REACH

Registration, Evaluation, Authorization and Restriction of Chemicals

ABSTRACT

REACH regulation was released by the European Union in December 2006 and went into effect on January 1, 2007. REACH ensures that manufacturers and suppliers assess the risks of chemical substances in their products and implement measures to manage the risk caused by such substances to human health and to the environment.

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EU REACH Reporting using DXC Compliance Solutions

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Introduction

All products commercially available from almost all industries, including automotive, electronics, heavy equipment, and aerospace sectors, whether for personal or industrial use, contain chemical substances in many of the parts that make up the whole product. With knowledge that many products with chemical substances impacting human health and the environment have been sold in European countries for many years, the European Union acknowledged the need for a regulatory compliance for assessment and management of chemical substance flow in a manufacturer's supply chain.

The responsibility for the management of the risks of substances lies with the natural or legal entities that manufacture, import, place on the market, or use these substances in the context of their professional activities. The European Union developed a regulation designed for manufacturers, importers, and downstream users to ensure that the products they manufacture, place on the market, or use do not adversely affect human health or the environment.

This regulatory compliance addresses the **Registration, Evaluation, Authorization and restrictions of Chemicals (REACH)**. The European Parliament approved REACH on December 13, 2006. The Council of Ministers formally adopted it on December 18, 2006, and REACH went into effect on January 1, 2007. At 849 pages, REACH is one of the most comprehensive regulations created for the European Union.

This document addresses EU REACH. Other jurisdictions, such as Turkey, Iceland, Japan and Taiwan also have REACH regulations. These alternate regulations have similarities and differences when compared to EU REACH, which are not addressed specifically in this document.

REACH applies to substances manufactured or imported into European Union in quantities of 1 tonne per year (tpa) or more. REACH covers substances on their own, in preparation, or in an article manufactured, imported, placed on the market, or used in the European Union.

> **Preparation:** A mixture or solution composed of two or more substances, for example, ink, or detergents. Substances in preparations are required to be registered separately.
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> **Article:** An object which, during production, is given a special shape, surface or design, which determines its function to a greater degree than its chemical composition, for example, cars, clothes, or toys. Thus, an article is a finished product, and it is a saleable object. In REACH: Once an Article, Always an Article (O5A).
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> **Substance:** A natural or manufactured chemical element and its compounds, including additives, necessary to preserve its stability and any impurities deriving from derivation processes, but excluding separable solvents, which do not affect the chemical stability or composition.

REACH is administratively managed by the European Chemical Agency (ECHA). ECHA is required to publish reports on the progress made in the registration and evaluation of registrants. These reports are required to include recommendations to potential manufacturers and importers to foster continuous improvement in the quality of information obtained from the registrants.

REACH was amended in April 2018 to include specific information requirements for nanomaterials.

REACH objectives that needed to be balanced within the overall framework of sustainable development are listed below:

- **Protection of human health and the environment:** Enables manufacturers, suppliers, and importers to protect human health and the environment through identification and management of properties of chemical substances that pose risks.
- **Increased transparency:** Identifies the most harmful chemicals and set incentives to substitute them with safer alternatives. In general, all substances are covered by this regulation unless they are explicitly exempted from its scope.

- **Maintenance and enhancement of the competitiveness of the EU chemical industry:** Fosters innovation, Research & Development for safer substances in industries involved in chemical and materials development, and enhances the competitiveness of the EU chemicals industry.
- **Conformity with EU international obligations under the World Trade Organization (WTO):** Addresses any data gaps related to properties and use of chemical substances in all types of products manufactured or imported into the EU, and maintains integration with international efforts.
- **Promotion of non-animal testing:** Requires companies to share data to avoid any unnecessary testing on vertebrate animals. Companies must obtain an approval from ECHA before performing any proposed tests. Registrants can only perform tests when they have exhausted all other relevant and available data sources.

