Ordinance on the reorganisation of secondary national legislation on biocidal products[[1]](#footnote-1)))[[2]](#footnote-2)))

Of 18 August 2021

On the basis of

* § 12h(1)(1) and (2)(2), § 14(1)(3)(a) in conjunction with paragraph 3 of the Chemicals Act [Chemikaliengesetz] in the version published on 28 August 2013 (Federal Law Gazette (BGBl.) I pp. 3498, 3991),
* of § 17(1)(1)(c) and (2)(c) and (d), each also in conjunction with paragraph 3, and of § 28(11) of the Chemicals Act, after a consultation with stakeholders,

of which § 14(1) was amended by Article 1(6)(a) of the Act of 18 July 2017 (BGBl. I p. 2774), § 17(1)(1)(c) by Article 1(8)(a) of the Act of 18 July 2017 (BGBl. I p. 2774), § 17(3)(1) by Article 1(8)(b) and § 28(11)(1) by Article 1(10)(b) of the Act of 18 July 2017 (BGBl. I p. 2774), the Federal Government decrees:



Ordinance on the notification and supply of biocidal products and on the implementation of Regulation (EU) No 528/2012

(Ordinance implementing the law on biocidal products – ChemBiozidDV)

* + - 2. Area of application; definitions

Scope of application

This Ordinance applies to biocidal products within the meaning of § 3(11) of the Chemicals Act in the version published on 28 August 2013 (BGBl. I p. 3498, 3991), last amended by Article 1 of the Act of 3 June 2021 (BGBl. I p. 1479).

Definitions

The following definitions shall be used for the purposes of this Ordinance:

* + - 1. supply: delivery or dispatch to the purchaser or the receiving person,
      2. person responsible for the handover: a natural person who undertakes the direct supply,
      3. purchaser: a natural person or legal entity that assumes ownership of, or the power of disposal over, goods as a result of supply,
      4. receiving person: a natural person commissioned by the purchaser who accepts the goods during the supply process,
      5. importer: a natural person or legal entity or an association of persons with no legal capacity who introduces a biocidal product within the scope of this Ordinance; this does not refer to an importer who merely carries out a transit operation under customs supervision, provided that no processing or treatment takes place.

The definitions set out in Article 3(1) and (2) of 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, 27.6.2012, p. 1; L 303, 20.11.2015, p. 109; L 280, 28.10.2017, p. 57), as last amended by Regulation (EU) 2019/1825 of 8 August 2019 (OJ L 279, 31.10.2019, p. 19), in the currently applicable version, also apply.

* + - 2. Notification of biocidal products

Application and indication of the registration number

* + 1. Biocidal products that are subject to the transitional provision under § 28(8)(1) of the Chemicals Act may be made available on the market within the scope of this Ordinance only if the biocidal product bears the registration number issued by the Federal Office for Chemicals for the biocidal product in accordance with § 5. Registration numbers issued in accordance with § 4(3) of the Ordinance on notification of biocidal products of 24 May 2005 (BGBl. I p. 1410) in the version in force until 13 May 2010 or in accordance with § 3(2)(4) of the Ordinance on notification of biocidal products of 14 June 2011 (BGBl. I p. 1085) shall be considered registration numbers within the meaning of § 5.
    2. Biocidal products referred to in paragraph 1 may only be offered for sale online or otherwise for dispatch within the scope of this Ordinance if the offer includes the registration number.

Notification of a biocidal product

* + 1. Any person who, as a manufacturer or importer of a biocidal product or by using his or her own trade name, makes a biocidal product, for which under § 3(1), a registration number is required, available on the market for the first time, shall notify the Federal Office for Chemicals of the biocidal product together with the information specified in paragraph 2 (those subject to the notification obligation). The notification shall be made using the electronic form made available on the website of the Federal Institute for Occupational Safety and Health. The notification may be made by an authorised representative domiciled in Germany. Once a notification is made, a request for a registration number to be issued is submitted at the same time.
    2. The notification must contain the following information:
       1. the trade name of the biocidal product,
       2. the name, address and e-mail address of those subject to the notification obligation and, if different, the name, address and e-mail address of the manufacturer,
       3. the product types pursuant to Annex V of Regulation (EU) No 528/2012 to which the biocidal product is to be assigned, and
       4. the description of biocidal active substances contained in the biocidal product, specifying
          1. the concentration of the active substance, and
          2. if available,

the Chemical Abstract Service number (CAS number) corresponding to the entry in Annex II to Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1; L 198, 28.7.2015, p. 28), as last amended by Commission Delegated Regulation (EU) 2019/227 of 28 November 2018 (OJ L 37, 8.2.2019, p. 1; L 249, 26.9.2019, p. 39), in the currently applicable version; and

the EC number corresponding to the entry in Annex II to Delegated Regulation (EU) No 1062/2014,

