Manual of
EUROPEAN
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POLICY

Manual of European Environmental Policy

The following pages are a section from the Manual of European Environmental Policy written by the Institute for European Environmental Policy.

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This section is the text of the Manual as published in 2012. It is therefore important to note the following:

- The contents have not been updated since 2012 and no guarantee is given of the accuracy of the contents given potential subsequent developments.
- The sections include links to external websites (e.g. to legal texts). These links continue to work as long as those links are not broken by those websites.
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Institute for European Environmental Policy

Genetically modified organisms: Transboundary movements

Formal references	
Regulation (EC) No 1946/2003 (OJ L287 5.11.03)	Regulation on the transboundary movements of genetically modified organisms
Proposed 18.2.2002 – COM(2002)85	
Legal base	Article 175(1)
Binding dates	
Entry into force	25 November 2003
Notification on penalty measures	5 November 2004
Commission implementation report	Intervals to be determined
Member State implementation reports	At regular intervals at least every three years

Purpose of the Regulation

The Regulation establishes a common system of notification and information for the transboundary movement of genetically modified organisms (GMOs). It thus complements other Community measures on the use of GMOs (see Sections on; GMOs: contained use; GMOs: deliberate release; GMO's: food and feed; and GMOs: traceability and labelling) by establishing an adequate level of protection for the safe transfer, handling and use of GMOs, taking into account risks to biodiversity and human health. In particular, it responds to concerns about the international movement of GMOs, including imports into the Community from third parties. The Regulation thus establishes amongst others procedures for the keeping of information in a widely accessible form on the Biosafety Clearing-House. This means that the Regulation is also the Community's main implementation tool for the Cartagena Protocol on Biosafety to The Convention on Biological Diversity.

Summary of the Regulation

Regulation (EC) No 1946/2003 is the EU's implementation tool for the Cartagena Protocol on Biosafety In particular, it regulates transboundary movements of GMOs, that is the intentional or unintentional movement of a GMO between one Party or non-Party to the Cartagena Protocol and another Party or non-Party. Intentional movements between Parties within the Community are excluded. It does so in accordance with the precautionary principle, and without prejudice to the provisions of Directive 2001/18/EC on the deliberate release into the environment of GMOs. GMOs are as defined in Directive 2001/18/EC.

The Regulation applies to the transboundary movements of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health. Pharmaceuticals for human use are not included as these are addressed by other relevant international agreements or organizations.

The Regulation distinguishes between the (intentional) export of GMOs and unintentional transboundary movements. It further specifies different provisions for:

- GMOs intended for deliberate release into the environment.
- GMOs intended for direct use as food or feed, or for processing.
- GMOs intended for contained use.

Three Annexes specify the information that must be provided under the various notification and information requirements of the Regulation. In particular, Annex I lists the information required in notifications of GMOs to be imported and intended for deliberate release into the environment; Annex II lists the information which has to be transmitted to the Biosafety Clearing-House (to be established under the Protocol) with regard to decisions on use and marketing of GMOs intended for direct use as food or feed, or for processing. Annex III lists information which has to be provided in the case of a release of a GMO that leads, or may lead, to an unintentional transboundary movement that is likely to have significant adverse effects on the conservation and sustainable use of biodiversity, taking risks to human health into account.

Export of GMOs intended for deliberate release into the environment

The exporter has to ensure notification, in writing, to the competent authority of the proposed importing country, whether or not a Party to the Cartagena Protocol. This must occur prior to the first intentional transboundary movement of a GMO intended for deliberate release into the environment (see Section on GMOs: deliberative release) and destined for the use specified in accordance with Annex I of the Regulation. The notification has to contain, at least the information specified in Annex I, and the exporter is to ensure the accuracy of this information. Without prior written consent of the importers, no first intentional transboundary movement of GMOs may be made. Failure by the importing country to acknowledge receipt of a notification or to communicate its Decision in response to a notification must not be taken to imply consent to a transboundary movement. Moreover, the exporter must not proceed with the first intentional transboundary movement of a GMO, unless the appropriate import procedures on acknowledgement of receipt and Decision have been followed. For Parties to the Protocol these are set out in Articles 9 and 10 of the Protocol, equivalent procedures required by non-Parties also need to be followed.

Where the Party of import does not communicate its decisions within 270 days from the date of receiving the notification, the exporter is required to send a written reminder to its competent authority, with a deadline for response of 60 days from receipt. A copy of this is also to be sent to the Secretariat of the Cartagena Protocol, to the Member State exporting, and to the Commission. Exceptions are made for cases of transboundary movements covered by simplified procedures or bilateral, regional and multilateral agreements, or arrangements entered into in accordance the Protocol.