REACH

Registration

Registration is a requirement of REACH compliance. Manufacturers are required to collect information on the chemical substances they manufacture or import into European Union, submit this information to the European Chemicals Agency (ECHA), and register the data using the **Registration Dossier**. Polymers and non-isolated intermediates are excluded from this requirement.

The Registration Dossier must include how the chemical substance is used, including its physico-chemical, ecotoxicological, and toxicological properties along with a hazard and risk assessment. The risk assessment should show the risks that the use of these chemical substances pose to human health and the environment and how the risks are controlled, including the substance safety to downstream users.

Who is required to Register?

Registration is required for all**:**

- **European Union Manufacturers**: Any natural or legal entity or person who makes or assembles an article within the European Union.
- **Only Representatives**: Entities defined as Only Representative are established within the EU and appointed by a manufacturer, formulator, or article producer that resides outside the EU. These designated representatives are required to fulfil the registration obligations of importers.
- **Importers:** Entities defined as Importers are established in the EU, who are responsible for the import. The registration should be made by such legal entities. The responsibility for import depends on many factors, such as who orders, who pays, who is dealing with the customs formalities, but this might not be conclusive on its own.

The registration process has been made simpler by employing the "**one substance, one registration**" principle. If a manufacturer and an importer are importing or manufacturing the same chemical substance, they can submit the registration jointly. Properties, based on analytical and/or spectral analysis, must be consistent to confirm identical substance use.

All substances on their own, substances in mixtures, and certain cases of substances in articles need to be registered. Those chemical substances that are already regulated by other legislations, such as medicines, or radioactive substances are partially or completely exempt from REACH Registration.

Registration Timelines: The following timeline was established for Registrations:

1 June 2007:
- REACH was launched.

1 June 2008:
- Pre-registration for existing (phase-in) substances started.
- Registration for new (non-phase-in) substances started.

30 November 2008:
- Pre-registration for 'phase-in' substances ended.

1 December 2008:
- Registration for existing substances (that have not been pre-registered) started.

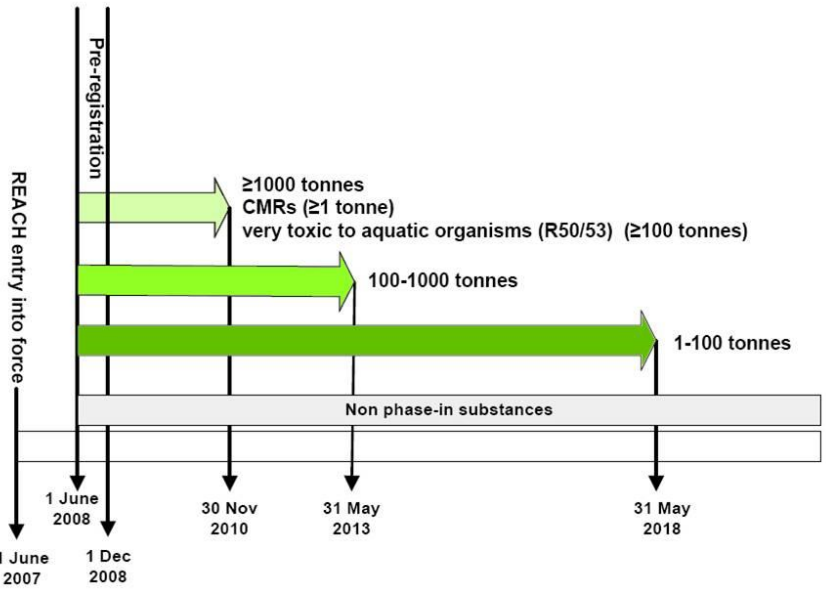
1 January 2009:
- List of pre-registered substances were published and Substance Information Exchange Forum (SIEF) were formed.

