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Act on Making Products Available on the Market (Produktsicherheitsgesetz – ProdSG)*

Product Safety Act as of 27 July 2021 (Federal Law Gazette I p. 3146, 3147), as last amended by Article 2 of the Act of 27 July 2021 (Federal Law Gazette I p. 3146)

*This Act implements

1. 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), as last amended by Directive (EU) No. 2016/2037 (OJ L 314 of 22 November 2016, p. 11),
2. 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 12 December 2000, p. 50) as last amended by Regulation (EU) No. 2019/1243 (OJ L 198 of 25 July 2019, p. 241),
3. 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), as last amended by Regulation (EC) No. 596/2009 (OJ L 188 of 18 July 2009, p. 14),
4. 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 last amended by Directive Council Regulation(EU) 2019/EC (OJ L 198 of 25 July 2019, p. 241),
5. 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),
6. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on toys (OJ L 170 of 30 June 2009, p. 1, L 355 of 31 December 2013, p. 92), as last amended by Directive (EU) 2019/1929 (OJ L 299 of 20 November 2019, p. 51),
7. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354 of 28 December 2013, p. 90; L 297 of 13 November 2015, p. 9),
8. Directive 2014/29/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 the making available on the market of simple pressure vessels (OJ L 96 of 29 March 2014, p. 45),

9. 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 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),
10. Directive 2014/35/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 electrical equipment designed for use within certain voltage limits market (OJ L 96 of 29 March 2014, p. 357),
11. Directive 2014/33/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 lifts and safety components for lifts (OJ L 96 of 29 March 2014, p. 251),
12. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 189 of 27 June 2014, p. 164; L 157 of 23 June 2015, p. 112).

Division 1 General Provisions

Section 1 Scope of application

- (1) This Act is to be applied 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 is not applicable to
 1. antiquities,
 2. used products which have to be repaired or reconditioned before use, provided the economic operator adequately informs the persons to whom he supplies the used products thereof,
 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 2 No. 1 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Directives 90/385/EEC and 93/42/EEC of the Council (OJ L 117 of 5 May 2017 p. 1; L 117 of 3 May 2019, p.9; L 334 of 27 December 2019, p. 165) which was amended by Regulation (EU) 2020/561 (OJ L 130 of 24 April 2020, p. 18), as amended and within the meaning of section Article 2 No. 2 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176; L 117, 3.5.2019, p. 11; L 334, 27.12.2019, p. 167), as amended,
 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 (1) of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 on bringing into circulation plant protection products and repealing Directives 79/117/EEC and 91/414/EEC of the Council (OJ L 309 of 24 November 2009, p. 1, L 45 of 18 February 2020, p. 81), as last amended by Council Regulation(EU) 2019/1009 (OJ L 170 of 25 June 2019, p. 1).
- (3) The provisions of this Act are not to be applied insofar
 1. as there are special provisions in other legislation on the products covered by this Act and

2. this other legislation regulates more specifically certain aspects of making available on the market.
- (4) This Act applies also in the exclusive economic zone within the limits of the Maritime Labour Convention of the United Nations of 10 December 1982 (Federal Law Gazette 1994 II p. 1799).

Section 2

Definitions

Within the meaning of this Act

1. "accreditation" means 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. "exhibition" means exhibiting or presenting products for marketing purposes,
3. "exhibitor" means any natural or legal person exhibiting a product,
4. "making available on the Union market" means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge,
5. "intended use" means
 - a) the use for which a product is intended according to the information by the person placing it on the market, or
 - b) the usual use that results from the design and construction of the product,
6. "authorised representative" means any natural or legal person based in the European Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks to comply with the relevant harmonisation legislation of the European Union or the requirements of this Act,
7. "CE marking" means a marking by which the manufacturer declares 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" means any natural or legal person based in the European Union who imports a product,
9. "import" means the first-time making available of a product from a third country on the Union market, treating used products as new products,
10. "serious risk" means that the product entails a risk where the relation between the likelihood of a hazard that may occur and the severity of the damage on the basis of the risk assessment and under consideration of the normal and foreseeable use of the product requires rapid intervention by the market surveillance authorities even if the risk has no immediate consequences,
11. "fulfilment service provider" means any natural or legal person offering at least two of the following services in the framework of their business activities: storage, packaging, labelling and dispatching of products not owned by the natural or legal person, with the exception of postal services within the meaning of Article 2 no.1 of Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of service (OJ L 15 of 21 January 1998, p. 14; L 23 of 30 January 1998, p. 39), as last amended by Directive 2008/6/EC (OJ L 52 of 27 February 2008, p. 3), parcel delivery services within the meaning of Article 2 no.2 of Regulation (EU) 2018/644 of the European Parliament and of the Council of 18 April 2018 on cross-border parcel delivery services (OJ L 112 of 2 May 2018, p. 19) and any other postal services or freight transport services,
12. "GS body" means a conformity assessment body which has been authorised by the authorising authority to award the GS mark,

13. “distributor” means any natural or legal person in the supply chain who makes a product available on the market, with the exception of the manufacturer and the importer,

