

Ordinance on the Release of Organisms into the Environment (Release Ordinance, RO)*

of 25 August 1999 (as of 23 November 1999)

The Swiss Federal Council,

in accordance with Articles 29b paragraph 3, 29c paragraphs 2 and 3, 29e paragraphs 2 and 3, 29g, 38 paragraph 3, 39 paragraph 1, 41 paragraph 2, 44 paragraph 3, 46 paragraphs 2 and 3, 48 paragraph 2 and 59b of the Federal Law relating to the Protection of the Environment of 7 October 1983 (LPE)¹ and Articles 29a paragraphs 2 and 3 as well as 29d of the Law on Epidemics of 18 December 1970²

as well as in implementation of Article 19 of the Convention on Biological Diversity of 29 December 1993³

and the Federal Law relating to Technical Barriers to Trade (THG) of 6 October 1995⁴,

ordains:

Chapter 1: General provisions

Art. 1 Purpose

The purpose of this Ordinance is to protect people and the environment, in particular animals and plants as well as their communities and habitats, against harmful effects or nuisances of the use of organisms in the environment. This Ordinance shall also contribute to maintaining biological diversity as well as soil fertility.

Art. 2 Scope

¹ This Ordinance regulates the use of organisms, in particular genetically modified or pathogenic organisms, in the environment.

² The contained use of organisms is regulated by the Ordinance on the Contained Use of Organisms (CO) of 25 August 1999⁵.

³ The protection of personnel working with microorganisms is regulated by the Ordinance on Occupational Safety in Biotechnology (SAMV) of 25 August 1999⁶.

*** Please note: This translation is for your convenience. It is not legally binding.**

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¹ SR 814.01

² SR 818.101

³ SR 0.451.43

⁴ SR 946.51

⁵ SR 814.912

⁶ SR 832.321

⁴ The placing on the market of pathogenic, but not genetically modified organisms for application in agriculture as plant protection products is regulated by the Ordinance on Plant Protection Products of 23 June 1992⁷.

⁵ This ordinance does not apply to the use of organisms in clinical experiments with people nor to the use of pathogenic, but not genetically modified organisms which are subject to the following regulations:

- a. Appendix 1 of the Ordinance on Plant Protection of 5 March 1962⁸;
- b. Appendix 1 of the Ordinance on the Control of San José Scale, Fire Blight and Fruit Viruses constituting a Public Danger of 28 April 1982⁹;
- c. Appendix 1 of the Ordinance on the Notification of Pests and Diseases constituting a Public Danger of 25 January 1982¹⁰;
- d. Appendix 2 of the Ordinance on Plant Protection in Forests of 30 November 1992¹¹.

Art. 3 Definitions

For the purposes of this Ordinance:

- a. *organism* shall mean any cellular or noncellular biological entity able to replicate or transfer genetic material, in particular animals, plants and microorganisms; these include mixtures and objects that contain such entities;
- b. *microorganism* shall mean any microbiological entity, in particular bacteria, algae, fungi, protozoa, viruses and viroids; these include cell cultures, parasites, prions and biologically active genetic material;
- c. *genetically modified organism* shall mean any organism in which the genetic material has been altered by methods of gene technology given in Appendix 1, in a way that does not occur under natural conditions by mating or natural recombination;
- d. *use of organisms in the environment* shall mean any deliberate activity using organisms whereby organisms enter the environment as intended or as a rule, in particular culturing, processing, multiplication, modification, release for experimental purposes, placing on the market, transport, storage or disposal;
- e. *placing on the market* shall mean any transfer of organisms to third parties in Switzerland for the use in the environment, in particular by sale, exchange, giving as a gift, renting, lending or giving on approval, as well as their import for the use in the environment. Transfer in association with the release for experimental purposes does not count as placing on the market.

⁷ SR 916.161

⁸ SR 916.20

⁹ SR 916.22

¹⁰ SR 916.201

¹¹ SR 921.541

Chapter 2: Requirements for the use of organisms in the environment

Section 1: General requirements

Art. 4 Obligation to take due care

¹ Anyone involved in the use of organisms in the environment must take all due care to ensure that organisms, their metabolic and waste products do not endanger people and the environment.

² In particular, applicable regulations as well as the distributor's instructions and recommendations must be followed.

Art. 5 Self-supervision for the placing on the market

¹ Anyone intending to place on the market organisms for the use in the environment must assess the possible effects on people or the environment and arrive at a justifiable conclusion that the organisms when used in the environment present no danger to people and the environment.

² To be assessed for this purpose, in particular, are:

- a. potential for survival, dissemination and replication of the organisms in the environment;
- b. possible interactions of the organisms with other organisms and communities as well as the effects on habitats.

Art. 6 Informing of the recipient

Anyone placing on the market or exporting organisms for the use in the environment must:

- a. inform the recipient of the identity of the organisms as well as their properties in relation to public health and the environment;
- b. so instruct the recipient that the use of the organisms in the environment according to the regulations and the instructions will not endanger people and the environment.

Section 2: Releases for experimental purposes with genetically modified or pathogenic organisms

Art. 7 Authorisation obligation

¹ Anyone intending to release for experimental purposes genetically modified, pathogenic or other organisms considered hazardous under Article 5 of the

Ordinance on the Contained Use of Organisms of 25 August 1999¹² must be in possession of a permit from the Swiss Agency for the Environment, Forests and Landscape (SAEFL).

