

Übersetzung durch den Sprachendienst des Bundesministeriums für Arbeit und Soziales.
Translation provided by the Language Service of the Federal Ministry of Labour and Social
Affairs.

Stand: Die Übersetzung berücksichtigt die Berichtigung vom 26.1.2012 (BGBl. I S. 131)

Version information: The translation includes the corrigendum of 26.1.2012 (Federal Law
Gazette I p. 131)

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Act on making products available on the market (Product Safety Act)

Act on making products available on the market of 8 November 2011 (Federal Law Gazette I
page 2178, 2012 I S. 131)

This Act shall implement

1. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11 of 15 January 2002, p.4), last amended by Regulation (EC) No. 596/2009 (OJ L. 188 of 18 July 2009, p. 14),
2. Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits (OJ L 374 of 27 December 2006, p. 10),
3. Directive 94/9/EC of the European Parliament and of Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 100, 19 April 1994, p.1, L 257 of 10 October 1996, p. 44, L 21 of 26 January 2000, p. 42) amended by Regulation (EC) No. 1882/2003 (OJ L 284 of 31 October 2003, p.1),
4. Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels (OJ L 264 of 8 October 2009, p. 12),
5. Directive 75/324/EEC of the Council of 20 May 1975, on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 147 of 9 June 1975, p. 40, L 220 of 8 August 1987, p. 22), as amended by Regulation (EC) No. 219/2009 (OJ L 87 of 31 March 2009, p. 109),
6. Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment (OJ L 181 of 9 July 1997, p.1, L 265 of 9 October 2009, p.110), as amended by Regulation (EC) No. 1882/2003 (OJ L 284 of 31 October 2003, p.1),
7. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC (OJ L 157 of 9 June 2006, p. 24, L 76 of 16 March 2007, p. 35), as amended by Directive 2009/127/EC (OJ L 310 of 25 November 2009, p. 29),
8. Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (OJ L 213 of 7 September 1995, p.1), as amended by Directive 2006/42/EC (OJ L 157 of 9 June 2006, p. 24),
9. Directive 2000/14/EC of the European Parliament and of the Council of 08 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, of 3 July 2000, p.

1, L 311 of 28 November 2001, p. 50) as amended by Regulation (EC) No. 219/2009 (OJ L 87 of 31 March 2009, p. 109),

10. Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels (OJ L 330 of 16 December 2009, p. 10),

11. Directive 89/686/EC of the Council of 21 December 1989 on the approximation of the laws of the Member States on personal protective equipment (OJ L 399 of 30 December 1989, p.18), as amended by Regulation (EC) No. 1882/2003 (OJ L 284 of 31 October 2003, p.1),

12. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170 of 30 June 2009, p. 1),

13. Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft (OJ L 164 of 30 June 1994, p. 15, L 127 of 10 June 1995, p. 27, L 41 of 15 February 2000, p. 20), as amended by Regulation (EC) No. 1137/2008 (OJ L 311 of 21 November 2008, p.1),

14. Decision No. 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Decision No. 93/465/EEC of the Council (OJ L 218 of 13 August 2008, p. 82).

Chapter 1 General Provisions

Article 1 Scope

(1) This Act shall apply whenever products are made available on the market, exhibited or used for the first time in the context of a commercial activity.

(2) This Act shall also apply to the erection and the operation of installations subject to inspection, which are used for commercial or economic purposes or which may put employees at risk, with the exception of installations subject to inspection

1. at vehicles of magnetic levitation trains insofar as these vehicles are subject to the federal provisions on the construction and operation of such trains,

2. at the rolling stock of railway companies, with the exception of freight containers, insofar as this material is subject to the provisions of the federal and state construction and operation regulations,

3. in mining companies, with the exception of their surface installations.

(3) This Act shall not apply to

1. antiquities,

2. second-hand products which have to be repaired or reconditioned before they can be used, provided the economic operator adequately informs the persons to whom he supplies the second-hand products,

3. products that are exclusively intended for military use due to their design,

4. food, feedstuffs, live plants and animals, produce of human origin and produce from plants and animals directly related to their future reproduction,

5. medical devices within the meaning of Article 3 of the Act on Medical Devices unless otherwise stipulated by the Act on Medical Devices,
6. containments (as non-stationary pressure equipment, packagings and tanks) for the transport of dangerous goods, where they are subject to transport regulations, and
7. plant protection products within the meaning of Article 2 item 9 of the Plant Protection Act or Article 2 (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 Directives 78/117/EEC and 91/414/EEC of the Council (OJ L 309 of 24 November 2009, p.1).

Sentence 1 items 2 and 5 shall not apply to the provisions of Chapter 9 of this Act.

(4) The provisions of this Act shall not apply where other legal provisions provide for corresponding or more far-reaching provisions. Sentence 1 shall not apply to the provisions of Chapter 9 of this Act.

Article 2 Definitions

For the purposes of this Act

1. "accreditation" shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral accreditation schemes, to perform a specific conformity assessment activity,
2. "exhibiting" shall mean the offering, installation or presentation of products with the purpose of advertising them or making them available on the market,
3. "exhibitor" shall mean any natural or legal person exhibiting a product,
4. "making available on the market" shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;
5. "intended use" shall mean
 - a) the use for which a product is intended in accordance with the information by the person placing it on the market, or
 - b) the ordinary use as determined by the design and construction of the product,
6. "authorised representative" shall mean any natural or legal person established within the European Economic Area who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under the relevant legislation of the European Union.
7. "CE marking" shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in harmonisation legislation of the European Union providing for its affixing,
8. "importer" shall mean any natural or legal person established within the European Economic Area who places a product on the market from a state which is not a member of the European Economic Area,

9. "serious risk" shall mean any risk requiring rapid intervention by the market surveillance authorities even if the risk has no direct impact,
10. "hazard" shall mean the potential cause of a damage,
11. "GS body" shall mean a conformity assessment body which has been authorised by the authorising authority to award the GS mark,
12. "distributor" shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market
13. "harmonised standard" shall mean a standard adopted by one of the recognised European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204 of 21 July 1998, p. 37) as last amended by Directive 2006/96/EC (OJ L 363 of 20 December 2006, p. 81) on the basis of a request made by the European Commission in accordance with Article 6 of that Directive,,
14. "manufacturer" shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark; the following persons shall also be deemed manufacturers
- a) a person attaching his name, trademark or any other differentiating mark to a product, thus acting as if he was the manufacturer, or
 - b) a person who reconditions a product or determines the safety properties of a consumer product and subsequently makes it available on the market,
15. "placing on the market" shall mean the first making available of a product on the market; the import into the European Economic Area shall be deemed equivalent to the placing on the market of a new product.
16. "conformity assessment" shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled,
17. "conformity assessment body" shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection,
18. "market surveillance" shall mean any activity carried out by the competent authorities and any measure taken by them, to ensure that the products comply with the requirements set out in this Act and do not endanger the safety and health of persons or any other aspect of public interest protection,
19. "market surveillance authority" shall mean any authority responsible for carrying out market surveillance,
20. "notified body" shall mean a conformity assessment body, which
- a) has been authorised by the authorising authority to carry out conformity assessment tasks in accordance with the ordinances pursuant to Article 8 (1) which have been issued in order to enforce or implement legislation of the European Union, and which have been notified by the authorising authority to the European Commission and the other Member States, or
 - b) was notified to the European Commission and the other Member States by a Member State of the European Union or any other Treaty state of the Agreement on the European Economic Area on the basis of a European act;

