Act on the protection against hazardous substances (German Chemicals Act [Chemikaliengesetz], or ChemG)

ChemG

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"Chemicals Act as amended in the notice of 28 August 2013 (German Federal Law Gazette (FLG) I p. 3498, 3991), last revised by Article 1 of the Regulation of 20 June 2014 (FLG I p. 824)"

Issued: Revised by the notice of 28/8/2013 I 3498, 3991;
last amended by Art. 1 of the Regulation of 20/6/2014 I 824

1 The law serves to implement the following Directives:

- Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ EU no. 196, p. 1), which was last amended by Directive 2013/21/EU (OJ L 158 of 10/6/2013, p. 240),
- Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Art. 16(1) of Directive 89/391/EEC (OJ EU no. L 131, p. 11), which was last amended by Directive 2009/148/EC (OJ L 330 of 16/12/2009, p. 28),
- Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 on the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ EU no. L 200, p. 1, 2002 no. L 6, p. 71), which was last amended by Directive 2013/21/EU (OJ L 158 dated 10/6/2013, p. 240),
- Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (codified version) (OJ EU no. L 50, p. 28), which was last amended by Regulation (EC) no. 219/2009 (OJ L 87 of 31/3/2009, p. 109), and
- Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version) (OJ EU no. L 50, p. 44), which was last amended by Regulation (EC) no. 219/2009 (OJ L 87 of 31/3/2009, p. 109).

Footnote

(+++ Text citations as of: 26/9/1980 +++)
(+++Official reference of the legislative body to EC law:
Implementation of
EEC Directive 548/67 (CELEX no: 31967L0548)
EC Directive 24/98 (CELEX no: 31998L0024)
EC Directive 45/99 (CELEX no: 31999L0045)
EC Directive 9/2004 (CELEX no: 32004L0009)
EC Directive 10/2004 (CELEX no: 32004L0010), see notice of 28/8/2013 I 3498 +++)
(+++ Stipulations based on the Unification Treaty, see ChemG annex EV;
Stipulations no longer applied as per Art. 1(9)
Law of 21/1/2013 I 91 with effect from 29/1/2013 +++)

This is a working translation of the German Chemicals Act (Chemikaliengesetz). No liability is assumed for the correctness and completeness.

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[2] Pursuant to Article 4(101) no. 1 in conjunction with Article 5(3) of the Act of 7 August 2013 (FLG I, p. 3154), on 14 August 2018 § 25a will be formulated in the table of contents as follows: "§ 25a Expenses of those required to provide information".

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Section one
Purpose, scope and definition of terms

§ 1 Purpose of the act

The purpose of the act is to protect people and the environment from the harmful effects of hazardous substances and mixtures, particularly to make them identifiable, avoid them and prevent their development.

§ 2 Scope

(1) The provisions of section three, §§ 16e, 17(1) no. 2, points a and b, and § 23(2) do not apply to:

1. cosmetic products within the meaning of the German Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch) and tobacco products within the meaning of the German Provisional Tobacco Act (Vorläufiges Tabakgesetz),
2. medications that are subject to an approval or registration process pursuant to the German Pharmaceuticals Act (Arzneimittelgesetz) or the German Animal Health Act (Tiergesundheitsgesetz), as well as other medications, provided they do not require approval pursuant to § 21(2) of the German Pharmaceuticals Act or specific packaging for distribution to consumers,

2a. medical products within the meaning of § 3 of the German Medical Devices Act (Medizinproduktegesetz) and their accessories. If it concerns medical products that are or contain preparations within the meaning of Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 on the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ EU no. L 200, p. 1), the provisions of section three apply, unless they are medical products that are used invasively or in contact with the body,

3. waste for disposal within the meaning of § 3(1), sentence 2, second half of the sentence of the German Closed Cycle and Waste Management Act (Kreislaufwirtschaftsgesetz),

4. radioactive waste within the meaning of the German Atomic Energy Act (Atomgesetz),

5. Wastewater within the meaning of the German Wastewater Levy Act (Abwasserabgabengesetz), provided it is discharged into bodies of water or wasterwater systems.

(2) The provisions of sections three and four, § 17(1), no. 2, points a and b and § 23(2) do not apply to foodstuffs, straight feeds, combined feeds and feed additives within the meaning of the German Food and Feed Code. However, the provisions of section three and §16e apply to:

1. foodstuffs that, because of their material properties, are not intended for direct human consumption in unaltered form by consumers within the meaning of § 3 no. 4 of the German Food and Feed Code,

2. straight feeds and combined feeds that are intended, in prepared, treated or processed form, to be used as feed for animals, as well as to feed additives within the meaning of the German Food and Feed Code.

(3) §§ 16d and 23(2) do not apply to substances and mixtures

1. that are solely intended to be used as an active substance in medications that are subject to approval or registration pursuant to the German Pharmaceuticals Act or the German Animal Health Act, or as active

substances in medical products in accordance with § 3, no. 2 and 8 in conjunction with no. 2 of the German Medical Devices Act, or

2. if they are subject to an approval process in accordance with phytosanitary regulations.

§ 17(1), no. 1 and 3 do not apply to substances and mixtures pursuant to sentence 1, no. 2, if corresponding regulations based on the German Plant Protection Act (Pflanzenschutzgesetz) can be met.

(4) The provisions of section three and §§16d, 17 and 23 apply to the manufacture, marketing or use of substances or mixtures pursuant to §3a(1), no. 2 to 5 and 15 as well as products that may release or that contain such substances or mixtures solely to the extent that such activity is carried out commercially in the framework of other economic enterprises or involving the employment of staff. This restriction does not apply to:

1. Regulations and orders

   a) regarding the transport of commodities,

   b) regarding the disposal of waste and abatement of air pollution,

2. environmentally hazardous substances or mixtures if measures to protect human health are taken, and

3. biocidal active substances and biocidal products.

(5) The provisions of sections one, three and four, §§ 17 and 18 as well as the provisions of sections seven and eight do not apply to the carriage of hazardous goods by rail, road, inland water, sea and air transport, with the exception of intra-company carriage.

§ 3 Definition of terms

The following are defined within the meaning of this act:

1. Substance:

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

2. (repealed)

3. (repealed)

3a. (repealed)

4. Mixture:
   Mixture or solution composed of two or more substances;
5. Product:
   An object which during production is given a specific shape, surface or design which determines its function to a greater degree than does its chemical composition;
6. Classification:
   The assignment to a category of hazardousness;
7. Manufacturer:
   A natural or legal person or an unincorporated association of persons that produces or obtains a substance, a mixture or a product;

8. Importer:
   A natural or legal person or an unincorporated association of persons that introduces a substance, a mixture or a product into the scope of this act; an importer is not someone who solely carries out transport under customs supervision, provided there is no treatment or processing;
9. Marketing:
   Delivery to third parties or preparation for third parties; the introduction of a product into the scope of this act is considered marketing to the extent it does not solely involve transport pursuant to no. 8, second half of the sentence;
10. Use:
    Utilisation, consumption, storage, safekeeping, treatment and processing, filling, transferring, mixing, removing, destroying and inter-company carriage;
11. Biocidal product:
    A biocidal product within the meaning of Article 3(1)a 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 of 27/6/2012, p. 1), as amended;
12. Biocidal active substance:
    An active substance within the meaning Art. 3(1)c of Regulation (EU) no. 528/2012.

Definitions of the terms listed in sentence 1 in regulations of the European Community or the European Union (EC or EU regulations) remain unaffected.

§ 3a Hazardous substances and hazardous mixtures

(1) Hazardous substances or hazardous mixtures are substances or mixtures that are
1. explosive,
2. oxidising,
3. extremely flammable,
4. highly flammable,
5. flammable,
6. very toxic,
7. toxic,
8. harmful,
9. corrosive,
10. irritant,
11. sensitising,
12. carcinogenic,
13. toxic for reproduction,
14. mutagenic or
15. dangerous for the environment;

the hazardous properties of ionising radiation are excluded.

(2) Substances or mixtures or their conversion products that are able to alter the composition of the ecosystem, water, soil or air, the climate, animals, plants or micro-organisms in such a way that hazards to the environment can be introduced immediately or subsequently, are dangerous for the environment.

(3) For the purpose of this act, those substances and mixtures that, pursuant to Art. 3 of Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No. 1907/2006 (OJ L 353 of 31/12/2008, p. 1), last amended by Regulation (EU) No.

286/2011 (OJ L 83 of 30/3/2011, p. 1), as amended, are also hazardous, even if they cannot be classified as hazardous according to the characteristics set out in (1).

(4) The German federal government shall be authorised to issue more detailed regulations on the specification of the hazardous characteristics set out in (1) through the promulgation of statutory ordinances with the approval of the Bundesrat.

§ 3b (repealed)

Section two
Implementation of Regulation (EC) no. 1907/2006 and Regulation (EC) no. 1272/2008

§ 4 Participating federal authorities

(1) Pursuant to this paragraph, the following authorities assist in implementation of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ EU no. L 396, p. 1, 2007 no. L 136 p. 3), as amended, and in implementation of Regulation (EC) No. 1272/2008:

1. the German Federal Institute for Occupational Safety and Health, which in this respect is under the supervisory control of the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, as the German Federal Office for Chemicals,

2. the German Federal Environment Agency as the environmental assessment office,

3. the German Federal Institute for Risk Assessment, which in this respect is under the supervisory control of the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, as the health and consumer protection assessment office, and

4. the German Federal Institute for Occupational Safety and Health, which in this respect is subject to the supervisory control of the German Federal Ministry of Labour and Social Affairs, as the occupational health and safety assessment office.