* + - 1. the date of submission of an application referred to in § 28(8)(2)(2) or (3) of the Chemicals Act and the corresponding case number assigned when the application was submitted, if such an application was submitted,
      2. for the product type or product types to which the biocidal product belongs, an indication of who, in accordance with the listing referred to in Article 95(1)(1) of Regulation (EU) No 528/2012, is acting as a
         1. substance supplier of the active substance of which the biocidal product consists, which it contains or which it produces, or
         2. product supplier of the biocidal product,
      3. confirmation that the biocidal product has the effect attributed to it by the product name, the instructions for use or the product advertising.

Issuance of the registration number

The Federal Office for Chemicals shall issue the registration number within 30 days of notification at the latest, provided that

* + - 1. the notification contains the information referred to in § 4(2),
      2. the biocidal product may be made available on the market at the time of the decision to issue the registration number in accordance with § 28(8)(2) of the Chemicals Act for all product types specified in the notification,
      3. the substance supplier or product supplier for the biocidal product specified in the notification is included in the list referred to in Article 95(1)(1) of Regulation (EU) No 528/2012 along with the product type or product types of the biocidal product, and
      4. all product types mentioned in the notification
         1. correspond to the product types set out in Annex II to Delegated Regulation (EU) No 1062/2014 for the active substance concerned, provided that the active substance is listed therein, or
         2. correspond to the product types for which the active substance concerned has been included in the review programme in accordance with Article 18 of Delegated Regulation (EU) No 1062/2014.

The registration number referred to in sentence 1 may be issued entirely by automatic means.

Update and confirmation of the notification

* + 1. Those subject to the obligation to notify under § 4 (1)(1) shall update the notification without delay if any of the information referred to in § 4(2) changes. The update must be carried out electronically using the form provided by the Federal Institute for Occupational Safety and Health on its website.
    2. Those subject to the obligation to notify under § 4 (1)(1) shall confirm the accuracy of the information in the notification to the Federal Office for Chemicals electronically by the end of the day on 31 March of the second calendar year following the notification and every two calendar years thereafter by the end of the day on 31 March in each case. Before submission of the confirmation, the information must be reviewed and, where necessary, updated. If the data are not confirmed within the period specified in sentence 1, the party subject to the obligation to notify may not make the biocidal product available on the domestic market until he or she has confirmed the data.
    3. The update and confirmation may also be carried out by an authorised representative domiciled in Germany.

Electronic register

* + 1. The Federal Office for Chemicals provides an electronic list of biocidal products for which a registration number has been issued on the website of the Federal Institute for Occupational Safety and Health.
    2. The list shall contain the information referred to in § 4(2)(1) to (5) and (7) from the information provided by the applicant.

Transfer of information to the federal state authorities

If a party subject to the obligation to notify under § 4(1)is no longer permitted to place the biocidal product on the market due to lack of confirmation under § 6(2)(1), the Federal Office for Chemicals shall inform the competent supervisory authorities of the federal states accordingly.

* + - 2. Provisions on the supply of biocidal products

Validity of restrictions on supply authorisation

If the authorisation of a biocidal product stipulates that the biocidal product may only be used by certain persons, the product may also only be supplied to these persons. This does not apply to sales to resellers.

Self-service ban

* + 1. The following biocidal products may only be offered and supplied in a form in which the purchaser does not have free access to the biocidal product:
       1. Biocidal products, where one or more uses of these products are not authorised to the general public according to the labelling specified by the authorisation.
       2. Biocidal products that do not fall under subparagraph 1, and that are classified under the following product types in Annex V to Regulation (EU) No 528/2012:
          1. Product type 14 ‘Rodenticides’ (products used for the control of mice, rats or other rodents, by means other than repulsion or attraction),
          2. 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), and
          3. 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).
    2. Biocidal products that do not fall under paragraph 1 and that are to be assigned to the following product types of Annex V to Regulation (EU) No 528/2012 may only be offered and supplied if it is ensured by organisational measures that, prior to the conclusion of the sales contract by a person who fulfils the requirements of § 13, an informational talk upon supply of the goods including the contents of § 11(2)(2) takes place and that § 11(2)(1) is complied with:
       1. 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, art works),
       2. Product type 8 ‘Wood preservatives’ (products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects) and
       3. Product type 10 ‘Construction material preservatives’ (products used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of microbiological, and algal attack).
    3. Paragraphs 1 and 2 shall not apply to biocidal products that are authorised under the simplified authorisation procedure under Article 25 of Regulation (EU) No 528/2012. A supply meeting pursuant to paragraph 2 shall not be required if the person responsible for the handover the biocidal product is already aware, or the purchaser provides evidence by submitting appropriate documentation, that the use of the biocidal product is a part of the professional activities of the purchaser.

