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

of 10 September 2008 (Status as of 1 September 2024)

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 This Ordinance is intended to protect human beings, animals and the environment, as well as biological diversity and its sustainable use, from hazards or harm 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 [AS 1974 1071; 1985 1992 No I 2; 1991 362 No II 405; 1997 1155 Annex No 5; 2000 1891 No III 2; 2001 2790 Annex No 6; 2003 4803 Annex No 7; 2004 4763 Annex No II 3; 2005 2293; 2006 2197 Annex No 95 4137; 2008 3437 No II 34; 2012 7281. AS 2015 1435 Art. 85 No 1]. See now the EpidA of 28 Sept. 2012 (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 (ContainO).⁶

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

⁴ Putting pathogenic organisms into circulation is regulated by:

- a. the Plant Protection Products Ordinance of 18 May 2005⁸, where the organisms are used as plant protection products in agriculture
- b. the Biocidal Products Ordinance of 18 May 2005⁹, where the organisms are used as biocidal products,

⁵ Putting alien insects, mites and nematodes in circulation for use as plant protection products in agriculture, and the experimental release of such organisms is governed by the Ordinance of 18 May 2005 on Plant Protection Products.

⁶ This Ordinance does not apply to handling organisms:

- a. in clinical trials on human beings;
- b.¹⁰ listed in the Ordinance issued by the Federal Department of Economic Affairs, Education and Research and the Federal Department of the Environment, Transport, Energy and Communications based on Articles 4 paragraph 3 of the Plant Health Ordinance of 31 October 2018¹¹, or for which the two aforementioned departments have designated a protected area based on Article 24 paragraph 2 of the Plant Health Ordinance;
- c.¹² that are listed as potential quarantine organisms in the ordinance issued by the Federal Office for Agriculture (FOAG) and the Federal Office for the Environment (FOEN) based on Article 5 paragraph 2 of the Plant Health Ordinance.

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 now: Ordinance of 12 May 2010 (SR **916.161**).

⁹ SR **813.12**

¹⁰ Amended by Annex 8 No 3 of the Plant Health Ordinance of 31 Oct. 2018, in force since 1 Jan. 2020 (AS **2018** 4209).

¹¹ SR **916.20**

¹² Inserted by Annex 8 No 3 of the Plant Health Ordinance of 31 Oct. 2018, in force since 1 Jan. 2020 (AS **2018** 4209).

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;
- b.¹³ *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.¹⁴ *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.¹⁵ *alien organisms* means organisms of a species, sub-species or lower taxonomic level that:
 - 1. do not naturally occur in Switzerland or in other EFTA and EU member states (not including overseas areas), and
 - 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.¹⁶ ...
- h. *invasive alien organisms* means alien organisms of which it is known or must be assumed that they will spread in Switzerland and could achieve such a high population density that biological diversity or its sustainable use could be harmed 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, putting into circulation, 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;

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

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

- k. *putting into circulation* 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.

² Transfer of organisms in order to carry out an experimental release is not regarded as putting organisms into circulation.

Chapter 2

Requirements for Handling Organisms in the Environment

Section 1 General Requirements for Handling Organisms

Art. 4 Self-supervision for putting organisms into circulation

¹ Any person who intends to put organisms into circulation for use in the environment must first:

- a. assess the possible hazards and harm 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 harm 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 putting organisms into circulation 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 harm 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 putting them into circulation 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 harm biological diversity or its sustainable use.

² In particular, the relevant regulations and the distributor's instructions and recommendations must be observed.

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 harms 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 harmed;
- g. important functions of the ecosystem in question, in particular the fertility of the soil, are not severely or permanently harmed;
- 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.¹⁷ they are classified into Group 3 or 4 in accordance with Article 6 ContainO¹⁸;
- 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.

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.¹⁹ subterranean waters and catchment areas S1 and, for microorganisms, catchment areas S2 and S_h of groundwater protection zones;
- d. forests;
- e. protected areas in accordance with Article 11 of the Hunting Act of 20 June 1986²⁰;
- 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;

¹⁷ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS 2012 2777).

¹⁸ SR 814.912

¹⁹ Amended by Annex No 3 of the Ordinance of 4 Nov. 2015, in force since 1 Jan. 2016 (AS 2015 4791).

