Sino-German Chemicals Management Joint Research Project Report

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SINO-GERMAN CHEMICALS MANAGEMENT JOINT RESEARCH PROJECT REPORT

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Contents

Executive Summary

China's environmental management of chemicals focuses on new chemical substances, import and export of toxic chemicals, risk assessment and management of existing chemical substances, and compliance with international chemical conventions.

Environmental management of new chemicals in China began in 2003 with the introduction of the Measures for the Environmental Management Registration of New Chemical Substances (Decree No. 12 of the Ministry of Ecology and Environment). Producers or importers of new chemical substances shall, prior to production or import, obtain a regular or simplified registration certificate for the chemicals, or file a record. In particular, new chemical substances refer to chemical substances that are not yet listed on the China Inventory of Existing Chemical Substances.

Environmental management of the import and export of toxic chemicals is developed to protect human health and environment, strengthen environmental management of chemicals import and export and fulfill international conventions. The Announcement on the Issuance of Catalog of Toxic Chemicals Strictly Restricted in China (2020) (MEE, MOFCOM and GAC Announcement 2019 No. 60) includes the Catalog of Toxic Chemicals Strictly Restricted in China (2020) as well as instructions for handling and obtaining the Clearance Notification for Environmental Management on Import of Toxic Chemicals and the Clearance Notification for Environmental Management on Export of Toxic Chemicals.

China has been carrying out environmental risk assessment and control of existing chemical substances. Currently, two batches of the Catalogue of Priority Chemicals have been published. The Catalogue of Priority Chemicals focuses on identifying chemicals that are inherently hazardous, may persist in the environment, and may pose great risks to the environment and human health. It is necessary to adopt one or more environmental risk control measures for chemicals on the Catalogue of Priority Chemicals. Such measures may be inclusion of chemicals in the relevant environmental management catalogs, implementation of cleaner production auditing and information disclosure system, and introduction of restrictive alternative measures.

China has concluded or acceded to such international treaties as the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the Stockholm Convention on Persistent Organic Pollutants and the Minamata Convention on Mercury. China fulfills its obligations as a party in accordance with the requirements of the conventions. China will actively engage in exchanges and cooperation with the international community in the field of environmental management of chemicals, so as to jointly address the environmental and health problems caused by chemicals.

Chemicals-related environmental legislation in Europe has undergone substantial development during the past decades. It comprises acts relating to the supply, use and transport of chemicals, to their use in consumer products, to emissions and releases into the different environmental compartments and to plant safety.

European environmental legislation is based on specified articles of the Treaty on the Functioning of the European Union (TFEU). European acts mostly take the shape of an EU Regulation or of an EU Directive: while the former has to be directly applied in all Member States in the same way, the latter instrument, for different reasons, must first be transposed into national law before it is applicable at national level.

The most prominent example for an EU Directive in the environmental area is the Seveso III Directive. It seeks to prevent accidents at plants where hazardous substances are used – and in the event of an accident, minimize the consequent health and environmental impacts. The Directive was transposed into German law; how this was done and who is involved in its implementation and enforcement is described in detail in the report.

EU Regulations are often applicable when it comes to substance law, e.g. for industrial chemicals for supply and use, pesticides, biocides, detergents and cosmetics. by Regulation (EU) 1907/2006 (REACH) and Regulation (EU) 1272/2008 (CLP) are key pieces of legislation for regulating the safe use of chemical substances and mixtures.

REACH came into force in June 2007. It aims at improving the protection of human health and the environment through the sufficiently comprehensive and earlier identification of the intrinsic properties of chemical substances and through safely managing chemicals throughout their life cycle. The Regulation contains requirements for the production, marketing and use of chemicals. A key feature is the close collaboration of all actors, i.e. of manufacturers, importers, downstream users and relevant authorities at EU and national level, as well as the close interlinkage between the different REACH processes. This is described in detail in this document.

Closely connected to REACH is CLP: Regulation (EU) No. 1272/2008 regulates the classification, labelling and packaging of substances and mixtures, thereby applying the UN globally harmonized system (GHS) in the EU. It entered into force in early 2009. CLP sets up a self-classification system for industry while at the same time establishing a list with substance classifications which are legally binding for all actors. CLP serves REACH in that it provides the classifications underpinning the key processes of REACH, i.e. registration, evaluation, authorization and restriction of substances. The databases run under both acts are closely interlinked. Meanwhile, more than 15000 companies submitted over 100000 registrations for around 23000 substances; key information of registrations and substance classifications is publicly available, thereby contributing to protecting health and the environment at the highest possible level.

Although the benefits of REACH as well as the current legislative framework in the EU are significant, specified challenges have been identified, based on experience with implementation of regulations as well as current policy and regulatory planning. General experience shows that there is some room for improvement of the overall regulatory efficiency and effectiveness. Another challenge refers to closing regulatory gaps. Key topics of interest are endocrine disruptors, essential uses, the combined effects of chemicals, and particularly persistent substances such as PFAS. Not at least the European Parliament calls for a comprehensive EU framework on endocrine disruptors (EDCs) to effectively minimize the extent to which humans and the environment are exposed to EDCs, and insert specific provisions into legislation on toys, food contact materials and cosmetics to treat EDCs like substances that are carcinogenic, mutagenic or toxic for reproduction. The “Chemicals Strategy for Sustainability”, as part of the “Green Deal” (see section 4.0), embarks on these topics, proposing approaches for solution.

Ultimately, and against the backdrop of the global sustainability debate as reflected in the Global Chemicals Outlook II, REACH and CLP are considered as being instrumental to reaching the sustainable development goals. A key challenge in the upcoming decade is to further develop the concepts of REACH towards the production, use and management of sustainable chemicals, and to consider the safety and sustainability of chemicals throughout their lifecycle. Sustainable chemistry as promising overall conceptual orientation and important incentives at EU and German level are outlined at the end of this report.

Sino-German joint research and exchange on chemicals environmental management policies and technologies will help promote understanding of relevant policies and management models and enhance the capacity of China's chemicals management. We shall work together to deal with risks and challenges, seek common interests and benefits, and achieve win-win development for mutual benefit. In the future, it is hoped that China and Germany will carry out more activities in the area of chemicals environmental management policies and technologies, such as joint policy or technical research, personnel visits and exchanges, and technical training.

1. Chemicals management system in China

Chemicals have become ubiquitous in modern society. They drive social development forward, but also bring along safety, health and environmental risks that cannot be ignored. Sound management of chemicals requires promotion of favorable conditions and elimination of harm, that is, minimizing the impact of chemical production and use on human health and the environment. This has become a global consensus and challenge.

1.1 Overall situation

According to the Globally Harmonized System on Classification and Labelling of Chemicals (GHS), hazards of chemical substances are broadly classified into three major groups, namely, physical hazards, health hazards and environmental hazards. The corresponding chemicals management fields include safety management, health management and environmental management. Management of "obvious" hazard classes such as flammability, explosibility, corrosiveness and acute toxicity falls within the scope of chemical safety management. Management of chemical toxicity, that is, managing hazards to human health caused by incidental contact with or ingestion of toxic chemicals, is health management. Dealing with environmental issues caused by chemicals or human health problems induced by the environment belongs to the scope of environmental management of chemicals.

Chemicals management in China involves several government departments. The Ministry of Emergency Management (MEMA) is responsible for safety supervision and management of hazardous chemicals, organizing the formulation, publication and amendment of the hazardous chemical catalogue, reviewing safety conditions of projects for new construction, renovation or expansion of production and storage facilities of hazardous chemicals, issuing the Hazardous Chemicals Workplace Safety Permit, the Hazardous Chemicals Safe Use Permit and the Hazardous Chemicals Business Permit, and maintaining a registry of hazardous chemicals[1]. Laws and regulations in this regard include the Regulations on the Safe Management of Hazardous Chemicals, the Measures for the Safety Supervision and Administration of Construction Projects Relating to Hazardous Chemicals, and the Administrative Measures for Registration of Hazardous Chemicals.

The Ministry of Ecology and Environment is responsible for the supervision and management of chemical pollution prevention and control at the national level; implementing environmental management registration of import and export of toxic chemicals that are strictly restricted in China as well as environmental management registration of new chemical substances[2]; investigating environmental pollution accidents and ecological damages resulting from hazardous chemicals; and monitoring the surrounding environment after a hazardous chemical accident[3]. Laws and regulations in this regard include the Measures for the Environmental Management Registration of New Chemical Substances, and the Provisions on Environmental Management of Import and Export of Toxic Chemicals.

The National Health Commission is responsible for the management of toxicity identification of hazardous chemicals, and for organizing and coordinating rescue work for people injured in chemical incidents[4]. It conducts occupational health risk assessment and health management.[5] Laws and regulations in this regard include the Law on Prevention and Control of Occupational Diseases and the Administrative Measures for Diagnosis and Identification of Occupational Diseases.

Other ministries that are involved in chemicals management include the National Development and Reform Commission (NDRC), which is responsible for implementing a negative list for

[1] http://www.gov.cn/zwgk/2011-03/11/content_1822783.htm
[2] http://www.mee.gov.cn/zjhb/bjg/gts/
[3] http://www.gov.cn/zwgk/2011-03/11/content_1822783.htm
[4] http://www.gov.cn/zwgk/2011-03/11/content_1822783.htm
[5] http://www.nhc.gov.cn/zyjks/pzyzz/lists.shtml

market access and promoting sustainable development strategies[6]. The Ministry of Industry and Information Technology (MIIT) is responsible for the management of the petrochemical and chemicals industries[7], and for the management of monitored and controlled chemicals[8]. The Ministry of Public Security is responsible for public safety management of hazardous chemicals, and for issuing purchase licenses and road transport permits for highly toxic chemicals.[9] The Ministry of Transport is responsible for managing safe transport of chemicals by road and waterway.[10] The Ministry of Commerce is responsible for formulating administrative measures for import and export commodities and processing trade, as well as technology catalogues.[11] The General Administration of Customs is responsible for inspection and quarantine of import and export goods, and supervising the flow of goods for banned or restricted articles.[12] The State Administration for Market Regulation is responsible for the monitoring of product quality and safety risks, conducting spot checks, and promoting a quality grading system and traceability system.[13]

1.2 Current situation of environmental management of chemicals

China's environmental management of chemicals focuses on new chemical substances, import and export of toxic chemicals, risk assessment and management of existing chemical substances, and compliance with international chemical conventions.

1.2.1 Environmental management of new chemical substances

Environmental management of new chemical substances is an internationally accepted system that requires identifying hazards and assessing environmental risks before any new chemical substance starts production or import. A system of registration and licensing shall be established as a "firewall" to manage new chemicals at source and to prevent those with unreasonable environmental risks from entering economy and the society.

1.2.1.1 Background

In 2003, China promulgated the Measures for Environmental Management of New Chemical Substances (Decree No. 17 of the former State Environmental Protection Administration), and in 2010 published a revised version (Decree No. 7 of the former Ministry of Environmental Protection, hereinafter referred to as Decree No. 7). Decree No. 17 and Decree No. 7 provides institutional guarantee for environmental management of new chemical substances in China, effectively strengthens control over their production and import, and plays a positive role in preventing and reducing environmental pollution.

To meet current requirements of environmental management, on April 29, 2020, the Ministry of Ecology and Environment promulgated the Measures for the Environmental Management Registration of New Chemical Substances (Decree No. 12 of the Ministry of Ecology and Environment, hereinafter referred to as Decree No. 12), a new revision of Decree No. 7. The main contents of revision are as follows:

(1) Focusing on environmental risks and highlighting control priorities. For the purpose of effective prevention of environmental risks, the focus of control will be on new chemical substances that are persistent, bio-accumulative, harmful to the environment and health, or may exist in the environment for a long time and may pose a greater risk to the eco-environment and public health.

(2) Optimizing the application procedures to alleviate burdens on enterprises. With reference to international practice in environmental management of chemicals and China's

[6] https://www.ndrc.gov.cn/fzggw/bnpz/
[7] http://www.miit.gov.cn/n1146285/n1146352/n3054355/n3057569/n3057570/c3558691/content.html
[8] http://www.miit.gov.cn/n1146295/n1146592/n3917132/n4061810/c4844772/content.html
[9] http://www.gov.cn/zwgk/2011-03/11/content_1822783.htm
[10] http://www.gov.cn/zwgk/2011-03/11/content_1822783.htm
[11] http://www.mofcom.gov.cn/mofcom/zhize.shtml
[12] http://jgs.customs.gov.cn/
[13] http://www.samr.gov.cn/jg/#zjzz

local experiences, and without compromising management and control of environmental risks, administrative procedures have been optimized: the former simplified declaration procedure is replaced by record-filing, and the former conventional declaration of medium and low levels has been adjusted to simplified declaration. Data requirements for declaration have also been further optimized.

(3) Refining eligibility for registration and improving approval requirements. The revision clarifies specific eligibility criteria for registration, and offers rules concerning re-application for registration, change, withdrawal and revocation of registration. It highlights environmental risk control especially at source and further improves the practice of registration.

(4) Strengthening oversight and improving management efficiency. According to Decree No. 12, enterprises shall assume main responsibility for controlling environmental risks of new chemical substances with well-designed measures. It also further clarifies information reporting requirements, supervision methods and key areas of focus. Environmental risk control measures mainly target new chemical substances that pose a significant environmental hazard. Post-registration information reporting is limited to the collection of information that is urgently needed for management. Individual and five-year activity reports are no longer required. The group of actors required to submit annual reports has been reduced. Oversight of new chemical substances follows the method of “random selection of inspection targets, random assignment of inspectors, and prompt release of results", which is conducive to improving management efficiency.

(5) Tracking new hazard information to prevent environmental risks. Decree No. 12 improves provisions on the tracking of new hazard information and environmental risks after registration of new chemical substances for environmental management, requiring researchers, producers, importers and processors of such substances to report to the Ministry of Ecology and Environment of the State Council in a timely manner, should they identify any new environmental or health hazard or environmental risks. Measures shall be taken to eliminate or reduce any potential environmental risks. After receiving relevant information such as new hazards, the competent authority shall organize a technical review and, if necessary, may change or revoke the corresponding certificate of registration according to the review results.

1.2.1.2 Introduction of laws and regulations

The latest version of the Measures for Environmental Management of New Chemical Substances is Decree No. 12 issued in 2020, which will be implemented from January 1, 2021.

1.2.1.2.1 Purpose and scope of management

Purpose of the Measures is as follows: to regulate registration of new chemical substances for environmental management, to scientifically and effectively assess and control environmental risks of new chemical substances, to monitor new chemical substances that may pose great risks to the environment and health, to protect the ecological environment, and to safeguard public health.

Scope of application: Decree No. 12 applies to the registration of activities related to new chemical substances, including research, production, import, processing and use within the territory of the People's Republic of China, with the exception of those that are stored in special supervised areas of the Customs after import and will be exported in their entirety without any processing. It does not apply to the following products or substances: (1) Products such as pharmaceuticals, pesticides, veterinary drugs, cosmetics, food, food additives, feed, feed additives and fertilizers, except those new chemical substances that are changed to other industrial uses, and except those used as raw materials and intermediates for the abovementioned products; (2) Radioactive substances. It shall be noted that articles designed to release the new chemical substances contained in them throughout their routine use shall fall within the scope of Decree No. 12 for such chemical substances.

New chemical substances refer to chemical substances that are not yet listed on the China Inventory of Existing Chemical Substances. Where the Inventory requires environmental management of chemical substances in the event of changed use, that is, for industrial use other than the permitted use cases, such substances shall be managed as new chemical substances.

China Inventory of Existing Chemical Substances: The China Inventory of Existing Chemical Substances is an updated version of the "List of Existing Chemical Substances Already Produced or Imported in China", which was promulgated for the implementation of the Measures for Environmental Management of New Chemical Substances (Decree No. 17 of the former State Environmental Protection Administration). It covers chemical substances that have been produced, processed, sold, used, or imported from abroad for commercial purposes in China during the period from January 1st, 1992 to October 15th, 2003 as well as chemical substances listed after October 15th, 2003 in accordance with relevant provisions on environmental management of new chemical substances.

The Inventory of Existing Chemical Substances in China is constantly updated. In January 2013, in line with the implementation of Decree No. 7, the former Ministry of Environmental Protection (MEP) issued the Announcement on the Publication of China Inventory of Existing Chemical Substances (former MEP Announcement No. 1, 2013[14]). The Inventory includes 45,612 chemical substances, including information on their English and Chinese names, molecular formula, and U.S. Chemical Abstract Number (CAS) or serial number. In March 2016, the former MEP issued the Announcement on Additions to the <China Inventory of Existing Chemical Substances> former MEP Announcement No. 20, 2016[15]), which included 31 new chemical substances that were registered under Decree No. 17 and met the requirements for inclusion. In November 2018, the Ministry of Ecology and Environment (MEE) issued the Announcement on Additions to the <China Inventory of Existing Chemical Substances (MOE Announcement 2018 No. 58[16]), adding 2 new chemical substances registered under Decree No. 7 and 43 new chemical substances registered under the Measures for Environmental Management of New Chemical Substances (Decree No. 17 of the former State Environmental Protection Administration) that met the requirements for inclusion. In January 2019, MEE issued the Announcement on Additions to the <China Inventory of Existing Chemical Substances (MOE Announcement 2019 No. 1[17]), adding 28 new chemical substances registered under Decree No. 7 that met the requirements for inclusion. In January 2020, MEE issued the Announcement on Additions to the <China Inventory of Existing Chemical Substances (MOE Announcement No. 1, 2020[18]), adding 29 new chemical substances registered under Decree No. 7 and 18 new chemical substances registered under the Measures for Environmental Management of New Chemical Substances (Decree No. 17 of the former State Environmental Protection Administration) that met the requirements for inclusion. During the period, work was underway for making additions to the Inventory. For chemical substances that had been legally produced or imported in the People's Republic of China before October 15th, 2003 but not included in the China Inventory of Existing Chemical Substances, relevant entities, including enterprises that produce, import and use such substances as well as industry associations can fill in the application form and submit it together with supporting documents to apply for inclusion in the China Inventory of Existing Chemical Substances. At present, there are 156 chemical substances added to the China Inventory of Existing Chemical Substances[19]. The Inventory currently (October 2020) includes 45,919 chemicals.

[14] Website: http://www.mee.gov.cn/gkml/hbb/bgg/201301/t20130131_245810.htm
[15] Website: http://www.mee.gov.cn/gkml/hbb/bgg/201603/t20160315_332884.htm
[16] Website: http://www.mee.gov.cn/xxgk2018/xxgk/xxgk01/201811/t20181130_676779.html
[17] Website: http://www.mee.gov.cn/xxgk2018/xxgk/xxgk01/201901/t20190117_689881.html
[18] Website: http://www.mee.gov.cn/xxgk2018/xxgk/xxgk01/202001/t20200113_758915.html
[19] Website: http://www.mee.gov.cn/xxgk2018/xxgk/xxgk01/202005/t20200508_778159.html

1.2.1.2.2 Management principles and priorities

Registration of new chemical substances follows the principle of science, efficiency, openness, fairness, impartiality and convenience. The work helps control access at source, prevent risks, and apply classified management. The focus shall be on controlling new chemical substances that are persistent, bio-accumulative, harmful to the environment or health, or may exist in the environment for a long time and may pose great risks to the environment and health.

1.2.1.2.3 Responsibilities of departments

MEE shall be responsible for national environmental management and registration of new chemical substances, formulating policies, technical specifications, guidelines and other supporting documents as well as evaluation rules for the purpose, and strengthening IT-based development for registration of new chemical substances.

MEE shall organize and set up an Expert Committee on Environmental Risk Assessment of Chemical Substances (hereinafter referred to as the Expert Committee). The Expert Committee is composed of experts with background in chemistry, chemical engineering, health, environment and economy, providing technical support for the assessment process.

Ecological and environmental competent authority at or above the municipal level shall be responsible for supervision and management of implementation of these Measures by enterprises and institutions involved in the research, production, import and processing of new chemical substances within their administrative areas.

The technical agency for environmental management of chemical substances under MEE shall participate in the review of new chemical substances and undertake tasks to register new chemical substances.

1.2.1.2.4 Management method

New chemical substances are subject to environmental management registration and follow-up management. Environmental management registration of new chemical substances consists of regular registration, simplified registration and record-filing. Producers or importers of new chemical substances shall, prior to production or import, obtain a regular or simplified registration certificate for the chemicals, or file a record. New chemical substances that have not been registered or filed are prohibited in research, production, import and processing.

The State shall follow up and manage new chemical substances through information communication, activity reports, new hazard information reports, supervision and random inspection.

1.2.1.2.5 Management requirements

New chemical substances are subject to regular registration, simplified registration and record-filing.

(1) Regular registration

Application of Enterprises: Enterprises shall submit an application for regular registration of new chemical substances to be manufactured or imported above the annual volume of 10 tons. Required documents: application form for regular registration; test reports or information on the physical and chemical properties, toxicology and ecotoxicological properties of new chemical substances; test reports and information shall meet the needs of environmental risk assessment of new chemical substances; ecotoxicological test reports shall include test data completed in accordance with relevant standards using test organisms from the People's Republic of China; environmental risk assessment report of new chemical substances, including assessment of potential environmental risks, proposed counter-measures and their appropriateness, and conclusion as to whether there are unreasonable environmental risks; a

letter of commitment to implement or communicate risk control measures and environmental management requirements; in the case of high-risk chemical substances, the applicant shall also submit an analysis of the socio-economic benefits related to the activities of the new chemical substances; and environmental and health hazards of the new chemical substances and other information on environmental risks that the applicant already has.

Formality examination: Upon receipt of the application materials for the environmental management registration of new chemical substances, MEE will conduct a formality examination. The application materials will be accepted if they are complete and conform to the legal form, or if the applicant submits all the supplementary materials as required.

Technical review: After receiving an application for regular registration, the competent ecological and environmental authority will organize a technical review by expert committee and its subsidiary technical agency for environmental management of chemical substances, and issue technical review opinions. The review shall focus on the following contents: Name and labeling of new chemical substance; quality of test reports or information on the new chemical substance; environmental and health hazard of the new chemical substance; environmental exposure scenarios and risks of the new chemical substance; eligibility for new use management when listing on the China Inventory of Existing Chemical Substances; appropriateness of environmental risk control measures; necessity of the application for highly hazardous chemical substances; necessity of protection of business secrets.

Review of the opinions: MEE shall review the opinions of the technical review, and if no unreasonable environmental risk is identified, register the new chemical substance and issue a regular registration certificate to the applicant.

(2) Simplified registration

If the annual production or import of new chemical substances is more than 1 ton and less than 10 tons, a simplified registration applies.

Application of Enterprises: Required documents: application form for simplified registration; reports or data on the physical and chemical properties of the new chemical substance, as well as ecotoxicological tests such as persistence, bioaccumulation and aquatic environmental toxicity; a letter of commitment to implement or communicate environmental risk control measures; and other information on the environmental and health hazards and risks of the new chemical substance that the applicant already has.

Formality examination: Upon receipt of the application materials for the environmental management registration of new chemical substances, MEE will conduct a formality examination. The application materials will be accepted if they are complete and conform to the legal form, or if the applicant submits all the supplementary materials as required.

Technical review: After receiving an application for simplified registration, MEE will organize a technical review by its subsidiary technical agency for environmental management of chemical substances, and issue technical review opinions. The review shall focus on the following contents: The name and labeling of the new chemical substance; quality of test reports or information on the new chemical substance; persistence, bioaccumulation and toxicity of the new chemical substance; cumulative environmental risks of the new chemical substance; and the need for trade secret protection.

Review of the opinions: MEE shall review the opinions of the technical review. If no persistent, bio-accumulative and toxic properties and no cumulative environmental risk are identified, the registration shall be granted and a simplified registration certificate shall be issued to the applicant.

(3) Record-filing

If the annual production or import of new chemical substances is less than 1 ton or the polymer in which the content of monomer or reactant of new chemical substances is no more than 2%

or low-attention polymer, a filing shall be made.

To file a record for new chemical substances, required documents include filing form, proof of fulfilling the abovementioned materials, as well as other available information on the environmental and health hazards and environmental risks of the new chemical substances.

Upon receipt of the materials for filing, MEE shall file the complete set of application materials and issue a reply slip for the record. After submitting the filing materials, the applicant can carry out activities related to new chemical substances in accordance with the contents of the filing.

MEE shall regularly publish record-filing information for the environmental management of new chemical substances.

(4) Tracking management

Tracking management of new chemical substances mainly includes information transfer, activity records, implementation of risk control measures, activity reports, and inspection.

Information transfer: Producers, importers, and processers of new chemical substances shall share the registration certificate number or filing receipt number with downstream users; new purpose of use of new chemical substances; environmental and health hazards and environmental risk control measures; and environmental management requirements.

Activity records: Researchers, producers, importers and processers of new chemical substances shall establish a record system for the activities of new chemical substances, which shall accurately record the time, quantity and use as well as environmental risk control measures and management requirements in place. Relevant documents including regular and simplified registration as well as records of activities of new chemical substances shall be kept for at least ten years. Record-filing and reports on first activities of new chemical substances shall be kept for at least three years.

Implementation of measures: Producers and processers that complete regular registration of new chemical substances shall implement environmental risk control measures and management requirements, and disclose relevant information on their official websites or through other means that are easily accessible to the public.

Activity reports: The holder of the registration certificate shall, within sixty days from the date of the first production, or within sixty days from the date of the first import and transfer to the processer, report to competent authority for ecology and environment under the State Council on such first activity of the new chemical substance.

Where the environmental management requirements set out in the regular registration certificate requires submitting an annual report, the owner of the certificate shall, starting from the year following the year of registration, report to the competent department of ecology and environment under the State Council before April 30 of each year on the actual production or import of the new chemical substance for which registration was granted in the previous year, the discharge to the environment, and implementation of environmental risk control measures and management requirements.

New information report: Where a new environmental or health hazard or environmental risk has been identified, researchers, producers, importers and processers of new chemical substances shall promptly report to the MEE. Measures shall be taken to promptly eliminate or reduce any potential environmental risks.

Collaboration with inspection: Researchers, producers, importers and processers of new chemical substances shall provide relevant information truthfully and accept supervision and random inspection by the competent ecological and environmental authority.

1.2.1.3 Transitional measures

Article 53 of Decree No. 12 stipulates that, if the environmental management registration of

new chemical substances has been carried out in accordance with the provisions of Measures for Environmental Management of New Chemical Substances (Decree No. 7 of the former Ministry of Environmental Protection) and Measures for Environmental Management of New Chemical Substances (Decree No. 17 of the former State Environmental Protection Administration), the relevant registration will continue to be effective after the implementation of Decree No. 12. Article 45 specifies the procedures and relevant requirements for inclusion in China Inventory of Existing Chemical Substances. In order to ensure orderly registration of new chemical substances, MEE issued the Notice on Publicly Soliciting Opinions on <Notice on Matters Relating to the Environmental Management Registration of New Chemical Substances (Draft for Public Comments)> (Huanbanbianhan [2020] No. 155)[20] in June 2020 to clarify situations concerning previously obtained environmental management registration certificates of new chemical substances. At the end of October 2020, MEE published the Announcement on the Transitional Issues of Environmental Management Registration for New Chemical Substances (Announcement No. 46 of 2020).

1.2.1.4 Supporting documents

To support environmental management of new chemical substances, the former Ministry of Environmental Protection issued a series of technical standards, such as the Guidelines for Chemical Testing (HJ/T 153-2004), Guidelines for Hazard Assessment of New Chemical Substances (HJ/T 154-2004), Guidelines for Qualified Laboratories for Chemical Testing (HJ/T 155-2004), and Guidelines for the Generic Name of New Chemical Substances (HJ/T 420-2008). In December 2020, the Ministry of Ecology and Environment issued three technical guidelines, which are the Technical Guidelines for Environmental and Health Hazard Assessment of Chemical Substances (for trial implementation), the Technical Guidelines for Environmental and Health Exposure Assessment of Chemical Substances (for trial implementation), and the Technical Guidelines for Environmental and Health Risk Characterization of Chemical Substances (for trial implementation), in a bid to guide and regulate environmental risk assessment of chemical substances

In order to smoothly implement Decree No. 7, the former Ministry of Environmental Protection issued the Notice on the Release of Six Supporting Documents of Environmental Management Measures for New Chemical Substances (Huanban [2010] No. 124) in September 2010, and formulated and released the Guidelines for Registration of New Chemical Substances, Norms for Supervision and Management of New Chemical Substances, Regular Registration of New Chemical Substances and Instructions of Form , Simplified Registration of New Chemical Substances and Instructions of Form, Record-filing of New Chemical Substances and Instructions of Form, and Report on First Activities of New Chemical Substances and Instructions of Form. To improve data management, in August 2017, the former MEP issued the Announcement on Adjusting Data Requirements for the <Guidelines for Registration of New Chemical Substances> (former MEP Announcement No. 42 of 2017), which adjusted the minimum data requirements for regular declaration of toxicological and ecotoxicological data and exemption conditions for physical and chemical properties, toxicological and ecotoxicological data as stipulated in the Guidelines for Registration of New Chemical Substances.