21. "notification" shall mean any communication by the authorising authority to the European Commission and the other Member States stating that a conformity assessment body may carry out conformity assessment tasks pursuant to Article 8 (1) of the ordinances issued to enforce or implement legislation of the European Union,
22. "products" shall mean goods, substances or preparations which have been manufactured in a production process,
23. "risk" shall mean the combination of the likelihood of a hazard and the severity of the potential damage,
24. "withdrawal" shall mean any measure aimed at preventing a product in the supply chain from being made available on the market,
25. "recall" shall mean any measure aimed at achieving the return of a product that has already been made available to the end user,
26. "consumer products" shall mean new, second-hand or reconditioned products that are intended for consumers or could be used by consumers under conditions which are reasonably foreseeable, even if they are not intended for them; consumer products shall also mean products made available to the consumer in the framework of a service,
27. products shall be "ready for use" if they can be used as intended without the insertion of additional parts; products shall also be deemed ready for use if
- a) all parts from which they are to be assembled, are placed on the market by one person only;
 - b) they only need to be mounted or plugged in, or
 - c) they are placed on the market without the parts that are usually procured separately and inserted for the intended use,
28. "foreseeable use" shall mean the use of a product in a manner that the person placing it on the market has not intended, but which could be reasonably foreseeable,
29. "economic operators" shall mean manufacturers, authorised representatives, importers and distributors,
30. "equipment subject to mandatory inspection" shall mean
- a) steam boiler systems with the exception of steam boiler systems on board seagoing vessels,
 - b) pressure vessel systems with the exception of steam boilers,
 - c) installations for the filling of compressed, liquefied gases or gases dissolved under pressure,
 - d) ducts under internal overpressure for combustible, corrosive or toxic gases, vapours or liquids,
 - e) elevators,
 - f) installations in potentially explosive atmospheres,
 - g) beverage dispensing systems and systems for the production of carbonic beverages,
 - h) acetylene plants and calcium carbide depots
 - i) installations for the storage, filling and transport of combustible liquids.

Installations subject to mandatory inspection shall also include measuring and control systems which are required for the safe operation of these installations subject to mandatory inspection; the installations subject to mandatory inspection mentioned under item 30 (b), (c) and (d) shall not include power plants within the meaning of the Energy Industry Act. Installations subject to mandatory inspection shall be deemed equal to products within the meaning of item 22, unless they are already covered by item 22.

31. The "competent authorities for the control of the external borders" shall be the customs authorities.

Chapter 2

Prerequisites for making products available on the market and for the exhibition of products

Article 3

General requirements for making products available on the market

(1) Where a product is subject to one or more ordinances in accordance with Article 8 (1), it may only be made available on the market if it

1. complies with the requirements stipulated therein and
2. does not put at risk the safety and health of persons or other legal goods, as stipulated in the ordinances in accordance with Article 8 (1) when used as intended or foreseeable.

(2) A product which is not subject to paragraph 1 may only be made available on the market if its intended or foreseeable use does not put the health and safety of persons at risk. In order to assess whether a product complies with the requirement pursuant to sentence 1, the following aspects shall be taken into account in particular:

1. the characteristics of the product, including its composition, packaging and instructions for assembly, installation, maintenance and useful life,
2. the impact of the product on other products, where it is reasonably foreseeable that it will be used together with other products,
3. the presentation of the product, its marking, any warnings, instructions for use and instructions for its disposal and any other product related data or information,
4. the groups of users that are exposed to greater risks than other groups.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute sufficient grounds for considering a product to be dangerous.

(3) If the protection of safety and health can only be guaranteed by the way the product is installed, this has to be indicated adequately when making the product available on the market, unless other ordinances pursuant to Article 8 stipulate otherwise.

(4) Where specific rules have to be complied with regarding the use, addition or maintenance of a product in order to guarantee safety and health, German language instructions for its use shall be supplied with the product when making it available on the market, unless Article 8 stipulates otherwise.

(5) A product which does not comply with the requirements under paragraph 1 or paragraph 2, may be exhibited if the exhibitor clearly indicates that it does not comply with the requirements and cannot be acquired unless compliance is reached. When a product is presented, the necessary precautions for the protection of the safety and health of persons

shall be taken.

Article 4 Harmonised standards

(1) Compliance of a product with the requirements under Article 3 (1) or (2) may be assessed on the basis of harmonised standards.

(2) A product complying with harmonised standards or parts thereof and whose references have been published in the Official Journal of the European Union, shall be presumed to comply with the requirements under Article 3 (1) or (2), insofar as they are covered by the corresponding standards or parts thereof.

(3) If the market surveillance authority considers that a harmonised standard does not entirely satisfy the requirements under Article 3 (1) or (2), it shall inform the Federal Institute for Occupational Safety and Health accordingly, stating its reasons. The Federal Institute for Occupational Safety and Health shall review the information received as to their completeness and coherence; it shall involve the Product Safety Commission. It shall forward the information thus received to the competent Federal Ministry.

Article 5 Standards and other technical specifications

(1) Standards and other technical specifications may be used to assess the compliance of a product with the requirements under Article 3 (2).

(2) A product complying with standards or other technical specifications or parts thereof which have been identified by the Product Safety Commission and whose references have been published by the Federal Institute for Occupational Safety and Health in the Joint Ministerial Gazette, shall be presumed to comply with the requirements under Article 3 (2) insofar as they are covered by the respective standards or other technical specifications or parts thereof.

(3) If the market surveillance authority considers that a standard or other technical specification does not fully cover the requirements under Article 3 (2), it shall inform the Federal Institute for Occupational Safety and Health accordingly, stating its reasons. The latter shall then inform the Product Safety Commission.

Article 6 Additional requirements for making consumer products available on the market

(1) In the framework of their respective business activities the manufacturer, his authorised representative and the importer shall have the following obligations when making a consumer product available on the market

1. to ensure that the user receives the information he needs in order to assess and take precautions against the risks related to the consumer product during the usual or reasonably foreseeable period of use, where such risks are not immediately obvious without adequate information..

2. to ensure that the name and contact address of the manufacturer or, if he is not established in the European Economic Area, the name and contact address of his authorised representative or the importer are affixed to the product.

3. to affix unambiguous markings allowing the identification of the consumer product.

The information pursuant to sentence 1 items 2 and 3 shall be affixed to the consumer product or, where this is not possible, to its packaging. Exemptions from the obligations pursuant to sentence 1 items 2 and 3 are admissible if it can be justified to omit this information, in particular as it is already known to the user or because it would involve disproportionate costs to affix it.

(2) The manufacturer, his authorised representative and the importer shall make precautions in the framework of their respective business activities to take appropriate measures in order to prevent potential risks related to the consumer product which they have made available on the market; the measures must be appropriate with respect to the product's characteristics and include the withdrawal, adequate and effective warning and recall.

(3) In the framework of their respective business activities the manufacturer, his authorised representative and the importer shall have the following obligations when making a consumer product available on the market

1. to carry out sample-testing,
2. to investigate complaints and, if necessary, keep a register of complaints as well as
3. to inform the distributors about further measures related to the consumer product in question.

The type of sample testing to be carried out shall depend on the risk level related to the products and on the possibility to prevent the risk.

(4) The manufacturer, his authorised representative and the importer shall in accordance with Annex I to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 concerning general product safety (OJ L 11 of 15 January 2002, p.4) immediately inform the competent market surveillance authority at the place where they are established if they know or ought to know, on the basis of the information or experience available to them, that a consumer product made available on the market by them, presents a risk for the safety and health of persons; they shall in particular inform the market surveillance authority about the measures they have taken to prevent such risk. The market surveillance authority shall immediately inform the Federal Institute for Occupational Safety and Health about the facts, in particular in the event of recalls. Information pursuant to sentence 1 shall not be used for criminal proceedings against the informant or for the purpose of starting proceedings in accordance with the Code of Administrative Offences against the informant.

(5) The distributor shall contribute to making only safe consumer products available on the market. In particular he shall not make any consumer product available on the market of which he knows or ought to know, on the basis of the information or experience available to him, that it does not comply with the requirements under Article 3. Paragraph 4 shall apply to the distributor accordingly.