²⁰ SR 922.0

- 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.
- ³ Any person who puts genetically modified organisms into circulation 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 puts genetically modified organisms or products made from such organisms into circulation 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 2004²¹ 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 puts genetically modified organisms or products made from such organisms into circulation 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.

²¹ OJ. L 10 of 16.1.2004, p. 5; the text of the Regulation can be obtained from FOEN, 3003 Bern.

Art. 10 Labelling of genetically modified organisms

¹ Any person who puts genetically modified organisms into circulation 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 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 authorisation 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 authorisation 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 put organisms into circulation 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 Confederation, its public corporations and institutions;

- b. the cantons and 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.²²

⁷ The suspension and termination of the guarantee, unless previously replaced by a different guarantee, become effective 60 days after receipt of notification by the competent executive authority.²³

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 harms 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 harmed, 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 harmed;
- f. important functions of the ecosystem in question, in particular the fertility of the soil, are not severely or permanently harmed.

² Pathogenic organisms which are classified into Groups 3 or 4 in accordance with Article 6 ContainO²⁴, or which are invasive, may not be handled directly in the environment; the foregoing does not apply to their primary detection in accordance with Article 5a ContainO.²⁵

²² Inserted by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012** 2777).

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

²⁴ SR **814.912**

²⁵ Amended by Annex No 2 of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).

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 authorisation 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 authorisation 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 put such organisms into circulation 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.²⁶

²⁶ 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.²⁷

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 harms 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 harmed, 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 harmed;
- f. important functions of the ecosystem in question, in particular the fertility of the soil, are not severely or permanently harmed.

² Invasive alien organisms in accordance with Annex 2.1 may not be handled directly in the environment, other than in the case of measures to control them. The FOEN may in exceptional cases grant authorisation for direct handling in the environment if the applicant can prove that he or she has taken all the measures required to observe paragraph 1.²⁸

^{2bis} Invasive alien organisms in accordance with Annex 2.2 may not be put into circulation for direct handling in the environment.²⁹

³ Soil that has been removed that is contaminated with invasive alien organisms in accordance with Annex 2.1 must be used only at the place of excavation or disposed of so as to prevent the spread of such organisms.³⁰

⁴ The provisions in the legislation on forests, hunting and fishing are reserved.³¹

²⁷ Inserted by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012** 2777).

²⁸ Amended by No I of the O of 1 March 2024, in force since 1 Sept. 2024 (AS **2024** 116).

²⁹ Inserted by No I of the O of 1 March 2024, in force since 1 Sept. 2024 (AS **2024** 116).

³⁰ Amended by No I of the O of 1 March 2024, in force since 1 Sept. 2024 (AS **2024** 116).

³¹ 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. 17³² Licensing requirement

Any person who intends to release the following organisms for experimental purposes shall require authorisation 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 Authorisation 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 Authorisation 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 Authorisation 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.

³² 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 Applications for authorisation for experimental releases of genetically modified organisms

¹ The application for authorisation 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 of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001³³ 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;

³³ OJ. 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 Applications for authorisation for experimental releases of pathogenic organisms

¹ The application for authorisation 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 Applications for authorisation for experimental releases of alien small invertebrates

¹ The application for authorisation 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 harm 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 being put into circulation 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 authorisation 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 authorisation holder must examine the measures listed in the authorisation 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 authorisation 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 authorisation 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 Putting Organisms into Circulation

Art. 25³⁴ Licensing requirement

Any person who intends to put the following organisms into circulation for use in the environment either for the first time or for a new use shall require authorisation 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

Authorisation 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 21 September 2018 ³⁵

³⁴ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012 2777**).

³⁵ SR **812.212.21**. The reference has been modified as of 1 Jan. 2019 pursuant to Art. 12 para. 2 of the Publications Act of 18 June 2004 (SR **170.512**). The change has been made throughout the text.

Application	Competent authority	Applicable licensing procedure
b. foodstuffs, additives and processing aids	Federal Food Safety and Veterinary Office (FSVO) ³⁶	Foodstuffs and Utility Articles Ordinance of 23 November 2005 ³⁷
c. plant propagation material exclusively for use in forests	FOEN	Release Ordinance of 10 September 2008
d. ³⁸ plant propagation material for all other uses	Federal Office for Agriculture (FOAG)	Seeds Ordinance of 7 December 1998 ³⁹
e. ⁴⁰ plant protection products	FSVO	Plant Protection Products Ordinance of 12 May 2010 ⁴¹
f. fertilisers	FOAG	Fertilisers Ordinance of 10 January 2001 ⁴²
g. animal feedstuffs	FOAG	Feedstuffs Ordinance of 26 May 1999 ⁴³
h. ⁴⁴ ...		
i. ⁴⁵ ...		
j. biocidal products	FOPH	Biocidal Products Ordinance of 18 May 2005 ⁴⁶
k. all other uses	FOEN	Release Ordinance of 10 September 2008

³⁶ 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.

