

REACH OVERVIEW

Understanding the New European Regulation on Chemicals

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Introduction

The European Union's (EU) REACH regulation, administered by the European Chemical Agency (ECHA), impacts businesses that export products directly to the EU or are part of a supply chain that exports products to the EU. This Workbook is intended to provide practical assistance to manufacturers that export directly to the EU or are part of a supply chain that supplies the EU in determining their Obligations under REACH. It does not, however, outline a facility's specific REACH requirements since REACH is dependent on a variety of issues including the type of product (substance, preparations, article), role of the company (exporter, importer, manufacturer, user, etc.), as well as, product use and life cycle. For details regarding REACH and its obligations please refer to the various guidance documents available on the REACH website <http://reach.jrc.it/> as well as the list of other reference sources provided at the end of this document. In addition, citations within REACH and references to REACH guidance documents are provided for clarification. Also flow charts are provided to assist users in identifying their obligations and a list of definitions are also contained within the document.



ECHA also provides a very useful tool to help industry determine its obligations under REACH and find the appropriate guidance on how to fulfill these obligations. The Navigator website is located at http://reach.jrc.it/navigator_en.htm.

Also if you wish to attend the CBIA's sponsored REACH Compliance Assistance event, please complete REACH Compliance Assistance Form included in Attachment #1 prior to attending the event.

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WHAT IS REACH?




Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH), impacts all manufactures that export products directly in to the EU or are part of a supply chain that exports to the EU. In summary, REACH addresses the registration and safe use of chemicals and requires that *Substances, Preparations* and *Articles with Intended Releases* that are imported to the EU be properly registered. In addition, *articles* (i.e. finished products) need to be evaluated and are potentially subject to *notification* or *communication* requirements. Also, certain substances will be subject to *Restrictions* and *Authorizations*. The aim of REACH is to improve the protection of human health and the environment by placing greater responsibility on industry to identify and manage the risks from chemicals and to provide safety information on the substances.

For REACH purposes, the EU includes Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom.

*Iceland, Lichtenstein and Norway, which are part of the **European Economic Area** are planning to transpose REACH to their national legislation. When this has taken place the same requirements apply to exports to these countries.*

WHO DOES REACH IMPACT?

If you or your customers produce or export any of the following to the **European Union** (EU) Member States, you may be subject to REACH:

- **Substance** - means a chemical element and its compounds. *The term substance includes both substances obtained by a chemical manufacturing process (for example formaldehyde or methanol) and substances in their natural state. The term substance also includes its additives and impurities where these are part of its manufacturing process, but excludes any solvent which can be separated without affecting the stability of the substance or changing its composition.* 
- **Preparation** - means a mixture or solution composed of two or more substances. *Typical examples of preparations include paints, varnishes, and inks. Preparations can contain several substances and are not the same as multi-constituents substances. The difference between the two is that a preparation is gained by the blending of two or more substances without any chemical reaction occurring, whereas a multi-constituent substance is the result of a chemical reaction.* 
- **Article** - any object that has been given a specific shape, surface or design which determines its function to a greater degree than does its chemical composition (e.g. manufactured goods such as textiles, electronic chips, furniture, books, toys, kitchen equipment). 

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However the following substances are exempt from REACH:

- (a) Radioactive substances within the scope of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation;
- (b) Substances, on their own, in a preparation or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
- (c) Non-isolated intermediates;
- (d) The carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air.

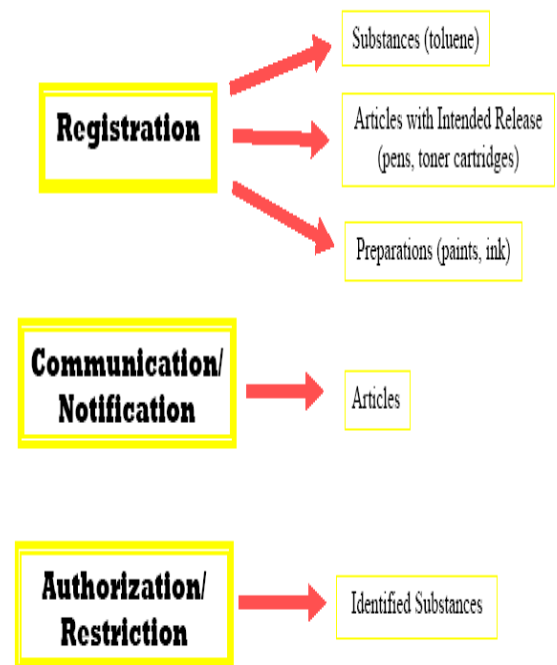
WHAT ARE THE REACH REQUIREMENTS?

REACH has very complex requirements that are dependent on the type of material (substance, preparation or article) being produced in or exported to the EU, role of the company (Manufacturer, Importer or a Downstream User), use of the material and its life-cycle. In particular, if you **export substances (i.e. toluene, aluminum, etc), preparations (inks, coatings, windshield washer fluid), or articles containing a substance intended for release** (the substance is intended to be released under normal or reasonably foreseeable conditions of use) to the EU, you have to register the substances if you export greater than one tonne per calendar year. (See REACH – Guidance on Registration for details).

In addition, if the **article contains above 0.1% (w/w) of certain Substances of High Concern (SVHC)**, you may be subject to Notification or

Communication requirements depend on the total amount of SVHC exported to the EU and the potential for exposure to humans and the environment (see REACH – Guidance on Requirements for Substances in Articles). ECHA will publish a list of SVHCs on its website following an extensive review process. As of October 2008, ECHA has issued a list of 15 SVHCs of the expected 1300 SVHCs which will include:

- Carcinogenic category 1 or 2
- Mutagenic category 1 or 2



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- Toxic for reproduction category 1 or 2
- Persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances or substances giving rise to an equivalent level of concern.