² A permit is not required for releases for experimental purposes involving:

- a. genetically modified or pathogenic organisms, the placing on the market of which has already been authorised as plant protection products, fertiliser or plant propagation material;
- b. not genetically modified microorganisms that are pathogenic to plants, fungi or lichens, so long as they fulfil the criteria given in Appendix 2.

³ Applicants must have a residence or business premise in Switzerland.

⁴ The authorisation application must be submitted with the required number of copies. For public information purposes, the required number of additional copies, which contain at least the information required by Article 34 paragraph 5, must be submitted.

Art. 8 Authorisation conditions

¹ Releases for experimental purposes are permitted if it is not expected that they:

- a. could damage populations of organisms that are protected or important for the ecosystem affected;
- b. could lead to the unintentional extinction of any species of organism;
- c. could strongly or permanently disturb the chemical equilibrium of the environment;
- d. could strongly or permanently damage important functions of the ecosystem affected, in particular soil fertility;
- e. could lead to the permanent dissemination of undesirable properties in other organisms.

² Releases for experimental purposes in particularly sensitive habitats or habitats requiring protection are permitted only if the use of the organisms in the environment will prevent or repair harmful effects or nuisances on people, animals, plants or the environment.

³ Particularly sensitive habitats or habitats requiring protection are:

- a. areas which, on the basis of federal or cantonal law, are proclaimed nature reserves, as long as the applicable regulations do not declare otherwise;
- b. surface waters and a strip 3 m wide along or around them;
- c. subterranean waters and catchment areas S1 of groundwater protection zones (Art. 29 para. 2 of the Ordinance on the Protection of Waters of 28 October 1998¹³);
- d. forests.

¹² SR 814.912

¹³ SR 814.201

⁴ Releases for experimental purposes with human pathogens of groups 3 and 4 according to Article 6 of the Containment Ordinance of 25 August 1999¹⁴ are prohibited in any case.

Art. 9 Authorisation applications

¹ An authorisation application for a release for experimental purposes must include the information required to assess the possible risks posed to people and the environment, in particular:

- a. for genetically modified organisms, the information required by Annex II of the Council Directive 90/220/EEC of 23 April 1990¹⁵ on the Deliberate Release into the Environment of Genetically Modified Organisms or, for pathogenic but not genetically modified organisms, the information required by Appendix 3.1 of this ordinance;
- b. data, results and assessments of other comparable releases for experimental purposes with the same organisms; data or results from other applicants may be quoted with their written permission;
- c. a risk assessment according to Appendix 4;
- d. a monitoring plan to determine at an early stage possibly harmful effects or nuisances of the release for experimental purposes on people and the environment during and after the release;
- e. evidence of the guarantee of liability.

² A single application may be submitted for releases for experimental purposes carried out with the same organisms for the same purpose and which will be carried out repeatedly or at different locations within a limited period.

³ A simplified authorisation procedure (Art. 21) may be applied for if a release for experimental purposes with comparable possible effects on people or the environment, i.e. involving the same organisms, has already been authorised. A risk assessment according to Appendix 4 must nevertheless be submitted.

⁴ The application must be amended if new findings become available that might require reassessment of the risk.

Art. 10 Liability guarantee

¹ The applicant must guarantee sufficient financial reserves for determining, preventing or repairing possible harmful effects or nuisances.

² A liability of up to 20 million Swiss francs (Article 59a LPE) must be guaranteed.

³ Guarantee of liability may be provided:

¹⁴ SR 814.912

¹⁵ OJ No. L 117 of 8 May 1990, page 15, modified by the directives:
– 94/15/EU (OJ No. L 103 of 22 April 1994, page 20),
– 97/35/EU (OJ No. 169 of 18 June 1997, page 72);
Available from SAEFL, 3003 Bern.

- a. by taking out a liability insurance with a company authorised to operate in Switzerland;
- b. by providing equivalent security.

⁴ The Federal Government, its public corporations and institutions and the cantons shall be exempt from this guarantee of liability.

Art. 11 Changes and new findings

¹ The permit holder must inform SAEFL without delay about:

- a. changes in the conditions of the release for experimental purposes;
- b. new findings that might require a reassessment of the risk.

² Concomitantly, the measures stipulated in the permit must be re-examined and measures necessary to protect people and the environment must be taken.

³ SAEFL shall inform the other interested authorities (Art. 18 para. 4).

Art. 12 Reporting

¹ The permit holder must submit a report to SAEFL within 90 days of completion of the release for experimental purposes. In particular, the report shall include the data and results of the monitoring carried out on the effects of the release for experimental purposes on people and the environment.

² SAEFL shall inform the other interested authorities.

Section 3: Placing on the market of genetically modified or pathogenic organisms

Art. 13 Authorisation obligation and definitive authorisation procedure

¹ Anyone intending to place on the market genetically modified or pathogenic organisms for the use in the environment either for the first time or for a new use requires a permit.

