

English is not an official language of the Swiss Confederation. This translation is provided for information purposes only and has no legal force.

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

of 10 September 2008 (Status as of 1 January 2016)

Please note: this translation does not yet include the amendments of 01.02.2016

The Swiss Federal Council,

in accordance with Article 29c paragraphs 2 and 3, 29d paragraphs 2 and 4, 29f, 38 paragraph 3, 39 paragraph 1, 41 paragraphs 2 and 3, 44 paragraph 3, 46 paragraphs 2 and 3, 48 paragraph 2 and 59b of the Environmental Protection Act of 7 October 1983¹ (EPA),

with Article 11 paragraph 2, 12 paragraph 2, 14, 17 paragraphs 1, 2, 4 and 5, 19, 20 paragraphs 1–3, 24 paragraphs 2 and 3, 25 and 34 of the Gene Technology Act of 21 March 2003² (GTA),

and Article 29a paragraphs 2 and 3 as well as 29d of the Epidemics Act of 18 December 1970³,

as well as in implementation of Articles 8 and 19 of the Convention on Biological Diversity of 5 June 1992⁴,

ordains:

Chapter 1: General Provisions

Art. 1 Purpose

¹ The purpose of this Ordinance is to protect human beings, animals and the environment, as well as biological diversity and the sustainable use thereof, from hazards or impairment caused by handling organisms, their metabolic products and wastes.

² It also aims, during the handling of genetically modified organisms, their metabolic products and wastes, to guarantee consumers' freedom of choice and protect production that does not use genetically modified organisms.

AS 2008 4377

¹ SR 814.01

² SR 814.91

³ SR 818.101

⁴ SR 0.451.43

Art. 2 Scope and area of validity

¹ This Ordinance regulates the handling of organisms, their metabolic products and wastes in the environment, in particular the handling of genetically modified, pathogenic or alien organisms.

² Handling organisms in contained systems is regulated by the Containment Ordinance of 9 May 2012⁵.

³ The protection of personnel working with microorganisms is regulated by the Ordinance of 25 August 1999⁷ on Protection of Employees from Dangerous Organisms.

⁴ The marketing of pathogenic organisms:

- a. for application as plant protection products in agriculture is regulated by the Plant Protection Products Ordinance of 18 May 2005⁸;
- b. for application as biocidal products, the Biocidal Products Ordinance of 18 May 2005⁹.

⁵ For the marketing of alien insects, mites and nematodes for use as plant protection products in agriculture as well as for experimental releases of such organisms, the Ordinance of 18 May 2005 on Plant Protection Products applies.

⁶ This Ordinance does not apply to uses of organisms:

- a. in clinical trials on human beings;
- b. which are listed in Annexes 1 and 2 of the Plant Protection Ordinance of 28 February 2001¹⁰.

Art. 3 Definitions

¹ In this Ordinance:

- a. *organisms* means cellular or non-cellular biological entities capable of replication or of transferring genetic material. Mixtures and articles and products containing such entities are also regarded as organisms;

⁵ SR **814.912**

⁶ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012 2777**).

⁷ SR **832.321**

⁸ [AS **2005 3035 4097 5211**, **2006 4851**, **2007 821** No III 1469 Annex 4 No 54 1843 4541 6291, **2008 2155 4377** Annex 5 No 11 5271, **2009 401** Annex No 3 2845, **2010 2101 3845**. AS **2010 2331** Art. 84]. See today: the Ordinance from 12. May 2010 (SR **916.161**).

⁹ SR **813.12**

¹⁰ [AS **2001 1191**, **2002 945**, **2003 548 1858 4925**, **2004 1435 2201**, **2005 1103 1443 2603** Art. 8 No 2, **2006 2531**, **2007 1469** Annex 4 No 55 2369 4477 No IV 69 4723 5823 No I 20, **2008 4377** Annex 5 No 13 5865, **2009 2593 5435**, **2010 1057**. AS **2010 6167** Art. 60 No 1]. See today: the Ordinance from 27 October 2010 (SR **916.20**).

- b.¹¹ *microorganisms* means microbiological entities, in particular bacteria, algae, fungi, protozoa, viruses and viroids; cell cultures, parasites, prions and biologically active genetic material are also regarded as microorganisms;
- c. *small invertebrates* means arthropods, annelids, nematodes and flatworms;
- d. *genetically modified organisms* means organisms in which the genetic material has been altered by methods of gene technology in accordance with Annex 1, in a way that does not occur under natural conditions by crossing or natural recombination, as well as pathogenic or alien organisms that have also been genetically modified;
- e.¹² *pathogenic organisms* means organisms that can cause diseases in human beings, livestock and useful plants, in wild flora or fauna or other organisms, as well as alien organisms that are also pathogenic;
- f.¹³ *alien organisms* means organisms of a species, sub-species or lower taxonomic level that:
1. as a species, do not occur in Switzerland, the other EFTA and EU member states (not including overseas areas) in their wild form,
 2. have not undergone selection for use in agriculture or horticultural production to such an extent that their viability in the wild is reduced;
- g.¹⁴ ...
- h. *invasive alien organisms* means alien organisms of which it is known or should be assumed that they will spread in Switzerland and could achieve such a high population density that biological diversity or the sustainable use thereof could be impaired or human beings, animals and the environment could be endangered;
- i. *handling of organisms in the environment* means any deliberate activity using organisms that takes place outside a contained system, in particular culturing, processing, multiplication, modification, experimental release, marketing, transport, storage or disposal;
- j. *direct handling of organisms in the environment* means handling organisms in the environment, not including the handling of therapeutic products, foodstuffs and animal feedstuffs;
- k. *marketing* means the transfer of organisms to third parties in Switzerland for use in the environment, in particular by sale, exchange, giving as a gift, renting, lending or sending on approval, as well as their import for the use in the environment.

¹¹ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS 2012 2777).

¹² Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS 2012 2777).

¹³ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS 2012 2777).

¹⁴ Repealed by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, with effect from 1 June 2012 (AS 2012 2777).

² Transfer of organisms in order to carry out an experimental release does not count as marketing.

Chapter 2: Requirements for the Handling of Organisms in the Environment

Section 1: General Requirements for Handling Organisms

Art. 4 Self-supervision for marketing

¹ Any person who intends to market organisms for use in the environment must first:

- a. assess the possible hazards and impairments caused by the organisms, their metabolic products and wastes to human beings, animals or the environment as well as to biological diversity or the sustainable use thereof; and
- b. arrive at a justifiable conclusion that no such hazards and impairments are to be expected.

² The assessment referred to in paragraph 1 letter a must in particular consider:

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

Art. 5 Informing the recipients

Any person marketing organisms for use in the environment must:

- a. inform the recipient of the identity of the organisms, their metabolic products and wastes, as well as of their properties in relation to public health and the environment;
- b. instruct the recipient in such a way that handling the organisms in the environment in accordance with the regulations and the instructions will not endanger human beings, animals or the environment, or impair biological diversity or the sustainable use thereof;
- c. instruct the recipient as to the safety measures to be taken in the event of unintentional release.

Art. 6 Taking due care

¹ Any person handling organisms in the environment in ways other than marketing must take all due care to ensure that organisms, their metabolic and waste products:

- a. cannot endanger human beings, animals or the environment;
- b. do not impair biological diversity or the sustainable use thereof.

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

Section 2: Requirements for Handling Genetically Modified Organisms

Art. 7 Protection of human beings, animals, the environment and biological diversity from genetically modified organisms

¹ The handling of genetically modified organisms in the environment must be carried out in such a manner that it neither endangers human beings, animals and the environment nor impairs biological diversity or the sustainable use thereof, and in particular so that:

- a. the health of human beings and animals cannot be endangered, in particular by toxic or allergenic substances or through the spread of antibiotic resistances;
- b. the genetically modified organisms cannot spread or multiply in an uncontrolled way in the environment;
- c. no undesired properties can be permanently passed on to other organisms;
- d. populations of protected organisms, in particular those included in the Red Lists, or organisms that are important for the ecosystem in question, in particular those that are important for the growth and reproduction of plants, are not affected;
- e. no species of non-target organisms can be endangered;
- f. the material balance of the environment is not severely or permanently impaired;
- g. important functions of the ecosystem in question, in particular the fertility of the soil, are not severely or permanently impaired;
- h. in experimental releases, none of the new properties based on genetic modification can be permanently passed on to wild flora or fauna.

² Genetically modified organisms may not be directly handled in the environment, if:

- a.¹⁵ they are classified into Group 3 or 4 in accordance with Article 6 of the Containment Ordinance of 9 May 2012¹⁶;
- b. they contain genes resistant to antibiotics inserted by gene technology that are authorised for use in human and veterinary medicine;
- c. the recipient organisms used for the genetic modification are invasive.

¹⁵ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS 2012 2777).

¹⁶ SR 814.912

Art. 8 Protecting habitats and landscapes that are particularly sensitive or worthy of protection against genetically modified organisms

¹ In habitats and landscapes that are particularly sensitive or worthy of protection, the direct handling of genetically modified organisms is permissible only if it serves to prevent or eliminate hazards to human beings, animals, the environment, biological diversity or the sustainable use thereof, or impairments to the same. For areas in accordance with paragraph 2 letters a, e and f, deviating provisions in the applicable protection regulations are reserved.

² Habitats and landscapes that are particularly sensitive or worthy of protection are:

- a. areas that are designated nature reserves, on the basis of federal or cantonal law;
- b. surface waters and a strip 3 m wide along or around them;
- c.¹⁷ subterranean waters and catchment areas S1 and, for microorganisms, catchment areas S2 und S_n of groundwater protection zones;
- d. forests;
- e. nature reserves in accordance with Article 11 of the Hunting Act of 20 June 1986¹⁸;
- f. areas under landscape protection in accordance with federal or cantonal law.

Art. 9 Protection of production that does not use genetically modified organisms

¹ Any person who handles genetically modified organisms directly in the environment must take the required technical, organisational and staffing measures to prevent undesired mixing with non-genetically modified organisms; in particular, he or she must:

- a. observe the required distances for production that does not use genetically modified organisms;
- b. clean all equipment and machines thoroughly after use in accordance with recognised methods, if they are also used for non-genetically modified organisms;
- c. take precautions to prevent losses of genetically modified organisms;
- d. keep the relevant information about the handling and forward it to the recipients in an appropriate form.

² Any person who handles genetically modified organisms directly in the environment must, in exceptional events, document losses of genetically modified organisms and take appropriate measures to restore the original conditions.

¹⁷ Amended by Annex No 3 of the Ordinance of 4 Nov. 2015, in force since 1 Jan. 2016 (AS 2015 4791).