Article 7 CE marking

(1) The general principles pursuant to Article 30 of Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 of the Council (OJ L 218 of 13 August 2008, p. 30) shall apply to the CE marking.

(2) It shall be prohibited to make a product available on the market,

1. if the product, its packaging or documentation enclosed are CE marked, but the CE marking is not provided for in the ordinances under Article 8 (1) or other legal provisions or the requirements under paragraphs 3 to 5 are not met, or
2. which does not have a CE marking although an ordinance under Article 8 (1) or any other legal provision stipulates its affixing.

(3) Unless an ordinance under Article 8 (1) or any other legal provision stipulates otherwise, the CE marking must be affixed visibly, legibly and indelibly to the product or to its data plate. If the type of product does not permit or justify this, the CE marking shall be affixed to the packaging and the documents accompanying the product, if such documents are mandatory.

(4) The CE marking shall be followed by the identification number of the notified body pursuant to Article 2 item 20 provided this body was involved in the production control phase. The identification number shall be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorized representative.

(5) The CE marking shall be affixed before the product is placed on the market. The CE marking and, if necessary, the identification number may be followed by a pictogram or any other mark indicating a special risk or use.

Article 8 **Authorisation to issue ordinances**

(1) The Federal Ministry of Labour and Social Affairs, the Federal Ministry of Economics and Technology, the Federal Ministry of Food, Agriculture and Consumer Protection, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, the Federal Ministry for Transport, Building and Urban Development and the Federal Ministry of Defence shall be authorised for their respective sphere of competence and after agreement by the other, aforementioned federal ministries and after hearing the Product Safety Commission and with the consent of the *Bundesrat* to issue ordinances so as to protect the safety and health of persons, to protect the environment as well as other legal goods from risks emanating from products, also with the purpose to implement obligations arising from bilateral agreements or to enforce or implement legal provisions enacted by the European Union. These ordinances can regulate the following:

1. Requirements concerning
 - a) the nature of products,
 - b) making products available on the market,
 - c) the exhibition of products,
 - d) the first-time use of products,
 - e) the marking of products,
 - f) conformity assessment bodies,

2. Product-related storage and information obligations

3. Obligations requiring action by conformity assessment bodies

as well as official measures and responsibilities referring to requirements under item 1 and the obligations under items 2 and 3 and which are necessary to enforce or implement legal acts enacted by the European Union.

(2) The Federal Government with the consent of the *Bundesrat* shall be authorised to determine by ordinance for specific product groups that a body which is responsible for the conformity assessment or the assessment and review of the constancy of performance of products, shall have to submit an accreditation certificate issued by the national accreditation body in order to provide evidence as to the legal requirements. An ordinance pursuant to sentence 1 may also require to transfer the supervision of the activities of these bodies to the German Accreditation Body for specific product groups. Where the Federal Government has not enacted an ordinance pursuant to sentence 1 the state governments shall be authorised to issue such ordinances.

(3) In urgent cases, ordinances under paragraph 1 or paragraph 2 can be issued without the consent of the *Bundesrat*, in particular when this is necessary for the immediate enforcement or implementation of legal acts of the European Union; they shall at the latest expire six months after their entry into force. Their validity may only be extended with the consent of the *Bundesrat*.

Chapter 3 **Regulations governing the authorising authority**

Article 9 **Tasks of the authorising authority**

(1) On request the authorising authority shall issue the authorisation to conformity assessment bodies to carry out defined conformity assessment activities. It shall be responsible for setting up and carrying out the respective procedures required in this context. It shall equally be responsible for setting up and carrying out the procedures necessary for the monitoring of the conformity assessment bodies to whom it has issued authorisation to carry out defined conformity assessment activities.

(2) The authorising authority shall carry out the notification of conformity assessment bodies.

(3) The authorising authority shall monitor whether the conformity assessment bodies to whom it has issued authorisation to carry out conformity assessment activities comply with the requirements and their statutory obligations. It shall give the necessary orders for corrective action regarding deficiencies found or in order to prevent future non-compliance.

(4) On request, the authorising authority shall give the competent market surveillance authority the information it needs to carry out its tasks.

Article 10 **Requirements relating to the authorising authority**

(1) The federal states shall establish the authorising authority in such a way that no conflict of interest with conformity assessment bodies occurs; in particular the authorising authority shall not offer or provide any activities that conformity assessment bodies perform, nor any consultancy services on a commercial or competitive basis.

(2) Staff of the authorising authority who carried out the assessment of a conformity assessment body, shall not be entrusted with the decision regarding the issuing of an authorisation to act as a conformity assessment body.

(3) The authorising authority shall have a sufficient number of competent staff at its disposal for the proper performance of its tasks.

Article 11 **Powers of the authorising authority**

(1) The authorising authority may request from the conformity assessment bodies to whom it has issued authorisation to carry out specified conformity assessment tasks, the information and any other support which it needs to comply with its monitoring tasks and it may give the orders required for this purpose. The authorising authority shall be specifically entitled to request the documentation on which the conformity assessment is based. The authorising authority and the persons commissioned by it shall be entitled to enter and inspect the business premises as well as the test laboratories of the conformity assessment body during business hours if this is necessary for the performance of its monitoring tasks.

(2) Persons obliged to provide information shall submit to the measures pursuant to paragraph 1. They may refuse to answer any questions, the reply of which would subject them or one of their relatives as defined in Article 383 (1) items 1 to 3 of the Code of Civil Procedure, to the risk of being prosecuted for a criminal offence or under the Regulatory Offences Act. They shall be informed about their right to refuse information.

Chapter 4 **Notification of conformity assessment bodies**

Article 12 **Applications for notification**

(1) A conformity assessment body may submit an application to the authorising authority to act as a notified body.

(2) The conformity assessment body shall have the application pursuant to paragraph 1 accompanied by a description of the conformity assessment activities, the conformity assessment procedure and the products for which it claims to be competent, as well as an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 13.

(3) Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the authorising authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 13. .

Article 13 **Notification requirements for the conformity assessment body**

(1) The conformity assessment body shall have legal personality. It shall have the capacity to conclude contracts, to acquire fixed assets and to dispose of them as well as to bring legal proceedings before a court and stand trial.

(2) The conformity assessment body shall be a third-party body independent of the organisation or the product it assesses. The requirement laid down in sentence 1 may also be fulfilled by a conformity assessment body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, if the conformity assessment body can demonstrate that membership in such an association or federation does not entail conflicts of interest in relation to its conformity assessment activities.

(3) The conformity assessment body, its top level management and the staff responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes. The conformity assessment body, its top level management and the staff responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to their conformity assessment activities. This shall in particular apply to consultancy services. The conformity assessment body shall ensure that activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of their conformity assessment activities.

(4) The conformity assessment body and its staff shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, by third parties, which might influence their judgement or the results of the conformity assessment activities, especially as regards persons or groups of persons with an interest in the result of that conformity assessment.

(5) The conformity assessment body shall be capable of carrying out all the conformity assessment tasks for which it claims competence in accordance with its application under Article 12 (2), whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. For each conformity assessment procedure and each kind and category of products in relation to which it has filed an application under Article 12 (2) the conformity assessment body shall have at its disposal:

1. the necessary number of staff with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks,
2. descriptions of procedures in accordance with which the conformity assessment is carried out, ensuring the transparency and the ability of reproduction of these procedures and it shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities, and
3. procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

The conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

(6) The conformity assessment body shall ensure that the staff responsible for carrying out conformity assessment activities

1. have completed technical and vocational training qualifying them for all conformity assessment activities in relation to which the conformity assessment body has filed an application pursuant to Article 12,
2. have satisfactory knowledge of the products and the conformity assessment procedures and adequate powers to carry out those conformity assessments,
3. have appropriate knowledge and understanding of the essential requirements of the applicable harmonised standards and of the relevant provisions of the harmonisation legislation of the European Union and of its implementing regulations, and
4. have the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

(7) The conformity assessment body shall ensure its impartiality, the impartiality of its top level management and of its conformity assessment staff. The remuneration of the top level management and the conformity assessment staff shall not depend on the number of conformity assessments carried out or on the results of those assessments.

