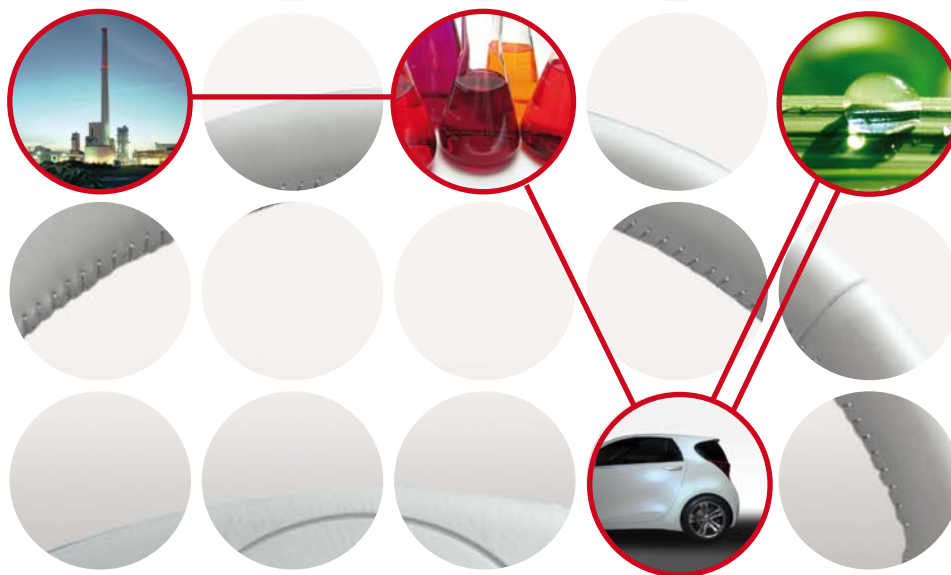


AUTOMOTIVE INDUSTRY GUIDELINE ON

REACH

Version 2



Task Force REACH is supported by:



CLEPA
European Association of
Automotive Suppliers





Disclaimer

This document contains guidance explaining the REACH obligations for the Automotive Industry and how to fulfil them. It is offered in good faith and reflects the best knowledge of the Global Automotive Industry experts and the state of the art at the time of its publication. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that a binding interpretation of Community legislation is the exclusive competence of the European Court of Justice. Therefore the information and guidance in this document are not legally binding. The Associations responsible for the publication of this document will not accept any liability regarding the contents of this document or arising from its use.

The Associations are committed without reservation to fair competition. As Trade Associations, their purpose is to promote the interest of their members and to facilitate their respective aims and objectives only through legitimate means and activities. In carrying out this role, the Associations shall proceed with caution to ensure against violation of anti-trust laws.

23 January 2008

Executive Summary	4
Foreword: About this guide	5
 Chapter 1 - Introduction: REACH and the Automotive Industry	 6
 Chapter 2: Main Definitions and Acronyms	 8
2.1 Main Definitions	8
2.2 Acronyms	14
 Chapter 3: “Important dates and deadlines to remember”	 16
 Chapter 4: Guidelines	 18
4.1 Guideline 1: Roles in the supply chain	18
4.2 Guideline 2: Scope and Exemptions	20
4.3 Guideline 3: Substance Inventory	22
4.4 Guideline 4: Imports of substances/preparations/articles	25
4.5 Guideline 5: Communication obligations along the supply chain	28
4.6 Guideline 6: Downstream User chemical safety report and reporting to the Agency	33
4.7 Guideline 7: Registration of substances in articles	34
4.8 Guideline 8: Notification of substances in articles	37
4.9 Guideline 9: Communication requirements for substances in articles	38
4.10 Guideline 10: Authorisation procedures	40
4.11 Guideline 11: List of REACH Implementation Projects	43
4.12 Guideline 12: Helpdesks and Information tools	44
4.13 Guideline 13: Industry-run helpdesks and Guidance	45
 Chapter 5: REACH compliance - a step-by-step process	 46
5.0 REACH Flow Chart 0 - Flow Chart Navigator	47
5.1 REACH Flow Chart 1 - Registration of substances/substances in preparations	48
5.2 REACH Flow Chart 2 - REACH authorisation procedures	49
5.3 REACH Flow Chart 3 - Registration of substances intended to be released from articles	50
5.4 REACH Flow Chart 4 - Notification of substances in articles	51
5.5 REACH Flow Chart 5 - How to use the Only Representative	52
5.6 REACH Flow Chart 6 - Obligations for Importers	53
 Chapter 6: AIG 8 step compliance schedule	 54
 Annex A: About Task Force REACH (TF-REACH)	 57
Annex B: Awareness letter	58
Annex C: Declaration of intent request letter	60
Annex D: Frequently Asked Questions (FAQ)	62
Annex E: List of changes	69



THE AUTOMOTIVE INDUSTRY GUIDELINE ON REACH (AIG) - EXECUTIVE SUMMARY

The European REACH Regulation ^{*1} came into force on 1 June 2007 and affects all industries. It requires immediate and ongoing action from the OEMs and suppliers. Under REACH, Substances of Very High Concern (SVHC) may require authorisation and may be restricted. Companies that do not comply with REACH will have no market, so REACH poses a threat to business continuity for any company doing business in the EU (and for businesses with customers or suppliers who do business in the EU).

In preparation for REACH, representatives of all the major vehicle manufacturers and the automotive supply chain formed a Task Force on REACH (TF-REACH). The TF recommends a common schedule and external communication strategy, which will harmonise the sector's response to REACH and avoid duplication and confusion. The TF's approach and recommendations are outlined in this Automotive Industry Guideline on REACH (AIG).

