ORGALIME

ORGALIME GUIDE

A practical guide for downstream users, article producers and article importers

to understanding

Regulation N°1907/2006 on the Registration, Evaluation, Authorisation of Chemicals (REACH)

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Updated Orgalime Guide – A practical guide for downstream users, article producers and article importers to understanding Regulation N°1907/2006 on the **R**egistration, **E**valuation, **A**uthorisation of **Ch**emicals (REACH)

Foreword

Regulation N°1907/2006 on the **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH) was published in the Official Journal of the European Union on 30 December 2006. It entered into force on 1 June 2007.

Orgalime, the European Engineering Industries Association, speaks for 34 trade federations representing some 130,000 companies in the mechanical, electrical, electronic and metalworking industries of 22 European countries. The industry employs some 11.1 million people in the EU and in 2008 accounted for some €1,885 billion of annual output. The industry not only represents more than one quarter of the output of manufactured products but also a third of the manufactured exports of the European Union.

In the context of REACH, Orgalime represents a major EU downstream user industry, as well as EU producers and importers of final articles including many of their components for both, professional customers and consumers: we are clients of the chemical industry and suppliers of capital goods to all other industry sectors, including the automotive, aerospace, chemical, food or textile industries as well as to the health and environment sectors.

Orgalime has been closely following the legislative development of the REACH Regulation, from the presentation of the European Commission's proposal in October 2003 until the final adoption of the Regulation by the Council in December 2006 in order to have downstream users', article producers' and article importers' views properly reflected.

This Orgalime guide is intended to provide practical guidance to downstream users using chemicals in their industrial (including engineering) processes as they prepare themselves to the new legislation. It is also addressed to producers and importers of articles. It does however not extensively address obligations of manufacturers or importers of chemicals, nor the obligations of formulators ("first level downstream users").

The guide has been structured in a way that readers learn about REACH requirements in a progressive manner:

- Firstly, basic facts of REACH, main definitions and acronyms are explained to foster a common understanding of the information given in the guide, followed by an overview of important dates and deadlines.
- Secondly, the guide provides for four quick screens for engineering companies to identify in how far they are affected by the Regulation and the following requirements in particular: Registration of substances used in engineering processes - Registration of substances in articles - Notification of substances in articles and communication requirements - Authorisation and restriction of substances.
- Thirdly, issues of particular relevance to Orgalime industries are explained in more detail in individual guidelines. Also, links to other guidance documents provided by authorities or industry are compiled in the Orgalime guide to facilitate information gathering for engineering companies.
- The guide finishes off with a one page summary of REACH timelines and main obligations for Orgalime industries.

Orgalime has issued in May 2007 a first version of this guide as well as a first update in May 2008. Since then, further REACH provisions have entered into force, i.e. provisions on authorisation and restriction. The October 2009 update of the guide therefore provides for additional information on selected issues in order to further help companies to understand REACH. These focus more particularly on communication requirements in the supply chain, substances in articles, restriction procedures, the Substance Information Exchange Forum and implementing legislation under REACH. The present guide also takes into account the publication of guidance documents of the European Chemicals Agency (ECHA) and the latest state of the art of REACH Implementation Projects (see second bullet point hereafter).

References, which are made in this guide, refer to the following documents:

- Regulation (EC) N° 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) no 793/93 and Commission Regulation (EC) no 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[1].

The legal references (Articles, Titles, Chapters) mentioned in this guide always refer to the above mentioned Regulation, which may be found at the following website:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF

The definition of "phase-in substance" in Article 3.20 of the REACH Regulation has been amended by Council Regulation (EC) N° 1354/2007 of 15 November 2007 to take account of the accession of Bulgaria and Romania to the EU in January 2007. The text may be found here:
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:304:0001:0002:EN:PDF

- European Chemicals Agency guidance documents (hereafter called “ECHA Guidance” or “Guidance Document”), and REACH Implementation Projects (or RIPs).

The ECHA Guidance Documents and IT-tools are the outcome of REACH Implementation Projects (RIPs), which have been developed for ECHA, industry and the authorities by the European Commission in collaboration with stakeholders. **In this guide, ECHA Guidance Documents, which are finalised are according to their specific title and no longer refer to their former RIP number. Draft named documents, which are still under development, however, are named after their RIP number.** Please see Orgalime guideline 13 for a list of ECHA guidance documents and RIPs.

ECHA Guidance Documents are published at the following website:
http://guidance.echa.europa.eu/guidance_en.htm#GD_PROCC

This Orgalime guide has been drafted by a specific Orgalime task force, which is composed of Orgalime members (see page 70) and representatives of European sector associations of the engineering industry (in particular CECED, COCIR, ESTAL and EUCOMED).

This Orgalime guide reflects the best knowledge of industry experts from all over Europe and the state of the art at the moment of its publication. The principles contained in this guide are however not legally binding. A binding interpretation of Community legislation is the exclusive competence of the European Court of Justice.

Since a number of implementation issues are not yet clarified, this guide may be modified to accommodate such new developments, as soon as these are available. Any update will be made available at Orgalime’s website: www.orgalime.org, with those, who have registered online, receiving an automatic notification.

[1] A corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 has been published in the Official Journal L136 Volume 50 of 29 May 2007. It is available here http://europa.eu.int/eur-lex/lex/JOHtml.do?uri=OJ:L:2007:136:SOM:EN:HTML . The main purpose of this corrigendum was to correct linguistic errors, with no changes on the content of the text. It is mostly applicable to other versions than the English one, which we refer to in this guide. A second corrigendum has been published in the Official Journal L 141 Volume 51 of 31 May 2008. It is available here: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:141:0022:0022:EN:PDF. It modifies the definition of “phase in substances” provided in Article 3.20 REACH.

Contents

Chapter 1: Introduction to Regulation N°1907/2006 on REACH

1.1. How REACH developed historically

REACH stands for "**R**egistration, **E**valuation, **A**uthorisation and Restriction of **CH**emicals".

The REACH system establishes an EU wide regulatory framework for the registration, evaluation and authorisation of chemicals. In 1998, the Environment Council decided to review existing EU chemicals legislation in order to establish a new, integrated piece of legislation, which would assess existing and new substances in an harmonised way throughout the EU. The European Commission's legislative proposal on REACH was issued on 29 October 2003 and was negotiated between the European Parliament and the Council under the so-called codecision procedure. Regulation N°1907/2006 on REACH was finally adopted on 18 December 2006 and published in the Official Journal of the European Union on 30 December 2006.

As this is a Regulation, REACH does not require transposition into national laws of Member States but is directly applicable and therefore fully harmonised throughout Member States. REACH requires, however, that each Member State sets up a system of controls and penalties for non-compliance. **REACH entered into force on 1 June 2007**. Most obligations under REACH will however apply at a later stage and in a progressive manner.

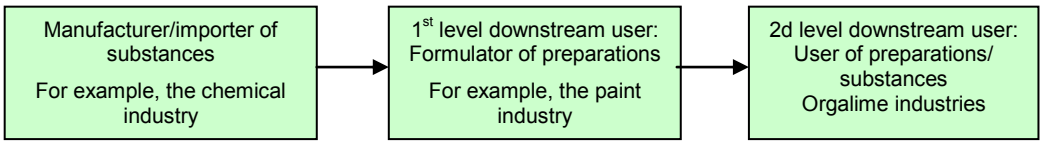
REACH aims at *"ensuring high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation"* (Article 1.1 REACH).

1.2. Basic facts about REACH

- The REACH Regulation **strengthens the responsibility of industry** to provide safety information on substances and to properly manage the risks arising from their use. All substances on their own, in preparations and in articles are covered by the Regulation except radioactive substances, non-isolated intermediates, substances which are transported by rail, road, inland waterway, sea or air and those which are waste. Member States may also grant exemption for substances used in the interest of defence. There are exemptions to some parts of REACH (see Orgalime guideline 2).

- Under REACH, **manufacturers** and **importers** (for every one of their legally incorporated or registered entities) are obliged to register with the European Chemical Agency substances on their own, or in preparations that they produce or import in quantities over 1 tonne per year (per manufacturer/importer), unless the substance is exempted from registration. Registration requirements also apply to substances in articles under certain conditions. The **article producer/importer** is, in this case, responsible that the registration of the substance intentionally released from the article is carried out (see Orgalime guideline 7). Non-Community manufacturers may appoint their "only representative" in order to carry out registration obligations as an importer (see Orgalime guideline 4). Failure to register means that the substance on its own, in preparation or in articles cannot be manufactured in the Community or placed on the EU market ("*no data - no market*").

- REACH reinforces communication obligations up and down the supply chain, that is, between manufacturers, importers of substances on their own or in preparations and downstream users. Downstream users may be formulators of preparations (for example, the paint industry). Orgalime considers them as "first level downstream users". **Orgalime industries,** however, represent **"second level" downstream users**, meaning that Orgalime industries mainly *use*, but *do not produce* substances or preparations in their engineering processes. For example, our industries use oils, lubricants, inks, glues, metals, alloys, plastics etc when producing articles (see Orgalime guideline 5).



- **Orgalime industries** may be **producers/importers of articles** such as electrical and electronic equipment, screws, motors or bolts. Important to note is that both article producers and article importers have specific obligations under REACH, in particular, the registration of substances intentionally released from articles and the notification of substances of very high concern present in the article under certain conditions. REACH, however, foresees that the registration or the notification of substances in article is not required if the substance has already been registered for that use (see Orgalime guidelines 7, 9 and 11).

- **Orgalime industry companies** may also **import** substances or preparations. In this case, downstream users have to comply with the importer's obligations[2], if there is no "only representative of a non Community manufacturer" appointed. The "only representative" will take over the obligations of the importer under REACH and the importer will be considered as a downstream user (see Orgalime guideline 4).

- A central element of the REACH system is the newly created **European Chemicals Agency** (hereafter called "ECHA"). Based in Helsinki, it is to be fully operational on 1 June 2008. The aim of ECHA is to collect the technical and scientific data, as well as manage the administrative aspects generated by REACH at Community level. ECHA shall also provide Member States and Institutions of the Community with scientific and technical advice on questions relating to REACH.

- REACH foresees **authorisation procedures** for substances, which have been identified as of very high concern and which are firstly included in the so-called future candidate list (substances liable for authorisation) and then further included in Annex XIV REACH. For those substances, manufacturers, importers and, in certain cases, downstream users, have to apply for an authorisation to ECHA in order to use or to put such substances on the EU market. These procedures might have an impact on substance availability on the market. It should be noted that downstream users do not need to apply for an authorisation if an authorisation for their use has been granted to an actor up the supply chain (see Orgalime guideline 13).

- Besides authorisation, REACH foresees **restriction procedures** which regulate conditions for the manufacture, placing on the market or use of certain substances on their own, in preparations or in articles where their use represents too high a risk to human health or the environment. Those substances will be listed in Annex XVII REACH and may no longer be used or marketed unless they comply with the restriction. Annex XVII REACH initially includes the current marketing and use restrictions of Directive 76/769/EEC. As of 1 June 2009, Directive 76/769/EEC will be repealed (see Orgalime guideline 14).

- REACH builds on existing legislation regarding the **classification and labelling of dangerous substances and preparations**, that is, Directives 67/548/EEC and 1999/45/EC. On 16 December 2008, the European Parliament and the Council adopted a new Regulation to implement the **UN's Globally Harmonised System for Classification and Labelling of Chemicals (GHS) into EU law** (Regulation 1272/2008), which would repeal Directives 67/548/EEC and 1999/45/EC. REACH provisions would later be made consistent with the Regulation implementing GHS, the EU Classification, Labelling and Packaging of Substances and Mixtures (CLP-Regulation). More information on GHS is available at: http://ec.europa.eu/enterprise/sectors/chemicals/classification/index_en.htm

[2] Please note that the obligations of importers of substances and preparations are not extensively covered in this guide. We invite the reader to check alternative sources of information regarding this particular matter (see initial list of other industry guidance and helpdesks in Orgalime guideline 18).

Chapter 2: Main definitions and acronyms

2.1. Definitions

Actors in the supply chain: means *"all manufacturers and/or importers and/or downstream users in a supply chain"* (Article 3.17 REACH).

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), for example, electrical and electronic equipment, a screw, a bolt, a motor, a battery, a metal sheet, packaging (packaging therefore needs to be assessed independently from its content).

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

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 life-cycle 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).

Identified use: means *"a use of a substance on its own or in a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user"* (Article 3.26 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 or marketed or put on the market prior to the entry into force of REACH.

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 European Union on 1 January 1995, on 1 May 2004 or on 1 January 2007, 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 European Union on 1 January 1995, on 1 May 2004 or on 1 January 2007, by the manufacturer or importer at any time between 18 September 1981 and 31 October 1993 inclusive, and before the entry into force of this Regulation it was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC in the version of Article 8(1) resulting from the amendment effected by Directive 79/831/EEC, but it 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).[3]

Preparation: means *"a mixture or solution composed of two or more substances"* (Article 3.2 REACH), for example, a paint, a lubricant, an ink, welding and brazing consumables, ingots.

[3] As amended by Council Regulation (EC) N° 1354/2007 of 15 November 2007 to take account of the accession of Bulgaria and Romania to the EU in January 2007, and which is available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:304:0001:0002:EN:PDF. A corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 has been published in the Official Journal L 36 of 5 February 2009. It is available here: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:036:0084:0084:EN:PDF. It modified litera c of this definition.

Registrant: means *"the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance"* (Article 3.7 REACH).

Restriction: means *"any condition for or prohibition of the manufacture, use or placing on the market"* (Article 3.31 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), for example, ethanol, elemental metals.
Detailed information on the identification and naming of substances in REACH, including the definition of "impurity", are to be found in the *Guidance for Identification and Naming of Substances under REACH (June 2007)*.

Substances of very high concern: 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, toxic for reproduction according to Directive 67/547/EEC ("CMR-substances") category 1 or 2.
(b) Substances which are persistent, bioaccumulative and toxic according to Annex XIII REACH ("PBT-substances").
(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.

Sunset date: means *"the date(s) from which the placing on the market or the use of the substance shall be prohibited unless an authorisation is granted which should take into account, where appropriate, the production cycle specified for that use"* (Article 58.1 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).

NOTE: Please check further definitions in Orgalime guideline 1 regarding the identification of roles in the supply chain, and Orgalime guideline 4 on imports by downstream users.

2.2. Acronyms

CAS: Acronym for chemical abstracts service. The CAS number is a means to identify the substance. Information on CAS numbers may be found here:
http://webnet3.oecd.org/echemportal/.

CMR: Acronym for carcinogenic, mutagenic, toxic for reproduction.

COM: Acronym for European Commission.

CSA: Acronym for Chemical safety assessment.

CSR: Acronym for Chemical safety report.

DU: Acronym for downstream user.

ECHA: Acronym for European Chemicals Agency.

EINECS: Acronym for European Inventory of Existing Commercial Chemical Substances, that is the list of substances on the EC market between 1 January 1971 and 18 September 1981. The EINECS list can be consulted at http://ecb.jrc.it/esis/.

ELINCS: Acronym for European List of Notified Chemical Substances, that is, the list of substances marketed as of 18 September 1981 and notified under Directive 67/548/EEC. The ELINCS list can be consulted at http://ecb.jrc.it/esis/. The substances listed in ELINCS are regarded as registered (see also Article 24 REACH).

ES: Acronym for exposure scenario.

MS: Acronym for Member State.

PBT: Acronym for persistent, bio-accumulative and toxic.

REACH: Acronym for registration, evaluation, authorisation and restrictions of chemicals.

RIP: Acronym for REACH Implementation Project. These are technical guidance documents and IT-tools developed for the Agency, industry and the authorities by the European Commission in collaboration with stakeholders. More information can be found at:
http://guidance.echa.europa.eu/guidance_en.htm#GD_PROCC and in Orgalime guideline 16.

RMM: Acronym for risk management measure.

SDS: Acronym for safety data sheet.

SVHC: Acronym for substance of very high concern.

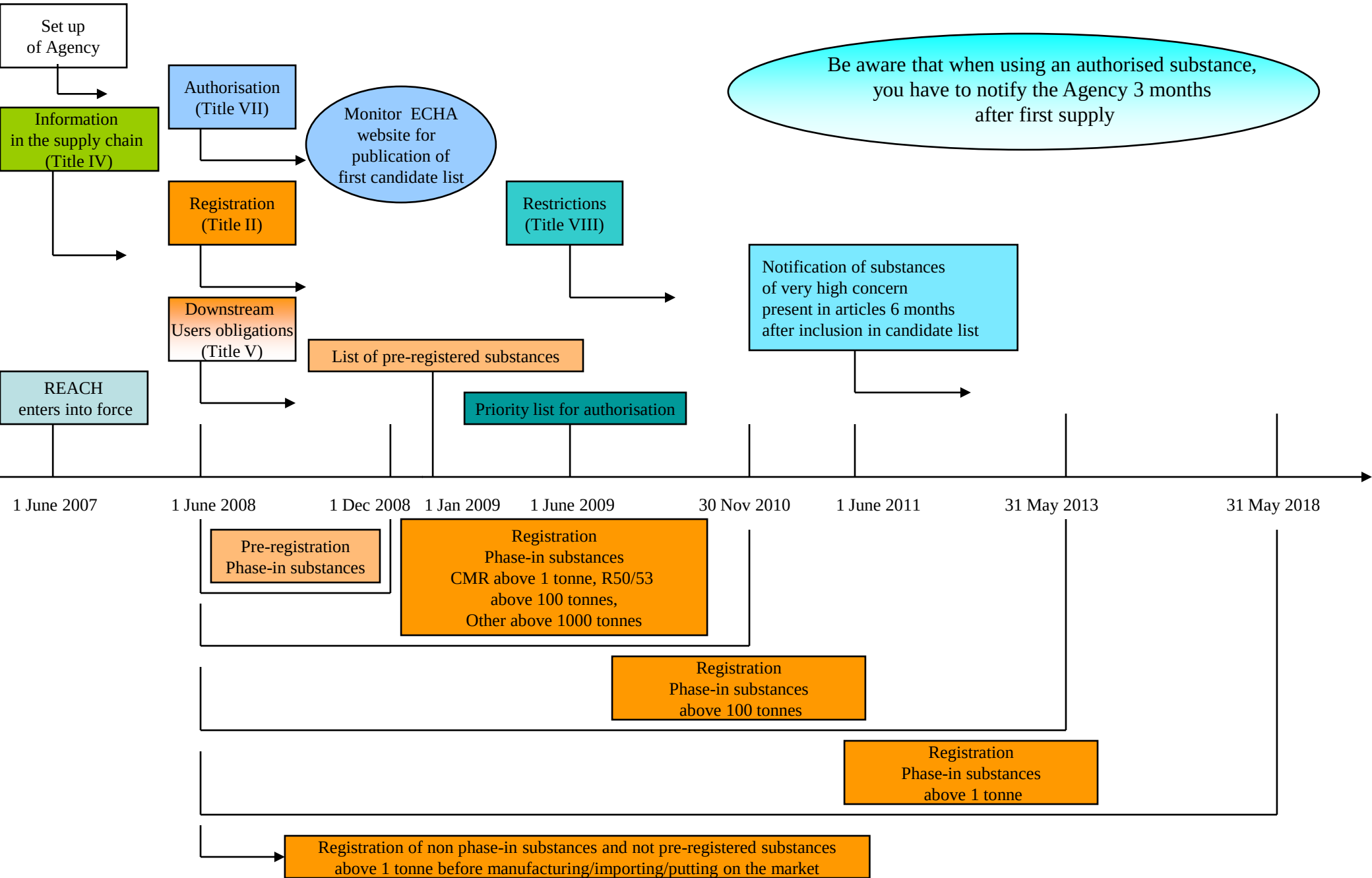
vPvB: Acronym for very persistent and very bioaccumulative.

