Ordinance on Handling Organisms in Contained Systems

(Containment Ordinance, ContainO)

of 9 May 2012 (Status as of 1 January 2020)

The Swiss Federal Council,

on the basis of Articles 29*b* paragraphs 2 and 3, 29*f*, 38 paragraph 3, 39 paragraph 1, 41 paragraphs 2 and 3, 44 paragraph 3, 46 paragraphs 2 and 3, 48 paragraph 2 and 59*b* of the Environmental Protection Act of 7 October 1983[1] (EPA),
and Articles 10 paragraph 2, 14, 19, 20, 24 paragraphs 2 and 3, 25 and 34 of the Gene Technology Act of 21 March 2003[2] (GTA),
on Articles 26 paragraphs 2 and 3, 29 and 78 paragraph 1 of the Epidemics Act of 28 September 2012[3]
and in implementation of Articles 8 letters g, h and l as well as 19 paragraph 4 of the Convention of 5 June 1992[4] on Biological Diversity,[5]

ordains:

Chapter 1 General Provisions

Art. 1 Aim

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 in contained systems.

Art. 2 Subject matter and scope of application

[1] This Ordinance regulates the handling of organisms, in particular genetically modified, pathogenic or alien organisms, in contained systems.

[2] The transport of organisms intended for handling in contained systems is governed by Articles 4, 15 and 25 only.

AS **2012** 2777

1 SR **814.01**
2 SR **814.91**
3 SR **818.101**
4 SR **0.451.43**
5 Amended by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).

3 Handling organisms in the environment is governed by the Release Ordinance of 10 September 2008[6].

4 The protection of people and the environment against serious damage resulting from major accidents involving microorganisms is regulated by the Major Accidents Ordinance of 27 February 1991[7].[8]

5 The protection of employees when handling microorganisms is governed by the Ordinance of 25 August 1999[9] on the Protection of Employees from Dangerous Microorganisms.

6 This Ordinance does not apply to the handling of organisms:

a. in accordance with the Ordinance of 20 September 2013[10] on Clinical Trials in Human Research;

b. in the case of personal use of medical devices for the purposes of in-vitro diagnostics, the dispensing of which is authorised in accordance with Article 17 paragraph 3 of the Medical Devices Ordinance of 17 October 2001[11].[12]

Art. 3 Definitions

In this Ordinance:

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

b. *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. *pathogenic organisms* means organisms that can cause diseases in human beings, domesticated animals and plants, in wild flora or fauna or other organisms, as well as alien organisms that are also pathogenic;

6 SR **814.911**
7 SR **814.012**
8 Amended by No III 2 of the O of 29 April 2015, in force since 1 June 2015 (AS **2015** 1337).
9 SR **832.321**
10 SR **810.305**
11 SR **812.213**
12 Amended by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).

f. *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. *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;

h. *contained system* means a system that uses physical barriers or a combination of physical and chemical or biological barriers to limit or prevent contact between organisms and people or the environment;

i. *handling* means any deliberate activity involving organisms, and in particular use, processing, propagation, modification, detection, transport, storage or disposal;

j.[13] *improper use* means the handling of organisms subject to a containment obligation which illegally and intentionally endangers or harms humans, animals, the environment or biological diversity and their sustainable use.

Chapter 2
Requirements for Handling Organisms in Contained Systems

Section 1 General Requirements

Art. 4 Duty of care

[1] Any person handling organisms in contained systems must take all due care to ensure that organisms, their metabolic products or wastes:

a. cannot endanger people, animals or the environment;

b. do not harm biological diversity or its sustainable use.

[2] The relevant regulations and the distributor's instructions and recommendations must be observed.

[3] Compliance with the duty of care must be clearly documented. The documentation must be retained for ten years following the conclusion of the activity and must be made available on request to the enforcement authorities.

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

Art. 5 Containment obligation and prior assessments

[1] The following organisms must be handled only in contained systems unless they may be handled in the environment in accordance with the Release Ordinance of 10 September 2008[14], the Plant Protection Products Ordinance of 12 May 2010[15] or the Biocidal Products Ordinance of 18 May 2005[16]:

a. genetically modified organisms;

b. pathogenic organisms;

c.[17] organisms subject to a containment obligation:

1. alien small invertebrates,
2. invasive alien organisms as defined in Annex 2 of the Release Ordinance, and
3. harmful organisms that are considered particularly dangerous in accordance with 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, 24 paragraph 2 and 29 paragraph 2 of the Plant Health Ordinance of 31 October 2018[18], and organisms that are considered potential quarantine organisms in accordance with 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.

[2] Any person who handles organisms in contained systems must first determine and assess the risk of the occurrence of the organisms (allocate the organisms to a group) and thereafter determine and assess the risk due to the planned activities with the organisms (classify the activities).

[3] Any person who handles genetically modified animals and plants in contained systems must first ensure by weighing the interests in accordance with Article 8 GTA that the dignity of living beings is respected.

Art. 5*a*[19] Primary detection outside contained systems

[1] Where a pathogenic organism with the potential to do considerable harm naturally occurs on a frequent basis, is released intentionally or unintentionally or if it is suspected that it has been released, its primary detection may take place exceptionally outside of contained systems if:

a. there is no threat to humans, animals, the environment or biological diversity;

14 SR **814.911**
15 SR **916.161**
16 SR **813.12**
17 Amended by Annex 8 No 4 of the Plant Health Ordinance of 31 Oct. 2018, in force since 1 Jan. 2020 (AS **2018** 4209).
18 SR **916.20**
19 Inserted by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).

b. the analyses are carried out in order help an assessment of the situation;

c. appropriate security measures are respected; and

d. the rapid detection systems used can be shown to be reliable.