Key messages

- REACH imposes different obligations for each role the sector performs: as a Downstream user of substances (e.g. magnesium) and preparations (e.g. engine oil), a Producer of articles (e.g. car, engine, bumper manufactured in the EU), or an Importer of articles/preparations/substances (from outside EU). The flowcharts in Chapter 4 will help you determine what your obligations are and direct you to the appropriate section of the AIG for guidance on what to do next.
- Depending on the role(s) they perform in REACH, companies should develop an inventory of the substances/preparations they use. This will help them assess their obligations and next steps.
- Downstream users will expect their uses to be registered by their suppliers.
- It is very important that suppliers take advantage of the pre-registration option, which runs from 1 June to 1 December 2008 (inclusive). Pre-registration is simple, free of charge and allows continued production and use of phase-in substances until

2010–2018, depending on tonnage. Without Pre-registration, substances have to be registered immediately.

- AIG also recommends that non-EU suppliers appoint an "Only Representative" in the EU, which will take on the importer responsibilities, instead of each of their customers duplicating the importer role (see AI Guideline 4).
- To fulfil their REACH obligations, the entire supply chain needs to communicate - data, uses, control measures for safe use, etc. (see AI Guideline 5 and the standard REACH awareness letter in Annex B).
- Each player in the supply chain should appoint a REACH representative and develop a Strategic Action Plan to ensure compliance and minimize the business risks posed by REACH.
- The sector has considered whether any substance releases from articles are considered to be intended releases for the purposes of REACH and our conclusions are set out in AI Guideline 7.
- Chapter 6 summarises the main obligations and recommendations for the AI response to REACH. It identifies the tools available to help, along with a timeline for each activity. These activities are broadly grouped into the AIG 8 step compliance schedule: raising awareness; developing a substance inventory; declaration of intent (three steps); Substances of Very High Concern; and risk management measures and uses.

The AIG will be a living document, which will be updated in light of guidance such as the REACH Implementation Projects (RIPs) and the practical experience we gain through REACH implementation.

^{*1}) Regulation EC 1907/2006 on Registration, Evaluation, Authorisation (and Restriction) of Chemicals

FOREWORD: ABOUT THIS GUIDE

The new European “REACH Regulation” affects all industries. As the Automotive Industry is made up of vehicle manufacturers and many tiers of the supply chain, it has several roles under REACH (see Chapter 5). In preparation for REACH, representatives of all the major vehicle manufacturers (ACEA, JAMA, KAMA), the European automotive supply chain (CLEPA), along with AIAG (North American vehicle manufacturers and suppliers) have formed a Task Force on REACH (TF-REACH*). The TF aims to establish a common schedule and external communication strategy, which will harmonise the sector’s REACH implementation process.

The Task Force cannot impose its recommendations on members, but hopes they will be widely adopted to avoid duplication of effort and confusion all along the supply chain. Agreements in this guide are based on consensus between all participants, not on majority votes.

This guide will be a living document, which will be modified along the timeline of REACH implementation. It will be updated with the release of the final **REACH Implementation Projects (RIPs)** and the practical experiences that will be made during REACH implementation.

The Automotive Industry guideline (AIG) is intended to provide practical help to Downstream Users using substances and/or preparations and/or articles in their industrial processes. It is also addressed to producers and importers of articles. It should be seen as an “aide mémoire” to assist with preparation for compliance with the new legislation. It does not, however, extensively address obligations of manufacturers or importers of chemical substances and/or preparations, or the obligations of formulators (“first level Downstream Users”).

This guide will reference the legal text of REACH. REACH stands for **R**egistration, **E**valuation, **A**uthorisation (and **R**estriction) of **C**hemicals. REACH Regulation (EC) No. 1907/2006 and Directive 2006/121/EC amending Directive 67/548/EEC were published in the Official Journal on 30 December 2006 and in the corrected text version dated 29 May 2007, which can be found at

<http://europa.eu.int/eur-lex/lex/JOHtml.do?uri=OJ:L:2007:136:SOM:EN:HTML>.

This guideline should be used in conjunction with the actual REACH regulation and RIPs in order to understand the specific legal obligations of each member (actor) in the automotive industry supply chain.

Text in italics

The structure and main content of this Automotive Industry Guideline follows the first version of the Orgalime REACH Guide, A Practical Guide For Downstream Users, Article Producers and Article Importers (May 2007), which can be downloaded free of charge from the Orgalime (The European Engineering Industries Association) website, <http://www.orgalime.org/publications/guides/reach.htm>. Within the AIG you will find the content originating from the Orgalime REACH guide highlighted in italic letters. The beginning and end of any Orgalime REACH Guide quote is indicated with “ and “. Any modifications made to the Orgalime text in this Automotive Industry Guideline represent the position of Automotive Industry and do not necessarily reflect the position of Orgalime. For Orgalime positions, please consult <http://www.orgalime.org> or the Orgalime Secretariat at secretariat@orgalime.org.

Comments and updates of the Automotive Industry Guideline on REACH

This version, and future updates of the Automotive Industry Guideline on REACH, will be available to download free of charge at <http://www.acea.be/reach>. Comments and suggestions for the Task Force are welcome, via the Secretary to TF-REACH: rm@acea.be. However, to spread the workload, please contact the association of which you are a member (see Annex A). A list of changes comparing the current version with the previous one can be found in Annex E of this Guideline.

* See Annex A for a full list of TF-REACH member organisations and a list of all the major vehicle manufacturers, who are represented by ACEA, JAMA and KAMA.

CHAPTER 1 - INTRODUCTION: REACH AND THE AUTOMOTIVE INDUSTRY

This Introduction will explain why the automotive industry needs such guidelines, but will not give a complete overview of “What is REACH?”

The European Commission (EC) REACH Regulation* was adopted into European Union (EU) law in December 2006 and came into force on 1 June 2007. As an EC Regulation, it automatically becomes law in each Member State, so it does not need transposition in the same way as a Directive. REACH requires action from the OEMs and suppliers immediately and continuing over the coming 11 years and beyond.