The main components of REACH are discussed below and flowcharts are provided to assist in determining one's REACH requirements. In addition a chart outlining important dates is provided. Keep in mind that Substances are subject to Registration, Restrictions and Authorizations while Articles are subject to Notifications and Communications.

Registration (Title II) – substances and preparations are subject to Registration. In addition, substances incorporated in articles which are intended for release (i.e. chemicals used as fragrances, ink in a pen, toner in a cartridge, etc.) have to be registered if they are present in the article in quantities over 1 tonne per year, and are “intended to be released during normal or foreseeable conditions of use” ([article 6.1](#)). It is important note that REACH exempts certain substances that are adequately regulated under other legislation from registration, including:



- Medicinal products for human or veterinary use within the scope of Regulation (EEC) No 2309/93, Directive 2001/82/EC of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.
- Food additive in foodstuffs within the scope of Council Directive 89/107/EEC.
- Flavoring in foodstuffs within the scope of Commission Decision 1999/217/EC.
- Additive in feeding stuffs within the scope of Council Directive 70/524/EEC.
- Animal nutrition within the scope of Council Directive 82/471/EEC.”
- Registered substances that are exported (out of the EU) by an actor in the same supply chain as the registrant and re-imported by an actor in the same supply chain do not have to be re-registered.
- Substances included in Annex IV and V of REACH
- Recycled or recovered materials already covered by REACH
- Polymers (however monomers and additives are normally subject to registration).
- Re-imported substances
- Substances for use of the product and process orientated research and Development (PPORD)

In addition, the following substances are regarded as registered under REACH:

- Active substances in biocides
- Active substances in plant protection products

REACH differentiates between *Phase In* and *Non-Phase In* Substances. In particular, substances which, under certain conditions, were already being manufacturer or placed on the EU market before June 1, 2007 and were not notified according to Directive 67/548/EEC are considered Phase-In Substances (see Definitions for further details)

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are eligible to take advantage of the pre-registration process which allows extended registration periods based on tonnage. All substances that do not meet the criteria of a *Phase-In Substance* are considered *Non-Phase In Substances* and need to be registered before they can be placed on the EU market.

Pre-registration: Substances must be pre-registered between June 1, 2008 and November 30, 2008 in order to take advantage of the extended registration deadlines. As of January 2009, items not pre-registered cannot be marketed without a full registration. A single pre-registration deadline, irrespective of tonnage, is planned to permit joint submission of registrations by multiple registrants and data sharing. Pre-registration is recommended as pre-registered substances can continue to be marketed before completing the full registration and allows for the extended registration period outlined under the Registration section of this summary. To complete registration the following information needs to be submitted to ECHA via their website:

- The name of the substance
- The name of the contact person
- The envisaged deadline for the registration/ tonnage band

Based on the information submitted, ECHA will place the registrants into Substance Information Exchange Forums (SIEF) based on the substance pre-registered and its use. The purpose of the SIEF is to exchange information on the substance in question and thereby reduce the necessity of testing to collect the information to complete a registration. **You must utilize a European legal entity or Only Representative to complete the pre-registration and Registration.** A list of Only Representatives is available at http://reach.jrc.it/navigator_en.htm.

Registration - Any substance not pre-registered by November 30, 2008, must be fully registered prior to being marketed in the EU. For all pre-registered substances, the following registration deadlines apply.

Dec 1, 2010	Registration deadline for manufacturers/importers supplying a substance above 1,000 tonnes per year, or a CMR cat.1 or 2 substance (carcinogenic substances and substances that alter human DNA or damage human fertility) above 1 tonne per year, or an R50-53 substance above 100 tonnes per year.
June 1, 2013	Registration deadline for manufacturers/importers supplying a substance between 100 and 1,000 tonnes per year.
June 1, 2018	Registration deadline for manufacturers/importers supplying a substance between 1 and 100 tonnes per year.

Information required to complete a registration will be dependent on the tonnage range. All tonnage ranges will need to submit a **Technical Dossier** which contains information required to determine the properties of a substance. The higher the tonnage the more information on the intrinsic properties of the substances will be

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required. The information requirements are outlined in Annexes VI to XI of the REACH regulation. If a registrant manufactures or exports greater than 10 Tonnes per year into the EU then a **Chemical Safety Report** must be completed. The chemical safety report documents the chemical safety assessment which includes an analysis of hazards, and for substances classified as dangerous, an assessment of exposure (“exposure assessment”) and an assessment of risks for health and the environment (“risk characterization”). When the substance is classified as dangerous, the chemical safety report must identify appropriate risk management measures for all uses identified by the manufacturer or the importer and their downstream users. See ECHA’s Guidance for registration for details on registration.

Notifications and Communications – Articles that contain SVHCs above 0.1% will be subject to Notification or Communication depending on whether there is a potential for exposure to humans and/or the environment and the tonnage exported to the EU. SVHCs will include carcinogens and chemicals that are mutagenic and toxic to reproduction (CMRs); substances which are persistent, bioaccumulative and toxic (PBTs and vPvBs); endocrine disruptors and substances “which give rise to an equivalent level of concern” ([article 54](#)). It is estimated that 1,500 substances will be listed as SVHCs. If the substance is not intended to be released, for example dye in clothing, the substance will be subject to notification if it is a SVHC, is present above 1 ton and above the concentration of 0.1%. Substances are exempt from notification if the producer can exclude any exposure, during normal conditions of use including disposal (see Appendix 1 of Guidance on requirements for substances in articles– Definitions and Explanations)



Notification (Article 7) is required if:

- the article contains over 1 tonne of SVHCs;
- the article’s SVHC concentration exceeds 0.1%; and
- Exposure to humans and the environment cannot be eliminated.