² The permit will be issued by one of the following authorities, according to the application of the organisms, as part of the applicable authorisation procedure:

Application	Competent authority	Applicable authorisation procedure
a. immunological products for use in humans	Federal Office of Public Health (FOPH)	Ordinance on Immunological Products of 23 August 1989 ¹⁶
b. foodstuff	FOPH	Ordinance on Foodstuffs of 1 March 1995 ¹⁷
c. plant propagation material for use in forests	SAEFL	Ordinance on Plant Protection in Forests of 30 November 1992 ¹⁸
d. plant propagation material for all other uses	Federal Office of Agriculture (SFOA)	Ordinance on Seeds of 7 December 1998 ¹⁹
e. plant protection products containing genetically modified organisms	SFOA	Ordinance on Plant Protection Products of 23 June 1999 ²⁰
f. fertiliser	SFOA	Ordinance on Fertilisers of 26 May 1994 ²¹
g. animal feed	SFOA	Ordinance on Animal Feed of 26 May 1999 ²²
h. immunological products for veterinary use	Federal Veterinary Office (FVO)	Ordinance on Immunological Products for Veterinary Use of 27 June 1995 ²³
i. all other uses	SAEFL	Ordinance on the Release of Organisms into the Environment of 25 August 1999

Art. 14 Authorisation application

¹ For assessment of the risks posed to people and the environment, the authorisation application made as part of the applicable authorisation procedure must include the following information (environmental data):

- a. for genetically modified organisms, the information required by Annexes II and III of Council Directive 90/220/EEC of 23 April 1990²⁴ on the Deliberate Release into the Environment of Genetically Modified Organisms or, for pathogenic, but not genetically modified organisms, the information required by Appendix 3.2 of this ordinance;

¹⁶ SR 812.111

¹⁷ SR 817.02

¹⁸ SR 921.541

¹⁹ SR 916.151

²⁰ SR 916.161

²¹ SR 916.171

²² SR 916.307

²³ SR 916.445.2

²⁴ OJ No. L 117 of 8 May 1990, page 15, modified by the directives:

– 94/15/EU (OJ No. L 103 of 22 April 1994, page 20),

– 97/35/EU (OJ No. 169 of 18 June 1997, page 72);

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- b. data and results of previous studies using the same organisms relating to effects to people or the environment; data or results from other applicants may be quoted with their written permission;
- c. any available permits and assessments of foreign authorities relating to releases for experimental purposes and the placing on the market of the same organisms;
- d. a risk assessment according to Appendix 4;
- e. a monitoring plan to determine at an early stage possibly harmful effects or nuisances of the placing on the market on people and the environment; the effects include indirect and delayed consequences of the placing on the market;
- f. the commercial name of the organism and any specific conditions for the intended placing on the market;
- g. a draft of the information addressed to the recipient (Art. 6 and 16) as well as the suggested packaging;
- h. information on the appropriate climatic or geographical area of application;
- i. an indication of the measures that could be taken if the organisms are incorrectly used or enter the environment by unforeseen means.

² Authorisation applicants must have a residence or business premise in Switzerland.

³ The information stipulated in paragraph 1 must be submitted with the required number of copies. For public information purposes, the required number of additional copies, containing at least the information stipulated by Article 34 paragraph 5, must be submitted.

Art. 15 New findings

¹ The permit holder must inform the competent authority (Art. 13 para. 2) without delay about new findings that might require a reassessment of the risk.

² The measures stipulated in the permit must also be re-examined and measures necessary to protect people and the environment must be taken.

Art. 16 Labelling of genetically modified organisms

¹ Anyone placing on the market genetically modified organisms must inform the recipient about the nature of the organisms by an easily recognisable label or some other equivalent means.

² The information stipulated in paragraph 1 is not required for mixtures or objects that contain genetically modified organisms:

- a. in small amounts that are unavoidable despite reasonable care;
- b. not at all or in trace amounts; in this case, the recipient may be informed that the mixtures or objects contain no genetically modified organisms.

³ The corresponding requirements for the labelling of genetically modified organisms stipulated by the regulations on foodstuffs and the regulations on agricultural auxiliary substances remain in force.

Section 4: Export of genetically modified organisms

Art. 17

¹ Anyone intending to export genetically modified organisms to a particular country for the first time, which are intended for the use in the environment, must:

- a. notify the import country prior to exportation, and
- b. submit a copy of the notification to SAEFL.

² For this purpose, the import country must be provided with at least the following information:

- a. name and address of the importer;
- b. identity of the genetically modified organisms;
- c. description of the genetic modification and the properties of the genetically modified organisms;
- d. summary information on the possible effects on people and the environment in the import country;
- e. date of the intended import;
- f. number of organisms or culture volumes as well as their physical condition;
- g. all requirements for ensuring the safe use in the environment, including all measures for safe disposal as well as dealing with emergencies.

³ A register of these exports must be kept, organised according to species and numbers of organisms and the country of destination, which must be made available to the authorities on demand.

Chapter 3: Responsibilities of the authorities

Section 1: Authorisation of releases for experimental purposes

Art. 18 Control of application documentation, publication and orientation

¹ SAEFL shall examine whether the documentation submitted for judging the application is complete. If necessary, it shall return the documentation to the applicant for supplementation or revision.