¹⁸ SR 922.0

³ Any person who markets genetically modified organisms must have an appropriate quality control system, which ensures, in particular, that:

- a. weak points at which mixtures or confusions could occur are recognised;
- b. the required technical, organisational and staffing measures to prevent mixtures are established and enforced;
- c. regular checks are carried out to examine the workability of the measures;
- d. the persons responsible are adequately trained;
- e. complete records are kept.

⁴ Any person who markets genetically modified organisms or products made from such organisms must:

- a. provide written information of the corresponding unique identifier, in accordance with the Annex to the Commission Regulation (EC) No 65/2004 of 14 January 2004¹⁹ establishing a system for the development and assignment of unique identifiers for genetically modified organisms, or, if this is lacking, the identity of the organisms, giving the essential characteristics, if the organisms and products require labelling in accordance with Article 10;
- b. provide the name and address of the person from whom further information can be obtained;
- c. forward all further relevant information that comes from their own supplier, in particular such information about the properties of the organisms, if it is significant for the protection of production that does not use genetically modified organisms, and information about the handling in the environment, to prevent the provisions on the protection of production that does not use genetically modified organisms being contravened.

⁵ Any person who markets genetically modified organisms or products made from such organisms must keep the following details for five years:

- a. the information in accordance with paragraph 4;
- b. the name and address of the recipient, but not those of the consumers;
- c. the name and address of the supplier.

⁶ Corresponding provisions in the legislation on foodstuffs and agriculture are reserved.

Art. 10 Labelling of genetically modified organisms

¹ Any person who markets genetically modified organisms must inform the recipient of the nature of the organisms through an easily recognisable label, with the note “genetically modified”.

² Labelling may be waived for mixtures, articles and products that contain genetically modified organisms if it is demonstrated that the mixtures, articles and products

¹⁹ ABl. L 10 of 16.1.2004, p. 5; the text of the Regulation can be obtained from FOEN, 3003 Bern.

contain only unintentional traces of authorised genetically modified organisms. The content of such traces may not:

- a. exceed 0.1 percent by mass for mixtures, articles and products that are handled directly in the environment;
- b. exceed 0.9 percent by mass for all other mixtures, articles and products.

³ The corresponding requirements for the labelling of mixtures, articles and products that contain genetically modified organisms stipulated by the regulations on therapeutic products and agriculture are reserved.

⁴ The requirements for foodstuffs guaranteeing freedom of choice for consumers are regulated in the legislation on foodstuffs.

Art. 11 Liability guarantee for genetically modified organisms

¹ Any person who intends to release genetically modified organisms that require a licence for experimental purposes (Art. 17) must guarantee sufficient financial reserves for determining, preventing or correcting possible hazards or impairments caused by genetically modified organisms.

² Any person who intends to release genetically modified organisms that require a licence for experimental purposes must guarantee legal liability:

- a. of 10 million Swiss francs to cover damage to persons or property (Art. 30 GTA); and
- b. of 1 million Swiss francs to cover damage to the environment (Art. 31 GTA).

³ Any person who intends to market organisms for direct handling in the environment for the first time must guarantee legal liability:

- a. of 20 million Swiss francs to cover damage to persons or property (Art. 30 GTA); and
- b. of 2 million Swiss francs to cover damage to the environment (Art. 31 GTA).

⁴ The obligation to guarantee liability can be fulfilled:

- a. by taking out insurance from an insurance company that is authorised to do business in Switzerland;
- b. by providing securities of equivalent value.

⁵ The following are exempt from this guarantee of liability:

- a. the Federal Government, its public corporations and institutions;
- b. the cantons as well as their public corporations and institutions, where the cantons cover their liabilities.

⁶ The person who guarantees liability must notify the competent executive authority of the start, suspension and termination of the guarantee.²⁰

⁷ The suspension and termination of the guarantee, unless previously replaced by a different guarantee, shall become effective 60 days after receipt of notification by the competent executive authority.²¹

Section 3: Requirements for Handling Pathogenic Organisms

Art. 12 Protection of human beings, animals, the environment and biological diversity from pathogenic organisms

¹ The handling of pathogenic organisms in the environment must be carried out in such a manner that it neither endangers human beings, animals or the environment nor impairs biological diversity or the sustainable use thereof, and in particular so that:

- a. the health of human beings and animals cannot be endangered, in particular not by toxic or allergenic substances or through the spread of antibiotic resistances;
- b. the organisms cannot spread or multiply in an uncontrolled way in the environment;
- c. populations of protected organisms are not impaired, in particular those included in the Red Lists, or organisms that are important for the ecosystem in question, in particular those that are important for the growth and reproduction of plants;
- d. no species of non-target organisms species can be endangered;
- e. the material balance of the environment is not severely or permanently impaired;
- f. important functions of the ecosystem in question, in particular the fertility of the soil, are not severely or permanently impaired.

² Pathogenic organisms which are classified into Groups 3 or 4 in accordance with Article 6 of the Containment Ordinance of 9 May 2012²², or which are invasive, may not be handled directly in the environment.²³

²⁰ Inserted by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012 2777**).

²¹ Inserted by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012 2777**).

²² SR **814.912**

²³ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012 2777**).

Art. 13 Protecting habitats that are particularly sensitive or worthy of protection against pathogenic organisms

¹ In habitats that are particularly sensitive or worthy of protection in accordance with Article 8 paragraph 2 letters a–d, the direct handling of pathogenic organisms is permissible only if it serves to prevent or eliminate hazards to human beings, animals, the environment, biological diversity or the sustainable use thereof, or impairments to the same.

² For areas in accordance with Article 8 paragraph 2 letter a, deviating provisions in the applicable protection regulations are reserved.

Art. 14 Liability guarantee for pathogenic organisms

¹ Any person who intends to release pathogenic organisms that require a licence for experimental purposes (Art. 17) must guarantee sufficient financial reserves for determining, preventing or correcting possible hazards or impairments caused by such organisms.

² Any person who intends to release pathogenic organisms that require a licence for experimental purposes must guarantee legal liability:

- a. of 1 million Swiss francs to cover damage to persons or property (Art. 59a^{bis} para. 1 EPA); and
- b. of 100,000 Swiss francs to cover damage to the environment (Art. 59a^{bis} para. 9 EPA).

³ Any person who intends to market such organisms for direct handling in the environment for the first time must guarantee legal liability:

- a. of 2 million Swiss francs to cover damage to persons or property (Art. 59a^{bis} para. 1 EPA); and
- b. of 200,000 Swiss francs to cover damage to the environment (Art. 59a^{bis} para. 9 EPA).

⁴ The obligation to guarantee liability can be fulfilled:

- a. by taking out insurance from an insurance company that is authorised to do business in Switzerland;
- b. by providing securities of equivalent value.

⁵ The following are exempt from this guarantee of liability:

- a. the Federal Government, its public corporations and institutions;
- b. the cantons as well as their public corporations and institutions, where the cantons cover their liabilities.

⁶ The person who guarantees liability must notify the competent executive authority of the start, suspension and termination of the guarantee.²⁴

²⁴ Inserted by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS 2012 2777).

⁷ The suspension and termination of the guarantee, unless previously replaced by a different guarantee, shall become effective 60 days after receipt of notification by the competent executive authority.²⁵

Section 4: Requirements for Handling Alien Organisms

Art. 15 Protection of human beings, animals, the environment and biological diversity from alien organisms

¹ The handling of alien organisms in the environment must be carried out in such a manner that it neither endangers human beings, animals or the environment nor impairs biological diversity or the sustainable use thereof, and in particular so that:

- a. the health of human beings and animals cannot be endangered, in particular not by toxic or allergenic substances;
- b. the organisms cannot spread or multiply in an uncontrolled way in the environment;
- c. populations of protected organisms are not impaired, in particular those included in the Red Lists, or organisms that are important for the ecosystem in question, in particular those that are important for the growth and reproduction of plants;
- d. no species of non-target organisms species can be endangered;
- e. the material balance of the environment is not severely or permanently impaired;
- f. important functions of the ecosystem in question, in particular the fertility of the soil, are not severely or permanently impaired.

² Invasive alien organisms in accordance with Annex 2 may not be handled directly in the environment, other than in the case of measures to control them. The Federal Office for the Environment (FOEN) may in exceptional cases grant a licence for direct handling in the environment if the applicant can prove that he or she has taken all the measures required to observe paragraph 1.²⁶

³ Soil that has been removed that is contaminated with invasive alien organisms in accordance with Annex 2 must be used only at the place of excavation or disposed of so as to prevent the spread of such organisms.²⁷

⁴ The provisions in the legislation on forests, hunting and fishing are reserved.²⁸

²⁵ Inserted by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS 2012 2777).

²⁶ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS 2012 2777).

²⁷ Amended by Annex 6 No 12 of the Waste Management Ordinance of 4 Dec. 2015, in force since 1 Jan. 2016 (AS 2015 5699).

²⁸ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS 2012 2777).

Art. 16 Protecting habitats and landscapes that are particularly sensitive or worthy of protection against alien organisms

¹ In habitats that are particularly sensitive or worthy of protection in accordance with Article 8 paragraph 2 letters a–d, the direct handling of alien organisms is permissible only if it serves to prevent to eliminate hazards to human beings, animals, the environment, biological diversity or the sustainable use thereof, or impairments to the same.

² For areas in accordance with Article 8 paragraph 2 letter a, deviating provisions in the applicable protection regulations are reserved.

Chapter 3: Licensing and Notifications

Section 1: Experimental Releases

Art. 17²⁹ Licensing requirement

Any person who intends to release the following organisms for experimental purposes shall require a licence from the FOEN:

- a. genetically modified organisms;
- b. pathogenic organisms;
- c. alien small invertebrates that are intended for use in the environment and not as pets.

Art. 18 Exceptions from the licensing requirement

¹ A licence is not required for experimental releases involving genetically modified organisms, if they are authorised for a particular direct application in the environment in accordance with Article 25 and if the experimental release aims to gather further information for the same application.

² A licence is not required for experimental releases involving pathogenic organisms if they:

- a. are authorised for a particular direct application in the environment in accordance with Article 25; or
- b. are not alien and are not pathogenic to human beings or vertebrates.

³ A licence is not required for experimental releases involving alien small invertebrates if they are authorised for a particular direct application in the environment in accordance with Article 25.

²⁹ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS 2012 2777).

Art. 19 Licence applications for experimental releases of genetically modified organisms

¹ The licence application for an experimental release of genetically modified organisms must contain all the required information to prove that the experimental release cannot contravene the requirements of Articles 7–9 and 11.