(2) The German Federal Office for Chemicals shall involve other higher federal authorities on an individual basis, provided these authorities have particular specialist knowledge about individual aspects of the assessment of substances, mixtures or products for the purposes of Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008, and the respective question cannot be definitively answered by the authorities set out (1).

§ 5 Duties of the German Federal Office for Chemicals

(1) In implementation of Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008, the following duties in particular are considered acts of cooperation pursuant to § 21(2), sentence 2, for which the German Federal Office for Chemicals is responsible:

1. Statements on draft decisions of the European Chemicals Agency pursuant to Art. 9(8), sentence 2 of Regulation (EC) No. 1907/2006,

2. The duties of the responsible authority of the Member State in the assessment pursuant to Title VI of Regulation (EC) No. 1907/2006,

3. Involvement in the determination of substances as set out in Art. 57 pursuant to Art. 59(3) and (5) of Regulation (EC) No. 1907/2006,

4. Involvement in the harmonised classification and labelling pursuant to Art. 37(1), also in conjunction with (6), of Regulation (EC) No. 1272/2008.

(2) In addition to the duties assigned to it by this act, the German Federal Office for Chemicals shall also carry out the following duties in implementation of Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008:

1. Preparation of dossiers for the initiation of restriction processes pursuant to Art. 69(4) of Regulation (EC) No. 1907/2006,

2. Preparation of proposals to review existing restrictions pursuant to Art. 69(5), sentence 3 of Regulation (EC) No. 1907/2006,

3. Providing support to the German members of the committees and the forum of the European Chemicals Agency in all questions to be considered in these committees and in the forum,

4. Co-operation with the European Commission, the European Chemicals Agency and the responsible authorities of other Member States pursuant to Art. 121 and 122 of Regulation (EC) No. 1907/2006 as well as co-operation with the responsible authorities of other Member States pursuant to Art. 43 of Regulation (EC) No. 1272/2008,

5. Providing information to the public pursuant to Art. 123 of Regulation (EC) No. 1907/2006 about the risks in connection with substances,

6. Submission pursuant to Art. 124(1) of Regulation (EC) No. 1907/2006 of all available information about registered substances, the registration dossiers for which do not contain all of the information pursuant to Annex VII of Regulation (EC) No. 1907/2006 to the European Chemicals Agency,

7. Acting as the national helpdesk pursuant to Art. 124(2) of Regulation (EC) No. 1907/2006 and the national helpdesk pursuant to Art. 44 of Regulation (EC) No. 1272/2008,

8. Advising the federal government in all matters related to Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008 and their further development.

§ 6 Duties of the assessment offices

(1) The assessment offices support the German Federal Office for Chemicals in its duties pursuant to § 5(1), no. 1 to 4 and (2) no. 1 to 3 by carrying out the assessment duties in their respective area of responsibility independently and conclusively. With respect to the duties of the German Federal Office for Chemicals pursuant to § 5(1), no. 1 and (2) no. 4 to 8, they co-operate in the questions that pertain to their respective area of responsibility. The assessment offices support one another by providing expert opinions, provided doing so is necessary for carrying out their duties.

(2) The specialist area of responsibility of the environmental assessment office is environmental risk assessment, including the assessment of risk-mitigating measures.

(3) The specialist area of responsibility of the health and consumer protection assessment office is health risk assessment, including the assessment of risk-mitigating measures.

(4) The specialist area of responsibility of the occupational health and safety assessment office is occupational safety risk assessment, including the assessment of risk-mitigating measures.

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§ 7 Co-operation between the German Federal Office for Chemicals and the other participating higher federal authorities

(1) The German Federal Office for Chemicals coordinates collaboration amongst the higher federal authorities set out in § 4 and also ensures the coherence and consistency of the overall position. It determines the overall position if coherence and consistency cannot otherwise be achieved in individual cases and the submission of a report cannot be delayed. Decisions pursuant to sentence 2 in which the German Federal Office for Chemicals differs from the assessment of an assessment office pursuant to § 6(1), sentence 1 require a detailed explanation, which must be put on record and forwarded to the assessment offices.

(2) The German Federal Office for Chemicals represents the overall position externally. In doing so, it shall involve representatives of the other participating higher federal authorities to the extent it considers this necessary or they so request.

§ 8 No fees for the national helpdesk

For its role as the national helpdesk pursuant to Art. 124(2) of Regulation (EC) No. 1907/2006 and pursuant to Art. 44 of Regulation (EC) No. 1272/2008, the German Federal Office for Chemicals receives no fees.

§ 9 Exchange of information between federal and state authorities

(1) The German Federal Office for Chemicals shall inform the relevant state authority in particular about notices from the European Chemicals Agency regarding:

1. process-oriented research and development pursuant to Art. 9(3), sentence 3 and draft decisions pursuant to Art. 9(8), sentence 1 of Regulation (EC) No. 1907/2006,
2. substances regarded as registered pursuant to Art. 16(1), sentence 2 of Regulation (EC) No. 1907/2006,
3. registration dossiers pursuant to Art. 20(4), sentences 1, 4 and 5 as well as pursuant to Art. 22(1), sentence 2 and (2), sentence 2 of Regulation (EC) No. 1907/2006,
4. dossier evaluation pursuant to Art. 41(2), Art. 42(2), sentence 1 and Art. 43(3) and regarding follow-up measures to the substance evaluation pursuant to Art. 48, sentence 3 of Regulation (EC) No. 1907/2006,
5. the review of intermediate products in other Member States pursuant to Art. 49, sentence 4 of Regulation (EC) No. 1907/2006,
6. the discontinuation of the manufacture, import or production of products pursuant to Art. 50(2), sentence 2 and (3), sentence 3 of Regulation (EC) No. 1907/2006,
7. the evaluation of substances set out in Art. 57 pursuant to Art. 59(2), sentence 3 and Art. 59(3), sentences 1 and 3 and the approval process pursuant to Art. 64(5), sentences 4 and 7 of Regulation (EC) No. 1907/2006,
8. the results of applications to use an alternative chemical name pursuant to Art. 24(5) of Regulation (EC) No. 1272/2008.

(2) The responsible state authorities inform the German Federal Office for Chemicals in particular about:

1. findings about the use of on-site isolated intermediate products from which there may be a risk to human health or the environment pursuant to Art. 49 of Regulation (EC) No. 1907/2006,

2. findings obtained in the course of implementation and monitoring activities pursuant to Art. 124(1), sentence 1 of Regulation (EC) No. 1907/2006 on the basis of which there is a suspicion of risk,

3. the arrangement of provisional measures pursuant to § 23(2) upon presentation of the required documents pursuant to Art. 129(1) of Regulation (EC) No. 1907/2006 or pursuant to Art. 52(1) of Regulation (EC) No. 1272/2008.

(3) § 22 remains unaffected.

§ 10 Provisional measures

(1) If, on the basis of this act, a provisional measure pursuant to Art. 129 of Regulation (EC) No. 1907/2006 or pursuant to Art. 52 of Regulation (EC) No. 1272/2008 is issued, the German Federal Office for Chemicals shall immediately inform the European Commission and the other Member States of the European Union, providing the reasons for the decision that is taken and presenting the scientific or technical information on which this provisional measure is based.

(2) The German Federal Office for Chemicals shall inform the responsible state authorities about the decision of the European Commission pursuant to Art. 129(2) of Regulation (EC) No. 1907/2006 or pursuant to Art. 52(2) of Regulation (EC) No. 1272/2008.

§ 11 (repealed)

§ 12 (repealed)

Section IIa
Implementation of Regulation (EU) no. 528/2012

§ 12a Participating federal authorities

(1) Upon implementation of Regulation (EU) No. 528/2012, the offices set out in § 4(1) shall co-operate pursuant to the stipulations of this paragraph. The German Federal Institute for Risk Assessment, as the health and consumer protection assessment office, is in this respect subject to the supervisory control of the German Federal Ministry of Food, Agriculture and Consumer Protection.

(2) If the authorities set out in § 4(1) numbers 2 to 4, the Julius Kühn Institute, the German Federal Institute for Materials Research and Testing or the Robert Koch Institute have special expertise in the evaluation of the effectiveness and of the unacceptable effects on target organisms, the German Federal Office for Chemicals may request a report from these authorities in order to make a decision as to whether the approval requirements pursuant to Art. 19(1), point b, sub-para. i and ii of Regulation (EU) No. 528/2012 have been met. Furthermore, the German Federal Office for Chemicals shall involve the German Federal Institute for Materials Research and Testing in the evaluation of dangerous characteristics pursuant to § 3a(1), numbers 1 to 5 and the durability of containers and packaging material, provided the German Federal Institute for Materials Research and Testing has the specialist knowledge for the relevant question on the basis of other legal responsibilities and the question cannot be definitively answered by the German Federal Office for Chemicals.

(3) Paragraph 1 notwithstanding, the following authorities are responsible for granting, renewing, reviewing and cancelling exception authorisations pursuant to Art. 55(1) of Regulation (EU) No. 528/2012, including initiating the related Commission processes:

1. The Robert Koch Institute in relation to biocidal products that must be used for disinfections pursuant to § 18 of the German Infection Protection Act (Infektionsschutzgesetz),

2. the German Federal Office of Consumer Protection and Food Safety in relation to biocidal products that

a) pursuant to § 18 of the German Infection Protection Act, must be used to remove infestations and for measures to combat vertebrates that can spread pathogens, or

b) pursuant to § 17f of the German Animal Diseases Act (Tierseuchengesetz), may be used for disinfections and infestation removals prescribed for animal health purposes.