14. “harmonised standard” means a standard within the meaning of Article 2 No. 1 subparagraph c of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316 of 14 November 2012, p. 12) which has been amended by Directive (EU) 2015/1535 (OJ L 241 of 17 September 2015, p.1),

15. “manufacturer” means any natural or legal person who manufactures or develops a product or has it manufactured and markets this product in his own name or under his own trademark; a manufacturer is also deemed any person, who for business purposes, affixes his name, his trademark or another differentiating mark to a product thus acting as if he was the manufacturer, or who reconditions a product or influences the safety properties of a consumer product and subsequently makes this product available on the market,

16. “placing on the market” means the first making available of a product on the Union market,

17. “conformity assessment” means the procedure for assessing whether specific requirements for a product, a procedure, a service, a system, a person or a body have been complied with,

18. “conformity assessment body” means a body carrying out conformity assessment activities including calibration, testing, certification and inspection,

19. “notified body” means a conformity assessment body which has been authorised by the authorising authority to carry out conformity assessment tasks in accordance with the statutory instruments referred to in section 8 (1) that have been issued to enforce or implement European Union legislation and has been notified by the authorising authority to the European Commission and the other Member States of the European Union or has been notified as notified body to the European Commission and the other Member States of the European Union by a Member State of the European Union or another state party to the Agreement on the European Economic Area on the basis of a European legal act;

20. “notification” means any communication by the authorising authority to the European Commission and the other Member States of the European Union stating that a conformity assessment body may carry out conformity assessment tasks in accordance with the statutory instruments as referred to in section 8 (1) issued to enforce or implement EU legislation,

21. “product” means a good, a substance or a mixture manufactured in a manufacturing process,

22. “risk” means the combination of the likelihood of a hazard and the severity of the potential damage,

23. “withdrawal from the market” means any measure aimed at preventing that a product which is part of the supply chain from being made available on the Union market,

24. “recall” means any measure aiming at the return of a product that has already been made available to the end user,

25. “consumer product” means a new, used or reconditioned product that is intended for consumers or can be used by consumers under conditions which are reasonably foreseeable, even if it is not intended for them; a consumer product also means a product made available to the consumer in the framework of a service,

26. “ready for use” means a product can be used as intended without the insertion of additional parts; a product is also ready for use

- a) all parts from which it is to be assembled, are placed on the market by a single person,
 - b) if it only needs to be mounted or plugged in, or
 - c) it is placed on the market without the parts that are usually procured separately and inserted for the intended use,
27. “foreseeable use” means the use of a product in a manner that the person placing it on the market has not intended, but which is reasonably foreseeable,
28. “economic operator” means the manufacturer, authorised representative, importer, distributor, fulfilment service provider or any other natural or legal person who is subject to obligations in connection with the manufacturing of products, their being made available on the market or their taking into operation in accordance with the relevant legal provisions.

Division 2

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

Section 3

General requirements for making products available on the market

- (1) Where a product is subject to one or more statutory instruments pursuant to section 8 (1), it may only be made available on the market if it
- 1. complies with the requirements laid down in the statutory instruments and
 - 2. does not put the safety and health of persons or other legal goods listed in the statutory instruments pursuant to section 8 (1) at risk as long as these legal goods are used as intended or foreseeable.
- (2) A product may only be made available on the market unless it is subject to paragraph 1 if it does not put the safety and health of persons at risk when used as intended or foreseeable. In order to assess whether a product complies with the requirement pursuant to sentence 1, the following aspects are to be taken into account in particular:
- 1. the properties 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 possibility of achieving a higher level of safety or the availability of other products presenting a lower risk does not constitute sufficient grounds for considering a product to be dangerous.
- (3) If the protection of safety and health of persons 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 statutory instruments pursuant to section 8 provide otherwise.
- (4) Where specific rules have to be complied with when using, supplementing or maintaining a product in order to ensure the safety and health of persons, German language instructions for use and operation of the product are to be supplied with the product when making it available on the market, provided the statutory instruments pursuant to section 8 do not provide for other provisions.
- (5) A product which does not comply with the requirements under paragraph 1 or paragraph 2, may be exhibited only if the exhibitor clearly indicates that it does not comply with the requirements and cannot be acquired before compliance is reached. When a product is presented, the necessary precautions for the protection of the safety and health of persons are to be taken.

Section 4 **Harmonised standards**

- (1) Harmonised standards may be used to assess compliance of a product with the requirements under section 3 (1) or (2).
- (2) A product complying with harmonised standards or parts thereof and whose references have been published in the Official Journal of the European Union, are presumed to comply with the requirements under section 3 (1) or (2) insofar as these requirements are covered by the corresponding standards or parts thereof.
- (3) If the market surveillance authority considers that a harmonised standard does not fully cover the requirements under section 3 (1) or (2), it informs the Federal Institute for Occupational Safety and Health accordingly, stating its reasons. The Federal Institute for Occupational Safety and Health checks the notifications received under the aspects of completeness and consistency and informs the Product Safety Commission. It forwards notifications to the responsible Federal Ministry that is to transfer them to the European Commission.

