at establishing common rules for the transboundary movement 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 the legal framework governing the use of GMOs within the European Union. As presented above, the cornerstone of this legal framework is Directive 2001/18/EC. The provisions of Directive 2001/18/EC are supplemented by the **Regulation on the transboundary movements of GMOs** (Regulation (EC) No 1946/2003).

The Regulation (EC) No 1946/2003 was adopted in June 2003 to address specifically export obligations necessary to align the existing regulatory framework with the provisions of the Biosafety Protocol. 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.

3. Regulatory challenges

The implementation of the revised regulatory framework has met a number of challenges. Difficulties are found during the decision making process for authorising the placing on the market of GMOs. Moreover, various environmental and safety concerns remain despite of the revision of the regulatory framework and have led various Member States to invoke safeguard clauses. Last but not least, the difficult development of national coexistence measures and the unresolved definition of seed thresholds hamper a comprehensive approach to the cultivation of GMOs.

The division of opinion amongst Member States during the authorisation process is leading to the application of the Community procedure to all products notified under Part C of Directive 2001/18/EC as of January 2006. In the absence of the necessary

majority at the Council level, the decisions for authorisation go back to the European Commission for adoption. This situation has been criticised by various Member States as the final decision may go against a majority of them.

A number of Member States have invoked the so-called “**safeguard clause**” under Article 16 of the previous Directive 90/220/EEC. This clause is also included in Directive 2001/18/EC, which replaced the aforementioned Directive. The safeguard clause provides that where a Member State has justifiable reasons to consider that a GMO, authorised 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 of the nine bans remained in place (UK withdrew its ban) and were considered under the safeguard provision (Article 23) of Directive 2001/18/EC. The GMOs in question (Bt 176, T25 and MON 810 maize, Ms1xRf1 and Topas 19/2 oilseed rape) had been authorised under Directive 90/220 for all uses (including cultivation) with the exception of Topas 19/2 (import and processing). The Commission examined the additional information provided by certain Member States, which has also been reviewed by EFSA. In addition, in January 2005, Hungary invoked the safeguard clause in order to prohibit the cultivation of MON 810 in its territory.

In June 2005, the Environment Council reached qualified majority against eight proposals to lift the eight bans invoked by five Member States. As a result, DG Environment has consulted EFSA again in order to obtain an updated opinion. The Commission now has three options, namely to submit either the same or amended proposals back to the Council or to submit proposals for adoption through codecision, on the basis of the awaited EFSA opinion.

The issues of coexistence measures and seed thresholds, which are closely linked with approval and cultivation of GMOs, remain partially unresolved. Pollen flow between adjacent fields is a natural phenomenon. Due to the labelling requirements for GM food and feed, this may have economic implications for farmers who want to produce traditional plants intended for food.

Coexistence is about giving farmers the practical choice between conventional, organic and GM crop production in compliance with the legal obligations for labelling and purity standards. On 5 March 2003, the Commission agreed that it should be up to the Member States to develop and implement management measures concerning co-existence, in accordance with the subsidiarity principle.

On 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 farming¹¹. The Recommendation states that approaches to co-existence need to be 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. Furthermore, 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.

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 specific region). These measures should be justified for each crop and type (e.g. seed and crop production separately).

In spite of the guidelines for establishing a framework for co-existence provided in the Commission Recommendation, some national measures have been refused by the European Commission as disproportionate to their objective and representing a potential barrier to free circulation of authorised GMOs. In addition, a number of Member States consider the Commission guidelines on coexistence insufficient and have demanded more precision in terms of guidelines or legislation.

Finally, **thresholds** below which adventitious traces of GM **seeds** in conventional seed lots do not require labelling have still to be established by the European Commission. These threshold levels would address labelling of approved GMOs and should be both low enough to serve their purpose and workable and enforceable in practice.



⁽¹¹⁾ http://europa.eu.int/comm/agriculture/publi/reports/coexistence2/guide_en.pdf

4. Current situation: overview of GMOs authorised in the EU

Under the “deliberate release” legislation (Directive 2001/18/EC and, previously, Directive 90/220/EC) numerous GMOs have been approved for different uses, which include cultivation, import and processing and feed and food, depending on the specific cases. Varieties of agricultural products include maize, oil seed rape, soybean and chicory.



One GM soy and one GM maize were approved for **use in food products** under Directive 90/220/EC prior to the entering into force of Regulation (EC) No 258/1997 on Novel Foods. Further applications for the placing on the market of GM food products have been introduced under the Novel Foods Regulation and the GM food and feed Regulation 1829/2003.

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 originally 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.

Since April 2001 and prior to the entry into force of Regulation (EC) No 1829/2003, the Directive 2001/18/EC covered the approval of GMOs for use in feed. Accordingly, certain applications submitted under Directive 2001/18/EC before April 2004 have been processed and consequently approved under the Directive during the transition period.

Products authorised under Regulation (EC) No 1829/2003 on GM food and feed are entered into a public register, which is available at: http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm.

As of January 2006, five products have been approved, under the Directive 2001/18/EC, for **import and processing and in some cases also use in animal feed**. These products are MON 863, NK 603, MON 863 x MON 810 and 1507 maize and GT73 oilseed rape. Eight applications for the placing on the market of GMOs (e.g. maize, oil seed rape, cotton, carnation and potato) for authorisation under Directive 2001/18/EC are pending. Several applications have a scope restricted to import and processing, while others also include cultivation as a requested use.