Information to be notified (Article 7.4 REACH):

- The identity and contact details of the producer or importer as specified in section 1 of Annex VI REACH (except own use sites).
- The registration number, referred to in Article 20.1 REACH, if available.
- The identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI REACH.
- The classification of the substance as specified in sections 2.1 to 2.3.4 of Annex VI REACH.
- A brief description of the use of the substance in the article as specified in section 3.5 of Annex VI REACH and of the use(s) of the article.
- The tonnage range of the substance, such as 1-10 tonnes, 10-100 tonnes.

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Notification must be provided to ECHA and to downstream users by June 1, 2011 and within 6 months of the listing of any new SVHC.

Communication (Article 33) is required if:

- the article's SVHC concentration exceeds 0.1%; and
- Exposure to humans and the environment can be eliminated.

Article 33 of REACH further requires that the supplier of an article (see definition) communicates information available on substances present in the article to the article recipient in order to allow safe use of the article, including, as a minimum, **the name of that substance**. In addition, a communication must be forwarded to a consumer within 45 days of receipt of a request for information. REACH does not specify a format for communication only that the format chosen will ensure that the recipient can readily become aware of the information.

Restrictions (Title VIII and Annex XVII)– Any substance on its own, in a preparation, or in an article may be subject to restrictions EU-wide. Member States can make a proposal to the Agency to ban or restrict the marketing and use of a substance. Based on the opinion from the ECHA, the Commission will make the final decision on the restriction of a substance. The Restrictions stage of REACH is similar to the existing directive on restrictions on the marketing and use of certain dangerous substances and preparations (Directive 76/769/EEC). To determine if any substances used within a product are subject to Restrictions, the substances and uses listed in Annex XVII of REACH must be reviewed. An example restriction:



Mercury compounds: The placing on the market of batteries and accumulators, containing more than 0.0005 % of mercury by weight, including in those cases where these batteries and accumulators are incorporated into appliances shall be prohibited. Button cells and batteries composed of button cells with a mercury content of no more than 2 % by weight shall be exempted from this prohibition.

Authorizations (Title VII and Annex XIV) – ECHA will review and evaluate the list of SVHCs and prioritize the SVHCs based:

- PBT or vPvB properties; or
- Wide dispersive use; or
- High volumes.



ECHA will then evaluate the prioritized SVHCs. If it is determined that the SVHC poses significant threat to humans and the environment it will be placed on the Annex XIV and be subjected to Authorizations and the use of the substance will not be allowed unless the applicant can show that the risks associated with the uses of that substance are adequately controlled ([article 57.2](#)). If this is not the case, it must be shown that socio-economic benefits outweigh the risk to human health or the environment and that there

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are no suitable alternatives. All applications for authorization must be accompanied by an analysis of substitutes. Authorizations will be subject to a time-limited review determined on a case-by-case basis. If an Authorization is granted it will specify:

- Person to whom authorization granted
- Identity of substance
- Use and any required monitoring
- Conditions of use
- Time period of use

RECOMMENDED REACH ACTIONS

As you are aware, if you are a part of a supply chain exporting to the European Union (EU), you are affected by REACH. Your company's requirements are dependent on the type of products (substances vs. articles), amount of product, and their composition, as well as your position within the supply chain. Ultimately, your REACH compliance process must be integrated into your overall product compliance process and built into the fabric of your standard product development, supply chain, and risk management operations. It's important to not lose sight of these long term goals as your organization develops its immediate plan for REACH. Use the ten-step process below as a guide as you prepare your products, and organization.



1. Build a Multidisciplinary Team to Address REACH

Since REACH will impact all areas of your company, creating a cross-functioning team that includes representatives from engineering, manufacturing, procurement, legal, sales, and marketing should be considered. Representatives from these groups should be knowledgeable and ensure that company personnel are aware of REACH, its impacts, and understand the importance of completing Registrations/Notifications and responding to information requests.

2. Understand the Regulation, the Guidelines, and Your Unique Obligations

Your company must understand the REACH regulation and how it will impact your business. Are you covered by REACH exemptions? There are some product categories and some substances not covered by REACH. Have your customers developed unique candidate SVHC lists? Leverage the expertise of others, including legal experts. Learn from the leaders and your peers in your industry.

3. Complete REACH Training

Relevant personnel should be trained on the applicability and requirements of REACH so they can efficiently respond to REACH requests.

4. Inventory and Review Substances and Articles Exported to the EU

An inventory must be completed to identify at a minimum:

- Articles and quantities of substances and articles introduced into the EU;
- Composition of articles introduced into the EU;
- Customers and their use of the products;
- Available exposure data regarding substances/articles introduced into the EU;
- Suppliers of substance and articles to your company;
- What are your supplier's intentions?

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Based on the inventory, gaps in data, information collection methods, and organizational structure, a compliance strategy should be identified and prioritized. A significant component of collecting this data is to establish a communication channel with your suppliers and customers. Develop a plan to collect the following information:

Key Question	Related REACH Article	Source of Data	Data Readiness Assessment		
			Scope/Coverage	Status	Location(s)
Do you export any substances or preparations to the EU?	Article 2	Internal, Customers			
Do you export any substances intended to be released to the EU?	Article 7	Internal, Customers			
What is the physical amount of each of these substances per as-built product?	Article 7	Internal			
What substances have already been registered and for what uses?	Article 7	Suppliers, Customers, Internal			
What SVHCs are in my product?	Article 33	Suppliers, Internal			
What is the physical amount of each of these SVHCs per as-built product?	Article 33	Suppliers, Internal			
How are SVHCs used in my product and what are the exposure scenarios?	Article 33	Suppliers, Internal			
What are the SVHCs – both “candidate” and “official”?	Article 33	Authorities, Industry experts			
What are the SVHCs in the eyes of my customers?	Article 33	Customers			

In addition, use the REACH Navigator located at http://reach.jrc.it/navigator_en.htm to determine your obligations.