To ensure quality of test data, regulate intermediary services for chemicals testing related to environmental management registration of new chemical substances, and strengthen supervision, the former MEP issued the Announcement on Regulating the Management of Chemical Testing Organizations in December 2016 (former MEP Announcement No. 85 of 2016). To regulate on-site verification of ecotoxicological test data for the registration of new chemical substances, the former MEP issued the Announcement on the Issuance of <Guidelines for the On-Site Verification of Ecotoxicological Test Data for the Environmental Management Registration of New Chemical Substances> in December 2017 (former MEP Announcement 2017 No. 70)

[20] http://www.mee.gov.cn/xxgk2018/xxgk/xxgk06/202006/t20200603_782493.html

MEE is revising the Guidelines for Environmental Management Registration of New Chemical Substances and its supporting documents. It will further refine and improve the data requirements for declaration, hazard assessment, environmental risk assessment, socio-economic benefit analysis, and environmental management registration of new purpose of use, as well as the forms and instruments required before and after registration. In August 2020, MEE issued the Notice on Publicly Soliciting Opinions on the Guidelines for Environmental Management Registration of New Chemical Substances (Draft for Public Comments) (Huanbanbianhan [2020] No. 278) to solicit opinions from the public. In November 2020, the Ministry of Ecology and Environment issued the Announcement on the Publication of the Guidelines for Environmental Management Registration of New Chemical Substances and Related Supporting Forms and Fill-In Form Instructions (Announcement No. 51, 2020), which will enter into force on January 1, 2021. The Notice on the Release of Six Supporting Documents of Environmental Management Measures for New Chemical Substances (Huanban [2010] No. 124) and the Announcement on Adjusting Data Requirements for the <Guidelines for Registration of New Chemical Substances> (former MEP Announcement No. 42 of 2017) shall be repealed at the same time.

1.2.2 Environmental management of import and export of toxic chemicals

1.2.2.1 Background

In 1994, in order to implement the London Guidelines for the Exchange of Information on Chemicals in International Trade, the former State Environmental Protection Administration, the General Administration of Customs and the former Ministry of Foreign Trade and Economic Cooperation jointly issued the Notice on the Issuance of Provisions on Environmental Management of the First Import of Chemicals and Import and Export of Toxic Chemicals (Huanguan [1994] No. 140), which came into effect on May 1, 1994.

In 2003, the Measures for Environmental Management of New Chemical Substances (the former State Environmental Protection Administration Decree No. 17) was released, which brought forward separate regulations concerning new chemical substances. In 2007, according to the Decision on the Abolition and Amendment of Certain Regulations and Normative Documents (State Environmental Protection Administration Decree No. 41), provisions related to “the First Import of Chemicals" in the Provisions on Environmental Management of the First Import of Chemicals and Import and Export of Toxic Chemicals were deleted.

The inventory under these Regulations is updated every year according to the increased number of chemical substances to be strictly restricted and adjusted customs code. MEE, Ministry of Commerce (MOFCOM) and the General Administration of Customs jointly issued the Announcement on the Issuance of Catalog of Toxic Chemicals Strictly Restricted in China (2020) (MEE, MOFCOM and GAC Announcement 2019 No. 60[21]) in December 2019. The announcement includes the Catalog of Toxic Chemicals Strictly Restricted in China (2020) as well as instructions for handling and obtaining the Clearance Notification for Environmental Management on Import of Toxic Chemicals and the Clearance Notification for Environmental Management on Export of Toxic Chemicals.

1.2.2.2 Introduction of laws and regulations

1.2.2.2.1 Purpose and scope of management

Purpose: In order to protect human health and environment, strengthen environmental management of chemicals import and export and fulfill international conventions, Provisions on Environmental Management of Import and Export of Toxic Chemicals have been formulated.

Scope of application: The Catalog of Toxic Chemicals Strictly Restricted in China (2020) includes 8 types/classes of chemicals, namely, Perfluorooctanesulfonate and its salts (PFOS)

[21] Website: http://www.mee.gov.cn/xxgk2018/xxgk/xxgk01/201912/t20191231_756318.html

and Perfluorooctanesulfonyl fluoride (PFOS/F), hexabromocyclododecane (HBCD), mercury, tetramethyl lead, tetraethyl lead, polychlorinated terphenyls (PCT), tributyltin compounds (TBT) and short-chained chlorinated paraffins (SCCPs). They are all listed as substances under control in the Stockholm Convention on POPs (referred to as the Stockholm Convention), the Minamata Convention on Mercury (referred to as the Mercury Convention) or the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (referred to as the Rotterdam Convention).

1.2.2.2.2 Responsibilities of departments

MEE is responsible for receiving and examining application materials submitted by enterprises for clearance for import (or export) of toxic chemicals, and for issuing the Clearance Notification for Environmental Management on Import/Export of Toxic Chemicals to those that meet all the requirements. The customs authority shall inspect and release chemicals listed on the Catalog of Toxic Chemicals Strictly Restricted in China (2020) on the basis of the Clearance Notification for Environmental Management on Import/Export of Toxic Chemicals issued by MEE. MEE, MOFCOM and the General Administration of Customs jointly issue the Catalog of Toxic Chemicals Strictly Restricted in China.

1.2.2.2.3 Application requirements for the Clearance Notification for Environmental Management on Import of Toxic Chemicals

(1) Conditions:

(a) Chemicals under the control of the Stockholm Convention on Persistent Organic Pollutants (POPs) and amendments

The purpose for the import shall be in line with the acceptable uses specified in the Announcement on the Entry into Force of the Amendment to the New Addition of Hexabromocyclododecane in the Stockholm Convention on Persistent Organic Pollutants (MEP Announcement No. 84, 2016), the Announcement on the Prohibition of Production, Circulation, Use, Import and Export of Persistent Organic Pollutants such as Lindane (MEE Announcement No. 10, 2019), or within the validity period of the registration of specific exemptions.

(b) Chemicals under the control of the Minamata Convention on Mercury

The purpose for the import shall be in line with the time-limited allowable uses in the Notice on the Entry into Force of the Minamata Convention on Mercury (MEP Notice No. 38,2018).

If the exporting country is a non-party to the Mercury Convention, a certificate shall be provided to prove that the exported mercury does not come from primary mercury mines that do not meet the requirements of the Mercury Convention or is from decommissioning of chlor-alkali facilities.

(c) Chemicals under the control of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade and amendments

The purpose of the import shall be in line with the permitted uses specified by authorities in China (excluding PCTs).

To import PCTs, an application for registration of new chemical substances shall be made.

(2) Application materials:

(a) Application form for the Clearance Notification for Environmental Management on Import of Toxic Chemicals (hereinafter also referred to as Clearance Notification for Import).

(b) The import contract signed with foreign enterprise.

(c) When importing chemicals controlled under the Stockholm Convention and its amendments, evidence materials that indicate the imported chemicals are to be used only for acceptable purposes or for specific exempted purposes within the validity period of the registration shall be submitted.

(d) For imports of chemicals controlled under the Mercury Convention, the following materials shall be submitted: ①Evidence that the imported chemical is to be used only for the time-limited allowable use in the Notice on the Entry into Force of the Minamata Convention on Mercury; ②If the exporting country is a non-party to the Mercury Convention, a certificate from the non-party regarding the source of the imported mercury; and ③data information on the use of imported chemicals consistent with the requirements of the Mercury Convention.

(e) When importing chemicals controlled by the Rotterdam Convention and its amendments, the exporting country shall provide evidence of compliance with the conditions for registration.

(f) In the case of repeated imports, the import, destination and use of each previous batch shall be submitted.

1.2.2.2.4 Application requirements for the Clearance Notification for Environmental Management on Export of Toxic Chemicals

(1) Conditions:

(a) Chemicals under the control of the Stockholm Convention and amendments

The purpose for the export shall be in line with the acceptable uses specified in the Announcement on the Entry into Force of the Amendment to the New Addition of Hexabromocyclododecane in the Stockholm Convention on Persistent Organic Pollutants (MEP Announcement No. 84, 2016), the Announcement on the Prohibition of Production, Circulation, Use, Import and Export of Persistent Organic Pollutants such as Lindane (MEE Announcement No. 10, 2019), or within the validity period of the registration of specific exemptions. When exporting to a country which is a party to the Stockholm Convention and its amendments, the exported chemicals shall be used only for acceptable purposes or for specific exempted purposes within the validity period of registration.

If the importing country is a non-party to the Stockholm Convention and its amendments, it shall submit an annual certificate to prove that it takes necessary measures to reduce or prevent release into the environment, comply with the requirements to reduce or eliminate releases from stockpiles and wastes, and ensure that wastes are disposed of, collected, transported and stored in an environmental manner.

Where the importing country is a party to the Rotterdam Convention and its amendments and imports chemicals not under the control of the Rotterdam Convention and its amendments, it (the foreign party) shall acknowledge receipt of the notification for the export of chemicals. For export of chemicals controlled by the Rotterdam Convention and its amendments, relevant provisions of the Rotterdam Convention and its amendments shall apply.

(b) Chemicals under the control of the Mercury Convention

The purpose for the export shall be in line with the time-limited allowable uses in the Notice on the Entry into Force of the Minamata Convention on Mercury (MEP Announcement No. 38, 2017). If the importing country is a party to the Mercury Convention, it shall also comply with the allowable uses of the importing country under the Mercury Convention.

If the importing country is a Party to the Mercury Convention, it shall provide written consent and documentary evidence of compliance with the allowable uses under the Mercury Convention.

If the importing country is a non-party to the Mercury Convention, it shall provide written

consent certifying that the use will be limited to uses allowed to the party under the convention, that the provisions of the convention for environmentally sound interim storage are being complied with, that the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal and its guidelines are being complied with, and that measures have been taken to protect human health and the environment.

(c) Chemicals under the control of the Stockholm Convention and its amendments

If the importing country is a party to the Rotterdam Convention and its amendments, the conditions in the importing country's response to the Secretariat of the Convention regarding the exported chemical shall be met:

If the import responses provided to the Convention Secretariat is no consent to import, the export shall not be allowed;

If the import responses provided to the Convention Secretariat is “to import under specific conditions”, such conditions set by the Secretariat shall be met;

If the importing country has not submitted a response to the Secretariat, it shall ensure that: the chemical is registered at the importing party at the time of import; or there is evidence that the chemical has been used or imported within the jurisdiction of the importing party and no regulatory action has been taken to prohibit it; or the exporter has requested and received explicit consent from the party's designated national authority.

(2) Application materials:

(a) Application form for the Clearance Notification for Environmental Management on Export of Toxic Chemicals (hereinafter also referred to as Clearance Notification for Export).

(b) Declaration and certification that the exported chemicals meet the requirements of the Stockholm Convention, Mercury Convention and Rotterdam Convention.

1.2.2.2.5 Other provisions

A Clearance Notification for Environmental Management on Import/Export of Toxic Chemicals is required for every batch and is valid for six months. It can only be used once for customs clearance during its validity period.

Entities importing chemicals shall set up accounts (breakdown records) to accurately record the import, flow and use of chemicals. MEE shall organize on-site inspection of the applicant entity and check the accounts of chemicals.

In accordance with the requirements of the Rotterdam Convention, when exporting chemicals controlled by the Rotterdam Convention and its amendments, entities shall affix labels and attach safety data sheets in an internationally recognized format with latest information to ensure that sufficient information is provided on risks and/or hazards to human health or the environment.

1.2.3 Risk assessment and control of chemicals

1.2.3.1 Background

In April 2015, the State Council issued the Action Plan for Water Pollution Prevention and Control (Guofa [2016] No. 17, hereinafter referred to as Ten Measures on Water), requiring the former MEP to take the lead in organizing environmental and health risk assessments of existing chemical substances, to publish Catalogue of Priority Chemicals by the end of 2017, to strictly restrict production and use of high-risk chemicals, and to phase them out progressively. In October 2017, the former MEP issued the Letter on Soliciting Opinions on the <Catalogue of Priority Chemicals (First Batch) (Draft)> (Huanbanturanghan [2017] No. 1542) to solicit extensive opinions from the society. In December 2017, the former MEP, Ministry of Industry and Information Technology and the former Health and Family Planning Commission jointly issued the Announcement on the Release of the <Catalogue of Priority

Chemicals (First Batch)> (No. 83, 2017). In November 2020, the Ministry of Ecology and Environment, the Ministry of Industry and Information Technology and the National Health Commission jointly issued the Announcement on the Release of the <Catalogue of Priority Chemicals (Second Batch) (No. 47, 2020), with a view to implementing the Opinions of the CPC Central Committee and the State Council on Comprehensively Strengthening Eco-Environmental Protection and Winning the Battle for Pollution Prevention and Control.

1.2.3.2 Listed substances

The Catalogue of Priority Chemicals (First Batch) focuses on identifying chemicals that are inherently hazardous, may persist in the environment, and may pose great risks to the environment and human health. The catalogue is as follows.

Table 1 Catalogue of Priority Chemicals (First Batch)

Serial no.	Chemical name	CAS number
PC001	1,2,4-Trichlorobenzene	120-82-1
PC002	1,3-Butadiene	106-99-0
PC003	5-tert-butyl-2,4,6-trinitro-m-xylene (xylene musk)	81-15-2
PC004	N,N'-Dimethylphenyl-p-phenylenediamine	27417-40-9
PC005	Short-chained chlorinated paraffins	85535-84-8 68920-70-7 71011-12-6 85536-22-7 85681-73-8 108171-26-2
PC006	Dichloromethane	75-09-2
PC007	Cadmium and cadmium compounds	7440-43-9 (cadmium)
PC008	Mercury and mercury compounds	7439-97-6(mercury)
PC009	Formaldehyde	50-00-0
PC010	Hexavalent chromium compounds	
PC011	Hexachloro-1,3-cyclopentadiene	77-47-4
PC012	Hexabromocyclododecane	25637-99-4 3194-55-6 134237-50-6 134237-51-7 134237-52-8
PC013	Naphthalene	91-20-3

Serial no.	Chemical name	CAS number
PC014	Lead compounds	
PC015	Perfluorooctanesulfonic acid (PFOS) and its salts and PFOSF	1763-23-1 307-35-7 2795-39-3 29457-72-5 29081-56-9 70225-14-8 56773-42-3 251099-16-8
PC016	Nonylphenol and nonylphenol polyoxyethylene ether	25154-52-3 84852-15-3 9016-45-9
PC017	Trichloromethane	67-66-3
PC018	Trichloroethylene	79-01-6
PC019	Arsenic and arsenic compounds	7440-38-2 (arsenic)
PC020	Decabromodiphenyl ether	1163-19-5
PC021	Perchlorethylene	127-18-4
PC022	Acetaldehyde	75-07-0

Table 2 Catalogue of Priority Chemicals (Second Batch)

Serial no.	Chemical name	CAS number
PC023	1,1-Dichloroethylene	75-35-4
PC024	1,2-Dichloropropane	78-87-5
PC025	2,4-Dinitrotoluene	121-14-2
PC026	2,4,6-Tri-tert-butylphenol	732-26-3
PC027	Benzene	71-43-2
PC028	Polycyclic aromatic hydrocarbons, including:	
	Benz[*a*]anthracene	56-55-3
	Benzo[*a*]phenanthrene	218-01-9

Serial no.	Chemical name	CAS number
	Benzo[*a*]pyrene	50-32-8
	Benzo[*b*]fluoranthene	205-99-2
	Benzo[*k*]fluoranthene	207-08-9
	Anthracene	120-12-7
	Dibenzo[*a,h*]anthracene	53-70-3
PC029	Polychlorinated dibenzo-p-dioxins and Polychlorinated dibenzofurans	-
PC030	Toluene	108-88-3
PC031	o-Toluidine	95-53-4
PC032	Tris (2-chloroethyl) phosphate	115-96-8
PC033	Hexachlorobutadiene	87-68-3
PC034	Chlorobenzenes, including:	
	Pentachlorobenzene	608-93-5
	Hexachlorobenzene	118-74-1
PC035	Perfluorooctanoic acid (PFOA) and its salts and related compounds	335-67-1 (PFOA)
PC036	Cyanide*	-
PC037	Thallium and thallium compounds	7440-28-0 (thallium)
PC038	Pentachlorophenol and its salts and esters	87-86-5 131-52-2 27735-64-4 3772-94-9 1825-21-4
PC039	Pentachlorothiophenol	133-49-3
PC040	Isopropylphenyl phosphate	68937-41-7

*Note: refers to hydrocyanic acid, all simple cyanide (mostly cyanide of alkali metal and alkaline earth metal) and zinc cyanide complex, excluding ferricyanide complex, ferrous cyanide complex, copper cyanide complex, nickel cyanide complex and cobalt cyanide complex

1.2.3.3 Control measures

For chemicals listed in the Catalogue of Priority Chemicals, one or more of the following risk control measures shall be taken in accordance with relevant policies, regulations and economic and technical feasibility to minimize impact of the production and use of the chemicals on human health and the environment.

(1) Inclusion in the management system of Permission for Discharging Pollutants

The Law of the People's Republic of China on the Prevention and Control of Atmospheric Pollution: MEE shall work with the department of health administration under the State Council to publish a catalogue of toxic and harmful air pollutants. Enterprises and institutions emitting toxic and harmful air pollutants listed in the catalogue shall obtain a permit to discharge such pollutants.

The Law of the People's Republic of China on Water Pollution Control: MEE shall work with the department of health administration under the State Council to publish a catalogue of toxic and harmful water pollutants. Enterprises, institutions and other operators discharging toxic and harmful water pollutants listed in the catalogue shall monitor their outfalls and the surrounding environment, disclose information on toxic and harmful water pollutants, and take effective measures to prevent environmental risks. Enterprises and institutions that directly or indirectly discharge industrial wastewater into water bodies and other wastewater and sewage that shall be discharged only with a discharge permit in accordance with regulations shall obtain a discharge permit.

(2) Implementation of restrictive measures

Restricted use: Revise relevant national mandatory standards to restrict their use in certain products.

Alternatives and substitution: See the Catalogue of Substitutes for Toxic and Hazardous Materials (Products) Encouraged by the State.

(3) Implementation of cleaner production auditing and information disclosure system

The Law of the People's Republic of China on Promotion of Cleaner Production: Enterprises that use toxic or hazardous raw materials for production or that emit toxic or hazardous substances in their production shall implement mandatory cleaner production audits.

Measures for Cleaner Production Audits: Enterprises that use toxic or hazardous raw materials for production or that emit toxic or hazardous substances in their production shall implement mandatory cleaner production audits. Enterprises that carry out mandatory cleaner production audits shall publish relevant information in a manner that is easily accessible to the public, including the name, quantity and purpose of the toxic and hazardous raw materials used, and the name, concentration and quantity of toxic and hazardous substances discharged.

1.2.4 Compliance with international conventions

1.2.4.1 Conclusion of conventions

China has concluded or acceded to such international treaties as the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the Stockholm Convention on Persistent Organic Pollutants and the Minamata Convention on Mercury.

China signed the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (hereinafter referred to as the Rotterdam Convention) on August 24th, 1999. The Standing Committee of the Tenth National People's Congress at its Thirteenth Meeting decided to ratify the Rotterdam Convention on December 29th, 2004. The Rotterdam Convention entered into force for China on June 20th, 2005[22].

China signed the Stockholm Convention on Persistent Organic Pollutants (hereinafter referred to as the "Stockholm Convention") on May 23rd, 2001. The Standing Committee of the Tenth National People's Congress at its Thirteenth Meeting decided to ratify the Stockholm Convention on June 25th, 2004. The Convention entered into force for China on November 11th, 2004 and applies also to the Hong Kong Special Administrative Region and the Macao

[22] http://treaty.mfa.gov.cn/Treaty/web/detail1.jsp?objid=1531876074835

Special Administrative Region[23].

China signed the Minamata Convention on Mercury on October 10th, 2013[24]. The Standing Committee of the Twelfth National People's Congress at its Twentieth Meeting decided to ratify the Minamata Convention on Mercury on April 28th, 2016. The Convention officially entered into force for China on August 16th, 2017[25].

1.2.4.2 Compliance in China

As a Party to the Rotterdam Convention, China actively fulfills its responsibilities as a Party to the Convention and carries out environmental management of chemical substances.

1.2.4.2.1 Rotterdam Convention

China submits final regulatory actions to the Convention Secretariat as required by the Rotterdam Convention; provides import response in accordance with Convention procedures; send export notifications; respond to export notifications; exchange import response information with domestic stakeholders; promote the Convention and provide information.

1.2.4.2.2 POPs Convention

In April 2009, the former Ministry of Environmental Protection, together with ten ministries and commissions including the National Development and Reform Commission (NDRC), issued the Announcement on the Prohibition of the Production, Circulation, Use, Import and Export of DDT, Chlordane, Mirex and Hexachlorobenzene (Announcement No. 23 of 2009), which stipulates that from May 17th, 2009, production, circulation, use, import and export of DDT, chlordane, mirex and hexachlorobenzene will be prohibited in the territory of the People's Republic of China. Production and use of DDT for vector control in emergency situations will be resolved through consultations among relevant authorities[26].

In March 2014, the former Ministry of Environmental Protection, together with 12 ministries and commissions, including the Ministry of Foreign Affairs, issued the Public Notice on the Entry into Force of the Amendments to Annexes A, B and C to the Stockholm Convention on Persistent Organic Pollutants with Nine Newly Listed POPs and the Amendment to Annex A to the Stockholm Convention on Adding Endosulfan (Notice 2014 No. 21)[27]. The document stipulates that production, circulation, use, import and export of alpha-hexachlorocyclohexane, beta-hexachlorocyclohexane, chlordecone, pentachlorobenzene, hexabromobiphenyl, tetrabromodiphenyl ether and pentabromodiphenyl ether, hexabromodiphenyl ether and heptabromodiphenyl ether are prohibited from 26 March 2014. From 26 March 2014, production, circulation, use, import and export of lindane, PFOS and its salts and PFOSF and endosulfan are prohibited, except for specific exemptions and acceptable purposes. For specific exempted uses, research and development of alternatives shall be accelerated to ensure complete phase-out before the expiration of the exemption; for acceptable uses, management and risk prevention shall be enhanced, and efforts shall be made to phase out their production and use.

In December 2016, the former Ministry of Environmental Protection, together with the Ministry of Foreign Affairs and 11 other ministries and commissions, issued the Announcement on the Entry into Force of the Amendment to the Stockholm Convention on Persistent Organic Pollutants to Add HBCD (Announcement 2016 No. 84)[28]. It provides for a ban on the production, use, import and export of HBCD, except for specified exempted uses, from December 26th, 2016.

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[23] http://treaty.mfa.gov.cn/Treaty/web/detail1.jsp?objid=1531876075437
[24] http://treaty.mfa.gov.cn/Treaty/web/detail1.jsp?objid=1535341836874
[25] http://www.mee.gov.cn/gkml/hbb/bgg/201708/t20170816_419736.htm
[26] Website: http://www.mee.gov.cn/gkml/hbb/bgg/200910/t20091022_174552.htm
[27] Website: http://www.mee.gov.cn/gkml/hbb/bgg/201404/t20140401_270007.htm
[28] Website: http://www.mee.gov.cn/gkml/hbb/bgg/201612/t20161228_378327.htm

In March 2019, MEE and the Ministry of Foreign Affairs as well as 11 ministries and commissions, issued the Announcement on Prohibition of Production, Circulation, Use, Import and Export of Persistent Organic Pollutants such as Lindane (Announcement 2019 No. 10)[29], which prohibits production, circulation, use, import and export of lindane and endosulfan from March 26th, 2019. The production, circulation, use, import and export of PFOS, its salts and PFOSF except for acceptable purposes, will be prohibited with effect from March 26th, 2019.

1.2.4.2.3 Minamata Convention on Mercury

In August 2017, the former Ministry of Environmental Protection, together with 17 ministries and commissions, including the Ministry of Foreign Affairs, issued the Notice on the Entry into Force of the <Minamata Convention on Mercury> (Notice No. 38 of 2017) [30], which sets out requirements to prohibit mining of new primary mercury mines, the use of mercury or mercury compounds as catalysts or the use of mercury-containing catalysts in the newly-established production processes of acetaldehyde, vinyl chloride monomer, and polyurethane. The use of mercury or mercury compounds is prohibited in newly-constructed production processes of sodium methanol, potassium methanol, sodium ethanol, and potassium ethanol from August 16th, 2017.

To implement the requirements of international treaties such as the Rotterdam Convention, the Stockholm Convention, and the Minamata Convention on Mercury in import and export processes, in December 2019, MEE, MOFCOM and General Administration of Customs jointly issued the Announcement on the Issuance of Catalog of Toxic Chemicals Strictly Restricted in China (2020) (MOE, MOFCOM, GAC Announcement No. 60 of 2019). The Announcement publishes the Catalog of Toxic Chemicals Strictly Restricted in China (2020), which includes 8 types/classes of chemicals (as the specific exemption registration expires, import and export of lindane is also prohibited). Among them, 2 types/classes are controlled by the Stockholm Convention and its amendments, 1 by the Minamata Convention on Mercury, and 7 by the Rotterdam Convention and its amendments (2 substances/classes are duplicated with substances controlled by the Stockholm Convention and its amendments).

1.3 Hazardous chemicals management

1.3.1 Regulations on the safe management of hazardous chemicals

1.3.1.1 Background

The Chinese Government attaches great importance to the safe management of chemicals and has formulated a series of regulations and standards that have played a positive role in the effective prevention and control of chemical hazards.

In order to strengthen management of hazardous chemicals, ensure workplace safety, safeguard people's lives and property, and protect the environment, the State Council issued the Regulations on the Safe Management of Hazardous Chemical Substances on February 17th, 1987, making specific provisions on the safety requirements for the production, use, storage, operation, transportation and loading/unloading of hazardous chemical substances. In order to effectively prevent incidents involving hazardous chemicals, the Regulations on the Safe Management of Hazardous Chemical Substances were comprehensively revised and promulgated on January 26th, 2002, as the Regulations on the Safe Management of Hazardous Chemicals (State Council Decree No. 344). In order to adapt to the new situation and issues, and to strengthen safe management of hazardous chemicals, the State revised the Regulations on the Safe Management of Hazardous Chemicals (State Council Decree No. 344) and issued the Regulations on the Safe Management of Hazardous Chemicals (State Council Decree No. 591) on March 2nd, 2011.

[29] Website: http://www.mee.gov.cn/xxgk2018/xxgk/xxgk01/201903/t20190312_695462.html
[30] Website: http://www.mee.gov.cn/gkml/hbb/bgg/201708/t20170816_419736.htm

1.3.1.2 Introduction of laws and regulations

1.3.1.2.1 Purpose

These Regulations are formulated in order to strengthen management of hazardous chemicals, prevent and reduce incidents involving hazardous chemicals, protect people's lives and property, and protect the environment.

1.3.1.2.2 Management targets

Hazardous chemicals refer to highly toxic chemicals and other chemicals with poisonous, corrosive, explosive, combustive, combustion and other properties, which are harmful to people, facilities and the environment.

Hazardous chemicals are determined mainly by the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), namely, 16 physical hazards including explosives, flammable gases, aerosols, oxidizing gases, gases under pressure, flammable liquids, flammable solids, self-reactive substances and mixtures, pyrophoric liquids, pyrophoric solids, self-heating substances and mixtures, substances and mixtures that emit flammable gases in contact with water, oxidizing liquids, oxidizing solids, organic peroxides and corrosive to metals; 10 health hazards including acute toxicity, skin corrosion/irritation, severe eye damage/eye irritation, respiratory or skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity-single exposure, specific target organ toxicity - repeated exposure, aspiration hazards; and 2 environmental hazards including hazardous to the aquatic environment (acute and chronic) and hazardous to the ozone layer[31].

On February 27th, 2015, the General Administration of Safety Supervision, together with the Ministry of Industry and Information Technology, the Ministry of Public Security, the Ministry of Environmental Protection, the Ministry of Transport, the Ministry of Agriculture, the National Health and Family Planning Commission, the General Administration of Quality Supervision, Inspection and Quarantine, the Railway Administration, and the Civil Aviation Administration jointly released the Catalogue of Hazardous Chemicals (2015 Edition), which includes 2,828 hazardous chemicals.[32]

1.3.1.2.3 Management content

The Regulations on the Safe Management of Hazardous Chemicals stipulate safe management of the production, storage, use, operation and transport of dangerous chemicals. For example, the State shall carry out overall planning and rational layout for the production and storage of hazardous chemicals; the conditions of use (including processes) of entities using hazardous chemicals shall comply with the provisions of laws and administrative regulations and the requirements of national and industry standards; enterprises engaged in the business of hazardous chemicals shall obtain the required license of operation; enterprises engaged in road or waterway transport of hazardous chemicals shall obtain permission from relevant administrative departments.[33]

1.3.1.3 Catalogue of Specially Controlled Hazardous Chemicals

The Ministry of Emergency Management, the Ministry of Industry and Information Technology, the Ministry of Public Security and the Ministry of Transport jointly formulated the Catalogue of Specially Controlled Hazardous Chemicals (First Edition) to strengthen management of whole life cycle of hazardous chemicals, prevent and control risks, effectively prevent and contain major incidents, and safeguard people's lives and property. The Catalogue identifies

[31] https://www.mem.gov.cn/gk/zcjd/201503/t20150331_233183.shtml
[32] https://www.mem.gov.cn/gk/gwgg/xgxywj/wxhxp_228/201503/t20150309_232632.shtml
[33] http://www.gov.cn/zwgk/2011-03/11/content_1822783.htm

20 types of specially controlled hazardous chemicals, including 4 types of explosive chemicals, 6 types of toxic chemicals, 5 types of flammable gases and 5 types of flammable liquids.

For the hazardous chemicals listed in the Catalogue of Specially Controlled Hazardous Chemicals (First Edition), the following control measures shall be promoted to minimize their safety risks and effectively prevent and contain major incidents under the conditions of laws and regulations as well as economic and technical feasibility. The first is to build an information platform for traceability and control of whole life cycle information; the second is to standardize packaging management; the third is to strictly control access to production; the fourth is to strengthen transportation management; and the fifth is to implement management of fixed storage[34].

1.3.2 Other safety management regulations of hazardous chemicals

In order to supervise and manage hazardous chemical projects and regulate safety review of such projects, the former State Administration of Work Safety promulgated the Measures for the Safety Supervision and Administration of Construction Projects Relating to Hazardous Chemicals (former State Administration of Work Safety Decree No. 45, amended in May 2015) in January 2012[35].