2 Detection as defined in paragraph 1 is only permissible if carried out by employees of the following competent authorities who possess the requisite specialist expertise:

a. the cantonal emergency services for B-incidents in accordance with Article 3 letter e of the Ordinance of 29 April 2015[20] on Microbiological Laboratories;

b. the competent veterinary authorities responsible for measures to combat disease in accordance with Article 63 of the Epizootic Diseases Ordinance of 27 June 1995[21];

c. the federal or cantonal plant protection services responsible for preventive measures in accordance with Article 10, for monitoring in accordance with Article 18 and for surveying in accordance with Article 19 of the Plant Health Ordinance of 31 October 2018[22] (PHO);

d. the establishments authorised in accordance with Article 76 PHO to conduct assessments in accordance with Article 84 PHO.

Art. 6 Grouping of organisms

1 In order to determine the risk of an occurrence of organisms, the extent and probability of harmful effects to human beings, animals or the environment and to biological diversity and its sustainable use must be estimated. In doing so, the criteria in Annex 2.1 number 1 must be taken into account.

2 In order to assess the risks determined, the organisms must be allocated to one of the following groups according to the criteria in Annex 2.1 number 2:

a. Group 1: organisms whose occurrence presents no risk or a negligible risk;

b. Group 2: organisms whose occurrence presents a low risk;

c. Group 3: organisms whose occurrence presents a moderate risk;

d. Group 4: organisms whose occurrence presents a high risk.

3 If certain organisms have already been grouped according to the list in Article 26, no new risk determination and assessment need be carried out unless there are indications of an increased or reduced risk in an occurrence of these organisms. In the event of significant new findings, the risk must be determined and assessed again.

20 SR **818.101.32**
21 SR **916.401**
22 SR **916.20**

Art. 7 Classification of activities

1 In order to determine the risk of a planned activity with organisms in the contained system, the extent and probability of harmful effects to human beings, animals or the environment, biological diversity and its sustainable use must be estimated. In doing so, the group of organisms concerned, the nature of the planned activity and the environmental conditions according to the criteria in Annex 2.2 number 1 must be taken into account.

2 In order to assess the risks determined, the planned activity must be allocated to one of the following classes according to the criteria in Annex 2.2 number 2:

a. Class 1: activities with no risk or a negligible risk;

b. Class 2: activities with a low risk;

c. Class 3: activities with a moderate risk;

d. Class 4: activities with a high risk.

3 The risk must be determined and assessed again if the activity is modified or significant new findings are made.

4 In activities where employees may be exposed to microorganisms, the risk determination and assessment in accordance with this Ordinance may be combined with the risk assessment in accordance with Articles 5–7 of the Ordinance of 25 August 1999[23] on the Protection of Employees from Dangerous Organisms.

Section 2
Requirements for Handling Genetically Modified or Pathogenic Organisms or Alien Organisms subject to a Containment Obligation

Art. 8 Notification of Class 1 activities

1 Any person who wishes to carry out Class 1 activities with genetically modified organisms must notify this globally, at the latest when beginning the activities.

2 Any change in the globally notified activities or their termination must be notified.

Art. 9 Notification of Class 2 activities

1 Any person who wishes to carry out a Class 2 activity with genetically modified or pathogenic organisms or alien organisms subject to a containment obligation must notify this at the latest when beginning the activity.

2 Any technical or administrative change in the notified activity or its termination must be notified.

23 SR **832.321**

3 If an authorisation is required under Article 49 paragraph 2 of the Epizootic Diseases Ordinance of 27 June 1995[24] (EzDO), this must be obtained before starting the activity.

Art. 10 Authorisation of activities in Classes 3 and 4

1 Any person who wishes to carry out a Class 3 or a Class 4 activity with genetically modified or pathogenic organisms or alien organisms subject to a containment obligation requires authorisation.

2 Any technical change in the authorised activity requires further authorisation.

3 Any administrative change must be notified.

Art. 11 Submission to the authorities

1 Notifications and authorisation applications must be submitted to the Federal Coordination Centre for Biotechnology.

2 Notifications and authorisation applications must include the information listed in Annex 3. In the information, procedures and methods related in their nature, extent and purpose may be summarised.

3 The information must be entered directly into the ECOGEN electronic database (Art. 27*a*).[25]

Art. 12 Safety measures

1 Any person involved in the contained handling of genetically modified or pathogenic organisms or alien organisms subject to a containment obligation must:

a. ensure in the case of activities in Classes 1 and 2 that any escape by these organisms is limited to the extent that human beings, animals and the environment as well as biological diversity and its sustainable use cannot be endangered;

b. ensure in the case of activities in Classes 3 and 4 that these organisms cannot escape.

2 The general safety measures listed in Annex 4 and the special safety measures required according to the type and class of activity must be taken, and an operational safety concept must be devised which takes appropriate account of whether organisms could potentially be put to improper use. The safety measures taken must take account of the risk determined in the individual case and the state of the art of safety technology.[26]

3 The competent federal office may order in specific cases that:

a. individual special safety measures accordingly specified in Annex 4 may be modified, replaced or omitted if the Applicant has proven that the protection

24 SR **916.401**
25 Amended by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).
26 Amended by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).

of human beings, animals and the environment as well as biological diversity and its sustainable use is nevertheless guaranteed;

b. further special safety measures not listed in Annex 4 for the relevant type and class of activity must be taken if such measures have been recommended by international organisations or the Swiss Expert Committee for Biosafety (SECB) and are regarded as necessary by the competent federal office.

Art. 13 Guarantee of liability

1 Any person who carries out an activity in contained systems with genetically modified or pathogenic organisms of Classes 3 or 4 must guarantee legal liability:

a. of 20 million francs to cover damage to persons and property (Art. 30 GTA, Art. 59*a*bis para. 1 EPA); and

b. of 2 million francs to cover damage to the environment (Art. 31 GTA, Art. 59*a*bis para. 9 EPA).

2 The obligation to guarantee liability may be fulfilled:

a. by obtaining liability insurance from an insurance company that is authorised to do business in Switzerland;

b. by providing security of equivalent value.

3 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, provided the cantons cover their liabilities.