Chapter 3: Important dates and deadlines to remember

2007	
1 June 2007	• REACH entry into force. • Title IV REACH "Communication in the supply chain" applies. **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.
2008	
between 1 June 2008 and 1 December 2008	• Pre-registration of phase-in substances on their own, in preparation or intentionally released from articles (Article 28 REACH). Pre-registration is a mandatory pre-requisite to benefit from transition periods for registration. **Note**: Beyond 1 December 2008 deadline, particular pre-registration rules apply: - For phase-in substances, which are manufactured or imported in quantities of 1 tonne or more per year for the first time. - For phase-in substances, which are used for production of articles for the first time. - For article imported for first time and containing a phase-in substance requiring registration (Article 28.6 REACH).
1 June 2008	• Registration of non phase-in substances on their own, in preparations or intentionally released from articles before they are manufactured/imported/put on the market. • Title V REACH "Downstream users obligations" applies. • Title VII REACH "Authorisation" applies, including procedures establishing candidate list for authorisation (Article 59 REACH). • Duty to communicate information on substances of very high concern present in articles and included in the candidate list to article recipient/consumer upon request under certain conditions (Article 33 REACH). • Title IX REACH "fees and charges" applies.
2009	
By 1 January 2009 **By 1 June 2009** **1June 2009**	• 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 authorisation to be issued by ECHA (Article 58.3 REACH). • Title VIII REACH "Restrictions" applies – Repeal of Directive 76/769/EEC.
2010	
From 1 June 2008 until 30 November 2010	• Registration of: -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 intentionally released from articles in quantities of 1000 tonnes/year and above per manufacturer/importer (Article 23.1 REACH).
2011	
As of 1 June 2011	• Notification of substances in articles (Article 7.2 REACH) 6 months after they have been included in the candidate list (Article 7.8 REACH).
2013	
From 1 June 2008 until 31 May 2013	• Registration of substances on their own, in preparations or intentionally released from articles in quantities of 100 tonnes/year and above per manufacturer/importer (Article 23.2 REACH).
2018	
From 1 June 2008 until 31 May 2018	• Registration of substances on their own, in preparations or intentionally released from articles in quantities of 1 tonne/year and above per manufacturer/importer (Article 23.3 REACH).

The following flowchart gives an overview about REACH main dates and deadlines to remember.

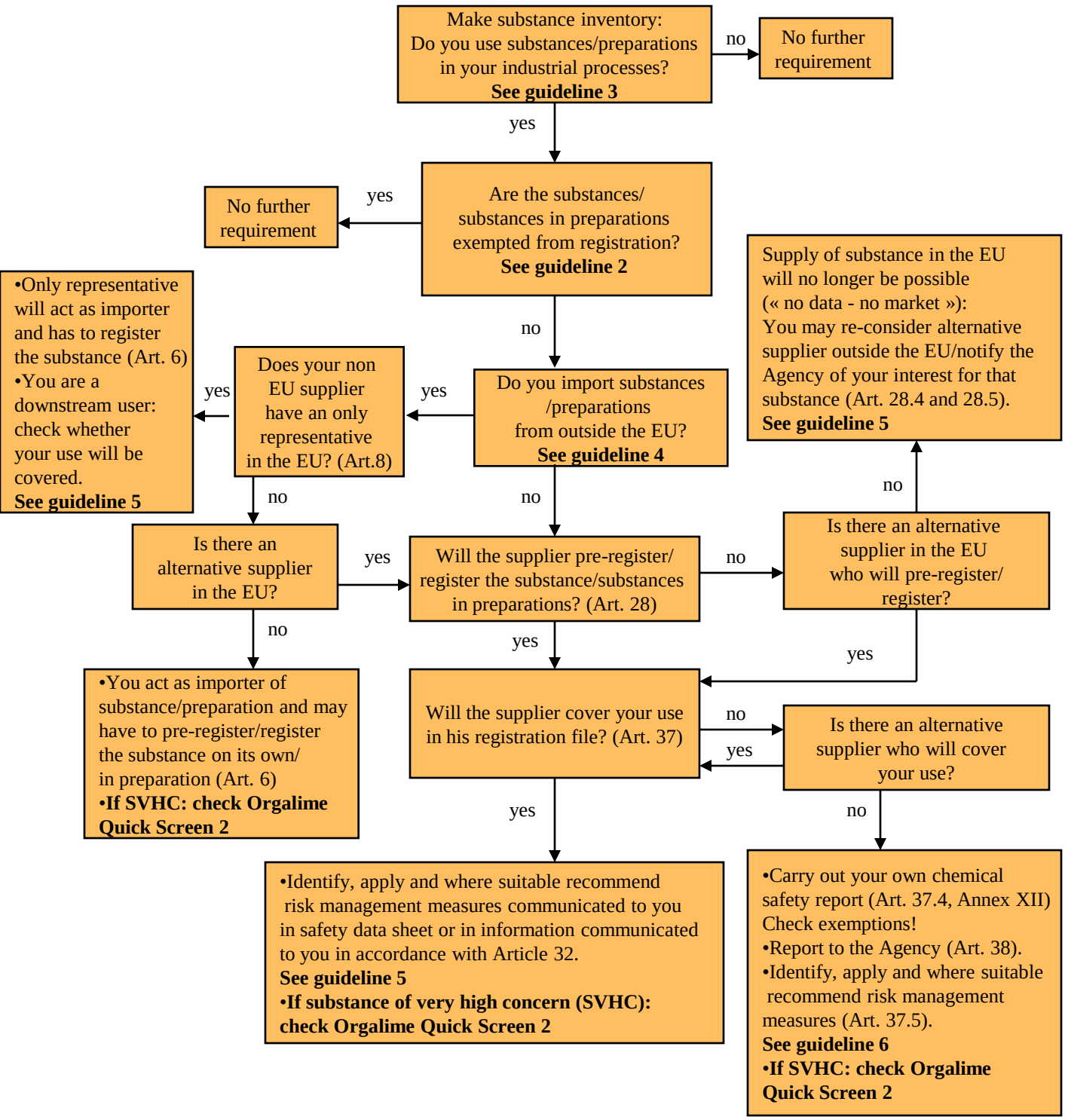
REACH timelines - summary



Chapter 4: Overview how to comply with REACH step by step

The following Orgalime quick screens have been designed in order to help companies to determine what their obligations under REACH are. Orgalime quick screens 1 to 4 are complementary. More information on individual steps is given in the guidelines of Chapter 5 of this guide. Where such Orgalime guidelines exist, references to them have been integrated in the quick screens.

4.1. Orgalime REACH Quick Screen 1
Registration of substances/substances in preparations used in industrial (including engineering) processes



RECOMMENDATIONS:

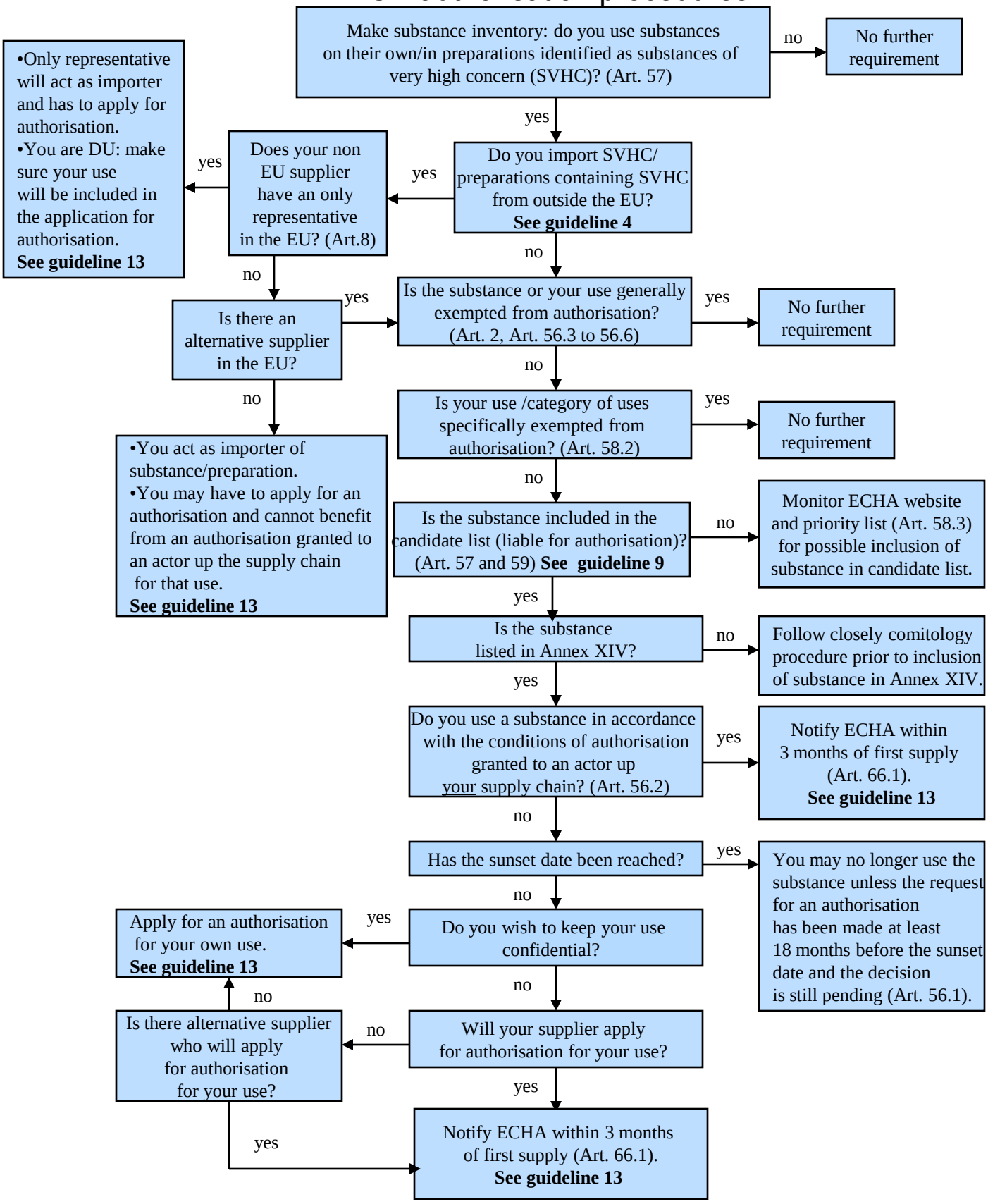
•**Start your substance inventory NOW**.

•**Start communicating with suppliers EARLY**: to ensure continuous supply of a substance, be PRO-ACTIVE, don't wait until the supplier has registered the substance you are using in processes to start communicating!

•Make sure **the substance you use will be pre-registered**. In case the substance you use has not been pre-registered, you have the possibility to notify the Agency of your interest in that substance. The Agency shall publish on its website the name of that substance and, on request, provide your contact details to a potential registrant (Article 28.5 REACH). Transition periods for registration will however not be allowed.

•**Check also Orgalime Quick Screens 2, 3 and 4 for further possible obligations.**

4.2. Orgalime REACH Quick Screen 2
REACH authorisation procedures



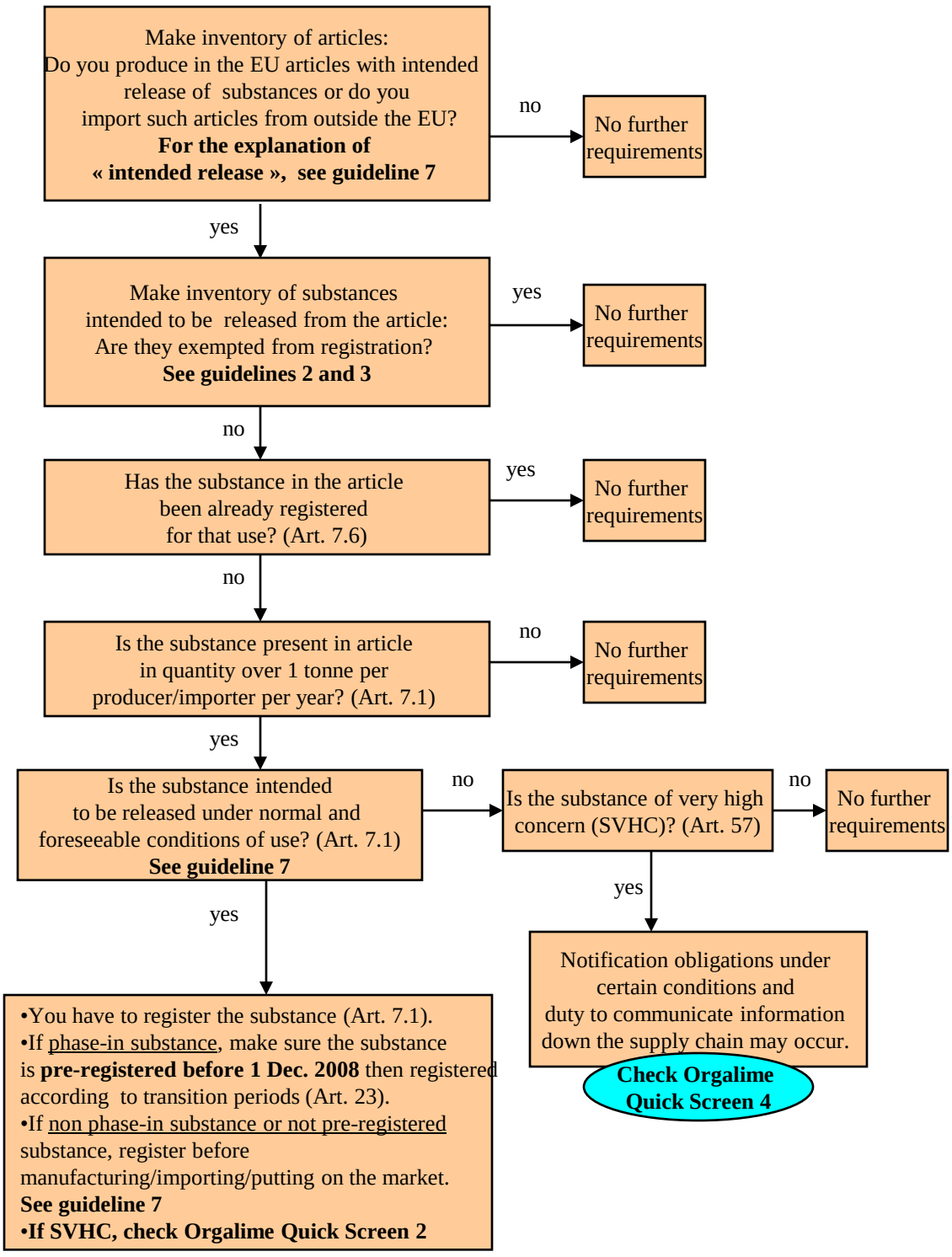
RECOMMENDATIONS:

•Please be aware that authorisation may cause substance withdrawal from the market.

•Application for authorisation must include an analysis of alternatives (Article 62.4 REACH). Please consider Article 62.4 REACH at an early stage, especially if the use of the substance is critical to your processes.

•**Check also Orgalime Quick Screens 1, 3 and 4 for further possible obligations.**

4.3. Orgalime REACH Quick Screen 3
Registration of substances intended to be released from articles



RECOMMENDATIONS:

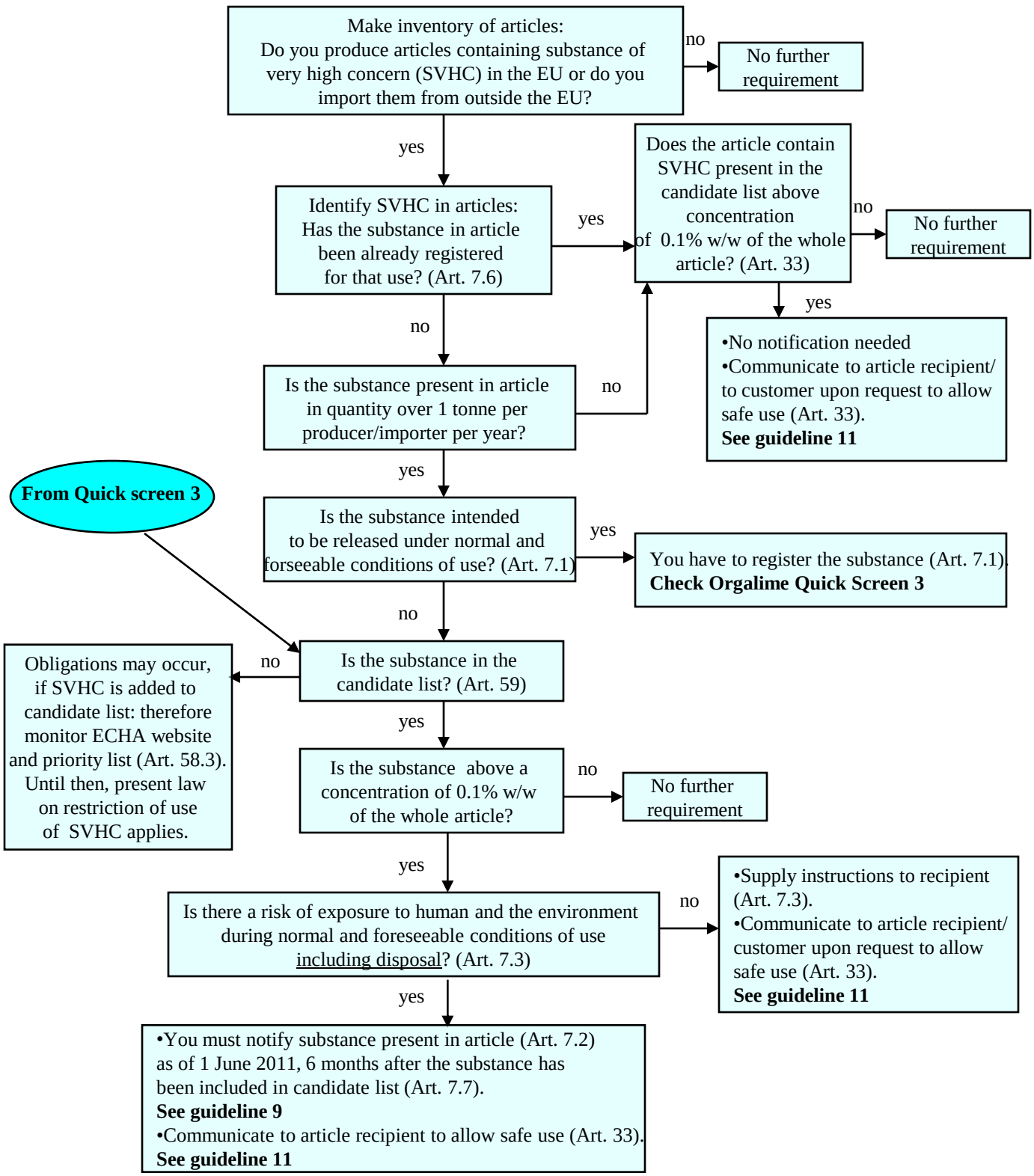
Article producers/importers should pay attention under which provision of the REACH Regulation the substance/substance in preparation intended to be released should be registered:

•If the substance that requires registration is considered as a substance delivered in a container, the substance has to be registered according to Article 6 REACH. Please note that the container itself may be considered as an article according to Article 3.3 REACH.