It is of key importance to Downstream Users and importers to take advantage of the pre-registration option in REACH. Existing substances manufactured or imported on their own or in preparations as well as substances intended to be released from articles on the EU market need to be pre-registered between 1 June and 1 December 2008 (inclusive). Taking advantage of pre-registration allows for a transitional period to the registration process and allows continued production and use of substances until 2010 – 2018, depending on tonnage. Without Pre-registration, substances must be registered immediately. Pre-registration is free of charge and is very simple, requiring only basic information:

- Name and identification number (e.g. CAS, EINECS) of the substance
- Identification of manufacturer/importer and name of contact person
- Tonnage band and registration deadline
- The name of other substances for which the available information is relevant for performing adaptations to the testing requirements

It is recommended for non-EU suppliers to appoint an Only Representative in the EU to take on the responsibilities of an importer. In this case, non-EU suppliers can continue to deliver into the EU without each of their customers becoming importers under REACH.

REACH Myths

- ➔ REACH is a chemical industry issue.
- ➔ REACH is an EU-based company issue.
- ➔ REACH is an issue only for environmental, health and safety specialists.

REACH Realities

- ➔ Companies that do not comply with REACH will have no market. REACH poses a threat to any company doing business in the EU (and businesses with customers or suppliers who do business in the EU).
- ➔ Business continuity can be adversely impacted by REACH and supply chains can be disrupted.
- ➔ Companies that understand the business implications and impacts of REACH and develop strategic action plans will gain competitive edge over those that do not.
- ➔ Substitutions need to be phased-in with product development programmes to minimize cost.

Aims of REACH

REACH aims to ensure a “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).

The main objectives of REACH are therefore:

- ➔ To reduce the risk from chemicals to humans and the environment and to reduce animal testing
- ➔ To encourage substitution of unsafe substances
- ➔ To require authorisation for use or restriction of substances of very high concern (SVHC)

* See link in the Foreword to this AIG for full details of the REACH legal text.



Obligations

REACH puts the responsibility on industry to provide safety information for substances and to properly manage the risks arising from their use. Under the previous regime, the burden of proof was on governments to prove substances were unsafe and to restrict their use. REACH covers all substances on their own, in preparations and in articles, but there are exemptions for radioactive substances, non-isolated intermediates, substances used during transportation, and wastes (Article 2). (These are covered by other existing regulations.) Member States may also grant exemption for substances used in the interest of defence.

Under REACH, manufacturers and importers have a duty to register, for each legal entity, substances on their own, or in preparations that they produce or import in quantities over 1 tonne per year (per legal entity), unless the substance is exempt from registration. Registration requirements also apply to substance(s) intended to be released from articles under certain conditions, in which case the article producer/importer is responsible for ensuring that the substances are registered. To fulfil these obligations, the entire supply chain needs to communicate (data, uses, quantities, control measures for safe use, etc.). Downstream Users have a specific set of rights and obligations under REACH and will have to work closely with their suppliers to have their uses registered.

Each player in the supply chain should develop a Strategic Action Plan (see Chapter 6) to ensure compliance and minimise the business risks posed by REACH.

The Automotive Industry includes producers of articles (e.g. car, engine, bumper), importers of articles (e.g. screw from China), importers of preparations (e.g. engine oil from USA), and importers of substances (e.g. elemental magnesium from Australia). Article producers and article importers have specific obligations under REACH; in particular, the registration of substances intended to be released from articles and the communication/notification to Downstream Users and the Agency (ECHA) of SVHC present in the article

under certain conditions. Under the REACH regime it is not required to register or to notify the Agency of substances in articles if they are already registered or authorized for that use. However, the presence of SVHC must be communicated to Downstream Users in this case. Companies that import substances or preparations from outside the EU are no longer considered to be Downstream Users but Importers and have to comply with the Importer's obligations under REACH. Re-imported substances or preparations which originally have been produced in the EU are considered as being registered.

Substances have to undergo an authorisation process if they have been identified as being of very high concern and are included in the so-called candidate list (substances for which review for authorisation has been requested) and have then been included in REACH Annex XIV (list of substances subject to authorisation). This authorisation procedure may restrict the availability of a substance to the market. It should be noted that Downstream Users do not need to apply for an authorisation if the authorisation for their use has already been granted to an actor further up the supply chain.

In addition to these registration and notification procedures, REACH builds on existing legislation regarding restriction, classification and labelling of dangerous substances. A proposal for integrating the United Nations (UN) Globally Harmonised System for Classification and Labelling of Chemicals (GHS) into REACH has recently been issued by the EU Commission, which will lead to further adaptations of REACH*¹.

*1) The Commission proposed a Regulation to align the current EU system of classification of chemical substances and mixtures to the United Nations Globally Harmonised System (GHS). The proposal has yet to go through the legal process in the European Parliament and the Council. After entry into force, the proposed deadline for substance reclassification will be 1 December 2010 and for mixtures 1 June 2015. For more information see: http://ec.europa.eu/enterprise/reach/ghs_en.htm.