Requirements for the person responsible for the handover, supply meeting

* + 1. Biocidal products under § 10(1) may only be supplied by a person that is employed by the company and who fulfils the qualification requirements pursuant to § 13.
    2. Biocidal products under § 10(1) may only be supplied if
       1. the person responsible for the handover is aware, or has obtained confirmation from the purchaser, or been provided with evidence through the submission of the appropriate documentation, that the purchaser belongs to the category of users specified in the authorisation and intends to use the biocidal products in an appropriate and proper manner,
       2. in the case of biocidal products under § 10(1)(2),the person responsible for the handover has informed the purchaser during the supply meeting about
          1. possible preventive measures to control harmful organisms and possible alternative low-risk measures,
          2. the intended and appropriate use of the biocidal product in accordance with the instructions for use, in particular concerning prohibitions and restrictions,
          3. the risks associated with the use of the biocidal product and possible measures to mitigate the risks,
          4. the precautionary measures required when the substance or mixture is used as intended and in the event of unforeseen spillage or release, as well as
          5. proper storage and proper disposal.
    3. Further provisions pursuant to the Chemical Prohibition Ordinance [Chemikalien-Verbotsverordnung] remain unaffected.

Requirements for supply in online and mail order trade

If the supply takes place in online trade or otherwise by mail order, § 10(2) and § 11 (2) shall apply with the stipulation that technical or organisational measures shall be taken to ensure that, before the conclusion of the contract of sale of the biocidal product

* + - 1. compliance with the requirements of § 11(2)(1) has been verified by a qualified person in accordance with § 13, and
      2. a telephone conversation or a conversation via video transmission in accordance with § 11(2)(2) has been demonstrably conducted by a qualified person in accordance with § 13.

Qualifications for supply

* + 1. A qualified person in accordance with § 11 for the supply of biocidal products refers to a person who fulfils the requirements under:
       1. § 11 (1)(1) and (2), also in conjunction with paragraph 3 of the Chemical Prohibition Ordinance of 20 January 2017 (BGBl. I, p. 94; 2018 I p. 1389), as last amended by Article 300 of the Ordinance of 19 June 2020 (BGBl. I p. 1328), in the currently applicable version, provided that the qualifications also cover the supply of biocidal products,
       2. § 9 (1)(4) of the Plant Protection Act [Pflanzenschutzgesetz] of 6 February 2012 (BGBl. I p. 148, 1281), last amended by Article 19 of the Act of 27 July 2021 (BGBl. I p. 3146), in the currently applicable version, in conjunction with the Ordinance Governing Specialist Qualifications in Plant Protection [Pflanzenschutz-Sachkundeverordnung] of 27 June 2013 (BGBl. I p. 1953), as last amended by Article 376 of the Ordinance of 31 August 2015 (BGBl. I p. 1474), in the currently applicable version, provided that it can be demonstrated that a training course pursuant to § 11(1)(2) of the Chemical Prohibition Ordinance, that imparts knowledge of biocidal products, was attended for the first time or repeated and that the course was not attended longer in the past than the period specified in § 11(1)(2) of the Chemical Prohibition Ordinance, or
       3. § 15c(3) in conjunction with Annex I(4.4) of the Hazardous Substances Ordinance [Gefahrstoffverordnung] of 26 November 2010 (BGBl. I pp. 1643, 1644), as last amended by Article 2 of the Ordinance of 21 July 2021 (BGBl. p. 3115), provided that the qualifications relate to the product type to which the biocidal product supplied is to be assigned.
    2. Evidence of the professional qualifications or acquired competence issued in other Member States of the European Union or other contracting parties of the Agreement on the European Economic Area shall meet the requirements set out in paragraph 1 insofar as the authority responsible for recognising equivalence has established this equivalence.

