# Hazardous Substances Ordinance\*) (Gefahrstoffverordnung – GefStoffV)

**GefStoffV** 

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**Notice:** Amendment by Article 2 of the Ordinance of 21 July 2021 I 3115 (No 48) citations in text, awaiting

final documentation

- \*) The purpose of Article 1 of this Ordinance is to implement the following Directives:
  - 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 (OJ L 131 of 5 May 1998, p. 11), amended by Directive 2007/30/EC (OJ L 165 of 27 June 2007, p. 21),
  - Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 142 of 16 June 2000, p. 47), last amended by Directive 2009/161/EU (OJ L 338 of 19 December 2009, p. 87),
  - Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC (OJ L 38 of 9 February 2006, p. 36),
  - Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directive 2000/39/EC (OJ L 338 of 19 December 2009, p. 87),
  - Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 158 of 30 April 2004, p. 50, L 229 of 29 June 2004, p. 23, L 204 of 4 August 2007, p. 28),
  - Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330 of 16 December 2009, p. 28),
  - Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196 of 16 August 1967, p. 1), last amended by Directive 2009/2/EC (OJ L 11 of 16 January 2009, p. 6),
  - Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (OJ L 200 of 30 July 1999, p. 1, L 6 of 10 January 2002, p. 71), last amended by Regulation (EC) No 1272/2008 (OJ L 353 of 31 December 2008, p. 1),
  - Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123 of 24 April 1998, p. 1, L 150 of 8 June 2002, p. 71), last amended by Directives 2010/7/EU, 2010/8/EU, 2010/9/EU, 2010/10/EU and 2010/11/EU (OJ L 37 of 10 February 2010, p. 33, 37, 40, 44, 47),
  - Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) (OJ L 243 of 24 September 1996, p. 31), amended by Regulation (EC) No 596/2009 (OJ L 188 of 18 July 2009, p. 14),
  - Directive 1999/92/EC of the European Parliament and of the Council of 16 December 1992 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (OJ L 23 of 28 January 2000, p. 57), amended by Directive 2007/30/EC (OJ L 165 of 27

June 2007, p. 21).

#### **Footnote**

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(+++ Wording as of: 1 December 2010 +++)
(+++ Official references of the legislative body to EU law:
    implementation of
      EGRL
             24/98
                                (CELEX No: 31998L0024)
      EGRL
              39/2000
                                (CELEX No: 32000L0039)
                                (CELEX No: 32006L0015)
(CELEX No: 32009L0161)
      EGRL
              15/2006
      EURL 161/2009
                                (CELEX No: 32004L0037)
      EGRL
             37/2004
                                (CELEX No: 32009L0148)
      EGRL 148/2009
      EWGRL 548/67
                                (CELEX No: 31967L0548)
                                (CELEX No: 31999L0045)
      EGRL 45/99
             8/98
                               (CELEX No: 31998L0008)
      EGRL
      EGRL
            59/96
                                (CELEX No: 31996L0059)
      EGRL 92/99
                                (CELEX No: 31999L0092) +++)
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The Ordinance was issued as Article 1 of the Ordinance of 26 November 2010 I 1643 by the Federal Government, the Federal Ministry of Labour and Social Affairs and the Federal Ministry of Economics and Technology after hearing the parties concerned and with the approval of the Federal Council (*Bundesrat*). It entered into force on 1 December 2010 in accordance with Article 6 sentence 1 of the aforementioned Ordinance.

#### **Table of contents**

## Section 1 Objective, Scope and Definitions

Article 1	Objective and scope
Article 2	Definitions
	Section 2 Information about Hazardous Substances
Article 3	Hazard classes
Article 4	Classification, labelling and packaging
Article 5	Safety data sheet and other information requirements
	Section 3

### Section 3 Risk Assessment and Basic Obligations

Article 6	Information collection and risk assessment
Article 7	Basic obligations

# Section 4 Protective Measures

Article 8	General protective measures
Article 9	Additional protective measures
Article 10	Special protective measures for activities involving hazardous substances classified in Categories 1A or 1B for carcinogenicity, germ cell mutagenicity or reproductive toxicity
Article 11	Special protective measures to safeguard against physicochemical effects, particularly fire and explosion hazards

Article 12	(repealed)
Article 13	Plant malfunctions, accidents and emergencies
Article 14	Obligation to inform and train workers
Article 15	Co-operation between companies

#### Section 4a

# Requirements for the Use of Biocidal Products Including Fumigation Activities and Fumigation with Plant Protection Products

Article 15a	Use restrictions
Article 15b	General requirements for the use of biocidal products
Article 15c	Special requirements for the use of specific biocidal products
Article 15d	Special requirements for fumigation activities
Article 15e	Additional documentation requirements
Article 15f	Requirements for handling transport units
Article 15g	Special requirements for the fumigation of ships
Article 15h	Exemptions from Section 4a

### Section 5 Prohibitions and Restrictions

Article 16	Manufacturing and use restrictions
Article 17	National exemptions from restriction provisions according to Regulation (EC) No 1907/2006

## Section 6 Enforcement Provisions and Committee on Hazardous Substances

Article 18	Notification of authorities
Article 19	Official exemptions, orders and powers
Article 19a	Recognition of foreign qualifications
Article 20	Committee on Hazardous Substances

# Section 7 Infringements, Criminal Offenses and Interim Provisions

Article 21	Chemicals Act – Notifications
Article 22	Chemicals Act – Activities
Article 23	(repealed)
Article 24	Chemicals Act – Manufacturing and use restrictions
Article 25	Interim provisions

#### Annex I

(to Article 8 paragraph 8, Article 11 paragraph 3, Article 15b paragraph 3, Article 15c paragraphs 2 and 3, Article 15d paragraphs 1, 3, 4, 6 and 7, Article 15f paragraph 2, Article 15g paragraph 2)

Special Provisions for Specific Hazardous Substances and Activities

Number 1	Fire and explosion hazards
Number 2	Particulate hazardous substances
Number 3	(repealed)

Number 4 Biocidal products and fumigation activities with biocidal products or plant protection

products

Number 5 Ammonium nitrate

# Annex II (to Article 16 paragraph 2) Special Restrictions for the Manufacture and Use of Specific Substances, Mixtures and Articles

Number 1	Asbestos
Number 2	2-Naphthylamine, 4-aminobiphenyl, benzidine, 4-nitrobiphenyl
Number 3	Pentachlorophenol and its compounds
Number 4	Metalworking fluids and corrosion inhibitors
Number 5	Biopersistent fibres
Number 6	Extremely hazardous carcinogenic substances

# Annex III (to Article 11 paragraph 4) Special Requirements for Activities Involving Organic Peroxides

Number 1 Scope and definitions

Number 2 Activities involving organic peroxides

# Section 1 Objective, Scope and Definitions

#### Article 1 Objective and scope

- (1) The objective of this Ordinance is to protect persons and the environment against substance-related damage by prescribing
- 1. regulations for the classification, labelling and packaging of hazardous substances and mixtures,
- 2. measures to protect workers and other persons when carrying out activities with hazardous substances, and
- restrictions on the manufacture and use of specific hazardous substances, mixtures and articles.
- (2) Section 2 applies to the placing on the market of
- 1. hazardous substances and mixtures,
- specific substances, mixtures and articles that are subject to special labelling requirements pursuant to Directive 96/59/EC of the Council of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) (OJ L 243 of 24 September 1996, p. 31), which was amended by Regulation (EC) No 596/2009 (OJ L 188 of 18 July 2009, p. 14),
- 3. biocidal products within the meaning of Article 3 number 11 of the Chemicals Act (*Chemikaliengesetz, ChemG*) that are not hazardous substances or mixtures, and
- 4. biocidal active substances within the meaning of Article 3 number 12 of the Chemicals Act that are biological agents within the meaning of the Biological Agents Ordinance (*Biostoffverordnung*, *BioStoffV*), and biocidal products within the meaning of Article 3 number 11 of the Chemicals Act that contain such biological agents as active substances.

Section 2 does not apply to human food articles or animal feed in the form of finished articles intended for final

#### consumption.

- (3) Sections 3 to 6 apply to activities during which workers are exposed to substances, mixtures or articles that are potentially hazardous to their health and safety. They shall equally apply if the safety and health of other persons may be at risk because of activities within the meaning of Article 2 paragraph 5 performed by workers or independent entrepreneurs without employees. Sentences 1 and 2 shall also apply to activities involving the transport of substances, mixtures and articles. The provisions of the Hazardous Goods Transport Act (*Gefahrgutbeförderungsgesetz*, *GGBefG*) and the ordinances enacted on the basis of this Act shall remain unaffected.
- (4) Unless expressly stated otherwise, this Ordinance does not apply to
- 1. biological agents within the meaning of the Biological Agents Ordinance and
- 2. private households.

In addition, this Ordinance does not apply to facilities that fall within the scope of the Federal Mining Act (*Bundesberggesetz, BBergG*) if this Act or the ordinances enacted on the basis of this Act contain relevant statutory provisions.

#### **Article 2 Definitions**

- (1) Hazardous substances within the meaning of this Ordinance are defined as
- 1. hazardous substances and mixtures according to Article 3,
- 2. explosive substances, mixtures and articles,
- 3. substances, mixtures and articles that lead to the formation or release of substances specified under numbers 1 or 2 during their manufacture or use,
- 4. substances and mixtures that do not fall under numbers 1 to 3, but which may endanger the health and safety of workers on account of their physicochemical, chemical or toxic properties and the manner in which they occur or are used at the workplace,
- 5. all substances that have been assigned an occupational exposure limit.
- (2) The terms substance, mixture, article, supplier, downstream user and manufacturer are defined using the same definitions as Article 2 of the Regulation (EC) No 1272/2008 of the European Parliament and Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353 of 31 December 2008, p. 1), which was last amended by Regulation (EU) 2015/1221 (OJ L 197 of 25 July 2015, p. 10).
- (2a) Substances or mixtures are hazardous to the environment beyond the scope of the hazard class of substances or mixtures classified as hazardous to the aquatic environment according to Regulation (EC) No 1272/2008 if they or their metabolic products are able to modify the ecological balance, the composition of soil or air, or affect the climate, animals, plants or micro-organisms in such a way as to give rise to immediate or delayed hazards to the environment.
- (3) Substances that induce carcinogenicity, germ cell mutagenicity or reproductive toxicity are
- substances that have been classified in categories for carcinogenicity, germ cell mutagenicity or reproductive toxicity in Annex VI of the current version of Regulation (EC) No 1272/2008,
- 2. substances that satisfy the criteria for classification in a category for carcinogenicity, germ cell mutagenicity or reproductive toxicity according to Annex I of the current version of Regulation (EC) No 1272/2008,
- mixtures that contain one or more of the substances listed in Article 2 paragraph 3 numbers 1 or 2 if
  the concentration of this substance or these substances reaches or exceeds the specific concentration
  limits or generic concentration limits set forth in the current version of Regulation (EC) No 1272/2008
  for the classification of mixtures in categories for carcinogenicity, germ cell mutagenicity or
  reproductive toxicity,
- 4. substances, mixtures or processes that are classified in a category for carcinogenicity, germ cell mutagenicity or reproductive toxicity according to the rules and knowledge published in accordance with Article 20 paragraph 4.
- (4) Organic peroxides within the meaning of Article 11 paragraph 4 and of Annex III are substances derived from

hydrogen peroxide that are formed by the substitution of one or both hydrogen atoms with organic groups as well as mixtures that contain these substances.

- (5) An activity is defined as any handling of substances, mixtures or articles including the manufacture, mixing, use and consumption, warehousing, storage, treatment and processing, filling and decanting, removal, disposal and destruction. Activities include in-house transport in addition to operating and monitoring work.
- (5a) Fumigation is defined as the application of biocidal products or plant protection products
- 1. involving the intentional release of substances in a gaseous state
  - a) that are classified in Categories 1, 2 or 3 for acute toxicity or
  - b) for which authorisation has been granted under the provision that the concentrations of the active substance or oxygen are to be measured or monitored,
- 2. for which authorisation has been granted under the provision that respiratory protective equipment using a supply of breathing-quality air from an independent source be made available and used, or
- 3. for the room disinfection of all surfaces of an enclosed room by applying formaldehyde from an aqueous formaldehyde solution in the form of a suspension of liquid droplets.
- (6) Storage is defined as the process of holding items available for later use and for delivery to others. The term also describes the act of holding an item available for transport if the transport does not occur within 24 hours of availability or on the following working day. If the working day falls on a Saturday, the deadline shall be the end of the next regular working day.
- (7) The following are deemed as equivalents:
- 1. workers and homeworkers, pupils, students and other persons, particularly those working in scientific facilities who perform activities involving hazardous substances; however, the provisions of the present Ordinance concerning the involvement of employee representatives shall not apply to pupils and students,
- 2. employers and independent entrepreneurs without employees, contractors and intermediaries within the meaning of the Homeworking Act (*Heimarbeitsgesetz, HAG*) in the amended version published in the Federal Law Gazette (*Bundesgesetzblatt, BGBI*) Part III, Section number 804-1, last amended by Article 225 of the Ordinance of 31 October 2006 (Federal Law Gazette I, p. 2407).
- (8) The occupational exposure limit is defined as the time-weighted average of the concentration of a chemical substance in the air within a worker's breathing zone in relation to a specified reference period. These values identify the concentrations at which substances are generally not expected to induce adverse acute or chronic effects on workers' health.
- (9) The biological limit value is defined as the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect. The biological limit value is derived on the basis of data from the fields of occupational health and toxicology. The values identify the concentrations at which adverse effects on worker health are generally not induced.
- (9a) Physicochemical effects include the hazards that arise by carrying out activities with
- 1. substances, mixtures or articles that represent a physical hazard according to Regulation (EC) No 1272/2008 or
- other hazardous substances that are not classified as a physical hazard according to Regulation (EC) No 1272/2008, but that react either with one another or as a result of other interactions, thereby causing fires or explosions.
- (10) An explosive mixture is a mixture of combustible gases, vapours, mists, dispersed dust and air or other oxidising agents that, after initiation by an ignition source, gives rise to freely propagating flames, in general leading to a sudden rise in temperature and pressure.
- (11) Chemically unstable gases that, even in the absence of an oxidising agent, may give rise to freely propagating flames after initiation by an ignition source, leading to a sudden rise in temperature and pressure, are equivalent to explosive mixtures as defined in paragraph 10.

- (12) A hazardous explosive mixture is an explosive mixture that occurs in such quantities that special precautions are necessary to ensure the safety and health of workers or other persons.
- (13) A hazardous explosive atmosphere is a hazardous explosive mixture under atmospheric conditions (ambient temperature from –20 °C to +60 °C at a pressure from 0.8 bar to 1.1 bar) that contains air as an oxidising agent.
- (14) A potential explosion site is a hazard area in which a hazardous explosive atmosphere may occur.
- (15) State of the art refers to the developmental stage of advanced processes, facilities and operational methods, which seems to guarantee the practical suitability of a measure to protect the safety and health of workers. When determining the state of the art, special consideration shall be given to comparable processes, facilities or operational methods that have proved successful in practical operation. The same shall apply to requirements in terms of occupational health care and hygiene at work.
- (16) A person with professional expertise (*fachkundige Person*) is defined as a person who has acquired the knowledge and skills necessary to carry out an activity set forth in this Ordinance. The requisite competency depends on the nature of the respective task. The requirements include relevant professional training, professional experience, or the recent performance of applicable professional activities as well as participation in specific further training courses.
- (17) A person with expert knowledge (sachkundige Person) is defined as a person who has further developed their competency by completing a course of expert knowledge officially recognised by the competent authority. Depending on the area of activity, it may be necessary to pass an examination at the end of the course in order to prove attainment of the qualification. A qualified person is further defined as a person who has acquired a professional qualification that is recognised as equivalent by the competent authority or a professional qualification deemed equivalent by the current Ordinance.
- (18) A user category refers to a group of persons entitled to use a specific biocidal product. It describes the level of qualification that is necessary for its use. The user category is established for each biocidal product during the approval process according to the current version 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 June 2012, p. 1), which was last amended by the Commission Delegated Regulation (EU) 2019/1825 (OJ L 279 of 31 October 2019, p. 19). User categories are:
- 1. general public,
- 2. professional user,
- 3. trained professional user.

