



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)**

published in N° L396 of the Official Journal
of the European Union on
30 December 2006

May 2007



All rights reserved
© May 2007 ORGALIME
Editeur responsable: Adrian Harris, Secretary General

ORGALIME –
The European Engineering Industries Association
secretariat@orgalime.org - www.orgalime.org

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)

2

Foreword

Regulation N°1907/2006 on the **Registration, Evaluation, Authorisation of Chemicals (REACH)** was published in the Official Journal of the European Union on 30 December 2006. It will enter into force on 1 June 2007.

Orgalime, the European Engineering Industries Association, speaks for 36 trade federations representing some 130,000 companies in the mechanical, electrical, electronic and metalworking industries of 24 European countries. The industry employs some 10.6 million people in the EU and in 2006 accounted for some €1,779 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 articles¹ including many of their components for both, professional customers and consumers: we are clients of the chemical industry and supplier 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 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.

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 Articles may include screws, bolts, motors, electrical and electronic equipment.

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/site/en/oj/2006/l_396/l_39620061230en00010849.pdf

- REACH Implementation Projects (RIPs)

RIPs are technical guidance documents and IT-tools developed for the Agency, industry and the authorities by the European Commission in collaboration with stakeholders.

REACH Implementation projects are hereafter in the guide referred to as “RIP” or “RIPs”.

RIP documents are published at the following website: <http://ecb.jrc.it/reach/rip/>.

This Orgalime guide has been drafted by a specific Orgalime task force, which is composed of Orgalime members 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.

Contents

Foreword	3
Chapter 1: Introduction to Regulation N°1907/2006 on REACH	6
1.1. How REACH developed historically.....	6
1.2. Basic facts about REACH.....	6
Chapter 2: Main definitions and acronyms	8
2.1. Definitions.....	8
2.2. Acronyms.....	9
Chapter 3: Important dates and deadlines to remember	10
Chapter 4: How to comply with REACH step by step	12
4.1. Quick screen 1: Registration of substances used in industrial (including engineering) processes.....	13
4.2. Quick screen 2: Authorisation of substances.....	14
4.3. Quick screen 3: Registration of substances in articles.....	15
4.4. Quick screen 4: Notification of substances in articles and communication requirements.....	16
Chapter 5: Guidelines on specific aspects of REACH	17
5.1. Guideline 1: Roles in the supply chain.....	17
5.2. Guideline 2: Scope and exemptions.....	18
5.3. Guideline 3: Substance inventory.....	20
5.4. Guideline 4: Import of substances/preparations/articles.....	21
5.5. Guideline 5: Communication obligations along the supply chain.....	22
5.6. Guideline 6: Downstream user chemical safety report.....	25
5.7. Guideline 7: Registration of substances in articles.....	26
5.8. Guideline 8: Notification of substances in articles.....	27
5.9. Guideline 9: Communication requirements on substances in articles.....	28
5.10. Guideline 10: Authorisation procedures.....	29
5.11. Guideline 11: List of REACH Implementation Projects (RIPs).....	32
5.12. Guideline 12: List of helpdesks and tools of EU and national authorities.....	33
5.13. Guideline 13: Industry-run guidance and helpdesks.....	35
Chapter 6: Flowchart “REACH timelines and main obligations”	36
List of Orgalime member associations	37

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 of **C**hemicals”.

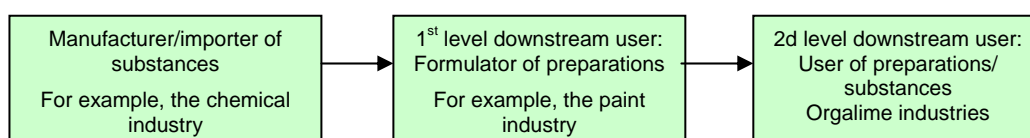
The REACH system establishes an EU wide regulatory framework for the registration, evaluation and authorisation of chemicals. In 1998, the Environment Council decided to review existing EU chemicals legislation in order to establish a new, integrated piece of legislation, which would assess existing 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 enters 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 further 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, 8 and 9).
- **Orgalime industry companies** may also **import** substances or preparations. In this case, downstream users have to comply with the importer's obligations², 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 the "Agency"). Based in Helsinki, it is supposed to be fully operational on 1 June 2008. The aim of the Agency is to collect the technical and scientific data, as well as manage the administrative aspects generated by REACH at Community level. The Agency 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 the Agency 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 10).
- 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 will initially include the current marketing and use restrictions of Directive 76/769/EEC. As of 1 June 2009, Directive 76/769/EEC will be repealed.
- 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. The European Commission is at present preparing a proposal for a Regulation to implement the UN's Globally Harmonised System for Classification and Labelling of Chemicals (GHS), which would repeal Directives 67/548/EEC and 1999/45/EC. REACH provisions would later be made consistent with the Regulation implementing GHS, in particular as far as the classification and labelling inventory is concerned.

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 13).

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.

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:

- It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).
- It was manufactured in the Community or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this.
- It was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this (Article 3.20 REACH).

Preparation: means “a mixture or solution composed of two or more substances” (Article 3.2 REACH), for example, a paint, a lubricant, an ink.

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, metals (detailed information Identification and Naming of Substances in REACH are to be found in RIP 3.10).

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.

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

DU: Acronym for downstream user.

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).

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

REACH: Acronym for registration, evaluation, authorisation 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://ecb.jrc.it/reach/rip/> and in Orgalime guideline 12.

Svhc: Acronym for substance of very high concern.

TGD: Acronym for technical guidance document.

