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

of 10 September 2008 (Status as of 1 January 2022)

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*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 1983<sup>1</sup> (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 2003<sup>2</sup> (GTA),  
and Article 29a paragraphs 2 and 3 as well as 29d of the Epidemics Act of 18 December 1970<sup>3</sup>,  
as well as in implementation of Articles 8 and 19 of the Convention on Biological Diversity of 5 June 1992<sup>4</sup>,  
*ordains:*

### **Chapter 1    General Provisions**

#### **Art. 1            Purpose**

<sup>1</sup> 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.

<sup>2</sup> 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

<sup>1</sup> SR 814.01

<sup>2</sup> SR 814.91

<sup>3</sup> [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).

<sup>4</sup> SR 0.451.43

**Art. 2** Scope and area of validity

<sup>1</sup> 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.

<sup>2</sup> Handling organisms in contained systems is regulated by the Containment Ordinance of 9 May 2012<sup>5</sup> (ContainO).<sup>6</sup>

<sup>3</sup> The protection of personnel when working with microorganisms is governed by the Ordinance of 25 August 1999<sup>7</sup> on Protection of Employees from Dangerous Organisms.

<sup>4</sup> The marketing of pathogenic organisms:

- a. for application as plant protection products in agriculture is regulated by the Plant Protection Products Ordinance of 18 May 2005<sup>8</sup>;
- b. for application as biocidal products, the Biocidal Products Ordinance of 18 May 2005<sup>9</sup>.

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

<sup>6</sup> This Ordinance does not apply to handling organisms:

- a. in clinical trials on human beings;
- b.<sup>10</sup> 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 2018<sup>11</sup>, or for which the two aforementioned departments have designated a protected area based on Article 24 paragraph 2 of the Plant Health Ordinance;
- c.<sup>12</sup> 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.

<sup>5</sup> SR **814.912**

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

<sup>7</sup> SR **832.321**

<sup>8</sup> [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**).

<sup>9</sup> SR **813.12**

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

<sup>11</sup> SR **916.20**

<sup>12</sup> 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

<sup>1</sup> 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.<sup>13</sup> *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.<sup>14</sup> *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.<sup>15</sup> *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.<sup>16</sup> ...
- 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, marketing, transport, storage or disposal;

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

<sup>14</sup> Amended by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, in force since 1 June 2012 (AS **2012** 2777).

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

<sup>16</sup> Repealed by Annex 5 No 10 of the Containment Ordinance of 9 May 2012, with effect from 1 June 2012 (AS **2012** 2777).

- j. *direct handling of organisms in the environment* means handling organisms in the environment, not including the handling of therapeutic products, foodstuffs and animal feedstuffs;
- k. *marketing* means the transfer of organisms to third parties in Switzerland for use in the environment, in particular by sale, exchange, giving as a gift, renting, lending or sending on approval, as well as their import for the use in the environment.

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

## Chapter 2

### Requirements for Handling Organisms in the Environment

#### Section 1 General Requirements for Handling Organisms

##### Art. 4 Self-supervision for marketing

<sup>1</sup> Any person who intends to market organisms 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.

<sup>2</sup> The assessment referred to in paragraph 1 letter a must in particular consider:

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

##### Art. 5 Informing the recipients

Any person marketing organisms for use in the environment must:

- a. inform the recipient of the identity of the organisms, their metabolic products and wastes, as well as of their properties in relation to public health and the environment;
- b. instruct the recipient in such a way that handling the organisms in the environment in accordance with the regulations and the instructions will not endanger human beings, animals or the environment, or 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

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

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

<sup>2</sup> 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

<sup>1</sup> 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.

<sup>2</sup> Genetically modified organisms may not be directly handled in the environment, if: