

## **Manual of European Environmental Policy**

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# Genetically modified organisms: Deliberate release

Note: Directive 2001/18/EC was amended by Regulation (EC) No [1829/2003](#) and Regulation (EC) No [1830/2003](#). The following legislation is repealed by Directive 2001/18/EC: Directives [90/220/EEC](#), [94/15/EC](#), [97/35/EC](#). Regulation (EC) No [258/97](#) concerning novel foods and novel food ingredients was also effectively superseded by Directive 2001/18/EC.

<b>Formal references</b>	
<a href="#">2001/18/EC</a> (OJ L106 17.4.2001)	Directive on the deliberate release into the environment of genetically modified organisms and repealing Council Directive <a href="#">90/220/EEC</a>
Proposed 23.2.1998 – <a href="#">COM(98)85</a>	
<a href="#">91/274/EEC</a> (OJ L135 30.05.1991)	Commission Decision concerning a list of Community legislation on environmental risk assessment of products
<a href="#">94/730/EC</a> (OJ L292 12.11.1994)	Commission Decision concerning a simplified procedure for authorizing multi-site research programmes on GMOs
<a href="#">2002/623/EC</a> (OJ L200 30.7.02) guidance notes	Commission Decision establishing guidance notes supplementing annex II
<a href="#">2002/811/EC</a> (OJ 280 18.10.2002)	Council Decision establishing guidance notes supplementing Annex VII to Directive <a href="#">2001/18/EC</a>
<a href="#">2002/812/EC</a> (OJ L280 18.10.2002)	Council Decision establishing pursuant to Directive <a href="#">2001/18/EC</a> 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
<a href="#">2002/623/EC</a> (OJ L200 30.7.2002)	Commission Decision establishing guidance notes supplementing Annex II to Directive <a href="#">2001/18/EC</a>
<a href="#">2002/813/EC</a> (OJ L280 18.10.2002)	Commission Decision establishing summary notification format for notification of deliberate release
<a href="#">2003/701/EC</a> (OJ L254 8.10.2003)	Commission Decision establishing a format for presenting the results of the deliberate release of genetically modified higher plants for purpose other than placing on the market
Regulation (EC) No <a href="#">1829/2003</a> (OJ L268 18.10.2003)	Regulation on genetically modified food and feed
Regulation (EC) No <a href="#">1830/2003</a> (OJ L268 18.10.2003)	Regulation concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs and amending Directive <a href="#">2001/18/EC</a>
<a href="#">2004/204/EC</a> (OJ L65 3.3.2004)	Commission Decision laying down detailed arrangements for the operation of the register for recording information on genetic modifications in GMOs, provided for in Directive <a href="#">2001/18/EC</a>
<a href="#">2008/27/EC</a> (OJ L 81 20.3.2008)	Directive <a href="#">2008/27/EC</a> of the Parliament and of the Council amending Directive <a href="#">2001/18/EC</a> on the deliberate release into the environment of genetically modified organisms, regarding the implementing powers conferred on the Commission

<a href="#">2009/770/EC</a> (OJ L 275/9 21.10.2009)	Commission Decision of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council
<b>Legal base</b>	Article 114 TFEU (originally Article 95 TEC)
<b>Binding dates</b>	
Implementation Report to Commission	Every three years
Summary of implementation by the Commission	Every three years
Commission report on 2003 and then every 3 years experience with GMOs on the market	2003 and then every three years
Specific report on the operation of 2003 parts B and C of the Directive	2003
Commission report on critical issues	Every year

## Purpose of the Directive

The Directive replaces earlier measures regulating the placing on the market of novel foods. It is designed to complement rules on the [contained use](#) of genetically modified micro-organisms (GMMOs), by regulating the commercial and non-commercial release of genetically modified organisms (GMOs) or products containing or consisting thereof. Like other Community measures on GMOs, the Directive seeks to protect human health and the environment from possible adverse effects that may arise from such a release. Moreover, it is aimed at harmonizing Member States' law, regulations and administrative provisions concerning the authorization of release.

## Summary of the Directive

Directive 2001/18/EC is based on Article 95 of the EC Treaty (now Article 114 TFEU) and can be seen primarily as a harmonizing measure. It regulates the deliberate release of GMOs into the environment and their 'placing on the market', which means making available to third parties, whether in return for payment or free of charge. Three types of operation are not regarded as 'placing on the market':

- The making available of GMMOs under Council Directive 90/219/EEC on the contained use of GMMOs.
- The making available of GMOs based on the same principles of containment as laid down in Directive 90/219/EEC.
- The making available of GMOs to be used exclusively for deliberate release as laid down in the requirements of part B of this Directive.

It does not apply to the transport of GMOs, nor where genetic modification is obtained through certain techniques listed in Annex I B.

Essential terms are defined and a general obligation is placed on Member States to ‘ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment’. Member States are to designate competent authorities responsible for complying with the requirements of the Directive and must ensure that they organize inspections and other appropriate control measures, including the availability of termination measures, to ensure compliance.

Two systems of notification are established under part B and C of the Directive; one for deliberate release for any purpose other than ‘placing on the market’ and the other for ‘placing on the market’ of GMOs as, or in, products, respectively. Before submitting a notification there is a general obligation to carry out an environmental risk assessment, the procedure for which is laid down in Annex III. Member States are also obliged to identify and phase out the use of antibiotic resistance markers by 31 December 2004, in the case of GMOs ‘placed on the market’ under part C and by 31 December 2008 under part B. The Directive also invites the Commission to bring forward a legislative proposal for implementing the [Cartagena Protocol](#) on Biosafety. This was subsequently established primarily by means of Regulation (EC) No 1830/2003.