•If the substance to be registered is considered as a substance in an article, the substance requires registration according to Article 7.1 REACH.

•Check also Orgalime Quick Screens 1, 2 and 4 for further possible obligations.

4.4. Orgalime REACH Quick Screen 4
Notification of substances in articles and obligation to communicate information



RECOMMENDATIONS

•According to Article 7.2 REACH, the **calculation of the 0.1% w/w** concentration **refers to the whole article**, not at the level of the homogeneous material/component of the article (see ECHA Guidance document on requirements for substances in articles (May 2008), p. 16). Six Member States (Austria, Belgium, Denmark, France, Germany, Sweden), however, are challenging this interpretation.

•Please be aware that according to Article 7.5 REACH, **ECHA may require you to register the SVHC under certain conditions.**

•**Check also Orgalime Quick Screens 1, 2 and 3 for further possible obligations.**

Chapter 5: Guidelines on specific aspects of REACH

5.1. Guideline 1: Roles in the supply chain

REACH distinguishes the following roles in the supply chain and defines them as follows:

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).

Manufacturer: means *"any natural or legal person established within the Community who manufactures a substance within the Community"* (Article 3.9 REACH).

Importer: means *"any natural or legal person established within the Community who is responsible for import"* (Article 3.11 REACH).

Producer of an article: means *"any natural or legal person who makes or assembles an article within the Community"* (Article 3.4 REACH).

Recipient of an article: means *"an industrial or professional user, or a distributor, being supplied with an article but does not include consumers"* (Article 3.34 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).

Distributor: means *"any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties"* (Article 3. 14 REACH). Distributors have specific tasks under REACH regarding the transmission of information downstream and upstream the supply chain (see Articles 31, 32, 34, 36 and 37 REACH).

NOTE:

- Orgalime companies **may play several roles under REACH** and have specific obligations, depending on whether they:

  -**Use** substances/preparations supplied by an EU supplier: in this case companies bear the obligations of downstream users (See Orgalime guideline 5).
  -**Import** substance/preparations from outside the EU: in this case, companies bear the obligations of importers, if there is no EU "only representative" (that is exclusive representative) of the non EU chemicals supplier appointed (See Orgalime guideline 4).
  -**Produce articles**: in this case, companies bear the obligations of article producers (see Orgalime guidelines 7, 9, 11).
  -**Import articles** from outside the EU: in this case, companies bear the obligations of importers, if there is no EU "only representative" of the non EU supplier appointed (see Orgalime guidelines 7, 9, 11).

- Important to note for downstream users is that substances, which may result from chemical reaction upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market, are exempted from registration (See Annex V REACH). Further exemptions to register substances resulting from a chemical reaction, which may be of relevance to downstream users, are listed in Annex V REACH.

- In case the article producer/importer subcontracts a certain treatment of the article to a second company (for example, for surface treatment), registration/notification obligations of the substance in the article remains with the initial article producer/importer in the absence of transfer of ownership. REACH compliance for the treatment activities, however, has to be ensured by the subcontractor.

For more information, please check
Article 3, Annex V REACH
ECHA Guidance on requirements for substances in articles (May 2008), ECHA Guidance for Downstream Users (January 2008), ECHA Guidance on Registration (May 2008)

5.2. Guideline 2: Scope and exemptions

REACH covers all substances on their own, in preparations and in articles.

However, REACH does not apply to:

- Radioactive substances (Directive 96/29/Euratom).
- Substances on their own, in preparations or in articles subject to customs supervision and which are in temporary storage for re-exportation or in transit.
- Non-isolated intermediates.
- The carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air.
- Certain substances on their own, in preparations or in articles exempted by Member States in the interests of defence.
- Waste, which as defined in Directive 2006/12/EC, is not a substance according to REACH.

REACH applies without prejudice to:

- Community workplace legislation (Directive 89/391/EEC), (Directive 98/24/EC) and (Directive 2004/37/EC).
- Community environment legislation (Directive 96/61/EC) and (Directive 2000/60/EC).
- Directive 76/768/EEC with regards testing involving vertebrate animals.

There are a number of exemptions from certain Titles of REACH, generally defined according to the following criteria:

Tonnage:
Substances on their own, in preparations or in articles manufactured or imported in volume below 1 tonne per manufacturer/importer per year are exempted from registration (Title II REACH). Note that the volume limit does not apply to authorisation, restrictions, classification and labelling as well as safety data sheet requirements.

Use:
Registration (Title II REACH), downstream user's obligations (Title V REACH), evaluation (Title VI REACH) and authorisation (Title VII REACH) shall not apply to substances used:

- In human and medicinal products (Regulation 726/2004), (Directive 2001/82/EC), and (Directive 2001/83/EC).
- In food or feedingstuffs (Regulation 178/2002), including food additives in foodstuffs (Directive 89/107/EEC), flavourings in foodstuffs (Directive 88/388/EEC), (Decision 1999/217/EC), (Regulation 2232/96), as an additive in feedingstuffs (Regulation 1831/2003) and animal nutrition (Directive 82/471/EEC).

Nature of substance:
Registration (Title II REACH), downstream user's obligations (Title V REACH) and evaluation (Title VI REACH) shall not apply to:

- Substances listed in Annex IV and Annex V REACH.
- Re-imported substances on their own or in preparations, already registered.
- Substances, on their own, in preparations or in articles, already registered and resulting from a waste recovery process.

Nature of preparation:
Title IV REACH “information in the supply chain” shall not apply to the following preparations in the finished state, intended for the final user:

- Human and veterinary medicinal products (Regulation 726/2004), (Directive 2001/82/EC) and (Directive 2001/83/EC).
- Cosmetic products (Directive 76/768/EEC).
- Medical devices under certain circumstances.

- Food or feedingstuffs (Regulation 178/2002), including use as food additives (Directive 89/107/EEC), as flavourings (Directive 88/388/EEC), (Decision 1999/217/EC), (Regulation 2232/96), as feedingstuffs additives (Regulation 1831/2003) and in animal nutrition (Directive 82/471/EEC).

Product and process oriented research and development (PPORD):
Substances manufactured or imported for the purposes of product and process oriented research and development (PPORD) by manufacturer or importer or producer of articles are exempted from Articles 5, 6, 7, 17, 18 and 21 of Title II REACH (registration) for a period of five years. ECHA may prolong the five year period by another five years to ten years for certain substances and uses. The manufacturer, importer or producer of articles shall in this case notify certain information to ECHA (Article 9 REACH).

On-site isolated intermediates and transported isolated intermediates:
On-site isolated intermediates and transported isolated intermediates are exempted from Chapter 1 of Title II REACH (registration) with the exception of Articles 8 and 9 REACH. They are also exempted from authorisation (Article 2.8 REACH). However, specific registration obligations and information requirements for certain types of isolated intermediates are described in Chapter 3 of Title II REACH.

Polymers:
Polymers are exempted from registration and evaluation, but may still be subject to authorisation and restrictions.
However, manufacturers or importers of a polymer shall submit a registration to ECHA for the monomer substances or any other substances that have not already been registered by an actor up the supply chain if both following conditions are met: the polymer consists of 2% weight by weight (w/w) or more of such monomer substance or other substance in the form of monomeric units and chemically bound substance AND the quantity of such monomer is at or above 1 tonne per year (Article 6.3 REACH).

The following substances are regarded as being registered and therefore are not subject to registration under REACH:

- Active substances and co-formulants for use in plant protection products only (Directive 91/414/EEC), (Regulation 3600/92), (Regulation 703/2001), (Regulation 1490/2002), (Decision 2003/565/EC) and biocidal products only (Directive 98/8/EC), and (Regulation 2032/2003).
- Substances already notified (Directive 67/548/EEC) listed in the European List of Notified Chemical Substances (ELINCS).

Other
For substances in food contact materials (Regulation 1935/2004) and cosmetics (Directive 76/768/EEC), the chemical safety report need not cover risks to human health.

NOTE:
- **By 1 June 2008, the European Commission shall review Annexes IV and V REACH** (Article 138.4 REACH) (see Orgalime guideline 15).
- **By 1 June 2012, the European Commission shall assess the scope of REACH** in order to avoid overlaps with other existing legislations and, on that basis, issue a legislative proposal (Article 138.6 REACH).
- For exemptions from authorisation and restriction chapter in particular, please check Orgalime guidelines 13 and 14.

For more details, please check
Articles 1, 2, 6, 9, 138.4, 138.6 REACH
ECHA Guidance on Registration (May 2008), ECHA Guidance on PPORD (February 2008), ECHA Guidance for Intermediates (February 2008), ECHA Guidance for Monomers and Polymers (May 2008)

5.3. Guideline 3: Substance Inventory

A key step for downstream users to comply with the REACH Regulation is to have a full understanding of what substances/preparations the company uses or imports and what are the substances in articles that the company produces or imports. Establishing an inventory will allow the company to determine:

- **Which substances/preparations the company purchases from EU suppliers and for what purpose they are used**: you may then contact the chemicals supplier to ensure that the substance/preparation will continue to be supplied (supported by pre-registration of the substance on its own or in preparations) and that the company's use will be covered in the substance registration dossier (see Orgalime guideline 5).

- **Which substances/preparations the company imports**: unless an "only representative of a non-Community manufacturer" (that is, an exclusive representative), who will take over the obligations as an importer, has been appointed, you will have to comply with REACH obligations as an importer. This may result in the obligation to go through pre- and full registration of that substance/substances in preparations. These cases may not be obvious: for example, if you import a lubricant from a non-EU supplier in order to supply it to your customer (either with equipment or as part of a service contract), you may be obliged to generate the data package for registration in order to be allowed to continue to supply that substance/preparation (see Orgalime guideline 4).

- **Which substances are intended to be released from an article that the company produces**: If you produce articles with intended release of substances, you will be obliged to register the substances released under certain conditions (see Orgalime guideline 7). **For substances present in the article, you will have to identify whether they are of very high concern**. Under certain conditions, you will have to notify ECHA for such substances (see Orgalime guideline 9).

- **Which substances are intended to be released from an article that the company imports**: Unless an "only representative of a non-Community manufacturer" has been appointed, you will have the same obligations as the article producer (see above). **You will also have to identify if the imported article contains substances of very high concern, and notify them to ECHA** under certain conditions (see Orgalime guideline 4 and 9).

You need to collect the following key information in order to determine your REACH obligations[4] (if any):

- Substance/preparation name (suppliers proprietary name, if any)
- Chemical name
- CAS number (if any)
- ELINCS / EINECS number (if any)
- Amount used per year (kg)
- Supplier name and address
- Is it imported by you?
- Is the substance identified as of very high concern?
- Is the substance critical for your business?
- Is there a safety data sheet delivered with the substance/preparation?

Possible further information you may add to your inventory is:

- Have you contacted the supplier about registration for your use?
- Is there a confidentiality issue regarding specific uses?
- Will the substance be pre-registered/registered? When?

[4] Please note that the level of details of the information to be collected may vary, depending on the above-mentioned different roles that a company may play.

- Will the substance/preparation continue to be available for purchase?
- Is the substance included in the candidate list?
- Can it be substituted (if it is likely to be withdrawn in future)?
- If you need to produce data package for registration, what data is necessary?
- Who else supplies the substance or preparation and can you form a consortium?
- Who are your downstream users and what use do they use the substance for?

NOTE:
Information about substances is available in:

- **The ESIS database** (European chemical substance information system) at: http://ecb.jrc.it/esis/

The database provides among others information on:

- EINECS number (European Inventory of existing Commercial substances)
- ELINCS number (European list of notified chemical substances)
- NLP substances (No longer polymer)
- PBT substances (Persistent bioaccumulative and Toxic) or vPvB substances (very persistent very bioaccumulative)
- PBD (Biocidal Product Directive)

Please note that Annex XIII REACH provides for criteria for the identification of PBT and vPvB substances.

The consolidated version of Annex I of Directive 76/769/EEC (repealed since 1 June 2009) included a consolidated list of CMR substances (entries 29, 30, 31). As of 1 June 2009, Annex XVII REACH replaces Annex I of Directive 76/769/EEC.
Annex XVII REACH has been amended by Commission Regulation 552/2009 of 22 June 2009. It is available at:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:EN:PDF.

- **OECD "eChemPortal" at the following address:** http://webnet3.oecd.org/echemportal/

ECHEM portal is an integrated system that allows users to search multiple databases worldwide prepared for government chemical review programmes.

Information can be retrieved by searching on chemical names or CAS Registry numbers.

The ESIS database participates in "eChemPortal".

5.4. Guideline 4: Imports of substances/preparations/articles

Import under REACH means *"the physical introduction into the customs territory of the Community"* (Article 3.10 REACH). The importer is further defined as *"any natural or legal person established within the Community who is responsible for the import"* (Article 3.11 REACH). Substances on their own, or in preparations which are imported from outside the EU have to be registered, following the same rules as substances manufactured in the EU. Registration is also required for substances intended to be released from an imported article[5], following the same regime as substances intended to be released from an article produced in the EU (see Orgalime guideline 7).

Registration procedures for such imported substances may be carried out by:

The "only representative of a non-Community manufacturer": Article 8.1 REACH foresees that *"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 fulfil, as his only representative, the obligations on importers under Title II. The representative shall also comply with all other obligations of importers under this Regulation"*.

If an "only representative" (that is, an exclusive representative) is appointed, the EU importers within the same supply chain, whether they are affiliated with the non EU supplying company or not, **are regarded as downstream users and do not need to carry out registration procedures**. The non EC supplying company is obliged to inform the EU importers within the same supply chain, that he has appointed an "only representative" (Article 8.3 REACH). The only representative of the non-EU chemicals supplier has the legal responsibility to comply with all relevant obligations under REACH and must be based in the EU (Article 8.2 REACH).

In the absence of an only representative appointed in the EU, downstream users/article importers (for every one of their legally incorporated or registered entities) importing the substance or preparation or article into the Community market **are regarded as importers and are responsible for carrying out registration procedures** whether they:

- Import a substance on its own/in preparation in quantities of 1 tonne and above per year/per importer, to be used in industrial processes.
- Import a substance on its own/in preparation in quantities of 1 tonne and above per year/per importer, to be supplied to customer together with an article.
- Import an article intentionally releasing a substance and the substance is present in article in quantities of 1 tonne and above per year/per importer.

NOTE:

- The supply of substances/preparations/articles from EU Member States to other EU Member States is not considered as import.
- The European Economic Area (EEA) Joint Committee has adopted the REACH Regulation on 14 March 2008, including REACH in the EEA Agreement, so that substances supplied from Iceland, Liechtenstein, Norway (which are members of the EEA, but are not members of the EU) will no longer be considered as imports. REACH entered into force in these three States in June 2008 following the adoption of the Regulation by their national parliaments.
- Switzerland is not a member of the EEA and therefore substances supplied from Switzerland will be continued to be considered as imports.

[5] In case of the import or the producing of an article containing substances of very high concern, the article producer or importer has to notify ECHA under certain conditions. According to Article 7.5 REACH, ECHA may also decide that the article producer/importer has to register that substance (see Orgalime guideline 9).

- If a global acting company manufactures a substance on its own, preparations or articles intentionally releasing substances outside the EU and imports it via its own European affiliates into the EU, the latter are the importers. Each individual legal entity (that is a commercial country organisation or each distribution centre for finished products of a global company) importing from their parent company or from any other company located outside the EU, has to register the substance. Parts of the registration dossier need to be submitted jointly (see Joint submission of data by multiple registrants in Article 11 REACH).

- When importing an identical substance from different suppliers in different countries outside the EU, is it not necessary for the EU importer to carry out repetitive registrations for each supplier. The importer may instead register per substance imported, provided that the substance is identical.

For more details, please check:
ECHA Guidance on Registration (May 2008), ECHA Guidance on Data Sharing (September 2007)

5.5. Guideline 5: Communication obligations along the supply chain

Introduction

In order to secure a continued supply of a substance on its own/in preparations for their use(s), downstream users (hereafter called "DU") have to check whether the supplier will support their use(s) and include them in the substance registration dossier, in case so called "exposure scenarios" are required. It is in the interest of DU to **communicate early** with their suppliers with view to having their use(s) included in the supplier's registration dossier.

The supplier might be a downstream user, which, in turn, may decide either to carry out a registration by himself or to communicate the use(s) to his own supplier. The final actor of that chain is the manufacturer/importer of the substance/only representative of a non Community manufacturer who may finally carry out the registration obligations. Distributors must pass on the information to the next actor in the supply chain.

Outline of obligations of the supplier (as a registrant): exposure scenario

Suppliers have to submit a registration dossier to ECHA for substances they manufacture or import in quantities at or above one tonne per year. Provided that the supplier has pre-registered the phase-in substance to ECHA, he will benefit from the transitional regime for registering the substance (depending on substance volumes and properties, that is, 30 November 2010 – 31 May 2013 – 31 May 2018).

If the supplier manufactures or imports substances in quantities of 10 tonne and above per year, he must include in the registration dossier a chemicals safety assessment (CSA), which he will document in the chemical safety report (CSR), in accordance with Article 10 and 14 REACH. If the substance is considered as "dangerous" according to Directive 67/548, PBT or vPvB (according to the criteria set in Annex XIII REACH), the CSA must be completed with an **exposure scenario (ES).**

The ES describes the conditions according to which the risks to human health and the environment are "adequately controlled". More specifically, it describes how the substance on its own, in preparations or in articles is manufactured or used during its whole life cycle, from the production phase to the waste phase (see also Annex I.03 and Annex I.5.1.1 REACH), what are the recommended risk management measures (for example wearing protective equipment, local exhaust ventilation) and operational conditions (for instance the duration and frequency of use), so as to ensure safe use of the substance.

