

The REACH Regulation:
A regulation that concerns ALL of us.



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expect more⁺

REACH

Stands for ...

Registration, Evaluation, Authorisation and Restriction of **C**hemicals

Registration

Substance assessment, preparation of a dossier and registration by industry

Evaluation

Evaluation of registration dossiers by the agency (ECHA*); checking for quality and completeness

Authorisation

Authorisation of Substances of Very High Concern (SVHC**) for certain uses by the agency

Restriction

Restriction of the manufacture, use or placing on the market of hazardous substances by the agency

With the objectives:

- ⊕ Protection of human health and the environment
- ⊕ Single system for the regulations for existing and new substances

*ECHA – European Chemicals Agency

**SVHC – Substances of Very High Concern

REACH

Scope & Principle

Regulation (EU) No. 1907/2006 (REACH Regulation) is an EU chemicals regulation that entered into force on June 1, 2007.

Scope

- + EU Member States (uniformly, directly)
- + EFTA States which are members of the EEA (Iceland, Norway, Lichtenstein)
- + CAUTION: Switzerland is NOT part of the EU nor of the EEA

- + REACH concerns all companies that manufacture, import or use chemicals
- + Import from Non-EU countries shall be deemed to be equivalent to manufacture

PRINCIPLE: NO DATA NO MARKET

- + Chemical substances may only be manufactured, used or placed on the market in the EU if they are registered under REACH
- + Key task of manufacturers and importers is to assess substances and register them with the ECHA.
- + It is the responsibility of industry (manufacturers, importers, users) to demonstrate the safe handling of the substances in all their applications. To this effect, a substance evaluation and assessment is performed on the basis of defined set of criteria. Data requirements for substances are specified dependent on their tonnage band.



REACH

What Must be Registered?

Companies are affected by REACH if they manufacture a chemical substance in volumes ≥ 1 tonne per year or import it from a Non-EU country.

- ⊕ **Substances on their own** (single substances and no mixtures)
- ⊕ **Substances** as components of mixtures (incl. metal alloys)
- ⊕ **Substances** in articles
 - if these are intended to be released under normal or reasonably foreseeable conditions of use (e.g. scented candles, perfumed textiles).
 - > does not apply for Chemetall
 - In the case of wipes, these are considered as mixtures on a carrier material
 - In the case of aerosol spray cans, these are considered as articles (spray can) containing mixtures
- ⊕ **Substances** as a component of articles with properties of very high concern (SVHC*) that are named on the Authorisation List (REACH Annex XIV) and contained in products at a concentration of ≥ 0.1 %.
 - > does not apply for Chemetall

Note:

Under REACH, only chemical substances, NOT products/product names are registered.

*SVHC – Substances of Very High Concern
**eSDS – extended Safety Data Sheet

REACH

Company Obligations

Obligations or potential obligations in the supply chain

Role	Obligations	Potential obligations
Manufacturer of substances	<ul style="list-style-type: none"> • Pre-registration • Registration 	<ul style="list-style-type: none"> • Application for authorisation • Compliance with the restrictions
Importer of substances, mixtures, articles	<ul style="list-style-type: none"> • Sharing information with customers • Information archiving 	<ul style="list-style-type: none"> • Notification of hazardous substances in the classification and labelling inventory • Chemical Safety Assessment
Importer of articles	–	<ul style="list-style-type: none"> • Notification of the SVHC* • Sharing information about SVHC* • Compliance with the restrictions • Information archiving
Downstream users	<ul style="list-style-type: none"> • Check of eSDS** • Implementing risk management measures • Information archiving 	<ul style="list-style-type: none"> • Feedback to supplier about the use • Preparation of the SDS • Sharing information with customers
Traders	<ul style="list-style-type: none"> • Information archiving 	<ul style="list-style-type: none"> • Sharing information with customers (e.g. SDS) • Sharing information with suppliers (e.g. use, substance release)

REACH

Timeline & Transition Periods

REACH will be implemented gradually

- ⊕ Pre-registration is the prerequisite to benefit from the extended registration deadlines.
- ⊕ Late pre-registration for substances manufactured for the first time or imported substances is possible even now, but only for tonnage bands up to 100 t/a. For volumes > 100 t/a, registration is needed before placing on the market.
- ⊕ After June 1, 2017 a late pre-registration is no longer possible.

Transition periods for registration

Tonnage band	Transition period
Pre-registration	
• all substances ≥ 1 t/a	June 1 to December 1, 2008
Registration	
• Substances ≥ 1000 t/a • Substances dangerous for the environment ≥ 100 t/a • CMR* Substances ≥ 1 t/a	November 30, 2010
• Substances ≥ 100 to 1000 t/a	May 31, 2013
• Substances ≥ 10 to 100 t/a • Substances ≥ 1 to 10 t/a	May 31, 2018

*CMR – carcinogenic, mutagenic or toxic to reproduction

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Exemptions from REACH

Substances exempted from REACH

- + Substances contained in waste
- + Radioactive substances
- + Substances in transit (customs supervision)
- + Non-isolated intermediates

Substances considered as being already registered

- + NONS (Notification Of New Substances) = ELINCS substances (registered new substances as per Directive 67/548/EEC), provided that the next higher REACH tonnage threshold is not exceeded.

