Ordinance on the Transboundary Movements of Genetically Modified Organisms

(Cartagena Ordinance, CartO)

of 3 November 2004 (Status as of 1 June 2012)

The Federal Council,

based on Article 19 paragraph 2 letter a of the Federal Act of 21 March 2003[1] on Non-Human Gene Technology (Gene Technology Act, GTA);
and in implementation of the Cartagena Protocol on Biosafety of 29 January 2000[2] (Cartagena Protocol) in relation to the Convention on Biological Diversity,

ordains:

Section 1 General Provisions

Art. 1 Scope of application

[1] This Ordinance regulates the transboundary movements of genetically modified organisms.

[2] It does not apply to the transboundary movements of pharmaceutical products intended for human consumption that contain genetically modified organisms.

Art. 2 Definitions

In this Ordinance:

a.[3] handling in the environment means any handling in the environment in terms of Article 3 letter i of the Release Ordinance of 10 September 2008[4] (RO);

b.[5] genetically modified organism means any organism that has been genetically modified in terms of Article 3 letter d RO;

AS **2004** 4801

1 SR **814.91**
2 SR **0.451.431**
3 Amended by Annex 5 No 7 of the Release Ordinance of 10 Sept. 2008, in force since 1 Oct. 2008 (SR **814.911**).
4 SR **814.911**
5 Amended by Annex 5 No 7 of the Release Ordinance of 10 Sept. 2008, in force since 1 Oct. 2008 (AS **2008** 4377).

c.[6] contained system means a contained system within the meaning of Article 3 letter d of the Containment Ordinance of 9 May 2012 (ContainO)[7];

d. transboundary movement means the import, export or transit of genetically modified organisms;

e. Biosafety Clearing House means an international exchange centre for the prevention of biotechnological risks in terms of Article 20 of the Cartagena Protocol.

Section 2
Requirements for the Transboundary Movement of Genetically Modified Organisms

Art. 3 Duty of care

Any person who imports or exports genetically modified organisms or is responsible for their transit:

a. must take the necessary precautions required by the situation to prevent genetically modified organisms, their metabolites or the waste thereby engendered from endangering animals, the environment or, indirectly, human beings;

b. must ensure that their handling, packaging, labelling and transportation takes account of all relevant national and international norms and regulations;

c. must ensure that accompanying documentation is provided for each transboundary movement in accordance with Article 4 below.

Art. 4 Accompanying documentation

[1] The documentation accompanying the transboundary movements of genetically modified organisms for handling in the environment must contain the following information:

a. a clear indication that the goods in question are genetically modified organisms;

b. the unique identifier in accordance with the Annex to the Regulation (EC) No 65/2004 of the European Commission of 14 January 2004[8] establishing a system for the development and assignment of unique identifiers for genetically modified organisms or, in the absence of this identifier, specification of the identity of the organisms with the relevant properties and characteristics;

c. instructions on the safe handling, storage, transport and use of the organisms;

6 Amended by Annex 5 No 11 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012** 2777).
7 SR **814.912**
8 OJ L 10 of 16 January 2004, p. 5, available from the Federal Office for the Environment (FOEN), 3003 Bern.

d. the name and address of a person to contact for any additional information that might be required;

e. the name and address of the recipient;

f. a declaration certifying that the movement conforms to the provisions of the Cartagena Protocol as these apply to the exporter.

2 If genetically modified organisms are to be processed for use or to be used directly as foodstuffs for humans or animals or as veterinary medicines, the indication in accordance with paragraph 1 letter a above must also specify that the genetically modified organisms in question may not under any circumstances be introduced directly into the environment.

3 If the genetically modified organisms are intended for use in a contained system, only the requirements of paragraph 1 letters a–e above apply.

Art. 5 Import

1 Any person who intends to import genetically modified organisms for handling in the environment requires authorisation in accordance with Articles 7 and 13 RO[9].[10]

2 Any person who intends to import genetically modified organisms for handling in a contained system must fulfil the requirements of Article 17 or 25 ContainO[11].[12]

Art. 6 Export

1 Any person who intends to export genetically modified organisms to a given country for the first time for handling in the environment must first obtain the consent of the competent national authority of the country in question.