ES must cover the identified uses of a substance, which DU have the right communicate to their suppliers.

From the downstream user perspective: How to communicate with supplier?

DU may assist in the preparation of a registration. They have the right to make known in writing (on paper or electronically) their identified use(s) to the supplier. DU can also apply a system of brief general descriptions of uses that can be used as a minimum to identify such uses to the supplier. In making their use(s) known, DU shall provide sufficient information to allow the supplier to prepare an exposure scenario (ES) /use and exposure category to be included in the chemical safety assessment (Article 37.2 REACH).

According to the definition provided in REACH, ES *"may cover one specific process or use or several processes or uses as appropriate".* ES can therefore cover a broader range of uses, describing in a more generic way how to use the substance safely.

REACH further foresees that an exposure scenario can be expressed by means of use and exposure category, which REACH defines as *"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).

For DU, communicating by means of use and exposure category provides the possibility to protect confidential data and avoid carrying out their own chemical safety report.

Practically, in order to ensure smooth continuity of supply, DU should therefore:

- As a first step, identify the substances and preparations used in their industrial processes (see Orgalime guideline 3).

- As a second step, ask their suppliers whether they intend to pre-register/register substance/substances in preparations that they supply. If the supplier does not intend to pre-register a phase-in substance, DU may look for an alternative supplier, who would pre-register the substance. Pre-registration was only be possible between 1 June 2008 and 1 December 2008. ECHA had, by 1 January 2009, to publish a list of pre-registered substances and the first envisaged registration deadline (Article 28.4 REACH). The complete list is available at:
  http://apps.echa.europa.eu/preregistered/prsDownload.aspx.
  ECHA also developed a tool to find a substance in the list (in using a number or the substance's name), which is available at:
  http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx#whatisthislistheader.
  DU of a certain substance, which does not appear on this list of pre-registered substances, have the possibility to notify ECHA of their interest in that substance. ECHA shall publish on its website the name of that substance and on request provide details of DU to a potential registrant (Article 28.5 REACH). The potential registrant would however not be able to rely on registration transition periods for that substance. Despite this provision, it is in the DU's interest to make sure that the substances they use are pre-registered in due time by his supplier, especially since the list of pre-registered substances on ECHA website does not show the identity of the pre-registrant.

- If a phase-in substance is not pre-registered, no transition periods for registration is allowed and the substance has to be registered before the supplier can continue manufacturing, importing or putting the substance on the market. This situation may have consequences on the continuity of the supply of the substance to DU.
  To facilitate communication in the supply chain, Orgalime has developed a model letter for communication with the upstream supplier with regards his policy towards pre-registration and registration (See Annex A of this guide).

- As third step, if the supplier intends to carry out registration procedures, ask whether the supplier has already established use and exposure categories/exposure scenarios covering their use(s). DU may check the safety data sheets (SDS) provided to them to see whether their uses are already covered in these. If the supplier has not elaborated a use and exposure category/exposure scenario yet, DU may take a pro-active role and provide their supplier with information to develop an exposure scenario/use and exposure category in order to ensure that their uses will be covered and start the dialogue on appropriate risk management measures to be recommended for his use.
  DU should note that the development of exposure scenario is an iterative process, which will lead to the development of tentative ("draft") exposure scenarios by the registrant. Modifications to risk management measures and operational conditions of use may be brought along the process. The output is the final exposure scenario, which will be annexed to the safety data sheet, as described below.

Further information and examples of ES are available in the appendices of the *ECHA guidance document for downstream users* and *ECHA guidance document on Information Requirements and Chemical Safety Assessment (May 2008)*.

Safety Data Sheets (Article 31 REACH): a key communication tool

The main tool to communicate down the supply chain from suppliers to DU is the safety data sheet (SDS). REACH provides for changes to the legislation ruling on SDS (both, Directive 1991/155 EEC and Article 14 of Directive 1999/45 were repealed with the entry into force of REACH).

According to REACH, SDS are required not only for substances or preparations classified as dangerous according to Directive 67/548 and 1999/45, but also for substances meeting the criteria as PBT and vPvB (according to Annex XIII REACH) as well as for those substances added to the candidate list. A further new requirement is that the supplier must annex to the SDS the ES developed for identified uses, once available.

While new requirements for SDS started to apply as soon as REACH entered into force (that is, 1 June 2007), new data generated during the registration phase to be included in the updated SDS according to REACH will in practice only be made available at a later stage according to transition periods for registration.

Considering the information it contains, the SDS with the attached ES is a key document that DU must carefully look at in order to check whether their uses are covered and whether the risk management measures are applicable to their uses.

We highly recommend that DU start the dialogue with suppliers before the completion of the registration dossier and the release of the updated SDS, with the final ES annexed, so as to ensure that their use(s) will taken into account as early as possible in the process, which will ensure smooth continuity of business.

SDS must be provided free of charge on paper or electronically in the official language of the member state where the substance/preparation is put on the market.

SDS must be kept up to date with information on imposed restrictions or granted or refused authorisations or new information hazard or on risk management measure. Once updated the SDS must be re-sent free of charge to the recipients of the substance or the preparation.

DU may receive SDS for substances or preparations, which may have one or several ES attached. For further information, please check *ECHA guidance for downstream users* and *ECHA guidance document on Information Requirements and Chemical Safety Assessment (May 2008)*.

SDS may also include so called “uses advised against”.

“Uses advised against”/use outside supplier’s ES

Once DU have made their formal request in writing to the supplier to have their use(s) of the substance included in the registration dossier, **the supplier, having assessed the use in accordance with Article 14 REACH, cannot refuse to support it for reasons other than the protection of human health or the environment.** In case of a non supported use (“use advised against”), the supplier has to inform ECHA and downstream users in writing without delay of the reasons for not including the use(s) in the chemical safety assessment. **The supplier can continue supplying the substance to the DU but must include these reasons in the SDS or in the information to be provided according to Article 32 REACH** (Article 37.3 REACH).

For any use outside the conditions described in an exposure scenario or use and exposure category communicated in a safety data sheet, or for any use(s) the registrant advises against, DU have several possibilities. They may:

- Implement condition of use as described in the exposure scenario/use and exposure category by modifying processes/find alternative substance if at all possible or
- Seek another registrant who will support that particular use(s) or
- Carry out their own DU chemical safety report (Article 37.4 REACH) and notify ECHA as described in Article 38.2 REACH (see Orgalime guideline 6).

Article 32 information

For substances, for which no safety data sheet is required, but for which risk management measures must be applied, the supplier of the substance on its own or in preparations has communication obligations to the recipient, that is, the supplier has to provide information on:

- The registration number, if available.
- If the substance is subject to authorisation and details of any authorisation granted or denied in this supply chain.
- Details of any restriction.
- Any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied.

Any updated information on authorisation, restriction, risk management measures, registration number must be made available by the supplier to all former recipients, having received the substance or preparation the 12 preceding months free of charge, on paper or electronically (Article 32 REACH). To be noted is that REACH does not foresee any specific format for communicating information according to Article 32 REACH.

Risks management measures

DU must identify, apply, and, where suitable recommend, appropriate risk management measures, as indicated in the safety data sheet communicated to them, and information on risk management measures supplied to them in accordance with Article 32 REACH, or in their own chemical safety assessment (Article 37.5 REACH).

Any actor in the supply chain of a substance, or a preparation also has the obligation to communicate to the next actor up the supply chain:

- New information on hazardous properties, regardless of the use concerned.
- Any other information that might call into question the appropriateness of the risk management measures identified in the safety data sheet supplied to them which shall be communicated for identified uses (Article 34 REACH). DU therefore has the possibility to discuss the applicability of risk management measures for his use with the supplier.

Further DU duties

Workers shall be granted access by their employers to the information provided in the safety data sheet and in accordance with Article 32 REACH on substances or preparations that they use or may be exposed to during their work (Article 35 REACH).

DU, as well as manufacturers, importers and distributors shall keep the information on REACH available for at least 10 years after they have last used, imported, supplied or manufactured the substance or preparation. This information shall be made available without delay and upon request to Member States competent authority or ECHA (Article 36 REACH).
If DU are using SVHC, authorisation procedures might also apply (see Orgalime guideline 13). The substance may also be subject to restrictions, which DU should comply with (see Orgalime guideline 14).

Compliance deadline

- *Communication of uses*

For phase in substances, which have not been registered yet, the supplier must assess the use communicated to him by a DU before the expiry of the registration deadline, provided that the DU has made his request **at least 12 months prior to that deadline** (Article 37.3 REACH). For registered substances, the supplier must assess the use communicated to him before he next supplies the substance or preparation to the DU, provided that the DU made his request **at least one month before the supply** or within one month after the request whichever is the later (Article 37.3 REACH).

- *Application of downstream users' obligations*

While the legal obligation to comply with Article 37 REACH applies at the latest 12 months after receiving the registration number of the substance from their suppliers (Article 39.1 REACH), it is strongly advised that DU **start communicating as early as possible** with their suppliers.

Stocks of non pre-registered substances supplied before 1 June 2008

DU may continue using non pre-registered substances that were supplied to him before 1 June 2008 with no time limit since at the time of the supply, REACH (pre-)registration obligations were not yet applicable (see also *ECHA Guidance on Data Sharing, September 2007, p.23* and *ECHA FAQs, June 2009 p. 20*).

Recovered substances

Waste, as defined in Directive 2006/12/EC, is excluded from REACH. Regarding recovered substances, REACH rules as follows: if substances on their own, in preparation or in article, resulting from a recovery process in the Community are the same as the registered substance and the SDS or the information according to Article 32 is available to the establishment undertaking the recovery, then the recovered substance is exempted from registration, downstream user and evaluation obligations (Article 2.7(d) REACH).

Discussions on further details on this issue are still pending. In the meantime, we recommend that DU using such recovered substances ask their suppliers to pre-register any recovered substance, especially if these are not the same as the substances they originate from, in order to ensure that there would benefit from transitional period for registration, in case that registration would be confirmed to be required.

Unless imported or placed on the market themselves, by-products are exempted from registration, downstream user and evaluation obligations (Article 2.7(b) and Annex V REACH). A revised Annex V has been published in the EU Official Journal of 8 October 2008: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:268:0014:0019:EN:PDF
The provision related to by-products however remains unchanged.

NOTE:

- DU have the possibility to communicate with their supplier by means of use and exposure categories, especially if it is deemed necessary to:
  - Protect confidential data.
  - Avoid having to carry out an own DU chemical safety report and to report to ECHA, which requires expertise and may be costly, besides being time consuming (see Orgalime guideline 6).
- Identified uses may include the use of a substance to produce an article.
- DU should communicate with each of their suppliers, even if they supply the same substances/preparations to them.

  Practical information on communication in the supply chain/use and exposure categories is not thoroughly explained in the REACH Regulation.
  Orgalime has developed a model letter on communication with upstream suppliers, which is included in Annex A of this guide with regards the pre-registration of substances on their own, in preparation or in articles.
- REACH also foresees communication requirements in the supply chain for substances in articles (see Orgalime guideline 11), which would come in addition to the communication requirements outlined in the present guideline.

For more details, please check
Title IV, Title V, Annex VI n°6 REACH
ECHA guidance document on Information Requirements and Chemical Safety Assessment (May 2008), including ECHA guidance R.18: Estimation of exposure from waste life stage (July 2008), ECHA Guidance on requirements for substances in articles (May 2008), *ECHA Guidance for Downstream Users (January 2008), ECHA Guidance on Data Sharing (September 2007), ECHA FAQs (June 2009), ECHA Guidance for Identification and Naming of Substances under REACH (June 2007)*

5.6. Guideline 6: Downstream user chemical safety report and reporting to ECHA

In principle, the use of a substance on its own/in preparations by Orgalime industries should be covered in the supplier's registration dossier. Downstream users (hereafter called "DU") must nevertheless check early whether or not their supplier will effectively support their use(s) in order to ensure continuous supply of the substance/preparation (see Orgalime guideline 5).

In some specific cases, however, that is, for any use outside the conditions described in the exposure scenario or use and exposure category communicated to DU in a safety data sheet, or in case of any uses the supplier advises against for reasons of protection of health and the environment, DU may have to perform their own chemical safety report in accordance with Article 37.4 and Annex XII REACH.

Please note that the following exemptions to the duty of performing a DU chemical safety report are foreseen in Article 37.4 REACH:

- A safety data sheet is not required for the substance or preparation.
- A chemical safety report is not required to be completed by the supplier (that is, the manufacture/import of a substance is less than 10 tonnes per year).
- The substance or preparation is used in quantities of less than 1 tonne per year.
- The downstream user implements or recommends a relevant exposure scenario as communicated to him in the safety data sheet.
- The substance is present in the preparation in a concentration lower than the concentrations set out in Article 14.2 REACH.
- The downstream user uses the substance for product and process oriented research and development.

DU relying on the 1 tonne exemption still need to consider the use(s) of the substance and identify, apply and recommend appropriate risk management measures. Where necessary, DU shall prepare a safety data sheet to include this information.

In case DU carry out their own chemical safety report or rely on the tonnage exemption or on the product and process oriented research exemption, DU have to comply with reporting obligations to ECHA before starting or continuing with a use of a substance registered by an actor up the supply chain (Article 38.1 and 38.2 REACH).

DU must comply with Article 38 REACH at the latest 6 months after receiving a registration number communicated to them by their supplier in a safety data sheet (Article 39.2 REACH).

For more details, please check
Articles 37.4, 38, 39.2 Annex XII REACH
ECHA Guidance for Downstream Users (January 2008)

5.7. Guideline 7: Registration of substances in articles

Both, producers of articles in the EU and importers of articles from outside the EU/the "only representative of non EU manufacturer" of articles (that is, the exclusive representative), must register substances in articles to ECHA if **both** the following conditions are met:

- The substance is intended to be released under normal or reasonably foreseeable conditions of use.
- The total amount of the substance present in articles is in quantities totalling over 1 tonne per producer/importer per year (Article 7.1 REACH).

Registration of substances in article is not required:

- **If the substance has already been registered for that use** (Article 7.6 REACH) or
- If the conditions explained above are not met or
- If the substance is exempted from registration (see Orgalime guideline 2).

Timeline to pre-register and register substances

Substances intended to be released from the article must be pre-registered to ECHA in order to benefit from the registration transition periods described below (Article 28 REACH). Pre-registration of substances took place between 1 June 2008 and 1 December 2008. The aim of pre-registration is also to ensure that industry shares information and submits joint registration via the Substance Information Exchange Forum (SIEF) (see Orgalime guideline 8 and also Article 29 REACH).

The registration transition periods for substances intended to be released from the article are the same as those applying for the registration of a substance on its own or in a preparation (Article 23 REACH).

Producers of articles are recommended to make sure that their suppliers will pre-register and register the substance intended to be released from the article, so as to avoid having to carry out these obligations by themselves. Importers of articles should make sure that their suppliers outside the EU will nominate an "only representative", who will carry out the (pre-)registration duties (See Orgalime guideline 4).

Orgalime has developed a model letter for communication with the upstream supplier on his policy towards pre-registration and registration (See Annex A of this guide).

Overview of (pre)-registration deadlines

Registration of non phase-in substances in quantities of 1 tonne and above per year	**As of 1 June 2008**, before manufacturing/importing/putting the substance on the market
Registration of phase-in substances, provided that the substance has been pre-registered between 1 June 2008 and 1 December 2008	**From 1 June 2008 until 30 November 2010 for**: • "CMR-substances" (category 1 and 2) in quantities of 1 tonne and above per year. • R 50/53 substances in quantities of 100 tonnes and above per year. • Other substances in quantities of 1000 tonnes and above per year. **From 1 June 2008 until 31 May 2013 for**: • Other substances in quantities of 100 tonnes and above per year. **From 1 June 2008 until 31 May 2018 for**: • Other substances in quantities of 1 tonne and above per year.

Please note that producers and importers of articles with intended release may rely on registration transition periods in case of production or import of article with intended release **for the first time after 1 December 2008**. In order to benefit from this specific regime, the following conditions must be fulfilled: the pre-registration information must be submitted to ECHA within 6 months after first manufacturing, importing or using the substance and no later than 12 months before the relevant registration deadline (Article 28.6 REACH).

Fees

Fees required for the registration of substances in articles are specified in a European Commission's Regulation 340/2008 (see Orgalime guideline 15). No fees are required for the registration of a substance between 1 and 10 tonnes where the registration dossier contains the full information specified in Annex VII REACH.

Explanation of "intended to be released"

The REACH Regulation does not contain a definition of "substance intended to be released" mentioned in Article 7.1 REACH. The *ECHA Guidance on requirements for substances in articles* (May 2008) provides for explanation to the phrase "intended release". **Hereafter are some extracts of the guidance which are quoted in italics. For the full text, please refer to the *Guidance on requirements for substances in articles*.**

"As a general rule, the intention of the article producer in relation to the release of the substance is relevant. The question "Is it wanted that a substance/preparation is released from the article during its normal and reasonably foreseeable use because this is necessary for it to fulfil a certain function of the article?" should be answered with yes. Intended releases are deliberately planned and have a specific function for the article, which is frequently not the main but an accessory function of the object.

A release of substances from articles is intended when:

- *The release contributes to a (accessory) function of the article, or, in other words the, release contributes to the 'added value' of the article, which is not directly connected to the end use function. If the release would not happen, that function could not be fulfilled.(...)*

A release is not considered to be an intended release in the following cases:

- *A release occurs during removal of 'impurities' from a semi-finished or finished article during its production process (before marketing as a finished article). (…)*
- *A release occurs during use or maintenance of the article and is meant to improve the product quality in a wide sense or the safety as a side effect but the released substances do not contribute to the function of the article. (…)*
- *A release of substances is an unavoidable side-effect of the functioning of the article. Without the release, the article would not work, but the release is not directly intended. (….)*
- *A release of substances formed during chemical reactions of any kind. (…)*
- *A release is incidental, could be forced by undue use or in an accident. (…)"*

The *Guidance on requirements for substances in articles* further mentions that *"The list is not comprehensive, further situations where releases are intended / not intended are possible".*

Orgalime considers the following illustrative examples as "**no intended release"** under REACH, that is, leakage of oil during use/maintenance of compressors, release of particles from brake pads in machinery, ozone release from copy machines, release of gas from pressure equipments.

Please note that basic elemental substances such as hydrogen, oxygen, noble gases (argon, helium, neon and xenon) and nitrogen are specifically excluded from the registration obligation (Annex V.9 REACH).

Even if not subject to Article 7.1 REACH, the article producer/importer has to check whether the substances present in articles are subject to the requirements of Article 7.2 and Article 33 REACH.

Other legislation than REACH may apply to those substances which are released (intended or not) from articles, as well to the articles themselves.

