1. ------IND- 2021 0042 D-- EN- ------ 20210223 --- --- PROJET

Draft Bill

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

Ordinance on the reorganisation of secondary national legislation on biocidal products

А. Problem and objective

The Ordinance aims to ensure a high level of protection of human and animal health as well as of the environment from the effects of biocidal products by improving the practical application of Regulation (EU) No 528/2012 in Germany through accompanying provisions. Regulation (EU) No 528/2012 contains directly applicable provisions of Union law, in particular on the authorisation and labelling of biocidal products. With regard to the use of biocidal products, it only contains general principles, and no specific provisions. Biocidal products are intended to kill or otherwise control harmful organisms. Due to this intended effect, biocidal products pose a high potential risk to human health, to non-target organisms and to the environment, which in principle also applies to products for which authorisation has been granted. The anticipated adverse effects based on this potential risk must be countered by ensuring the implementation of (or compliance with) the conditions of use contained in the authorisation. The provisions on the supply of biocidal products take this objective into account by providing information to the purchaser with a view to improving compliance with use-related requirements. In addition, the existing provisions of the Ordinance on notification of biocidal products [Biozid-Meldeverordnung] and the Biocidal product authorisation ordinance [Biozid-Zulassungsverordnung] are outdated and need to be adapted.

B. Solution

For the first time, the Ordinance lays down national provisions on the supply of biocidal products, the primary purpose of which is to ensure compliance with the substantive requirements of the authorisations for biocidal products, in particular the restrictions on supply contained therein. The unrestricted supply of certain biocidal products to the general public is a matter of concern due to the risk posed to human health and the environment. The introduction of compulsory talks by qualified personnel upon the supply of biocidal products is intended to inform the consumer about the risks of using biocidal products in order to ensure proper use of the products and to avoid any unnecessary applications. The existing secondary legislation of the Biocidal product authorisation ordinance and the Ordinance on notification of biocidal products will be merged with the new provisions to create a single uniform statutory instrument (Ordinance implementing the law on biocidal products [Biozidrechts-Durchführungsverordnung]). The provisions of the Ordinance on notification of biocidal products are to be adapted to the current legal status as well as further developed. The provisions of the Biocidal product authorisation ordinance can largely be repealed without replacement.

C. Alternatives

None.

D. Budgetary expenditure exclusive of compliance costs

At the Federal Institute of Occupational Safety and Health (BAuA), one-off budgetary costs of EUR 40 000 will be incurred for the adaptation of existing IT systems and the development of a new database.

The additional costs incurred by the Federal Government are to be fully and permanently offset directly, financially and in terms of staffing by the ministries concerned, within the framework of existing appropriations.

E. Compliance costs

E.1 Compliance costs for citizens

Citizens shall not incur any additional compliance costs.

E.2 Compliance costs for businesses

For businesses, annual compliance costs of around EUR 20.4 million and one-off compliance costs of around EUR 94 million arise. In accordance with the ‘one in, one out’ principle, the annual compliance costs are offset by savings already produced by the Federal Ministry for the Environment.

Administrative costs associated with obligations to provide information

Of the calculated compliance costs, EUR 348 000 are attributable to administrative costs arising from obligations to provide information.

E.3 Compliance costs for administrations

Administration will incur annual compliance costs amounting to approximately EUR 35 000. Of this amount, approximately EUR 2 000 is allocated to the federal level and approximately EUR 33 000 to the regional level. In addition, there are one-off conversion costs of EUR 653 000 for the federal states.

F. Further costs

Minor cost-induced individual price adjustments cannot be ruled out. Effects on general price levels, in particular on the consumer price level, are not to be expected, however.

Draft Bill of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

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

Оf [date]

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), § 17(1)(1)(c) by Article 1(8)(a), § 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:

Article 1

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)

Section 1

* + - 1. 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, No 3991), last amended by Article 4 of the Act of 23 October 2020 (BGBl. I p. 2232).

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 substance, mixture or product within the scope of this Act; 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.

Section 2

* + - 1. 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.
		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, importer of a biocidal product or by using his or her own trade name, makes a biocidal product available on the market for the first time within the scope of this Ordinance for which a registration number is required under § 3(1), 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 28.11.2018 (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 the 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 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,
			2. 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
			3. all product types mentioned in the notification
				1. 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. 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.

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. Access to the list is free of charge.
		2. The list shall contain at least the information referred to in § 4(2).

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.

Section 3

* + - 1. 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 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), as last amended by Article 300 of the Ordinance of 19 June 2020 (BGBl. I S. 1328), in the currently applicable version, provided that the qualifications also covers the supply of biocidal products, or
			2. § 9(1)(4) of the Plant Protection Act [Pflanzenschutzgesetz] of 6 February 2012 (BGBl. I p. 148, 1281), last amended by Article 278 of the Ordinance of 19 June 2020 (BGBl. I p. 1328), 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,
			3. § 15b(1) in conjunction with Annex I(3.4) 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 [insert: date of issue and reference to the Ordinance amending the Biological Substances Ordinance and other Ordinances on Occupational Health and Safety [Arbeitsschutzänderungsverordnung – ArbSchÄndV], 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.

Section 4

* + - 1. Provisions on the authorisation of biocidal products

Prohibition of the authorisation of certain types of biocidal products

* + 1. Authorisation of the following biocidal products is not permitted:
			1. Biocidal products of product type 15 ‘Avicides’ of Annex V to Regulation (EU) No 528/2012,
			2. Biocidal products of product type 17 ‘Piscicides’ of Annex V to Regulation (EU) No 528/2012, and
			3. Biocidal products of product-type 20 ‘Control of other vertebrates’ of Annex V to Regulation (EU) No 528/2012.
		2. No mutual recognition under Article 32 of Regulation (EU) No 528/2012 shall be granted in respect of the biocidal products referred to in paragraph 1.

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.

Section 5

* + - 1. Obligation to notify

Notification of biocidal products made available on the market

* + 1. Someone who, as manufacturer, importer or by using his or her own trade name, 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 report 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.

Section 6

* + - 1. 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. offers a biocidal product in violation of § 3(2),
			2. supplies a biocidal product in violation of § 9(1), § 10(2) in conjunction with § 12(1) or (2) or § 11(1) or (2), each also in conjunction with § 12(1) or (2), or
			3. offers or supplies a biocidal product in violation of § 10(1) or (2),.
		2. A regulatory offence within the meaning of § 26(1)(10a) of the Chemicals Act is committed by any party which wilfully or negligently
			1. makes a biocidal product available on the market in violation of § 3(1)(1) or § 6(2)(3),
			2. fails to notify of a biocidal product, or does not do so correctly, in full or in good time, in violation of § 4(1)(1),,
			3. fails to update a notification, or does not do so correctly, in full or in good time, in violation of § 6(1)(1),, or
			4. fails to confirm the information, or fails to do so correctly or promptly, in violation of § 6(2)(1),.
		3. 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 belonging of value of another individual is liable to prosecution under § 27(2) of the Chemicals Act.

Transitional provision

* + 1. The provisions of Section 2 shall first apply as of 1 January 2022.
		2. For biocidal products that have been notified before [insert: date of entry into force of this Act] to the Federal Office for Chemicals, the confirmation pursuant § 6(2) shall first be made after 31 March 2022.
		3. § 10 to § 13 shall first apply as of 1 January 2025.

Article 2

Entry into force, abrogation

* + 1. This Ordinance shall enter into force on the day following its 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. 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.