² The application must contain the following documents, in particular:

- a. a description of the experiment with at least the following details:
 1. details of the objective and context of the experiment,
 2. reasons why the information sought cannot be obtained through experiments in contained systems,
 3. a presentation of the anticipated new scientific results in terms of the impacts on human beings, animals or the environment, biological diversity and the sustainable use thereof and the efficacy of safety measures which can be gained thanks to the experiment;
- b. a technical dossier with the information in accordance with Annexes IIIA or IIIB and IV of the Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001³⁰ on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, but without details of the monitoring plans;
- c. the results of previous experiments, in particular:
 1. results of preliminary experiments in contained systems to determine biological safety,
 2. data, results and evaluations of experimental releases carried out with the same organisms or their host organisms under comparable climatic conditions and with comparable fauna and flora;
- d. the risk determination and assessment in accordance with Annex 4;
- e. a monitoring plan to show how the applicant will examine whether the assumptions of the risk determination and assessment in accordance with Annex 4 are correct and whether the measures to adhere to the requirements of Article 6 paragraphs 1 and 2 and Art. 7 GTA are sufficient, and which contains at least the following details:
 1. the type, specificity, sensitivity and reliability of the methods,
 2. the duration and frequency of the monitoring;
- f. an evaluation of interests in accordance with Article 8 GTA that shows that the genetic modification of the genetic material of animals or plants has not failed to respect the dignity of living beings;
- g. a public information plan that gives information about how, when and where the public will be informed about the object, time and place of the planned experimental release;

³⁰ ABl. L 106 of 17.4.2001, p. 1; the text of the Directive can be obtained from the FOEN, 3003 Bern.

h. proof that the liability guarantee has been fulfilled.

³ The documentation of the results of previous experiments in accordance with paragraph 2 letter c subsection 2 may refer to data or results from another applicant if this person has given written permission.

⁴ The FOEN may waive certain details of the technical dossier in accordance with paragraph 2 letter b if the applicant can prove that these details are not necessary for an evaluation of the application.

⁵ A single application may be submitted if an experimental release is being carried out for the same purpose and within a limited period:

- a. with a single genetically modified organism at different places;
- b. with a combination of organisms at the same place or in different places.

Art. 20 Licence applications for experimental releases of pathogenic organisms

¹ The licence application for an experimental release of pathogenic organisms must contain all the required information to prove that the experimental release cannot contravene the requirements of Articles 12–14.

² The application must contain the following documents, in particular:

- a. details of the objective and context of the experiment;
- b. a technical dossier with the information in accordance with Annex 3.1;
- c. the results of previous experiments, in particular:
 - 1. results of preliminary experiments in contained systems to determine biological safety,
 - 2. data, results and evaluations of experimental releases carried out with the same organisms under comparable climatic conditions and with comparable fauna and flora;
- d. the risk determination and assessment in accordance with Annex 4;
- e. a monitoring plan to show how the applicant will examine whether the assumptions of the risk determination and assessment in accordance with Annex 4 are correct and whether the measures to adhere to the requirements of Articles 12 and 13 are sufficient, and which contains at least the following details:
 - 1. the type, specificity, sensitivity and reliability of the methods,
 - 2. the duration and frequency of the monitoring;
- f. details of whether the public will be informed about the planned experimental release;
- g. proof that the liability guarantee has been fulfilled.

³ The documentation of the results of previous experiments in accordance with paragraph 2 letter c subsection 2 may refer to data or results from another applicant if this person has given written permission.

⁴ The FOEN may waive certain details of the technical dossier in accordance with paragraph 2 letter b if the applicant can prove that these details are not necessary for an evaluation of the application.

⁵ A single application may be submitted if an experimental release is being carried out for the same purpose and within a limited period:

- a. with a single pathogenic organism at different places;
- b. with a combination of pathogenic organisms at the same place or in different places.

Art. 21 Licence applications for experimental releases of alien small invertebrates

¹ The licence application for an experimental release of alien small invertebrates must contain all the required information to prove that the experimental release cannot contravene the requirements of Articles 15 and 16.

² The application must contain the following documents, in particular:

- a. details of the objective and context of the experiment;
- b. a technical dossier with the information in accordance with Annex 3.3;
- c. the results of previous experiments, in particular:
 1. results of preliminary experiments in contained systems to determine biological safety,
 2. data, results and evaluations of experimental releases carried out with the same organisms under comparable climatic conditions and with comparable fauna and flora;
- d. the risk determination and assessment in accordance with Annex 4;
- e. a monitoring plan to show how the applicant will examine whether the assumptions of the risk determination and assessment in accordance with Annex 4 are correct and whether the measures to adhere to the requirements of Articles 15 and 16 are sufficient, and which contains at least the following details:
 1. the type, specificity, sensitivity and reliability of the methods,
 2. the duration and frequency of the monitoring;
- f. details of whether the public will be informed about the planned experimental release.

³ The documentation of the results of previous experiments in accordance with paragraph 2 letter c subsection 2 may refer to data or results from another applicant if this person has given written permission.

⁴ The FOEN may waive certain details of the technical dossier in accordance with paragraph 2 letter b if the applicant can prove that these details are not necessary for an evaluation of the application.

⁵ A single application may be submitted if an experimental release is being carried out for the same purpose and within a limited period:

- a. with a single alien organism at different places;
- b. with a combination of alien organisms at the same place or in different places.

Art. 22 Simplified licensing procedure

¹ The applicant may request a simplified licensing procedure for experimental releases of genetically modified organisms, pathogenic organisms or alien small invertebrates if:

- a. an experimental release with comparable possible hazards and impairments has been authorised in Switzerland, in particular, if it involves the same organisms;
- b. these organisms originate from the crossing of two organisms that have already been authorised for marketing for direct use in the environment, and it can be shown that the sum of the properties of the crossing do not differ from the sum of the properties of the authorised organisms.

² For a simplified licensing procedure, at least the documents in accordance with Article 19 paragraph 2 letters a, d, e and h or in accordance with Article 20 paragraph 2 letters a, d, e and g or Article 21 paragraph 2 letters a, d and e must be submitted.

Art. 23 Changes and new findings

¹ The applicant or licence holder must inform the FOEN without delay about:

- a. new findings and observations that might require a reassessment of the risk;
- b. changes to the experimental conditions and the monitoring plan.

² The applicant or licence holder must examine the measures listed in the licence and, if the observance of the requirements in accordance with Articles 7–9, 12 and 13 or 15 and 16 is directly and seriously endangered, take the additional measures required.

³ The FOEN shall inform the specialist agencies concerned (Art. 37 para. 1).

Art. 24 Reporting

¹ The licence holder must submit a report to the FOEN within 4 months of completion of the experimental release. The FOEN may extend the deadline upon reasonable request. The report shall be publicly accessible and shall encompass, in particular, the following details:

- a. the actual course of the experimental release;
- b. description of the deviations from the planned course of the experiment and their evaluation in terms of a hazard to human beings, animals or the environment or an impairment of biological diversity and the sustainable use thereof;

c. results and conclusions of the monitoring.

² The applicant or licence holder must submit to the FOEN as soon as possible the rest of the results and findings of the experiment. If these are published in a scientific organ, a copy of the article must be submitted to the FOEN on its publication.

³ The FOEN shall inform the specialist agencies (Art. 37 para. 1).

Section 2: Marketing

Art. 25³¹ Licensing requirement

Any person who intends to market the following organisms for use in the environment either for the first time or for a new use shall require a licence from the FOEN:

- a. genetically modified organisms;
- b. pathogenic organisms;
- c. alien small invertebrates that are intended for use in the environment and not as pets

Art. 26 Applicable licensing procedure

The licence in accordance with Article 25 shall be issued by one of the following authorities, in accordance with the product, as part of the applicable licensing procedure:

Application	Competent authority	Applicable licensing procedure
a. therapeutic products	Swiss Agency for Therapeutic Products	Therapeutic Products Ordinance of 17 October 2001 ³²
b. foodstuffs, additives and processing aids	Federal Food Safety and Veterinary Office of Public Health (FSVO) ³³	Foodstuffs and Utility Articles Ordinance of 23 November 2005 ³⁴
c. plant propagation material exclusively for use in forests	FOEN	Release Ordinance of 10 September 2008
d. ³⁵ plant propagation material for all other uses	Federal Office for Agriculture (FOAG)	Seeds Ordinance of 7 December 1998 ³⁶

³¹ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012** 2777).

³² SR **812.212.21**

³³ The name of this administrative unit was changed in application of Art. 16 para. 3 of the Publications Ordinance of 17 Nov. 2004 (AS **2004** 4937) on 1 Jan. 2014. The change has been made throughout the text.

³⁴ SR **817.02**

³⁵ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012** 2777).

³⁶ SR **916.151**

Application	Competent authority	Applicable licensing procedure
e. plant protection products	FOAG	Plant Protection Products Ordinance of 18 May 2005 ³⁷
f. fertilisers	FOAG	Fertilisers Ordinance of 10 January 2001 ³⁸
g. animal feedstuffs	FOAG	Feedstuffs Ordinance of 26 May 1999 ³⁹
h. immunological products for veterinary use	FSVO	Therapeutic Products Ordinance of 17 October 2001
i. import of harmful organisms that are not genetically modified nor particularly hazardous for agricultural crops or horticultural production	FOAG	Plant Protection Ordinance of 28 February 2001 ⁴⁰
j. biocidal products	FOPH	Biocidal Products Ordinance of 18 May 2005 ⁴¹
k. all other uses	FOEN	Release Ordinance of 10 September 2008

Art. 27 Exceptions from the licensing requirement

A licence is not required for marketing:

- a. plant reproductive material in accordance with Article 14a of the Seeds Ordinance of 7 December 1998⁴²;
- b. animal feedstuffs in accordance with Article 21b Feedstuffs Ordinance of 26 May 1999⁴³;
- c. foodstuffs, if the requirements of Article 23 of the Foodstuffs and Utility Articles Ordinance of 23 November 2005⁴⁴ have been fulfilled.

³⁷ [AS 2005 3035 4097 5211, 2006 4851, 2007 821 No III 1469 Annex 4 No 54 1843 4541 6291, 2008 2155 4377 Annex 5 No 11 5271, 2009 401 Annex No 3 2845, 2010 2101 3845. AS 2010 2331 Art. 84]. See today: the Ordinance from 12. May 2010 (SR 916.161).