5. Review Applicability of Existing Data Bases

A review should be completed to determine if existing data bases are in place, can be expanded or should a new database system be created to collect and maintain the required information. For example, if the company does not maintain a material database that determines and lists the SVHC content of an articles and the total SVHCs introduced into the EU, then a database to collect and maintain such information should be considered.

6. Address Supply Chain Documentation Requests

Throughout the process your company will receive information requests from customers and suppliers. In addition, you will need to request information to fill data gaps. Generic responses/requests should be considered for the following:

- Downstream users requesting article content, registration, documentation, information, etc;
- Suppliers requesting information on your use of a substance and/or article;
- Registration and content information on products you obtain from suppliers; and
- Downstream uses of your product to evaluate exposure scenarios.

Also procedures should be established to respond to specific requests. The collected information will be used to address information gaps to determine compliance requirements, as well as, provide suppliers with relevant information so that substance uses are properly registered for use by your company.

7. Determine Product Content and Expose Evaluation

Based on the collected information, the use of a database should be considered to determine the product content and amount of SVHC introduced into the EU. In addition, a life cycle review of the products based on product use information collected from customers needs to be completed to evaluate potential releases and exposures. This information will be used to assist in the identification and evaluation of the exposure scenarios.

8. Identify Potential SVHC Subject to Restrictions and Authorizations

A list of potential substances subject to Restrictions and Authorizations (Carcinogens, etc) should be compared with article compositions to identify potentially impacted articles and any substances potentially subject to Restrictions or Authorizations.

9. Complete Applicable Pre-Registration, Registration, Notification and Communication Requirements

Based on the REACH requirements, collect and supply the company's EU representative or Representative Only with the required information to complete the required submittals. In addition, complete Communications where applicable.

10. Maintain Database of REACH Requirements

To assist marketing, sales, and technical personnel a REACH database should be established information on each substance and article requirements and relevant information so that information requests can be quickly addressed.

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Resources

<http://ecb.jrc.ec.europa.eu/esis>

ESIS (European Chemical **S**ubstances **I**nformation **S**ystem) is an IT System which provides information on chemicals.

http://echa.europa.eu/news/press_en.asp

The Press office of the European Chemicals Agency is available to answer questions from journalists, to provide replies to written questions from the general public, and to set up interviews with the Executive Director and other senior officials of the Agency.

<http://www.buyusa.gov/europeanunion/reach.html>

U.S. Mission to the European Union

http://reach.jrc.it/index_en.htm

This website assists industry and authorities to understand their obligations under REACH and provides guidance on how to fulfill them. It contains 5 main elements.

http://echa.europa.eu/home_en.asp

European Chemical Agency

http://ecb.jrc.it/REACH/RIP_PROJECTS

Commission guidance documents (See RIP-3: Guidance documents for industry).



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DEFINITIONS

Actors in the supply chain: means “all manufacturers and/or importers and/or Downstream Users in a supply chain” (Article 3.17 REACH).

Agency: means “the European Chemicals Agency as established by this Regulation” (Article 3.18 REACH). Abbreviation: ECHA.

Article: means “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” (Article 3.3 REACH). **Example: Vehicle, engine, seat, generator, wiper, windscreen, headlamp, screw, bolt, brake pads or linings. Not considered to be articles: Touch-up paint sticks, cleaning agents in cans, liquid tyre repair kits, engine oil in cans, etc; they are considered to be preparations in containers (borderline cases).**

Candidate list: List of substances of very high concern for potential inclusion in REACH Annex XIV, which itself lists substances subject to authorization (Article 59 REACH). The establishment of the candidate list is subject to specific procedures described in Article 59 REACH.

Downstream User: means “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” (Article 3.13 REACH).

European Union (EU) - Member States of the European Union. In addition as REACH is of EEA (European Economic Area) relevance, Iceland, Liechtenstein and Norway will apply REACH after it has been incorporated into the agreement of European Economic Area. Substances imported in the Community from Switzerland (a non EU country belonging to EFTA (European Free Trade Association) but not to EEA) are treated under REACH in the same way as substances imported from any other non-EU country.

Exposure scenario: means “the set of conditions, including operational conditions and risk management measures, that describe 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. These exposure scenarios may cover one specific process or use, or several processes or uses as appropriate” (Article 3.37 REACH).

Importer: means “any natural or legal person established within the Community who is responsible for import” (Article 3.11 REACH). The Only Representative has the same status under REACH as an Importer.

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Intended to be released: means that the releases are deliberately planned and have a specific function for the article, which is not the main function of the object, but an additional attribute. If a release is incidental, this is not an intended release. In cases where an intended release of substances is the main function of an object, it is to be regarded as a container with substances/preparations inside but not an article. Basic Criteria: Does the Article still work without the release? If yes, the release is not intended. A release is not considered to be an intended release in the following cases:

- A size (stiffener) is added to a fabric to improve its process ability. Sizes are released during further wet processing of the textile.
- Release of substances from articles catching fire and ozone released from copy machines.
- Release of particles or wear debris from tires or rubber belts, brake linings and discs, carbon brushes, etc.

Legal entity: means any individual, partnership, proprietorship, corporation, association or other organization that has, in the eyes of the law, the capacity to make a contract or an agreement and the abilities to assume an obligation and to pay off its debts. A legal entity under the law is responsible for its actions and can be sued for damages.

Manufacturer: means “any natural or legal person established within the Community who manufactures a substance within the Community” (Article 3.9 REACH) **Example: ethanol manufacturer, copper manufacturer.**

Manufacturing: means “production or extraction of substances in the natural state” (Article 3.8.REACH).