The Commission and the Member States are to facilitate decision-making and promote compliance with the provisions of the Protocol. This is to take place in consultation with the Secretariat of the Cartagena Protocol.

The exporter is required to keep a record of the notification, the acknowledgement of receipt and the Decision of the importing country for a minimum of five years. The exporter also has to send a copy of these documents to the competent authority of the Member State from

which the GMO is exported and to the Commission. The Commission is to make these documents available to the public in accordance with EU rules on access to environmental information.

A review of the Decision on notification may be requested of the Party or non-Party of import, if the exporter considers that a change in circumstances has occurred that may influence the outcome of the risk assessment upon which the Decision was based, or that additional relevant scientific or technical information has become available. Where no response to such a request is given within 90 days, the exporter may send a written reminder to the competent authority of the importing country, with a copy to the Secretariat of the Cartagena Protocol, requesting a response within a set period following receipt of the reminder.

Rules on notification and consent do not apply to GMOs intended for deliberate release and identified as being unlikely to have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health. An evaluation of impact on conservation and sustainable use is to be based on a Decision taken by the Conference of the Parties to The Convention on Biological Diversity serving as the Meeting of the Parties to the Protocol. Importantly, these rules also do not apply to GMOs intended for direct use as food or feed, or for processing. Moreover, where the Party of import has specified in advance to the Biosafety Clearing-House that certain imports of GMOs are to be exempt from the Advance Informed Agreement Procedure set out under the Biosafety Protocol, these are then also exempt from the above rules on notification and consent. Adequate measures must still be applied to ensure their safe intentional transboundary movement in accordance with the objective of the Protocol.

The following general information has to be provided by the exporter for all exports in a document accompanying the GMO, and has to be transmitted to the importer:

- A declaration stating that the export contains or consists of GMOs.
- The unique identification code(s) assigned to those GMOs, if such codes exist.

In addition, the exporter has to supply a declaration, setting out:

- The identity and relevant traits and characteristics of the GMOs.
- Any requirements for the safe handling, storage, transport and use of these GMOs.
- The contact point for further information and, as appropriate, the name and address of the importer and exporter.
- A declaration that the movement is in conformity with the requirements of the Protocol applicable to the exporter.

The identification and accompanying documentation is without prejudice to other specific requirements imposed by Community legislation and to international identification requirements to be developed in accordance with Article 18 of the Cartagena Protocol.

For exports in transit, the exporter must ensure notification of the transit of GMOs to Parties that have taken the Decision to regulate transit of GMOs through their territory and have informed the Biosafety Clearing-House of this decision.

Export of GMOs intended for direct use as food or feed, or for processing

The Commission on behalf of the Community or, where appropriate, the relevant Member State is to inform the Biosafety Clearing-House and, through it, other Parties of any final Decision regarding the use, including placing on the market, within the Community or use within a Member State (see Section on GMOs – food and feed), of a GMO that may be subject to transboundary movements for direct use as food or feed or for processing. This information is to be made available within 15 days of the adoption of the decision, and has to contain as a minimum the information specified in Annex II to the Regulation.

If any of the national focal points, designated under the Cartagena Protocol to act as links to the Secretariat, do not have access to the Biosafety Clearing-House, a copy of the relevant information must be sent to the focal point in writing. Requests from any Party or non-Party for additional information regarding the decisions on the use and marketing in the Community of likely candidates for transboundary movements have to be submitted to and processed by the Commission or the Member State which has taken the decision.

No GMO that may be subject to transboundary movements for direct use as food or feed, or for processing may be exported, unless it is authorized within the Community, or the competent authority of a third country has expressly agreed to the import as required under Regulation (EC) No 178/2002 concerned with food law and food safety procedures. Failure by the importing country to acknowledge receipt of a notification or to communicate its Decision on the basis of an impact assessment and within a predictable timeframe must not be taken to imply its consent or refusal to the import of a GMO intended for direct use as food or feed, or for processing.

Any Decision on the import of GMOs for such uses and taken by the importing country under its domestic regulatory framework, provided it is consistent with the objective of the Cartagena Protocol, must be respected by the exporter. There is a special condition for importers which are from developing countries or countries in transition, and which have declared through the Biosafety Clearing-House that they will take a Decision prior to an import of a specific GMO intended for direct use as food or feed, or for processing, on the basis of a risk assessment undertaken in accordance with Annex III of the Cartagena Protocol, and within a predictable timeframe, not exceeding 270 days. In these cases, the exporter shall not proceed with the first export of such GMOs, unless these conditions have been met.

