

German Hazardous Substances Law

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ABSTRACT: German hazardous substances law serves as a national supplement to the requirements of European hazardous substances legislation. Its specific provisions must be taken into account - alongside European rules - when distributing products within the Federal Republic of Germany. Key German regulatory instruments in this field include the German Chemicals Act, the Ordinance on the Prohibition of Chemicals, the Hazardous Substances Ordinance, and the Technical Rules for Hazardous Substances. Their essential contents are presented and discussed. The national legal hierarchy regarding hazardous substances and the enforcement and compliance monitoring carried out by various stakeholders are also addressed.

KEYWORDS: Hazardous substances, European chemicals legislation, German Chemicals Act, Ordinance on the Prohibition of Chemicals, Hazardous Substances Ordinance, Technical Rules for Hazardous Substances

INTRODUCTION

There is consensus among European Union (EU) member states that environmental and chemicals legislation should be largely harmonized [1, 2]. Consequently, European Union law - comprising the founding treaties (primary law) and regulations, directives, and decisions adopted at the EU level (secondary law) - takes precedence over national law. This constitutes a primacy of application that has evolved over time [3].

Harmonized chemicals legislation is primarily achieved through the adoption of key legal frameworks in the form of EU regulations [4]. These are directly binding on all member states. In certain areas, the European Union issues directives requiring member states to incorporate new rules into their national legal frameworks by a specified deadline. This allows individual member states to adopt the EU minimum standard while simultaneously maintaining stricter regulations. One example of this is the European occupational exposure limits for hazardous substances [5], which are further tightened by German national requirements [6].

MATERIALS AND METHODS

The specific features of German hazardous substances law are manifested particularly in the Chemicals Act [7], the Ordinance on Hazardous Substances [8], the Ordinance on the Prohibition of Chemicals [9], and the Technical Rules for Hazardous Substances [10]. These regulatory texts were examined and analyzed in their original versions.

RESULTS

The national hierarchy of legal statutes and norms [11] regarding hazardous substances in the Federal Republic of Germany (FRG) is structured as follows. Primary and secondary European law are followed by the national constitution - the Basic Law (Grundgesetz). Formal statutes are derived from this; in the field of chemical products, examples include the Chemicals Act, the Explosives Act, and the Detergents and Cleaning Agents Act. Statutory ordinances occupy the next level down in the hierarchy; these include the Ordinance on the Prohibition of Chemicals and the Ordinance on Hazardous Substances. Bylaws are issued by non-state bodies, such as local municipalities. Finally, administrative regulations - taking the form of technical guidelines or technical rules, relevant directives, or DIN standards - form the fundamental framework for practitioners.

1. German Chemicals Act

The established hierarchy of legal norms dictates that the Act on Protection against Dangerous Substances [7] - also known as the German Chemicals Act - incorporates EU requirements and transposes them into national law. Specifically, these include Directives 98/24/EC [12], 67/548/EEC [13], 1999/45/EC [14], 2004/9/EC [15], and 2004/10/EC [16], which cover occupational health protection, Good Laboratory Practice, and the classification, labeling, and packaging of hazardous substances.



Figure 1: Hierarchical order of German law

The Act comprises eight sections containing 31 articles and two annexes (as of March 29, 2026). It focuses on protecting people and the environment from the harmful effects of hazardous chemicals. Explicitly excluded are cosmetics, tobacco products, pharmaceuticals, medical devices, food and feed (subject to certain limitations), general and radioactive waste, and wastewater. To implement the REACH Regulation [17], the CLP Regulation [18], the Biocidal Products Regulation [19], and the F-Gas Regulation [20], the Chemicals Act designates specific lead German federal authorities. These are:

- the Federal Institute for Occupational Safety and Health, acting as the Federal Chemicals Agency;
- the German Environment Agency, acting as the assessment body for environmental aspects;
- the Federal Institute for Risk Assessment, acting as the assessment body for health issues and consumer protection; and
- the Federal Institute for Occupational Safety and Health, acting as the assessment body for worker safety and health protection.

Articles 12i and 12j of the Act set out supplementary obligations regarding the F-Gas Regulation, aimed at achieving a sustainable reduction in the quantity of fluorinated greenhouse gases. The section on notification obligations specifically addresses the reporting of hazardous substance mixtures and certain products by manufacturers. Furthermore, physicians are required to submit a notification if they suspect that patients have fallen ill due to exposure to hazardous substances, hazardous mixtures, or hazardous products.

Section 17 governs prohibitions and restrictions regarding the supply of hazardous substances; it forms the basis for the Ordinance on the Prohibition of Chemicals. Section 19 provides the authorization to issue an ordinance on hazardous substances for the protection of employees. Sections 19a through 19d, as well as Annex I of the Chemicals Act, address the implementation and verification of Good Laboratory Practice standards. These requirements form the basis for official oversight of the respective laboratories.

