



Standard Guide for European Union's Registration, Evaluation, and Authorization of Chemicals (REACH) Supply Chain Information Exchange¹

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1. Scope

1.1 This guide will assist companies that manufacture, buy, or sell, or both, substances, preparations, and articles to ensure that supply chains comply with the European Union's Registration, Evaluation, and Authorization of Chemicals (REACH) regulation. This is accomplished by identifying the specific information elements that must be specified, requested and exchanged in communication between actors in the supply chain.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

F2576 Terminology Relating to Declarable Substances in Materials

2.2 European Union Directives and Regulations:³

67/548/EEC Directive on Dangerous Substances

1999/45/EC Dangerous Preparations Directive

2006/121/EC Amending Directive 67/548/EEC

Regulation (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

2.3 REACH Guidance Standards:³

Annex 1: Automotive Industry Guidance

Annex 2: Aerospace Industry Guidance

Annex 3: European Engineering Industries (Orgalime) Guidance

Annex 4: Fragrance Industry Guidance

Annex 5: Semiconductor Industry Guidance

Annex 14: List of Substances Subject to Authorisation

REACH Title II Registration of Substances

REACH Title IV Information in the Supply Chain

2.4 REACH Implementation Project (RIP) Guidance Documents:³

Annex 6: RIP 3.4 Guidance on Data Sharing

Annex 7: RIP 3.5 Guidance for Downstream Users

Annex 8: RIP 3.8 Guidance on Requirements for Articles

Annex 9: EU Commission publication: REACH-in-Brief

Annex 17: List of Restricted Substances and Conditions of Restriction

3. Terminology

3.1 Definitions:

3.1.1 Terms and definitions related to declarable substances in materials may be found in Terminology **F2576**.

3.1.2 Terms and definitions in this guide not found in Terminology **F2576** may be found in a common dictionary or other reference documents such as the *ASTM Dictionary of Engineering Science & Technology*.⁴

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *actors in the supply chain, n*—all manufacturers, importers, or downstream users in a supply chain.

3.2.2 *article, n*—object that during production is given a special shape, surface, or design that determines its function to a greater degree than does its chemical composition.

3.2.3 *candidate list, n*—list of substances that are subject to appear on Annex 14 (authorization) list of substances and will someday require an authorization application for use.

3.2.4 *chemical safety report (CSR), n*—findings of a chemical safety assessment that shall consider the hazards and risks of a substances that is manufactured or imported in quantities greater than 10 metric tonnes per year.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from ec.europa.eu or www.echa.eu.

⁴ Available from ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428-2959, ASTM Stock Number: DEF00.

3.2.5 *community, n*—27-member states of the European Union.

3.2.6 *downstream user, n*—any natural or legal person established within the European 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 or her industrial or professional activities.

3.2.6.1 *Discussion*—A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to REACH Article 2 (7)(c) in Directive 2006/121/EC shall be regarded as a downstream user.

3.2.7 *exposure scenario, n*—set of conditions, including operational conditions and risk management measures, that describes how the substance is manufactured or used during its lifecycle and how the manufacturer or importer controls, or recommends downstream users to control exposures of humans and the environment.

3.2.7.1 *Discussion*—These exposure scenarios may cover one specific process or use or several process or uses as appropriate.

3.2.8 *import, v*—physical introduction into the customs territory of the community.

3.2.9 *importer, n*—any natural or legal person established within the community who is responsible for the import.

3.2.10 *intermediate, n*—substance that is manufactured for and consumed in or used for chemical processing to be transformed into another substance.

3.2.11 *manufacturer, n*—any natural or legal person established within the community who manufactures a substance within the community.

3.2.12 *manufacturing, v*—production or extraction of substances in the natural state.

3.2.13 *mixture, n*—combination or solution of two or more substances that do not react.

3.2.14 *only representative, n*—third party who may serve as importer of record on behalf of natural or legal persons established outside of the community (see *preparation*).