1 December 2010 (Phase 1):
By this date the following pre-registered 'phase-in' substances should have been registered when supplied at the following:

- >1000 tpa or;
- >100 tpa and classified under Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (CHIP) as very toxic to aquatic organisms or;
- > 1 tpa and classified under CHIP as Cat 1 or 2 carcinogens, mutagens or reproductive toxicants
- Substances either manufactured or imported into EU in quantities <1 tpa are not covered by REACH.

1 June 2013 (Phase 2):
- Deadline for registration of substance quantities between 100 - 1000 tpa.

1 June 2018 (Phase 3):
- This deadline concerns companies that manufacture or import substances in low volumes, between 1 - 100 tpa.



Timeline Reference: http://www.cirs-reach.com/REACH/REACH_Registration_Deadlines.html

Evaluation

The information submitted by manufacturers and importers to the EU using the Registration process is evaluated to examine the quality of the "Registration Dossiers" and to assess / clarify if the chemical substances pose risk to human health or the environment.

The Evaluation process consists the following steps:

- **Compliance Checking:** ECHA checks and examines the quality of the information submitted by the registrants.
- **Dossier Evaluation:** If the substances registered are at the higher tonnage levels (≥100 tpa), the registrant is required to submit a proposal detailing any animal tests considered required from the list of standard tests in Annexes IX and X of REACH. ECHA evaluates these testing proposals to prevent unnecessary animal testing and to avoid any cost.
- **Substance Evaluation**: Chemical substance evaluation is conducted by Competent Authorities on substances within the European Economic Area (EEA) member states. Substance evaluation prioritization and possible regulatory action is a collaborative effort between the EC and the Competent Authorities. Evaluation may result in multiple outcomes, including a finding of no significant hazard or the imposition of restrictions on the manufacture, supply, or use of a substance, and/or the substance being added to the priority list for authorization, or a proposal to change the classification and labelling requirements.

Authorization

REACH authorization process starts when either ECHA or a Member State proposes that a chemical substance or collection of chemical substances are identified as SVHCs, hazardous substances have serious consequences to human health. They cause cancer (carcinogenic), or they have other harmful properties and remain in the environment for a long time (persistent) and gradually build up in animals (bio-accumulative). A list of substances from REACH SVHC requiring authorization from ECHA have been provided in REACH Annex XIV (updated 10 January 2018). Manufacturers and importers are required to obtain authorization from ECHA, if any substance from this list need to be placed in use within European Union.

REACH has identified the following SVHC criteria:

- Substances that are Carcinogenic, Mutagenic, or toxic for Reproduction (CMR) category 1A or 1B in accordance with the Classification, Labelling and Packaging (CLP) Regulation. CLP is a European Union regulation introduced in 2009.
- Persistent, Bio-accumulative and Toxic (PBT) substances.
- Very Persistent, Very Bio-accumulative (vPvB) substances, according to REACH Annex XIII.
- Substances, identified on a case-by-case basis, that cause an equivalent level of concern as CMR or PBT/vPvB substances.

After identification, the substance is added to a Candidate List. This list is a means to communicate issues to substance manufacturers, importers, and suppliers and asking them to:

- Supply a Safety Data Sheet (SDS): The Safety Data Sheet is meant for documenting information on classified chemical substances and preparation. It is used for distributing appropriate safety information on classified substances and preparations, including information from the relevant Chemical Safety Report down the supply chain to the immediate downstream users. The intent of SDS is to help users of chemical substances and preparation in their raw form prepare for managing risk posed by handling of such substances and preparations. The Material Safety Data

Sheets (MSDS) is meant for documenting information content of a finished product, i.e. an Article. The main goal of MSDS is to enable protection of customers and the environment.

