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Ordinance on Protection against Dangerous Substances and Preparations

(Chemicals Ordinance, ChemO)

of 5 June 2015 (Status as of 5 May 2022)

The Swiss Federal Council,

based on Article 19 paragraphs 2 and 3 of the Animal Protection Act of 16 December 2005[1],
on the Chemicals Act of 15 December 2000[2] (ChemA),
on Article 26 paragraph 3, 29, 30*a*–30*d*, 38 paragraph 3, 39 paragraph 1, 41 paragraph 3, 44 paragraphs 2 and 3, 46 paragraphs 2 and 3 and 48 paragraph 2 of the Federal Act of 7 October 1983[3] on the Protection of the Environment (EPA),
and on Article 9 paragraph 2 letter c, 27 paragraph 2 and 48 paragraph 2 of the Waters Protection Act of 24 January 1991[4],
and in implementation of the Federal Act of 6 October 1995[5] on Technical Barriers to Trade,[6]

ordains:

Title 1 General Provisions

Art. 1 Aim and scope

[1] This Ordinance regulates:

a. the determination and assessment of dangers and risks that substances and preparations may pose to human life and health and to the environment;

b. the conditions under which substances and preparations that may endanger people or the environment are placed on the market;

c. the handling of substances and preparations that may endanger people or the environment;

AS **2005** 2917
1 SR **455**
2 SR **813.1**
3 SR **814.01**
4 SR **814.20**
5 SR **946.51**
6 Amended by No I of the O of 31 Jan. 2018, in force since 1 March 2018 (AS **2018** 801).

d. the way in which data relating to substances and preparations is processed by the enforcement authorities.

2 This Ordinance applies to biocidal products and the active substances contained therein, and to plant protection products and the active substances and co-formulants contained therein, insofar as they are referred to in the Ordinance of 18 May 2005 on Biocidal Products[7] or the Ordinance of 12 May 2010[8] on Plant Protection Products.

3 This Ordinance applies to radioactive substances and preparations, excluding effects attributable to the radioactive nature of these substances and preparations.

4 Only Articles 5–7 and 81 apply to cosmetic products within the meaning of Article 53 paragraph 1 of the Ordinance of 16 December 2016[9] on Foodstuffs and Utility Articles in the form of finished products intended for private or professional users, and only with regard to environmental protection and to classification or assessment in relation to risks to the environment.[10]

5 This Ordinance does not apply to:

a. the transport of substances and preparations by road, rail, water, air or pipelines, with the exception of Article 10 paragraph 1 letter b;

b. the transit of substances and preparations under customs supervision, provided that this does not involve any processing or transformation;

c. substances and preparations in the form of finished products ready for supply to private and professional users that fall into the following categories:[11]

1.[12] foodstuffs as defined by Article 4 of the Foodstuffs Act of 20 June 2014[13] (FoodA),

2. medicinal products as defined by Article 4 paragraph 1 letter a and medical devices as defined by Article 4 paragraph 1 letter b of the Therapeutic Products Act of 15 December 2000[14],

3. animal feedingstuffs as defined by Article 3 paragraph 1 of the Feedstuffs Ordinance of 26 October 2011[15];

d. weapons and ammunition as defined by Article 4 paragraphs 1 and 5 of the Weapons Act of 20 June 1997[16];

e. substances, preparations and objects which are waste according to Article 7 paragraph 6 of the EPA.

6 Articles 57, 62 and 67 apply to imported substances and preparations that are simply relabelled and then exported without alteration.[17]

7 SR **813.12**
8 SR **916.161**
9 SR **817.02**
10 Amended by No I of the O of 31 Jan. 2018, in force since 1 March 2018 (AS **2018** 801).
11 Amended by No I of the O of 31 Jan. 2018, in force since 1 March 2018 (AS **2018** 801).
12 Amended by No I of the O of 31 Jan. 2018, in force since 1 March 2018 (AS **2018** 801).
13 SR **817.0**
14 SR **812.21**
15 SR **916.307**
16 SR **514.54**

7 Dangerous substances and preparations that are exported are also governed by the PIC Ordinance of 10 November 2004[18].[19]

Art. 2 Definitions and applicable legislation

1 By way of clarification of the definitions given in the Chemicals Act, in this Ordinance:

a. *substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

b. *manufacturer* means:

1. any natural or legal person domiciled in Switzerland or with a registered office or branch in Switzerland, who manufactures, extracts or imports substances, preparations or objects in a professional or commercial capacity, and

2.[20] any person who obtains substances, preparations or objects in Switzerland and supplies them on a commercial basis, without altering their composition:
   - under his own name, without specifying the name of the original manufacturer,
   - under his own trade name,
   - in packaging other than that provided by the original manufacturer,
   - for a different intended use, or
   - at a location where the labelling in accordance with Article 10 paragraph 3 letter b has not been applied in the official language by the original manufacturer,

3.[21] a person is deemed to be the sole manufacturer if he arranges for the manufacture of a substance, preparation or object in Switzerland by a third party, and if he is domiciled or has a registered office or branch in Switzerland; if he has neither his domicile, a registered office or branch in Switzerland, the third party is the sole manufacturer.