² It shall announce receipt of the application in the Federal Law Gazette, when the application is complete, and see to it that the non-confidential documents are displayed for 30 days for examination:

- a. at SAEFL;

- b. in the local community where the release for experimental purposes will take place.

³ During the display period, any person may submit a statement on the documents. A statement made does not establish additional party rights, as stipulated by the Law on Administrative Procedure (LAP) ²⁵.

⁴ Concomitantly, SAEFL shall forward the application to the following authorities, who shall state their position within 50 days:

- a. FOPH, FVO and SFOA;
- b. the Swiss Expert Committee for Biosafety (SECB) and the Swiss Ethics Committee on Non-human Gene Technology (ECNH);
- c. the designated authority of the canton in which the release for experimental purposes will occur.

⁵ As requested, it shall inform the State Secretariat for Economic Affairs (seco) and the Swiss Accident Insurance Organisation (SUVA).

⁶ It may take part in public orientation meetings or organise such meetings on its own initiative or at the request of the canton.

Art. 19 Issue of a permit

¹ SAEFL shall examine and judge the application, taking into account the statements received, in particular from the SECB and the designated authority of the canton in which the release for experimental purposes will take place. As a rule, it shall issue a permit within 90 days of the appearance of the corresponding announcement in the Federal Law Gazette if:

- a. examination of the application, in particular the risk assessment, leads to the conclusion that, given the current state of scientific knowledge and experience, the release for experimental purposes cannot endanger people and the environment;
- b. FOPH, FVO and SFOA, on the basis of their examination of the application, in particular the risk assessment, give their consent to the carrying out of the release for experimental purposes.

² If examination shows that the documentation submitted is insufficient to judge the application, SAEFL may demand additional information from the applicant, in which case the period stipulated in paragraph 1 shall be extended accordingly.

³ SAEFL shall link the permit to requirements and conditions necessary for protecting people and the environment. It may in particular:

- a. demand that the site of the release for experimental purposes be marked, fenced in or specially secured;
- b. order that, in addition to the monitoring plan (Art. 9), the site of the release for experimental purposes and surroundings be kept under observation

²⁵ SR 172.021

during and after the release for experimental purposes and that samples be taken and tested, all at the expense of the applicant;

- c. order that the carrying out of and monitoring of the release for experimental purposes be inspected by a support group (Art. 27) at the expense of the applicant;
- d. demand interim reports.

⁴ SAEFL shall inform the interested authorities (Art. 18 para. 4) about the authorisation decision and publish it in the Federal Law Gazette. It shall display the non-confidential documents on which the decision was based for a period of 30 days for examination.

Art. 20 New findings

¹ Should SAEFL, or one of the interested authorities, come into possession of new findings on the risks posed by the release for experimental purposes after issue of the permit, it may at any time prescribe appropriate measures. In particular, it may require that:

- a. the risk assessment (Art. 9 para. 1c) be revised;
- b. the conditions of the release for experimental purposes be changed;
- c. the release for experimental purposes be interrupted or if necessary terminated and, as far as possible, the original conditions restored.

² It shall consult the interested authorities.

Art. 21 Simplified authorisation procedure

¹ SAEFL shall carry out an accelerated and in content simplified authorisation procedure if the conditions given in Article 9 paragraph 3 are met.

² In particular, it may:

- a. waive the submission of a complete application;
- b. abstain from announcing receipt of the application in the Federal Law Gazette;
- c. shorten the period allowed for submitting statements.

Section 2: Authorisation of placing on the market

Art. 22 Control of the application documentation

¹ The competent authority (Art. 13) shall check whether the authorisation application includes all the environmental data (Art.14). If necessary, it shall return the documentation to the applicant for revision.

² It shall forward the environmental data for a statement of their position to:

- a. FOPH and SAEFL; as well as

- b. FVO and SFOA, if the application falls within their area of responsibility.

Art. 23 Forwarding and publication of the environmental data

¹ SAEFL shall forward the environmental data to SECB and ECNH for their statement.

² It shall announce receipt of the environmental data in the Federal Law Gazette, when the application is complete, and see to it that the non-confidential documents are displayed for 30 days for examination.

³ During the display period, any person may submit a statement on the documents. A statement made does not establish additional party rights, as stipulated by the LAP²⁶.

Art. 24 Issue of a permit

¹ The competent authority shall issue a permit if:

- a. the requirements of the applicable authorisation procedure are fulfilled;
- b. examination of the environmental data, in particular the risk assessment, leads to the conclusion that, given the current state of scientific knowledge and experience, the placing on the market cannot endanger people and the environment;
- c. FOPH and SAEFL and, if appropriate, FVO and SFOA, give their consent to the placing on the market.

² If the environmental data are insufficient to verify that the placing on the market will not endanger people and the environment, the authorities may demand a release for experimental purposes to be carried out before giving their consent. They may associate their consent with certain conditions; in particular they may:

- a. limit the use of the organisms or permit the use only under certain conditions;
- b. demand, at the expense of the applicant, further investigations in addition to the monitoring plan (Art. 14) to identify possible delayed consequences for people or the environment, and the production of a report.

³ A permit or consent issued after assessment of the environmental data shall be valid for 10 years. It may be extended for a further 10 years if the competent authority, taking into account possible new findings, concludes that the conditions given in Article 24 paragraphs 1b and c continue to be met.

Art. 25 New findings

¹ Should one of the authorities whose consent, on the basis of the environmental data, is required for issue of a permit come into possession of relevant new findings, it may demand, in particular, that the competent authority:

²⁶ SR 172.021

- a. change the conditions imposed for the placing on the market;
- b. if necessary, prohibit the placing on the market either temporarily or indefinitely;
- c. in serious cases, order the return of organisms placed on the market.

² Should the competent authority come into possession of such new findings, it shall inform without delay the authorities whose consent is required for the issue of a permit.

Section 3: Monitoring of the use of organisms in the environment

Art. 26 Monitoring of the obligation to take due care

¹ The cantonal authorities shall monitor observance of the obligation to take due care during use of organisms in the environment.

² If the results from monitoring give cause for complaint, the cantonal authorities shall stipulate the measures to be taken.

Art. 27 Monitoring of releases for experimental purposes

¹ SAEFL shall monitor the carrying out of releases for experimental purposes.

² For this purpose, it may appoint a support group with representatives, in particular, of the canton in which the release for experimental purposes takes place. The support group shall:

- a. monitor the carrying out of the release for experimental purposes by spot checks at the site and keep a record;
- b. report the results of the monitoring to SAEFL in writing.

³ SAEFL shall inform the authorities as well as the applicant of the monitoring results.

Art. 28 Post-authorisation monitoring (supervising the market) according to other regulations

¹ Post-authorisation monitoring (supervising the market) shall be carried out:

- a. for immunological products for use in humans according to the Ordinance on Immunological Products of 23 August 1989²⁷;
- b. for foodstuffs and utensils according to the Law on Foodstuffs of 9 October 1992²⁸;
- c. for plant propagation materials exclusively for use in forests according to the Ordinance on Plant Protection in Forests of 30 November 1992²⁹;

- d. for plant propagation materials for all other uses according to the Ordinance on Seeds of 7 December 1998³⁰;
- e. for plant protection products containing genetically modified organisms according to the Ordinance on Plant Protection Products of 23 June 1999³¹;
- f. for fertilisers according to the Ordinance of Fertilisers of 26 January 1994³²;
- g. for animal feed according to the Ordinance on Animal Feed of 26 May 1999³³;
- h. for immunological veterinary products according to the Ordinance on Immunological Products for Veterinary Use of 27 June 1995³⁴.

² The responsible authorities shall inform SAEFL and FOPH about orders issued, if the requirements of this ordinance are affected.

Art. 29 Post-authorisation monitoring (supervising the market) under this ordinance

¹ The cantonal authorities shall be responsible for post-authorisation monitoring (supervising the market) of organisms placed on the market which are not subject to the controls stipulated by Article 28.

² The cantonal authorities shall monitor by spot checks or at the request of SAEFL, in particular, whether:

- a. the regulations regarding informing recipients (Art. 6) are being observed;
- b. the placing on the market of genetically modified or pathogenic organisms has been authorised;
- c. the conditions linked to the issue of the permit are being observed;
- d. genetically modified organisms are correctly labelled (Art. 16);
- e. the measures prescribed by SAEFL according to paragraph 4 are being implemented.

³ Should the monitoring show that the requirements according to paragraph 2 b-e are being violated, the authorities of the canton in which the distributor is resident or has business premises shall prescribe the necessary measures and inform SAEFL.

⁴ Should the monitoring show that paragraph 2a or other requirements of this ordinance related to placing on the market are being violated, the cantonal authorities shall inform SAEFL. SAEFL shall conduct an appropriate investigation, in particular as to whether the self-supervision (Art. 5) has been fulfilled, and prescribe the necessary measures.

²⁷ SR 812.111

²⁸ SR 817.0

²⁹ SR 921.541

³⁰ SR 916.151

³¹ SR 916.161

³² SR 916.171

³³ SR 916.307

³⁴ SR 916.445.2

⁵ If the monitoring requires samples, detection methods and materials, they shall be provided to the cantonal authorities without charge.

⁶ Should the monitoring show that requirements in this ordinance are being violated, the persons responsible shall pay the costs of the monitoring. The monitoring authorities shall issue an invoice directly to these persons.

Art. 30 Monitoring of exports covered by this ordinance

¹ SAEFL shall monitor observation of the regulations on export of genetically modified organisms (Art. 17).

² Should the results of the monitoring give cause for complaint, SAEFL shall prescribe the necessary measures after consultation with the responsible authorities.

Art. 31 Inspection of the self-supervision

¹ For organisms which according to this ordinance may be placed on the market without a permit, SAEFL may demand from the distributor evidence of exercise of the self-supervision according to Article 5 together with documentation, if there is reason to believe that organisms placed on the market present a danger to people or the environment. The distributor shall be given sufficient time to respond. SAEFL shall first consult SFOA if the said organisms are of significance for agriculture.

² SAEFL may:

- a. demand that exercise of the self-supervision be repeated within a certain period and, if necessary, supplemented or amended;
- b. prescribe the form and the content of the information supplied to recipients, in particular the description of the properties of the organisms and the recommendations and instructions for use;
- c. demand that inappropriate or misleading labelling and information be removed.