³⁸ SR 916.171

³⁹ [AS 1999 1780 2748 Annex 5 No 6, 2001 3294 No II 14, 2002 4065, 2003 4927, 2005 973 2695 No II 19 5555, 2007 4477 No IV 70, 2008 3655 4377 Annex 5 Ziff. 14, 2009 2599, 2011 2405. AS 2011 5409 Art. 77]. See today: the Ordinance from 26 October 2011 (SR 916.307).

⁴⁰ [AS 2001 1191, 2002 945, 2003 548 1858 4925, 2004 1435 2201, 2005 1103 1443 2603 Art. 8 No 2, 2006 2531, 2007 1469 Annex 4 No 55 2369 4477 No IV 69 4723 5823 No I 20, 2008 4377 Annex 5 No 13 5865, 2009 2593 5435, 2010 1057. AS 2010 6167 Art. 60 No 1]. See today: the Ordinance from 27 October 2010 (SR 916.20).

⁴¹ SR 813.12

⁴² SR 916.151

⁴³ [AS 1999 1780 2748 Annex 5 No 6, 2001 3294 No II 14, 2002 4065, 2003 4927, 2005 973 2695 No II 19 5555, 2007 4477 No IV 70, 2008 3655 4377 Annex 5 No 14, 2009 2599, 2011 2405. AS 2011 5409 Art. 77]. See today: the Ordinance from 26 October 2011 (SR 916.307).

⁴⁴ SR 817.02

Art. 28 Licence applications for marketing genetically modified organisms

¹ The licence application for placing genetically modified organisms on the market, which must be submitted as part of the applicable licensing procedure in accordance with Article 26, must contain all the required information to prove that the handling of the organisms cannot contravene the requirements of Articles 7–11.

² The application must contain the following documents, in particular:

- a. a technical dossier with the information in accordance with Annexes IIIA or IIIB and IV of the Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001⁴⁵ on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC;
- b. the results of previous experiments using the same organisms concerning hazards to human beings or the environment, or impairments caused to the same, in particular, experiments in contained systems or, possibly, field trials;
- c. if available, any licences and evaluations from Swiss and foreign authorities for experimental releases and marketing of the same organisms;
- d. a risk determination and assessment in accordance with Annex 4;
- e. a monitoring plan to show how the applicant will examine whether the assumptions of the risk determination and assessment in accordance with Annex 4 are correct and whether the measures to adhere to the principles of Article 6 paragraphs 1 and 3 and Art. 7 GTA are sufficient, and which contains at least the following details:
 1. the type, specificity, sensitivity and reliability of the methods,
 2. the duration and frequency of the monitoring;
- f. an evaluation of interests in accordance with Article 8 GTA that shows that the genetic modification of the genetic material of animals or plants has not failed to respect the dignity of living beings;
- g. a proposal for the labelling (Art. 10), informing the recipients (Art. 5), and for any packaging of the organisms;
- h. proof that the liability guarantee has been fulfilled.

³ The documentation of the results of previous experiments in accordance with paragraph 2 letter b may refer to data or results from another applicant, if this person has given written permission.

Art. 29 Licence applications for marketing pathogenic organisms

¹ The licence application for placing pathogenic organisms on the market, which must be submitted as part of the applicable licensing procedure in accordance with

⁴⁵ ABl. L 106 of 17.4.2001, p. 1; the text of the Directive can be obtained from the FOEN, 3003 Bern.

Article 26, must contain all the required information to prove that the handling of the organisms cannot contravene the requirements of Articles 12–14.

² The application must contain the following documents, in particular:

- a. a technical dossier with the information in accordance with Annex 3.2;
- b. the results of previous experiments using the same organisms concerning hazards to human beings or the environment, or impairments caused to the same, in particular, experiments in contained systems or field trials;
- c. if available, any licences and evaluations from Swiss and foreign authorities for experimental releases and marketing of the same organisms;
- d. a risk determination and assessment in accordance with Annex 4;
- e. a monitoring plan to show how the applicant will examine whether the assumptions of the risk determination and assessment in accordance with Annex 4 are correct and whether the measures to adhere to the principles of Articles 12 and 13 are sufficient, and which contains at least the following details:
 1. the type, specificity, sensitivity and reliability of the methods,
 2. the duration and frequency of the monitoring;
- f. a proposal for informing the recipients (Art. 5), and for any packaging of the organisms;
- g. proof that the liability guarantee has been fulfilled.

³ The documentation of the results of previous experiments in accordance with paragraph 2 letter b may refer to data or results from another applicant, if this person has given written permission.

Art. 30 Licence applications for marketing alien small invertebrates

¹ The licence application for placing alien small invertebrates on the market, which must be submitted as part of the applicable licensing procedure in accordance with Article 26, must contain all the required information to prove that the handling of the organisms cannot contravene the requirements of Articles 15 and 16.

² The application must contain the following documents, in particular:

- a. a technical dossier with the information in accordance with Annex 3.4;
- b. the results of previous experiments using the same organisms concerning hazards to human beings or the environment, or impairments caused to the same, in particular, experiments in contained systems or, possibly, field trials;
- c. if available, any licences and evaluations from Swiss and foreign authorities for experimental releases and marketing of the same organisms;
- d. a risk determination and assessment in accordance with Annex 4;
- e. a monitoring plan to show how the applicant will examine whether the assumptions of the risk determination and assessment in accordance with An-

nex 4 are correct and whether the measures to adhere to the principles of Articles 15 and 16 are sufficient, and which contains at least the following details:

1. the type, specificity, sensitivity and reliability of the methods,
 2. the duration and frequency of the monitoring;
- f. a proposal for informing the recipients (Art. 5), and for any packaging of the organisms.

³ The documentation of the results of previous experiments in accordance with paragraph 2 letter b may refer to data or results from another applicant, if this person has given written permission.

Art. 31 New findings

¹ The applicant or the licence holder must inform the licensing authority without delay of new findings or observations that might require a reassessment of the risk.

² At the same time, the licence holder must examine the measures given in the licence and, if adherence to any of the requirements of Articles 7–9, 12 and 13 or 15 and 16 is directly and seriously endangered, take the additional measures required.

³ The FOEN shall inform the specialist agencies (Art. 43 para. 1).

Art. 32 Notification of the release of genetically modified organisms in the environment

¹ Any person who releases directly in the environment genetically modified organisms that are authorised for marketing must notify the FOEN by two weeks after the release at the latest of:

- a. his or her name and address;
- b. the unique identifier of the genetically modified organisms, in accordance with the Annex to the Commission Regulation (EC) No 65/2004 of 14 January 2004⁴⁶ establishing a system for the development and assignment of unique identifiers for genetically modified organisms, or, if this is lacking, the identity of the organisms, giving the essential characteristics;
- c. the sites on which the organisms are being released;
- d. the timeframe, in particular the beginning and end of the release of the organisms;
- e. the type of use and release of the organisms.

² Any person who releases genetically modified organisms directly in the environment must keep records of this; he or she must give the required information to the FOEN and carry out or tolerate investigations if necessary.

⁴⁶ ABl. L 10 of 16.1.2004, p. 5; the text of the Regulation can be obtained from the FOEN, 3003 Bern.

Section 3: Common Provisions

Art. 33 Residence, business premises

¹ Any person who applies to release organisms for experimental purposes or to place them on the market must have a residence or business premises in Switzerland.

² In relation to the placing on the market of foodstuffs, the provisions of the legislation on foodstuffs are reserved.

Art. 34 Number of copies of application

¹ The licence application should be submitted in the required number of copies. For experimental releases, the application should also be submitted in the official language of the local community where the experimental release will take place.

² Further copies in the required number should be submitted for public information purposes; these must contain at least the details in accordance with Article 54 paragraph 4.

Art. 35 Legal succession

¹ The legal successor of the holder of a licence for experimental releases or marketing in accordance with Article 26 letters c and k, must request transfer of the licence from the FOEN.

² The licence shall be transferred once the conditions for the licence have been fulfilled.

Chapter 4: Responsibilities of the Authorities

Section 1: Experimental Releases

Art. 36 Application documents, publication and public information

¹ The FOEN shall examine whether the documentation submitted (Art. 19, 20 or 21) for evaluating the application is complete. If the documentation is incomplete, it shall return this to the applicant for supplementation or revision, indicating which information is lacking.

² It shall give notice of receipt of the application in the Federal Gazette, when the application is complete, and shall ensure that the non-confidential documents are displayed for 30 days for examination:

- a. at the FOEN;
- b. in the local commune where the experimental release will take place.

³ Any person who claims party rights in accordance with the the Federal Act of 20 December 1968⁴⁷ on Administrative Procedure must object in writing during the display period, giving details of their party status.

⁴ During the display period all further persons may submit a written statement on the files.

⁵ The FOEN may take part in public information events to inform the public about the progress of the procedure.

Art. 37 Examination of the application, involvement of the specialist agencies

¹ The FOEN shall examine the application. Concomitantly with announcement of the receipt of the application in the Federal Gazette, the FOEN shall forward the application to the following other authorities, who shall evaluate it in their field of responsibility and state their position within 50 days:

- a. the FOPH, FSVO and FOAG;
- b. the Federal Expert Committee for Biosafety (FECB) and the Federal Ethics Committee on Non-human Biotechnology (ECNH);
- c. the designated authority of the canton in question for information about local features.

² The FOEN shall supply the specialist agencies with the submissions in accordance with Article 36 paragraphs 3 and 4.

³ It shall supply the specialist agencies' statements to the parties for their comments and the specialist agencies reciprocally for their information.

⁴ If the examination shows that the documents submitted are insufficient for assessing the application, the FOEN shall request additional documents from the applicant, stating the reasons therefor, and request comments on them from the parties and the specialist agencies. In this case the deadline shall be extended accordingly.

⁵ On request, it shall inform the State Secretariat for Economic Affairs (seco) and the Swiss Accident Insurance Organisation (SUVA) of the application.

Art. 38 Issue of a licence

¹ The FOEN shall authorise the experimental release, taking into consideration the statements received from the parties and the specialist agencies, as a rule within 3 months of announcing the receipt of the application in the Federal Gazette plus any extension of deadline, if:

- a. examination of the application, in particular the risk assessment in accordance with Annex 4, leads to the conclusion that, given the current state of scientific knowledge and experience, the experimental release cannot endan-

ger human beings, animals and the environment or impair biological diversity and the sustainable use thereof (Art. 7 and 8, 12 and 13, or 15 and 16);

- b. the information sought cannot be gained through further experiments in contained systems;
- c. in the case of genetically modified organisms, additionally:
 - 1. production that does not use genetically modified organisms and consumers' freedom of choice are not impaired (Art. 9),
 - 2. the assessment of the application, in particular based on the evaluation of interests in accordance with Article 8 GTA, leads to the conclusion that the genetic modification has not failed to respect the dignity of living beings in the animals or plants used,
 - 3. it has been shown that in terms of direct handling in the environment, the experimental release contributes to researching the biosafety of genetically modified organisms;
- d. based on the assessment of the application, in particular based on the risk assessment, the experimental release is permissible under the laws enforced by the FOPH, FSVO and FOAG, and if these offices approve carrying out the experimental release.

