



REACH Restriction Regime The Basics

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Please visit the REACH section of the Cefic website for more information: <http://cefic.org/en/reach-for-industries-documents-and-tools.html>

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The aim of this guide

REACH¹ aims at “ensuring a high level of protection of human health and the environment as well as the free movement of substances, on their own, in mixtures and in articles, while enhancing competitiveness and innovation. REACH should also promote the development of alternative methods for the assessment of hazards of substances” (Recital (1)).

A main objective is to establish a coherent registration system designed to identify relevant risk management measures based on hazard and risk information on new and existing chemical substances manufactured in or imported into the EU.

In parallel, the REACH Regulation provides the continuity of the existing restriction system, with some new features, and the introduction of an authorisation process. So, both are regulatory instruments for authorities to manage the risks of hazardous chemicals under REACH. They aim to ensure a Community wide control of substances.

The Restriction provision is triggered by Member States or the European Commission and can be applied to almost any chemical. The authorities have to demonstrate that manufacture, placing on the market and/or uses of a substance on its own or in a preparation or in an Article, are posing unacceptable risks which need to be addressed on a Community-wide basis. The Commission, via a comitology procedure with scrutiny, allowing the Member States (via the Council) and the EU parliament to be involved, takes the final decision to add new or to amend the existing entries of Annex XVII (listing the restrictions). Companies have to comply with the conditions of restrictions.

The comparison of the Authorisation and the Restriction provisions will be presented in the next guide.

The present Introduction to the REACH Restriction regime focuses on the Restriction process by presenting the main documents, the actors and actions to be performed and the timeline of the process.

1. Restriction – Title VIII of REACH legislation

1.1. Restriction principles in REACH

Manufacturing, placing on the market (including import) or use of substances may be subject to restriction under REACH legislation. This process is considered as a safety net in REACH, to manage risks that are not sufficiently addressed by other processes.

A restriction can take the form of a total ban of the substance but this is rare in practice. In most cases, the restriction process is used to ban or put conditions on specific uses or use categories. On the contrary, all uses of a restricted substance which are not specifically restricted under Annex XVII are allowed under REACH (except if also listed on Annex XIV or subject to other legislation) within the limits of the Exposure Scenarios of manufacturers'/importers' registration.

Practically, the decision for the restriction on a substance must be based on the two following cumulative elements:

- a) an unacceptable risk to human health or environment, and
- b) the risk needs to be addressed at a community wide basis level.

A list containing all restricted substances, specifying which particular uses are restricted, is set up under the Annex XVII of REACH.

The existing restrictions set out in the Marketing and Use Directive (76/769/EEC) were carried over to REACH. Directive 76/769/EEC was repealed on 1 June 2009. One must pay attention to Article 67(3) referring to more severe national restrictions¹, to be maintained until 1 June 2013, provided they have been notified. The Commission has compiled and published an inventory of these restrictions by 1 June 2009.

1.2. Substances: included and exempted

The Restriction title of REACH has a broad scope.

Any substance on its own, in a preparation or in an article may be subject, where justified, to restrictions. Moreover, restrictions of a substance can apply to manufacturing, placing on the market (including importing) and/or all uses or to specific uses. And finally, as for authorisation, there is no tonnage threshold for a substance subject to restriction provisions.

There are, however, a few exemptions from the restriction regime in the REACH Regulation.

They include manufacturing, placing on the market or use of a substance

- in scientific research and development,
- for on-site isolated and non-isolated intermediates,
- in PPORD, if this as well as the exempted quantities are specified in the Annex XVII,
- for the use of substances in cosmetic products, with regard to risks to human health within the scope of the Cosmetics Directive.

In addition, it should be noted that when a substance is listed in the Persistent Organic Pollutants Regulation (POPs Regulation 850/2004²), an existing entry in the Annex XVII should be deleted to the extent that it is less restrictive than the POPs Regulation.