Explanatory notes

A. General part

1. Objective of and need for the provisions

The Ordinance aims to ensure a high level of protection of human and animal health as well as of the environment from the effects of biocidal products by improving the practical application of Regulation (EU) No 528/2012 in Germany through accompanying provisions. Biocidal products are intended to kill or otherwise control harmful organisms; because of this mode of action, they present a high potential risk to human health, non-target organisms and the environment, which is often a persistent issue even after authorisation has been granted. The anticipated adverse effects based on this potential risk must be countered by ensuring the implementation of (or compliance with) the conditions of use contained in the authorisation. The provisions on the supply of biocidal products take this objective into account by providing information to the purchaser with a view to improving compliance with use-related requirements. In addition, the existing provisions of the Ordinance on notification of biocidal products [Biozid-Meldeverordnung] and the Biocidal product authorisation ordinance [Biozid-Zulassungsverordnung] are outdated and need to be adapted.

1. Main content of the draft

For the first time, the Ordinance implementing the law on biocidal products lays down national provisions on the supply of biocidal products, the primary purpose of which is to ensure compliance with the substantive requirements of the authorisations for biocidal products, in particular the restrictions on supply contained therein. This is because a positive decision for authorisation, which certifies that a biocidal product has no unacceptable effects on health and the environment, is based on the assumption that certain restrictions on use, such as a restriction of use to indoor areas, are actually complied with. Unrestricted supply of biocidal products intended for professional use and of certain other biocidal products poses risks to human health and the environment in this respect. The consumer should be informed about the risks of using biocidal products by means of a supply meeting given by qualified personnel. Unnecessary applications should be avoided and proper use of the products in accordance with the provisions in the approval should be ensured.

The existing secondary legislation of the Biocidal product authorisation ordinance and the Ordinance on notification of biocidal products will be merged with the new provisions to be created in a single uniform statutory instrument (Ordinance implementing the law on biocidal products). In this context, the Ordinance on notification of biocidal products shall be adapted to the current state of the law, including the inclusion of the provisions to prevent free-riding in accordance with Article 95 of Regulation (EU) No 528/2012. The Biocidal product authorisation ordinance, which governs the national authorisation procedure for biocidal products, has largely become obsolete due to the harmonisation of the authorisation procedure by Regulation (EU) No 528/2012 and therefore the provisions can largely be repealed without replacement.

1. Alternatives

There are no apparent alternatives. In particular, it is not feasible that voluntary commitments to supply and use biocidal products would hold much promise of success, as getting all the participants in the retail sector to commit themselves to such a voluntary scheme appear to be inherently unrealistic.

1. Power to enact legislation

The provisions in Article 1 of the Ordinance on the notification of biocidal products (§ 3 to § 7 of the Ordinance implementing the law on biocidal products) are based on § 28(11) of the Chemicals Act, and the obligation to apply the registration number (§ 3(1) of the Ordinance implementing the law on biocidal products) is based on § 14(1)(3)(a), insofar as biocidal products not classified as hazardous are also covered by the provisions, also in conjunction with § 14(3) of the Chemicals Act. The provisions on the supply of biocidal products (§ 8 to § 11 of the Ordinance implementing the law on biocidal products) are based on § 17(1)(1)(c) and (2)(c) and (d) of the Chemicals Act, insofar as the provisions also cover biocidal products not classified as hazardous, each also in conjunction with § 17(3) of the Chemicals Act. The provisions on the authorisation of certain biocidal products (§ 12 and § 13 of the Ordinance implementing the law on biocidal products) are based on § 12h(1)(1) and (2)(2)(b) of the Chemicals Act. The notification obligations with regard to the type and quantity of biocidal products placed on the market (§ 14 of the Ordinance implementing the law on biocidal products) are based on § 12h(2)(2) of the Chemicals Act.

1. Compatibility with EU law and international treaties

The Ordinance contributes to the achievement of the objectives of Regulation (EU) No 528/2012 by regulating the unrestricted supply and use of certain biocidal products where a restriction is included in the authorisation. The harmonisation effect of Regulation (EU) No 528/2012, which is based on internal market competence under Article 114 TFEU, does not preclude national provisions. Regulation (EU) No 528/2012 itself does not contain any provisions on the way biocidal products are supplied. Thus, the provision in Section 3 of the Ordinance implementing the law on biocidal products on the supply of biocidal products are not covered by the harmonisation effect of Regulation (EU) No 528/2012.

1. Consequences of the provisions
	1. Legal and administrative streamlining

By integrating the provisions of Article 95 of Regulation (EU) No 528/2012 into the notification procedure, market participants will be able to easily check whether its requirements have been met for the active substances they place on the market, i.e. whether product manufacturers actually purchase the active substances from the active substance suppliers included in the list. This allows for rapid action to be taken against free riders by means of competition law and, in this respect, simple and effective self-regulation within the industry.

* 1. Sustainability aspects

The proposed legislation is expected to have a positive impact on environmental pollution (in particular surface water, drinking water and soil) caused by biocides. The risks to non-target organisms and to human health are also expected to be reduced. This will be achieved through an expected avoidance of the use of biocidal products due to the provision of informed advice when supplying biocidal products that are subject to the self-service ban. This way, unnecessary applications can be avoided, inter alia by providing information on alternatives as well as through preventive measures. Also, self-service bans and compulsory advice can minimise misuse and better ensure compliance with the risk mitigation measures associated with the authorisation.

* 1. Budgetary expenditure exclusive of compliance costs

The Federal Institute for Occupational Safety and Health (BAuA), incurs costs in Department 5 (Federal Office for Chemicals) for the adaptation of the existing notification database for biocidal products and the development of a new database for the notification of biocidal products placed on the market. The cost of these IT projects is estimated at 40 person/days, which corresponds to costs of EUR 40 000.

The additional costs incurred by the Federal Government are to be fully and permanently offset directly, financially and in terms of staffing by the ministries concerned, within the framework of existing appropriations.

* 1. Compliance costs

a) Compliance costs for citizens

The draft Ordinance does not contain any requirements for citizens. Therefore, there are no compliance costs for them.

b) Compliance costs for businesses

For businesses, the Biocidal Products Implementing Regulation (Article 1) will result in annual compliance costs of approximately EUR 20 440 000, of which EUR 348 000 are administrative costs arising from obligations to provide information, as well as one-off compliance costs of roughly EUR 93 947 000.

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| --- | --- | --- | --- | --- |
|  |  |  | **Annual costs in EUR** | **One-off costs in EUR** |
|  | **Requirement description** | **Personnel costs** | **Material costs** | **Compliance costs** | **Personnel costs** | **Material costs** | **Compliance costs** |
| 1 | § 6(1): Updating the notification in the event of changes (obligation to provide information) | 25 025 | - | 25 025 | - | - | - |
| 2 | § 6(2): Confirmation of notification every 2 years (obligation to provide information) | 19 892 | - | 19 892 | - | - | - |
| 3 | § 10(1) and (2) Introduction of a self-service ban  | - | 1 122 000 | 1 122 000 | - | 17 000 000  | 17 000 000 |
| 4 | § 11: Supply by a qualified person (education, further training) and advice |  13 029 100 | 5 361 000 | 18 390 100 | 45 715 280 | 31 110 000 | 76 825 280 |
| 5 | § 12 Supply regulation for online and mail order trade | 575 325 | 4 545 | 579 870 | 40 320 | 81 450 | 121 770 |
| 6 | § 16: Notification of biocidal products (obligation to provide information) | 303 333 | - | 303 333 | - | - | - |
|  | **Total** | 13 952 675 | 6 487 545 | 20 440 220 | 45 755 600 | 48 191 450 | 93 947 050 |
|  | **of which obligation to provide information** | 348 250 | - | 348 250 | - | - | - |

Re 1: Updating notifications (§ 6(1))

With regard to the obligation to update, it was assumed that annual changes would occur in 5% of the notifications (with a total number of approximately 65 000 notifications), i.e. 3 250 updates will be carried out annually on the basis of § 6(1). For the time expenditure involved with notification, the time value table for businesses on page 53 of the Guideline on compliance costs was used and the times of the matching standard activities have been added. A time expenditure of twelve minutes is assumed for updating the notification in case of changes (standard activities: verification of data, simple complexity level, time required: one minute; error correction, complexity level: medium, time required: 10 minutes; data transmission, degree of complexity: simple, time required: one minute). For the calculation of personnel costs, the average wage rate of industry C (manufacturing industry) of EUR 38.50/hour (wage cost table for businesses, p. 55) was used.