³ Should the distributor not comply with the demands within the set period, then SAEFL may prohibit placing on the market of the said organisms.

⁴ SAEFL shall inform the cantonal authorities of the measures prescribed.

Section 4: Control

Art. 32

¹ Should organisms appear which are damaging to the environment, especially animals and plants, the cantonal authorities may prescribe appropriate control measures and, if necessary and useful, measures to prevent their future occurrence.

² The cantonal authorities shall inform SAEFL about the occurrence and control of such organisms.

³ Regulations in other federal legislation on the control of harmful organisms remain in force.

Section 5: Obtaining, processing and publication of information

Art. 33 Inquiries

¹ SAEFL shall carry out inquiries necessary to assess damage to the environment by certain organisms, by certain properties of organisms or by certain genetic material.

² The results of the inquiries shall be public and, if not confidential, may be published in full or in part.

Art. 34 Confidentiality

¹ The authorities responsible for the enforcement of this ordinance shall treat as confidential information for which there are grounds for confidentiality. They shall classify this information as such when forwarding it to other authorities.

² In particular, the protection of business and production secrets shall be grounds for confidentiality.

³ Anyone submitting documents to the authorities must:

- a. indicate information which is confidential; and
- b. give the grounds for confidentiality.

⁴ An authority that does not wish to accede to a request for confidentiality shall investigate whether the grounds given for confidentiality are justifiable. If their assessment differs from the proposal of the persons supplying the information, the authorities, after consultation with the notifier, shall inform the notifier by order which information they do not find worthy of protection.

⁵ The following information shall in no case be confidential:

- a. the names and addresses of those responsible for the release for experimental purposes or the placing on the market;
- b. a general description of the organisms and their properties;
- c. the aim of the release for experimental purposes or the use of the organisms to be placed on the market;
- d. approximate information about the site of the release for experimental purposes;
- e. methods and plans for monitoring the genetically modified or pathogenic organisms in the environment and emergency measures;
- f. a summary of the risk assessment, including an estimate of the relevant and foreseeable pathogenic and ecological effects together with the scientific basis of the assessment.

Art. 35 Register

¹ SAEFL shall maintain a register of all authorised releases for experimental purposes. The register shall record whether, when, where, by whom and with what a release for experimental purposes was carried out.

² SAEFL shall also maintain a register of genetically modified organisms authorised for placing on the market. The federal and cantonal authorities responsible for enforcing this ordinance shall provide the necessary information.

³ The register shall contain no confidential information and shall be public. It may be published in full or in part.

Section 6: Fees**Art. 36** Obligation

¹ Anyone using the services of SAEFL or instigating the issue of an order in connection with this ordinance must pay a fee. Expenses shall be charged separately.

² If several persons share a service, they are jointly liable to the fee.

Art. 37 Scale of fees

¹ The Federal Department of the Environment, Transport, Energy and Communication (DETEC) shall set the fees for the following services:

- a. the authorisation and monitoring of releases for experimental purposes;
- b. the authorisation of and statement on placing on the market.

² It sets the charges:

- a. per hour for services without a set fee;
- b. per page for written work.

³ The charge for examination of repeated applications may be up to 50 percent of the set fee.

⁴ Services without a set fee will be charged according to time invested.

Art. 38 Expenses

Expenses shall mean the additional costs arising during provision of individual services, in particular:

- a. honoraria according to the Ordinance of 12 December 1996³⁵ on the Remuneration of Members of Extraparliamentary Commissions;
- b. costs arising from hearings, scientific investigations, special tests or the procurement of documents;

- c. international postage and telephone charges;
- d. travel and transport costs;
- e. costs of tasks delegated to third parties by SAEFL.

Art. 39 Settlement

¹ Payment shall be due:

- a. 30 days after issue of an invoice to the party liable;
- b. with the final ruling in case of dispute.

² The period allowed for payment shall be 30 days after the due date.

Section 7: Guidelines, training and further education**Art. 40**

¹ SAEFL may issue guidelines on the enforcement of this ordinance if required, in particular with respect to exercising and recording the self-supervision as well as to the content and amount of information provided to recipients. It shall carry out prior consultations with FOPH, FVO, SFOA, SECB and the cantonal authorities.

² SAEFL, jointly with FOPH, shall ensure that training and further education events are organised periodically for people who carry out tasks according to this ordinance.

Chapter 4: Final provisions**Art. 41** Transitional provisions

¹ Organisms for which the requirements for the labelling of genetically modified organisms (Art. 16) have not been fulfilled may be placed on the market until 30 April 2000.

² Genetically modified organisms intended for the use in the environment may be exported until 31 October 2000 without the import country being notified (Art. 17). After this date, a copy of the notification must be forwarded to SAEFL.

Art. 42 Entry into force

This Ordinance shall enter into force on 1 November 1999.

Definition of gene technology methods

¹ Methods of gene technology include, in particular:

- a. recombinant nucleic acid techniques, in which nucleic acid molecules synthesised outside the organism are inserted into viruses, bacterial plasmids or other vector systems to produce novel combinations of genetic material, which are then transferred to a recipient (host) organism in which they would not naturally occur but are capable of continued propagation;
- b. techniques in which genetic material produced outside the organism is inserted directly into an organism, in particular by microinjection, macroinjection and microencapsulation, electroporation or on microprojectiles;
- c. cell fusion or hybridisation techniques in which cells with novel combinations of genetic material are produced by the fusion of two or more cells through processes that do not occur under natural conditions.