Substance in article versus substance/preparation in a container

According to the interpretation provided in the *ECHA guidance on requirements for substances in articles*, the following further distinction should be made in case of intended release:

"In case where an intended release of a substance is the main function of an object, it is to be regarded as a "container with substance/preparation inside but not an article".

NOTE:
Article producers/importers should pay attention under which provision of the REACH Regulation the intentionally released substance/substance in preparation should be registered:

- If the substance that requires registration is considered as a substance delivered in a container, the substance has to be registered according to Article 6 REACH. Please note that the container itself may be considered as an article according to Article 3.3 REACH.

- If the substance to be registered is considered as a substance in an article intended to be released, the substance requires registration according to Article 7.1 REACH (for the definition of an article, please see Chapter 2 of the Orgalime guide).

Detailed and complete explanation on that matter is provided in the above mentioned *Guidance on requirements for substances in articles*.

For more details, please check
Articles 6, 7, 23, 28 REACH
ECHA Guidance on requirements for substances in articles (May 2008), *ECHA Guidance on Data Sharing (September 2007), ECHA Guidance on Registration (May 2008).* Practical information on pre-registration is available here:
http://echa.europa.eu/sief/pre-registration_en.asp.

5.8. Guideline 8: Substance Information Exchange Forum (SIEF)

Introduction

"SIEF" is the acronym for "substance information exchange forum". According to Article 29 REACH, all potential registrants, downstream users and third parties who have pre-registered phase-in substances shall be participants in SIEFs. The purpose of the SIEF is:

- To have companies share information relevant for the registration and avoid the duplicate studies (in order to inter alia reduce the need for animal testing).
- To agree on the classification and labelling (C&L) where there is a difference in C&L of the substance between the potential registrants.

SIEF participants shall provide other participants with existing studies, react to information requests, and arrange for further studies to be carried out.

Each SIEF shall be operational until 1 June 2018. The REACH Regulation does not foresee provisions how SIEFs will be operated. It is up to participating companies to organise themselves in the SIEF.

Pre-SIEF

When the pre-registration period ended on 1 December 2008, all registrants were placed in different pre-SIEFs. Pre-SIEFs are not foreseen in the REACH Regulation but have been introduced in REACH IT in order to facilitate the SIEF formation. All companies that have pre-registered the same substance with either the same name or chemical identifiers have been placed in the same pre-SIEF. This is done automatically by REACH-IT.

From Pre-SIEF to creating SIEF

In the pre-SIEF it is up to companies to determine whether the substance that they have pre-registered is identical with the other pre-registered substances. As soon as an agreement is found, companies form a SIEF.

Some companies have formed consortia in order to make the registration process run more smoothly by providing practical help with data-sharing and preparation of the registrations. There is no obligation under REACH to form consortia.

Pre-registrants, who find out that the substance they have pre-registered is different, shall form new SIEF or join other SIEFs. The pre-SIEF page in REACH-IT has a "similar to" box for helping companies to find the most appropriate SIEF. The contact information of all other pre-SIEF members is available in REACH-IT.

A company which has pre-registered a substance but does not intend to submit a full registration may deactivate their membership to a pre-SIEF by clicking on the "deactivate" function in the REACH-IT system. Even if the pre-SIEF membership is deactivated, the pre-registration remains valid i.e. the manufacture or import of the substance may continue until the registration deadline. It is possible to reactivate later. According to ECHA FAQs 9.11 of 29 June 2009 "*during the pre-SIEF phase you can de-activate yourself from the pre-SIEF to indicate that you are not interested in registering the substance e.g. in a situation where you decide to cease manufacture or import of the specific substance. Note, however, that even as a non-active participant you still may be required to share your data".*

NOTE:
A member of a pre-SIEF or a SIEF cannot charge another member with fees for services, unless this has been mutually agreed.

Roles in the SIEFs

The SIEF Formation Facilitator (SFF)
While not foreseen in REACH, the SFF role was introduced in REACH IT in order to initiate the discussions after the pre-registration and exchange of information in view of forming the SIEF. Any pre-registrant may volunteer to be a SFF via REACH-IT. Companies should be aware that registrants have no legal obligation to refer to a SFF in view of SIEF formation and that SFF may not legally force other pre-SIEF participants to co-operate and cannot request information or fees for their services unless mutually agreed.

Lead registrant
Contrary to the SFF, the lead registrant is a mandatory role laid down in the REACH Regulation. All SIEFs must appoint a lead registrant, whose task is to submit the joint dossier containing information on the intrinsic properties of the substance to be registered. The other registrants will have to submit their company specific information (see also Article 11 REACH for further details). The lead registrant may be different from the SFF.

To be noted is that industry has developed a classification of pre-registrants in 4 categories, according to their desired involvement in the SIEFs. These are: Leader, Active, Passive and Dormant. While this terminology has no legal status in REACH, companies may come across these terms in their further contacts within the SIEF.

For more details, please check

Article 25, 29, 11 REACH
ECHA guidance on data sharing (September 2007), *ECHA FAQs* (June 2009)
The SIEF - Key Principles document is available on the ECHA website at:
http://echa.europa.eu/doc/reachit/sief_key_principles.pdf
Pre-SIEF information in the ECHA REACH IT Industry User Manual:
http://echa.europa.eu/doc/reachit/industry_user_manual/reachit_presief_en.pdf
On industry classification of pre-registrant, please check www.cefic.org

5.9. Guideline 9: Notification of substances in articles

Both, producers of articles in the EU and importers of articles from outside the EU/the "only representative of non EU manufacturer" of articles (that is, the exclusive representative) must notify ECHA in case the substance present in the article meets **all** the following conditions:

- The substance has been identified as of very high concern (Article 57 REACH), that is,
  - (a) The substance meets the criteria for classification as carcinogenic, mutagenic, toxic for reproduction ("CMR-substances") category 1 or 2.
  - (b) The substance is persistent, bioaccumulative and toxic according to Annex XIII REACH ("PBT-substances").
  - (c) The substance is very persistent and very bioaccumulative according to Annex XIII REACH ("vPvB-substances").
  - (d) The substance has 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.
- The substance has been included in the candidate list for inclusion in Annex XIV REACH,
- The substance is present in the articles in quantities totalling over 1 tonne per year (per producer/importer), and
- The substance present in the articles is above a concentration of 0.1% weight by weight (Article 7.2 REACH).[6]

Notification is not required:

- **If the substance has already been registered for that use** (Article 7.6 REACH) or
- If all the conditions explained above are not met or
- If the article producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In this case, the article producer or importer must supply the appropriate information to the recipient of the article (Article 7.3 REACH).

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 4.1 to 4.2 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 …

Timeline (Article 7.7 REACH)

From 1 June 2011, Articles 7.2, 7.3 and 7.4 REACH shall apply 6 months after a substance has been included in the candidate list.

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[6] Dissenting views (http://guidance.echa.europa.eu/docs/guidance_document/dissenting_en.pdf), questioning the application of the 0.1 % threshold to the entire article have been notified by six Member States (Austria, Belgium, Denmark, France, Germany and Sweden) and publication of this part of the guidance document was not endorsed by these Member States.

According to Article 7.5 REACH, ECHA may still require the article producer/importer to submit a registration for ANY substance in articles if **all** the following conditions are met:

- The substance is present in articles in quantities over 1 tonne (per producer/importer) per year.
- ECHA has grounds for suspecting that the substance is released from the articles, and the release of the substance from the articles presents a risk to human health or the environment.
- The substance is not subject to Article 7.1 REACH.

Outline of the process for identifying substances in the candidate list for inclusion in Annex XIV (Article 59 REACH - see also guideline 13 on authorisation)

Who	What	When
MS /ECHA (upon COM request)	Preparation of Annex XV dossier for substances meeting the criteria of Art. 57 ("SVHC"). Dossier may be limited to a reference to Annex I of Directive 67/458/EEC	From 1 June 2008
ECHA	To circulate the dossier to all MS	Within 30 days of receipt
ECHA	Publication of a notice on ECHA website that an Annex XV dossier has been prepared	
All interested parties	Possibility to submit comments on Annex XV dossier	By specific deadline set by ECHA
MS/ECHA	Possibility to submit comments on identification of the substance	Within 60 days of circulation
ECHA	**If no comments are received,** ECHA **WILL INCLUDE THE SUBSTANCE IN THE CANDIDATE LIST** ECHA MAY include the substance in the priority list for inclusion in Annex XIV	
ECHA	**If comments are made,** ECHA to refer the dossier to "Member State Committee"	Within 15 days after end of 60 day consultation period
Member State Committee (of ECHA)	MS requested to provide their opinion on the identification of the substance	Within 30 days after referral of the dossier
ECHA	If MS reach unanimous agreement, ECHA **WILL INCLUDE THE SUBSTANCE IN THE CANDIDATE LIST** ECHA MAY include the substance in the priority list for inclusion in Annex XIV	
COM	**If MS fail to reach unanimous agreement, COM to prepare a draft proposal on the identification of the substance via comitology (regulatory procedure)**	Within 3 months of receipt of the opinion of the MS Committee
ECHA	ECHA to update its website after decision of inclusion of a substance in candidate list has been taken.	

Substances in articles and authorisation

According to the *Guidance on requirements for substances in articles* (p. 14), *"(…) Substances being (an integral) part of imported articles can not be subject to authorisation. However, if an EU-based producer of an article incorporates a substance as such or in preparation into the article, that use of the substance may have to be authorised (if the substance is listed in REACH Annex XIV). If such a substance is acquired on the EU market, the supplier has to give this information in section 16 of the safety data sheet or via information according to article 32. If the article producer imports such substances himself, he has to apply for an Authorisation for continued use.(…)".*

Substances in articles and restriction

While authorisation does not apply to substances in imported articles, any Member State or the Commission have the possibility to initiate a restriction procedure if they consider that a substance in the article either produced in the EU or imported represents too high a risk for human health or the environment and needs to be addressed on a community wide basis (Title VIII REACH). Restriction procedures are further explained in Orgalime guideline 14.

NOTE:
According to Article 7.2 REACH, the calculation of the concentration "0.1% w/w" refers to the article and not at the level of the homogeneous material/component of that article. Notwithstanding that the *Guidance on requirements for substances in articles* supports this interpretation (see page 16), six Member States (Austria, Belgium, Denmark, France, Germany and Sweden) challenge it.

According to the definition provided in REACH, most spare parts or accessories are to be considered as articles. We recommend producers of such spare parts and accessories to carefully check the definition of article to see whether their products fall under REACH provisions related to substances in articles.

REACH also foresees communication requirements for SVHC present in articles (see Orgalime guideline 11).

For more details, please check
Articles 7, 57, 59 REACH
ECHA Guidance on requirements for substances in articles (May 2008)

5.10. Guideline 10: Update of the REACH Candidate List

Article 59(1) REACH foresees that a candidate list indentifying substances of very high concern (SVHC) for eventual inclusion in Annex XIV shall be established, following a specific procedure (see Orgalime guideline 9 for the detailed process). The publication of the candidate list is not only a first step possibly leading to the inclusion of a substance in Annex XIV REACH (see Orgalime guideline 13 on authorisation) but also triggers among other immediate communication duties in the supply chain for articles producers/article importers according to Article 33 REACH (see Orgalime guideline 5).

The first candidate list was published on 28 October 2008 and contains 15 substances which have been identified as of very high concern. The candidate list is available here: http://www.echa.europa.eu/chem_data/candidate_list_table_en.asp

The REACH legal text foresees no provision with regards the frequency of the update of the candidate list. Basically, whenever a Member State or ECHA on behalf of the Commission introduces an Annex XV dossier for the identification of a SVHC, the process leading to the possible inclusion of the substance in the candidate list is launched.

In order to improve the predictability of the update of the candidate list, Member States Competent Authorities have agreed at their meeting of March 2009 to introduce Annex XV dossiers launching the process for the identification of the SVHC in a coordinated manner at fixed dates. Two dates per year are in principle foreseen. The periodicity may change, according to the number of the dossiers to be submitted. This does not prevent Member States from introducing Annex XV dossiers any time. ECHA has proposed in March 2009 to the following dates for 2009 and 2010 as deadlines for submitting Annex XV dossiers: 3 August 2009, 8 February 2010 and 2 August 2010. The final inclusion of the substance in the candidate list is subject to a specific process with given deadlines underlined below:

Outline of the process for identifying substances in the candidate list

Who	What	When
MS /ECHA (upon COM request)	Preparation of Annex XV dossier for substances meeting the criteria of Art. 57 ("SVHC"). Dossier may be limited to a reference to Annex I of Directive 67/458/EEC	From 1 June 2008
ECHA	To circulate the dossier to all MS	Within 30 days of receipt
ECHA	Publication of a notice on ECHA website that an Annex XV dossier prepared	
All interested parties	Possibility to submit comments on Annex XV dossier	By specific deadline set by ECHA
MS/ECHA	Possibility to submit comments on identification of the substance	Within 60 days of circulation
ECHA	**If no comments are received,** ECHA **WILL INCLUDE THE SUBSTANCE IN THE CANDIDATE LIST** ECHA MAY include the substance in the priority list for inclusion in Annex XIV	
ECHA	**If comments are made,** ECHA to refer the dossier to "Member State Committee"	Within 15 days after end of 60 day consultation period
Member State Committee (of ECHA)	MS requested to provide their opinion on the identification of the substance	Within 30 days after referral of the dossier

ECHA	If MS reach unanimous agreement, ECHA **WILL INCLUDE THE SUBSTANCE IN THE CANDIDATE LIST** ECHA MAY include the substance in the priority list for inclusion in Annex XIV	
COM	**If MS fail to reach unanimous agreement, COM to prepare a draft proposal on the identification of the substance via comitology**	Within 3 months of receipt of the opinion of the MS Committee
ECHA	ECHA to update its website after decision of inclusion of a substance in candidate list has been taken.	

In the so called "Registry of Intentions" (ROI) on the ECHA website, it is possible to view the intention of Member States and the Commission to introduce Annex XV dossiers. It is available here: http://www.echa.europa.eu/chem_data/reg_intentions_en.asp

Orgalime has developed a model letter for facilitating communication in the supply chain according to Article 33 REACH, available in Annex B to this guide (see Orgalime guideline 12).

Obligations linked with the publication of the candidate list are as follows:

For articles:
Article 33 applies as soon as a substance is included in the candidate list (see Orgalime guideline 12)

Article 7.2 applies from 2011, 6 months after a substances has been included in the candidate list (see Orgalime guideline 9)

- For substances included in the candidate list before 1 December 2010, the notifications have to be submitted not later than 1 June 2011.
- For substances included in the candidate list on or after 1 December 2010, the notifications have to be submitted no later than 6 months after the inclusion

For substances:
Suppliers of substances on the candidate list have to provide their customers with a safety data sheet from the date of inclusion (Article 31.1 REACH).

For preparations:
Suppliers of preparations not classified as dangerous according to Directive 1999/45/EC have to provide the recipients, at their request, with a safety data sheet if the preparations contain at least one substance on the candidate list and its individual concentration is at least 0.1% (w/w) for non gaseous preparations and at least 0.2% by volume for gaseous preparations (Article 31.3 REACH).

For further information, please check:
ECHA guidance on requirements for substances in articles (May 2008)

5.11. Guideline 11: Communication requirements on substances in articles

Important to note is that communication requirements are already present in existing legislation applying to Orgalime industries, such as in Directive 2001/95/EEC on General Product Safety or in product specific legislation, such as Directive 2005/32/EC on Energy Using Products.

Article 33 REACH further requires that the supplier of an article (see definition in Orgalime guideline 1) communicates sufficient information available to him 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.

Communication requirements apply to substances in articles meeting <u>all</u> the following criteria:

- The substance is identified as of very high concern according to Article 57 REACH, that is,
    (a) The substance meets the criteria for classification as carcinogenic, mutagenic, toxic for reproduction ("CMR-substances") category 1 or 2.
    (b) The substance is persistent, bioaccumulative and toxic according to Annex XIII REACH ("PBT-substances").
    (c) The substance is very persistent and very bioaccumulative according to Annex XIII REACH ("vPvB-substances").
    (d) The substance has 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.
- The substance is included in the candidate list for inclusion in Annex XIV REACH.
- The substance is present in the article in a concentration above 0.1% weight by weight.

The information requirement shall extend to consumers upon request. The information must be provided free of charge within 45 days of receipt of the request.

In order to facilitate the implementation of article 33 information requirements, Orgalime has developed a model letter for communication with suppliers as well as with recipients. (See Annex B to this guide and Orgalime guideline 12).

If notification is not required, under the condition that the article producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal, the article producer or importer must supply the appropriate information to the recipient of the article (Article 7.3 REACH).

NOTE:

- The obligation to communicate information in the supply chain (Title IV REACH) applies from 1 June 2007. However the obligation to communicate information on substances in articles shall not start before the substance is included in the candidate list. The procedures establishing the candidate list shall apply from 1 June 2008 (see also Orgalime guideline 10).

- REACH does not prescribe any specific data format for communicating information according to Article 33 REACH. However, ECHA may issue further guidance on this.

- According to Article 33 REACH, the calculation of the concentration "0.1% w/w" refers to the article and not at the level of the homogeneous material/component of the article. Notwithstanding that the *Guidance on requirements for substances in articles* supports this interpretation (see page 16 & 17), six Member States (Austria, Belgium, Denmark, France, Germany and Sweden) challenge it.

- The process for inclusion of a substance in the candidate list is explained in Orgalime guidelines 9 and 10.

For more details, please check
Articles 7.3, 33 REACH
ECHA Guidance on requirements for substances in articles (May 2008)

5.12. Guideline 12: Implementation of Article 33 REACH information requirements to recipients down the supply chain and to consumers

Introduction

This guideline is meant to help suppliers of articles (*e.g.* products, parts, equipment, packaging) to fulfill the information requirements foreseen in Article 33 of the Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and restrictions of Chemicals (REACH), by providing recommendations and suggested phrasing. It also refers to an electronic format (IEC PAS 61906:2005) that may be used to communicate information according to Article 33 REACH.

Article 33(1) REACH requires that the supplier of an article communicates to the recipient of the article sufficient information available to him on certain substances present in the article in order to allow safe use, including as a minimum, the name of the substance. Article 33.1 REACH applies to substances in articles meeting all the following criteria:

- The substance is identified as of very high concern according to Article 57 REACH.
- The substance is included in the candidate list for inclusion in Annex XIV REACH.
- The substance is present in the article in a concentration above 0.1% weight by weight (w/w).

According to Article 33.2 REACH, the information requirement shall extend to consumers upon request. The information must be provided free of charge within 45 days of receipt of the request.

The REACH Regulation defines a recipient of an article as "*an industrial or professional user, or a distributor, being supplied with an article but does not include consumers*" (Article 3.35 REACH).

A supplier of an article is defined in Article 3.33 REACH as "*any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market"*.