Art. 14 Start, suspension and termination of the guarantee

1 The person who guarantees liability must notify the specialist agency appointed by the canton of the start, suspension and termination of the guarantee.

2 The suspension and termination of the guarantee, unless previously replaced by a different guarantee, become effective 60 days after receipt of notification by the specialist agency appointed by the canton.

Art. 15 Transport

1 Any person transporting genetically modified or pathogenic microorganisms must observe the applicable national and international transport regulations, in particular with regard to labelling and packaging.

2 In the case of transport in a manner not covered by paragraph 1 of genetically modified or pathogenic organisms or alien organisms subject to a containment obligation, it must be ensured that any escape of organisms is either limited or prevented, depending on the risk.

3 The distributor must inform the recipient of:

a. the identity and the quantity of the organisms;

b. the properties of the organisms, and in particular whether they are genetically modified, pathogenic or alien organisms;

c. that the organisms must be handled in contained systems.

Art. 16 Reporting incidents

1 The specialist agency appointed by the canton must be informed immediately in the event that, when handling organisms in contained systems:

a. organisms that should have been prevented from escaping into the environment under Article 12 paragraph 1 have done so;

b. there was a genuine risk of organisms being released into the environment in the course of activities in Classes 3 and 4; or

c.[27] there is a strong suspicion of improper use.

2 The cantons shall inform the competent federal office of any reported incidents.

Chapter 3 Duties of the Authorities

Section 1 Examination of Notifications and Authorisation Applications

Art. 17 Federal Coordination Centre for Biotechnology

1 The Confederation operates a Coordination Centre for Biotechnology within the Federal Office for the Environment (FOEN).

2 The Coordination Centre has the following administrative duties:

a. it accepts notifications and authorisation applications under Articles 8–12 as well as notifications under the Ordinance of 25 August 1999[28] on the Protection of Employees from Dangerous Organisms;

b. it examines the notifications and authorisation applications, requests any missing information within 20 days and confirms to the person filing the notification or application that the document is complete;

c. it forwards complete notifications and authorisation applications to the competent federal office (Art. 18 para. 1) for a decision and to the specialist agencies (Art. 18 para. 2) for an opinion;

d. it gives notice of receipt of notifications and authorisation applications in the Official Federal Gazette and makes these notifications and authorisation applications available for public inspection unless they are confidential;

27 Inserted by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).
28 SR **832.321**

e. it monitors progress in processing the notifications and authorisation applications received;

f.[29] it maintains the ECOGEN electronic database (Art. 27*a*);

g. it maintains a register of notified and authorised activities and makes this information, and the results of surveys under Article 27, publicly accessible via automated information and communications services unless they concern confidential information;

h. it is the information and advice centre for enquiries about:
   1. procedures and the status of notification procedures and authorisation applications,
   2. forms, guidelines and foreign standards as well as contact addresses within the Federal Administration,
   3. the list of classified organisms;

i. it may run courses and training sessions in its capacity as an information and advice centre;

j. it receives information and reports from the cantons on their supervisory activities under Article 23, forwards them immediately to the responsible federal offices and issues an annual report on supervisory activities under this Ordinance.

Art. 18 Competent federal office and specialist agencies

[1] The following offices are competent to take the decisions required in connection with activities subject to notification or authorisation:

a. the Federal Office of Public Health (FOPH) where the main risk of an activity concerns human beings;

b. the FOEN for all other activities.

[2] The following are the specialist agencies:

a. for all activities, the FOPH, the FOEN, the Federal Ethics Committee on Non-Human Biotechnology (ECNH), the specialist agency appointed by the canton, and, at its request, the State Secretariat for Economic Affairs (SECO);

b. for activities in Classes 2–4, the Swiss National Accident Insurance Fund (SUVA);

c. for activities in Classes 3 and 4 and applications under Article 12 paragraph 3 letter a, the SECB;

d. for activities with organisms pathogenic to animals, the Federal Food Safety and Veterinary Office (FSVO)[30];

29 Amended by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).
30 The name of the federal office was changed on 1 Jan. 2014 in accordance with Art. 16 para. 3 of the Publications Ordinance of 17 Nov. 2004 (AS **2004** 4937). The change has been made throughout the text.

e. for activities with organisms pathogenic to plants and alien organisms subject to a containment obligation, the Federal Office for Agriculture (FOAG).

3 If the FOPH, the FOEN, the FOAG or the FSVO are the specialist agencies, the competent federal office decides with their consent in cases where the matter in question relates to compliance with the legislation enforced by these agencies.

4 In the case of activities with highly contagious epizootic diseases under Article 2 EzDO[31] that are intended to be carried out outside the Institute for Virology and Immunology (IVI)[32], the competent federal office coordinates its decision with that of the FSVO under Article 49 paragraph 2 EzDO.

Art. 19 Notification procedure

1 The competent federal office verifies whether the requirements of Articles 4–7 have been met. In doing so, it takes account of any opinions from the specialist agencies.

2 The competent federal office may prohibit the activity entirely or in part if there is reason to assume that the requirements of Articles 4–7 have not been met. It communicates its decision within 90 days of confirmation of its completeness to the notifying person, the specialist agencies, and the Federal Coordination Centre for Biotechnology.

3 If the competent federal office fails to issue a decision within the said period, Class 1 activities subject to notification and changes to Class 2 activities of which the office has already been notified are deemed to be in compliance with this Ordinance, unless this is contradicted by substantial new findings.[33]

Art. 20 Authorisation procedure

1 The competent federal office verifies whether the requirements of Articles 4–7 and 13 have been met. In doing so, it takes account of the opinions received from the specialist agencies.

2 The competent federal office decides on the authorisation application within 90 days of confirmation of its completeness. Authorisation is valid for a maximum of five years.

3 If there is a risk in delay, and in particular if a rapid diagnosis of new microorganisms is required, the competent federal office may, following a provisional examination of the risk determination and assessment and having informed the specialist agencies, grant authorisation limited until the conclusion of the ordinary procedure.