(8) The conformity assessment body shall take out liability insurance which shall adequately cover the risks connected with its activities.

(9) The staff of the conformity assessment body shall not disclose or use, without authorisation, any information they obtained in the framework of the conformity assessment whose confidentiality is in the interest of the conformity assessment body or of a third party even if they have ceased to work for the conformity assessment body. The provisions to be complied with by the conformity assessment body concerning the protection of personal data shall remain unaffected.

Article 14 Presumption of conformity

(1) Where a conformity assessment body demonstrates by its accreditation its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article 13 in so far as the applicable harmonised standards cover those requirements.

(2) If the authorising authority considers that a harmonised standard does not fully correspond to the requirements set out in Article 13, it shall inform the Federal Institute for Safety and Health accordingly, stating its reasons. The Federal Institute for Occupational Safety and Health shall review the information received as to their completeness and consistency; it shall involve the Product Safety Commission. It shall give the information to the Federal Ministry of Labour and Social Affairs.

Article 15 Notification procedure, issuing of an authorisation

Where the authorising authority has ascertained that a conformity assessment body complies with the requirements pursuant to Article 13, it shall issue authorisation to the conformity assessment body to perform conformity assessment tasks according to the legal provisions in Article 8 (1) enacted in order to enforce or implement the legal provisions of the European Union and shall subsequently notify it using the electronic notification tool

developed and managed by the European Commission. The authorisations shall be issued subject to the condition precedent that neither the European Commission nor the other Member States have raised objections

1. within two weeks after notification in cases where an accreditation certificate has been submitted in accordance with Article 12 (2), or
2. within two months after notification in cases where no accreditation certificate has been submitted in accordance with Article 12 (2),

Authorisation may be granted under additional conditions and may be made conditional on requirements. It may be granted for a limited period of time and reserving the right of withdrawal or imposing subsequent requirements.

(2) Where attestation of competence is not based on an accreditation certificate referred to in Article 12 (2), the authorising authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence. It shall furthermore submit the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to satisfy the requirements laid down in Article 13.

(3) The authorising authority shall notify the European Commission and the other Member States of any subsequent relevant changes to the notification.

(4) On request, the authorising authority shall provide the Commission with any information related to the basis for notification or the maintenance of the competence of the body concerned.

Article 16 **Obligations of the notified body**

(1) The notified body shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in the ordinances under Article 8 (1) and in a proportionate manner .

(2) Where the notified body finds that requirements laid down in ordinances under Article 8 (1) have not been met by a manufacturer,, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

(3) Where, in the course of the monitoring of conformity following the issue of a conformity certificate, the notified body finds that the product no longer complies, it shall require the manufacturer to take appropriate corrective measures ;it shall suspend or withdraw the certificate if necessary.

(4) Where corrective measures are not taken or do not suffice to ensure compliance with the requirements, the notified body shall restrict, suspend or withdraw all corresponding conformity certificates .

(5) The notified body shall participate in, or ensure that its conformity assessment staff are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant harmonisation regulations of the European Union. It shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group. .

Article 17
Information obligations on the notified body

- (1) The notified body shall inform the authorising authority of the following:
1. any refusal, restriction, suspension or withdrawal of a conformity certificate ,
 2. any circumstances affecting the authorisation issued to the notified body pursuant to Article 15 (1),
 3. any request for information which it has received from market surveillance authorities regarding conformity assessment activities,
 4. on request, conformity assessment activities performed and any other activity performed, including cross-border activities and subcontracting .
- (2) The notified body shall provide the other bodies notified under the relevant harmonisation regulation of the European Union carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessments results..

Article 18
Subsidiaries of and subcontracting by a notified body

- (1) Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 13 and shall inform the authorising authority accordingly.
- (2) The notified body shall take full responsibility for the tasks performed by the subcontractors or subsidiaries wherever these are established.
- (3) Tasks may be subcontracted or carried out by a subsidiary only with the agreement of the client .
- (4) The notified body shall keep at the disposal of the authorising authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under the ordinances pursuant to Article 8 (1).

Article 19
Revocation of authorisations issued

- (1) Where the authorising authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 13, or that it is failing to fulfil its obligations, it shall revoke the authorisation issued in full or in part. It shall immediately inform the European Commission and the other Member States accordingly.
- (2) In the event of a revocation pursuant to paragraph 1 or where the notified body has ceased its activity , the authorising authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the authorising authority and the market surveillance authorities at their request.

Chapter 5 GS mark

Article 20 Award of the GS mark

- (1) A ready-to-use product may bear the GS mark as specified in the Annex when a GS body has awarded the mark upon request of the manufacturer or his authorised representative.
- (2) This shall not apply when the ready-to-use product bears the CE marking and the requirements for such CE marking are at least equivalent to the requirements of Article 21 (1).

Article 21 Obligations of the GS body

- (1) A GS body may award the GS mark only when
1. the examined type satisfies the requirements of Article 3, and, in case of a consumer product, satisfies also the requirements of Article 6,
 2. the examined type satisfies the requirements of other legislation in terms of ensuring the protection of the health and safety of persons,
 3. the specifications for the award of the GS mark as defined by the Product Safety Commission were applied in the type examination,
 4. measures ensuring conformity of the ready-to-use products with the examined type have been taken.

The GS body shall document that these requirements are met.

- (2) The GS body shall issue a certificate of the award of the GS mark. The award shall be limited to a period of not more than five years or to a certain production batch or lot. The GS body shall publish a list of the certificates issued.
- (3) The GS body shall take the necessary measures when it becomes aware that a product bears the GS mark without a valid award. It shall immediately notify the other GS bodies and the authorising authority of the abuse of the GS mark.
- (4) The GS body shall make its information about cases of abuse of the GS mark available to the public by electronic communication.
- (5) The GS body shall monitor the manufacturing of the ready-to-use products and the lawful use of the GS mark through appropriate measures. When there is evidence that the requirements for the award of the GS mark are no longer met, the GS body shall withdraw the award. It shall inform the other GS bodies and the authorising authority of the withdrawal of the award. The GS body may suspend the award when there is reason to doubt the lawfulness of the award of the GS mark.

Article 22 Obligations of the manufacturer and the importer

- (1) The manufacturer shall ensure that the ready-to-use products he manufactures are in conformity with the examined type. He shall submit to the activities specified in Article 21 (5).

(2) The manufacturer may apply the GS mark and use it as a selling point only if the GS body issued him a certificate according to Article 21 (2) and only as long as the requirements of Article 21 (1) are met. He shall not apply the GS mark nor use it as a selling point if he was not issued a certificate according to Article 21 (2) or if the GS body withdrew the award according to sentence 2 of Article 21 (5) or suspended it according to sentence 4 of Article 21 (5).

(3) In the design of the GS mark the manufacturer shall observe the rules set out in the Annex.

(4) The manufacturer shall not apply a mark that could be confused with the GS mark or nor use such a mark as a selling point.

(5) An importer may place a product with the GS mark on the market only after having verified that the product has a certificate according to Article 21 (2). Before placing the product on the market he shall document the verification undertaken according to sentence 1; the documentation shall show at least the date of the verification according to sentence 1, the name of the GS body that issued the certificate according to Article 21 (2) and the number of the certificate concerning the award of the GS mark.