Finally, the EU legislation on **seeds**¹² concerning the marketing of seed varieties of agricultural plant and vegetable species requires that GM varieties have to be authorised in accordance with the Directive 2001/18/EC, before they are included in the Common Catalogue and marketed in the EU. So far, 31 GM varieties derived from MON 810 maize are inscribed in the Common Catalogue of Varieties of Agricultural Plant Species. If the seed is intended for use in food, it also has to be authorised in accordance with the GM food and feed Regulation.

5. Research and development in support of biotechnology

Life sciences and biotechnology can provide a major contribution to strengthening the European Union's competitiveness. The life sciences and biotechnology industry have the potential to be leading areas of science, industry and employment over the coming decades. As a leading edge technology, they can contribute to the modernisation of Europe's industrial base and to the creation of growth and new jobs.

The European Commission has been supporting biotechnology through its research programmes over the last years. Since 1985 the European Commission has been financing research projects focusing on the safety of GMOs. A project funded under the 5th Framework Programme for Research (FP5), involving more than forty-five research centres, concluded that GMO crops evaluated were as safe as conventionally grown crops.

The 6th Framework Programme for Research (FP6) has provided a major incentive for research in the area of biotechnology. FP6 continues to give a strong impetus, in particular in terms of critical mass of human and financial resources, sharing of knowledge and facilities, strengthening of scientific excellence, coordination of national activities and support for EU policies. A number of projects have received a total contribution of over EUR36 million, addressing risk assessment methods and coexistence challenges.

On 6 April 2005, the Commission adopted a proposal for the Seventh EC Research Framework Programme 2007-2014 (FP7). Life sciences and biotechnology research will remain a priority in FP7. The proposal includes further research to support the implementation of the regulatory framework on GMOs under its theme "Agriculture, food and biotechnology".

The EU also provides scientific support in relation to GMOs through its in-house Joint Research Centre (JRC). The JRC is undertaking research on underlying mechanisms for integrating foreign genes into host plants, and evaluating their long-term stability.



⁽¹²⁾ Notably Directives 2002/53/EC and 2002/55/EC

Research is also carried out to develop detection and quantification methods for the presence of GMOs in raw materials, ingredients and final products. The JRC co-ordinates as well the European Network of GMO Laboratories, which brings together more than forty-five EU control laboratories to share information and methods for sampling, detection, identification and quantification of GMOs.



6. Conclusion

The implementation of the revised regulatory framework started in April 2004, which provides the Commission with limited experience to date. Throughout 2004 and 2005, the European Commission has progressed with the pending decisions concerning the placing on the market of new genetically modified products and the lifting of national safeguard clauses through comitology procedures, in accordance with the provisions of the EU legislation on GMOs.

In its most recent orientation debate on 22 March 2005, the Commission confirmed its full confidence in the existing regulatory framework on GMOs and concluded that it would continue to comply fully with its legal obligations and proceed with the approval of pending authorisations, as appropriate. However, in spite of notable improvements in the regulatory framework, public and political concerns about GMOs still exist.

Reports concerning the implementation and operation of the regulatory framework, as required by Directive 2001/18/EC, Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003, are being prepared by the Commission for adoption in 2006. The Commission is compiling a report on the experience gained in the Member States concerning the implementation of measures to address co-existence.

In 2006 as well, a report on the implementation of Regulation (EC) No 1946/2003 will start to be compiled from information to be submitted by the Member States. Some of these reports may feed a debate foreseen at the Environment Council in 2006, in order to discuss constraints and opportunities related to GMO technology, as well as difficulties found in the decision-making process.

As part of the implementation of the Strategy on Life Sciences and Biotechnology, the Commission will carry out a comprehensive assessment and cost-benefit analysis of the consequences, opportunities and challenges that applications of modern biotechnology present for Europe in terms of economic, social and environmental aspects. The results of this study will contribute to a midterm review of the Strategy in 2006-2007.

The Commission will continue its efforts to address the outstanding challenges, which could increase cooperation in decision making and ultimately result in a wider consensus amongst institutions, Member States and other stakeholders. In parallel, the political debate foreseen in 2006 and the various technical reports expected in 2006 and 2007 will contribute to obtaining a more comprehensive picture of the implementation of the regulatory framework on GMOs and of the challenges ahead.

Further reading:

- **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**

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

- **GMO products – pending notifications under Directive 2001/18/EC**

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_authorized_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_authorized_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 (safeguard clauses)**

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

Useful links:

- The European Commission **Biotechnology website**: <http://europa.eu.int/comm/biotechnology/>
- The **Food Safety Website**: http://europa.eu.int/comm/food/food/biotechnology/index_en.htm
- DG Sanco **Register** to food and feed: http://www.europa.eu.int/comm/food/dyna/gm_register/index_en.cfm
- The **Biotechnology and GMOs information** website: <http://gmoinfo.jrc.it/default.asp>
- The **EFSA** website: http://www.efsa.eu.int/index_en.html
- The **GMO Methods Database**: <http://biotech.jrc.it/methodsdatabase.htm>

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