4 The competent federal office communicates its decision to the applicant, the specialist agencies and the Federal Coordination Centre for Biotechnology.

31 SR **916.401**
32 The name of this administrative unit was modified in application of Art. 16 para. 3 of the Publications Ordinance of 17 Nov. 2004 (SR **170.512.1**) on 1 May 2013.
33 Amended by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).

Art. 21 Authorisation to modify, replace or omit certain special safety measures

[1] Within 90 days of confirmation that the application is complete, the competent federal office authorises requested deviations from special safety measures provided the requirements (Art. 12 para. 3 let. a) are met. In doing so, it takes account of the opinions received from the specialist agencies.

[2] The competent federal office communicates its decision the applicant, the specialist agencies and the Federal Coordination Centre for Biotechnology.

Art. 22 Standard deadlines

[1] If additional information must be submitted in order to consider notifications and authorisation applications, the standard deadlines in this Section are extended accordingly.

[2] If the competent federal office is unable to comply with the deadline for issuing a decision under this Section, it notifies the notifying person or applicant and the specialist agencies before expiry of the deadline and informs them when the decision is to be expected.

Section 2 Monitoring in Establishments

Art. 23 Duties of the cantons

[1] The cantons monitor shall compliance with the duty of care, the containment obligation and the safety measures.

[2] They also verify by means of spot checks whether:

a. the documentation required by Article 4 paragraph 3 has been prepared and preserved;

b. notification has been given or authorisation granted, if required, for an activity that has been carried out;

c. the information on the organisms to be used and the activity given in the notification or authorisation application corresponds with the organisms actually used and the activity carried out;

d. a significant change in the proposed activity has been made such that the risk determination and assessment under Article 7 paragraph 3 must be repeated;

e. public liability is guaranteed.

[3] The samples, detection methods and materials required for monitoring are made available to the cantons.

[4] If the monitoring shows cause for complaint, the canton in question orders the required measures to be taken and inform the Federal Coordination Centre for Biotechnology.

5 If there is justified doubt whether an activity that has only been documented is not subject to a notification or authorisation obligation, the canton informs the Federal Coordination Centre for Biotechnology.

6 The cantons wherever possible coordinate monitoring under this and other legislation.

7 The cantons submit an annual report to the Federal Coordination Centre for Biotechnology on their monitoring activities. To do so, they use the template provided by the Coordination Centre.

Art. 24 Duties of the Confederation

1 If the requirements for a notified activity or an authorisation are not met despite a complaint from the canton, the competent federal office, having consulted the canton, shall prohibit the continuation of the notified activity or revoke authorisation.

2 The competent federal office decides based on information provided by the canton whether an activity that is only documented is subject to the notification or authorisation obligation or not.

Section 3 Monitoring Transport

Art. 25

The responsibility for monitoring the transport of genetically modified or pathogenic organisms or alien organisms subject to a containment obligation and for ordering any measures is governed by the relevant transport regulations.

Section 4 Obtaining, Processing and Confidentiality of Data

Art. 26[34] Lists of classified organisms

1 The FOEN maintains with consent of the FOPH, SECO, FSVO, FOAG and SUVA and after consulting the SECB a publicly accessible, non-conclusive list in which organisms are classified in one of the four groups according to the criteria in Annex 2.1.

2 The FOPH maintains with the consent of the FOEN and after consulting SECO, the FSVO, the FOAG, the Federal Office for Civil Protection, SUVA and the SECB, a publicly accessible, non-conclusive list of organisms with a high potential for improper use.

3 The FOEN and the FOPH shall take account of existing lists, in particular those of the European Union and its member states and of international organisations.

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

Art. 27 Surveys

The FOEN and the FOPH may carry out surveys of all activities involving genetically modified, pathogenic and alien organisms in contained systems, in particular as to the type and number of and time schedule for these activities.

Art. 27*a*[35] ECOGEN electronic database

[1] Data required to conduct the following tasks are recorded and processed in the ECOGEN electronic database:

a. the notification and authorisation procedures specified in Articles 19 and 20;

b. reporting incidents under Article 16 paragraph 2;

c. receiving information and reports on supervisory activities under Article 17 paragraph 2 letter j;

d. providing information and advice under Article 17 paragraph 2 letter h;

e. conducting other tasks relating to the implementation of this Ordinance.

[2] The following persons have access to ECOGEN and may process the data it contains:

a. employees of the Federal Coordination Centre for Biotechnology and of the offices and agencies responsible listed in Article 18 paragraphs 1 and 2: in accordance with their appointed tasks;

b. persons making a notification or application: to the extent that the data concerns them.

Art. 28 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 classify this information as such when forwarding it to other authorities.

[2] There is a legitimate interest in particular in preserving trade and manufacturing secrecy.

[3] Any person submitting documents to the authorities must:

a. indicate the information which is to be treated as confidential; and

b. justify the need for confidentiality.

[4] An authority that does not wish to accede to a request for confidentiality shall investigate whether the grounds given for confidentiality are justifiable. If 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.

35 Inserted by No I of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).

5 The following information shall always be accessible to the public:

a. the name of the persons responsible for the activity and for monitoring biological safety;

b. address of the establishment and the installation (location of the activity);

c. the type of installation, safety measures and waste disposal;

d. a general description of the organisms and of their properties;

e. a general description of the activity, and in particular its purpose and its approximate size (e.g. culture volume);

f. a summary of the risk assessment;

g. the class of the activity.

Section 5 Fees

Art. 29 Obligation to pay a fee

1 Any person who causes the Federal Coordination Centre for Biotechnology, the FOEN or the FOPH to provide a service or the offices to issue a ruling under this Ordinance must pay a fee.

2 Unless this Ordinance contains special regulations, the provisions of the General Fees Ordinance of 8 September 2004[36] apply.