§ 12b Duties of the German Federal Office for Chemicals

(1) In the implementation of Regulation (EU) No. 528/2012, the following duties in particular are considered acts of o-operation pursuant to § 21(2), sentence 2:

1. The duties of the competent evaluating authorities

a) in approving an active substance and in renewing and reviewing the approval of an active substance pursuant to Chapters II, III and XI of Regulation (EU) No. 528/2012,

b) in granting and renewing as well as cancelling, reviewing or amending Union authorisations pursuant to Chapters VIII and IX of Regulation (EU) No. 528/2012,

2. The involvement as part of a work programme to systematically review all old active substances pursuant to Art. 89(1) of Regulation (EU) No. 528/2012,

3. The involvement in the co-ordination group pursuant to Art. 35 and in the committee for biocidal products pursuant to Art. 75 of Regulation (EU) No. 528/2012.

(2) In addition to the duties assigned to it by this act, the German Federal Office for Chemicals shall also carry out the following duties in implementation of Regulation (EC) No. 528/2012:

1. The filing of applications with the Commission pursuant to Art. 3(3) and Art. 15(1)(1) of Regulation (EU) No. 528/2012,

2. The duties of the competent evaluating authority as part of the simplified approval process pursuant to Art. 26, also in conjunction with Chapter IX, of Regulation (EU) No. 528/2012,

3. The receipt of information from the authorisation holder pursuant to Art. 27(1), sentence 2 and exercising the authorities of the Member State pursuant to Art. 27(2) and Art. 28(4)(1) of Regulation (EU) No. 528/2012,

4. The duties of the competent authority in granting, renewing and reviewing national authorisations pursuant to Chapter VI, also in conjunction with Chapter IX, of Regulation (EU) No. 528/2012,

5. The duties of the competent authority of the affected Member State or reference Member State in the process of mutual recognition pursuant to Chapter VII, also in conjunction with Chapter IX, as well as in exercising the authorities of the Member State pursuant to Art. 37 of Regulation (EU) No. 528/2012,

6. The filing of applications with the Commission pursuant to Art. 44(5)(2) of Regulation (EU) No. 528/2012,

7. The duties of the competent authority of the Member State of importation in relation to parallel trade pursuant to Chapter X of Regulation (EU) No. 528/2012,

8. The granting, renewing, reviewing and cancelling of exception authorisations pursuant to Art. 55 of Regulation (EU) No. 528/2012, including initiating the related Commission processes, provided the authorities set out in § 12a(3) are not competent,

9. The duties of the competent authority of the Member State pursuant to Art. 56 of Regulation (EU) No. 528/2012,

10. Advising the federal government in all matters related to Regulation (EU) No. 528/2012 and its further development.

§ 12c Duties of the assessment offices

(1) The assessment offices support the German Federal Office for Chemicals in its duties pursuant to § 12b(1) and (2), no. 1 to 9 by carrying out the assessment duties in their respective area of responsibility independently and conclusively. Furthermore, they cooperate in the area of questions related to their respective area of responsibility. The assessment offices support one another by providing expert opinions, provided doing so is necessary for carrying out their duties.

(2) The specialist area of responsibility of the environmental assessment office is environmental risk assessment, including the assessment of risk-mitigating measures.

(3) The specialist area of responsibility of the health and consumer protection assessment office is

1. risk assessment in relation to the health of people and domestic and farm animals, including assessment of risk-mitigating measures, as well as

2. preparation of proposals to determine maximum amounts pursuant to Art. 19(1), point e of Regulation (EU) No. 528/2012.

(4) The specialist area of responsibility of the occupational health and safety assessment office is risk assessment in relation to occupational safety, including assessment of risk-mitigating measures.

§ 12d Co-operation between the German Federal Office for Chemicals and the other participating higher federal authorities

(1) The German Federal Office for Chemicals coordinates collaboration amongst the higher federal authorities set out in § 12a and also ensures the coherence and consistency of decisions and statements as a whole.

(2) To the extent that the German Federal Office for Chemicals is responsible for evaluating whether the authorisation requirements pursuant to Art. 19(1) of Regulation (EU) No. 528/2012 are met as part of its activities pursuant to § 12b, it takes decisions with respect to the requirements

1. pursuant to Art. 19(1), point b(iv) of Regulation (EU) No. 528/2012 in agreement with the environmental assessment office,

2. pursuant to Art. 19(1), point b(iii) of Regulation (EU) No. 528/2012 regarding the effects on the health of employees in agreement with the occupational health and safety assessment office, and

3. pursuant to Art. 19(1), point b(iii) of Regulation (EU) No. 528/2012, also in conjunction with Art. 19(1), point e of Regulation (EU) No. 528/2012 regarding a proposal to determine maximum residue levels for food or feed in agreement with the health and consumer protection assessment office.

Furthermore, the German Federal Office for Chemicals takes decisions in agreement with the assessment offices, to the extent that their area of responsibility pursuant to § 12c(2)-(4) is affected, regarding

1. the necessity of risk-mitigating measures,

2. the fulfilment of authorisation requirements pursuant to Art. 19(5) of Regulation (EU) No. 528/2012,

3. the results of a comparative assessment pursuant to Art. 23 of Regulation (EU) No. 528/2012,

4. the granting of an authorisation pursuant to Art. 26(3) of Regulation (EU) No. 528/2012,

5. exception authorisations pursuant to Art. 55 of Regulation (EU) No. 528/2012, to the extent that the authorities set out in § 12a(3) are not competent, and

6. opinions and decisions pursuant to Art. 56(2), sub-para. 2 and (3) of Regulation (EU) No. 528/2012.

(3) With the exception of the cases set out in (4), the German Federal Office for Chemicals shall represent the overall position externally. It shall involve representatives of the other participating higher federal authorities to the extent it considers this necessary or they so request.

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(4) Decisions by the higher federal authorities set out in § 12a(3) regarding authorisations pursuant to Art. 55(1) of Regulation (EU) No. 528/2012 are represented externally by the authority that is responsible for the decision. This authority shall in each case immediately inform the German Federal Office for Chemicals about the start of the respective decision-making process and about the measures that it decides.

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§ 12e Helpdesk, informing the public

(1) The German Federal Office for Chemicals shall establish a helpdesk to meet the requirements pursuant to Art. 81(2) of Regulation (EU) No. 528/2012. The helpdesk is to be maintained in conjunction with the helpdesk pursuant to § 5(2), number 7. § 8 shall apply mutatis mutandis.

(2) Pursuant to Art. 17(5)(3) of Regulation (EU) No. 528/2012, the German Federal Office for Chemicals shall inform the public about

1. the benefits and risks of using biocidal products,

2. physical, biological, chemical and other measures as alternatives to using biocidal products or as an opportunity for reducing the use of biocidal products, and

3. the competent, appropriate and sustainable use of biocidal products.

(3) The other higher federal authorities set out in § 12a shall support the German Federal Office for Chemicals in carrying out its duties pursuant to (1) and (2).

§ 12f Exchange of information between federal and state authorities

(1) The German Federal Office for Chemicals shall inform the relevant state authority in particular about

1. the following decisions taken by it or reports received by it:

a) notifications pursuant to Art. 17(6), sentence 1 and Art. 27(1), sentence 2 of Regulation (EU) No. 528/2012,

b) measures pursuant to Art. 27(2)(2) of Regulation (EU) No. 528/2012,

c) the granting, renewal or cancellation of a national authorisation pursuant to Chapter VI of Regulation (EU) No. 528/2012,

d) the recognition of an authorisation pursuant to Chapter VII of Regulation (EU) No. 528/2012,

e) the granting or cancellation of a parallel trade authorisation pursuant to Chapter X of Regulation (EU) No. 528/2012,

f) the granting of exception authorisations pursuant to Art. 55 of Regulation (EU) No. 528/2012,

g) the rejection of experiments or tests or the setting of conditions pursuant to Art. 56(3) of Regulation (EU) No. 528/2012,

h) orders pursuant to § 12g(1), sentence 1 and (3).

2. Notifications by the European Chemicals Agency regarding the following decisions taken by it or the European Commission or reports received by it or the European Commission:

a) the acceptance or rejection of an application for authorisation or renewal of authorisation for an active substance as well as the result of the authorisation process pursuant to Chapters II and III of Regulation (EU) No. 528/2012,

b) the acceptance or rejection of an application for the granting, renewal or cancellation of a Union authorisation for a biocidal product as well as the results of the authorisation process, and

c) reports pursuant to Art. 17(6), sentence 3 of Regulation (EU) No. 528/2012.

(2) The higher federal authorities set out in § 12a(3) shall inform the competent state authority about their decisions as well as renewal decisions by the Commission pursuant to Art. 55(1) of Regulation (EU) No. 528/2012.

(3) The responsible state authorities inform the German Federal Office for Chemicals in particular about:

1. findings obtained in the course of implementation and monitoring activities that could be of significance for decisions pursuant to Art. 27(2), Art. 48(1) or Art. 56(3) of Regulation (EU) No. 528/2012 or pursuant to § 12g(1), sentence 1,

2. monitoring measures pursuant to § 12g(1), sentence 3.

3. the arrangement of provisional measures pursuant to § 23(2) upon presentation of the documents required pursuant to Art. 88, sub-para. 1, sentence 2 of Regulation (EU) No. 528/2012.

(4) The information pursuant to (1) to (3) also includes information about whether appeals have been filed and if so what the result was.

(5) § 22 remains unaffected.

§ 12g Authority of the German Federal Office for Chemicals, provisional measures

(1) Where, on the basis of new evidence, there is justifiable grounds to consider that a biocidal product, although authorised in accordance with Regulation (EU) No. 528/2012, constitutes a serious immediate or long-term risk to the health of humans, particularly of vulnerable groups, or animals, or to the environment, the German Federal Office of Chemicals, in agreement with the assessment groups, may take appropriate provisional measures, in particular a temporary prohibition against bringing the biocidal product to the market pursuant to Art. 3(1), point i of Regulation (EU) No. 528/2012 or making it dependent on compliance with certain requirements. Appeals of the arrangements as set out in sentence 1 shall not have a suspensive effect. The arrangements of the German Federal Office for Chemicals pursuant to sentence 1 shall be enforced by the competent state authority pursuant to the respective state legal provisions via administrative enforcement proceedings. § 23(2) remains unaffected.