³⁷ [AS **2005** 5451; **2006** 4909; **2007** 1469 Annex 4 No 47; **2008** 789 4377 Annex 5 No 8 5167 6025; **2009** 1611; **2010** 4611; **2011** 5273 Art. 37 5803 Annex 2 No II 3; **2012** 4713 6809; **2013** 3041 No I 7 3669; **2014** 1691 Annex 3 No II 4 2073 Annex 11 No 3; **2015** 5201 Annex No II 2; **2016** 277 Annex No 5. AS **2017** 283 Art. 94 para. 1]. See now the O of 16 Dec. 2016 (SR **817.02**).

³⁸ Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012** 2777).

³⁹ SR **916.151**

⁴⁰ Amended by Annex No 2 of the O of 17 Nov. 2021, in force since 1 Jan. 2022 (AS **2021** 760).

⁴¹ SR **916.161**

⁴² [AS **2001** 522; **2003** 940 Annex No 3, 4793 No I 7, 4923; **2005** 2695 No II 18; **2007** 6295; **2008** 4377 Annex 5 No 12; **2010** 2631 Annex No 3; **2011** 2403, 2699 Annex 8 No II 3; **2013** 3971; **2015** 1903 Annex 6 No 7; **2016** 277 Annex No 8; **2018** 4205; **2020** 5125 Annex No 4; **2021** 686; **2022** 265 Annex No 2. AS **2023** 711]. See now: O of 1. Nov. 2023 (SR **916.171**).

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 now: O of 26 Oct. 2011 (SR **916.307**).

⁴⁴ Repealed by Annex No 3 of the O of 23 Nov. 2022, with effect from 1 Jan. 2023 (AS **2022** 723).

⁴⁵ Repealed by Annex 8 No 3 of the Plant Health Ordinance of 31 Oct. 2018, with effect since 1 Jan. 2020 (AS **2018** 4209).

⁴⁶ SR **813.12**

Art. 27 Exceptions from the licensing requirement

Authorisation is not required for putting the following into circulation:

- a. plant reproductive material in accordance with Article 14a of the Seeds Ordinance of 7 December 1998⁴⁷;
- b. animal feedstuffs in accordance with Article 21b Feedstuffs Ordinance of 26 May 1999⁴⁸;
- c. foodstuffs, if the requirements of Article 23 of the Foodstuffs and Utility Articles Ordinance of 23 November 2005⁴⁹ have been fulfilled.

Art. 28 Applications for authorisation to put genetically modified organisms into circulation

¹ The application for authorisation to put genetically modified organisms into circulation, 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 2001⁵⁰ 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 authorisations and evaluations from Swiss and foreign authorities for the experimental release and putting into circulation 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

⁴⁷ SR **916.151**

⁴⁸ [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 now: O of 26 Oct. 2011 (SR **916.307**).

⁴⁹ [AS **2005** 5451; **2006** 4909; **2007** 1469 Annex 4 No 47; **2008** 789 4377 Annex 5 No 8 5167 6025; **2009** 1611; **2010** 4611; **2011** 5273 Art. 37 5803 Annex 2 No II 3; **2012** 4713 6809; **2013** 3041 No I 7 3669; **2014** 1691 Annex 3 No II 4 2073 Annex 11 No 3; **2015** 5201 Annex No II 2; **2016** 277 Annex No 5. AS **2017** 283 Art. 94 para. 1]. See now the O of 16 Dec. 2016 (SR **817.02**).

⁵⁰ OJ. L 106 of 17.4.2001, p. 1; the text of the Directive can be obtained from the FOEN, 3003 Bern.

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;
- i.⁵¹ in respect of organisms that are used genetic resources or whose development is based on used genetic resources or on traditional knowledge based thereon, the register number in accordance with Article 4 paragraph 3 or 8 paragraph 5 of the Nagoya Ordinance of 11 December 2015⁵².

