Ordinance on the Placing on the Market and Handling of Biocidal Products

(Ordinance on Biocidal Products, OBP)

of 18 May 2005 (Status as of 5 May 2022)

The Swiss Federal Council,

based on the Chemicals Act of 15 December 2000[1] (ChemA),
on Articles 29, 29*d* paragraph 4 and 30*b* paragraphs 1 and 2 letter a of the Environmental Protection Act of 7 October 1983[2] (EPA),
and on Article 17 of the Gene Technology Act of 21 March 2003[3] (GTA)
and in implementation of the Federal Act of 6 October 1995[4] on Technical Barriers to Trade,

ordains:

Chapter 1 General Provisions

Art. 1[5] Purpose

This Ordinance regulates:

a. the placing on the market of biocidal products and of treated articles (Art. 2 para. 2 let. j); it also regulates, in particular, for biocidal products and for active substances for use in biocidal products:
   1. the types of authorisation, including the recognition of authorisations of a Member State of the European Union (EU) or the European Free Trade Association (EFTA) and of Union authorisations, and including parallel trade in biocidal products,
   2. the authorisation procedures,

AS **2005** 2821

1 SR **813.1**
2 SR **814.01**
3 SR **814.91**
4 SR **946.51**
5 Amended by No I of the O of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

3. the protection and use of owners' data from previous applications for the benefit of subsequent applicants,
4. classification, packaging, labelling and the safety data sheet;

b. particular aspects of the handling of biocidal products and treated articles.

Art. 1*a*[6] Scope

[1] This Ordinance applies to biocidal products and treated articles. In the absence of provisions to the contrary, biocidal product families are deemed to be equivalent to biocidal products.

[2] With regard to biocidal products and treated articles consisting of or containing pathogenic microorganisms, the provisions of this Ordinance on placing on the market are also applicable to import for non-professional or non-commercial purposes.

[3] This Ordinance does not apply to:

a. biocidal products or treated articles which are placed on the market solely in accordance with legislation on therapeutic products, foodstuffs, feedstuffs or plant protection products for the specified purposes;

b. the transit of biocidal products or treated articles under customs supervision, provided that they do not undergo any processing or transformation;

c. the transport of biocidal products or treated articles by road, rail, water, air or pipelines;

d. foodstuffs or feedstuffs used as repellents or attractants;

e. biocidal products used as processing aids as defined in Article 3 paragraph 2 letter i of the Feedstuffs Ordinance of 26 October 2011[7] (FsO) and in Article 2 paragraph 1 No 23 of the Foodstuffs and Utility Articles Ordinance of 16 December 2016[8] (FUO)[9];

f[10] ...

[4] For imported biocidal products and treated articles that are simply relabelled and exported otherwise unmodified, Articles 42 and 45 apply.[11]

[5] For biocidal products and treated articles that are exported and which contain hazardous substances or preparations, the PIC Ordinance of 10 November 2004[12] applies.[13]

6 Inserted by No I of the O of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
7 SR **916.307**
8 SR **817.02**
9 The reference was amended on 1 May 2017 pursuant to Art. 12 para. 2 of the Publications Act of 18 June 2004 (SR **170.512**).
10 Repealed by No III 2 of the O of 22 March 2017, with effect from 1 May 2017 (AS **2017** 2593).
11 Inserted by No III 2 of the O of 22 March 2017, in force since 1 May 2017 (AS **2017** 2593).
12 SR **814.82**

Art. 1*b*[14] Changes to this Ordinance and priority of international treaties

[1] Where it is empowered to do so under this Ordinance, the Federal Department of Home Affairs (FDHA), in consultation with the Federal Department of the Environment, Transport, Energy and Communications (DETEC) and the Federal Department of Economic Affairs, Education and Research (EAER), shall make changes to provisions of this Ordinance concerning the authorisation and placing on the market of biocidal products in order to take scientific and technical progress into account.

[2] Where procedural aspects for the authorisation or placing on the market of biocidal products are not specified in this Ordinance, the details shall be regulated by the FDHA, if it is empowered to do so, in consultation with DETEC and the EAER.

[3] With regard to changes as specified in paragraphs 1 and 2, the FDHA shall take into consideration delegated acts or implementing acts adopted by the European Commission in accordance with Regulation (EU) No 528/2012[15].[16]

[4] Adjustments to technical details of minor importance in this Ordinance shall be made by the Federal Office of Public Health (FOPH), if it is empowered to do so, in consultation with the Federal Office for the Environment (FOEN) and the State Secretariat for Economic Affairs (SECO).