- Communicate on safe substance use: REACH SDS is supplied, either in paper format or electronically, to the customers before or at time of the first delivery of chemical if the chemical substance is classified as hazardous, i.e Substance of Very High Concern (SVHC).
- Provide Safe Use Instructions (SUI): Suppliers are required to provide Safe Use Instructions for downstream users. The SUIs include relevant exposure scenarios from the use of SVHCs, and other relevant information.
- Respond to consumer requests within 45 days: REACH Article 33 entitles consumers to ask manufacturers or importers for information if a product or its packaging contains Substances of Very High Concerns (SVHC) in a concentration of above 0.1%. This information must be provided within 45 days free of charge.
- Notify ECHA if an article produced contains an SVHC in quantities >1 metric ton/year per producer/importer, and if the substance is present in those articles above a concentration of 0.1% (w/w).

Restriction of Chemicals

Restrictions provide a procedure that regulates the manufacturers and importers of products and chemical substances into European Union of dangerous chemical substances that pose risk to human health and the environment. Restrictions, therefore, act as a safety net to manage such risks that otherwise may not be controlled.

Restrictions can be applied to any substance, including those that do not require registration. If any substance and preparation pose a particular risk, requiring community-wide action, it can be restricted. Restrictions take many forms, for example, from a total ban to not being allowed to supply an article to retail consumers.

REACH Annex XIV (updated 10 January 2018) lists substances selected from the REACH SVHC list subject to authorization under EU REACH regulation. Substances on this list, 43 SVHCs, cannot be placed on the market or used after a given date ("sunset date"), unless an authorization is granted for their specific use, or the use is exempted from authorization.

The REACH Annex XVII regulation provides list of restrictions of hazardous substances, mixtures, and articles for their marketing and their use in the EU market. REACH Annex XVII also provides a list of substances restricted for manufacture, import use or presence in articles in the EU. This list is known as REACH Restricted Substance List.

REACH Annex XVII has also banned some substances. These substances are Polychlorinated terphenyls (PCTs), asbestos fibers, pentachlorophenol and its salts and esters, and monomethyl-tetrachlorodiphenyl methane. Many of these substances are persistent organic pollutants (POPs).

REACH Scope and Exemptions

REACH restrictions apply to virtually all products manufactured in or imported into the European Union for general use. Some exceptions apply to this REACH compliance policy.

REACH Titles II (Authorization), V (Downstream User), VI (Evaluation), and VII (Authorization) do not apply to:

- Medical products for human or veterinary use.
- Food, food flavorings, and food additives.
- Substances used for Research & Development.
- Specific substances listed in Annex IV and Annex V.

- Cosmetics (expected to be regulated by other compliances).

Other exclusions from REACH Compliance are:

- Radioactive substances which are expected to be regulated by other compliances
- Substances for re-export or in transit are expected to be regulated by other compliances.
- Non-isolated intermediates, such as reaction chemicals, which are further processed and no longer exist after the further processing.
- Waste, as regulated by Waste Directive Framework (WDF). The WDF is currently targeted to be available by January 2020 and reporting will be required from January 1, 2021.

Manufacturers and importers outside the European Union have direct legal responsibilities to report the SVHC substances identified by REACH in their products, which are sold in the European Union. Manufacturers and importers who have established operations within the European Union have direct legal responsibilities for fulfilling REACH regulation and compliance.

REACH requirements to report SVHC generally apply to product packaging, as well as to the product itself. Packaging materials, such as cardboard boxes, may contain boric acid or borate flame retardant SVHCs. REACH Annex XVII restrictions often apply to packaging, especially if supplied to consumers.

Packaging also applies to shipping products, such as pallets and banding. Before REACH, lead was commonly used to secure the steel bands used to secure products to pallets, and companies would have hundreds of small clumps of lead amounting to tens or hundreds of kilos of lead fragments from broken clasps littering their unloading docks.

Is REACH Mandatory?

REACH compliance is mandatory on products produced in or shipped into the European Union (EU) and member countries. There are now many more REACH-style regulations in other jurisdictions, and there is also greater recognition that services, such as eBay, result in products being sold into jurisdictions other than those originally intended. Therefore, while REACH is an EU-specific regulation, companies may find themselves compelled to follow REACH compliance, even without intended business operations in the EU.