2 In addition, in this Ordinance:

a. *professional user* means:

1. any natural or legal person who obtains substances, preparations or objects in Switzerland for use in professional activities,

2. also deemed to be a professional user is:

17 Amended by No III 1 of the O of 22 March 2017, in force since 1 May 2017 (AS **2017** 2593).
18 SR **814.82**
19 Inserted by No III 1 of the O of 22 March 2017, in force since 1 May 2017 (AS **2017** 2593).
20 Amended by No I of the O of 11 March 2022, in force since 1 May 2022 (AS **2022** 220).
21 Amended by No I of the O of 31 Jan. 2018, in force since 1 March 2018 (AS **2018** 801).

– any natural or legal person who obtains substances, preparations or objects in Switzerland for use in the course of training or for research purposes,
– any legal person who obtains substances, preparations or objects in Switzerland for use in charitable activities;

b. *private user* means any natural person who obtains or uses substances, preparations or objects for non-professional purposes;

c. *trader* means any natural or legal person who obtains substances, preparations or objects in Switzerland and supplies them unchanged on a commercial basis;

d. *only representative* means any natural or legal person that is authorised by a manufacturer whose domicile or registered office is located abroad to notify a substance in Switzerland and represents several importers designated by that manufacturer;

e. *object* means an article, consisting of one or more substances or preparations, which during production is given a special shape, surface or design which determines its end use function to a greater degree than does its chemical composition;

f.[22] *existing substance* means the substance that is registered in accordance with Article 5 of Regulation (EC) No 1907/2006 (REACH Regulation)[23], with the exception of substances that:

1.[24] are placed on the market in larger quantities than those registered in the European Economic Area (EEA), or

2. are registered solely as intermediates, unless they are monomers;

g. *polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising:

1. a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant, and

2. less than a simple weight majority of molecules of the same molecular weight; these molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units;

h. *monomer* means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

22 Amended by No I of the O of 11 March 2022, in force since 1 May 2022 (AS **2022** 220).
23 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396 of 30.12.2006, p. 1; last amended by Regulation (EU) No (EU) 2021/2204, OJ L 446 of 14.12.2021, p. 34.
24 The correction of 5 May 2022 concerns the French text only (AS **2022** 273).

i. *monomer unit* means the reacted form of a monomer substance in a polymer;

j. *intermediate* means a substance manufactured and used solely for chemical processing during which it is transformed into one or more other substances;

k. *secondary product* means any substance formed by chemical or biochemical transformation during the storage, use or disposal of a substance or preparation;

l. *scientific research and development* means any scientific experimentation, analysis or chemical research carried out under controlled conditions and involving quantities of less than 1 tonne per year;

m. *product and process-orientated research and development* means any scientific development related to product development or the further development of a substance on its own, in preparations or in objects in the course of which pilot plant or production trials are used to define the production process or test the fields of application of the substance;

n. *robust study summary* means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study, minimising the need to consult the full study report;

o. *exposure scenario* means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer controls, or recommends customers to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

p. *hazard class* means the nature of the physical, health or environmental hazard;

q. *nanomaterial* means a material containing particles in an unbound state or as an aggregate or as an agglomerate, where one or more external dimensions is in the size range 1–100 nm, or a material where the specific surface area by volume is greater than 60 m^2/cm^3. A material is only considered to be a nanomaterial if it is deliberately produced to utilise the properties arising from the defined external dimensions of the particles it contains, or from the defined surface area by volume of the material. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm are considered to be nanomaterials;

r.[25] *colorants* means substances and preparations that primarily contain colouring agents, colour pigments and effect-producing pigments which are added solely for the purpose of colouring or producing effects.

[3] Any other terms which are used in various senses in the legislation underlying this Ordinance are used here as defined in the Chemicals Act.

[4] The equivalence of expressions between the REACH Regulation, Regulation (EC) No 1272/2008 (CLP Regulation)[26] and Directive 75/324/EEC[27], and this Ordinance as specified in Annex 1 number 1 applies.[28]

25 Inserted by No I of the O of 11 March 2022, in force since 1 May 2022 (AS **2022** 220).