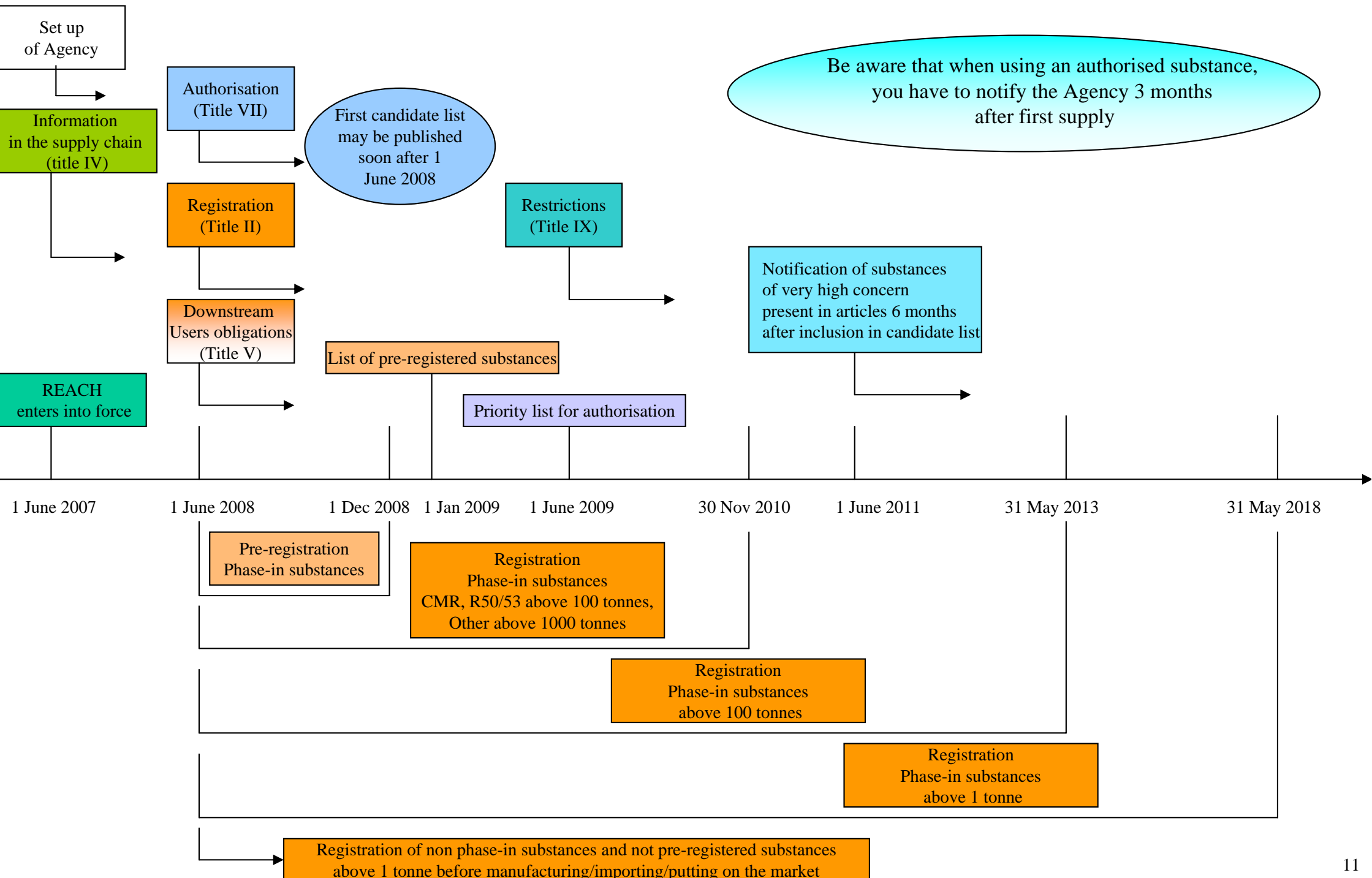
vPvB: Acronym for very persistent and very bioaccumulative.

Chapter 3: Important dates and deadlines to remember

2007	
1 June 2007	<ul style="list-style-type: none"> REACH enters into force. Title IV REACH “Communication in the supply chain” applies. <p>Note: New data to be included in the safety data sheet will only be made available at a later stage according to transition periods for registration.</p>
2008	
between 1 June 2008 and 1 December 2008	<ul style="list-style-type: none"> Pre-registration of phase-in substances on their own, in preparation or intentionally released from articles (Article 28 REACH). <p><u>Pre-registration is a mandatory pre-requisite to benefit from transition periods for registration.</u></p> <p>Note: Beyond 1 December 2008 deadline, particular pre-registration rules apply:</p> <ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> 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 <u>and included in the candidate list</u> 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	<ul style="list-style-type: none"> Publication on Agency website of pre-registered phase-in substances with first envisaged registration deadline (Article 28.4 REACH). First recommendation for a priority list of substances for authorisation to be issued by the Agency (Article 58.3 REACH). Title VIII REACH “Restrictions” applies – repeal of Directive 76/769/EEC.
2010	
From 1 June 2008 until 30 November 2010	<ul style="list-style-type: none"> Registration of: <ul style="list-style-type: none"> -Substances classified as “CMR”, category 1 and 2 in quantities of 1 tonne/year and above per manufacturer/importer. -Substances classified as very toxic to aquatic organisms (R50/53) in quantities of 100 tonnes/year and above per manufacturer/importer. -Other substances on their own, in preparations or 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	<ul style="list-style-type: none"> Notification of substances in articles (Article 7.2 REACH) 6 months after they have been included in the candidate list (Article 7.8 REACH).
2013	
From 1 June 2008 until 31 May 2013	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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