Section 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 section 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, are presumed to comply with the requirements under section 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 section 3 (2), it informs the Federal Institute for Occupational Safety and Health accordingly, stating its reasons. It informs the Product Safety Commission which reviews the identification of the standard or the technical specification. If the standard or the technical specification does not or not fully cover the requirements under section 3 (1), the publication of the standard or of the technical specification will be restricted or reversed.

Section 6 **Additional requirements for making consumer products available on the market**

- (1) When making a consumer product available on the market, the manufacturer, his authorised representative and the importer have the following obligations in the framework of their respective business activities:

1. that the consumer receives the information he or she 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 and where such risks are not immediately obvious without adequate information,
2. to ensure that the names and contact address of the manufacturer or, if he is not based in the European Economic Area, the names 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 nos. 2 and 3 are to be affixed to the consumer product or, where this is not possible, to its packaging. Exemptions from the obligations pursuant to sentence 1 nos. 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 have to 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 may extend to the withdrawal of the product, adequate and effective warnings and recall.

(3) In the framework of their respective business activities, the manufacturer, his authorised representative and the importer have the following obligations regarding the consumer products made available on the market

1. to carry out sample testing,
2. to review complaints and, if necessary, keep a complaints book 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 depends 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 must in accordance with Annex I of 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) as amended by Regulation (EC) No. 596/2009 (OJ L 188 of 18 July 2009, p. 14), immediately inform the competent market surveillance authority at the place of their registered office 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 have to in particular inform the market surveillance authority about the measures they have taken to prevent such risk. The market surveillance authority immediately informs the Federal Institute for Occupational Safety and Health about the facts, in particular in the event of recalls. Information pursuant to sentence 1 may not be used for criminal proceedings against the informant or for the purpose of starting proceedings against the informant pursuant to the Act on Regulatory Offences (Gesetz über Ordnungswidrigkeiten).

(5) The distributor has to contribute to making only safe consumer products available on the market. In particular he may 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 section 3. Paragraph 4 applies to the distributor accordingly.

(6) The fulfilment service provider has to contribute to making only safe consumer products available on the market. In particular he may not pass on any consumer product 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 section 3. Paragraph 4 applies to fulfilment service providers accordingly.

Section 7

CE marking

(1) For the CE marking 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 on the provisions for the accreditation and repealing Regulation (EEC) No 339/93 of the Council (OJ L 218 of 13 August 2008, p. 30), as last amended by Council Regulation (EU) 2019/1020 (OJ L 169 of 25 June 2019, p. 1) apply.

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

1. if the product, its packaging or accompanying documentation are CE marked, but the CE marking is not provided for in the statutory instruments referred to in section 8 (1) or in other legal provisions, or the requirements under paragraphs 3 to 5 are not met, or
2. the product does not bear a CE marking although a statutory instrument referred to in section 8 (1) or any other legal provision requires its affixing.

(3) Unless a statutory instrument referred to in section 8 (1) or any other legal provision requires otherwise, the CE marking must be affixed visibly, legibly and indelibly to the product or to its type plate. If the type of product does not permit or justify this, the CE marking is to be affixed to the packaging and the documents accompanying the product, if such documents are mandatory.

(4) The CE marking is followed by the identification number of the notified body pursuant to section 2 number 19 provided this body was involved in the production control phase. The identification number is to be affixed by the notified body itself or, under its instructions, by the manufacturer or his authorised representative.

(5) The CE marking has to 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 symbol indicating a special risk or a use.

Section 8

Authorisation to issue statutory instruments

(1) The Federal Ministry of the Interior, Building and Community, the Federal Ministry for Economic Affairs and Energy, the Federal Ministry of Labour and Social Affairs, the Federal Ministry of Defence, the Federal Ministry of Food and Agriculture, the Federal Ministry for Transport and Digital Infrastructure, the Federal Minister for the Environment, Nature Conservation and Nuclear Safety are authorised for their respective sphere of competence and after consent by the other, aforementioned federal ministries to issue statutory instruments. Statutory instruments under sentence 1 require a hearing of the Product Safety Commission and the consent of the Bundesrat. Statutory instruments under sentence 1 may be issued 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, in particular also with the purpose to implement obligations arising from bilateral agreements or to enforce or implement legal provisions enacted by the European Union. These statutory instruments can regulate the following:

1. Requirements for
 - a) the nature of products,
 - b) making products available on the market,
 - c) exhibiting products,
 - d) the first-time use of products,
 - e) the labelling of products,
 - f) conformity assessment bodies,
2. product-related safekeeping and information obligations and
3. obligations requiring action by conformity assessment bodies.

Statutory instruments may also govern official measures and competences related to sentence 3 nos. 1 to 3 which are necessary to enforce or implement legal acts enacted by the European Union.

(2) The Federal Government is authorised, with the consent of the Bundesrat, to regulate by statutory instrument the restrictions and prohibition of making products available, which present a high risk to the safety or health of persons, animals, plants, soil, water, the atmosphere or significant property.