### **Notification – deliberate release for any other purpose than for ‘placing on the market’**

No person or company may release a GMO unless they have consent to do so – and in order to get such consent, that person or company must make a ‘notification’ to the relevant competent authority. Notifications must include a technical dossier supplying information necessary for an environmental risk assessment, specified in Annex III, in particular providing:

- General information relating to the GMO.
- Specifications for information on the conditions of release and the potential receiving environment.
- Information on the interactions between GMOs and the environment.
- Information on monitoring, control, waste treatment and emergency response plans.

The competent authority may accept one notification covering releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and a limited period. The notifier may refer to data or results from notifications previously submitted by other notifiers (provided that the information, data and results are not confidential or they have agreement in writing), or he may submit additional information he considers relevant.

After having received and acknowledged the notification, the competent authority must examine it for compliance with the Directive, evaluate the risks of release, record its conclusions in writing, and carry out tests or inspections if necessary. The competent authority must respond within 90 days of receipt of the notification, indicating either that the notification is in compliance with the requirements of the Directive or that it has failed the conditions. Member States may extend this 90-day period by an extra 30 days for the purpose of consulting the public. The 90-day period is subject to the rule that any period of time in

which the authority is waiting for further information (e.g. that it has requested from the notifier) does not count towards the 90 days. The notifier may proceed with release only after he receives explicit consent from the competent authority. After completion of a release, and thereafter in regular intervals, the notifier has to send the result of the release in respect of any risk to human health or the environment to the competent authority. For genetically modified higher plants not intended for marketing, a report format to be used when presenting these results was established by Commission Decision 2003/701/EC pursuant to Article 10 of the Directive.

If the competent authority feels it has sufficient experience in dealing with certain GMOs in certain ecosystems it may put a proposal for a differentiated procedure under Article 7 of the Directive. The only current example of such a procedure is the so-called ‘first simplified procedure’ (Commission Decision 94/730/EC), which is designed to enable the authorization of multi-site programmes of work (e.g. for research) on GM crop plants that take place over extended periods of time.

### **Notification – placing GMO products on the market**

The notification procedure (part C) for GMO products under this Directive requires the manufacturer or importer to the Community to submit a notification to the competent authority of the Member State where the product is to be placed on the market for the first time. The notification must supply the necessary information (as required in Annex II) for ‘an environmental risk assessment’ (which should be undertaken in accordance with Annex III); details on use and handling conditions; labelling and monitoring; packaging proposals which meet the requirements of Annexes IV, VI and VII (subsequently supplemented by Council Decision 2002/811/EC) and a summary of all of the above ‘dossier’. A proposed period for consent for deliberate release should not exceed ten years.

Council Decision 2002/812/EC subsequently established a ‘Summary Information Format’, to be used in drawing up the summary of the dossier, which is to be submitted to the competent national authority under Directive 2001/18/EC.

The notifier may propose not to comply with some of these requirements on the basis of a previously notified release under part B or on other ‘substantive, reasoned scientific grounds’ and may also refer to data or results from notifications previously submitted by other notifiers and additional information he considers relevant. However, in order for a GMO or combination of GMOs to be used for a different purpose to that already approved, a separate notification must be submitted.

The competent authority must then immediately forward the summary of the notification dossier to the competent authorities of other Member States and to the Commission. The competent authority must examine the notification for compliance with the Directive and within 90 days of receipt of the notification, the competent authority must either inform the notifier that the conditions of the Directive are not met and that the consent application (notification) is rejected, or forward a dossier to the Commission and other Member States with a favourable opinion. However, an assessment report must be sent back to the notifier before or at the same time as such notification is given to the Commission. The Commission must then make available the summary dossier from the notification proposal and the assessment report to the public, who have a period of 30 days to comment.

The standard procedure allows 60 days, following the date of circulation of the assessment report to other Member States, for those Member States to ask for further information, make comments, or present reasoned objections to the placing on the market of the GMO in question. Replies must be directed to the Commission and circulated to all competent authorities. Any outstanding issues between the Commission and the competent authorities must be agreed within 105 days from the date of circulation of the assessment report. If there is no reasoned objection the competent authority can give consent in writing for 'placing on the market' and shall inform all other parties within 30 days. The notifier may proceed with the 'placing on the market' only when he has received the written consent of the competent authority. The written consent must explicitly specify the scope of the consent and the identity of the GMO, the period of validity of the consent, the conditions for the placing on the market and the labelling and monitoring requirements.

However, where a reasoned objection is raised by the competent authority or the Commission, a Decision shall be adopted and published within 120 days in accordance with the procedure in Article 30(2). A competent authority or the Commission may, on its own initiative, make a proposal on criteria and information requirements to be met for notification, by way of derogation from the usual 'notification procedure' (Article 13). These can be adopted after consultation with the relevant Scientific Committee(s), but prior to this, the proposal must be made available to the public and comments may be made to the Commission for a period of 60 days. These comments can then be fed into the Committee decision.

These provisions were amended in 2003 by Regulation (EC) No [1829/2003](#), which introduces transitional measures, for a period of three years starting 7 November 2003, for adventitious or technically unavoidable traces of GMOs that have benefited from a favourable risk evaluation. These are exempt from notification, consent and labelling provisions, provided that they meet certain conditions under Regulation (EC) No 1829/2003.

Moreover, following further amendments through Regulation (EC) No 1829/2003, Member States may take appropriate measures to avoid the unintended presence of GMOs. The Commission is responsible for gathering and coordinating relevant information, and for observing developments regarding the coexistence of genetically modified and conventional varieties. On the basis of this information the Commission is to develop guidelines.