(2) For the decision-making process under EU law pursuant to Art. 88 of Regulation (EU) No. 528/2012 on provisional measures that are issued on the basis of (1) or other provisions of this act, § 10 shall apply mutatis mutandis.

(3) The German Federal Office for Chemicals can, in agreement with the assessment offices, authorise a biocidal product for key uses pursuant to Art. 5(1) of Commission Regulation (EC) No. 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Art. 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325 of 11/12/2007, p. 3), which was amended by Commission Regulation (EU) No. 298/2010 of 9 April 2010 (OJ L 90 of 10/4/2010, p. 4), provided the European Commission has taken a decision for the

respective biocidal active substance pursuant to Art. 5(3) of Regulation (EC) No. 1451/2007, also in conjunction with Art. 89(1) of Regulation (EU) No. 528/2012 and the requirements contained therein have been met.

§ 12h Statutory authorisations

(1) The federal government shall be authorised, to the extent permitted by European Union law and through the promulgation of statutory ordinances with the approval of the Bundesrat, to regulate in more detail the requirements, substance and procedures for the decisions or acts of co-operation of the higher federal authorities set out in § 12a as part of the implementation of Regulation (EU) No. 528/2012, particularly to determine:

1. that certain biocidal products

a) are not capable of being authorised or

b) may only be authorised for certain purposes, applications or locations, for distribution to certain groups of users or under other specific restrictions,

2. that certain substantive or procedural requirements must be met during

a) the application for and granting of exception authorisations pursuant to Art. 55 of Regulation (EU) No. 528/2012 and

b) the reporting of and official review of experiments and tests pursuant to Art. 56 of Regulation (EU) No. 528/2012.

(2) Furthermore, the federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat, to establish measures for the sustainable use of biocidal products, particularly to determine:

1. that equipment that is used in order to utilise the biocidal products is subject to certain control processes,

2. how the manner and scope of utilisation of biocidal products can be effectively defined; this can also comprise the introduction of reporting requirements for quantities of biocidal products that are brought to market and used as well as the establishment of conditions for a nationwide monitoring programme,

3. whether and in what form persons called on to treat or evaluate acute and chronic cases of poisoning of non-target organisms by biocidal products must report such cases to the German Federal Office for Chemicals or another appropriate higher federal authority.

Section three
Classification, labelling and packaging

§ 13 Classification, labelling and packaging requirements

(1) The classification, labelling and packaging of substances and mixtures is based on the provisions of Regulation (EC) No. 1272/2008.

(2) Those who bring substances or mixtures to market as manufacturers or importers must classify them pursuant to the statutory ordinance in accordance with § 14, to the extent that

1. they must, pursuant to the transitional provisions of Art. 61 of Regulation (EC) No. 1272/2008, apply the provisions based on Directive 67/548/EEC or Directive 1999/45/EC, or

2. the statutory ordinance pursuant to § 14 contains provisions that exceed the requirements of Regulation (EC) No. 1272/2008.

(3) Those who bring substances of mixtures to market as suppliers pursuant to Art. 2, number 26 of Regulation (EC) No. 1272/2008 must label and package these pursuant to the statutory ordinance in accordance with § 14 to the extent that

1. they, pursuant to the transitional provisions of Art. 61 of Regulation (EC) No. 1272/2008, apply or must apply the provisions based on Directive 67/548/EEC or Directive 1999/45/EC, or

2. the statutory ordinance pursuant to § 14 contains provisions that exceed the requirements of Regulation (EC) No. 1272/2008.

In meeting the requirements pursuant to sentence 1, suppliers who are not required to classify the substance or mixture themselves pursuant to (2) can take the classification of the manufacturer or importer as the basis, provided they have no knowledge that it is inaccurate.

(4) Further requirements regarding labelling and packaging pursuant to other statutory provisions remain unaffected.

§ 14 Authorisation to institute classification, labelling and packaging requirements

(1) The federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat,

1. to classify substances or mixtures as hazardous,

2. to prescribe calculation processes, according to which certain mixtures are to be classified on the basis of the classification of the substances contained in the mixture,

3. to determine

a) how hazardous substances and mixtures and whether and how certain products that contain or can release certain hazardous substances or mixtures must be packaged or labelled in order to prevent dangers to the life and health of people and the environment during foreseeable use,

b) whether and how certain information about hazardous substances and mixtures or products that contain or can release hazardous substances or mixtures, including recommendations for precautions when using them or immediate measures in the event of accidents, must be provided and kept up-to-date by those who bring the substances, mixtures or products to market, particularly in the form of a safety data sheet or user instructions,

c) the minimum considerations that the manufacturer or importer must take into account when classifying substances pursuant to § 13(2),

d) who must package and label the hazardous substances, mixtures or products if they were brought to market before the entry into force of the statutory ordinance that resulted in the labelling or packaging requirement,

e) whether and how certain mixtures and products that do not contain certain hazardous substances, which must be defined in greater detail, are to be labelled or can be labelled, and

f) whether and by whom the labelling of certain substances, mixtures or products following their marketing is to be maintained or reattached.

(2) The statutory ordinance pursuant to (1) can also include exceptions to the requirement to package and label, provided that doing so does not impair the protective purpose pursuant to (1), number 3(a). The statutory ordinance can also stipulate that, in place of labelling, the corresponding information can be provided in another suitable manner.

(3) Regulations pursuant to (1) and (2) can also be adopted for biocidal active substances and biocidal products that are not hazardous substances or mixtures pursuant to § 3a as well as for substances, mixtures and products pursuant to § 19(2).

§ 15 (repealed)

§ 15a (repealed)

Section four
Notification requirements

§ 16 (repealed)

§ 16a (repealed)

§ 16b (repealed)

§ 16c (repealed)

§ 16d Notification requirements for mixtures

(1) The federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat, for the purpose of determining the hazards that can arise from mixtures as well as the type and scope of the use of hazardous substances in mixtures, require the manufacturer, importer or user of certain mixtures to notify the German Federal Office for Chemicals within an appropriate period of time in writing of the

1. name of these mixtures and their trade names,
2. their labelling,
3. information about the composition of these mixtures,
4. the quantity of these mixtures manufactured, imported or used annually,
5. their areas of application,
6. test certificates that they have on file or that can be obtained for a reasonable expense pursuant to Regulation (EC) No. 440/2008, to the extent that such certificates are required to identify the hazardous characteristics of these mixtures where said characteristics cannot be determined with the help of the calculation processes pursuant to or on the basis of this act, and
7. the contents of safety data sheets, if there is evidence, particularly a reasonable suspicion based on the latest scientific findings, that harmful effects are produced from these mixtures for people or the environment.

(2) The notification requirement can be limited to certain information about the composition, made dependent on the quantity manufactured, imported or used and extended to include subsequent modifications of the composition. The statutory ordinance must contain provisions as to whether and how, at the request of the notifying party, the confidentiality of the information that is sent must be ensured.

§ 16e Notification requirements for poisoning information and treatment centres

(1) Those who market a hazardous mixture or biocidal product as a manufacturer or importer or under a dedicated trade name must notify the German Federal Institute for Risk Assessment of the

1. trade name,
2. information about the composition,

3. the labelling,

4. directions for use,

5. recommendations for precautions when using it and immediate measures in the event of accidents as well as any subsequent changes to this information that may be of significance for the treatment of illnesses that may arise as a result of the effects of its mixture or its biocidal product. Notification shall not be required if the information pursuant to sentence 1 has already been sent to the German Federal Institute for Risk Assessment. Notification must be provided before initial placement on the market or the occurrence of the change.

(2) Doctors called on to treat or evaluate an illness for which there is at least a suspicion that the symptoms are the result of hazardous substances, hazardous mixtures, products that release or contain hazardous substances or mixtures or biocidal products, must report the substance or the mixture, the age and gender of the patient, the method of exposure, the amount ingested or absorbed and the identified symptoms to the German Federal Institute for Risk Assessment. With respect to the patient, the notification must be provided in anonymised form. § 8(1) number 1, second half of the sentence of the German Infection Protection Act of 20 July 2000 (FLG I, p. 1045) shall apply mutatis mutandis. Sentence 1 shall not apply if this information must be provided to a statutory accident insurance institution; said institution must provide the information pursuant to sentence 1 to the German Federal Institute for Risk Assessment.

(3) The German Federal Institute for Risk Assessment shall forward the information pursuant to (1), even if this information is forwarded to it on the basis of other statutory provisions, to the medical establishments designated by the states, collect and analyse the findings of the health consequences of hazardous substances or hazardous mixtures, and, in the event of substance-related illnesses, provide advice and treatment (poisoning information and treatment centres). The authorities designated in sentence 1 shall report to the German Federal Institute for Risk Assessment concerning the findings obtained as a result of their activities and which are of general significance for the consultation and treatment of substance-related illnesses.

(4) The information pursuant to (1) and (2) must be handled confidentially. The information pursuant to (1) may only be used to

1. answer medical questions by offering prevention and treatment measures, particularly in emergency cases, or

2. at the request of the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, identify the need for improved risk management measures on the basis of a statistical analysis.