Article 23 GS bodies

(1) A conformity assessment body may apply to the authorising authority for authorisation to act as GS body for a specific field. The process of examining the application may be entrusted to a single body in accordance with the provisions of the Administrative Procedure Act and shall be completed within six months. This period shall commence when all documents have been received. The authorising authority may extend this period once by not more than three months. It shall give the grounds for the extension and notify the applicant in due time.

(2) The authorising authority may grant authorisation to act as a GS body only to conformity assessment bodies which satisfy the requirements of Articles 13 and 18. The provisions of Article 14 (1) and Article 19 (1) sentence 1 and Article 19 (2) shall apply accordingly.

(3) Authorisation may be granted under specific terms and may be attached to requirements. It may be granted for a limited period of time and reserving the right of withdrawal or imposing subsequent requirements.

(4) The authorising authority shall notify the GS bodies to the Federal Institute for Occupational Safety and Health. The Federal Institute for Occupational Safety and Health shall make the GS bodies publicly known via electronic means.

(5) A conformity assessment body established in another Member State of the European Union or of the European Free Trade Area may be designated by the authorising authority as a GS body for a specific field and notified as such to the Federal Institute for Occupational Safety and Health. Such a designation may be made provided that

1. an administrative agreement was concluded between the Federal Ministry of Labour and Social Affairs and the respective Member State of the European Union or the European Free Trade Area, and
2. an authorisation procedure established that the requirements of the administrative agreement specified in item 1 are met.

The administrative agreement according to sentence 2 shall lay down

1. the requirements for the GS body referred to in paragraph 2 and in Article 21 (2) to (5),
2. the involvement of the authorising authority in the authorisation process carried out in the respective Member State, and
3. the monitoring of the GS body in accordance with the principles of Article 9.

Chapter 6 Market surveillance

Article 24 Responsibilities and cooperation

(1) Subject to the provisions of sentences 2 and 3, market surveillance shall be the responsibility of the competent authorities under the law of the respective Federal State. Responsibilities for the implementation of this Act defined in other legislation shall remain unaffected. When, in accordance with Article 1 (4), the provisions of this Act are applied complementary to the provisions of other legislation, the competent authorities for the implementation of such other legislation shall also be responsible for the implementation of the provisions of this Act unless otherwise provided. Within the jurisdiction of the Federal Ministry of Defence, market surveillance shall be the responsibility of the Federal Ministry of Defence and the bodies designated by it.

(2) The market surveillance authorities specified in paragraph 1 shall cooperate with the authorities in charge of external border controls in accordance with Chapter III, Article 3 of Regulation (EC) No. 765/2008. In the framework of such cooperation the authorities in charge of border controls may, on request of the market surveillance authorities, transmit information which they obtained in connection with the release of products for free circulation and which are necessary for the performance of the tasks of the market surveillance authorities.

(3) The authorities in charge of external border controls and the market surveillance authorities shall protect commercial secrets or preserve personal data pursuant to applicable legislation.

Article 25 Tasks of the market surveillance authorities

(1) The market surveillance authorities have to ensure effective market surveillance based on a surveillance concept. The surveillance concept shall comprise in particular:

1. the collection and evaluation of information for the purpose of identifying key deficiencies and flows of goods,
2. the preparation and implementation of market surveillance programmes as a basis for the product checks; the market surveillance programmes shall be updated regularly.

The market surveillance authorities shall periodically, at least every four years, review and assess the effectiveness of the surveillance concept.

(2) The market surveillance authorities shall make the market surveillance programmes specified in paragraph 1 item 2 of this Article available to the public by way of electronic communication and, where appropriate, by other means.

(3) The Federal States shall ensure that the market surveillance authorities can properly

perform their tasks. They shall equip them with the resources necessary for that purpose. They shall ensure effective cooperation and an efficient exchange of information among their market surveillance authorities as well as between their market surveillance authorities and those of other Member States of the European Union. They shall ensure the development and updating of the surveillance concept and the preparation of measures to prevent serious risk involving two or more Federal States.

(4) The market surveillance authorities shall give the market surveillance authorities of other Member States assistance on the scale necessary for the performance of their tasks. For that purpose they shall supply the necessary information and documentation, carry out appropriate investigations and participate in investigations initiated in other Member States.

Article 26 **Market surveillance measures**

(1) Market surveillance authorities shall perform appropriate checks, on the basis of adequate samples and on an adequate scale, to establish whether the products fulfil the requirements laid down in Chapter 2 or in other legislation providing for the supplementary application of the provisions of this Act pursuant to Article 1 (4). To this end they shall carry out documentary checks and, where appropriate, physical and laboratory checks. For the sample checks according to sentence 1 they shall use 0.5 samples per 1,000 inhabitants and per year as an indicative target for each Federal State; this shall not apply to products where Article 1 (4) provides for the supplementary application of the provisions of this Act. Market surveillance authorities shall take account of established principles of risk assessment, complaints and other information.

(2) Market surveillance authorities shall take appropriate measures when they have reason to suspect that a product does not fulfil the requirements laid down in Chapter 2 or in other legislation providing for the supplementary application of the provisions of this Act pursuant to Article 1 (4). They shall in particular be authorised to

1. prohibit the exhibition of a product which does not fulfil the requirements of Article 3 (5),
2. take measures ensuring that a product is not placed on the market unless it fulfils the requirements of Article 3 (1) or (2),
3. order that a product be checked by a notified body, a GS body or a body that is similarly suited,
4. prohibit a product's being made available on the market or a product's exhibition for the period absolutely needed to carry out such checks,
5. require that appropriate, clear and easy-to-understand information in German about the risks which the product represents be affixed to the product,
6. prohibit that a product is placed on the market,
7. order that a product that was made available on the market be withdrawn or recalled,
8. seize a product, destroy that product or have it destroyed or otherwise rendered unusable,
9. order that the public be warned about the risks posed by a product available on the market; market surveillance authorities may alert the public themselves if the

economic operator fails to alert or alert in time or fails to take a similarly effective measure or fails to take it in time.

(3) The market surveillance authorities shall promptly withdraw or amend any measure referred to in paragraph 2 upon the economic operator's demonstrating that he has taken effective action.

(4) The market surveillance authorities shall order that products presenting a serious risk to the safety and health of persons in particular, be withdrawn or recalled or shall prohibit that such products are placed on the market. The decision whether a product represents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence; the feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

(5) Where the market surveillance authorities decide to withdraw a product manufactured in another Member State of the European Union or in another Contracting Party of the Agreement creating the European Economic Area, it shall inform the economic operator concerned as provided for in Article 19 (3) of Regulation (EC) No 765/2008.

Article 27 **Addressees of market surveillance measures**

(1) The measures of the market surveillance authority shall be addressed to the economic operator or exhibitor concerned. Measures addressed to any other person shall only be permissible when an imminent serious risk cannot be averted otherwise. If that other person suffers damage from such measure he shall receive compensation unless he can obtain compensation otherwise or unless the measure has served to protect his assets.

(2) Prior to the adoption of the measure the person concerned referred to in paragraph 1 shall be heard as provided for in Article 28 of the Administrative Procedure Act, it being understood that the hearing shall take place within a period of not less than ten days. If action has been taken without hearing the person concerned, the person shall be given the opportunity to be heard as soon as possible. The action taken shall be reviewed promptly thereafter.

Article 28 **Access rights and powers**

(1) Market surveillance authorities and the persons commissioned by them are entitled to enter, during business hours, business premises where, in the course of a commercial activity, products are

1. manufactured,
2. used for the first time,
3. stored for the purpose of making them available on the market, or
4. exhibited,

when this is necessary for the purpose of carrying out their surveillance activities. They shall be authorised to visually inspect or test such products, or to have them tested and put into service for this purpose. Market surveillance authorities and the persons commissioned by

them shall also have these visual inspection and testing powers if the products are available for shipment at sea ports. When the controls have revealed that the product does not comply with the requirements set out in Chapter 2, market surveillance authorities shall recover the costs of visual inspections and testing provided for in sentences 2 and 3 from the persons manufacturing the product or importing, storing or exhibiting it for the purpose of making it available on the market.