In order to strictly regulate safety production conditions of hazardous chemical manufacturers and to improve issuance and management of safety production licenses, the former State Administration of Work Safety issued the Measures for the Implementation of Safety Production Licenses for Manufacturers of Hazardous Chemicals (former State Administration of Work Safety Order No. 41) in August 2011[36].

In November 2012, the former State Administration of Work Safety issued the Measures for the Implementation of Safe Use Permits for Hazardous Chemicals (former State Administration of Work Safety Decree No. 57, amended in May 2015)[37] in order to strictly enforce safety production conditions of chemical enterprises that use hazardous chemicals in production and to regulate the issuance and management of such permits.

In July 2012, the former State Administration of Work Safety promulgated the Measures for the Administration of Business License for Hazardous Chemicals (former State Administration of Work Safety Decree No. 55, amended in May 2015) in order to strictly implement work safety requirements, regulate business activities relating to hazardous chemicals, and safeguard people's lives and property[38].

In order to ensure safe management of hazardous chemical pipelines, prevent and reduce production incidents relating to hazardous chemical pipelines, and protect people's lives and property, the former State Administration of Work Safety issued the Regulations on the Safety Management of Hazardous Chemical Pipelines in January 2012 (former State Administration of Work Safety Decree No. 43, amended in May 2015)[39].

In order to strengthen safety management of hazardous chemicals, standardize registration process, and provide technical and information support for incident prevention and emergency rescue, the former State Administration of Work Safety promulgated the Measures for the Administration of Registration of Hazardous Chemicals (former State Administration of Work Safety Decree No. 53) in July 2012[40].

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[34] http://yjglt.hainan.gov.cn/xxgk/0200/xxgkml/202007/t20200710_2817225.html
[35] https://www.mem.gov.cn/fw/flfgbz/gz/201202/t20120210_233438.shtml
[36] https://www.mem.gov.cn/fw/flfgbz/gz/201108/t20110828_233434.shtml
[37] https://www.mem.gov.cn/gk/gwgg/agwzlfl/zjl_01/201505/t20150527_233719.shtml
[38] https://www.mem.gov.cn/gk/gwgg/agwzlfl/zjl_01/201505/t20150527_233724.shtml
[39] https://www.mem.gov.cn/gk/gwgg/agwzlfl/zjl_01/201505/t20150527_233770.shtml
[40] https://www.mem.gov.cn/fw/flfgbz/gz/201207/t20120711_233446.shtml

1.4 Differences between environmental management and safety management of chemicals

Environmental and safety management of chemicals are important but different in the following four aspects.

1.4.1 Purpose of management

The main purpose of environmental management of chemicals is to protect the ecological environment and safeguard public health by assessing and controlling environmental risks of chemical substances, ultimately realizing ecological civilization and the dream of building a Beautiful China. The main purpose of chemical safety management is to enhance safety of hazardous chemicals, prevent and reduce hazardous chemical incidents, protect people's lives and properties, and ultimately achieve public safety.

1.4.2 Management targets

The environmental management of chemicals focuses on those with persistent, bio-accumulative, carcinogenic, mutagenic, reproductive and developmental hazards and other chronic or hidden hazards. The main risk of these chemicals is environmental risk, which comes from daily, non-emergent, long-term, low-dose environmental exposure, which may result in long-term adverse effects on the environment and human health. Safety management of chemicals focuses on those with acute or obvious hazards such as flammability, explosivity, corrosion and high toxicity. The main risk brought by these chemicals is safety risk, which comes from short-term and high-dose environmental exposure caused by incidents.

1.4.3 Management means

The source of risk for environmental management of chemicals is the release of chemical substances into the environment in the course of daily production and use. Therefore, management measures are taken to prohibit or restrict the use and release of high-risk chemical substances, so as to prevent their release into the environment from the source. The source of risk in safety management of chemicals is incidents caused by improper management, aging equipment and inappropriate operation of personnel. Therefore, management of facilities, equipment and relevant personnel in production, storage, use and operation shall be enhanced to prevent potential incidents.

1.4.4 Management core

Environmental management of chemicals is a way to manage chemicals through enterprise efforts. The core of management is chemical substances. Safety management of chemicals is a way to implement management requirements of corporate behavior through the management of hazardous chemicals, and the core of management is corporate behavior.

2. Chemicals Management system in Germany

2.1 Controlling Emissions of Chemicals in Germany: Plant Safety Management and Accident Prevention, Preparedness and Response

2.1.1 Overview

Plant safety and industrial accident prevention measures aim first and foremost to prevent accidents at plants where hazardous substances are used – and in the event of an accident, minimize the consequent health and environmental effects.

Safety management at sites where large amounts of dangerous substances (including chemicals) are present[41] includes technical and organizational measures

- to prevent incidents and accidents,
- to minimize the emissions of releases, fires and explosions occurring nevertheless,
- to minimize their impacts, e.g. by emergency planning and evacuation,
- to minimize their effects by response, e.g. limitation of access to contaminated areas or restoration of damage caused (e.g. to nature and environment),
- to investigate causes of incidents and accidents and to communicate lessons learnt,
- to improve the safety measures and management by individual and organizational learning.

The elements of this approach are implemented in the European and German legal system.

Germany's framework for the regulation of plant safety comprises provisions contained in:

1. Hazardous Incident Regulation (German: Störfall-Verordnung), Federal Immission Control Act (German: Bundes-Immissionsschutzgesetz) and several acts of German environmental legislation, all of which implementing the European Seveso III Directive, see section 2.1.2.2 below,
2. Several acts of German legislation implementing the European Industrial Emissions Directive, see section 2.1.2.4 below,
3. Environmental Impact Assessment Act (German: Umweltverträglichkeitsprüfungsgesetz), see section 2.1.2.5 below,

and relevant acts from the chemicals sector and other areas of legislation:

4. CLP Regulation (EU) 1272/2008 (German: Gefahrstoffverordnung; implements the classification and labelling System of the UN GHS) and related Technical Rules (so-called TRGS),
5. Safety at Work Act (German: Arbeitsschutzgesetz) and the related Plant Safety Ordinance (German: Betriebssicherheitsverordnung) and related Technical Rules (so-called TRBS), the related Work Place Ordinance (German: Arbeitsstättenverordnung) and related Technical Guidelines (so-called ASR),
6. Product Safety Act (German: Produktsicherheitsgesetz) and the related Product Safety Ordinances,
7. Explosives Act (German: Sprengstoffgesetz) and the related Explosives Ordinance,

[41] According to the Seveso-Directive: "present "or are anticipated to be present or may be generated during loss of control of the processes, including storage".

8. Federal Building Code,
9. Model Building Act (German: Muster-Bauordnung), Model Administrative Provision (German: Muster-Verwaltungsvorschrift) and related Technical Specifications, and others.

The focus of this section will be on the legislation under points 1-3 above.

2.1.2 Description of the legislation at European level and the German legislative framework

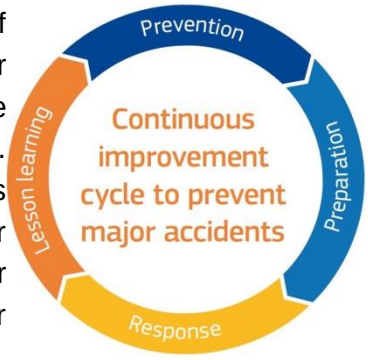
2.1.2.1 European Seveso III Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances and its implementation in Germany

In 1976, the catastrophic accident in the Italian town of Seveso where unknown amounts of the highly toxic dioxin TCDD were released into the environment, resulted in severe contamination of the surrounding area with long-term evacuation of inhabitants and extensive damage to the surrounding eco-systems. Based on this and other, similar major accidents, the European Economic Community (EEC) passed EU Directive 82/501/EEC to prevent and control the risk of such major accidents at specific industrial activity (Seveso-I-Directive) in 1982. With further similar accidents in the following years (i.a. at Bhopal, Enschede, Toulouse), the Directive was amended several times, finally resulting in the Seveso-III-Directive (2012/18/EU) published in July 2012.

The Seveso-III-Directive applies to more than 12,000 establishments in the EU that use or store hazardous substances, mainly in the chemical and petrochemical industry.

In Germany around 2.500 establishments are subject to the so-called lower-tier requirements, and 1.200 to the more comprehensive upper-tier requirements. About one third of the establishments are biogas installations.

Upper tier establishments are those, where large amounts of dangerous substances are present, equal or more than the upper tier values in Annex I of the directive. Operators of these establishments have to comply with all obligations for operators. Lower tier establishments are those, where less dangerous substances are present, but equal or more than the lower tier values in Annex I of the Directive. The operators of these lower tier establishments have to comply with a part of the obligations for operators for higher tier establishments.



2.1.2.1.1 Principles

The Seveso III Directive (2012/18/EU)[42] aims at the prevention of major accidents involving dangerous substances. However, as accidents may nevertheless occur, it also aims at limiting the consequences of such accidents both for human health and for the environment.

[42] Legal text (in all EU languages): https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32012L0018

The Directive covers establishments where hazardous substances may be present (e.g. during processing or storage) in quantities exceeding certain thresholds. Excluded from the Directive are certain industrial activities which are subject to other legislation providing a similar level of protection (e.g. nuclear establishments or the transport of dangerous substances).

The term "major accident" “means an occurrence such as a major emissions, fire, or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by this Directive, and leading to serious danger to human health or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substances” (Article 3 (13)). As the Directive does not distinguish between inside and outside the establishment, it also protects persons on site (e.g. personal of the operator or of contractors) and the environment in the establishment (e.g. habitats).

2.1.2.1.2 Main obligations for operators

Operators are obliged to take all necessary measures to prevent major accidents and to limit their consequences for human health and the environment. The requirements include:

- General obligations of operators (Article 5);
- Notification of establishments (Article 7);
- Deploying and updating a major accident prevention policy and its implementation, by means of a safety management system (Article 8);
- If an establishment is determined to be possibly involved in “domino effects” in case of a major accident: cooperation and exchange of information in relation to accident prevention policy, safety management systems, safety reports, and emergency plans (Article 9);
- Producing and updating a safety report for upper tier establishments (Article 10);
- Updating the notification, the major accident prevention policy, the safety management system and the safety report in case of relevant modifications (Article 11);
- Producing and updating internal emergency plans, submit information required for drafting of the external emergency plans for upper tier establishments (Article 12);
- Information to the public (parts of Article 14);
- Providing information and actions to be taken in case of accidents (Article 16).

Annex II part 2 of the Directive requires that the location of the establishment be described in safety reports (of upper-tier establishments) including meteorological, geological and hydrographic conditions. Annex II part 4 paragraph 1(iii) of the Directive requires explicitly that risks due to natural hazards be considered in accidental risk analysis and determination of required major accident prevention measures in safety reports. According to this, natural hazards should be considered in identification and evaluation of major hazards as a part of the safety management system of all establishments.

2.1.2.1.3 Main obligations for Member State authorities

Member States need to ensure that a number of requirements are fulfilled, those include:

- Establishing or determination of the authorities in charge for enforcement of the Directive (Article 6),
- Determination of establishments where “domino-effects” in case of major accidents are possible, communication of this and coordination of the operators of these establishments (Article 9);
- Producing external emergency plans for upper tier establishments (Article 12);
- Deploying land-use planning for the siting or modification of establishments and certain neighboring developments (Article 13);
- Information to the public (parts of Article 14);
- Public consultation and participation in decision-making (Article 15)
- Ensuring that any necessary action is taken after an accident; inspections and investigations to gain the information required for a complete accident analysis, inform the persons that may have been affected (Article 17);
- Reporting accidents and near misses giving lessons learnt to the Commission (Article 18);
- Prohibiting the unlawful use or operation of establishments (Article 19);
- Conducting inspections, establishing inspection plans and programs (Article 20);
- Exchange information on experiences; draft a report on the enforcement of the Directive and submit it to the Commission.

Member States may maintain or adopt stricter measures than those contained in the Seveso Directive.

An overview of which public German bodies are responsible for the implementation of the Seveso III Directive as well as other acts regulating plant safety is provided in section III below.

2.1.2.1.4 Member State authorities: obligations in relation to citizens' rights

- Member State authorities have to make sure that the public concerned is involved when external emergency plans are being established or substantially modified (Article 12 (5));
- They have to make sure that certain information on the establishment, the hazards caused by it, and the appropriate behavior in case of accidents is publicly available (including by electronic systems), and that in case of upper tier establishments, specified information is communicated by the operator to the public that may be affected, including schools, hospitals and neighboring facilities, and that the safety report and the inventory of dangerous substances is made accessible (Articles 14 and 22);

- The public concerned (including E-NGO´s) needs to be consulted and involved in the decision making for specific individual projects like siting or modification of an establishment or certain developments in their neighborhood (Article 15);
- Access to justice needs to be granted on the cases listed in Article 23.

An overview of which public German bodies are responsible for the implementation of the Seveso III Directive as well as other acts regulating plant safety is provided in section 2.2 below.

2.1.2.1.5 Identification of hazardous substances in the scope of the Seveso III Directive

Dangerous substances under the Seveso Directive are identified in two ways – as a named list of specific substances, and generically, covering substances with given hazard classifications under the CLP Regulation.

The European Chemicals Agency (ECHA) makes available the list of substances triggering requirements under the Seveso Directive in the C&L Inventory (Annex I of the Seveso III Directive) (https://echa.europa.eu/information-on-chemicals/cl-inventory-database).

Seveso Annex I Part 1 covers hazardous substances identified by Seveso hazard category. For these substances ECHA experts have made a mapping of the listed Seveso hazard categories against the substances with a corresponding harmonised classification on these categories. It should be noted that it is not only the EU harmonized classifications which may trigger obligations under the Seveso III Directive, but also any self-classifications performed by manufacturer, importers or downstream users of chemicals as defined by CLP.

Seveso Annex I Part 2 covers a specific set of named hazardous substances, identified by CAS number.
Using the Advanced Search for chemicals (https://echa.europa.eu/advanced-search-for-chemicals)
it is possible to search for those chemical substances subject to the Seveso Directive in the classification & labelling details block.

2.1.2.1.6 EU data bases on information pertaining to accidents involving hazardous substances

Further data relating to accidents involving hazardous substances and the implementation of the Seveso Directive can be found on the MINERVA portal[43]. It contains the details of major accidents which have occurred within the territory of the EU. The portal was created by the Major Accident Hazards Bureau of the European Commission Joint Research Centre with the objective to provide access to all information on current activities, relevant publications and tools on control of major chemical hazards.

The Minerva portal contains two user applications: (a) eSPIRS (Seveso Plants Information Retrieval System) which is a database of establishments in each country subject to the obligations of the Directive and (b) eMARS (the Major Accident Reporting System).

[43] Please see at (https://minerva.jrc.ec.europa.eu/en/minerva)

2.1.2.2 German legislation and instruments implementing the provisions of the Seveso III Directive

The Seveso III Directive, being created in form of a specific EU legal instrument, namely a directive, has to be transposed into national law before it is applicable. The reasons for creating a directive are normally laid down in the recitals („whereas-clauses“) right in the beginning of the European act. In some cases, pre-existing national frameworks can be the reason.

It was by means of a specified German act, named „Gesetz zur Umsetzung der Richtlinie 2012/18/EU zur Beherrschung der Gefahren schwerer Unfälle mit gefährlichen Stoffen, zur Änderung und anschließenden Aufhebung der Richtlinie 96/82/EG des Rates“ that the provisions of the Seveso III Directive were transposed into German legislation. The transposition was 100%, i.e. all obligations of the Seveso III Directive were taken over into the (pre-existing) German legislative framework[44]. The “Umsetzungsgesetz“ entered into force on 7 December 2016; it comprised amendments to

(1) Hazardous Incident Regulation (German: Störfall-Verordnung; 12th BImSchG)[45]
(2) Federal Emission Control Act (German: Bundesimmissionsschutzgesetz; BImSchG)[46]
(3) Ordinance on the licensing procedure (9th BImSchG)[47]
(4) Law on Environmental Impact Assessment (Gesetz über die Umweltverträglichkeitsprüfung, UVPG)[48]
(5) Environmental Appeals Act (Umwelt-Rechtsbehelfsgesetz, UmwRG)[49]
Legal text: http://www.gesetze-im-internet.de/umwrg/

The 12th Federal Emission Control Act and the **Ordinance on the Licensing Procedure** (9. BImSchV) were re-drafted.

2.1.2.2.1 Hazardous Incident Regulation

In Germany, the former Seveso II Directive was mainly implemented via the **Hazardous Incident Regulation** (German: Störfall-Verordnung, StörfallVO; full name: Zwölfte Verordnung zum Bundes-Immissionsschutzgesetz; 12th BImSchG). It lays down regulations concerning the construction, quality and operations for various types of plant elements. For example, the law requires plant operators to conform with the state of the art in safety engineering, to use a safety management system, and to elaborate and apply an accident prevention plan. Larger plant elements are subject to more stringent requirements such as

[44] As mentioned in the text further down, the so-called Störfallverordnung implemented provisions of the Seveso Directive. As the Störfall-Verordnung is a little bit older than the Seveso-Directive, there are still today some provisions in the Störfall-Verordnung which do not exist or do not exist in this form in the Seveso-Directive. This is especially relevant for the obligations of operators in § 3 to §6.

[45] Legal text: https://www.gesetze-im-internet.de/bimschv_12_2000/12._BImSchV.pdf. For the nomenclature, please refer to footnote 20.

[46] Legal text: https://www.gesetze-im-internet.de/bimschg/

[47] Legal text: http://www.gesetze-im-internet.de/bimschv_9/; as to the nomenclature, please see footnote 20 below.

[48] Legal text: http://www.gesetze-im-internet.de/uvpg/

[49] Legal text: http://www.gesetze-im-internet.de/umwrg/

submitting safety reports and elaborating alarm and hazard prevent plans.

The first Hazardous Incident Regulation was promulgated on 27 June 1980. The Hazardous Incident Regulation is therefore slightly older than the Seveso Directive. As a result of this, **there are currently still some provisions in the Hazardous Incident Regulation which do not exist or do not exist in this form in the Seveso Directive. This is especially relevant for the obligations of operators in § 3 to §6.** For the full text of the Hazardous Incident Regulation (which if often translated as "Major Accident Ordinance"), please see the link provided under section 2.1.2.2 above.[50]

§ 3 General obligations of operators

Paragraph 1 and 3 include the very basic obligation for operators

- to take safety measures to avoid major accidents and
- to take precautions to minimize the consequences of accidents occurring nevertheless.

The latter point addresses precautions that are taken as a result of the safety analysis for single installations and the analysed accidents scenarios. This obligation is valid for all establishments. For upper-tier establishments an internal emergency plan is additionally required. These internal emergency plans usually base on more general scenarios which are valid for the whole establishment.

Paragraph 4 requires that technical and organizational safety measures have to comply with the state of the art in safety technology. This is required for new and existing establishments and their installations. Operators shall themselves determine what state of the art in safety technology is and improve their installations by themselves if they do not comply with it. This obligation is the core of the Hazardous Incident Regulation.

Being applicable already since 1980, paragraph 2 requires the consideration of natural impacts (now called "Natech risks") and impacts by unauthorized persons. These hazard sources discussed "new" in the last years were already included.

§ 4 Requirements for the prevention of major accidents

Paragraph 1 addresses not only the prevention of fires and explosions in an installation of an establishment but as well the possible interference between installations and the possible impact from outside of an establishment.

Paragraph 1a addresses the prevention of releases, as they are not addressed in Paragraph 1. Please note that Paragraph 1a requires the prevention of all releases including those, that do not cause a major accident, e.g. releases of fire water.

Paragraph 2 and 3 regulate safety relevant equipment. This includes all types of equipment mechanical (e.g. fire water retention ponds) or electronical systems (e.g. functional safety

[50] Further information which is relevant for the German context can be found at https://www.vci.de/services/leitfaeden/vci-orientierungshilfe-zur-zuordnung-von-stoffen-gemaess-stoffliste-stoerfall-verordnung-anlagensicherheit.jsp and at https://www.lanuv.nrw.de/fileadmin/lanuv/anlagen/notfallplanung.pdf

systems).

Paragraph 4 is relevant for all kind of safety relevant parts of the establishment (e.g. tanks and computers used) and all kind of access to it (e.g. by foot or via the internet).

§ 5 Requirements intended to limit the effects of major accidents

Paragraph 1 point 1 requires that in the civil engineering of the foundations and the load bearing parts of constructions, possible impacts of fires and explosions are considered to avoid a collapse in case of a major accidents causing risks for first responders on site or risks of propagation of the accident.

§ 6 Additional requirements

Paragraph 1 points 1 and 2 describe the required maintenance of installations.

No. 3 is the obligation to avoid negative influences by human factors.

No. 4 goes beyond that, what is usually regarded as prevention of human errors. The operator has to take measures to avoid “incorrect behavior” e.g. this would include not to ware required personal protection equipment, to smoke or playing video games in the control room, if not allowed.

Paragraph 2 regulates the required communication if two or more establishments were identified to may have a “domino effect” major accident.

Paragraph 3 allows the competent authorities to request specific information from operators, e.g. characteristics of a nano-material.

For further provisions please see the chapter about the Seveso Directive above.

2.1.2.2.2 Federal Emission Control Act and Hazardous Incident Regulation

Main changes due to the Seveso III Directive as compared to its predecessor (96/82/EU) are reflected in BImSchG §§ 16a (major accident-relevant modifications of installations requiring a permit), 23a (notification procedure for installations not requiring a permit which are an operating area or part of an operating area), 23b (licensing procedure under major accident law, 23c (approval of operating plans under the Federal Mining Act), in addition to what is included in the Major Accident Ordinance. It is these acts to be checked for the obligations of operators in relation to any provisions deriving from the Seveso III Directive.

The numerous new provisions, particularly in the Federal Emission Control Act and the Hazardous Incident Regulation (12th BImSchV), entail new obligations for the companies affected, including notification, information and licensing requirements.

a. Extended notification and information obligations towards authorities and the public

The Hazardous Incident Regulation of 2017 now requires operators to provide more information to authorities and the public.

The notification for new establishments pursuant to Art. 7 of the Hazardous Incident Regulation requires not only information on conditions in the immediate vicinity of the establishment, but also on neighbouring establishments and on other establishments that are

not included in the application of the Ordinance. This also applies to the safety report that is to be prepared. Information obligations to the public, which have been extended in scope and quality, are to be made available proactively by the company. A separate official request for this is not necessary.

b. Monitoring systems

The responsible monitoring authority sets up a monitoring system. In this way, the authority ensures that a scheduled and systematic examination of the technical, organisational and management-specific systems of the operating areas concerned is performed. Should there be complaints, an on-site inspection is required within six months.
The competent authority may entrust an appropriate expert with on-site visits or other monitoring measures and with the preparation of the report.

c. Public participation through licensing procedures in accordance with major accident regulations

Article 23a of the Federal Immission Control Act (BImSchG) introduces a licensing procedure under major accident regulations for plants not requiring a permit under immission control regulations. This procedure has a two-tiered structure:

In a preliminary procedure, which is initiated by an obligation of the plant operator to notify when an operating area (area where dangerous substances are stored) is constructed or in case of an accident-relevant modification, the authority determines whether the plant maintains an appropriate safety margin (§ 23a para 1-3 BImSchG).

Where the safety margin is not maintained, a licensing procedure under the law on hazardous incidents is required, which is regulated in Article 23a para 4-6 of the Federal Immission Control Act. It includes, inter alia, public participation. There are, however, no rules as to when the safety margin is appropriate. This uncertainty is in turn to be eliminated by a new administrative regulation “Technical Guidance - Distance" (German: TA Abstand), to which § 48 para. 1 Nr. 5 BImSchG expressly authorizes.

For this reason, the Seveso III implementation process in Germany is not yet complete. The next steps are the elaboration of the Technical Guidance - Distance and an administrative regulation on the new notification procedure of § 23a BImSchG.

2.1.2.2.3 The Commission on Process Safety (KAS)

The Commission on Process Safety (KAS) was established in 2005 according to § 51a BImSchG. The Commission is the successor to the former Major Accident Commission (SFK) and the Technical Commission for Installation Safety (TAA).

The main tasks of the KAS according to § 51a BImSchG are

- to regularly prepare, and due to specified reasons, expert statements on possibilities to improve process safety,
- to develop and propose rules and guidance according to the state of the art in process safety.

Rules and guidance may be published by the Ministry for the Environment (BMU), after a

hearing of the authorities of the German states (Länder) as Technical Rules on Process Safety.

The guidance documents of SFA, TAA and KAS are published on the internet, some of them are also available in English.

2.1.2.2.4 The Technical Rules on Process Safety (TRAS)

Technical Rules on Process Safety are prepared by KAS. Currently there are five TRAS:

110 Safety of Ammonia Refrigeration Installations[51]

120 Safety of Biogas Installations[52]

310 Precautions and Measures due to Hazards by Precipitation and Floods[53]

320 Precautions and Measures due to Hazards by Wind, Snow- and Ice-loads[54]

410 Detection and Control of Exothermic Chemical Reactions[55]

2.1.2.2.5 Central Reporting and Evaluation Office in Germany (ZEMA)

ZEMA is an office for the central reporting and evaluation of hazardous incidents and incidents in process engineering facilities (ZEMA = *Ze*ntrale *M*elde- und *A*uswertestelle für Störfälle und Störungen in verfahrenstechnischen Anlagen)[56] in Germany. ZEMA records, evaluates and publishes in annual reports all events which must be reported to the authorities, see section 2.2 below, pursuant to the 12th Federal Immission Control Act. ZEMA's tasks in case of an accident are outlined in detail at the relevant website, in the LAI Guidance on reportable accidents according to the Hazardous Incident Regulation. (German: LAI-Leitfaden meldepflichtige Ereignisse im Sinne der Störfall-Verordnung). Any reportable events are sub-divided according to their hazard potential into major accidents and disturbance of normal operation. The systematic recording and evaluation of events will provide information which acts as an important basis for a further development of the state of the art of safety technology. Between 1980 and 2000, 336 events were registered in the ZEMA database. Statistical evaluations are available for the period 1991 to 1999.

2.1.2.3 European Directive 2010/75/EC on industrial emissions (integrated pollution prevention and control)

The Industrial Emissions Directive (Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions; IE Directive)[57] is the central regulatory framework for emission control in Europe. It covers the licensing, operation, monitoring and decommissioning of approximately 52,000 industrial plants across Europe. All emissions in air and waste water, but also noise, waste and influences on the soil are taken

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[51] Legal text: Safety of Ammonia Refrigeration Installations (under review)

[52] Legal text: Safety of Biogas Installations

[53] Legal text: Precautions and Measures due to Hazards by Precipitation and Floods (under review, short version in English)

[54] Legal text: Precautions and Measures due to Hazards by Wind, Snow- and Ice-loads (under review, non-official English Version)

[55] Legal text: Detection and Control of Exothermic Chemical Reactions

[56] Please see at https://www.umweltbundesamt.de/themen/wirtschaft-konsum/anlagensicherheit/zentrale-melde-auswertestelle-fuer-stoerfaelle

[57] Legal text (in all EU languages): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010L0075

into consideration. In addition, the IE Directive sets requirements for energy efficiency and the prevention of accidents.

The Industrial Emissions Directive forms the basis for the approval of industrial plants of particular environmental relevance. Emission reduction techniques and binding emission bands for different industries are summarized and defined in information sheets on best available techniques in order to harmonize European environmental standards.

The IE Directive aims not only to create fairer competitive conditions in the internal market, but also to further develop the model of sustainable production. The aim is to achieve a high level of protection for the environment as a whole. The integrative approach serves this purpose: In addition to pollutant emissions into the various media, other aspects of the production process must also be taken into consideration in order to reduce the consumption of resources and energy and other environmental impacts during operation and after the closure of an industrial plant. The IE Directive is also intended to contribute to a reduction in accidents. The IE Directive's regulatory framework covers about 52,000 industrial plants in Europe, including about 9,000 in Germany. Particularly high emission industries such as the chemical industry, combustion plants, food industry, raw material processing industry (mineral raw materials, ferrous and non-ferrous metals, wood), waste treatment and incineration and the textile and leather industry are taken into consideration. The selection of industrial sectors and their plant size is consistent with the 4th BImSchV (4th Federal Immission Control Ordinance)[58] on plants subject to approval.

One of the main innovations of the IE Directive is the strengthening of the so-called **BREF documents** (BREF = best available techniques), which contain regulations on the best available techniques in the areas of industrial installations of particular environmental relevance. One chapter of the BREF documents are the so-called BREF conclusions, which are binding for all Member States and mandatory for transposition into national law, see also the section below. BREF documents are introduced in the IE Directive in Article 13(1).

The Industrial Emissions Directive requires coordination between Member States, industry and non-governmental organizations to adopt Best Available Techniques Reference Documents (BREF documents) to reduce emissions. The development process of these BREF documents is an information exchange, also called the Seville process, see below.

2.1.2.4. German legislation and instruments implementing the provisions of the Industrial Emissions Directive

The German legislator has transposed the IE Directive into national law with the "Act on the Implementation of the Industrial Emissions Directive" (IndEmissRLUG) of 08.04.2013 and two article ordinances of 02.05.2013. The provisions have been in effect since 02.05.2013. Changes were made mainly in the Federal Immission Control Act (BImSchG), Recycling Management Act (KrwG) and Water Management Act (WHG), see the sections below. In addition, d. the Waste Water Ordinance (AbwV) also implements regulations of the IE Directive.

[58] For an explanation of the nomenclature, please see footnote 20.

2.1.2.4.1 Federal Immission Control Act (BImSchG)[59]

This law lays down the requirements concerning the construction, quality, and operation of industrial installations that could potentially provoke environmental harm and other hazards due to accidents or incidents. The most important legal principle laid down by the Act is the duty to adhere to the state of the art. The Act distinguishes between plants whose construction and operation do not require a permit and are merely required to avoid and minimize environmental degradation, and plants that are required to obtain a construction and operation permit and for which “other hazards” are relevant.