## **Renewal of consent**

Part C consents issued under Directive 2001/18/EC are limited to a maximum duration of 10 years. After this, in order to continue marketing the GMO, consent holders would have to make another notification for renewal of consent. A similar procedure also applies to GMOs with Part C consents issued under the previous Directive 90/220/EEC. All such consents must be renewed before the end of 2006. A report on the results of monitoring must be included with the notification along with any new information with regard to the risks of the product and a proposal for amending the conditions of the original consent, as appropriate. Under notification for the renewal of consent, the notifier may continue to place the GMO on the market under the conditions of the consent until a final Decision has been taken.

## **Labelling**

Any GMO authorized under Directive 2001/18/EC, or product containing this GMO, is required to be labelled. Regulation (EC) No 1831/2003 on the traceability and labelling of GM products amends the Directive, adding the following paragraph on labelling thresholds:

*‘For products intended for direct processing, paragraph 1 shall not apply to traces of authorised GMOs in a proportion no higher than 0.9 per cent or lower thresholds established under the provisions of Article 30(2), provided that these traces are adventitious or technically unavoidable’.*

## **Safeguard clause**

Where a Member State as a result of new information has detailed grounds for considering that a GMO properly authorized under Part C poses a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of the GMO on its territory. The Member State must immediately inform the Commission and other Member States of such a decision, supplying an environmental risk assessment and indicating how the conditions of the consent should be amended/terminated. A Decision (by the regulatory committee) must be taken within 60 days unless the Scientific Committee(s) is approached and its opinion awaited, in which case a further 60 day time period is permitted.

## **Reports and exchange of information**

The Commission is required to meet Member States regularly and to exchange information on the experience acquired with regard to placing GMOs on the market. It must also establish several registers for the purpose of recording the information on genetic modifications in GMOs, as mentioned in Annex IV. A part of these registers will be accessible to the public. A public register, established under Commission Decision 2004/204, is to record information on the genetic modification which can be used to detect and identify particular GMO products to facilitate post-market control under the Directive. This should include the location, details of nucleotide sequences and a methodology, where appropriate, for detecting and identifying the GMO product.

Every three years, Member States must send to the Commission a report on the measures taken to implement the provisions of the Directive and from 2003 and every three years thereafter, a summary report on the experience of Member States should be presented to Parliament and the Council.

The Commission and competent authorities must not divulge confidential information to third parties; the notifier may indicate and justify where they consider that disclosure might harm their competitive position, but the basic details of notification may in no case be kept confidential.

## **Related acts**

Related acts placing GMOs on the market in accordance with Directive 2001/18/EC include:

- Decision [2010/135/EU](#) – potato product (*Solanum tuberosum* L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch, developed by BASF Plant Science GmbH
- Decision [2009/244/EC](#) – carnation (*Dianthus caryophyllus* line 123.8.12) genetically modified for flower colour, developed by Florigene Ltd.
- Decision [2007/364/EC](#) – carnation (*Dianthus caryophyllus* line 123.2.38) genetically modified for flower colour, developed by Florigene Ltd.
- Decision [2007/232/EC](#) – oilseed rape products (lines MS8, RF3 and Ms8xRf3) genetically modified for tolerance to the herbicide glufosinate-ammonium, developed by Bayer Bioscience NV.
- Decision [2006/47/EC](#) – maize hybrid product MON863 x MON810, developed by Monsanto Europe S.A.
- Decision [2005/772/EC](#) – maize product 1507, developed by Monsanto Europe S.A.
- Decision [2005/635/EC](#) – oilseed rape product GT73, developed by Monsanto Europe S.A.
- Decision [2005/608/EC](#) – maize product MON 863, developed by Monsanto Europe S.A.
- Decision [2004/643/EC](#) – maize product NK603, developed by Pioneer Hi-Bred International INC and Mycogen Seeds.

## Development of Directive 2001/18/EC

The proposal for the original deliberate release Directive 90/220/EEC was published with that on [contained use](#) of GMMOs in May 1988. Policy on the deliberate release to the environment of GMOs was not developing as rapidly as that on contained use, but most Member States were establishing guidelines or regulatory structures, notably in Denmark and Germany. The proposal was not amended greatly, although the information required in notifications was expanded, before being agreed by the Council. In February 1996 the Commission published a review of Directive 90/220/EEC, following consultation with Member States, competent authorities and interested parties. The review called for a number of changes to be made to the Directive and following this and a considerable political debate the Commission adopted a proposal to amend Directive 90/220/EEC in November 1997. Much controversy arose within the Decision making process, which began in October 1998 and did not end until agreement was reached in Conciliation in mid-December 2000. The amendments to the Directive were finally adopted on the 16 February 2001 and the text was published on the 12 March 2001.

The adoption of Directive 2001/18/EC, repealing Directive 90/220/EEC, was only one of the undertakings agreed by the Commission. On 13 July 2000, it launched a new Strategy to restore public trust in the GMO authorization process. The Commission's Strategy was an attempt to re-launch the approvals process in response to continued pressure to 'break the GMO approval deadlock', or *de facto* moratorium (now lifted) as it is commonly known, and accompanying threats of legal action. The strategy had four elements:

- An agreement to adopt the main provisions on GMO labelling, monitoring, traceability, etc., as proposed in the amended version of Directive 90/220/EEC, as soon as it is agreed at Community level, prior to transposition by national governments.
- Proposals for labelling both GMOs and their products.
- A proposal for establishing a traceability system for GMOs.

- Accelerated work on related research issues, including on environmental liability, the monitoring of possible long-term effects on biodiversity and international developments such as the Biodiversity Protocol.