² The FOEN shall make the licence subject to conditions and stipulations necessary for protecting human beings, the environment, biological diversity and the sustainable use thereof. It may in particular:

- a. demand that the site of the experimental release be marked, fenced in or specially secured;
- b. order that, in addition to the monitoring plan (Art. 19 para. 2 letter e, 20 para. 2 letter e, or 21 para. 2 letter e), the site of the experimental release and surroundings be kept under observation during and after the experimental release, 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 experimental release be inspected by a support group (Art. 41 para. 2) at the applicant's expense;
- d. demand interim reports;
- e. demand that the samples, detection methods and materials required for monitoring be made available free of charge.

³ The FOEN shall inform the parties and the specialist agencies of its decision (Art. 37 para. 1) and make it publicly accessible via automated information and communication services.

Art. 39 Simplified licensing procedure

¹ If the conditions of Article 22 have been fulfilled, the FOEN shall carry out a simplified licensing procedure.

² It may in particular:

- a. waive the need to submit the documentation in accordance with Article 19 paragraph 2 letters b, c, f and g, or in accordance with Article 20 paragraph 2 letters b, c and f, or Article 21 paragraph 2 letters b, c and f;
- b. shorten the deadlines for statements to be submitted.

Art. 40 New findings

¹ If any of the specialist agencies involved in the procedure (Art. 37 para. 1) comes into possession of new findings on the risks posed by the experimental release after issue of the licence, it shall inform the FOEN.

² In the case of information in accordance with paragraph 1 and Article 23, the FOEN shall, with the consent of the federal agencies involved in the procedure, prescribe appropriate measures. In particular, it may require that:

- a. the risk determination and assessment (Art. 19 para. 2 letter d, 20 para. 2 letter d, or 21 para. 2 letter d) be carried out again;
- b. the conditions of the experimental release be changed;
- c. the experimental release be interrupted or if necessary terminated and, as far as possible, the original conditions restored.

³ It shall consult the SECB and the ECNH.

Art. 41 Monitoring of authorised experimental releases

¹ The FOEN shall monitor the carrying out of experimental releases and order the necessary measures.

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

- a. shall monitor the carrying out of the experimental release by spot checks at the site and examine, in particular, adherence to the conditions and stipulations associated with the licence; in particular it shall have unannounced access to the site of the experimental release, it may take samples, and it may view all documents;
- b. shall inform the FOEN without delay about deviations from the conditions and stipulations associated with the licence or about other observations and findings relevant to safety;
- c. may, with the agreement of the FOEN, provide public information about its mandate and planned procedure;
- d. shall keep records of its activities as well as its observations and findings;
- e. shall, after conclusion of the experiment, draw up a report of the results of the monitoring and transmit it to the FOEN.

³ The FOEN shall inform the specialist agencies and the applicant of the monitoring results.

Section 2: Marketing

Art. 42 Application documents and publication

¹ The licensing authority under Article 26 shall examine whether the documentation submitted (Art. 28, 29 or 30) is complete. If the documentation is incomplete, it shall return this to the applicant for supplementation or revision, indicating which information is lacking.

² If the application concerns organisms that will be handled directly in the environment, the licensing authority shall announce receipt of the application in the Federal Gazette, once the application is complete, and shall ensure that the non-confidential documents are displayed for 30 days for examination.

³ During the display period, any person may submit a written statement on the application. Any person who makes use of this opportunity does not acquire party rights in the licensing procedure through this alone.

⁴ If the organisms concerned are genetically modified or pathogenic organisms that will be handled directly in the environment, the environmental protection organisations in accordance with Article 28 GTA or in accordance with Article 55f EPA may register their objections during the display period.

Art. 43 Examination of the application, involvement of federal offices and committees

¹ The licensing authority in accordance with Article 26 shall examine the application. It shall forward it to the following other specialist agencies, who shall evaluate it in their field of responsibility and state their position:

- a. the FOPH and FOEN;
- b. the FSVO and FOAG, if the application falls within their area of responsibility;
- c. the SECB and the ECNH.

² The licensing authority shall supply the specialist agencies with the details in accordance with Article 42 paragraphs 3 and 4.

³ It shall supply the specialist agencies' statements to the parties concerned for their comments and the specialist agencies reciprocally for their information.

⁴ If the examination shows that the documents submitted are insufficient for assessing the application, the FOEN shall request additional documents from the applicant and request comments on them from the parties and the specialist agencies.

Art. 44 Issue of a licence

¹ The licensing authority shall authorise marketing, taking into consideration the statements received from the parties and the specialist agencies, if the assessment of the application leads to the conclusion that:

- a. the requirements of the applicable licensing procedure have been fulfilled;

- b. marketing cannot endanger human beings, animals and the environment or impair biological diversity and the sustainable use thereof (Art. 7 and 8, 12 and 13, or 15 and 16);
- c. in the case of genetically modified organisms, additionally:
 - 1. production that does not use genetically modified organisms (Art. 9) and consumers' freedom of choice are not impaired,
 - 2. the assessment of the application, in particular based on the evaluation of interests in accordance with Article 8 GTA, leads to the conclusion that the genetic modification has not failed to respect the dignity of living beings in the animals or plants used;
- d. marketing is permissible under the laws enforced by the FOPH and FOEN, and if applicable the FSVO and FOAG, and these offices therefore approve marketing.

² The licensing authority may make the licence subject to conditions, and may in particular:

- a. limit the use of the organisms or permit the use only under certain conditions;
- b. demand, at the applicant's expense, further investigations in addition to the monitoring plan (Art. 28 para. 2 letter e 29 para. 2 letter e and 30 para. 2 letter e) to identify possible delayed consequences for human beings, animals or the environment, for biological diversity and the sustainable use thereof, or for the protection of production that does not use genetically modified organisms; and the production of a report.

³ A licence is valid for up to 10 years. It may be extended for a further 10 years maximum if the competent authority and the specialist agencies, taking into account possible new findings, conclude that the conditions given in paragraph 1 continue to be met.

Art. 45 New findings

¹ If one of the specialist agencies involved in the procedure comes into possession of new findings about the risks posed by the marketing, it shall inform the licensing authority.

² The specialist agencies whose agreement is necessary for the issue of a licence may demand that the licensing authority, in particular:

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

³ If the licensing authority comes into possession of such new findings or if such new findings are reported by the applicant or licence holder (Art. 31), it shall order the necessary measures after consulting the SECB and the ECNH, and with the agreement of the federal agencies involved in the procedure. No consultation is required for precautionary measures if the risk is imminent. The licensing authority

shall inform without delay the specialist agencies about the new findings and the measures taken.

Art. 46 Monitoring of self-supervision

¹ For organisms that may be marketed without a licence, the FOEN may demand evidence from the distributor that he or she is exercising self-supervision, together with documentation, if there is reason to believe that organisms placed on the market could endanger human beings, animals or the environment, or could impair biological diversity or the sustainable use thereof. It shall give the distributor sufficient time to respond. The FOEN shall consult further federal agencies as required.

² The FOEN may:

- a. demand that the person marketing the organisms repeat the self-supervision within a certain period and, if necessary, supplement or amend it;
- b. prescribe the form and the content of the information supplied to recipients, in particular the details of the organisms' properties and the recommendations and instructions for their handling in the environment;
- c. demand that the person marketing the organisms remove inappropriate or misleading labelling or information.

³ If the distributor does not comply with the demands within the deadline set, the FOEN may then prohibit marketing of the organisms in question.

⁴ The FOEN shall inform the cantons of the measures prescribed.

Art. 47 Subsequent monitoring (supervising the market) in accordance with other regulations

¹ Subsequent monitoring (supervising the market) shall be carried out:

- a. for therapeutic products in accordance with the Therapeutic Products Act of 15 December 2000⁴⁸;
- b. for foodstuffs and utensils in accordance with the Foodstuffs Act of 9 October 1992⁴⁹;
- c. for plant propagation materials exclusively for use in forests in accordance with the Forests Ordinance of 30 November 1992⁵⁰;
- d. for plant propagation materials for all other uses in accordance with the Seeds Ordinance of 7 December 1998⁵¹;

⁴⁸ SR **812.21**

⁴⁹ SR **817.0**

⁵⁰ SR **921.01**

⁵¹ SR **916.151**

- e. for plant protection products in accordance with the Plant Protection Products Ordinance of 18 May 2005⁵²;
- f. for fertilisers in accordance with the Fertilisers Ordinance of 10 January 2001⁵³;
- g. for animal feedstuffs in accordance with the Feedstuffs Ordinance of 26 May 1999⁵⁴;
- h. for immunological products for veterinary use in accordance with the Therapeutic Products Act of 15 December 2000;
- i. for the import of organisms that are not genetically modified nor particularly hazardous for agricultural crops and horticultural production in accordance with the Plant Protection Ordinance of 28 February 2001⁵⁵;
- j. for biocidal products in accordance with the Biocidal Products Ordinance of 18 May 2005⁵⁶.

² The responsible authority shall inform the FOEN and FOPH about orders it has issued, if the requirements of this Ordinance are affected.

³ The samples, detection methods and materials required for monitoring shall be made available to the competent authorities.

⁴ If the monitoring shows that provisions of this Ordinance have been contravened, the person responsible shall bear the costs of the monitoring.

Art. 48 Subsequent monitoring (supervising the market) in accordance with this Ordinance

¹ The cantons are responsible for subsequent monitoring (supervising the market) of organisms placed on the market which are not subject to the controls stipulated by Article 47.

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

- a. the regulations regarding the informing of recipients (Art. 5) are being observed;

⁵² [AS 2005 3035 4097 5211, 2006 4851, 2007 821 No III 1469 Annex 4 No 54 1843 4541 6291, 2008 2155 4377 Annex 5 No 11 5271, 2009 401 Annex No 3 2845, 2010 2101 3845. AS 2010 2331 Art. 84]. See today: the Ordinance from 12 May 2010 (SR 916.161).

⁵³ SR 916.171

⁵⁴ [AS 1999 1780 2748 Annex 5 No 6, 2001 3294 No II 14, 2002 4065, 2003 4927, 2005 973 2695 No II 19 5555, 2007 4477 No IV 70, 2008 3655 4377 Annex 5 No 14, 2009 2599, 2011 2405. AS 2011 5409 Art. 77]. See today: the Ordinance from 26 October 2011 (SR 916.307).

