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

(Ordinance on Biocidal Products, OBP)

of 18 May 2005 (Status as of 23 December 2014)
Please note: this translation does not yet include the amendments of 01.07.2015
Please note: this translation does not yet include the amendments of 01.09.2015

The Swiss Federal Council,

based on the Chemicals Act of 15 December 2000[1] (ChemA),
on Article 29, Article 29*d* paragraph 4 and Article 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,
   3. the protection and use of owners' data from previous applications for the benefit of subsequent applicants,

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 Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

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 letter n of the Foodstuffs and Utility Articles Ordinance of 23 November 2005[8] (FUO);

f. biocidal products and treated articles which are imported, relabelled and then exported; these are governed exclusively by Article 34*d* and Article 34*e* paragraph 1 letter a of the Chemicals Ordinance of 18 May 2005[9] (ChemO).

Art. 1*b*[10] 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

6 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
7 SR **916.307**
8 SR **817.02**
9 SR **813.11**
10 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

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[11].

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[12] the responsibilities arising from the international treaty.

Art. 2[13] Definitions

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 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:

11 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.

12 www.bag.admin.ch > Chemikalien > Organisation der Chemikaliensicherheit > Anmeldestelle [not available in English]

13 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

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:

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[14], and that is present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Article 1 paragraph 2 in conjunction with Articles 5, 6 and 7 of Directive 1999/45/EC[15],
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)[16], 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
3. a substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004[17], 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)[18];

b. *biocidal product family* means a group of biocidal products having the following properties in common:

14 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.

15 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.

16 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.

17 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.

18 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.

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[19];

i. *residue* means a substance present in or on products of plant or animal origin, water resources, drinking water, food, feed or elsewhere in the environment and resulting from the use of a biocidal product, including such a substance's metabolites, breakdown or reaction products;

j *treated article* means a substance, preparation or object which does not have a primary biocidal function, but which has been treated with, or intentionally incorporates, one or more biocidal products;

k. *national authorisation* means an authorisation granted by the competent authority of an EU or EFTA Member State for the placing on the market of a biocidal product in its territory;

l. *Union authorisation* means an authorisation granted by the European Commission for the placing on the market of a biocidal product in the territory of the EU;

m. *nanomaterial* means a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions are in the size

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

range 1–100 nm; fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm are deemed to be nanomaterials; in addition, for nanomaterials, the following definitions apply:

1. *particle* means a minute piece of matter with defined physical boundaries,
2. *agglomerate* means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components,
3. *aggregate* means a particle comprising strongly bound or fused particles;

n. *technical equivalence* means similarity, as regards the chemical composition and hazard profile, between a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process or manufacturing location, and the substance from the reference source in respect of which the initial risk assessment was carried out;

o. *vulnerable groups* means persons needing specific consideration when assessing the acute and chronic health effects of biocidal products; these include pregnant and breastfeeding women, the unborn, infants and children, the elderly, and workers and other persons subject to high exposure to biocidal products over the long term.

3 The following terms are to be understood as defined in Article 2 of the ChemO[20]:

a. *substance*;

b. *object*;

c. *product and process-orientated research and development*;

d. *scientific research and development*.

4 For the correct interpretation of Regulation (EU) No 528/2012, to which reference is made in this Ordinance, the correspondences specified in Annex 3 apply.

5 Any other terms which are used in various senses in the legislation underlying this Ordinance are used here as defined in the ChemA.

20 SR **813.11**

Chapter 2: Conditions for Placing on the Market[21]

Section 1: General Provisions

Art. 3[22] Authorisation or declaration and labelling

1 Biocidal products may only be placed on the market or used professionally or commercially if they are authorised by the Notification Authority and labelled in accordance with this Ordinance.

2 For biocidal products which are imported for professional or commercial purposes, the condition specified in paragraph 1 must be fulfilled before they are first supplied or first used.

3 The following biocidal products may be placed on the market or used professionally or commercially without authorisation, provided that they have been declared to the Notification Authority in accordance with Article 13*c*, 13*d* or 13*f* and no opinion has been issued by the Notification Authority within the time limits specified in Article 19 paragraph 2:

a. biocidal products which have been authorised in an EU or EFTA Member State under the simplified procedure specified in Article 26 of Regulation (EU) No 528/2012[23];

b. biocidal products belonging to an authorised biocidal product family;

c. biocidal products released for purposes of research and development.

4 As regards the handling of biocidal products in accordance with paragraph 3 letter c, if these products are or contain microorganisms, they are subject to the provisions of the Containment Ordinance of 9 May 2012[24] (ContainO) and of the Release Ordinance of 10 September 2008[25] (RO).

Art. 4[26] Biocidal products not eligible for authorisation

1 Biocidal products of the following product types according to Annex 10 are not to be authorised:

a. Product type 15 (avicides);

b. Product type 17 (piscicides);

c. Product type 20 (control of other vertebrates).

2 Biocidal products as specified in paragraph 1 may be used for purposes of research and development in accordance with Articles 13*e* and 13*f*.

21 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
22 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
23 See footnote to Art. 1*b* para. 3.
24 SR **814.912**
25 SR **814.911**
26 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

3 They may be authorised in order to deal with exceptional situations in accordance with Article 30.

4 Use or authorisation according to paragraphs 2 and 3 are subject to the restrictions specified in the Chemical Risk Reduction Ordinance of 18 May 2005[27] (ORRChem) and the provisions of the ContainO[28] and the RO[29].

Art. 5[30] Scope of authorisation and person making the application

1 Authorisation applies:

a. to an individual biocidal product:
   1. with a particular composition,
   2. with a particular trade name,
   3. for particular uses,
   4. from a particular manufacturer;

b. to a biocidal product family.

2 Authorisation is granted to a particular person; it is personal and non-transferable.

3 Only persons domiciled in Switzerland or with a registered office or branch in Switzerland may apply for and hold an authorisation. This is without prejudice to the provisions of an international treaty.

Art. 6[31]

Art. 7[32] Types of authorisation

1 The following types of authorisation exist for biocidal products:

a. *authorisation A_L* based on a comprehensive evaluation of the biocidal product: for biocidal products which:
   1. contain at least one active substance listed in Annex 2, and
   2. otherwise contain only active substances listed in Annex 1;

b. *authorisation A_{nL}* based on a comprehensive evaluation of the biocidal product and its active substances: for biocidal products containing at least one active substance which is not listed either in Annex 1 or in Annex 2 or included in the list of notified active substances for use in biocidal products

27 SR **814.81**
28 SR **814.912**
29 SR **814.911**
30 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
31 Repealed by No I of the Ordinance of 20 June 2014, with effect from 15 July 2014 (AS **2014** 2073).
32 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

referred to in Regulation (EC) No 1451/2007[33] (list of notified active substances);

c. *authorisation A_N*: for biocidal products:
   1. containing at least one active substance included in the list of notified active substances but for which a decision on listing in Annex 1 or 2 is still outstanding, and
   2. whose other active substances are included in one of these lists;

d. *authorisation A_C* (confirmation) based on a summary procedure: for biocidal products:
   1. containing at least one active substance included in the list of notified active substances but for which a decision on listing in Annex 1 or 2 is still outstanding,
   2. whose other active substances are included in one of these lists,
   3. for which an application for authorisation A_C was submitted to the Notification Authority no later than 31 July 2006, and
   4. which are still on the market when the Amendment of 20 June 2014 to this Ordinance comes into force;

e. *authorisation for exceptional situations*: for biocidal products used to deal with exceptional situations;

f. *simplified authorisation*: for biocidal products which are eligible for the simplified procedure in accordance with Article 25 of Regulation (EU) No 528/2012[34];

g. *recognition*: for biocidal products:
   1. which have been authorised in an EU or EFTA Member State in accordance with Article 30 of Regulation (EU) No 528/2012, or
   2. for which an application has been submitted in accordance with Article 34 of Regulation (EU) No 528/2012;

h. *recognition of a Union authorisation*: for biocidal products for which a Union authorisation has been granted by the European Commission;

i. *authorisation of the same biocidal products*: for biocidal products which:
   1. are identical to biocidal products already authorised, and
   2. are placed on the market by the authorisation holder or by third parties under the same terms and conditions as the biocidal products already authorised;

33 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16 paragraph 2 of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, OJ L 325 of 11 December 2007, p. 3; last amended by Regulation (EU) No 613/2013, OJ L 173 of 26 June 2013, p. 34.

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

j. *authorisation for parallel trade*: for biocidal products which have been authorised in an EU or EFTA Member State and are identical to a biocidal product which has been authorised in Switzerland.

2 Unless otherwise indicated by a provision of this Ordinance, *authorisation* in this Ordinance is to be understood as referring to all the types of authorisation listed in paragraph 1.

Art. 8[35] Period of validity

1 Authorisations and the placing on the market of biocidal products for which authorisation is not required are subject to a time limit. The following maximum periods of validity apply:

a.	for authorisation A_L:	1. 10 years, without prejudice to numbers 2–4,
		2. 7 years for biocidal products with an active substance which is a candidate for substitution, if a comparative assessment has been performed in accordance with Article 23 of Regulation (EU) No 528/2012[36],
		3. 5 years for biocidal products with active substances authorised in accordance with Article 5 paragraph 2 of Regulation (EU) No 528/2012,
		4. 4 years for biocidal products with an active substance which is a candidate for substitution, if no comparative assessment has been performed in accordance with Article 23 of Regulation (EU) No 528/2012;
b.	for authorisation A_{nL}:	1. 4 years, or

35 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
36 See footnote to Art. 1*b* para. 3.

		2. if earlier, until the following time: – until 3 years after the last active substance in the biocidal product has been listed in Annex 1 or 2, or – until the Notification Authority, having regard to the European Commission's decision not to approve the active substance or include it in Annex I to Regulation (EU) No 528/2012, cancels the authorisation;
c.	for authorisations A_N and A_C:	1. 6 months after the last active substance in the biocidal product is listed in Annex 1 or 2, 2. 3 years after the last active substance in the biocidal product is listed in Annex 1 or 2, provided that the authorisation holder meets the requirements of Article 22 paragraph 2, or 3. until the Notification Authority, having regard to the European Commission's decision not to approve the active substance or include it in Annex I to Regulation (EU) No 528/2012, cancels the authorisation;
d.	for authorisation for exceptional situations:	180 days;
e.	for recognition:	for as long as the national authorisation is valid;
f.	for recognition of a Union authorisation:	for as long as the Union authorisation is valid;
g.	for authorisation for parallel trade:	1. for as long as the authorisation of the reference product is valid, or 2. if the authorisation of the reference product is withdrawn at the request of the authorisation holder and the requirements specified in Article 11 are still met: until the date on which the authorisation for the reference product would normally have expired;

h.	for the placing on the market of a biocidal product authorised under a simplified procedure in an EU or EFTA Member State:	for as long as the authorisation is valid in the EU or EFTA Member State;
i.	for the placing on the market of a product within a biocidal product family:	for as long as the authorisation for the biocidal product family is valid;
j.	for release for purposes of research and development:	for the declared test duration.

2 After expiry of the authorisation in accordance with paragraph 1 letters a, b and e–i, biocidal products may continue to be supplied to end consumers for 180 days and to be used professionally and commercially for a further 180 days.

3 In the cases specified in paragraph 1 letter c numbers 1 and 3, biocidal products may continue to be supplied to end consumers for 12 months, and to be used professionally and commercially for 18 months, following the listing of the last active substance in Annex 1 or 2, or the decision of the European Commission not to approve the active substance or include it in Annex I to Regulation (EU) No 528/2012.

4 Biocidal products placed on the market on the basis of an authorisation A_L, a simplified authorisation, a recognition or an authorisation for parallel trade, rather than an authorisation A_N or A_C, may continue to be supplied to end consumers or used professionally or commercially with the existing label for 12 months after these authorisations are granted.

5 Article 26 applies to the renewal of an authorisation.

Section 2: Active Substances

Art. 9[37] Lists of active substances

1 With regard to authorisation, the following lists of active substances apply:

a. list of active substances eligible for the simplified procedure according to Annex 1;

b. list of active substances approved by the European Commission in accordance with Article 9 paragraph 1 letter a of Regulation (EU) No 528/2012[38], according to Annex 2;

c. list of notified active substances.

37 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
38 See footnote to Art. 1*b* para. 3.

2 Active substances in the list specified in paragraph 1 letter b which are considered candidates for substitution in accordance with Article 10 of Regulation (EU) No 528/2012 are designated as such in Annex 2.

3 For active substances containing nanomaterials, Article 4 paragraph 4 of Regulation (EU) No 528/2012 applies *mutatis mutandis*.

4 The FDHA, in consultation with DETEC and the EAER, shall issue a list of substances which may be used under an authorisation A_{nL}, indicating their uses.

5 The FOPH, in consultation with the FOEN, shall amend:

a. Annexes 1 and 2;

b. the reference in paragraph 1 letter c to the applicable list of notified active substances.

6 The Notification Authority shall publish, in an appropriate form, the list corresponding to the reference in paragraph 1 letter c[39].

Art. 10[40]

Section 2*a*: Conditions for Authorisations A_L and A_{nL} and Special Provisions for Biocidal Product Families[41]

Art. 11[42] General conditions

1 Without prejudice to Article 11*g*, a biocidal product shall be granted authorisation A_L or A_{nL} if the following conditions are met:

a. It is established, according to the common principles specified in Annex VI to Regulation (EU) No 528/2012[43], that:

1. the biocidal product is sufficiently effective;

2. it has no unacceptable effects on target organisms, such as unacceptable resistance or cross-resistance, or unnecessary suffering or pain for vertebrates;

3. no immediate or delayed unacceptable effects are to be expected, from the biocidal product or its residues, on the health of humans, and in particular that of vulnerable groups, or animals, either directly or indirect-

39 The updated list of notified active substances can be accessed free of charge on the FOPH website (www.cheminfo.ch); it can also be obtained against payment or consulted free of charge at the Chemicals Notification Authority, CH-3003 Bern.

40 Repealed by No I of the Ordinance of 20 June 2014, with effect from 15 July 2014 (AS **2014** 2073).

41 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

42 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

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

ly, through drinking water, food, feed, air, or through other indirect effects; and

4. no unacceptable effects are to be expected, from the biocidal product or its residues, on the environment, having particular regard to the following considerations:
   – the fate and distribution of the biocidal product in the environment,
   – contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
   – the impact of the biocidal product on non-target organisms,
   – the impact of the biocidal product on biodiversity and the ecosystem.

b. The chemical identity, quantity and technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant and relevant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined using analytical methods referred to in Annexes II and III to Regulation (EU) No 528/2012.

c. The physical and chemical properties are acceptable for purposes of use, transport and storage.

d. The risk to human health and the environment posed by nanomaterials used in the biocidal product has been assessed separately.

e. Existing or, where appropriate, newly specified maximum concentrations, maximum residue levels or specific migration limits in or on food or feed, in accordance with the following provisions, are complied with:
   1. Article 34 paragraph 2 and Article 48 paragraph 1 letter e of the FUO[44],
   2. Article 36 paragraph 1 of the FsO[45].

2 Biocidal products with active substances listed in Annex 1 or 2 must additionally meet the requirements specified for the active substances in these lists.

3 If biocidal products contain active substances which are not listed in Annex 1 or 2 or included in the list of notified active substances, the active substances must meet the requirements specified in Articles 4 and 5 of Regulation (EU) No 528/2012.

4 Biocidal products intended for direct application to the human body may only contain non-active substances designated by the FDHA as permissible for the category concerned in accordance with Article 35 paragraph 4 of the FUO. This does not exclude the presence of technically unavoidable residues, provided that they do not pose a health risk.

5 Biocidal products consisting of or containing genetically modified organisms must meet the requirements of the RO[46].

44 SR **817.02**
45 SR **916.307**

Art. 11*a*[47] Request for setting of limits

[1] In connection with an application for authorisation, the applicant may submit a request to the Notification Authority for maximum levels, maximum concentrations or specific migration limits to be set for active substances for which none are specified in the legislation referred to in Article 11 paragraph 1 letter e.

[2] The Notification Authority shall forward the request referred to in paragraph 1:

a. for Article 11 paragraph 1 letter e number 1: to the Federal Food Safety and Veterinary Office (FSVO);

b. for Article 11 paragraph 1 letter e number 2: to the Federal Office for Agriculture (FOAG).

Art. 11*b*[48] Evaluation factors

The evaluation of whether a biocidal product meets the criteria specified in Article 11 paragraph 1 letter a shall take into account the following factors:

a. realistic worst case conditions under which the biocidal product may be used;

b. the way in which treated articles treated with or containing the biocidal product may be used;

c. the consequences of use and disposal of the biocidal product;

d. cumulative effects;

e. synergistic effects.

Art. 11*c*[49] Restriction of authorisation to particular uses

The Notification Authority shall only authorise a biocidal product for those uses for which the information required in accordance with Annex 5 is available.

Art. 11*d*[50] Biocidal products for use by the general public

A biocidal product shall not be authorised for placing on the market for use by the general public if:

a. it has properties meeting the criteria specified in Directive 1999/45/EC[51] and is therefore classified as:

   1. toxic or very toxic,

46 SR **814.911**
47 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
48 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
49 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
50 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
51 See footnote to Art. 2 para. 2 let. a no 1.

2. a category 1 or 2 carcinogen,
3. a category 1 or 2 mutagen, or
4. toxic for reproduction category 1 or 2;

b. it has properties meeting the criteria specified in the CLP Regulation[52] and is therefore classified as:
1. acute oral toxicity category 1, 2 or 3,
2. acute dermal toxicity category 1, 2 or 3,
3. acute inhalation toxicity (gases and dust/mist) category 1, 2 or 3,
4. acute inhalation toxicity (vapours) category 1 or 2,
5. specific target organ toxicity by single or repeated exposure category 1,
6. a category 1A or 1B carcinogen,
7. a category 1A or 1B mutagen, or
8. toxic for reproduction category 1A or 1B;

c. it consists of, contains or generates a substance with properties meeting the criteria for being PBT or vPvB in accordance with Annex XIII to the REACH Regulation[53];

d. it has endocrine-disrupting properties; or

e. it has developmental neurotoxic or immunotoxic effects.

Art. 11*e*[54] Exceptions to the requirements

[1] A biocidal product which does not fully meet the conditions specified in Article 11 paragraph 1 letter a numbers 3 and 4 or which has the properties specified in Article 11*d* letter c may be authorised in exceptional cases where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

[2] The use of a biocidal product authorised in accordance with paragraph 1 shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised.

Art. 11*f*[55] Special provisions for biocidal product families

[1] A biocidal product family must be assessed according to the common principles specified in Annex VI to Regulation (EU) No 528/2012[56]. The assessment must consider the maximum risks to human health, animal health and the environment

52 See footnote to Art. 2 para. 2 let. a no 2.
53 See footnote to Art. 2 para. 2 let. a no 3.
54 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
55 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
56 See footnote to Art. 1*b* para. 3.

and the minimum level of efficacy over the whole potential range of products within the biocidal product family.