The compliance costs are calculated by multiplying the time spent per hour (12/60) by the wage rate per hour (EUR 38.50) and the annual number of cases (3 250). This results in annual compliance costs of EUR 25 025.

Re 2: Confirmation of the notification (§ 6(2))

It is assumed that no changes will occur in 95% of the notifications (cf. above under 1.), i.e. 61 750 confirmations out of a total number of 65 000 notifications. Confirmation of notification is only required every two years, reducing the number of cases to around 31 000 (30 875).

A time expenditure of one minute is assumed for the confirmation of the notification (simple data transmission one minute; time value table for businesses, p. 53), as it is assumed that the confirmation can be sent without a major review.

The average wage rate for the manufacturing industry of EUR 38.50/hour (wage cost table for businesses, p. 55) was used. The compliance costs are calculated by multiplying the time spent (1/60) by the wage rate per hour (EUR 38.50) and the number of cases (around 31 000). This results in annual compliance costs of approx. EUR 19 892.

Re 3: Introduction of a self-service ban (§ 10(1)(2))

The total number of stores affected by the self-service ban is assumed to be around 34 000 (34 285) (4 635 chemists, 10 870 supermarkets, 1 098 large supermarkets, 16 162 discount stores, 1 520 retail stores with zoological supplies). Pharmacies and DIY stores as well as Raiffeisen markets are not included. Pharmacies sell substances and mixtures that are already subject to a self-service ban under the Chemical Prohibition Ordinance, so there is no need to purchase new equipment. DIY stores and Raiffeisen markets already supply plant protection products that are subject to a self-service ban under the Plant Protection Act, so there is no need to purchase new equipment in this case either.

For a new lockable cabinet of a simpler design, the branches incur one-off material costs of EUR 500. The time allowed for the depreciation of such a cabinet is 15 years. Accordingly, after this period, a new cabinet must be purchased as a new investment. The annual cost of materials is therefore EUR 33 (500/15).

The one-off compliance costs of approximately EUR 17 000 000 are calculated by multiplying the number of cases and the material costs per case. The annual compliance costs amount to roughly EUR 1 100 000.

Re 4: Supply by a qualified person and advice (§ 11)

The supply of biocidal products covered by the self-service ban must be carried out by a qualified person. In order for one employee per branch to be able to advise at all times and for two employees to act as substitutes, at least three employees of a branch must take part in a training course. Continuing education must be completed every three years.

Pursuant to § 13, a person is deemed, inter alia, qualified if he or she attends further training programmes pursuant to § 11(1)(2) of the Chemical Prohibition Ordinance, which also covers the supply of biocidal products. In order to make the necessary adjustments to training courses and further education, various organisers may have to adapt already established events and tailor them to the clientele concerned.

The number of cases for initial or in-service training programmes results from the number of stores (roughly 34 000) multiplied by two employees (102 000), as at least one person with qualifications must be present per branch and two other persons are provided for as substitutes. Furthermore, the stores also recruit new staff every year. It is assumed here that about 10% of new employees require an initial test each year (10 200).

Since the number of qualified advisers remains constant at three, the annual number of cases for training courses, which must be attended every three years, is based on the number of stores (34 000 stores \* employees/3 years). DIY stores and Raiffeisen markets are also affected by the further training courses, as plant protection product qualifications is only recognised if a further training course is attended in accordance with § 13(1)(2). Accordingly, the annual number of cases for this target is around 37 500 ((34 000 stores + 2 106 DIY stores + 1 429 Raiffeisen markets) x 3 employees/3 years).

The number of consultations is based on the number of sales. It is known that 5 478 011 plant protection products were sold in 2006. Assuming that the number of biocidal products sold and the number of plant protection products sold are related, a case number was calculated by taking the ratio of authorised biocidal products to authorised plant protection products (1738 plant protection products and 389 biocidal products; i.e. a ratio of 4.5 to 1). Accordingly, the number of cases for biocidal products is around 1 217 000 (1 217 336).

The number of organisers is estimated at about 50. The basis for this is the number of different organisers in the federal state of Bavaria for the year 2021 (six different organisers). Assuming that in about half of the cases an adaptation of the training programme in connection with the Chemical Prohibition Ordinance is implemented, a one-time case number of three is applied. For the national territory, this corresponds to a unique case number of about 50 organisers (48=3x16).

Time expenditure:

In Hesse, the plant protection training programme, which is comparable to the training programme on biocidal products, lasts 16 hours (960 minutes) and the further training programme every three years lasts four hours (240 minutes). It is assumed that the training programme or further training programme in the other federal states will take a similar amount of time.

For the duration of the consultation on the conditions of use of the authorisation (e.g. precautions to be observed during use), the information sheet on the plant protection specialist examination in North Rhine-Westphalia is used as a basis. According to this, a technical discussion of a maximum of ten minutes is considered to be part of the specialist examination. Likewise, a similar specification from OnDEA can be used as a basis (cf: also the specification: Advice and information for first-time use in the cosmetic field; ID-IP: 2018111410535902). For these, a time expenditure of 5 minutes applies. For the rest of the procedure, it is assumed for the supply of biocidal products that the duration of an average customer discussion will be between these time figures. It is therefore estimated at 7.5 minutes per sales call.

It is estimated that gathering new information on biocidal products and adapting the training programme will take about one working day (480 minutes). Wage rates:

The average wage rate for the retail sector of EUR 28/hour (wage cost table for businesses, p. 55) is used for training programmes, further training programmes and consultancy. A high qualification level of the business section ‘Provision of other economic services’ is assumed for the provision of training (EUR 48.20 per hour).

Material costs:

Costs are incurred for training in a similar way as with the plant protection sector. This includes participation costs for preparatory seminars or training courses, fees for examinations and fees for the issue of the certificate of qualifications or the certificate of attendance of training courses. Events may be offered by public bodies or by institutions recognised for this purpose (cf. § 11 Chemical Prohibition Ordinance). As this places public authorities in competition with other economic actors, all organisers have been allocated in full to the norm addressee businesses in the following.

The costs for preparatory seminars and further training courses for plant protection qualifications vary depending on the organiser and the federal state. In Saxony, costs would amount to about EUR 150, whereas in Hesse it would be about EUR 200 per course. In North Rhine-Westphalia, the costs range between EUR 263 and 373 and in Bavaria, about EUR 360 is estimated. An average value of EUR 270 has therefore been used. For the examination, contributions of approximately EUR 35 are incurred, resulting in total material costs for the training courses including the examination of EUR 305. Contributions of between EUR 35 and EUR 96 have been identified for the cost of the training courses. An average value of EUR 60 per training event is therefore applied.

Compliance costs:

The one-off compliance costs amount to EUR 76.8 million for the initial training. Of this amount, approximately EUR 45.7 million are personnel costs (102 000 staff x 960 minutes/60 x EUR 28/h) and EUR 31.1 million are material costs (102 000 x EUR 305). The costs resulting from the adaptation of training and education programmes (EUR 19 000) falls under the category ‘Adaptation of organisational structures’ (personnel costs: 50 x 480/60 x EUR 48.20/h).