## Implementation of the Directives

### Supporting implementation

Supplementary guidance to the Directive 2001/18/EC has been provided by the Commission in the form of:

- Decision [2002/623/EC](#) establishing guidance notes supplementing Annex II to Directive 2001/18 /EC.
- Decision [2002/811/EC](#) establishing guidance notes supplementing Annex VII to Directive 2001/18/EC.
- Decision [2002/812/EC](#) establishing summary information relating to the placing on the market of GMOs.
- Decision [2002/813/EC](#) establishing summary notification format for notification of deliberate release.
- Decision [2002/813/EC](#) establishing summary notification format for notification of deliberate release.
- Decision [2003/701/EC](#) establishing a format for presenting the results of the deliberate release of genetically modified higher plants for purpose other than placing on the market.
- Decision [2004/204/EC](#) laying down detailed arrangements for the operation of the register for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC.

### Co-existence of GM production with non-GM production

The Directive on deliberate release encompasses provisions, by way of the final consent of the authorization procedure, for specific measures to protect the environment and human health in relation to co-existence. Nonetheless, the Commission published guidelines on 23 July 2003 ‘for the development of national strategies and best practices to ensure coexistence of genetically modified crops with conventional and organic crops’ (Recommendation [2003/556/EC](#)). While the guidelines complement the regulatory framework set up by the EU, they are not legally binding, and thus fall short of answering the calls for legally binding rules made by environmental NGOs and certain Member States. In light of the debate on co-existence the issue of GM-free zones was revisited, and the then Agriculture Commissioner Fischler stated that ‘cooperation between farmers in the same region and the sharing of information and experience will be enormously important’, and that he supported ‘voluntary grouping farmers into GM-free or organic zones’<sup>1</sup>. In June 2005, the Commission issued a Decision to establish a network group for exchange and coordination of information on scientific studies and best practice in the field of coexistence of GM and non-GM crops. The group is to be comprised of experts from Member States and chaired by a Commission representative.

As part of a new package on GMO cultivation published on 13 July 2010, the Commission issued a new Recommendation on co-existence (Recommendation [2010/C 200/01](#), on

*guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops*), under which Member States are granted the right to introduce measures to restrict or even prohibit the cultivation of GM crops approved through the EC's authorization procedure, on socio-economic grounds. Prohibitions can be applied to specific strains or GM crops as a whole, for discrete areas or country-wide, depending on interpretation by the Member State. The package furthermore included a draft Regulation to amend Directive 2001/18/EC to give a firm legal basis to the right of Member States to prohibit or restrict cultivation of GMOs on their territory for reasons other than those covered by the environment and health safeguard clause. The draft Regulation awaits adoption by the European Parliament and Council. After the October 2010 Agriculture Council called on the Commission to provide a list of indicative exclusion criteria which would justify bans on GMO cultivation, on 8 February 2008 the Commission released a staff working document ([SEC\(2011\)184](#)) on complimentary considerations on legal issues regarding GMO cultivation. The aim was to address the fear of some Member States to be legally challenged on GMO bans by the European Court of Justice (ECJ) and the World Trade Organisation (WTO). The Commission provides a list of seven reasons the countries could apply to ban GMO cultivation, including public morals, the avoidance of GMOs in other products (e.g. from organic farming), social policy objectives (e.g. occupation level in mountain areas), land use, cultural policy (e.g. societal traditions) and general environmental policy objectives (e.g. maintenance of habitats and ecosystems).

Increasing subsidiarity is anticipated to free up the procedure of authorization on the basis of health and environmental impact assessment at the EU level, previously impeded by the polarised positions of Member States. GMO-sceptic nations are free to ban cultivation without preventing the authorization on scientific grounds from being granted, so leaving proponents of GM crops to proceed.

## **Overviews of implementation**

In April 2006, the Commission published its first report on the progress of national measures for coexistence ([COM\(2006\)104](#)). By the end of 2005, specific coexistence legislation had been adopted in Germany, Denmark, Portugal and six of the Austrian Länder (see the Annex to the Communication for an overview of the state of national coexistence measures). For instance on 23 November 2005, the Commission agreed to allow a Danish compensation scheme for conventional or organic farmers who experience economic losses due to the presence of GMOs in their crops. The scheme would be financed by a special tax for GMO farmers. Denmark was the first Member State to receive this kind of authorization from the Commission. The Commission's work on coexistence is supported by an expert group established in June 2005 (Commission Decision [2005/463/EC](#)).

In 2006, the Commission published a [report](#) on GMOs in the EU which outlined the development and content of existing EU legislation and discussed current challenges. The Commission had carried out a stakeholder consultation on experiences related to Directive 2001/18/EC, which provided input to the Commission's second report on the experiences of Member States with GMOs placed on the market under Directive 2001/18/EC (COM(2007)81). This second Commission report covering Member States' their experience of the Directive between October 2002 and October 2006 was published on 5 March 2007 ([COM\(2007\)81](#)). Those Member States which had handled applications were generally positive about their experience with the implementation of the Directive, despite a number of technical issues which had yet to be adequately addressed such as a cost-effective and

practical sampling and detection system, as well as greater consistency, more detail and better allocation of responsibilities in post-market monitoring measures. Other stakeholders were less positive in their assessment of the Directive.