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 Applications for authorisation to put pathogenic organisms into circulation

¹ The application for authorisation to put pathogenic organisms into circulation, 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 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 authorisations and evaluations from Swiss and foreign authorities for the experimental release and putting into circulation 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,

⁵¹ Inserted by Annex No 4 of the Nagoya Ordinance of 11 Dec. 2015, in force since 1 Feb. 2016 (AS 2016 277).

⁵² SR 451.61

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;
- h.⁵³ in respect of organisms that are used genetic resources or whose development is based on used genetic resources or on traditional knowledge based thereon, the register number in accordance with Article 4 paragraph 3 or 8 paragraph 5 of the Nagoya Ordinance of 11 December 2015⁵⁴.

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 Applications for authorisation to put alien small invertebrates into circulation

¹ The application for authorisation to put alien small invertebrates into circulation, 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 authorisations and evaluations from Swiss and foreign authorities for the experimental release and putting into circulation 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 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;

⁵³ Inserted by Annex No 4 of the Nagoya Ordinance of 11 Dec. 2015, in force since 1 Feb. 2016 (AS 2016 277).

⁵⁴ SR 451.61

g.⁵⁵ in respect of organisms that are used genetic resources or whose development is based on used genetic resources or on traditional knowledge based thereon, the register number in accordance with Article 4 paragraph 3 or 8 paragraph 5 of the Nagoya Ordinance of 11 December 2015⁵⁶.

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 authorisation 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 authorisation holder must examine the measures given in the authorisation 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 being put into circulation 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 2004⁵⁷ 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.

⁵⁵ Inserted by Annex No 4 of the Nagoya Ordinance of 11 Dec. 2015, in force since 1 Feb. 2016 (AS **2016** 277).

⁵⁶ SR **451.61**

⁵⁷ OJ. 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 put them into circulation must have a residence or business premises in Switzerland.

² In relation to putting foodstuffs into circulation, the provisions of the legislation on foodstuffs are reserved.

Art. 34 Number of copies of application

¹ The application for authorisation 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 authorisation for experimental release or putting into circulation in accordance with Article 26 letters c and k must request transfer of authorisation from the FOEN.

² Authorisation shall be transferred once the conditions for authorisation 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 1968⁵⁸ 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 Swiss Expert Committee for Biosafety (SECB) 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 authorisation

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 endanger human beings, animals and the environment or harm 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 harmed (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 authorisation 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 let. e, 20 para. 2 let. e, or 21 para. 2 let. 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 supervisory 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 authorisation, 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 let. d, 20 para. 2 let. d, or 21 para. 2 let. 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 supervisory group with representatives, in particular, of the canton in which the experimental release is taking place. The supervisory 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 authorisation; 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 authorisation 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 Putting Organisms into Circulation

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 Authorisation

¹ The licensing authority shall authorise putting the organisms into circulation, 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. putting the organisms into circulation cannot endanger human beings, animals and the environment or harm 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. putting the organisms into circulation is permissible under the laws enforced by the FOPH and FOEN, and if applicable the FSVO and FOAG, and these offices therefore approve putting the organisms into circulation;
- e.⁵⁹ in respect of organisms that are used genetic resources or whose development is based on used genetic resources or on traditional knowledge based thereon, the duty to register in terms of Article 4 or 8 paragraph 3 of the Nagoya Ordinance of 11 December 2015⁶⁰ has been complied with.

² The licensing authority may make authorisation 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 Authorisation 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 putting the organisms into circulation, it shall inform the licensing authority.

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

- a. change the conditions imposed for the putting the organisms into circulation;

⁵⁹ Inserted by Annex No 4 of the Nagoya Ordinance of 11 Dec. 2015, in force since 1 Feb. 2016 (AS 2016 277).

⁶⁰ SR 451.61

- b. if necessary, prohibit putting the organisms into circulation temporarily or indefinitely;
- c. in serious cases, order the return of organisms put into circulation.

³ If the licensing authority comes into possession of such new findings or if such new findings are reported by the applicant or authorisation 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 put into circulation without authorisation, 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 put into circulation could endanger human beings, animals or the environment, or could harm 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 responsible for putting the organisms into circulation 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 responsible for putting the organisms into circulation 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 putting the organisms in question into circulation.