The annual compliance costs amount to EUR 7.7 million for the initial training of the new employees hired each year (approx. EUR 4.6 million in personnel costs and EUR 3.1 million in material costs; personnel costs: 10 200 employees x 960/60 x EUR 28/h; material costs: 10 200 x 305) plus EUR 6.5 million for training every three years (EUR 4.2 million in personnel costs: 37 500 employees x 240/60 x EUR 28/h and EUR 2.3 million material costs: 37 500 x 60) plus EUR 4.3 million from the consultations (personnel costs: 1 217 000 employees x 7.50/60 x 28), i.e. a total of EUR 18.4 million.

The provisions take into account the German government concept of increasing transparency concerning conversion costs for businesses and of limiting it in an effective and proportionate manner. In connection with the introduction of the self-service ban for certain biocidal products (see ‘Re 4.’ above), the conversion costs are reduced by merely specifying the objective rather than specifically prescribing how this objective is to be achieved. The companies concerned are thus free to decide how to implement the self-service ban in concrete terms, for example by purchasing lockable cabinets or by moving the products to an area not accessible by the customer combined with a notice on the product on the sales floor. For the qualification provision under § 11 of the Ordinance implementing the law on biocidal products (see ‘Re 4.’ above), the conversion costs are limited by the connection to already existing qualification provisions, preventing companies that already supply plant protection products or products that fall under the Chemical Prohibition Ordinance from having to conduct additional training for their employees. In addition, an implementation deadline of 1 January 2025 is provided so that there is sufficient time for staff to attend the required training events.

Re 5: Supply in online and mail order trade (§ 12)

Pursuant to § 12, biocidal products may only be supplied after a pre-consultation, even in the case of online and mail order sales. For this purpose, online portals must also take appropriate organisational precautions, in particular to ensure that a supply meeting is held. The costs involved in adapting the training content by the training providers has already been calculated under 4. and is not listed again for this specification.

Number of cases:

It is likely that all major retail chains will also offer online supply. The number of cases is based on the supermarket chains for those companies that have a market share of more than 10%. According to the evaluation of LZ Retailytics, this applies to Edeka, Schwarz Gruppe, Rewe Group and Aldi. The larger DIY stores include the Tengelmann Group (OBI), Bauhaus, Toom/B1, Zeus and Hornbach, so that the number of companies that have to make central technical arrangements for their online platform is 9. It is assumed that consultation talks will be conducted from a central location. The number of employees per online trading company is expected to be 10. Accordingly, the number of cases for one-off training is 90 (10 staff x 9 online platforms). As described under 4., 9 employees are expected for the annual training (90 employees x 0.1) and 30 employees are expected for the training every three years (90 employees/3 years).

The number of consultations is based on the number of sales, as mentioned under 4. In order to determine this number of cases, the ratio between online and offline sales has been used. For this purpose, the HDE Online Monitor was used as the basis, which compares the rates of change by industry. Due to a lack of segmentation in the online monitor, biocidal products are assigned to the ‘DIY & Garden’ sector for this estimate. The per capita costs in this industry in 2019 was EUR 656 per capita in offline trade and EUR 63 in online trade. The ratio is therefore about 10:1. Applied to the calculated case number of biocidal products in offline trade (1 217 000 products; see requirements in 4), about 121 700 biocidal products are sold via online trade.

Time spent and wage rate:

The wage rate of EUR 28 per hour and the time spent of 960 minutes on training and 240 minutes on in-service training are mirrored with those in 4. The time required for online consultations may be somewhat higher, since the qualified person must also explain the further procedure for activating the product, so that about 10 minutes are assumed.

For the implementation of the technical requirements, a cost of EUR 1 200 per programming workday is estimated after evaluating similar specifications from OnDEA. It is assumed that about one working week is required per online platform to program a password-based activation system for specific products. This means that the material costs per online platform amount to EUR 6 000.

The one-off compliance costs amount to around EUR 68 000 for the initial training [of which around EUR 27 000 are material costs (90 employees x EUR 305) and around EUR 40 000 are personnel costs (90 employees x 960 minutes/60 x EUR 28/h); they are to be assigned to the category ‘training costs’] and around EUR 54 000 for the implementation of the technical requirements (material costs: 9 online platforms x EUR 6 000; category: Introduction or adaptation of digital process flows). In total for these requirements, there will be a one-off compliance cost of around EUR 122 000.

The annual compliance costs amount to around EUR 7 000 for the training of new staff each year (personnel costs: 9 employees x 960/60 x EUR 28/h; material costs: 9 x 305), to around EUR 5 000 for training (personnel costs 30 staff x 240 minutes/60 x EUR 28/h; material costs: 30 employees x 60) and around EUR 580 000 for the online consultations (personnel costs: 121 700 employees x 10/60 x 28). The total annual change in compliance costs is therefore around EUR 580 000.

Re 6: Notification of biocidal products (§ 16)

The type and quantity of biocidal products supplied or exported to domestic recipients shall be reported electronically on an annual basis.

According to the database of the Federal Institute for Occupational Safety and Health, there are about 65 000 reported biocidal products. The notification shall be made electronically using a form provided. It is assumed that the notification will take ten minutes, as all the necessary information is already available through the one-off notification (data check average eight minutes, data transmission average two minutes; Time value table for businesses, p. 53). The average wage rate for the retail sector of EUR 28/hour (Wage cost table for businesses, p. 55) has been used. The annual compliance costs for the notification of biocidal products therefore amounts to EUR 303 333.

c) Administrative compliance costs

For the administration, the Ordinance implementing the law on biocidal products (Article 1) creates annual compliance costs of around EUR 35 000. Of this amount, approximately EUR 2 000 is allocated to the federal level and approximately EUR 33 000 to the regional level. In addition, there are one-off conversion costs of EUR 653 000 for the federal states.

|  |  |  |
| --- | --- | --- |
|  | **Annual costs in EUR** | **One-off costs in EUR** |
| **§§** | **Requirement description** | **Cost of staff** | **Compliance costs** | **Cost of staff** | **Compliance costs** |
| 8 | Exchange of information with federal states (Federal Office for Chemicals) | 1 881 | 1 881 | - | - |
| 6, 10, 11, 12, 16 | Supervision of compliance with business-related regulations (federal state authorities) | 32 640 | 32 640 | 652 800 | 652 800 |
| **Total** | 34 521 | 34 521 | 652 800 | 652 800 |
| **of which at federal level** | 1 881 | 1 881 | - | **-** |
| **of which from federal state level** | 32 640 | 32 640 | 652 800 | 652 800 |

The largest share of the supervision activities conducted by the federal state authorities is made up of supervising the specialist examinations (§ 11). In this context, the enforcement authorities will check compliance with the self-service ban in the sales outlets, as well as the conducting of the supply meeting. A one-off total of around 16 000 (16 122) audits nationwide is estimated. Annually, it is estimated to be 5% of that, or approximately 800 (806) audits of new employees. According to the guidelines, an audit by public authorities takes 60 minutes (Audit by public authorities, medium; Time value table for businesses, p. 54). For supervision by staff of the upper grade of the civil service, EUR 40.80/hour is applied (Wage rate table for administration, p. 56). The one-off compliance costs amount to EUR 652 800. The annual compliance costs amount to EUR 32 640.

* 1. Additional costs

Minor cost-induced individual price adjustments cannot be ruled out. Effects on general price levels, in particular on the consumer price level, are not to be expected, however.