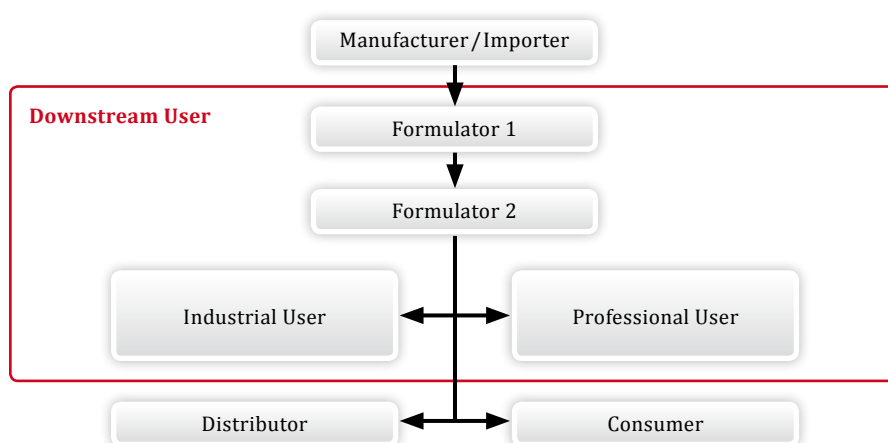


CHAPTER 2: MAIN DEFINITIONS AND ACRONYMS

2.1 Main Definitions

- **Actors in the supply chain:** means “all manufacturers and/or importers and/or Downstream Users in a supply chain” (Article 3.17 REACH).
- **Agency:** means “the European Chemicals Agency as established by this Regulation” (Article 3.18 REACH). Abbreviation: ECHA.
- **Article:** means “an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition” (Article 3.3 REACH).
Example: Vehicle, engine, seat, generator, wiper, windscreen, headlamp, screw, bolt, brake pads or linings.
- **Not considered to be articles:** Touch-up paint sticks, cleaning agents in cans, liquid tyre repair kits, engine oil in cans, etc; they are considered to be preparations in containers (borderline cases).
- **Candidate list:** List of substances of very high concern for potential inclusion in REACH Annex XIV, which itself lists substances subject to authorisation (Article 59 REACH). The establishment of the candidate list is subject to specific procedures described in Article 59 REACH.
- **Competent authority:** means “the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation” (Article 3.19 REACH).
- **Consumer:** means any natural person who is acting primarily for purposes which are not related to his or her trade, business or profession.*¹
- **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).
- **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).

*1) European Parliament, Committee on the Internal Market and Consumer Protection, “Working Document on European contract law and the revision of the acquis: State of play and the notion of consumer”, 17.5.2006, 615453EN).





Remark: 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, or Norway (which are members of the EEA, but are not members of the EU) would not be considered imports. Please consider Q53 of AIG Annex C for further information

- **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).
- **Import:** means “the physical introduction into the customs territory of the Community” (Article 3.10 REACH).
- **Importer:** means “any natural or legal person established within the Community who is responsible for import” (Article 3.11 REACH). The Only Representative has the same status under REACH as an Importer.

- **Intended to be released:** means that the releases are deliberately planned and have a specific function for the article, which is not the main function of the object, but an additional attribute. If a release is incidental, this is not an intended release. In cases where an intended release of substances is the main function of an object, it is to be regarded as a container with substances/preparations inside but not an article.

Basic Criteria: Does the Article still work without the release? If yes, the release is not intended.

A list of Automotive Industry specific examples of intended release is given in Guideline 7.

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

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

- **Intermediate:** means “a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance” (hereinafter referred to as “synthesis”): (Article 3.15 REACH);

(a) **non-isolated intermediate:** means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipe work for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) is/are stored after the manufacture;

(b) **on-site isolated intermediate:** means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an) other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

(c) **transported isolated intermediate:** means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.

- **Legal entity:** means any individual, partnership, proprietorship, corporation, association or other organization that has, in the eyes of the law, the capacity to make a contract or an agreement and the abilities to assume an obligation and to pay off its debts. A legal entity under the law is responsible for its actions and can be sued for damages.
- **Manufacturer:** means “any natural or legal person established within the Community who manufactures a substance within the Community” (Article 3.9 REACH)
Example: ethanol manufacturer, copper manufacturer.

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

- **Monomer:** means “a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process” (Article 3.6 REACH).

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

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

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

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

a) It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

b) It was manufactured in the Community or in the countries acceding to the EU on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this.



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

- **Placing on the market:** means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market (Article 3.12 REACH).
- **Preparation:** means “a mixture or solution composed of two or more substances” (Article 3.2 REACH).
Example: Paint, lubricant, adhesive, windshield-washer fluid, engine oil, a metallic alloy (e.g. steel, brass; Article 3.41 and RIP 3.8)
- **Producer of an article:** means “any natural or legal person who makes or assembles an article within the Community” (Article 3.4 REACH).
Example: Vehicle manufacturer, parts manufacturer (e.g. engine, component, bolt)
- **Polymer:** means “a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units”. (Article 3.5. REACH)

A polymer comprises the following:

(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

(b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a “monomer unit” means the reacted form of a monomer substance in a polymer.

Example: PP, PA6, PVC, POM, PTFE, EPDM, SBR, NBR, ECO, etc.

- **Product and process orientated research and development (PPORD):** means “any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance” (Article 3.22 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 3.35 REACH).
- **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).
- **Registrant's own use:** means “an industrial or professional use by the registrant” (Article 3.25 REACH).
- **Scientific research and development:** means “any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year” (Article 3.23 REACH).
- **Site:** means “a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared” (Article 3.16 REACH).
- **Substance:** means “a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition” (Article 3.1 REACH).



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

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

(a) Substances meeting the criteria for classification as carcinogenic, mutagenic, or toxic for reproduction according to Directive 67/548/EEC (“CMR-substances”) category 1 or 2.

(b) Substances which are persistent, bioaccumulative and toxic according to Annex XIII REACH (“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.