2 A biocidal product family shall only be authorised if:

a. the following are explicitly identified in the application:
   1. the maximum risks to human health, animal health and the environment, and the minimum level of efficacy, on which the applicant's assessment is based, and
   2. the permitted variations in composition and uses referred to in Article 2 paragraph 2 letter b, together with the respective classification, hazard and precautionary statements and any appropriate risk mitigation measures; and

b. it is evident from the assessment referred to in paragraph 1 that all the biocidal products within the family comply with the conditions specified in Article 11.

Art. 11*g*[57] Comparative assessment of biocidal products with an active substance which is a candidate for substitution

1 In the examination of an application for authorisation of a biocidal product containing an active substance which is a candidate for substitution, the assessment authorities shall perform a comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012[58] as part of the evaluation specified in Article 17.

2 The Notification Authority, in consultation with the assessment authorities, shall prohibit or restrict the placing on the market or the professional or commercial use of a biocidal product containing an active substance which is a candidate for substitution if the comparative assessment demonstrates that:

a. for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages; and

b. the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the harmful organism.

3 By way of derogation from paragraphs 1 and 2, a biocidal product may, in exceptional cases, be authorised without a comparative assessment if it is necessary to acquire experience first through using the product in practice.

57 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
58 See footnote to Art. 1*b* para. 3.

Section 2*b*:[59] Conditions for Simplified Authorisation

Art. 11*h*

A biocidal product shall be authorised under a simplified procedure if the following conditions are met:

a. All the active substances contained in the biocidal product are listed in Annex I and satisfy any restriction specified in that Annex.

b. The biocidal product does not contain any substance of concern.

c. The biocidal product does not contain any nanomaterials.

d. The biocidal product is sufficiently effective.

e. The handling of the biocidal product and its intended use do not require personal protective equipment.

Section 3:[60] Conditions for Recognition, Authorisation A_N and Authorisation for Parallel Trade

Art. 12 Recognition

1 An authorisation from a Member State of the EU or EFTA shall be recognised if there is nothing to suggest that the product could not also be authorised in Switzerland.

2 The Notification Authority, in consultation with the assessment authorities, may amend the conditions or requirements imposed with the authorisation in an EU or EFTA Member State on the basis of the evaluation in accordance with Article 17 or a comparative assessment in accordance with Article 11*g*, provided that such a measure can be justified on the following grounds:

a. the protection of the environment;

b. the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;

c. public policy or public security;

d. the protection of national treasures possessing artistic, historic or archaeological value; or

e. the target organisms not being present in harmful quantities.

3 The labelling and safety data sheet must be adapted to the requirements set out in Articles 38 and 40.

59 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

60 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

4 Authorisations of biocidal products consisting of or containing genetically modified microorganisms shall not be recognised.

5 Article 14*a* applies to the recognition of a Union authorisation.

Art. 13 Authorisation A_N

A biocidal product shall be granted authorisation A_N if, according to the latest scientific and technical knowledge, and when used as intended:

a. no unacceptable effects on humans, animals or the environment are to be expected from it or its residues; and

b. in the case of a wood preservative or a disinfectant: it is sufficiently effective.

Art. 13*a* Authorisation for parallel trade

1 For a biocidal product which is authorised in an EU or EFTA Member State (state of origin), the Notification Authority, in consultation with the assessment authorities, shall, upon receiving an application to this effect, grant an authorisation for parallel trade if it determines that the biocidal product is identical to a biocidal product which it has already authorised (reference product).

2 A biocidal product shall be considered identical to the reference product if the following conditions are met:

a. It has been manufactured by the same company, by an associated undertaking or under licence in accordance with the same manufacturing process.

b. The products are identical in specification and content in respect of the active substances and the type of formulation.

c. The products are identical in respect of the non-active substances present.

d. The products are either the same or equivalent in packaging size, material or form, in terms of the potential adverse impact on human health, animal health or the environment.

Section 3*a*:[61] Liability Guarantee for Biocidal Products with Microorganisms

Art. 13*b*

Anyone who wishes to place biocidal products consisting of or containing pathogenic microorganisms on the market must comply with the obligation to guarantee liability in accordance with Article 14 of the RO[62].

61 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
62 SR **814.911**

Section 3*b*:[63]
Declaration Requirements for Biocidal Products from the EU or EFTA Authorised under the Simplified Procedure and for Biocidal Product Families

Art. 13*c* Biocidal products from the EU or EFTA authorised under the simplified procedure

Anyone who professionally or commercially imports biocidal products which have been authorised in an EU or EFTA Member State under the simplified procedure specified in Article 26 of Regulation (EU) No 528/2012[64] must declare the trade name and the authorisation number to the Notification Authority at least 30 days before placing them on the market for the first time.

Art. 13*d* Biocidal products within a biocidal product family

1 The holder of an authorisation for a biocidal product family must declare to the Notification Authority each product within the biocidal product family at least 30 days before placing it on the market for the first time.

2 The declaration must indicate the exact composition, the trade name and the authorisation number for the biocidal product family.

3 Declaration is not required if:

a. a particular product is explicitly identified in the authorisation for the biocidal product family; or

b. the variation in composition concerns only pigments, perfumes and dyes within the variations permitted according to the authorisation, unless the variation is associated with a change in the trade name.

Section 3*c*:[65]
Record-keeping and Declaration Requirements for Research and Development

Art. 13*e* Record-keeping requirements for research and development

1 Anyone who, for purposes of research and development, handles unauthorised biocidal products or non-approved active substances for use in biocidal products must keep records detailing the following:

a. identity of the biocidal products or active substances;

b. labelling data;

63 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
64 See footnote to Art. 1*b* para. 3.
65 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

c. quantities supplied;

d. name and address of the person receiving the biocidal products or active substances;

e. all available data concerning possible effects on humans, animals or the environment.

2 The records shall be made available to the Notification Authority on request.

3 The Notification Authority may, if necessary, request further information.

Art. 13*f* Declaration requirements for handling in release tests

1 Anyone who, for purposes of research and development, handles unauthorised biocidal products or non-approved active substances for use in biocidal products in such a way that they may be released into the environment must declare this to the Notification Authority 45 days before they are so handled for the first time.

2 The declaration must include the records specified in Article 13*e* paragraph 1.

3 If the proposed release tests could have unacceptable effects on humans, particularly on vulnerable groups, on animals or on the environment, the Notification Authority may:

a. make the conduct of the test subject to conditions, concerning in particular:
   1. the duration of experiments or tests,
   2. the maximum quantities to be used,
   3. restriction of the area of use;

b. prohibit the test.

4 If the biocidal products or active substances under investigation are genetically modified or pathogenic microorganisms, or if they contain such microorganisms, the procedure shall be based on the RO[66].

Section 4:[67] Procedure for Applications for Authorisations

Art. 14 General provisions

1 An application for authorisation of a biocidal product must be submitted to the Notification Authority.

2 The content of the application shall be in accordance with the following Annexes:

a. for applications for authorisation A_L or A_{nL}: Annex 5;

b. for applications for simplified authorisation: Annex 6;

c. for applications for recognition: Annex 7;

66 SR **814.911**

67 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

d. for applications for authorisation A_N: Annex 8;

e. for applications for authorisation for parallel trade: Annex 8*a*.

3 An application for authorisation of a biocidal product consisting of or containing genetically modified microorganisms must additionally comply with the requirements of the RO[68].

4 The application and documents must be submitted:

a. in the electronic format specified by the Notification Authority;

b. in an official language or in English; if the application concerns a biocidal product consisting of or containing genetically modified or pathogenic microorganisms, at least the summary of the application must be written in an official language.

5 The Notification Authority may, at the request of an assessment authority, require the provision of models or drafts of the packaging, labelling or leaflets.

Art. 14*a* Recognition of a Union authorisation

1 For the recognition of a Union authorisation, the same regulations apply as for the recognition of an authorisation from an EU or EFTA Member State, unless the Union authorisations are the subject of an international treaty with the EU.

2 If the Union authorisations are the subject of an international treaty with the EU, and if the data specified in Article 14*b* paragraph 3 letter b is accessible to the Notification Authority, the following provisions apply for the recognition of a Union authorisation:

a. An application submitted to the European Chemicals Agency (ECHA) for the granting, renewal, amendment or withdrawal of a Union authorisation shall be considered to have been submitted to the Notification Authority at the same time.

b. The Notification Authority, in consultation with the assessment authorities, shall take a decision on the application within 30 days after the adoption of a decision by the European Commission; it shall be guided by the European Commission's decision, having regard to the criteria specified in Article 12 paragraph 2.

Art. 14*b* Waiving of data requirements

1 Data which it is not scientifically necessary to supply or which it is not technically possible to generate need not be provided. The justification for adaptations to data requirements shall be stated in the application.

2 The FDHA, in consultation with DETEC and the EAER, shall define when the waiving of data requirements is justified on the basis of likely exposure; in so doing,

68 SR **814.911**

it shall take into consideration delegated acts adopted by the European Commission in accordance with Article 21 paragraph 3 of Regulation (EU) No 528/2012[69].

3 The Notification Authority shall indicate the data which does not need to be provided because:

a. it has been published by the ECHA; or

b. it is accessible to the Notification Authority under an international treaty.

Art. 15 Identical biocidal products

1 A biocidal product that is the same as a biocidal product which has already been granted authorisation A_N, A_C, A_L or recognition, or for which an application to this effect is pending, may be authorised as an identical biocidal product under a special procedure.

2 The FDHA may, in consultation with DETEC and the EAER, specify the details of the procedure referred to in paragraph 1; in so doing, it shall take into consideration any implementing act adopted by the European Commission in accordance with Article 17 paragraph 7 of Regulation (EU) No 528/2012[70].

3 If the applicant is not identical with the holder of the authorisation for the same biocidal product already authorised, or with the submitter of a pending application, then the applicant must submit a letter of access under the procedure referred to in paragraph 1.

Art. 16 Advance on costs, validation and forwarding

1 The Notification Authority shall require the applicant to pay an advance on costs.

2 Upon receipt of the advance on costs, the Notification Authority shall verify, within the set time limit (Art. 19 para. 1 let. a and b), if necessary in consultation with the assessment authorities, whether the application is complete (validation), without assessing the quality or the adequacy of the data or justifications submitted.

3 If the application is incomplete, it shall, after consulting the applicant, set a reasonable time limit for the submission of additional information. This time limit shall not normally exceed 90 days.

4 It shall validate the additional information submitted, if necessary in consultation with the assessment authorities, within the set time limit (Art. 19 para. 1 let. c).

5 After validation, it shall forward the application with the complete documentation to the assessment authorities.

6 If the application concerns a biocidal product consisting of or containing genetically modified microorganisms, it shall conduct the authorisation procedure itself, taking account of the RO[71].

69 See footnote to Art. 1*b* para. 3.
70 See footnote to Art. 1*b* para. 3.
71 SR **814.911**

Art. 17 Evaluation

1 The assessment authorities shall evaluate the documents within their area of responsibility as follows:

a. documents for authorisations A_L, A_{nL} and simplified authorisations, and for recognitions: according to the principles specified in Annex VI to Regulation (EU) No 528/2012[72];

b. other documents: according to the latest scientific and technical knowledge.

2 If, for an active substance which has not yet been approved or listed in Annex 1 or 2, the applicant presents the evaluation and the recommendation of an EU or EFTA Member State, these shall be taken into account by the assessment authorities.

3 For biocidal products containing an active substance which is a candidate for substitution, the assessment authorities shall perform a comparative assessment as specified in Article 11*g*.

4 The assessment authorities shall inform the Notification Authority of the results of their evaluation.

5 In the case of applications for authorisation A_L, A_{nL} and simplified authorisation, the Notification Authority, after validation, shall, in consultation with the assessment authorities, within the set time limit (Art. 19 para. 1 let. d–j), prepare an assessment report summarising the conclusions of the evaluation and the reasons for granting or refusing to grant authorisation.

6 Where it appears that additional information is necessary to carry out the evaluation, the Notification Authority shall ask the applicant to submit such information within a specified time limit. The Notification Authority may ask the applicant to provide samples, if this is necessary for the evaluation.

7 The Notification Authority shall send the draft assessment report to the applicant and provide him with the opportunity to submit comments within 30 days.

Art. 18

Repealed

Art. 19 Time limits for processing

1 Subject to receipt of the advance on costs, the Notification Authority shall take a decision, without undue delay and at the latest within the following time limits, on:

a.	validation of an application for authorisation A_L or A_{nL}:	30 days
b.	validation of an application for recognition:	30 days
c.	validation of additional information for an application for authorisation A_L or A_{nL}:	30 days
d.	evaluation of an application for authorisation A_L:	365 days

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

e.	evaluation of an application for authorisation A_{nL}:	550 days
f.	evaluation of an application for recognition:	90 days
g.	evaluation of an application for recognition in accordance with Article 34 of Regulation (EU) No 528/2012[73] after receipt of the draft assessment report from the reference Member State:	120 days
h.	evaluation of an application for simplified authorisation:	90 days
i.	evaluation of an application for authorisation for parallel trade:	60 days
j.	evaluation of an application for authorisation A_N:	60 days
k.	assessment of whether, for the renewal of an authorisation A_L or A_{nL}, a full evaluation as specified in Article 26 paragraph 5 is required:	90 days
l.	full evaluation for the renewal of an authorisation A_L or A_{nL}:	365 days
m.	non-full evaluation for the renewal of an authorisation A_L or A_{nL}:	180 days

2 For biocidal products for which authorisation is not required, as specified in Article 3 paragraph 3, the Notification Authority shall, if necessary, issue an opinion within the following time limits:

a.	biocidal products authorised under a simplified procedure in an EU or EFTA Member State:	30 days
b.	biocidal products within an authorised biocidal product family:	30 days
c.	biocidal products released for purposes of research and development:	45 days

3 If the Notification Authority asks for additional documents, the time limit "clock" shall be stopped until the additional information has been submitted. Altogether, the clock shall be stopped for no more than 180 days, unless a longer period is justified on account of the type of additional information requested or exceptional circumstances.

4 The FDHA may, in consultation with DETEC and the EAER, specify further time limits for processing. Otherwise, the limits specified in the Ordinance of 25 May 2011[74] on Principles and Time Limits for Authorisation Procedures apply.

Art. 20 Ruling

1 The Notification Authority shall decide on authorisation in the form of a ruling.

73 See footnote to Art. 1*b* para. 3.
74 SR **172.010.14**

2 The ruling, except in the case of an authorisation A_N, shall include:

a. the conditions for the placing on the market and use of the biocidal product;

b. a summary of the biocidal product characteristics, comprising:

1. the trade name of the biocidal product,
2. the name and address of the authorisation holder,
3. the date of the authorisation and the date of its expiry,
4. the product type and, where relevant, an exact description of the authorised use,
5. the categories of users,
6. the Swiss authorisation number, together with, in the case of a biocidal product family, the suffixes to apply to individual biocidal products within the biocidal product family,
7. the name and address of the manufacturer of the biocidal product and of the active substances it contains, including details of the manufacturing sites,
8. the type of formulation of the biocidal product, and the qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for proper use of biocidal products; in the case of a biocidal product family, a minimum and maximum percentage shall be indicated for each active and non-active substance, where the minimum percentage indicated for certain substances may be 0%,
9. the hazard and precautionary statements,
10. the target harmful organisms,
11. the application doses and instructions for use,
12. the particulars of likely direct or indirect adverse effects,
13. first aid instructions and emergency measures to protect the environment,
14. instructions for safe disposal of the product and its packaging,
15. conditions of storage and shelf-life of the biocidal product under normal conditions of storage,
16. where relevant, other information about the biocidal product;

c. information on the amount of fees.

3 The ruling for an authorisation A_N shall include:

a. the conditions for the placing on the market and use of the biocidal product;

b. the trade name of the biocidal product;

c. the name and address of the authorisation holder;

d. the date of the authorisation and the date of its expiry;

e. the Swiss authorisation number;

f. the product type and, where relevant, an exact description of the authorised use;

g. the categories of users;

h. the name and address of the manufacturer of the biocidal product and of the active substances it contains;

i. each active substance and its content in the product;

j. where relevant, other information or details of the safety data sheet;

k. information on the amount of fees;

l. where relevant, other information.

Art. 21 Obligation to report unexpected effects

The holder of an authorisation must spontaneously and immediately report to the Notification Authority any new information concerning the biocidal product or the active substances it contains which could affect the authorisation, and in particular:

a. new findings on the adverse effects of any active substance or of the biocidal product for humans, in particular vulnerable groups, animals or the environment;

b. development of resistance;

c. new data or information indicating that the biocidal product is not sufficiently effective.

Art. 22 Listing of a notified active substance in Annex 1 or 2

1 If a notified active substance is approved by the European Commission or included in Annex I to Regulation (EU) No 528/2012[75] and if the listing of this notified active substance in Annex 1 or 2 is published, the Notification Authority shall immediately inform the holder of an authorisation A_N or A_C for a biocidal product with this active substance accordingly.

2 If all notified active substances in a biocidal product have been listed in Annex 1 or 2, the holder of the authorisation for this biocidal product must, by the date of the inclusion of the last active substance, submit to the Notification Authority:

a. an application for authorisation A_L;

b. an application for simplified authorisation;

c. an application for recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012; or

d. evidence that a Union authorisation is being sought for this biocidal product.

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

Art. 23 Review

1 The Notification Authority may review an authorisation at any time.

2 It shall carry out a review if:

a. it receives new information in accordance with Article 21;

b. there are indications that the conditions for authorisation specified in Article 11 or 11*b* are no longer met.

3 Either on its own initiative or at the request of an assessment authority, it shall ask the holder for additional information, documents or investigations which are required for the review.

Art. 24 Amendment

1 The Notification Authority, in consultation with the assessment authorities, shall amend an authorisation if:

a. the conditions for authorisation specified in Article 11 or 11*b* are no longer met;

b. the authorisation was granted on the basis of false or misleading information;

c. after the authorisation was granted, the holder failed to comply with the obligations arising from this Ordinance.

2 It shall amend an authorisation at the reasoned request of the authorisation holder. Such amendments shall be handled in accordance with the following procedures:

a. administrative change: under a simplified notification procedure;

b. minor change: under a procedure with a reduced evaluation period;

c. major change: under a procedure with an evaluation period proportionate to the extent of the proposed change.

3 The FDHA, in consultation with DETEC and the EAER, shall specify the details of the procedures referred to in paragraph 2; in so doing, it shall take into consideration the implementing act adopted by the European Commission in accordance with Article 51 of Regulation (EU) No 528/2012[76].

Art. 25 Cancellation

1 For cancellation, the conditions specified in Article 24 paragraph 1 apply.

2 In the event of cancellation of an authorisation, the Notification Authority may grant periods of grace. These shall be:

a. for placing on the market: no more than 180 days;

b. for supply to end consumers and for professional and commercial use: no more than 360 days.

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

3 The Notification Authority may, in consultation with the assessment authorities, withdraw an authorisation for parallel trade if the authorisation of the biocidal product is cancelled in the state of origin for reasons of efficacy or safety.