In its seventh section, the Act authorizes the Federal Government to appoint committees to provide advice or assist in drafting regulations for the competent ministries.

Compliance with the provisions of this Act and the statutory ordinances based upon it is monitored by state authorities. In the federal state of North Rhine-Westphalia, for example, these responsibilities are assigned to the five district governments of Arnsberg, Detmold, Düsseldorf, Cologne, and Münster. Inspectors are vested with extensive powers. Customs authorities provide support when necessary. Serious violations may be punishable by imprisonment for several years.

2. Ordinance on the Prohibition of Chemicals

The Ordinance on Prohibitions and Restrictions on the Placing on the Market and the Supply of Certain Substances, Mixtures, and Articles under the Chemicals Act - referred to for short as the Ordinance on the Prohibition of Chemicals [9] - was revised on April 21, 2026. It comprises four sections containing 14 paragraphs and two annexes. It governs two aspects: firstly, it supplements the prohibitions and restrictions on the supply of certain hazardous chemicals arising from Article 67 and Annex XVII of the REACH Regulation; secondly, it defines requirements to be met when supplying certain hazardous chemicals to specific groups of recipients. According to Annex 1 of this Ordinance, the prohibitions apply to chemicals such as formaldehyde, certain specifically listed dioxins and furans, and biopersistent fibers. Pentachlorophenol, which was also listed until early 2024, was removed due to directly



applicable EU regulations; the same applies to the entry for formaldehyde as of August 7, 2026. In addition to the definitions of prohibitions, the Ordinance lists exemptions for the chemicals in question, allowing for their use within a specified scope. A few national exemptions from the restrictions set out in the REACH Regulation are defined in Paragraph 4 of the Chemicals Prohibition Ordinance; these concern asbestos fibers in diaphragms, in vintage means of transport, and in historical artifacts.

Additionally, Annex 2 lists chemicals that may be supplied provided that the relevant requirements are met. This concerns products classified with the hazard pictograms GHS06 (skull and crossbones) or GHS08 (health hazard), the signal word "Danger," and one of the hazard statements H340, H350, H350i, H360, H360F, H360D, H360FD, H360Fd, H360Df, H370, or H372. These statements indicate serious health hazards. Chemicals marked in this way can cause genetic defects, impaired fertility, harm to the unborn child, and damage to other organs.

Furthermore, the provisions of this annex apply to chemicals marked with the hazard pictogram GHS03 (flame over a circle) or GHS02 (flame) and one of the following hazard statements: H224 (Extremely flammable liquid and vapour), H241 (Heating may cause a fire or explosion), or H242 (Heating may cause a fire). The list in Annex 2 also includes chemicals that release phosphine when used as intended.

The regulation bases its supply requirements on the target group. To this end, the table in Annex 2 is divided into three columns. Column 1 lists the regulated substances and mixtures. Column 2 sets out the general requirements for the supply of these products, while Column 3 lists the relaxed requirements applicable to supplies made to resellers, professional users, and public research, testing, and educational institutions.

Section 6 of the Chemicals Prohibition Ordinance establishes a requirement for official authorization regarding the supply of substances or mixtures listed in Annex 2. This obligation does not apply to sales to resellers, professional users, public research, testing, and educational institutions, or pharmacies. Under Section 7, persons exempt from the licensing requirement are obliged to notify the competent authority in writing of the initial supply or making available of the substances or mixtures before commencing such activity; however, holders of a license under Section 6 and pharmacies are exempt from this notification requirement.

Sections 8 and 9 of the Ordinance set out the fundamental requirements for the supply of chemicals. Only trained personnel are permitted to inform buyers of potential hazards and provide them with relevant guidance on the proper handling of the products and on what to do in the event of an emergency. Furthermore, personnel must verify that buyers intend to use or resell the products only in a permitted manner and that they are at least 18 years of age. Other key elements of the Chemicals Prohibition Ordinance include the supply log - in which the essential details of every transfer of hazardous products must be documented - the requirement for personnel to provide proof of specialized knowledge, and restrictions on shipping via courier, express, and parcel services.

3. Hazardous Substances Ordinance

The Ordinance on Protection against Hazardous Substances was revised on December 17, 2025 [8]. It incorporates eleven EU directives into German law: Directive 98/24/EC [12], Directive 2000/39/EC [21], Directive 2006/15/EC [22], Directive 2009/161/EU [23], Directive 2004/37/EC [24], Directive 2009/148/EC [25], Directive 67/548/EEC [13], Directive 1999/45/EC [14], Directive 98/8/EC [26], Directive 96/59/EC [27], and Directive 1999/92/EC [28]. These relate to occupational health and safety, biocidal products, and polychlorinated chemicals.