Article 33 REACH applies as soon as a substance has been included in the candidate list. The first candidate list has been officially published on 28 October 2008 and contains 15 substances which have been identified as of very high concern. The candidate list will be periodically reviewed by the European Chemicals Agency (ECHA). Further information about the candidate list is available here: http://echa.europa.eu/chem_data/candidate_list_en.asp (see Orgalime guideline 10).

How do I provide required information according to Article 33 REACH to recipients and consumers?

There are different ways of providing information to the supply chain according to Article 33.1 REACH. The information may be transmitted automatically to the recipient via *e.g*.

- Electronic means.
- Explicit, easily accessible information included in the product literature.
- Reference to a webpage in the product literature containing up-to-date information.

Regarding the information requirements according to Article 33.2 REACH, the information to be provided to consumers at their request can be provided in a number of ways, for example:

- Electronic information delivered to the retailer.
- Explicit information in the product literature, in so far as the upstream supplier has provided them.

- Webpage indicated in the product literature containing up-to-date information.

What is important is that the information is readily available.

Please also take note of the following considerations:

- When communicating information according to Article 33 REACH, it is recommended to refer to the name of the substance which is used in the candidate list.
- Information on the safe use of the article to be provided on the packaging or in user manuals or in the product description are already required according to existing product safety legislation applying to Orgalime industries (*e.g.* Directive 2001/95/EC on General Product Safety).
- Even if not required by Article 33 REACH, suppliers may, on a voluntary basis, also communicate on the absence of substances included in the candidate list above a concentration of 0.1% weight by weight in order to:
  - Avoid receiving repeated requests.
  - Reassure recipients and consumers that the information requirement according Article 33 REACH has been investigated.

Suggested language to be used when communicating in the context of Article 33 REACH information provisions

a) Preliminary remarks

- Suppliers of articles have the legal obligation to keep themselves informed about the status of the candidate list and automatically inform their recipients in case Article 33.1 REACH applies. Suppliers of articles must not wait for the request of their recipients to communicate information. Recipients, though, may send requests to their suppliers on a voluntary basis (see *Orgalime* model letter for communication up the supply chain in order to implement Article 33.1 REACH information requirements in the Annex B of this guide).
- The information to consumers (Article 33.2 REACH) has to be delivered within 45 days, provided that it was requested by the consumer, in accordance with the provisions of REACH. There is no such obligation to "automatically" transmit information, as is the case for Article 33.1 REACH.
- Important to remember is that packaging is considered as an article and therefore information under Article 33 REACH relates to both the article itself and the packaging.
- *ECHA guidance on requirements for substances in articles* (May 2008) p. 17 clarifies that Article 33 REACH information requirement applies to articles which are supplied after the publication of the candidate list. While these articles may have been imported or produced prior to the publication of the candidate list, it is the date of supply of the article which is relevant.
- The calculation of the 0.1% w/w threshold value is to be based on the weight of the whole article.

b) Suggested phrases

In case the information has to be automatically provided to a recipient as soon as the candidate list has been published, communication may start as follows:

"The candidate list according to Article 59 of the Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and restrictions of Chemicals (REACH) has been published on 28 October 2008. We are aware about the legal obligations this publication triggers, that is the information requirements according to Article 33.1 REACH and will comply with them".

In case a request has been made by a consumer or a recipient, the standard reply may start with the following phrase:

"We thank you for your request regarding the application of Article 33 of the Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and restrictions of Chemicals (REACH) further to the publication of the candidate list according to Article 59 REACH on 28 October 2008. We are aware about our legal obligations and will comply with them".

If Article 33 REACH applies, the next paragraph may read as follows:

"Current knowledge available to us on the presence of substances included in the candidate list above a concentration of 0.1% weight by weight in our articles is as follows: {to be completed, at least the name of the substance must be mentioned}. *We are in constant dialogue with our suppliers in order to gather further information."*

The following additional phrase may be added, if relevant:

"Information on the safe use of the article is available ... {to be completed}"

Further information on the substances present in article and subject to Article 33.1 REACH may be provided on a voluntary and case by case basis. It may also be subject to contractual arrangements.

Alternatively, if the article does not contain substances included in the candidate list above a concentration of 0.1% w/w, the following phrase may be used on a voluntary basis:

"The article contains none of the substances included in the candidate list published on 28 October 2008 on http://echa.europa.eu/chem_data/candidate_list_table_en.asp *above a concentration of 0.1% weight by weight".*

Suppliers of articles have to adapt their communication:

- If new information is made available to them from upstream suppliers for example.
- If an updated version of the candidate list is published.

Electronic communication of information according to Article 33 REACH

The communication of information via an electronic format may be used, based on already existing data exchange formats.

IEC PAS 61906:2005 "procedure for the declaration of materials in products of the electrotechnical and electronic industry" defines a process to provide information about materials in (hardware) products (articles).

We recommend using the IEC PAS 61906:2005 for the electronic communication of data according to Article 33 REACH. The IEC PAS is available here:
http://webstore.iec.ch/webstore/webstore.nsf/artnum/034398

For more details, please check
Articles 33, 57 and 59 REACH
ECHA Guidance on requirements for substances in articles (May 2008)

5.13. Guideline 13: Authorisation procedure

A manufacturer, importer/the "only representative of a non-Community manufacturer" (that is, the exclusive representative) or downstream user (hereafter called "DU") needs an authorisation to place on the market or to use a substance of very high concern on its own, in preparation or incorporated into an article, which has been included in Annex XIV REACH (Article 56.1 REACH).

However, using or placing the substance subject to authorisation on the market may continue as long as the so called "sunset date", has not been reached. The sunset date is the date(s) from which the placing on the EU market and the use of the substance shall be prohibited unless an authorisation has been granted. The sunset date should take into account, where appropriate, the production cycle specified for that use. The sunset date is specified in Annex XIV REACH.

If the sunset date has been reached, but the request for an authorisation has been received at least 18 months before this date and the decision to grant the authorisation is still pending, then the use of that substance is allowed to continue (Article 58.1 REACH).

There is no tonnage threshold for a substance to be subject to authorisation. Authorisation procedures therefore apply independently from any volume bands.

NOTE:

- **DU may use a substance subject to authorisation provided that they use the substance in accordance with the conditions of authorisation granted to an actor up the supply chain for that use** (Article 56.2 REACH).

- DU shall notify the ECHA within three months of first supply of the substance if they use this substance in accordance with the authorisation granted for that use (Article 66.1 REACH).

- Uses and categories of uses may be exempted from authorisation if, on the basis of existing community legislation imposing minimum requirements related to the protection of human health and the environment for the use of the substance, the risk is properly controlled (Article 58.2 REACH). Use and exposure exempted, if any, and the conditions for such exemption, if any, shall be listed in Annex XIV REACH (Article 58.1 REACH).

Exemptions to authorisation (see also further exemptions in Orgalime guideline 2)

No application for an authorisation is required for a substance listed in Annex XIV REACH which is used in scientific research and development (PPORD). Such substances used for PPORD shall be specified in Annex XIV REACH as well as maximum quantity exempted (Article 56.3 REACH).

The following uses are exempted (Article 56.4 REACH):

- Uses in plant protection products within the scope of Directive 91/414/EEC.
- Uses in biocidal products within the scope of Directive 98/8/EC.
- Use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels.
- Uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.

Under specific conditions, the following uses are exempted (Article 56.5 REACH):

- Uses in cosmetic products within the scope of Directive 76/768/EEC.
- Uses in food contact materials within the scope of Regulation (EC) N°1935/2004.

Further exemptions include the use of substances when they are present in preparations (Article 56.6 REACH):

- For substances referred to in Article 57(d), (e) and (f) REACH, below a concentration limit of 0.1 % weight by weight.
- For all other substances, below the lowest of the concentration limits specified in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC which result in the classification of the preparation as dangerous.

Inclusion of substances in Annex XIV REACH

a) Establishment of the candidate list

The Agency shall establish and publish a candidate list **for potential inclusion of substances of very high concern in Annex XIV**, that is:

(a) Substances meeting the criteria for classification as carcinogenic, mutagenic, toxic for reproduction ("CMR-substances") category 1 or 2.
(b) Substances which are persistent, bioaccumulative and toxic according to Annex XIII REACH ("PBT-substances").
(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.

Before including a substance in the candidate list, the Commission may ask ECHA to prepare a dossier in accordance with Annex XV REACH. Any member State may also prepare an Annex XV Dossier. The dossier may be limited to a reference to an entry in Annex I of Directive 67/548/EEC (Article 59.3 REACH). ECHA shall publish a notice on its website that an Annex XV dossier has been prepared**. ECHA shall invite all interested parties to submit comments within a specific deadline to ECHA** (Article 59.4 REACH).

Within 60 days of circulation, ECHA or other MS may comment on the identification of the substance. If no comments are received, ECHA shall include the substance in the candidate list. If comments are made, Annex XV dossier will then be referred by ECHA to a Member State Committee.

If Member States reach unanimous agreement, ECHA shall include the substance in the candidate list. If no agreement can be found, the final decision on the inclusion in the candidate list will be made by the Commission via comitology (regulatory procedure) referred to in Article 133.3 REACH [7] (Article 59.9 REACH).

b) Recommendation for a priority list for inclusion in Annex XIV

ECHA shall make its first recommendation of priority substances to be included in Annex XIV REACH by 1 June 2009. Priority shall be given to substances with "PBT" or "vPvB" properties, wide dispersive use or high volumes. ECHA shall make further recommendations at least every second year with a view to including further substances in Annex XIV REACH (Article 58.3 REACH).

[7] Please note that Decision 1999/468/EC setting up comitology rules, which is referenced in Article 133 REACH, has been amended by Council Decision 2006/512/EC of 17 July 2006, establishing a new regulatory procedure with scrutiny. In the context of REACH, whether the regulatory procedure applies with scrutiny or not, depends on a case by case basis.

Before ECHA sends its recommendation to the European Commission, it shall make it publicly available on its website. **ECHA shall invite all interested parties to submit comments within three months of the publication, in particular on uses which should be exempted from the authorisation requirement** (Article 58.4 REACH).

ECHA has published on its website its first recommendation for priority substances to be included in Annex XIV on 1 June 2009. The list is available at the following address: http://www.echa.europa.eu/doc/authorisation/annex_xiv_rec/annex_xiv_subst_inclusion.pdf.

c) Inclusion of the substance in Annex XIV REACH

Finally, the inclusion of a substance into Annex XIV REACH is subject to a decision, following comitology (regulatory procedure with scrutiny) referred to in Article 133.4 REACH (Article 58.1 REACH).

The supplier must inform the DU in the safety data sheet or in the information according to Article 32 that a substance on its own or in a preparation has been included in Annex XIV. Annex XIV will also be made available on the ECHA website.

Application for authorisation

Before applying for an authorisation, DU should first check whether an actor up the supply chain has applied for an authorisation for his use. If not, the application for an authorisation shall be made to ECHA. **Annex XIV REACH shall mention a date, or dates at least 18 months before the sunset date, by which applications must be received, if the applicant wishes to continue using the substance or place it on the market for certain uses after the sunset date** (Article 58.1 REACH).

The application may be made by the manufacturer(s), importer(s) and/or DU(s) of the substance and may be made by one or several persons, for one or several uses (Article 62 REACH). A fee has to be paid for each application (Article 62.7 REACH).

The application for authorisation shall include all relevant documentation, including *inter alia* an analysis of alternatives and where suitable alternatives are available, substitution plans including a timetable for proposed action by the applicant. Research and Development plans may also be part of the application, if appropriate (Article 62.4 REACH).

The application may include a socio-economic analysis and a justification for not considering risks to human health and the environments in specific cases (Article 62.5 REACH). The application shall not include the risks to human health arising from the use of substances in medical devices regulated by (Directive 90/385/EEC), (Directive 93/42/EEC) and (Directive 98/79/EC) (Article 62.6 REACH).

Granting of an authorisation

The European Commission is responsible for taking the decisions on applications for authorisation. An authorisation will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled (see also Annex I section 6.4 REACH). The “adequate control route” does not apply for substances for which it is not possible to determine thresholds and substances with “PBT” or “vPvB” properties. If it cannot be demonstrated that the risk is adequately controlled, an authorisation may still be granted, if it is proven that the socio-economic benefits outweigh the risks and no suitable alternative substances or technologies exist (Article 60 REACH).

Authorisation shall be subject to a time-limited review (without prejudice to any decision on a future review period), which shall be determined on a case-by-case basis. Annex XIV REACH shall include the review periods for certain uses if appropriate (Article 58.1 REACH). There is a possibility for third parties to give information on alternative substances or technologies

during the procedure for authorisation decisions (Article 64.2 REACH). The applicant also has an opportunity to give his arguments during the procedure for the authorisation decision (Article 64.5 REACH).

If you are a downstream user selling preparations, please also consider Article 65 REACH.

Review of an authorisation

The authorisation is regarded as valid until the European Commission decides to review it, provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time limited review period (see also Article 61 REACH).

For more details, please check
Title VII REACH
ECHA Guidance for Downstream Users (January 2008), ECHA Guidance for the Preparation of Annex XV Dossier on the Identification of Substances of Very High Concern (June 2007), RIP 3.7, *ECHA Guidance on Socio-Economic Analysis (May 2008)*

5.14. Guideline 14: Restriction procedure

Title VIII of the REACH Regulation foresees a restriction procedure for the manufacture, placing on the market and use of substances on their own, in preparations or in articles, which represent too high a risk for human health or the environment and which need to be addressed on a Community-wide basis.

If a DU uses a substance either on its own, in preparations or in articles, which is subject to a restriction, he is allowed to continue using it, only if he complies with the conditions of the restriction.

Restrictions are listed in Annex XVII REACH. Annex XVII initially includes the current marketing and use restrictions of Directive 76/769/EEC. As of 1 June 2009, Directive 76/769/EEC will be repealed.

Restrictions, whether new or amending an Annex XVII entry, take the shape of a Commission decision, which is adopted according to comitology (regulatory procedure with scrutiny). Decisions must take into account the socio economic impact of the restriction, including the availability of alternatives.

Exemptions to the restriction procedure (Article 67 REACH)

Restriction shall not apply to the manufacture, placing on the market or use of a substance:

- In scientific research and development.
- In PPORD if Annex XVII mentions it, as well as the quantities exempted.
- For the use of substances in cosmetic products, as defined by Directive 76/768/EEC, regarding restrictions addressing the risks to human health.

Preparation of a proposal for restriction (Article 69 REACH)

ECHA (at the request of the Commission) or any Member State may initiate a restriction procedure by compiling a so-called “Annex XV” dossier.

Member States have 12 months to prepare the dossier, from the date of notification to ECHA of their intention to prepare such dossier. ECHA will suggest a restriction within 12 months of the receipt of the request by the Commission.

ECHA has the duty to publish the Commission or Member State’s intention to launch a restriction procedure for a substance and has to inform those who submitted a registration dossier for that substance. ECHA will further maintain a list of substances for which an “Annex XV” dossier is underway or planned. No other restriction dossier on the same substance present on the list may be introduced.

Before suggesting a restriction, it has to be demonstrated in the dossier that the risk is not adequately controlled and requests action on a Community–wide basis, beyond measures already in place.

The dossiers conforming with Annex XV REACH and suggested restrictions must further be made publicly available on the ECHA website (without prejudice to Article 118 and 119 REACH, that is protection of confidential business information). Interested parties are invited to submit within 6 months of the publication:

a) Comments on dossiers and suggested restrictions.
b) A socio economic analysis or information contributing to the suggested restrictions, providing input on the advantages and drawbacks of proposal. It must conform to the requirements in Annex XVI REACH.

ECHA committees' opinions (Articles 70 and 71 REACH)

The Committee for Risk Assessment, within 9 months of the publication of the suggested restriction, has to provide an opinion as to whether the suggested restriction will appropriately reduce the risk to human health and the environment. In its opinion, the Committee must take into account the Annex XV dossier and the views of interested parties.

Within 12 months of the publication of the suggested restriction, the Committee for Socio Economic Analysis also has to formulate an opinion on it, based on the socio economic impact and socio economic analysis or information provided by interested parties. ECHA must publish the draft opinion of the Socio Economic Analysis Committee on its website and invite interested parties to submit comments no later than 60 days from the publication of the draft opinion.

If the opinion of the Risk Assessment Committee diverges significantly from the suggested restriction, ECHA has the possibility to postpone the deadline for the opinion of the Committee for Socio Economic Analysis by a maximum of 90 days.

Once finalised, ECHA will publish the opinion of the two committees (without prejudice to Article 118 and 119 REACH) on its website without delay.

Commission Decision

The Commission has the duty to prepare a draft amendment to Annex XVII REACH in the form of a Commission Decision within three months of the reception of the opinion of the Committee of Socio Economic Analysis or by the end of the deadline established in Article 71 REACH if that Committee does not form an opinion. A final Decision will be taken according to the comitology (regulatory procedure with scrutiny) following Article 133.4 REACH. The draft amendment must be sent to Member States at least 45 days before voting. The Commission must provide explanation if the draft amendment diverges from the original proposal or does not take the opinions of the committees into account.

Restriction procedure in summary

WHO	WHAT	WHEN
MS	Preparation of Annex XV dossier (to be completed within 12 months of date of notification to ECHA)	From 1 June 2009
ECHA on request of COM	Preparation of Annex XV dossier (within 12 months of request of COM)	From 1 June 2009
ECHA	To maintain a register of Annex XV dossiers planned or underway	
ECHA	To publish on ECHA website Annex XV dossier and proposed restriction	
Interested parties	To submit comments on dossier or socio economic analysis	Within 6 months of publication on ECHA website
Committee for Risk Assessment (RAC)	To provide an opinion	Within 9 months of publication on ECHA website
Committee for Socio Economic Analysis (SEAC)	To provide an opinion	Within 12 months of publication on ECHA website
ECHA	To publish the draft opinion of SEAC	
Interested parties	To submit comments on draft SEAC opinion (upon invitation by ECHA)	No later than 60 days from the publication of draft opinion
ECHA	To possibly postpone deadline for opinion of SEAC	Maximum of 90 days
ECHA	To publish on ECHA website final opinion of RAC and SEAC	Without delay

COM	Preparation of amendment to Annex XVII	Within 3 months of reception of SEAC opinion or by the end of deadline set in Article 71

NOTE:

- In June 2009, Annex XVII REACH has been amended for the first time. The Commission Regulation 552/2009 of 22 June 2009 is available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:EN:PDF. Further amendments are pending.

- The Commission cannot grant an authorisation for a restricted use, if the authorisation would mean a relaxation of that restriction (Article 60.6 REACH).

- As soon as a substance has been included in Annex XIV REACH, it cannot be subject to new restrictions (Article 58.5 REACH).

- However, after the inclusion of a substance in Annex XIV REACH, substances in articles can be subject to a restriction if ECHA considers that the use of the substance in article causes a risk for human health or the environment, which is not adequately controlled (Article 69.2 REACH).