* 1. Benefit

These compliance costs are offset by a benefit for environmental and health protection, which involves the reduction of risks arising from the use of biocidal products for human, animal and environmental health (e.g. for water, biodiversity, insects). In addition, a benefit in resistance management and thus in ensuring the long-term usability of products once they have been developed can be expected. In particular, it prevents consumers from using products that are only authorised for professional users. It also aims to raise awareness among consumers who use biocidal products that handling biocidal products is inherently risky and that biocidal products should only be used when absolutely necessary and when in compliance with the applicable conditions for use.

This benefit is only quantifiable to a small extent. For the extent that it is quantifiable, the avoidance of costs for the medical treatment of humans and domestic animals in the case of poisoning can be cited here as an example, which alone amounts to around EUR 2.4 million annually.

The example benefit in the form of the avoidance of medical treatment costs can be broken down as follows:

On the basis of the data collected from the poison information centres within the framework of the research project ‘Pilot Project Monitoring of Poisonings (PiMont)’, the Federal Institute for Risk Assessment (BfR) assumes a number of approx. 2 400 poisonings due to biocidal products each year. Within the pilot project, poisonings with ‘pesticides’ were collected for a period of 10 months by the eight German poison information centres. Assuming that only 50% of these cases require outpatient treatment and assuming a medical cost of EUR 250[[3]](#footnote-3))), this results in treatment costs of EUR 300 000. In addition, there are about 120 cases of biocide poisonings requiring inpatient treatment. With an estimated treatment cost of EUR 10 000 per case, this results in health care costs of EUR 1.2 million. Treatment costs for humans therefore account for a total of EUR 1.5 million.

Since it can be assumed that not all cases of poisoning can be avoided by the provisions on the supply of biocides, a reduced rate should be applied. The deliberate misuse of biocides (approx. 3% of biocide poisonings are suicidal) will probably not be reduced at all, and misuse by children, which accounts for approx. 60% of poisonings, will only be partially reduced by the provisions. It is therefore assumed that about 2/3 of the cases of poisoning requiring treatment could be prevented by the supply regulations. As a result, it is estimated that the total savings for the health care system will amount to EUR 1 million.

In addition, there are also treatment costs for pets. 14.8 million cats and 9.4 million dogs live in German households. According to statistics, 75% of animal owners go to the veterinarian at least once a year (i.e. about 18.15 million cases). 1% of all veterinary visits are due to cases of poisoning (181 500). It can be assumed that about 10% of all poisonings are due to biocides[[4]](#footnote-4))) (18 150). The most frequent cases of biocide poisoning in cats and dogs are attributed to intoxication with rodenticides (coumarin derivatives) and insecticides (in particular pyrethroids) used in the household and therefore covered by the provisions of this Ordinance. According to the Veterinary Fees Ordinance (2017) [Gebührenverordnung der Tierärzte], there is a treatment cost of around EUR 100 for treating a dog in the case of suspected rat poison intoxication. In case of severe poisoning with curcumin derivatives, a treatment of several weeks including antidote administration and blood transfusions is to be assumed. This is based on a cost of EUR 1 000. If one assumes that only 15% of the cases are serious poisonings, the costs for this amount to EUR 2.7 million. The treatment costs for the 85% mild cases are around EUR 1.5 million. Overall, costs of around EUR 4.2 million can therefore be assumed. Assuming that about 1/3 of the cases of poisoning of pets could be avoided by the supply regulations, about EUR 1.4 million of treatment costs for pets could be saved by the provisions.

The economic benefit of the provisions in terms of avoiding the costs of medical treatment for humans and domestic animals is therefore estimated at approximately EUR 2.4 million.

The savings in production downtime costs can also be cited as an example for the much more extensive range of benefits that cannot be quantified in more detail. These include wage costs due to the poisoning of workers with pesticides and the resulting days of absence from work.

It can be assumed that the supply regulations will reduce the number of days that employees are incapable of working due to poisoning. Thus, production downtime costs can be saved by the provisions of this Ordinance.

* 1. Further consequences of the provisions

The implications for equal opportunities policy were analysed in accordance with § 2 of the Gender Equality Act within the Federal administration and in Federal courts and in accordance with § 2 of the Joint Rules of Procedure of the Federal Ministries using the guideline of the interministerial working group entitled ‘Gender mainstreaming in the preparation of legislation’. The audit found that women and men are not affected differently, either directly or indirectly, by this Ordinance.

1. Time limitation; evaluation

A time limit for the provisions is not envisaged, as the provisions serve to accompany the EU-wide provisions for biocidal products on a permanent basis. A need for a fixed evaluation period is not envisioned. Both the Federal Office for Chemicals and the competent monitoring authorities of the federal states are continuously dealing with regulatory governance – also concerning the continued authorisation of biocidal products which have so far been covered by the transitional arrangements.

B. Specific part

Re Article 1 (Ordinance on the notification and supply of biocidal products and on the implementation of Regulation (EU) No 528/2012)

The new ordinance ‘Ordinance implementing the law on biocidal products’ replaces the previous Ordinance on notification of biocidal products and the Biocidal product authorisation ordinance.

Re Section 1 (Scope of application, definitions)

Re § 1 (Scope of application)

This provision regulates the scope of the Ordinance. It stipulates that the Ordinance applies in principle to all biocidal products as defined in § 3(1)(11) of the Chemicals Act. Restrictions on certain biocidal products are included in the respective regulations.

Re § 2 (Definitions)

The provision contains definitions of key terms used in the Ordinance. Subparagraphs 1 to 4, which are based on the corresponding definitions of the Chemical Prohibition Ordinance, are central for the supply regulations of Section 3 of the Ordinance. The definition of importer in subparagraph 5 has been adopted from § 3(8) of the Chemicals Act. The definitions in Article 3 of Regulation (EU) No 528/2012 also apply.

Re Section 2 (Notification of biocidal products)

The provisions of Section 2 essentially continue and update the provisions of the Ordinance on notification of biocidal products.

Re § 3 (Application and indication of the registration number)

Re paragraph 1

Paragraph 1 provides that biocidal products that are subject to the transitional provisions of § 28(8) of the Chemicals Act may only be made available on the market within the scope of application of this Ordinance if a registration number is applied that has been issued by the Federal Office for Chemicals in accordance with the provisions of this Ordinance. The authorisation to issue ordinances under § 28(11) of the Chemicals Act allows placing on the market within the meaning of the definition in § 3(9) of the Chemicals Act to be made dependent on a prior notification by means of a provision to be issued by ordinance. In order to avoid ambiguities that could arise from the fact that the definition of placing on the market in Regulation (EU) No 528/2012 deviates from the definition in the Chemicals Act, placing on the market within the meaning of Article 3(1)(i) of Regulation (EU) No 528/2012 is initially referred to here, but this is limited geographically to the provision within the scope of this Ordinance. Since making available in Germany is covered by the definition of placing on the market under § 3(9) of the Chemicals Act, the provisions are within the scope of the authorisation granted by the Ordinance.

Re paragraph 2

Paragraph 2 is based on § 17(1)(c) of the Chemicals Act. It contains the specific requirement for online and mail order trade that a biocidal product may only be offered for sale if the registration number is evident in the offer itself. This serves to facilitate the supervision of the notification requirements of this Ordinance in internet trade by the supervising authorities of the federal states. As such, a proof of sale is not necessary in order to prove an infringement in the context of administrative offence proceedings. The term ‘offering’ is to be understood broadly and includes all cases in which biocidal products are offered for sale with the possibility of ordering. The provision applies to all offers directed at customers who reside in the area of application of this Ordinance and thus also includes offers abroad.