Art. 30 Level of fees

1 The fees are as follows:

		Francs
a.	Examination of notifications under Article 19	100−2000
b.	Examination of authorisation applications under Article 20	300−4000
c.	Examination of authorisation applications under Article 21	100−4000

2 The fee is assessed on a time and material basis. If the work involved is unusually high, the fee may be increased by up to 50 per cent.

3 When examining applications for a re-assessment, fees of up to 50 per cent of the rates fixed may be charged.

4 For services without a fee rate, the fee amounts to 130–190 francs per hour.

Art. 31 Outlays

Outlays are the costs additionally incurred for an individual service, and in particular:

36 SR **172.041.1**

a. remuneration for members of extra-parliamentary committees under the Government and Administration Organisation Ordinance of 25 November 1998[37];

b. costs incurred in gathering evidence, conducting scientific investigations or special examinations or obtaining documents;

c. costs of work that the Federal Coordination Centre for Biotechnology, the FOEN or the FOPH arranges to be carried out by third parties.

Section 6 Guidelines, Basic and Continuing Professional Education

Art. 32

[1] The FOEN and the FOPH may issue joint guidelines on the implementation of this Ordinance, in particular on the determination and assessment of the risks posed by the occurrence of organisms or activities with organisms, transport of organisms, safety measures and related quality controls. They consult the specialist agencies (Art. 18 para. 2) beforehand.

[2] The FOEN and the FOPH jointly ensure, in consultation in particular with the SECB, that basic and continuing professional education events are held regularly for persons who carry out duties under this Ordinance.

Chapter 4 Final Provisions

Art. 33 Repeal of current legislation

The following ordinances are repealed:

1. Containment Ordinance of 25 August 1999[38];
2. Ordinance of 15 October 2001[39] on Fees for Services under the Containment Ordinance.

Art. 34 Amendment of Current Legislation

The amendment of current legislation is regulated in Annex 5.

Art. 35 Transitional provisions

[1] Activities that are authorised in the proper manner when this Ordinance comes into force may be continued until expiry of authorisation in accordance with the previous law.

37 SR **172.010.1**
38 [AS **1999** 2783, **2003** 4793 No I 3, **2006** 4705 No II 82, **2007** 4477 No IV 35, **2008** 4377 Annex 5 No 6]
39 [AS **2001** 2878]

2 Activities that have been properly notified before this Ordinance comes into force must within five years of this Ordinance coming into force be reviewed by the notifying person to verify compliance herewith. If changes to the activity or the safety measures are required due to this Ordinance, they must be notified within the same five-year deadline.

3 Notification of previous activities with genetically modified organisms in Class 1 must be replaced within one year of this Ordinance coming into force by a global notification under Article 8.

4 Activities with alien organisms subject to a containment obligation may only be carried out without a notification or an authorisation application for one year from the date on which this Ordinance comes into force.

Art. 35*a*[40] Transitional provision to the Amendment of 31 October 2018

The duty to contain particularly dangerous plants as listed in Annex 6 of the Plant Protection Ordinance of 27 October 2010[41] in accordance with Article 5 paragraph 1 letter c applies until 31 December 2023.

Art. 36 Commencement

This Ordinance comes into force on 1 June 2012.

40 Inserted by Annex 8 No 4 of the Plant Health Ordinance of 31 Oct. 2018, in force since 1 Jan. 2020 (AS **2018** 4209).

41 AS **2010** 6167, **2011** 3331, **2012** 6385, **2014** 4009, **2015** 4567, **2016** 2445 3215, **2017** 6141, **2018** 2041

Annex 1
(Art. 3 let. 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 an 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 organism in which they do 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 is regarded as a gene technology method. 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 are not regarded as gene technology methods 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

Determination and Assessment of Risk

Annex 2.1[42]
(Arts 6 and 26)

Assigning organisms to groups

1 Risk determination

[1] In order to determine the risk due to the occurrence of an organism for human beings, animals or the environment as well as biological diversity and its sustainable use, the following criteria in particular must be taken into account:

a. pathogenicity and lethality;
b. virulence or attenuation;
c. mode of infection, effective infection dose and the infection routes;
d. production of non-cellular components such as toxins and allergens;
e. the reproductive cycle and survival structures;
f. host range;
g. the degree of natural or acquired immunity of the host;
h. pattern of resistance or sensitivity to antibiotics and other specific agents;
i. availability of appropriate prophylaxis and therapy;
j. the presence of oncogenic nucleic acid sequences;
k. mutagenicity;
l. virus production and viral shedding in cell lines;
m. parasitic properties;
n. potential contamination with pathogenic microorganisms;
o. environmental aspects;
p. experience with the spread of closely related types of organism in Switzerland or in other countries (invasive potential);
q. the availability of suitable techniques to record, detect, identify, monitor and combat these organisms;
r. potential for improper use.

[2] In order to determine the risk arising when a genetically modified organism occurs, both donor and receptor organisms, introduced genetic material (inserts), the vector

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

or the vector-receptor system and the genetically modified organism itself must be taken into account, in particular according to the following criteria:

a. function of the genetic changes;

b. degree of purity and characterisation of the genetic material used in recombination;

c. properties of vectors, in particular relating to replication capacity, host range, host specificity, existence of a transfer system, mobilisation and independent infectivity;

d. properties of affected nucleic acid sequences, in particular regulatory effects on cell growth, cell cycle and immune system;

e. production and supply of organisms and active pharmaceutical substances, allergens or toxins via the genetically modified organism;

f. stability and expression of recombinant genetic material;

g. mobilisation potential of recombinant genetic material;

h. selection pressure for recombinant genetic material.