2 The application submitted to the said authority must as a minimum contain the information specified in Annex I.

3 The applicant must submit a copy of the application and of the decision of the importing country to the Federal Office for the Environment (the FOEN)[13].

Art. 7 Obligation to keep a record of exports

1 Any person who exports genetically modified organisms for handling in the environment must keep a register recording each export, classified according to the type and quantity of the organism, the country of destination and the year of export.

2 This information must be made available to the FOEN on request.

9 SR **814.911**

10 Amended by Annex 5 No 7 of the Release Ordinance of 10 Sept. 2008, in force since 1 Oct. 2008 (AS **2008** 4377).

11 SR **814.912**

12 Amended by Annex 5 No. 7 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012** 2777).

13 The designation of the administrative authority has been amended by Art. 16 para. 3 of the Publications Ordinance of 17 Nov. 2004 (SR **170.512.1**). This amendment has been made throughout the text.

3 Such information must be held in safekeeping for a minimum of 30 years following the final export.

Section 3 Duties of the Authorities

Art. 8 Duties of the FOEN

The FOEN is the coordinating body for all questions relating to the transboundary movements of genetically modified organisms. Its main duties in this context are as follows:

a. it ensures the liaison with the Secretariat in accordance with Article 24 of the Convention of 5 May 1992 on Biological Diversity[14];

b.[15] it keeps a public register of information concerning notifications and decisions that is not of a confidential nature in accordance with Article 6 paragraph 3; the confidentiality of such information is determined by Article 34 RO[16];

c. it advises exporters in cases when an importing country does not respect the deadlines required by the Cartagena Protocol;

d. it informs the Federal Office of Public Health, the Federal Office for Agriculture, the Federal Veterinary Office and the Swiss Agency for Therapeutic Products in accordance with their responsibilities as defined by the RO and the ContainO[17] about transboundary movements as well as about any unintended transboundary movement of genetically modified organisms;

e. it publishes a periodical report on the transboundary movements of genetically modified organisms;

f. it provides the forms needed for accompanying documentation in terms of Article 4.

Art. 9 Participation in the International Clearing-House Mechanism

1 The FOEN publishes, through the Biosafety Clearing House, the following information:

a. the federal legislation relevant to the implementation of this Ordinance;

b. any international agreements concluded by Switzerland that relate to transboundary movements of genetically modified organisms;

c. the names and addresses of the federal authorities mentioned in Article 8 letter d, and Article 10;

14 SR **0.451.43**
15 Amended by Annex 5 No 7 of the Release Ordinance of 10 Sept. 2008, in force since 1 Oct. 2008 (AS **2008** 4377).
16 SR **814.911**
17 SR **814.912**

d. all decisions concerning the import and distribution of genetically modified organisms or their release for experimental purposes;

e. all decisions concerning the handling in the environment of genetically modified organisms that are to be processed or used directly as food for humans or animals; this publication, which must be issued within 15 days of notification of the decision, must contain the information required in Annex 2 as a minimum;

f. summaries of available studies relating to biosafety, as well as summaries of other relevant environmental studies;

g. information on cases of unintentional transboundary movements (Article 10);

h. reports drawn up to meet the requirements of Article 8 letter e.

2 The federal authorities mentioned in Article 8 letter d shall make the information and documents referred to in Paragraph 1 above available to the FOEN.

Art. 10 Measures to be taken in the event of unintentional transboundary movements

1 In the case of an extraordinary event that may result in a transboundary movement of genetically modified organisms, the cantons concerned notify the FOEN and inform the public, neighbouring cantons and the relevant regional authorities in neighbouring countries.

2 The FOEN shall notify the relevant national authorities of neighbouring countries about such events.

3 The formal notification of the authorities of neighbouring countries must contain the following information as a minimum:

a. the properties and characteristics of the genetically modified organisms and the estimated quantities involved;

b. the date of the release and the circumstances as well as the use made of the genetically modified organisms in question;

c. the potential dangers to humans, animals and the environment as well as the potential risks to biological diversity and to its sustainable use;

d. possible risk management measures.

4 In the case of an extraordinary event in an establishment in terms of Article 1 paragraph 2 letter b and paragraph 3 letter b of the Ordinance on Protection against Major Accidents of 27 February 1991[18], the provisions of this Ordinance relating to information and giving the alert are also applicable.