In April 2009 the Commission published its second report on the coexistence of GMOs with conventional and organic farming. The report provided an overview of the state of implementation of national and regional coexistence measures. Based on the findings the Commission will undertake the following actions in relation to coexistence:

- The Commission will conclude an economic impact assessment concerning the establishment of potential future seeds thresholds and propose appropriate legislative follow up based on this.
- The Commission will continue the activity of COEX-NET (The Network Group for the Exchange and Coordination of Information concerning Coexistence of Genetically Modified, Conventional and Organic Crops) to foster an exchange of information on coexistence with Member States.
- The Commission will develop technical guidance on crop-specific coexistence measures through the European Coexistence Bureau, (ECoB). The ECoB consists of a Secretariat and crop-specific Technical Working Groups.
- The Commission will report on the coexistence situation in Member States.

As part of the continuous process of reviewing the existing legislation and the improvement of its implementation, the Commission carried out an evaluation of the GMO legislation under Directive 2001/18/EC between 2009 and early 2011. The main goal was to gather information on the issues faced by those involved in the implementation of the legislative framework, and to generate ideas and options on how any problems might be addressed. It included a large scale stakeholder consultation. The study, which was published in October 2011, highlighted ways in which the legislation is not fulfilling its core objectives in the intended way, nor is it fulfilling needs and expectations, and it discussed options for improvement of the Directive, particularly regarding efficiency and transparency. Whilst the stakeholder survey found a need for a thorough debate on the options, their implications (including the national, EU and international legal issues) and timescales, it also highlighted the risks of opening up the entire legal text for review, introducing new uncertainty and risk of regulatory lock-in.<sup>2</sup>

## **Authorizations**

At EU level, a number of applications for the marketing and/or release of GMOs continue to be made, and some have been authorized. In May 2004, the *de facto* moratorium on authorization was finally broken, with the first GMO authorized since 1998. However, this development was not without controversy, and effectively opposed the position of the Member States. In accordance with EU rules, the Commission unilaterally decided to lift the *de facto* moratorium by authorizing the import, processing and marketing of a variety of GM sweetcorn (Bt 11) (note that this application was submitted under a predecessor to Regulation (EC) No 2001/18/EC, i.e. Regulation 258/97). This had become possible, after both the Regulatory Committee, charged with the authorization of GMOs, and the Council failed to reach the qualified majority needed to either accept or reject authorization. In such cases, the Commission is required to proceed with the authorization process without the approval of the Member States. Applications are, however, taken forward on a case-by-case basis, meaning that Member States can potentially block each of the applications in turn. In May and July

2004, the first GMOs were approved (also by Commission Decision) under Directive 2001/18/EC.

In August 2005, the Commission authorized another two GMOs under Directive 2001/18/EC for import and processing as animal feed (GT73: 2005/635/EC, and MON863). Both products are subject to the labelling requirements under Regulation (EC) No [1829/2003](#). For one of the approved products, the GM oilseed rape GT73, the Commission has also taken additional precaution measures by complementing the authorization Decision with a Recommendation on how to deal with spillage throughout the distribution chain ([2005/637/EC](#)). In November 2005, GM Maize 1507 became the fourth product to be authorized after the entry into force of Directive 2001/18/EC. Since this product had also been notified for use in food, this Decision could not enter into force until the same GMO had also been authorized for use in food. Such authorization was granted GM Maize 1507 under Regulation (EC) No [1829/2003](#) in March 2006. In January 2006, the Commission authorized *Zea mays* L. hybrid MON863x810 for import and industrial processing (under Directive 2001/18/EC; a parallel application concerning the same product for use in feed has been submitted under Regulation (EC) No 1829/2003), and GA21 and MON863 for use as food and food ingredients. GA21 and MON863 were the last products to be authorized under the Novel Food Regulation (EC) No 258/97 (which preceded Directive 2001/18/EC and which has been replaced by Regulation (EC) No 1829/2003 since 18 April 2004). The placing on the market of oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) genetically modified for tolerance to the herbicide glufosinate-ammonium, authorized by the Commission in 2007 (Decision [2007/232/EC](#)). Some Member States had raised concerns relating to this notification referring to *inter alia* allergenicity, toxicity, the proposed monitoring plan and accidental spillage. Nevertheless, the three *Brassica napus* L. lines were judged safe by the European Food Safety Authority (EFSA) for import and processing, including use in feed. EFSA also agreed to the suggested monitoring plan for these uses. In all of the above instances, the Commission obtained the power to adopt a Decision autonomously as a consequence of the Council failing to act by a qualified majority for or against the proposal. The Decision to authorize the use of the three GM oilseed rape products for a period of ten years was adopted by the Commission on 17 April 2007 (Decision 2007/232/EC). Commission Decision [2009/244/EC](#) allowed the placing on the market of the GM carnation *Dianthus carophyllus* which has been modified for flower colour. A Decision regarding is still pending. The GM potato product *Solanum tuberosum* L. Line EH92-527-1 was approved by the Commission on the 2 March 2010 (Decision [2010/135/EU](#)) for cultivation and industrial use, following failure to win a qualifying majority for or against the proposal in votes of the Council in February and July 2007.

## **Member States' reactions**

Strong feelings against GMOs remain in certain EU Member States, and there have been a number of attempts by Member States to restrict either growth or approval of GMOs in certain regions under the safeguard clauses of either the deliberate release Directive (previous and current) or Article 95 of the EC Treaty. Cases have included attempts by Austria, Luxembourg and France to ban the commercial growth of Bt maize on their national territories after it was authorized by the EU in 1996, by Wales to impose greater separation distances between GM and non-GM crops in 2001, and by Austria to declare the Upper Austria Region a GM-free zone in 2003.