The law (as amended) obliges plant operators to report more comprehensively to the authorities on compliance with the requirements of the permit. The requirements for monitoring are generally strengthened (implementation of environmental inspections, establishment of environmental inspection plans by authorities). There are also extended obligations for public disclosure to increase transparency.

The law (as amended) requires plant operators to prepare a status report for the plant site under certain conditions, and when plants are closed, there may be an obligation to return them to their original condition.

New requirements from the BAT conclusions are implemented in sectoral, general administrative regulations or taken into consideration in amendments to Technical Instructions on Air Quality Control[60] and by amending the relevant Federal Immission Control Ordinances (BImSchV) or other relevant ordinances.

Changes result for example for the following legal regulations[61]:

(1) Ordinance on plants subject to approval (4. BImSchV)
(2) Ordinance on the licensing procedure (9. BImSchV)
(3) Ordinance on landfills
(4) Ordinance on large combustion and gas turbine plants (13. BImSchV)
(5) Ordinance on the incineration and co-incineration of waste (17. BImSchV)
(6) Ordinances on solvents (2. and 31. BImSchV)
(7) Ordinance on the limitation of emissions from the titanium dioxide industry (25. BImSchV)

Another new issue was the Industrial Waste Water Treatment Plant Licensing and Monitoring Ordinance (so-called IZÜV).

2.1.2.4.2 BREF documents

The BREF documents are very comprehensive documents with a high information content. Plant operators and licensing authorities may refer to them for guidance. They are however

[59] Legal text BImSchG: https://www.gesetze-im-internet.de/bimschg/
[60] TA Luft = ”Erste Allgemeine Verwaltungsvorschrift zum Bundes–Immissionsschutzgesetz”, which is technical guidance to control the air quality
[61] Explanation onf the nomenclature: The legal text of the mentioned Federal Immission Control Ordinances can be found by googling on the web for the term ”x. BImSchV”. These abbreviations refer to individual amendments (=ordinances) to the ”Bundes-Immissionschutzgesetz”; they are commonly used in German jurisdiction and administration, instead of always using the full long term, which would be in German e.g. ”Vierte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes”.

not legally binding in their entirety in the Federal Republic of Germany. The associated techniques, requirements for emissions from a plant and operating conditions and all relevant organizational aspects of the operation of industrial plants are presented for various sectors at the highest possible level of environmental protection.

The chapter on BAT conclusions is the only element that has a special status in the BREF document. It is part of the BREF document and is also published as an implementation decision. The requirements specified are binding in all EU member states. They apply to new installations immediately after publication and to existing installations after four years at the latest. The BAT conclusions contain, in addition to emission bands and the associated emission reduction techniques, binding requirements for the permitting and operation of installations in the relevant sector. In German, the English terms for “BVT-Merkblätter” is “BREF documents” [62] (*B*est Available Techniques *Ref*erence Document) and for “BVT-Schlussfolgerungen” it is “BAT conclusions” (*B*est *A*vailable *T*echnique Conclusion) and are quite common and used synonymously in discussions[63].

Information exchange/Seville process

The BREF documents are developed and amended in a process established by the IE Directive and by implementation resolution 2012/119/EU[64]. This process is named information exchange or "Seville process". The name Seville process derives from the fact that the responsible European office (European Integrated Pollution Prevention and Control Bureau) is based in Seville and all meetings that take place during the exchange of information at European level are held in Seville.

2.1.2.4.3 Recycling Management Act (KrwG)

Requirements in connection with the obligations to draw up monitoring plans and programs by the landfill monitoring authorities have been incorporated into the **Recycling Management Act (KrwG)**[65] and new information and data transfer obligations have been formulated. The "information contained in BREF documents" has been included as a new element in the criteria for determining the status of technology (Annex 3 of the Recycling Management Act).

[62] Please see under this link: BREF documents

[63] Information relevant for the German context**:**

- Industry sectors
- Innovative techniques: Best available techniques (BAT) in selected industrial areas - Subproject 3 - Foundries Vol. 1
- Innovative techniques: Best available techniques (BAT) in selected industrial areas - Subproject 3 - Foundries Vol. 2
- Innovative techniques: Best available techniques (BAT) in selected industrial sectors Sub-project 3: Foundries Vol. 3
- Innovative techniques: Best available techniques in selected industrial sectors

[64] Legal text: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012D0119&from=EN

65 Legal text KrwG: https://www.gesetze-im-internet.de/krwg/

2.1.2.4.4 Water Resources Act (WHG) and Ordinance on Installations for Handling Substances Hazardous to Water (AwSV)

Plants that handle substances that are hazardous to water are subject to requirements as regards construction, quality, maintenance, operation, and decommissioning, pursuant to Article 62(f) of the Act. Such installations must be constructed, operated and decommissioned in accordance with the generally accepted state of the art. The Act's stipulations are fleshed out in greater detail in a federal regulation.

Changes have been made to the **Water Resources Act** (WHG)[66] by the law implementing the Industrial Emission Directive, ensuring that the most important European requirements of this directive are implemented. § 54 WHG, for example, includes definitions such as the BREF document, BAT conclusions and emission ranges that were previously unknown in German water legislation. § 57 WHG in particular, with its requirements for the discharge of waste water into bodies of water, has been revised in order to take into consideration the specific requirements of the IE directive. Important keywords are: Prevention of the transfer of pollutants from water to other environmental media, mandatory application of BAT conclusions, implementation deadlines for existing waste water discharges, obligations for regulators, enforcement authorities and operators, including possibilities for derogation.

Where substances hazardous to water[67] are treated in plants, the requirements for construction, condition, maintenance, operation and decommissioning result from Article 62 f of the Water Resources Act. Such installations need to be constructed, maintained, operated and decommissioned in accordance with the generally accepted status of technology. Legislative requirements are to be specified further in a federal ordinance.[68]

The treatment of substances hazardous to water was previously regulated in Germany by the differing regulations of the German federal states (VAwS). Since August 1, however, the nationwide "Ordinance on Installations for the Treatment of Substances Hazardous to Water" (AwSV)[69] has been in effect.

The German Chemical Industry Association (VCI) has formulated appropriate Interpretation Guidelines (in German only) based on the questions received from member companies regarding the interpretation of the new regulations. These interpretation notes address practical questions initially and provide appropriate information on possible implementation. In a second phase, changes compared to previous regulations in the individual federal states are explained.

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[66] Legal text WHG: http://www.gesetze-im-internet.de/whg_2009/

[67] https://www.umweltbundesamt.de/en/topics/chemicals/substances-hazardous-to-waters

[68] Information relevant for the German context:

- https://www.umweltbundesamt.de/themen/chemikalien/wassergefaehrdende-stoffe
- https://cms.umweltbundesamt.de/sites/default/files/medien/369/dokumente/info_awsv_2019_dd_4_web_.pdf
- https://www.umweltbundesamt.de/service/termine/fachinformationsveranstaltung-wgk-einstufung-nach-0
- https://webrigoletto.uba.de/rigoletto/public/welcome.do

[69] Legal text AwSV: https://www.gesetze-im-internet.de/awsv/

2.1.2.4.5 Waste Water Ordinance (AbwV)

The protection of water and soil is an important concern of the chemical industry. The IE Directive has therefore also triggered far-reaching changes to the Waste Water Ordinance (AbwV)[70] which defines and specifies the requirements for the discharge of waste water. An important aspect in this respect is to prevent water-polluting substances from leaking from plants and causing contamination in surface waters and groundwater.

Whereas the Waste Water Ordinance (AbwV) used to be a specification on minimum requirements for the water authorities, which was required as a basis for the granting of a discharge permit, the new AbwV basically addresses the discharger/operator of the plant directly. The discharger/operator is obliged to comply with all general requirements and the emission limit values specified in the attachments of the Waste Water Ordinance (AbwV). Additional requirements may be required in compliance with other requirements or may be specified by the competent authority when issuing a discharge permit.

Continuous changes of the waste water ordinance as a result of BAT conclusions

When new BAT conclusions are published in the EU Official Journal, they apply to existing installations after four years at the latest. The relevant appendices of the Waste Water Ordinance (AbwV) (i.e. the corresponding sectors) are to be reviewed during this period and adapted where necessary. The same applies to the water rights notices and also to the installations concerned, which must then comply with the new BAT requirements. An ad hoc working group (WG) consisting of experts from the federal states and the federal government is formed for each newly published BAT finding to check whether the national requirements laid down in the WFD correspond to European BAT. The ad hoc working group examines whether new BAT conclusions require adjustments to an annex. The national requirements of the appendices of the WFD concerned are then revised in the light of the new BAT in such a way that compliance with the European requirements is guaranteed.

2.1.2.5 Environmental Impact Assessment Act (UVPG) in Germany

The obligation to conduct environmental assessments is regulated by the Environmental Impact Assessment Act (UVPG)[71]. Detailed regulations on the principles, procedures, necessary contents and projects, plans and programs subject to inspection are provided. Other important legal principles are the 9th Ordinance on the Implementation of the Federal Immission Control Act (Ordinance on the Approval Procedure = 9. BImSchG, see above) and the EIA laws of the German federal states.

The German regulations are based on European law, especially on EIA Directive 2011/92/EU[72] and its amendments by Directive 2014/52/EU[73], and on SEA Directive 2001/42/EU[74], as well as on international agreements, especially the Convention on

[70] Legal text Waste Water Ordinance (AbwV): https://www.gesetze-im-internet.de/abwv/AbwV.pdf
[71] Legal text UVPG: https://www.gesetze-im-internet.de/uvpg/
[72] Legal text EIA Directive: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0092&from=EN
[73] Legal text: https://ec.europa.eu/environment/eia/pdf/EIA_Directive_informal.pdf
[74] Legal text: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0042&from=EN

Environmental Impact Assessment in a cross-border context (Espoo Convention) and the Protocol on Strategic Environmental Assessment (SEA Protocoll).

The environmental tests relevant in Germany include

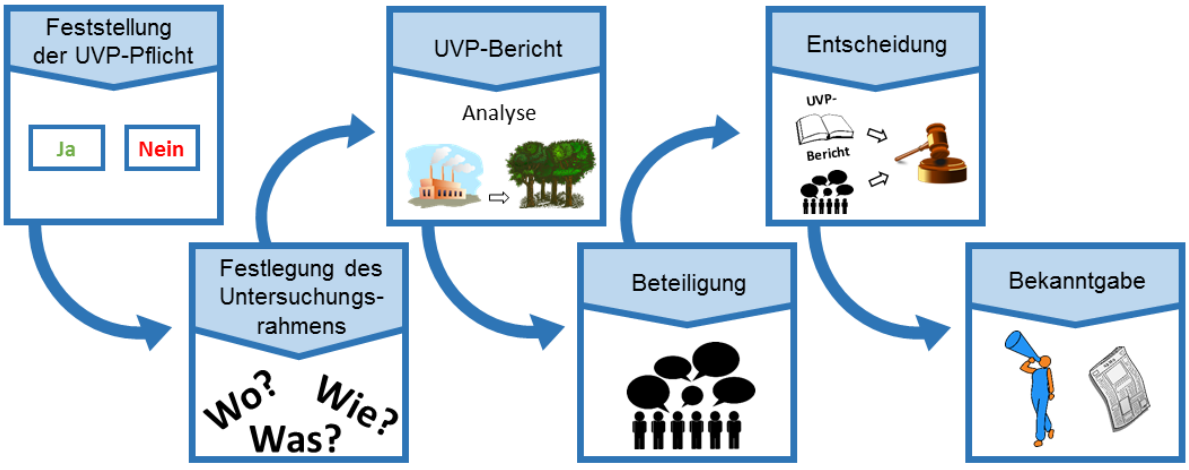
- The Environmental Impact Analysis (Engl. EIA, German UVP) and
- the Strategic Environmental Assessment (SEA).

The environmental impact assessment is integrated into the approval procedure for industrial plants and infrastructure projects or other projects. In contrast, the Strategic Environmental Assessment is conducted when certain plans and programs are prepared (e.g. municipal urban land use plans).

2.1.2.5.1 Principles

The principles of the EIA and SEA test procedures are the same. The aim of both test procedures is to determine and describe the effects on the environment and humans at an early stage.

The public and the authorities responsible for environmental issues are able to comment on the project or plan/program and the expected environmental effects on the basis of appropriate documentation. The public and the authorities of the other country may also participate in the procedure for projects and plans/programmes that may have cross-border environmental impacts. The authority responsible for the project or the body responsible for drawing up a plan/programme then evaluates the information provided by the procedure. It takes this information and the opinions of the public and the authorities into consideration when deciding on the admissibility of the project or the further procedure in the process of drawing up the plan or program.



Source: EIA portal of the German federal government

Annex 1 to the German EIA Act (UVPG, see above) contains a list of projects that require an EIA. A total of 149 project types are listed in Annex 1, mostly with threshold values indicating

the order of magnitude above which an environmental impact assessment is required. Appendix 1 includes project types from the following areas, among others:

- Stones and earths, glass, ceramics, building materials
- Steel, iron and other metals including processing
- **Chemical products, pharmaceuticals, petroleum refining and processing**
- Surface treatment of plastics
- Recycling and disposal of waste and other materials
- Storage of substances and mixtures
- Construction and operation of a pipeline system for the transport of substances hazardous to water within the meaning of § 21 paragraph 4 sentence 7 of this Act (Section 19.3 of Annex 1, see below)
- Construction and operation of a pipeline system for transporting substances (Section 19.6 of Annex 1, see below)

Sections 19.3 and 19.6 are regulated by the **Technical Rules for Pipelines (TRFL)[75].** It reflects the latest status of technology for the construction and operation of pipeline systems in Germany, which are subject to the **Pipeline Ordinance (RohrfltgV)[76].** It is prepared and updated by the Pipelines Committee, which is based at the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU)

The aforementioned list of project types in Annex 1 to the EIA Act, see above, distinguishes between projects for which an EIA is always conducted and those where a preliminary assessment is undertaken. A preliminary assessment of the individual case applies to projects for which, in accordance with the assessment of the legislator, significant adverse environmental impacts are possible but not to be expected in each individual case. The aim of the preliminary assessment is then to make a rough estimate of possible environmental effects of the project and to decide whether an EIA is required for a specific project.

2.1.2.5.2 Cross-border environmental assessments

Cross-border environmental assessments may pose a particular challenge due to the different legal requirements, administrative structures, cultural differences and language barriers in each country. International agreements have been concluded between Germany and various neighbouring countries on the specific details of such procedures to ensure that cross-border environmental assessments are performed swiftly and without conflict.

2.1.2.5.3 Database with information on approval procedures subject to EIA in Germany

Information on all current EIA-required approval procedures in Germany, including documents for ongoing public participation, are accessible via the EIA portals of the federal and state governments on the internet. The EIA portal of the Federal Government is operated by the Federal Environment Agency. The federal regulatory authorities are obliged

[75] Legal text TRFL: https://www.arbeitssicherheit.de/schriften/dokument/0%3A7889081%2C1.html

[76] Legal text RohrfltgV: http://www.gesetze-im-internet.de/rohrfltgv/index.html

by § 20 EIA (UVPG) to provide information in the federal portal on the environmental impact assessments to be conducted by them. The responsible regulatory authorities in the federal states are required to provide access to EIA information on the respective state portal. They are retrievable via the combined national portal of the federal states.

2.1.2.5.4 Information relevant for the German context

Further relevant information on EIA and SEA is available on the website of the Federal Ministry for the Environment, Nature Conservation, Construction and Nuclear Safety[77], including

- current developments in federal law,
- federal legislation, EC directives, international agreements,
- rulings of the European Court of Justice,
- guidelines, handouts, cross-border agreements of the federal government and
- brief information on important issues of environmental assessments.

2.1.2.5.5 Tailings Management Facilities

The failure of Tailings Management Facilities (TMF) leads worldwide to severe disasters. The United Nations Economic Commission for Europe (UNECE) thus developed in 2009 “Safety Guidelines and Good Practices for Tailings Management Facilities”.

These comprise recommendations to authorities on the necessary legal basis for permits for the safe operation of TMFs and recommendations to operators on their safety design.

In the frame of an Advisory Assistance Project[78] the following tools have been developed by UBA and several partner organizations:

1. a checklist, which inspectors and operators of TMFs can use to identify safety shortcomings of facilities and to derive measures to address them;
2. a Tailing Hazard Index that can be used by competent authorities and inspectors to get a preliminary overview on possible problems, prioritize TMFs of concern on a national and international level and define first actions to be taken.

The developed instruments were tested at two Ukrainian facilities and have been available for use in the entire UNECE region since 2016.

Meanwhile, a range of checklists could be made available (in English); they are accessible at the following website:

https://www.umweltbundesamt.de/en/checklists-for-tailings-management-facilities

[77] Please see at https://www.bmu.de/en/topics/education-participation/citizen-participation-your-opinion-matters/general-information-environmental-assessments/

[78] Please see at https://www.umweltbundesamt.de/en/topics/sustainability-strategies-international/cooperation-eeca-centraleastern-european-states/project-database-advisory-assistance-programme/improving-the-safety-of-tailings-management

2.2 Responsible bodies for implementation of German law pertaining to plant safety management and accident prevention

2.2.1 Federal level: Responsibilities of Ministries

In Germany, the following ministries are responsible for the implementation of German legislation pertaining to plant safety and accident prevention:

Body	German act(s)	Main tasks
Federal Ministry for the Environment, Nature Conservation and Nuclear Safety	Federal Immission Control Act Hazardous Incident Regulation	prevention of major accidents involving hazardous substances, limitation of impacts of such accidents for humans and the environment.
Federal Ministry of Labour and Social Affairs	Safety at work act Plant safety ordinance and related Technical Rules (TRBS, see above) Work place ordinance and related Technical Guidelines (ASR, see above)	occupational health and safety: Safeguarding of health protection when tools are provided for and used at work. This includes the safety during the operation of equipment and machinery which requires monitoring and control as well as the organisation of occupational health and safety.
Federal Ministry of the Interior, Building and Community	Law on civil protection and disaster assistance Federal Building Code	the responsibility for civil protection is with the federal government, the responsibility for disaster assistance is with the states. The Federal Building Code regulates all responsibilities pertaining to infrastructure.

2.2.2 Federal level: Responsibility of the German Environment Agency

The **German Environment Agency** (German: Umweltbundesamt, UBA) is an agency at federal level and as such closely related to the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. Accordingly, it assumes responsibilities in relation to plant

safety, in particular as regards the optimization of principles, technical rules and the state of scientific knowledge as well as promoting implementation. These tasks are as follows:

- In the interest of promoting plant safety, UBA conducts own research, supports research activities of the Ministry of the Environment and assists with the process of putting the findings of such research into practice. UBA is also an active participant in commissions that promulgate rules and regulations. Moreover, UBA documents and analyzes industrial accidents in Germany and elsewhere with the goal of avoiding future accidents or at least keeping them to a minimum.
- As German, European and international plant safety requirements are largely based on laws and standards, UBA is actively involved in (a) the elaboration and optimization of laws and standards; and (b) supporting and improving their application in practice. The laws are

  a) Federal Immission Control Act (Bundes-Immissionsschutzgesetz)

  b) EU Seveso Directive and the German Hazardous Incident Regulation

  c) Water Resources Act

  d) Environmental Impact Assessment Act

UBA is part of the following panels and committees which have a role in plant safety:

- In Germany, the Federal Ministry for the Environment receives industrial safety-related support from a special advisory panel that was set up pursuant to Article 15 of the Federal Immission Control Act (BImSchG).
- A pipeline commission (Ausschuss für Rohrfernleitungen (AfR)) was set up pursuant to Article 9 of the Pipeline Regulation (Rohrfernleitungsverordnung) as an advisory panel to the BMU.
- An emissions avoidance and accident prevention committee known as “Allgemeiner Immissionsschutz/Störfallvorsorge” (AISV), which is under the aegis of a regional-state/federal working group known as “Bund/Länder-Arbeitsgemeinschaft für Immissionsschutz” (LAI), is concerned with matters such as nationwide implementation of federal work safety regulations by the authorizing bodies of the regional states.
- A similar role is played by a joint regional-state/federal working group called “Umgang mit wassergefährdenden Stoffen” that deals with substances that are hazardous to water.
- UBA is also a member of various committees and working groups that engage in activities such as elaborating technical rules and standards and promoting the implementation of legal regulations.

Under the Federal Emission Control Act, UBA seeks ways to flesh out and optimize the basic requirements pertaining to state of the art safety technology in connection with the following:

- Avoiding operator errors.
- Preventing access by unauthorized third parties.
- Natural hazards that are intrinsic to their surroundings.

Apart from the human and technological factors, the organizational structure for safety measures also plays a major role when it comes to plant safety. Under German law, safety management systems are required to integrate the following elements: an organizational structure; spheres of responsibility; actions; procedures; processes; and resources. Such organizational structures are required to promote the following: high quality in terms of establishment, operation, change, maintenance, monitoring and emergency planning; accident prevention; and limiting the negative effects of accidents. UBA has established support resources that can be used to promote effective safety management.

In view of the supreme health and environmental importance of competent risk and hazard communication before, during and after an accident or incident, UBA has conducted research on communication processes for accidents and have created entities that can provide assistance in such situations.

As outlined in section 2.1.2.2.5 above, the central reporting and evaluation office (ZEMA) documents, assesses and publicizes in a database and annual reports all accidents and incidents that are subject to statutory reporting requirements. UBA hosts the ZEMA office. The goal here is to lay the groundwork for optimization of the state of the art in the field of safety technology.

At European level, UBA's main industrial safety focus is on the Seveso Directive, whose implementation is being supported by a standing committee of the member states to whose work UBA contributes.

At the international stage, one of the UBA's main focuses is the OECD chemical accident working group and the UN Economic Commission for Europe (UNECE)'s working group for implementation and optimization of the industrial accident convention.

2.2.3 State and regional level: authorities, agencies and offices

In relation to the preparation of safety reports, the following bodies are reponsible:

Body	Main tasks
Supreme state authorities	
State [79] ministries for the environment	responsible i.a. for environmental protection and emission control, state legislation, the Federal Emission Control Act (BImSchG) and the ordinances issued on the basis of this Act (technical supervision), in this case inter alia on the implementation of the StörfallVO/Seveso III Directive, reporting to the BMU

[79] The 16 German states are Baden-Württemberg, Bavaria, Berlin, Brandenburg, Bremen, Hamburg, Hesse, Mecklenburg-Western Pomerania, Lower Saxony, North Rhine-Westphalia, Rhineland-Palatinate, Saarland, Saxony, Saxony-Anhalt, Schleswig-Holstein and Thuringia.

	in accordance with Art. 9, 15 and 19 of the Seveso III Directive, and for implementing the relevant provisions of the BImSchG for non-commercial establishments
State ministries for economic affairs	responsible for the energy industry, here in particular for natural gas storage facilities in the scope of the Federal Mining Act
State ministries of the interior	supreme disaster assistance authority: responsible for legislation and technical supervision of civil protection and disaster assistance in the German states
Upper state authorities	upper state authorities are subordinate to the supreme state authority; they act as competent authorities throughout the state and usually have no subordinate administrative substructure
State environmental agencies, structural and approval authorities, state administration offices	depending on the state, upper technical and supervisory authority: execution of the BImSchG and its implementing ordinances, including the Hazardous Incident Regulation (plant safety, safety in handling hazardous substances, in some federal states also responsibilities for occupational health and safety); issuing licences under immission control law and issuing orders, receiving the notification of the establishment, in some cases preparing the reporting pursuant to Art. 9, 15 and 19 of the Seveso III Directive and supporting the supervisory authorities in examining the safety reports.
State offices for mining	enforcement and monitoring according to mining law and the obligations of the authorities according Articles 8, 9(4), 14(2) and 18 of the Seveso III Directive.
Civil protection authorities, state administration Offices	responsible for civil protection and disaster assistance management, as well as for general disaster prevention (fire department, emergency services)
Central state authorities	central state authorities are directly subordinate to a supreme state authority; they have their own administrative sub-structure
District governments (regional	implementation of the StörfallVO/Seveso III Directive (plant safety, safety in handling hazardous

councils)	substances, in some federal states also responsibilities for occupational health and safety); issuing emission control permits (in consultation with industrial inspectorates or the offices for environmental protection), they draw up and coordinate monitoring systems and programmes and are responsible for summarising and forwarding inspection reports.
Industrial inspectorates / state offices for environment and environmental protection	implementation of the BImSchG and its implementing ordinances with regard to the operating areas within the meaning of Art. 3.1 of the Seveso III Directive (monitoring and inspection as well as the receipt of notifications of major accidents, preparation of reports in accordance with Art. 9, 15 and 19 of the Seveso III Directive; granting of licences under immission control law - in coordination with the regional councils), in some cases also enforcement of the corresponding state laws for non-commercial establishments
Lower state authorities	
County administrative authorities / district offices / administrative districts and independent cities	responsible for the enforcement of the StörfallVO/Seveso-II-RL in non-commercial enterprises (e.g. universities, research institutes): • Lower civil protection authorities draw up external emergency plans taking into account the operators' internal emergency plans; coordination pursuant to Art. 11 of the Hazardous Incident Regulation • Building authorities are responsible for monitoring the settlement within the framework of urban land use planning.

2.3 Environmental Chemicals Management for Supply and Use

2.3.1 Overview

The environmental chemicals management in Germany is mainly regulated at European level. When we speak about chemical safety regulations in the EU, that are applicable in Germany, we mean a comprehensive framework of approximately 40 pieces of legislation, referring to

- Chemicals for supply and use: Safety of use of substances and mixtures in the EU and in Germany is mainly regulated by Regulation (EU) 1907/2006 (REACH) and Regulation (EU) 1272/2008 (CLP; implements the UN GHS into European legislation). Apart from this, there are a couple of acts which regulate safety and health at work, e.g. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work;
- Chemicals for specific uses, the most prominent being biocidal products, regulated by Regulation (EU) 528/2012, and pesticides, regulated by Regulation (EU) 1107/2009
- Chemicals in products, e.g. in toys, regulated by the EU toy safety Directive 2009/48/EC, cosmetic products, regulated by Regulation (EU) 1223/2009 and detergents, regulated by Regulation (EU) 648/2004;
- The “substances in articles” provisions in Art. 7 and 33 REACH Regulation
- Chemicals in wastes: Decision 2000/532/EC on assessment and classification of waste and Directive 2008/98/EC (Waste Framework Directive WFD); the 2018 Amendment of this Directive established a specific link to the “substances in articles” provisions in Art. 44 REACH Regulation
- Chemicals during transport: Transport by road, rail and inland waterway is covered by a single EU directive – EU Directive 2008/68. Transportable pressure equipment is governed by EU Directive 2010/35.

Chemicals for specific uses will as well as the transport of dangerous goods including chemicals is not in the focus of this report. The management of chemical safety in installations has been presented in the preceding chapter, see above.

2.3.2 REACH & CLP

2.3.2.1 REACH as milestone of regulatory chemicals management

The EU Regulation on the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals 1907/2006 (**REACH**) came into force in 2007 and aims at improving the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances while promoting alternative methods for the assessment of hazards of substances. The regulation contains requirements for the production, marketing and use of chemicals. REACH also aims to enhance innovation and competitiveness of the EU chemicals industry.[80]

2.3.2.1.1 History of REACH

Before REACH, the production and use of substances in industrial processes were practically unlimited in time and content. Action was just taken if negative effects on humans and the environment became visible. The only consequence, however, was that the substance had to be classified and labelled according to Directive 67/548/EEC. The manufacturers were not obliged to test their substances for adverse effects. Instead, the “Existing Substance Regulation” (ESR), installed an administrative risk assessment program. This program aimed at identifying the risks and proposing risk mitigation measures for the most relevant substances. For this process, significant resources were invested. Nevertheless, the result was not satisfactory, as only a maximum of four substances per year went through the process. With this regulatory approach, the problem of "toxic ignorance" obviously could not be solved in the near future. In response to this problem constellation, the legislators of the European Union decided to merge major parts of the previous legislation in the REACH Regulation replacing about 40 former legal texts.[81]

2.3.2.1.2 Basic principles of REACH and CLP

REACH heralds a paradigm shift in the regulation of chemicals by implementing the principle of substance responsibility, whereas actors within the chemical supply chain are responsible “to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment”. The regulatory approach therefore no longer focuses on administrative programs but rather strengthens the self-responsibility of the economic actors. Emphasizing that REACH “provisions are underpinned by the precautionary principle”, Art. 1(3) REACH obliges all industry actors to “adequately” control the chemical-related risks.

To achieve a “high level of protection of human health and the environment” (Article 1(1) REACH), the regulation establishes different mechanisms which primarily aim at information, communication and co-operation of the economic actors, but to a considerable degree give leeway as long as “adequate risk management” is achieved. With these impulses, REACH

[80] For an introduction into the legislative framework on chemicals (including case law on REACH) see also: *Führ, M./Schenten, J.*, **Industrial Chemicals in the Regulatory Laboratory: Self-responsibility and Inclusive Governance**, in: Peters, M./Eliantonio, M. (Eds.), Research Handbook on EU Environmental Law, Edward Elgar Publishing, 2020, 344–363 (Chapter 22). https://doi.org/10.4337/9781788970679.00033.

[81] For further information, see also “The birth of EU chemicals legislation: How REACH came to life” - Presentation from Bjørn Hansen, Executive Director of the European Chemicals Agency on how chemicals management has developed in Europe: https://www.youtube.com/watch?v=FiuCBwxD2Y0.

aims to trigger innovations in material, technical or organizational terms, thus contributing to the subordinate aims of REACH, namely “enhancing competitiveness and innovation”.