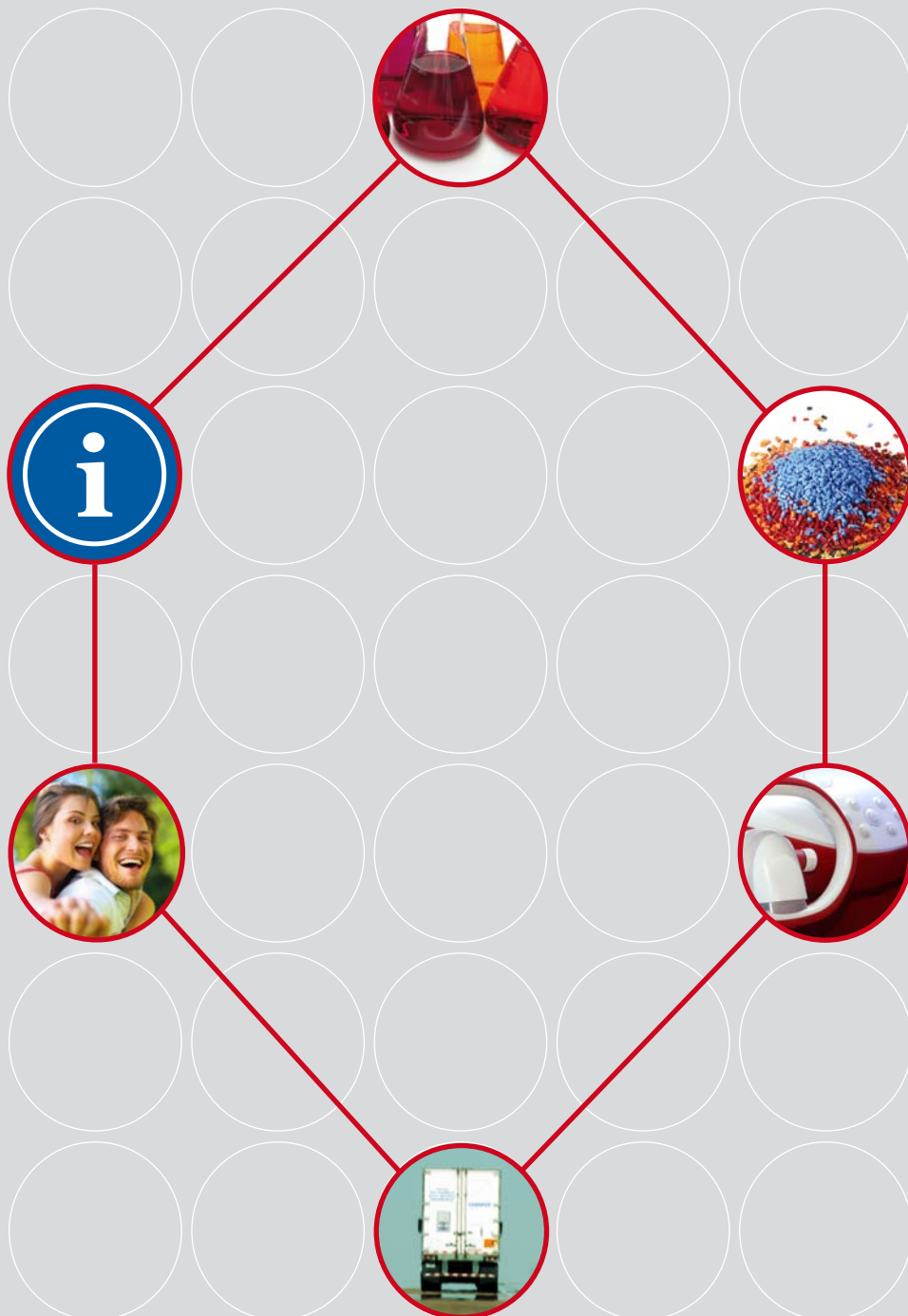
- **Sunset date:** means “the date(s) from which the placing on the market or the use of the substance shall be prohibited unless an authorisation is granted which should take into account, where appropriate, the production cycle specified for that use” (Article 58.1 REACH).
- **Supplier of a substance or a preparation:** means “any manufacturer, importer, Downstream User or distributor placing on the market a substance, on its own or in a preparation, or a preparation” (Article 3.32 REACH).

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

- **Use:** means “any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization” (Article 3.24 REACH).

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





2.2 Acronyms

ACEA

European Automobile Manufacturers Association

AIAG

Automotive Industry Action Group

AIG

Automotive Industry Guideline for REACH

CAS

Chemical Abstracts Service. The CAS number is a means to identify the substance.

CLEPA

European Association of Automotive Suppliers

CMR

Carcinogenic, Mutagenic, Toxic for Reproduction

CSR

Chemical Safety Report

DU

Downstream User

ECHA

European Chemical Agency

EINECS

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

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).

ELV

End-of-Life Vehicle Directive (2000/53/EC)

EPER

European Pollutant Emission Register
<http://www.eper.cec.eu.int/eper>

GADSL

Global Automotive Declarable Substance List.
See <http://www.gadsl.org>

GHS

Globally Harmonised System for classification and labelling of chemicals
http://ec.europa.eu/enterprise/reach/ghs_en.htm

IMDS

International Material Data System.
See <http://www.mdssystem.com>

IUCLID

International Uniform Chemical Information Database

JAMA

Japan Automobile Manufacturers Association, Inc.

KAMA

Korea Automobile Manufacturers Association

MACSI

Material Composition Information System (PSA System for material declaration)

OSOR

One Substance, One Registration

ORGALIME

The European Engineering Industries Association

PBT

Persistent, Bio-accumulative and Toxic.

PPORD

Product and Process Oriented Research and Development



PRTR

Pollution Release and Transfer Register

REACH

Registration, Evaluation, Authorisation (and Restriction) of Chemicals

RIP

REACH Implementation Project. These are technical guidance documents and IT-tools developed for the Agency, industry and the authorities by the EC in collaboration with stakeholders. See <http://ecb.jrc.it/reach/rip> and Guideline 11.