[3] In order to determine the risk due to the occurrence of an alien organism for human beings, animals or the environment as well as biological diversity and its sustainable use, the following criteria in particular must be taken into account:

a. life cycle and reproduction, in particular with regard to asexual reproduction, generation time and the number of offspring;

b. presence of host organisms in the environment;

c. environmental aspects and viability, in particular cold tolerance and diapause;

d. potential contamination with microorganisms that may be pathogenic for humans, animals and plants;

e. invasiveness and ability to suppress native species;

f. threat to human, animal and plant health by the organism due to its allergicity, pathogenicity, toxicity or property as a vector;

g. harm to other organisms, in particular through competition and hybridisation;

h. harm to resource cycles;

i. effects on the functioning of the ecosystem;

j. resistance or sensitivity to pesticides, herbicides and other agents;

k. availability of suitable techniques to detect the organism in the environment and to combat it.

2 Risk assessment

[1] When making a risk assessment, the effects of the organisms on healthy people, animals and plants must generally be considered.

[2] The risk is considered inexistent or negligible (Group 1) if:

a. it is unlikely that an organism will cause illness in people, animals or plants or some other damage to the environment or to biological diversity and its sustainable use; and

b. such damage is not severe.

[3] The risk is considered low (Group 2) if:

a. an organism may cause illness in people, animals or plants or some other damage to the environment or to biological diversity and its sustainable use;

b. such illness or damage is rarely severe;

c. the organism is unlikely to spread; and

d. normally effective preventive or therapeutic measures to combat the illness or damage are available.

[4] The risk is considered moderate (Group 3), if:

a. an organism may cause severe illness in people, animals or plants or other severe damage to the environment or to biological diversity and its sustainable use;

b. the organism is likely to spread; and

c. normally, effective preventive or therapeutic measures to combat the illness or damage are available.

[5] The risk is considered high (Group 4), if:

a. an organism may cause severe illness in people, animals or plants or other severe damage to the environment or to biological diversity and its sustainable use;

b. the organism is likely to spread; and

c. normally, no effective preventive or therapeutic measures to combat the illness or damage are available.

[6] If, in an individual case, it is unclear to which of two groups an organism belongs, the risk must be assessed by weighing the seriousness of the illness and damage, and the probability that the organism will spread, against the availability of effective preventive or therapeutic measures. In the event of any doubt, an organism must be assigned to the higher of two groups.

Annex 2.2[43]
(Art. 7)

Classification of activities

1 Risk determination

In order to determine the risk arising from planned activities with organisms in a contained system, the following criteria in particular should be taken into account while considering the group to which the organisms concerned have been assigned:

a. the nature, extent and purpose of the activity, such as diagnosis, research, production or storage;

b. the known or suspected geographical distribution and frequency in Switzerland of the organisms concerned or of their hosts and vectors and if applicable of the recombinant genetic material involved endemically, by natural occurrence, immigration, reproduction or genetic transfer;

c. the potential for survival, replication and dissemination of the organisms in Switzerland, in particular the formation of long-lasting forms;

d. the interaction of the organisms concerned with other organisms or involvement in biogeochemical processes;

e. host or vector occurrence in Switzerland;

f. the impact of the activity on pathogenicity, detectability and transmissibility, ability to survive and disseminate, virulence, host spectrum or tropism of the organisms used;

g. the influence of the activity on the effectiveness of vaccines, antibiotics, antivirals or other agents with a medical or agricultural use against pathogenic organisms;

h. the purpose of the activity in producing novel pathogenic organisms or restoring extinct or extinct pathogenic organisms;

i. the potential of the pathogenic organisms for improper use.

2 Risk assessment

2.1 In general

1 The class of an activity normally corresponds to the group to which the organisms have been assigned. However, the class differs from the group of organisms if the risk assessment indicates, based on the activity and environmental conditions, a considerably increased or reduced risk compared with the group to which the organisms have been assigned.

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2 An activity is assigned to Class 1 if it presents no risk or a negligible risk to people, animals, the environment and biological diversity and its sustainable use, in particular if no impact or a negligible impact on these targets can be expected should organisms escape from the contained system.

3 An activity is assigned to Class 2 if it presents a low risk to people, animals, the environment and biological diversity and its sustainable use, in particular if a limited, reversible impact on these targets can be expected should organisms escape from the contained system.

4 An activity is assigned to Class 3 if it presents a moderate risk to people, animals, the environment and biological diversity and its sustainable use, in particular if an irreversible but limited impact on these targets can be expected should organisms escape from the contained system.

5 An activity is assigned to Class 4 if it presents a high risk to people, animals, the environment and biological diversity and its sustainable use, in particular if an irreversible impact on these targets can be expected or epidemics with serious consequences may possibly occur should organisms escape from the contained system.

6 If, in an individual case, it is unclear to which of two classes an organism belongs, it must be assigned to the higher of two classes.

2.2 In particular

1 The following activities are normally assigned to Class 1:

a. analyses of soil, water, air or food samples, provided it can be assumed that the samples are not so contaminated that they pose an increased risk to human beings, animals, the environment and biological diversity and its sustainable use;

b. analyses of organisms in Groups 1 and 2 from clinical and other biological material for diagnostic purposes, if organisms can be shown to be present by direct or indirect methods without propagation, or if organisms can be shown to be present following slight enrichment carried out exclusively in closed containers;

c. activities with certain strains of Group 2 organisms, provided such strains have proved in experiments or over many years of experience to be as safe as Group 1 organisms.

2 Analyses of organisms from clinical and other biological material for diagnostic purposes with exception of analyses under paragraph 1 must normally be assigned to Class 2.

3 Where Group 3 pathogenic organisms have been enriched for diagnostic purposes and if this results in an increased risk to human beings, animals or the environment as well as biological diversity and its sustainable use, this activity must be assigned to Class 3.

4 When Group 4 organisms are processed, the activity should in most cases be assigned to Class 4. However, if a primary diagnostics of Group 4 organisms from

non-inactivated clinical material is performed by direct or indirect methods without replication, this activity may be assigned to Class 3. Where further testing is carried out using the same source material containing Group 4 organisms, this activity must in all cases be assigned to Class 4.

5 Primary diagnosis of Group 3 organisms that are pathogenic to animals may in exceptional cases and in accordance with Article 49 para. 2 EzDO[44] be assigned to Class 2 if it can be assumed that there is a high probability that no pathogen organisms are present in the samples.