² Self-cloning of pathogenic organisms shall be regarded as a method of gene technology. This consists of the removal of nucleic acid sequences from one cell of an organism and the complete or partial insertion of this nucleic acid or a synthetic equivalent (possibly after a previous enzymatic or mechanical treatment) into cells of the same species or cells which are closely related phylogenetically and which can exchange genetic material by natural physiological processes.

³ Self-cloning of non-pathogenic organisms and the following methods shall not be regarded as methods of gene technology, so long as they are not used in association with recombinant nucleic acid molecules or genetically modified organisms:

- a. mutagenesis;
- b. cell and protoplast fusion of prokaryotic microorganisms that exchange genetic material by natural physiological processes;
- c. cell and protoplast fusion of eukaryotic cells, including the production of hybridoma cell lines and the fusion of plant cells;
- d. in vitro fertilisation;
- e. natural processes such as conjugation, transduction and transformation;
- f. changes in ploidy level, including aneuploidy and the elimination of chromosomes.

Appendix 2
(Art. 7 para. 2b)

Criteria

No authorisation is required for releases for experimental purposes with not genetically modified microorganisms that are pathogenic to plants, fungi or lichens if they:

- a. are not pathogenic to animals and people;
- b. are a species widely distributed in Switzerland (endemic);
- c. do not damage non-target populations;
- d. do not cause disease in plant, fungus or lichen species in the Swiss Red Data Books, according to current knowledge;
- e. are not listed in Appendix 1 of the Ordinance on Plant Protection of 5 March 1962³⁶;
- f. as an isolate show no resistance to plant protection products used in Switzerland, except if such resistance is present in Switzerland; and
- g. as an isolate show no specific virulence with which they could evade the natural or induced resistance of crops, except if such virulence is widely distributed in Switzerland.

³⁶ SR 916.20

Appendix 3
(Art. 9 and 14)

Information required for authorisation applications concerning pathogenic but not genetically modified organisms

Notes

¹ The following lists give the information to be included in authorisation applications for releases for experimental purposes (Art. 9) or placing on the market (Art. 14) of pathogenic, but not genetically modified organisms.

² In well-founded cases, specific information may be omitted or substituted by other equally or more suitable information.

³ The extent and the degree of detail of specific information shall be appropriate to the particular situation.

Appendix 3.1
(Art. 9 para. 1a)

Authorisation applications for releases for experimental purposes

1 General information

11 Name(s) and address(es) of the applicant(s) (company or other institution);
12 name(s), qualifications and experience of the responsible scientist(s);
13 description of the project, including the aim;
14 information about previous experiments and the results (releases for
experimental purposes, greenhouse, climate chambers, micro-
environments).

2 Identity and characterisation of the organisms

21 Scientific and other names;
22 taxonomic data;
23 phenotypic and genetic markers;
24 *pathological, ecological and physiological properties:*
241 pathogenicity;
242 resistance or sensitivity to antibiotics and other specific agents;
243 survival potential, generation time, type of reproduction, routes of
biological dispersal;
244 involvement in environmental processes;
245 geographical distribution and natural habitat.

3 Implementation of the release for experimental purposes

31 Description of the release for experimental purposes, including the
methods and the number of organisms to be released;
32 timetable;
33 interventions at the site of the release for experimental purposes before,
during and after the release for experimental purposes;
34 measures to protect operators during the release for experimental purposes;
35 processes for inactivating the organisms after completion of the release for
experimental purposes.

4 Site of the release for experimental purposes

41 Geographical situation, size of the site of the release for experimental
purposes and description of the surroundings;
42 climatic, geological and pedological characteristics of the site of the release
for experimental purposes and the closer neighbourhood;

43 flora and fauna, including crops, farm animals and migratory species;
44 description of the ecosystem.

5 Possible effects on the environment

51 Effects on biogeochemical processes;
52 effects on target organisms;
53 effects on non-target organisms;
54 other possibly relevant effects;
55 short- or long-term damage which could result from these effects.

6 Safety measures

61 *Monitoring:*

611 Methods of monitoring the organisms;
612 specificity, sensitivity and reliability of the methods;
613 duration and frequency of the monitoring.

62 *Precautions:*

621 Methods and procedures to prevent or minimise the spread of organisms
beyond the site of the release for experimental purposes;
622 methods and procedures to prevent trespass;
623 methods and procedures to prevent other organisms from entering the site
of the release for experimental purposes.

63 *Waste disposal:*

631 Nature and amount of waste produced;
632 possible hazards;
633 description of the planned disposal procedure.

64 *Emergency plan:*

641 Methods and procedures for controlling the organisms in case of
unexpected spread;
642 methods for decontaminating the areas affected;
643 methods for disposing of or treating plants, animals, soil etc. affected by
the spread of the organisms;
644 methods for the isolation of the area affected by the spread;
645 plans for protecting people and the environment in the event of undesirable
effects occurring.