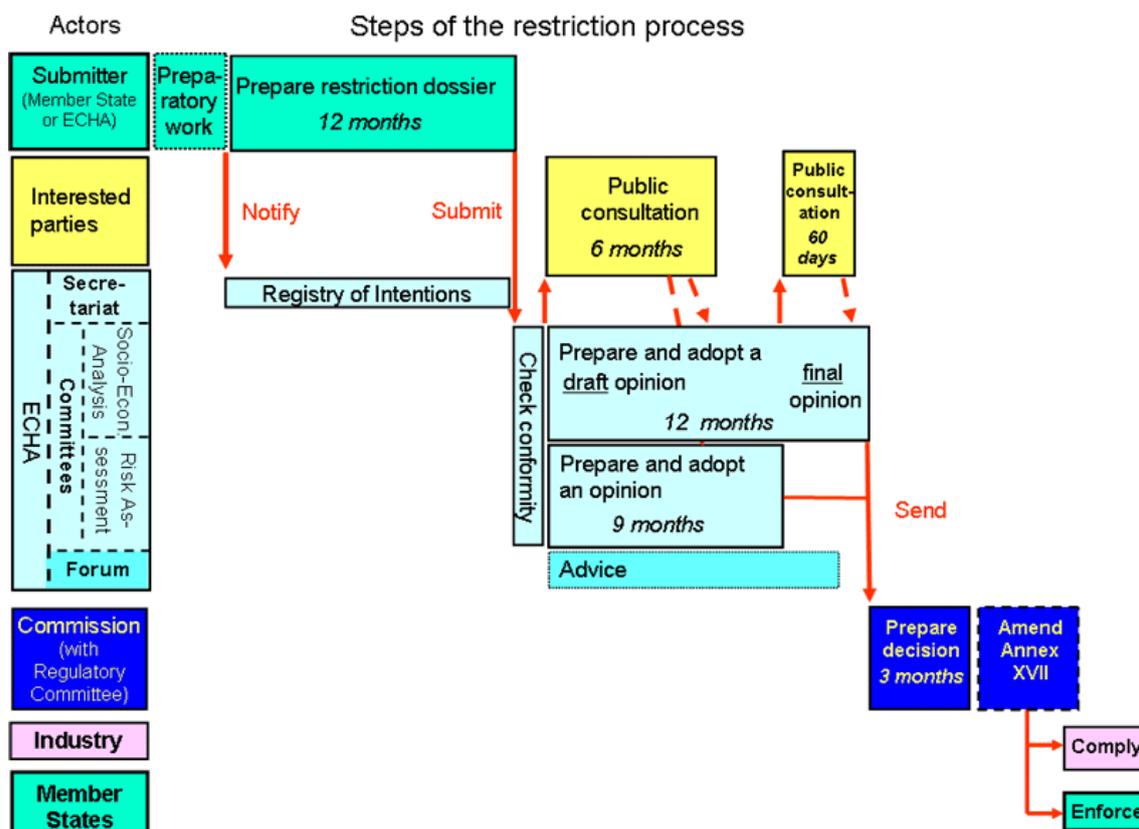
When a substance is solely manufactured for export, the restriction does not apply unless manufacturing is specifically prohibited.

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:130:0003:0004:en:PDF>

² http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/l21279_en.htm

1.3. Actors and their actions within the restriction process

(source: http://echa.europa.eu/reach/restriction/restriction_process_en.asp)



1.3.1. ECHA: EUROPEAN CHEMICALS AGENCY

- Manages a list of substances (the Registry of Intentions) for which an Annex XV dossier is planned; develops and communicates an updated planning for submission dates of the Annex XV dossiers
- Prepares an Annex XV dossier for Restriction proposal on request by the Commission, containing:
 - Information on hazard and risk
 - Information on alternatives
 - Justification for action at EU level
 - Why a restriction is the most appropriate EU-wide measure
 - Socio-economic impacts of the proposed restriction(s)
- Manages the meeting of Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC). The committees check whether the dossier conforms to the requirements of Annex XV.
- RAC and SEAC to formulate opinions on the suggested restriction(s), based on the information given in Annex XV restriction reports, and on the additional information received during public consultation.
 - The opinion from the RAC focuses on “whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier” (REACH Art. 70).
 - The opinion from the SEAC is based on its consideration of the relevant parts of the dossier and on the socio-economic impact (REACH Art. 71). Publishes without delay all Annex XV dossiers including the suggested restrictions, and publishes the draft opinion of the SEAC and the final opinions of RAC and SEAC
- Submits to the Commission the opinions of RAC and SEAC

1.3.2. THE EUROPEAN COMMISSION ('THE COMMISSION')

- May request ECHA to prepare an Annex XV dossier for Restriction proposal
- Can follow a fast track procedure (Article 68 (2) of REACH) to make amendments to Annex XVII on restriction for consumer use of a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1A or 1B (CLP criteria).
- Takes a decision on whether an existing restriction should be re-examined on the basis of evidence presented by the Member State of the Agency
- Makes the final adoption of the restriction (via comitology procedure).