44 SR **916.401**

Annex 3
(Art. 11 para. 2)

Information for the Notification and Authorisation of Activities

Annex 3.1

Information for the global notification of activities with Class 1 genetically modified organisms

The global notification under Article 8 includes the following information:

a. the names and postal addresses of the establishment, of the persons responsible for the activities and the persons responsible for monitoring biological safety;

b. the location and type of the installations where the activities are carried out;

c. confirmation that in these installations Class 1 activities with genetically modified organisms are carried out;

d. confirmation that a weighing of interests under Article 8 GTA has been carried out for activities with genetically modified animals covered by the Animal Protection Ordinance of 23 April 2008[45].

45 SR **455.1**

Annex 3.2[46]

Information for the notification and authorisation of activities in Classes 2–4

1 Principles

[1] The extent and the level of detail of the technical information required depend on the risk of the activity. In the case of Class 2 activities, the technical information for one organism may be used for other organisms with similar properties, provided the activities concerned carry similar risks.

[2] The documents must indicate what information must be treated as confidential. The need for confidentiality must be justified (Art. 28).

2 Administrative information

a. The names and postal addresses of the establishment, the persons responsible for the activities and persons responsible for monitoring biological safety;

b. A description of the activities;

c. The duration the activities;

d. The location and type of the installation;

e. Confirmation of the guarantee of liability for activities with genetically modified and pathogenic organisms of Classes 3 and 4 (Art. 13);

f. Confirmation that a weighing of interests under Article 8 GTA has been carried out for activities with genetically modified animals covered by the Animal Protection Ordinance of 23 April 2008[47].

3 Technical information

a. A description and the group of the organisms and genetic materials to be used or analysed, and in particular of the reference organisms;

b. A description of the activities, and in particular of their purpose and the methods to be used;

c. The maximum volume of culture media for the organisms to be used;

d. A verifiable record of the procedure under Article 7 for determining and assessing the risks of the activities;

e. The type of waste and method of disposal;

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47 SR **455.1**

f. The planned safety levels and safety measures for the activities and, if applicable, the individual procedures;

g. Information on the time and place that the human pathogens in Groups 3 and 4 are brought into the country.

Annex 4[48]
(Art. 12)

Safety Measures

1 General safety measures

The following safety measures apply to all species and classes of activity:

a. Compliance with the generally recognised codes of building practice in the construction and maintenance of buildings and installations, in particular with a view to their stability, the safety of persons and property and fire prevention;

b. Compliance with the operational safety concept and the related operating instructions and codes of conduct;

c. Employment of at least one person to monitor biological safety and prevent the improper use of organisms; the person must have sufficient knowledge of and competence in both technical matters and safety issues to carry out his or her duties; the tasks include in particular preparing, updating and implementing the safety concept, informing, advising and training staff, verifying compliance with biosafety rules and communicating with the authorities in relation to notifications, authorisation applications, safety measures and the safety concept;

d. Employment of a sufficient number of staff adequately trained on security issues;

e. Compliance with the principles of good microbiological practice in accordance with Annex 3 number 1 paragraph 1 of the Ordinance of 25 August 1999[49] on the Protection of Employees from Dangerous Organisms, including the provision of washing and decontamination facilities for the staff;

f. Appropriate inspections and maintenance of the monitoring measures and the equipment;

g. If required, testing for the occurrence of viable forms of the organisms used outside the primary physical barriers;

h. Use of suitable storage facilities for equipment and materials that could be contaminated;

i. Provision of effective decontaminants and disinfectants and procedures in case of a release of organisms;

j. Measures against any pests and vermin;

k. Appropriate measures to minimise any previously identified risk of improper use of the organisms, such as restricting access to premises and recording the identity of persons with access to the organisms used.

48 Revised by No 2 of the O of 27 Sept. 2019, in force since 1 Jan. 2020 (AS **2019** 3131).
49 SR **832.321**

2 Special safety measures

2.1 Activities with genetically modified or pathogenic organisms

Depending on the nature and class of the activity, special safety measures that go beyond the general safety measures must be taken which:

a. must take account of the risk determined in the specific case;

b. must correspond to the state of the art in safety technology;

b^{bis}. take account of the possibility of improper use of organisms;

c. are listed according to the safety levels in specific installations in the following table, whereby the information under Safety Levels 1–4 corresponds to the requirements for the conduct of activities in Classes 1–4;

d. apply mutatis mutandis to the storage and the transport within the installation of organisms.

Table

Key
P means that the measure is required for production activities.
L means that the measure is required for all other laboratory activities.
G means that the measure is required for activities in greenhouses.
V means that the measure is required for activities in installations with animals.
[ ] means that the measure is required for the field of activity in brackets, but may be modified, replaced or omitted with the authorisation of the competent federal office.
– means that the relevant measure is not required.

MSC II/III means the Class II/III microbiological safety cabinet.
HEPA filter means High Efficiency Particulate Air Filter

No	Safety measures	Safety level			
		1	2	3	4
	Building				
1	Separate work area	– – – –	P – – –	P L G V	P L G V
2	Restricted access to the work area	– – – –	P L G V	P L G V	P L G V
3	Animal rooms separated by lockable doors	– – – V Only in installations with vertebrates	– – – V Only in installations with vertebrates	– – – V	– – – V