The Austrian Permanent Representation, in a letter to the European Commission dated 13 March 2003, notified the Commission pursuant to Treaty Article 95(5) of a draft Upper Austrian Act on the prohibition of genetic engineering 2002. The ban was designed as a temporary measure for three years, banning the use of GMOs (including seeds and other planting materials) in the Region of Upper Austria in derogation of the provisions of the Directive. The main aim of the proposed Act was to protect conventional, especially organic, farming and other production systems (e.g. forestry), as well as natural biodiversity from damage through genetic contamination. In addition, it was considered necessary also to protect traditional agricultural crops from cross-pollination. To this end, the draft legislation primarily sought to ban the use of GM seeds – including those with Community authorization – recognizing, however, the need to accept adventitious traces of GM seeds in conventional stocks to a level of 0.1 per cent for both authorized and non-authorized varieties. It also sought to ban transgenic animals for breeding and in particular their release for hunting and fishing. The region of Upper Austria would have provided compensation in the case of monetary losses suffered by individuals due to the presence of GMOs in conventional products. The following key points were given for justification:

- The type and level of risk associated with the use of GMOs.
- The current inability to rule out long-term negative effects on domestic and wild varieties.
- The inability to control co-existence of GM and conventional varieties.
- The impracticability of carrying out the procedure of provisionally restricting or prohibiting the use and sale of certain GMOs under Article 23 of the Directive following every approval procedure conducted in relation to a GMO.

In accordance with an independent study, it was concluded that ‘genetically modified-free areas represent the only approach, which could ensure long-term security in relation to the problems of coexistence within the small structured Austrian agricultural sector’, particularly in Upper Austria.

In its Decision [2003/653/EC](#) on the proposed Austrian Act, the Commission concluded that the draft provisions were incompatible with those set out in Directive 2001/18/EC, and thus rejected the draft national legislation. In particular, the Commission considered the proposed ‘blanket ban’ in contradiction with the principal of case-by-case analysis required by the Directive. Member States, in the Commission's view, do not have discretion in judging which quantities of GMOs are dangerous, and to introduce thresholds. Moreover, the Commission sought the scientific opinion of the EFSA on the issue of novelty of evidence. EFSA concluded that the scientific information presented in the Austrian report ‘provided no new data that would invalidate the provisions for the environmental risk assessment established under Directives 90/220/EEC and 2001/18/EC’. EFSA also found that the information provided ‘no new scientific evidence, in terms of risk to human health and the environment, that would justify a general prohibition of cultivation [...] and use’ of GMOs. Moreover, it was noted that ‘no scientific evidence was presented which showed that Austria had unusual or unique ecosystems that required separate risk assessments’. Finally, the Commission pointed out that ‘recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty’. The Commission based this interpretation on the Court of Justice's analysis of the precautionary principle in earlier judgments, in which it held that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been ‘fully’

demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken. Therefore, the Commission considered that Austrian references to the precautionary principle are ‘too general and lack substance’, particularly as the EFSA had not identified a risk that would justify taking action on the basis of the precautionary principle at Community or national level. The Commission's Decision was challenged in the ECJ by the Land of Upper Austria and the Republic of Austria but their joint action for annulment was dismissed by the Court of First Instance on 5 October 2005 and their appeal against this judgment rejected by the Court of Justice on 13 September 2007 ([Joined Cases C-439/05 P and C-454/05 P](#)).

In September 2004, the Commission listed 17 seed varieties of MON 810 maize in the EU Common Catalogue of Seeds. This Decision received criticism by a majority of the Member States referring to the lack of coexistence regulations. In April 2005, Greece had notified the Commission of a provisional prohibition for the 2005 and 2006 growing seasons, of the marketing of 17 maize hybrids listed in the common catalogue of seeds. In January 2006, the Commission ordered Greece to lift its national ban on cultivation of GM maize seeds. It issued a proposal to deny the Greek ban claiming that the maize varieties concerned do not pose any health or environmental risks. When the Council voted on the proposal in June 2005, it was unable to act by a qualified majority and consequently the dossier was returned to the Commission for adoption within three months. Despite this, in January 2006, the Greek authorities extended the scope of the ban. Likewise, in January 2006, the Hungarian government announced that it will extend its national ban on cultivation of GM maize (MON810), which was introduced in January 2005.

On 9 October 2006, the Commission resubmitted to the Council two proposals to require Austria to lift the bans imposed on the marketing of two GM maize varieties (MON810 and T25) ([COM\(2006\)509](#); [COM\(2006\)510](#)). The proposals were again rejected by the Environment Council on 18 December 2006. One of the key supporting arguments was that different agricultural structures and regional ecological characteristics in the EU need to be taken into account in a more systematic manner in environmental risk assessment of GMOs. The two proposals were discussed in the Council for the third time on 30 October 2007. However, no qualified majority for either adoption or rejection of the proposals could be obtained. In February 2007, the Environment Council had also rejected a proposal by the Commission to request Hungary to lift its national ban ([COM\(2006\)713](#)). One of the motivations behind rejecting the proposal was that the GMO in question had not yet undergone risk assessment under the current rules.

Though the Commission continued pushing against national bans and proposed the lifting of the safeguard clauses previously imposed by Austria, France, Germany, Greece and Luxembourg on eight authorised GM products, in May 2006 the Commission also agreed to a Polish ban on the use of 16 varieties of genetically modified (GM) maize and around 700 varieties of non-GM maize listed in the EU Common Catalogue of Seeds, with the motivation that they are not suitable for the climatic conditions in Poland.