Re § 4 (Notification of a biocidal product)

Re paragraph 1

Paragraph 1 regulates who is required to submit the notification to the Federal Office for Chemicals for the biocidal products subject to notification under § 3. The content of the provision is based on the previous § 3(1) of the Ordinance on notification of biocidal products. Manufacturers, importers or persons placing a biocidal product on the market under their own trade name must then submit the notification using an electronic template provided on the website of the Federal Institute for Occupational Safety and Health (BAuA).

Re paragraph 2

Paragraph 2 sets out the information required for the notification referred to in paragraph 1. Subparagraphs 1 to 4 have largely been adopted from the previous § 3(1)(2) of the Ordinance on notification of biocidal products, with the exception of minor adjustments. The obligation to indicate the concentration of the active substance in accordance with subparagraph 4(a) is new. This is intended to support supervisory activities by countries in relation to biocidal products that appear to be ineffective and whose placing on the market may constitute an infringement of Article 72 of Regulation (EU) No 528/2012 or of product safety legislation. Another new point is that in subparagraph 4(b)(bb), instead of referring to the Biocide Directive [Biozid-Richtlinie], reference is made to Delegated Regulation (EU) No 1062/2014, as the approved active substances are included in its Annex.

The information pursuant to subparagraphs 5 and 6 has been newly included vis-à-vis § 3 of the Ordinance on notification of biocidal products. Under subparagraph 5, the applicant is to state the date on which an application referred to in § 28(8)(2)(2) and (3) of the Chemicals Act was made. This may be either an application for authorisation or an application for mutual recognition. The information on this date is relevant as it has an impact on the duration of the marketability of the product pursuant to § 28(8)(2)(2) and (3) of the Chemicals Act. The case number to be indicated in the application in accordance with subparagraph 5 shall be assigned at the time of application in the register (‘R4BP’) provided by the European Chemicals Agency in accordance with Article 71 of Regulation (EU) No 528/2012.

Subparagraph 6 requires the applicant, when submitting the application, to indicate who the supplier of the active substance is or who the product supplier for the biocidal product is for which the registration number is requested, which shall at the same time be included in the list referred to in Article 95 of Regulation (EU) No 528/2012. Article 95 provides that biocidal products may only be made available on the market if the active substances they contain are obtained from a supplier who has participated in the active substance procedure. The information required here serves to verify that this provision, which is designed to prevent free-riding, is complied with and that the product may be made available on the market in accordance with Article 95(2) of Regulation (EU) No 528/2012.

In accordance with subparagraph 7, the applicant shall also confirm that the biocidal product has the effect attributed to it by the product name, the instructions for use or the product advertising. This indication is sanctioned as an indication of registration via § 17(2)(2).

Re § 5 (Issuing a registration number)

§ 5 provides for the material requirements for the issuance of the registration number. The purpose of the registration number is to have a first point of reference when checking a product that is allegedly marketable under the transitional arrangements. The marketability of the product is checked when the application for the registration number is submitted. The issue of the registration number does not serve the function of an authorisation for the biocidal product. The application of a registration number, once issued, is a prerequisite under § 3(1) for making the product available on the market in accordance with the provisions of the Ordinance on notification of biocidal products.

An essential substantive requirement for issuing the registration number is that the biocidal product may be made available on the market in accordance with the transitional provisions of § 28(8) of the Chemicals Act (subparagraph 1). This serves to achieve the objective of the notification procedure for biocidal products, i.e. to obtain an overview from the authorities of the biocidal products which may still be made available on the market on the basis of the transitional provision in § 28(8) of the Chemicals Act.

Article 95(2) of Regulation (EU) No 528/2012 provides that a biocidal product may be made available on the market only if the active substance supplier or the product supplier is included in the list referred to in Article 95 of Regulation (EU) No 528/2012. Following on from this point, a registration number is only to be issued under subparagraph 2 if these conditions are met. This ensures that a product that is not allowed to be provided on the market in accordance with Article 95 of Regulation (EU) No 528/2012 does not receive a registration number either and is not marketable in accordance with § 3(1).

Subparagraph 3 also provides that the granting of the registration number is subject to the condition that the product type specified in the application also corresponds to the product types referred to in Regulation (EU) No 1062/2014. If the active substance is not or is not yet included with the corresponding product type in Regulation (EU) No 1062/2014, then the registration number can also be issued if the active substance is included with the product type in the existing active substance programme (cf. Article 18 of Regulation (EU) No 1062/2014). This scenario occurs when the active substance has been notified and thus marketability has already been established, but the active substance has not yet been formally included in the Annex to Regulation (EU) No 1062/2014.

Re § 6 (Updating and confirmation of the notification)

In paragraph 1, the provision regulates an obligation to update. The parties obliged to notify shall also update the notification as soon as any information relevant to the application under § 4(2) changes. This ensures that the information in the electronic directory is up to date.

Paragraph 2 also contains an obligation to confirm the information provided in the application every two years. If the data are not confirmed, the person required to notify the biocidal product shall not make the product available on the market until he or she has confirmed the accuracy of the data. This prohibition shall apply only to those obliged to notify under Article 4(1). The other participants in the supply chain, in particular distributors, may continue to make the product available on the market.

Paragraph 3 clarifies that the update and the confirmation may also be carried out by an authorised representative, provided that the party subject to the notification obligation is domiciled abroad. However, the latter must have its registered office in Germany.

Re § 7 (Electronic register)

The provision essentially corresponds to the former § 4 Ordinance on notification of biocidal products. It stipulates that the Federal Office for Chemicals shall make available on the website of the Federal Institute for Occupational Safety and Health an electronic register which is publicly accessible and which contains the details of the applicant pursuant to § 4(2) in any case. The publicly accessible list is an essential element of the notification procedure, the main purpose of which is to provide transparency during the transitional period until the biocidal products in question have been authorised by giving consumers and surveillance authorities an overview of the products on the market under the transitional arrangements of Regulation (EU) No 528/2012.

Re § 8 (Transfer of information to the federal state authorities)

The provision regulates the exchange of information between the Federal Office for Chemicals and the federal states authorities on the fact that a biocidal product may not be made available on the market by a certain actor due to the failure to confirm the information in accordance with § 6(2)(1).

Re Section 3 (Provisions on the supply of biocidal products)

Re § 9 (Validity of restrictions on supply authorisation)

Sentence 1 of the provision stipulates that if a biocidal product may only be used by a certain group of people (e.g. trained professional users) in accordance with the authorisation, the product may also only be supplied to these people. This is also the case if, out of several possible uses, only one use is restricted to one group of users. The provision serves to effectively implement the authorisation requirements. A product that should not be used by a person should also not be supplied to that person. The respective authorised user categories are indicated on the label.

Re § 10 (Self-service ban)

The provision establishes the prohibition of self-service for certain biocidal products. Paragraphs 1 and 2 differentiate between different forms of the self-service ban. The classification of biocidal products into a product type results from the authorisation number or, in the case of biocidal products that are marketable based on the transitional provisions under § 28(8) of the Chemicals Act, from the information in the electronic register under § 7 on the website of the Federal Institute for Occupational Safety and Health. If the list includes one of the product types referred to in paragraphs 1 or 2, the biocidal product is subject to the self-service ban.

Re paragraph 1

Re subparagraph 1

Biocidal products that are subject to the self-service ban referred to in paragraph 1 are not to be presented in the trade location in a form that allows the customer to have free access to the product. The self-service ban makes it possible to check compliance with the approval-related requirements with regard to the respective approved recipient and user group at the time of supply and makes it possible to pass on important information within the supply meeting in accordance with § 11. Plant protection products which, like biocidal products, have an intended effect on living organisms, are already subject to a comprehensive prohibition on self-service for consumer products under § 23(2) of the Plant Protection Act. Pursuant to subparagraph 1, biocidal products are subject to the self-service ban if the authorisation specifies that they may not be used by the general public.