5 The FOEN registers notifications from abroad and inform the cantons concerned. The latter informs the public in the appropriate manner.

18 SR **814.012**

Art. 11 Monitoring

[1] The FOEN monitors the implementation of the legal provisions on the export of genetically modified organisms for handling in the environment.

[2] It ensures that the necessary measures are taken if there is any dispute over the said provisions.

[3] The responsibilities involved in monitoring implementation of the legal provisions with regard to the import and transit of genetically modified organisms and the enactment of the necessary measures are defined in the ContainO[19] and the RO[20].

Art. 12 Basic and advanced training

The FOEN ensures that events are organised on a regular basis for the purpose of the basic and advanced training of all persons involved in implementation of this Ordinance.

Art. 13 Delegation of duties

The FOEN may delegate certain duties to third parties, particularly with regard to the compilation of statistics.

Section 4 Final Provisions

Art. 14 Amendment of current legislation

…[21]

Art. 15 Commencement

This Ordinance comes into force on 1 January 2005.

19 SR **814.912**
20 SR **814.911**
21 The amendments may be consulted under AS **2004** 4801.

Annex 1
(Article 6)

Information required in Applications submitted under Article 6

a. Name and address of the exporter;

b. Name and address of the importer;

c. Name of the genetically modified organism, the unique identifier in terms of the annex to the Regulation (EC) No 65/2004 of the European Commission of 14 January 2004[22] establishing a system for the development and assignment of unique identifiers for genetically modified organisms, if such an identifier exists, and an indication of the group to which the organism belongs, in accordance with Article 6 ContainO[23];

d. Dates planned for transboundary movements;

e. Common name and taxonomy, collection or acquisition point, and characteristics of the recipient organism relevant from the point of view of biosafety;

f. Centres of origin and centres of genetic diversity of the recipient organism and the parental organisms, when these centres are known, and description of habitats in which the organisms can subsist or proliferate;

g. Common name and taxonomy, collection or acquisition point, and characteristics of the parental organism or organisms that are relevant from the point of view of biosafety;

h. Description of the nucleic acid or of the genetic modification practised, or the technique used and the characteristics of the genetically modified organism which results;

i. Use intended for the genetically modified organisms or of the derivative products that originate from the genetically modified organisms and contain detectable new combinations of replicable genetic material obtained with the help of modern biotechnology;

j. Quantity or volume of genetically modified organisms being transferred;

k. Risk assessment, in accordance with the requirements of Annex 4 of the RO[24];

l. Methods proposed for the secure handling, storage, transport and use of the genetically modified organisms, including packaging, labelling, documentation, disposal and emergency procedures;

m. Legal status of genetically modified organisms in Switzerland;

n. Decisions taken by other States on applications for the export of the genetically modified organism;

o. Declaration that the above-mentioned information is correct.

22 OJ L 10 of 16 January 2004, p. 5. Available from the FOEN, 3003 Bern.
23 SR **814.912**
24 SR **814.911**

Annex 2
(Article 9 para. 1 let. e)

Information to be provided under Article 9 paragraph 1 letter e

a. Name and address of the applicant;

b. Name and address of the authority responsible for the decision;

c. Name and identity of the genetically modified organism;

d. Description of the genetic modification, the technique used and the characteristics of the genetically modified organism which results;

e. The unique identifier in terms of the annex to the Regulation (EC) No 65/2004 of the European Commission of 14 January 2004[25] establishing a system for the development and assignment of unique identifiers for genetically modified organisms;

f. Common name and taxonomy, collection or acquisition point, and characteristics of the recipient organisms relevant from the point of view of biosafety;

g. Centres of origin and centres of genetic diversity of the recipient organism and the parental organisms, when these centres are known, and a description of the habitats in which the organisms can subsist or proliferate;

h. Common name and taxonomy, collection or acquisition point, and characteristics of the organism or organisms relevant from the point of view of biosafety;

i. Authorised uses of the genetically modified organisms;

j. Evaluation of the risks, in accordance with Annex 4 RO[26];

k. Methods proposed for the secure handling, storage, transportation and use of the genetically modified organisms, including packaging, labelling, documentation, disposal and emergency procedures.

25 OJ L 10 of 16 January 2004, p. 5. Available from the FOEN, 3003 Bern.
26 SR **814.911**