Art. 26 Renewal

1 The holder of an authorisation may apply for it to be renewed when it expires.

2 The application for renewal must be submitted to the Notification Authority:

a. 550 days before the expiry of an authorisation A_L or A_{nL};

b. 2 months before the expiry of a simplified authorisation;

c. 2 months before the expiry of a recognition;

d. 1 month before the expiry of an authorisation for exceptional situations.

3 For the renewal of an authorisation A_L or A_{nL}, the application must include the following:

a. all the data required in accordance with Annex 5 which the applicant has generated since the initial authorisation or, where appropriate, previous renewal;

b. the applicant's assessment of whether the conclusions of the initial or, where appropriate, previous assessment remain valid and any supporting information.

4 The Notification Authority shall review the existing authorisation. In order to assess the risks of the biocidal product, it may ask the applicant to provide samples or additional information.

5 For authorisations A_L or A_{nL}, the Notification Authority, in consultation with the assessment authorities, shall decide within the set time limit (Art. 19 para. 1 let. k) whether a full evaluation is required in accordance with Article 31 paragraph 5 of Regulation (EU) No 528/2012[77], and it shall issue a ruling within the set time limit (Art. 19 para. 1 let. l and m), taking into account, where applicable, a comparative assessment carried out in accordance with Article 11*g*.

6 It may extend the period of validity of an existing authorisation until the final decision on renewal has been taken.

7 For renewals, the maximum periods of validity specified in Article 8 paragraph 1 apply.

8 The Notification Authority may renew an authorisation A_N or A_C if the evaluation of an application for authorisation A_L is delayed due to a request for submission of additional information in accordance with Article 19 paragraph 3.

9 Authorisations A_{nL} based on an evaluation and recommendation of an EU or EFTA Member State cannot be renewed.

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

Section 5: Use of Data from Previous Applicants and Data Protection Period

Art. 27[78] Use of other owners' data

1 The Notification Authority shall waive the requirement for data from the applicant and rely on the owner's data if:

a. the applicant presents a letter of access from the data owner; or

b. the data protection period has expired.

2 For all data submitted, the applicant shall indicate to the Notification Authority whether it is the data owner or is authorised to use the data on the basis of a letter of access.

3 If a letter of access is held, the applicant shall also indicate to the Notification Authority the name and address of the data owner.

4 The applicant shall inform the Notification Authority without delay about any changes to the ownership of the data.

5 Anyone who holds a letter of access to active substance data may allow applicants for authorisation of a biocidal product containing this active substance to make reference to this letter of access.

6 The provisions of this Section are without prejudice to the rules of competition law and intellectual property law.

Art. 27*a*[79] Letter of access

1 A letter of access must contain at least the following information:

a. the name and contact details of the data owner and the beneficiary;

b. the name of the active substance or biocidal product for which access to the data is authorised;

c. the date on which the letter of access takes effect;

d. a list of the submitted data to which reference may be made on the basis of the letter of access.

2 Revocation of a letter of access shall not affect the validity of the authorisation issued on the basis of the letter of access.

78 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

79 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

Art. 28[80] Data protection period

[1] For data submitted to the Notification Authority in accordance with this Ordinance, the following protection periods apply:

a. *for data submitted with a view to the approval of an existing active substance:* 10 years from the first day of the month following the date of the approval of the relevant active substance for the particular product type by the European Commission in accordance with Article 9 of Regulation (EU) No 528/2012[81];

b. *for data submitted with a view to the approval of a new active substance:* 15 years from the first day of the month following the date of the approval of the relevant active substance for the particular product type by the European Commission in accordance with Article 9 of Regulation (EU) No 528/2012;

c. *for data submitted with a view to the renewal or review of the approval of a new active substance*: 5 years from the first day of the month following the date of the renewal or review of the approval by the European Commission in accordance with Article 14 paragraph 4 of Regulation (EU) No 528/2012;

d. *for data submitted with a view to the authorisation of a biocidal product containing only existing active substances:* 10 years from the first day of the month following the date of the authorisation by the Notification Authority or by the competent authority in accordance with Regulation (EU) No 528/2012;

e. *for data submitted with a view to the authorisation of a biocidal product containing a new active substance:* 15 years from the first day of the month following the date of the authorisation by the Notification Authority or by the competent authority in accordance with Regulation (EU) No 528/2012;

f. *for data submitted with a view to the renewal or amendment of the authorisation of a biocidal product:* 5 years from the first day of the month following the date of the authorisation by the Notification Authority or the date of the decision concerning the renewal or amendment of the authorisation by the competent authority in accordance with Regulation (EU) No 528/2012.

[2] The protection period shall start when data is submitted for the first time.

[3] It cannot be renewed.

[4] By way of derogation from paragraph 1, the data protection periods for existing active substances listed in combination with a product type in Annex II to Regulation (EC) No 1451/2007[82] – including data not involving tests on vertebrates – but for which a decision on inclusion in Annex I to Directive 98/8/EC[83] was not taken before 1 September 2013 shall expire no later than 31 December 2025.

80 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
81 See footnote to Art. 1*b* para. 3.
82 See footnote to Art. 9 para. 1 let. c.
83 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L 123 of 24 April 1998, p. 1; last amended by Directive 2013/44/EU, OJ L 204 of 31 July 2013, p. 49.

Art. 29[84] Obligation to make advance enquiries so as to avoid tests on vertebrates and the Notification Authority's obligations to provide information

[1] For the applicant's obligation to make advance enquiries so as to avoid tests on vertebrates and the Notification Authority's obligations to provide information concerning the use of data from such tests, Article 22 paragraph 1 and Article 23 paragraphs 1 and 2 of the ChemO[85] apply *mutatis mutandis*; where reference is made in the ChemO to the notification of substances, this shall be understood for the purposes of this Ordinance as the authorisation of biocidal products, and where reference is made to the previous notifiers, this shall be understood as the data owners.

[2] When making advance enquiries, the applicant must provide evidence that he intends to apply for an authorisation himself.

Art. 29*a*[86] Compensation for data sharing

[1] The applicant and the data owner shall make every effort to reach an agreement on the sharing of the data to be used in accordance with Article 23 paragraph 2 letter a number 1 of the ChemO[87].

[2] The parties may seek an arbitrator's opinion.

[3] The Notification Authority shall be bound by the arbitrator's opinion unless, within 30 days, the parties raise objections in accordance with Article 189 paragraph 3 of the Civil Procedure Code[88].

[4] If no agreement can be reached between the parties, the applicant shall inform the Notification Authority accordingly, at the earliest one month after receipt of the information specified in Article 23 paragraph 2 letter b of the ChemO. At the same time, the applicant shall inform the data owner.

[5] At the earliest 60 days after being informed by the applicant, the Notification Authority shall inform the parties that it will use the data for the benefit of the applicant, provided that the latter can demonstrate that he:

a. has made every effort to reach an agreement; and

b. has paid the owner a share of the costs incurred in producing the data or has undertaken to do so via a signed acknowledgement of indebtedness.

[6] At the request of the owner, the Notification Authority shall determine the appropriate level of compensation, taking into account the acknowledgment of indebtedness issued by or the payment already made by the applicant.

84 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
85 SR **813.11**
86 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
87 SR **813.11**
88 SR **272**

7 In deciding on the level of compensation for data sharing, the Notification Authority shall ensure that due consideration is given to the principles of fairness, transparency and non-discrimination.

Art. 29*b*[89] Use of data for subsequent applications

1 If the protection period specified in Article 28 has expired, the applicant may request that the data from an existing authorisation be used by the Notification Authority for his benefit, if he provides evidence:

a. where the protection period has expired for data on the active substance used: that it is technically equivalent to the active substance in a biocidal product already authorised, including the degree of purity and the nature of any impurities;

b. where the protection period has expired for data on the biocidal product:
   1. that it is the same as the biocidal product already authorised, or
   2. that the differences are not significant in relation to the risk assessment and the active substances are technically equivalent as defined in letter a.

2 The Notification Authority shall issue a general ruling, published in the Federal Gazette. It shall inform the holder of the existing authorisation and, if known, the owner of the data on the active substance or the biocidal product.

3 Depending on the particular case, the applicant shall submit the following data to the Notification Authority:

a. all the data required for the identification of the biocidal product, including its composition;

b. the data required to identify the active substance and to establish technical equivalence;

c. the data required to demonstrate that the biocidal product is comparable to the authorised biocidal product with regard to risks and efficacy.

Section 6:[90] Authorisation for Exceptional Situations

Art. 30

1 In order to deal with an unforeseen danger which cannot be contained by other means, the Notification Authority may, in consultation with the assessment authorities, authorise certain biocidal products for limited and controlled use in derogation

89 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
90 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

from the provisions of Articles 4 and 5 and Sections 2–4 of this Chapter (authorisation for exceptional situations).

2 With regard to biocidal products consisting of or containing genetically modified microorganisms, authorisation for exceptional situations is excluded.

3 With regard to biocidal products consisting of or containing pathogenic microorganisms, the requirements of the ContainO[91] and the RO[92] must additionally be met for authorisation for exceptional situations.

Chapter 3:[93] Treated Articles

Art. 31 Placing on the market

1 A treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates:

a. are listed in Annex 2 for the relevant product type and use, or in Annex 1, and any conditions or restrictions specified therein are met; or

b. are employed in a biocidal product granted authorisation A_{nL} for the relevant use.

2 Active substances in a biocidal product in accordance with paragraph 1 letter b must be appropriately included in the list specified in Article 9 paragraph 4.

3 Paragraph 1 does not apply to treated articles where the sole treatment undertaken was the fumigation or disinfection of premises or containers used for storage or transport and where no residues are expected to remain from such treatment.

Art. 31*a* Labelling

1 Anyone who is responsible for the placing on the market of treated articles must:

a. label them in accordance with Article 58 paragraphs 3, 4 and 6 of Regulation (EU) No 528/2012[94]; and

b. include in the instructions for use the relevant information specified in the ORRChem[95].

2 The labelling must be in the official language or languages of the place where the treated article is placed on the market.

91 SR **814.912**
92 SR **814.911**
93 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
94 See footnote to Art. 1*b* para. 3.
95 SR **814.81**

Art. 31*b* Additional obligations

[1] Anyone who is responsible for the placing on the market of treated articles must, on request, provide consumers with information on the biocidal treatment of the treated articles within 45 days.

[2] The duty of care specified in Article 41 paragraphs 1 and 2 applies *mutatis mutandis*.

[3] The above provisions are without prejudice to the restrictions specified in the ORRChem[96].

Art. 32

Repealed

Chapter 4:[97] Manufacturing and Commercial Secrecy, Privacy and Safety of the Person Concerned

Art. 33 Confidentiality

[1] The applicant must identify any data which, in his view, is subject to manufacturing and commercial secrecy, or whose disclosure would jeopardise the privacy or safety of the person concerned, and is therefore to be treated as confidential. A detailed justification must be provided.

[2] The Notification Authority, in consultation with the assessment authorities, shall decide which data is to be treated as confidential.

[3] Disclosure of the following data shall normally be deemed to undermine the protection of the commercial interests or the privacy or safety of the person concerned:

a. details of the full composition of a biocidal product;

b. the precise tonnage of the active substance or biocidal product manufactured or placed on the market;

c. links:

1. between the manufacturer of an active substance and the applicant for or holder of the authorisation of a biocidal product, or

2. between the applicant for or holder of the authorisation of a biocidal product and the persons responsible for distribution of the product;

d. names and addresses of persons involved in testing on vertebrates.

[4] Data on biocidal products and active substances which is classified as confidential by the Notification Authority shall be treated as confidential by the enforcement authorities in accordance with Articles 85–88 of the ChemO[98].

96 SR **814.81**

97 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

5 Data for the recognition of an authorisation which is classified as confidential by an EU or EFTA Member State, or by the ECHA, shall be treated as confidential.

6 Access to data on biocidal products or active substances consisting of, containing or obtained from genetically modified microorganisms is governed by Article 18 of the GTA.

Art. 34 Exclusion of confidentiality

1 After authorisation has been granted, the following information shall not be treated as confidential under any circumstances:

a. the name and address of the applicant;

b. the name and address of the biocidal product manufacturer;

c. the name and address of the active substance manufacturer;

d. the content of the active substances in the biocidal product;

e. the name of the biocidal product;

f. physical and chemical data concerning the biocidal product;

g. a summary of the results of the tests required to establish the efficacy of the active substance or the biocidal product, effects on humans, animals and the environment, and, where applicable, resistance-promoting properties;

h. analytical methods which can reliably determine active substances as specified in Article 11 paragraph 1 letter b;

i. any methods for rendering the active substance or biocidal product harmless;

j. recommended methods and precautions to reduce dangers from handling, transport and use, as well as from fire or other hazards;

k. procedures to be followed and measures to be taken in the event of spillage or leakage;

l. first aid and medical advice to be given in the event of injury to persons;

m. methods for disposal of the biocidal product and its packaging;

n. information contained in the safety data sheet.

2 The publication of non-confidential data on biocidal products is governed by Article 85 paragraph 6 of the ChemO[99].

98 SR **813.11**
99 SR **813.11**

Chapter 5: Classification, Packaging, Denaturation, Labelling and Safety Data Sheet

Art. 35[100] Classification

[1] Article 10 paragraph 2 of the ChemO[101] applies *mutatis mutandis* to the classification of biocidal products; where the ChemO refers to the manufacturer, this shall be understood for the purposes of this Ordinance as the applicant for authorisation.[102]

[1bis] Where appropriate, the information included in the ruling referred to in Article 20 shall be taken into account.[103]

[2] Articles 8 and 9 of the ChemO apply to the classification of active substances for use in biocidal products.

Art. 36[104] Packaging

[1] Biocidal products must be packaged in accordance with Article 34*e* of the ChemO[105] *mutatis mutandis*, and active substances for use in biocidal products must be packaged in accordance with Article 34*a* of the ChemO *mutatis mutandis*. Where the ChemO refers:

a. to the manufacturer, this shall be understood for the purposes of this Ordinance as the authorisation holder;

b. to dangerous substances and preparations, this shall be understood for the purposes of this Ordinance as all biocidal products and active substances for use in biocidal products.

[2] Where appropriate, the information included in the ruling referred to in Article 20 shall be taken into account.

[3] Biocidal products which may be mistaken for foodstuffs within the meaning of the Foodstuffs Act of 9 October 1992[106] or for animal feedstuffs within the meaning of Article 3 paragraph 1 of the Feedstuffs Ordinance of 26 May 1999[107] must be packaged to minimise the likelihood of such a mistake being made.[108]

100 Amended in accordance with Annex No 1 of the Ordinance of 7 Nov. 2012, in force since 1 Dec. 2012 (AS **2012** 6103).
101 SR **813.11**
102 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
103 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
104 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
105 SR **813.11**
106 SR **817.0**
107 SR **916.307**
108 Correction of 23 Dec. 2014 (AS **2014** 4719).

Art. 37 Denaturation

Biocidal products which may be mistaken for foodstuffs or animal feedstuffs and which are available to the general public must contain components to discourage their consumption.

Art. 38[109] Labelling

[1] The label must not be misleading in respect of the risks from the biocidal product to human health, animal health or the environment or its efficacy. It must not, in any case, mention the indications "low-risk biocidal product", "non-toxic", "harmless", "natural", "environmentally friendly", "animal friendly" or similar indications.

[2] Biocidal products must be labelled:

a. in accordance with the summary of the biocidal product characteristics referred to in Article 20 paragraph 2 letter b; and

b. in accordance with Articles 34*b* und 34*e* of the ChemO[110] *mutatis mutandis*; where the ChemO refers:

1. to the manufacturer, this shall be understood for the purposes of this Ordinance as the authorisation holder,

2. to dangerous substances and preparations, this shall be understood for the purposes of this Ordinance as all biocidal products and active substances for use in biocidal products.

[3] In addition to the details specified in paragraph 2, the following must be indicated:

a. the identity of every active substance and its concentration in metric units;

b. the Swiss authorisation number;

c. the type of formulation;

d. the uses for which the biocidal product is authorised;

e. directions for use; in particular, for each use provided for under the terms of the ruling, the following are to be specified:

1. the frequency of application,

2. the dose rate, expressed in metric units, in a manner which is meaningful and comprehensible to the user;

f. particulars of likely direct or indirect adverse side effects and any directions for first aid;

g. the nanomaterials contained in the product, if any, and any specific related risks, and, following each reference to nanomaterials, the word "nano" in brackets;

h. if accompanied by a leaflet: the sentence "Read attached instructions before use" and, where applicable, warnings for vulnerable groups;

109 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
110 SR **813.11**

i. directions for the safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on the reuse of packaging;

j. the formulation batch number or designation;

k. the expiry date relevant to normal conditions of storage;

l. where applicable, the following details:

1. the time to onset of the biocidal effect,
2. the interval to be observed between applications of the biocidal product,
3. the interval to be observed between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning:
   – decontamination means and measures and duration of necessary ventilation of treated areas
   – adequate cleaning of equipment
   – precautionary measures during use and transport.

4 Where applicable, the following must also be indicated:

a. the categories of users;

b. information on any specific danger to the environment, particularly concerning protection of non-target organisms and avoidance of contamination of water;

c. for biocidal products consisting of or containing microorganisms: labelling requirements in accordance with Directive 2000/54/EC[111].

5 The information specified in paragraph 3 letters c, e, f, i–l and paragraph 4 letter b shall be indicated:

a. on the packaging; or

b. where this is necessary because of the size or the function of the biocidal product: in an accompanying leaflet integral to the packaging.

6 Article 34*b* paragraphs 1–3 of the ChemO apply *mutatis mutandis* to the labelling of active substances for use in biocidal products.

Art. 39[112] Special labelling for genetically modified microorganisms

1 In addition to the requirements specified in Article 38, biocidal products consisting of or containing genetically modified microorganisms must be appropriately labelled.

2 One of the following descriptions must be used for the labelling:

111 Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work, OJ L 262 of 17 October 2000, p. 21.

112 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

a. “aus gentechnisch verändertem X/produit à partir de X modifié par génie génétique/da X modificato/a con tecnologia genetica”; or

b. “aus genetisch verändertem X/produit à partir de X génétiquement modifié/da X geneticamente modificato/a”.

3 The information specified in Article 38 paragraph 4 letter b shall be indicated on the label. The other information shall be indicated in accordance with Article 38 paragraph 5 letter a or b, depending on the conditions met.

4 No labelling is required for biocidal products containing unintentional traces of approved genetically modified microorganisms accounting for less than 0.1 per cent by mass.

Art. 40[113] Safety data sheet

1 For biocidal products and for active substances for use in biocidal products, safety data sheets must be compiled, provided and updated in accordance with Articles 7 and 51–55 of the ChemO[114] *mutatis mutandis*; where the ChemO refers to the manufacturer, this shall be understood for the purposes of this Ordinance as the applicant.

2 For active substances included in the lists specified in Article 9 paragraph 1 letters a–c, the exposure scenarios referred to in Article 53 paragraph 3 of the ChemO need not be attached.