Subparagraph 2 enumerates product types for which the self-service ban always applies, irrespective of the existence of specific requirements in the marketing authorisation for the intended user category referred to in subparagraph 1. This therefore applies to the products referred to in subparagraph 2 even if they are authorised for use by the general public. Subparagraph 2 also includes products that have not yet been authorised in accordance with Regulation (EU) No 528/2012 and are marketable based on the transitional arrangements under § 28(8) of the Chemicals Act. This is made clear by the fact that the provision focuses on the products to be classified under the product types and not on the content of the authorisation.

The basis for the selection of the product types is, to a high degree, products that are regularly used for their intended purpose in the environment and in close proximity to people. In conjunction with the obligation to provide a consultation talk upon supply (§ 11), the aim is to ensure that any unnecessary applications of biocidal products are avoided and that biocidal products are actually used in accordance with the specifications of the authorisation and that the user is informed about the risks and possible alternatives.

The assignment of a specific product to a product type is to be made by the seller, i.e. the retailer.

Re paragraph 2

Paragraph 2 contains a formulation of the self-service ban that deviates from paragraph 1 and that allows for a more flexible organisation of the processes in the sales outlet for the products listed therein, since the product types listed in subparagraphs 1 to 3 are typically offered in large containers and in a wide range of variations. In contrast to the self-service ban in paragraph 1, this exempts the shopkeeper from the obligation to offer products in a form that is not freely accessible to the customer. These products may therefore be offered in such a way that customers can take the product from the shelf themselves as usual. However, it must be ensured that, prior to the conclusion of the purchase contract, which usually takes place at the cash desk, a qualified person verifies that the purchaser meets the personal requirements (§ 11(2)(1)) and conducts a supply meeting that includes the contents specified in § 11(2)(2). The business owner is to decide how to ensure that this occurs and how to facilitate a smooth supply process. One possible arrangement could be that the customer brings the biocidal product to a central consultancy counter in the store where a qualified person is available. After the check has been carried out and the product has been supplied, the checkout assistant marks the product so that it is clear to the checkout staff that the requirements of the self-service ban have been met. In order to ensure that the respective organisational form is not overlooked by the customer and that there are no subsequent obstructions at the checkout, clear notices (possibly also in the form of a QR code and app) of the organisational form of the self-service ban would have to be displayed both on the shelf and at the checkout area. In addition, further possibilities are feasible, for example placing the qualified person at the counter where cash is collected at the same time.

Re paragraph 3

Paragraph 3 contains exceptions. Pursuant to sentence 1, products for which a simplified authorisation has been granted in accordance with Article 25 of Regulation (EU) No 528/2012 in association with Annex I are excluded, since a favourable profile for the environment or human or animal health can generally be assumed in this case. These biocidal products are identifiable by their authorisation number. Pursuant to sentence 2, an exclusion exists for the products covered by paragraph 2, provided that the purchaser is able to prove that the purchaser uses the product in the course of his or her main professional activity (for example, use of a biocide-treated paint by a painter) or the person responsible for the handover is aware of that fact. The exclusion exists for the products listed in paragraph 2, as these are typically also purchased by professional users in consumer markets such as DIY stores.

Re § 11 (Requirements for the person responsible for the handover, supply meeting)

The provision regulates requirements for the supply of biocidal products that are subject to a self-service ban under § 10. These products may only be supplied by a person who meets the requirements of § 13. The specific requirements for the person responsible for the handover and for the supply process are further defined in paragraph 2.

Paragraph 2(1) is based on § 8(3)(1) of the Chemical Prohibition Ordinance. It applies directly to products that are subject to the self-service ban under § 10(1) and – via the reference in § 10(2) – to the products listed therein. The person responsible for the handover is to ensure that the purchaser belongs to the category of users specified in the authorisation and that he or she intends to use the product in an appropriate and proper manner. For authorised biocidal products, the user category results from both the authorisation itself and the product labelling. Specifications for the use of the product can result from the authorisation itself (e.g. ban of certain application techniques or areas of application). However, they can also result from abstract general provisions, such as the Hazardous Substances Ordinance, which imposes personal requirements on the user in the form of technical and specialist knowledge requirements. With regard to the type of proof for the personal requirements, the provision does not contain any more concrete specifications, meaning that it is able leave room for the diversity of cases possible. However, as also stated in the explanatory memorandum to the Chemical Prohibition Ordinance, the federal states may develop common principles in the form of guidelines on how the evidence is to be provided in detail (cf. Bundesrat document 559/16, p. 45).

Paragraph 2(2) stipulates the minimum content of the information that the person responsible for the handover must provide to the purchaser during the supply meeting. The supply meeting does not apply to products under § 10(1)(1). Since the use of a biocidal product is restricted to certain categories of users (professional or trained professional users), it is to be assumed that these users have a more extensive level of knowledge of the contents under § 11(2)(2) as compared to the general public. Pursuant to point (a), such content shall include information on ways to prevent or otherwise control infestations of harmful organisms. Point (b), which requires information on the proper and appropriate use of the product, is based on § 23(3) of the Plant Protection Act. The requirements under points (c) to (e) were essentially adopted from § 8(2) of the Chemical Prohibition Ordinance, which regulates the contents of the supply meeting for certain hazardous substances and mixtures.

Paragraph 3 contains a clarifying reference to the fact that further-reaching provisions under the Chemical Prohibition Ordinance remain unaffected. Overlaps with the provisions of the Chemical Prohibition Ordinance may occur if the biocidal products listed here are simultaneously subject to the supply regulations of § 8 in conjunction with Annex 2 of the Chemical Prohibition Ordinance. Annex 2 of the Chemical Prohibition Ordinance, i.e. if they exhibit special hazard characteristics listed therein. In this case, the respective further-reaching provisions must be observed.

Re § 12 (Requirements for supply via online and mail order trade)

The provision contains special arrangements with regard to the implementation of supply in online and mail order trade as compared to § 11. Its purpose is to transfer the requirements for the supply of biocidal products to the online and mail order trade, taking into account the specific circumstances of this case. Therefore, § 11 applies with the stipulation that it must be ensured by means of technical or organisational requirements that compliance with the personal requirements pursuant to § 11(2)(1) is verified by a qualified person and that a supply meeting pursuant to § 11(2)(2) takes place before the purchase contract is concluded. This makes it possible to create appropriate provisions that are technology neutral. For the supply meeting, subparagraph 2 explicitly mentions conducting a supply meeting by telephone or video transmission. By way of derogation from § 11(1), the qualified person does not have to be a company employee, which makes it possible to establish cross-platform solutions. No specific means of communication is mentioned for the verification of the personal requirements under § 11(2)(1). Therefore, the substantiation and the submission of relevant documents can also be made via video transmission. The documents could also be submitted by e-mail, however. In any case, it must be verified that a purchaser fulfils the personal requirements and that a supply meeting has actually taken place. This can be done, for example, by giving the purchaser a code at the end of the supply meeting, which he or she must then provide when ordering the product, i.e. when concluding the purchase contract. In any case, organisational requirements shall be in place to prevent the product from being sold without the requirements of subparagraphs 1 and 2 having been met.

Re § 13 (Qualifications for supply)

The provision regulates in detail the requirements for the qualifications required for the person responsible for the handover pursuant to § 11.