# Section 2 Information about Hazardous Substances

#### **Article 3 Hazard classes**

- (1) Hazardous within the meaning of this Ordinance are substances, mixtures and specific articles that meet the criteria set forth in Annex I of Regulation (EC) No 1272/2008.
- (2) The hazard classes below specify the type of hazard and are listed with the numbering used in Annex I of Regulation (EC) No 1272/2008:

Numbering according to Annex I of Regulation (EC) No 1272/2008

1.	Physi	Physical hazards	
	a)	Explosive substances/mixtures and articles containing explosives	2.1
	b)	Flammable gases	2.2
	c)	Aerosols	2.3
	d)	Oxidising gases	2.4
	e)	Gases under pressure	2.5

	f)	Flammable liquids	2.6
	g)	Flammable solids	2.7
	h)	Self-reactive substances and mixtures	2.8
	i)	Pyrophoric liquids	2.9
	j)	Pyrophoric solids	2.10
	k)	Self-heating substances and mixtures	2.11
	I) Substances and mixtures which in contact with water emit flammable gases		2.12
	m)	n) Oxidising liquids	
	n)	Oxidising solids	2.14
	o)	Organic peroxides	
	p)	p) Corrosive to metals	
2.	Health h	nazards	3
	a)	Acute toxicity (oral, dermal and inhalation)	3.1
	b)	Skin corrosion/irritation	3.2
	c)	Serious eye damage/eye irritation	3.3
	d)	Respiratory or skin sensitisation	3.4
	e)	Germ cell mutagenicity	3.5
	f)	Carcinogenicity	3.6
	g)	Reproductive toxicity	3.7
	h)	Specific target organ toxicity, single exposure (STOT SE)	3.8
	i)	Specific target organ toxicity, repeated exposure (STOT RE)	3.9
	j)	Aspiration hazard	3.10
3.	Environmental hazards		4
	Hazardous to the aquatic environment (acute and chronic)		4.1
4.	Additional hazards		5
	Hazardous to the ozone layer		5.1

#### Article 4 Classification, labelling, packaging

- (1) The classification, labelling and packaging of substances and mixtures and of articles containing explosives shall comply with the provisions of Regulation (EC) No 1272/2008. Mixtures placed on the market prior to 1 June 2015 that are labelled and packaged in compliance with the provisions of Directive 1999/45/EC are not required to fulfil the classification, labelling and packaging requirements according to Regulation (EC) No 1272/2008 until 31 May 2017.
- (2) The classification of substances and mixtures must observe the rules and knowledge published according to Article 20 paragraph 4.
- (3) The labelling of substances and mixtures placed on the market in Germany must be in German.
- (4) If hazardous substances or hazardous mixtures are placed on the market without packaging, each delivery unit must include the relevant safety information or a safety data sheet in German.
- (5) In addition to the labelling requirements set forth in paragraph 1, suppliers of biocidal products, for which a third party is the authorisation holder, must ensure that the additional labelling applied by the authorisation holder according to Article 69 paragraph 2 sentence 2 of Regulation (EU) No 528/2012 has not been removed or has been re-applied at the time of delivery of the product to a third party. Biocidal products that have been placed on the market without authorisation according to Article 28 paragraph 8 of the Chemicals Act, must, in addition to the labelling as set forth in paragraph 1, be labelled in accordance with Article 69 paragraph 2 sentences 2 and 3 of Regulation (EU) No 528/2012, whereby the information requirements set forth in sentence 2 letters c and d of the

Regulation are not applicable and the information provided in compliance with sentence 2 letters f and g are to be relevant for the intended use.

- (6) Biocidal active substances that are biological agents within the meaning of Article 2 paragraph 1 of the Biological Agents Ordinance must additionally be classified according to Article 3 of the Biological Agents Ordinance. Biocidal active substances within the meaning of sentence 1 and biocidal products containing a biological agent as the active substance must additionally be labelled with the following information:
- 1. the identity of the organism according to Annex II title 2 numbers 2.1 and 2.2 of Regulation (EU) No 528/2012,
- the risk group classification for the microorganisms according to Article 3 of the Biological Agents Ordinance, and
- 3. for products classified in risk group 2 or higher according to Article 3 of the Biological Agents Ordinance, the biohazard symbol according to Annex I of the Biological Agents Ordinance.
- (7) Decontaminated equipment containing PCBs within the meaning of Directive 96/59/EC must be labelled according to the requirements set forth in the Annex of this Directive.
- (8) The labelling of specific restricted substances, mixtures and articles must additionally comply with Article 67 in conjunction with Annex XVII of Regulation (EC) No 1907/2006, in each case in the version currently in force.
- (9) The supplier of a mixture or substance must, if requested by a downstream user, make available without delay all information required for the classification of new mixtures according to the regulations if
- 1. the labelling information or the safety data sheet of the mixture or
- the contamination or admixture information provided on the label or the safety data sheet of the substance

is not sufficient for classification.

#### Article 5 Safety data sheet and other information requirements

- (1) The supplier is to observe the safety data sheet requirements laid down in Article 31 in conjunction with Annex II of Regulation (EC) No 1907/2006 for the placing on the market of substances and mixtures. If a safety data sheet is not required according to these provisions, the information requirements according to Article 32 of Regulation (EC) No 1907/2006 shall apply.
- (2) The information that is to be made available according to Annex II numbers 15 and 16 of Regulation (EC) No 1907/2006 must in particular take into account the rules and knowledge published according to Article 20 paragraph 4 relating to the classification of substances or activities in categories for carcinogenicity, germ cell mutagenicity or reproductive toxicity.
- (3) (repealed)

#### Section 3

#### **Risk Assessment and Basic Obligations**

#### Article 6 Information collection and risk assessment

- (1) As part of the risk assessment carried out in the context of the evaluation of the working conditions according to Article 5 of the Occupational Safety and Health Act (*Arbeitsschutzgesetz*, *ArbSchG*), the employer must determine whether workers are carrying out activities involving hazardous substances or whether hazardous substances may form or be released during work activities. If this is the case, the employer is to assess all hazards to the safety and health of the workers arising from these activities, taking the following into consideration:
- 1. the hazardous properties of the substances or mixtures, including their physicochemical effects,
- 2. the safety and health information provided by the supplier, particularly in the safety data sheet
- 3. the kind and extent of exposure, considering all routes of exposure; this shall take into account the results of the determinations and evaluations carried out according to Article 7 paragraph 8,
- possible substitutions,

- 5. the working conditions and processes, including work equipment and the quantities of hazardous substance,
- 6. occupational exposure limits and biological limit values,
- 7. the effectiveness of the protective measures taken or to be taken,
- 8. the knowledge gained from occupational preventive medical examinations carried out according to the Ordinance on Occupational Health Care.
- (2) The employer must obtain the information required for the risk assessment from the supplier or other sources accessible to the employer with reasonable effort. In particular, the employer is to use the information that has been made available according to Title IV of Regulation (EC) No 1907/2006; this comprises safety data sheets and information about substances or mixtures that do not require a safety data sheet. If an information requirement according to Regulation (EC) No 1907/2006 does not apply, the supplier is to make available the information about the hazardous substances necessary to carry out a risk assessment to the employer on request.
- (3) Substances and mixtures that have not been classified or labelled by a supplier according to Article 4 paragraph 1, such as substances or mixtures produced within the company, are to be classified by the employer. However at minimum, the employer must evaluate the potential hazards to workers from exposure to the substances and mixtures; this shall apply also to hazardous substances according to Article 2 paragraph 1 number 4.
- (4) The employer is to determine whether handling the substances, mixtures and articles may lead to a fire and explosion hazard, taking into account the equipment and processes used, the working environment and possible interactions. The employer must evaluate:
- 1. whether hazardous substances that may lead to fire or explosion hazards occur in hazardous quantities or concentrations; substances and mixtures classified as physical hazards according to Regulation (EC) No 1272/2008, other hazardous substances that may cause fire or explosion hazards and substances that react with each other in a hazardous manner are to be taken into consideration,
- 2. whether ignition sources or conditions are present that may lead to a fire or explosion, and
- 3. whether fires or explosions may lead to adverse effects on the safety and health of workers.

The employer is to determine in particular whether the substances, mixtures and articles may form explosive mixtures due to their properties or the manner in which they occur or are used at the workplace. For non-atmospheric conditions, possible changes to the safety parameters relating to explosion prevention and protection are to be evaluated and taken into account.

- (5) The risk assessment must also include an evaluation of the activities that represent a potential hazard even after implementing all possible technical safety measures. This shall apply in particular to maintenance and repair work, including routine maintenance activities. Furthermore, other activities such as operating and monitoring activities are to be evaluated if these have the potential to place workers at risk by exposure to hazardous substances.
- (6) The inhalation, dermal and physicochemical hazards associated with the activities shall be assessed individually and the findings compiled in a risk assessment. If more than one hazardous substance is present during an activity, the interactions and combined effects of the hazardous substances that affect the health and safety of the workers are to be included in the risk assessment if these types of effects are known.
- (7) The employer may determine which protective measures are to be taken using a risk assessment prepared by the supplier if the information and provisions of this risk assessment correspond to the working conditions and processes, including the equipment and quantities of hazardous substances used, of the company.
- (8) Irrespective of the number of workers, the employer must document the risk assessment prior to the commencement of the activity. The following information is to be included:
- the hazards posed by activities involving hazardous substances,
- 2. the results of the substitution assessment according to paragraph 1 sentence 2 number 4,
- the reasons for deciding against a substitution that would be technically possible, provided that protective measures according to Article 9 or Article 10 are to be taken,
- the protective measures to be taken including

- a) any additional protective measures taken after exceeding an occupational exposure limit and any protective measures to be taken in future to observe the occupational exposure limit or
- b) additional protective measures taken or to be taken in future (action plan) taking into consideration the criteria for carcinogenic substances that were published according to Article 20 paragraph 4,
- 5. the reasons for deviating from the rules and knowledge published according to Article 20 paragraph 4, and
- 6. the findings of the evaluation demonstrating that occupational exposure limits are observed or, in the case of substances for which an occupational exposure limit has not been set, the effectiveness of the technical safety measures taken.

The risk assessment may also be documented on the basis of existing risk assessments, documents or other equivalent reports that were prepared in compliance with requirements laid down in other statutory provisions.

- (9) The employer is to include a separate section in the documentation prepared in compliance with paragraph 8 detailing the risks from hazardous explosive mixtures (explosion protection document) depending on the findings established according to paragraph 4. In particular, this is to document
- 1. that the explosion hazards have been identified and evaluated,
- 2. that appropriate precautions are being taken to meet explosion prevention and protection targets (presentation of an explosion protection plan),
- 3. whether areas and if so, which areas, have been divided into zones according to Annex I number 1.7,
- 4. in which areas explosion protection measures according to Article 11 and Annex I number 1 have been taken,
- 5. how the provisions according to Article 15 are implemented, and
- 6. which inspections according to Article 7 paragraph 7 and which explosion protection testing according to Annex 2 section 3 of the Ordinance on Industrial Safety and Health (*Betriebssicherheitsverordnung, BetrSichV*) are planned.
- (10) Low-risk activities within the meaning of paragraph 13 do not require detailed documentation. In other cases, plausible reasons must be given if detailed documentation is not compiled. The risk assessment is to be reviewed regularly and updated if necessary. The documents are to be updated immediately in the event of major changes or new information, or if modifications prove to be necessary due to the results of occupational preventive medical examinations carried out in compliance with the Ordinance on Occupational Health Care.
- (11) The risk assessment shall be compiled only by competent persons. If the employer does not have the requisite competency, the employer is obligated to seek the advice of a competent person. Examples of persons with the requisite competency are occupational safety and health specialists and company physicians.
- (12) As set forth in sentence 2, the employer is obligated to maintain a list of the hazardous substances used by the company including references to the relevant safety data sheets. The list must include, at minimum, the following information:
- 1. the name of the hazardous substance,
- 2. the classification of the hazardous substance or information about its hazardous properties,
- 3. the quantitative range of the amount of substance used by the company,
- 4. designation of the working areas in which workers may be exposed to the hazardous substance.

Sentences 1 and 2 shall not apply if only low-risk activities according to paragraph 13 are performed. The workers and their representatives must have unrestricted access to the information according to sentence 2 numbers 1, 2 and 4.

- (13) If the risk assessment demonstrates only a low overall risk for workers during specific activities as a result of
- 1. the hazardous properties of the hazardous substance,
- 2. the small quantities of substance used,
- 3. the low level and duration of exposure, and
- 4. the working conditions

and if the measures to be implemented according to Article 8 offer sufficient protection for the workers, no other measures from Section 4 need to be taken.

(14) If test data for substances and mixtures or other meaningful information for the effects of acute toxicity, irritation, skin sensitisation, germ cell mutagenicity or for specific target organ toxicity after repeated exposure are not available, the substances or mixtures must be evaluated for the risk assessment using the same criteria as for substances classified in Category 3 for acute toxicity (oral, dermal and inhalation), in Category 2 for skin corrosion/irritation, in Category 1 for skin sensitisation, in Category 2 for germ cell mutagenicity or in Category 2 for specific target organ toxicity, repeated exposure (STOT RE). The applicable classification categories are to be determined taking into account the rules and knowledge published according to Article 20 paragraph 4.

#### Article 7 Basic obligations

- (1) The employer shall allow activities involving hazardous substances to commence only after a risk assessment according to Article 6 has been completed and the requisite protective measures according to Section 4 have been taken.
- (2) To protect the safety and health of workers during all activities involving hazardous substances, the employer must implement the measures laid down in the Occupational Safety and Health Act in addition to the measures laid down in the present Ordinance. In doing so, the employer is to take into account the rules and knowledge published according to Article 20 paragraph 4. If these rules and knowledge are observed, it may generally be assumed that the requirements of the present Ordinance have been fulfilled. Derogation from these rules and knowledge is permissible if other measures are in place that protect the safety and health of workers at least to an equivalent extent.
- (3) The employer is obligated to make substitution a priority on the basis of the results of the substitution assessment carried out in compliance with Article 6 paragraph 1 sentence 2 number 4. The employer must replace hazardous substances or processes with substances, mixtures, articles or processes that are not or less hazardous to the safety and health of the workers under the specific conditions of use.
- (4) The employer is to rule out any hazards to the safety and health of workers carrying out activities involving hazardous substances. If this is not possible, the employer is obligated to reduce these to the minimum necessary. The employer must comply with these provisions by identifying and implementing suitable protective measures. In doing so, the employer is to observe the following order of precedence:
- 1. the design of appropriate processes and technical control facilities for these processes, the use of zero or low emission forms and the use of suitable work equipment and materials according to the state of the art,
- 2. the use of technical collective protection systems at the hazard source, such as adequate aeration and exhaust ventilation, and the implementation of suitable organisational measures.
- 3. if a hazard cannot be prevented by implementing measures according to numbers 1 and 2, individual protective measures are to be taken, including the availability and use of personal protective equipment.
- (5) Workers must use the personal protective equipment made available to them as long as the hazard persists. The use of burdensome personal protective equipment is only permissible as a temporary measure. For each worker, its use is to be reduced to the absolute minimum necessary.
- (6) The employer shall ensure that
- 1. the personal protective equipment is stored according to expert professional practice at a location intended for that purpose,
- 2. the personal protective equipment is checked prior to use and cleaned after each use, and
- 3. defective personal protective equipment is repaired or replaced prior to the next use.
- (7) The employer must inspect the functioning and effectiveness of technical safety measures regularly, but at least every three years. The findings of these inspections are to be documented and preferably saved together with the documentation compiled according to Article 6 paragraph 8.
- (8) The employer is obligated to ensure that occupational exposure limits are observed. The employer shall ensure that the limits are not exceeded by monitoring them at the workplace or applying other suitable methods to determine exposure levels. Determinations are to be taken also if conditions change that may affect the exposure of workers. The results of the determinations must be documented, stored and made available to workers and

their representatives. If activities are carried out according to a criterion for a specific procedure or substance that was published in accordance with Article 20 paragraph 4, the employer may in general assume that the occupational exposure limits have been observed; in this case, sentence 2 shall not apply.

- (9) If activities are carried out involving hazardous substances for which an occupational exposure limit has not been established, the employer must regularly monitor the effectiveness of the technical safety measures taken using suitable methods of assessment, which may include determinations at the workplace.
- (10) Any person who determines levels of hazardous substances at the workplace must be competent and have access to the necessary equipment. If an employer hires a company certified to determine levels of hazardous substances at workplaces, the employer may in general assume that the findings determined by this company are correct.
- (11) For the evaluation and determination, the employer is obligated to take into account the methods, rules of determination and limit values published according to Article 20 paragraph 4, which have been issued on the basis of the relevant provisions of the following directives:
- 1. 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 Article 16 paragraph 1 of Directive 89/391/EEC) (OJ L 131 of 5 May 1998, p. 11), last amended by Directive 2014/27/EU (OJ L 65 of 5 March 2014, p. 1), including the directives relating to occupational exposure limits that were enacted according to Article 3 paragraph 2 of Directive 98/24/EC,
- Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (sixth individual Directive within the meaning of Article 16 paragraph 1 of Council Directive 89/391/EEC) (codified version) (OJ L 158 of 30 April 2004, p. 50, L 229 of 29 June 2004, p. 23, L 204 of 4 August 2007, p. 28), last amended by Directive 2014/27/EU, in addition to
- 3. Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330 of 16 December 2009, p. 28).

# Section 4 Protective Measures

#### **Article 8 General protective measures**

- (1) The employer must implement the following protective measures for carrying out activities involving hazardous substances:
- appropriate design of the workplace and appropriate organisation of work systems,
- availability of suitable work equipment for activities involving hazardous substances and the implementation of suitable maintenance procedures for ensuring the safety and health of workers during these activities,
- 3. minimisation of the number of workers who are or may become exposed to hazardous substances,
- 4. minimisation of the duration and extent of exposure,
- 5. appropriate hygiene measures, particularly for the purpose of contamination prevention, and regular cleaning of the workplace,
- 6. limitation of the amount of hazardous substance present at the workplace to the amount required for the continuation of activities,
- 7. suitable working methods and processes that do not adversely affect the safety and health of workers or that keep the risk as low as possible, including precautionary measures for the safe handling, storage and transport of hazardous substances and of waste containing hazardous substances at the workplace.
- (2) The employer is to ensure that
- 1. all substances and mixtures used are identifiable,
- 2. the hazardous substances and mixtures used within the company bear labelling with sufficient information about the classification, the hazards of handling and the safety measures to be observed; preferably, the labelling should comply with the provisions of Regulation (EC) No 1272/2008,

3. apparatus and piping are labelled in such a way that, at minimum, the hazardous substances these contain and the hazards posed by these substances are clearly identifiable.