(3) The Federal Government is authorised, with the consent of the Bundesrat, to provide by statutory instrument for specific product groups that a body taking care of the conformity assessment or the assessment and review of the constancy of performance of products, has to present an accreditation certificate issued by the national accreditation body to furnish evidence that it is compliant with the legal requirements addressed to them. A statutory instrument pursuant to sentence 1 may also require to transfer the monitoring of the activities of these bodies to the national accreditation body of the Federal Republic of Germany (Deutsche Akkreditierungsstelle) for specific product groups. If the Federal Government has

not issued a statutory instrument pursuant to sentence 1, the Land governments are authorised to issue such a statutory instrument.

(4) In urgent cases, statutory instruments referred to in paragraph 1, 2 or 3, 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 expire at the latest six months after their entry into force. Their validity may only be extended with the consent of the Bundesrat.

Division 3

Regulations governing the authorising authority

Section 9

Tasks of the authorising authority

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

(2) The authorising authority carries out the notification of conformity assessment bodies to which it has issued an authorisation.

(3) The authorising authority monitors 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 gives the necessary instructions for action on deficiencies found or for the prevention of future non-compliance.

(4) On request, the authorising authority gives the responsible market surveillance authority the information it needs to carry out its tasks. This includes in particular the decisions by the authorising authority and other information that impacts the performance of the conformity assessment procedures.

Section 10

Requirements relating to the authorising authority

(1) The Länder have to establish the authorising authority in such a way that there is no conflict of interest with the conformity assessment bodies; in particular the authorising authority may not offer or provide any activities carried out by conformity assessment bodies or 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, may not be entrusted with the decision regarding the issuing of an authorisation to act as a conformity assessment body.

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

Section 11

Powers of the authorising authority

(1) The authorising authority may require the conformity assessment bodies to which it has authorised the performance of certain conformity assessment activities to provide the information necessary to carry out their monitoring tasks, including the release of personal data to the extent necessary to verify the competence of the body, and other support, as well as making the necessary arrangements. The authorising authority is specifically entitled to request the documentation on which the conformity assessment is based. The personal data include first name, last name, address, professional qualifications, completed continued education and training courses and previous career positions. The personal data collected by the authorising authority have to be deleted as soon as they are no longer required, at the latest three years after expiry of the authorisation. Exceptions to this are first name, last

name and address which have to be deleted after ten years. Section 75 (4) of the Federal Data Protection Act remains unaffected.

(2) When issuing the authorisation and at regular intervals, the authorising authority may require the management, the top level management and the staff responsible for the conformity assessment activities to present a German certificate of conduct (Führungszeugnis) pursuant to section 30 (5) of the Federal Central Criminal Register Act (Bundeszentralregistergesetz) insofar as this is necessary to verify the reliability of the body. From the data which the authorising authority was allowed to consult according to sentence 1 it may only record that it consulted the document, the date of issue of the certificate of conduct and the information whether the person to which the check relates has been legally convicted of a relevant criminal offence pursuant to sections 202a to 202d, 263, 264, 266, 267 to 269, 271, 274, 298 and 299 of the German Criminal Code (Strafgesetzbuch). The authorising authority may only use the collected data if this is necessary to exclude persons from the conformity assessment which was the reason for consulting the certificate of conduct. Technical and organisational measures have to ensure that unauthorised persons cannot access these data. The data are to be deleted without delay if no conformity assessment is carried out following the consultation of the document. In all other cases the data are to be deleted three months after the end of such an activity at the latest. Section 75 (4) of the Federal Data Protection Act remains unaffected.

(3) The authorising authority and the persons commissioned by it are authorised 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.

(4) The parties obliged to provide information have to tolerate the measures referred to in paragraphs 1 to 3. They may refuse to answer any questions, the reply of which would subject them or one of their relatives as defined in section 383 (1) nos. 1 to 3 of the Code of Civil Procedure (Zivilprozessordnung), to the risk of being prosecuted for a criminal offence or under the Administrative Offences Act. They are to be informed about their right to refuse information.

Division 4 **Notification of conformity assessment bodies**

Section 12 **Applications for notification**

(1) A conformity assessment body may apply to the authorising authority for authorisation to act as a notified body.

(2) The application referred to in paragraph 1 is accompanied by the following:

1. a description of the conformity assessment activities, the conformity assessment procedure and the products for which it claims to be competent, and
2. an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down section 13.

(3) Where the conformity assessment body concerned cannot provide an accreditation certificate, it provides 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.

Section 13 **Requirements for the notification of the conformity assessment body**

(1) The conformity assessment body must possess legal personality. It must 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 has to 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 which is a member of a business association or

professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses. The prerequisite for this is that the conformity assessment body demonstrates 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 may not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintenance company of the products they assess, nor the authorised representative of any of those parties. This does not preclude the use of assessed products that are necessary for the activities 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 may 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 may not engage in any activity that may conflict with their independence of judgement or their integrity in relation to their conformity assessment activities. This applies in particular to consultancy services. The conformity assessment body ensures that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of their conformity assessment activities.

(4) The conformity assessment body and its staff have to carry out the conformity assessment activities with the highest degree of professionalism and the requisite technical competence in the specific field. They must be free from any influence, particularly financial, exerted by third parties, which could have an impact on their judgement or the results of the conformity assessment activities, which specifically emanates from persons or groups of persons having an interest in the result of that conformity assessment.