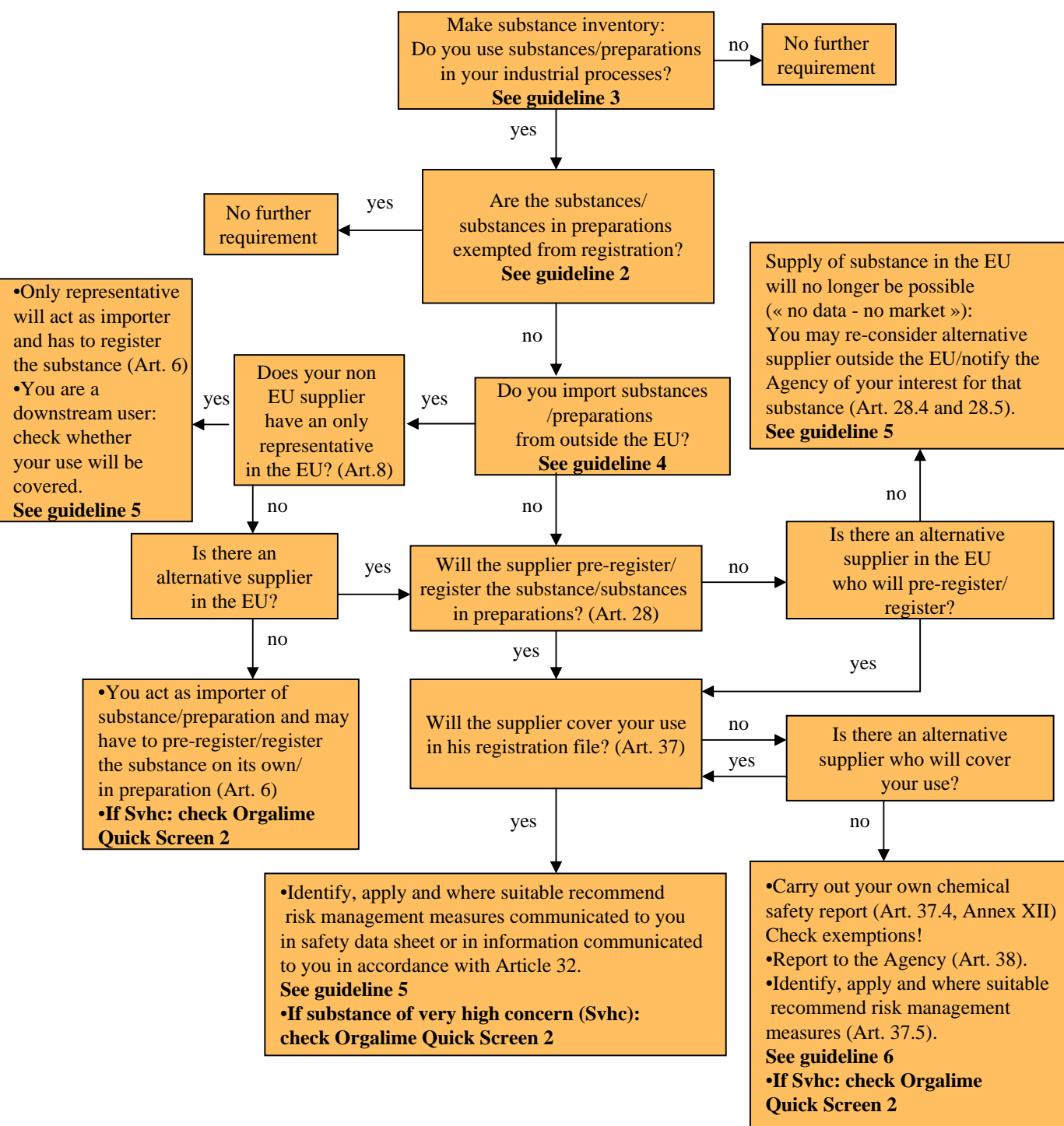


Chapter 4: Overview how to comply with REACH step by step

The following Orgalime quick screens have been designed in order to help companies to determine what are their obligations under REACH. 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