These measures shall not affect the labelling obligations laid down in other statutory provisions. If the employer has not fulfilled the obligations set forth in sentence 1, the employer is prohibited from having activities carried out with the substances and mixtures listed there. Sentence 1 number 2 does not apply to new substances that were prepared for research and development purposes or for purposes of academic instruction that could not have been evaluated before. Exposure of workers to these substances during handling is to be avoided.

- (3) The employer is to ensure, in accordance with the results of the risk assessment carried out according to Article 6, that workers do not consume foods or beverages in work areas in which they may be exposed to hazardous substances. The employer is obligated to set up suitable areas for this purpose prior to the commencement of the activities.
- (4) The employer is to ensure safe storage, handling and transport of hazardous substances, also during disposal, by using sealable containers.
- (5) The employer is to ensure that hazardous substances are kept or stored in such a way that they do not pose a danger to human health or the environment. The employer must take effective precautions to prevent misuse or improper use. In particular, hazardous substances shall not be stored or kept in containers in which the contents could be mistaken for food through the shape or labelling of the container. They must be kept and stored in an orderly fashion and not in the immediate vicinity of medicines, food or animal feed, including their additives. For the storage of hazardous substances intended for delivery to others or for immediate use, the labelling according to paragraph 2 must be applied in such a way that it is clearly visible and legible.
- (6) The employer is to ensure that hazardous substances that are no longer needed and containers that have been emptied but may contain residues of hazardous substances are handled safely, removed from the workplace and stored or disposed of according to expert professional practice.
- (7) The employer is to ensure that substances and mixtures that are classified in Categories 1, 2 or 3 for acute toxicity, in Category 1 for specific target organ toxicity, in Categories 1A or 1B for carcinogenicity and in Categories 1A or 1B for germ cell mutagenicity are either locked away or securely stored and kept in an area that is only accessible to competent and reliable persons. Activities involving these substances and mixtures may be performed only by competent persons or persons who have received specialised training. Sentence 2 shall apply also to activities involving substances and mixtures that are classified in Categories 1A or 1B for reproductive toxicity or as sensitising to the airways. Sentences 1 and 2 shall not apply to fuels at petrol stations or other fuel loading facilities or to substances or mixtures that are classified in Category 3 for acute toxicity if these have been formerly classified as hazardous to health according to Directive 67/548/EEC or Directive 1999/45/EC. For the evaluation of substances that are harmful to human health, the relevant rules and knowledge published according to Article 20 paragraph 4 number 1 shall be taken into account.
- (8) For activities involving hazardous substances according to Annex I numbers 2 to 5, the employer must observe both Articles 6 to 18 and the relevant provisions of Annex I numbers 2 to 5.

#### **Article 9 Additional protective measures**

- (1) If the general protective measures according to Article 8 do not sufficiently counteract the risks arising from exposure by inhalation, absorption through the skin or swallowing, the employer must additionally implement those measures according to paragraphs 2 to 7 that were deemed necessary on the basis of the risk assessment carried out according to Article 6. This shall apply in particular
- 1. if occupational exposure limits or biological limit values are exceeded,
- 2. if there is a risk of skin or eye contact with hazardous substances that are absorbed through the skin or induce damage to the skin or eyes, or
- 3. to hazardous substances for which an occupational exposure limit or biological limit value has not been established, but a risk is assumed on the basis of the hazard class in which they have been classified according to Article 3 and exposure by inhalation.
- (2) The employer is to ensure that hazardous substances are produced and used in a closed system if
- 1. it is technically not possible to substitute the hazardous substances as set forth in Article 7 paragraph 3

with substances, mixtures, articles or processes that are not or less hazardous to the safety and health during handling, and

2. workers are at an increased risk as a result of inhalation exposure to these hazardous substances.

If the use of a closed system is technically not possible, the employer is to ensure that exposure of the workers is kept to the minimum necessary in accordance with the state of the art and in compliance with Article 7 paragraph 4.

- (3) If an occupational exposure limit is exceeded, the employer shall conduct a new risk assessment according to Article 6 without delay and take suitable additional protective measures to maintain levels below the occupational exposure limit. If the occupational exposure limit is exceeded although all technical and organisational safety measures have been taken, the employer is to make personal protective equipment available without delay. This shall apply in particular to demolition, renovation and maintenance work.
- (4) If a risk of skin or eye contact with hazardous substances that are absorbed through the skin or induce damage to the skin or eyes remains even though all technical and organisational safety measures have been taken, the employer is to make personal protective equipment available without delay.
- (5) The employer must provide sufficient storage facilities to store laboratory and protective clothing and street clothing separately. The employer is obligated to clean work clothing contaminated by hazardous substances.
- (6) The employer must implement suitable measures to ensure that work areas in which workers are at an increased risk are only accessible to those workers who must enter them to perform their work or to perform certain tasks.
- (7) If activities involving hazardous substances are carried out by one worker alone, the employer is obligated to take additional protective measures or to ensure suitable supervision. This obligation may be satisfied also by technical means.

## Article10 Special protective measures for activities involving hazardous substances classified in Categories 1A or 1B for carcinogenicity, germ cell mutagenicity or reproductive toxicity

- (1) For activities involving hazardous substances classified in Categories 1A or 1B for carcinogenicity for which no occupational exposure limit has been published according to Article 20 paragraph 4, the employer is to implement an appropriate, risk-related concept of measures in compliance with the risk minimisation requirement set forth in Article 7 paragraph 4. The rules, knowledge and assessment criteria published according to Article 20 paragraph 4 must be taken into account. For activities involving hazardous substances that have been classified in Categories 1A or 1B for carcinogenicity, germ cell mutagenicity or reproductive toxicity, the employer must additionally comply with the provisions laid down in paragraphs 3 to 5, notwithstanding paragraph 2. The special provisions of Annex II number 6 must be observed.
- (2) Paragraphs 3 to 5 shall not apply if
- 1. an occupational exposure limit has been published according to Article 20 paragraph 4, this limit has not been exceeded and the observance of this limit has been verified by determinations at the workplace or by other methods suitable for determining exposure levels or
- 2. activities are performed according to a criterion for a specific procedure or substance that was published in accordance with Article 20 paragraph 4.
- (3) For activities involving hazardous substances classified in Categories 1A or 1B for carcinogenicity, germ cell mutagenicity or reproductive toxicity, the employer is to ensure that
- the level of worker exposure is monitored by determinations at the workplace or using other appropriate methods of determination, also for the immediate detection of increased levels of exposure resulting from unforeseeable events or an accident,
- 2. the boundaries of the hazard areas in which workers are exposed or may be exposed to these hazardous substances have been demarcated and warning and safety signs have been placed, including the prohibitory signs "No access for unauthorised persons" and "No smoking" according to Annex II number 3.1 of Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (OJ L 245 of 26 August 1992, p. 23), last amended by Directive 2014/27/EU (OJ L 65 of 5 March 2014, p. 1).

- (4) For activities that are expected to lead to a marked increase in the level of worker exposure to hazardous substances classified in Categories 1A or 1B for carcinogenicity, germ cell mutagenicity or reproductive toxicity and after implementing all possible technical safety measures to limit the level of exposure, the employer shall, after consultation with the workers or their representatives, take measures to reduce the duration of exposure of the workers to the greatest possible extent and to ensure the safety of the workers during these activities. The employer is to make personal protective equipment available to the workers concerned, which they must wear during the entire period of increased exposure.
- (5) If activities involving hazardous substances classified in Categories 1A or 1B for carcinogenicity, germ cell mutagenicity or reproductive toxicity are being carried out in a work area, the air exhausted from this area shall not be returned to the work area. This provision shall not apply if these substances have been removed from the air in sufficient amounts using methods or equipment approved by the authorities or social accident insurance institutions. The air must be ducted or purified in such a way that substances that induce carcinogenicity, germ cell mutagenicity or reproductive toxicity are not introduced into the breathing air of other workers.

# Article 11 Special protective measures to safeguard against physicochemical effects, particularly fire and explosion hazards

- (1) The employer is to implement measures to safeguard workers and other persons against physicochemical effects in accordance with the findings of the risk assessment. The employer must choose the measures in such a way that hazards are avoided or reduced to the greatest possible extent. This applies particularly to activities that may lead to fire and explosion hazards, including storage. The employer must observe Annex I numbers 1 and 5. This shall not affect the provisions of the Explosives Act (*Sprengstoffgesetz, SprengG*) and the statutory provisions arising from this Act.
- (2) To prevent fire and explosion hazards, the employer is to implement measures in the following order of priority:
- 1. to avoid the occurrence of hazardous levels or concentrations of hazardous substances that lead to fire or explosion hazards,
- 2. to avoid ignition sources or conditions that give rise to fires or explosions,
- 3. to reduce the adverse effects of fires or explosions on the safety and health of workers and other persons to the greatest possible extent.
- (3) Work areas, workplaces, work equipment and their connecting elements must be designed, built, assembled, installed, used and maintained in such a way that fire and explosion hazards do not occur.
- (4) For activities involving organic peroxides, the employer must, in addition to complying with the provisions of paragraphs 1 and 2 and of Annex I number 1, in particular implement measures that
- 1. minimise the risk of unintended explosions and
- 2. limit the effects of fires and explosions.

The employer must observe Annex III while implementing these measures.

#### Article 12 (repealed)

#### Article 13 Plant malfunctions, accidents and emergencies

- (1) To protect the safety and health of workers in the event of a plant malfunction, accident or emergency, the employer must establish a plan of emergency measures in time that is to be implemented if an incident occurs. This includes the availability of appropriate first aid equipment and the performance of safety training exercises at regular intervals.
- (2) In the event of an incident as set forth in paragraph 1 sentence 1, the employer must immediately implement the measures laid down in paragraph 1 with the aim of
- 1. informing the workers concerned about the hazard situation that has developed at the workplace as a result of this incident,
- 2. mitigating the effects of this incident, and
- 3. returning to normal operations.

Besides the emergency and rescue services, only those workers who perform activities for the purpose of achieving the targets set forth in sentence 1 numbers 2 and 3 may remain in the hazard area.

- (3) The employer is to make available appropriate protective clothing and personal protective equipment to workers who carry out activities in the hazard area prior to commencement of the work, in addition to special safety equipment and work equipment, if applicable. The workers must wear the protective clothing and the personal protective equipment in the hazard area until normal operations can be restored. The individual worker may be expected to use burdensome personal protective equipment only for a limited period of time. Unprotected and unauthorised persons may not enter the designated hazard area.
- (4) The employer is to ensure the availability of warning systems and other communications systems that warn of an increased hazard to safety and health, thus enabling an appropriate response and the immediate implementation of remedial measures as well as relief, evacuation and rescue measures.
- (5) The employer is to ensure that information is available about the measures to be taken in the event of an emergency involving hazardous substances. The responsible company or external emergency and accident response services must have access to this information. This information includes:
- 1. advance notification of the relevant hazards arising during work, of hazard detection measures and of safety precautions and procedures, thus enabling the emergency and rescue services to prepare their own remedial and safety measures,
- 2. all information available about specific hazards that occur or may occur in the event of an accident or emergency including information about procedures as set forth in paragraphs 1 to 4.

#### **Article 14 Obligation to inform and train workers**

- (1) The employer is to ensure that workers have access to a written copy of the safe operating procedures that take into account the risk assessment according to Article 6; these are to be written in a form and language that are easily understood by the workers. The safe operating procedures must contain at least the following information:
- 1. information about the hazardous substances occurring or formed at the workplace, including the name of the hazardous substances, their labelling and potential safety and health hazards,
- 2. information about appropriate safety precautions and measures that workers are to observe for their own protection and for the protection of other workers at the workplace; these include in particular
  - a) hygiene regulations,
  - b) information about measures that are to be taken to prevent exposure,
  - c) information about wearing and using personal protective equipment and protective clothing,
- 3. information about the measures to be taken by workers, in particular rescue teams, in the event of a plant malfunction, accident or emergency and for the prevention of these incidents.

The safe operating procedures must be revised after significant changes to the working conditions. Furthermore, the employer is to ensure that workers

- 1. have access to all information according to Article 35 of Regulation (EC) No 1907/2006 relating to the substances and mixtures being handled, particularly safety data sheets and
- 2. are instructed of the methods and procedures that must be used to protect workers while handling hazardous substances.
- (2) The employer is to ensure that workers receive verbal instructions about any relevant hazards and the appropriate protective measures to be taken as set forth in the safe operating procedures according to paragraph 1. These instructions shall include general recommendations relating to occupational health and toxicology. In addition, the objective is to inform workers about the circumstances under which they are entitled to preventive occupational health examinations according to the Ordinance on Occupational Health Care and about the purpose of these preventive health examinations. The consultation is to be carried out in the presence of a physician according to Article 7 paragraph 1 of the Ordinance on Occupational Health Care if this should be necessary. The initial instruction must take place prior to the commencement of work and then at least once every year and provide information related to the individual workplace. The form of instruction and language used must be easily understood by the workers. A written record of the contents and time of the instruction is to be kept including a signed confirmation by the workers of having received the instruction.
- (3) For activities involving hazardous substances classified in Categories 1A or 1 B for carcinogenicity, germ cell

mutagenicity or reproductive toxicity, the employer is to ensure that

- 1. workers and their representatives are able to verify whether the provisions of this Ordinance have been complied with, specifically with respect to
  - a) the selection and use of personal protective equipment and the burden placed on workers by the equipment,
  - b) the measures to be implemented within the meaning of Article 10 paragraph 4 sentence 1,
- 2. workers and their representatives are immediately informed about increased levels of exposure, including the cases listed in Article 10 paragraph 4 sentence 1, about the causes and the countermeasures that have already been taken or are still to be taken.
- 3. a record is kept and consistently updated of workers who carry out activities that involve hazardous substances classified in Categories 1A or 1B for carcinogenicity or germ cell mutagenicity and have been found to pose a safety or health hazard for workers on the basis of the risk assessment according to Article 6; the record is to include data for the level and duration of worker exposure,
- 4. the record according to number 3 and all updated versions are archived for 40 years following the end of exposure; at termination of employment, the employer must give the workers a complete copy of the data included in the record that are pertinent to them. A document verifying that these data were given to the workers is to be kept in compliance with the same requirements as apply to employee documents,
- 5. the physician according to Article 7 paragraph 1 of the Ordinance on Occupational Health Care, the competent authority and all persons responsible for safety and health at the workplace have access to the record as set forth in number 3,
- 6. all workers have access to any personal data included in the record,
- 7. workers and their representatives have access to all general information that is included in the record and does not relate to any specific person.
- (4) With the consent of the workers concerned, the employer may transfer the obligation to retain records and to enable access to them according to paragraph 3 number 4 to the competent social accident insurance institution. For this purpose, the employer shall transfer the necessary documents to the social accident insurance institution in a digital form suitable for electronic data processing. On request, the social accident insurance institution will give the workers a copy of the records that contain information relevant to them.

#### Article 15 Co-operation between companies

- (1) If external contractors are carrying out activities involving hazardous substances in the company, the employer, as the contracting party, is to ensure that only external contractors are hired who have the competency and experience necessary for these activities. As the contracting party, the employer must inform the external contractor about sources of hazards and specific rules of conduct.
- (2) If the workers of one employer engage in activities that may potentially place the workers of the other employers at risk from hazardous substances, all employers concerned must co-operate to carry out risk assessments according to Article 6 and co-ordinate their protective measures. This is to be documented. The employers are to ensure that effective measures have been taken to prevent workers of all companies involved from being affected by hazards from hazardous substances.
- (3) Each employer shall be responsible for ensuring that their workers implement the jointly established protective measures.
- (4) If the workers of one employer engage in activities that place the workers of the other employers at an increased risk from hazardous substances, a co-ordinator must be appointed by the employers concerned. If a co-ordinator has been appointed in accordance with the provisions of the Construction Sites Ordinance (Baustellenverordnung, BaustellV) of 10 June 1998 (Federal Law Gazette I p. 1283), amended by Article 15 of the Ordinance of 23 December 2004 (Federal Law Gazette I p. 3758), the obligations according to sentence 1 shall be deemed to have been fulfilled. The employers concerned must grant the co-ordinator access to all requisite safety information and to information about the protective measures that have been established. The appointment of a co-ordinator shall not release the employers from the obligations laid down in the present Ordinance.
- (5) Prior to the commencement of demolition, renovation, maintenance and construction work, the employer must collect information for the risk assessment according to Article 6, in particular from the contracting party or building owner or developer, to determine whether hazardous substances, particularly asbestos, are present or

are expected to occur based on the past use or structural history of the building. This does not affect the more comprehensive information, safety and monitoring obligations placed upon the contracting party or building owner or developer in compliance with other statutory provisions.

#### Section 4a

# Requirements for the Use of Biocidal Products Including Fumigation Activities and Fumigation with Plant Protection Products

#### **Article 15a Use restrictions**

- (1) Biocidal products shall not be used if their use in a particular case is expected to lead to damaging effects on the health of persons, non-target organisms or the environment.
- (2) Anyone who uses biocidal products must do so according to the established conditions of use. The established conditions of use specifically involve,
- 1. limiting the use of biocidal products to the minimum necessary by:
  - a) weighing the risks and benefits of using the biocidal product, and
  - b) applying qualified knowledge to consider physical, biological, chemical and other alternatives,
- 2. using the biocidal product only for the intended purposes specified in its labelling or authorisation,
- 3. using the biocidal product in compliance with the conditions of use specified in its labelling or authorisation, and
- 4. ensuring that the qualifications of the user comply with the criteria of the specific user category specified in the authorisation.
- (3) Paragraphs 1 and 2 shall also apply for private households.