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 2000⁶¹;
- b. for foodstuffs and utensils in accordance with the Foodstuffs Act of 9 October 1992⁶²;

⁶¹ SR 812.21

⁶² [AS 1995 1469; 1996 1725 Annex No 3; 1998 3033 Annex No 5; 2001 2790 Annex No 5; 2002 775; 2003 4803 Annex No 6; 2005 971; 2006 2197 Annex No 94 2363 No II; 2008

- c. for plant propagation materials exclusively for use in forests in accordance with the Forests Ordinance of 30 November 1992⁶³;
- d. for plant propagation materials for all other uses in accordance with the Seeds Ordinance of 7 December 1998⁶⁴;
- e. for plant protection products in accordance with the Plant Protection Products Ordinance of 18 May 2005⁶⁵;
- f. for fertilisers in accordance with the Fertilisers Ordinance of 10 January 2001⁶⁶;
- g. for animal feedstuffs in accordance with the Feedstuffs Ordinance of 26 May 1999⁶⁷;
- h. for immunological products for veterinary use in accordance with the Therapeutic Products Act of 15 December 2000;
- i.⁶⁸ ...
- j. for biocidal products in accordance with the Biocidal Products Ordinance of 18 May 2005⁶⁹.

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 put into circulation 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:

785; **2011** 5227 No I 2.8; **2013** 3095 Annex 1 No 3. AS **2017** 249 Annex No I]. See now: the FA of 20 June 2014 (SR **817.0**).

⁶³ SR **921.01**

⁶⁴ SR **916.151**

⁶⁵ [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 now: O of 12 May 2010 (SR **916.161**).

⁶⁶ SR **916.171**

⁶⁷ [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 now: O of 26 Oct. 2011 (SR **916.307**).

⁶⁸ Repealed by Annex 8 No 3 of the Plant Health Ordinance of 31 Oct. 2018, with effect from 1 Jan. 2020 (AS **2018** 4209).

⁶⁹ SR **813.12**

- a. the regulations regarding the informing of recipients (Art. 5) are being observed;
- b. the putting of genetically modified or pathogenic organisms into circulation has been authorised;
- c. the handling of particular organisms is not prohibited;
- c^{bis},⁷⁰ the putting of specific organisms into circulation is not prohibited;
- d. the conditions and stipulations linked to the authorisation for putting the organisms into circulation 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 on putting organisms into circulation 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 put into circulation without authorisation, 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.

Art. 48a⁷¹ Enforcement by the Federal Office for Customs and Border Security in relation to prohibited invasive alien organisms

¹ The Federal Office for Customs and Border Security (FOCBS) shall monitor whether the import of organisms complies with the obligations in Article 15 paragraphs 2 and 2^{bis}; to this end it shall in consultation with the FOEN conduct physical checks for limited periods of time.

² If it detects or suspects an offence, the FOCBS may seize the goods temporarily; it shall inform the FOEN, which shall decide on how to proceed. If the FOEN orders the forfeiture of the goods, the FOCBS shall advise the person required to declare the goods that the goods may be disposed of at their current location rather than being forfeited.

³ The FOCBS shall provide the FOEN with the data required to enforce Article 15 paragraphs 2 and 2^{bis}.

⁷⁰ Inserted by No I of the O of 1 March 2024, in force since 1 Sept. 2024 (AS **2024** 116).

⁷¹ Inserted by No I of the O of 1 March 2024, in force since 1 Sept. 2024 (AS **2024** 116).

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 order 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 Ordinance of 23 October 2013⁷² on Information Systems in the Agriculture Sector, the Direct Subsidies Ordinance of

⁷² SR 919.117.71

23 October 2013⁷³, the Organic Farming Ordinance of 22 September 1997⁷⁴ and the Ordinance of 7 December 1998⁷⁵ on the Evaluation of Sustainability in Agriculture.⁷⁶

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 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 harm 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 authorisation 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 authorisation or who put organisms not subject to authorisation into circulation, if it can be shown with sufficient probability that they have caused the damage.

⁷³ SR **910.13**

⁷⁴ SR **910.18**

⁷⁵ SR **919.118**

⁷⁶ Amended by Annex 8 No 3 of the Plant Health Ordinance of 31 Oct. 2018, in force since 1 Jan. 2020 (AS **2018 4209**).