The Ordinance adopts European requirements regarding hazard classes as well as the classification, labeling, and packaging of hazardous substances and mixtures; it also references information obligations associated with the sale of chemicals—specifically the requirement to provide a safety data sheet when dealing with hazardous substances or mixtures. Furthermore, it prescribes measures to protect employees and other persons during activities involving hazardous substances and restricts the production and use of certain hazardous substances, mixtures, and articles.

With reference to Section 5 of the national Occupational Health and Safety Act [29], it obliges the employer to conduct a workplace risk assessment when work involves chemicals. This is based on the requirement that the employer must eliminate risks to employees or limit them to a minimum. In detail, the ordinance requires the employer to obtain information regarding:

- the hazardous properties of substances or mixtures, including their physicochemical effects,
- health protection and safety, particularly as detailed in the safety data sheet,
- the nature and extent of exposure, taking into account all routes of exposure; this includes considering - where applicable - current measurement results, duration of exposure, personal protective equipment, operational protective measures, and other aspects,



- options for product substitution,
- working conditions and work processes, including work equipment and the quantities of hazardous substances involved,
- workplace exposure limits and biological limit values,
- the effectiveness of protective measures already implemented or planned,
- findings from occupational medical examinations conducted in accordance with the Ordinance on Occupational Medical preventive care.

If a substitution assessment reveals that a hazardous product can be replaced, the employer must prioritize the use of products or processes that pose no risk - or a lower risk - to the health and safety of employees under the specific conditions of use. If activities involving more than a negligible risk to employees are carried out at the workplace, the employer must maintain a register of the hazardous substances used.

In addition to personal protective equipment and other general or specific measures to protect against hazardous chemicals, the ordinance mandates further protective measures when activities involve hazardous substances classified as carcinogenic, germ cell mutagenic, or toxic to reproduction (Categories 1A and 1B), or when there is a risk of physicochemical hazards, particularly fire and explosion risks. The ordinance details the rules governing the use of asbestos and activities involving this material. The employer is required to draw up appropriate plans for operational disruptions, accidents, and emergencies, and must regularly inform and instruct employees. The employer must make written operating instructions generally accessible to employees. Based on these instructions, employees must receive regular oral briefings regarding potential hazards and the corresponding protective measures and rules of conduct. These briefings must include general occupational medical and toxicological advice, drawing attention to the need for medical preventive examinations.

Another section of the Ordinance on Hazardous Substances is dedicated to the requirements for the use of biocidal products, particularly during fumigation. Proper use entails limiting the use of biocidal products to the absolute minimum necessary, using the products exclusively for their designated purposes, adhering to the conditions of use specified by the manufacturer, and ensuring the user possesses the qualifications required for the specific user category. The first two requirements also apply to private households.

The sixth section addresses enforcement regulations and defines the Committee on Hazardous Substances [30], which serves as an advisory body to the Federal Ministry of Labour and Social Affairs. This section obliges employers to notify the authorities on their own initiative if accidents or operational disruptions involving hazardous substances result in serious harm to employees' health, or if employees fall ill or die as a result of activities involving hazardous substances.

Furthermore, employers must provide additional information upon the authority's request - for example, regarding the results of a risk assessment, activities involving hazardous substances, the persons responsible under Section 13 of the Occupational Health and Safety Act, protective and preventive measures, or the expertise of employees responsible for preparing safety data sheets.

The seventh section defines administrative offenses, criminal offenses, and transitional provisions.

Annex I sets out specific regulations for certain hazardous substances and activities. It defines measures for protection against fire and explosion hazards and particulate hazardous substances, as well as requirements for handling biocidal products, fumigation with biocidal products or plant protection products, and the storage and handling of ammonium nitrate.

Annex II outlines specific restrictions on the manufacture and use of certain substances, mixtures, and products. These include, for example, naphthylamine, cooling lubricants and corrosion inhibitors, biopersistent fibers, and particularly hazardous carcinogenic substances.

Annex III specifies requirements for activities involving organic peroxides. In particular, it is noted that for any activity involving an organic peroxide, the substance must have been assigned a hazard group by the Federal Institute for Materials Research and Testing.

4. Technical Rules for Hazardous Substances

The Technical Rules for Hazardous Substances (TRGS) provide detailed specifications for the Ordinance on Hazardous Substances [10]. They are developed by the Committee on Hazardous Substances and revised as necessary. They are published by the Federal Ministry of Labour and Social Affairs.