- CMR substances category 1 and 2 for which a restriction to consumer use has been proposed by the Commission, do not require the compilation of an "Annex XV" dossier. Restriction of these substances for that specific use will be directly subject to comitology (regulatory procedure with scrutiny) (Article 68.2 REACH).

- Member States may keep existing restrictions, which are more stringent until 1 June 2013. The Commission will compile and publish an inventory of these restrictions by 1 June 2009 (Article 67.3 REACH).

For further details, please check
ECHA Guidance for the Preparation of an Annex XV Dossier for Restrictions (June 2007),
ECHA Guidance on Socio-Economic Analysis (May 2008)

5.15. Guideline 15: Implementing legislation on selected issues

This guideline provides an overview of implementing legislation foreseen in REACH on selected issues, whether adopted or in preparation. This guideline also includes information on the review of REACH Annexes. It reflects current state of play of the implementation process and will require update as the legislative process progresses.

Adopted legislation

COMMISSION REGULATION (EC) No 1238/2007 of 23 October 2007 on laying down rules on the qualifications of the members of the Board of Appeal of the European Chemicals Agency. It is available at:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:280:0010:0010:EN:PDF.

COMMISSION REGULATION (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). It is available at:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:107:0006:0025:EN:PDF.

COMMISSION REGULATION (EC) No 440/2008 of 30 May 2008 on laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). It is available at:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:142:0001:0739:EN:PDF.

COMMISSION REGULATION (EC) No 771/2008 of 1 August 2008 laying down the rules on the organisation and procedure of the Board of Appeal of the European Chemicals Agency. It is available at:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:206:0005:0013:EN:PDF.

The Commission is supported by a Regulatory Committee composed of representatives of all Member States in the context of comitology procedure.

Review of REACH Annexes

According Article 138.4 REACH, the Commission must carry out a review of Annexes I, IV and V by 1 June 2008 with a view to proposing amendments, if appropriate under comitology (regulatory procedure with scrutiny).

COMMISSION REGULATION (EC) No 987/2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex IV and V is available here:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:268:0014:0019:EN:PDF

According Article 138.5 REACH, the Commission must carry out a review of Annex XIII by 1 December 2008 to assess the criteria for indentifying substances which are PBT, vPvB with a view to proposing an amendment to it, if appropriate under comitology (regulatory procedure with scrutiny).

COMMISSION REGULATION (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII is available at:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:EN:PDF

More information on the review of REACH Annexes (I, IV, V, XI, XIII, and XVII) can be found at: http://ec.europa.eu/enterprise/reach/com_reviews_en.htm.

5.16. Guideline 16: List of ECHA guidance documents, finalised or under finalisation - REACH Implementation Projects (RIPs)

ECHA Guidance Documents and IT-tools are the outcome of RIPs (REACH Implementation Projects), which have been developed for ECHA, industry and the authorities by the European Commission, JRC in collaboration with stakeholders.

ECHA Guidance Documents which are finalised are named according to their specific title and no longer referenced with their former RIP number. Draft Guidance Documents, which are still under development, however, are referred to according to their RIP number.

NOTE:
ECHA Guidance Documents and RIPs are not legally binding.
ECHA is in the process of launching the update of selected ECHA guidance documents as well as developing new guidance documents. Further information is available here: http://guidance.echa.europa.eu/guidance4_en.htm

Finalised ECHA Guidance Documents are listed below.
They are also available at: http://guidance.echa.europa.eu/

- **ECHA Guidance for Downstream Users (January 2008)**
  Description of the roles and obligations of downstream users, and advises them on how to prepare for the implementation for REACH.
  http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm?time=1243501435

- **ECHA Guidance on Registration (May 2008 – Updated November 2008)**
  Description of when and how to register a substance under REACH.
  http://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm?time=1243335990

- **ECHA guidance on pre-registration**
  Description of how to identify the substances that can be pre-registered as well as when and how to pre-register them.
  http://guidance.echa.europa.eu/03_rdds_web_content/pre-registration_en/pre-registration_en.pdf?time=1253622660

- **ECHA Guidance on Requirements for Substances in Articles (May 2008)**
  Description of how producers and importers of articles can identify whether they have obligations under REACH, in particular in relation to registration and notification according to Article 7, and in relation to article supply chain communication according to Article 33.
  http://guidance.echa.europa.eu/docs/guidance_document/articles_en.htm?time=1243501416

- **ECHA Guidance on Data Sharing (September 2007)**
  Description of data sharing mechanisms for phase-in and non phase-in substances under REACH. It includes the communication within the SIEF and the cost sharing guidance. The document also describes the Confidential Business Information and Competition Law issues in the context of data sharing.
  http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.htm?time=1243336177

- **ECHA Guidance for Identification and Naming of Substances under REACH (June 2007)**
  Description of how to name and identify a substance under REACH.
  http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.htm?time=1243336295

- **ECHA Guidance for Intermediates (February 2008)**
  Description of when and how the specific provisions for the registration of intermediates under REACH can be used.
  http://guidance.echa.europa.eu/docs/guidance_document/intermediates_en.htm?time=1243336196

- **ECHA Guidance for Monomers and Polymers (May 2008)**
  Description of the specific provisions for polymers and monomers under REACH.
  http://guidance.echa.europa.eu/docs/guidance_document/polymers_en.htm?time=1243336231

- **ECHA Guidance on Product and Process Oriented Research and Development (PPORD) (February 2008)**
  Description of specific provisions under REACH for substances manufactured, imported or used in Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD).
  http://guidance.echa.europa.eu/docs/guidance_document/ppord_en.htm?time=1243501130

- **ECHA Guidance on IUCLID (June 2007)**
  Description of how to use IUCLID 5 and how to prepare the dossiers for different REACH requirements.
  http://guidance.echa.europa.eu/docs/guidance_document/iuclid_en.htm?time=1243501168

- **ECHA Guidance on Dossier and Substance Evaluation (June 2007)**
  Description of the evaluation tasks to be performed by the Authorities: evaluation of testing proposals and compliance check by ECHA and substance evaluation by the Member States Competent Authorities.
  http://guidance.echa.europa.eu/docs/guidance_document/evaluation_en.htm?time=1243501207

- **ECHA Guidance for the Preparation of an Annex XV Dossier on Harmonised Classification and Labelling (June 2007)**
  Description of how Member States Competent Authorities can prepare an Annex XV dossier for a Harmonised Classification and Labelling proposal under REACH.
  http://guidance.echa.europa.eu/docs/guidance_document/harmonised_classification_en.htm?time=1243501268

- **ECHA Guidance for the Preparation of an Annex XV dossier on the Identification of Substances of Very High Concern (June 2007)**
  Description of how the authorities (Member States Competent Authorities or ECHA) can prepare an Annex XV dossier to identify a substance of very high concern.
  http://guidance.echa.europa.eu/docs/guidance_document/svhc_en.htm?time=1243501240

- **ECHA Guidance for the Preparation of an Annex XV Dossier for Restrictions (June 2007)**
  Description of how the authorities (Member States Competent Authorities or ECHA on request from the Commission) can prepare an Annex XV dossier to propose a restriction under REACH.
  http://guidance.echa.europa.eu/docs/guidance_document/restriction_en.htm?time=1243501296

- **ECHA Guidance on Socio Economic Analysis (May 2008)**
  Description of how the different actors can prepare a socio-economic analysis or input as part of the Authorisation and Restriction procedures.
  http://guidance.echa.europa.eu/docs/guidance_document/sea_restrictions_en.htm?time=1243501338

- **ECHA Guidance on Information Requirements and Chemical Safety Assessment (May 2008)**
  Description on how actors can collect and assess the available information on the intrinsic properties of the substances to be registered, on the requirements specified by REACH, on the identification of data gaps and on the generation of the additional information required to comply with the Regulation. It also aims at assisting industry in conducting Chemical Safety Assessments and preparing Chemical Safety Reports, when required, as part of a registration dossier (for a substance on its own or as part of a preparation or as released from an article), as part of an authorisation application or as part of downstream user obligations. It also sets out the basic principles for authorities preparing a risk assessment in support of a restriction proposal or a proposal to include substances into the authorisation regime, and when required as part of a Substance Evaluation.
  http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1243501382

- **Guidance on Inclusion of Substances in Annex XIV (substances subject to Authorisation) (August 2008)**
  Description of how the authorities (ECHA in co-operation with the Member States Competent Authorities) will include substances in the authorisation system. Guidance is given on the elaboration of the dossier that supplements each recommendation of a substance for inclusion in Annex XIV.
  http://guidance.echa.europa.eu/docs/guidance_document/annex_xiv_en.htm?time=1243502032

- **Guidance on Priority Setting for Evaluation (August 2008)**
  Aim: Description of the different priority setting methods developed to prioritise dossiers, testing proposals or substances for evaluation and gives guidance for ECHA and the Member States Competent Authorities on the application of these methods.
  http://guidance.echa.europa.eu/docs/guidance_document/prioritisation_evaluation_en.htm?time=1243501994

Guidance documents under finalisation are the following. Further information is available at: http://ecb.jrc.it/reach/rip/

- **RIP 3.6: DRAFT Guidance on Classification, Packaging and Labelling**
  Aim: Assisting industry and authorities to implement the new GHS criteria within the EU which are based on the UN Globally Harmonised System for the Classification and Labelling of chemicals (GHS) and to fulfil the relevant procedures.

- **RIP 3.7: DRAFT Guidance on the Preparation of an Application for Authorisation**
  Aim: Description of how to prepare an application for authorisation and provides guidance on analysis of the alternatives and substitution plan. It also describes how third parties may prepare and submit information on alternatives.

5.17. Guideline 17: Helpdesks and tools of EU and national authorities

According to Article 124 REACH, Member States are required to set up REACH helpdesks in their Member State (see list below, which will be updated as REACH implementation progresses). National helpdesks are built into an EU wide cooperation network coordinated by ECHA that meets regularly in order to discuss and coordinate REACH implementation issues. ECHA has set up a specific helpdesk. The European Commission has further developed helping tools. You will find the link to these helpdesks and tools below.

ECHA (European Chemicals Agency)

The link to the ECHA website is: http://echa.europa.eu/home_en.asp

ECHA has developed an IT-tool to help industry determine its obligations under REACH, called *"Navigator"*. It is available at: http://reach.jrc.it/.

ECHA *"Frequently Asked Questions on REACH by industry"* are available at: http://echa.europa.eu/doc/reach/reach_faq.pdf (29 June 2009)

ECHA has an own-run helpdesk. It is available at: http://echa.europa.eu/help/echahelp_en.asp

To assist with chemical data management and registration submission under REACH, ECHA is finalising two software tools:

- **REACH IT**
  Information is available at: http://echa.europa.eu/reachit_en.asp
- **IUCLID 5**
  Information is available at: http://echa.europa.eu/reach/software/iuclid5_en.asp and http://iuclid.echa.europa.eu/

European Commission helping tools

DG Enterprise webpages on REACH: http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm

DG Environment webpages on REACH: http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

"Question and Answers on REACH" http://ec.europa.eu/environment/chemicals/pdf/qa.pdf

"REACH in brief" http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf

List of national helpdesks (to be completed according to developments at national level)

ECHA also published the list of national helpdesk, available at: http://echa.europa.eu/help/nationalhelp_contact_en.asp

AUSTRIA
Website: www.reachhelpdesk.at
E-Mail: Office@reachhelpdesk.at
Phone: +43 1 31 00 472

ESTONIA
Gonsiori 29
Website: www2.sm.ee/reach/
E-Mail: reach@sm.ee

BELGIUM
FPS Economy – REACH Helpdesk
Rue du Progrès, 50
B-1210 Brussels
Website:
mineco.fgov.be/organization_market/reach/ home_fr.htm
E-Mail : reachinfo@economie.fgov.be
Phone: +32 800 120 33
Fax: +32 2 277 53 04

BULGARIA
67, W. Gladstone Str.
Sofia 1000
Website: www.chemicals.moew.government.bg
E-Mail: reachhelpdesk@moew.government.bg
Fax: + 359 2 980 33 17

CYPRUS
Department of Labour Inspection
CY-1493, Nicosia
Website: Greek: www.mlsi.gov.cy/dli
English:
www.mlsi.gov.cy/mlsi/dli/dli.nsf/dmlindex_en/dmlindex_en
E-Mail: reach@dli.mlsi.gov.cy
Phone: +357 22405609 | +357 22405608
Fax: +357 22663788

CZECH REPUBLIC
CENIA
Kodanska 10, 100 10 Prague 10
Website: www.cenia.cz/reach
E-Mail: jaroslav.zich@cenia.cz - jan.kolar@cenia.cz
Phone: +420 267 225 315 | +420 267 225 323
Fax: +420 271 742 306

DENMARK
Frontlinien
Rentemestervej 8
DK - 2400 Copenhagen NV
Website: www.reachhelpdesk.dk - www.mst.dk
E-Mail: frontlinien@frontlinien.dk
Phone: + 45 7012 0211

ICELAND
Environment Agency of Iceland
Suðurlandsbraut 24 ;108 Reykjvik
Website: www.ust.is/efniogefnavorur/REACH/
E-mail: ust@ust.is
Phone: +354 591 2000
Fax: +354 591 2010

IRELAND
Health and Safety Authority
Metropolitan Building
James Joyce Street, Dublin 1
Website: www.reachright.ie
E-Mail: reachright@hsa.ie
Phone: +353 1890289389
Fax: +353 1 6147125

FINLAND
Finnish Environment Institute and the National Product Control Agency for Welfare and Health
P.O.Box 210
00531 Helsinki
Website: www.reachneuvonta.fi
Phone: +358 400 393 033 during office hours and +358 40 590 4141 on working days from 9 to 12 a.m. or through a contact form found in the website.

The website www.reachinfo.fi may also be consulted. It is maintained by the Advisory Committee on Chemicals, which consists of authorities and industry representatives.

FRANCE
BERPC
62 rue d'Hauteville 75010 PARIS
Website: www.reach-info.fr
E-Mail: reach-helpdesk@berpc.fr
Phone: +33 1 55 07 89 89
Fax: +33 1 47 70 63 13

GERMANY
BAuA – Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
Federal Institute for Occupational Safety and Health
Friedrich-Henkel-Weg 1 – 25
D-44149 Dortmund
Website: www.reach-helpdesk.de
E-Mail: reach-info@baua.bund.de
Phone: +491803243643
Fax: +491803243644

GREECE
16, An. Tsocha str.
Website: www.gcsl.gr
E-Mail: elhelpdesk@ath.forthnet.gr
Phone: +30 210 64 79 407
Fax: +30 210 64 66 917

HUNGARY
National Institute of Chemical Safety
H-1096 Budapest, Nagyvárad tér 2
Website: www.okbi.hu/reach/
E-Mail: csengody.krisztina@okbi.antsz.hu
Phone: +36 1 476 11 84
Fax: +36 1 476 12 27

NETHERLANDS
Ministery of Housing spatial planning and the environment (VROM)
Postbox 20951 , 2500 EZ The Hague
Website: www.REACH-Helpdesk.nl
E-Mail: Info@REACH-Helpdesk.nl
Phone: +31 70 3735905

ITALY
Ministry of economic development
Via Veneto, 33
Roma
Website: www.helpdesk-reach.it
E-Mail: info@helpdesk-reach.it

LATVIA
Latvian Environment, Geology and Meteorology Agency (LEGMA)
Chemicals Department
Maskavas iela 165
Riga, LV-1019
Website: http://www.lvgma.gov.lv - http://www.lvgma.gov.lv/chemical/
E-Mail: REACH@lvgma.gov.lv
Phone: +371 67146138
Fax: +37167145154

LIECHTENSTEIN
Office of Environmental Protection
Dr. Grass-Str. 12
Postfach 684 , 9490 Vaduz
Website: www.reach-helpdesk.llv.li
E-mail: reach@aus.llv.li
Phone: +423 236 61 95

LITHUANA
A. Juozapaviciaus str. 9, LT-09311
Vilnius
Website: www.infochema.lt
E-Mail: reach@aaa.am.lt
Phone: +3705 212 6097
Fax: +3705 266 2800

LUXEMBOURG
CRTE/CRP Henri Tudor
Helpdesk REACH
66, rue de Luxembourg
B.P. 144
L-4002 Esch-sur-Alzette
Website: www.reach.lu
E-Mail: reach@tudor.lu
Phone: +352 42 59 91 600
Fax: +352 42 59 91 555

MALTA
Malta Standards Authority
2nd Floor Evans Building, Merchants Street
Valletta
Website: www.msa.org.mt
E-Mail: ingrid.borg@msa.org.mt
Phone: +356 21 242420
Fax: +356 21 242406

NORWAY
Norwegian Pollution Control Authority
P.O. Box 8100, Dep.
0032 Oslo
Website: http://www.sft.no
http://www.sft.no/seksjonsartikkel____41633.aspx
E-mail: reach@sft.no
Phone: +47 22 57 34 00

POLAND
Bureau for Chemical Substances and Preparations
Sw. Teresy 8
91-348 Lodz
Website: www.reach.gov.pl
E-Mail: helpdesk@reach.gov.pl
Phone: +48 42 6314 722 | +48 42 6314573
Fax: +48 42 6314 679

PORTUGAL
Direcção-Geral das Actividades Económicas
Avenida Visconde de Valmor, n.72
1069-041 Lisboa
Website:http://www.reachhelpdesk.pt
E-mail:reach@dgae.min-economia.pt

ROMANIA
National Agency for Dangerous Substances and Preparations (NADSP)
36-38 MENDELEEV STREET, FLOOR: 7,
DISTRICT: 1
010366 BUCHAREST
Website: www.anpm.ro
E-Mail: helpdesk.reach@anspcp.ro
Phone: +40 21 316 79 94
Fax: +40 21 316 79 96

SLOVAKIA
Centre for Chemical Substances and Preparations
Mierova 19, 827 15 Bratislava
Website: http://reach.ccsp.sk
E-Mail: chemicals@cchlp.sk
Fax: +421 2 4854 4555

SLOVENIA
National Chemicals Bureau
Mali trg 6, SI-1000 Ljubljana
Website: www.mz.gov.si
E-Mail: blaz.omahen@gov.si
Phone: +386 1 478 6290
Fax: +386 1 478 6053

SPAIN
CENTRO REFERENCIA REACH
Parque Científico
Edificio ZYE, 1ª planta
UNIVERSIDAD DE ALCALÁ
28871-Alcalá de Henares
Madrid
Website: www.reach-pir.es
E-Mail: tarazona@inia.es - info@reach-pir.es
Phone: +34 91 877 24 70 | +34 901 00 00 25
Fax: +34 91 347 40 08

SWEDEN
Swedish Chemicals Agency
P.O Box 2, SE 172 13 Sundbyberg
Website: www.kemi.se/reach - www.kemi.se/reach_en
E-Mail: reach@kemi.se
Phone: +46 8 519 41 345

UNITED KINGDOM
REACH UK CA Help Desk
Health and Safety Executive
2.3 Redgrave Court, Merton Road
L20 7HS Bootle, Merseyside
Website: www.hse.gov.uk/reach/
E-Mail: UKREACHCA@hse.gsi.gov.uk
Phone: +44 84 54 08 95 75

5.18. Guideline 18: Industry-run guidance and helpdesks on REACH implementation (non exhaustive list)

DI (Confederation of Danish Industries)
http://www.reach-klarbesked.dk

WSM (Wirtschaftsverband Stahl- und Metallverarbeitung e.V.)
www.wsm-net.de

BDI (Bundesverband der Deutschen Industrie)
http://www.bdi-online.de/de/fachabteilungen/7240.htm

CEFIC (European Chemical Industry Council)
http://www.reachcentrum.org/

CEPI (Confederation of European Paper Industries)
www.cepi.org

EUROMETAUX (European Association of Metals)
http://www.eurometaux.org/

Automotive Industry Guidelines
www.acea.be

ASD (Aerospace and Defence Industries Association of Europe)
http://www.asd-europe.org/Content/Default.asp?PageID=41

01.06.2007 | 01.06.2008 | 01.12.2008 | 01.01.2009 | 01.06.2009 | 30.11.2010 | 01.06.2011 | 31.05.2013 | 31.05.2018

As of 01.06.2007: REACH enters into force

Title IV « Information in the supply chain » applies

Start preparing for REACH NOW!