Monomer: means “a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process” (Article 6.REACH).

Non phase-in substance: means “a substance which does not meet the criteria of phase-in substance” (defined below); that is, a substance which was not manufactured, marketed, or put on the market prior to the entry into force of REACH.

Notified substance: means “a substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC” (Article 3.21 REACH).

Only Representative: means a natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfill, as his Only Representative, the obligations of importers. The Only Representative can represent one or several manufacturers, formulators, or producers of articles outside the EU and exporting to the EU.



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Phase-in substance: means “a substance which meets at least one of the following criteria”:

- a) It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).
- b) It was manufactured in the Community or in the countries acceding to the EU on 1 January 1995 or on 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 this Regulation, provided the manufacturer or importer has documentary evidence of this.
- c) It was placed on the market in the Community, or in the countries acceding to the EU on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this (Article 3.20 REACH).

Placing on the market: means 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 REACH).

Preparation: means “a mixture or solution composed of two or more substances” (Article 3.2 REACH). **Example: Paint, lubricant, adhesive, windshield washer fluid, engine oil, a metallic alloy (e.g. steel, brass; Article 3.41 and RIP 3.8)**

Producer of an article: means “any natural or legal person who makes or assembles an article within the Community” (Article 3.4 REACH). **Example: Vehicle manufacturer, parts manufacturer (e.g. engine, component, bolt)**

Polymer: means “a substance consisting of molecules characterized by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units”. (Article 3.5. REACH) A polymer comprises the following:

- (a) A simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
- (b) Less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a “monomer unit” means the reacted form of a monomer substance in a polymer. **Example: PP, PA6, PVC, POM, PTFE, EPDM, SBR, NBR, ECO, etc.**

Product and process orientated research and development (PPORD): means “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

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production trials are used to develop the production process and/or to test the fields of application of the substance” (Article 3.22 REACH).

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” (Article 3.1 REACH). **Example: methane, hydrocarbons, sulphuric acid, ethanol, calcium carbonate, silicon dioxide, elemental metals (e.g. copper, aluminum)** (Detailed information on Identification and Naming of Substances in REACH can be found in RIP 3.10 – Guidance for identification and naming of substances under REACH).

Substances of Very High Concern (SVHC): the following substances are considered as of very high concern according to Article 57 REACH:

- (a) Substances meeting the criteria for classification as carcinogenic, mutagenic, or toxic for reproduction according to Directive 67/548/EEC (“CMR substances”) category 1 or 2.
- (b) Substances which are persistent, bioaccumulative and toxic according to Annex XIII REACH (“PBTsubstances”).
- (c) Substances which are very persistent and very bioaccumulative according to Annex XIII REACH (“vPvB-substances”).
- (d) Substances which have endocrine-disrupting, persistent, bioaccumulative and toxic or very persistent and very bioaccumulative properties, which give rise to an equivalent level of concern to those of other substances listed in points (a-c) and which are identified on a case-by-case basis in accordance with the procedures set out in Article 59 REACH.

Supplier of a substance or a preparation: means “any manufacturer, importer, Downstream User, or distributor places on the market a substance, on its own or in a preparation, or a preparation” (Article 3.32 REACH).

Supplier of an article: means “any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market” (Article 3.33 REACH).

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” (Article 3.24 REACH).

Use and exposure category: means “an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use” (Article 3.38 REACH).

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Important Dates and Deadlines

2007

1 June 2007	<ul style="list-style-type: none"> • REACH entered into force. • Title IV REACH “Communication in the supply chain” applies. <p>Note: New data to be included in the safety data sheet will only be made available at a later stage according to transition periods for registration.</p>
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2008

Between 1 June 2008 and 1 December 2008 (inclusive)	<ul style="list-style-type: none"> • Pre-registration of phase-in substances on their own, in preparations or intended to be released from articles (Article 28 REACH) <p><i>Pre-registration is a mandatory pre-requisite to benefit from transition periods for registration.</i></p> <p>Note: Beyond 1 December 2008 deadline, particular pre-registration rules apply:</p> <ul style="list-style-type: none"> – For phase-in substances that are manufactured or imported in quantities of 1 tonne or more per year for the first time. – For phase-in substances that are used for production of articles for the first time. – For articles imported for first time and containing a phase-in substance requiring registration (Article 28.6 REACH).
1 June 2008	<ul style="list-style-type: none"> • Registration of non phase-in substances on their own, in preparations or intended to be released from articles before they are manufactured/imported/put on the market. • Title V REACH “Downstream User’s obligations” applies. • Title VII REACH “Authorization” applies, including procedures establishing candidate list for authorization (Article 59 REACH).

2009

By 1 January 2009	<ul style="list-style-type: none"> • Publication on Agency website of pre-registered phase-in substances with first envisaged registration deadline (Article 28.4 REACH). • First recommendation for a priority list of substances for authorization to be issued by the Agency (Article 58.3 REACH).
By 1 June 2009	<ul style="list-style-type: none"> • Title VIII REACH “Restrictions” applies – repeal of Directive 76/769/EEC.