Closely interlinked with REACH, Regulation (EU) No. 1272/2008 regulates classification labelling and packaging (CLP) thereby transfering the UN globally harmonized system (GHS) to the EU. Similarly to REACH, it implements the "definition principle", which obliges industry actors to classify substances themselves following a self-classification scheme based on Annex I CLP. Under certain conditions the authorities issue a "harmonized" classification, which is then legally binding for all actors. Besides requirements for labelling and packaging, the classification is linked to occupational health mechanism and regulatory instruments for plant safety management (in particular the Seveso Directive) and the handling of waste.

REACH and CLP are EU Regulations. These are directly applicable as they are; in contrast to an EU Directive, they are not transposed into national law.

2.3.2.1.3 Definition of chemical products under REACH & CLP

(1) Substances

Substances are the primary legal object in REACH and CLP, defined by Art. 3(1) REACH / Art. 2(7) CLP as a "chemical element and its compounds in the natural state or obtained by any manufacturing process”. Substances are seen in their in their actual form, i.e. in the form in which they are brought to the market, which includes “any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition”.

(2) Mixtures

Mixtures under REACH and CLP are "mixture or solution composed of two or more substances" (Art.3(2) REACH / Art. 2(8) CLP). They are created by an intentional mixing process, for example by dissolving in water, not by chemical reaction of substances or mixtures (that would create a separate substance).

(3) Articles

An ‘article’ is “an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition” (Art.3(3) REACH). This e.g. describes a pencil or a bicycle. A 2015 ruling by the European Court of Justice clarified that this classification applies regardless of whether the object is isolated or part of a complex object.[82] An article thus remains an article even if it is assembled in a more complex object, a concept described as ‘once an article always an article’. Following this clarification, any constituent part of e.g. a personal computer, from a metal pin in a transistor on a circuit board to the housing represents an article.
Some goods consist not only of articles in terms of REACH but are also combinations of an article (functioning as a container or a carrier material) and a substance or mixture. This applies e.g. for fluid products and their packaging. In that case, the substance or mixture and the article are to be regarded separately concerning obligations.

[82] The court rouling can be accessed in full at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62014CJ0106

2.3.2.1.4 Main pillars of REACH & CLP

(1) Registration

The registration of chemical substances is governed by Title II REACH and Article 5 enshrines the principle "No data, no market". According to this principle, only substances that are registered may be manufactured or placed on the market. This means: without registration, companies may neither manufacture or import a substance or mixture nor use it in articles. Every manufacturer or importer is responsible for the registration of his chemical substance. The obligation to register applies from a quantity threshold of one tonne per year that is to be manufactured or imported. With a view to efficiency and consistency, REACH, as a general rule, requires joint data submissions from registrants of substances with the same identity ("one substance, one registration" or "OSOR" principle). There are exceptions from registration for various substances, such as pharmaceuticals, for which special regulations already apply.

To register a substance, the manufacturer or importer submits a registration dossier to the European Chemicals Agency (ECHA). The registration dossier contains a technical dossier. The technical dossier contains data on the identity of the registrant and the registered substance. It also lists the properties of the substance in question and provides information on use and safe handling. To this end, the substance is subjected to appropriate tests and investigations with regard to the risks for humans and the environment. The results of these tests have to be attached to the dossier in the form of study summaries. The extent of the tests to be carried out depends on the tonnage: the larger the registered quantity, the more data and sometimes other data have to be submitted. The quantity thresholds of 10, 100 and 1000 tons per year are decisive. Above 10 tons per year, the registration dossier must contain a chemical safety report in addition to the technical dossier, and the chemical safety report identifies concrete risk management measures for the various applications in which the substance is used.

All information that has to be submitted for the registration of substances according to the REACH regulation is generally recorded and forwarded electronically. In order to ensure the uniform transmission of registration information to the ECHA, ECHA defines the formats and makes the necessary software packages available free of charge via its website. Internet access is provided via the "REACH-IT" portal on the ECHA website. IUCLID (International Uniform Chemical Information Database) is the central software tool available to companies to collect and submit substance data for registration, to exchange data between companies, to manage the process and to exchange information such as guidance documents.

Guides for registration:

Registration in a Nutshell (2017): This Guidance in a Nutshell aims to give a simple and concise introduction to the information content of registration dossiers for chemical substances under REACH, including the information requirements, i.e. the data on physicochemical, toxicological and ecotoxicological properties, and to the chemical safety assessment. In addition, a brief outline of how to prepare and submit a registration dossier is provided. Finally, essential follow-up activities required by ECHA and the registrants upon registration submission are outlined.

Registration (2016): The aim of this guidance is to assist industry in determining which tasks and

obligations have to be complied with to fulfil their registration requirements under REACH. This document guides potential registrants to answer the following questions: Who has registration obligations? Which substances are within the scope of REACH? Which substances need to be registered? When to pre-register and when to submit an inquiry? What is the registration dossier? When does a registration dossier have to be submitted to ECHA? What is a joint submission? What are registrants' obligations regarding data-sharing? When and how to update the registration dossier? What is the registration fee? What are the duties of ECHA once the registration dossier is submitted?

(2) Evaluation

Evaluation is one of the tasks that the competent authorities take on within the REACH system. The evaluation process is divided into two main areas covered by ECHA and the Member States.

Dossier evaluation: The evaluation of the registration dossiers serves primarily to ensure the quality of the data and to avoid unnecessary animal experiments. Under Article 41, ECHA can examine individual registration dossiers to ascertain whether the relevant requirements are met. At least 5% of the dossiers submitted must be examined for each quantity band (Article 41 (5)). If ECHA evaluates a registration dossier as incomplete, it will first request data from the responsible registrant. If no or insufficient information is provided, ECHA will contact the competent authorities of the Member State on whose territory the registrant is located and ask them to initiate monitoring measures with the registrant concerned.

Substance evaluation: The national authorities of the member states carry out the substance evaluation (see section 2.3.2.2.1 paragraph (4) for a detailed description). In cooperation with the ECHA, a list of substances to be subjected to substance evaluation is being compiled. This is done if there is a suspicion that the substance poses a corresponding risk to human health and the environment. Such an assessment is carried out regardless of the tonnage in which the substance is manufactured, imported or used. The data submitted during registration are used to carry out the substance evaluation. The results of a substance evaluation can lead to a restriction being imposed on a substance or the substance being included in the candidate list of substances of very high concern (SVHC).

Guides for evaluation:

How to act in dossier evaluation (2020): The purpose of this practical guide is to explain in simple terms your duties regarding the content of your registration dossier and how the dossier is processed under dossier evaluation. The guide aims to give you and the other recipients of a draft or adopted decision information on how to act after receiving the decision. It also highlights the opportunities and obligations that you as registrants have in making sure that your dossier is compliant with the REACH Regulation. The guide also reminds you of your other obligations, such as data sharing, to make sure the information is generated in a reasonable manner and demonstrates the safe use of chemicals. Finally, the practical guide also provides advice and recommendations based on ECHA's experience with the dossier evaluation processes.

How to act in substance evaluation (2020): The purpose of this Practical Guide is to explain in simple terms what substance evaluation is, and how substances are selected and subsequently evaluated.

This guide aims also to highlight the opportunities as well as the obligations that you, as a registrant, have in providing the information requested under substance evaluation. This guide describes (i) what kind of different administrative outcomes you can expect from the substance evaluation process and (ii) how and when you can react to communications received from an evaluating Member State competent authority (eMSCA) or from ECHA.

(3) Authorisation

Substances may be identified as causing a “very high concern” (SVHC), if they meet the criteria set out in Article 57, i.e.

substances classified as carcinogenic, mutagenic or toxic for reproduction (so-called CMRs),

substances that are persistent, bioaccumulative and toxic (PBT),

vPvB substances for which there is scientific evidence of increased persistence (vP)

as well as increased bioaccumulation (vB) and other substances linked to a “equivalent level of concern”.

Those substances are subject to the long-term goal of progressive replacement and to the multi-stage authorisation procedure under Title VII REACH (see Figure 1, Führ 2013/201983).

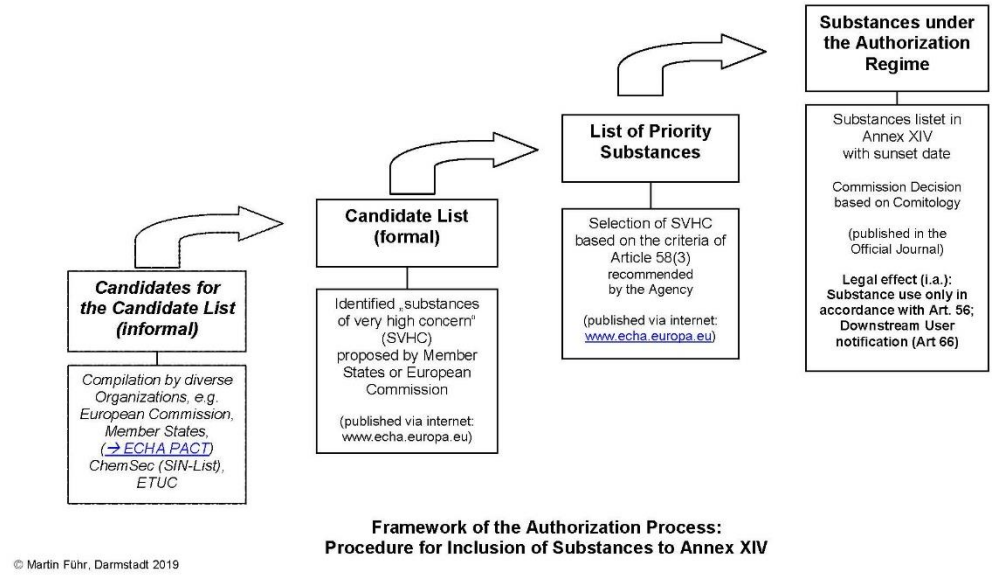


Figure 1 Procedure for Inclusion of Substances to REACH Annex XIV (Führ 2013/2019)

A substance is classified as SVHC by inclusion in the "Candidate List of Substances of Very High Concern". The next step is the recommendation of ECHA as priority substances. According to Article 58(3) “priority shall normally be given to substances with: (a) PBT or vPvB properties; or (b) wide dispersive use; or (c) high volumes.” The final decision to include a SVHC in Annex XIV is made by the European Commission through comitology “regulatory procedures with scrutiny”. It takes the form of an amendment to the REACH regulation.

[83] Figure from *Führ/Schenten* 2019 (see supra note 80), p. 353; adapted from *Führ, M.*, **Chemikalienrecht**; in: Ehlers/Fehling/Pünder (Hg.), Besonderes Verwaltungsrecht, Bd. 2,³2013, § 58, C.F.Müller, Heidelberg-

Inclusion in Annex XIV makes a substance subject to authorisation. Placing these substances on the market or using them is then not permitted. Exceptions only exist if the specific use was explicitly exempted from the authorisation obligation or was permitted as a result of an application approval process. An authorisation shall only be granted if the applicant company can demonstrate that it can adequately control the risks arising from the use of the substance or if the socio-economic benefits outweigh the risks and no suitable alternatives are available.

Guides for authorisation:

How to apply for authorisation (2017): The purpose of this guide is to give potential applicants practical advice on how to prepare a 'fit-for-purpose' application for authorisation under the EU REACH Regulation, including choosing an appropriate 'use description'. The guide describes the essential information that should be included in an application for authorisation and presents examples from previous applications. It identifies the important documents that applicants should familiarise themselves with before preparing an application. It also outlines some key issues that should be considered when developing an application strategy, gathering information (including supply chain communication) and application planning.

How to prepare an application for authorisation (2020): The purpose of this manual is to assist in the preparation of an application for authorisation and its submission to the European Chemicals Agency (ECHA). More particularly it outlines the IUCLID sections and fields to be filled-in in order to prepare an application according to Title VII of REACH. It should be noted that the aim of this manual is to help the applicants to identify which of the numerous IUCLID fields are of prime importance for a successful submission of an application: all the "mandatory" sections (see chapter 7 How to create a substance dataset) need to be filledin to enable ECHA to process the application. The generated IUCLID application for authorisation dossier can then be submitted to ECHA through REACH-IT.

(4) Restriction

Annex XVII of REACH lists substances that may not be manufactured, placed on the market or used, or may be used only in a restricted manner, because of unacceptable risks to human health or the environment. A restriction may be set for a substance on its own, in a mixture or in an article. The substances listed in Annex XVII may be manufactured, placed on the market or used "only if the conditions of this restriction are met". This broad wording allows the legislator to impose a variety of requirements, for example specific risk reduction measures such as the use of certain protective gloves. Depending on the type of restriction, all actors in the supply chain, i.e. manufacturers, importers, distributors or marketers of substances, mixtures and articles, but also downstream users, may be affected by the implementation.

(5) Classification, Labelling and Packaging

CLP obliges all industry actors to classify every substance (as such or in mixtures) with hazardous properties (for example, toxic, carcinogenic, explosive or environmentally hazardous) on the basis of legally established criteria. In this respect the 1 tonne/year threshold of the registration obligation under REACH does not apply. Thus, the number of

notified classifications in the ECHA classification and labeling (C&L) inventory[84] is significantly higher than the number of registered substances[85]. ECHA maintains the C&L Inventory, but does not review or verify the accuracy of the information.

In addition, the Commission can make harmonized classifications according to Art. 36 and 37 REACH, which are listed in Part 3 of Annex VI to CLP.

By means of an obligation to notify, the classification information flows into the ECHA classification and labeling inventory. Substances and mixtures placed on the market shall be labelled and packaged by the supplier according to their classification. The labels are intended to give evidence of the associated hazards to persons who deal with a substance or mixture and take risk mitigation measures, e.g. by using suitable protective gear.

Guides on CLP:

How to prepare a classification and labelling notification (2020): The purpose of this manual is to assist in the preparation of an IUCLID Classification and Labelling (C&L) notification dossier under the CLP Regulation (EC) No 1272/2008. More particularly, it outlines the IUCLID sections and fields to be filled-in in order to prepare a complete C&L notification dossier according to Article 40(1) of the CLP Regulation. The aim of this users' manual is to help the notifiers to identify which of the numerous IUCLID fields are of prime importance for a successful submission of a C&L notification.

2.3.2.2 Roles and responsibilities

This chapter ensembles a description of the different roles of administrative bodies (section 0, the enforcement efforts (section 2.3.2.2.2) as well as an overview on the obligations of industry actors (section 03.2.2.3)

2.3.2.2.1 Roles of administrative organisations

The predominant administrative body in the implementation of REACH and CLP is the European Chemicals Agency (ECHA or Agency) as a mature and independent regulatory agency. A number of decisions, however, are taken by the European Commission. In the decision-making process, moreover, the national competent authorities are obliged with specific tasks; the Member States are also involved in the decision-making process of ECHA by means of the Member States Committee (MSC). The roles of the different administrative bodies in the European chemicals arena are reflected under paragraph (4) below, describing the systematic evaluation of specific substances that raise concerns in terms of protection of human health and the environment and the process of establishing a "Community Rolling Action" Plan (CoRAP).

(1) ECHA

The European Chemicals Agency (ECHA) established in Helsinki is responsible for the technical, scientific and administrative management of the REACH system. ECHA is

[84] The Classification & Labelling Inventory contains the classification and labelling elements of registered substances and further substances covered by the CLP Regulation: https://echa.europa.eu/regulations/clp/cl-inventory.

[85] The C&L inventory contains more than 180.000 results (as of 20.11.2020); the registration database contains circa 23.000 unique substances.

composed of several internal bodies (see the list in Art. 76 REACH). The ECHA secretariat It is mainly responsible for the following tasks (Art. 77 REACH):

- Receipt of (pre-)registrations, notifications and applications for approval
- Conduct the dossier evaluation
- Review and decision on test proposals
- Development of an ongoing substance evaluation plan
- scientific opinions during the authorisation procedure and in the development of restriction rules
- Development and maintenance of a database with information on all registered substances
- Providing technical and scientific tools for the application of the regulation
- Advising the Member States and the institutions of the European Union on questions relating to chemical substances
- Providing technical and scientific guidance to industry, in particular SMEs and competent authorities

The Agency “is managed by its Executive Director, who shall perform his duties in the interests of the Community [European Union], and independently of any specific interests” (Art. 83 REACH). The Agency is not a subsidiary entity of the European Commission; rather it can be characterised as a “independent and mature” regulatory agency within the institutional framework of the European Union.

The highest decision-making body within the Agency is the Management Board (Art. 78 REACH). It adopts, i.a., the annual and multi-annual work programmes and the budget of the Agency. Furthermore, it is in charge of defining “the internal rules and procedures of the Agency”. The Management Board appoints the Executive Director (Art. 84 REACH) and exercises “disciplinary authority over the Executive Director” (Art. 78(5) REACH).

(2) European Commission

The European Commission has the competence to issue implementing legislative acts (derogated regulations). In this way it is possible to update and complete the EU Regulations on chemicals (REACH/CLP/Biocides/PIC). By these means the Commission prepares implementing legislation necessary for the provisions to be put into effect, for example:

- a regulation on fees, setting out the fees to be paid by industry for REACH and Biocides-related activities e.g. registration or authorisation applications;
- the rules of procedure for the ECHA Board of Appeal; and
- a regulation on test methods.

The Commission, furthermore, is charged with specific tasks connected to several of decisions making processes managed by ECHA. When there is an unacceptable risk to human health or the environment new restrictions can be adopted (by amending REACH Annex XVII). The Commission also is in charge of defining which substances of very high concern (SVHC) are be subject to authorisation procedure (by amending REACH Annex XIV). In both aforementioned cases, the Commission can ask ECHA to prepare a dossier underpinning the need for regulatory action (in accordance with Annex XV).

The Commission also decides upon the granting of authorisations under the REACH and Biocides Regulations.

In cases where the ECHA's Member State Committee is not able to come to a unanimous agreement (the identification of Substances of Very High Concern, on the results of the evaluation of registration dossiers or the evaluation of specific substances) the decision-making power is transferred to the European Commission.

More generally, the Commission – in line with its power to initiate legislative proposals on the EU level – is tasked with developing and negotiating proposals for EU policy on the management of risks and hazards from chemical substances, and may ask the Agency to provide scientific advice, including in support of the EU's international activities, in this regard.

In its implementation tasks, the Commission is assisted by Committees or other meetings composed of representatives from the Member States competent authorities (e.g., the informal expert group CARACAL - Competent Authorities for REACh and CLP[86]).

(3) Member states authorities

The national Competent Authorities participate in the evaluation process, in particular by carrying out substance evaluations (see section 0). In Germany, the REACH Adaptation Act of 20 May 2008 (BGBl. I p. 922) establishes the national Competent Authorities. According to this, within the Federal Institute for Occupational Safety and Health (BAuA) in Dortmund, the division 5 also acts as Federal Office for Chemicals (BfC)[87], performs duties under European chemicals regulations, often in a coordinating role. Together with the Federal Environment Agency (UBA) and the Federal Institute for Risk Assessment (BfR) in Berlin, it is the national evaluation authority.

(4) Roles of the actors exemplified by Substance Evaluation and the CoRAP process

The objective of Substance Evaluation (SEv) under the REACH Regulation is to allow for the generation of more information on the substance to clarify a potential risk to human health or the environment. According to Article 45(1) of the REACH Regulation, ECHA is responsible for coordinating the substance evaluation process and ensuring that substance on the Community Rolling Action Plan (CoRAP) are evaluated.[88] In doing so, ECHA shall rely on the Member State competent authorities (MSCA).

In cooperation with the Member States, ECHA has developed criteria for prioritising substances as a prerequisite. ECHA and the Member States use these criteria for selecting substances for evaluation. The resulting Community rolling action plan is the list of substances, which the Member States will evaluate in the three years covered, specifying for each substance:

- the assessment year;
- the Member State responsible for the evaluation; and

[86] http://ec.europa.eu/environment/chemicals/reach/competent_authorities_en.htm and https://ec.europa.eu/growth/sectors/chemicals/key-players_en.
[87] https://www.baua.de/EN/About-BAuA/Organisation/Division-5/Division-5_node.html.
[88] The evaluation process is explained in more detail under https://echa.europa.eu/regulations/reach/evaluation/evaluation-procedure.

- the initial grounds for concern.

In each update, ECHA can add new substances and revise the year of evaluation for already listed substances, when necessary. ECHA publishes the proposal on its website and asks the opinion of the Member State Committee. ECHA adopts the updated CoRAP once the Member State Committee has provided a favourable opinion and publishes the result on its website.

The flowchart (Figure 2) below illustrates the process of establishing an update of the CoRAP.[89] ECHA describes the process as follows:

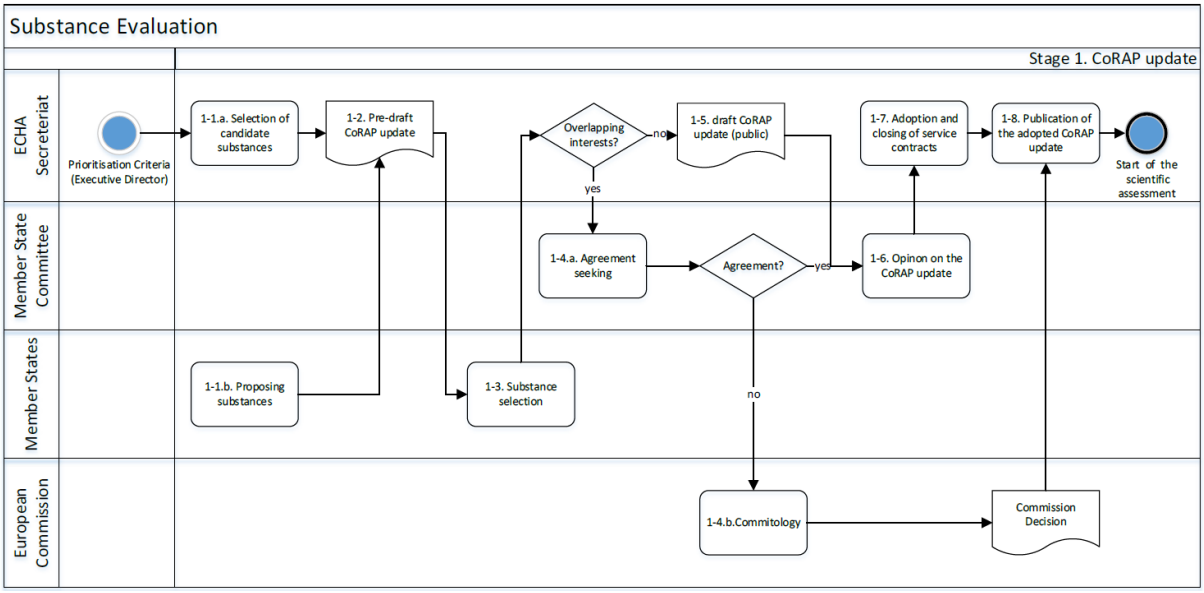


Figure 2 Establishing updates on the CoRAP (ECHA 2020)

Step 1-1. Selection of candidate substances: Every year and based on agreed criteria, ECHA establishes a list containing additional substances for evaluation (a). Simultaneously, Member States can propose additional substances (b).

Step 1-1.a. Preparation of a SEV pre-candidate list: The ECHA secretariat identifies potential new candidates for substance evaluation. The ECHA secretariat identifies such additional substances:

– in the dossier evaluation process; or

– during screening of the REACH registration database.

Step 1-1.b. Member State proposing substances: Whenever a Member State has information for any substance which indicates that it is a priority for evaluation, it notifies this additional substance to ECHA. The ECHA secretariat inserts such notified additional substances in the preliminary draft CoRAP and allocates the substance to the proposing Member State.

Step 1-2. Pre-draft CoRAP update: The ECHA secretariat prepares a pre-draft CoRAP containing the list of substances identified in Steps 1.a. and b. ECHA then verifies that the substances included in the preliminary draft CoRAP fulfil the prioritisation criteria posing a possible risk to human health or the environment. The ECHA secretariat also considers the potential capacity of the Member States for evaluating substances when preparing the list. The ECHA secretariat collects for each potential CoRAP candidate substance information concerning

[89] ECHA document "Procedure on Substance Evaluation-Establishing updates of the Community Rolling Action Plan" (CoRAP), page 6 (PRO-0022.10, last online access 20.11.2020).

already ongoing regulatory processes or available assessment reports of such processes. This search covers any national or international activity. The ECHA secretariat submits the preliminary draft CoRAP to the Member States for comments and expressions of interest for evaluating one or several of the substances.

Step 1-3. Substance selection: In this Step, the Member States volunteer to evaluate a given substance from the list. The Member State takes ownership of the respective case including the documentation prepared so far. The ECHA secretariat considers cases where no Member State volunteers as priority candidates for the next CoRAP update (see Step 1-2.).

In cases where two or more Member States are interested in evaluating the same substance and they cannot agree how to proceed, the ECHA secretariat refers the matter to the Member State Committee (Step 1-4.a.).

Step 1-4.a. Agreement seeking: The ECHA secretariat refers cases where two or more Member States are interested in evaluating the same substance and cannot agree on how to proceed to the Member State Committee (MSC) for resolution. The MSC has 60 days to reach agreement on which Member State will evaluate the respective substance.

Step 1-4.b. Referral to the Commission (Article 45(3)): The ECHA secretariat submits the conflicting opinions to the European Commission in cases where the MSC fails to reach a unanimous agreement. The Commission decides then in a Comitology procedure, which authority will evaluate the substance(s).

Step 1-5. Prepare the draft CoRAP and obtain an opinion from the MSC: The resulting list assigns the evaluating Member State for each substance. It indicates such cases that the ECHA secretariat referred to the Member State Committee for agreement seeking (Step 1-4.a.). The ECHA secretariat submits this resulting draft CoRAP to the Member State Committee to obtain its opinion. The ECHA secretariat simultaneously informs the Member States of the draft CoRAP and publishes a non-confidential version on its website to inform stakeholders and the broad public of its intention to include certain substances in the new CoRAP.

Step 1-6. Forming an opinion: The MSC forms an opinion on the draft CoRAP update. The process of obtaining an MSC opinion on the draft CoRAP update preferably happens in parallel to the agreement seeking (step 1-4.a.).

Step 1-7. Adoption and closing service contracts: Based on a favourable opinion of the MSC, the ECHA secretariat closes a service contract with the respective evaluating Member State competent authority or the appointed institution. This applies to all cases listed for evaluation within the first year of the agreed CoRAP. ECHA will move cases where neither the Member States nor MSC could find an agreement on the evaluating Member State to a later CoRAP update. (The timing of the decision making in the Commission may not align with the timetable for adopting the CoRAP update in question.)

Step 1-8. Publication of the adopted CoRAP update: ECHA publishes the adopted CoRAP update on its website.

According to Article 48, the evaluating MSCA decides and notifies ECHA on how it intends to utilise the information obtained in substance evaluation and which risk management route it anticipates will be chosen, where relevant. The possible risk management routes include: authorisation, restriction, harmonised classification, other Community wide actions (e.g. regarding Water Framework Directive 2000/60/EC, worker protection legislation) or even appropriate national actions. ECHA will share this information with the Commission, the Registrant(s) and the Competent Authorities of the other Member States.

The substance evaluation process following the establishment and updates of the CoRAP can

be divided in three stages:

(a) Coordination of Substance Evaluation

The evaluating MSCA shall submit to ECHA a SEv IUCLID dossier that contains a draft decision (if necessary), a (interim) substance evaluation report and a time recording sheet.

To ensure that the substance evaluation is based on sound and consistent judgement, and that requests for further information are necessary, consistent, scientifically robust and legally accurate ECHA is supporting the evaluating MSCA during the 12-month evaluation period through an early interaction with an ECHA Substance Manager. If agreed between the ECHA Substance Manager and the evaluating MSCA, a preliminary SEv draft decision can be submitted for a consistency screening to ECHA, no later than two months before the end of the 12-month evaluation period.

(b) Processing of substance evaluation draft decisions

ECHA is responsible for notifying any draft decision issued by the evaluating MSCA to the relevant Registrant(s). The final decision shall be taken following involvement of the Registrant(s), consultation of the other MSCAs and ECHA, and possibly the Member State Committee (MSC) and the Commission following the procedure described by Articles 50 and 52.

(c) Evaluation of obtained information

At this stage an updated dossier, referring to the substance evaluation decision with a set deadline, is expected from the Registrant(s). The responsible MSCA evaluates the updated dossier and informs ECHA of its conclusions concerning the suitability and application of the information obtained. Subsequently, ECHA shall inform the Commission, the Registrant(s) and other MSCAs of the conclusions in a timely manner.

The evaluating Member State competent authorities have 12 months from the date of the CoRAP publication to evaluate the substances indicated for the respective first year and prepare a draft decision to request further information, if necessary. If registrants do not need to generate additional information to address a concern indicated, the competent authorities provide a conclusion document.

The outcome of substance evaluation may be:

- Decision requesting further information from the Registrant(s), in order to clarify the potential risk. This request can address intrinsic properties or exposure of the substance, but normally not information which is standard information requirement listed in Annexes VII – X of the REACH Regulation.
- Notification of the evaluating Member State Competent Authority to ECHA that no further information needs to be requested for an evaluated substance. This notification includes a report on the analysis performed and the conclusions taken.

2.3.2.2.2 Enforcement

The Member States are responsible for the implementation of REACH on national level. Thus,

Article 125 of REACH requires "Member States shall maintain a system of official controls and other activities as appropriate to the circumstances". Furthermore, REACH itself does not stipulate any sanctions for infringements, but instead instructs the Member States in Article 126 REACH to determine sanctions. The sanctions shall be "effective, proportionate and dissuasive".

In Germany, the Chemicals Act (ChemG) and the Ordinance on Chemical Sanctions (ChemSanktionsV) lay down a number of penalties and fines. According to § 21 (1) and (2) ChemG, enforcement is the responsibility of the federal states, which appoint state authorities for monitoring. The market monitoring authorities of the German federal states inspect and support the companies on site with regard to compliance with their obligations arising from REACH. For monitoring purposes, those authorities can request information and inspect the company premises according to § 21(4) No. 3 and 4 ChemG.