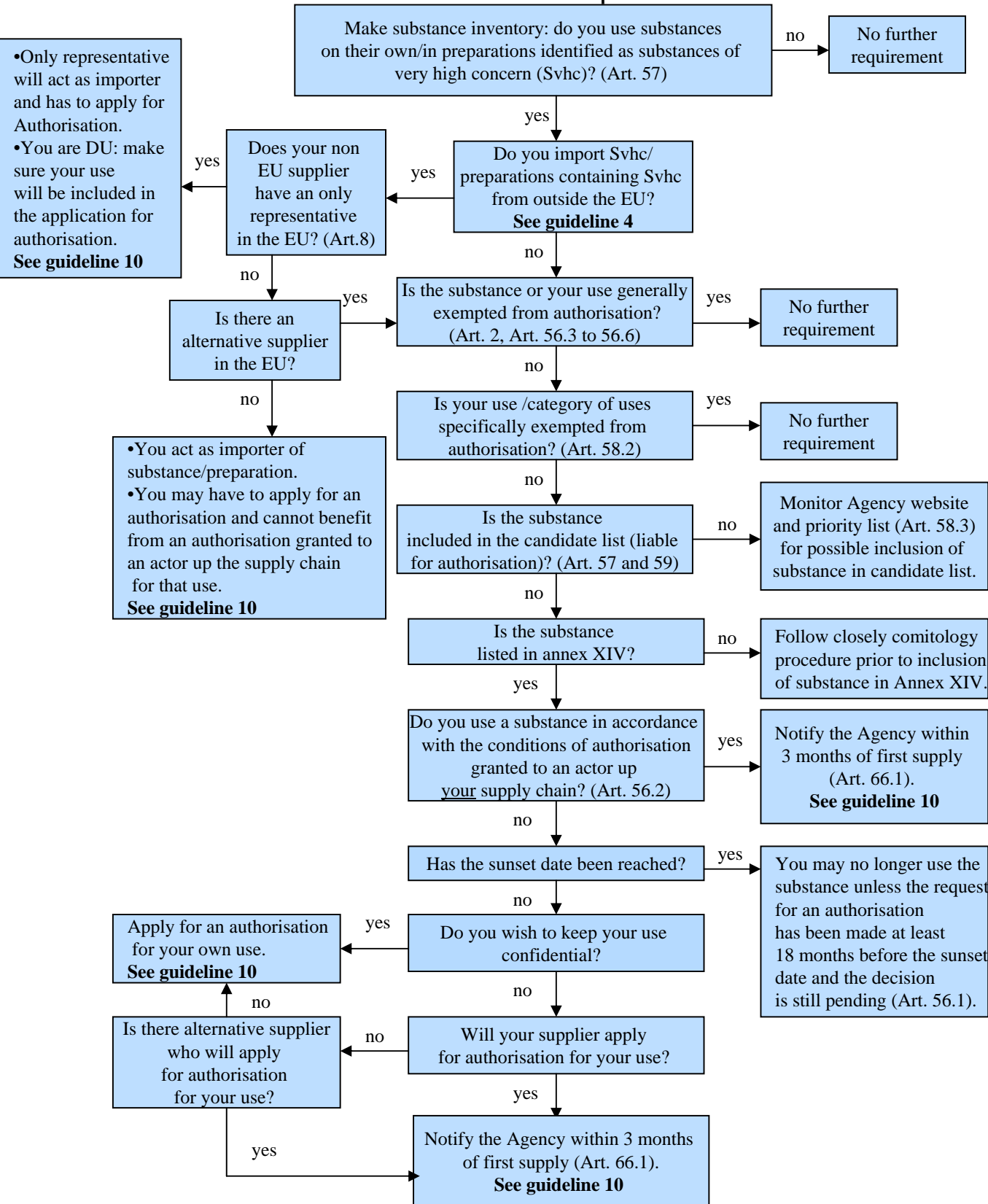


RECOMMENDATIONS:

- 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

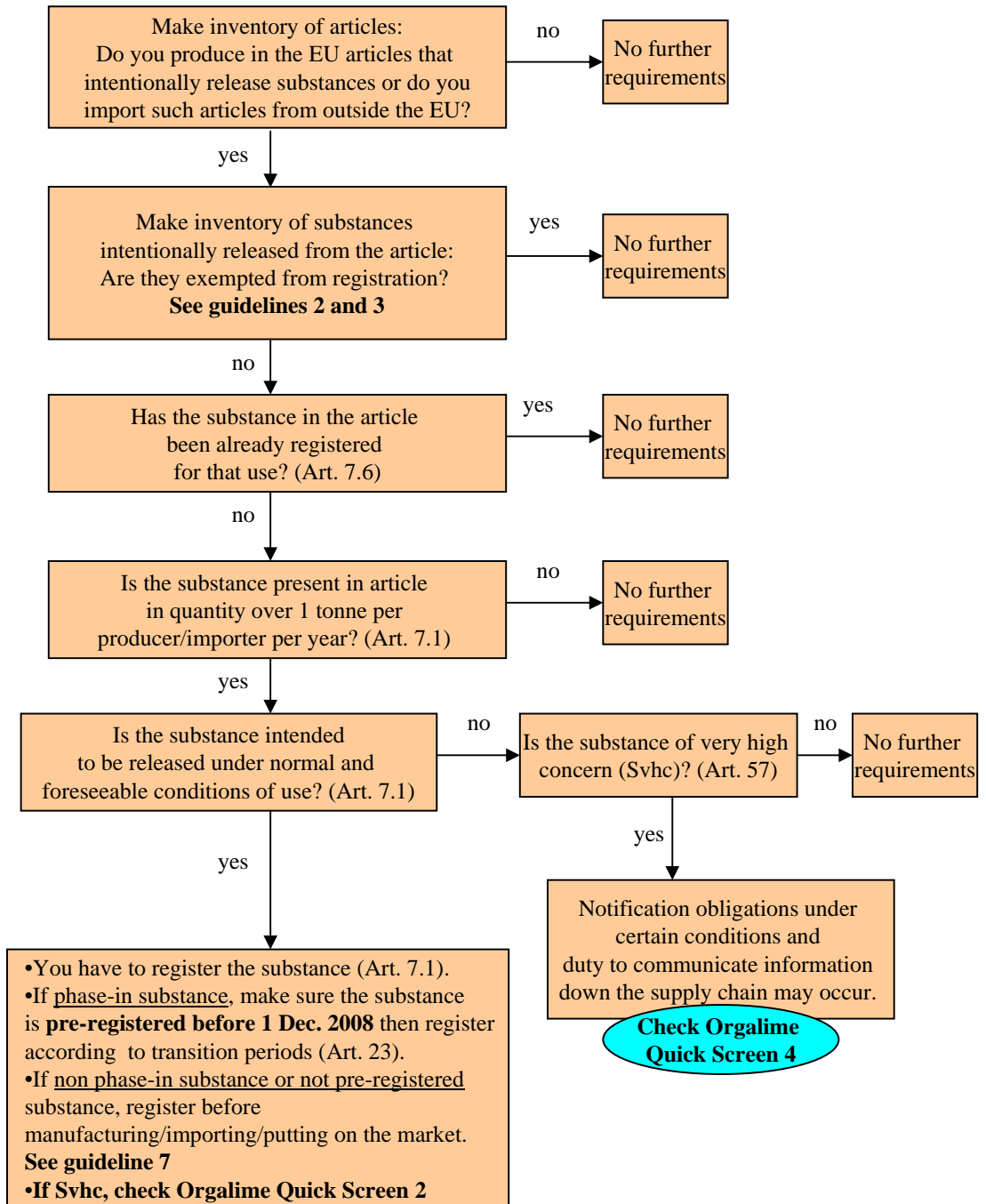


RECOMMENDATIONS:

- 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 intentionally released from articles