⁵⁵ [AS 2001 1191, 2002 945, 2003 548 1858 4925, 2004 1435 2201, 2005 1103 1443 2603 Art. 8 No 2, 2006 2531, 2007 1469 Annex 4 No 55 2369 4477 No IV 69 4723 5823 No I 20, 2008 4377 Annex 5 No 13 5865, 2009 2593 5435, 2010 1057. AS 2010 6167 Art. 60 No 1]. See today: the Ordinance from 27 October 2010 (SR 916.20).

⁵⁶ SR 813.12

- b. the marketing of genetically modified or pathogenic organisms has been authorised;
- c. the handling of particular organisms is not prohibited;
- d. the conditions and stipulations linked to the issue of the marketing licence are being observed;
- e. genetically modified organisms are correctly labelled (Art. 10);
- f. the measures prescribed by the FOEN in accordance with paragraph 4 are being implemented.

³ If the monitoring shows that the provisions of paragraph 2 letters b-f are being contravened, the canton in which the distributor is resident or has business premises shall prescribe the necessary measures and inform the FOEN and the other cantons.

⁴ If the monitoring shows that provisions of this Ordinance concerning marketing are being contravened, the canton shall inform the FOEN. The FOEN shall conduct the necessary investigations, and prescribe the necessary measures. If the organisms in question may be placed on the market without a licence, Article 46 applies.

⁵ The samples, detection methods and materials required for monitoring shall be made available to the competent authorities.

⁶ If the monitoring shows that requirements in this Ordinance are being contravened, the persons responsible shall pay the costs of the monitoring. The monitoring authorities shall issue an invoice directly to these persons.

Section 3: Monitoring the Duty of Care

Art. 49

¹ The cantonal authorities shall monitor observance of the duty of care when handling organisms in the environment, in accordance with Articles 6–9, 12, 13, 15 and 16.

² If the monitoring shows cause for complaint, the canton in question shall prescribe the necessary measures to be taken.

Section 4: Monitoring Environmental Pollution and Control of Organisms

Art. 50 Surveys

¹ The FOEN shall carry out surveys that are necessary to assess the environmental pollution caused by particular organisms, by particular properties of organisms, or by particular genetic material.

² For this purpose it shall ensure, as required:

- a. the development of appropriate methods to detect these organisms, these properties or this genetic material in the environment;
- b. the targeted investigation of environmental samples for the presence of these organisms, these properties or this genetic material.

Art. 51 Environmental monitoring

¹ The FOEN shall ensure the establishment of a monitoring system for the early recognition of possible hazards to the environment and impairments of biological diversity by genetically modified organisms and their transgenic genetic material, or by invasive alien organisms.

² For this purpose, it shall designate the specific monitoring objectives and shall stipulate the required methods, indicators and assessment criteria. Before establishing the methods, indicators and assessment criteria, it shall consult the federal agencies and cantons concerned and the stakeholders.

³ For the monitoring, it shall use, as far as possible, data from existing monitoring systems in the environmental and agricultural sector, and shall also examine particular observations of third parties.

⁴ The federal and cantonal authorities responsible for enforcing this Ordinance shall provide the FOEN with the necessary information on request; in particular the FOAG shall supply the data on the basis of the Agricultural Data Ordinance of 7 December 1998⁵⁷, the Direct Subsidies Ordinance of 7 December 1998⁵⁸, the Environmental Quality Ordinance of 4 April 2001⁵⁹, the Organic Farming Ordinance of 22 September 1997⁶⁰ and the Ordinance of 7 December 1998⁶¹ on the Evaluation of Sustainability in Agriculture as well as on the basis of Article 27 paragraph 3 of the Plant Protection Ordinance of 28 February 2001⁶².

⁵ If the analysis of the data and observations produces indications of damage or impairment:

- a. the FOEN, together with other affected federal agencies, shall investigate scientifically whether a causal connection could exist between these damage

⁵⁷ [AS 1999 540, 2000 1492, 2001 3554, 2003 3687 Annex No II 5 4963, 2006 897, 2007 141 Art. 12 6443, 2008 3857, 2010 2551 5885, 2011 5297 Annex 2 No 9 5453 Annex 2 No II 5, 2012 6859 Annex No 3. AS 2013 4009 Art. 29]. See today: the Ordinance from 23 October 2013 through information systems in the field of agriculture (SR 919.117.71).

⁵⁸ [AS 1999 229, 2000 1105 Art. 20 No 2, 2001 232 1310 Art. 22 No 1 3539, 2003 1998 5321, 2006 883 4827, 2007 6117, 2008 3777 5819, 2009 2575 6091, 2010 2319 5855, 2011 2361 5295 5297 Annex 2 No 3 5453 Annex 2 No 3, 2013 1729. AS 2013 4145 Art. 116 No 1]. See today: the Ordinance from 23 October 2013 (SR 910.13).

⁵⁹ [AS 2001 1310, 2003 4871, 2007 6157, 2009 6313, 2010 5855 Ziff. II 3. AS 2013 4145 Art. 116 Ziff. 3]

⁶⁰ SR 910.18

⁶¹ SR 919.118

⁶² [AS 2001 1191, 2002 945, 2003 548 1858 4925, 2004 1435 2201, 2005 1103 1443 2603 Art. 8 No 2, 2006 2531, 2007 1469 Annex 4 No 55 2369 4477 No IV 69 4723 5823 No I 20, 2008 4377 Annex 5 No 13 5865, 2009 2593 5435, 2010 1057. AS 2010 6167 Art. 60 No 1]. See today: the Ordinance from 27 October 2010 (SR 916.20).

or impairments and the presence of the monitored organisms in accordance with paragraph 1;

- b. the FOEN shall inform the cantons.

Art. 52 Control

¹ If organisms appear that could endanger human beings, animals or the environment or could impair biological diversity and the sustainable use thereof, the cantonal authorities shall prescribe appropriate control measures and, if necessary and useful, measures to prevent their future occurrence.

² The cantonal authorities shall inform the FOEN and other affected federal agencies about the occurrence and control of such organisms. They may draw up a publicly accessible cadastral register of the sites of the organisms.

³ The FOEN shall coordinate, as far as is necessary, the control measures and shall develop, together with the other affected federal agencies and the cantons, a national strategy to control the organisms.

⁴ Regulations in other federal legislation on the control of harmful organisms are reserved.

Art. 53 Costs

¹ If scientific investigations lead to the conclusion that it may be assumed with sufficient probability that there is a causal connection between damage to human beings, animals or the environment or impairments of biological diversity and the sustainable use thereof and the presence of pathogenic, alien or genetically modified organisms or their transgenic material, the licence holder shall bear the costs:

- a. of determining the damage, the impairment and the causal connection;
- b. of the prevention and remediation of the damage and the impairment.

² The costs in accordance with paragraph 1 shall also be borne by persons who carry out experimental releases that are not subject to a licence or who place organisms not subject to a licence on the market, if it can be shown with sufficient probability that they have caused the damage.

Section 5: Accessibility of Information

Art. 54 Public nature of the information

¹ Information obtained in the enforcement of this Ordinance or other federal legislation on the handling of genetically modified organisms or products obtained from them, or of pathogenic or alien organisms, shall be made public, in the absence of any legitimate and overriding private or public interests.

² The FOEN shall provide public information about the results of the surveys (Art. 50), of the monitoring (Art. 51) and the control (Art. 52), in the absence of any legitimate and overriding private or public interests.

³ In particular, the protection of business and production secrets shall be worthy of protection.

⁴ The following information shall in every case be made public:

- a. the names and addresses of those responsible for the experimental release or the marketing;
- b. a general description of the organisms and their properties;
- c. the aim of the experimental release or the use of the organisms to be placed on the market;
- d. the site of the experimental release;
- e. the site where genetically modified organisms authorised for marketing are directly released (Art. 32 para. 1 letter c);
- f. methods and plans for monitoring the genetically modified or pathogenic organisms in the environment and emergency measures;
- g. a summary of the risk determination and assessment in accordance with Annex 4;
- h. the report in accordance with Article 24 paragraph 1, in which the FOEN has determined correctness and completeness.

Art. 55 Confidentiality of information

¹ The authorities responsible for the enforcement of this Ordinance shall treat as confidential information where there is a legitimate and overriding interest in doing so. They shall classify this information as such when forwarding it to other authorities.

² Any person submitting documents to the authorities must:

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

³ 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.

Art. 56 Registers

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

² It shall also maintain a register of genetically modified organisms authorised for marketing. The federal and cantonal authorities responsible for enforcing this Ordinance shall provide the necessary information.

³ It shall maintain a register of genetically modified organisms authorised for marketing that are released directly (Art. 32); the register shall record what, when, where and for what purpose the release was carried out.

⁴ The registers shall contain no confidential information and shall be publicly accessible via automated information and communication services. They may be published in full or in part.

Section 6: Fees

Art. 57

¹ Fees shall be charged for orders and services provided by the FOEN in accordance with the Ordinance of 3 June 2005⁶³ on the Fees charged by the FOEN.

² A fee shall be charged for statements from federal agencies that submit a statement as part of the issuing of orders and the provision of services by the FOEN in accordance with Article 8 of the General Ordinance on Charges of 8 September 2004⁶⁴.

Section 7: Further Duties of the FOEN and of DETEC

Art. 58 Guidelines, training and further education

¹ The FOEN may issue guidelines on the enforcement of this Ordinance if required. It shall first consult the specialist agencies concerned.

² The FOEN together with the FOPH shall ensure that training and further education events are organised periodically for people who carry out tasks in terms of this Ordinance.

Art. 59 Modification of the lists in Annex 2

DETEC shall modify the lists in Annex 2 after consulting the federal agencies concerned and the stakeholders if it comes into possession of new findings about the invasiveness of alien organisms.

Chapter 5: Final Provisions

Art. 60 Repeal of current legislation

The Release Ordinance of 25 August 1999⁶⁵ is repealed.

⁶³ SR 814.014

⁶⁴ SR 172.041.1

⁶⁵ [AS 1999 2748, 2001 522 Annex No 4 1191 Art. 51 No 2 3294 No II 9, 2003 4793 No I 2, 2004 4801 Art. 14, 2005 973 No II 2603 Art. 8 No 1 2695 No II 14 3035 Art. 69 No 2, 2006 4705 No II 81]

Art. 61 Amendment of current legislation

The amendments to current legislation are regulated in Annex 5.