Art. 40*a*[115] Documentation and samples

1 The manufacturer of a biocidal product shall maintain, in relation to the manufacturing process, appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market.

2 The documentation shall include as a minimum:

a. safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product;

b. records of the various manufacturing operations performed;

c. results of internal quality controls;

d. identification of production batches.

3 The manufacturer shall store production batch samples.

4 The documentation and the samples must be retained in accordance with Article 58 paragraph 2 of the ChemO[116].

5 Safety data sheets must be retained in accordance with Article 56 of the ChemO.

113 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
114 SR **813.11**
115 Inserted by No I of the Ordinance of 28 Feb. 2007 (AS **2007** 851). Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
116 SR **813.11**

Chapter 6: Handling of Biocidal Products

Art. 41 Duty of care

[1] Anyone handling a biocidal product and its wastes must use them properly and ensure that they cannot endanger humans, animals or the environment.

[1bis] Proper use shall involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken.[117]

[2] The information given on the packaging and safety data sheet and the instructions for use must be taken into account.

[3] The biocidal product must be used only for the intended purpose. Only equipment which allows the biocidal product to be applied correctly and in a targeted manner may be used.

[4] …[118]

Art. 41*a*[119]

Art. 42[120] Storage

Articles 72 and 77 of the ChemO[121] apply *mutatis mutandis* to the storage of biocidal products.

Art. 43[122] Supply

For the supply of biocidal products, the following apply;

a. the terms of the ruling referred to in Article 20;

b. Articles 73, 74 and 78–81 of the ChemO[123] *mutatis mutandis*.

117 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
118 Repealed by No I of the Ordinance of 20 June 2014, with effect from 15 July 2014 (AS **2014** 2073).
119 Inserted in accordance with Enclosure No. 1 of the Ordinance of 10 Nov. 2010 (AS **2010** 5223). Repealed by Annex No. 1 of the Ordinance of 7 Nov. 2012, with effect from 1 Dec. 2012 (AS **2012** 6103).
120 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
121 SR **813.11**
122 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
123 SR **813.11**

Art. 44 Take-back and return obligations

[1] Anyone who places biocidal products on the market must take back from the user any biocidal products supplied which are no longer being used and must dispose of them appropriately; biocidal products supplied retail must be taken back free of charge.

[2] The obligation to return biocidal products is regulated by Number 5 of Annex 2.4 to the ORRChem[124].

Art. 45[125] Theft, loss, erroneous placing on the market

Article 82 of the ChemO[126] applies *mutatis mutandis* to the theft, loss or erroneous placing on the market of biocidal products.

Art. 46[127]

Art. 47[128] Restrictions on use

[1] The restrictions specified in Article 13 of the RO[129] apply to biocidal products consisting of or containing pathogenic microorganisms.

[2] In addition, the restrictions specified in Annex 2.4 to the ORRChem[130] apply to biocidal products of product types 6, 7, 8, 14 and 21.

Art. 48 Authorisation for use

An authorisation is required for the use of certain biocidal products; the provisions are set out in Articles 4–6 of the ORRChem[131].

Art. 49[132] Certificate

Anyone who uses biocidal products as specified in Article 7 paragraph 1 letter a numbers 2–4 and paragraph 2 of the ORRChem[133] requires a certificate in accordance with Articles 7–12 of the ORRChem.

Art. 50[134] Advertising

124 SR **814.81**
125 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
126 SR **813.11**
127 Repealed by No I of the Ordinance of 20 June 2014, with effect from 15 July 2014 (AS **2014** 2073).
128 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
129 SR **814.911**
130 SR **814.81**
131 SR **814.81**
132 Correction of 23 Dec. 2014 (AS **2014** 4719).
133 SR **814.81**

[1] Biocidal products must not be promoted unless they:

a. are authorised; or

b. are placed on the market or used in accordance with Article 3 paragraph 3 letter a or b.

[2] Article 38 paragraph 1 applies *mutatis mutandis* to advertising.

[3] Any advertisement for biocidal products must include the following phrases, which shall be clearly distinguishable and legible in relation to the whole advertisement:

a. "Use biocides safely"; the word "biocides" may be replaced with a reference to the product type according to Annex 10;

b. "Always read the label and product information before use".

[4] Anyone who advertises dangerous biocidal products which the general public can purchase without seeing the labelling beforehand must indicate their hazardous properties in a comprehensible and clearly legible or audible manner.

[5] Otherwise, Article 75 and, for samples, Article 83 of the ChemO[135] apply *mutatis mutandis*.

Chapter 7: Enforcement

Section 1: Confederation

Art. 50*a*[136] Harmonisation of enforcement

[1] In the enforcement of this Ordinance, the Swiss authorities shall be guided by the legislation currently applicable in the EU, and in particular by delegated acts or implementing acts adopted by the European Commission in accordance with Regulation (EU) No 528/2012[137] and by Technical Notes for Guidance issued by the European Commission and the ECHA.

[2] The Notification Authority, in consultation with the assessment authorities, shall prepare guidelines for the harmonisation of enforcement. It shall publish the guidelines on its website[138].

Art. 51 Notification Authority and steering committee

Provisions concerning the Notification Authority and the associated steering committee are set out in Article 89 of the ChemO[139].

134 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
135 SR **813.11**
136 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
137 See footnote to Art. 1*b* para. 3.
138 www.cheminfo.ch
139 SR **813.11**

Art. 52 Assessment authorities

The assessment authorities for biocidal products are:

a. the Federal Office of Public Health (FOPH): for matters concerning the protection of human life and health;

b. the Federal Office for the Environment (FOEN): for matters concerning protection of the environment and indirect protection of human beings;

c. the State Secretariat for Economic Affairs (SECO): for matters concerning the protection of workers;

d.[140] the Federal Office for Agriculture (FOAG): for agronomic matters;

e.[141] the Federal Food Safety and Veterinary Office (FSVO): for matters concerning food safety and animal health.

Art. 53 Duties of the Notification Authority and cooperation

[1] The Notification Authority has the following duties:

a. it obtains the evaluations and opinions of the competent assessment authorities;

b. it makes decisions in consultation with the assessment authorities;

c. using random sampling, it analyses the composition of biocidal products placed on the market;

d.[142] it publishes the following lists in an appropriate form:

1. the list referred to in Article 95 paragraph 1 of Regulation (EU) No 528/2012[143],
2. the list of persons who have submitted the following documents:
   - documents complying with Annex II to Regulation (EU) No 528/2012 or with Annex IIA or IVA and, where relevant, IIIA to Directive 98/8/EC[144] or
   - a letter of access to active substance data as referred to in letter d number 2 first indent,
3. [145] the list of persons for whose benefit it has used data in accordance with Article 29*a* paragraph 5.

e.[146] It shall make available the electronic formats for the submission of applications for authorisation and for declarations.

140 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
141 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
142 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
143 See footnote to Art. 1*b* para. 3.
144 See footnote to Art. 28 para. 4.
145 Correction of 23 Dec. 2014 (AS **2014** 4719).
146 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

2 It shall request the cantonal enforcement authorities, where appropriate at the request of the assessment authorities:

a. to carry out checks in accordance with Article 58;

b. to take random samples for analyses in accordance with paragraph 1 letter c.

3 Requests made by the assessment authorities under Articles 23–25 and 56 are binding on the Notification Authority.

Art. 54 Toxicological Information Centre

Article 91 of the ChemO[147] applies with regard to the Toxicological Information Centre.

Art. 54*a*[148] Biocidal products helpdesk

1 The Notification Authority shall operate a biocidal products helpdesk in cooperation with the assessment authorities.

2 The helpdesk shall provide advice to applicants, in particular to SMEs, and to any other interested parties on their respective responsibilities and obligations under this Ordinance.

3 In particular, it shall provide advice to applicants about the possibility of adapting the data requirements specified in Annex 5 Number 2.2 paragraph 1.

Art. 55[149]

Art. 56 Monitoring of imports and exports

1 Customs offices shall check, at the request of the Notification Authority, whether biocidal products or treated articles comply with the provisions of this Ordinance.[150]

2 The assessment authorities may ask the Notification Authority to submit a request as specified in paragraph 1.

Art. 57[151] Fees and advance on costs

1 The obligation to pay fees and the calculation of fees for administrative action by the federal enforcement authorities in accordance with this Ordinance is based on the Chemicals Fees Ordinance of 18 May 2005[152].

147 SR **813.11**
148 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
149 Repealed by No I of the Ordinance of 20 June 2014, with effect from 15 July 2014 (AS **2014** 2073).
150 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
151 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
152 SR **813.153.1**

2 No fees are payable for the recognition of a Union authorisation in accordance with Article 14*a* paragraph 2.

3 For an application for authorisation or for the amendment thereof, the applicant must pay an advance on costs. This shall be determined by the Notification Authority on the basis of the likely amount of fees.

4 Payment of the advance on costs is a prerequisite for the processing of the application by the Notification Authority.

5 Paragraphs 3 and 4 do not apply to authorisations A_C and A_N, or to authorisations of identical biocidal products which are identical to an authorisation A_C or A_N.

Section 2: Cantons

Art. 58 Further checks

1 The cantonal enforcement authorities shall inspect biocidal products and treated articles which are placed on the market or used by the manufacturers themselves.[153]

2 They shall verify whether:

a. the biocidal products placed on the market have an authorisation;

b. for biocidal products used for purposes of research and development, the provisions of Articles 13*e* and 13*f* are being complied with;

c. the rulings issued under Article 20 are being complied with, especially whether the rules concerning packaging and labelling and concerning the compilation of safety data sheets are being followed;

d. the rules concerning the provision and retention of safety data sheets are being followed;

e. the special provisions concerning the handling of biocidal products are being complied with;

f. the requirements for treated articles specified in Articles 31 and 31*a* are being complied with;

g. the provisions of Article 13*a* concerning parallel trade are being complied with.[154]

3 They shall carry out random sampling at the request of the Notification Authority.

4 In addition, they have the powers set out in Article 42 of the ChemA.

5 If the biocidal products inspected give grounds for complaint, the inspection authority must inform the Notification Authority and the cantonal authority responsible for issuing an order in accordance with Article 59.

153 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
154 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

Art. 59[155] Order of the cantonal enforcement authority

If an inspection reveals infringements of the provisions set out in Article 58 paragraph 2, the competent authority in the canton in which the authorisation holder or the manufacturer, distributor or user is domiciled or has its registered office or branch must order the necessary measures.

Section 3: Delegation of Duties and Powers to Third Parties

Art. 60

1 The competent federal bodies may delegate to appropriate public corporations or private persons all or some of the duties and powers assigned to them by this Ordinance.

2 To the extent that enforcement of health protection is concerned, delegation is limited to the following:

a. analytical examination of random samples (Art. 53 para. 1 let. c);

b.[156] checking of applications for completeness in accordance with Article 16 paragraph 2 and evaluation of documents in accordance with Article 17.

Section 4: Passing-on of Data

Art. 61

Articles 86–88 of the ChemO[157] apply *mutatis mutandis* to the passing-on of data concerning biocidal products.

Chapter 8: Final Provisions

Section 1: Transitional Provisions Concerning the Amendment of 20 June 2014[158]

Art. 62[159] Pending applications

1 An application for authorisation A_L or A_{nL}, or for recognition of a biocidal product, which is pending at the time the Amendment of 20 June 2014 to this Ordinance comes into force shall be evaluated by the Notification Authority in accordance with

155 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
156 Correction of 23 Dec. 2014 (AS **2014** 4719).
157 SR **813.11**
158 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
159 Amended by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

existing legislation.

2 The risk assessment of the active substance in the biocidal product for which an application for authorisation is pending shall, however, be carried out:

a. in accordance with Articles 11–11*f*, if the active substance has not been approved by the European Commission or listed in Annex 2;

b. in accordance with Article 11*g*, if the active substance is a candidate for substitution on the basis of a decision adopted by the European Commission.

3 Where the risk assessment of the active substance under the new legislation identifies concerns arising from the provisions newly applicable with the entry into force of the Amendment of 20 June 2014 to this Ordinance, the applicant shall be given the opportunity to submit additional information to the Notification Authority.

Art. 62*a*[160] Biocidal products placed on the market in accordance with existing legislation

1 Biocidal products already placed on the market with a classification and labelling in accordance with Articles 35 and 38 before the commencement of the Amendment of 20 June 2014 to this Ordinance may be placed on the market until the expiry of the authorisation or registration and may subsequently be supplied to end consumers in accordance with Article 8 paragraph 2.

2 For biocidal products with an existing authorisation based on the existing classification and labelling system, the holder must submit to the Notification Authority by 31 December 2014 an application for amendment, with a proposal for classification and labelling in accordance with Articles 35 and 38.

3 Biocidal products with an existing authorisation based on the existing classification and labelling system may continue to be supplied to end consumers with the existing classification and labelling until 31 May 2017. If a ruling concerning the new classification and labelling is issued after 31 May 2016, the Notification Authority, in consultation with the FOPH, the FOEN and SECO, shall permit the holder to supply the biocidal product in question to end consumers for one year from the date of the ruling.

4 The Notification Authority may, in consultation with the FOPH, the FOEN and SECO, in response to a reasoned request, grant an extension to the deadline for submission of the application for amendment referred to in paragraph 2, in particular if the decision on the listing or non-inclusion of a notified active substance in Annex 2 is to be expected within a year.

Art. 62*b*[161] Products newly deemed to be biocidal products

1 For products with biocidal effects placed on the market which were not covered by the existing scope of this Ordinance until the commencement of the Amendment of

160 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

161 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

20 June 2014 to this Ordinance, but which, with the commencement of this Amendment, are deemed to be biocidal products, an application for authorisation must be submitted by 31 August 2017.

2 If an application is submitted in accordance with paragraph 1, the products newly deemed to be biocidal products may be placed on the market until authorisation is granted by the Notification Authority. If the application is rejected, the products may continue to be placed on the market for 180 days and be supplied to end consumers for a further 180 days.

3 If an application is not submitted in accordance with paragraph 1, the products newly deemed to be biocidal products must no longer be placed on the market after 31 August 2017. They may continue to be supplied to end consumers for 180 days after this date.

Art. 62*c*[162] Treated articles

1 By way of derogation from Article 31 paragraph 1, a treated article may, after the commencement of the Amendment of 20 June 2014 to this Ordinance, be placed on the market until the date specified in paragraph 2 if it meets one of the following conditions:

a. It was treated with or intentionally incorporates one or more biocidal products containing only active substances that are included in the list of notified active substances.

b. For the active substances it contains, an application for approval for the relevant product type is submitted to the European Commission by 1 September 2016.

c. It contains only a combination of active substances included in the list of notified active substances and active substances included in the list drawn up in Annex 2 for the relevant product type and use or included in Annex 1.

2 The treated articles specified in paragraph 1 may be placed on the market until one of the following dates:

a. the date on which approval is granted by the European Commission for the relevant product type and use of the last active substance which is to be authorised and is contained in the biocidal product;

b. the date falling 180 days after a decision by the European Commission not to approve one of the active substances for the relevant use.

3 A treated article treated with or intentionally incorporating one or more biocidal products containing any active substances other than those referred to in paragraph 1 letters a–c may be placed on the market until 28 February 2017.

162 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

Art. 62*d*[163] Access to active substance data

[1] For biocidal products granted authorisation A_N or A_C, the authorisation holder must provide the Notification Authority with the following information by 1 September 2015:

a. evidence that the persons supplying the active substances contained in the biocidal product are included in the list specified in Article 95 paragraph 1 of Regulation (EU) No 528/2012[164];

b. a copy of the decision by the ECHA concerning the inclusion in the above-mentioned list of the persons supplying the active substances contained in the biocidal product;

c. documents complying with Annex II to Regulation (EU) No 528/2012 or with Annex IIA or IVA and, where relevant, IIIA to Directive 98/8/EC[165];

d. a letter of access to active substance data as referred to in letter c; or

e. a reference to data for which the protection period specified in Article 28 has expired.

[2] Biocidal products for which none of the conditions specified in paragraph 1 is met may no longer be placed on the market from 1 September 2016 and may no longer be supplied to end consumers from 1 September 2017.

[3] Paragraphs 1 and 2 do not apply to biocidal products containing only active substances listed in Annex 1 in categories 1–5 and 7.

Art. 63 Commencement

This Ordinance comes into force on 1 August 2005.

163 Inserted by No I of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
164 See footnote to Art. 1*b* para. 3.
165 See footnote to Art. 28 para. 4.

Annex 1[166]
(Art. 9 para. 1 let. a)

List of active substances referred to in Article 25 letter a of Regulation (EU) No 528/2012[167] (simplified procedure)

EC number	Name/group	Restriction	Comment
Category 1 – Substances authorised as food additives according to Regulation (EC) No 1333/2008[168]			
200-018-0	Lactic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC[169] or the CLP Regulation[170]	E 270
204-823-8	Sodium acetate	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or the CLP Regulation	E 262
208-534-8	Sodium benzoate	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or the CLP Regulation	E 211
201-766-0	(+)-Tartaric acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or the CLP Regulation	E 334
200-580-7	Acetic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or the CLP Regulation	E 260
201-176-3	Propionic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or the CLP Regulation	E 280

166 Amended by No II para. 1 of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
167 See footnote to Art. 1*b* para. 3.
168 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354 of 31 December 2008, p. 16; last amended by Regulation (EU) No 506/2014, OJ L 145 of 16 May 2014, p. 35.
169 See footnote to Art. 2 para. 2 let. a no 1.
170 See footnote to Art. 2 para. 2 let. a no 2.