[5] Where this Ordinance regulates matters which are the subject of an international treaty, responsibilities shall be governed, not by this Ordinance, but by the treaty, insofar as responsibilities are regulated by the latter.

[6] The Notification Authority shall publicise on its website[17] the responsibilities arising from the international treaty.[18]

Art. 2[19] Definitions and applicable law[20]

[1] By way of clarification of the definitions given in the ChemA, in this Ordinance:

a. *biocidal products* means:

1. substances, preparations or objects, in the form in which they are supplied to the user, consisting of, containing or generating one or more active substances, intended to destroy, deter, render harmless, prevent the

13 Inserted by No III 2 of the O of 22 March 2017, in force since 1 May 2017 (AS **2017** 2593).
14 Inserted by No I of the O of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
15 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167 of 27 June 2012, p. 1; last amended by Regulation (EU) No 334/2014, OJ L 103 of 5 April 2014, p. 22.
16 Amended by Annex No 1 of the O of 11 March 2022, in force since 1 May 2022 (AS **2022** 220).
17 www.anmeldestelle.admin.ch > Topics > Chemicals Legislation and Guidelines > Chemicals Legislation > Ordinance on Biocidal Products (OBP) > MRA Switzerland-EU
18 Amended by No I of the O of 5 June 2015, in force since 1 July 2015 (AS **2015** 1985).
19 Amended by No I of the O of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
20 Amended by No I of the O of 31 Jan. 2018, in force since 1 March 2018 (AS **2018** 817).

action of, or otherwise exert a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

2. substances or preparations generated from substances or preparations which are not themselves biocidal products as defined in number 1, and which are intended for the purpose for which biocidal products as defined in number 1 are intended;

b. *product type* means one of the categories of biocidal products specified in Annex 10;

c. *manufacturer* means any natural or legal person who, by way of profession or trade, manufactures or extracts substances or preparations.

[2] In addition, in this Ordinance:

a. *substance of concern* means a substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect; such a substance, unless there are other grounds for concern, would be, in particular:[21]

1. a substance classified as dangerous or that meets the criteria to be classified as such according to Article 2 paragraph 2 in conjunction with Annex VI Numbers 2–5 of Directive 67/548/EEC[22], and that is present in the biocidal product at a concentration leading the product to be classified as dangerous within the meaning of Article 1 paragraph 2 in conjunction with Articles 5, 6 and 7 of Directive 1999/45/EC[23],

2. a substance classified as hazardous or that meets the criteria to be classified as such according to Article 2 paragraph 2 in conjunction with Parts 2–5 of Annex I to Regulation (EC) No 1272/2008 (CLP Regulation)[24], and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation, or

21 Amended by No I of the O of 5 June 2015, in force since 1 July 2015 (AS **2015** 1985).

22 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 196 of 16 August 1967, p. 1; last amended by Directive 2013/21/EU, OJ L 158 of 10 June 2013, p. 240.

23 Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, OJ L 200 of 30 July 1999, p. 1; last amended by Directive 2013/21/EU, OJ L 158 of 10 June 2013, p. 240.

24 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006, OJ L 353 of 31 December 2008, p. 1; last amended by Regulation (EU) No 944/2013, OJ L 261 of 3 October 2013, p. 5.

3. a substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004[25], or which meets the criteria for being persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006 (REACH Regulation)[26];

b. *biocidal product family* means a group of biocidal products having the following properties in common:
   1. similar uses,
   2. the same active substances,
   3. similar composition with specified variations,
   4. similar level of risk,
   5. similar efficacy;

c. *harmful organism* means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans or their activities, on products they use or produce, or on animals or the environment;

d. *microorganisms* means microbiological entities, especially bacteria, algae, fungi, protozoa, viruses and viroids; cell cultures, prions and biologically active genetic material are also included in this category;

e. *letter of access* means a document, signed by the person authorised to use protected data, which states that the data may be used by the Notification Authority and, if necessary, by the competent authority of a state party for the purpose of granting an authorisation of a biocidal product;

f. *existing active substance* means a substance which was on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development;

g. *new active substance* means an active substance of a biocidal product which is not an existing active substance;

h. *active substance which is a candidate for substitution* means an active substance which meets the criteria specified in Article 10 paragraph 1 of Regulation (EU) No 528/2012[27];

25 Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC, last amended by Regulation (EU) No 519/2012, OJ L 159 of 20 June 2012, p. 1.

26 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 December 2006, p. 1; last amended by Regulation (EU) No 474/2014, OJ L 136 of 9 May 2014, p. 19.

27 See footnote to Art. 1*b* para. 3.