Re paragraph 1

Re subparagraph 1

Pursuant to subparagraph 1, a person is always considered qualified if the qualifications pursuant to § 11 Chemical Prohibition Ordinance are met. The provisions of the Chemical Prohibition Ordinance already apply directly to the supply of biocidal products insofar as these are subject to the special hazard characteristics specified therein in Annex 2. For the other biocidal products for which special requirements are imposed on the supply in accordance with this Ordinance, the existence of qualifications in accordance with § 11 of the Chemical Prohibition Ordinance is also regarded as sufficient in principle. The other qualifications under § 11(3) of the Chemical Prohibition Ordinance are also covered by the reference, so that they do not need to be listed again.

However, the restriction on qualifications pursuant to the Chemical Prohibition Ordinance, which includes the supply of biocidal products, means that if a restricted specialist examination has been passed in accordance with § 11(2)(2) of the Chemical Prohibition Ordinance, then qualifications pursuant to § 11 are only met if the specialist examination entitles the holder to supply biocidal products in accordance with the Chemical Prohibition Ordinance. In order to maintain qualifications in accordance with § 11 of the Chemical Prohibition Ordinance in such a way that it entitles the holder to supply biocidal products, the training course attended must also relate to the supply of biocidal products (cf. Notes and recommendations on the proof of qualifications pursuant to § 11 of the Chemical Prohibition Ordinance of 17.5.2015, eBAnz AT 08.06.2018 B3, p. 5). The requirements for examinations and further training should be designed in such a way that an appropriate quality for the supply meeting is ensured, also by taking into account the respective application.

Re subparagraph 2

Pursuant to subparagraph 2, if the requirements pursuant to § 9 of the Plant Protection Act are met, the qualifications for supply under this Ordinance are valid if, in addition, a further training course pursuant to § 11(1)(2) of the Chemical Prohibition Ordinance, which imparts knowledge concerning biocidal products, has been attended either for the first time or as a repeat course within the periods specified in § 11(1)(2) of the Chemical Prohibition Ordinance. Biocidal products and plant protection products overlap considerably in terms of content. In this respect, similar knowledge is required in many cases when supplying these products in order to be able to provide information on the use of the products resulting from the authorisation, their properties and the necessary risk reduction measures. However, this additional requirement exists as biocidal products cover a much broader range of application areas and therefore the qualifications under the Plant Protection Act do not qualify for the supply of all biocidal products.

Re subparagraph 3

Pursuant to subparagraph 3, the qualification requirement for the application of biocidal products pursuant to § 15b(1) of the Hazardous Substances Ordinance shall also be recognised for the supply of biocidal products under this Ordinance, provided that the qualifications relate to the product type to which the biocidal product supplied is assigned. The qualification requirements for the use of biocidal products to be specified in detail in accordance with the requirements of Annex I No. 3.4 of the Hazardous Substances Ordinance include knowledge which clearly goes beyond the contents of the supply meeting in accordance with § 11(2)(2). Persons qualified in accordance with the Hazardous Substances Ordinance are therefore qualified to provide the necessary information on the use of biocidal products during the supply meeting.

Re paragraph 2

Paragraph 2 allows for the recognition of certificates acquired in other EU Member States or other signatory states to the Agreement on the European Economic Area, to be decided on a case-by-case basis by the competent federal state authority.

Re Section 4 (Provisions on the authorisation of biocidal products)

Re § 14 (Prohibition of the authorisation of certain types of biocidal products)

The provision is a continuation of the previous § 4 of the Biocidal product authorisation ordinance. Even after the harmonisation of the authorisation procedure for biocidal products by Regulation (EU) No 528/2012, there is still a need for the provision, as Article 37(4) of the Regulation allows Member States to refuse mutual recognition of authorisations for products of product types 15 (avicides), 17 (piscicides) and 20 (products for control of other vertebrates) on the grounds of animal welfare. This applies all the more – even if not explicitly regulated in the relevant provision of Regulation (EU) No 528/2012 – to the issuance of an initial authorisation. The provision makes use of this regulatory option.

Re § 15 (Restriction of the authorisation of biocidal products based on certain active substances)

The provision serves to implement the requirement of Article 5(2)(3) of Regulation EU (No 528/2012), which requires appropriate risk mitigation measures to be taken when authorising a biocidal product containing an active substance covered by the exclusion criteria in order to minimise exposure of humans, animals and the environment. An exception exists if certain circumstances make an authorisation necessary for further users as well. For the definition of these circumstances, reference is made to the exemption criteria set out in Article 5(2)(b) and (c) of Regulation (EU) No 528/2012 for the approval of a biocidal active substance despite the fulfilment of the exclusion criteria (avoidance of serious disadvantages caused by the harmful organism to be controlled). It follows from the authorisation for trained professional users only that the products may only be used by qualified persons. Qualifications in the use of biocidal products also refers to knowledge about the safe use and low-exposure application of biocidal products.

Re Section 5 (Notification obligation)

Re § 16 (Notification of biocidal products made available on the market)

The provision is based on the authorisation to issue ordinances in § 12h(2)(2) of the Chemicals Act and is similar in content to § 64 of the Plant Protection Act. It lays down an obligation to notify the annual quantity of biocidal products made available on the market or exported in Germany. Manufacturers, importers and persons who supply or export biocidal products under their own trade name for the first time in Germany are obliged to notify. The notification shall be made electronically to the Federal Office for Chemicals by the end of the day on 31 March each year using an electronic form made available on the website of the Federal Institute for Occupational Safety and Health. The obligation to notify serves to create underlying data for the targeted design of measures to reduce risks and the tailored development of supervisory programmes. The information referred to in paragraph 2 defines the scope of the obligations to notify. Within this framework, the Federal Office for Chemicals can and should provide for additional differentiations in the design of the forms, for example to ensure better data organisation.

Re Section 6 (Concluding provisions)

Re § 17 (Criminal offences and administrative offences)

The provision establishes which violations of the provisions of this Ordinance can be punished as administrative offences on the basis of the blanket provisions of the Chemicals Act.

Re § 18 (Transitional provision)

The provision stipulates in paragraph 1 that the provisions of Section 2, which establish the notification procedure for biocidal products, are not to be applied until 1 January 2022. This is intended to give the Federal Office for Chemicals sufficient time to create the technical prerequisites for the expansion of the civil register. The transitional provision stipulates in paragraph 2 that the confirmation of notification for products already notified at the time of entry into force of the Ordinance must be made for the first time by 31 March 2022. Furthermore, the provision provides for a transitional period until 1January2025 for the supply regulations pursuant to § 10 to § 12, which is intended to ensure that the employees entrusted with the supply of biocidal products are able to acquire the necessary qualifications in good time.

Re Article 2 (Entry into force, abrogation)

This provision specifies the entry into force of the Regulation. The Ordinance shall enter into force one day after its promulgation in the Federal Law Gazette; at the same time, the Biocidal product authorisation ordinance shall cease to be in force. The Ordinance on notification of biocidal products is to be maintained until 31 December 2021, as the new notification requirements of Section 2 of the Ordinance implementing the law on biocidal products will only apply as of 1 January 2022 (see § 18(1)).

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)
3. ) According to Alison K. Krajewski & Lee S. Friedman (2015) Hospital outcomes and economic costs from poisoning cases in Illinois, Clinical Toxicology, 53:5, 433-445, DOI: 10.3109/15563650.2015.1030677, the cost of outpatient treatment of such cases in the USA is assumed to be EUR 1 000. EUR 100 are to be estimated for a simple medical treatment in Germany, therefore it is concluded here that the outpatient costs in Germany are comparatively lower. [↑](#footnote-ref-3)
4. ) McFarland, SE., Mischke, RH., Hopster-Iversen, C., von Krueger, X., Ammer, H., Potschka, H., Stürer, A., Begemann, K., Desel, H., Greiner, M. (2017) Systematic account of animal poisonings in Germany, 2012-2015, Veterinary Record 180, 327. [↑](#footnote-ref-4)