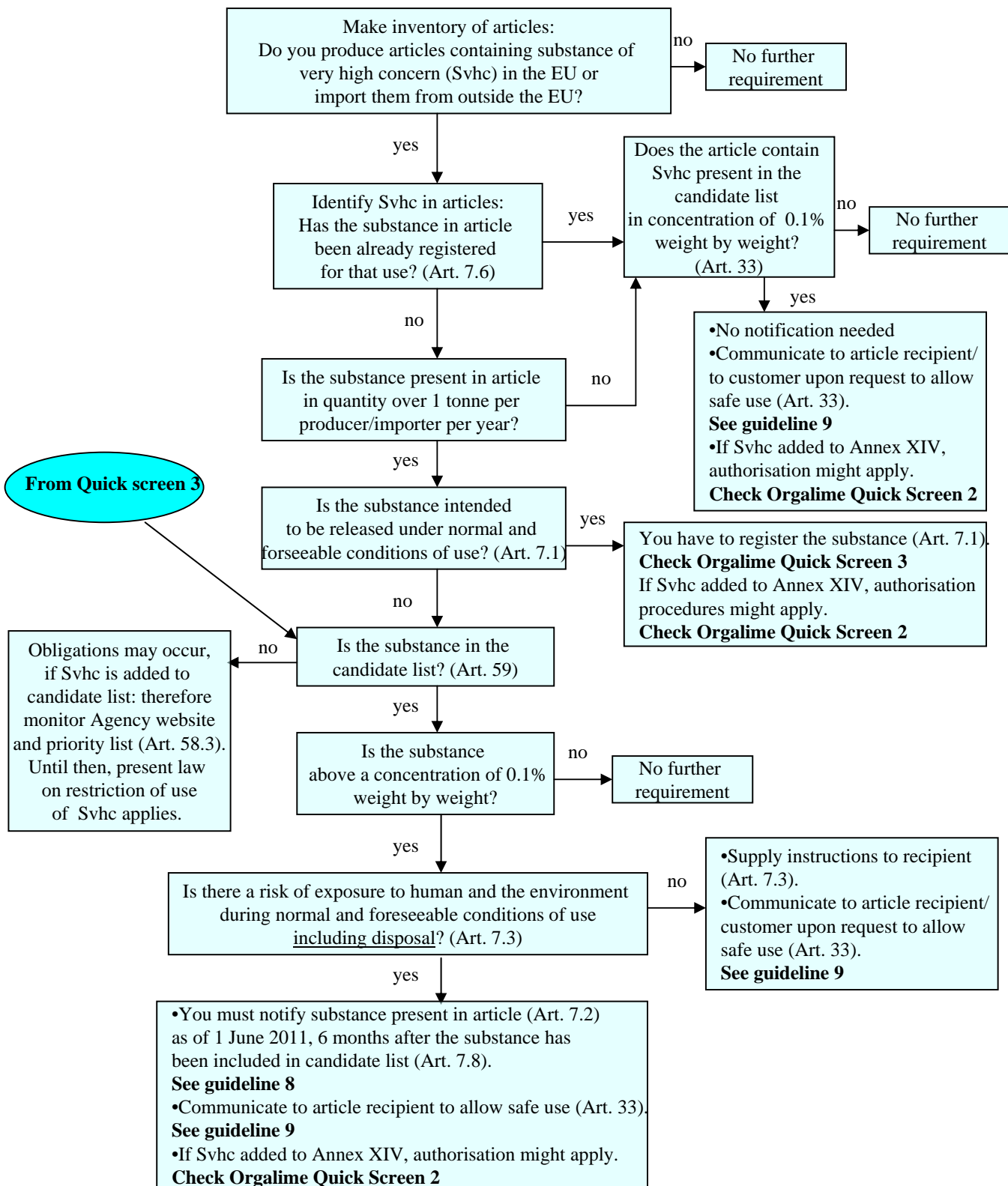


RECOMMENDATIONS:

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, 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 article**, not at the level of the homogeneous material.
- Please be aware that according to Article 7.5 REACH, **the Agency 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 actors 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).

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, 8, 9).
 - 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, 8, 9).
- 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 (Annex V n°4 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
RIP 3.2, RIP 3.5, RIP 3.8

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 article 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](#) (currently under revision), 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 76/769/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 feedingsstuffs ([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 feedingsstuffs ([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](#)).

The following substances are regarded as being registered:

- 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).

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. The Agency 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 the Agency (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 the Agency for the monomer substances or any other substances that have not already been registered by an actor up the supply chain under certain conditions (Article 6.3 REACH).

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).
- **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 in particular, please check Orgalime guideline 11.

For more details, please check

Articles 1, 2, 6, 9, 138.4, 138.6 REACH

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 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 intentionally released from an article that the company produces:** If you produce articles intentionally releasing 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 the Agency for such substances (see Orgalime guideline 8).
- **Which substances are intentionally released from an article that the company imports:** if no "only representative of a non-Community manufacturer" has been appointed, you will be obliged to register the substances intentionally released from the article that you import under certain conditions. **You will also have to identify if the article contains substances of very high concern, and notify them to the Agency** under certain conditions (see Orgalime guideline 4).

You need to collect the following key information in order to determine your REACH obligations³ (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?

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?
- Will the substance/preparation continue to be available for purchase?
- Is the substance on 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?

³ 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.

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 preparation 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 intentionally released from an imported article⁴, following the same regime as substances intentionally 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 of 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 (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 are not considered as imports.
- Negotiations are currently taking place to have REACH included in the European Economic Area (EEA) Agreement before pre-registration starts, so that substances supplied from Iceland, Liechtenstein, Norway (which are members of the EEA, but are not members of the EU) would not be considered as imports.
- 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. Joint submission of data by multiple registrants is possible (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.

⁴ 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 the Agency under certain conditions. According to Article 7.5 REACH, the Agency may also decide that the article producer/importer has to register that substance (see Orgalime guideline 8).

5.5. Guideline 5: Communication obligations along the supply chain

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 to be submitted to the Agency. DU may only use substances on their own/in preparations which have been registered for their use(s) after the registration deadline has passed. It is therefore 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.

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/use and exposure category to be included in the chemical safety assessment (Article 37.2 REACH).

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 will only be possible between 1 June 2008 and 1 December 2008. The Agency shall, by 1 January 2009, publish a list of pre-registered substances and the first envisaged registration deadline (Article 28.4 REACH)⁵. If a phase-in substance is not pre-registered, no transition periods for registration will be allowed and the substance will have 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.
- As third step, if the supplier intends to carry out registration procedures, ask whether the supplier has already established use and exposure categories/exposure scenarios⁶ covering their use(s). DU may also check 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.

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, the supplier has to inform the Agency and downstream users in writing without delay of the reasons for not including the use(s) in the chemical safety assessment. The supplier shall not supply DU with the substance without including these reasons in the SDS or in the information to be provided according to Article 32 REACH (Article 37.3 REACH).