EC number	Name/group	Restriction	Comment
Category 2 – Substances included in Annex IV to the REACH Regulation[171]			
200-066-2	Ascorbic acid		
232-278-6	Linseed oil		
Category 3 – Weak acids			
Category 4 – Traditionally used substances of natural origin			
Natural oil	Lavender oil		CAS-No. 8000-28-0
Natural oil	Peppermint oil		CAS-No. 8006-90-4
Category 5 – Pheromones			
222-226-0	Oct-1-en-3-ol		
Mixture	Webbing clothes moths pheromone		
Category 6 – Substances for which a Member State has validated an active substance dossier in accordance with Article 7 paragraph 3 of Regulation (EU) No 528/2012 or accepted such a dossier in accordance with Article 11 paragraph 1 of Directive 98/8/EC[172]			
204-696-9	Carbon dioxide	Only for use in ready-for-use gas canisters functioning together with a trapping device	
231-783-9	Nitrogen	Only for use in limited quantities in ready-for-use canisters	
250-753-6	(Z,E)-Tetradec-9,12-dienyl acetate		
	Powdered corn cob	Only for use in the form of pellets in dry locations	
Category 7 – Other			
	Baculovirus		
215-108-5	Bentonite		
203-376-6	Citronellal		
231-753-5	Iron sulphate		

171 See footnote to Art. 2 para. 2 let. a no 3.
172 See footnote to Art. 28 para. 4.

Annex 2[173]
(Art. 9 para. 1 let. b)

List of approved active substances according to Art. 9 of the regulation (EU) No. 528/2012[174] (Union list of approved active substances)

Explanatory notes

1 The date on which the inclusion of the substance takes effect is given in the column "Date of inclusion" column.

2 The approved active substances in the Union list are sorted as follows: first special characters, then numbers in ascending order, then letters in alphabetical order.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
1R-trans phenothrin	1R-trans phenothrin IUPAC name: 3-phenoxybenzyl(1R,3R)-2,2-dimethyl-3-(2-methylprop-1-	89 % w/w of 1R-trans phenothrin	1 September 2015	31 August 2025	18	The Union level risk assessment did not address all potential uses and exposure scenarios. When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particu-

173 Amended in accordance with No I of the FOPH Ordinance of 2 November 2009, in force since 15 November 2009 (AS **2009** 5401). Revised in accordance with No I of the FOPH Ordinance of 28 April 2010 (AS **2010** 1863), of 26 Oct. 2010 (AS **2010** 4925), of 4 April 2011 (AS **2011** 1403), of 16 Sept. 2011 (AS **2011** 4383), of 26 March 2012 (AS **2012** 1517), of 11 Oct. 2012 (AS **2012** 5549), of 21 January 2013 (AS **2013** 315), of 11 June 2013 (AS **2013** 1711), of 27 January 2014 (AS **2014** 369), No II para. 2 of the Ordinance of 20 June 2014 (AS **2014** 2073), and No I of the Ordinance of 17 Nov. 2014, in force since 1 Dec. 2014 (AS **2014** 3871).

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

175 International Union of Pure and Applied Chemistry: www.iupac.org

176 For the implementation of the common principles of Annex VI of Directive 98/8/EC of the European Parliament and Council of 16 Feb. 1998 on the Placing on the Market of Biocidal Products, the content and conclusions of assessment reports are available on the Commission website: http://ec.europa.eu/environment/biocides/index.htm

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	enyl)cyclopropanecarboxylate EC No: 247-431-2 CAS No: 26046-85-5					lar product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Authorisation is subject to the following conditions: 1. safe operational procedures shall be established for ultra low volume (ULV) application, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means; 2. for products containing 1R-trans phenothrin that may lead to residues in food or feed, the assessment authorities shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[177] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[178] (FsBO), and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded; 3. where appropriate, measures shall be taken to protect honey bees.
	Sum of all isomers: IUPAC name: (3-Phenoxyphenyl)methyl 2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropane-1-carboxylate EC No: 247-404-5 CAS No: 26002-80-2	95,5 % w/w for the sum of all isomers				
4,5-Dichlor-2-octyl-2H-isothiazol-3-one (DCOIT)	4,5-Dichloro-2-octylisothiazol-3(2*H*)-one EC No: 264-843-8 CAS No: 64359-81-5	950 g/kg	1 July 2013	30 June 2023	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure

177 SR **817.021.23**
178 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. Products shall not be authorised for treatment of wood that will be continually exposed to the weather, protected from the weather but subject to frequent wetting or in contact with fresh water, unless data have been submitted demonstrating that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. Authorisation is subject to the following conditions: 1. for products authorised for industrial or professional use, safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means; 2. labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing under roof, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
4,5-Dichloro-2-octyl-2H-isothiazol-3-one	IUPAC Name: 4,5-Dichloro-2-octylisothiazol-3(2H)-one EC No: 264-843-8 CAS No: 64359-81-5	950 g/kg	1 January 2016	31 December 2025	21	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Persons making products containing 4,5-Dichloro-2-octyl-2H-isothiazol-3-one available on the market for non-professional users shall make sure that the products are supplied with appropriate gloves. Authorisations are subject to the following conditions: 1. For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. 2. Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry. 3. Labels and, where provided, safety data sheets of products authorised shall indicate that application, maintenance and repair activities shall be conducted within a contained area, on impermeable hard standing with bunding or on soil covered with an impermeable material to prevent losses and minimize emissions to the environment, and that any losses or waste containing 4,5-Dichloro-2-octyl-2H-isothiazol-3-one shall be collected for reuse or disposal. 4. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						1995[179] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[180] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. Where an article has been treated with or intentionally incorporates one or more biocidal products containing 4,5-Dichloro-2-octyl-2H-isothiazol-3-one and where necessary due to the possibility of skin contact as well as the release of 4,5-Dichloro-2-octyl-2H-isothiazol-3-one under normal conditions of use of the article, the person responsible for placing the article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
Abamectin	Abamectin is a mixture of avermectin B $_{1a}$ and avermectin B $_{1b}$ *Abamectin:* IUPAC name: n.a. EC No: n.a. CAS No: 71751-41-2 *Avermectin B $_{1a}$:* IUPAC name: (10E,14E,16E,22Z)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)- 6'-	The active substance shall comply with all the following purities: *Abamectin:* minimum 900 g/kg *Avermectin B $_{1a}$:* minimum 830 g/kg *Avermectin B $_{1b}$:* maximum 80 g/kg	1 July 2013	30 June 2023	18	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. Products applied in such a way that emission to a sewage treatment plant cannot be prevented shall not be authorised for those application rates for which the

179 SR **817.021.23**
180 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	[(S)-secbutyl]-21,24-dihydroxy- 5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.1$_{4,8}$.0$_{20,24}$]pentacosa- 10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabinohexopyranoside EC No: 265-610-3 CAS No: 65195-55-3 *Avermectin B 1b:* IUPAC name: (10E,14E,16E,22Z)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.1$_{4,8}$.0$_{20,24}$]pentacosa- 10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl					EU level risk assessment showed unacceptable risks, unless data are submitted demonstrating that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. Authorisations shall be subject to appropriate risk mitigation measures. In particular, appropriate risk mitigation measures shall be taken to minimise the potential exposure of infants and children.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L- arabi-nohexopyranoside EC No: 265-611-9 CAS No: 65195-56-4					
Acrolein	Acrylaldehyde EC No: 203-453-4 CAS No: 107-02-8	913 g/kg	1 September 2010	31 August 2020	12	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, the populations that may be exposed to the product and the use or exposure scenar-ios that have not been representatively addressed in the EU level risk assessment. Authorisation is subject to the following conditions: 1. Waste waters containing acrolein shall be monitored prior to discharge, unless it can be demonstrated that risks for the environment can be reduced by other means. Where necessary in view of the risks to marine environment, waste waters shall be held in suitable tanks or reservoirs or appropriately treated before discharge.
Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride; C_{12-16}-ADBAC	IUPAC name: Not appli-cable EC No: 270-325-2 CAS No: 68424-85-1	Dry weight: 940 g/kg	1 February 2015	31 January 2025	8	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals and exposure of food or feed, were excluded. When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the as-

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						sessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Authorisation is subject to the following conditions: 1. For industrial or professional users safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means. 2. Products shall not be used for treatment of wood with which children may enter in direct contact, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level. 3. Labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal. 4. Products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions near or above water, continually exposed to the weather or subject to frequentwetting, unless data is submitted to demonstrate that the product will meet the requirements of

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						Article 11 and 17 OBP, if necessary by the application of appropriate mitigation measures.'
Alphachloralose	(R)-1,2-O-(2,2,2-Trichloroethylidene)-α-D-glucofuranose EC no.: 240-016-7 CAS no.: 15879-93-3	825 g/kg	1 July 2011	30 June 2021	14	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those populations that may be exposed to the product and those use or exposure scenarios that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Products cannot be authorised for outdoor use unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. Authorisation is subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 40 g/kg. 2. Products shall contain an aversive agent and a dye. 3. Only products for use in tamper resistant and securely closed bait boxes shall be authorised.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Aluminium phosphide releasing phosphine	Aluminium phosphide EC no.: 244-088-0 CAS no.: 20859-73-8	830 g/kg	1 February 2012	31 January 2022	18	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the EU level risk assessment. In particular, where relevant, the assessment authorities shall assess outdoor use. Before the notification authority grants the product authorisation, the assessment authorities shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Authorisation is subject to the following conditions: 1. Products shall only be supplied to and used by specifically trained professionals in the form of ready for-use products. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas. 3. For products containing aluminium phosphide that may lead to residues in food or feed, labels and/or

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in Xenobiotic Substances and Components Ordinance of 26 June 1995[181] (XCO).
Aluminium phosphide releasing phosphine	Aluminium phosphide EC no.: 244-088-0 CAS no.: 20859-73-8	830 g/kg	1 September 2011	31 August 2021	14	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Products cannot be authorised for indoor use unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. Authorisation is subject to the following conditions: 1. Products shall only be sold to and used by specifically trained professionals.

[181] RS **817.021.23**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. These include, amongst others, the use of appropriate personal protective equipment, the use of applicators and the presentation of the product in a form designed to reduce operator exposure to an acceptable level. 3. In view of the risks identified for terrestrial non-target species, appropriate risk reduction measures must be applied. These include, amongst others, the non-treatment of areas where other burrowing mammals than the target species are present.
Aluminium phosphide releasing phosphine	IUPAC Name: Aluminium phosphide EC No: 244-088-0 CAS No: 20859-73-8	830 g/kg	1 July 2015	30 June 2025	20	Biocidal products of the product type 20 (control of other vertebrates) are not authorized in Switzerland according to article 4 OBP, except for purposes of research and development and in order to deale with exceptional situations.
Bacillus thuringiensis subsp. *israelensis* Serotype H14, Strain AM65-52	Not applicable	No relevant impurities	1 October 2013	30 September 2023	18	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. Products authorised for professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						authorisation that risks to professional users can be reduced to an acceptable level by other means. For products containing Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52 that may lead to residues in food or feed, the assessment authorities shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[182] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[183] (FsBO), and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.
Basic copper carbonate	Copper(II) carbonate-copper(II) hydroxide (1:1) EC No: 235-113-6 CAS No: 12069-69-1	957 g/kg	1 February 2014	31 January 2024	8	When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Authorisation is subject to the following conditions: 1. Products shall not be authorised for application by dipping, unless data have been submitted in the application for product authorisation demonstrating that that application meets the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate

182 SR **817.021.23**
183 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						risk mitigation measures. 2. For products authorised for industrial use, safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means. 3. Labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal. 4. Products shall not be authorised for treatment of wood that will be used in outdoor constructions near or above water, or for the treatment of wood in direct contact with fresh water, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate mitigation measures.
Bendiocarb	2,2-dimethyl-1,3-benzodioxol-4-yl methylcarbamate CAS-No: 22781-23-3 EC No: 245-216-8	970 g/kg	1 February 2014	31 January 2024	18	The Union level risk assessment did not address all potential uses, but concerned, for example, application by professionals only, and excluded contact with feed or food and direct application on soil. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						compartments that have not been representatively addressed in the Union level risk assessment. Authorisation is subject to the following conditions: 1. Products shall not be used for the treatment of surfaces that are prone to frequent wet cleaning, other than crack and crevice or spot treatment, unless data are submitted demonstrating that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. 2. Products authorised for industrial or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 3. Where relevant, measures shall be taken to prevent foraging bees from gaining access to treated nests by removing the combs or blocking the nest entrances.
Benzoic acid	IUPAC Name: Benzoic acid EC No: 200-618-2 CAS No: 65-85-0	990 g/kg	1 July 2015	30 June 2025	3	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 1. For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						2. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[184] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[185] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
Benzoic acid	IUPAC Name: Benzoic acid EC No: 200-618-2 CAS No: 65-85-0	990 g/kg	1 July 2015	30 June 2025	4	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 1. For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. 2. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[186] (XCO) or Feedstuffs Book Ordinance of 26

184 SR **817.021.23**
185 SR **916.307.1**
186 SR **817.021.23**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						October 2011[187] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. 3. Products containing benzoic acid shall not be incorporated in materials and articles in the sense of the ordinance of the FDHA of 23 Novembre 2005[188] intended to come into contact with food, unless specific limits on the migration of benzoic acid into food are established or it was determined pursuant to that ordinance that such limits are not necessary.
Bifenthrin	IUPAC name: 2-methylbiphenyl-3-ylmethyl (1RS)-cis-3-[(Z)-2-chloro- 3,3,3-trifluoroprop-1- enyl]-2,2-dimethylcyclopropane-carboxylate EC No: n.a. CAS No: 82657-04-3	911 g/kg	1 February 2013	31 January 2023	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. Authorisation is subject to the following conditions: 1. Products shall be authorised only for industrial or professional use, unless it is demonstrated in the application for product authorisation that risks to non-professional users can be reduced to acceptable levels in accordance with Articles 11 and 17 OBP. 2. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the appli-

187 SR **916.307.1**
188 SR **817.023.21**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						cation for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 3. Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hardstanding, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal. 4. Products shall not be authorised for the in situ treatment of wood outdoors, or for treatment of wood that will be either continually exposed to the weather or protected from the weather but subject to frequent wetting, unless data have been submitted demonstrating that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures.
Boric acid	Boric acid EC no.: 233-139-2 CAS no.: 10043-35-3	990 g/kg	1 September 2011	31 August 2021	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those populations that may be exposed to the product and those use or exposure scenarios that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Authorisation is subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. In particular, labels or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
Boric oxide	Diboron trioxide EC no.: 215-125-8 CAS no.: 1303-86-2	975 g/kg	1 September 2011	31 August 2021	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those populations that may be exposed to the product and those use or exposure scenarios that have not been representatively addressed in the EU level risk assessment.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Authorisation is subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. In particular, labels or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Brodifacoum	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-napthyl]-4-hydroxycoumarin EC No: 259-980-5 CAS No: 56073-10-0	950 g/kg	1 February 2012	31 January 2017	14	Authorisation is subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
Bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one EC no.: 249-205-9 CAS no.: 28772-56-7	969 g/kg	1 July 2011	30 June 2016	14	Authorisation is subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Bromoacetic acid	IUPAC Name: 2-bromo-ethanoic acid EC No: 201-175-8 CAS No: 79-08-3	946 g/kg	1 July 2015	30 June 2025	4	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following condition: 1. For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. 2. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[189] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[190] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. 3. Products containing bromoacetic acid shall not be incorporated in materials and articles in the sense of the ordinance of the FDHA of 23 Novembre 2005[191] intended to come into contact with food, unless specific limits on the migration of bromoacetic acid into food are established or it has been established pursuant to that ordinance that such limits are not necessary.

189 SR **817.021.23**
190 SR **916.307.1**
191 SR **817.023.21**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						Where a treated article has been treated with or intentionally incorporates bromoacetic acid, and where necessary due to the possibility of skin contact as well as the release of bromoacetic acid under normal conditions of use, the person responsible for placing the treated article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012[192].
Carbon dioxide	Carbon dioxide EC no.: 204-696-9 CAS no.: 124-38-9	990 ml/l	1 November 2009	31 October 2019	14	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess those populations that may be exposed to the product and those use or exposure scenarios that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.

192 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.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Carbon dioxide	Carbon dioxide EC no.: 204-696-9 CAS no.: 124-38-9	990 ml/l	1 November 2012	31 October 2022	18	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Authorisation is subject to the following conditions: 1. Product shall only be sold to and used by professionals trained to use them. 2. Appropriate measures to protect operators shall be taken to ensure minimum risk, including the availability of personal protective equipment if necessary. 3. Appropriate measures shall be taken to protect bystanders, such as exclusion from the treatment area during fumigation.
Chlorfenapyr	IUPAC name: 4-bromo -2-(4-chlorophenyl)-1-ethoxymethyl-5-trifluoromethylpyrrole-3-carbonitrile EC No: Not allocated CAS No: 122453-73-0	940 g/kg	1 May 2015	30 April 2025	8	The Union level risk assessment did not address all potential uses and exposure scenarios. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Authorisation is subject to the following conditions:

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						1. for industrial or professional users safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means; 2. products shall not be authorised for non-professional users, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level; 3. labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal; 4. products shall not be authorised for treatment of wood that will be used outdoors, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate mitigation measures.
Chlorophacinone	Chlorophacinone EC No: 223-003-0 CAS No: 3691-35-8	978 g/kg	1 July 2011	30 June 2016	14	Authorisation is subject to the following conditions: 1. The nominal concentration of the active substance in products other than tracking powder shall not exceed 50 mg/kg and only ready-for use products shall be authorised. 2. Products to be used as tracking powder shall only be placed on the market for use by trained professionals.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						3. Products shall contain an aversive agent and, where appropriate, a dye. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
cis-tricos-9-ene (Muscalure)	*cis*-Tricos-9-ene; (Z)-Tricos-9-ene EC No: 248-505-7 CAS No: 27519-02-4	801 g/kg	1 October 2014	30 September 2024	19	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as outdoor use and exposure of food or feed, were excluded. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. For products containing *cis*-tricos-9-ene that may lead to residues in food or feed, the assessment authorities shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[193] (XCO) or Feedstuffs Book Ordinance

193 SR **817.021.23**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						of 26 October 2011[194] (FsBO), and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.
Clothianidin	(E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine EC no.: 433-460-1 CAS no.: 210880-92-5	950 g/kg	1 February 2010	31 January 2020	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess those populations that may be exposed to the product and those use or exposure scenarios that have not representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks. The Notification Authority shall ensure, by specifying conditions or requirements that appropriate measures are taken to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Authorisation is subject to the following conditions: 1. In view of the risk identified for the soil, surface water and groundwater compartments, products cannot be authorised for the treatment of wood that will be used outdoors unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. 2. Labels or safety-data sheets of products authorised for industrial use shall indicate that freshly treated

194 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for reuse or disposal.
Copper hydroxide	Copper (II) hydroxide EC No: 243-815-9 CAS No: 20427-59-2	965 g/kg	1 February 2014	31 January 2024	8	When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Authorisation is subject to the following conditions: 1. Products shall not be authorised for application by dipping, unless data have been submitted in the application for product authorisation demonstrating that that application meets the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. 2. For products authorised for industrial use, safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means. 3. Labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						the application of the product shall be collected for reuse or disposal. 4. Products shall not be authorised for treatment of wood that will be used in outdoor constructions near or above water, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate mitigation measures.
Copper (II) oxide	Copper (II) oxide EC No: 215-269-1 CAS No: 1317-38-0	976 g/kg	1 February 2014	31 January 2024	8	When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Authorisation is subject to the following conditions: 1. For products authorised for industrial use, safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means. 2. Labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						3. Products shall not be authorised for treatment of wood that will be used in outdoor constructions near or above water or for the treatment of wood in contact with fresh water, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate mitigation measures.
Copper sulphate pentahydrate	IUPAC Name: copper sulphate pentahydrate EC No: 231-847-6[195] CAS No: 7758-99-8	999 g/kg	1 July 2015	30 June 2025	2	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following condition: For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
Coumatetralyl	Coumatetralyl EC no.: 227-424-0 CAS no.: 5836-29-3	980 g/kg	1 July 2011	30 June 2016	14	Authorisation is subject to the following conditions: 1. The nominal concentration of the active substance in products other than tracking powder shall not exceed 375 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Primary as well as secondary exposure of humans,