#### Article 15b General requirements for the use of biocidal products

- (1) Prior to the use of a biocidal product, the employer is to ensure compliance with the requirements according to Article 15a. This involves, in the case of the requirements set forth in
- 1. Article 15a paragraph 2 sentence 2 number 1, an assessment of the possibility of a substitution according to Article 6 paragraph 1 sentence 2 number 4,
- 2. Article 15a paragraph 2 sentence 2 number 3, a risk assessment according to Article 6 paragraph 1. When performing the risk assessment, the employer must take into consideration particularly:
  - a) the measures for the protection of safety and health as well as the environment as stipulated in the authorisation.
  - b) the labelling according to Article 4 paragraphs 5 and 6 including, if applicable, the accompanying leaflet.
- (2) The employer must determine and implement the necessary measures, in compliance with the order of precedence set forth in Article 7 paragraph 4 sentence 4 and taking into consideration the sustainable use of the biocidal products, in such a way that hazards to workers, other persons or the environment are prevented or kept to a minimum.
- (3) Professional expertise (*Fachkunde*) within the meaning of Annex I number 4.3 is required for the use of biocidal products
- 1. belonging to main group 3 "pest control" according to Annex V of the Regulation (EU) No 528/2012 or
- 2. containing active substances with endocrine-disrupting properties according to Article 5 paragraph 1 letter d of Regulation (EU) No 528/2012.

Sentence 1 shall not apply if the biocidal product is authorised for use by the general public or if use of the biocidal product requires expert knowledge (*Sachkunde*) according to Article 15c paragraph 3.

#### Article 15c Special requirements for the use of specific biocidal products

(1) The employer must fulfil the obligations set forth in paragraphs 2 and 3 if biocidal products are to be used

- 1. that are classified in
  - a) Categories 1, 2 or 3 for acute toxicity,
  - b) Categories 1A or 1B for carcinogenicity, germ cell mutagenicity or reproductive toxicity, or
  - c) Category 1 for specific target organ toxicity, SE (single exposure) or RE (repeated exposure) or
- 2. for which, beyond the cases covered by number 1, authorisation has been granted for the intended use only if applied by persons belonging to the user category "trained professional user".
- (2) The employer must notify the competent authority in writing or in electronic form of:
- 1. the first use of biocidal products according to paragraph 1 and
- 2. the resumption of the use of biocidal products as specified in paragraph 1 after ceasing to use the biocidal products for a period of more than one year.

Notification shall be submitted at the latest six weeks prior to the commencement of use. Annex I number 4.2.1 must be observed.

- (3) The use of biocidal products according to paragraph 1 shall be restricted to persons with expert knowledge (sachkundige Person) in the use of the respective biocidal product according to Annex I number 4.4. The criteria that the expert knowledge (*Sachkunde*) must satisfy depend on the type of product, the applications for which the biocidal product has been authorised and the hazard potential for humans and the environment.
- (4) In derogation from paragraph 3, expert knowledge for the use of the biocidal products listed in paragraph 1 shall not be required if the activities are performed under the direct and constant supervision of a person with expert knowledge.

#### Article 15d Special requirements for fumigation activities

- (1) Any employer carrying out fumigation activities must be issued a permit for fumigation by the competent authority. The permit is to be applied for in writing or in electronic form as set forth in Annex I number 4.1 before fumigation is carried out for the first time. The permit may be granted for a limited period, be subject to conditions and include the proviso that approval may be revoked at any time. Conditions may also be imposed retroactively.
- (2) A permit shall not be required if the fumigation activity leads to the release of only small quantities of the active substance that do not present a hazard to humans and the environment. The rules and knowledge published in accordance with Article 20 paragraph 4 are to be taken into consideration.
- (3) The employer must notify the competent authority of any fumigation in writing or in electronic form according to Annex I number 4.2.2 at the latest one week before the fumigation. The competent authority may
- 1. waive compliance with this deadline for good cause or
- 2. allow the submission of only one application for more than one fumigation operation if the fumigation activities are carried out on a routine basis and under the same conditions as described in the application.

For the fumigation of ships and containers in ports, the deadline specified in sentence 1 is reduced to 24 hours.

- (4) The employer shall appoint one person in charge of each fumigation operation who has acquired a certificate of competence (*Befähigungsschein*; holder of a certificate of competence (*Befähigungsscheininhaber*)) according to Annex I number 4.5. The responsibilities of the person in charge shall include:
- in the case of fumigation operations inside rooms, the posting of a written notice to warn the
  occupants of adjacent rooms and buildings of the fumigation at the latest 24 hours before the
  fumigation including information about the hazards posed by the biocidal products or plant protection
  products used and
- 2. ensuring that
  - a) the fumigation is carried out by a holder of a certificate of competence,
  - b) notices containing the information specified in Annex I number 4.6 are placed at all entrances to the hazard areas, and
  - in addition to the holder of a certificate of competence, at least one other person with expert knowledge shall be on site when fumigation activities are carried out with biocidal products for which authorisation was granted with the stipulation that

- aa) the concentrations of the active substance or oxygen are to be determined and continuously monitored, or
- bb) respiratory protective equipment with a supply of breathing-quality air from an independent source is made available and used.
- (5) In the event of a plant malfunction, an accident or an emergency,
- 1. the holder of a certificate of competence who is present on site must secure the hazard area and restrict access to the area until the hazard has been eliminated and hazardous residues have been cleared,
- 2. the person with expert knowledge must assist the holder of a certificate of competence; this particularly applies to establishing perimeters and implementing rescue measures.
- (6) For fumigation activities involving plant protection products, the qualification requirements according to Annex I number 4.4 are regarded as met if expert knowledge according to plant protection regulations has been acquired.
- (7) In the case of fumigation activities involving transport units,
- 1. if the fumigation activities are carried out outdoors, a safety zone shall be established between the units and the adjacent buildings of at least 10 metres in all directions,
- 2. the units are to be sealed by the person in charge, inspected for gas tightness, locked and sealed with security seals for the duration of the fumigation. Warning signs that are visible from all directions must be posted in accordance with Annex I number 4.6.

#### Article 15e Additional documentation requirements

- (1) The employer is to ensure that a record of the fumigation operations is kept. The record must include:
- 1. the name of the person in charge,
- 2. the type and quantity of biocidal products or plant protection products used,
- 3. the place, date and time of the beginning and end of fumigation,
- 4. the time of clearance,
- 5. the names of othe<mark>r employers involved within the meaning of Article 15, and</mark>
- 6. all measures taken.
- (2) The employer is to provide the competent authority with a copy of the record upon request.
- (3) If plant protection products are used for the fumigation, the record may be prepared together with the records kept in accordance with Article 67 paragraph 1 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC of the Council (OJ L 309 of 24 November 2009, p. 1; L 111 of 2 May 2018, p. 10; L 45 of 18 February 2020, p. 81), which was last amended by Regulation (EU) 2019/1381 of 20 June 2019 (OJ L 231 of 6 September 2019, p. 1).

#### Article 15f Requirements for handling transport units

- (1) If it cannot be ruled out whether transport units such as vehicles, railway wagons, ships, tanks, containers or other transport containers have been fumigated, the employer must ascertain this prior to opening the transport units.
- (2) If it is ascertained that the transport unit has been fumigated, the employer must implement the requisite safety precautions. In particular, it is to be ensured that workers are not exposed to biocidal products or plant protection products. If exposure cannot be ruled out, the transport unit is to be opened, vented and cleared for entry by a person with professional expertise (*fachkundige Person*) according to Annex I number 4.3.

#### Article 15g Special requirements for the fumigation of ships

- (1) The fumigation of ships shall be permissible only if
- 1. the fumigant has been authorised for this use, and

- 2. the necessary measures have been taken to ensure the safety of the crew and other persons to a sufficient degree and at all times.
- (2) When carrying out a fumigation on a ship, the person in charge is to
- 1. ensure that labelling has been posted in accordance with Annex I number 4.6,
- 2. notify the skipper prior to the commencement of fumigation in writing of:
  - a) the date and time and the rooms being fumigated,
  - b) the type, scope and duration of the fumigation including information about the fumigant used.
  - c) the safety measures and precautions that have been taken including all necessary technical modifications to the ship,
- 3. provide written confirmation to the skipper prior to leaving the port or loading site that
  - a) the fumigated rooms have been rendered sufficiently gas tight,
  - b) no fumigants were detected in the adjacent rooms.
- (3) The fumigated rooms must be checked for gas tightness at least every eight hours. The findings are to be documented. At the latest 24 hours prior to the arrival of the ship, the skipper must notify the port authority or the person in charge of the port of discharge of the type, date and time of fumigation; the report shall include information about which rooms were fumigated.
- (4) Fumigated transport units may be transported on ships only if it has been ensured that hazardous concentrations of gas will not develop outside the transport units. This is subject to the duty of notification according to paragraph 3 sentence 3.

#### Article 15h Exemptions from Section 4a

- (1) Not applicable are
- Section 4a and Annex I number 4 for fumigation activities carried out exclusively for purposes of research and development or institutional suitability testing of biocidal products, plant protection products or their methods of application,
- 2. Article 15c paragraph 3 for the use of biocidal products belonging to main group 3 "pest control", which have been classified in Categories 1, 2 or 3 for acute toxicity if they are subject to equivalent requirements prescribed by other regulatory provisions,
- 3. Articles 15d and 15e for the fumigation of fully automatic, programme-controlled sterilisers in the medical sector where the activities are performed in accordance with a process-specific and substance-specific criterion that was published in accordance with Article 20 paragraph 4,
- 4. Article 15d paragraph 3 for fumigation activities performed
  - a) in the medical sector or
  - b) within stationary sterilisation chambers.
- (2) The exemptions set forth in paragraph 1 do not apply to biocidal products if specified otherwise in the authorisation documents of the respective biocidal product.

#### Section 5

#### **Prohibitions and Restrictions**

#### **Article 16 Manufacturing and use restrictions**

- (1) Manufacturing and use restrictions for specific substances, mixtures and articles are laid down in Article 67 in conjunction with Annex XVII of Regulation (EC) No 1907/2006.
- (2) Annex II mandates additional manufacturing and use restrictions for the substances, mixtures and articles listed therein.
- (3) The employer may instruct homeworkers to perform only low risk activities within the meaning of Article 6 paragraph 13.

### Article 17 National exemptions from restriction provisions according to Regulation (EC) No 1907/2006

- (1) For facilities completed before 1 December 2010, the restrictions according to Article 67 in conjunction with Annex XVII number 6 of the Regulation (EC) No 1907/2006 shall not apply to the use of diaphragms containing chrysotile for the chlor-alkali process or for chrysotile that is used exclusively to maintain and service these diaphragms until 1 July 2025 if
- 1. no alternative, asbestos-free substances, mixtures or articles are available on the market or
- 2. the use of alternative, asbestos-free substances, mixtures or articles would cause unreasonable hardship

and the concentration of the asbestos fibres in the air at the workplace remains below 1 000 fibres per cubic metre. Operators of facilities that make use of the provision set forth in sentence 1 shall file a report to the Federal Office for Chemicals (*Bundesstelle für Chemikalien, BfC*) by 31 January of each calendar year notifying the amount of chrysotile used in the diaphragms that are subject to this exemption during the preceding year. This report shall include the results from determinations taken at the workplace. The Federal Office for Chemicals shall submit a copy of this report to the European Commission.

(2) The provision prohibiting use according to Article 67 in conjunction with Annex XVII numbers 16 and 17 of Regulation (EC) No 1907/2006 shall not apply to the use of lead compounds in paints listed therein that are manufactured for the conservation or historically correct restoration of works of art, historic component parts or furnishings of listed historic buildings if the use of alternative substances is not possible.

#### Section 6

#### Enforcement Provisions and Committee on Hazardous Substances

#### **Article 18 Notification of authorities**

- (1) The employer is to immediately notify the competent authority of
- 1. any accident or any malfunction that led to serious adverse effects on the health of workers during activities involving hazardous substances,
- 2. cases of illness or death for which there is concrete evidence that they were caused by activities involving hazardous substances; this must include exact data for the activity and the risk assessment according to Article 6.

If the information required for the notification according to sentence 1 is equivalent to the information required for notifications filed in compliance with other statutory provisions, the obligation to notify is considered fulfilled by the submission of copies of these notifications to the competent authority. The employer is to provide the workers concerned or their representatives with copies of the notifications according to sentence 1 or sentence 2.

- (2) Without prejudice to Article 22 of the Occupational Safety and Health Act, the employer must submit the following to the competent authority on request:
- the results of the risk assessment according to Article 6 and the data on which it was based, including the documentation of the risk assessment,
- 2. the activities during which workers were actually exposed or may possibly have been exposed to hazardous substances and the number of workers concerned,
- 3. the persons responsible according to Article 13 of the Occupational Safety and Health Act,
- 4. the protective and precautionary measures taken, including the safe operating procedures.
- (3) For activities involving hazardous substances that are classified in Categories 1A or 1B for carcinogenicity, germ cell mutagenicity or reproductive toxicity, the employer must in addition submit the following information to the competent authority on request:
- 1. the results of the substitution assessment,
- 2. information about
  - a) activities carried out and industrial processes applied and the reasons for using the hazardous substances concerned,
  - b) the amount of hazardous substance manufactured and used,
  - c) the type of protective equipment to be used,

- d) the type and extent of exposure,
- e) substitutions made.
- (4) Evidence of the competency required by Annex II of the Regulation (EC) No 1907/2006 for the compilation of safety data sheets is to be submitted to the competent authority on request.

#### Article 19 Official exemptions, orders and powers

- (1) On application by the employer either in written or electronic form, the competent authority may grant exemptions from Articles 6 to 15 if compliance with these provisions in a specific case would lead to disproportionate hardship and the derogation is compatible with worker protection. The employer must include the following information in the application submitted to the competent authority:
- 1. the reasons for applying for the exemption,
- 2. the amount of hazardous substance used annually,
- 3. the activities and processes involved,
- 4. the expected number of workers involved,
- 5. the measures planned to protect the safety and health of the workers involved,
- 6. the technical and organisational measures intended to reduce or prevent exposure of the workers.
- (2) An exemption according to paragraph 1 may also be applied for in connection with administrative procedures carried out in compliance with other statutory provisions.
- (3) Without prejudice to Article 23 of the Chemicals Act, the competent authority may in individual cases place a duty on the manufacturer, supplier or employer to implement measures to fulfil the obligations laid down in Sections 2 to 5 of this Ordinance; in particular, it may place a duty on the employer
- 1. to implement the measures necessary to control specific hazards,
- 2. to determine whether and to what extent a suspected hazard does in fact exist and which measures are to be taken to control the hazard,
- 3. to stop any work that poses a hazard to workers if the employer does not implement the prescribed measures to control the hazard immediately or within the deadline.

In exigent circumstances, a duty may also be placed upon persons in the company with the authority to issue directives.

- (4) On request, evidence is to be submitted to the competent authority that the risk assessment was compiled by competent persons according to Article 6 paragraph 9.
- (5) The competent authority may prohibit the employer from carrying out activities involving hazardous substances or having such activities carried out; in particular, it may order a discontinuation of operations in the work areas concerned if the employer fails to fulfil the obligation to notify according to Article 18 paragraph 2 number 1.

#### Article 19a Recognition of foreign qualifications

- (1) On application, the competent authority shall recognise training and further training courses completed in other countries as equivalent to qualifications acquired as set forth in Article 2 paragraph 17 if the course of instruction comprised knowledge that fulfils the qualification requirements of the rules and knowledge published according to Article 20 paragraph 4.
- (2) The authority shall decide on the equivalence of a foreign qualification on the basis of the documents available to the authority or documents additionally submitted by the applicant. The documents are to be submitted in German. The equivalence will be confirmed by a certificate.

#### **Article 20 Committee on Hazardous Substances**

(1) The Federal Ministry of Labour and Social Affairs shall establish a Committee on Hazardous Substances (*Ausschuss für Gefahrstoffe (AGS)*) with appropriate members from among the employers, trade unions, authorities of the Federal States and the statutory accident insurance and with other appropriate persons, particularly of the scientific community. The total number of members is not to exceed 21 persons. A deputy shall be appointed for each member. Membership in the Committee on Hazardous Substances shall be

#### honorary.

- (2) The Federal Ministry of Labour and Social Affairs shall appoint the members of the Committee and a deputy for each member. The Committee shall adopt rules of procedure and shall elect the chair from among its members. The rules of procedure and the election of the chair shall be subject to the approval of the Federal Ministry of Labour and Social Affairs.
- (3) The responsibilities of the Committee shall include:
- determining the current state of knowledge in science, technology, occupational medicine and occupational hygiene as well as other established knowledge relating to activities involving hazardous substances including their classification and labelling and making appropriate recommendations,
- 2. determining how the requirements laid down in the present Ordinance are to be fulfilled and developing relevant rules and knowledge reflecting the current state of knowledge in technology and medicine,
- 3. advising the Federal Ministry of Labour and Social Affairs in all matters relating to hazardous substances and chemical safety, and
- proposing occupational exposure limits, biological limit values and other assessment criteria for hazardous substances and reviewing these regularly, taking the following into account:
  - a) the limit values and assessment criteria are to be established to safeguard worker health,
  - b) for each substance for which an occupational exposure limit or a biological limit value has been established in the legal acts of the European Union, a national limit value is to be proposed taking this limit value into account.