1.3.3. MEMBER STATES COMPETENT AUTHORITIES (MSCA)

- Is asked to notify their intention to ECHA (via the Registry of Intentions) to prepare an Annex XV dossier to trigger a restriction process
- Prepare an Annex XV dossier to start the restrictions process and submits it within twelve months after the publication in the Registry of Intentions
- Notifies the Commission of any existing restriction more stringent than those listed in Annex XVII that is applicable in the Member State

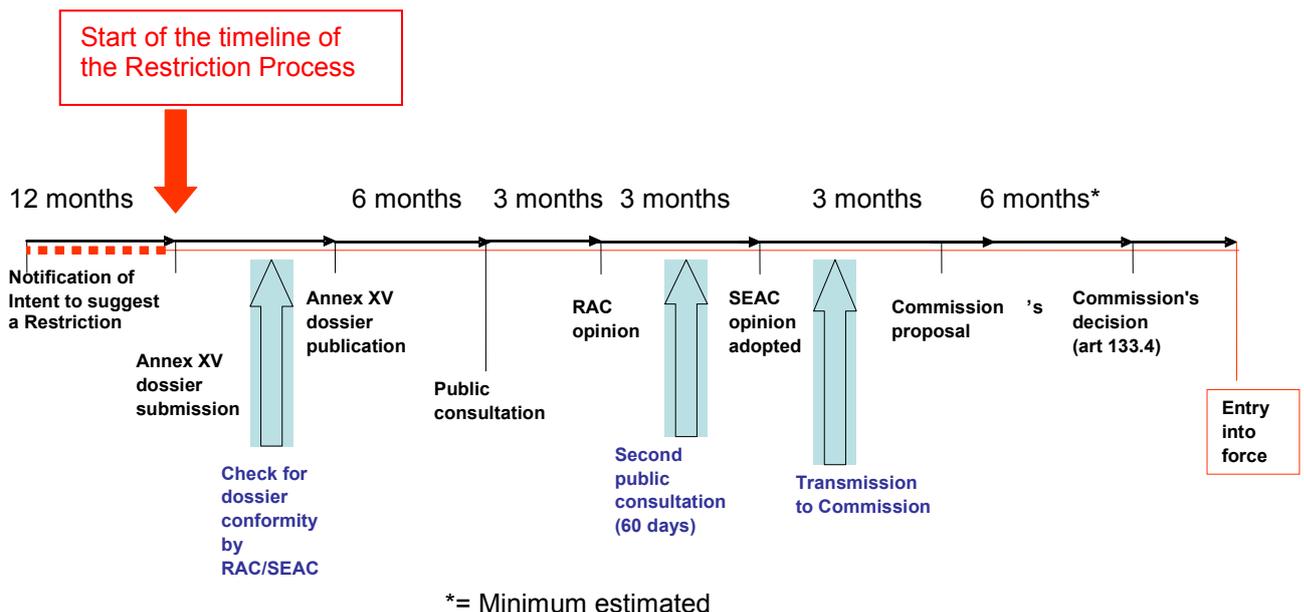
1.3.4. FORUM OF ENFORCEMENT

- May give advice on enforceability of the proposed restrictions

1.3.5. INTERESTED PARTIES: INDUSTRY, MEMBER STATE AUTHORITIES, NGOs, GENERAL PUBLIC

- Make comments on Annex XV dossiers, including submission of a socio-economic analysis or information contributing to such an analysis
- Make comments on the draft opinion of the SEAC

1.4. Main stages of restriction process



1.4.1. ANNEX XV RESTRICTION DOSSIER

The restriction process can be triggered either by a Member State or, on request of the Commission, by the Agency.

To start the process, a Member State should notify its intention to the Agency. The Member State then has 12 months to submit the Annex XV Restriction dossier to ECHA.

ECHA manages a list of substances – the so called Registry of Intentions (RoI), for which a suggested restriction may be expected and for which an Annex XV Restriction dossier is planned or being prepared.