With regard to the conformity of products supplied within a commercial acitivity (in terms of REACH mostly “articles”, see section 2.6.2 and 2.6.3) Regulation (EC) 765/2008 defines the framework conditions for the market surveillance. According to Art. 16 of the regulation, all products covered by Community harmonisation in Europe (except food/feed/drug) must be monitored on the national level. Market surveillance authorities shall carry out adequate checks based on appropriate sampling on the characteristics of products by documentary reviews or, where appropriate, by physical inspections and laboratory tests (Art. 19 Regulation 765/2008).

In the event of non-compliance, they may impose official orders in accordance with Section 23 (1) ChemG. In addition, they can impose fines in the case of administrative offences in accordance with § 35 OWiG and, in the case of criminal offences, they can involve the public prosecutor's office in accordance with § 160 of the Code of Criminal Procedure (StPO). In German law, however, the prosecution of criminal offences only applies to natural persons, since violations of the law by companies are generally regulatory offences.

The National authorities exchange information and coordinate activities related to enforcement through the Forum for Exchange of Information on Enforcement (the Forum) [90]. The forum is an integral part of the ECHA and deals among other topics with the following tasks:

- coordinate enforcement activities,
- development of minimum criteria for inspection,
- promote cooperation, coordination, and the exchange of information between EU countries, the ECHA, and the Commission regarding enforcement,
- development of a procedure for electronic information exchange,
- establishing contacts with industry and other interested parties.

The Forum also provides an indication of the effectiveness of enforcement through its REF projects (REACH-EN-FORCE). The projects are designed to harmonize enforcement in each Member State and to review the current status of compliance with certain obligations imposed on industry, including those imposed by the REACH Regulation. To this end, they use a common methodological basis to perform sample checks of companies' compliance in all

[90] For more Information on the Forum see https://echa.europa.eu/about-us/who-we-are/enforcement-forum

member states and in this context also identify potential for improvement in enforcement.

The German member of the Forum is provided by the Federal Office for Chemicals (BfC) at the Federal Institute for Occupational Safety and Health (BAuA). The national member is accompanied by a permanent representative of the federal states.

2.3.2.2.3 Obligations of Industry Actors

REACH and CLP define roles to assign obligations to industry actors. From a regulatory perspective, the duties of the industry actors are essential for the functioning of the risk management measures stipulated by REACH. The regulatory concept relies to a large extent on self-responsibility of the industrial actors.[91] The REACH framework provides incentives to fulfil the related obligations, whilst at the same time reducing the transaction cost by means of standardized risk assessment, information requirements and means of communication along the supply chain.[92]

The roles of the industry actors have specific characteristics that allow for a differentiation. For example, they can be classified by chemical object. The first group consists of actors who manufacture or supply substances and mixtures. These include manufacturers of substances, importers, downstream users (including formulators of mixtures), suppliers and distributors. In the second group are actors who produce, import or supply articles, namely producers, importers and suppliers.

The following table[93] provides an overview of the profiles of the roles in REACH and CLP, which allows to compare those profiles with the actual activities of an industry actor in order to determine its obligations. The columns indicate the roles from left to right. The rows are grouped into the products substance, mixture and article and distinguish between the respective role-defining activities. The cells of the table show for each role in relation to each product whether performing this action is a necessary (✓) or an excluding (✘) condition or not relevant for the assignment (○). The table also shows the relevant legal texts.

✓- necessary condition ✗- excluding condition ◯ - not relevant		Legal Role						
		Manufacturer	Importer	Downstream user	Distributor	Supplier of a substance or a mixture	Producer of an article	Supplier of an article
lega	REACH	Art. 3(9)	Art. 3(11)	Art. 3(13)	Art. 3(14)	Art. 3(32)	Art. 3(4)	Art. 3(33)

[91] Führ, M./Lahl, U., **Self-responsibility as a regulatory concept – as illustrated by the REACh decision-making process,** in: Th. Ormond/M. Führ/R. Barth: Environmental law and policy at the turn to the 21st century, Berlin (Lexxion) 2006, p. 209 – 220.

[92] In this respect, see section 2.6.

[93] Table adapted from Winkler-Portmann, Simon, **Umsetzung einer wirksamen Compliance in globalen Lieferketten am Beispiel der Anforderungen aus der europäischen Chemikalien-Regulierung an die Automobilindustrie**, sofia-Studien zur Institutionenanalyse 20-1, Darmstadt 2020, p. 30

	CLP	Art. 2(15)	Art. 2(17)	Art. 2(19)	Art. 2(20)	Art. 2(26)	Art. 2(10)	-
Substance	Manufacturing	✓	✗	✗	✗	○	○	○
	(responsible for) Import	✗	✓	✗	○	○	○	○
	Use	○	○	✓	✗	○	○	○
	Placing on the market	○	○	○	✓	✓	○	○
Mixture	Formulation	○	✗	✓	✗	○	○	○
	(responsible for) Import	○	✓	✗	○	○	○	○
	Use	○	○	✓	✗	○	○	○
	Placing on the market	○	○	○	✓	✓	○	○
Article	Production	○	✗	○	○	○	✓	○
	(responsible for) Import	○	✓	○	○	○	✗	○
	Placing on the market	○	○	○	○	○	○	✓

Table 3 Delimitation and categorization of roles in Art. 3 REACH and Art. 2 CLP (adapted from Winkler-Portmann 2020)

It is worth mentioning that the roles defined in REACH and CLP in most cases result in a situation, in which a company has several roles at the same time. For example, any commercial or industrial operators established in the EU that purchases a chemical product for use from another company (and does not itself manufacture or import) is considered a “downstream user” according to Art. 3(13) REACH and Art. 2(19) CLP, including so-called "formulators" that produce mixtures of several substances or mixtures. Use in this case means “any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation (Art. 3(24) REACH / Art. 2(25) CLP).

Such downstream users must take appropriate measures to adequately control the risks in their operations (Article 37(5) REACH). For this purpose, they shall use the risk management requirements contained in the safety data sheets (SDS) or other safety information transmitted through the supply chain to take appropriate risk mitigation measures. A downstream user envisaging other uses has to prepare a separate chemical safety assessment and report it to ECHA (Art. 37 and 38 REACH).

If a downstream user places a substance or a mixture on the market, he additionally takes the role of “supplier of a substance or mixture” as defined by Art. 3(32) REACH and Art. 2(26) CLP.

According to Art. 3(12) REACH, placing on the market means supplying and making available to third parties, whether in return for payment or free of charge. This creates information obligations (see section 2.1.2.2.2).

Guides for downstream user:

Downstream users in a Nutshell (2013): This Guidance in a Nutshell provides a concise and simple introduction to the obligations which the downstream users have to comply with according to the Regulation (EC) No 1907/2006 (the REACH Regulation). It explains in brief how to identify the downstream user's roles and illustrates the different circumstances that a downstream user may encounter. The different obligations and possible actions which a downstream user can choose to take according to the situation are also briefly presented. Furthermore, principles and requirements which suppliers of mixtures have to fulfil to comply with the obligation of providing relevant information to their customers are outlined.

Downstream user (2014): This guidance helps the reader to clarify the role(s) under REACH. It covers the obligations that a downstream user may face under REACH, as well as the different circumstances that a downstream user may encounter. Information is also provided on the downstream users web page of the ECHA website. The Navigator tool4 provides an additional form of help to identify roles and obligations under REACH with regard to the substances you are using.

How to prepare a downstream user report (2020): The purpose of this manual is to assist in the preparation of a IUCLID Downstream User Report under the REACH Regulation (EC) No 1907/2006. More precisely it outlines the IUCLID sections and fields to be filled-in in order to prepare a complete DU Report according to Article 38 of the REACH Regulation.

2.4 Differences of environmental chemicals management and plant and process safety management including industrial-accident prevention

The EU legal framework on environmental chemicals management, on the one hand, and the plant and process safety management (including industrial-accident prevention), on the other hand, can be both grouped under the label “substance related legislations” in a broader sense. In a narrow senses REACH addresses the “substance as such” and can be characterized as “originary substance law”, whilst the plant and process related provision depend on the results of the REACH processes (e.g., in terms of classification and labelling). In this sense they are of derivative nature (“derivative substance law”). Relying on the assessment results under “originary substance law” it stipulates specific duties from a plant safety perspective.

In a nutshell, the different pieces fulfil specific functions. It follows, that the scope differs to some extent, whilst the general aim of providing a “high level of protection for human health and the environment” is the same. As outlined in the following section, both legal frameworks in fact support each other mutally.

2.5 Complementarity of chemicals management instruments in Germany and Europe

Risks related to chemical substances can arise at different steps of the “life-cycle” of an industrial chemical. Notably, the nature of the problem differs in the various steps. The legal frameworks in the EU formulates a specific response in each case. The legislation on industrial-accident prevention isbased on the assumption that chemicals are (mostly) handled in a contained manner. The containment is provided by the industrial installations (including storage and handling). Thus, the legal framework focusses on situations in which the containment loses its barrier-function (accident). It obliges industrial actors to invest in prospective risk analysis in order to identify “weak points” and address them with adequate technical and managerial measures.

In this effort, they can build upon the outcome of the REACH mechanisms. This provides a common ground for plant and process related safety management. To a large extent the related duties are triggered by the chemical, physical and (eco)toxicological properties of the substances uses in the industrial processes.

Under REACH the risk analysis has to consider the entire life-cycle of a chemical. Thus, the scope of the assessment is much broader. In includes post-production steps as well where release of the substance and exposition of man and environment is more common. In the registration dossier under REACH the registrant has to demonstrate that risk management measures are foreseen “to ensure, when substances are manufactured, placed on the market and used, that exposure to these substances including discharges, emissions and losses, throughout the whole life-cycle is below the threshold level beyond which adverse effects may occur” (Recital 70 REACH).

For the conditions in the productions process, often related to higher pressure or temperature, the intensity of risk analysis under REACH is not sufficient. Here, the specific requirements under the Seveso-Directive comes into play. This underpins the conclusion that both regulatory approaches mutually complement and reinforce each other.

2.6 Information on hazards and uses of chemicals in the supply chain – regulation, communication tools and standards

Information on hazards and uses of chemicals is transmitted in the supply chain as safety data sheets, safety-related information according to Art. 32 REACH and as labels applied on the packaging (see section 0). Additionally, information on safe use have to be transmitted in the supply chain regarding SVHCs in articles (section 0). Communication tools support the communication processes (section 0)

2.6.1 Obligations concerning substances and mixtures

When placing a substance or mixture on the market, a supplier shall provide a safety data sheet (SDS) or safety related information to his professional customers. According to Art.31 REACH, SDS is required if the substance or mixture is hazardous according to CLP or if it is or contains a persistent, bioaccumulative and toxic substance (PBT) or a very persistent, very bioaccumulative substance (vPvB). The supplier must provide the SDS no later than the day of the first delivery (electronically or on paper). The SDS has to in the official language of the EU member state in which the mixture is placed on the market. If no SDS is required, the supplier must provide the safety-related information pursuant to Art. 32 REACH at the latest with the first delivery. This includes e.g. the registration number, the conditions of a possible authorisation or restriction, but also risk mitigation measures. Both the SDS and the safety-related information must be updated if new relevant information arises.

Downstream users must use the safety information received through the supply chain to take appropriate risk mitigation measures in their operations (Article 37(5) REACH). However, they must not rely blindly on the information provided but must rather check whether the proposed measures suffice to use the substance or mixture in a safe manner. A downstream user envisaging other uses has to prepare a separate chemical safety assessment and report it to ECHA (Art. 37 and 38 REACH). Employees and employee representatives must have access to the SDS and the information provided under Article 32 REACH on the substances and mixtures they use or to which they may be exposed (Art. 35 REACH).

The information transmission also goes upstream in the supply chain. If any supply chain actor gains new insights or receives them from his customer(s) regarding the risk mitigation measures or the hazardous properties of a substance or mixture, he has to pass it on to his supplier (Article 34 REACH).

Suppliers have to classify substances or mixtures placed on the market according to Art. 4 CLP under their own responsibility. Classifications can be adopted from the supply if available. If the substances or mixtures are classified as hazardous the suppliers have to label and package them accordingly. The label includes according to Art. 17-28 CLP Information on the substance or mixture and the hazards in the form of product identifiers, hazard pictograms, signal words and hazard and safety instructions. For substances subject to authorisation, the authorisation number must be included on the label (Art. 65 REACH).

In addition, if a downstream user uses a substance in the context of an authorisation of an upstream actor, he has to inform ECHA, which creates a register from this information, to

which the authorities have access (Art. 66 REACH).[94]

Guides to fulfill the obligations of the industry actors:

Safety data sheets in a Nutshell (2015): This Guidance in a Nutshell provides a concise and simple introduction to the obligations related to compilation and provision of a safety data sheet (SDS) as foreseen by Article 31 and Annex II to Regulation (EC) No 1907/2006 (the REACH Regulation), in particular as amended by Commission Regulation (EU) 2015/830. It describes in brief the main principles related to compilation of SDSs and the requirements which suppliers of substances and mixtures have to fulfil to comply with the obligation of providing an SDS to their customers.

Compilation of safety data sheets (2015): The aim of this guidance is to assist industry in determining which tasks and requirements have to be complied with in order to fulfil their obligations under Article 31 of REACH (Requirements for safety data sheets) and Annex II of REACH. This guidance provides information especially on: issues to consider when compiling an SDS; details of the requirements for information to be included in each Section of an SDS; who should compile the SDS and what competences the author should have.

Information requirements and chemical safety assessments (2020): This guidance describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, in the context of the chemical safety assessment. It is part of a series of guidance documents that are aim to help all stakeholders with their preparation for fulfilling their obligations under the REACH Regulation. The Guidance covers: the collection of available information regarding the intrinsic properties of substances to be registered; the assessment of this information against the requirements specified by REACH; the identification of data gaps and; the generation of the additional information required to fill the data gaps. The Guidance also aims to assist industry in conducting Chemical Safety Assessments and preparing Chemical Safety Reports, when required. A CSR may be required as part of a registration dossier (for non-intermediates > 10 t/a), as part of an authorisation application, or as part of downstream user obligations. It also sets out the basic principles for authorities preparing a risk assessment. This may be needed in support of a restriction proposal, of a proposal to include substances into the authorisation regime, or as part of a Substance Evaluation.

2.6.2 Obligations concerning substances in articles

If an industry actor places an article on the European market, he becomes a ‘supplier of an article’ (see 0 (3)). As such he is obliged under Art. 33(1) REACH for each article that contains an SVHC in a concentration of more than 0.1 mass percentage of that article to provide to the recipient “sufficient information, available to the supplier, to allow safe use of the article”. According to interpretations by ECHA, the supplier does not have to provide specific instructions if not necessary for a safe use, e.g. if exposure can be excluded throughout the entire life cycle of the article, including disposal.[95] The European court of justice has decided that the SVHCs must be named in any case. According to Art. 33(2) REACH, the supplier shall provide consumers with the same information upon request free of charge within 45 days.

[94] The authorisation list is available on the ECHA website: https://echa.europa.eu/de/authorisation-list.

[95] For more detailed information we recommend the ECHA Guidance on requirements for substances in articles: www.echa.europa.eu/documents/10162/23036412/articles_en.pdf.

In addition, a revision of the European Waste Framework Directive (WFD) from 2018 obligates suppliers of articles to provide the information to the new SCIP database managed by ECHA (Art. 9(1 and 2) WFD).

Guides to substances in articles:

Substances in articles in a Nutshell (2017): This Guidance in a Nutshell explains in brief the provisions of Regulation (EC) No 1907/2006 (REACH Regulation) that apply to substances in articles. This Guidance in a Nutshell is aimed at managers and decision-makers of companies producing, importing and/or supplying articles in the European Economic Area (EEA, but henceforth referred to simply as "EU") 1 , particularly if they have little experience with chemicals regulatory affairs. Reading this document will allow them to decide whether they need to read the full Guidance on requirements for substances in articles or not, in order to identify their obligations under REACH concerning substances in articles. Companies located outside of the EU may use this Guidance in a Nutshell to understand the requirements for substances in articles the importers of their articles in the EU have to fulfil.

Requirements for substances in articles (2017): This guidance document explains and illustrates the provisions of Regulation (EC) No 1907/2006 (REACH Regulation) that apply to substances in articles. The guidance particularly assists companies in deciding if they have to fulfil registration (Article 7(1)), communication (Article 33) and/or notification (Article 7(2)) requirements related to substances in articles (these obligations are outlined in Table 3). This might be the case for companies producing, importing and/or supplying articles, who, like industry in general, have the responsibility to determine their obligations under REACH.

How to prepare a substances in articles notification (2020): The purpose of this manual is to assist forthcoming notifiers in the preparation of a IUCLID Substance in Articles (SiA) notification dossier under the REACH Regulation (EC) No 1907/2006. More precisely it outlines the IUCLID sections and fields to be further filled-in after downloading the substance datasets from the website of the European Chemicals Agency (ECHA), in order to prepare a complete SiA notification dossier according to Article 7 (2) of the REACH Regulation and submit it successfully.

2.6.3 Communication Tools in the supply chain and standardization efforts

The core elements of REACH and CLP are based on the regulatory concept of self-responsibility of industrial actors.[96] In this regard – and unwithstanding of the role of the administrative entities (see section 0) – the key features of chemicals management can be grouped around a symphonie of gaining information, communication and cooperation (IC&C). The safety data sheet (SDS) itself is meant as a communication instrument.

2.6.3.1 ChemInfo database

Up-to-date, comprehensive, and reliable information on chemical substances and mixtures in all areas of environmental protection and for averting danger is compiled in the GSBL database,[97] primarily targeted to public authorities, but in recent years to the general public as well.

[96] See *Führ, M./Bizer, K.*, **REACh as a paradigm shift in chemical policy - responsive regulation and behavioural models**; in: Journal of Cleaner Production (JCLP), 15, 2007 (4), 327-334, Elsevier, Exeter (UK).

[97] For more information, visit: https://www.gsbl.de/eng_home.htm.

2.6.3.2 SCIP Database

The revised Waste Framework Directive 2008/98/EC, which entered into force in July 2018, provided a role for ECHA to establish and maintain a database with information on **S**ubstances of **C**oncern **I**n articles, as such or in complex objects (**P**roducts), named the "SCIP database".[98] As from **5 January 2021**, information on articles containing SVHCs (on the Candidate List) in a concentration above 0.1 % w/w placed on the EU market needs to be notified to ECHA.[99]

The information will be submitted by companies supplying articles containing SVHCs on the Candidate List placed on the EU market. EU producers and assemblers, EU importers and EU distributors of articles and products as well as other actors who place articles on the market need to provide information to ECHA[100]. The SCIP database will ensure that this information is available throughout the whole lifecycle of articles and materials, including at the waste stage. The obligation applies to any article as such or in a complex object, i.e. an object made up of more than one article, because articles that are assembled or joined together remain articles. Furthermore, an import is deemed to be 'placing on the market', thus any imported article into the EU is covered by the obligation, including any supply via internet sales that involve an import.

The information required for the SCIP database must already be communicated throughout the supply chain under REACH Article 33(1). Therefore, besides administrative contact details, suppliers of articles need to submit the following information[101] to ECHA:

- information that allows the identification of the article;
- the name, concentration range and location of the Candidate List substance(s) present in that article; and
- other information to allow the safe use of the article, notably information to ensure proper management of the article once it becomes waste.

The information submitted to the SCIP database will be publicly available and therefore readily available to waste operators to bridge the current gap in the information flow. ECHA will publish the information, as received, on its website. The quality of the data remains the responsibility of each duty holder. At the same time, ECHA will ensure the protection of confidential business information where justified. For example, the required mandatory data that allow to establish links between actors in the same supply chain will not be made publicly available.

The obligations of the Waste Framework Directive are to be transposed into the national law of each EU Member State, the enforcement of which is the responsibility of these Member States.

2.6.3.3 LIFE AskREACH Tools

LIFE AskREACH has the overall goal to enhance substitution of SVHC in articles along the

98 ECHA webinar: https://echa.europa.eu/de/-/introducing-the-scip-database-prototype.
99 Leaflet: SCIP database - What you need to know.
100 ECHA support material for suppliers of articles: https://echa.europa.eu/scip-support.
101 A detailed list of all information requirements is given in the "Detailed Information Requirements" document,

supply chain by increasing the market demand for SVHC free articles and supporting industrial actors to identify SVHC in their articles. AskREACH develops IT tools to foster communications about SVHCs in articles, thereby contributing to the implementation of REACH Art. 33.

2.6.3.3.1 Scan4Chem App

AskREACH developed the smartphone application Scan4Chem that allows consumers to send 'right to know' requests after scanning an article's barcode. Scan4Chem-App is available in 12 languages in numerous European countries. All country versions of the app are connected to a database where companies can enter their information on substances of very high concern contained in their products. Companies can use the app to answer enquiries centrally and thus fulfil their obligation to provide information more efficiently. The first companies have already entered information on their products into the database. The aim is that in the long term data on most products will be found in the database, so that users of Scan4Chem will directly receive information on substances of very high concern in products.

2.6.3.3.2 Supply Chain Communication Tool

AskREACH promotes a supply chain communication approach increasing the capacity of companies to meet their obligation to inform about SVHCs in articles. With selected pilot companies, the project team develops case studies for real articles from various sectors. The project team developed and tests a supply chain communication tool[102] provided by iPoint systems that is based on a MDS material data system. In the MDS, suppliers report data on their materials. The purpose of the MDS is to generate a structure tree of all materials present in a certain final product subject to reporting, which is usually a complex object incorporating more than one individual article. The structure follows the different stages in the production process, e.g. from the semi-finished article (plastic sheet), further processed component (after machining and coating), to incorporation in the final product. The tool enables companies to request compliance statements, partial and full material declarations from their suppliers.

2.6.3.4 Proactive Alliance

The Proactive Alliance brings together industry representatives (automotive, chemicals, childcare products, electrical and electronic, furniture, home textiles, mechanical, medical devices, metalworking and metal articles, textiles and sporting goods) to contribute to the development of a global cross-sector standard for the communication on substances in articles. With a view to successful supply chain communication, the Proactive Alliance develops policy recommendations and builds on existing standards and consider, where required, to enhance existing ones, where these, e.g., show gaps, towards a harmonized global cross-sector approach. In addition, the Proactive

[102] For more information, visit https://www.askreach.eu/supply-chain-tool/.

Alliance proposes criteria and technical details for such a standard, in particular in terms of data generation and collection (i.e. data quality, reliability, comprehensiveness and exchange formats as well as basic rules governing data protection and security) and in terms of the development and maintenance of Restricted Substance Lists.[103] The Proactive Alliance has published a discussion paper with policy recommendations and is looking for feedback from industry actors around the globe.[104]

[103] For more information see https://www.proactive-alliance.info/mission-goals.
[104] For the text of the document see https://www.proactive-alliance.info/our-progress.

3. Comparison between China and Germany/Europe

This chapter compares the chemical management systems of China and Europe/Germany based on the two country reports. Finally, a needs assessment is carried out to identify those areas where international cooperation could be particularly beneficial.

3.1 Commons and differences

China	Germany (EU)
Registration: Which chemicals are included?	
New chemical substances that are not yet listed on the **China Inventory of Existing Chemical Substances**. New chemical substances that have not been registered or filed are prohibited in research, production, import and processing. Producers or importers of new chemical substances shall, prior to production or import, obtain a **Regular registration** - new chemical substances to be manufactured or imported above the annual volume of 10 tons **Simplified registration** - annual production or import of new chemical substances is more than 1 ton and less than 10 tons **Record filling** - less than 1 ton or the polymer in which the content of monomer or reactant of new chemical substances is no more than 2% or low-attention polymer	**Substances** - chemical element and its compounds in the natural state or obtained by any manufacturing process **Mixtures** - mixture or solution composed of two or more substances **Every substance from a quantity threshold of one tonne per year** that is to be manufactured or imported: Only substances that are registered may be manufactured or placed on the market. This means: without registration, companies may neither manufacture or import a substance or mixture nor use it in articles. Every manufacturer or importer is responsible for the registration of his chemical substance. With a view to efficiency and consistency, REACH, as a general rule, requires joint data submissions from registrants of substances with the same identity (“one substance, one registration” or “OSOR” principle).
Registration: What are the exceptions?	
(1) Products such as pharmaceuticals, pesticides, veterinary drugs, cosmetics, food, food additives, feed, feed additives and fertilizers, except those new chemical substances that are changed to other industrial uses, and except those used as raw materials and intermediates for the abovementioned products; (2) Radioactive substances. It shall be noted that articles designed to release the new chemical substances contained in them throughout their routine use shall fall within the scope of Decree No. 12 for such chemical substances.	There are exceptions from registration for various substances, such as pharmaceuticals, for which special regulations already apply.
Registration: Involved Actors	
Ministry of Ecology and Environment (MEE) - national environmental management and	**European Chemicals Agency (ECHA)** - technical, scientific and administrative

registration of new chemical substances, formulating policies, technical specifications, guidelines and other supporting documents as well as evaluation rules for the purpose, and strengthening IT-based development for registration of new chemical substances **Expert Committee on Environmental Risk Assessment of Chemical Substances** - set up by the MEE, composed of experts with background in chemistry, chemical engineering, health, environment and economy, providing technical support for the review process **Technical agency for environmental management of chemical substances** – under MEE, participate in the review of new chemical substances and undertake tasks to register new chemical substances **Ecological and environmental competent authority at or above the municipal level -** responsible for supervision and management of implementation of these Measures by enterprises and institutions involved in the research, production, import and processing of new chemical substances within their administrative areas.	management of the REACH system; Receipt of (pre-)registrations, notifications and applications for approval; Conduct the dossier evaluation; Review and decision on test proposals; Development and maintenance of a database with information on all registered substances; Providing technical and scientific tools for the application of the regulation; Advising the Member States and the institutions of the European Union on questions relating to chemical substances; Providing technical and scientific guidance to industry, in particular SMEs and competent authorities **Actors within the chemical supply chain** - responsible "to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment". The regulatory approach therefore no longer focuses on administrative programs but rather strengthens the self-responsibility of the economic actors.
Registration: Content	
Regular registration – application form for regular registration ,test reports or information on the physical and chemical properties, toxicology and ecotoxicological properties, environmental risk assessment, in case of high-risk chemical substances: analysis of the socio-economic benefits related to the activities of the new chemical, environmental and health hazards **Simplified registration** – application form for simplified registration; reports or data on the physical and chemical properties of the new chemical substance, as well as ecotoxicological tests such as persistence, bioaccumulation and aquatic environmental toxicity **Record-filling** - filing form, proof of fulfilling the form, as well as other available information on the environmental and health hazards and environmental risks of the new chemical	**<10t per year**: the manufacturer or importer submits a registration dossier to the European Chemicals Agency (ECHA). The registration dossier contains a technical dossier. The technical dossier contains data on the identity of the registrant and the registered substance. It also lists the properties of the substance in question and provides information on use and safe handling. To this end, the substance is subjected to appropriate tests and investigations with regard to the risks for humans and the environment **>10t per year**: registration dossier must contain a chemical safety report in addition to the technical dossier. In particular, the chemical safety report identifies concrete risk management measures for the various applications in which the substance is used

substances	
Evaluation of Registration	
Formality examination through MEE **Technical review:** MEE will organize a technical review by expert committee (just for regular registration) and its subsidiary technical agency for environmental management of chemical substances, and issue technical review opinions **Review of the opinions:** MEE shall review the opinions of the technical review, and if no unreasonable environmental risk is identified, register the new chemical substance and issue a regular registration certificate to the applicant	To ensure the quality of the data and to avoid unnecessary animal experiments ECHA can examine individual registration dossiers to ascertain whether the relevant requirements are met. If ECHA identifies a registration dossier as incomplete, no registration number is granted and thus the “no data, no market”-barrier applies. If insufficient information is provided, ECHA will issue a “compliance check” decision: after consulting the registrant a draft decision is put forward to the MSC. c ontact the competent authorities of the Member State on whose territory the registrant is located and ask them to initiate regulatory measures with the registrant concerned.
After registration: Requirements	
Information transmission: producers, importers, and processers of new chemical substances shall pass the registration certificate number or record receipt number to downstream users; the application for use of new chemical substances; the environmental and health hazard characteristics of new chemical substances and environmental risk control measures; environmental management requirements for new chemical substances. **Activity records**: for the activities of new chemical substances, which shall accurately record the time, quantity and use as well as environmental risk control measures and management requirements in place **New hazard report**: Where a new environmental or health hazard or environmental risk has been identified, researchers, producers, importers and processers of new chemical substances shall promptly report to the MEE. They shall also carry out the first activity reporting and / or annual reporting, implement environmental risk control measures and environmental management requirements, support supervision and	**Information requirements**: When placing a substance or mixture on the market, a supplier shall provide a safety data sheet (SDS) or safety related information to his professional customers. A SDS is required if the substance or mixture is hazardous according to CLP or if it is or contains a persistent, bioaccumulative and toxic substance (PBT) or a very persistent, very bioaccumulative substance (vPvB). The information transmission also goes upstream in the supply chain. If any supply chain actor gains new insights or receives them from his customer(s) regarding the risk mitigation measures or the hazardous properties of a substance or mixture, he has to pass it on to his supplier. If an industry actor places an article on the European market, he becomes a ‘supplier of an article’. As such he is obliged for each article that contains an SVHC in a concentration of more than 0.1 mass percentage of that article to provide to the recipient “sufficient information, available to the supplier, to allow safe use of the article”. The European court of justice has decided that the SVHCs must be named in any case. According to Art. 33(2) REACH, the supplier shall provide

inspection, etc.	consumers with the same information upon request free of charge within 45 days.
Toxic / hazardous chemicals: Which chemicals are affected?	
Import and Export - Chemicals under the control of the Stockholm Convention on Persistent Organic Pollutants (POPs) and amendments; Chemicals under the control of the Minamata Convention on Mercury; Chemicals under the control of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade and amendments **Priority chemicals -** The Catalogue of Priority Chemicals focuses on identifying chemicals that are inherently hazardous, may persist in the environment, and may pose great risks to the environment and human health **Hazardous chemicals -** highly toxic chemicals and other chemicals with poisonous, corrosive, explosive, combustive, combustion and other properties, which are harmful to people, facilities and the environment released in the Catalogue of Hazardous Chemicals	Substances may be identified as causing a "**very high concern" (SVHC)**, if they meet the criteria set out in Article 57, i.e. substances classified as carcinogenic, mutagenic or toxic for reproduction (so-called CMRs), substances that are persistent, bioaccumulative and toxic (PBT), vPvB substances for which there is scientific evidence of increased persistence (vP) as well as increased bioaccumulation (vB) and other substances linked to a "equivalent level of concern". Substances may be identified as **hazardous** according to the criteria in Annex I CLP, by showing a physical hazard (e.g. explosive or flammable), human health hazard (e.g. toxic, irritating, carcinogenic) or environmental hazard (e.g. bioaccumulative).
Toxic / hazardous chemicals: Actors	
Ministry of Ecology and Environment (MEE) – receiving and examining application materials for clearance for import (or export) of toxic chemicals that are strictly restricted in China. **Ministry of Emergency Management (MEMA)** - safety supervision and management of hazardous chemicals, organizing the formulation, publication and amendment of the hazardous chemical catalogue, and maintaining a registry of hazardous chemicals **National Health Commission** - the management of toxicity assessment of hazardous chemicals **National Development and Reform Commission (NDRC**) - implementing a negative list for market access and promoting sustainable development strategies **Ministry of Industry and Information**	**European Chemicals Agency (ECHA) -** Development of an ongoing substance evaluation plan; Scientific opinions during the authorisation procedure and in the development of restriction rules Bodies within ECHA are, i.a., the **Management Board** electing and overseeing the **Executive Director and the** **Secretariat** that, i.a., perform tasks related to dossier submission and evaluation in the registration pillar and supports the decision making processes within the **Risk Assessment Committee (RAC)** and the **Socio-Economic Analysis Committee (SEAC)** **Member State Committee (MSC)** **European Commission:** taking decisions in the