The work programme of the Committee on Hazardous Substances shall be co-ordinated with the Federal Ministry of Labour and Social Affairs; the Federal Ministry of Labour and Social Affairs shall be vested with the power of final decision. The Committee shall co-operate closely with other committees of the Federal Ministry of Labour and Social Affairs.

- (4) Following review, the Federal Ministry of Labour and Social Affairs may
- 1. publish the rules and knowledge according to paragraph 3 sentence 1 number 2 established by the Committee on Hazardous Substances as well as the occupational exposure limits and assessment criteria according to paragraph 3 sentence 1 number 4 in the Joint Ministerial Gazette (Gemeinsames Ministerialblatt, GMBI), and
- 2. publish the recommendations according to paragraph 3 sentence 1 number 1 as well as the results of the deliberations according to paragraph 3 sentence 1 number 3 in an appropriate manner.
- (5) The Federal Ministries and the Supreme Federal State Authorities (*Oberste Landesbehörden*) may delegate representatives to attend the meetings of the Committee. On request, these representatives shall be permitted to take the floor during meetings.
- (6) The Federal Institute for Occupational Safety and Health (*Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA*) shall manage the affairs of the Committee.

# Section 7 Regulatory Offences, Criminal Offences and Interim Provisions

#### **Article 21 Chemicals Act - Notifications**

Pursuant to Article 26 paragraph 1 number 8 letter b of the Chemicals Act, a person shall be deemed to have committed a regulatory offence if that person, wilfully or negligently,

- 1. contrary to Article 8 paragraph 8 in conjunction with Annex I number 2.4.2 paragraph 1 sentence 1 or paragraph 2, fails to notify, fails to do so properly, completely or in time,
- 2. contrary to Article 8 paragraph 8 in conjunction with Annex I number 5.4.2.3 paragraph 1 or paragraph 2, fails to notify, fails to do so properly, completely or in time,
- 3. contrary to Article 8 paragraph 8 in conjunction with Annex I number 5.4.2.3 paragraph 3, fails to notify of a change or fails to do so in time,
- 4. contrary to Article 15d paragraph 3 sentence 1, Article 15g paragraph 3 sentence 3 or Article 18 paragraph 1, fails to notify, fails to do so properly, completely or in time

5. contrary to Article 18 paragraph 2, fails to inform, fails to do so properly, completely or in time.

#### Article 22 Chemicals Act – Activities

- (1) Pursuant to Article 26 paragraph 1 number 8 letter b of the Chemicals Act, a person shall be deemed to have committed a regulatory offence if that person, wilfully or negligently,
- 1. contrary to Article 6 paragraph 8 sentence 1, fails to document a risk assessment, fails to do so properly, completely or in time,
- 2. contrary to Article 6 paragraph 12 sentence 1, fails to maintain an inventory of hazardous substances, fails to do so properly or completely,
- 3. contrary to Article 7 paragraph 1, approves the commencement of an activity,
- 4. contrary to Article 7 paragraph 5 sentence 2, approves the use of burdensome personal protective equipment as a long-term measure,
- 5. contrary to Article 7 paragraph 7 sentence 1, fails to inspect or inspect in time the functioning and effectiveness of technical safety measures,
- 6. contrary to Article 8 paragraph 2 sentence 3, allows the performance of an activity,
- 7. contrary to Article 8 paragraph 3 sentence 2, fails to establish an area or establish it in time,
- 8. contrary to Article 8 paragraph 5 sentence 3, keeps or stores hazardous substances,
- 9. contrary to Article 8 paragraph 8 in conjunction with Annex I number 2.4.2 paragraph 3 sentence 2, fails to ensure that a qualified person with the authority to issue directives is on site,
- 10. contrary to Article 8 paragraph 8 in conjunction with Annex I number 2.4.4 sentence 1, fails to establish a work plan or fails to do so in time.
- 11. contrary to Article 8 paragraph 8 in conjunction with Annex I number 5.4.2.1 paragraph 2, stores or transports substances or mixtures classified in Group A,
- 12. contrary to Article 8 paragraph 8 in conjunction with Annex I number 5.4.2.1 paragraph 3, stores flammable materials.
- 13. contrary to Article 8 paragraph 8 in conjunction with Annex I number 5.4.2.2 paragraph 3, fails to divide substances or mixtures into smaller quantities or fails to do so in time,
- 14. contrary to Article 8 paragraph 8 in conjunction with Annex I number 5.4.2.3 paragraph 5, stores substances or mixtures,
- 15. contrary to Article 9 paragraph 3 sentence 2 or Article 9 paragraph 4, fails to make personal protective equipment available or fails to do so in time,
- 15a. contrary to Article 9 paragraph 5, fails to ensure that separate storage areas are available,
- 16. contrary to Article 10 paragraph 4 sentence 2, fails to make protective clothing or respiratory protective equipment available,
- 17. contrary to Article 10 paragraph 5 sentence 1, returns exhaust air to a work area,
- 18. contrary to Article 11 paragraph 1 sentence 3 in conjunction with Annex I number 1.3 paragraph 2 sentence 1, fails to prohibit smoking or the use of naked flames or naked lights,
- 19. contrary to Article 11 paragraph 1 sentence 3 in conjunction with Annex I number 1.5 paragraph 4 or number 1.6 paragraph 5, fails to designate or properly designate an area as specified therein,
- 19a. contrary to Article 11 paragraph 4 sentence 2 in conjunction with Annex III number 2.3 paragraph 1 sentence 1, allows the performance of an activity involving organic peroxides,
- 19b. contrary to Article 11 paragraph 4 sentence 2 in conjunction with Annex III number 2.6 sentence 2 letter a, fails to ensure that a building or a room as specified therein is built according to safety standards,
- 19c. contrary to Article 11 paragraph 4 sentence 2 in conjunction with Annex III number 2.7, fails to designate an area as specified therein or fails to designate it in time,
- 20. contrary to Article 13 paragraph 2 sentence 1, fails to take a measure as specified therein or fails to do so in time.
- 21. contrary to Article 13 paragraph 3 sentence 1, fails to equip a worker or fails to do so in time,
- 22. contrary to Article 13 paragraph 4, fails to ensure the availability of warning or other communications

systems.

- 23. contrary to Article 13 paragraph 5 sentence 1, fails to ensure the availability of information about emergency measures,
- 24. contrary to Article 14 paragraph 1 sentence 1, fails to ensure that a written copy of the safe operating procedures is made available to workers in the prescribed manner,
- 25. contrary to Article 14 paragraph 2 sentence 1, fails to ensure that workers are given verbal instructions about the hazards that occur and the relevant protective measures,
- 26. contrary to Article 14 paragraph 3 number 2, fails to ensure that workers and their representatives are instructed and informed, or fails to do so in time,
- 27. contrary to Article 14 paragraph 3 number 3, fails to ensure that an updated inventory is maintained,
- 28. contrary to Article 14 paragraph 3 number 4, fails to ensure that an updated inventory is archived for 40 years after the end of exposure,
- 29. contrary to Article 15c paragraph 3 sentence 1, uses a biocidal product,
- 30. contrary to Article 15d paragraph 4 sentence 2 number 2 letter a, fails to ensure that fumigation is carried out by a person as specified therein,
- 31. contrary to Article 15d paragraph 4 sentence 2 number 2 letter c, fails to ensure that, in addition to the holder of a certificate of competence, another qualified person is present, or
- 32. contrary to Article 15d paragraph 5 number 1, fails to secure a hazard area or to secure it in time or allows entry to a hazard area.
- (2) A person who, by an action referred to in paragraph 1, endangers the life or health of another person or puts at risk objects of high value belonging to others, shall be liable to legal prosecution according to Article 27 paragraphs 2 to 4 of the Chemicals Act.

#### Article 23 (repealed)

#### Article 24 Chemicals Act - Manufacturing and use restrictions

- (1) Pursuant to Article 26 paragraph 1 number 7 letter a of the Chemicals Act, a person shall be deemed to have committed a regulatory offence if that person, wilfully or negligently,
- 1. contrary to Article 15a paragraph 2 sentence 1, uses a biocidal product improperly in the cases set forth in Article 15a paragraph 2 sentence 2 numbers 2 or 3, or
- 2. contrary to Article 16 paragraph 2 in conjunction with Annex II number 6 paragraph 1, uses a substance listed therein.
- (2) Pursuant to Article 27 paragraph 1 number 1, paragraphs 2 to 4 of the Chemicals Act, a person shall be prosecuted if that person, wilfully or negligently,
- 1. contrary to Article 8 paragraph 8 in conjunction with Annex I number 2.4.2 paragraph 3 sentence 1 or paragraph 4 sentence 1, carries out demolition, renovation or maintenance work,
- 2. contrary to Article 16 paragraph 2 in conjunction with Annex II number 1 paragraph 1 sentence 1 as well as in conjunction with sentence 3, carries out work,
- 3. contrary to Article 16 paragraph 2 in conjunction with Annex II number 1 paragraph 1 sentence 4, carries out covering, superstructure, mounting, cleaning or coating work,
- 4. contrary to Article 16 paragraph 2 in conjunction with Annex II number 1 paragraph 1 sentence 5, reuses objects or materials that contain asbestos for other purposes,
- 5. contrary to Article 16 paragraph 2 in conjunction with Annex II number 2 paragraph 1, manufactures the substances or mixtures listed therein,
- 6. contrary to Article 16 paragraph 2 in conjunction with Annex II number 3 paragraph 1, uses the articles listed therein,
- 7. contrary to Article 16 paragraph 2 in conjunction with Annex II number 4 paragraph 1, paragraph 3 sentence 1 or paragraph 4, uses the metalworking fluids or corrosion inhibitors listed therein, or
- 8. contrary to Article 16 paragraph 2 in conjunction with Annex II number 5 paragraph 1, manufactures or uses the substances, mixtures or articles listed therein.

#### **Article 25 Interim provisions**

- (1) For the use of biocidal products that are subject to the interim provisions of Article 28 paragraph 8 of the Chemicals Act, the provisions below shall not apply insofar as compliance would require authorisation according to Regulation (EU) No 528/2012:
- 1. Article 15a paragraph 2 sentence 2 number 4,
- 2. Article 15b paragraph 1 number 2 letter a and paragraph 3,
- 3. Article 15c paragraph 1 number 2.

For these biocidal products, the relevant rules and knowledge published according to Article 20 paragraph 4 are to be taken into account until an authorisation is granted.

(2) For the use of biocidal products according to Article 15c paragraph 1, the use of which was not subject to qualification requirements until 30 September 2021, evidence of qualification is to be submitted by 28 July 2025 at the latest.

Annex I (to Article 8 paragraph 8, Article 11 paragraph 3, Article 15b paragraph 3, Article 15c paragraphs 2 and 3, Article 15d paragraphs 1, 3, 4, 6 and 7, Article 15f paragraph 2, Article 15g paragraph 2)

Special Provisions for Specific Hazardous Substances and Activities

(Source: Federal Law Gazette I 2010, 1660 - 1673; see footnote for individual changes)

#### Table of contents

	Table of Contents
Number 1	Fire a <mark>nd</mark> exp <mark>los</mark> ion hazards
Number 2	Partic <mark>ula</mark> te <mark>haz</mark> ardous substances
Number 3	(repealed)
Number 4	Biocidal pr <mark>odu</mark> cts and fumigation activities with bio <mark>cida</mark> l products or plant protection products
Number 5	Ammonium nitrate

## Number 1 Fire and explosion hazards

#### 1.1 Scope

Number 1 applies to the measures laid down in Article 11 for activities involving hazardous substances that may cause fire and explosion hazards.

#### 1.2 Basic requirements for protection against fire and explosion hazards

- (1) On the basis of the findings of the risk assessment according to Article 6, the employer is to implement the organisational and technical safety measures according to the current state of knowledge in technology that are required to protect the safety and health of workers or other persons against the risks of explosion and fire.
- (2) The quantities of hazardous substances are to be limited with respect to fire load, fire propagation and explosion hazards to ensure that the risk of fire and explosions is reduced to the minimum possible.
- (3) Appropriate measures are to be taken to protect against the unintentional release of hazardous substances that may lead to fire or explosion hazards. In particular, it must be ensured that
- hazardous substances in work equipment and installations are kept safely contained and conditions such as hazardous temperatures, positive and negative pressures, overfilling, corrosion and other hazardous conditions do not arise,
- 2. it is possible to stop the flow of hazardous substances by shutting down the feed at a location that is accessible quickly and without obstruction,
- 3. incompatible hazardous substances do not come into contact with one another.

Where the risk assessment shows it is necessary, it must be possible to automatically limit or interrupt the flow of hazardous substances.

(4) Any hazardous substances that are released and may cause a fire or explosion hazard are to be safely captured at the point of exit or formation if this is possible given the current state of knowledge in technology. Liquid hazardous substances that have escaped shall be collected. Pools of liquid and dust deposits must be removed safely.

#### 1.3 Protective measures in work areas that pose fire and explosion hazards

- (1) Work areas that pose fire and explosion hazards must
- 1. have an adequate number of evacuation and rescue routes and exits to ensure that, in the event of a hazardous situation, the workers are able to evacuate the work areas quickly, safely and without obstruction and it is possible to rescue persons who have sustained injuries at any time,
- 2. be designed and arranged to prevent the spread of fires and explosions as well as to keep the effects of fires and explosions from affecting adjacent areas.
- 3. be equipped with a sufficient number of fire extinguishing devices; the fire extingu<mark>ishi</mark>ng devices must be labelled, easily accessible and easy to use if they are not automatic,
- 4. have fire attack routes that are laid out and designated to ensure that they can be reached with extinguishing and work equipment quickly and without obstruction.
- (2) In work areas that pose a fire or explosion hazard, smoking and the use of naked flames and naked lights must be prohibited. Unauthorised persons are to be prohibited from entering areas that pose a fire or explosion hazard. Clearly recognisable and permanent notices of these prohibitions must be posted.
- (3) Suitable measures are to be taken to ensure that, in the event of a hazardous situation, persons are warned in time and in an appropriate, clearly noticeable and unmistakeable manner.
- (4) Where the risk assessment shows it is necessary,
- 1. it must be possible to maintain equipment and protective systems in a safe state of operation independently of the rest of the installation in the event of power failure,
- manual override must be possible to shut down the equipment and protective systems incorporated within automatic processes that deviate from the intended operating condition provided that this does not compromise safety, and
- 3. on operation of the emergency shutdown, accumulated energy must be dissipated as quickly and as safely as possible or isolated.

#### 1.4 Organisational measures

- (1) The employer shall assign activities involving hazardous substances that may lead to fire or explosion hazards only to workers who are reliable, familiar with these activities, the hazards arising during these activities and the requisite safety measures and who have received relevant instructions.
- (2) If highly hazardous activities and activities that may interact with other activities to cause hazards are being carried out in work areas with hazardous substances that may lead to fire or explosion hazards, a system of permits to work must be applied with written instructions issued by the employer. Permits to work must be issued by a person with responsibility for this function prior to the commencement of the activities.
- (3) If workers have been assigned to work areas in which activities involving hazardous substances that may give rise to fire or explosion hazards are performed, and if these workers should be at higher risk while carrying out their work, persons who are reliable and familiar with the activities, the hazards arising during these activities and the requisite safety measures are to be placed in charge of supervision. The person in charge of supervision is to ensure in particular that
- 1. the activities only commence after the measures set forth in the risk assessment according to Article 6 have been implemented and their effectiveness has been verified and
- 2. a quick evacuation of the work area is possible at all times.

#### 1.5 Safety measures for storage

- (1) Hazardous substances shall be stored only at locations and in facilities appropriate for this purpose. They may not be stored in places or stored in the vicinity of places where this may pose a risk to workers or other persons.
- (2) Hazardous substances shall be stored in work rooms only if storage is compatible with worker safety and if special installations are used that reflect the current state of knowledge in technology.
- (3) Hazardous substances must not be stored together in the same place if this increases the risk of fires or explosions, particularly through the formation of hazardous mixtures, or if the stored hazardous substances could react with one another to cause a hazard. Moreover, hazardous substances must not be stored together in the same place if, in the event of a fire or an explosion, this increases the risk to workers or other persons.
- (4) Areas in which flammable hazardous substances are stored in such quantities as to present an increased fire hazard shall be designated with the warning sign "Warning of flammable material or high temperature" according to Annex II number 3.2 of the Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16 paragraph 1 of Directive 89/391/EEC) (OJ L 245 of 26 August 1992, p. 23).
- (5) Where the risk assessment shows it is necessary, separation and safety distances from sites used for the storage of hazardous substances must be maintained. The separation distance is the minimum distance required between a storage area and persons requiring protection, the safety distance is the minimum distance required to protect the storage area from adverse external effects.

## 1.6 Minimum requirements for explosion protection when carrying out activities in areas containing hazardous explosive mixtures

- (1) Protective measures according to Article 11 paragraph 2 number 1 must be chosen taking in particular measures according to the following order of priority into account:
- 1. the use of substances and mixtures that cannot form explosive mixtures insofar as this is possible according to the current state of knowledge in technology,
- 2. if this is not possible, the formation of hazardous explosive mixtures is to be prevented or limited insofar as this is possible according to the current state of knowledge in technology,
- 3. hazardous explosive mixtures are to be disposed of safely according to the current state of knowledge in technology.

Where the risk assessment shows it is necessary, the measures implemented to prevent the formation of hazardous explosive mixtures are to be monitored by appropriate technical equipment.