The dossier must be in conformity with the requirements described in Section 3 of Annex XV of REACH. It will include identification of risks, evidence that Risk Management Measures RMM are not sufficient, as well as available information on alternatives.

Moreover, the Member State is requested to justify that the restriction process is the most appropriate Community wide measure (criteria to be checked: effectiveness, practicability for management, implementation and enforcement, and monitor ability of the results should be demonstrated).

1.4.2. CHECK OF CONFORMITY

It is one of the duties of the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC) to make a conformity check to the Annex XV dossier. If the latter does not conform, ECHA or the Member State having developed the Annex XV dossier must bring it into conformity.

1.4.3. PUBLIC CONSULTATION

ECHA will publish all the conforming Annex XV Restriction dossiers for Restriction proposal received on its website.

All interested parties have the possibility to submit comments, an SEA analysis or any information to contribute to an SEA on the suggested restrictions. At this stage, the timeline for public consultation is 6 months on both the RAC draft opinion and the SEAC draft opinion. The updated draft SEAC opinion, undergo a second public consultation during 60 days.

1.4.4. RAC AND SEAC OPINIONS³

The final opinion of the RAC shall be published within 9 months after dossier publication. The SEAC one shall be published within 12 months after dossier publication.

Both SEAC and RAC opinions must take into account the comments made by the interested parties. When the opinion of RAC differs significantly from the suggested restrictions, ECHA can extend the deadline for the SEAC adoption of its final opinion no more than 90 days.

The Commission receives both RAC and SEAC opinions. If no opinion has been adopted by either of the Committees within the deadlines, the Agency must state the reasons for this. .

1.4.5. DECISION

Within three months of the receipt of the opinions, the Commission will prepare a draft amendment of Annex XVII.

The Commission has to justify its decision either when the amendment is different from the originally suggested restriction or when the Agency opinions are not taken into account. The Commission decision is adopted under the comitology procedure with scrutiny (i.e. both the Member States and the European Parliament are involved).

³ See Section 1.3 of the present document

2. Glossary, acronyms and useful web sites

Annex XIII

Criteria for the identification of PBTs and vPvBs

Annex XV dossier

A dossier produced in compliance with Annex XV. This consists of two parts, a technical dossier and the Annex XV report. There are 3 different type of Annex XV: for substance of VHC, for restriction proposal, and for harmonised classification and labelling proposal

Annex XVII

Restrictions on the manufacturing, placing on the market and use of certain dangerous substances

Article

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;

CLP

Classification, Labelling and Packaging

Competent authority

The authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;

Downstream user

Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user

ECHA – the Agency

Stands for **E**uropean **C**hemicals **A**gency, and has been established by REACH

Importer

Any natural or legal person established within the Community who is responsible for import.

Intermediate

Means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis"):

- (a) Non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;
- (b) On-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;
- (c) Transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.

Manufacturer

Any natural or legal person established within the Community who manufactures a substance within the Community

MSCA

Member State Competent Authority (see above “Competent Authority”).

POP

Persistent Organic Pollutant

PPORD

Product and process orientated research and development

Any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance

Preparation

Means a mixture or solution composed of two or more substances;

RAC

Risk Assessment Committee (or Committee for Risk Assessment)

http://echa.europa.eu/about/organisation/committees/riskassessment_en.asp

RMM

Risk Management Measure

RoI

Registry of Intention, available at ECHA website:

http://echa.europa.eu/chem_data/reg_int_tables/reg_int_en.asp?substance_type=Restriction&substance_state=current

SEA(C)

Socio-Economic Analysis (Committee)

http://echa.europa.eu/about/organisation/committees/socioeconomic_en.asp

Substance

Means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including 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

Use

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 utilization.

Web sites:

European Commission web site on Restriction:

http://ec.europa.eu/enterprise/sectors/chemicals/reach/restrictions/index_en.htm

ECHA web site on Restriction (with Guidance):

http://echa.europa.eu/reach/restriction_en.asp

ⁱ REACH: Regulation (EC) No 1907/2006 of the European Parliament and of the council of 18 Dec 2006 concerning Registration, Evaluation, Authorisation and Restrictions of Chemicals – Entered into Force on 1 June 2007.