(2) Market surveillance authorities and the persons commissioned by them may take samples and demand specimens of products and request the documentation and information necessary for carrying out their activities. Samples, specimens, documentation and information shall be made available to them free of charge.

(3) Market surveillance authorities may request the notified bodies and the GS bodies as well as the staff of those bodies responsible for the management and performance of the specialist tasks to provide all information and documentation necessary for carrying out their activities. When they take action in accordance with sentence 1, they shall notify the authorising authority.

(4) Economic operators and exhibitors shall submit to the measures set out in paragraphs 1 and 2 and support the market surveillance authorities and the persons commissioned by them. Economic operators, exhibitors and the staff specified in sentence 1 of paragraph 3 shall be obliged to provide to the market surveillance authorities, upon request, such information as are necessary for carrying out their activities. Persons obliged to provide information may refuse to answer any questions the reply of which would subject them, or one of their relatives specified in Article 383 paragraph 1 items 1 to 3 of the Code of Civil Procedure, to the risk of being prosecuted for a criminal offence or an offence under the Regulatory Offences Act. They shall be informed about their right to refuse information.

Chapter 7 **Information and notification obligations**

Article 29 **Assistance obligation, notification procedure**

(1) Market surveillance authorities and the Federal Institute for Occupational Safety and Health shall assist each other and inform each other about measures taken pursuant to this Act.

(2) Where market surveillance authorities take a measure pursuant to Article 26 (2) to prohibit or restrict a product's being made available on the market, to withdraw it from the market or to recall it, they shall notify the Federal Institute for Occupational Safety and Health of such measure stating the grounds on which it is based. At the same time they shall state whether the reasons which prompted the measure or the effects of the measure reach beyond the territory in which this Act applies.. Where the CE marking has been affixed to the product followed by the identification number of the notified body, the market surveillance authority shall inform the notified body as well as the authorising authority of the measure it has taken. Where the GS mark is affixed to the product, the market surveillance authority shall inform the GS body that has awarded the GS mark as well as the authorising authority of the measure it has taken.

(3) The Federal Institute for Occupational Safety and Health shall review the notifications received pursuant to paragraph 2 sentence 1 under the aspects of completeness and consistency. It shall forward the notifications to the European Commission and the other Member States in cases where the market surveillance authority has stated that the reasons

which prompted the measure or the effects of the measure reach beyond the territory in which this Act applies

(4) The Federal Institute for Occupational Safety and Health shall inform market surveillance authorities and the responsible Federal Ministries of notifications by the European Commission or other Member States of the European Union.

Article 30 **The Rapid Exchange of Information System RAPEX**

(1) When market surveillance authorities take or intend to take measures pursuant to Article 26 (4), they shall inform the Federal Institute for Occupational Safety and Health thereof without delay. At the same time they shall state whether the reasons which prompted the measure or the effects of the measure reach beyond the territory in which this Act applies. They shall also inform the Federal Institute for Occupational Safety and Health without delay of the modification or withdrawal of any such measure.

(2) If a product presenting a serious risk has been made available on the market, the market surveillance authority shall notify the Federal Institute for Occupational Safety and Health of any voluntary measures an economic operator has taken and communicated to the market surveillance authority.

(3) The information provided in accordance with paragraphs 1 and 2 shall include all available details, in particular the data necessary for the identification of the product, the origin and the supply chain of the product, the risk posed by the product, the nature and the duration of the measures taken and any voluntary measures taken by economic operators.

(4) The Federal Institute for Occupational Safety and Health shall review the information received under the aspects of completeness and consistency. It shall forward the notifications without delay to the European Commission and the other Member States in cases where the market surveillance authority has stated that the reasons which prompted the measure or the effects of the measure reach beyond the territory in which this Act applies. For the purposes of such information, the market surveillance and information exchange system provided for in Article 12 of Directive 2001/95/EC shall be used. The Federal Institute for Occupational Safety and Health shall notify the market surveillance authorities and the responsible Ministries of information received through that system.

Article 31 **Publication of information**

The Federal Institute for Occupational Safety and Health shall make public any orders issued pursuant to Article 26 (2) sentence 2 items 6, 7, 8 and 9, or Article 26 (4) which have become unappealable or immediately enforceable. Personal data may only be made public when necessary for the identification of the product. When the conditions for the publication of the personal data are no longer met, the data shall not be made public. Data that were already made public by electronic means shall be deleted without delay where technically feasible.

(2) Market surveillance authorities and the Federal Institute for Occupational Safety and Health shall inform the public, preferably by electronic communication, of any other findings available to them relating to products which present a risk to the health and safety of persons. This shall apply in particular to information for the identification of the products, the

type of risks and the measures taken. Where the information involved the disclosure of business or industrial secrets or competition-relevant details that, in essence, are equivalent to business secrets, the data subjects shall be heard before the information is made public. This publication of personal data shall be permitted only when

1. the data subject has given his consent, or
2. it is indispensable for averting risks to the health and safety of persons and not contrary to legitimate interests of the data subject.

The data subject shall be heard before the information is made public. When the conditions for the publication of the personal data are no longer met, the data shall not be made public. Data that were already made public by electronic means shall be deleted without delay where technically feasible.

(3) Information specified in paragraph 2 shall not be made public where

1. this could affect the confidentiality of consultations of authorities or cause substantial danger to public order and security,
2. it includes data which are the subject of pending legal proceedings, criminal investigative proceedings, disciplinary proceedings or regulatory offence proceedings, or
3. the protection of intellectual property rights, in particular copyright, outweigh the right to information.

(4) The Federal Institute for Occupational Safety and Health may draw public attention to the fact that the data subject has already informed the public of withdrawal or recall actions he initiated.

(5) If it is subsequently found that the information which the market surveillance authorities and the Federal Institute for Occupational Safety and Health passed on to the public is inaccurate or that the underlying circumstances were inaccurately communicated, they shall inform the public without delay in the same way in which they previously communicated such information whenever

1. this is necessary to protect substantial concerns of public interest, or
2. the data subject so requests.

Chapter 8 Special provisions

Article 32

Tasks of the Federal Institute for Occupational Safety and Health

(1) In the framework of its general research mandate the Federal Institute for Occupational Safety and Health shall at an early stage identify and assess safety and health risks posed by the use of products and make proposals for the reduction of such risks.

(2) In individual cases the Federal Institute for Occupational Safety and Health, in consultation with the market surveillance authorities, shall make a risk assessment for products when there is sufficient evidence that they present a direct risk to the health and safety of persons or that they represent a serious risk. It shall communicate without delay the outcome of the assessment to the competent market surveillance authority and, in consultation with that authority, to the economic operator concerned.

(3) In individual cases the Federal Institute for Occupational Safety and Health shall carry out risk assessments of products under its own responsibility where required due to obligations

vis-a-vis the organs of the European Union.

(4) The Federal Institute for Occupational Safety and Health shall support the market surveillance authorities in the development and implementation of the surveillance concept pursuant to Article 25 (1) particularly by scientifically analysing the identified shortcomings in the nature of the product. It shall regularly inform the market surveillance authorities and the Product Safety Commission of the state of findings and publish its findings at the central Product Safety Portal it operates. The provisions on the collection, processing and use of personal data for scientific research purposes shall remain unaffected.

Article 33 Product Safety Commission

(1) A Product Safety Commission shall be set up at the Federal Ministry of Labour and Social Affairs.

(2) The Product Safety Commission shall have the tasks

1. to advise the Federal Government in matters relating to the safety of products,
2. to identify standards and other technical specifications when there is no harmonised standard for a product,
3. to identify the specifications mentioned in Article 21 (1) sentence 1 item 3, and
4. to make recommendations as to whether a product qualifies for the award of the GS mark.