- (2) If it is not possible to reliably prevent the formation of hazardous explosive mixtures after implementing the measures according to paragraph 1, the employer must evaluate
- 1. the likelihood that hazardous explosive mixtures will occur and their persistence,
- 2. the likelihood that ignition sources, including electrostatic discharges, will be present and become active and effective.
- 3. the scale of the anticipated effects of the explosion.

If explosive mixtures contain several types of flammable gases, vapours, mists or dusts at the same time, the protective measures must be appropriate to the greatest potential risk.

- (3) If the occurrence of hazardous explosive mixtures cannot be prevented with certainty, protective measures must be taken to avoid ignition. For the selection of measures and work equipment, the employer may divide potentially explosive areas into zones according to number 1.7 and make the relevant classifications according to number 1.8.
- (4) If an explosion cannot be prevented with certainty, structural explosion protection measures must be taken to limit the spread of the explosion and to mitigate the detrimental effects of the explosion on workers to the greatest possible extent.
- (5) Work areas in which a hazardous explosive atmosphere may occur must be designated at all entry points with warning signs according to Annex III of Directive 1999/92/EC of the European Parliament and of the Council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (fifteenth individual Directive within the meaning of

Article16 paragraph 1 of Directive 89/391/EEC) (OJ L 23 of 28 January 2000, p. 57, L 134 of 7 June 2000, p. 36), amended by Directive 2007/30/EC (OJ L 165 of 27 June 2007, p. 21).

#### 1.7 Zoning of potentially explosive areas

#### Zone 0

is an area in which an explosive atmosphere consisting of a mixture with air of flammable substances in the form of gas, vapour or mist is present continuously or for long periods or frequently.

#### Zone 1

is an area in which an explosive atmosphere consisting of a mixture with air of flammable substances in the form of gas, vapour or mist is likely to occur in normal operation occasionally.

#### Zone 2

is an area in which an explosive atmosphere consisting of a mixture with air of flammable substances in the form of gas, vapour or mist is not likely to occur in normal operation but, if it does occur, will persist for a short period only.

#### Zone 20

is an area in which an explosive atmosphere in the form of a cloud of combustible dust in air is present continuously, or for long periods or frequently.

#### Zone 21

is an area in which an explosive atmosphere in the form of a cloud of combustible dust in air is likely to occur in normal operation occasionally.

#### Zone 22

is an area in which an explosive atmosphere in the form of a cloud of combustible dust in air is not likely to occur in normal operation but, if it does occur, will persist for a short period only.

Normal operation means the situation when installations are used within their design parameters. In case of doubt, the more restrictive zone shall be chosen. Layers, deposits and heaps of combustible dust must be considered as any other source that can form an explosive atmosphere. The classification into zones must be documented as part of the risk assessment (Explosion Protection Document).

# 1.8 Minimum requirements for installations in potentially explosive areas and for installations in non-explosive areas that are relevant for explosion protection in potentially explosive areas

- (1) Means of work including plants, equipment, protective systems and any associated connecting devices must only be brought into service if the documentation for the risk assessment indicates that they may be safely used in potentially explosive areas. This applies also to work equipment and associated connecting devices that are not regarded as equipment and protective systems within the meaning of Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96 of 29 March 2014, p. 309) if their incorporation into an installation can in itself give rise to an ignition hazard. Necessary measures must be taken to prevent confusion between connecting devices.
- (2) Unless stated otherwise in the risk assessment, equipment and protective systems for all places in which explosive atmospheres may occur must be selected on the basis of the categories set out in Directive 2014/34/EU.
- (3) In particular, the following categories of equipment must be used in potentially explosive areas that have been divided into zones:
- in zone 0 or zone 20: category 1 equipment,
- in zone 1 or zone 21: category 1 or category 2 equipment,
- in zone 2 or zone 22: category 1, category 2 or category 3 equipment.

- (4) For potentially explosive areas that have not been divided into zones according to number 1.7, measures must be determined and implemented on the basis of the risk assessment. This applies in particular to
- 1. activities being carried out in a limited area and for a limited period of time that are expected to give rise to a hazardous explosive atmosphere only for the duration of the activity,
- start-up and shutdown processes in facilities that are required only very rarely or in the exceptional case, and
- 3. assembly or maintenance work.

### Number 2 Particulate Hazardous Substances

#### 2.1 Scope

Number 2 applies to activities involving exposure to all respirable and inhalable dusts. Number 2.4 additionally applies to activities in which asbestos dust or dust from materials containing asbestos is released or may be released. Derogations from numbers 2.4.2 to 2.4.5 are possible in the case of activities that lead to only low levels of exposure.

#### 2.2 Definitions

- (1) Dusts, including fumes, means a disperse distribution of solids in air, brought about in particular by mechanical, thermal or chemical processes or stirred up.
- (2) "Inhalable" means the fraction of dusts in the breathing zone of workers that can be taken up by the respiratory tract. "Respirable" means the fraction of inhalable dusts that are able to reach the alveoli and bronchioles.
- (3) Asbestos within the meaning of number 2 and Annex II number 1 means the following fibrous silicates:
- 1. actinolite, CAS number\*) 77536-66-4,
- 2. amosite, CAS number 12172-73-5,
- anthophyllite, CAS number 77536-67-5,
- 4. chrysotile, CAS number 12001-29-5 and CAS number 132207-32-0,
- 5. crocidolite, CAS number 12001-28-4,
- 6. tremolite, CAS number 77536-68-6.

#### 2.3 Additional protective measures for activities involving exposure to inhalable dusts

- (1) The risk assessment according to Article 6 that is carried out for activities involving substances, mixtures and articles that may release dusts must consider their dustiness.
- (2) For activities involving exposure to inhalable dusts for which a substance-related occupational exposure limit has not been determined, the protective measures set forth in the risk assessment according to Article 6 must be established to ensure compliance at a minimum with the occupational exposure limit values for the inhalable dust fraction and for the respirable dust fraction.
- (3) Machines and equipment must be selected and operated to keep dust emissions to an absolute minimum. Installations, machines and equipment emitting dust are to be equipped with effective dust collection systems to the extent possible according to the current state of knowledge in technology and if other measures have not been taken to prevent the emission of dust.
- (4) For activities involving exposure to dust, the dust must be prevented from spreading to unaffected work areas to the extent possible according to the current state of knowledge in technology.
- (5) Dusts must be captured as completely as possible at the points of emission or creation and disposed of safely. The exhausted air must be ducted in such a way that as little dust as possible enters the breathing air of workers. The exhausted air may be returned to the work area only once it has been adequately purified.

- (6) The settling of dust deposits must be prevented. If this is not possible, dust deposits must be removed by means of wet or dry methods according to the current state of knowledge in technology or by means of suction processes using suitable vacuum cleaners or dedusting devices. Cleaning of the work area by dry sweeping without dust-binding measures or the use of compressed air to blow dust deposits away are generally not permissible.
- (7) Equipment for the separation, collection and precipitation of dusts must comply with the current state of knowledge in technology. During commissioning, the equipment must be evaluated for adequate effectiveness. The equipment must be inspected for operational capability, serviced and, if necessary, overhauled at least once a year. The results of the inspections according to sentences 2 and 3 are to be recorded and archived.
- (8) For activities involving the generation of large quantities of dust, appropriate organisational measures must be taken to shorten the duration of exposure to the greatest extent possible. Where the risk assessment according to Article 6 shows that the occupational exposure limits referred to in paragraph 2 cannot be complied with, the employer must make available appropriate personal protective equipment, particularly respiratory protective equipment. This must be worn by the workers. Separate storage facilities for work clothing and street clothing as well as washrooms must be made available to workers.

#### 2.4 Additional provisions for protection against risks from asbestos

#### 2.4.1 Identification and evaluation of risks from asbestos

As part of the risk assessment according to Article 6, the employer must ascertain whether workers are or may potentially be exposed to asbestos dust or dust from materials containing asbestos while performing work activities. This applies in particular to demolition, renovation and maintenance work involving articles or materials containing asbestos. The employer must in particular determine whether the asbestos is held together by weak bonds.

#### 2.4.2 Notification of the authority

- (1) Notification of activities according to number 2.1 sentence 2 must be submitted to the competent authority. The employer must grant workers and their representatives access to the notification.
- (2) The notification must be filed by the employer at the latest seven days prior to the commencement of the activity and must contain at least the following information:
- 1. the location of the worksite,
- 2. the types and quantities of asbestos used or handled,
- 3. the activities and processes involved,
- 4. the number of workers involved.
- 5. the starting date and duration of the work,
- the measures taken to limit the release of asbestos and to limit the exposure of workers to asbestos.
- (3) Demolition, renovation and maintenance work involving asbestos shall be performed only by specialist companies with specially trained personnel and the appropriate technical safety equipment for these activities. At least one qualified person with the authority to issue directives must be on site during these activities. Professional qualification shall be demonstrated by the completion of a course of qualification officially recognised by the competent authority. Certificates of qualification are valid for a period of six years. By way of derogation from sentence 4, certificates of qualification that were acquired prior to 1 July 2010 shall remain valid until 30 June 2016. If an officially recognised further training course is completed while the certificate of qualification is still valid, the period of validity shall be extended by six years from the date of issue of the certificate for the further training course.
- (4) Demolition and renovation work involving weakly bonded asbestos must be carried out by specialist companies that have been authorised to perform such activities by the competent authority. The authorisation is to be issued following the submission of a written or electronic application by the employer demonstrating that the personnel and technical safety equipment required for these activities are available in the requisite scope and quantity.

#### 2.4.3 Additional protective measures for activities involving exposure to asbestos

- (1) The spread of asbestos dust must be prevented by setting up dust-tight barriers between work areas or by implementing appropriate protective measures that provide an equivalent standard of safety.
- (2) An air-conditioning system of adequate dimensions must be installed to ensure that the work area is ventilated and an adequate level of negative pressure is maintained.
- (3) The work area must be equipped with an airlock with shower facilities and a materials lock.
- (4) Appropriate respiratory protective equipment, protective clothing and, if necessary, other personal protective equipment must be made available to workers. The employer must ensure that workers make use of the personal protective equipment.
- (5) Contaminated personal protective equipment and work clothing must be either cleaned or disposed of. The equipment and clothing may be cleaned at suitable off-site facilities. The cleaning is to be performed in such a way that workers are not exposed to asbestos dust. The materials to be cleaned must be stored and transported in closed and labelled containers.
- (6) Suitable washrooms with shower facilities must be made available to workers.
- (7) Prior to the commencement of demolition processes, materials containing asbestos shall be removed to the greatest extent possible.

#### 2.4.4 Work plan

The employer must establish a work plan prior to the commencement of activities involving asbestos, in particular demolition, renovation and maintenance work. The plan must specify the following:

- a description of the work processes and the equipment used to remove and dispose of asbestos and materials containing asbestos,
- 2. information about the personal protective equipment,
- 3. a description of how the absence of asbestos exposure risks in the workplace shall be verified once demolition and renovation work has been completed.

#### 2.4.5 Additional provisions relating to the instruction of workers

- (1) Workers must regularly be instructed in the specific activities relevant to their work. The instruction is to take into account the work plan according to number 2.4.4.
- (2) The instruction must in particular include the following topics:
- 1. the properties of asbestos and its effects on health, including the exacerbating effects of smoking,
- the types of articles and materials that may contain asbestos,
- 3. the activities that may lead to exposure to asbestos and the importance of taking measures to minimise exposure,
- 4. the use of safe processes and personal protective equipment according to expert professional practice,
- 5. the measures to be taken in the event of a disruption in operations.
- 6. waste disposal according to expert professional practice,
- 7. occupational preventive medical examinations according to the Ordinance on Occupational Health Care.

Number 3 (repealed)

Number 4
Biocidal Products and Fumigation Activities with
Biocidal Products or Plant Protection Products

#### 4.1 Permit

- (1) A permit according to Article 15d paragraph 1 shall be issued if
- the employer has submitted proof that
  - a) the personnel and technical safety equipment necessary for the activities are on site,
  - b) the relevant occupational safety regulations are observed, and
- 2. there are no concerns regarding the reliability of the employer.
- (2) The employer must submit the permit application according to Article 15d paragraph 1 sentence 2 together with the following:
- 1. a description of the areas intended for fumigation,
- 2. the active substances that will be applied,
- 3. proof that the physical facilities and technical safety equipment of the company are adequate and suitable for the planned fumigation,
- 4. information relating to the number of
  - a) workers who will carry out the planned fumigation,
  - b) persons with expert knowledge (sachkundige Person),
  - c) holders of certificates of competence (Befähigungsscheininhaber), and
- 5. copies of the certificates of expert knowledge (Sachkundenachweise) held by the persons with expert knowledge and the certificates of competence (Befähigungsschein) held by the holders of certificates of competence.

#### 4.2 Notification (Anzeige)

#### 4.2.1 Notification of company information

The notification submitted by the employer according to Article 15c paragraph 2 must include:

- 1. the name of the applicant,
- 2. the address of the facility, and
- 3. information relating to
  - a) the personnel, physical facilities and technical safety equipment available to the company, and
  - b) the type and intended use of the biocidal products or biocidal active substances.

#### 4.2.2 Notification of the activities

The notification submitted by the employer according to Article 15d paragraph 3

- must include
  - a) the date of the activities including the individual steps of the activities, the anticipated beginning and end of the activities, the dates and times of testing for gas tightness and the date and time of clearance, if required,
  - b) the name, authorisation number or registration number of the biocidal product or the plant protection product and the quantity of the product applied,
  - the name of the person in charge (verantwortliche Person) and, if applicable, other holders of certificates of competence

and

- 2. must submit
  - a) copies of the certificates of competence, and
  - b) a map of the area or the layout of the object to be fumigated.

#### 4.3 Professional Expertise (Fachkunde)

Professional expertise (Fachkunde) as defined in Article 15b paragraph 3 and Article 15f paragraph 2 refers to the

professional knowledge and skills required to apply the biocidal products in accordance with their intended purpose and good professional practice. With regard to the contents and scope of the professional expertise, the rules and knowledge published according to Article 20 paragraph 4 are to be taken into consideration.

#### 4.4 Expert knowledge (Sachkunde)

- (1) Demonstration of the requisite expert knowledge shall require the submission of a certificate proving the successful completion of a course of expert knowledge (*Sachkundelehrgang*). The course of expert knowledge must satisfy the criteria in paragraphs 3 and 4 and be recognised by the competent authority. The competent authority may recognise a different training or further education programme as equivalent to a course of expert knowledge if the requisite practical and theoretical knowledge and skills within the meaning of paragraph 3 have been acquired for the application of the respective biocidal products in accordance with their intended purpose and expert professional practice. If the relevant knowledge and skills have been acquired in compliance with other regulatory provisions, for example with the provisions of plant protection regulations, the requirements of expert knowledge (*Sachkundeanforderungen*) shall be considered fulfilled.
- (2) If the biocidal products are intended for use only in specific application areas, expert knowledge that is limited in scope to these specific areas may also be recognised. This shall apply
- for certificates acquired upon completion of training and further training courses included in a publication according to Article 20 paragraph 4, and
- 2. with respect to the relevant areas of pest control, for
  - a) examinations passed in compliance with the Ordinance on Occupational Training for Pest Control Officers (*Verordnung über die Berufsausbildung zum Schädlingsbekämpferin*) of 15 July 2004 (Federal Law Gazette I, p. 1638),
  - b) examinations passed in compliance with the Ordinance on the Certification Examination for the Licensed Qualification of Approved Pest Control Officers (*Verordnung über die Prüfung zum anerkannten Abschluss Geprüfter Schädlingsbekämpfer/Geprüfte Schädlingsbekämpferin*) of 19 March 1984 (Federal Law Gazette I, p. 468), and
  - c) examinations passed in compliance with laws no longer in force in the Federal Republic of Germany or the law of the German Democratic Republic to become a pest control specialist.
- (3) The course of expert knowledge is to impart the practical and theoretical knowledge and skills necessary for the application of the respective biocidal products in accordance with their intended purpose and expert professional practice. Depending on the biocidal product and the type of application, this includes the requisite basic knowledge of toxicology and ecotoxicology, and:
- 1. knowledge of the relevant regulatory provisions and official notifications according to Article 20 paragraph 4,
- 2. knowledge of the effects induced by the relevant biocidal products on human health and the environment,
- knowledge of how to identify and evaluate target areas and target animal species for the use of biocidal products,
- 4. knowledge and skills to use the relevant biocidal products sustainably and with a minimum of risk,
- 5. knowledge of how to prevent an infestation and alternative methods for pest control and the requisite skills,
- 6. knowledge and proficiency in dosing and application,
- 7. knowledge of methods for monitoring performance and effectiveness, and
- 8. knowledge of disposal methods in accordance with good professional practice.
- (4) The course includes theoretical and practical examinations covering the most important contents of the course of expert knowledge. The official notifications according to Article 20 paragraph 4 are to be taken into consideration.
- (5) Certificates of expert knowledge are valid for a period of six years from the date of issue. The period of validity is extended by six years from the date of issue of the certificate following the completion of an officially recognised further training course.