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

1. the necessary number of staff with technical knowledge and sufficient and relevant 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 must 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 must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner. It must have access to all necessary equipment or facilities.

(6) The conformity assessment body ensures 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 section 12,
2. have sufficient knowledge of the products and the conformity assessment procedure and have the corresponding authority to carry out such conformity assessments,

3. have appropriate knowledge and understanding of the essential requirements of the applicable harmonised standards and the relevant provisions of the harmonisation legislation of the European Union and its implementing regulations, and
4. have the ability to prepare certificates, minutes and reports as evidence for conformity assessments performed.

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

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

(9) The staff of the conformity assessment body may 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 remain unaffected.

Section 14

Presumption of conformity

(1) Where a conformity assessment body demonstrates, by means of accreditation, that it complies with the criteria laid down in the relevant harmonised standards the references of which have been published in the Official Journal of the European Union, or parts thereof, it is presumed to comply with the requirements referred to in section 13 to the extent that the applicable harmonised standards cover those requirements.

(2) If the authorising authority considers that a harmonised standard does not fully correspond to the requirements referred to in section 13, it informs the Federal Institute for Safety and Health accordingly, stating its reasons. The Federal Institute for Occupational Safety and Health reviews the information received under the aspects of completeness and consistency and informs the Product Safety Commission. It forwards the notifications to the responsible Federal Ministry for transmission to the European Commission.

Section 15

Granting of authorisation, notification procedure

(1) Where the authorising authority has established that a conformity assessment body complies with the requirements referred to in section 13, it authorises the conformity assessment body to carry out conformity assessment tasks according to the statutory instruments referred to in section 8 (1) issued in order to enforce or implement European Union legislation. Subsequently, the authorising authority notifies the conformity assessment body using the electronic notification tool developed and managed by the European Commission.

(2) The authorisation is to be issued under the condition that following the notification neither the European Commission nor the other European Union Member States raise objections within the following period:

1. within two weeks of notification where an accreditation certificate referred to in section 12 (2) has been submitted, or
2. within two months after notification where no accreditation certificate referred to in section 12 (2) has been submitted.

The authorisation may be issued subject to further prerequisites and may be subject to requirements. It can be issued for a limited period and subject to revocation and to subsequent requirements.

(3) Where attestation of competence is not based on an accreditation certificate referred to in section 12 (2), the authorising authority provides the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's

competence. It furthermore submits the agreements in place entered into in order to ensure that the conformity assessment body will be monitored regularly and will continue to satisfy the requirements laid down in section 13.

(4) The authorising authority notifies the European Commission and the other Member States of any subsequent changes to the notification.

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

Section 16

Obligations of the notified body

(1) The notified body performs the conformity assessment in line with the conformity assessment procedure pursuant to the statutory instruments referred to in section 8 (1) and with due regard for proportionality.

(2) Where the notified body ascertains that the requirements laid down in statutory instruments referred to in section 8 (1) have not been met by a manufacturer, it requires the manufacturer to take appropriate corrective measures and does not issue a conformity certificate.

(3) Where the notified body has already issued a certificate of conformity and finds, in the course of the monitoring of conformity, that the product no longer meets the requirements, it requires the manufacturer to take appropriate corrective measures; if necessary, it suspends or withdraws the certificate of conformity.

(4) Where corrective measures are not taken or do not suffice to ensure compliance with the requirements, the notified body restricts, suspends or withdraws all corresponding conformity certificates.

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

Section 17

Reporting obligations of the notified body

(1) The notified body notifies the authorising authority of

1. any refusal, restriction, suspension or withdrawal of a conformity certificate,
2. any circumstances that have an impact on the authorisation issued to the notified body referred to in section 15 (1),
3. any request for information which it has received from market surveillance authorities regarding conformity assessment activities,
4. on request, any conformity assessment activities and any other activities it performed, including cross-border activities and subcontracting.

(2) The notified body provides the other notifying bodies notified under the relevant harmonisation legislation of the European Union carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Section 18

Subsidiaries of a notified body and subcontracting

(1) Where a notified body subcontracts specific tasks related to conformity assessment or transfers these tasks to a subsidiary, it has to ensure that the subcontractor or subsidiary meets the requirements referred to in section 13 and informs the authorising authority accordingly.

(2) The notified body takes full responsibility for the work carried out by the subcontractors or subsidiaries wherever they are based.

(3) Work may be subcontracted or carried out by a subsidiary only with the consent of the client.

(4) The notified body keeps at the disposal of the authorising authority the relevant documentation concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by him in accordance with the statutory instruments referred to in section 8 (1).

Section 19

Revocation of authorisation issued

(1) Where the authorising authority has ascertained or has been informed that a notified body no longer meets the requirements referred to in section 13 or that it is failing to fulfil its obligations, it withdraws, in whole or in part, the authorisation granted. It immediately informs the European Commission and the other Member States thereof.

(2) In the event of a revocation pursuant to paragraph 1 or where the notified body has ceased its activity, the authorising authority takes appropriate measures 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.