Art. 62 Transitional provisions

Genes inserted by gene technology methods and inducing resistance to antibiotics that are authorised for use in human and veterinary medicine may be used in field trials up to 31 December 2008.

Art. 63 Commencement

This Ordinance comes into force on 1 October 2008.

Annex 1
(Art. 3 letter d)

Definition of Gene Technology Methods

¹ Gene technology methods means, 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, as 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.

Annex 2
(Art. 15 para. 2)

Prohibited Invasive Alien Organisms

1 Plants

Scientific name	Deutscher Name	English name	Nom français	Nome italiano
<i>Ambrosia artemisiifolia</i>	Aufrechte Ambrosie, Beifussblättriges Traubenkraut	Common ragweed, Roman ragweed	Ambroisie à feuilles d'armoise, Ambroisie élevée	Ambrosia con foglie di artemisia
<i>Crassula helmsii</i>	Nadelkraut	Cockayne, New Zealand pigmyweed, Australian swamp stonecrop	Orpin de Helms	Erba grassa di Helms
<i>Elodea nuttallii</i>	Nuttalls Wasserpest	Planch St John, Nuttall's waterweed	Elodée de Nuttall	Peste d'acqua di Nuttall
<i>Heraclium mantegazzianum</i>	Riesenbärenklau	Giant hogweed, Giant cow parsnip	Berce du Caucase, Berce de Mantegazzi	Panace di Mantegazzi
<i>Hydrocotyle ranunculoides</i>	Grosser Wassernabel	Floating marshpennywort, Water pennywort	Hydrocotyle fausse-renoncule	Soldinella reniforme
<i>Impatiens glandulifera</i>	Drüsiges Springkraut	Himalayan balsam, ornamental jewelweed, Policeman's helmet, Indian touch-me-not	Impatiente glanduleuse	Balsamina ghiandalosa
<i>Ludwigia spp.</i> (<i>L. grandiflora</i> , <i>L. peploides</i>)	Südamerikanische Heusenkräuter	South American water primroses	Jussies sudaméricaines	Porracchie sudamericane
<i>Reynoutria spp.</i> (<i>Fallopia spp.</i> , <i>Polygonum polystachyum</i> , <i>P. cuspidatum</i>)	Asiatische Staudenknöteriche inkl. Hybride	Asian knotweeds incl. hybrids	Renouées asiatiques, hybrides incl.	Poligono asiatici, incl. ibridi
<i>Rhus typhina</i>	Essigbaum	Staghorn sumac	Sumac	Sommacco maggiore
<i>Senecio inaequidens</i>	Schmalblättriges Greiskraut	Narrow-leaved ragwort	Sénéçon du Cap	Senecione sudafricano
<i>Solidago spp.</i> (<i>S. canadensis</i> , <i>S. gigantea</i> , <i>S. nemoralis</i> ; ohne <i>S. virgaurea</i>)	Amerikanische Goldruten inkl. Hybride	American goldenrod incl. hybrids	Solidages américains, Verges d'or américaines, hybrides incl.	Verge d'oro americane, incl. ibridi

2 Animals

Scientific name	Deutscher Name	English name	Nom français	Nome italiano
<i>Harmonia axyridis</i>	Asiatischer Marienkäfer	Asian ladybeetle, harlequin ladybird	Coccinelle asiatique	Coccinella asiatica
<i>Trachemys scripta elegans</i>	Rotwangen-Schmuckschildkröte	Red-eared slider	Tortue de Floride	Tartaruga dalle orecchie rosse
<i>Rana catesbeiana</i>	Amerikanischer Ochsenfrosch	North American bullfrog	Grenouille taureau	Rana toro

Annex 3

Information for Licence Applications concerning Pathogenic and Alien Organisms

Licence Applications for Releases of Pathogenic Organisms for Experimental Purposes

1 General information

- 11 Name and address of the applicant (company or institution);
- 12 Name, qualifications and experience of the responsible scientists.

2 Identity and characterisation of the organisms

- 21 Scientific and other names;
- 22 Taxonomic data, including subspecies, strain or biotype;
- 23 Phenotypic and genetic markers and description of the ways of identifying the organisms unambiguously in the environment;
- 24 Methods of culturing and producing the organisms;
- 25 Precise source and purity of the strains and cultures intended for the experiment;
- 26 Regions in which the organisms have already been deliberately or accidentally released and experience gained;
- 27 Biology and ecology:
 - 271 Type of pathogenicity, host organisms;
 - 272 Toxins and other environmentally hazardous metabolites;
 - 273 Resistance or sensitivity to antibiotics, fungicides or other agents;
 - 274 Geographic distribution and natural habitat;
 - 275 Persistence and reproduction under conditions in Switzerland;
 - 276 Mobility;
 - 277 Involvement in environmental processes.

3 Performing the experimental release

- 31 Description of the experimental release, including the methods and the quantity of organisms to be released;
- 32 Timetable;
- 33 Interventions at the site of the experimental release before, during and after the experimental release;
- 34 Measures to protect operators during the experimental release;
- 35 Processes for inactivating the organisms after completion of the experimental release.

4 Site of the experimental release

- 41 Geographical situation, size of the site of the experimental release and description of the surroundings;
- 42 Climatic, geological and pedological characteristics of the site of the experimental release and its surroundings;
- 43 Flora and fauna including crops, livestock and migratory species;
- 44 Description of the ecosystem.

5 Possible effects

- 51 Effects on human beings and animals, in particular, health hazards (e.g. allergic, pathogenic or toxic effect, skin irritation);
- 52 Effects on the environment and biological diversity:
 - 521 Effects on environmental processes or important soil functions;
 - 522 Potential for establishment and spread at the site of the experimental release;
 - 523 Anticipated ecological role at the site of the experimental release, identification and description of the target organisms, consequences of the effects on the target organisms;
 - 524 Indigenous enemies of the target organisms at the site of the experimental release that may be indirectly affected;
 - 525 Possible direct and indirect effects on non-target organisms;
 - 526 Possible competition with or displacement of indigenous species;
 - 527 Potential for hybridisation with indigenous strains or biotypes;
 - 528 Effects on plants;
 - 529 Other possible significant effects.

6 Safety measures

- 61 Precautions:
 - 611 Methods and procedures to prevent or minimise the spread of organisms beyond the site of the experimental release;
 - 612 Methods and procedures to prevent trespass on the site of the experimental release;
 - 613 Methods and procedures to prevent other organisms from entering the site.
- 62 Waste disposal:
 - 621 Type and amount of waste produced;
 - 622 Possible hazards;
 - 623 Description of the planned disposal procedure.
- 63 Emergency plans:
 - 631 Methods and procedures for controlling the organisms in case of unexpected spread;
 - 632 Methods for decontaminating the areas affected;
 - 633 Methods for disposing of or treating plants, animals, soil etc. affected by the spread of the organisms;

- 634 Plans for protecting human beings and animals, and the environment and biological diversity in the event of undesirable effects occurring.

Licence Application for Placing Pathogenic Organisms on the Market

1 General information

- 11 Name and address of the applicant (company or institution);
- 12 Description of the type and extent of the intended uses;
- 13 Description of the geographic areas and parts of the environment in which the organisms are to be used.

2 Identity and characterisation of the organisms

- 21 Scientific and other names;
- 22 Taxonomic data, including subspecies, strain or biotype;
- 23 Phenotypic and genetic markers and description of the ways of identifying the organisms unambiguously in the environment;
- 24 Methods of culturing and producing the organisms;
- 25 Precise source and purity of the strains and cultures intended for marketing;
- 26 Regions in which the organisms have already been deliberately or accidentally released and experience gained;
- 27 Biology and ecology:
 - 271 Type of pathogenicity, host organisms;
 - 272 Toxins and other environmentally hazardous metabolites;
 - 273 Resistance or sensitivity to antibiotics, fungicides or other agents;
 - 274 Geographic distribution and natural habitat;
 - 275 Persistence and multiplication under conditions in Switzerland;
 - 276 Mobility;
 - 277 Involvement in environmental processes.

3 Possible effects

- 31 Effects on human beings and animals, in particular, health hazards (e.g. allergenic, pathogenic or toxic effect, skin irritation);
- 32 Effects on the environment and biological diversity:
 - 321 Effects on environmental processes or important soil functions;
 - 322 Potential for establishment and spread at the site of the experimental release;
 - 323 Anticipated ecological role at the site of use, effects on target organisms, biology and spread of target organisms;
 - 324 Indigenous enemies of the target organisms at the site of use;
 - 325 Possible direct and indirect effects on non-target organisms;
 - 326 Possible competition with or displacement of indigenous species;
 - 327 Potential for hybridisation with indigenous strains or biotypes;

- 328 Effects on plants;
- 329 Other possible significant effects.

4 Safety measures

- 41 Precautions:
Methods and procedures to prevent or minimise the spread of organisms beyond the site of use;
- 42 Waste disposal:
- 421 Type and amount of waste produced by handling directly in the environment;
- 422 Possible hazards;
- 423 Appropriate disposal by the user;
- 43 Emergency plans:
- 431 Methods and procedures for controlling the organisms in case of unexpected spread;
- 432 Methods for decontaminating the habitats affected;
- 433 Methods for disposing of or treating plants, animals, soil etc. affected by the spread of the organisms;
- 434 Plans for protecting human beings and animals, and the environment and biological diversity in the event of undesirable effects occurring.

Licence Application for Experimental Releases of Alien Invertebrates (arthropods, annelids, nematodes, platyhelminths)

1 General information

- 11 Name and address of the applicant (company or institution);
- 12 Name, qualifications and experience of the responsible scientist.

2 Identity and characterisation of the organisms

- 21 Scientific and other names;
- 22 Taxonomic data, including subspecies, strain or biotype;
- 23 Confirmation of the taxonomic data by a recognised scientific authority, as well as name and address of the institution in which reference animals are archived;
- 24 Phenotypic and genetic markers and description of the ways of identifying the organisms unambiguously in the environment;
- 25 Methods of culturing and producing the organisms;
- 26 Precise source and purity of the strains and biotypes intended for the experiment, as well as name and address of the organisation that breeds the animals and precise information about the site (longitude and latitude, height above sea level, habitat, hosts) and seasons of field collection;
- 27 Regions in which the organisms have already been deliberately or accidentally released and experience gained;
- 28 Biology and ecology:
 - 281 Natural spread of the organisms;
 - 282 Role and significance of the organisms in their original ecosystem;
 - 283 Description of the biology, in particular of their reproduction, paths of biological spread, and the host, habitat and climate requirements of the organisms and of their possible host range;
 - 284 Description of the organisms tested as hosts and methods of investigating the host specificity;
 - 285 Description of the possible associated organisms (natural enemies, pathogens commensals) and methods of eliminating them;
 - 286 Particular resistances or sensitivities (cold, dryness, plant protection products etc.);
 - 287 Current geographic distribution;
 - 288 Persistence and multiplication under conditions in Switzerland;
 - 289 Information on invasive behaviour in other areas by the organisms themselves or by closely related organisms.