The following general information has to be provided by the exporter for all exports, in a document accompanying the GMO, and has to be transmitted to the importer:

- A declaration stating that the export contains or consists of GMOs.
- The unique identification code(s) assigned to those GMOs if such codes exist.

For GMOs intended for direct use as food or feed, or for processing, the exporter in addition has to supply a declaration:

- Stating that the GMOs are intended for direct use as food or feed, or for processing, indicating clearly that they are not intended for deliberate release into the environment.
- Giving details of the contact point for further information.

An exception is made for products consisting of, or containing mixtures of, GMOs to be used only and directly as food or feed, or for processing, where information on contact points is not required. These products are to be subject to the traceability requirements under Directive 2001/18/EC and, when applicable, future Community legislation covering traceability, labelling and identification of such GMOs.

The identification and accompanying documentation is without prejudice to other specific requirements imposed by Community legislation and to international identification requirements to be developed in accordance with Article 18 of the Cartagena Protocol.

For exports in transit, the exporter must ensure notification of the transit of GMOs to Parties that have taken the Decision to regulate transit of GMOs through their territory and have informed the Biosafety Clearing-House of this decision.

Export of GMOs intended for contained use

The provisions on notification and consent for GMOs intended for deliberate release do not apply to transboundary movements of GMOs intended for contained use. In this case, transboundary movements are undertaken in accordance with the standards of the importing country, without prejudice to any right of a Party or non-Party to subject all GMOs to risk assessment prior to decisions on import and to set standards for contained use within their jurisdiction.

The following general information has to be provided by the exporter for all exports in a document accompanying the GMO and has to be transmitted to the importer:

- A declaration stating that the export contains or consists of GMOs.
- The unique identification code(s) assigned to those GMOs if such codes exist.

This needs to be supplemented by a declaration specifying:

- Any requirements for the safe handling, storage, transport and use of these GMOs.
- The contact point for further information, including the name and address of the individual or institution to whom or which the GMOs are consigned.

This information is without prejudice to other specific requirements imposed by Community legislation and to international identification requirements to be developed in accordance with Article 18 of the Cartagena Protocol.

For exports in transit, the exporter must ensure notification of the transit of GMOs to Parties that have taken the Decision to regulate transit of GMOs through their territory and have informed the Biosafety Clearing-House of this decision.

Unintentional Transboundary movement of GMOs

Member States have to take appropriate measures to prevent unintentional transboundary movements of GMOs. As soon as a Member State becomes aware of an occurrence, under its jurisdiction, resulting in a release of GMOs that leads, or may lead, to an unintentional transboundary movement that is likely to have significant adverse effects, that Member State must:

- Take the appropriate measures to inform the public and inform without delay the Commission, all other Member States, affected or potentially affected States, the Biosafety Clearing-House, and, where appropriate, relevant international organizations.
- Without delay consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures in order to minimize any significant adverse effects.

Any information arising from paragraph 2 shall include the information specified in Annex III to the Regulation.

Participation in the international information procedures

The Member States are required, without prejudice to the protection of confidential information and in accordance with the provisions of the Cartagena Protocol, to inform the Biosafety Clearing-House and the Commission of:

- National legislation and guidelines relevant to the implementation of the Cartagena Protocol.
- National contact points for notification of unintentional transboundary movements, as required by the Protocol.
- Any bilateral, regional and multilateral agreement and arrangements entered into by the Member State regarding intentional transboundary movements of GMOs.
- Any information concerning cases of unintentional or illegal transboundary movements pertaining to them.
- Any final Decision taken by a Member State, on the use of GMOs within that Member State, including decisions:
    - on contained use classified in risk class 3 or 4 (see Section on GMOs – contained use) of GMOs which are likely to be subject to transboundary movements;
    - on the deliberate release of GMOs in accordance with part B of Directive 2001/18/EC; and
    - on import into the Community of GMOs, must be forwarded within 15 days of the adoption of that decision.
- Any summary of risk assessments or environmental reviews of GMOs generated by the Community's regulatory process and carried out in accordance with the Protocol, including, where appropriate, relevant information regarding products thereof.
- vii) Any review of national decisions regarding an intentional transboundary movement.
- viii) Any Decision taken by a Member State on safeguard measures under Directive 2001/18 or emergency measures taken by a Member State under Community legislation on genetically modified food and feed.