⁵ DU of a certain substance, that does not appear on this list of pre-registered substances, have the possibility to notify the Agency of their interest in that substance. The Agency 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), who 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.

⁶ Exposure scenarios must be compiled by the registrant, as part of the registration dossier, for certain substances on their own or in preparations, which are imported/manufactured in quantities over 10 tonnes per year.

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 the Agency as described in Article 38.2 REACH (see Orgalime guideline 6).

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).

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 the Agency, which requires expertise and may be costly, besides being time consuming (see Orgalime guideline 6).
- 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. Further information is given at the following industry helpdesk <http://reach.bdi.info/>. Standard questionnaires/example of use and exposure categories may also be found at this address. RIP 3.2 will deal with the issue of communication in the supply chain. However, it still needs to be finalised.
- REACH also foresees communication requirements in the supply chain for substances in articles (see Orgalime guideline 9), which would come in addition to the communication requirements outlined in the present guideline.

Further DU obligations

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).

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 the Agency (Article 36 REACH).

If DU are using substances of very high concern, authorisation procedures might also apply (see Orgalime guideline 10).

Compliance deadline

While the legal obligation to comply with Article 37 REACH applies at the latest 12 months after receiving the registration number of the substance (Article 39.1 REACH), it is strongly advised that DU **start communicating as early as possible** with their suppliers⁷.

For more details, please check

Title IV, Title V, Annex VI n°6 REACH
RIP 3.2, RIP 3.5, RIP 3.8

⁷ REACH foresees further deadlines, in particular for DU selling preparations (Article 37.3 REACH). Those are under discussion in the ongoing RIP 3.5.

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

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 the product and process oriented research exemption, DU also have to comply with reporting obligations to the Agency before starting or continuing with a use of a substance registered by an actor up the supply chain (Article 38 REACH). This must be done 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
RIP 3.5

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 the Agency 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 with intended release 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 register substances

A substance intended to be released from an article should be registered according to the same timelines as those applying for the registration of a substance on its own or in a preparation by the substance manufacturer (Article 23 REACH):

For 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
For 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: <ul style="list-style-type: none">• “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: <ul style="list-style-type: none">• Other substances in quantities of 100 tonnes and above per year. From 1 June 2008 until 31 May 2018 for: <ul style="list-style-type: none">• Other substances in quantities of 1 tonne and above per year.

Substances intentionally released from the article must be pre-registered in order to benefit from the registration transition periods described above (Article 28 REACH). Pre-registration of substances shall take 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 also Article 29 REACH).

Fees

Fees required for the registration of substances in articles will be specified in a European Commission’s Regulation by 1 June 2008. 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.

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, the substance requires registration according to Article 7.1 REACH (for the definition of an article, please see Chapter 2 of the Orgalime guide).

For more details, please check

Articles 6, 7, 23, 28 REACH

RIP 3.8

5.8. Guideline 8: 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 the Agency 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).

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 2.1 to 2.3.4 of Annex VI REACH.
- A brief description of the use of the substance in the article as specified in section 3.5 of Annex VI REACH and of the use(s) of the article.
- The tonnage range of the substance, such as 1-10 tonnes, 10-100 tonnes ...

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.

According to Article 7.5 REACH, the Agency 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.
- The Agency 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.

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.
REACH also foresees communication requirements for substances of very high concern present in articles (see Orgalime guideline 9).

For more details, please check

Articles 7, 57, 59 REACH
RIP 3.8

5.9. Guideline 9: 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 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 all 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.

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).
- The REACH Regulation does not provide for a definition for “consumer” nor consider a consumer as an actor in the supply chain.

For more details, please check

Articles 7.3, 33 REACH
RIP 3.8

5.10. Guideline 10: Authorisation procedures

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 Agency 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

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 Agency shall prepare a dossier in accordance with Annex XV REACH. The dossier may be limited to a reference to an entry in Annex I of Directive 67/548/EEC (Article 59.3 REACH). The Agency shall publish a notice on its website that an Annex XV dossier has been prepared. **The Agency shall invite all interested parties to submit comments within a specific deadline to the Agency** (Article 59.4 REACH).

The Annex XV dossier will then be referred to a Member State Committee. If Member States reach unanimous agreement, the Agency 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 via comitology procedure referred to in Article 133.3 REACH⁸ (Article 59.9 REACH).

The Agency 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. The Agency shall make further recommendations at least every second year with a view to including further substances in Annex XIV REACH (Article 58.3 REACH).

Before the Agency sends its recommendation to the European Commission, it shall make it publicly available on its website. **The Agency 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).

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

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 its use. If not, the application for an authorisation shall be made to the Agency. **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).

⁸ 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 how far Decision 2006/512/EC will impact REACH, is unclear at this stage.

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
RIP 3.5, RIP 3.7, RIP 3.9

5.11. Guideline 11: List and status of REACH Implementation Projects (RIPs)

RIPs are technical guidance documents and IT-tools developed for the Agency, industry and the authorities by the European Commission in collaboration with stakeholders. RIPs tackle seven main areas and a number of sub-projects, which are outlined below.

NOTE:

RIP guidance documents are not legally binding.

More information on RIPs can be found at: <http://ecb.jrc.it/reach/rip/>.

RIP 1: REACH Process Description (project running)

RIP 2: REACH-IT (project running)

RIP 3: Technical Guidance and Tools for Industry

RIP 3.1: Preparing technical dossier for registration (project running)

RIP 3.2: Preparing Chemical Safety Report (CSR)

RIP 3.2-1A: Technical Guidance Document (TGD) on preparing the CSR (preliminary project finalised)

RIP 3.2-1B: TGD on preparing the CSR (preliminary project finalised)

RIP 3.2-2: TGD on preparing the CSR (project running)

RIP 3.3: Information requirements on intrinsic properties of a substance

RIP 3.3-1: TGD on information requirements (Scoping) (preliminary project finalised)

RIP 3.3-2: TGD on information requirements (project running)

RIP 3.4: Data sharing (pre-registration)

TGD on data sharing (project running)

RIP 3.5: Downstream user requirements

RIP 3.5-1: TGD on downstream user requirements (preliminary study finalised)

RIP 3.5-2: TGD on downstream user requirements (project running)

RIP 3.6: Classification and labelling and GHS

On hold until the European Commission adopts proposal for implementing GHS

RIP 3.7: Preparing application dossier for authorisation (project running)

RIP 3.8: Requirements for substances in articles

Final report of draft TGD finalised. It will be updated.