Member States concerned about the safety of GMOs maintained their pressure on the Commission and the EFSA to improve risk assessment procedures. A meeting between the EFSA and Member State experts in May 2006 resulted in a statement by the EFSA which indicated that it would seek more collaboration and dialogue with Member States. In May 2007, the European Commission, following the line of many of the Community's Member States, underlined its precautionary stance with regard to GM technology by stalling on a

Decision to authorize the cultivation of a number of genetically modified crops in the EU. This was justified on the basis of evidence suggesting that two types of hybrid maize being considered for approval produce an insecticide that could negatively impact wildlife. At the same time a Decision on a type of GM potato was delayed since it contains a gene which results in resistance to anti-biotics, thus potentially impacting on human health.

Following the decisions of an increasing number of Member States to ban the cultivation of GM maize MON 810, in September 2009, soon after his confirmation in office for a second term, Commission President Barroso stated he would 'respect the freedom for Member States to decide whether or not they wish to cultivate GMOs on their territory'. Soon after in November 2009, the Commission was notified by Portugal on a Regional legislative decree declaring the autonomous region of Madeira to be an area free of genetically modified organisms pursuant to Article 95(5) of the EC Treaty. In its justification, Portugal referred to agricultural reasons such as the impossibility of co-existence between GM crops and conventional and/or organic crops in the area, and natural reasons, inter alia the invasive capacity of GM varieties.

The possibility of an increased subsidiarity on the cultivation of GMO crops was subsequently discussed in a Council meeting of the EU Agriculture Ministers at the end of 2009. The July 2010 package on GMO cultivation delivered on this agenda, essentially providing Member States the right to ban cultivation of GMOs for grounds other than health or environmental reasons (which would continue to be solely assessed by the European Food Safety Authority).

Both sides on the GM debate showed dissatisfaction with the package. The anti-GMO camp expresses fears that it is a token measure to appease GMO-sceptical Member States, masking a deregulation of the authorisation procedure and fast-track approval. NGOs judge that the grounds for opt-outs are legally vulnerable. In March 2010 Greenpeace and Avaaz<sup>3</sup> delivered a petition to the Commissioner for Health and Consumer Policy John Dalli, calling for a 'moratorium on GM crops and the creation of an independent, scientific and ethical body to research the impacts of GM crops and to determine regulation'. The petition was the first of its kind to be presented under the European Citizens' Initiative, signed by over one million EU citizens (see section on [public participation](#)). As the initiative was not yet formally approved and entered into force, the Commission has not acted upon the petition so far. Conversely, pro-GMO states and stakeholders such as the biotechnology industry declare it is a dangerous break from science-based policy. At a more fundamental level, concerns have been raised (France, Belgium) that the move undermines the "Community method" and sets an unwelcome precedent for reversing integration and the seeking of common, cross-border solutions to policy issues. Negotiations in the Council of Ministers are currently blocked, whilst in July 2011 the European Parliament adopted in its first reading a legislative [resolution](#) on the proposal for a regulation that backs Member States' right to ban GM crops on environmental grounds as well as other grounds (such as socio-economic, ethical or moral). In April 2011 the Commission's report ([COM\(2011\) 214](#)) on Member States' responses to its questionnaire on socio-economic implications of GMO cultivation concluded that understanding of the meaning and scope of the socio-economic dimension of GMO cultivation varies widely, and suggested the initiation of 'an advanced reflection at European level, with sound scientific basis' with wide stakeholder involvement in particular to define a set of factors that capture the actual ex ante and ex post socio-economic consequences of |GMOs cultivation, taking into consideration Member States' expertise and approaches. Funding has been allocated for further studies and a series of conferences. The Commission

followed up by launching on 18 October 2011 a process to help Member States collect and share information.

In March 2012, the Council discussed, on the basis of a compromise text from the Danish Presidency, the July 2010 package on GMO cultivation for a regulation amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation, in all or part of their territory of GMOs that have been authorised at EU level on grounds other than health and environment. Although a large number of Member States could accept the presidency proposal, it was not yet possible to reach agreement in the Council. Some Member States still expressed concern regarding: the compatibility of the regulation with the World Trade Organisation rules, as well as how to avoid overlaps and/or inconsistencies between the mandatory risk assessment at EU level and national government measures.<sup>4</sup>

## **The United States of America and the World Trade Organization**

The Commission has maintained pressure on Member States to end their individual bans on new GMOs, which together constitute the *de facto* moratorium, but a number of resistant Member States refused to lift their bans before the entry into force of all the new legislative safeguards contained in the Commission's Strategy. Finally, after repeated threats, the United States brought a WTO case against the EU over the moratorium in May 2003. The United States took this action despite there being no formal moratorium at EU level and despite the fact that subsequent to the entry into force of Directive 2001/18/EC there had been approvals of new GMOs by the EU. The European Commission responded to the United States' action by referring to the fact that the proposals for new regulations on GM food and feed and traceability and labelling would be in place and the Member States could drop the moratorium before the WTO dispute panel would have time to make a judgment on the case. While the *de facto* moratorium was indeed lifted (see below), the WTO dispute settlement proceedings were continued, and the WTO Panel issued its final report in September 2006, in which it found that the EU had violated several of its obligations under the WTO agreements. The EU decided not to lodge an appeal against the judgment, as it was not thought to have any implications for the prevailing regulations<sup>5</sup>. In a related development, an NGO brought a complaint against the European Commission for refusing access to one of the key documents of the WTO dispute which expresses some uncertainty regarding the safety of GMOs. In July 2006, a Decision of the European Ombudsman [[Decision of the European Ombudsman](#)] concluded that the Commission's refusal to grant access to the document was not well founded and thus a case of maladministration.

Despite the revised Recommendation pertaining to co-existence of GM, organic and conventional crops and the opening to authorizations anticipated to emerge as a consequence, US farming lobbies called for trade sanctions to be imposed by the US government on the EU in July 2010 (Actions to increase US agricultural exports – American Farm Bureau Federation), following the 2006 ruling of the WTO.