3 Performing the experimental release

- 31 Description of the experimental release, including the methods and the quantity of organisms to be released;
- 32 Timetable;
- 33 Interventions at the site of the experimental release before, during and after the experimental release;
- 34 Processes for inactivating the organisms after completion of the experimental release.

4 Site of the experimental release

- 41 Geographical situation, size of the site of the experimental release and description of the surroundings;
- 42 Climatic, geological and pedological characteristics of the site of the experimental release and its nearby surroundings;
- 43 Flora and fauna including crops, livestock and migratory species;
- 44 Description of the ecosystem.

5 Possible effects

- 51 Effects on human beings and animals, in particular, health hazards (e.g. allergenic, pathogenic or toxic effect, skin irritation, transmission of disease);
- 52 Effects on the environment and biological diversity:
 - 521 Effects on environmental processes or important soil functions;
 - 522 Potential for establishment and spread at the site of the experimental release;
 - 523 Anticipated ecological role at the site of the experimental release, identification and description of the target organisms, consequences of the effects on the target organisms;
 - 524 Indigenous enemies of the target organisms at the site of the experimental release that may be indirectly affected;
 - 525 Possible direct and indirect effects on non-target organisms;
 - 526 Possible competition with or displacement of indigenous species;
 - 527 Potential for hybridisation with indigenous strains or biotypes;
 - 528 Effects on plants;
 - 529 Other possible significant effects.

6 Safety measures

- 61 Precautions:
 - 611 Methods and procedures to prevent or minimise the spread of organisms beyond the site of the experimental release;
 - 612 Methods and procedures to prevent trespass on the site of the experimental release;
 - 613 Methods and procedures to prevent other organisms from entering the site.
- 62 Waste disposal:

- 621 Type and amount of waste produced;
- 622 Possible hazards;
- 623 Description of the planned disposal procedure.
- 63 Emergency plans:
- 631 Methods and procedures for controlling the organisms in case of unexpected spread;
- 632 Methods for decontaminating the areas affected;
- 633 Methods for disposing of or treating plants, animals, soil etc. affected by the spread of the organisms;
- 634 Plans for protecting human beings and animals, and the environment and biological diversity in the event of undesirable effects occurring.

Licence Application for Placing Alien Invertebrates (arthropods, annelids, nematodes, platyhelminths) on the Market

1 General information

- 11 Name and address of the applicant (company or institution);
- 12 Description of the type and extent of the intended uses;
- 13 Description of the geographic areas and parts of the environment in which the organisms are to be used.

2 Identity and characterisation of the organisms

- 21 Scientific and other names;
- 22 Taxonomic data, including subspecies, strain or biotype;
- 23 Confirmation of the taxonomic data by a recognised scientific authority, as well as name and address of the institution in which reference animals are archived;
- 24 Phenotypic and genetic markers and description of the ways of identifying the organisms unambiguously in the environment;
- 25 Methods of culturing and producing the organisms;
- 26 Precise source and purity of the strains and biotypes intended for the experiment, as well as name and address of the organisation that breeds the animals and precise information about the site (longitude and latitude, height above sea level, habitat, hosts) and seasons of field collection;
- 27 Regions in which the organisms have already been deliberately or accidentally released, or countries in which they are already marketed, and experience gained;
- 28 Biology and ecology:
 - 281 Natural spread of the organisms;
 - 282 Role and significance of the organisms in their original ecosystem;
 - 283 Description of the biology, in particular of their reproduction, generation time, paths of biological spread, and the host, habitat and climate requirements of the organisms and of their possible host range;
 - 284 Description of the organisms tested as hosts and methods of investigating the host specificity;
 - 285 Description of the possible associated organisms (natural enemies, pathogens commensals) and methods of eliminating them;
 - 286 Particular resistances or sensitivities (cold, dryness, plant protection products etc.);
 - 287 Current geographic distribution;
 - 288 Persistence and multiplication under conditions in Switzerland;

289 Information on invasive behaviour in other areas by the organisms themselves
or by closely related organisms.

3 Possible effects

31 Effects on human beings and animals, in particular, health hazards (e.g. aller-
genic, pathogenic or toxic effect, skin irritation, transmission of disease);

32 Effects on the environment and biological diversity:

321 Effects on environmental processes or important soil functions;

322 Potential for establishment and spread at the site of use;

323 Anticipated ecological role at the site of use, identification and description of
the target organisms, consequences of the effects on the target organisms;

324 Indigenous enemies of the target organisms at the site of use that may be
indirectly affected;

325 Possible direct and indirect effects on non-target organisms;

326 Possible competition with or displacement of indigenous species;

327 Potential for hybridisation with indigenous strains or biotypes;

328 Effects on plants;

329 Other possible significant effects.

4 Safety measures

41 Precautions:

Methods and procedures to prevent or minimise the spread of organisms
beyond the site of use;

42 Waste disposal:

421 Type and amount of waste produced by handling directly in the environment;

422 Possible hazards;

423 Appropriate disposal by the user;

43 Emergency plans:

431 Methods and procedures for controlling the organisms in case of unexpected
spread;

432 Methods for decontaminating the habitats affected;

433 Methods for disposing of or treating plants, animals, soil etc. affected by the
spread of the organisms;

434 Plans for protecting human beings and animals, and the environment and
biological diversity in the event of undesirable effects occurring.

Determination and Assessment of Risk

1 Purpose and procedure

¹ The purpose of determining the risk is to determine and assess the consequences of the real case of handling organisms in the environment, for:

- a. human beings, animals or the environment and biological diversity and the sustainable use thereof;
- b. in the case of genetically modified organisms, the long-term preservation of production that does not use genetically modified organisms.

² The risk assessment must evaluate the justifiability of the risk.

³ The determination of risk must be carried out in accordance with scientific criteria and methods and be based on available scientific and technical data, scientific publications, results of calculations and detailed analyses. The evaluation of the risks for their justifiability must be presented in a grounded and understandable way.

2 Identification of hazards and determination of risk

2.1 Identification of hazards

¹ The potential of organisms, when handled in the environment, to impair the two protection targets given under Number 1 paragraph 1 shall be determined. In particular, the following must be taken into consideration:

- a. the properties of the organisms;
- b. experience in using the organisms;
- c. the genetic modifications in the case of genetically modified organisms;
- d. the interactions with the environment;
- e. the customary transport and processing paths for these organisms.

² This determination shall be based on details in accordance with Articles 19, 20 or 21, or 28, 29 or 30.

2.2 Determination of risk

¹ The risk is determined by the extent of the possible damage to the protection targets given under Number 1 paragraph 1 and the probability that this damage will occur.

² To protect human beings, animals and the environment, as well as biological diversity and the sustainable use thereof, the following damage scenarios, at least, must be examined:

- a. *Endangerment to human health caused by the organisms or their gene products*: the type (allergenicity, pathogenicity, toxicity etc.) and the severity of possible effects must be indicated;
- b. *Establishment and spread of the organisms*: the paths of escape from the site of use, the conditions for establishment in the environment, the development of population density, the extent of displacement of other organisms (single individuals, whole populations, whole species) and the species affected (cultivated or wild organisms, endangered or useful species) must be indicated;
- c. *Gene transfer*: the paths for a transmission of genetic material, the mechanisms of crossing out or recombination and the possible crossing partners, the fertility of the offspring and their selective advantages must be indicated;
- d. *Impairment of other organisms (non-target organisms)*: the type of direct effects (e.g. through toxic gene products) or indirect effects (e.g. through an alteration of soil cultivation) and the duration (acute, chronic) and severity of the effects must be indicated;
- e. *Endangerment of material cycles*: the type of alteration of pollutants and nutrients in the soil or in water and the degree of the alteration must be indicated and must be evaluated in terms of the disturbance of important ecosystem functions (nitrogen fixation, soil respiration etc.);
- f. *Development of resistance*: the type of resistance developed, the consequences for control strategies and the ecological impacts of alternative control strategies must be indicated.

³ In the case of genetically modified organisms, to protect production that does not use genetically modified organisms the following damage scenarios, at least, must be examined:

- a. *Contamination of production areas through vertical gene transfer*: gene transfer through sexual recombination (e.g. crossing-out mechanisms, pollen flight distances, possible crossing partners within the species cultivated or used, fertility of offspring and their selective advantages) must be indicated;
- b. *Contamination of products without genetically modified organisms through the use of equipment*: the use of equipment to release and process the organisms (e.g. sowing or harvesting machines), customary usage (e.g. one's own machines and those borrowed from cooperatives), as well as cleaning procedures must be indicated;
- c. *Contamination of products without genetically modified organisms through unintentional losses*: possible escape paths (e.g. second growth, drift of plant protection products, losses in transport), as well as the establishment and spread of the organisms (e.g. conditions for establishment in the environment, development of population density) must be indicated;
- d. *Contamination of products without genetically modified organisms in processing*: the usual processing paths, steps and locations at which mixtures and ambiguities could occur must be indicated.

⁴ The probability that damage could occur during handling in the environment must be determined for all damage scenarios.

⁵ The information must be quantified as far as possible.

3 Risk assessment and risk management

3.1 Evaluation of safety measures

¹ On the basis of the risk determination, the possible safety measures must be determined; their efficacy in terms of reducing the risk should be evaluated.

² If several equivalent safety measures are available, the choice of the proposed measure must be justified.

3.2 Assessment of risk

¹ The risk of the planned handling in the environment shall be examined for its justifiability, on the basis of the type, severity and probability of possible damage, and taking account of the planned safety measures.

² Reasons must be presented as to why the risk determined in Number 2 is justifiable for the protection targets given in section 1 paragraph 1.

³ When assessing justifiability, the following should be considered:

- a. the precautionary principle in accordance with Article 2 GTA and Article 1 paragraph 2 EPA;
- b. the effectiveness of the safety measures determined in accordance with Number 3.1;
- c. other risks within the meaning of Article 6 paragraph 4 GTA and Article 8 EPA;
- d. whether damage could be reversed;
- e. that the greater the extent of possible damage, the smaller the probability of its occurrence must be.

Annex 5
(Art. 61)

Amendments to existing Ordinances

...⁶⁶

⁶⁶ The amendments may be consulted under AS **2008** 4377.