Substances exempted from the registration obligation

- + Substances manufactured and/or imported in volumes < 1 t/a
- + Active substances in plant protection and biocidal products
- + Substances regulated more strictly under other regulations, e.g. food additives, pharmaceuticals, cosmetic products
- + Polymers (for the time being), HOWEVER: monomers must be registered
- + Substances included in REACH Annex IV
Substances whose risks are largely known and small (natural substances such as water, certain sugars, noble gases, natural oils, etc.)
- + Substances covered by Annex V
Special reaction products, e.g.:
 - in aqueous ionic mixtures
 - by using antifoamer or chelating agents
 - by adjusting the pH-value
 - occurring upon end use (e.g. coating formation on substrates)

REACH

Special Regulations

PPORD

Product and Process Oriented R&D substances

Substances intended to be used for product and process orientated research and development can be exempted from the obligation of registration for a period of five years by submitting a PPORD notification to ECHA against a payment of a fee.

The following information must be provided in the PPORD notification dossier:

- ⊕ Identity of the manufacturer or importer
- ⊕ Identity of the substance
- ⊕ Classification of the substance, if any
- ⊕ Estimated quantity of the substance
- ⊕ List of customers, including their names and addresses

The exemption applies to the volume of the substance used in the framework of the research and development activities. Consequently, this volume may exceed 1 t/a.

REACH

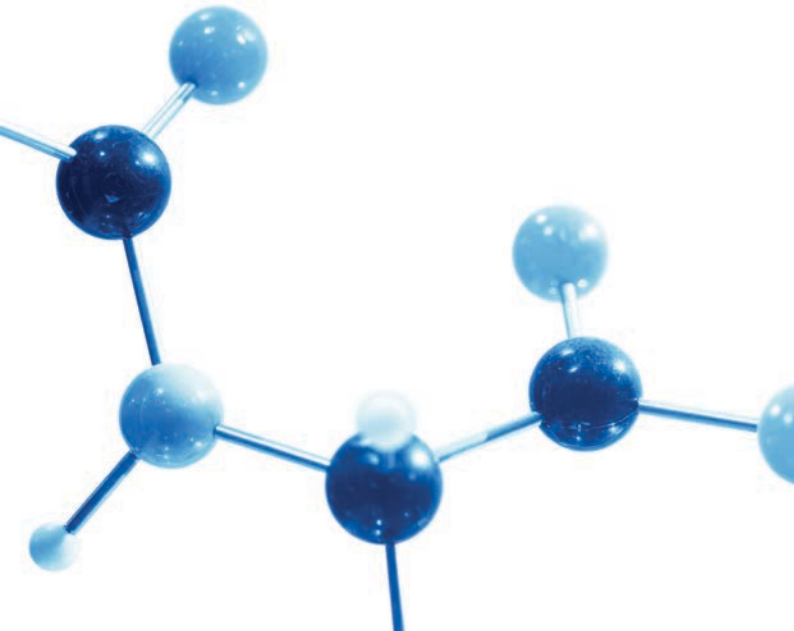
Specific Provisions

Intermediates

- ⊕ Intermediates according to Article 17 (on-site isolated intermediates)
- ⊕ Intermediates according to Article 18 (transported isolated intermediates)

These may be registered with reduced registration information if it is confirmed that they are used under strictly controlled conditions.

For intermediates pursuant to Art. 18: A written confirmation of the use under strictly controlled conditions (SCC confirmation) from all customers using the intermediate irrespective of the quantities supplied is required.



REACH

Authorisation of SVHC*

The REACH Regulation provides for an authorisation process for Substances of Very High Concern (SVHC*).

The objective is:

- ⊕ to properly control the risks arising from the substance.
- ⊕ a replacement by suitable alternative substance or technologies while at the same time ensuring the smooth functioning of the EU internal market. Alternatives must be economically and technically viable.

Substances of Very High Concern are

- ⊕ CMR (carcinogenic, mutagenic or toxic to reproduction) category 1 or 2 (as per GHS 1A or 1B)
- ⊕ PBT** (persistent, bioaccumulative, toxic)
- ⊕ vPvB** (very persistent and very bioaccumulative) according to REACH Annex XIII
- ⊕ Endocrine disruptors (substances that interfere the hormone system)
- ⊕ Substances giving rise to an equivalent level of concern, e.g. strong respiratory sensitizers (at a later date possibly also strong skin sensitizers)

*SVHC – Substances of Very High Concern

**PBT, vPvB

persistent: substance with a high resistance to degradation

bioaccumulative: substance accumulates in an organism by intake from the surrounding medium or via nutrition

REACH

Authorisation of SVHC*

SVHC* are identified by the Member States and the ECHA (European Chemicals Agency) in a multi-step process.