The set of technical rules comprises nine numerically categorized sections:

- TRGS 001–099: General aspects, structure, and compliance (currently only TRGS 001),

- TRGS 100–199: Definitions (currently no TRGS),
- TRGS 200–299: Placing substances, mixtures, and articles on the market,
- TRGS 300–399: Occupational medical surveillance (currently no TRGS),
- TRGS 400–499: Risk assessment,
- TRGS 500–599: Protective measures for activities involving hazardous substances,
- TRGS 600–699: Substitute substances and substitute processes,
- TRGS 700–899: Fire and explosion protection,
- TRGS 900–999: Limit values, classifications, justifications, and other decisions of the Committee on Hazardous Substances.

The Technical Rules address both general and specific subject areas. According to TRGS 001 [31], the rules reflect the state of the art in technology, occupational medicine, and occupational hygiene, as well as other established findings regarding activities involving hazardous substances.

Examples of Technical Rules of a general nature include TRGS 400 (Risk assessment for activities involving hazardous substances) [32], TRGS 510 (Storage of hazardous substances in non-stationary containers) [33], or TRGS 600 (Substitution) [34].

The following TRGS examples are designed for specific activities and, consequently, for specific types of operations:

- TRGS 519 Asbestos: Demolition, reconstruction or maintenance work [35],
- TRGS 528 Welding work [36].

The editions of the TRGS 900 series [37] are of particular importance to employers and other responsible persons within companies. They cover occupational exposure limits and biological limit values, as well as chemicals posing significant health risks: carcinogenic, germ-cell mutagenic, and reproductive-toxic substances, as well as sensitizing agents.

DISCUSSION

The aforementioned statutory hierarchy - comprising European mandates, national laws, ordinances, and subordinate regulations - can be clearly illustrated using the example of the Technical Rules for Hazardous Substances.

Specific EU directives are incorporated into the national German Chemicals Act. At the same time, Section 19 of the Act establishes the legal basis for the Ordinance on Hazardous Substances. This ordinance implements the requirements of further EU directives that fit the level of an ordinance rather than the primary legislative hierarchy. The Ordinance on Hazardous Substances delegates further to a lower hierarchical level; Section 20 mandates the formation of a Committee on Hazardous Substances [30], which is responsible for drafting and revising the Technical Rules for Hazardous Substances. This committee receives support from bodies such as the Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area [38], which regularly addresses MAK and BAT values.

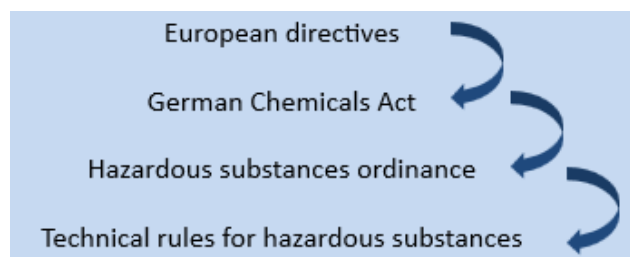


Figure 2: Statutory sequence in the area of hazardous substances

The European Commission monitors whether Member States have implemented EU mandates correctly in terms of both timing and content [39]. Infringement proceedings are initiated in the event of discrepancies. A significant number of such proceedings occur each year; between 2014 and 2023, the number of new proceedings initiated annually ranged from 529 to 986 [40]. Most of the proceedings pending in 2026 relate to the environmental sector [41]. A small number concern chemicals policy. For instance, two proceedings involving the Federal Republic of Germany have taken place in recent years and have since been concluded [42]. One



concerned the protection of laboratory animals and lasted from 2018 to 2022. The other was initiated in 2020 due to non-compliant implementation of the Seveso III Directive and was concluded in 2025.

Compliance with these statutory requirements by market actors occurs at various levels and, ultimately, also gives rise to criticism. As early as September 2020, the European Chemicals Agency (ECHA) [43] reported that approximately one-quarter of all chemical products imported into the EU failed to comply with European legal requirements. A review of online retail in December 2021 revealed that more than half of the chemical products violated applicable law [44]. Consequently, ECHA will continue to deploy inspectors [45].

At the national level in Germany, inspections are carried out by state authorities - specifically, environmental and trade inspectorates. Customs authorities also assist with inspection tasks. Regarding occupational health and safety, workplace inspections may be conducted by the relevant statutory accident insurance institutions (Berufsgenossenschaften). The corresponding authorizations are set out in the Chemicals Act and other relevant regulations.

CONCLUSION

Legislation is a dynamic process that must adapt to changing circumstances. In the realm of hazardous substances, this framework is defined primarily by environmental and health policy considerations and is regularly updated at both the European and national levels.

The significantly improved coordination between European and national institutions - compared to the past - means that manufacturers and traders operating in the European market must not only comply with numerous rules, deadlines, and other requirements but also adapt to more frequent changes than was the case twenty years ago. Furthermore, they are subject to comprehensive inspections.

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