Division 5

GS mark

Section 20

Award of the GS mark

(1) A ready-for-use and suitable 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. Insofar as the manufacturer is not based in the European Union or in the European Free Trade Area or has no summonable address in the European Union or in the European Free Trade Area, an authorised representative has to file the application.

(2) A ready-for-use product bearing the CE marking may not additionally bear the GS mark if the prerequisites for the CE marking are at least equivalent to those required for the award of the GS mark referred to in paragraph 3.

(3) The GS body may only award the GS mark to the manufacturer if

1. the type tested complies with the requirements referred to in section 3,
2. the type tested complies with the requirements of other legislation regarding the protection of safety and health of persons,
3. in the award procedure, it has applied the specification which the Product Safety Commission has identified for the award of the GS mark,
4. it has found during an inspection on the ground that the production facilities fulfil the requirements that products can be manufactured in accordance with the type tested and
5. it has concluded agreements with the manufacturer or authorised representative, which ensure that an inspection of the manufactured products is possible during the ongoing manufacturing process to ensure that the manufactured products can be checked for compliance during production.

(4) The GS body has to document that the requirements set out in paragraph 3 are met.

(5) The GS body has to issue a certificate on the award of the GS mark. The award has to be limited to a maximum validity of five years or has to be limited to a specific production quota or batch.

Section 21

Authorisation to act as a GS body

(1) A conformity assessment body which is based within the scope of application of this Act may apply to the authorising authority for authorisation to act as GS body for specific tasks. The procedure for examining the application may be handled by a single body in accordance with the provisions of the Administrative Procedure Act (Verwaltungsverfahrensgesetz) and

must be completed within six months. The period for the procedure commences upon receipt of the complete documents. The authorising authority may extend this period once by not more than three months. The reasons for extension of the period are to be given and the new period communicated to the applicant in due time.

(2) The authorising authority may only issue the authorisation to act as a GS body to such conformity assessment bodies which meet the requirements of section 13 and the specifications of section 23. Section 19 (1) sentence 1 and sentence 2 apply accordingly.

(3) The authorisation may be issued under conditions and may be made conditional on special requirements. It may be granted for a limited period of time and reserving the right of revocation or imposing subsequent requirements.

(4) The authorising authority notifies the GS bodies to the Federal Institute for Occupational Safety and Health. The Federal Institute for Occupational Safety and Health publishes the list of GS bodies on its website.

(5) A conformity assessment body based in another Member State of the European Union or of the European Free Trade Area may also be designated by the authorising authority as a GS body for specific tasks and notified as such to the Federal Institute for Occupational Safety and Health. This notification requires 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 of the European Free Trade Area and that

2. it was established in the procedure for the award of an authorisation that the requirements for the administrative agreement have been fulfilled pursuant to no. 1.

The administrative agreement referred to in sentence 2 no. 1 has to specify

1. the requirements for the GS body in accordance with paragraph 2 and section 22 (1) to (6),

2. the involvement of the authorising authority in the procedure for the award of an authorisation which is carried out in the respective Member State of the European Union or of the European Free Trade Area and

3. that monitoring of the GS body is carried out in accordance with the principles referred to in section 9 (3).

Section 22

Obligations of the GS bodies

(1) The GS body has to publish a list of all certificates issued regarding the award of the GS mark. To this end, every certificate has to include all the data required to clearly identify the respective product bearing the GS mark. The GS bodies should also publish suitable illustrations thereto.

(2) If the GS body becomes aware that a product bears its GS mark without valid award it takes the necessary measures. It immediately notifies the other GS bodies and the authorising authority of the abuse of the GS mark.

(3) If the GS body has information about cases of abuse of the GS mark it makes them available to the Federal Institute for Occupational Safety and Health by electronic communication. The Federal Institute for Occupational Safety and Health publishes this information on its website.

(4) In order to demonstrate that products bearing the GS mark are in conformity with the tested type, the GS body must carry out regular checks from the start of manufacturing the product. The checks include, for example, periodic inspections of the production or withdrawal of products from manufacturing, from the market or from a warehouse.

(5) If such documentary proof as referred to in paragraph 4 cannot be furnished, or if it can be proven that the prerequisites for the award of the GS mark pursuant to section 20 (3) are no longer fulfilled, the GS body has to withdraw the awarded GS mark.

(6) The GS body informs the other GS bodies and the authorising authority about the withdrawal of an awarded GS mark.

(7) The GS body can suspend the award of the GS mark if there are reasonable doubts as to the lawfulness of the award of the GS mark.

(8) If the award of a GS mark has been suspended, or if the GS mark for a product has been withdrawn and if the manufacturer has been awarded further GS marks, the lawfulness of the use of the GS mark has to be directly reviewed.

(9) The GS body has to participate in the periodic exchange of experience circles and has to ensure that its conformity assessment staff are informed of the results. It has to participate in the drafting of the GS specifications relevant for it, and it also has to contribute to other publications and it has to ensure that these decisions and documents are applied.