### 4.5 Certificate of competence (Befähigungsschein)

- (1) A certificate of competence (*Befähigungsschein*) according to Article 15d paragraph 4 may be issued by the competent authority upon application if the applicant
- 1. is at least 18 years old,
- 2. has the requisite professional training or equivalent professional qualifications,
- 3. demonstrates the requisite reliability,
- 4. is both physically and mentally suited. This is certified by a physician according to Article 7 paragraph 1 of the Ordinance on Occupational Health Care (*Verordnung zur arbeitsmedizinischen Vorsorge, ArbMedVV*); the certificate may not be older than one year at the time of the application for a certificate of competence,
- 5. can demonstrate specific expert knowledge relating to the activity through the successful completion of a course of expert knowledge recognised by the competent authority, and
- 6. has the language skills necessary for the safe performance of the activity.
- (2) The certificate of competence is issued for a period of up to six years. The period of validity may be extended for another six years if the applicant is able to demonstrate that
- 1. the criteria listed in paragraph 1 have been met and
- 2. the holder of the certificate of competence has completed a course of further training according to number 4.4 paragraph 5 prior to the expiration of the period of validity.
- (3) The competent authority may extend the period of validity of a certificate of competence for a maximum of six months if participation in an officially recognised further training course prior to the expiration date would mean disproportionate hardship.
- (4) The certificate of competence may be revoked if the requisite requirements according to paragraph 1 are no longer fulfilled.

### 4.6 Labelling of rooms and transport units under fumigation

- (1) Labelling according to Article 15d paragraph 4 sentence 2 number 2 letter b, Article 15d paragraph 7 number 2 and Article 15g paragraph 2 number 1 must be posted at the entrances of fumigated rooms and transport units and at the entrances of rooms or transport units that contain goods that were fumigated. The name and telephone number of the person in charge must be included. Furthermore, warning signs are to be posted at the entrances. The warning sign must be rectangular and at least 400 mm wide and 300 mm high. The minimum width of the outer line must be 2 mm. The text must be in black print on a white background. The warning sign must include at least the following information:
- 1. the warning DANGER,
- 2. the relevant hazard symbol for the fumigant (the skull and crossbones symbol for hazardous substances that are classified in Categories 1 to 3 for acute toxicity),
- 3. the statement: THIS UNIT IS UNDER FUMIGATION,
- 4. the name of the fumigant,
- 5. the date and time of the fumigation,
- 6. the date of ventilation, should this have occurred, and
- 7. the statement: DO NOT ENTER.
- (2) The layout of the warning sign must be as shown in the following figure:

\* Insert information as appropriate.

GEFAHR	DANGER	
DIESE EINHEIT IST BEGAST	THIS UNIT IS UNDER FUMIGATION	
MIT:	WITH:	
Bezeichnung des Begasung <mark>smi</mark> ttels	[fumigant name*]	
SEIT	APPLIED ON:	
Datum	[date*]	
Stunde	[hour*]	
Belüftet am:	Ventilated on:	
Datum	[date*]	
ZUTRITT VERBOTEN	DO NOT ENTER	

### Number 5 Ammonium Nitrate

### 5.1 Scope

- (1) Number 5 applies to the storage, transfer and transport on company premises of
- ammonium nitrate,
- 2. mixtures containing ammonium nitrate.
- (2) Number 5 does not apply to
- 1. mixtures containing up to 10 per cent by weight of ammonium nitrate,
- 2. ammonium nitrate and mixtures containing ammonium nitrate that are classified in Groups A and E in quantities of up to 100 kilograms,
- 3. mixtures containing ammonium nitrate that are classified in Groups B, C and D in quantities of up to 1 tonne,
- 4. ammonium nitrate and mixtures containing ammonium nitrate possessing properties that fall within the scope of the Explosives Act.

### 5.2 Definitions

Ammonium nitrate and its mixtures are classified in the following groups:

#### 1. Group A:

ammonium nitrate and mixtures containing ammonium nitrate that are able to undergo detonation or have been classified in Subgroup A I, A II, A III or A IV according to number 5.3 paragraph 7 table 1 based on the amount of ammonium nitrate they contain;

#### 2. Group B:

mixtures containing ammonium nitrate that are able to undergo self-sustaining, progressive thermal decomposition;

#### Group C:

mixtures containing ammonium nitrate that do not undergo self-sustaining, progressive thermal decomposition or detonation, but form nitrogen oxide when heated;

#### 4. Group D:

mixtures containing ammonium nitrate that are not hazardous in aqueous solution or suspension, but may undergo detonation in crystalline form following a reduction of the original fraction of water;

#### 5. Group E:

mixtures containing ammonium nitrate that occur as water-in-oil emulsions and are used as precursors in the production of explosives.

### 5.3 General provisions

- (1) Number 5.4 applies to ammonium nitrate and mixtures containing ammonium nitrate that are classified in the groups listed in number 5.2.
- (2) The constituents of ammonium nitrate and mixtures containing ammonium nitrate that are classified in Group A, B, C or E must be finely dispersed and intimately mixed and may not separate during storage, transport or transfer.
- (3) Ammonium nitrate fertilisers in blends containing nitrogen and potassium or nitrogen, phosphorus and potassium (NK or NPK bulk blends) must be stored according to the provisions laid down for Group B or only according to the requirements specified for the established degree of hazard. If fertilisers classified in Group A are included in a blend, they must be stored according to the provisions laid down for Group A or likewise according to the requirements specified for the established degree of hazard.
- (4) All nitrate ions occurring with an equivalent number of ammonium ions shall be considered ammonium nitrate.
- (5) No limit has been set for the fraction by weight of combustible constituents in mixtures containing ammonium nitrate that are classified in Subgroup B II according to paragraph 7 table 1; the fraction of these constituents in ammonium nitrate and mixtures containing ammonium nitrate that are classified in Subgroup A I according to paragraph 7 table 1 must be limited to 0.2 per cent by weight, and the fraction in mixtures containing ammonium nitrate that are classified in any other subgroup of Groups A, B, C and D according to paragraph 7 table 1 must be limited to 0.4 per cent by weight.
- (6) In the case of organic substances, carbon is considered to be a combustible constituent of ammonium nitrate and mixtures containing ammonium nitrate that are classified in Subgroup A I according to paragraph 7 table 1.
- (7) Inert substances within the meaning of number 5 are substances that do not increase the thermal sensitivity or the sensitivity to the effects of a detonation. In case of doubt, this is to be verified by an expert opinion prepared by the Federal Institute for Materials Research and Testing (*Bundesanstalt für Materialforschung und -prüfung, BAM*).

Table 1

Framework compositions and limits for ammonium nitrate and mixtures containing ammonium nitrate for classification in one of the groups according to number 5.2

Subgroups	Fraction of ammonium nitrate in per cent (%) by weight	Other constituents	Special provisions
AI	≥ 90	Chloride content ≤ 0.02% inert substances ≤ 10%	The use of other ammonium salts is not permissible.

AII	> 80 to < 90	Limestone, dolomite or calcium carbonate < 20%	
A III	> 45 to < 70	Ammonium sulphate	Inert substances are permissible.
A IV	> 70 to < 90	Potassium salts, phosphates in NP, NK or NPK fertilisers, sulphates in N fertilisers; inert substances	
ВІ	≤ 70	Potassium salts, phosphates, inert substances and other ammonium salts in NK or NPK fertilisers	If the fraction of ammonium nitrate is greater than 45% by weight, the combined fraction of ammonium nitrate and other ammonium salts shall not exceed 70% by weight.
BII	≤ 45	Excess nitrates ≤ 10%	No limit for the fraction of combustible constituents; any nitrates in excess of the fraction of ammonium nitrate are counted as potassium nitrate.
CI	≤ 80	Limestone, dolomite or calcium carbonate ≥ 20%	Limestone, dolom <mark>ite o</mark> r calcium carbonate with a purity of at least 90%.
CII	≤ 70	Inert substances	
CIII	≤ 45	Phosphates and other ammonium salts in NP fertilisers	
	> 45 to < 70	Phosphates and other ammonium salts in NP fertilisers	The combined fraction of ammonium nitrate and other ammonium salts must not exceed 70% by weight.
CIV	≤ 45	Ammonium sulphate	In <mark>ert subst</mark> ances a <mark>re p</mark> ermissible.
DI	≤ 45	Urea, water	In aqueous solution
DII	≤ 45	Excess nitrates ≤ 10%, potassium salts, phosphates and other ammonium salts in NP, NK or NPK fertilisers; water	In aqueous solution or suspension. Excess nitrates are counted as potassium nitrate. The limit fraction specified in column 2 must not be exceeded either in the liquid phase or in the solid phase in suspensions.
D III	≤ 70	Ammonia, water	In aqueous solutio <mark>n</mark>
DIV	> 70 to ≤ 93	Water	In aqueous solutio <mark>n</mark>
Е	> 60 to ≤ 85	≥ 5% to ≤ 30% water, ≥ 2% to ≤ 8% combustible constituents, ≥ 0.5% to ≤ 4% emulsifiers	Inorganic salts; additives

- (8) Ammonium nitrate and mixtures containing ammonium nitrate that do not fall within the framework compositions and limits specified for Group A, B, C, D or E according to paragraph 7 table 1 or that do not meet the requirements of paragraphs 2 and 5 must be stored, transferred or transported on company premises only after an expert opinion has been prepared by the Federal Institute for Materials Research and Testing to determine their respective degree of hazard and in compliance with the requirements laid down in the expert opinion.
- (9) Mixtures containing ammonium nitrate that are classified in Group B may be stored, transferred or transported on company premises in compliance with the requirements laid down for Group C if the expert opinion prepared by the Federal Institute for Materials Research and Testing verifies that these mixtures are not

at risk of undergoing self-sustaining, progressive thermal decomposition.

(10) For the classification of ammonium nitrate and mixtures containing ammonium nitrate according to paragraphs 3, 8 or 9, the group shall be designated in accordance with the findings of the expert opinion of the Federal Institute for Materials Research.

### 5.4 Precautionary measures

5.4.1 Basic measures for the storage of substances and mixtures classified in the groups listed under number 5.2

The following protective measures must be taken for the storage of substances and mixtures classified in Groups A, B, C, D and E:

- 1. protection against the effects of the weather,
- 2. protection against contamination and the storage of hazardous combinations of substances,
- 3. protection against unauthorised access,
- 4. fire safety,
- 5. protection against inadmissible load.
- 5.4.2 Additional measures for substances and mixtures classified in Groups and Subgroups A, D IV and E
- 5.4.2.1 General measures
- (1) Substances and mixtures that have leaked or been spilled and substances and mixtures that have been contaminated must be used immediately or disposed of safely.
- (2) Substances and mixtures classified in Group A must be stored and transported only in packaged form.
- (3) No combustible materials shall be stored in the storage area or within a radius of 10 metres of sites used for the storage of substances and mixtures classified in Group A.
- (4) Mixtures classified in Groups and Subgroups D IV and E must be protected against thermal decomposition.
- 5.4.2.2 Additional measures for the storage of quantities exceeding 1 tonne
- (1) Substances and mixtures classified in Group A in quantities exceeding 1 tonne shall be stored only in suitable buildings after taking appropriate protective measures and in accordance with the current state of knowledge in technology.
- (2) Mixtures classified in Groups and Subgroups D IV and E in quantities exceeding 1 tonne shall be stored only in suitable storage containers after taking appropriate protective measures and in accordance with the current state of knowledge in technology.
- (3) Substances and mixtures classified in Group A and mixtures classified in Group E must be divided into smaller storage quantities of up to 25 tonnes prior to storage.
- (4) Substances and mixtures classified in Group A may be stored in smaller storage quantities of up to 25 tonnes only if
- each storage quantity is separated from the others by walls made of bricks or blocks of similar strength or by walls made of concrete, the hollow cavities of which are completely filled with non-combustible materials, and if the walls including the cavities are of a minimum thickness d, which is calculated from the largest storage quantity M using the following equation: d = 0.1 M<sup>1/3</sup> where d is expressed in "metres" and M in "kilograms",
- 2. the materials are stored only up to a height of 1 metre below the upper edge of the partition if the partition walls do not extend to the ceiling.
- (5) The storage site must be located at a minimum distance (safety distance) *E* from buildings intended for continuous human occupancy; the safety distance is calculated from the largest storage quantity *M* using

the following equation:

 $E = 11 \ M^{1/3}$  where E is expressed in "metres" and M in "kilograms".

This applies to plant buildings only if they are also used for residential purposes.

- (6) The safety distance to public traffic routes is equal to two-thirds of the distance calculated according to paragraph 5.
- (7) In derogation from paragraphs 5 and 6, a safety distance of at least 50 metres from occupied buildings and public traffic routes must be maintained for the storage of quantities up to 3 tonnes.
- 5.4.2.3 Additional measures for the storage of quantities exceeding 25 tonnes
- (1) Any person who intends to store substances and mixtures classified in Groups and Subgroups A, D IV and E in quantities exceeding 25 tonnes must notify the competent authority of this in written or electronic form at least two weeks in advance. If the notification is filed electronically, the competent authority may request additional copies or the documents filed with the notification in printed form.
- (2) The notification must include the following information:
- 1. the name and address of the person subject to the notification requirement,
- the type and maximum quantity of the substances or mixtures to be stored,
- 3. a description of the type of structure and equipping of the storage facility including floor plans and crosssections,
- 4. a site plan that clearly shows the position of the storage facility in relation to buildings and public traffic routes within a radius of 350 metres.
- 5. the identification of the buildings on the site plan according to number 4 that are intended for continuous human occupancy or residential purposes.
- (3) The employer must immediately notify the competent authority of any changes to the information submitted according to paragraph 2.
- (4) Rooms in buildings used for the storage of substances and mixtures classified in Group A must not be used for continuous human occupancy, with the exception of supervisory and operating personnel.
- (5) Substances and mixtures classified in Group A shall be stored only in single storey buildings.
- 5.4.3 Additional measures for mixtures classified in Group B
- 5.4.3.1 General measures

Firing installations and other ignition sources are not permissible in storage rooms.

- 5.4.3.2 Additional measures for the storage of quantities exceeding 100 tonnes
- (1) The temperature of the mixtures must not exceed 70 degrees Celsius at the time of storage.
- (2) Material-handling equipment and its structural installations must be constructed and operated in such a way that any heat produced will not lead to the decomposition of the materials stored.
- 5.4.3.3 Additional measures for mixtures in unpackaged form exceeding 1 500 tonnes or for mixtures only in packaged form exceeding 3 000 tonnes
- (1) Mixtures must be divided into smaller quantities of maximally 3 000 tonnes per storage unit. The individual storage units shall be separated by fireproof partitions, by piles of non-combustible stored materials or by a space at least 2.50 metres in width that is to be kept clear at all times. If the partition walls do not extend to the ceiling, the stored materials may be piled only to a height of 1 metre below the upper edge of the partition.
- (2) Paragraph 1 does not apply if, concurrently,
- 1. appropriate fire-extinguishing systems have been installed,
- 2. water for fire-fighting purposes is available in sufficient quantities,

- 3. a works fire brigade is available at all times,
- 4. the materials being placed into storage have been separated by sieving, and
- 5. the air in the storage room and in the disposal ducts located below the storage area is continuously monitored.
- 5.4.4 Technical safety measures for mixtures classified in Group D

Mixtures must be kept from drying out.

### 5.5 Relieving provisions

5.5.1 Relieving provisions for specific substances and mixtures

Substances and mixtures classified in Subgroups A I and A II and mixtures containing inert substances classified in Subgroups A IV and Group E may

- 1. in derogation from number 5.4.2.2 paragraph 3, be separated into smaller quantities (stacks) of at most 100 tonnes and
- 2. in derogation from number 5.4.2.2 paragraphs 5 and 6, be stored at a safety distance equal to half the distance prescribed for that location.

These provisions may be used only after verification by an expert opinion of the Federal Institute for Materials Research and Testing that the substances and mixtures classified in Subgroups A I, A II and A IV meet the composition requirements set forth in Annex III of Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304 of 21 November 2003, p. 1), last amended by Regulation (EC) No 1020/2009 (OJ L 282 of 29 October 2009, p. 7), and that the substances and mixtures classified in Group E are not able to undergo detonation.

5.5.2 Relieving provisions for companies manufacturing ammonium nitrate and explosives

For companies manufacturing ammonium nitrate and explosives

- 1. number 5.4.2.1 paragraph 2 and number 5.4.2.3 paragraphs 1 to 3 do not apply to substances and mixtures classified in Group A;
- 2. the safety distance according to number 5.4.2.2 paragraphs 5 and 6 is reduced by one half.

### 5.6 Exemptions

Any exemptions according to Article 19 paragraph 1 from the measures imposed by number 5.4.2 for substances and mixtures classified in Groups and Subgroups A, D IV and E shall be granted by the competent authority after consultation with the Federal Institute for Materials Research and Testing.

\*) Chemical Abstracts Service (CAS) registry number

# Annex II (to Article 16 paragraph 2) Special Restrictions for the Manufacture and Use of Specific Substances, Mixtures and Articles

(Source: Federal Law Gazette I 2010, 1674 - 1676; see footnote for individual changes)

#### **Table of contents**

Number 1	A
sbestos	
Number 2	2-Naphthylamine, 4-aminobiphenyl, benzidine, 4-nitrobiphenyl
Number 3	Pentachlorophenol and its compounds
Number 4	Metalworking fluids and corrosion inhibitors
Number 5	Biopersistent fibres

Number 6 Extremely hazardous carcinogenic substances

### Number 1 Asbestos

- (1) Work on parts of buildings, equipment, machinery, installations, vehicles and other articles containing asbestos is prohibited. Sentence 1 does not apply to
- 1. demolition work,
- 2. renovation and maintenance work, except for work resulting in the surface removal of asbestos products, unless this work is carried out using low emission processes approved by the authorities or statutory accident insurance institutions. Work processes that result in the prohibited removal of asbestos-containing surfaces are in particular abrasion, pressure cleaning, brushing off and drilling activities,
- 3. activities supported by technical measuring tools that result in the surface removal of asbestos products, but that must be performed in order to be approved as a low emissions process.