2010

From 1 June 2008 until 30 November 2010	<ul style="list-style-type: none"> • Registration of: <ul style="list-style-type: none"> – Substances classified as “CMR, category 1 and 2 in quantities of 1 tonne/year and above per manufacturer/importer. – Substances classified as very toxic to aquatic organisms (R50/53) in quantities of 100 tonnes/year and above per manufacturer/importer. – Other substances on their own, in preparations or intended to be released from articles in quantities of 1000 tonnes/year and above per manufacturer/importer (Article 23.1 REACH).
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2011

As of 1 June 2011	<ul style="list-style-type: none"> • Notification of substances in articles (Article 7.2 REACH) 6 months after they have been included in the candidate list (Article 7.8 REACH). <p>Warning: Information requirements to Downstream Users apply as of inclusion in the candidate list.</p>
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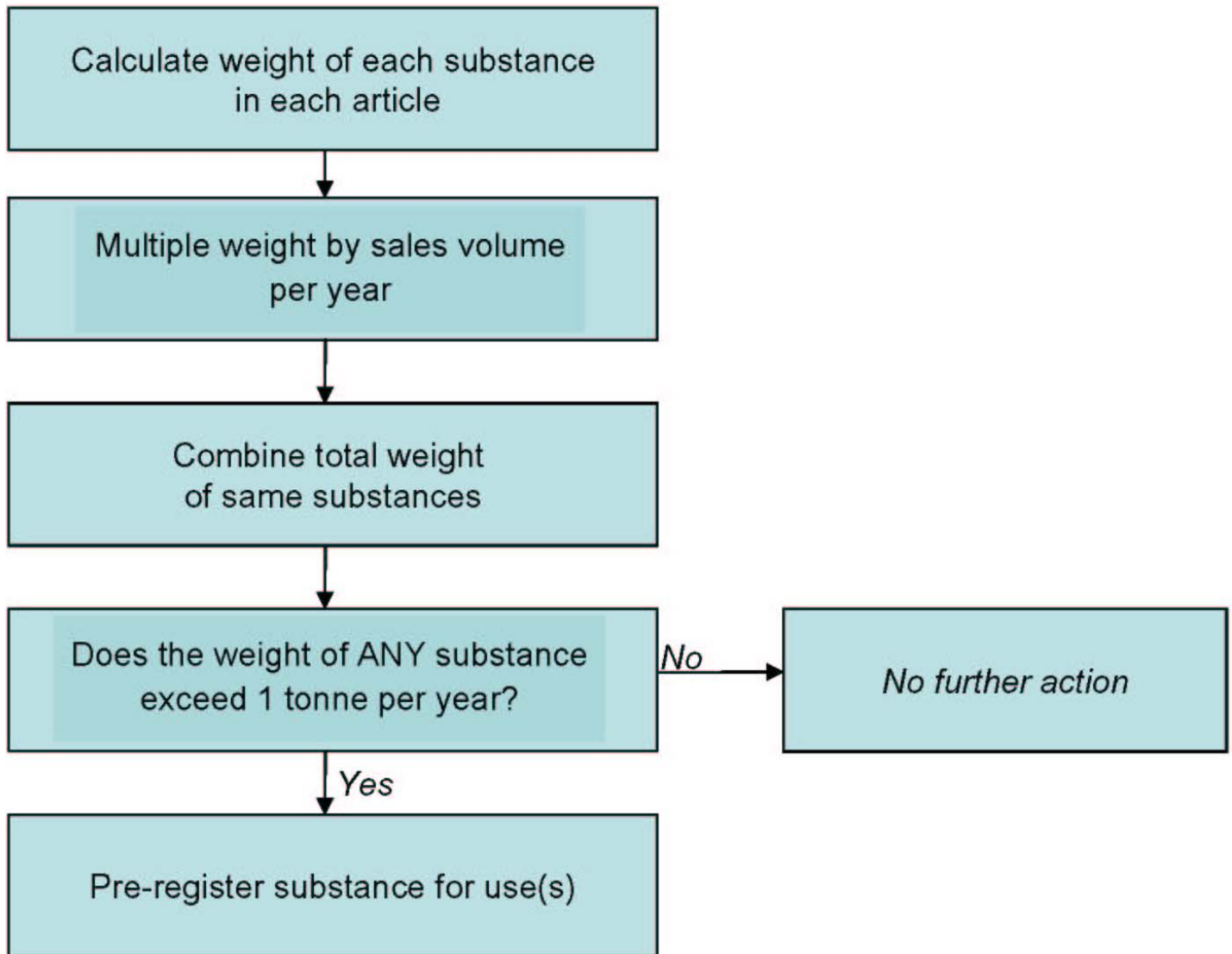
2013