RIP 3.9: Carrying out a socio-Economic analysis

RIP 3.9-1: Preliminary study finalised

RIP 3.9-2: project running

RIP 3.10: Identification and naming of substance (project finalised)

RIP 4 Technical Guidance and Tools for Authorities

RIP 4.1: Dossier evaluation (project running)

RIP 4.2: Substance evaluation (project running)

RIP 4.3: Inclusion of substances in Annex XIV (project running)

RIP 4.4: Preparation of Annex XV dossiers (project finalised)

RIP 4.5: Priority setting for evaluation (project running)

RIP 5 & 6 Setting up the Agency (project running)

Overall guidance package

To facilitate the accessibility to the guidance RIP 1, 2, 3 and 4, a web application is under development and is supposed to be up and running at entry into force of REACH.

5.12. Guideline 12: Helpdesks and tools of EU and national authorities

According to Article 124 REACH, Member States are required to set up REACH helpdesks in each 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 the Agency that meets regularly in order to discuss and coordinate REACH implementation issues. The Agency will also set up a specific Agency helpdesk.

List of EU helpdesk and tools

REACH helpdesk network (coordinated by the Agency)

http://ec.europa.eu/enterprise/reach/helpnet_en.htm

European Chemical Agency helpdesk

http://ec.europa.eu/enterprise/reach/helpdesks_ECHA_en.htm

European Commission helping tools

Question and Answers on REACH

<http://ec.europa.eu/environment/chemicals/pdf/ga.pdf>

“REACH in brief”

http://ec.europa.eu/environment/chemicals/reach/reach_in_brief04_09_15.pdf

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

Belgium

<http://economie.fgov.be/reach.htm>

Email: reachinfo@economie.fgov.be

Tel: + 32 (0)800 12 033

Fax: +32 (0)2 277 53 04

Bulgaria

<http://www.chemicals.moew.government.bg/chemical/site/Pages/nogo>

Denmark

<http://www.mim.dk/Nyheder/Engelsk+nyhedsbrev/Arkiv/2005/Danish+Environment+Newsletter+no.+9+2005/chemicals.htm>

Finland

A group has been set up to prepare the helpdesk and can be contacted at reach@sttv.fi and reach@ymparisto.fi (See also <http://www.sttv.fi/kemo/apua.htm>)

Some information can also be found on the website of the Ministry of Social Affairs and

Health: <http://www.kemikaalineuvottelukunta.fi/Resource.phx/orgns/neuvt/kenk/reach.htx>

France

http://www.environnement.gouv.fr/Adoption-du-reglement-REACH.html?var_recherche=REACH

Germany

<http://www.baua.de/de/Chemikaliengesetz-Biozidverfahren/Neue-Chemikalienpolitik/Helpdesk/Reach-Helpdesk.html>

Ireland

<http://www.hsa.ie/publisher/index.jsp?1nID=93&pID=101&nID=466>

Tel.: +353 (0)1890 289 389 or email reachright@hsa.ie

Luxemburg

CRTE : Centre de ressource des technologies pour l'environnement

Contact: Mrs Caroline Fedrigo caroline.fedrigo@tudor.lu

Tel.: +352 (0)42 59 91 600

The Netherlands

<http://www.vrom.nl/pagina.html?id=22887>
www.reach-helpdesk.nl

Poland

<http://www.chemikalia.mz.gov.pl/>

Sweden

http://www.kemi.se/templates/FAQFormPage_4838.aspx

United Kingdom

<http://www.defra.gov.uk/news/2006/061010b.htm>

5.13. Guideline 13: 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/content/showevent.asp?menuid=1482&level=1&folderid=1849>

ORGALIME MEMBER ASSOCIATIONS

AUSTRIA

FEEI

Mariahilfer Straße 37/39, A - 1060 Vienna
Tel : (43).1.588.39.0 - Fax : (43).1.586.69.71
Url : <http://www.feei.at>

FMMI

Wiedner Hauptstraße 63, A - 1045 Vienna
Tel : 43.5.90.900-34.82 - Fax : (43).1.505.10.20
Url : <http://www.fmmi.at>

BELGIUM

AGORIA

"Diamant Building", 80, Bld Reyers, B - 1030 Brussels
Tel : (32).2.706.78.00 - Fax : (32).2.706.78.01
Url : <http://www.agoria.be>

CZECH REPUBLIC

ELA

Doudlebská 5 140 00 Praha 4
Tel : (420).261.213.623 - Fax : (420).261.213.624
Url : <http://www.electroindustry.cz>

DENMARK

DI

H.C. Andersens Boulevard 18, DK - 1787 Copenhagen V
Tel : (45).33.77.33.77 - Fax : (45).33.77.33.00
Url : <http://www.di.dk>

FINLAND

The Technology Industries of Finland

Etelaranta 10, SF - 00131 Helsinki 13
Tel : (358).9.192.31 - Fax : (358).9.624.462
Url : <http://www.teknologiatoeillisuus.fi>

FRANCE

Alliance TICS

Tour Neptune, place de Seine 20, F - 92 086 Paris la Défense Cedex 1
Tel : (33).1.49.00.30.30 - Fax : (33).1.49.00.30.35
Url : <http://www.alliance-tics.com>

FIEEC

rue de l'Amiral Hamelin 11-17, F - 75 783 Paris Cedex 16
Tel : (33).1.45.05.70.70 - Fax : (33).1.45.53.03.93
Url : <http://www.fieec.fr>

FIM

Rue Louis Blanc, 39-41, F - 92 400 Courbevoie
Tel : (33).1.47.17.60.00 - Fax : (33).1.47.60.16
Url : <http://www.fim.net>