3.2.15 *per year, n*—per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years; quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years.

3.2.16 *phase-in substance, n*—substance that meets at least one of the following criteria: (1) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) and (2) it is manufactured in the community, or in the countries acceding to the European Union on January 1995 or 1 May 2004, but not placed on the market by the manufacturer or importer at least once in the 15 years before the entry into force of the REACH regulation, provided the manufacturer or importer has documentary evidence of this.

3.2.17 *placing on the market, v*—supplying or making available, whether in return for payment or free of charge, to a third party.

3.2.17.1 *Discussion*—Import shall be deemed to be placing on the market.

3.2.18 *preparation, n*—mixture or solution composed of two or more substances; preparations can contain several substances; they are not the same as multiconstituent substances; the difference between preparation and multiconstituent substance is that a preparation is gained by blending of two or more substances without any chemical reaction occurring, whereas a multiconstituent substance is the result of a chemical reaction; examples of preparations include paints, varnishes, and inks.

3.2.18.1 *Discussion*—REACH obligations apply individually to each of those substances depending on whether within the scope of REACH. Within the GHS, a preparation is known as a “mixture.”

3.2.19 *producer of an article, n*—any natural or legal person who makes or assembles an article in the community.

3.2.20 *restriction, n*—any condition for a prohibition of the manufacture, use, or placing on the market.

3.2.21 *safety data sheet, n*—hazard and risk information required by community law to be passed on from supplier to customer for dangerous substances and dangerous substances in mixtures above a certain concentration.

3.2.22 *substance, n*—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 that may be separated without affecting the stability of the substance or changing its composition.

3.2.23 *use, n*—any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transferring from one container to another, mixing, production of an article, or any other utilization.

3.3 Acronyms:

3.3.1 *CAS*—Chemical Abstracts Service

3.3.2 *ECHA*—European Chemicals Agency

3.3.3 *EINECS*—European Inventory of Existing Commercial Chemical Substances

3.3.4 *ELINCS*—European List of Notified Chemical Substances

3.3.5 *ELV*—End-of-Life Vehicles Directive

3.3.6 *EPA*—Environmental Protection Agency

3.3.7 *EU*—European Union

3.3.8 *GHS*—Globally Harmonized System of Classification and Labeling of Chemicals

3.3.9 *IMDS*—International Materials Data System

3.3.10 *REACH*—Registration, Evaluation, and Authorization of Chemicals

3.3.11 *RIP*—REACH Implementation Project—technical guidance documents published by EU RoHS Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment

3.3.12 *SIEF*—Substance Information Exchange Forum

3.3.13 *SVHC*—substances of very high concern

4. Summary of Guide

NOTE 1—This guide does not provide assistance on the legal requirements of REACH such as registration, evaluation, authorization, and restrictions. For a basic introduction to REACH and guidance for assessing your legal obligations under the regulation, please consult the documentation in Annex 9. For actual text of REACH, see: <http://>

reach.jrc.it/legislation_en.htm.

4.1 What is REACH?

4.1.1 **Regulation (EC) No. 1907/2006** of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). REACH replaces 40 existing legal acts and creates a single system for all chemical substances.

4.1.1.1 **Registration**—Registration requires producers and importers to obtain and submit relevant information on chemical substances produced in or imported to the EU market in quantities greater than 1 tonne per year.

4.1.1.2 **Evaluation**—Evaluation allows the regulatory authorities to decide on proposals for further testing and assess whether dossier information provided by industry complies with the requirements.

4.1.1.3 **Authorization**—Authorization may be required for SVHC (carcinogens; mutagens; reproductive toxins; substances toxic, persistent, and bioaccumulative; substances very persistent and very bioaccumulative; and substances giving rise to equivalent concern).

4.1.1.4 **Restriction**—The safety net of the system; any substance on its own, in a preparation or in an article may be subject to community-wide restrictions if its use poses unacceptable risks to human health or the environment.