(3) The Commission shall be made up of experts from market surveillance authorities, conformity assessment bodies, statutory accident insurance institutions, the German Institute for Standardisation (DIN), the Commission for Occupational Health and Safety and Standardization (KAN), employers' associations, trade unions and the associations involved, particularly those of manufacturers, distributors and consumers. Membership shall be honorary.

(4) The Federal Ministry of Labour and Social Affairs, in consultation with the Federal Ministry of Food, Agriculture and Consumer Protection and the Federal Ministry of Economics and Technology, shall appoint the members of the Commission and a deputy for each member. The Commission shall adopt its rules of procedure and elect a chairperson from among its members. The Commission shall not have more than 21 members. The rules of procedure and the election of the chairperson shall be subject to the approval of the Federal Ministry of Labour and Social Affairs.

(5) The Federal Ministries and the Federal and Higher State Authorities for Safety and Health and the Environment shall have the right to be represented and heard in the Commission's meetings.

(6) The Commission's business shall be conducted by the Federal Institute for Occupational Safety and Health.

Chapter 9 Installations subject to mandatory inspection

Article 34 **Authorisation to issue ordinances**

(1) To protect employees and third parties from hazards arising from installations that require special inspection due to their hazardous nature (installations subject to mandatory inspection) the Federal Government, after consultation of the stakeholders, shall be authorised to issue ordinances, with the consent of the *Bundesrat*, to determine

1. that the erection of such installations, their operation, any alterations to existing installations and other installation-relevant circumstances shall be notified and that specific documents shall be added to the notification;
2. that the erection of such installations, their operation and any alterations to existing installations shall require the approval of an authority specified in the ordinance or of a competent authority as defined by Federal or State legislation;
3. that, following a type examination, such installations or parts of such installations may be generally approved and that the general approval may be made conditional on requirements concerning operation and maintenance;
4. that such installations and in particular the erection, the production, the design, the materials used, the equipment, the maintenance and the operation shall satisfy specific requirements corresponding to the state of technology;
5. that such installations shall be subject to inspections before being put into operation, to regular in-service inspections and inspections based on official orders.

(2) The ordinances issued pursuant to paragraph 1 may make provision for the establishment of technical committees. The committees shall advise the Federal Government or the competent Federal Ministry in technical matters. They shall propose rules in accordance with the state of technology (technical rules) taking account of existing rules for other protection goals, and in consultation with the Commission on Process Safety established pursuant to Article 51a (1) of the Federal Immission Control Act where its competence is affected. Apart from representatives from the Federal authorities and the higher State authorities concerned, from academia and the approved inspection bodies as defined in Article 37, in particular representatives of employers, trade unions and the statutory accident insurance institutions shall be appointed to these committees.

(3) Technical Rules may be published by the Federal Ministry of Labour and Social Affairs in the Joint Ministerial Gazette.

(4) An approval under an ordinance pursuant to paragraph 1 item 2 shall cease to be valid if the approval holder has failed to start erecting the installation within two years after the date of the approval, has suspended the construction work for two years or has not operated the installation for a period of three years. Upon request the approval authority may extend the time-limits for significant reasons.

Article 35 **Powers of the competent authority**

(1) In individual cases the competent authority may order that the necessary measures be taken to fulfil the obligations imposed by ordinance pursuant to Article 34. It may, in addition, prescribe measures that are necessary in individual cases to avert hazards to employees or third parties.

(2) The competent authority may order the shutdown or removal of an installation that was

constructed, operated or altered without the approval required by ordinance pursuant to Article 34 (1) item 2 or without inspection by an approved inspection body required by ordinance pursuant to Article 34 (1) item 5.

(3) If an order pursuant to paragraph 1 was issued, the competent authority may stop the operation of the respective installation until its condition is such as to satisfy the requirements of the order. The same applies when an order is issued pursuant to other provisions relating to the facility or the workplace in which the installation is operated.

Article 36

Access rights of the commissioner of the approved inspection body

Upon request the owners of installations subject to mandatory inspection and the persons producing or operating such installations shall grant the commissioner of the approved inspection body responsible for the inspection of the installation access to the installation, allow him to carry out the inspection required by law or ordered by the authorities, make available the staff and the tools and appliances needed for this purpose and provide the information and documents required for the performance of his tasks. The fundamental right enshrined in Article 13 of the Basic Law shall be restricted to that extent.

Article 37

Performance of inspections and monitoring, authorisation to issue ordinances

(1) Unless otherwise provided in the ordinances issued pursuant to Article 34 (1) inspections of installations subject to mandatory inspection shall be carried out by approved inspection bodies.

(2) As regards installations subject to mandatory inspection

1. of the Federal Police, the Federal Ministry of the Interior
2. within the jurisdiction of the Federal Ministry of Defence, that Ministry
3. of the Federal Railways where such installations serve rail operations, the Federal Ministry of Transport, Building and Urban Development

shall determine the bodies to perform inspections and monitoring.

(3) In the ordinances pursuant to Article 34 (1) the Federal Government, with the consent of the *Bundesrat*, may lay down requirements which the approved inspection bodies according to paragraph 1 have to satisfy beyond the general requirements for authorisation specified in paragraph 5.

(4) Through ordinances the governments of the Federal States may

1. regulate the details of the procedure for granting authorisation according to paragraph 5,
2. lay down other conditions for granting authorisation to approved inspection bodies according to paragraph 1 where required to ensure the safety of installations, and
3. provide for the registration of installations subject to mandatory inspection in a data base.

The ordinances referred to in sentence 1 may also create obligations for approved inspection bodies

1. to monitor that recurrent inspections provided for in ordinances pursuant to Article 34 (1) including verification that the deficiencies are remedied and information of the competent authority in case of non-compliance are arranged for within the prescribed period,
2. to ensure the nationwide inspection capacities required for the inspection of the installations subject to mandatory inspection,
3. to establish and maintain data bases of installations,
4. to transmit to the competent authority the information it needs to carry out its tasks,
5. to share in the costs of the establishment and maintenance of data bases of installations arising for the bodies running such data bases, and
6. to transmit to the bodies running such data bases the information they need to carry out their tasks.

(5) An approved inspection body shall be any inspection body that the competent State authority designates to the Federal Ministry of Labour and Social Affairs as an inspection body for a specific field and whose designation was communicated by the Ministry in the Joint Ministerial Gazette. The inspection body may be designated when the authorising authority has ascertained that compliance with the following general requirements as well as with the specific requirements laid down in an ordinance pursuant to Article 34 (1) is guaranteed:

1. independence of the inspection body and its staff responsible for the management and performance of the specialist tasks from any persons involved in the design or production, the sale, operation or maintenance of installations subject to mandatory inspection or in other ways dependent on the outcome of the inspection or certification;
2. availability of the organisational structures, the staff and the means and equipment necessary for an adequate independent performance of the tasks;
3. adequate specialist competence, professional integrity and experience as well as technical independence of the staff entrusted with the technical tasks;
4. liability insurance coverage;
5. protection of business and industrial secrets, that became known in the course of the activities of the approved inspection body, against unauthorised disclosure;
6. compliance with the procedures laid down for inspections and the award of certificates:
7. collection and evaluation of the insights gained from inspections and information of the staff through regular exchange of experience;
8. cooperation with other approved inspection bodies for the purpose of sharing insights gained from inspections where this could help to prevent damage.

Without satisfying the requirements of sentence 2 of item 1 inspection bodies of companies or groups of companies may also be designated as approved inspection bodies, in particular for the purpose of implementing acts of the Council or the Commission of the European Union that affect the material scope of this Act, when this is provided for in an ordinance pursuant to Article 34 (1) and when the requirements laid down therein are met.