The Commission, in accordance with the provisions of the Protocol, has to inform, on behalf of the Community, the Biosafety Clearing-House of:

- Community legislation and guidelines relevant for the implementation of the Protocol.
- any bilateral, regional and multilateral agreement and arrangements at Community level regarding intentional transboundary movements of GMOs.

- any final Decision taken at Community level regarding the use of a GMO within the Community, including decisions on the placing on the market or the importation of a GMO.
- any summary of risk assessments or environmental review of GMOs generated by the Community regulatory process and carried out in accordance with procedures similar to those laid down in Annex II to Directive 2001/18/EC, including, where appropriate, relevant information regarding products thereof.
- any review of decisions at Community level regarding an intentional transboundary movement.
- any application of Community legislation instead of the procedures of the Protocol for intentional movements of GMOs within the Community and imports of GMOs into the Community.
- reports submitted pursuant to Article 19 of Regulation (EC) No 1946/2003, including those on implementation of the advanced informed agreement procedure.

Confidentiality

The Regulation also provides for a common standard of confidentiality amongst the Member States and the Commission. Importantly, the Commission and the Member States may not reveal to third parties any confidential information received or exchanged under this Regulation. To this end, the exporter may indicate what information in the notification of export of a GMO intended for deliberate release into the environment should be treated as confidential. In such cases, the exporter has to provide justification upon request.

However, it is under no circumstances permitted to keep the following information confidential:

- Name and address of the exporter and importer.
- General description of the GMO or GMOs.
- A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
- Any methods and plans for emergency response.

If, for whatever reasons, the exporter withdraws the notification, the Member States and the Commission must respect the confidentiality of commercial and industrial information, including research and development information, as well as information on which the Party or non-Party of import and the exporter disagree as to its confidentiality.

Competent authorities and focal points

The Commission has to designate a Community focal point and, where appropriate, identify any Community competent authority. Likewise, each Member State is required to designate one focal point, and one or more competent authorities, although a single entity may fulfil the functions of both focal point and competent authority. The Commission, on behalf of the Community, and each Member State respectively has to, no later than the date of entry into force of the Protocol, inform the Secretariat of the names and addresses of their focal points and their competent authorities. Where a Member State or the Commission designates more than one competent authority, it must include relevant information on the respective responsibilities of those authorities. Where applicable, such information, as a minimum, is to specify which competent authority is responsible for which type of GMO. The Commission

and the Member States are then required to inform the Secretariat of any changes in the designation of their focal points or in the name and address or responsibilities of their competent authorities.

Penalties

The Member States are required to lay down the rules on penalties applicable to infringements of the provisions of the Regulation and must take all measure necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive, and Member States have to notify relevant provisions to the Commission, no later than 5 November 2004. The Commission has to be notified without delay of any subsequent amendment affecting them.

Monitoring and reporting

At regular intervals and at least every three years, unless otherwise determined under Article 33 of the Cartagena Protocol, Member States have to forward to the Commission a report on the implementation of this Regulation. Subsequently, the Commission must, at intervals to be determined by the Conference of the Parties to The Convention, compile a report on the basis of the information provided by the Member States and present it to the Conference of the Parties.

Development of the Regulation

The Cartagena Protocol on Biosafety was adopted on 29 January 2000, and the EC ratified it in June 2002. It is a supplementary agreement to the UN Convention on Biological Diversity. The overall objective of the Biosafety Protocol is to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on biodiversity, taking into account risks to human health, and specifically focussing on transboundary movements.

The Protocol is based on the precautionary approach and establishes a procedure to ensure that countries are provided with the information necessary to make informed decisions before agreeing to the import of GMOs into their territory. It entered into force in September 2003. The EU played a leading role in the conclusion of the Protocol and its rapid ratification was seen to be an important and strong political signal of commitment.

In February 2002, the Commission first proposed a Regulation on the cross-border movement of GMOs (COM(2002)85), to serve as the main implementation tool for the Cartagena Protocol. The Commission stated that it considered the proposed measures essential for the protection of biodiversity at international level, particularly in developing countries. The proposal complemented existing EU legislation on biotechnology, mainly in the field of exporter obligations and information sharing at international level and the deliberate release of GMOs (see Section on GMOs – contained use) but did not entail any modification of the existing legal framework, which had been proven consistent with the provisions of the Protocol.