From 1 June 2008 until 31 May 2013	<ul style="list-style-type: none"> • Registration of substances on their own, in preparations or intended to be released from articles in quantities of 100 tonnes/year and above per manufacturer/importer (Article 23.2 REACH).
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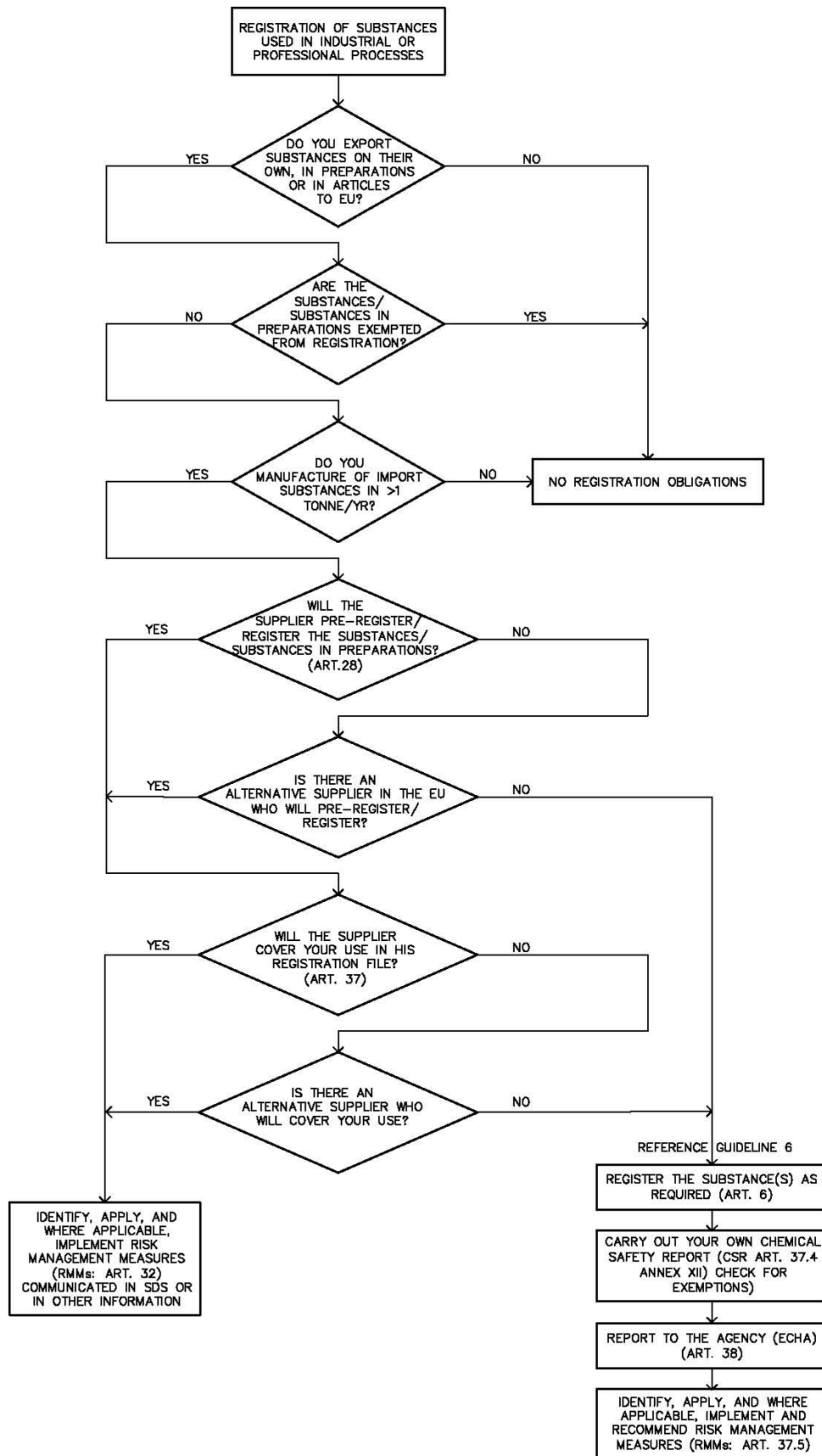
2018

From 1 June 2008 until 31 May 2018	<ul style="list-style-type: none"> • Registration of substances on their own, in preparations or intended to be released from articles in quantities of 1 tonne/year and above per manufacturer/importer (Article 23.3 REACH).
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REACH Calculation of Annual Tonnage