Section 23

Involvement of external bodies

(1) The GS body may subcontract certain tasks related to the award of the GS body to external bodies. These bodies have to comply with the requirements in section 13. The following tasks may only be performed by the GS body's own staff that are tied to the GS body by a contract of employment and by receiving pay from it:

1. assessment of the application pursuant to section 20 (1),
2. assessment of the inspection results pursuant to section 20 (3) and
3. the decision about the award of the GS mark.

(2) The involvement of external bodies requires the consent of the client.

(3) The GS body has to submit an application to the authorising authority if it wants to involve external bodies. The GS body attaches the following documentation to the application:

1. a description of the tasks and products for which it intends to involve the external body, and
2. documentary proof that the external bodies fulfil the requirements set out in section 13.

(4) The GS body takes full responsibility for the activities performed by the external bodies, regardless of where they are based. It ensures through regular monitoring that the prerequisites and requirements of paragraph 1 are complied with.

(5) The GS body keeps the relevant documents about the monitoring measures referred to in paragraph 4 sentence 2 and about the activities performed by the external bodies in respect of the awarding of the GS mark ready for the authorising authority.

Section 24

Obligations of the manufacturer and the importer

(1) The manufacturer has to ensure that the ready-for-use products he manufactures are in conformity with the type tested.

(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 section 20 (5) and only as long as the requirements of Article 20 (3) are met. He may not use the GS mark or use it as a selling point if the GS body has withdrawn the award in accordance with section 22 (5) or has suspended it in accordance with section 22 (7).

(3) When designing the GS mark, the manufacturer has to observe the requirements set out in the Annex and the specifications identified by the Product Safety Commission.

(4) The manufacturer must not use or use a mark as a selling point that can be confused with the GS mark.

(5) An importer may place a product with the GS mark on the market only after having verified that the product has a certificate in accordance with section 20 (5). He has to document the search in accordance with sentence 1 before placing the product on the market. The documentation has to include at least the following information:

1. The date of the inspection in accordance with sentence 1,
2. The name of the GS body that has issued the certificate in accordance with section 20 (5), and
3. the number of the certificate on the award of the GS mark.

Division 6
Market surveillance, Federal Institute for Occupational Safety and Health and Product Safety Commission

Section 25
Market surveillance

- (1) Subject to sentences 2 and 3, market surveillance is the responsibility of the competent authorities under the law of the respective Land (market surveillance authorities). Responsibilities for the implementation of this Act, which are assigned by other legislation remain unaffected. When, in accordance with section 1 (3), the provisions of this Act are applied complementary to the provisions of other legislation, the competent authorities for the implementation of such other legislation are also responsible for the implementation of the provisions of this Act unless otherwise provided.
- (2) For the sample checks according to Article 11 (3) sentence 1 of Regulation (EU) 2019/1020, the market surveillance authorities use 0.5 samples per 1,000 inhabitants and per year as an indicative target for each Land; this does not apply to products where section 1 (4) provides for the supplementary application of the provisions of this Act.
- (3) Where the market surveillance authority takes a measure for a product bearing a GS mark pursuant to section 8 of the Market Surveillance Act to prohibit or restrict a product's being made available on the market, to withdraw it from the market or where the withdrawal or recall has been ordered, the market surveillance authority notifies the respective GS body that awarded the GS mark and the authorising authority of the measure taken.
- (4) The market surveillance authorities may require the notified bodies, the GS bodies and the staff of those bodies commissioned by the GS bodies to perform the technical tasks, to provide any information and documentation necessary for carrying out their tasks.
- (5) The market surveillance authorities may, on a case-by-case basis, order
1. the necessary measures to fulfil the obligations imposed on the notified body in accordance with section 16 (3) or (4), or
 2. the necessary measures to comply with the obligations imposed on a GS body in accordance with section 22 (2) sentence 1 or paragraph 4 sentence 2.
- (6) Persons obliged to provide information have to tolerate measures referred to in paragraph 4 and they have to support the market surveillance authorities and their authorised representatives. The notified bodies and the GS bodies as well as the staff specified in paragraph 4 are obliged to provide to the market surveillance authorities, upon request, with the information and documents necessary for the performance of their tasks. 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 section 383 (1) nos. 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 are to be informed about their right to refuse information.
- (7) The market surveillance authorities may, on a case-by-case basis, order the economic operator to take the necessary measures to comply with the obligations imposed on him pursuant to section 6 or section 24.
- (8) When taking action in accordance with paragraphs 4, 5 and 7, the market surveillance authorities have to notify the authorising authority thereof.

Section 26
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 identifies and assesses, as a preventative measure, safety and health risks posed by the use of products and makes 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, carries out risk assessments of products if there is sufficient evidence that they pose an immediate risk to the safety and health of persons or that they pose a serious risk. It communicates 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 carries 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 supports the market surveillance authorities in the development and implementation of the market surveillance strategy pursuant to section 6 (2) of the Market Surveillance Act particularly by scientifically analysing the identified defects in the nature of the product. It regularly informs the market surveillance authorities and the Product Safety Commission of the state of play of its findings and regularly publishes its findings on the central Product Safety Portal it operates. The provisions on the processing of personal data for the purpose of scientific research remain unaffected.