Appendix 3.2
(Art. 14 para. 1a)

Authorisation application for placing on the market

1 General information

11 Name(s) and address(es) of the applicant(s) (company or other institution);
12 description of the project, including the aim.

2 Identity and characterisation of the organisms

21 Scientific and other names;
22 taxonomic data;
23 phenotypic and genetic markers;
24 *pathological, ecological and physiological properties:*
241 pathogenicity;
242 resistance or sensitivity to antibiotics and other specific agents;
243 survival potential, generation time, type of reproduction, routes of
biological dispersal;
244 involvement in environmental processes;
245 geographical distribution and natural habitat.

3 Possible effects on the environment

31 Effects on biogeochemical processes;
32 effects on target organisms;
33 effects on non-target organisms;
34 other possibly relevant effects;
35 short- or long-term damage which could result from these effects.

4 Safety measures

41 *Suggestion for specific monitoring:*
411 Methods for monitoring the organisms;
412 specificity, sensitivity and reliability of the methods;
413 duration and frequency of the monitoring.
42 *Precautions:*
Methods and procedures for preventing or minimising the spread of
organisms outside of the application area.
43 *Waste disposal:*
431 Nature and amount of waste produced by using organisms in accordance
with the regulations;
432 possible hazards;
433 disposal by the user in accordance with the regulations.

- 44 *Emergency plan:*
441 Methods and procedures for controlling the organisms in the event of an
 unexpected spread;
442 methods for decontaminating affected habitats;
443 methods for disposing of or treating plants, animals, soil etc. affected by
 the spread of the organisms;
444 plans for protecting people and the environment in the event of undesirable
 effects occurring.

Risk assessment

Note

The risk assessment must be scientific and comprehensible and be based on scientific and technical experience, scientific publications, the results of calculations and detailed analyses.

1 Determination of the damage potential of organisms

¹ The damage potential of organisms which could have harmful effects or nuisances on people or the environment must be determined. In particular, the following must be taken into consideration:

- a. the properties of the organisms;
- b. experience in use the organisms;
- c. the genetic modifications;
- d. interactions with the environment.

² This evaluation shall be based on the information referred to in Articles 9 and 14.

2 Determination of the extent of possible damage

¹ The extent of possible damage must be determined from the damage potential of the organisms. In particular, it must be considered whether:

- a. only individuals or the whole population of a species is affected;
- b. endangered or useful species are affected;
- c. a function of the ecosystem is altered;
- d. the effect is for a limited period or is long-term;
- e. the damage is reversible or irreversible.

² If possible, the extent of possible damage must be quantified.

3 Determination of the probability of damage occurring

The probability that damage to people or the environment will occur through use of organisms in the environment must be determined. In particular, the following must be taken into account:

- a. the nature of the affected environment;
- b. the interactions of the released organisms with the affected environment;

- c. the nature and scale of the use in the environment, in particular the number of organisms to be released.

² If possible, the probability of occurrence must be quantified.

4 Determination of the safety measures required

¹ The safety measures needed to protect people or the environment must be determined on the basis of;

- a. the damage potential of the organisms determined;
- b. the extent of possible damage determined;
- c. the probability of damage occurring determined.

² In particular, measures to limit the duration and area of the use in the environment must be determined, such as:

- a. monitoring and control measures;
- b. waste disposal measures;
- c. emergency plans.

5 Risk assessment

The risks posed by the planned use in the environment must be assessed as to the extent and probability of possible damage, taking into account the planned safety measures.

Amendments to existing statutes1. The Ordinance on Immunological Products of 23 August 1989³⁷:*Art. 12 para. 2m*

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Art. 13 para. 1m

...

Art. 14 para. 1

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Art. 15 para. 1^{bis}

...

2. The Ordinance on Foodstuffs of 1 March 1995³⁸:*Art. 15 paras. 2–4*

...

3. The Ordinance on Seeds of 7 December 1998³⁹:*Art. 9a*

...

Art. 9b

...

Art. 17 para. 4^{bis}

...

³⁷ SR 812.111. The changes given below are inserted in the ordinance mentioned.

³⁸ SR 817.02. The change given below is inserted in the ordinance mentioned.

³⁹ SR 916.151. The changes given below are inserted in the ordinance mentioned.

4. The Ordinance on Plant Protection Products of 23 June 1999⁴⁰:

Art. 10 Abs. 2–4

...

5. The Ordinance on Fertilisers of 26 January 1994⁴¹:

Art. 11 para. 1c and 3

...

Art. 12a

...

Art. 19 para. 1^{bis}

...

6. The Ordinance on Animal Feed of 26 May 1999⁴²:

Art. 6 para. 2b and 4

...

Art. 17 para. 3

...

Art. 18 para. 2

...

7. The Ordinance on Immunological Products for Veterinary Use of 27 June 1995⁴³:

Art. 11 para. 2l

...

Art. 12 para. 1^{bis}

...

⁴⁰ SR 916.161. The change given below is inserted in the ordinance mentioned.

⁴¹ SR 916.171. The changes given below are inserted in the ordinance mentioned.

⁴² SR 916.307. The changes given below are inserted in the ordinance mentioned.

⁴³ SR 916.445.2. The changes given below are inserted in the ordinance mentioned.

Art. 13 para. 1 second sentence

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Art. 26 para. 2

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