## **Organic farming**

The development of GMO and coexistence legislation is related to the rules for organic farming, labelling in particular. In March 2005, the Parliament adopted an own-initiative report on organic food and farming. On 21 December 2005, the Commission published proposals for revised rules on organic farming and labelling ([COM\(2005\)671](#)). The proposals were one of the main outcomes of the European Action Plan for Organic Farming and Food

of June 2004 and the subsequent response of the Council in its conclusions of October 2004. One of the proposals concerned amendment to Regulation (EC) No [2092/92](#), which set the original EU standards for organic farming. The amending Regulation was published in February 2007 ([OJ L027 02.02.2007](#)). A second proposal presented a revised framework for rules on certified organic production and labelling. A political agreement on this proposal was reached in the Council meeting of June 2007, leading to the adoption of the Council Regulation (EC) No [834/2007](#) on organic production and labelling of organic products repealing Regulation (EEC) No [2092/91](#). The new Regulation entered into force on 1 January 2009. The Regulation bans the use of GMOs in organic food; however, it allows for products containing up to 0.9 per cent of 'adventitious or technically unavoidable' GMO content to be labelled and sold as organic. This 0.9 per cent threshold was, however, regarded as a disappointment by the Parliament and several environmental groups that had called for reducing the threshold for GMO presence in organic products to 0.1 per cent.

## Enforcement and court cases

The following cases have been concluded in the European Court of Justice relating to Directive 2001/18/EC:

- [C-442/09](#). This was a judgement on contamination by GM Maize MON810 of honey and pollen products. This ruling further challenged EU laws on GMO co-existence and paved the way for compensation claims to farmers and beekeepers whose crops were contaminated by GMO cultivations.
- Joined cases [C-58/10 to C-68/10](#). These cases considered the lawfulness of two provisional national measures which suspended and then prohibited the use of seeds of GM maize MON810 varieties in France whilst the EU authorization for MON810 varieties is pending renewal. The European Court of Justice ruled that the a French ban based on Article 23 of Directive 2001/18/EC was not legitimate; however Member States are entitled to adopt national bans of those GM crops that are pending renewal of authorization by the EU if the bans are pursuant to Article 34 of Regulation (EC) No 1829/2003, which authorizes a Member State to adopt emergency measures if they can establish the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health or the environment. The Court also considered that it is the responsibility of the French national court to ascertain whether such a ban would be compliant with Regulation (EC) No 1829/2003.
- Joined Cases [C-439/05 P and C-454/05 P](#). This was an appeal by the Province of Upper Austria and the Austrian Republic against a Commission Decision that had determined the act prohibiting genetic engineering to be incompatible with Directive 2001/18/EC. They lost the appeal. For more information see the further developments section.
- [C-165/08](#). This was a judgement against Poland for the incompatibility of its Law on Seeds with the system of free circulation established by Articles 22 and 23 of Directive 2001/18/EC.

In a judgment of 17 February 2009, the European Court of Justice has interpreted the provisions of Directive 2001/18/EC on the deliberate release of GMOs as requiring extensive disclosure of information to the public. In principle, all information submitted to the competent authorities by the notifier is to be disclosed. Considerations relating to public order

and security cannot be invoked to refuse disclosure of information relating to the location of a release.

## Related legislation

The following legislation and policy has a strong interaction with Directive 2001/18/EC on the deliberate release of GMOs:

- Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and the traceability of food and feed products from [GMOs](#).
- Regulation (EC) No 1829/2003 on [GMOs – food and feed](#).
- Regulation (EC) No 1946/2003 on the transboundary movements of [GMOs](#).
- Directive 79/409/EEC on the conservation of [wild birds](#) and Directive 92/43/EC on the conservation of natural habitats and of [wild fauna and flora](#) as well as [EU biodiversity policy](#).
- Common Agriculture Policy and [related legislation](#).
- Forestry and [related legislation](#).

The Directive affects and is affected by provisions set in the framework of legislation on GMOs, in particular regarding their cultivation and labelling. Due to issues such as co-existence between conventional, organic and GM crop production, or the use of genetically modified trees in the forestry sector, Directive 2001/18/EC also has strong interactions with the Common Agriculture Policy and policy instruments implemented for the forestry sector. In addition, this Directive plays an important role with regards to the two nature Directives and EU biodiversity policy due to the potential impact of the release of GMOs into the environment on Europe's wild flora and fauna, and biodiversity.

## References

1 European Commission website,

[http://ec.europa.eu/agriculture/publi/reports/coexistence2/speak\\_en.pdf](http://ec.europa.eu/agriculture/publi/reports/coexistence2/speak_en.pdf)

2 European Commission (2011), Evaluation of the EU Legislative Framework in the Field of Cultivation of GMOs,

[http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo\\_cultivation\\_report\\_en.pdf](http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo_cultivation_report_en.pdf)

3 European Commission, Midday Express, GMOs: Commissioner Dalli receives a petition from Greenpeace and Avaaz, 09/12/2010

<http://europa.eu/rapid/pressReleasesAction.do?reference=MEX/10/1209&format=HTML&aged=0&language=EN&guiLanguage=en>

4 The Council of the European Union, Press Release, 3152<sup>nd</sup> Council meeting, 09/03/2012, [http://www.consilium.europa.eu/ueDocs/cms\\_Data/docs/pressData/en/envir/128883.pdf](http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/envir/128883.pdf)

5 Euractiv 22/11/06 <http://www.euractiv.com/en/trade/eu-accepts-trade-ruling-gmos/article-159918>