RRR

Directive on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability (2005/64/EC)

SDS

Safety Data Sheet

SIEF

Substance Information Exchange Forum

SMMT

Society of Motor Manufacturers and Traders, UK

SVHC

Substance of Very High Concern

TGD

Technical Guidance Document (Resulting documents from a RIP)

VDA

German Automotive Industry Association

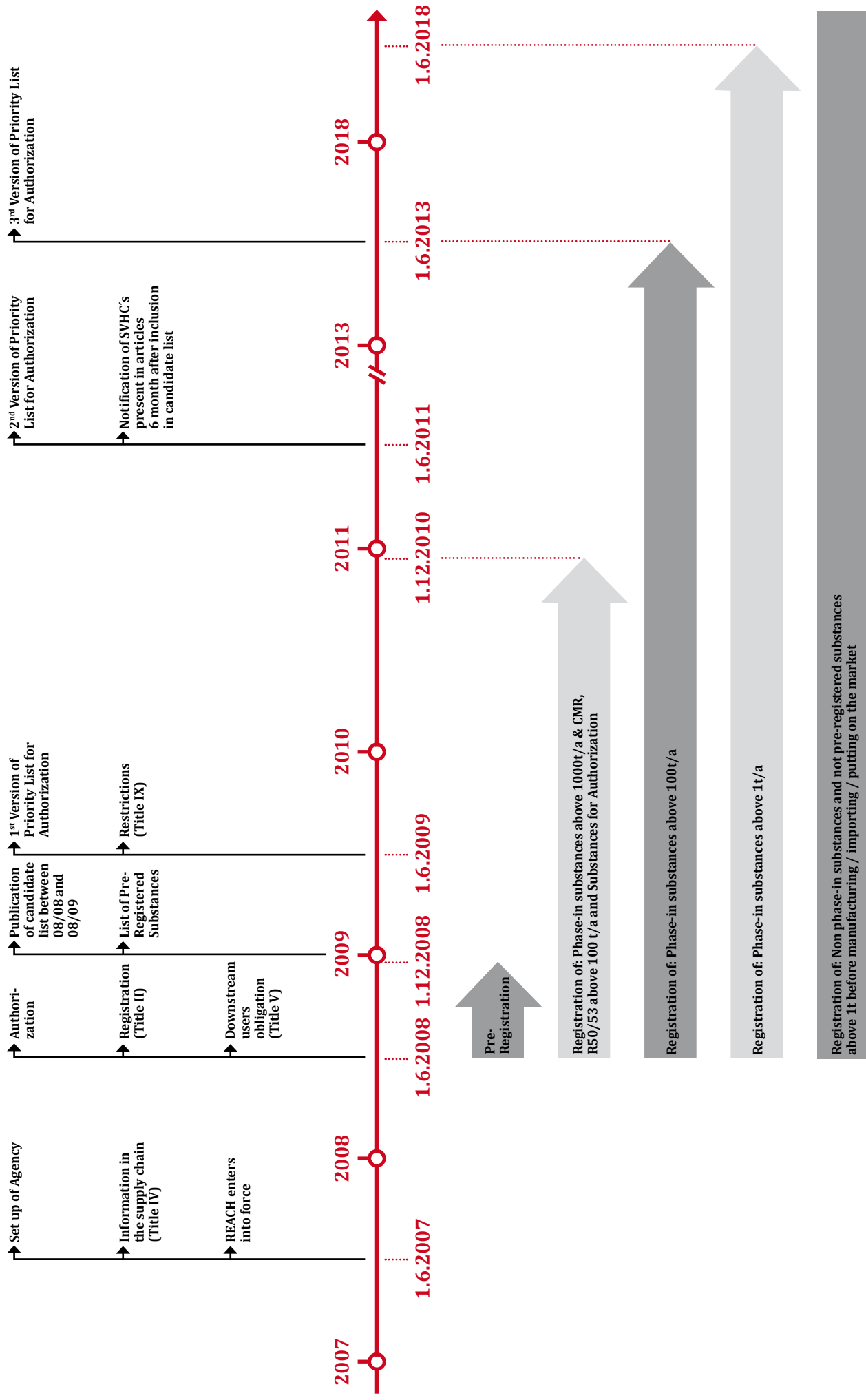
vPvB

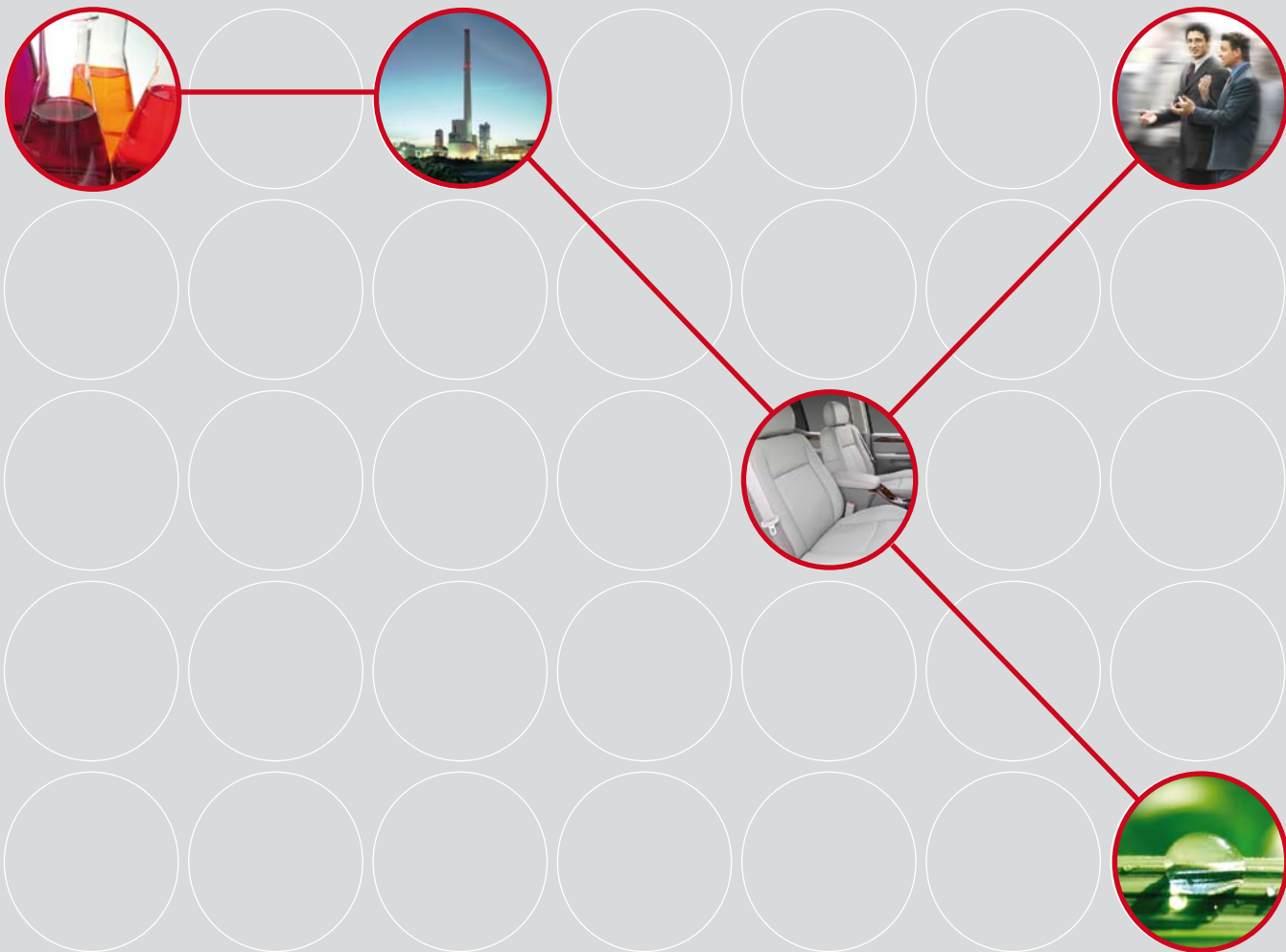
very Persistent and very Bioaccumulative