(5) The federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat,

1. to extend the requirements pursuant to (3) to other authorities whose duty it is to answer medical questions by offering prevention and treatment measures,

2.

a) to also extend the notification requirement pursuant to (1) to substances and other mixtures that can have harmful effects on people,

b) to extend the notification requirement pursuant to (1) to products that can foreseeably release hazardous substances or mixtures that can have harmful effects on people if knowledge of

the substances, mixtures or products is necessary for the poisoning information and treatment centres or for the authorities pursuant to number 1 to carry out their assigned duties,

c) to exempt certain mixtures from the notification requirement pursuant to (1), if this is compatible with the protective purpose of this provision and is permitted under European Union law, and

3. to adopt more detailed provisions regarding the type and scope of the information pursuant to (1) and the information requirements pursuant to (2) and (3) as well as the confidential treatment and the purposes pursuant to (4).

§ 16f (repealed)

Section five
Authorisation to institute bans and restrictions as well as measures to protect employees

§ 17 Bans and restrictions

(1) After hearing from stakeholders, the federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat, and provided this is required for the purpose set out in § 1 and permitted under European Union law,

1. to stipulate that certain hazardous substances, certain hazardous mixtures or products that contain or can release such substance or such mixture,

a) may not be manufactured, marketed or used, may only be manufactured, marketed or used in certain compositions or for certain purposes,

b) may only be used in a certain manner, or

c) may only be distributed under certain conditions or only to certain persons,

2. to stipulate that those who manufacture, market or use certain hazardous substances, certain hazardous mixtures or products that contain or can release such substance or such mixture,

a) must indicate this,

b) require permission to do so,

c) must meet certain reliability and health requirements, or

d) must verify their expertise in a process, the details of which are to be defined,

3. to ban manufacturing processes or uses involving certain hazardous substances.

(2) The provisions of (1) can also be used to establish bans and restrictions that take account of the development of substances, mixtures, products or processes the manufacture, use, removal or application of which is associated with a lower risk to people or the environment.

This is a working translation of the German Chemicals Act (Chemikaliengesetz). No liability is assumed for the correctness and completeness.

(3) Para. 1 also applies to biocidal active substances and biocidal products that are not hazardous substances or mixtures pursuant to § 3a, to substances, mixtures and products pursuant to § 19(2) and to substances, mixtures or products whose conversion products are hazardous pursuant to § 3a(1), numbers 1 to 14. The provisions of (1) in conjunction with sentence 1 can also be used to issue regulations regarding best practice with respect to the use of biocidal products.

(4) Para. 1, numbers 1 and 2 also apply to substances, mixtures and products for which there is evidence, particularly a reasonable suspicion based on the latest scientific findings, that the substance, the mixture or the product is hazardous.

(5) The federal government can also define procedural regulations as well as methods for reviewing compliance with them in the statutory ordinances pursuant to (1). In particular, it can stipulate the collection of samples and the processes necessary to carry this out and the analysis procedures required to determine the individual substances and groups of substances.

(6) In urgent cases, the federal government can issue a statutory ordinance pursuant to (1), numbers 1 and 3 without the approval of the Bundesrat and without hearing from stakeholders. It shall expire no later than 12 months after it enters into force. It can only be extended with the approval of the Bundesrat.

(7) The stakeholders are comprised of representatives to be selected from academia, consumer associations, trade unions and professional associations, industry participants, the public health system and environmental, animal protection and nature conservation associations.

§ 18 Poisonous animals and plants

(1) The federal government shall be authorised, to the extent it is necessary for the protection of the life or health of people and taking account of the interests of nature conservation and animal protection, through the promulgation of statutory ordinances with the approval of the Bundesrat, to decree that specimens

1. of certain poisonous animal species

a) may not be imported or owned,

b) may only be imported or owned if suitable antitoxins and treatment recommendations are provided by the importer or animal owner, or

c) may only be imported or owned if this is reported to the competent authorities in advance,

2. of certain poisonous plant species

a) may not be planted in certain areas or

b) may only be offered in catalogues and stock lists if there is a note regarding their poisonousness.

The ownership permission pursuant to sentence 1, number 1, points b and c can be linked to conditions.

(2) Para. 1, number 1 shall apply mutatis mutandis for dead specimens of poisonous animals species or for parts of these. Para. 1, number 2, point b shall apply mutatis mutandis to poisonous seeds, poisonous plants and reproductive material and dead specimens or parts of poisonous plant species.

(3) § 17(1), numbers 1 and 2, points c and d shall apply mutatis mutandis to the animal carcasses or parts of these set out in (2), sentence 1 as well as to certain species of poisonous seeds and dead specimens or parts of poisonous plant species.

This is a working translation of the German Chemicals Act (Chemikaliengesetz). No liability is assumed for the correctness and completeness.

§ 19 Measures to protect employees

(1) The federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat, to the extent necessary for the protection of the life and health of people, including the protection of workers and humane working conditions, to decree the types of measures as set out in (3) for the manufacture and use of substances, mixtures and products as well as for activities that involve such hazards. Sentence 1 shall not apply to measures pursuant to (3) if corresponding provisions exist pursuant to the German Atomic Energy Act, the German Federal Pollution Control Act (Bundes-Immissionsschutzgesetz), the German Plant Protection Act or the German Explosives Act (Sprengstoffgesetz).

(2) Hazardous substances pursuant to this provision are

1. hazardous substances and mixtures pursuant to § 3a(1),

2. substances, mixtures and products that are explosive,

3. substances, mixtures and products from which substances pursuant to number 1 or number 2 occur or are released during their manufacture or use,

4. substances and mixtures that do not meet the criteria pursuant to numbers 1 to 3, but as a result of their physico-chemical, chemical or toxic properties and the manner in which they are available or used in the workplace could endanger the safety of employees,

5. all substances that are assigned a workplace exposure limit within the meaning of the statutory ordinance pursuant to (1).

(3) The statutory ordinance pursuant to (1) can, in particular, set out

1. how those who employ others in the manufacture and use of substances, mixtures or products must determine whether the intended manufacture or use involves a hazardous substance, if there is not already a classification according to the provisions of section three,

2. that those who employ others in the manufacture and use of hazardous substances are required to review whether substances, mixtures or products or manufacturing processes or uses with a lower risk to human health are available and that they should or must use these, to the extent that this is reasonable,

2a. that the manufacturer or importer must, upon request, provide the employer with information on the hazardous components of the hazardous substances as well as the applicable thresholds and, if they have not already been provided, recommendations for substance concentrations that must be maintained and the risks arising from hazardous substances or the measures that must be taken against them,

3. how workplaces, including technical systems, technical equipment and work processes, must be procured, set up or operated in order to meet the latest technology, occupational health and hygienic regulations as well as the definitive safety, occupational health, hygienic and other workplace-related findings intended to protect employees,

4. how the company must be organised, particularly

a) that substances and mixtures must be marked and how hazardous substances must be packaged, labelled and recorded within the company to ensure that employees are not

endangered as a result of unsuitable packaging and are informed about the hazards of a package by the labelling,

b) how the manufacturing processes or uses must be organised to ensure that employees are not endangered and that limits and thresholds for the concentration of hazardous substances or mixtures in the workplace according to the latest information are not exceeded,

c) which precautions must be taken to ensure that hazardous substances do not fall into the hands of unauthorised parties or otherwise go astray,

d) which personal protective equipment must be made available and must be used by employees in accordance with regulations,

e) how the number of employees exposed to hazardous substances must be limited and how the duration of such activity must be limited,

f) how employees must conduct themselves to ensure that they do not endanger themselves or others, and which precautions must be taken to this end, particularly what knowledge and skills employees must have and what proof must be provided in this regard,

g) under what circumstances access and employment restrictions must be arranged to protect employees,

h) that a project manager must be employed for certain manufacturing processes and uses, what responsibilities are to be assigned to this person and what expertise he/she must document,

5. how employees are to be informed of the regulations to be applied in a job-based user manual on an ongoing basis and at what intervals instructions are to be provided via the user manual regarding the potential hazards and the necessary protective measures,

6. which precautions are to be taken to prevent business disruptions and to limit their impact for employees and which measures are to be taken to organise first aid,

7. whether and which responsible supervisors must be hired for areas in which employees are exposed to particular hazards and which authorisations must be assigned to them so that they can carry out their occupational safety duties,

8. that with a view to the protection of employees, a hazard assessment is to be carried out, which documents are to be prepared for this and that these documents can be submitted by the competent state authority to the German Federal Institute for Occupational Health and Safety for a review of the hazard assessment,

9. which documents for eliminating risks for employees are to be kept on file for inspection by the component state authority and provided upon request,

10. that a manufacturing process or use that entails or could result in particular risks for employees must be reported to the competent state authority or permitted by the competent state authority,

11. that work during which certain hazardous substances or mixtures can be released may only be carried out by companies that have the approval of the authorities,

12. that the health of employees must be monitored, records in this regard are to be maintained and for this purpose

a) those who employ others in the manufacture or use of hazardous substances can be required, in particular, to have employees examined by a physician,

b) the physician who is tasked with the preventive examination must meet certain requirements in connection with the findings of the examination, particularly with regard to the contents of the certificates to be prepared by him/her and reporting and providing advice about the results of the examination,

c) the competent authorities decide if the physician's findings are deemed inappropriate,

d) the information to be included in the report is to be communicated to the competent statutory accident insurance institution or an office authorised by it for the purpose of determining work-related health hazards or occupational illnesses,

13. that the employer must notify the works council or staff council of the procedures it must implement in order to meet its duties,

14. that the competent state authorities are authorised to issue certain orders in individual cases for the purpose of implementing statutory ordinances, particularly if there is imminent danger and including against supervisors and other employees,

15. that company equipment and work processes in which certain hazardous substances are manufactured or used must be reviewed by a professional or an expert.