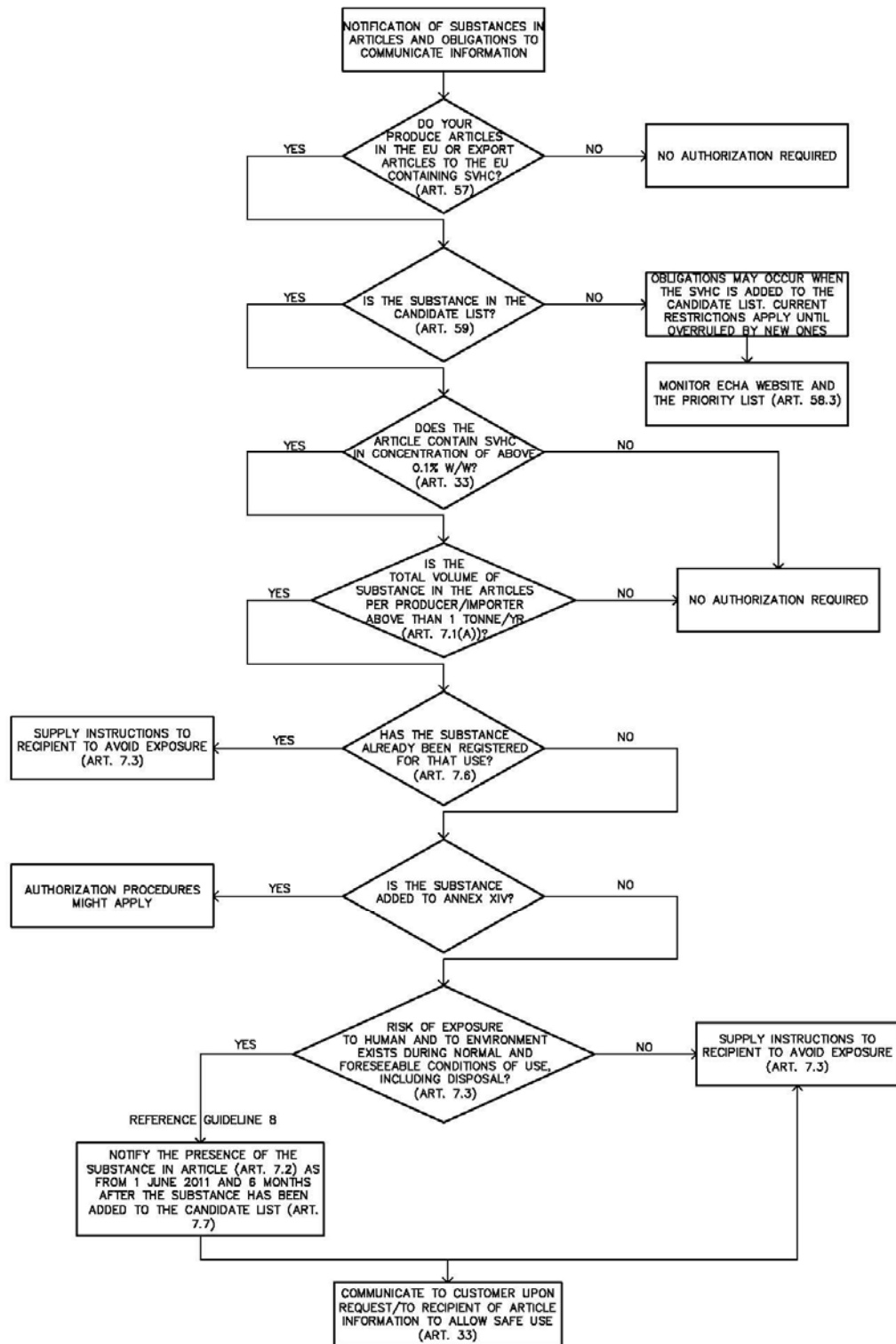


Registration of Substances/Substances in Preparations



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Notification of Substances in Articles and Obligation to Communicate Information



**Attachment #1
REACH Compliance Assistance**

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CBIA REACH Compliance Assistance

To assist your company in identifying your obligations under REACH please complete the accompanying CBIA REACH Compliance Review Form on the following page to the best of your ability and bring to the CBIA REACH review sponsored event. Instructions to collect the information are provided below and refer to the document for assistance. The goal of the review is identify your company's unique REACH Obligations and assist you in establishing a REACH compliance strategy. If you are not sure if your products are a substance, preparation or article we can clarify its status during the CBIA sponsored meeting. In addition, it may be helpful to bring MSDS for materials in question.

A) Do you export any of the following items to the EU?

- **Substance** - means a chemical element and its compounds. The term substance includes both substances obtained by a chemical manufacturing process (for example formaldehyde or methanol) and substances in their natural state. The term substance also includes its additives and impurities where these are part of its manufacturing process, but excludes any solvent which can be separated without affecting the stability of the substance or changing its composition.

- **Preparation** - means a mixture or solution composed of two or more substances. Typical examples of preparations include paints, varnishes, and inks. Preparations can contain several substances and are not the same as multi-constituents substances. The difference between the two is that a preparation is gained by the blending of two or more substances without any chemical reaction occurring, whereas a multi-constituent substance is the result of a chemical reaction.

- **Articles Containing a Substance Intended for Release** - the substance is intended to be released under normal or reasonably foreseeable conditions of use (i.e. pens, toner cartridge, etc.)

- **Article** - any object that has been given a specific shape, surface or design which determines its function to a greater degree than does its chemical composition (e.g. manufactured goods such as textiles, electronic chips, furniture, books, toys, kitchen equipment).

B) If you export or are part of a supply chain that exports to the EU please complete the Table on the following page. An example table is provided below.

Material Type	Name of Material*	Description	Est. Amount exported to the EU	Projected Amount in next 1 to 2 yrs	Required Action
Substance	Acetone/ 67-64-1/200-662-2	Used in production of nail polish remover	4 tonnes per yr	Increase by 50%	
Preparation	Nail Polish remover	Nail polish remover containing 3 substances	Appr. 10 tonnes total containing 50% acetone, 10% ethylene glycol and 1% pigment	Increase by 50%	
Glass Bottles	Containers	Glass bottles containing nail polish	1 tonne of glass bottles	Increase by 50%	

Material Type - Substance, preparation or Article

Name of Material- provide unique name for each material. If you export or are part of a supply chain that exports a substance or preparation containing a substance to the EU, if possible, please provide the CAS# and EINECS available at <http://ecb.jrc.ec.europa.eu/esis/>

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Est. Amount Exported to EU – provide a total of the substance, preparation or article exported by your entire company to the EU in tones.

Projected increase/Decrease next 1 to 2 yrs - provide an estimate of your company estimated increase in product shipments to the EU.

Required Actions –will be completed during review.

C) Complete the following questions to provide insight to your company's EU status

Do you have manufacturing operations in the EU? ___ Yes ___ No
Are part of an EU Concern? ___ Yes ___ No
Approximately how many customers do you have in the EU? ___
How do you disturbed products into the EU? ___ Distributor ___ Directly to Customer

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CBIA REACH Compliance Review Form

Date _____ Company Name and Address _____ Contact _____
 _____ Phone # _____
 _____ E-Mail _____

Please complete the following information and bring to the review session to facilitate an evaluation of your company's REACH obligations.

A) Do you export any of the following items to the EU?

Substance Preparation Articles Containing a Substance Intended for Release Article

B) If export or are part of a Supply Chain that exports any of the items noted above to the EU please complete the following Table.

Material Type	Name of Material	Description	Approx. Amount Exported to the EU	Projected Amount in next 1 to 2 yrs	Required Action

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Material Type	Name of Material	Description	Approx. Amount Exported to the EU	Projected Amount in next 1 to 2 yrs	Required Action

Material Type - Substance, Preparation, Articles Containing a Substance Intended for Release or Article
Name of Material- provide unique name for each material. If you export or are part of a supply chain that exports a substance or preparation containing a substance to the EU, if possible, please provide the CAS# and EINECS available at <http://ecb.jrc.ec.europa.eu/esis/>
Est. Amount Exported to EU – provide a total of the substance, preparation or article exported by your entire company to the EU in tones.
Projected increase/Decrease next 1 to 2 yrs - provide an estimate of your company estimated increase in product shipments to the EU.
Required Actions –will be completed during review.

C) Complete the following questions

Do you have manufacturing operations in the EU?

Yes No

Are part of an EU Concern?

Yes No

Approximately how many customers do you have in the EU?

How do you distribute products into the EU?

Distributor Directly to Customer