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 for putting the organisms into circulation;
- b. a general description of the organisms and their properties;
- c. the aim of the experimental release or the use of the organisms being put into circulation;
- d. the site of the experimental release;
- e. the site where genetically modified organisms authorised for being put into circulation 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 information as confidential 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. justify the need 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 its assessment differs from the proposal of the persons supplying the information, the authority, after

hearing these persons, shall inform them in a ruling 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 being put into circulation. 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 being put into circulation 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 2005⁷⁷ 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 2004⁷⁸.

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 basic and continuing professional education events are held regularly for persons who carry out duties under this Ordinance.

⁷⁷ SR 814.014

⁷⁸ SR 172.041.1

Art. 59⁷⁹ Modification of the lists in Annexes 2.1 and 2.2

The DETEC shall modify the lists in Annex 2.1 and 2.2 after consulting the federal agencies concerned, the cantons and other stakeholders concerned 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 1999⁸⁰ is repealed.

Art. 61 Amendment of current legislation

The amendment of current legislation is 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.

⁷⁹ Amended by No I of the O of 1 March 2024, in force since 1 Sept. 2024 (AS **2024** 116).

⁸⁰ [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]

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 2.⁸¹
(Art. 15 para. 2)

Invasive alien organisms whose direct handling in the environment is prohibited

1 Plant

Scientific name	English name	German name	French name	Italian name
<i>Ailanthus altissima</i>	Ailanthus, tree of heaven	Götterbaum	Ailante	Ailanto
<i>Ambrosia</i> spp. (<i>A. artemisiifolia</i> , <i>A. confertiflora</i> , <i>A. psilostachya</i> , <i>A. trifida</i>)	Common ragweed, Roman ragweed	Ambrosien, Traubenkräuter	Ambroisies	Ambrosie
<i>Asclepias syriaca</i>	Common milkweed	Syrische Seidenpflanze	Asclépiade de Syrie	Albero della seta
<i>Cabomba caroliniana</i>	Carolina fanwort	Karolina-Haarnixe	Cabomba, Evantail de Caroline	Cabomba della Carolina
<i>Celastrus orbiculatus</i>	Oriental bittersweet	Rundblättriger Baumwürger	Bourreau des arbres asiatique	Celastro
<i>Crassula helmsii</i>	Cockayne, New Zealand pigmyweed, Australian swamp stonecrop	Nadelkraut	Orpin de Helms	Erba grassa di Helms
<i>Elodea</i> spp. (<i>E. canadensis</i> , <i>E. densa</i> , <i>E. nuttalli</i>)	Planch St John, Nuttall's waterweed	Wasserpest	Elodée	Peste d'acqua

⁸¹ Originally: Annex 2. Revised by No II para. 1 of the O of 1 March 2024, in force since 1 Sept. 2024 (AS **2024** 116).

Scientific name	English name	German name	French name	Italian name
<i>Heracleum mantegazzianum</i>	Giant hogweed, Giant cow parsnip	Riesenbärenklau	Berce du Caucase, Berce de Mantegazzi	Panace di Mantegazzi
<i>Humulus japonicus</i>	Japanese hop	Japanischer Hopfen	Houblon du Japon	Luppolo giapponese
<i>Hydrocotyle ranunculoides</i>	Floating marshpennywort, Water pennywort	Grosser Wassernabel	Hydrocotyle fausse- renoncule	Soldinella reniforme
<i>Impatiens glandulifera</i>	Himalayan balsam, ornamental jewelweed, Policeman's helmet, Indian touch-me-not	Drüsiges Springkraut	Impatiente glanduleuse	Balsamina ghiandalosa
<i>Lagarosiphon major</i>	Curly waterweed, Afri- can elodea	Schmalrohr	Grand lagarosiphon	Peste d'acqua arcuata
<i>Ludwigia</i> spp. (<i>L. grandiflora</i> , <i>L. peploides</i> , <i>L. x kentiana</i>)	Floating primrose willow, South American water primroses	Südamerikanische Heusenkräuter inkl. Hybride	Jussies sudaméricaines hybrides incl.	Porracchie sudamericane incl. ibridi
<i>Myriophyllum</i> spp. (<i>M. aquaticum</i> , <i>M. heterophyllum</i> , ausser einheimische Arten)	Water milfoil	Tausendblätter	Myriophylles	Miriofilli
<i>Pueraria lobata</i>	East Asian arrowroot	Kopoubohne	Puéraire hérissée	Kudzu
<i>Reynoutria</i> spp. (<i>Fallopia</i> spp., <i>Polygonum polystachyum</i> , <i>P. cuspidatum</i> , <i>P. perfoliatum</i>)	Asian knotweed incl. hybrids	Asiatische Knöteriche inkl. Hybride	Renouées asiatiques hybrides incl.	Poligoni asiatici incl. ibridi
<i>Rhus typhina</i>	Staghorn sumac	Essigbaum	Sumac	Sommacco maggiore
<i>Salvinia molesta</i>	Giant salvinia	Lästiger Schwimmfarn	Salvinie géante	Erba pesce gigante