CHAPTER 3: IMPORTANT DATES AND DEADLINES TO REMEMBER

2007	
1 June 2007	<ul style="list-style-type: none"> REACH entered into force. Title IV REACH "Communication in the supply chain" applies. <p>Note: New data to be included in the safety data sheet will only be made available at a later stage according to transition periods for registration.</p>
2008	
between 1 June 2008 and 1 December 2008 (inclusive)	<ul style="list-style-type: none"> Pre-registration of phase-in substances on their own, in preparations or intended to be released from articles (Article 28 REACH). <p><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 articles imported for first time and containing a phase-in substance requiring registration (Article 28.6 REACH).
1 June 2008	<ul style="list-style-type: none"> Registration of non phase-in substances on their own, in preparations or intended to be released from articles before they are manufactured/imported/put on the market. Title V REACH "Downstream User's obligations" applies. Title VII REACH "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	<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).
By 1 June 2009	<ul style="list-style-type: none"> Title VIII REACH "Restrictions" applies – repeal of Directive 76/769/EEC.
2010	
From 1 June 2008 until 30 November 2010	<ul style="list-style-type: none"> Registration of: <ul style="list-style-type: none"> - Substances classified as "CMR", category 1 and 2 in quantities of 1 tonne/year and above per manufacturer/importer. - Substances classified as very toxic to aquatic organisms (R50/53) in quantities of 100 tonnes/year and above per manufacturer/importer. - Other substances on their own, in preparations or intended to be released from articles in quantities of 1000 tonnes/year and above per manufacturer/importer (Article 23.1 REACH).
2011	
As of 1 June 2011	<ul style="list-style-type: none"> Notification of substances in articles (Article 7.2 REACH) 6 months after they have been included in the candidate list (Article 7.8 REACH). <p>Warning: Information requirements to Downstream Users apply as of inclusion on the candidate list</p>
2013	
From 1 June 2008 until 31 May 2013	<ul style="list-style-type: none"> Registration of substances on their own, in preparations or intended to be released from articles in quantities of 100 tonnes/year and above per manufacturer/importer (Article 23.2 REACH).
2018	
From 1 June 2008 until 31 May 2018	<ul style="list-style-type: none"> Registration of substances on their own, in preparations or intended to be released from articles in quantities of 1 tonne/year and above per manufacturer/importer (Article 23.3 REACH).





CHAPTER 4: GUIDELINES

4.1 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).

Exporter: means “any natural or legal person established outside the Community who is responsible for exporting goods into the EU.

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: Automotive Industry companies do play several roles under REACH and have specific obligations, depending on whether they:

Manufacture substances	In this case companies bear the obligations of a manufacturer (e.g. pre-registration/registration needs to be done by this company)	Guideline not yet developed (partly covered with guideline 4/ flow chart 1)
Formulate (Manufacture) Preparations	In this case companies bear the obligations of Downstream Users	See Guideline 5
Use substances/preparations supplied by an EU supplier	In this case companies bear the obligations of Downstream Users	See Guideline 5
Import substance/ preparation 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 Guideline 4
Produce articles	In this case, companies bear the obligations of article producers	See Guidelines 7, 8, 9
Import articles from outside the EU	In this case, and if intended release is given or SVHC >0.1% are present, companies bear the obligations of importers, if there is no EU “Only Representative” of the non EU supplier appointed	See 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, RIP 3.2, RIP 3.5, RIP 3.8”



4.2 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](#) (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 regard to marketing and use of certain dangerous substances and preparations.

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.

" ... " *1

Nature of substance: Registration (Title II REACH), Downstream Users' 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.

" ... " *1

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 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)."

Example for explanation: If vinyl chloride must be registered as a monomer for producing PVC, the polymer PVC is exempted from registration but may be restricted for specific uses depending on the residue monomer content.