(4) On account of the requirements pursuant to (3), reference may be made to publicly accessible announcements by expert groups; in doing so

1. the date of the announcement must be indicated in the statutory ordinance and the source identified precisely,

2. it must be ensured that the announcement is stored securely in the archive of the German Federal Institute for Occupational Health and Safety and that this is referenced in the statutory ordinance.

This is a working translation of the German Chemicals Act (Chemikaliengesetz). No liability is assumed for the correctness and completeness.

Section six
Good laboratory practice

§ 19a Good laboratory practice (GLP)

(1) Non-clinical health and environment-related safety reviews of substances or mixtures, the results of which should enable an evaluation of their potential risks to people and the environment as part of an authorisation, approval, registration, filing or notification process, are to be carried out in accordance with the principles of good laboratory practice pursuant to Annex 1 to this act, provided there is nothing specified to the contrary in Community law or Union law.

(2) The applicant or the person subject to filing or notification requirements who submits the results of a review as part of a procedure pursuant to (1) must verify that the reviews that led to the results meet the requirements pursuant to Annex 1. Verification is to be provided by

1. certification pursuant to § 19b and

2. a written declaration by the person who conducted the review regarding the extent to which the review was conducted in accordance with the principles of good laboratory practice.

If verification is not provided, the results of the review shall be regarded as not submitted.

(3) Federal authorities who conduct reviews pursuant to (1) shall be responsible for ensuring that the principles of good laboratory practice are upheld in their area of responsibility.

(4) The obligation to preserve records pursuant to number 10.2 of Annex 1 can be transferred by handing over the documents and signing a written agreement with the customer or a third party, which must be communicated to the competent authority.

(5) Para. 1 and 2 shall not apply to reviews initiated before 1 August 1990 and completed by 1 January 1995 if the competent authority has ascertained in individual cases that the reviews can still be used, even taking account of the principles of good laboratory practice.

§ 19b GLP certification

(1) Upon request, the competent authority must issue, after carrying out an inspection process, certification to those who conduct reviews pursuant to § 19a(1), verifying that the principles of good laboratory practice have been met, if the review facility or review location and the reviews or review phases that were carried out meet the principles of good laboratory practice pursuant to Annex 1. The request pursuant to sentence 1 can also be submitted by those who are not required to carry out reviews pursuant to § 19a(1), but who can substantiate a legitimate interest. In the case of § 19a(3), the certification shall be issued for the federal authority by its supervisory authority or an office designated by this authority. The certification pursuant to sentences 1 and 3 is to be issued in accordance with the model in Annex 2. A decision regarding a request to issue certification pursuant to sentence 1 must be taken within a period of three months; § 42a(2), sentences 2 to 4 of the German Administrative Procedure Act (Verwaltungsverfahrensgesetz) shall apply, with the stipulation that the period shall not commence before the conclusion of the prescribed inspection process pursuant to sentence 1. The procedure for requesting that certification be issued can be carried out by a single office. In reviewing the request to issue certification pursuant to sentence 1, documentation from another Member State of the European Union or another party to the Agreement on the European Economic Area shall be equivalent to domestic documentation if such documentation demonstrates that the requester meets the relevant

requirements of sentence 1 or, based on their objective, the substantially comparable requirements of the issuing country.

(2) The certification pursuant to (1), sentence 1 shall be equivalent to:

1. GLP certification of other Member States of the European Union or parties to the Agreement on the European Economic Area on the basis of Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ EU no. L 50, p. 28),

2. GLP certification of states that are not members of the European Union if mutual recognition of GLP certification has been assured,

3. confirmation from the German Federal Institute for Risk Assessment that a review facility located in a state that is not a Member State of the European Union and that does not assure mutual recognition of GLP certifications conducts reviews, according to the information available to the German Federal Institute for Risk Assessment, in accordance with the principles of good laboratory practice.

§ 19c Reporting

(1) The federal government shall submit a report on the application of the principles of good laboratory practice within the scope of this act to the European Commission each year by 31 March for the previous calendar year. The report shall contain a list of the inspected review facilities and review locations, the dates on which the inspections were conducted and a summary of the results of the inspections. The top-level state authorities shall cooperate in the preparation of the report and submit their contributions to the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety by 15 February for the previous calendar year.

(2) The German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety may publish a list of the review facilities and review locations that conduct the reviews or review phases in accordance with the principles of good laboratory practice in the German Federal Gazette.

§ 19d Supplemental provisions

(1) In addition to the duties assigned to it by law, statutory ordinances and other legislation, the German Federal Institute for Risk Assessment has the following duties in the area of good laboratory practice:

1. Preparation, maintenance and updating of the list pursuant to § 19c(2),

2. Providing expert advice to the federal government and the states, particularly for the specification of requirements regarding

a) the competence and the reliability of those entrusted with conducting the reviews,

b) the configuration and the equipment of review facilities and review locations,

c) the laboratory practice, e.g. the configuration of the review samples, the conducting and quality control of the reviews and review phases,

d) the manner in which data is obtained and documented,

e) the monitoring of compliance with the principles of good laboratory practice,

3. Providing expert advice to the federal government as part of the consultation process with the European Commission and other Member States of the European Union,

4. Cooperating in the implementation of agreements on good laboratory practice with states that are not members of the European Union.

(2) The federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat, to amend Annex 1 and 2 in order to enhance good laboratory practice.

(3) The federal government shall, with the approval of the Bundesrat, issue general administrative provisions concerning the regulatory monitoring process. The general administrative provisions can also stipulate that publication authorisation be transferred to the German Federal Institute for Risk Assessment.

This is a working translation of the German Chemicals Act (Chemikaliengesetz). No liability is assumed for the correctness and completeness.

Section seven

General provisions

§ 20 Application and notification documents, statutory authorisations

(1) The federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat,

1. to define in further detail the content and form of application and notification documents to be submitted to the German Federal Office for Chemicals or another federal authority pursuant to this act, a statutory ordinance based on this act or an EC or EU regulation specified in § 21(2), sentence 1,

2. to stipulate whether and for how long those who submit such application and notification documents to the German Federal Office for Chemicals or another federal authority must preserve a copy of these documents for inspection.

(2) For applications or documents that are submitted to it, the German Federal Office for Chemicals can

1. demand the use of specific forms or formats for other media,

2. authorise the forwarding of information via another medium,

3. demand the forwarding of additional copies of documents that have been submitted, provided this is necessary in view of the involvement of the other federal authorities set out in §§ 4 and 12a.

§ 20a (repealed)

§ 20b Committees

The federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat, to form committees, which may be assigned the following duties:

1. Advising the federal government or the competent federal ministry, particularly

a) in the development of methods for review verification pursuant to this act,

b) in the preparation of provisions for classification, labelling and packaging pursuant to §§ 14 and 19,

c) in the designation of substances and mixtures for which the notification requirement pursuant to § 16d is to be substantiated,

d) in the issuing of provisions for bans, restrictions and protection pursuant to § 17, § 18 or § 19 and

e) in the enhancement in good laboratory practice as well as

2.

a) safety, occupational health and hygiene regulations as well as other work-related research findings,

b) to prepare recommendations for the protection of people and the environment as well as

c) to propose substances, mixtures, products and processes that are not harmful or less harmful to people and the environment that the competent federal ministry can officially published.

§ 21 Monitoring

(1) The competent state authorities must monitor the implementation of this act and the statutory ordinances based on this act, unless this act provides otherwise.

(2) Para. 1 also applies to EC or EU regulations that involve areas of this act, insofar as monitoring their implementation is the responsibility of the Member States. If the collection and forwarding of information or other acts of co-operation by the Member States is necessary for the implementation of EC or EU regulations pursuant to sentence 1, the German Federal Office for Chemicals shall be responsible for this.

(2a) For the implementation of this act, the statutory ordinances based on this act and the EC or EU regulations specified in (2), sentence 1, the federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat,

1. to assign responsibility for certain authorisations and declarations of consent, (1) and (2), sentence 1 notwithstanding, to a higher federal authority if such authorisations or declarations of consent must be carried out nationally or require the evaluation of data that generally goes beyond the geographic area of responsibility of a state as well as

2. in cases of (2), sentence 2, to define another higher federal authority.

(3) The competent state authority shall be authorised to request all of the information necessary to implement this act, the statutory ordinances based on this act and the EC or EU regulations set out in (2), sentence 1 from natural and legal persons and unincorporated associations of persons. In cases of (2), sentence 2, these authorisations shall be assigned to the higher federal authorities designated therein, and in cases of (2a), they shall be assigned to the higher federal authorities designated in the statutory ordinances.

(4) Those tasked with monitoring shall be authorised

1. to enter and view premises, business offices and production areas during office and business hours, to request and remove samples of substances, mixtures and products of their choosing, and to inspect the business documents of those required to provide information,

2. to request the submission of documents related to applications, messages, notifications, registrations and approvals as well as other documents pursuant to this act, the statutory ordinances based on this act and the EC or EU regulations set out in (2), sentence 1,

3. to review work equipment and protective gear

4. to examine manufacturing processes and uses and in particular to ascertain and measure the existence and concentration of hazardous substances and mixtures.

To prevent imminent danger to public safety and order, the measures pursuant to sentence 1, numbers 1, 3 and 4 can also be carried out in residential areas at any time of the day or night. Those required to provide information must permit the measures pursuant to sentence 1, numbers 1, 3 and 4 and sentence 2 and support those tasked with monitoring, to the extent that this is necessary for them to complete their duties, in particular providing them with access to rooms, drums and containers upon request and enabling the collection of samples. The fundamental right of Art. 13 of the German Basic Law (Grundgesetz) to the inviolability of the home shall be restricted accordingly.

(5) Those required to provide information can refuse to answer those questions the responses to which might expose them or one of their associates as set out in § 383(1), numbers 1 to 3 of the German Code of Civil Procedure (Zivilprozessordnung) to the risk of prosecution for crimes or offences.