Scientific name	English name	German name	French name	Italian name
<i>Senecio inaequidens</i>	Narrow-leaved ragwort	Schmalblättriges Greiskraut	Séneçon du Cap	Senecione sudafricano
<i>Sicyos angulatus</i>	Oneseed bur cucumber	Haargurke	Sicyos anguleux	Sicios angoloso
<i>Solidago spp.</i> (<i>S. canadensis</i> , <i>S. gigantea</i> , <i>S. graminifolia</i> ; ohne <i>S. virgaurea</i>)	American goldenrod incl. hybrids	Amerikanische Goldruten inkl. Hybride	Solidages américains, Verges d'or américaines, hybrides incl.	Verghe d'oro americane, incl. ibridi
<i>Toxicodendron radicans</i>	Eastern poison ivy	Kletternder Giftsumach	Arbre à la gale	Edera velenosa

2 Animals

Scientific name	German name	French name	Italian name
<i>Harmonia axyridis</i>	Asian ladybeetle, harlequin ladybird	Coccinelle asiatique	Coccinella asiatica
<i>Trachemys scripta elegans</i>	Red-eared slider	Tortue de Floride	Tartaruga dalle orecchie rosse
<i>Rana catesbeiana</i>	North American bullfrog	Grenouille taureau	Rana toro

Annex 2.2⁸²
(Art. 15 para. 2^{bis})

Invasive alien organisms that may not be put into circulation for direct handling in the environment

Scientific name	English name	German name	French name	Italian name
<i>Acacia dealbata</i>	Silver wattle, mimosa	Falsche Mimose	Mimosa blanchâtre	Mimosa
<i>Amorpha fruticosa</i>	Desert false indigo, bastard indigobush	Bastardindigo	Amorphe buissonnante	Indaco bastardo
<i>Artemisia verlotiorum</i>	Chinese mugwort	Verlotscher Beifuss	Armoise des frères Verlot	Assenzio dei fratelli Verlot
<i>Aster novi-belgii</i> aggr. (<i>A. ×salignus</i> , <i>A. ×versicolor</i> , <i>A. lanceolatus</i> , <i>A. novi-belgii</i> , <i>A. parviflorus</i>)	New York aster	Neubelgische Aster (Weiden-Aster, Gescheckte Aster, Lanzettblättrige Aster, Neubelgische Aster, Tradescants Aster)	Aster de la Nouvelle-Belgique (Aster à feuilles de saule, Aster versicolore, Aster lancéolé, Aster de la Nouvelle-Belgique, Aster de Tradescant)	Astro americano (Astro a foglie di salice, Astro cangiante, Astro lanceolato, Astro americano, Astro di Tradescant)
<i>Azolla filiculoides</i>	Water fern	Grosser Algenfarn	Azolla fausse filicule	Azolla maggiore
<i>Broussonetia papyrifera</i>	Paper mulberry	Papiermaulbeerbaum	Mûrier à papier	Gelso da carta
<i>Buddleja davidii</i>	Summer lilac, butterfly bush	Schmetterlingsstrauch	Buddléia de David	Buddleja
<i>Bunias orientalis</i>	Turkish warty cabbage	Glattes Zackenschötchen	Bunias d’Orient	Cascellore orientale
<i>Cornus sericea</i>	Red osier	Seidiger Hornstrauch	Cornouiller soyeux	Corniolo serico

⁸² Inserted by No II para. 2 of the O of 1 March 2024, in force since 1 Sept. 2024 (AS 2024 116).