The main new elements of the proposal were:

- Notification obligations for exports of GMOs intended for deliberate release into the environment.
- Information obligations at international level on EU practices, legislation and decisions on GMOs, particular with regard to rules for identification of GMOs for exports in line with the then proposed Regulation (EC) No 1830/2003 on traceability and labelling.

The Proposal did not cover imports and intra-EU movements of GMOs as such.

The Protocol permits the use of existing legislation if consistent with the requirements of the Protocol. Existing EU legislation was considered adequate. The only exception concerned unintentional transboundary movements of GMOs, where, in accordance with the Protocol, rules for information were proposed.

In a report. published in 2002, the Parliament criticized the proposal for not being explicit enough about the need for a precautionary approach, and for being open to 'a great deal of room for interpretation'. It also expressed the view that the Community should take a lead in assisting developing countries in their attempts to apply the Protocol and in developing their capacity to do so. In its first reading, the Parliament thus duly adopted a number of key amendments alongside some more practical changes. In particular these concerned:

- The requirement for prior written consent of the importing country for the export of GMOs intended directly or indirectly for release into the environment.
- The requirement for exporters to respect decisions of importing counties regarding GMOs indented for direct use as food or feed, or for processing.
- The need to prohibit all exports to third countries of GMOs which are not authorized for use in the EU (with one exception).
- The need for exporters rather than 'notifiers' to be responsible for the accuracy of export notification.
- Issues of liability.
- Changes in the exclusion clause for pharmaceuticals.
- Changes in the provisions for information sharing.
- The need for Member States to be required to prevent unintentional trandboundary movements of GMOs.

The Commission, subsequently, did not accept reference in the proposed Regulation to the EU's role in capacity building and on liability, proposing that these might be dealt with in more suitable EU instruments on development and liability. It further recalled that 'limiting Community exports to GMOs that have been approved into the EU for direct use as food or feed, or for processing, […] contradicts Article 12 of Regulation (EC) No 178/2002/EC laying down the general principles and requirements of food law'. Moreover, the Commission believed that the concept of unintentional transboundary movements mainly refers to accidents, and is thus already adequately covered by Community legislation, notably Directive 2001/18/EC. It therefore rejected amendments on an obligation to prevent such movements (COM(2002)578).

The Council agreed to tighten up the obligations imposed on exporters from the Community going beyond what is required by the Cartagena Protocol. The Council accepted most of the

Parliamentary amendments, at least partially. Against the view of the Commission, the Council accepted that there should be no export without prior consent and that Member States should prevent unintentional transboundary movements. However, the Council did not agree with the need for *written* consent, nor did it categorically rule out exports where the importing party had not replied to a notification. Moreover, in the opinion of the Council, only 'first' transboundary movements should be notified and await consent, and only exports of GMOs which are intended for release should be notified. GMOs intended for food or feed, or for processing which were not authorized in the Community could be exported, in the opinion of the Council, although only under the condition set out in Regulation (EC) No 178/2002. The Council also did not agree to make export notifications publicly available.

In a second reading, the Parliament reaffirmed some of its earlier amendments which were not or not fully accepted by the Council. The Council subsequently accepted all amendments without debate in a Common Position. Importantly, this included amendments requiring 'prior written consent', improving public access to information, and exempting pharmaceuticals from the provisions of the Regulation.

Implementation of the Regulation

The Commission's Joint Research Center acts as the EC focal point, and the Directorate-General for Environment as a Secondary National Focal Point. The EU Biosafety Clearing-House is available on http://gmoinfo.jrc.it/.

Under the Cartagena Protocol on Biosafety, the European Community is required to monitor the implementation of its obligations. It hereby has submitted its interim report in 2005, followed by the first report in October 2007.

The Commission has not yet released a consolidated report on the implementation of the Regulation, although national reports have been submitted.

Further developments

The Cartagena Protocol on Biosafety (see Biodiversity: International conventions and cooperation) calls for international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms (i.e. GMOs) in Article 27. On 15 October 2010, the final plenary of COP/MOP5 successfully adopted the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, and the EU signed it on 11 May 2011, as determined by Council Decision of April 2011 (proposed by COM(2011)130) The measure will now need to be transposed into EU legislation.

Enforcement and court cases

No relevant cases have been concluded in the European Court of Justice.

Related legislation

The following legislation and policy has a strong interaction with Regulation (EC) No 1943/2003 on the transboundary movements of GMOs:

- Convention on Biological Diversity and related Cartagena Protocol on Biosafety.
- Directive 2001/18/EC. on the deliberate release into the environment 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.
- Directive 90/219/EEC on the contained use of genetically modified micro-organisms.