Check Orgalime quick screens 1, 2, 3, 4 (which are COMPLEMENTARY) and perform follow up actions as described:

- **Orgalime quick screen 1 for use of substances/ preparations in industrial processes**
- **Orgalime quick screen 2 for authorisation procedures**
- **Orgalime quick screen 3 for registration of substances in articles**
- **Orgalime quick screen 4 for notification of substances in articles**

IMPORTANT NOTES

1)Downstream users may only use substances on their own/in preparations which have been registered after registration deadline/ authorised for their uses after sunset date

2) No notification/registration of substances in articles is necessary if substance is already registered for that use (Art. 7.6)

between 01.06.08 and 01.12.08: manufacturer/ Importer of a substance on its own, in preparations/**articles intentionally releasing substance (Art.7.1)** to PRE-REGISTER **substances above 1 t/y**
No pre-registration means no transition periods for registration (Art.28)

As of 01.06.08 until 30.11.2010: manufacturer/ importer of a substance on its own or in preparations/ **articles intentionally releasing substance** (Art.7.1) **to REGISTER** phase-in substances which are CMR cat. 1 and 2 above 1t/y
- R50/53 above 100t/y
- Other above 1000t/y (Art. 23.1)

As of 01.06.08 until 31.05.2013: manufacturer/importer of a substance on its own or in preparations/**articles intentionally releasing substance** (Art. 7.1) **to REGISTER** phase-in substances above 100t/y (Art. 23.2)

As of 01.06.08 until 31.05.2018: manufacturer/importer of a substance on its own or in preparation/**articles intentionally releasing substance** (Art. 7.1) **to REGISTER** phase-in substances above 1t/y (Art. 23.3)

As of 01.06.08: manufacturer/importer of non phase-in/not pre-registered substance on its own/in preparations/article intentionally releasing substance (art. 7.1) is required to REGISTER substance BEFORE manufacturing /importing/putting on the market such substance (Art. 5)

By 01.01.09: Publication of pre-registered phase-in substances on Agency website (Art. 28.4)

Downstream users to comply with Article 37 (*i.a.* communicate with supplier / identify and apply risk management measures) at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet (Art. 39)

- **As of 01.06.08 : entry into force of procedures establishing candidate list for authorisation (Art. 59)**
- **Manufacturer/importer/downstream user to apply for authorisation for substances added to Annex XIV (Art. 55 ff)**

As soon as substance present in articles included in candidate list and present in concentration above 0.1% w/w : article supplier to provide information available to him to allow safe use (at least name of substance) to article recipient/customer upon request (Art. 33)

As of 01.06.09: Title VIII on « Restrictions » applies

By 01.06.09: first recommendation for priority substances for authorisation by Agency (Art. 58.3)

Downstream user using a substance authorised for his use up the supply chain has to NOTIFY the Agency within three months of first supply of the substance (Art. 66)

As of 01.06.2011: Article producer/importer to NOTIFY substances present in articles in quantity over 1 tonne per year, per producer/importer and present in concentration above 0.1% weight by weight, 6 months after the substance is put on candidate list for authorisation (Art. 7.2)
- **If no exposure (no notification needed) but instructions to be provided to recipient (Art. 7.3)**

ANNEX A: Orgalime model letter for structuring communication between engineering companies and upstream suppliers: pre-registration and registration of substances on their own, in preparations or in articles

(Letter to be adapted according to your company's needs)

Date

Object: REACH Regulation N°1907/2006[1]

Dear Supplier,

The European "REACH" Regulation N°1907/2006 on the Registration, Evaluation, Authorisation and restriction of Chemicals entered into force on 1 June 2007. While setting new rules for the management of chemical substances, REACH leads to the need for more communication between customers and suppliers on the substances, preparations and articles they buy and sell. Given the new legal requirements, we are writing to you to request some information about substances on their own, in preparations, and in articles that you supply to us, in order to allow us to fulfil our legal obligations under REACH.

You will therefore find enclosed in this letter our requests concerning:

1. Your policy towards pre-registration and registration of substances on their own, in preparations or intentionally released from articles. **To ensure smooth continuity of business, our common interest is that all substances on their own and/or in preparations and/or intentionally released from articles that you supply to us are pre-registered (between 1 June and 1 December 2008) and then registered.**
2. For our suppliers outside the European Union (EU), whom you have or will nominate as your "only representative" in the EU, fulfilling the obligations of importers under REACH.
3. Details of the contact person responsible for REACH issues.

These requests are detailed in Attachment 1 of this letter. To facilitate communication, we would suggest that you use the model questionnaire outlined in Attachment 2 to respond. You will also find some background information about REACH in Attachment 3.

If you are not in a position to answer our requests, would you please forward this letter to your upstream suppliers acting as registrants/having the requested information available and inform us as soon as possible, preferably by *(to be completed)*

Please note that this is a first communication letter that will be followed by further requests regarding the inclusion of our uses/brief description of uses in your registration dossier. We will also request information on substances of very high concern present in articles at the latest when the candidate list is available with a view to accomplishing our legal obligations under REACH. In order to prepare for this, we kindly ask you to already forward to us now any information on substances of very high concern you may have. In case of authorisation procedure for a substance of very high concern that we are using, information will follow.

Please return the requested information to: *(name of company sending the letter)*

We thank you for your time and hope to hear from you soon.

Yours sincerely,

(*Signature*)

[1] For more information on REACH, please consult the Orgalime practical guide to understanding REACH, downloadable free of charge at the following address: http://publications.orgalime.org.

Attachment 1: Our requests

Please complete the following information. You may use the model questionnaire attached.

1. Information on pre-registration and registration

You can understand that we need to ensure supply continuity of the input we use, to anticipate possible changes of the substance or preparation we use, as well as process re-approval. For these reasons, **we kindly ask you to answer the following questions:**

- Your roles as ***e.g.*** manufacturer (M), importer (I), distributor (D), downstream user (DU) (including formulators), article supplier (AS) according to the definitions in REACH with regard to the substance/preparation/article you supply to us.

- **If you are the registrant**, we need to know whether you intend to pre-register and register the substance on their own, in preparations or intentionally released from articles that you supply to us.

- **If you are not the registrant**, we need to know whether **all** substances on their own, and/or **all** substances in preparations and/or **all** substances intentionally released from articles that you supply to us are intended to be **pre-registered and registered by an actor up the supply chain**. In case you do not have the information available yet, please inform us by when it will be available (day/month/year). Please also inform us about the registrant's identity.

- **If there is no intention to pre-register or register a specific substance, we wish to know if the production and/or commercialisation of the substance or preparation/article containing that substance is to be abandoned, or the composition changed. Please fill in the column "remarks" in the table in Attachment 2**.

2. Suppliers outside the EU

REACH only applies to European Union (EU) based legal entities. If you are a manufacturer, formulator of preparations, producer of articles **who exports into the European Union, we recommend that you appoint an** "**only representative of a non Community manufacturer**" **(that is an exclusive representative) established in the EU**, according to Article 8 of the REACH Regulation. Your only representative will carry out the importers' required REACH obligations. **Please let us know whom you have appointed as your "only representative" and forward this letter to him. Thank you.**

3. Contact details of the contact person for REACH issues in your company

For more information on REACH, please consult the Orgalime practical guide to understanding REACH, downloadable free of charge at the following address: http://publications.orgalime.org.

Attachment 2: Questionnaire to be completed by supplier and returned to: (*coordinates of company sending the letter*)

1. Information on pre-registration and registration

Table to be completed by EU suppliers/only representatives of non EU supplier <u>of substances on their own</u>

Name of substance	EINECS or CAS number	Supplier's code	Role In the supply chain	**If you are the registrant** will you **pre-register** the substance? (yes/no)	**If you are the registrant** will you **register** the substance? (yes/no)	**If you are not the registrant**: will the substance be **pre-registered** up the supply chain? /Information available by (day/month/year) Registrant's identity?	**If you are not the registrant**: will the substance be **registered** up the supply chain? /Information available by (day/month/year) Registrant's identity?	Remarks
xxx								
xxx								

Table to be completed by EU suppliers/only representatives of non EU supplier <u>of preparations</u>

Name of prepa-ration	Supplier 's code	Role In the supply chain	**If you are the registrant** will you **pre-register ALL** substances in preparations? (yes/no)	**If you are the registrant** will you **register ALL** substances in preparations? (yes/no)	**If you are not the registrant** will **ALL** substances in preparations be **pre- registered** up the supply chain? / Information available by (day/month/year) Registrant's identity?	**If you are not the registrant** will **ALL** substances in preparations be **registered** up the supply chain? / Information available by (day/month/year) Registrant's identity?	Remarks
xxx							
xxx							

Table to be completed by EU suppliers /only representatives of non EU supplier <u>of articles intentionally releasing substances</u>

Name of article	Supplier's code	Role In the supply chain	**If you are the registrant** will you **pre-register ALL** substances intentionally released from articles? (yes/no)	**If you are the registrant** will you **register** ALL substances intentionally released from articles? (yes/no)	**If you are not the registrant** will ALL substances be **pre-registered** up the supply chain? /Information available by (day/month/year) Registrant's identity?	**If you are not the registrant** will ALL substances be **registered** up the supply chain? /Information available by (day/month/year) Registrant's identity?	Remarks
xxx							
xxx							

For more information on REACH, please consult the Orgalime practical guide to understanding REACH, downloadable free of charge at the following address: http://publications.orgalime.org.

2. Suppliers outside the European Union

Please let us know the coordinates of your appointed “only representative”.

3. Details of contact person for REACH issues

Thank you for your time.

For more information on REACH, please consult the Orgalime practical guide to understanding REACH, downloadable free of charge at the following address: http://publications.orgalime.org

Attachment 3: Basic facts about REACH

Please find below for information some basic facts about REACH, which you may find useful for your further proceedings.

Pre-registration and Registration of substances
You may know that according to REACH, European manufacturers and importers (*i.e.* each European legal entity) are obliged to register substances on their own or in preparations they manufacture or import in volumes **of one tonne and more** per year, per manufacturer/importer, unless exemptions apply. Registration also concerns substances in articles in case of intentional release of the substance under certain conditions.
Failure to register means that the substance may no longer be manufactured in the EU nor be placed on the EU market, according to the principle of "no data-no market".

In order to be granted transitional periods varying from 3.5 to 11 years for registration (depending on substance volumes and properties *i.e.* 30 November 2010 – 31 May 2013 – 31 May 2018), substances on their own/in preparations/intentionally released from articles already present on the market (so-called "phase-in substances") **must be PRE-REGISTERED with the European Chemicals Agency between 1 JUNE 2008 AND 1 DECEMBER 2008**.

Missing pre-registration means that manufacture or import of the substance must be suspended until the complete registration dossier has been submitted to the European Chemicals Agency. There is an additional three week delay after submission, before manufacture or import may start again. This situation may lead to supply disruption with availability for customers being a problem since the substance may no longer be available on the market for a certain period of time.

Substances of very high concern
REACH further foresees specific provisions for **substances of very high concern**, on their own, in preparations and present in articles.
Substances of very high concern include those
- Classified as Carcinogens, Mutagens and toxic to Reproduction (so called "CMRs") category 1 and 2,
- Persistent, Bioaccumulative and Toxic (PBTs),
- Very Persistent and very Bioaccumulative (vPvB)
- Substances of equivalent concern.

New legal requirements for substances of very high concern under REACH include *inter alia*:
- (Pre-)registration procedure (Title II REACH)
- Notification (Article 7.2 REACH and ff.)
- Communication duties (Article 33 REACH)
- Authorisation procedure (Title VII REACH)

The inclusion of substances of very high concern in the so-called "candidate list" (Article 59 REACH) will trigger the notification and communication requirements for substances in articles under certain conditions. The procedures for including substances of very high concern in the candidate list will start as of 1 June 2008. The authorisation procedures apply to substances of very high concern which have been included in Annex XIV REACH.

For more information on REACH, please consult the Orgalime practical guide to understanding REACH, downloadable free of charge at the following address: http://publications.orgalime.org

Annex B: Orgalime model letter for structuring communication up the supply chain in order to implement Article 33(1) REACH information requirements

28 October 2008

The content of this letter and attachment may be used as a contract clause, especially if the supplier is outside the EU and has no "only representative" in the EU.

Make sure that you have written evidence that the letter and attachment have been sent to your suppliers (e.g. fax receipt, registered mail...)

{Date}

Dear supplier,

We are writing to you in order to gather information on certain substances present in articles (*e.g.* products, parts, equipment, packaging) that you supply to us. This will allow you and {*if supplier outside the EU: remove "you and*"} us to fulfill our legal obligations with regards Article 33 of the European REACH Regulation N°1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals[1] which entered into force on 1st June 2007.

With the publication of the so called "candidate list" (Article 59 REACH) on 28 October 2008, Article 33(1) of the REACH Regulation obliges suppliers of articles to inform the recipients of the articles of the presence in the article of substances of very high concern included in the candidate list above a concentration of 0.1% weight by weight (w/w). Article suppliers have to provide their recipients with sufficient information available to them to allow safe use, including, as a minimum, the name of the substance.

At present, 15 substances have been included in the candidate list. We therefore kindly ask you to complete the attached questionnaire in order to let us know whether the articles that you supply to us contain one (or several) of the listed substances above a concentration of 0.1% w/w. The calculation is to be based on the weight of the whole article. Please indicate the precise concentration, where possible. If you supply several articles to us that contain one (or several) of these substances, please complete one questionnaire per article. Thank you.

Please return this information to us as soon as possible, but no later than xxx {*to be completed*}. Please note that if we receive no answer from your side by this date, this will be understood as meaning that you declare that the supplied articles do not contain the above mentioned candidate list substances in a concentration above 0.1% w/w.

Since we are also article suppliers, we may consolidate the information received in order to further communicate in the supply chain according to Article 33 REACH. We commit to guarantee confidentiality of sources when gathering and consolidating data.

The candidate list will be regularly updated. Please note that you have the legal obligation to {*if supplier outside the EU: remove "note that you have the legal obligation to*"} keep yourself informed about the substances that may be added to the candidate list and automatically inform us about their presence in the articles that you supply to us in accordance with Article 33(1) REACH.

Further information on the candidate list is available on the website of the European Chemicals Agency website at the following address: http://echa.europa.eu/chem_data/candidate_list_en.asp

We thank you for your time and look forward to hearing from you,

Yours sincerely,

[1] For more information about REACH, please consult the Orgalime practical guide to understanding REACH, downloadable free of charge at: http://publications.orgalime.org

Attachment: Questionnaire to be completed in view of achieving compliance with Article 33(1) REACH[i]

- Please indicate if one (or several) of the substances listed below are present in the supplied articles above a concentration of 0.1% w/w.
- Please indicate the precise concentration where possible. The calculation is to be based on the weight of the whole article.
- If you supply several articles to us that contain one (or several) of the substances listed below, please complete one questionnaire per article.

Substance name*	CAS number	EC number	Present in article xxx?	Weight of the article	Concentration (% w/w) Please indicate the precise concentration where possible	Remarks (voluntary)
Anthracene	120-12-7	204-371-1				
4,4'- Diaminodiphenylmethane (MDA)	101-77-9	202-974-4				
Dibutyl phthalate (DBP)	84-74-2	201-557-4				
Cobalt dichloride	7646-79-9	231-589-4				
Diarsenic pentaoxide	1303-28-2	215-116-9				
Diarsenic trioxide	1327-53-3	215-481-4				
Sodium dichromate	7789-12-0 and 10588-01-9	234-190-3				
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	201-329-4				
Bis (2-ethylhexyl)phthalate) (DEHP)	117-81-7	204-211-0				
Hexabromocyclododecane (HBCDD) and all major diastereoisomers indentified (alpha-HBCDD, beta-HBCDD, gamma-HBCDD)	25637-99-4 and 3194-55-6 (134237-50-6, 134237-51-7, 134237-52-8)	247-148-4 and 221-695-9				
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	287-476-5				
Bis(tributyltin)oxide (TBTO)	56-35-9	200-268-0				
Lead hydrogen arsenate	7784-40-9	232-064-2				
Triethyl arsenate	15606-95-8	427-700-2				
Benzyl butyl phthalate (BBT)	85-68-7	201-622-7				

* *Source: http://echa.europa.eu/chem_data/candidate_list_table_en.asp .*

Please have this attachment duly completed and return it to {*name of company sending the letter*} no later than xxx {*to be completed*}. By signing this Annex you acknowledge the content of the cover letter and certify that you are aware of your legal obligation to keep yourself regularly updated with substances that may be added to the candidate list. You further acknowledge that you are responsible to inform {*name of company sending the letter*} about the presence of any such substance(s) listed in the candidate list in the article that you supply to us in accordance with Article 33(1) REACH.

Name and function of the contact person responsible for REACH issues:
Date
Signature

[i] For more information about REACH, please consult the Orgalime practical guide to understanding REACH, downloadable free of charge at: http://publications.orgalime.org

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FMMI
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Url: http://www.fieec.fr
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Rue Louis Blanc, 39-41, F - 92 400 Courbevoie
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WSM
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Url: http://www.wsm-net.de
ZVEI
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Url: http://www.anie.it
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Fax: (39).02.4541.8545
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Url: http://www.fedil.lu

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METAALUNIE
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Tel: (31).3060.533.44 - Fax: (31).3060.531.22
Url: http://www.metaalunie.nl

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Oscars Gate 20, P.O. Box 7072,
N - 0306 Oslo 3
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Url: http://www.norskindustri.no

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Url: http://www.kig.pl/izba_gpe/

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Url: http://www.anemm.pt

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Url: http://www.sercobe.es

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