GERMANY

VDMA

Lyoner Straße 18, D - 60528 Frankfurt/Main
Tel : (49).69.660.30 - Fax : (49).69.660.31.511
Url : <http://www.vdma.org>

WSM

Kaiserswerther Straße 137; D - 40474 Düsseldorf
Tel : (49).211.4564.106 - Fax : (49).211.4564.169
Url : <http://www.wsm-net.de>

ZVEI

Stresemannallee 19, D - 60596 Frankfurt/Main
Tel : (49).69.630.20 - Fax : (49).69.630.23.17
Url : <http://www.zvei.de>

GREAT BRITAIN

BEAMA

Westminster Tower - 3 Albert Embankment,
GB - London SE1 7SL
Tel : (44).207.793.3000 - Fax : (44).207.793.3003

Url : <http://www.beama.org.uk/>

EAMA

Bayswater Road, 62 - London W2 3PS
Tel : (44).207.298.6450 - Fax : (44).207.298.6434
Url : <http://www.eama.info>

GAMBICA

Broadwall House - 21 Broadwall,
GB - London SE1 9PL
Tel : (44).207.642.8080 - Fax : (44).207.642.8096
Url : <http://www.gambica.org.uk>

HUNGARY

MAGOSZ

Kuny Domokos u.13-15, H - 1012 Budapest
Tel : (36).1.202.39.85 - Fax : (36).1.356.00.40
Url : <http://www.magosz.hu>

IRELAND

IEEF

Confederation House 84-86, Lower Baggot Street,
IRL - Dublin 2
Tel : (353).1.605.16.76 - Fax : (353).1.638.16.76
Url : <http://www.ibec.ie/ieef>

ITALY

ANIE

Via Gattamelata 34, I - 20149 Milano
Tel : (39).02.326.41 - Fax : (39).02.326.42.12
Url : <http://www.anie.it>

ANIMA

Via A. Scarsellini 13, I - 20161 Milan
Tel : (39).02.4541.8500 - Fax : (39).02.4541.8545
Url : <http://www.anima-it.com>

FEDERMACCHINE

Viale Fulvio Testi 128, I - 20092 Cinisello Balsamo
Tel : (39).02.262.55.288 - Fax : (39).02.262.55.880
Url : <http://www.federmacchine.it>

LATVIA

Association of Mechanical Engineering and Metalworking Industries of Latvia

Ezermalas 6, 1006 Riga
Tel : (371).755.48.25 - Fax : (371).708.97.76
Url : <http://www.masoc.lv>

LITHUANIA

LINPRA

Savanoriu pr. 176, LT - 03154 Vilnius
Tel : (370).5.231.25.20 - Fax : (370).5.231.25.20
Url : <http://www.linpra.lt>

LUXEMBOURG

ILTM

Rue Alcide de Gasperi 7, BP 1304, L - 1013 Luxembourg
Tel : (352).43.53.661 - Fax : (352).43.23.28
Url : <http://www.fedil.lu>

THE NETHERLANDS

FME-CWM

Boerhaavelaan 40, Postbus 190, NL - 2700 AD Zoetermeer
Tel : (31).79.353.11.00 - Fax : (31).79.353.13.65
Url : <http://www.fme-cwm.nl>

METAALUNIE

Einsteinbaan 1, Postbus 2600, NL - 3430 Nieuwegein
Tel : (31).3060.533.44 - Fax : (31).3060.531.22
Url : <http://www.metaalunie.nl>

NORWAY

Norsk Industri

Oscars Gate 20, P.O. Box 7072, N - 0306 Oslo 3
Tel : (47).22.59.00.00 - Fax : (47).22.59.00.01
Url : <http://www.norskindustri.no>

POLAND

Federation of the Chambers of the Electromechanical Industries

ul. Pozaryskiego 28 - PL 04703 Warszawa
Tel : (48).22.812.20.35 - Fax : (48).22.812.20.35
Url : http://www.kig.pl/izba_gpe/

PORTUGAL

AIMMAP

Rua dos Platanos 197 - 4100 Porto
Tel : (351).22.616.68.60 - Fax : (351).22.610.74.73
Url : <http://www.aimmap.pt>

ANEMM

Estrada do Paço do Lumiar, Polo tecnologico de Lisboa, Lote 13, P - 1600-485 Lisboa
Tel : (351).217.112.740 - Fax : (351).217.150.403
Url : <http://www.anemm.pt>

SLOVENIA

GZS-MPIA

Dimiceva 13, SL - 1000 Ljubljana
Tel : (386).1.58.98.000 - Fax : (386).1.58.98.100
Url : <http://www.gzs.si>

SPAIN

CONFEMETAL

Príncipe de Vergara 74, E - 28006 Madrid
Tel : (34).91.562.55.90 - Fax : (34).91.562.84.77
Url : <http://www.confemetal.es>

SERCOCBE

Calle Jorge Juan 47, E - 28001 Madrid
Tel : (34).91.435.72.40 - Fax : (34).91.577.09.10
Url : <http://www.sercocbe.es>

SWEDEN

TEKNIKFÖRETAGEN

Storgatan 5 Box 5510, S - 114 85 Stockholm
Tel : (46).8.782.08.00 - Fax : (46).8.782.09.00
Url : <http://www.teknikforetagen.se>

SWITZERLAND

SWISSMEM

Kirchenweg 4, Case Postale, CH - 8032 Zürich
Tel : (41).44.384.41.11 - Fax : (41).44.384.42.42
Url : <http://www.swissmem.ch>

BULGARIA (Associate member)

Bulgarian Chamber of Electrical Engineering

P.O. Box 76, BG - 1407 Sofia
Tel : (359).2.963.3532 or 963.3437 - Fax : (359).2.63.0727
Url : <http://www.bcee-bg.org>

CROATIA (Associate member)

HUP - Croatian Employers' Association

Ulica Pavla Hatza 12, 10 000 Zagreb
Tel : (385).1.4897.555 Fax : (385).1.4897.556
Url : <http://www.hup.hr>