Compliance Management Solutions for managing REACH

REACH regulation applies to almost all types of products. Automotive products are amongst the most complex ones. The 2000/53EG guidelines on End-of-Life Vehicles (ELV) required recycling only of lead, mercury, hex chrome, cadmium, and specific polymers. Ferrous metals, rubber, and many other constituent parts were out of scope. Other regulations have been enacted to go after these items, but we can't honestly say ELV targeted them all.

International Material Data Systems (IMDS)

The International Material Data System (IMDS, https://www.MDSystem.com). was introduced in 2000 as the result of collaboration between German Automotive OEMs, the chemicals and materials industries, and EDS (now DXC Technology). Originally a way for the auto makers to meet their obligations under ELV, the IMDS community has since broadened to include virtually all global automotive manufacturers and their supply chains, and addresses a much broader range of product material compliance regulations and concerns.

IMDS is a cloud-based, highly secure, materials data management system, and it is accessed through the internet via a web browser. All materials present in an automobile as sold to a customer are collected, maintained, analyzed, and archived throughout the entire supply chain. The automobile manufacturer using IMDS can easily obtain all the necessary data for meeting REACH compliance, including

declaration and management of substances. IMDS supports recyclability and recoverability of materials in an automobile and addresses the disposal of substances of concern.

The automotive industry guidelines on REACH have recommended that IMDS be used for collecting information on SVHCs in articles. Thus, the entire automotive industry is in an advantageous position, when compared with other industries, since it is able to comply with several REACH obligations easily and communicate (REACH Article 33) the data without developing new tools or processes.

Compliance Data Exchange (CDX)

The Compliance Data Exchange (CDX, www.CDXSystem.com) from DXC Technology is the leading solution for materials data management. CDX is a cloud-based, highly secured, centrally operated Software-as-a-Service (SaaS) solution optimized for manufacturers and suppliers in virtually any industry and requires almost no IT infrastructure to implement. CDX is accessible through the internet via a web browser.

CDX employs legal advisors who monitor regulation defining organizations, such as the European Chemical Agency (ECHA) for new revised regulations and directives and who update CDX with necessary information.

CDX also maintains data validation rules to simplify the effort of data collection and reduce the possibilities for errors. Lists of regulatory relevant substances and materials, curated by legal and material engineering consultants to ensure high quality chemical reporting are an integral part of CDX.

How CDX helps in REACH Compliance Management

DXC Technology recognizes your business is to manufacture and/or sell your products, and so CDX begins, not with regulations, but with identifying and creating the Bill of Materials and chemical composition of your products. Once your supply chain has helped document your product at the chemical level, CDX compares the collected full or partial chemical product declaration to multiple regulations, including REACH. As CDX helps your company compile the complete Bill of Materials and Bill of Substances for your products, CDX natively addresses the REACH Once an Article, Always an Article (O5A) reporting obligations, easily identifying the point at which materials transition into compositional REACH Articles.

The CDX Regulation Wizard walks you and your supply chain step by step through the process of building your product Material Data Sheet (MDS) with a focus on regulatory material product compliance. The Regulation Wizard guides CDX users through reporting against supported legal regulations, corporate responsibility concerns, and product sustainability topics. The Regulation Wizard supports both user-defined and pre-defined substance lists provided by our contracted regulatory and material engineering staff and regulations to simplify provisioning of the required substances to satisfy your reporting needs.

The Web Services Interface (WSI) allows CDX users to leverage data in your current systems and automatically exchange product and supplier data with CDX. The WSI integrates CDX data with in-house Product Lifecycle Management (PLM), Enterprise Resource Planning (ERP), Environment Health and Safety (EHS), and Product Data Management (PDM) processes and systems in your environment. This includes internal workflows to support product development and reporting.