(6) Authorisation may be granted under specific conditions and may be attached to

requirements. It shall be granted for a limited period of time and reserving the right of withdrawal or imposing subsequent requirements. Award of the authorisation, length of validity, recall, revocation and expiry shall be communicated to the Federal Ministry of Labour and Social Affairs without delay.

(7) The authorising authority shall monitor compliance with the general requirements specified in sentence 2 of paragraph 5 and the specific requirements laid down in Article 34 (1). It may request the approved inspection body as well as its staff responsible for the management and performance of the specialist tasks to provide information and any other support necessary for carrying out their tasks and issue the required orders. The persons entrusted with these tasks shall have the right to enter and inspect the business premises during business hours and to request the presentation of the documentation on which the certifications are based. The parties responsible for providing information shall submit to the activities specified in sentence 3.

(8) The authorities responsible for the implementation of the ordinances issued pursuant to Article 34 (1) may request the approved inspection bodies and the staff of those bodies responsible for the management and performance of the specialist tasks to provide information and any other support necessary for carrying out their tasks and issue the required orders. The persons entrusted with these tasks shall have the right to enter and inspect the property and the business premises during business hours and to request the presentation and the transmission of the documentation on which the certifications are based. They shall inform the authorising authority when taking action pursuant to sentences 1 and 2.

Article 38 Supervisory authorities

(1) The competent authorities under the law of the respective Federal State shall be responsible for supervising the implementation of the ordinances issued pursuant to Article 34 (1). Article 22 (1) and (2) and Article 23 (2) of the Act on Safety and Health at Work shall apply accordingly

(2) The supervision of installations subject to inspection by the federal administration may be delegated by ordinance pursuant to Article 34 (1) to the Federal Ministry of the Interior or another Federal Ministry for several operative areas of the federal administration; the Federal Ministry may delegate supervision to a body designated by it. Article 48 of the Federal Waterways Act and Article 4 of the Federal Trunk Roads Act shall remain unaffected.

Chapter 10 Provisions on penalties and regulatory fines

Article 39 Provisions on regulatory fines

- (1) A person is committing a regulatory offence when he, intentionally or by negligence,
1. fails to provide information or fails to provide it accurately, completely or in due time, thus violating Article 3 (3),
 2. fails to supply the instructions for use or fails to supply them accurately, completely, in the prescribed manner or in due time, thus violating Article 3 (4),

3. fails to affix a name or a contact address, fails to affix it accurately, completely and in due time, thus violating Article 6 (1) sentence 1 item 2,
4. fails to inform the competent market surveillance authority or fails to inform it accurately, completely or in due time, thus violating the Article 6 (4) sentence 1,
5. affixes a marking, symbol or inscription to a product, thus violating the provisions of Article 7 (1) in conjunction with Article 30 (5) sentence 1 of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 of the Council (OJ L 218 of 13 August 2008, p. 30),
6. places a product on the market in violation of Article 7 (2),
7. contravenes an ordinance pursuant to
 - a) Article (8) (1) sentence 2 item 1 or item 3 or Article 34 (1) item (2), (4) or (5), or
 - b) Article 8 (1) sentence 2 item 2 or Article 34 (1) item 1or an enforceable order based on any of these ordinances where such ordinance refers to these provisions on regulatory fines for a specific fact,
8. contravenes an enforceable order pursuant to
 - a) Article 11 (1) sentence 1 or 2, Article 26 (2) sentence 2 item 1 or item 3 or Article 37 (7) sentence 2, or
 - b) Article 26 (2) sentence 2 items 2, 4, 6 to 8 or item 9 or Article 26 (4) sentence 1,
9. applies a mark specified in Article 22 (2) sentence 2 or Article 22 (4) or uses it as a selling point, thus violating those provisions,
10. does not comply with a rule set out in the Annex in items 1, 2, 3, 4, 7, 8 sentence 1, item 9 sentence 2 or sentence 3 or item 10, thus violating the provisions of Article 22 (3),
11. fails to document a verification, fails to document it accurately, completely or in time, thus violating Article 22 (5) sentence 2,
12. fails to submit to a measure or to support a market surveillance authority or a person commissioned by it, thus violating Article 28 (4) sentence 1,
13. fails to provide information, fails to provide it accurately, completely or in time, thus violating Article 28 (4) sentence 2,
14. fails to grant access to an installation or to grant it in time, fails to allow an inspection, fails to make available staff or tools and appliances at all or in time, fails to provide information or fails to provide it accurately, completely or in time or fails to provide a document or to provide it in time, thus violating Article 36 sentence 1,
15. fails to submit to a measure, thus violating Article 38 (1) sentence 2 in conjunction with Article 22 (2) sentence 6 of the Act on Safety and Health at Work,
16. contravenes a directly applicable provision of an act of the European Community or the European Union which in substance amounts to a requirement or prohibition as set out in

- a) item 8 (b), or
- b) items 1 to 6, 8 (a) or items 11 to 13

where an ordinance pursuant to paragraph 3 refers to this provision on regulatory fines for a specific fact, or

17. contravenes a directly applicable provision of an act of the European Community or the European Union or an enforceable order based on such a provision which in substance amounts to a regulation authorised by the provisions set out in

- a) item 7 (a), or
- b) item 7 (b)

where an ordinance pursuant to paragraph 3 refers to this provision on regulatory fines for a specific fact.

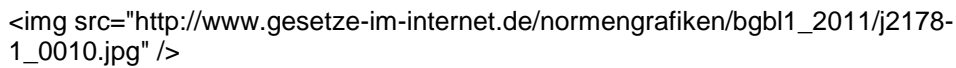
(2) A regulatory offence in the cases of paragraph 1 item 7 (a) item 8 (b), item 9, item 16 (a) and item 17 (a) may be punished with a fine of up to one hundred thousand Euro, in all other cases with a fine of up to ten thousand Euro.

(3) Where necessary for the implementation of acts of the European Community or the European Union the Federal Government shall have the power to specify by ordinance not requiring the consent of the *Bundesrat* the facts and events that may be punished as regulatory offences under paragraph 1 items 16 and 17.

Article 40 Provisions on penalties

A person who persistently repeats an intentional act specified in Article 39 (1) item 7 (a), item 8 (b), item 9, item 16 (a) or item 17 (a) or who, by such an intentional act, puts at risk the life or health of a third person or third-party property of substantial value shall be punished by a term of imprisonment of up to one year or by a fine.

Annex Design of the GS mark

1. The GS mark shall consist of the labelling and the frame.
2. The width of the frame shall be equal to one third of a grid interval.
3. The words "geprüfte Sicherheit" (tested safety) shall be set in font Arial and in bold and italic type, with 0.3 cm grid spacing and typeface 25 pt.


4. If the GS mark is reduced or enlarged, the proportion given in the grid drawing above shall be respected.
5. The grid shall only serve to determine proportions; it shall not be part of the GS mark.
6. For the design of the GS mark both dark letters on light background and light letters on dark background shall be permissible.

7. The GS mark shall be combined with the symbol of the GS body. The symbol of the GS body shall replace the word "Id-Zeichen" (identification symbol) in the above drawing. It shall permit a clear identification of the GS body and not allow confusion with other GS bodies.

8. The symbol of the GS body shall be anchored in the upper left corner of the GS mark. It may slightly extend beyond the outer border of the GS mark if necessary for space limitations unless the overall image of the GS mark is distorted.

9. When the GS mark is reproduced with a height of 2 cm or less, it shall be permissible to place the symbol of the GS body on the left of the GS mark. In this case, however, the symbol of the GS body shall touch the GS mark so that the unity of the safety sign is preserved. Moreover, the symbol of the GS body shall not be bigger than the GS mark so as not to dominate.

10. No other graphics and labelling shall be connected to the GS mark when these would distract from the nature or substance of the GS mark.