No	Safety measures	Safety level			
		1	2	3	4
4	Access to work area via airlock (separate room). The inside of the airlock must be separated from the outside by changing facilities, and preferably by lockable doors.	– – – –	– – – –	[P] [L] [G] [V]	P L G V Airlock doors lockable on both sides
5	Shower area in airlock	– – – –	– – – –	P L G V Depending on the risk this measure may be omitted without authorisation from the competent federal offices.	[P] [L] [G] [V]
6	Facilities for personal decontamination in the work area	– – – –	P L G V	P L G V	P L G V
7	Observation window or other means of monitoring the work area	– – – –	– – – –	[P] [L] [G] [V]	P L G V
8	Biohazard warning sign	– – – –	P L G V	P L G V	P L G V
9	Rooms with easily cleanable floors	P L – V	P L G V	P L G V	P L G V
10	Rooms with easily cleanable walls	– – – –	– – – –	P L G V	P L G V
11	Work area sealed so that fumigation is possible	– – – –	[P] – – –	[P] [L] [G] [V]	P L G V
12	Work area under negative air pressure with respect to the immediate surroundings	– – – –	– – – –	[P] [L] [G] [V]	P L G V
13	Air supply to the work area via HEPA filter	– – – –	– – – –	[P] – – –	[P] [L] [G] [V]

No	Safety measures	Safety level			
		1	2	3	4
14	Exhaust air outlet from the work area via HEPA filter	– – – –	– – – –	P [L] [G] [V]	P L G V For viruses that are not retained by HEPA filters, additional measures are required.
15	Microorganisms must be held in a primary contained system that physically separates the process from the rest of the work area. This primary contained system must be entirely within the work area	– – – –	P – – –	P – – –	P – – –
16	The work area must be constructed so that a release of the entire contents of the primary contained system can be captured and retained	P – – –	P – – –	P – – –	P – – –
17	Requirements for the air outlet from the primary contained system	– – – –	P – – – Minimise any escape of organisms	P – – – Prevent any escape of organisms	P – – – Prevent any escape of organisms
18	The work area must be ventilated so as to minimise the contamination of the air with organisms	– – – –	[P] – – –	[P] – – –	P – – –
	Equipment				
19	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontaminants	P L G V Work bench	P L G V Work bench	P L G V Work bench and floor	P L G V Work bench, floor, ceiling and walls
20	Work area with complete, independent equipment	– – – –	– – – –	[P] [L] [G] [V]	P L G V

No	Safety measures	Safety level			
		1	2	3	4
21	Microbiological safety cabinet (MSC) when working with microorganisms	– – – –	[P] [L] [G] [V]	P L G V	P L G V MSC III including airlock entry and exit system or MSC II with full protection; full protection may be omitted for activities with animal and plant pathogens if authorised by the competent federal office
22	Measures against aerosol formation and dissemination	– – – –	P L G V Minimise aerosol dissemination	P L G V Prevent aerosol dissemination	P L G V Prevent aerosol dissemination
23	...				
24	For the animal species concerned, suitable systems for keeping animals (e.g. cages), that are easily decontaminated	– – – V Washable	– – – V Decontaminable	– – – V Decontaminable	– – – V Decontaminable
25	Filter on isolation chambers (Isolation chamber = transparent container in which the animal is kept when inside or outside a cage) or isolation rooms (for large animals)	– – – –	– – – [V]	– – – V	– – – V
26	Requirements for seals on primary contained systems	– – – –	P – – – Minimise any escape of organisms	P – – – Prevent any escape of organisms	P – – – Prevent any escape of organisms

No	Safety measures	Safety level			
		1	2	3	4
	Work Organisation				
27	Suitable clothing for the work area	P L G V For laboratory activities: laboratory clothing	P L G V For laboratory activities: laboratory clothing	P L G V Suitable protective clothing and, if applicable, shoes	P L G V Change all clothing and shoes before entering or leaving
28	Personal safety equipment Personal safety measures must be adapted to the activity and the organisms used.	P L G V	P L G V	P L G V	P L G V
29	Regular disinfection of the workplaces	– – – –	P L G V	P L G V	P L G V
30	Inactivation of microorganisms in the outflow of sinks, pipes and showers	– – – –	– – – –	[P] [L] [G] [V]	P L G V
31	Escape of contaminated waste water	– – [G] – Minimise	– – [G] – Minimise	– – G – Prevent	– – G – Prevent
32	Escape of reproductive plant parts in the air or via vectors	– – [G] – Minimise	– – [G] – Minimise	– – G – Prevent	– – G – Prevent
33	...				
34	Inactivation of large volumes of culture medium prior to its removal from the primary contained system	– – – –	P – – –	P – – –	P – – –
35	Minimise or prevent the escape of organisms during internal transport between various work areas	P L G V Minimise	P L G V Minimise	P L G V Prevent	P L G V Prevent

No	Safety measures	Safety level			
		1	2	3	4
36	Inactivation of the microorganisms in contaminated material, in waste and on contaminated apparatus, from animals, plants and process fluid in production activities ‘P’	P L G V Harmless disposal; inactivation of genetically modified microorganisms on site or disposal as hazardous waste; Deactivation methods are permissible if their effectiveness is proven.	[P] [L] [G] [V] Autoclaving in the building, may take place outside the building if approval given by the federal office responsible; other equivalent deactivation methods are permissible if their effectiveness is proven; may be disposed of as hazardous waste: a. contaminated material, animal cadavers, diagnostic samples; b. solid cultures, if approval given by the federal office responsible	[P] [L] [G] [V] Autoclaving in the work area, may take place elsewhere in the building if approval given by the federal office responsible; other equivalent deactivation methods are permissible if validated; the autoclave may be omitted if approval given by the federal office responsible.	P L G V Deactivation and pass-through autoclave in work area

2.2 Activities with alien organisms subject to a containment obligation

[1] For activities with alien organisms subject to a containment obligation, all potential escape paths must be secured by appropriate special safety measures so as to ensure that any escape of alien organisms subject to a containment obligation:

a. is so limited in the case of Class 1 and 2 activities that human beings, animals and the environment cannot be endangered and biological diversity and its sustainable use cannot be harmed;

b. is prevented in the case of Class 3 and 4 activities.

[2] The special safety measures in Annex 4 number 2.1 apply mutatis mutandis.

Annex 5
(Art. 34)

Amendment of Current Legislation

...[50]

50 The amendments may be consulted under AS **2012** 2777.