Technology (MIIT) - management of monitored and controlled chemicals **Ministry of Public Security** - public safety management of hazardous chemicals	field of dossier and substance evaluation in cases where the MSC fails to reach unanimous agreement. Furthermore the Commission in is charge of the restriction decisions by amending Annex XVII and identifying substances that should be subject to authorisation (Annex XIV). It also decides upon the granting of authorisations under the REACH and Biocides Regulations. **Member State competent authorities:** carrying out substance evaluations **Regional authorities:** responsible to enforce chemicals legislation vis-à-vis industrial actors in the district (see below).
Handling of toxic / hazardous chemicals – Regulatory risk management	
Import and Export - Application form for the Clearance Notification for Environmental Management on Export of Toxic Chemicals. Declaration and certification that the exported chemicals meet the requirements of the Stockholm Convention, Mercury Convention and Rotterdam Convention. **Priority chemicals -** Defined risk control measures shall be taken in accordance with relevant policies, regulations and economic and technical feasibility to minimize impact of the production and use of the chemicals on human health and the environment **Hazardous chemicals - Catalogue of Hazardous Chemicals:** Enterprises engaged in the business of hazardous chemicals shall obtain the required license of operation; enterprises engaged in road or waterway transport of hazardous chemicals shall obtain permission from relevant administrative departments. **Catalogue of Specially Controlled Hazardous Chemicals:** build an information platform for traceability and control of whole life cycle information; standardize packaging management; strictly control access to production; strengthen transportation management; implement management of fixed storage	**Authorisation** - A substance is classified as SVHC by inclusion in the "Candidate List of Substances of Very High Concern". The next step is the recommendation of ECHA as priority substances. The final decision to include a SVHC in Annex XIV is made by the European Commission through comitology “regulatory procedures with scrutiny”. It takes the form of an amendment to the REACH regulation. Inclusion in Annex XIV makes a substance subject to authorisation. Placing these substances on the market or using them is then not permitted. Exceptions only exist if the specific use was explicitly exempted from the authorisation obligation or was permitted as a result of an application submitted. An authorisation shall only be granted if the applicant company can demonstrate that it can adequately control the risks arising from the use of the substance or if the socio-economic benefits outweigh the risks and no suitable alternatives are available. **Restriction -** Annex XVII of REACH lists substances that may not be manufactured, placed on the market or used, or may be used only in a restricted manner, because of unacceptable risks to human health or the environment. A restriction may be set for a substance on its own, in a mixture or in an article. The substances listed in Annex XVII may be

	manufactured, placed on the market or used "only if the conditions of this restriction are met". This broad wording allows the legislator to impose a variety of requirements, for example specific risk reduction measures such as the use of certain protective gloves.
Risk control / Enforcement	
All national ministries and commissions related to chemical management and relevant local administrative departments carry out relevant work within their own responsibilities and jurisdictions.	**Member state authorities (in Germany on a regional level):** responsible for the implementation of REACH; maintain a system of official controls and other activities as appropriate to the circumstances; determine sanctions **ECHA Forum for Exchange of Information on Enforcement**: National authorities exchange, supported by ECHA, information and coordinate activities related to enforcement; tasks: coordinate enforcement activities; development of minimum criteria for inspection; promote cooperation, coordination, and the exchange of information between EU countries, the ECHA, and the Commission regarding enforcement; development of a procedure for electronic information exchange; establishing contacts with industry and other interested parties

3.2 Needs assessments for international cooperation

The comparison of chemical management in China and Germany shows the similarities and the differences between these two systems. The following section shows where international cooperation might be helpful to strengthen the two chemical management systems.

Registration: Registration of substances only appears useful if the information provided is complete and correct. International cooperation can help to find best practice approaches in information collection and verification and based on these to improve the own system.

After registration: After registration, international cooperation can support the implementation of the information and activity requirements.

Hazardous chemicals: To avoid the application of hazardous chemicals it is important to find appropriate substitutes. Cooperation is needed to foster innovation in new substances and new ways of using substances to prevent harmful effects for humans and the environment.

Enforcement: There is a need for exchanges of enforcement processes and risk management practices to promote common standards, strengthen the enforcement activities and make the chemical management systems more efficient in the two countries.

4. German experiences and approaches in implementation of environmental chemicals management

This chapter explains the challenges with regard to environmental chemicals management that arise from the German perspective and describes options to address them in a Sino-German cooperation.

4.1 Major challenges

Chemicals Management has been on the global agenda for some decades. The United Nations Conference on Environment & Development (UNCED), Rio de Janerio, Brazil, 3 to 14 June 1992, resulted, i.a., in the AGENDA 21. Its chapter 19 addresses “Environmentally sound management of toxic chemicals, including prevention of illegal international traffic in toxic and dangerous products”, whilst the following chapters deal with “environmentally sound management” of different types of waste. The AGENDA 21 states under section 19.1 the overall challenge that still appears valid:

> “19.1. A substantial use of chemicals is essential to meet the social and economic goals of the world community and today's best practice demonstrates that they can be used widely in a cost-effective manner and with a high degree of safety. However, a great deal remains to be done to ensure the environmentally sound management of toxic chemicals, within the principles of sustainable development and improved quality of life for humankind.”

Ten years later the Johannesburg World Summit on Sustainable Development formulated the “Johannesburg Goal”: With the implementation plan adopted there, the aim is “to achieve and minimize the impact on human health and the environment of chemicals by 2020”: In 2012 at the so-called “Rio+20” summit, the UN General Assembly adopted[105] the “10-year framework of programmes on sustainable consumption and production patterns” (10YFP).[106]

These processes provide the background and the groundwork for further efforts on UN-level.

4.1.1 Global challenges as identified by the Global Chemicals Outlook II (GCO-II)

In September 2015, the General Assembly of the United Nations adopted under the title “Transforming our world” the “2030 Agenda for Sustainable Development”. It entails 17 “Sustainable Development Goals” (SDG). Links to environmental chemicals management can be found in various areas; in particular the sub-targets 3.9, 6.3, 8.4 and 12.4. SDG 12.1 integrate the post-Rio 10YFP into SDG 12 aiming to “Ensure sustainable consumption and production patterns”. SDG 12.4 reiterates the “Johannesburg Goal”:

> „By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment.“

Against this backdrop the Global Chemicals Outlook II (GCO-II), commissioned by the UN Environment Assembly in 2019, aims to raise awareness among policy-makers and other stakeholders of the crucial role of sound management of chemicals and waste for sustainable

105 UN Doc. A/RES/66/288 (2012) (The future we want), para 226.
106 United Nations, A 10-Year Framework of Programmes on Sustainable Consumption and Production Patterns, UN Doc. A/CONF.216/5 (2012), Annex (10YFP).

development. It takes the status quo of global trends and the progress and gaps in achieving the global goal of minimizing the negative impacts of chemicals and waste by 2020.[107]

Generally, it was recognized that a policy of "chemical safety" is not sufficient to reach these goals. Rather, a holistic approach is needed that takes into account ecological, economic and social aspects in the whole life cycle of chemicals - including the origin of raw and auxiliary materials and the waste phase - in order to make the production and use of chemicals sustainable. The key findings of GCO II show the main global challenges to reach a sound management of chemicals.

Key finding 1: The size of the global chemical industry exceeded United States dollars 5 trillion in 2017. It is projected to double by 2030. Consumption and production are rapidly increasing in emerging economies. Global supply chains, and the trade of chemicals and products, are becoming increasingly complex.

Key finding 2: Driven by global megatrends, growth in chemical-intensive industry sectors (e.g. construction, agriculture, electronics) creates risks, but also opportunities to advance sustainable consumption, production and product innovation.

Key finding 3: Hazardous chemicals and other pollutants (e.g. plastic waste and pharmaceutical pollutants) continue to be released in large quantities. They are ubiquitous in humans and the environment and are accumulating in material stocks and products, highlighting the need to avoid future legacies through sustainable materials management and circular business models.

Key finding 4: The benefits of action to minimize adverse impacts have been estimated in the high tens of billions of United States dollars annually. The World Health Organization estimated the burden of disease from selected chemicals at 1.6 million lives in 2016 (this is likely to be an underestimate). Chemical pollution also threatens a range of ecosystem services.

Key finding 5: International treaties and voluntary instruments have reduced the risks of some chemicals and wastes, but progress has been uneven and implementation gaps remain. As of 2018, more than 120 countries had not implemented the Globally Harmonized System of Classification and Labelling of Chemicals.

Key finding 6: Addressing legislation and capacity gaps in developing countries and emerging economies remains a priority. Also, resources have not matched needs. There are opportunities for new and innovative financing (e.g. through cost recovery and engagement of the financial sector).

Key finding 7: Significant resources can be saved by sharing knowledge on chemical management instruments more widely, and by enhancing mutual acceptance of approaches in areas ranging from chemical hazard assessment to alternatives assessment.

Key finding 8: Frontrunner companies – from chemical producers to retailers – are introducing sustainable supply chain management, full material disclosure, risk reduction beyond compliance, and human rights-based policies. However, widespread implementation of these initiatives has not yet been achieved.

Key finding 9: Consumer demand, as well as green and sustainable chemistry education and

[107] To read the full report see (30.11.2020): https://wedocs.unep.org/bitstream/handle/20.500.11822/28113/GCOII.pdf?sequence=1&isAllowed=y

innovation (e.g. though start-ups), are among the important drivers of change. They can be scaled up through enabling policies, reaping the potential benefits of chemistry innovations for sustainable development.

Key finding 10: Global knowledge gaps can be filled. This can be achieved, for example, by taking steps to harmonize research protocols, considering health or environmental impact information and harm caused to set and address priorities (e.g. emerging issues), and strengthening the science-policy interface through enhanced collaboration of scientists and decision-makers.

The GCO II points out, that more ambitious worldwide actions by all stakeholders are required to address those major global challenges.

From a Sino-German perspective the main link might be seen in the vast amount of products containing chemicals that are interchanged between the two economic areas. In terms of quantity (tons/year) and economic value this “substances in articles”-sector appears to be of particular relevance. Thus, the key findings 2, 6, 8 and 9 should be considered as points of reference for future cooperation measures (see chapter 5.1.1): Key finding 2 points at market opportunities based on enhanced chemicals management, most importantly in the design phase of chemicals and products, supported by “full material disclosure” and “risk reduction beyond compliance” as stipulated by key finding 8. Mutual learning in terms of “legislation and capacity gaps” (key finding 5) would underpin these efforts and stipulate “enabling policies” aiming at consumer empowerment (key finding 9).

4.1.2 Domestic challenges: REACH and the related legislative framework

In terms of REACH (for details see chapter 2.3.2) the status of the implementation can be summarized as follows. Three registration deadlines have passed, resulting in the following numbers (all EEA countries):[108] More than **15000 companies submitted over 100000 registrations for around 23000 substances.** The top three countries providing most of the registrations for the 2018 registration deadline are Germany (8.463 registrations for 4.792 substances), the United Kingdom (4.396 registrations for 2.298 substances) and France (3.455 registrations for 2.124 substances).

For the 2018 registration deadline (tonnage range 1-10 tons / year) in particular, there was a clear trend of registrations coming from outside the EU including a high number of submissions of high-volume chemicals. Two-thirds of all registrations were from countries outside Europe – 43 % from importers and 29 % from only representatives on behalf of non-EU entities.[109]

Looking at the domestic situation shows that in Germany 2.900 companies submitted 26.141 registrations for 11.255 substances by 2020. The biggest amount of registrations came from large companies (23.163) followed by SMEs (1.975) and micro size companies (239). The following figure shows the development of the amount of registrations since 2009 in Germany:

[108] As of 02.11.2020; see https://echa.europa.eu/documents/10162/23557847/registration_statistics_en.pdf/58c2d7bd-2173-4cb9-eb3b-a6bc14a6754b.

[109] Further information on all completed registrations since 2008, substances and EU/EEA country-specific figures can be found at https://echa.europa.eu/registration-statistics-infograph#

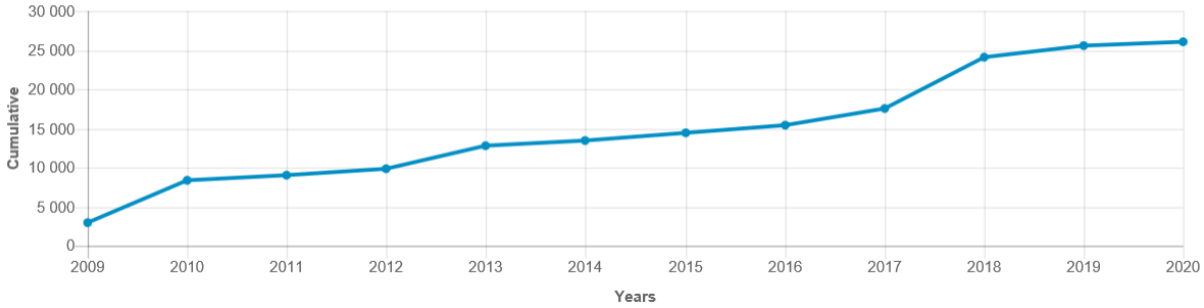


Figure 3 Number of registrations in Germany (ECHA 2020)

In general terms, REACH appears to be the most comprehensive and protective regulatory framework for chemicals globally, supported by the most advanced knowledge base**.** This regulatory framework is increasingly becoming a model for safety standards worldwide.[110] It has been effective in creating an efficiently functioning internal market for chemicals, in reducing the risks to humans and the environment posed by certain hazardous chemicals, such as carcinogens[111] and heavy metals, and in providing a predictable legislative framework for companies to operate in.

The functioning of REACH in relation to its objectives has been evaluated twice at EU level, in 2013 and 2017, as part of the programme for Regulatory Fitness and Performance (REFIT)[112] in accordance with the Commission's Better Regulation guidelines. Ten years after entry into force, in 2017, the evaluation of REACH showed the following:

- Progress has been made towards achieving the REACH objectives;
- The different building processes and actions envisaged in the intervention logic of REACH are being largely implemented;
- The different actions under REACH link well together and largely deliver internal coherence;
- REACH is an effective data generation and assessment system for chemicals manufactured and used in the EU, thus supporting the goal set for 2020 at the World Summit for Sustainable Development;
- REACH has led to a vast publicly available database on chemicals, unique in the world
- The benefits have started to materialize while most of the benefits will first occur in the coming years. The first signal of benefits observed are the effects of the adopted restrictions on chemicals for human health and the environment, the improvement of risk management in the workplace, the better knowledge of chemicals, the substitution of substances of very high concern and the improvement of the communication through the supply chain;
- REACH is increasing the expertise of public authorities and industry on chemicals and it has become a benchmark for third countries in terms of chemical regulation;
- REACH appears to be generally able to adapt to continuous scientific progress. REACH also responds to citizens' concerns, and is improving public perceptions of chemicals, with stakeholders involved in the decision-making process;

110 SeeBradford, Anu 2020; The Brussels effect, Oxford University Press, New York, NY (USA), tracing the development of the REACH chemicals regulation.

111 One million new cancer cases are estimated to have been prevented in the EU over the last 20 years; SWD(2019)199.

112 A comprehensive report about the REFIT evaluation of REACH is available at https://ec.europa.eu/growth/sectors/chemicals/reach/review_en.

In a general perspective, REACH has strengthened the internal EU market thanks to further harmonization of its governing rules.

Chemicals were also a topic of the "circular economy package" published in January 2018, as one of the documents elaborates on the issue of options to address the interface between chemicals, product and waste legislation.[113]

4.1.2.1 Specific Challenges

Although the benefits of REACH as well as the current legislative framework in the EU are significant, specified challenges have been identified, based on experience with implementation of regulations as well as current policy and regulatory planning.

General experience with the whole regulatory framework shows that there is some room for improvement of the overall regulatory efficiency: As for historic reasons, chemicals management is addressed in a variety of EU acts pertaining to different products groups (e.g. toys, cosmetics, pesticides) and employing different evaluation and risk management mechanisms, duplication of work and inconsistencies could be identified across legislations. The European Commission and the Member States have been working on the interfaces[114] between the various acts in order to use them in a meaningful and targeted manner to protect humans and reduce the entry of chemicals into the environment.[115]

Another challenge refers to closing regulatory gaps. Key topics of interest are endocrine disruptors, essential uses, the combined effects of chemicals and persistent substances such as PFAS. Not at least the European Parliament calls for a comprehensive EU framework on endocrine disruptors (EDCs) to effectively minimize the extent to which humans and the environment are exposed to EDCs, and insert specific provisions into legislation on toys, food contact materials and cosmetics to treat EDCs like substances that are carcinogenic, mutagenic or toxic for reproduction. The "Chemicals Strategy for Sustainability", as part of the "Green Deal" (see section 4.0), embarks on these topics, proposing approaches for solution.

In relation to REACH, distinct challenges could be identified as well. These, as well as the approaches taken to solve them, are presented in the following sections.

4.1.2.1.1 Non-compliant registration dossiers and data gaps

REACH and CLP have been in force for more than 10 years. In order for the system to work as it should, it is recognised that the availability of relevant data in REACH registration dossiers is key for the machinery to work and effectively protect humans and the environment from chemicals posing a risk.

Overall, during the 10 years of evaluation, ECHA checked, to various degrees, the compliance of 1 350 (7.33 %) dossiers in the >1000 tn/a tonnage band and 430 (3.79 %) of the dossiers in the 100-1000 t/a tonnage band. Due to the selection based on screening of suspected data gaps, in the vast majority of the cases (69 % and 77% respectively), the compliance checks

[113] See also https://ec.europa.eu/commission/publications/documents-strategy-plastics-circular-economy_en

[114] See the European Commission Comunication "on the implementation of the circular economy package: options to address the interface between chemical, product and waste legislation", COM(2018) 32 final as of 16.01.2018.

[115] Forum Enforcement projects: https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects

have confirmed one or more non-compliances and resulted in ECHA (draft) decisions. The picture was completed by findings of a UBA project, stating that almost a third of high-volume chemicals in Europe are being used in breach of REACH, the main EU regulation designed to protect citizens and the environment from harm.

Shortcomings in the dossier evaluation (DEv) practice of ECHA, at least until 2018 can be summarised as follows:

- The DEv administrative processes and the data generation is taking a lot of time, due to lengthy decision-making procedures (including consultations with the registrants and, in the case of TPE involving for vertebrates, the public).
- Lack of legal clarity in some information requirements hinders both registrants in achieving compliant dossiers and authorities to request missing data. Besides, obtaining adequate exposure data is a major issue.
- A lack of incentives for registrants to update their registration files despite their obligation, together with the enforcement difficulties, are the main cause of the delay to generate new information.

The REACH instruments, and the operationalisation thereof, aimed to ensure adequate dossier quality therefore require improvement in order to activate the self-responsibility of the registrants to ensure compliance effectively.

The debate on registration dossiers lacking compliance, stimulated by interventions of the European Parliament, in June 2019 led ECHA and the European Commission to launching a “REACH Evaluation Joint Action Plan” outlining 15 actions intended to ensure registrants’ compliance. The proposed actions are addressing some of the mentioned shortcomings. Positive effects on dossier quality might be expected notably with respect to Action 1 aimed at raising the 5% minimum target in Article 41(5) to 20% of dossiers selected for compliance checking. Respective implementing legislation was adopted in April 2020. Furthermore, Actions 5 and 6 probably entail modifications of Annexes VI to XI of REACH intended to clarify existing information requirements *de lege lata.* Unfortunately, the Action Plan does not provide a strategic approach with regard to shortcomings in dossiers related to descriptions of uses and exposure assessment. The REACH Exposure Expert Group (REEG) will foster a common understanding of which use and exposure data are needed to support REACH and CLP processes and may therefore provide a solid base for the identification of appropriate policy options.

In response to these findings, ECHA has increased the sampling rate for compliance checks from 5% of all dossiers to 20%, and aims for 30%. From the part of Industry, CEFIC launched an action plan to help REACH registrants review chemical safety data. The Action Plan Package consists of the following elements:

- **Declaration of Intent:** signed by individual companies, whereby companies express their intent to re-evaluate dossiers and to provide further information, where appropriate, in line with the Action Plan. Companies also commit to report to CEFIC on key performance indicators so that CEFIC can report on progress on an annual basis. To that effect, a **reporting template** has been developed.

- **Cooperation Agreement between CEFIC and ECHA:** outlines a series of specific activities to support the implementation of this Action Plan and guide registrants to a better understanding of how to meet ECHA's expectations under Article 41 of REACH ('Compliance Check').

The Action Plan is foreseen for 2019-2026. On 31 March 2020, CEFIC published the 1st progress report on the implementation of the Action Plan.

Despite all these efforts, voices have been raised[116] expressing the need for effective and proportionate sanctions in order to enforce the "no data - no market" principle.

4.1.2.1.2 Communication gaps in the supply chain

A recent project of ECHA's Enforcement Forum focussed on compliance with Articles 7(2) and 33(1) of the REACH Regulation by all types of suppliers of articles with a main focus on producers and importers of articles. A key finding was that candidate list substances of very high concern were found in 12% of inspected products (manufactured in the EU or imported) and, for these, 88 % of suppliers failed to communicate sufficient information to their customers. In addition to this, and in relation to substances that are restricted in the EU but are found in imported articles, Industry has repeatedly criticized that compliant companies abiding by the restriction are put at a disadvantage where there are companies importing articles which still contain restricted substances.
In order to allow for a clearer picture about e-commerce, a follow-up enforcement project was launched in early 2020. The project is to shed light on products sold online for the general public and professionals, available in private companies' web shops and in marketplace platforms, such as Amazon and eBay.[117] More specifically, it will investigate if buyers are informed about the existence of hazardous substances before the purchase is completed and if particular aspects of the regulations are fulfilled. The results of the project are expected to be published at the end of 2021.

The experience of non-compliance has led to claims for strengthening enforcement activities in the Member states. The discussions on this are ongoing in the EU. Moreover, proposals to enhance the legislative framework with respect to the "Substances in Articles" are discussed.[118]

4.1.2.1.3 Substitution

Substitution of substances of very high concern (SVHC) by safer alternatives is a key challenge under REACH.[119] The processes actively working towards substitution of SVHC are authorisation and restriction.[120] Yet substitution of the most harmful substances has not yet

116 For the state of play in this debate see UBA project "Advancing REACH" with the sub-project on "Dossier Evaluation" (Authors: Schenten/Führ, UBA-Texte 207/2020): download under https://www.umweltbundesamt.de/en/publikationen/advancing-reach-dossier-evaluation.
117 See https://echa.europa.eu/-/inspectors-to-check-products-sold-online-that-contain-harmful-substances.
118 For the state of play in this debate see UBA project "Advancing REACH" with the sub-project on "Substances in Articles" (Authors: Schenten/Führ, UBA-Texte 194/2020): download under https://www.umweltbundesamt.de/publikationen/advancing-reach-substances-in-articles.
119 ECHA substitution portal, see https://echa.europa.eu/substitution-to-safer-chemicals.
120 ECHA webinar on the GreenScreen hazard comparison method: https://echa.europa.eu/-/greenscreen-an-effective-tool-and-methodology-to-compare-chemical-hazards-and-identify-safer-alternatives.

occurred at the expected pace.[121] A recent study on the impacts of the REACH processes of restriction and authorisation on substitution in the EU issued by the European Chemicals Agency in July 2020 identified technical, economic and market barriers being typically associated with the substitution process. In particular technical barriers, i.e.

- Difficulty to identify a first list of potential alternatives
- Lack of available alternatives
- Constraints on internal R&D
- Technical difficulty to test the performance of the identified alternatives (e.g. lack of pilot testing capability)
- Non-availability of technically feasible alternative to meet customers' requirements (after testing)

Companies substituting in more than seven years were mostly constrained by the technical barriers, while companies substituting in four to six years were mostly affected by constraints on internal R&D. The training was prepared in 2019 by the Lowell Center for Sustainable Production. It is intended for practitioners working in authorities, industry and NGO organizations and focuses on the essential topics for assessment of alternatives to support informed substitution.

Despite of these efforts, critics argue that the current system legally allows for the substitution of a dangerous chemical – after the lengthy process of declaring it unsafe – with a very similar compound that could be equally hazardous. To give an example: in the case of the highly persistent PFAS, there have been public calls for a blanket ban. Proposals to tackle the issue aim at regulating groups of chemicals, as a potential way to get potentially unsafe chemicals off the market.

A prerequisite, however, of all efforts to substitute problematic chemicals in products, is the knowledge of the supply chain actors down to the retailer, who has the closest link to private consumers, that a certain substance is present in the material. In that respect, the Green Deal formulates the following conclusion (see also section 4.0):[122]

"Reliable, comparable and verifiable information also plays an important part in enabling buyers to make more sustainable decisions and reduces the risk of 'green washing'. Companies making 'green claims' should substantiate these against a standard methodology to assess their impact on the environment. The Commission will step up its regulatory and non-regulatory efforts to tackle false green claims. Digitalisation can also help improve the availability of information on the characteristics of products sold in the EU. For instance, an **electronic product passport could provide information on a product's origin, composition, repair and dismantling possibilities, and end of life handling**."

Thus, be using digital and automated tools, the knowledge base for self-responsibility of the supply chain actors has to be established (see also the proposed cooperation in section 2.3.0).

[121] ECHA online introductory training on analysis of alternatives:https://echa.europa.eu/online-training-on-analysis-of-alternatives.

[122] European Commission, Green Deal, COM (2019) 640, p. 8; emphasis added.

(1) Mapping exercise on plastic additives

In late 2016, ECHA and 21 industry sector organisations launched a joint project to characterise the uses of plastic additives and the extent to which the additives may be released from plastic articles.

The mapping focused on plasticisers, flame retardants, pigments, antioxidants, antistatic agents, nucleating agents and various types of stabilisers. Some thousand substances were screened to identify those being used and to validate data on their intrinsic properties. The data provided by the plastics industry enabled ECHA and a team of researchers to develop a model to calculate the 'release potential' of each additive into the environment. The potential for release to the environment means the potential for a given chemical to be released in air, water and soil during the use of that chemical in an article. The inventory does not provide actual (real life) or experimental data, only the relative release potential. However, comparing the release potential of additives with the same technical function can help in the substitution of hazardous substances with safer alternatives.[123]

(2) ECHA Proposal to restrict "intentionally added microplastics"

As a result of the aforementioned "administrative learning processes" ECHA published a formal proposal to restrict "intentionally added microplastics", being it a single substance or mixture containing a microplastic, in a cross-cutting manner.[124] The European Commission, for the time being (November 2020), did not adopt the restriction, that would amend RACH Annex XVII accordingly.

4.1.2.2 Green Deal: safer chemicals in products, sustainability and a circular economy

Key policies promoting the regulatory development in the chemicals sector in the EU and in Germany focus on Sustainable Development as a central topos. First of all, the European Green Deal needs to be mentioned here.[125] The strategy communication (COM(2019) 640, as of 11.12.2019) formulates as a starting point that it "resets the Commission's commitment to tackling climate and environmental-related challenges that is this generation's defining task." The document briefly explains the core challenges and continues as follows (p. 2)

„The European Green Deal is a response to these challenges. It is a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use.
It also aims to protect, conserve and enhance the EU's natural capital, and protect the health and well-being of citizens from environment-related risks and impacts. (…)
This Communication presents an initial roadmap of the key policies and measures needed to achieve the European Green Deal."

The Annex to the European Green Deal provides an action plan. In relation to chemicals, the Green Deal comprises i.a. the following elements:

123 See also https://echa.europa.eu/plastic-additives-initiative.
124 ECHA, Annex XV restriction report on intentionally added microplastics (as of 22.08.2019).
125 Information about European Green Deal: https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en.