Work that is prohibited according to sentence 1 includes covering, superstructure and mounting work on asbestos cement roofs and wall claddings in addition to cleaning and coating work on uncoated asbestos cement roofs and wall claddings. The re-use of asbestos-containing objects and materials obtained during work activities for any purpose other than their disposal or recycling is prohibited.

- (2) The extraction, preparation, further processing and re-use of naturally occurring mineral raw materials and mixtures and articles derived from these materials that contain more than 0.1 per cent by weight of asbestos are prohibited.
- (3) Asbestos-containing waste products must bear a label in accordance with Article 67 in conjunction with Annex XVII number 6 column 2 point 3 and Appendix 7 of this Annex of Regulation (EC) No 1907/2006.
- (4) Paragraphs 1 and 3 apply also to private households.

### Number 2 2-Naphthylamine, 4-aminobiphenyl, benzidine, 4-nitrobiphenyl

- (1) The manufacture of the following substances and mixtures that contain more than 0.1 per cent by weight of these substances is prohibited:
- 1. 2-naphthylamine and its salts,
- 2. 4-aminobiphenyl and its salts,
- 3. benzidine and its salts, and
- 4. 4-nitrobiphenyl.
- (2) The prohibition to manufacture according to paragraph 1 does not apply to activities carried out for purposes of research and analysis or for purposes of academic instruction in the requisite quantities.

### Number 3 Pentachlorophenol and its compounds

- (1) Beyond the use prohibitions according to Article 67 in conjunction with Annex XVII number 22 of Regulation (EC) No 1907/2006, the use of these types of articles is prohibited if they have been treated with a mixture that contains pentachlorophenol, sodium pentachlorophenol or one of the other pentachlorophenol compounds and if the treated components contain more than 5 milligrams per kilogram of these substances.
- (2) Paragraph 1 does not apply to wood components of buildings and furniture and to textiles treated prior to 23 December 1989 with mixtures containing pentachlorophenol, sodium pentachlorophenol or one of the other pentachlorophenol compounds. For the geographical area specified by Article 3 of the German Unification Treaty (*Einigungsvertrag*), 3 October 1990 applies instead of 23 December 1989.
- (3) Paragraph 1 does not apply to waste wood disposed of in accordance with the Waste Wood Ordinance (*Altholzverordnung, AltholzV*) of 15 August 2002 (Federal Law Gazette I, p. 3302), last amended by Article 2a of the Ordinance of 20 October 2006 (Federal Law Gazette I, p. 2298).

(4) Paragraphs 1 to 3 apply also to private households.

### Number 4 Metalworking fluids and corrosion inhibitors

- (1) The use of metalworking fluids with added constituents that include nitrosating agents is prohibited.
- (2) As part of the risk assessment according to Article 6, the employer must ensure that the metalworking fluids being handled do not contain nitrosating agents as an added constituent.
- (3) The use of corrosion inhibitors that also contain nitrosating agents or their precursors, for example nitrite, and secondary amines, including blocked secondary amines, is prohibited. Excepted from this are secondary amines that form *N*-nitrosamines that have not been found to be carcinogenic substances subject to classification in Categories 1 or 2.
- (4) The use of water-miscible and aqueous corrosion inhibitors that contain nitrosating agents or precursors such as nitrite on delivery is prohibited.
- (5) As part of the risk assessment carried out according to Article 6, the employer must ensure that the corrosion inhibitors used fulfil the requirements set forth in paragraphs 3 and 4.

### Number 5 Biopersistent fibres

- (1) The following hazardous substances that contain mineral fibres must not be manufactured or used for thermal and sound insulation in building construction, including technical insulation, and for ventilation systems:
- 1. synthetic mineral fibres (synthetically manufactured vitreous (silicate) fibres with a random orientation that contain in total more than 18 per cent by weight of the oxides of sodium, potassium, calcium, magnesium and barium).
- 2. mixtures and articles that contain in total more than 0.1 per cent by weight of synthetic mineral fibres.
- (2) Paragraph 1 does not apply if the synthetic mineral fibres fulfil one of the following criteria:
- 1. evidence of excessive carcinogenicity was not determined after performing a suitable intraperitoneal test,
- 2. after intratracheal installation of 2 milligrams of a fibrous suspension, the half-life for fibres with a length of more than 5 micrometres, a diameter of less than 3 micrometres and a length-to-diameter ratio of greater than 3 to 1 (WHO fibres) is at most 40 days,
- 3. the carcinogenicity index (CI) for synthetic mineral fibres, which is calculated from the difference between the total percentage by weight of the oxides of sodium, potassium, boron, calcium, magnesium and barium and twice the percentage by weight of aluminium oxide, is at least 40,
- 4. vitreous fibres intended for use in high temperature applications that
  - a) require a classification temperature between 1 000 degrees Celsius and 1 200 degrees Celsius have a half-life of at most 65 days according to the criteria specified under point 2, or
  - b) require a classification temperature above 1 200 degrees Celsius have a half-life of at most 100 days according to the criteria specified under point 2.
- (3) Spraying procedures that use carcinogenic mineral fibres are prohibited.
- (4) Paragraphs 1 to 3 apply also to private households.

### Number 6 Extremely hazardous carcinogenic substances

- (1) The manufacture and use of the following extremely hazardous carcinogenic substances are permitted only in closed systems:
- 1. 6-amino-2-ethoxynaphthalene,
- 2. bis(chloromethyl)ether,
- 3. cadmium chloride (in inhalable form),

- 4. chloromethyl methyl ether,
- 5. dimethylcarbamoyl chloride,
- 6. hexamethylphosphoric triamide,
- 7. 1,3-propane sultone,
- 8. *N*-nitrosamine compounds, with the exception of *N*-nitrosamine compounds that were not found to cause carcinogenic effects after appropriate testing,
- 9. tetranitromethane,
- 10. 1,2,3-trichloropropane, and
- 11. dimethyl and diethyl sulphate.

The restrictions for manufacture and use according to sentence 1 apply also to o-toluidine.

(2) The restrictions for manufacture and use according to paragraph 1 do not apply to purposes of research and analysis or to purposes of academic instruction in the requisite quantities.

## Annex III (to Article 11 paragraph 4) Special Requirements for Activities Involving Organic Peroxides

(Source: Federal Law Gazette I 2013, 2531 - 2534; see footnote for individual changes)

### **Table of contents**

Number 1 Scope and definitions

Number 2 Activities involving organic peroxides

### Number 1 Scope and definitions

- (1) The provisions of Annex III only serve the purpose of protecting workers and persons according to Article 1 paragraph 3 sentence 2 (other persons) against
- a) fire and explosion hazards and
- b) the effects of fires and explosions.

The provisions of Annex III do not address adverse effects on the health induced by activities involving organic peroxides.

- (2) Annex III uses the following definitions:
- a) risk groups are classifications for organic peroxides that are made on the basis of their burning behaviour in packaged form,
- hazardous objects are plant buildings, rooms or places in and at which activities involving organic peroxides are carried out,
- c) safety distance means the distance to be observed between hazardous objects and the surrounding environment, in particular residential areas and traffic routes,
- d) separation distance means the distance to be observed on the company premises,
- e) traffic routes are roads, railway lines and waterways to which the public has unrestricted access, with the exception of routes with low traffic density,
- f) residential area means an area with occupied residential buildings that does not belong to the company; occupied residential buildings include any buildings and facilities with rooms that are not intended or suited only for temporary residence by persons.

### Number 2 Activities involving organic peroxides

### 2.1 Scope

- (1) Number 2 applies to activities involving organic peroxides.
- (2) Number 2 does not apply to
- a) activities involving organic peroxides in the form of mixtures if
  - aa) the mixture does not contain more than 1.0 per cent available oxygen from the organic peroxides when containing not more than 1.0 per cent hydrogen peroxide or
  - bb) the mixture does not contain more than 0.5 per cent available oxygen from the organic peroxides when containing more than 1.0 per cent, but not more than 7.0 per cent, hydrogen peroxide,
- b) activities involving organic peroxides in small packaged units containing up to 100 grams of solid organic peroxides or up to 25 millilitres of liquid organic peroxides if
  - aa) the organic peroxides do not fall within the scope of the Explosives Act,
  - bb) the small packaged units were placed on the market ready for sale and the total quantity of organic peroxides available at the company in small packaged units does not exceed 100 kilograms in total,
- c) the storage of explosive organic peroxides if they are subject to the provisions of the Second Ordinance to the Explosives Act as published on 10 September 2002 (Federal Law Gazette I, p. 3543), last amended by Article 2 of the Ordinance of 26 November 2010 (Federal Law Gazette I, p. 1643).

### 2.2 Definitions

The following definitions are used for number 2:

- a) available (active) oxygen means the cleavable oxygen of the peroxide group that is available for oxidation reactions (one oxygen atom per peroxide group),
- b) the corrected mass flow rate Ak (expressed in kilogram/minute) characterises the burning behaviour of organic peroxides in packaged form based on a quantity of 10 000 kilograms. This value takes into account the completeness and uniformity of combustion and the emissivity of the flames.

### 2.3 Classification of organic peroxides into risk groups

- (1) The employer may approve the performance of an activity involving an organic peroxide only if the organic peroxide has been classified by the Federal Institute for Materials Research and Testing into a risk group according to paragraph 2. If the Federal Institute for Materials Research and Testing has published a Storage Group Classification I, II or III for explosive organic peroxides according to the Second Ordinance to the Explosives Act as published on 10 September 2002 (Federal Law Gazette I, p. 3543), last amended by Article 2 of the Ordinance of 26 November 2010 (Federal Law Gazette I, p. 1643), these organic peroxides shall be considered to have been published in Risk Group OP I, OP II or OP III. Sentence 1 does not apply to organic peroxides in mixtures containing below 10 per cent by weight of organic peroxides and below 5 per cent by weight of hydrogen peroxide.
- (2) The following criteria applies to the classification into risk groups:
- a) Risk Group OP I: organic peroxides of this group deflagrate violently, generating large quantities of heat; the fire spreads rapidly; individual packs of organic peroxides may explode with hardly any effects on pressure; the reaction may involve the entire contents of a pack; individual burning packs may be flung away; the risk to the surrounding environment from projectiles is low; buildings in the vicinity are in general not at risk from the effects on pressure; this risk group is divided into Subgroups Ia and Ib; Risk Group OP Ia comprises organic peroxides with a corrected mass flow rate Ak greater than or equal to 300 kilograms/minute; Risk Group OP Ib comprises organic peroxides with a corrected mass flow rate Ak greater than or equal to 140 kilograms/minute, but less than 300 kilograms/minute,
- b) Risk Group OP II: organic peroxides of this group deflagrate rapidly, generating large quantities of heat; the fire spreads rapidly; individual packs of organic peroxides may explode with hardly any effects on pressure; however, the reaction does not involve the entire contents of a pack; the primary hazard to the surrounding environment is posed by the flames and thermal radiation; buildings in the vicinity are not at risk from the effects on pressure; Risk Group OP II comprises organic peroxides with a corrected mass flow rate *Ak* greater than or equal to 60 kilograms/minute, but less than 140 kilograms/minute,
- c) Risk Group OP III: organic peroxides of this group deflagrate, the effects caused by the fire are the same as

- those caused by ordinary combustibles; Risk Group OP III comprises organic peroxides with a corrected mass flow rate *Ak* less than 60 kilograms/minute,
- d) Risk Group OP IV: organic peroxides of this group have low combustibility and burn so slowly that the surrounding environment is hardly at risk from flames and thermal radiation; a corrected mass flow rate *Ak* cannot be determined for this risk group.
- (3) If an organic peroxide has not been classified into a risk group, the employer must file an application for classification with the Federal Institute for Materials Research and Testing in written or electronic form. The application must be submitted together with the requisite documents. The Federal Institute for Materials Research and Testing shall publish the risk group classification.
- (4) In derogation from paragraph 3, the employer may have the risk group classification carried out by another suitable agency. In this case, the employer must submit the results of the evaluation to the Federal Institute for Materials Research and Testing together with the required documents. The Federal Institute for Materials Research and Testing shall publish the risk group classification upon review and approval.
- (5) Prior to the publication of the risk group classification by the Federal Institute for Materials Research and Testing, organic peroxides with a peroxide concentration of
- a) greater than or equal to 57 per cent must be handled as organic peroxides of Risk Group OP lb,
- b) greater than or equal to 32 per cent, but less than 57 per cent, must be handled as organic peroxides of Risk Group OP II,
- c) greater than or equal to 10 per cent, but less than 32 per cent, must be handled as organic peroxides of Risk Group OP III.
- (6) On approval by the competent authority, non-combustible organic peroxides with a peroxide concentration greater than or equal to 10 per cent may be handled as organic peroxides classified in Risk Group OP IV. The preliminary risk group classification may be used only for a limited period of up to two years.

### 2.4 Information collection and risk assessment

- (1) As part of the risk assessment carried out according to Article 6 for activities involving organic peroxides, the employer must determine if the risk group classification published by the Federal Institute for Materials Research and Testing for organic peroxides is applicable to these activities based on good professional practice. If the classification criteria coincide with the requirements for these activities, the employer must implement the protective measures required for that risk group. If the employer concludes that the published risk group classification is not appropriate for a specific activity, the employer must determine which other risk group would be appropriate for the respective activities based on good professional practice. If the employer does not possess the requisite competency, the employer must seek advice from a competent person.
- (2) If the risk assessment according to Article 6 indicates that mixtures may form during the manufacture, handling or processing of organic peroxides that may detonate or are liable to deflagrate rapidly or undergo violent thermal explosions, the employer must request the preparation of an expert opinion by the Federal Institute for Materials Research and Testing, which in particular specifies which protective measures are to be taken. This applies also if the activities involving organic peroxides are carried out in stationary outdoor installations, including their storage in tanks or silos.

### 2.5 Safety and separation distances

- (1) If buildings and outdoor installations are being used for activities with organic peroxides, the employer must establish appropriate safety distances between these sites and residential areas and public traffic routes and separation distances between these sites and other buildings and installations on the company premises. No safety or separation distances need to be maintained for buildings used for activities involving only organic peroxides classified in Risk Group OP IV.
- (2) Safety and separation distances must be established on the basis of the risk group classification and the quantity of organic peroxides available in addition to the position, arrangement and type of buildings and installations.
- (3) Safety and separation distances do not need to be maintained for the storage of organic peroxides classified in Risk Group OP Ia up to a net mass of 100 kilograms and for those classified in Risk Groups OP Ib, OP II and OP III up to a net mass of 200 kilograms. It has to be ensured, however, that any unintended reactions involving

organic peroxides shall not have any effect on the outside world or in any direction that may give rise to a hazard.

### 2.6 Structural requirements

The employer must ensure that buildings in which activities involving organic peroxides are carried out are constructed in such a way that, in the event of a plant malfunction or accident, the hazard to workers and other persons is kept to a minimum. If a hazard arises from the onset of decomposition, the employer must ensure that particularly the buildings and rooms in which organic peroxides are produced, handled, processed, transferred or destroyed

- a) are constructed according to safety standards,
- b) have sufficiently robust ceilings and walls, and
- c) have adequately dimensioned explosion vents in the walls or ceilings that rapidly reduce pressure levels in the event of an explosion; these vents must be made of lightweight building materials and be considerably less robust than the other structural components.

### 2.7 Ignition sources

As part of the risk assessment, the employer must identify areas where ignition sources must be avoided and take the requisite protective measures, including the labelling of these areas.

### 2.8 Transport on company premises

Organic peroxides shall only be transported on company premises by motor vehicles or industrial trucks that do not represent an ignition source for organic peroxides.

### 2.9 Requirements for the storage of organic peroxides

- (1) Organic peroxides that fall within the scope of the Explosives Act must be stored according to the provisions of the Second Ordinance to the Explosives Act as published on 10 September 2002 (Federal Law Gazette I, p. 3543), last amended by Article 2 of the Ordinance of 26 November 2010 (Federal Law Gazette I, p. 1643). Paragraphs 2 to 5 apply to the storage of organic peroxides that do not fall within the scope of the Explosives Act.
- (2) Buildings used for the storage of organic peroxides classified in Risk Groups OP I to OP III must be single storey structures. In derogation from sentence 1, a storage building may have more than one storey if the risk assessment demonstrates that the multi-storey design of the building will not increase the risk to workers and other persons.
- (3) Storage rooms for organic peroxides classified in Risk Group OP I to OP III must be equipped with explosion vents.
- (4) Storage rooms must be constructed and equipped in such a way that the maximum permissible storage temperature for organic peroxides is not exceeded.
- (5) The employer must ensure that organic peroxides are only stored together with or placed next to other substances, mixtures or articles if this does not lead to a significant increase in risk.

### 2.10 Requirements for plant facilities and installations

- (1) Plant facilities and installations must be designed and equipped in such a way that safety can be maintained and an uncontrolled release of organic peroxides can be avoided even in the event of plant malfunctions or accidents. It must be possible to empty them completely and safely.
- (2) Plant facilities must be constructed in such a way that they will not lead to a hazardous reaction of organic peroxides. They must be equipped with control and monitoring devices for safe operation.
- (3) The hazardous confinement of organic peroxides must be avoided.
- (4) The type and number of fire extinguishing devices must be suitable for the special properties of organic peroxides.