(6) If the competent state authority cannot evaluate the type and scope of the potential or actual harmful effects or measures necessary to avoid or prevent the effects of the substances, mixtures or products set out in § 19(2) during their manufacture or use, it may request that manufacturers or users have a report prepared, at their expense, by an expert to be determined by the authority and submit a copy of the report to it. Sentence 1 shall not apply if reviews or the conditions for arranging reviews are prescribed in this act.

(6a) If substances, mixtures and products within the meaning of this act that are imported into the country are rejected on the basis of this act or a statutory ordinance issued on the basis of this act, they can be transported outside the scope of this act for return to the foreign supplier, unless the competent state authority provides otherwise. This shall not affect intergovernmental agreements that the legislative bodies have approved in the form of a federal law as well as legal acts of the European Commission or the European Union.

(7) The German Federal Office for Chemicals and the offices set out in § 12a shall be obligated to provide the information that they collect and save pursuant to this act, the ordinances issued on the basis of this act and the EC or EU regulations specified in (2), sentence 1 to the authorities for occupational health and safety, public health, environment and nature conservation, general public safety, and fire and emergency management in the states and the statutory accident insurance institutions as a form of mutual assistance. § 16e(4) remains unaffected.

§ 21a Co-operation of customs offices

(1) The German Federal Ministry of Finance and the customs offices designated by it shall cooperate in monitoring imports and exports of those substances, mixtures and products subject to this act, or a statutory ordinance issued on the basis of this act or one of the EC or EU regulations set out in § 21(2), sentence 1. To the extent required to monitor implementation of this act, the ordinances issued on the basis of this act and the EC or EU regulations set out in sentence 1, they may communicate information that they obtain in the course of their customs activities to the competent authorities.

(2) If there is evidence of a violation of the regulations set out in (1), the customs offices shall report it to the competent authorities. The can reject the substances, mixtures and products as well as their means of transport and packaging at the cost and risk of the person authorised to dispose of them, or seize them until the deficiencies that have been discovered are corrected or until a decision by the competent authority.

§ 22 Information requirements

The German Federal Office for Chemicals and the competent state authorities shall provide one another with information about all findings that are necessary for carrying out their duties pursuant to this act, the statutory ordinances issued on the basis of this act or the EC or EU regulations set out in § 21(2), sentence 1, including the fulfilment of requirements contained therein to provide reports to the European Commission. The German Federal Office for Chemicals must provide advice to the competent state authorities upon request. Insofar as a different higher federal authority is stipulated in § 21(2a), number 2, the obligations set out in sentences 1 and 2 shall be between this authority and the competent state authorities.

§ 23 Administrative orders

(1) The competent state authority can issue orders in individual cases that are necessary to deal with identified violations of this act or of the statutory ordinances issued on the basis of this act or of an EC or EU regulation set out in § 21(2), sentence 1 or to prevent future violations.

(1a) If an order pursuant to (1) is not carried out within the prescribed period or if an order that is declared to be immediately enforceable is not carried out immediately, the competent authority can prohibit the work affected by the order in full or in part until there is compliance with the order, if the prohibition is necessary for the protection of the life or health of employees.

(2) The competent state authority can order, for a maximum period of three months, that a hazardous substance, a hazardous mixture or a product that contains or can release a hazardous substance or a hazardous mixture may not be manufactured, marketed or used, or may only be manufactured, marketed or used under certain conditions, in certain compositions or for certain purposes, if there is evidence, particularly a reasonable suspicion based on the latest scientific findings, that the substance, the mixture or the product gives rise to a significant danger to the life or health of people or the environment. The competent state authority can extend this order for good cause for up to one year. Sentences 1 and 2 shall also apply if there is evidence, particularly a reasonable suspicion based on the latest scientific findings, for assuming that a substance or a mixture is hazardous. Orders pursuant to sentences 1 and 2 can only be issued provided they are permitted under European Union law.

(3) Appeals of the orders set out in sentences 1a and 2 shall not have a suspensive effect.

§ 24 Enforcement in the area of the German armed forces

(1) Within the scope of the activities of the German Federal Ministry of Defence, responsibility for enforcement of this act, the statutory ordinances issued on the basis of this act and the EC or EU regulations set out in § 21(2), sentence 1 shall fall to the German Federal Ministry of Defence and the offices designated by it.

(2) The German Federal Ministry of Defence can authorise exemptions from the statutory provisions set out in (1) within the scope of its activities in individual cases as well as for certain substances, mixtures and products, if this is necessary in the interests of national defence and permitted under European Union law.

§ 25 Alignment with Community or Union law

Statutory ordinances pursuant to this act can also be issued for the purpose of alignment with the legal and administrative provisions of Member States of the European Union, provided this is necessary for implementation of legal acts of the European Communities or European Union involving the areas covered by this act.

§ 25a Fees and expenses

(1) Fees and expenses shall be collected for individually allocable public services pursuant to this act and the statutory provisions issued in implementation of this act as well as pursuant to EC or EU regulations within the meaning of § 21(2), sentence 1. § 8 remains unaffected.

(2) The federal government shall be authorised, through the promulgation of statutory ordinances, which shall not require the approval of the Bundesrat, to define in further detail the acts that are subject to fees and the fee amounts for individually allocable public services of the competent federal authorities pursuant to this act.

(3) Expenses incurred by those required to provide information as a result of the collection of samples of substances, mixtures and products or as a result of measurements shall be borne by them.

This is a working translation of the German Chemicals Act (Chemikaliengesetz). No liability is assumed for the correctness and completeness.

This is a working translation of the German Chemicals Act (Chemikaliengesetz). No liability is assumed for the correctness and completeness.

[4] § 25a applies pursuant to Article 4(101), number 2 in conjunction with Art. 5(3) of the Act of 7 August 2013 (FLG I, p. 3154) as from 14 August 2018 with the following wording:

"§ 25a
Expenses of those required to provide information

Expenses incurred by those required to provide information as a result of the collection of samples of substances, mixtures and products or as a result of measurements shall be borne by them."

§ 26 Penalties provisions

(1) Offences are committed by those who, intentionally or through negligence,

1. (repealed)

1a. (repealed)

1b. (repealed)

2. (repealed)

3. (repealed)

4. contravene an enforceable order pursuant to § 12g(1), sentence 1,

5.

a) contrary to § 13(2) in conjunction with a statutory ordinance pursuant to § 14(1), numbers 1, 2 or 3c, each also in conjunction with § 14(3), do not classify a substance or a mixture, do not classify a substance or a mixture correctly, completely, in the prescribed manner or in a timely manner,

a) contrary to § 13(3), sentence 1 in conjunction with a statutory ordinance pursuant to § 14(1), numbers 3a, d or e, each also in conjunction with § 14(3), do not label a substance or a mixture, do not label a substance or a mixture correctly, completely, in the prescribed manner or in a timely manner, or do not package a substance or a mixture, do not package a substance or a mixture correctly, completely, in the prescribed manner or in a timely manner, or

c) contravene a statutory ordinance pursuant to § 14(1), number 3a, b, d, e or f or (2), sentence 2, provided it refers to this penalties provision for a specific act,

5a. (repealed)

6. contravene a statutory ordinance pursuant to § 16d, provided it refers to this penalties provision for a specific act,

6a. contrary to § 16e(1), sentence 1 or sentence 3, each also in conjunction with a statutory ordinance pursuant to (5), number 2 or number 3, do not provide notification, do not provide notification correctly, completely or in a timely manner,

6b. (repealed)

7. contravene a statutory ordinance pursuant to

a) § 17(1) number 1b or number 2a, c or d, each also in conjunction with (3) sentence 1,

a) § 17(1) number 1c, also in conjunction with (3) sentence 1, or

c) § 17(5)

provided it refers to this penalties provision for a specific act,

8. contravene a statutory ordinance pursuant to

a) § 18(1) on poisonous animals and plants,

b) § 19(1) in conjunction with (3) on measures to protect employees,

provided it refers to this penalties provision for a specific act,

8a. (repealed)

9. contrary to § 21(3), do not provide information despite a reminder, contrary to § 21(4), sentence 1, number 2, do not submit documents or meet a requirement pursuant to § 21(4), sentence 3,

10. contravene an enforceable order

a) pursuant to § 23(1) or

b) pursuant to § 23(2), sentence 3 in conjunction with sentence 1 on the manufacture, marketing or use of substances, mixtures or products,

10a. contravene a statutory ordinance pursuant to § 28(11) on approval or reporting requirements for certain biocidal products, provided it refers to this penalties provision for a specific act,

11. contravene a directly applicable provision in legal acts of the European Communities or the European Union that involve areas of this act, provided a statutory ordinance pursuant to sentence 2 refers to this penalties provision for a particular act and the contravention is not punishable as a criminal offence pursuant to § 27(1), number 3 or (2). The federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat, to designate the individual elements of legal acts that can be punished by fines as offences pursuant to sentence 1, provided this is necessary for implementation of the legal acts.

(2) Offences in cases of (1), number 7b can be punished by a fine of up to EUR 200,000, in cases of (1), numbers 4, 5, 6, 7a, 8b, 10 and 11 by a fine of up to EUR 50,000 and in other cases by a fine of up to EUR 10,000.

(3) Pursuant to § 36(1), number 1 of the German Administrative Offences Act (Gesetz über Ordnungswidrigkeiten), the administrative authority is

1. in cases of (1), number 9 in conjunction with § 21(3), sentence 2

a) the German Federal Office for Chemicals for its scope of activities pursuant to § 21(2), sentence 2 or

b) the federal authority designated in the statutory ordinance pursuant to § 21(2a), to the extent it has the authorisation set out in § 21(3), sentence 1,

2. (repealed)

3. in other cases, the competent authority according to federal state law.