- A new Circular Economy Action Plan under the heading “For a cleaner and more competitive Europe”, launched in March 2020 (COM(2020) 98 final; see also section C.0); accompanied by
- An initiative on a ‘sustainable products’ policy to support the circular design of all products based on a common methodology and principles. For this, the scope of the Ecodesign Directive needs to be widened beyond energy related products, and made applicable to the broadest possible range of products. A legislative proposal is envisaged for the fourth quarter of 2021.
- The “farm to fork strategy” (COM(2020) 381, presented in May 2020) addresses the use of pesticides in agriculture. The European Commission promises to “take action to reduce the use of chemical and more hazardous pesticides by 50%”.[126]
- Chemicals Strategy for Sustainability (published in October 2020 as COM(2020) 667 final) tackles environmental chemicals management issues in a very fundamental manner (see section C. 1.2).
- Zero pollution action plan for water, air and soil
- Revision of measures to address pollution from large industrial installations

The proposals are or will be discussed by Member States, stakeholders and the European Parliament in the near future. For the time being, the European Commission met most of the timelines mentioned in the Annex to the Green Deal.

4.2 Options to address selected global and domestic challenges in chemicals management

The challenges identified by the GCO II as well as existing domestic or European challenges provide several leverage points that can be addressed in cooperation of China and Germany: knowledge and data gaps should be closed, frontrunner companies and industries may be better supported and circular economy and sustainability potentials may be used more.

4.2.1 Supply/Value chain management with focus on safe products

Following “key finding 8” of the GCO II, the supply and value chain management should be improved aiming for a comprehensive implementation of best practices with regard to full material disclosure, pro-active risk reduction and human rights-based policies. In that regard, the collaboration of governments and industry actors is inevitable to set up an effective infrastructure. The closely interwoven supply and value chains between China and Germany offer many starting points in this regard. This chapter looks at two approaches: the transfer of comprehensive material data on the product life cycle, including on the product supply chains, as a ‘full material disclosure’, and the evaluation of the production and use of chemicals according to criteria of ‘sustainable chemistry’.

4.2.1.1 Establishing an infrastructure that supports full material disclosure

The concept of full material disclosure (FMD) not only allows industry actors to better comply with regulatory obligations, but also promotes the proactive reduction of chemical-related product risks. It avoids the need to involve the stakeholders in the entire supply chain when

[126] For details see https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal/actions-being-taken-eu/farm-fork_en.

new regulatory obligations or contractual requirements are put in place (see following section). By disclosing the complete material composition of products once, upstream supply chain actors do not need to be asked again later whether their products contain a substance that has now been identified as hazardous. This way, all downstream supply chain actors can meet their present requirements from regulation as well as from sectoral or company specifications, and can prepare for future requirements. Full material disclosure however has two prerequisites: firstly, a uniform standard for the format of the disclosure, secondly, a database that enables the transmission of the disclosed data in the supply chain. China and Germany could work together to implement these prerequisites.

FMD requires an institutional framework that provides an appropriate level of trust among the supply chain actors, ideally a cross-sectoral agreement on a common data structure and exchange format. The conditions stipulated by the SCIP-database already trigger standardization efforts. The efforts of the Proactive Alliance mentioned in B.0 regarding harmonising existing standards includes compatibility with FMD, but also supports disclosure limited to regulatory obligations. This follows from the fact that the acceptance of a standard by stakeholders depends on the feasibility and proportionality, taking into account the widespread reservations towards FMD. As a first step in that direction, standards can support an “almost” (e.g., 95%) FMD approach which provides the option to use a joker (i.e. exempt from declaring to the recipients of the product) for a limited amount of substances under certain conditions.

Tools providing for the transmission of FMD data are based on material data systems (MDS). There are multi-stakeholder collaborations aiming to establish a multi-sectoral database in addition to the SCIP database which is limited to the European market, e.g. the AskREACH supply chain communication (see A.0).[127]

The purpose of the MDS is to generate a structure tree of all materials present in a certain final product subject to reporting, which is usually a complex object (incorporating more than one individual article under REACH). The structure follows the different stages in the production process of an article, e.g., from semi-finished article (e.g., plastic sheet), further processed component (e.g., machining, coating), to incorporation in the final article.

Such a material data system solution should support interoperation with existing tools and data repositories from different providers, for different sectors (see C.2.1.1.) and with complementary objectives, e.g. circular economy (see C.0). The resulting ecosystem of federated platforms can add more value for supply chain actors than conflicting tools. The system also requires governance mechanisms with reference to the FMD standards described above. In addition, for supply chain actors to trust the system, the disclosed confidential business information has to be protected from unauthorized access, both by encryption as well as by the governance framework.

The disclosed material data can be connected to a product using an “electronic product passport” (EPP), as envisaged in the European Green Deal. The EPP is represented on the product by a unique product identifier (UPI). Several options of UPI are currently under development, including optical identification as well as other electronically readable tags. The

[127] For more information, visit https://www.askreach.eu/supply-chain-tool/

EPP itself identifies the product and provides a bill of material based on an underlying database, mirroring the material composition in the stepwise production and assembling process of products along the supply chain. On this basis, the EPP can also indicate whether the product incorporates regulated chemicals of a relevant amount, e.g. SVHCs in an article above 0.1 mass percentage. Furthermore, the EPP can provide information on the products repair and dismantling possibilities and its end-of-life handling to support circular business models (see C.0). In this respect, the EPP concept is not tied to information provided by producers alone, but allows all actors within the lifecycle to provide additional information that can be of use for reuse or recycling. The EPP concept is being proposed by the European Commission's 'Green Deal' and reiterated in the 'New Circular Economy Action Plan', making this approach a realistic solution for the medium- and long-term.[128] A cooperation of China and Germany could work on making the EPP concept a new standard for the chemical management in global supply chains.

4.2.1.2 Setting up conceptual orientation and infrastructure to promote sustainable chemistry

The concept of sustainable chemistry takes the precautionary principle into account and builds on responsible chemicals management. It calls on all groups of stakeholders to carefully weigh up the benefits and risks of producing and using chemicals on the basis of the state of the art in science and technology, with the aim of finding a long-term viable solution that takes account of ecological, social and economic needs, thus making chemistry serve an all-embracing sustainable development.

A first step to approach the goals of sustainable chemistry at practical level is provided by the Guide on Sustainable Chemicals[129] and its corresponding IT-tool SubSelect[130] of the German Environmental Agency (UBA). Both of them help manufacturers, formulators and end users of substances to focus on sustainability aspects in the selection of substances and use of chemicals in the company.

The heart of SubSelect and the Guide on Sustainable Chemicals are specific criteria for eight important aspects of testing the sustainability of a substance, including hazardous properties for human health and for the environment, mobility of a substance, greenhouse gas emissions and resource consumption as well as responsibility in the supply chains.

At institutional level, the Federal Republic of Germany founded the International Sustainable Chemistry Collaborative Centre (ISC_3; www.isc3.org) in May 2017. The Gesellschaft für Internationale Zusammenarbeit (GIZ) is the hosting body. ISC_3 is composed of a headquarters in Bonn, a research and education hub at Leuphana University in Lüneburg and an innovation hub at DECHEMA in Frankfurt/Main.

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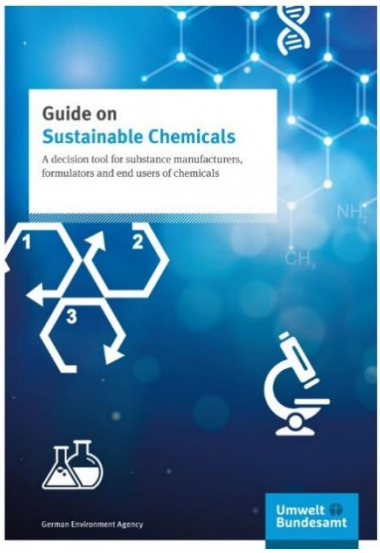
128 Several studies further develop the concept of an electronic product passport for different applications, e.g. Gligoric / Krco / Hakola / Vehmas / De / Moessner / Jansson / Polenz / van Kranenburg 2019: 'SmartTags: IoT Product Passport for Circular Economy Based on Printed Sensors and Unique Item-Level Identifiers'; *Sensors*, *2019,* 19(3), 586; https://doi.org/10.3390/s19030586 and Heinrich, Matthias/Lang, Werner (2019): 'Materials Passports - Best Practice. Innovative Solutions for a Transition to a Circular Economy in the Built Environment'; https://www.bamb2020.eu/wp-content/uploads/2019/02/BAMB_MaterialsPassports_BestPractice.pdf.

129 https://www.umweltbundesamt.de/en/document/subselect-guide-for-the-selection-of-sustainable.

130 https://www.umweltbundesamt.de/en/publikationen/guide-on-sustainable-chemicals.

ISC_3 operates by further developing, advancing, networking and merging knowledge, activities and competencies in the field of sustainable chemistry. ISC_3 links the existing concepts of chemical safety (SAICM and SMCW) as well as the principles of “green chemistry” and “green engineering” with sustainable chemistry and further develops them into a holistic approach.



Thereby, the ISC_3 is systematically strengthening the contributions of the chemicals sector to sustainable development (Agenda 2030), for example through its successful partnership with UNEP on GCO II and by developing a common understanding of sustainable chemistry, which is currently ongoing.

In order to achieve the ambitious goals of the Agenda 2030, it is necessary to involve all sectors that use and process chemicals and their products and/or require chemistry as an enabling factor. It is of central importance to make decisions transparent and to generate them cross-sectoral. Progress in one sustainability goal can unintentionally lead to disadvantages in another. The GCO II states in its key findings (No. 2)[131], that sustainable innovations with and through chemistry are necessary to achieve the goals of sustainable development. As regards this aspect, the ISC_3 focuses on the international promotion of innovations and start-ups by establishing a global start-up service, launching an "Innovation Challenge" and initiating an Investor Forum and Investor Round Table. These activities i.a. contribute to GCO II key finding No. 8[132].

In order to be able to generate even more sustainable ways of thinking and solutions in the future, it is essential to develop and to implement sustainability concepts for education and research. To this end, it is important to establish educational programs and scientific networks. ISC_3 is organizing an International School on Sustainable Chemistry, has established a Master's program in sustainable chemistry - an MBA is in preparation - and maintains partnerships with universities, e.g. with Cambridge and in Tunisia. The Sino-German cooperation could seek to integrate China into these sustainable chemistry efforts.

Besides close collaboration with ISC_3, UBA is also particularly engaged in the preparation of UNEP Manuals focused on sustainable chemistry[133].

4.2.2 Circular business models

Circular business models can i.a. preserve resources, allow re-use and recycling of products and materials while keeping a high level of protection of human health and the environment, and avoid waste and residual materials. At the same time, circular business models are able to positively address GCO II key finding No. 7.

At the same time, the circular business models bring new requirements for the different sectors,

131 See section 4.1.1.
132 Frontrunner companies – from chemical producers to retailers – are introducing sustainable supply chain management, full material disclosure, risk reduction beyond compliance, and human rights-based policies.
133 https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/policy-and-governance/sustainable-chemistry

as their successful introduction requires a fundamental paradigm shift of the actors. It calls for a transformation of industrial enterprises, the way we do business and the consumption patterns we know. To make this possible a number of conditions must be met. The transformation requires strong cooperation between the individual actors of the value cycles. Information along the value cycles regarding materials and substances must be accessible to all actors where necessary. Harmful substances must be removed from the cycles and replaced. Furthermore, all actors must have the knowledge of the possibilities and limitations of circular business models. Only in this way, circular business models can be effective in the long term.

China and Germany could work together to provide incentives for circular business models regarding chemicals. As an example for an already existing business model, chemical leasing is described in the next section.

4.2.3 Chemical leasing

Traditionally, chemicals are sold to customers who use them to provide certain functions. Chemicals suppliers have an economic interest in increasing the amount of chemicals sold. In a common business practice a main focus is placed on higher sales volumes ("the more you sell, the more you earn"). However, in many cases this is associated with negative impacts on the environment and negative consequences for the future availability of resources.

Chemical leasing can be one approach to change this way of business. UNIDO defines chemical leasing as following[134]:

"*Chemical Leasing is a service-oriented business model that shifts the focus from increasing sales volume of chemicals towards a value-added approach. The producer mainly sells the functions performed by the chemical and functional units are the main basis for payment.*[135] *Within Chemical Leasing business models the responsibility of the producer and service provider is extended and may include management of the entire life cycle. Chemical Leasing strives for a win-win situation. It aims at increasing the efficient use of chemicals while reducing the risks of chemicals and protecting human health. It improves the economic and environmental performance of participating companies and enhances their access to new markets. Key elements of successful Chemical Leasing business models are proper benefit sharing, high quality standards and mutual trust between participating companies."*

Chemical leasing inverts a supplier's commercial interest in a higher consumption of chemicals: under Chemical leasing the supplier sells the functions performed by the chemical, and functional units (number of pieces cleaned, amount of area coated, etc.) become the main basis for payment.

[134] source: http://www.chemicalleasing.com/what-chemical-leasing
[135] functions performed by a chemical might include: numbers of pieces cleaned; amount of area coated etc.

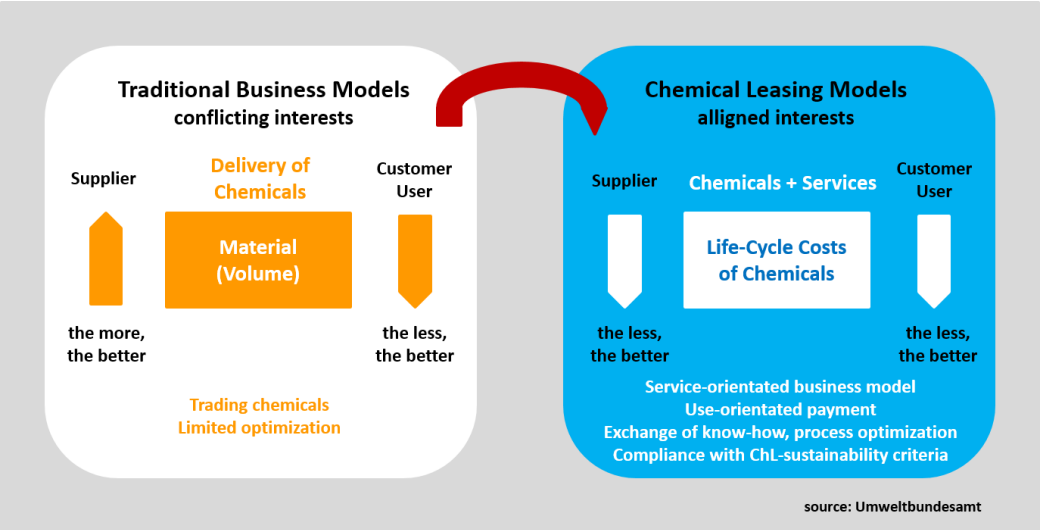


Figure 4 Comparison traditional business models and chemical leasing models

Chemical leasing is a one-of-a-kind sustainable business model, leading to more efficient and economic use of chemicals and to lower water, raw material and energy consumption, significantly reducing the environmental impact of the production process. It helps to reduce occupational health and safety risks and to protect human health from the hazardous effect of chemicals. By sharing the added value created through the more economic use of chemicals, both the chemical supplier and user can gain an economic advantage. It can also foster long-term collaboration between the partners, leading to innovation and the transfer of environmentally sound technology (see Figure 5).

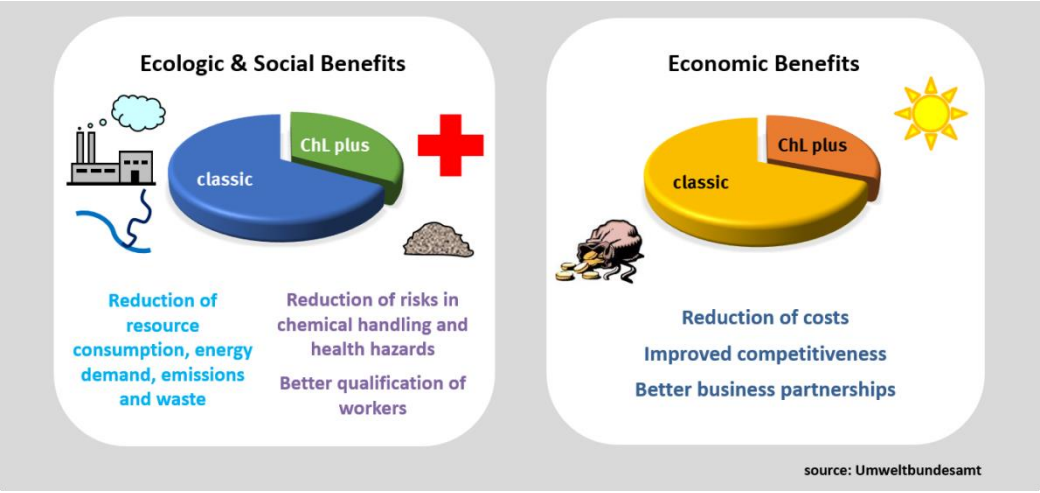


Figure 5 Benefits chemical leasing

In line with the concept of sustainable development, it is necessary to ensure that all chemical leasing activities follow the principles of sustainability. In response, five detailed sustainability criteria referring to chemical leasing have been developed[136]; they must be fulfilled by projects in order to be considered as a "chemical leasing" case. (figure 6).

[136] by international Chemical Leasing experts as a result of the first national Chemical Leasing initiative driven by the German Environment Agency in 2009

Figure 6 Five Sustainability Criteria for chemical leasing business models

The sustainability criteria are designed to protect the positive image of chemical leasing and to prevent the misuse of the term. The set of sustainability criteria, its sub-criteria and indicator compiled in the IT-tool "SMART 5"137 have proven to be helpful not only for evaluating projects, but also for facilitating the negotiation process on Chemical Leasing projects by building trust between parties.

A typical field of application is the cleaning of pipes, tanks, and containers in the food industry:

In classical business, chemicals are purchased on the basis of a price per unit volume or weight. This means that the more chemicals are used the greater is the supplier's profit. With chemical leasing, payment is based on the amount of the final product obtained (e.g. kegs of beer or tons of chocolate) or per operation hours of the cleaning system. Compliance with strict purity specifications and hygiene regulations is then a core element of the chemical leasing contract.

The chemical leasing business for the cleaning of pipes and tanks in the food industry was initiated by UBA[138]. Meanwhile it has been successfully implemented, and the use of quantitative chemical leasing has established a strong presence in this area: according to personal statements made by manufacturers of cleaning products, there are more than 300 chemical leasing contracts in place in the food industry in Germany. Overall, the main areas of application are breweries, dairies, fruit juice industry, bakery and confectionery products, fish processing, meat processing. In 2014, the supplier structure in Germany comprises 14 equipment suppliers and about 120 chemical suppliers.

4.2.4 Foster flaghip industries for chemical management: automotive, electronics, textiles

Addressing the global and domestic challenges in chemical management is a longterm process. It can thus be useful to consider that certain sectors can serve as flagships which inspire other sectors to follow, stimulated by 'economies of scale' cost reduction of the solutions and an enhanced perception of the additional benefits. China and Germany could work together in industry where they have similarly strong and interwoven supply chains such

137 sources: https://www.umweltbundesamt.de/themen/chemikalien/chemikalien-management/nachhaltige-chemie/chemikalienleasing/chemikalienleasing-in-der-praxis and http://www.chemicalleasing.com/smart-5-and-indicator-checklist

138 UBA has conducted chemical leasing case studies in various sectors; for more information see: https://www.umweltbundesamt.de/sites/default/files/medien/2332/dokumente/chemical_leasing_uba_project_2010_final.pdf, https://www.umweltbundesamt.de/sites/default/files/medien/2332/dokumente/final_report_chl_in_practice_final_summary.pdf and https://www.umweltbundesamt.de/sites/default/files/medien/2332/dokumente/final_report_chl_in_practice_final_extended.pdf.

as the automotive, the electronics and the textile industry. The following sections provide an overview on the state of the art in these industries.

4.2.4.1 Automotive

The automotive sector is relatively mature in terms of transmission of information on chemicals in the supply chain. The sector has established an industry-wide information management tool, the International Material Data System (IMDS), which is obligatory to use for suppliers in the automotive value chain. The IMDS contains information on the structure and material constitution of components, which is added to the system by the supplier. The common language of the IMDS is the 'Global Automotive Declarable Substance List' (GADSL). This is an industry-wide harmonised list, which is usually part of supply contracts and sets bans and declaration requirements as well as thresholds for substances with reference to the relevant legal provisions. The weak point of IMDS is that it does not automatically adapt to changes (product or legislation), thereby requiring regular manual updates. IMDS also requires a lot of maintenance as data sets coming from suppliers have to be checked manually for completeness and plausibility.

4.2.4.2 Electronics

The electronics sector has no harmonised information management system in place. There are however two material declaration standards for products that are predominately used at present: the IPC-1752 and IEC 62474 standards. IPC-1752 is mainly used for material declarations in business-to-business communication as well as by standard component data providers. It is a public standard using an XML scheme for the material declaration and the amended IPC-1752B (Class C+D) supporting composition declarations required by RoHS and REACH. There are also various platforms with different requirements and formats to collect and provide data along the supply chain (e.g. BOMcheck, Sustain-Hub). As a result, suppliers have to invest a great deal of resources to meet all the requirements.

4.2.4.3 Textiles

The textile sector is still quite immature concerning the information on chemicals in the supply chain. Companies use in-house tools (often Excel) to manage material and product information. There are some initiatives whose tools are however inadequate, such as the Higg Index.[139] This results in additional effort for suppliers, who usually provide products to more than one brand, each establishing its individual reporting scheme. These complexities involve pitfalls: according to actors along the textile chain, material information often gets lost during the data transfer between suppliers because each production unit has a different technical sheet. Additionally, brands and retailers have issues with verifying the data collected from suppliers, as the collection and reporting does not follow harmonised approaches.

4.2.4.4 Common risks and mutual benefits

All three aforementioned sectors are to some extent intertwined, e.g. automobiles contain not

[139] The Higg-Index is a self-assessment tool where at present the social and environmental impact of products is assessed in a contro-versial way (e.g. with a silk score higher than polyester, 1086 and 36, respectively) using a questionable methodology.

only textile parts, but also an increasing amount of electronic parts. In addition, the mentioned sectors also provide input to other sectors, e.g. textiles to furnitures.

The products manufactured in those sectors bear a core set of similarities. Consumers and other users are often in direct skin contact to the items. Sooner or later, a large amount of the products end up in the waste stream and thus might trigger risks to the environment in EoL treatment or as (contaminated) secondary raw material. In the latter option they often create a “risk-cycle”, thus hindering market entry of recycled material.

To overcome these challenges enhanced information exchange between the supply chain actors around the globe, often located either in China or in Germany, would reduce transaction costed and enable the responsible managers to (pro-)actively manage the material streams in a safe and environmentally safe manner. The proposed cooperation in the field of information infrastructure, aiming at a Full Material Disclosure (FMD) along the added value chain would create mutual benefits, not only between the different industrial sectors but also between China and Germany.

5. Outlook and options for follow-up cooperation

5.1 Outlook on advancements in chemicals management of China and Germany

5.1.1 Principles

Ensuring a high level of protection for human health and the environment laid down in Art. 114 and 191 TFEU and incorporated in, which “provisions are underpinned by the precautionary principle” (Art. 1(1) REACH), will continue to serve as basic principle for advancement in chemicals management in Europe and Germany.

In this context, Germany is guided by the principle of Sustainable Development formulated in Art. 20a of the German Constitution. Important milestones will continue to be set at the European Level, with German legislators transposing decisions into national law where necessary.

5.1.2 Fields and activities

The European Green Deal[140] sets a high standard with its ‘zero pollution ambition for a toxic free environment’. For that, it aims to minimize the risk posed by endocrine disruptors, hazardous chemicals in products including imports, combination effects of different chemicals and very persistent chemicals.

The Chemicals Strategy for Sustainability[141] translates the zero-pollution ambition into more concrete goals:

- Promoting safe and sustainable-by-design chemicals
- Achieving safe products and non-toxic material cycles
- Greening and digitalising the production of chemicals
- Protect consumers, vulnerable groups and workers from the most harmful chemicals
- Protecting people and the environment from the combination effects of chemicals
- Towards zero chemical pollution in the environment
- Strengthening international standards

Moreover, according to the EU “Chemicals Strategy for Sustainability” the EU is likely to address “emerging risks” in a coherent and structured manner.

Beside the Chemicals Strategy for Sustainability, other follow-up measures of the Green Deal are relevant in the field of environmental chemicals management. Options for follow-up cooperation in specific areas: possible formats and activities of Sino-German cooperation in environmental chemicals management.

[140] For more information about the European Green Deal, visit https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en.

[141] For more information on the Chemicals Strategy for Sustainability, visit https://ec.europa.eu/environment/strategy/chemicals-strategy_en.

5.2 Specific issues of concern / interest as picked for possible future cooperation

5.2.1 China

5.2.1.1 Outlook

The health and environmental risks caused by large-scale application of chemicals remain the focus of international attention. Reducing the risks to human health and the environment from chemicals throughout their life cycle is a huge challenge for every country. Sino-German joint research and exchange on chemicals environmental management policies and technologies will help promote understanding of relevant policies and management models, and enhance the capacity of China's chemicals management. We shall work together to deal with risks and challenges, seek common interests and benefits, and achieve win-win development for mutual benefit. In the future, it is hoped that China and Germany will carry out more activities in the area of chemicals environmental management policies and technologies, such as joint policy or technical research, personnel visits and exchanges, and technical training.

5.2.1.2 Areas for further cooperation

We would like to collaborate with the German side in the form of training that covers technical tasks of chemical environmental management, risk assessment and risk control. Regarding Good Laboratory Practice, the Chinese side would like to send personnel to Germany to further understand how to inspect GLP laboratories so as to ensure authenticity and reliability of test data.

5.2.1.3 Details of the next step of cooperation

Adequate technical support is needed for carrying out technical tasks of environmental management of chemicals and effective implementation of various laws and regulations.

In order to support the implementation of REACH and other chemical environmental management policies, what technical support has been done by Germany and the EU?

With regard to chemical risk assessment, according to REACH, the European Chemicals Agency prepares the Community Rolling Action Plan, which requires member states to assess given substances that pose risks to human health or the environment. How does Germany carry out risk assessment from the management perspective when assessing these chemical substances. What technical guidance documents, databases and models have been developed for the purpose and what is included in the risk assessment process.

In terms of chemical risk management, how management measures for a chemical substance are determined and how the effectiveness of REACH implementation is evaluated. How to assess the socio-economic benefits of newly produced or imported chemicals and of chemicals to be restricted or banned. Are there cases for sharing?

Good Laboratory Practice and test facility management. How does the EU and Germany make inspection of good laboratory practice that produces test data for registration? Could a Chinese representative join such an inspection?

5.2.2 Germany

This section provides an overview of topics that a possible Sino-German cooperation could work or focus on:

Germany seeks to improve communication in global supply and value chains with German and Chinese actors. In that direction, international cooperation could help to find best practice approaches in information collection and verification regarding the registration of substances. After registration, the cooperation may support the implementation of information and activity requirements. Cooperation could also foster innovation in new substances and new ways of using substances to prevent harmful effects of hazardous chemicals for humans and the environment.

Regarding chemicals in products ("Substances in Articles" in the terms of REACH), China and Germany may work together on implementing the prerequisites for a Full Material Disclosure (FMD) approach, a uniform standard for the format of disclosure and data systems that enables the transmission of disclosed data throughout the life cycle. In this respect, they can build on the outcome of the deliberations of the Proactive Alliance (see section 2.6.3.4).

The electronic product passport may be established as a standard for chemical information in global supply and value chains. They could also work on making sure that information obligations are met by upstream supply/value chain actors outside the respective jurisdiction, but within the sovereignty of each partner.

Furthermore, there is a specific need to coordinate enforcement processes and risk management practices to promote common standards, strengthen the enforcement activities and make the chemical management systems more efficient in the two countries.

In addition, Germany strives to intensify cooperation with China for innovation in the field of chemical management, thus taking up the ambitions towards sustainable chemistry and circular economy. This concerns especially the following topics:

- Chemical feedstock and product innovation opportunities for non-regrettable substitution of hazardous substances: bio-based and renewable feedstocks; CO_2 as a resource and feedstock; plastics and plasticizers; solvents; water, grease and dirt repellents; flame retardants; surfactants and chemical preservatives
- Process and innovation opportunities: Chemical Leasing, catalysis including earth abundant metal catalysis, organo-catalysis, bio-catalysis, photo-catalysis; batch vs. continuous processing; biofineries.

In particular the emerging technology of micro-reactors offering precise reaction control and thus allowing high material and energy efficiency combined with continuous processing at high-quality level appear to be advantageous.[142] Due to the design of the process, unintended by-products are reduced to a minimum.

The entire "chemical plant" can be integrated in a standard twenty-foot container. The production of input chemicals can take place at the premises of the respective downstream user. The risks linked to transportation processes can be reduced substantially as well as the "over-production" and the associated storage problems. A cooperation in this field would also

[142] For an example in the field of leather chemistry see https://sne.h-da.de/en/implementation-project/more-sustainable-chemistry-in-the-leather-supply-chains with a paper on micro reactors: Patrick Rojahn, Oliver Ruß, Lars Gössl, Matthias Kroschel, Frank Herbstritt, Joachim Heck und Frank Schael 2020: Mixing Performance in a Distributed-Feed Plate-Type Reactor with Multinozzle Injection for Fine Chemical Production Scale, in: Industrial & Engineering Chemistry Research (Vol 59), January 2020, p. 3655 – 3668..

contribute to the efforts to move forward towards all-embracing sustainable development, by a more sustainable chemistry, underpinned by the principles of “green chemistry” and “green engineering” (see section 4.0).