4.1.2 Who Are the Actors in the Supply Chain?

4.1.2.1 Manufacturers and importers of substances and preparations are obliged to register substances they produce or import in quantities greater than 1 tonne per year. Importers and producers of articles are required to register substances imported or produced in amounts greater than 1 tonne per year that are intentionally released from the articles. Failure to register means that the substance cannot be manufactured, imported, or used in the EU market.

4.1.2.2 Downstream users of chemicals shall apply the risk management measures for dangerous substances identified on the supplier safety data sheets. They shall also ensure that any substances they use in quantities greater than 1 tonne per year, which are manufactured or imported in quantities greater than 10 tonnes per year, are supported by a chemical safety report (CSR).

4.1.2.3 Other actors in the supply chain include distributors, retailers, and storage providers, all of whom are not classified as downstream users.

4.1.2.4 Consumers are not considered actors in the supply chain, but have certain rights under REACH, including the right to receive information about the presence of SVHC's in quantities >0.1 % in articles.

4.2 Why Must REACH Information be Exchanged in Supply Chains?

4.2.1 **REACH Title IV**, Information in the Supply Chain, specifically Articles 31 through 34, legally requires manufacturers and their supply chains to exchange certain information. Information exchange both upstream and downstream in the supply chain is also the only way to acquire the information necessary to meet many other requirements of the REACH regulation. Therefore, supply chain communication is both a legal requirement and a necessary activity ancillary to complying with other aspects of REACH.

4.2.1.1 Because of the often complex nature of global supply chains, a legal requirement falling upon an EU-based importer, manufacturer, or downstream user will often have both a downstream and upstream ripple effect that will extend beyond the EU and will require support from the entire supply chain. Therefore, companies based outside the EU, for example, in the United States, with no direct business in Europe, will be drawn into the supply chain information exchange process to support their customers' requirements to provide information. All global companies may find it helpful to map out their location within supply chains to determine if any substances, preparations, or articles are imported into, exported out of, or manufactured in the EU and, hence, at risk of being impacted by REACH.

4.2.2 **Fig. 1** illustrates how REACH has the potential to impact all but the most isolated supply chains. Your company need not sell product in, or buy products from, the EU to be impacted, either directly or indirectly.

4.2.3 **Fig. 2** depicts an example of "selling into a supply chain that imports into the EU." Note that there is no direct sale to an EU importer in this scenario, but that you sell to Customer A, who sells to the EU-based Customer D. Customer D's need for data will be cascaded down to you via the intermediary, Customer A. For example, Customer D may ask Customer A to identify the substance content of a preparation or article. Customer A may turn to you as having knowledge of this composition. Note that it is conceivable that you will need to turn to your own supplier(s) to obtain the chemical composition. Additionally, Customer D may need to describe their application to Customer A, who then may desire to provide related handling or toxicity information or both if available to help Customer D's registration process.

4.2.4 Similarly, **Fig. 3** depicts an example of "purchasing out of a supply chain that exports from the EU." In this scenario, you buy from U.S.-based Supplier D, who formulates a preparation or article from Substances A and B and Preparation C. The substances in Preparation C are provided from an EU-based exporter. Any of a number of potential issues could result in an impact, including the following scenarios:

4.2.4.1 Should any of the substances in Preparation C be incorporated into the EU's candidate for authorization list, Preparation C (and hence Preparation/Article D) may no longer be available, or at least be subject to substantially increased costs.

4.2.4.2 The cost of registration may exceed Supplier C's desire to continue producing Preparation C.

4.2.4.3 Supplier C may choose to substitute substances/preparations used in Preparation C and may or may not tell Supplier D, who may or may not be able to pass this information along.

4.2.5 To avert surprise supply changes or price increases or both, proactively mapping out the supply chain and making a determination about the reliability of Preparation/Article D's supply is highly recommended. Note that this effort may be complicated by the fact that you have no direct contractual relationship with Supplier C and may therefore need to coordinate the investigation via Supplier D to address confidentiality and other concerns adequately.