§ 27 Punitive provisions

(1) A prison sentence of up to two years or a fine shall be imposed on those who

1. contravene a statutory ordinance pursuant to § 17(1), number 1a, number 2b or number 3, each also in conjunction with (2), (3) sentence 1, (4) or (6) on the manufacture, marketing or use of the substances, mixtures, products, biocidal active substances or biocidal products designated there, provided it refers to this penal provision for a specific act,

2. contravene an enforceable order pursuant to § 23(2), sentence 1 on the manufacture, marketing or use of hazardous substances, mixtures or products, or

3. contravene a directly applicable provision in legal acts of the European Communities or the European Union the content of which corresponds to a rule enabled by the provisions specified in number 1, provided a statutory ordinance pursuant to sentence 2 refers to this penal provision for a specific act. The federal government shall be authorised, to the extent necessary for implementation of the legal acts of the European Communities or the European Union, through the promulgation of statutory ordinances with the approval of the Bundesrat, to designate acts that are punishable as criminal offences pursuant to sentence 1.

(1a) A prison sentence of up to three years or a fine shall be imposed on those who commit an act specified in (1), number 3, the part of the sentence before sentence 2 by manufacturing or marketing a commodity within the meaning of § 2(6) of the German Food and Feed Code.

(2) A prison sentence of up to five years or a fine shall be imposed on those who endanger the life or health of others or property of significant value by committing an intentional act specified in (1) or (1a) or § 26(1), numbers 4, 5, 7b, 8b, 10 or 11.

(3) Attempts to commit such acts are also punishable.

(4) If the offender acts negligently, the punishment shall be

1. in cases of (1) or (1a), a prison sentence of up to one year or a fine,

2. in cases of (2), a prison sentence of up to two years or a fine.

(5) The court can refrain from carrying out the punishment pursuant to (2) if the offender voluntarily averts the danger before there is considerable damage. Under the same conditions, the offender shall also not be punished pursuant to (4) number 2. If the danger is averted without any action on the part of the offender, his/her voluntary and sincere effort to achieve this goal shall suffice.

(6) Para. (1) to (5) shall not apply if the offence is punishable by the same or a greater penalty pursuant to §§ 328, 330 or 330a of the German Criminal Code (Strafgesetzbuch).

§ 27a False GLP declarations, obtaining GLP certification fraudulently

(1) Those who provide a declaration pursuant to § 19a(2), sentence 2, number 2 that is not true for the purpose of committing fraud in legal transactions or who provide a false declaration shall be punished by a prison sentence of up to five years or a fine.

(2) An officeholder who, as part of his/her responsibilities, issues a false certification pursuant to § 19b(1) or a false confirmation pursuant to § 19b(2), number 3, shall be punished by a prison sentence of up to five years or a fine.

(3) Those whose actions cause a false certification or confirmation pursuant to § 19b to be issued, or who use such certification or confirmation for the purpose of committing fraud in legal transactions shall be punished by a prison sentence of up to one year or a fine.

(4) Attempts to commit such acts are also punishable.

§ 27b Violations of Regulation (EC) No. 1907/2006

(1) Prison sentences of up to two years or a fine shall be imposed upon those who violate Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ EU no. L 396, p. 1, 2007 no. L 136, p. 3) by

1. contrary to Art. 5, manufacturing or marketing a substance as such, in a mixture or in a product,

2. not entering information correctly or completely in a registration dossier pursuant to Art. 6(1) or (3) or Art. 7(1), sentence 1 or (5), sentence 1 or in an approval application pursuant to Art. 62(1) in conjunction with (4).

3. contrary to Art. 37(4) in conjunction with Art. 39(1), not completing a substance safety report, not completing a substance safety report correctly, completely or in good time, or

4. contrary to Art. 56(1), marketing a substance specified therein for use or using it personally.

(2) Attempts to commit such acts are also punishable.

(3) A prison sentence of up to five years or a fine shall be imposed on those who endanger the life or health of others or property of significant value by committing an act specified in (1).

(4) If the offender acts negligently in cases outlined in (1), number 4, the punishment shall be a prison sentence of up to one year or a fine.

(5) Offences are committed by those who negligently commit an act specified in (1), number 1, 2 or 3. Offences can be punished by a fine of up to EUR 100,000.

§ 27c Violations of distribution provisions

(1) Those who commit an intentional act specified in § 26(1), number 7b, despite knowing that the hazardous substance, the hazardous mixture or the product will be used for an illegal act that constitutes an offence in criminal law shall be punished by a prison sentence of up to two years or a fine.

(2) If offenders in cases outlined in (1) recklessly fail to recognize that the hazardous substance, the hazardous mixture or the product will be used for an illegal act that constitutes an offence in criminal law, they shall be punished by a prison sentence of up to one year or a fine.

§ 27d Confiscation

Items that relate to a criminal act pursuant to §§ 27, 27b(1)-(4) or § 27c or an offence pursuant to § 26(1), numbers 4, 5, 7a or b, 10 or 11 or § 27b(5), sentence 1 can be confiscated. § 74a of the German Criminal Code and § 23 of the German Administrative Offences Act are applicable.

Section eight
Final provisions

§ 28 Transitional regulations

(1) (repealed)

(2) (repealed)

(3) (repealed)

(4) (repealed)

(5) (repealed)

(6) (repealed)

(7) (repealed)

(8) Within the scope of this act, biocidal products that solely contain biocidal active substances that were evaluated or are in the process of being evaluated pursuant to Regulation (EC) No. 1451/2007, may, in deviation from Art. 17(1) of Regulation (EU) No. 528/2012, be made available on the market and used for as long as the following amounts of time:

1. One year after publication of the decision pursuant to Art. 89(1)(3) of Regulation (EU) No. 528/2012 in the Official Journal of the European Union to not approve a biocidal active substance contained in the biocidal product for the respective product type, provided there is nothing to the contrary in the decision of the Commission,

2. For making products available on the market, 180 days and for their removal or use 365 days after the date specified in the decision of approval of the active substance or the active substances pursuant to Art. 89(3)(3) of Regulation (EU) No. 528/2012, if an application for approval or a parallel recognition pursuant to Art. 89(3)(2) of Regulation (EU) No. 528/2012 is not submitted or is not submitted in a timely manner,

3. During an ongoing decision-making process regarding an application for approval or mutual recognition in parallel of the biocidal product pursuant to Art. 89(3)(2) of Regulation (EU) No. 528/2012 until the date on which the approval or recognition becomes effective, or

4. For making products available on the market, 180 days and for their removal or use 365 days pursuant to Art. 89(4) of Regulation (EU) No. 528/2012, after the application for approval or mutual recognition in parallel pursuant to Art. 89(3)(2) of Regulation (EU) No. 528/2012 has been rejected.

(9) In the case of (8), number 3, the German Federal Office for Chemicals can, as part of the approvals for stocks of biocidal products under European Union law that were already made available on the market before issuance of the approval or the parallel recognition and that do not or do not fully meet the stipulations of the

approval or recognition decision or the labelling provisions related to the approval or recognition, define grace periods during which additional products may be brought to market or may continue to be used.

(10) Provided there is nothing to the contrary in Art. 91 of Regulation (EU) No. 528/2012, the provisions of this act in the version in force until the entry into force of the act in implementation of Regulation (EU) No. 528/2012 of 23 July 2013 (FLG I, p. 2565) shall continue to apply for applications for approval or mutual recognition of biocidal products that were fully received by the approval office before 1 September 2013.

(11) After hearing from stakeholders, the federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat, for the purpose set out in § 1, to stipulate that certain biocidal products within the meaning of (8) may only be brought to market and used after they have been approved by the German Federal Office for Chemicals until the end date of the work programme specified by the delegated act of the European Commission pursuant to Art. 89(1)(2) of Regulation (EU) No. 528/2012 for the systematic review of all existing active substances, but at least until 14 May 2014. The statutory ordinance can deviate from the requirements of Regulation (EU) No. 528/2012 to the extent permitted under European Union law. A reporting procedure can also be provided for rather than an approval.

(12) Notification pursuant to § 16e(1), sentence 1 shall not be required until 1 July 2016 for mixtures that do not meet any of the hazard characteristics pursuant to § 3a(1), numbers 6, 7, 9 or 11 to 14 or are not intended for consumers and which are not biocidal products, provided that for the relevant mixture

1. in the case of washing and cleansing agents within the meaning of the Washing and Cleansing Agents Act (Wasch- und Reinigungsmittelgesetz), the German Federal Institute for Risk Assessment is provided with an up-to-date information sheet pursuant to Annex VII, para. C of Regulation (EC) No. 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104 of 8/4/2004, p. 1), last amended by Regulation (EC) No. 551/2009 (OJ L 164 of 26/6/2009, p. 3),

2. in the case of other mixtures, the German Institute for Occupational Safety and Health of the German Social Accident Insurance association is provided with an up-to-date safety data sheet pursuant to Art. 31 of Regulation (EC) No. 1907/2006

each in the form specified by the respective institute and submitted electronically and for the purposes specified in § 16e(4). For mixtures pursuant to sentence 1 that were already on the market before 9 November 2011, the forwarding of documents pursuant to sentence 1 or the notification pursuant to § 16e(1), sentence 1 must be provided by 1 May 2012. The federal government shall be authorised, through the promulgation of statutory ordinances with the approval of the Bundesrat, to extend or shorten the deadline specified in sentence 1, taking account of the results of the review pursuant to Art. 45(4) of Regulation (EC) No. 1272/2008.

§ 29 (Abrogation)

§ 30 Berlin clause

(irrelevant)

§ 31 (Entry into force)