       2. Provisions on the authorisation of biocidal products

Restrictions on the authorisation of certain types of biocidal products

* + 1. Applications for authorisation for biocidal products of Product type 15 (avicides), 17 (piscicides) and 20 (control of other vertebrates) of Annex V to Regulation (EU) No 528/2012 are generally to be rejected for animal welfare reasons. The competent authority may, by way of exception, grant authorisation in individual cases in order to protect overriding public interests. When deciding on an exceptional authorisation, particular consideration shall be given to the following, applying a rigorous standard:
       1. whether the control of the vertebrate species concerned using a biocidal product is absolutely necessary, and
       2. the extent to which effects on non-target organisms are avoided.

The authorisation shall be limited to use by trained professional users.

* + 1. Paragraph 1 also applies to applications for mutual recognition under Article 32 of Regulation (EU) No 528/2012.

Restrictions on the authorisation of biocidal products based on certain active substances

Biocidal products containing active substances that meet an exclusion criterion under Article 5(1) of Regulation (EU) No 528/2012 shall only be authorised for use by trained professional users, unless an authorisation for further categories of users is required on the basis of the conditions referred to in Article 5(2)(1)(b) and (c) of Regulation (EU) No 528/2012.

* + - 2. Obligation to notify

Notification of biocidal products made available on the market

* + 1. Someone who, as manufacturer or importer, makes a biocidal product available on the market for the first time within the scope of this Ordinance, or exports a biocidal product manufactured within the scope of this Ordinance, shall notify the following to the Federal Office for Chemicals annually by the end of the day on 31 March for the preceding calendar year:
       1. the nature and quantity of the biocidal products which he or she has supplied to recipients that reside or are domiciled in the country, or products which he or she has exported, and
       2. the active substances contained in the biocidal products supplied or exported.
    2. The notification shall be made separately for each biocidal product and shall indicate
       1. the trade name,
       2. the registration number in accordance with § 3(1) and
       3. the case number assigned at the time of application or the authorisation number in accordance with Article 22(2)(d) of Regulation (EU) No 528/2012.
    3. The notification shall be made in electronic form using a form provided by the Federal Office for Chemicals on the website of the Federal Institute for Occupational Safety and Health.

       2. Final provisions

Criminal offences and administrative offences

* + 1. A regulatory offence within the meaning of § 26(1)(7)(b) of the Chemicals Act is committed by any party that wilfully or negligently
       1. contrary to § 3(2) or § 10 (1) or (2) offers a biocidal product or
       2. contrary to
          1. § 9 (1), § 10 (1) or § 11(1) or
          2. § 10 (2)or § 11(2),in each case in conjunction with § 12,

supplies a biocidal product.

* + 1. A regulatory offence within the meaning of § 26(1)(10a) of the Chemicals Act is committed by any party that wilfully or negligently
       1. contrary to § 3(1) sentence 1, also in conjunction with sentence 2, or contrary to § 6(2) sentence 3, makes a biocidal product available on the market,
       2. contrary to § 4(1) sentence 1 fails to notify a biocidal product, or does not do so correctly, in full or in good time, or
       3. contrary to § 6(1) sentence 1fails to update a notification, or does not do so correctly, in full or in good time.
    2. Any person who, by an intentional act as referred to in paragraph 1, endangers the life or health of another individual, or the property of significant value belonging to another individual is liable to prosecution under § 27(2) of the Chemicals Act.

Transitional provisions

* + 1. The provisions of Section 2 shall first apply as of 1 January 2022.
    2. For biocidal products which were notified to the Federal Office for Chemicals before 26 August 2021, confirmation according to § 6(2) shall be made for the first time by the end of 31 March 2022, citing all the information referred to in § 4(2).
    3. § 10 to § 13 shall first apply as of 1 January 2025.



Entry into force, abrogation

* + 1. This Ordinance shall, subject to paragraph 2, enter into force the day after promulgation. At the same time, the Biocidal product authorisation ordinance of 4 July 2002 (BGBl. I p. 2514), as amended by Article 15 of the Act of 22 August 2006 (BGBl. I p. 1970) shall cease to apply.
    2. § 13 (1)(3)shall enter into force on the day following promulgation of the Ordinance amending the biomaterials ordinance and other occupational health and safety ordinances of 21 July 2021 (BGBl. I p. 3115).
    3. The Ordinance on notification of biocidal products of 14 June 2011 (BGBl. I p. 1085) shall cease to apply on 31 December 2021.

The Bundesrat has granted its approval.

1. ) This Ordinance serves to implement Regulation (EC) 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, 27.6.2012, p. 1; L 303 20.11.2015, p. 109; L 280 of 28.10.2017, p. 57), last amended by Regulation (EU) 2019/1825 of 8 August 2019 (OJ L 279, 31.10.2019, p. 19). [↑](#footnote-ref-1)
2. ) Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1). [↑](#footnote-ref-2)