[195] Only copper sulphate pentahydrate should be considered under this EC number

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use secured bait boxes.
Creosote	Creosote EC No: 232-287-5 CAS No: 8001-58-9	Grade B or Grade C creosote as specified in European Standard EN 13991:2003	1 May 2013	30 April 2018	8	Biocidal products containing creosote may only be authorised for uses where the authorising Member State, based on an analysis regarding the technical and economic feasibility of substitution which it shall request from the applicant, as well as on any other information available to it, concludes that no appropriate alternatives are available. Those Member States authorising such products in their territory shall no later than 31 July 2016 submit a report to the Commission justifying their conclusion that there are no appropriate alternatives and indicating how the development of alternatives is promoted. The Commission will make these reports publicly available. The active substance is to be subject to a comparative risk assessment before its inclusion in this Annex is renewed. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, teh assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed at the EU level risk assess-

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						ment. Authorisation is subject to the following conditions: 1. Creosote may only be used under the conditions mentioned in point 2 of the second column of entry No 31 in Annex XVII to Regulation (EC) No 1907/2006[196] 2. Creosote shall not be used for the treatment of wood intended for those uses referred to in point 3 of the second column of entry No 31 in Annex XVII to Regulation (EC) No 1907/2006. 3. Appropriate risk mitigation measures shall be taken to protect workers, including down-stream users, from exposure during treatment and handling of treated wood in compliance with Regulation (EC) No 1907/2006 and Directive 2004/37/EC[197]. 4. Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
Cu-HDO	IUPAC Name: bis(N-cyclohexyl-	981 g/kg	1 September 2015	31 August 2025	8	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any

[196] See footnote to Art. 2 para. 2 let. a no 3.
[197] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) OJ L 158, 30.4.2004, p. 50–76

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	diazenium-dioxy)-copper EC nº: N/A CAS nº: 312600-89-8					uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisation is subject to the following conditions: 1. For industrial users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. 2. Appropriate risk mitigation measures shall be taken to protect the terrestrial compartment. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
Cypermethrin	Cypermethrin *cis*:*trans*/40:60 IUPAC Name: (RS)-α-cyano-3phenoxybenzyl-(1RS)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate EC No: 257-842-9 CAS No: 52315-07-8	920 g/kg	1 June 2015	31 May 2025	8	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 1. For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						equipment. 2. Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular: a) Labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal. b) Products shall not be authorised for industrial treatment by dipping or spraying of wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures. c) Products shall not be authorised for treatment of outdoor constructions near or above water, or for treatment of wood that will be used for outdoor constructions near or above water, unless data is submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Cyproconazole	IUPAC Name: (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol EC No: N/A CAS No: 94361-06-5 Cyproconazole has two diastereomers. Diastereomer A: enantiomeric pair, where the 2-hydroxy group and the 3-hydrogen are located on the same side (2S, 3S and 2R, 3R). Diastereomer B: enantiomeric pair, where the 2-hydroxy group and 3-hydrogen are located on opposite sides (2R, 3S and 2S, 3R). Technical cyproconazole is ca 1:1 mixture of the two diasteriomers, each of which is exactly a 1:1 mixture of the enantiomers.	940 g/kg Cyproconazole has two diastereomers (Diastereoisomer A: 430-500 g/kg, Diastereoisomer B: 470-550 g/kg).	1 November 2015	31 October 2020	8	Cyproconazole is considered a candidate for substitution in accordance with Article 10(1)(a) and (d) of Regulation (EU) No 528/2012. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 1. For industrial users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. 2. Products shall not be authorised for industrial use by double vacuum impregnation, unless data is submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures. 3. Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular: a) Labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						b) Products shall not be authorised for industrial treatment of wood that will be exposed to weathering, or for treatment of wood that will be used for outdoor constructions, unless data is submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures.
Dazomet	Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione EC No: 208-576-7 CAS No: 533-74-4	960 g/kg	1 August 2012	31 July 2022	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to compartments and populations that have not been representatively addressed in the EU level risk assessment. In particular, where relevant, the assessment authorities shall assess any other use than professional use outdoors for the remedial treatment of wooden poles by insertion of granules. Authorisation is subject to the following condition: Products authorised for industrial and/or professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by others means.
DDACarbonate	Reaction mass of N,N-Didecyl-N,N-dimethylammonium Carbonate and N,N-Didecyl-N,N-	Dry weight: 740 g/kg	1 February 2013	31 January 2023	8	The Union level risk assessment did not address all potential uses; certain uses, such as use by non-professionals, were excluded. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authori-

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	dimethylammonium Bicarbonate EC No: 451-900-9 CAS No: 894406-76-9					ties shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Authorisation is subject to the following conditions: 1. for industrial users safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means; 2. labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal; 3. products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions near or above water, or for treatment by dipping of wood that will be continually exposed to the weather or subject to frequent wetting, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate mitigation measures.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Decanoic acid	IUPAC Name: n-Decanoic acid EC No: 206-376-4 CAS No: 334-48-5	985 g/kg	1 September 2015	31 August 2025	4	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[198] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[199] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. Biocidal products containing decanoic acid shall not be incorporated in materials and articles intended to come into contact with food in the sense of the ordinance of the FDHA of 23 Novembre 2005[200] unless the FDHA has established specific limits on the migration of decanoic acid into food or it has been established pursuant to that Regulation that such limits are not

198 SR **817.021.23**
199 SR **916.307.1**
200 SR **817.023.21**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						necessary.
Decanoic acid	IUPAC Name: n-Decanoic acid EC No: 206-376-4 CAS No: 334-48-5	985 g/kg	1 September 2015	31 August 2025	18	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: Authorisations of products for non-professional use are subject to the packaging being designed to minimise user exposure, unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[201] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[202] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
Decanoic acid	IUPAC Name: n-Decanoic acid EC No: 206-376-4 CAS No: 334-48-5	985 g/kg	1 September 2015	31 August 2025	19	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

201 SR **817.021.23**
202 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Deltamethrin	(S)-α-cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2- dimethylcyclopropane carboxylate CAS-No: 52918-63-5 EC No: 258-256-6	985 g/kg	1 October 2013	30 September 2023	18	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. Products shall not be authorised for indoor treatments resulting in sewage treatment plant emissions of the scale for which the EU level risk assessment showed unacceptable risks, unless data are submitted demonstrating that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures
Dichlofluanid	N-(Dichlorofluoromethyl-thio)-N',N'-dimethyl-N-phenylsulfamide EC no.: 214-118-7 CAS no.: 1085-98-9	> 96% w/w	1 March 2009	28 February 2019	8	Authorisation is subject to the following conditions: 1. Products authorised for industrial or professional use must be used with appropriate personal protective equipment. 2. In view of the risks identified for the soil compartment, appropriate risk mitigation measures must be taken to protect that compartment. 3. Labels or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment on impermeable hard standing to prevent direct losses to soil and that any losses must be collected for reuse or disposal.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Didecyldimethylammonium Chloride; DDAC	N,N-Didecyl-N,N-dimethylammonium Chloride EC No: 230-525-2 CAS No: 7173-51-5	Dry weight: 870 g/kg	1 February 2015	31 January 2025	8	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals and exposure of food or feed, were excluded. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Authorisation is subject to the following conditions: 1. For industrial or professional users safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means. 2. Products shall not be used for treatment of wood with which children may enter in direct contact, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level. 3. Labels and, where provided, safety data sheets of products authorised shall indicate that industrial or professional application shall be conducted within a contained area or on impermeable hard standing with bunding, and that freshly treated timber shall be stored after treatment on impermeable hard standing to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						4. Products shall not be authorised for treatment of wood that will be in contact with fresh water or used for outdoor constructions near or above water, continually exposed to the weather or subject to frequent wetting, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate mitigation measures.
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin EC no.: 259-978-4 CAS no.: 56073-07-5	960 g/kg	1 April 2010	30 June 2018	14	Authorisation is subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 75 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
Difethialone	3-[3-(4'-bromo[1,1'biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-1-	976 g/kg	1 November 2009	30 June 2018	14	Authorisation is subject to the following conditions: 1. The nominal concentration of the active substance in the products shall not exceed 0.0025% w/w and only read-for-use baits shall be authorised.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	benzothiopyran-2-one EC no.: n/a CAS no.: 104653-34-1					2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use secured bait boxes.
Diflubenzuron	1-(4-chlorophenyl)-3-(2,6-difluorobenzoyl)urea EC No: 252-529-3 CAS No: 35367-38-5	960 g/kg	1 February 2015	31 January 2025	18	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as outdoor use, use by non-professionals, and exposure of livestock were excluded. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. For products containing diflubenzuron that may lead to residues in food or feed, the assessment authorities shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						26 June 1995[203] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[204] (FsBO), with special consideration to the *in vivo* genotoxic metabolite PCA, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded. The assessment authorities shall ensure that authorisations are subject to the following conditions unless it can be demonstrated in the application for product authorisation that the risks can be reduced to an acceptable level: 1. Professional users shall wear appropriate personal protective equipment. 2. Product information shall include the requirement that products shall only be used on dry manure, and that the manure must undergo complete aerobic composting by professionals prior to application on arable land. 3. Products shall not be used in water systems.
Disodium octaborate tetrahydrate	Disodium octaborate tetrahydrate EC no.: 234-541-0 CAS no.: 12280-03-4	975 g/kg	1 September 2011	31 August 2021	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those populations that may be exposed to the product and those use or exposure scenarios that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product

203 SR **817.021.23**
204 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Authorisation is subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. In particular, labels or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
Disodium tetraborate	Disodium tetraborate EC no.: 215-540-4 CAS no. (anhydrous):	990 g/kg	1 September 2011	31 August 2021	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	1330-43-4 CAS no. (pentahydrate): 12267-73-1 CAS no. (decahydrate): 1303-96-4					for the particular product, those populations that may be exposed to the product and those use or exposure scenarios that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Authorisation is subject to the following conditions: 1. Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. In particular, labels or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collect-

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						ed for reuse or disposal.
Ethyl butylacetylaminopropionate	IUPAC Name: 3-(N-acetyl-N-butyl)aminopropionic acid ethyl ester EC no: 257-835-0 CAS no: 52304-36-6	990 g/kg	1 November 2015	31 October 2025	19	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following condition: Primary exposure of humans to the product shall be minimized by considering and applying appropriate risk mitigation measures, including, where applicable, instructions on the amount and the frequency with which the product may be applied to human skin.
Etofenprox	3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether EC no.: 407-980-2 CAS no.: 80844-07-1	970 g/kg	1 February 2010	31 January 2020	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess those populations that may be exposed to the product and those use or exposure scenarios that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks. The Notification Authority shall ensure, by specifying conditions or requirements that appropriate measures are taken to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Authorisation is subject to the following conditions: 1. In view of the risk identified for users, products cannot be used year round unless dermal absorption data is provided to demonstrate that there are no

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						unacceptable risks from chronic exposure. 2. Products intended for industrial use must be used with appropriate personal protective equipment.
Etofenprox	IUPAC Name: 3-phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether EC No: 407-980-2 CAS No: 80844-07-1	970 g/kg	1 July 2015	30 June 2025	18	Etofenprox is considered a candidate for substitution in accordance with article 10(1) (d) of Regulation (EU) No 528/2012[205]. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 1. For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. 2. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[206] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[207] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to

205 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.
206 SR **817.021.23**
207 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						ensure that the applicable MRLs are not exceeded.
Fenoxycarb	IUPAC name: Ethyl [2-(4- phenoxyphenoxy) ethyl]carbamate EC No: 276-696-7 CAS No: 72490-01-8	960 g/kg	1 February 2013	31 January 2023	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. Authorisation is subject to the following conditions: 1. Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of products authorised shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hardstanding under roof, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal. 2. Products shall not be authorised for treatment of wood that will be used in outdoor constructions near or above water, unless data is submitted demonstrating that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures.'
Fenpropimorph	(+/-)-cis-4-[3-(p-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine EC no.: 266-719-9	930 g/kg	1 July 2011	30 June 2021	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those populations that may be exposed to the product and those use or exposure

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	CAS no.: 67564-91-4					scenarios that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Authorisation is subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
Fipronil	(±)-5-amino-1-(2,6-dichloro-α,α,α,- trifluoro-p-tolyl)-4- trifluoro-	950 g/kg	1 October 2013	30 September 2023	18	Only professional use indoors by application in locations normally inaccessible after application to man and domestic animals has been addressed in

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	methylsulfinylpyrazole-3-carbonitrile (1:1) EC No: 424-610-5 CAS No: 120068-37-3					the EU level risk assessment. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment
Flocoumafen	4-hydroxy-3-[(1RS,3RS;1RS,3RS)-1,2,3,4-tetrahydro-3-[4-(4-trifluoromethylbenzyloxy)phenyl]-1-naphthyl]coumarin EC No 421-960-0 CAS No 90035-08-8	955 g/kg	1 October 2011	30 September 2016	14	Authorisation is subject to the following conditions: 1. The nominal concentration of the active substance in products shall not exceed 50 mg/kg and only ready-for-use products shall be authorised. 2. Products shall contain an aversive agent and, where appropriate, a dye. 3. Products shall not be used as tracking powder.. 4. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. Those include, amongst others, the restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes
Flufenoxuron	1-[4-(2-chloro-alpha,alpha,alpha-trifluoro-para-tolyloxy)-2-fluorophenyl]-3-(2,6-difluorobenzoyl)urea EC No: 417-680-3 CAS No: 101463-69-8	960 g/kg	1 February 2014	31 January 2017	8	Flufenoxuron shall be subject to a comparative risk assessment before its inclusion in this Annex is renewed. The Union level risk assessment addressed treatment of wood which will not be used in animal housing or come into contact with food or feed. Products shall not be authorised for uses or exposure scenarios that have

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						not been representatively addressed in the Union level risk assessment. Authorisation is subject to the following conditions: 1. Products shall only be used for treatment of wood intended for indoor use. 2. For products authorised for industrial or professional use safe operational procedures shall be established, and products shall be used with appropriate personal protective equipment unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 3. Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular, labels and, where provided, safety data sheets of authorised products shall indicate that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.
Hydrochloric acid	Hydrochloric acid CAS No: not applicable EC No: 231-595-7	999 g/kg	1 May 2014	30 April 2024	2	When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						The assessment authorities shall ensure that authorisations of products for non-professional use are subject to the packaging being designed to minimise user exposure, unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means.
Hydrogen cyanide	hydrogen cyanide EC No: 200-821-6 CAS No: 74-90-8	976 g/kg	1 October 2014	30 September 2024	8, 14 and 18	When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Authorisations of products for use as a fumigant are subject to the following conditions: 1. product shall only be supplied to and used by professionals adequately trained to use them; 2. safe operational procedures during fumigation and venting shall be established for operators and bystanders; 3. products shall be used with adequate personal protective equipment including, where appropriate, self-contained breathing apparatus and gas-tight clothing; 4. re-entry into fumigated spaces shall be prohibited until the air concentration has reached safe levels for operators and bystanders by ventilation; 5. exposure during and after ventilation shall be prevented from exceeding safe levels for operators and

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						bystanders by the establishment of a supervised exclusion zone; 6. prior to fumigation, any food and any porous material with a potential to absorb the active substance, except wood intended to be treated, shall either be removed from the space to be fumigated or protected from absorption by adequate means, and the space to be fumigated shall be protected against accidental ignition.
Imidacloprid	(2E)-1-[(6-chloropyridin-3-yl)methyl]-N-nitroimidazolidin-2-imine EC No: 428-040-8 CAS No: 138261-41-3	970 g/kg	1 July 2013	30 June 2023	18	When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products shall not be authorised for uses in animal housings where emission to a sewage treatment plant or direct emission to surface water cannot be prevented, unless data is submitted demonstrating that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. Authorisations shall be subject to appropriate risk mitigation measures. In particular, appropriate risk mitigation measures shall be taken to minimise the potential exposure of infants and children. For products containing imidacloprid that may lead to residues in food or feed, assessment authorities shall

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						verify the need to set new or amended existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[208] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[209] (FsBO), and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.
Indoxacarb (enantiomeric reaction mass S:R 75:25)	Reaction mass of methyl(S)- and methyl(R)-7-chloro-2,3,4a,5-tetrahydro-2-[methoxycarbonyl-(4-trifluoromethoxyphenyl) carbamoyl]indeno[1,2-e][1,3,4]oxadiazine-4a-carboxylate (This entry covers the 75:25 reaction mass of the S and R enantiomers) EC no.: n/a CAS no.: S-enantiomer: 173584-44-6 and R-enantiomer: 185608-75-7	796 g/kg	1 January 2010	31 December 2019	18	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those populations that may be exposed to the product and those use or exposure scenarios that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Authorisation is subject to the following conditions: Appropriate risk mitigation measures must be taken to minimise the potential exposure of humans, of non-target species and of the aquatic environment. In particular, labels and/or safety-data sheets of products authorised shall indicate that:

208 SR **817.021.23**
209 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						1. Products shall not be placed in areas accessible to children and companion animals. 2. Products shall be positioned away from external drains. 3. Unused products shall be disposed of properly and not washed down the drain. For amateur uses, only ready-to-use products shall be authorised.
Iodine (including polyvinylpyrrolidone iodine)	IUPAC Name: Iodine EC No: 231-442-4 CAS No: 7553-56-2 IUPAC Name: Polyvinylpyrrolidone iodine EC No: n.a., CAS No: 25655-41-8	995 g/kg of iodine For polyvinylpyrrolidone iodine: the iodine content shall have a purity of 995 g/kg	1 September 2015	31 August 2025	1	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
Iodine (including polyvinylpyrrolidone iodine)	IUPAC Name: Iodine EC No: 231-442-4 CAS No: 7553-56-2 IUPAC Name: Polyvinylpyrrolidone iodine EC No: n.a., CAS No: 25655-41-8	995 g/kg of iodine For polyvinylpyrrolidone iodine: the iodine content shall have a purity of 995 g/kg	1 September 2015	31 August 2025	3	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						1995[210] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[211] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
Iodine (including polyvinylpyrrolidone iodine)	IUPAC Name: Iodine EC No: 231-442-4 CAS No: 7553-56-2 IUPAC Name: Polyvinylpyrrolidone iodine EC No: n.a., CAS No: 25655-41-8	995 g/kg of iodine For polyvinylpyrrolidone iodine: the iodine content shall have a purity of 995 g/kg	1 September 2015	31 August 2025	4	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 1. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[212] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[213] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. 2. Products containing iodine shall not be incorporated in materials and articles intended to come into contact with food in the sense of the ordinance of the FDHA of 23 Novembre 2005[214], unless the FDHA has established specific limits on the migration of iodine into food or it has been established pursuant to that Regula-

210 SR **817.021.23**
211 SR **916.307.1**
212 SR **817.021.23**
213 SR **916.307.1**
214 SR **817.023.21**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						tion that such limits are not necessary.
Iodine (including polyvinylpyrrolidone iodine)	IUPAC Name: Iodine EC No: 231-442-4 CAS No: 7553-56-2 IUPAC Name: Polyvinylpyrrolidone iodine EC No: n.a., CAS No: 25655-41-8	995 g/kg of iodine For polyvinylpyrrolidone iodine: the iodine content shall have a purity of 995 g/kg	1 September 2015	31 August 2025	22	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not adressed in the Union level risk assessment of the active substance. Authorisations are subject to the following condition: For professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
IPBC	3-iodo-2-propynyl butylcarbamate EC no: 259-627-5 CAS no.: 55406-53-6	980 g/kg	1 July 2010	30 June 2020	8	Authorisation is subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						that any losses must be collected for reuse or disposal.
IPBC	IUPAC Name: 3-iodo-2-propynyl butylcarbamate EC No: 259-627-5 CAS No: 55406-53-6	980 g/kg	1 July 2015	30 June 2025	6	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following condition: For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. Where a treated article has been treated with or intentionally incorporates IPBC, and where necessary due to the possibility of skin contact as well as the release of IPBC under normal conditions of use, the person responsible for placing the treated article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012[215].