CDX automatically matches the assigned substances in a Material Data Sheet (MDS) with the regulations that are considered in scope for the company, REACH as one of the regulations amongst many. A CDX user is able to use CDX to search and display any potential violations of regulations regarding limits, exceptions, and expiration dates. Reports generation and analysis tools in CDX makes management of REACH compliance for a company much easier.

CDX fully supports REACH, including Annexes XIV and XVII, REACH SVHCs, and REACH O5A. CDX also addresses other compliance topics, including RoHS, China RoHS, and other jurisdictional variations, California Proposition 65, Batteries, Packaging, ELV/GADSL, HKC, Conflict Minerals

reporting, and many others. CDX supports data collection and reporting using its own optimized user interface, or via data import and export using IMDS-AI, IPC-1752A, IPC-1754, IPC-1755, IEC-62474, CMRT, and .XLS formats.

The data validation rules related with REACH compliance are built into CDX, which simplifies data collection and reduces possibilities for errors. For example, if a supplier is reporting a product that is made of steel, CDX can ensure that iron is reported as a source material, and can identify typical steel additives often found within the scope of regulatory relevant substances, such as REACH SVHCs.

CDX contains standardized material declarations for thousands of materials produced to an industry standard and aids in the collection of product declarations from your supply chain to assist your company in building complete, accurate, and secure product declarations.

As a Software-as-a-Service (SaaS) Digital computing Cloud analytics service, CDX is available now, and ready to use with no complex IT requirements or in-house implementation tasks required. Companies and their supply chain can begin using CDX immediately, after registering at the CDX website (www.CDXSystem.com).

Definitions and Roles

Article: An article is a finished product and is saleable object. An object which during production is given a special shape, surface or design, which determines its function to a greater degree than its chemical composition. e.g. car, clothes, toys. In REACH, Once an Article, Always an Article (O5A).

Chemical Safety Report (CSR): The chemical safety report (CSR) for substances manufactured or imported in quantities starting at 10 tonnes, documents the hazards and classification of a substance and the assessment as to whether the substance is PBT or vPvB.

CHIP: Chemicals (Hazard Information and Packaging for Supply) Regulations 2002.

Distributor: Any natural or legal person or entity established within the EU, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties (Article 3(14)).

The European Economic Area: It was established via the EEA Agreement, an international agreement which allows for the extension of the EU's single market to non-EU member parties.

Importer: The physical introduction into the customs territory of the EU (Article 3(10)).

Manufacturer: Any natural or legal person or entity established within the European Union who manufactures a substance within the EU (Article 3(9)).

Manufacturing: Production or extraction of substances in the natural state (Article 3(8)) Guidance on registration Version 3.0 – November 2016.15.

Only Representative: A natural or legal person or entity established in the EU and appointed by a manufacturer, formulator, or producer of an article established outside the EU to fulfil the obligations of importers (Article 8).

Placing on the market: Supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market (Article 3(12)).

Downstream user: Any natural or legal person established within the EU, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities (Article 3(13)).

Producer of an article: An natural or legal person or entity who makes or assembles an article within the EU (Article 3(4)).

Safe Use Instructions (SUI): Suppliers are required to provide Safe Use Instructions for downstream users. The SUIs include relevant exposure scenarios from the use of SVHCs, and other relevant information.

Substance: A natural or manufactured chemical element and its compounds, including additives necessary to preserve its stability and any impurities deriving from derivation processes, but excluding separable solvents which do not affect the chemical stability or composition.

Substance Information Exchange Forum (SIEF): Specific cooperation for REACH registration. It is organized by co-registrants and usually set up for the phase-in scheme transitory period.

Supplier of a substance or a mixture: Any manufacturer, importer, downstream user or distributor placing on the market a substance on its own or in a mixture.

Supply a Safety Data Sheet (SDS): The Safety Data Sheet is meant for documenting information on classified chemical substances and preparation.

Use: Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization (Article (324)).

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