Scientific name	English name	German name	French name	Italian name
<i>Cotoneaster horizontalis</i>	Wall cotoneaster, rock cotoneaster	Korallenstrauch	Cotonéaster horizontal	Cotognastro orizzontale
<i>Echinocystis lobata</i>	Wild cucumber, prickly cucumber	Stachelgurke, Igelgurke	Concombre sauvage, C. piquant	Sicios lobata
<i>Erigeron annuus</i>	Annual fleabane, daisy fleabane	Einjähriges Berufkraut	Vergerette annuelle	Cespica annua
<i>Galega officinalis</i>	Galega, goat's-rue	Geissraute	Galéga officinal	Capraggine comune
<i>Glyceria striata</i>	Fowl mannagrass, ridged glyceria	Gestreiftes Süßgras	Glycérie striée	Gramignone striato
<i>Lonicera henryi</i>	Fragrant grove honeysuckle, vine honeysuckle	Henrys Geissblatt	Chèvrefeuille de Henry	Caprifoglio di Henry
<i>Lonicera japonica</i>	Japanese honeysuckle	Japanisches Geissblatt	Chèvrefeuille du Japon	Caprifoglio giapponese
<i>Lupinus polyphyllus</i>	Large-leaved lupin	Vielblättrige Lupine	Lupin à folioles nombreuses	Lupino fogliuto
<i>Oenanthe javanica</i>	Java waterdropwort, Japanese parsley	Wasserfenchel, Japanische Petersilie	Persil japonais	Finocchio acquatico di Giava
<i>Parthenocissus quinquefolia</i> aggr. (<i>P. inserta</i> , <i>P. quinquefolia</i>)	Virginia creeper, five-leaved ivy	Fünffingerige - / Gewöhnliche Jungfernrebe	Vigne vierge à cinq folioles / - commune	Vite del Canada comune / Vite del Canada domestica
<i>Paulownia tomentosa</i>	Princess tree, empress tree	Blauglockenbaum	Paulownia	Paulownia
<i>Pennisetum setaceum</i>	Crimson fountaingrass	Afrikanisches Lampenputzergras	Herbe aux écouvillons, Herbe fontaine	Penniseto allungato
<i>Phyllostachys aurea</i>	Fishpole bamboo, golden bamboo	Gold-Bambus	Bambou moyen	Bambù dorato
<i>Prunus laurocerasus</i>	Cherry laurel, common laurel	Kirschlorbeer	Laurier-cerise	Lauroceraso

Scientific name	English name	German name	French name	Italian name
<i>Prunus serotina</i>	Black cherry	Herbst-Traubenkirsche	Merisier tardif	Pruno autunnale
<i>Pseudosasa japonica</i>	Arrow bamboo, metake	Japanischer Bambus	Bambou du Japon	Pseudosasa giapponese
<i>Rubus armeniacus</i>	Armenian blackberry, Himalayan blackberry	Armenische Brombeere	Ronce d'Arménie	Rovo d'Armenia
<i>Rubus phoenicolasius</i>	Japanese wineberry, wine raspberry, dew-berry	Rotborstige Himbeere	Framboisier du Japon	Lampone del Giappone
<i>Sagittaria latifolia</i>	Broadleaf arrowhead, Indian potato	Breitblättriges Pfeilkraut	Sagittaire à larges feuilles	Sagittaria americana
<i>Sedum spurium</i>	Caucasian stonecrop, two-row stonecrop	Kaukasus-Fettkraut	Orpin bâtard	Borracina caucasica
<i>Sedum stoloniferum</i>	Lesser-Caucasian stonecrop	Ausläuferbildendes Fettkraut	Orpin stolonifère	Borracina stolonifera
<i>Trachycarpus fortunei</i>	Chinese windmill palm	Chinesische Hanfpalme, Fortunes Hanfpalme	Palmier chanvre	Palma di Fortune

*Annex 3***Information for applications for authorisation concerning
pathogenic and alien organisms**

Applications for authorisation 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. allergenic, 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.

Application for authorisation to put pathogenic organisms into circulation

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 being put into circulation;
- 26 Regions in which the organisms have already been deliberately or accidentally released or countries in which they have already been put into circulation 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. allergic, 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.

Annex 3.3
(Art. 21)**Application for authorisation 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.

Annex 3.4
(Art. 30)**Application for authorisation to put alien invertebrates (arthropods, annelids, nematodes, platyhelminths) into circulation****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 being put into circulation, 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 have already been put into circulation, 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. allergenic, 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.

Annex 4
(Art. 19, 20, 21, 28, 29 and 30)

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

...⁸³

⁸³ The amendments may be consulted under AS **2008** 4377.