Section 27

Product Safety Commission

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

(2) The Commission has the following tasks:

1. advise the Federal Government in matters relating to the safety of products,
2. identify standards and other technical specifications when there is no harmonised standard for a product;
3. identify specifications for the award of the GS mark, and
4. make recommendations on the general suitability of a product prior to the award of the GS mark and publish them.

(3) The Commission should 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, in particular those representing manufacturers, distributors and consumers. Membership is honorary.

(4) The Federal Ministry of Labour and Social Affairs, in consultation with the Federal Ministry of Food and Agriculture and the Federal Ministry for Economic Affairs and Energy appoints the members of the Commission and a deputy for each member. The Commission adopts its own rules of procedure and elects a chairperson from among its members. The Commission should not have more than 21 members. The rules of procedure and the election of the chairperson are 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 have the right to be represented and consulted in the Commission's meetings.

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

Division 7

Provisions on penalties and administrative fines

Section 28

Administrative fines provisions

(1) A regulatory offence is committed by any person intentionally or negligently who

1. fails to supply information, or fails to supply it accurately, completely, or in due time, thus violating section 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 section 3 (4),

3. fails to supply a name or a contact address, or fails to supply it accurately, completely, or in due time, thus violating section 6 (1) sentence 1 no. 2,
4. fails to inform the competent market surveillance authority, or fails to inform it accurately, completely, in the prescribed manner or in due time, thus violating section 6 (4) sentence 1,
5. affixes a marking, symbol or inscription on a product, thus violating the provisions of section 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 repealing Regulation (EEC) No 339/93 of the Council (OJ L 218 of 13 August 2008, p. 30), as amended by Regulation (EU) 2019/1020 (OJ L 169 of 25 June 2019, p. 1),
6. makes a product available on the market, thus violating section 7(2),
7. fails to comply with a statutory instrument referred to in section 8 (1) sentence 4 no. 1 or 3 or paragraph (2), section 8 (1) sentence 4 no. 2 or with an enforceable order based on such a statutory instruments insofar as the statutory instrument refers to this provision on administrative fines regarding a specific fact,
8. fails to comply with an enforceable order pursuant to section 11 (1) sentence 1 or section 25 (5) or (7),
9. contrary to section 24 (2) sentence 2 or paragraph (4), uses or advertises a sign referred to therein,
10. contrary to section 24(3), fails to comply with any of the requirements of Annex nos. 1, 2, 3, 4, 7, 8, sentence 1, no. 9 sentence 2 or no. 10,
11. fails to document an inspection, or fails to document it accurately, completely, or in due time, thus violating section 24 (5) sentence 2,
12. 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 set out in nos. 1 to 6, 8 or 11, insofar as a statutory instrument referred to in paragraph 3 refers to this provision on administrative fines regarding a specific fact, or
13. contravenes a directly applicable provision of an act of the European Community or the European Union which in substance amounts to a regulation authorised by the provisions set out in
 - a) no. 7 (a), or
 - b) no. 7 (b),

insofar as a statutory instrument pursuant to paragraph (3) refers to this provision on administrative fines regarding a specific fact.

(2) A regulatory offence may in the cases of paragraph (1) no. 7 (a), no. 9 and no. 13 (a) be punished with a fine of up to one hundred thousand euros, in all other cases with a fine of up to ten thousand euros.

(3) Where necessary for the implementation of acts of the European Community or the European Union, the Federal Government is authorised to specify by statutory instrument not requiring the consent of the Bundesrat the facts that may be punished as regulatory offences under paragraph (1) nos. 12 and 13.

Section 29

Provisions on penalties

A person who persistently repeats an intentional act specified in section 28 (1) no. 7 (a), no. 9 or no. 13 (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 is punished by a term of imprisonment of up to one year or by a financial penalty.

Annex

Design of the GS mark

(Reference: Federal Law Gazette I 2021, p. 3161)

1. The GS mark consists of the inscription and the frame.
2. The width of the frame is one third of the grid spacing.
3. The words "geprüfte Sicherheit" (tested safety) have to be set in font Arial and in bold and italic type, with 0.3 cm grid spacing and font size 25 pt.
www.gesetze-im-internet.de/normengrafiken/bgbl1_2021/j3146-1_0010.pdf
4. If the GS mark is reduced or enlarged, the proportion given in the grid drawing above are to be respected.
5. The grid only serves to determine proportions; it is not 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 are permissible.
7. The GS mark has to be combined with the symbol of the GS body. The symbol of the GS body replaces the word "Id-Zeichen" (identification mark) in the above illustration. It must allow a clear identification of the GS body and may not lead to any confusion with other GS bodies.
8. The symbol of the GS body is to be affixed in the upper left corner of the GS mark. It may extend beyond the outer edge of the GS mark if necessary for space reasons and provided the overall image of the GS mark is not distorted.
9. It is permissible to display the symbol of the GS body to the left of the GS mark. In this case, however, the symbol of the GS body has to touch the GS mark so that the unity of the safety sign is preserved.
10. Other graphical representations and markings may not be linked to the GS mark when these would distract from the nature or substance of the GS mark.