Using the example of chromium trioxide:

	Registry of Intention Proposal as SVHC* and inclusion in the Registry of Intention
Dec 15, 2010	Candidate List Confirmation of the SVHC* status by inclusion in the Candidate List; publication on the ECHA homepage
Dec 20, 2011	Proposal for prioritisation of the substance
Apr 17, 2013	REACH Regulation Annex XIV Inclusion in the Authorisation List (Annex XIV) of the REACH Regulation; after expiry of the corresponding transitional periods an authorisation is required
Mar 21, 2016	Application Date Last date for submission of the authorisation dossier
Sep 21, 2017	Sunset Date no use, production, placing on the market without authorisation

- ⊕ No tonnage threshold exists for substances requiring an authorisation
- ⊕ A substance may be granted authorisation if it can be demonstrated that the risk during use can be properly controlled or if the socioeconomic benefit of its use can be evidenced and no alternative substances exist
- ⊕ Authorisations are limited in time

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Restrictions & Bans

The manufacture, marketing or use of a substance may be restricted or banned.

The process for restrictions was amended and included in the REACH Regulation under Annex XVII. It may be initiated by the Member States or the ECHA.

The aim is to protect human health and environment from unacceptable risks posed by chemical substances.

- ⊕ Unlike an authorisation, restrictions do not necessarily refer to a SVHC.
- ⊕ Restrictions are independent from the manufactured and imported quantity of a substance.
- ⊕ A restriction may relate to the substance on its own, in a mixture or in an article. It also applies to imported substances, mixtures and articles.
- ⊕ Depending on the type of restriction, implementation may affect the manufacturers, importers or placers on the market of substances, mixtures and articles, and also the downstream users.
- ⊕ If the use of a substance has not been assessed as being safe, the restriction process may also lead to a complete ban of its use within the EU.

REACH

Restrictions & Bans

- ⊕ Substance-specific types of manufacture and use that are subject to restrictions are listed in Annex XVII of the REACH Regulation.
- ⊕ Annex XVII came into force with Commission Regulation No. 552/2009 amending the REACH Regulation effective from 27 June 2009.
- ⊕ The restrictions mentioned formerly in Council Directive 76/769/EEC (ban directive) were included largely unchanged in Annex XVII.
- ⊕ With the coming into force of Annex XVII, the corresponding substance restrictions of the German Chemicals Prohibition Ordinance (ChemVerbotsV) became void.

With the entering into force of this regulation the clauses contained in its Annex XVII have superseded the below listed directives:

- Azocolourants Directive 2002/61/EC
 - "Blue Colourant" Directive 2003/3/EC
 - Cadmium Directive 91/338/EEC
 - Nickel Directive 94/27/EC
 - Phthalates Directive 2005/84/EC
- ⊕ Typical hazardous substances subject to the restrictions in articles are for example lead, azocolourants, DMF, phthalates, nickel, etc. These in particular are contained in consumer products and mixtures.

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Important Definitions

Phase-in substance (corresponds to the former term 'existing substance')

+ EINECS substances

(European Inventory of Existing Commercial Chemical Substances); Inventory of substances that were reported to be on the market before 1981 [existing substances].

+ No Longer Polymers

A substance classified as a polymer until the early 1990s but no longer considered so as a result of the 7th Amendment of the Directive passed at that time.

Note:

Only phase-in substances can be pre-registered and/or are eligible for late pre-registration.

NONS (Notification Of New Substances) – already notified substances

+ ELINCS substances

(European List of Notified Chemical Substances)

- > Registration pursuant to Directive 67/548/EEC is deemed to be a registration pursuant to REACH (Art. 24); as such a REACH registration number has already been assigned by the ECHA in December 2008.

Non phase-in substance (corresponds to the former term 'new substance')

- + Substances placed on the market after 1981
- + Substances without EINECS, NLP or ELINCS number
- + e.g. R&D products

Note:

Volumes ≥ 1 tonne per year may only be manufactured and placed on the market with a prior REACH registration.

Chemical Regulatory Compliance



Note:

The information provided in this brochure shall serve as an overview of the main aspects to be considered under REACH. The information was carefully compiled by Chemetall GmbH based on the current REACH regulation (status: April 2014) and on our company's current state of knowledge.

The user/customer continues to be responsible for checking and complying with all applicable statutory provisions and shall be solely responsible for ensuring that the substances he uses are used and in particular registered in line with the provisions of the REACH Regulation.

Chemetall GmbH does NOT assume any guarantee or liability for the information contained in this document, and in particular not for its completeness and accuracy.

The information contained in this document does not relieve the user/customer from his obligations under REACH.



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Chemical Regulatory Compliance

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