215 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.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
K-HDO	Cyclohexylhydroxy-diazene 1-oxide, potassium salt EC No: n/a CAS No: 66603-10-9 (This entry also covers the hydrated forms of K-HDO)	977 g/kg	1 July 2010	30 June 2020	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess those populations that may be exposed to the product and those use or exposure scenarios that have not been representatively addressed in the EU level risk assessment. Authorisation is subject to the following conditions: 1. in view of the possible risks for the environment and workers, products shall not be used in other systems than industrial, fully automated and closed ones unless the application for product authorisation demonstrates that risks can be reduced to acceptable levels in accordance with Articles 11 and 17 OBP; 2. in view of the assumptions made during the risk assessment, products must be used with appropriate personal protective equipment, unless the application for product authorisation demonstrates that risks to users can be reduced to acceptable levels by other means; 3. in view of the risk identified for infants, products shall not be used for the treatment of wood that may enter in direct contact with infants.
Lambda-Cyhalothrin	Reaction mass of (R)-α-cyano- 3-phenoxybenzyl (1S,3S)-3-[(Z)-2- chloro-3,3,3-trifluoropro- penyl]-2,2-dimethylcyclopropane-carboxylate and (S)-α-cyano-3-phenoxybenzyl	900 g/kg	1 October 2013	30 September 2023	18	When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment.Products applied in such a way that emission to a

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	(1R,3R)-3-[(Z)-2-chloro-3,3,3- trifluoropropenyl]-2,2- dimethylcyclopropanecarboxylate (1:1) CAS-No: 91465-08-6 EC No: 415-130-7					sewage treatment plant cannot be prevented shall not be au- thorised, unless data are submitted demonstrating that the product will meet the requirements of 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. Products authorised for professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by other means. For products containing lambda-cyhalothrin that may lead to residues in food or feed, the assessment authorities shall verify the need to set new or amended existing maximum residue levels (MRLs) according to FIV or FMBV, and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.
Lauric acid	IUPAC Name: Dodecanoic acid EC No: 205-582-1 CAS No: 143-07-7	980 g/kg	1 November 2015	31 October 2025	19	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
Magnesium phosphide releasing phosphine	Trimagnesium diphosphide EC No: 235-023-7 CAS No: 12057-74-8	880 g/kg	1 February 2012	31 January 2022	18	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. In particular, where relevant, the assessment

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						authorities shall assess outdoor use. Before the notification authority grants the product authorisation, the assessment authorities shall ensure that adequate residue trials are provided to allow consumer risk assessment and that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Authorisation is subject to the following conditions: 1. Products shall only be supplied to and used by specifically trained professionals in the form of ready-for-use products. 2. In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation, the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas. 3. For products containing magnesium phosphide that may lead to residues in food or feed, labels and/or safety data sheets for authorised products must contain instructions for use, such as the adherence to waiting periods, which ensure compliance with the provisions laid down in the Xenobiotic Substances and Components Ordinance of 26 June 1995[216] (XCO).

216 SR **817.021.23**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Margosa extract	IUPAC name: Not applicable CAS-No: 84696-25-3 EC No: 283-644-7 Description: margosa extract from the kernels of *Azadirachta indica* extracted with water and further processed with organic solvents	1 000 g/kg	1 May 2014	30 April 2024	18	When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. The assessment authorities shall ensure that authorisations are subject to appropriate risk mitigation measures for the protection of surface water, sediment and non-target arthropods.
Methyl nonyl ketone	Undecan-2-one CAS No: 112-12-9 EC No: 203-937-5	975 g/kg	1 May 2014	30 April 2024	19	The Union level risk assessment was based on indoor use by non-professional users. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.
Metofluthrin	RTZ isomer:2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl-(1R,3R)-2,2-dimethyl-3-(Z)-(prop-1-enyl)cyclopropanecarboxylate EC No: n.a. CAS No: 240494-71-7	The active substance shall comply with both the following minimum purities: RTZ isomer:754 g/kg Sum of all isomers:930 g/kg	1 May 2011	30 April 2021	18	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	Sum of all isomers:2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (EZ)-(1RS,3RS;1SR,3SR)-2,2-dimethyl-3-prop-1-enylcyclopropanecarboxylate EC No: n.a. CAS No: 240494-70-6					
N,N-diethyl-meta-toluamide (DEET)	N,N-diethyl-m-toluamide EC No: 205-149-7 CAS No: 134-62-3	970 g/kg	1 August 2012	31 July 2022	19	Authorisation is subject to the following conditions: 1.primary exposure of humans shall be minimized by considering and applying appropriate risk mitigation measures, including, where applicable, instructions for the amount and frequency of application of the product on human skin; 2.labels on products intended for application on human skin, hair or clothing shall indicate that the product is intended only for restricted use on children between two and twelve years old, and that it is not intended for use on children less than two years old, unless it can be demonstrated in the application for product authorisation that the product will meet the requirements of Articles 11 and 17 OBP without such measures; 3. products must contain deterrents for ingestion.
Nitrogen	Nitrogen EC no.: 231-783-9 CAS no.: 7727-37-9	999 g/kg	1 September 2011	31 August 2021	18	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those populations that may be exposed to the product and those use or exposure

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						scenarios that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Authorisation is subject to the following conditions: 1. Products may only be sold to and used by professionals trained to use them. 2. Safe working practices and safe systems of work must be in place to ensure minimum risk, including the availability of personal protective equipment if necessary.
Nonanoic acid, Pelargonic acid	IUPAC name: Nonanoic acid EC No: 203-931-2 CAS No: 112-05-0	896 g/kg	1 February 2013	31 January 2023	19	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment.
Nonanoic acid, Pelargonic acid	IUPAC Name: Nonanoic acid EC No: 203-931-2 CAS No: 112-05-0	896 g/kg	1 October 2015	30 September 2025	2	The product assessment in accordance with Articles 11 and 17 OBP shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 1. Unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means, authorisation shall be subject to the following conditions: a) Instructions for use informing on how to minimize aerosol exposure. b) Authorisation of products for non-professional users are subject to the packaging being designed to minimise user exposure. 2. Authorisation of products used as algaecide for outdoor remedial treatment of construction materials shall be subject to safe operating procedures and risk mitigation measures in order to protect the environment.
Octanoic acid	IUPAC Name: n-Octanoic acid EC No: 204-677-5 CAS No: 124-07-2	993 g/kg	1 September 2015	31 August 2025	4	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 1. For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. 2. For products that may lead to residues in food or feed, the need to set new or to amend existing maxi-

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						mum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[217] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[218] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. 3. Biocidal products containing octanoic acid shall not be incorporated in materials and articles intended to come into contact with food in the sense of the ordinance of the FDHA of 23 Novembre 2005[219], unless the FDHA has established specific limits on the migration of octanoic acid into food or it has been established pursuant to that Regulation that such limits are not necessary.
Octanoic acid	IUPAC Name: n-Octanoic acid EC No: 204-677-5 CAS No: 124-07-2	993 g/kg	1 September 2015	31 August 2025	18	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 1. Authorisations of products for non-professional use are subject to the packaging being designed to minimise user exposure, unless it can be demonstrated in the application for product authorisation that risks for human health can be reduced to acceptable levels by other means.

217 SR **817.021.23**
218 SR **916.307.1**
219 SR **817.023.21**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						2. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[220] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[221] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.
Powdered corn cob	Not allocated	1 000 g/kg	1 February 2015	31 January 2025	14	When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment.
Propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole EC no.: 262-104-4 CAS no.: 60207-90-1	930 g/kg	1 April 2010	31 March 2020	8	Authorisation is subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures

220 SR **817.021.23**
221 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						must be taken to protect those compartments. In particular, labels or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. 3. In addition, products cannot be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures.
Propiconazole	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole EC No: 262-104-4 CAS No: 60207-90-1	930 g/kg	1 June 2015	31 May 2025	9	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following condition: For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. Where a treated article has been treated with or intentionally incorporates propiconazole, and where necessary due to the possibility of skin contact as well as the release of propiconazole under normal conditions of use, the person responsible for placing the treated article on the market shall ensure that the label pro-

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						vides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012[222].
Pyriproxyfen	4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether EC No: 429-800-1 CAS No: 95737-68-1	970 g/kg	1 February 2015	31 January 2025	18	The Union level risk assessment did not address all potential uses and exposure scenarios; certain uses and exposure scenarios, such as use by non-professionals, were excluded. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. For products containing pyriproxyfen that may lead to residues in food or feed, the assessment authorities shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[223] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[224] (FsBO), and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded. Authorisation is subject to the following conditions:

222 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.
223 SR **817.021.23**
224 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						1. Products authorised for professionals shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level by other means. 2. Products shall not be authorised for direct use on surface water, unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level. 3. Products intended to be used in waste treatment facilities shall be subject to appropriate risk mitigation measures to avoid contamination of the area outside the waste treatment site.
S-methoprene	IUPAC Name: Isopropyl-(2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate EC No: N/A CAS No: 65733-16-6	950 g/kg	1 September 2015	31 August 2025	18	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following condition: For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[225] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[226] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

225 SR **817.021.23**
226 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Spinosad	EC No: 434-300-1 CAS No: 168316-95-8 Spinosad is a mixture of 50-95 % spinosyn A and 5-50 % spinosyn D. *Spinosyn A* (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-[(6-deoxy-2,3,4-tri-O-methyl-α-L mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione CAS No: 131929-60-7 *Spinosyn D* (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-[(6-	850 g/kg	1 November 2012	31 October 2022	18	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. Authorisation is subject to the following conditions: 1. Authorisations shall be subject to appropriate risk mitigation measures. In particular, products authorised for professional use by spraying shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by others means. 2. For products containing spinosad that may lead to residues in food or feed, the assessment authorithies shall verify the need to set new and/or amended existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[227] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[228] (FsBO), and take any appropriate risk mitigation measures ensuring that the applicable MRLs are not exceeded.

227 SR **817.021.23**
228 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyl)oxy]-13-[[(2R,5S,6R)-5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecin-7,15-dione CAS No: 131929-63-0					
Sulfuryl fluoride	Sulfuryl difluoride EC no.: 220-281-5 CAS no.: 2699-79-8	> 994 g/kg	1 January 2009	31 December 2018	8	Authorisation is subject to the following conditions: 1. The product may only be sold to and used by professionals trained to use it. 2. Appropriate risk mitigation measures are included for operators and bystanders. 3. Concentrations of sulfuryl fluoride in remote tropospheric air are monitored. 4. Authorisation holders shall submit reports of the monitoring referred to in point 3 to the Notification Authority every fifth year, starting from 1 January 2009.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Sulfuryl fluoride	Sulfuryl difluoride EC no.: 220-281-5 CAS no.: 2699-79-8	994 g/kg	1 July 2011	30 June 2021	18	Authorisation is subject to the following conditions: 1. Products shall only be sold to and used by professionals trained to use them. 2. Appropriate measures to protect fumigators and bystanders during fumigation and venting of treated buildings or other enclosures must be taken. 3. Labels or safety-data sheets of products shall indicate that, prior to fumigation of any enclosure, all food items must be removed. 4. Concentrations of sulfuryl fluoride in remote tropospheric air are monitored. 5. Authorisation holders shall submit reports of the monitoring referred to in point 4 directly to the Notification Authority every fifth year, starting at the latest five years after authorisation. The limit of detection for the analysis shall be at least 0.5 ppt (equivalent to 2.1 ng sulfuryl fluoride/m^3 of tropospheric air).
Synthetic amorphous silicon dioxide (nano)	IUPAC Name: Silicon dioxide EC No: 231-545-4 CAS No: 112926-00-8 This approval covers synthetic amorphous silicon dioxide as a nanomaterial in the form of stable aggregated particles of particle size > 1 μm, with primary	800 g/kg	1 November 2015	31 October 2025	18	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	particles of nanosize.					
Tebuconazole	1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol EC no.: 403-640-2 CAS no.: 107534-96-3	950 g/kg	1 April 2010	31 March 2020	8	Authorisation is subject to the following conditions: 1. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. 2. Products cannot be authorised for the in situ treatment of wood outdoors or for wood that will be in continuous contact with water unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures.
Tebuconazole	IUPAC Name: 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol EC No: 403-640-2	950 g/kg	1 July 2015	30 June 2025	7	Tebuconazole is considered a candidate for substitution in accordance with Article 10(1)(d) of Regulation (EU) No 528/2012[229]. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but

229 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.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
	CAS No: 107534-96-3					not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following condition: For industrial users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
Tebuconazole	IUPAC Name: 1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol EC No: 403-640-2 CAS No: 107534-96-3	950 g/kg	1 July 2015	30 June 2025	10	Tebuconazole is considered a candidate for substitution in accordance with Article 10(1) (d) of Regulation (EU) No 528/2012. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following conditions: 1. For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. 2. In the view of the risk for the soil compartment, tebuconazole shall not be used in a sealant that will be used to seal vertical joints outside residential facades (e.g. between two houses), unless it can be demonstrated in the application for product authorisation that risks

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						can be reduced to an acceptable level by other means.
Thiabendazole	2-thiazol-4-yl-1H-benzoimidazole EC no: 205-725-8 CAS no.: 148-79-8	985 g/kg	1 July 2010	30 June 2020	8	Authorisation is subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial or professional use, with respect to the double-vacuum and dipping application tasks, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. 3. Products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures.

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
Thiacloprid	(Z)-3-(6-chloro-3-pyridylmethyl)-1,3-thiazolidin-2-ylidencyanamide EC no.: n/a CAS no.: 111988-49-9	975 g/kg	1 January 2010	31 December 2019	8	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those populations that may be exposed to the product and those use or exposure scenarios that have not been representatively addressed in the EU level risk assessment. Before the notification authority grants the product authorisation, the assessment authorities shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels. Authorisation is subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or dis-

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						posal. 3. Products shall not be authorised for the in situ treatment of wooden structures near water, where direct losses to the aquatic compartment cannot be prevented, or for wood that will be in contact with surface water, unless data have been submitted to demonstrate that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures.
Thiamethoxam	Thiamethoxam EC no.: 428-650-4 CAS no.: 153719-23-4	980 g/kg	1 July 2010	30 June 2020	8	Authorisation is subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels or safety data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal. 3. In addition, products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will meet the require-

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						ments of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures.
Thiamethoxam	Thiamethoxam EG-Nr.: 428-650-4 CAS-Nr.: 153719-23-4	980 g/kg	1. Februar 2015	31. Januar 2025	18	The Union level risk assessment did not address all potential uses; certain uses, such as outdoor application and use by non-professionals, were excluded. When assessing the application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, where relevant for the particular product, those uses or exposure scenarios and those risks to human populations and to environmental compartments that have not been representatively addressed in the Union level risk assessment. Products shall not be authorised for application by brushing, unless data are submitted demonstrating that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. For products containing thiamethoxam that may lead to residues in food or feed, the assessment authorities shall verify the need to set new or to amend existing maximum residue levels (MRLs) according to the Xenobiotic Substances and Components Ordinance of 26 June 1995[230] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[231] (FsBO), and take any appropriate risk mitigation measures ensuring that the applica-

230 SR **817.021.23**
231 SR **916.307.1**

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						ble MRLs are not exceeded. Products applied in such a way that emission via a sewage treatment plant or directly to surface water cannot be prevented shall not be authorised, unless data are submitted demonstrating that the product will meet the requirements of Articles 11 and 17 OBP, if necessary by the application of appropriate risk mitigation measures. Authorisation is subject to the following conditions: 1. Products authorised for professional use shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to professional users can be reduced to an acceptable level by other means. 2. Where appropriate, measures shall be taken to protect honey bees.
Tolylfluanid	Dichloro-N-[(dimethylamino)sulphonyl]fluoro-N-(p-tolyl)methanesulphenamide EC No: 211-986-9 CAS No: 731-27-1	960 g/kg	1 October 2011	30 September 2021	8	Products shall not be authorised for the in situ treatment of wood outdoors or for wood that will be exposed to weathering. Authorisation is subject to the following conditions: 1. In view of the assumptions made during the risk assessment, products authorised for industrial or professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means. 2. In view of the risks identified for the soil and aquatic compartments, appropriate risk mitigation measures

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial or professional use shall indicate that freshly treated timber must be stored after treatment under shelter and/or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.
Transfluthrin	IUPAC Name: 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate or 2,3,5,6-tetrafluorobenzyl (1R)-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylate EC No: 405-060-5 CAS No: 118712-89-3	965 g/kg of 1R trans configuration	1 November 2015	31 October 2025	18	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Authorisations are subject to the following condition: In view of the risks for water, sediment and soil compartments, transfluthrin shall not be used in vaporisers for indoor use or insecticidal coils unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.
Warfarin	(RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl)coumarin EC No: 201-377-6 CAS No: 81-81-2	990 g/kg	1 February 2012	31 January 2017	14	Authorisation is subject to the following conditions: 1. the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; 2. products shall contain an aversive agent and, where appropriate, a dye;3.primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
Warfarin sodium	Sodium 2-oxo-3-(3-oxo-1-phenylbutyl)chromen-4-olate EC No: 204-929-4 CAS No: 129-06-6	910 g/kg	1 February 2012	31 January 2017	14	Authorisation is subject to the following conditions: 1. the nominal concentration of the active substance shall not exceed 790 mg/kg and only ready-for-use products shall be authorised; 2. products shall contain an aversive agent and, where appropriate, a dye; 3. primary and secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, amongst others, the possibility of restriction to professional use only, setting an upper limit to the package size and laying down obligations to use tamper resistant and secured bait boxes.
(Z,E)-tetradeca-9, 12-dienyl acetate	(9Z,12E)-Tetradeca-9, 12-dien-1-yl acetate EC No: n.a. CAS No: 30507-70-1	977 g/kg	1 February 2013	31 January 2023	19	When assessing an application for authorisation of a product in accordance with Articles 11 and 17 OBP, the assessment authorities shall assess, when relevant for the particular product, those uses or exposure scenarios and those risks to human populations and environmental compartments that have not been representatively addressed in the EU level risk assessment. Authorisation is subject to the following conditions: Labels for biocidal products containing (Z,E)- tetradeca-9,12-dienyl acetate shall indicate that those products

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						shall not be used in spaces where un-packaged food or feed is kept.
Zineb	IUPAC Name: Zinc ethylenebis(dithiocarbamate) (polymeric) EC No: 235-180-1 CAS No: 12122-67-7	940 g/kg	1 January 2016	31 December 2025	21	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. Persons making products containing zineb available on the market for non-professional users shall make sure that the products are supplied with appropriate gloves. Authorisations are subject to the following conditions: 1. For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. 2. Labels and, where provided, instructions for use shall indicate that children shall be kept away until treated surfaces are dry. 3. Labels and, where provided, safety data sheets of products authorised shall indicate that application, maintenance and repair activities shall be conducted within a contained area, on impermeable hard standing with bunding or on soil covered with an impermeable material to prevent losses and minimise emissions to the environment, and that any losses or waste containing zineb shall be collected for reuse or disposal. 4. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs according to the Xenobiotic

Common name	IUPAC[175] name Identification numbers	Minimum purity of the active substance in the biocidal product as placed on the market	Date of inclusion	Expiry date of inclusion	Product type	Specific provisions [176]
						Substances and Components Ordinance of 26 June 1995[232] (XCO) or Feedstuffs Book Ordinance of 26 October 2011[233] (FsBO) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. Where a treated article has been treated with or intentionally incorporates zineb, and where necessary due to the possibility of skin contact as well as the release of zineb under normal conditions of use, the person responsible for placing the treated article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012[234].

232 SR **817.021.23**
233 SR **916.307.1**
234 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.

Annex 3[235]
(Art. 2 para. 5)

Correspondences between expressions, legislation and individual provisions

For the correct interpretation of Regulation (EU) No 528/2012[236], to which reference is made in this Ordinance, the following correspondences between expressions, legislation and individual provisions apply:

1 Equivalent expressions

Expression used in EU legislation	Expression used in this Ordinance
Mixture	Preparation
Article	Object
Making available on the market	Placing on the market as defined in Article 4 paragraph 1 letter i of the Chemicals Act of 15 December 2000
Placing on the market	Placing on the market for the first time
Micro-organism	Microorganisms as defined in Article 2 paragraph 2 letter d
Letter of access	Letter of access as defined in Article 2 paragraph 2 letter e
Receiving/evaluating competent authority	Notification Authority/assessment authorities
Simplified authorisation procedure	Simplified authorisation

2 Swiss provisions corresponding to EU legislation cited in Regulation (EU) No 528/2012 and to individual EU provisions

EU legislation and individual provisions	Swiss legislation and individual provisions
Rules on the transport of dangerous goods	Regulations concerning transport by post, rail, road, air, water and pipelines

235 Amended by No II para. 1 of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
236 See footnote to Art. 1*b* para. 3.

EU legislation and individual provisions	Swiss legislation and individual provisions
Directive 98/24/EC	Legislation on the protection of workers
Directive 2004/37/EC	Legislation on the protection of workers
Directive 2008/98/EC	Technical Ordinance of 10 December 1990[237] on Wastes; Ordinance of 22 June 2005[238] on the Movement of Wastes
Regulation (EC) No 850/2004	Annexes 1.1, 1.9 and 1.16 ORRChem[239]
Regulation (EC) No 689/2008	PIC Ordinance of 10 November 2004[240]
Art. 31 of the REACH Regulation	Art. 53 ChemO[241]
Art. 59 of the REACH Regulation	Annex 7 ChemO
Art. 24 of the CLP Regulation	Art. 43 ChemO
Annex V to Regulation (EU) No 528/2012	Annex 10

237 SR **814.600**
238 SR **814.610**
239 SR **814.81**
240 SR **814.82**
241 SR **813.11**

Annex 4[242]

242 Repealed by No II para. 1 of the Ordinance of 28 Feb. 2007, with effect from 1 April 2007 (AS **2007** 851).

Annex 5[243]
(Art. 14 para. 2 let. a)

Application for authorisation A_L or A_{nL}

1 Documents concerning the product and the active substances

The following must be submitted to the Notification Authority together with the application for authorisation:

a. the documents concerning the biocidal product;

b. the documents concerning each active substance.

2 Dossier requirements

2.1 General provisions

1 The documents must be presented to the Notification Authority in the form of technical dossiers.

2 The requirements of the Annexes to Regulation (EU) No 528/2012[244] must be met in accordance with the latest scientific and technical developments.

2.2 Quantitative and qualitative requirements

1 The technical dossiers must contain the information specified in the following Annexes to Regulation (EU) No 528/2012:

a. concerning the product: as specified in Annex III; adaptation of the data requirements, and the statement of reasons for such adaptation, is subject to the rules set out in Annex IV;

b. concerning the active substances: as specified in Annex II; adaptation of the data requirements is subject to the rules set out in Annex IV.

2 Where Annexes II and III to Regulation (EU) No 528/2012 refer to other EC law for classification and labelling, Articles 35 and 38 of the present Ordinance apply.

3 If an active substance meets the exclusion criteria specified in Article 5 paragraph 1 of Regulation (EU) No 528/2012, evidence must be provided that the provisions concerning exceptions specified in Article 3 paragraph 2 of the present Ordinance are applicable.

243 Amended by No II para. 1 of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
244 See footnote to Art. 1*b* para. 3.

4 For biocidal products, a summary of the product characteristics must be presented in accordance with Article 20 paragraph 1 letter a point ii of Regulation (EU) No 528/2012.

5 Apart from the information specified in Article 17 paragraph 6, the Notification Authority may ask the applicant to provide the following documents:

a. the summary of the biocidal product characteristics, from the EU or EFTA authorities, in accordance with Article 22 of Regulation (EU) No 528/2012 and the assessment report with the authority's conclusions in accordance with Article 30 paragraph 3 of Regulation (EU) No 528/2012, or, for active substances, in accordance with Article 8 paragraph 1 of Regulation (EU) No 528/2012, insofar as they are accessible to the applicant;

b. samples of packaging, drafts for labelling and for leaflets, as well as a draft label.

6 The dossiers must include a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods.

7 They must be sufficient to permit an evaluation of the effects and properties referred to in Article 11.

2.3 Prescribed methods of detection and identification

1 Detection and identification must be carried out using the methods described in Regulation (EC) No 440/2008[245].

2 If a method is inappropriate or is not described, internationally recognised methods should be used as far as possible; these must be justified.

3 Detection and identification must be carried out, if applicable:

a. in accordance with Directive 2010/63/EU [246]; and

b. in compliance with the principles and requirements of Good Laboratory Practice specified in Article 34 paragraphs 4 and 5 of the ChemO[247].

4 Paragraph 3 does not apply to detection and identification tests which were started before 1 March 2000.

245 Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 142 of 31 May 2008, p. 1; last amended by Regulation (EC) No 260/2014, OJ L 81 of 19 March 2014, p. 1.

246 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276 of 20 October 2010, p. 33.

247 SR **813.11**

2.4 Other methods of detection and identification

1 Where detection and identification data exist that were generated before the commencement of this Ordinance by methods other than those laid down in Annex V to Directive 67/548/EEC[248], the adequacy of such data for the purposes of this Ordinance, or the need to conduct new detection and identification tests in accordance with to Regulation (EC) 440/2008, must be determined on a case-by-case basis.

2 Testing on vertebrates must be minimised.

3 Letter of access and reference

If the Notification Authority is already in possession of the complete documentation specified in Numbers 1 and 2, the applicant may:

a. submit a letter of access; or

b. if the data protection period specified in Article 28 has expired: make reference to the documentation.

4 Assessment and conclusions of an EU or EFTA Member State

With regard to a biocidal product containing an active substance not listed in Annex 1 or 2 or included in the list of notified active substances, the applicant may enclose the summary of the biocidal product characteristics in accordance with Article 22 paragraph 2 of Regulation (EU) No 528/2012 and the assessment report with the conclusions in accordance with Article 30 paragraph 3 of Regulation (EU) No 528/2012, or, for active substances, in accordance with Article 8 paragraph 1 of Regulation (EU) No 528/2012, from the competent authority of an EU or EFTA Member State.

248 See footnote to Art. 2 para. 2 let. a no 1.

Annex 6[249]
(Art. 14 para. 2 let. b)

Application for simplified authorisation

1 With the application for simplified authorisation, evidence must be provided to the Notification Authority that the conditions for the simplified procedure specified in Article 11*h* are met.

2 In addition to the information specified in paragraph 1, the dossiers for the biocidal product must contain the following details:

a. name and address of the applicant;

b. name and address of the manufacturer of the biocidal product and the active substances;

c. trade name of the biocidal product;

d. full composition of the biocidal product;

e. a summary of the biocidal product characteristics in accordance with Article 20 paragraph 1 letter a point ii of Regulation (EU) No 528/2012[250];

f. efficacy data;

g. justified proposals for classification and labelling, as well as information concerning the packaging as specified in Articles 35, 36 and 37;

h. if necessary, proposal for the safety data sheet in accordance with Article 40.

3 The Notification Authority may ask the applicant to provide the following additional documents:

a. assessment reports from EU or EFTA authorities concerning the product and the active substances, if such reports are available and accessible to the applicant;

b. samples of packaging, drafts for labelling and for leaflets, as well as a draft label.

249 Amended by No II para. 1 of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
250 See footnote to Art. 1*b* para. 3.

Annex 7[251]
(Art. 14 para. 2 let. c and Art. 14*a*)

Application for recognition of an authorisation

1 The following documents must be submitted together with the application for recognition of an authorisation:

a. for recognition of an authorisation granted by an EU or EFTA Member State:
   1. a copy of the authorisation granted by the EU or EFTA Member State,
   2. assessment reports from EU or EFTA authorities concerning the authorisation of the biocidal product, if they are accessible to the applicant,
   3. a letter of access for the active substances contained in the biocidal product;

b. for recognition of a Union authorisation:
   1. a summary of the biocidal product characteristics in accordance with Article 20 paragraph 1 letter a point ii of Regulation (EU) No 528/2012[252],
   2. a letter of access for the active substances contained in the biocidal product,
   3. assessment reports from EU or EFTA authorities or the ECHA opinion concerning the authorisation of the biocidal product, if they are accessible to the applicant.

2 The following documents must be submitted together with the application for recognition in parallel in accordance with Article 34 of Regulation (EU) No 528/2012:

a. the name of the EU or EFTA Member State which carries out the initial assessment (reference Member State);

b. a summary of the biocidal product characteristics in accordance with Article 20 paragraph 1 letter a point ii of Regulation (EU) No 528/2012;

c. a letter of access for the active substances contained in the biocidal product.

3 In addition to the documents specified in paragraph 2, the following documents must be submitted directly upon receipt:

a. the draft assessment report and the draft summary of the biocidal product characteristics;

b. the final assessment report and summary of the biocidal product characteristics.

251 Amended by No II para. 1 of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
252 See footnote to Art. 1*b* para. 3.

[4] The Notification Authority may request from the applicant, for the biocidal product and the active substances contained therein, the documents specified in Annexes II, III and IV to Regulation (EU) No 528/2012.

Annex 7bis [253]

[253] Inserted by No II para. 3 of the Ordinance of 22 April 2009 (AS **2009** 1759). Repealed by No II para. 3 of the Ordinance of 20 June 2014, with effect from 15 July 2014 (AS **2014** 2073).

Annex 8[254]
(Art. 14 para. 2 let. d)

Application for authorisation A_N

1 Documents concerning the applicant, the manufacturer and the product

1.1 General

The application documents must contain the following details:

a. name and address of the applicant;

b. name and address of the manufacturer of the biocidal product and the active substances;

c. trade name of the biocidal product;

d. full composition of the biocidal product;

e. list of the active substances contained in the biocidal product;

f. information on physical and chemical properties, and toxicology and ecotoxicology data;

g. information about certain active substances (Number 2);

h. assignment of the biocidal product to product type and field of use;

i. categories of users;

j. proposals and justification for classification and labelling, as well as information concerning the packaging, in accordance with Articles 35, 36 and 38;

k. if required, proposals for the safety data sheet in accordance with Article 40;

l. information concerning disposal;

m. for disinfectants and wood preservatives: evidence that the biocidal product is sufficiently effective for the intended uses.

1.2 …[255]

2 Additional documents

[1] The Notification Authority may ask the applicant to provide the following additional documents:

254 Amended by No II para. 1 of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).
255 Comes into force on 1 Sep. 2015.

a. test reports, scientific opinions or publications or other papers which support the information specified in Number 1;

b. information specified in Annex II to Regulation (EC) No 1896/2000[256];

c. in justified cases, information on exposure levels for the public and the operator or for the environment;

d. samples of packaging, drafts for labelling and for leaflets, as well as a draft label.

2 The documents must include a detailed and full description of the studies conducted and of the methods used or a bibliographical reference to those methods.

3 Methods of detection and identification

3.1 Prescribed methods of detection and identification

1 As a general rule, detection and identification must be carried out using the methods described in Regulation (EC) No 440/2008[257].

2 If a method is inappropriate or is not described, internationally recognised methods should be used as far as possible; these must be justified.

3 Detection and identification must be carried out, if applicable:

a. in accordance with Directive 2010/63/EU[258]; and

b. in compliance with the principles and requirements of Good Laboratory Practice specified in Article 34 paragraphs 4 and 5 of the ChemO[259].

4 Paragraph 3 does not apply to detection and identification tests which were started before 1 March 2000.

3.2 Other methods of detection and identification

1 Where detection and identification data exist that were generated before the commencement of this Ordinance by methods other than those laid down in Annex V to Directive 67/548/EEC[260], the adequacy of such data for the purposes of this Ordinance, or the need to conduct new detection and identification tests in accordance with Regulation (EC) 440/2008, must be determined on a case-by-case basis.

2 Testing on vertebrates must be minimised.

256 Commission Regulation (EC) No 1896/2000 of 7 September 2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products, OJ L 228 of 8 September 2000, p. 6; last amended by Regulation (EC) No 2032/2003, OJ L 307 of 24 November 2003, p. 1.
257 See footnote to Annex 5 No. 2.3 para. 1.
258 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ L 276 of 20 October 2010, p. 33.
259 SR **813.11**
260 See footnote to Art. 2 para. 2 let. a no 1.

Annex 8a[261]
(Art. 14 para. 2 let. e)

Application for authorisation for parallel trade

1 The application for authorisation for parallel trade must contain the following information:

a. name and authorisation number of the biocidal product in the country of origin;

b. name and address of the competent authority of the country of origin;

c. name and address of the authorisation holder in the country of origin;

d. original label and instructions for use with which the biocidal product is placed on the market in the country of origin, if this is considered by the Notification Authority to be necessary for the evaluation;

e. name and address of the applicant;

f. name to be given to the biocidal product which is to be placed on the market;

g. a draft label for the biocidal product intended to be placed on the market, in two official languages;

h. a sample of the biocidal product which is to be imported, if this is considered necessary by the Notification Authority;

i. name and authorisation number of the reference product.

2 The Notification Authority may require a translation of the relevant parts of the original instructions for use referred to in paragraph 1 letter d.

261 Inserted by No II para. 4 of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

Annex 9[262]

[262] Repealed by No II para. 3 of the Ordinance of 20 June 2014, with effect from 15 July 2014 (AS **2014** 2073).

Annex 10[263]
(Art. 2 para. 1 let. b, Art. 4 para. 1 and Art. 50 para. 3 let. a, and Annexes 6–8)

Product types

Main group 1: Disinfectants

These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

Product type 1: Human hygiene biocidal products

Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.

Product type 2: Disinfectants and algaecides not intended for direct application to humans or animals

a. Products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, *inter alia*, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities.

b. Products used for disinfection of air, water not used for human or animal consumption, chemical toilets, waste water, hospital waste and soil.

c. Products used as algaecides for treatment of swimming pools, aquariums and other waters and for remedial treatment of construction materials.

d. Products used to be incorporated in textiles, tissues, masks, paints and other objects or materials with the purpose of producing treated articles with disinfecting properties.

Product type 3: Veterinary hygiene biocidal products

a. Products used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with antimicrobial function.

b. Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.

Product type 4: Food and feed area biocidal products

a. Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport,

263 Amended by No II para. 1 of the Ordinance of 20 June 2014, in force since 15 July 2014 (AS **2014** 2073).

storage or consumption of food or feed or drinks (including drinking water) for humans and animals;

b. Products used to be incorporated into materials which may enter into contact with food.

Product type 5: Drinking water disinfectants

Products used for the disinfection of drinking water for both humans and animals.

Main group 2: Preservatives

Unless otherwise stated, these product types include only products to prevent microbial and algal development.

Product type 6: Preservatives for products during storage

a. Products used for the preservation of manufactured products, other than foodstuffs, feedingstuffs, cosmetics, medicinal products or medical devices, by the control of microbial deterioration to ensure their shelf life;

b. Products used as preservatives for the storage or use of rodenticide, insecticide or other baits.

Product type 7: Film preservatives

Products used for the preservation of films or coatings by the control of microbial deterioration or algal growth in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers and art works.

Product type 8: Wood preservatives

Products used for the preservation of wood, from and including the sawmill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects.

This product-type includes both preventive and curative products.

Product type 9: Fibre, leather, rubber and polymerised materials preservatives

a. Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration.

b. This product type includes substances which antagonise the settlement of microorganisms on the surface of materials and therefore hamper or prevent the development of odour or offer other kinds of benefits.

Product type 10: Construction material preservatives

Products used for preservation of masonry, composite materials or other construction materials other than wood by the control of microbiological and algal attack.

Product type 11: Preservatives for liquid-cooling and processing systems

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Products used for the disinfection of drinking water or of water for swimming pools are not included in this product type.

Product type 12: Slimicides

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood or paper pulp, porous sand strata in oil extraction.

Product type 13: Working or cutting fluid preservatives

Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.

Main group 3: Pest control

Product type 14: Rodenticides

Products used for the control of mice, rats or other rodents, by means other than repulsion or attraction.

Product type 15: Avicides

Products used for the control of birds, by means other than repulsion or attraction.

Product type 16: Molluscicides, vermicides and products to control other invertebrates

Products used for the control of molluscs, worms and invertebrates not covered by other product-types, by means other than repulsion or attraction.

Product type 17: Piscicides

Products used for the control of fish, by means other than repulsion or attraction.

Product type 18: Insecticides, acaricides and products to control other arthropods

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction.

Product type 19: Repellents and attractants

Products used to control harmful organisms (invertebrates such as fleas; vertebrates such as birds, fish and rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals.

Product type 20: Control of other vertebrates

Products used for the control of vertebrates other than those already covered by the other product types of this main group, by means other than repulsion or attraction.

Main group 4: Other biocidal products

Product type 21: Antifouling products

Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.

Product type 22: Embalming and taxidermist fluids

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.