"... "*1

NOTE

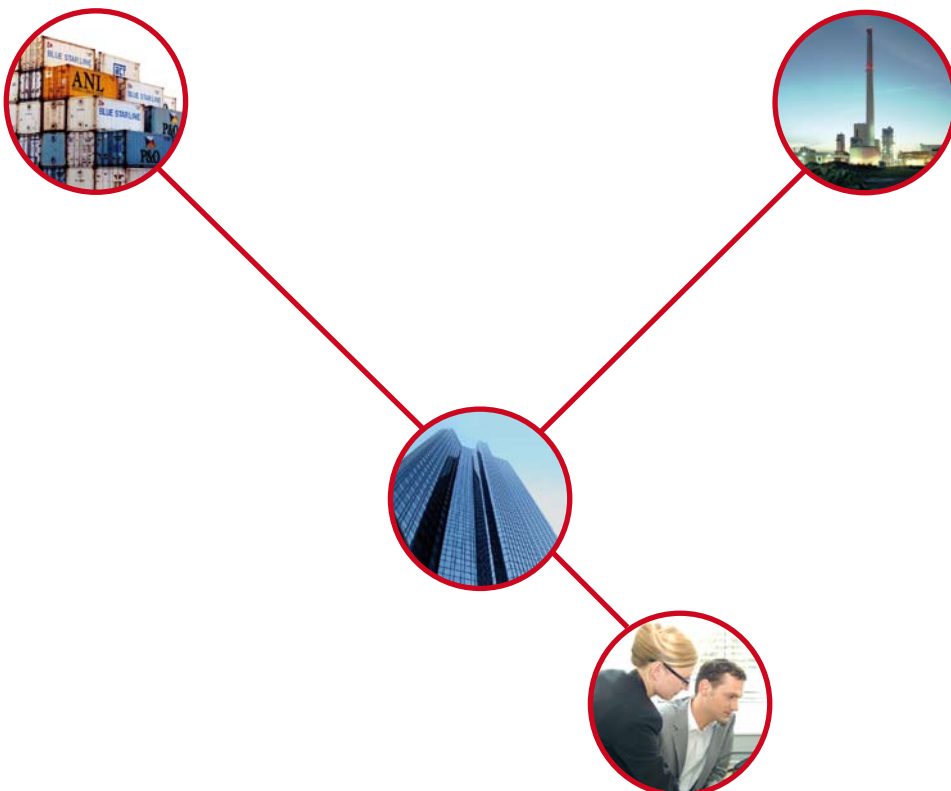
By 1 June 2008, the European Commission shall review Annexes IV and V REACH (Article 138.4 REACH).

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, please check Guideline 11.

For more details, please check Articles 1, 2, 6, 9, 138.4, 138.6 of the REACH legislation"

*1) Modification to Orgalime REACH Guide, pages 18 & 19, paragraphs "Use", "nature of preparation" and "substances regarded as being registered" due to no relation to Automotive Industry. For original, please see <http://www.orgalime.org/publications/guides/reach.htm>



4.3 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 (SVHC, substances intended to be released) 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, in the Chemical Safety Reports and in any exposure scenarios (see Guideline 5)."

An efficient way of data collection is to request suppliers to deliver SDS for all substances and preparations, independent of their concern.

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 those 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 pre-register and generate the data package for registration in order to be allowed to continue to supply that substance/preparation (s. Guideline 4)."

Which substances are intended to be released from an article that the company produces?

If you produce articles in the EU, intentionally releasing substances, without that this substance has been pre-registered/registered by an actor up the supply chain, you will be obliged to register the substances released under certain conditions (see Guideline 7).

***For substances present in the article, you will have to identify whether they are of very high concern and communicate this information to recipients of the article per Article 33 requirements under REACH. This information must be made available to consumers within 45 days of any request for such information. Under certain conditions, you will have to notify the Agency for such substances (see Guideline 8). "..."*^{*1}**

Which substances are intended to be 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 pre-register and 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 Guideline 4), and communicate this information to recipients of the article (Article 33 REACH). This information must be made available to consumers within 45 days of any request for such information. Under certain conditions, you will have to notify the Agency of such substances (see Guideline 8). "..."*^{*1}

"Depending on your role under REACH, you need to collect the following key information in order to determine your REACH obligations (if any):

- Substance/preparation name
(supplier's proprietary name, if any)
- Chemical name
- CAS number (if any)
- ELINCS / EINECS number (if any)
- Amount used(imported into EU) per year (kg) or amount used in EU if you are a DU
- Supplier name and address
(responsible individual for each supplier)
- Is it imported by you?
- Is the substance identified as of very high concern?
- Is the substance critical for your business?
- Registration number, if available



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 a 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?"
- SIEF/consortia partner contact information and other details about data sharing

Additional considerations:

Please note that the level of details of the information to be collected may vary, depending on the different roles that a company may play. The matrix below gives an overview of these roles and the necessary information for each.

Recommended data for inventories, depending on the different roles:

Recommendation of information to be gathered:	Substances			Preparations			Articles		
	Manufacturer in EU	Importer into EU	Downstream User	Formulator/Distributor in EU	Importer into EU	Downstream User	Producer in EU	Importer into EU	Recipient of Articles *1
REACH Representative per Company	X	X	X	X	X	X	X	X	X
Substances purchased from inside EU and purpose of use	X		X	X		X			
Preparations purchased from inside EU and purpose of use				X		X			
Substances imported from outside EU and purpose of use	X	X	X	X		X			
Preparations imported from outside EU and purpose of use				X	X	X			
Availability of SDS for purchased Substances		X	X	X					
Availability of SDS for purchased Preparations				X	X	X			
Produced articles, intentionally releasing substances (incl. Substance information)							X		
Imported articles, intentionally releasing substances (incl. Substance information)							X	X	
SVHC in Articles							X	X	X
Imported SVHC	X	X	X	X	X	X	X		
SVHC in EU-production	X		X	X		X	X		

*1) Addition to Orgalime REACH Guide, pages 20, paragraphs "Which substances are intended to be released from an article that the company produces" and "Which substances are intended to be released from an article that the company imports?". For original, please see <http://www.orgalime.org/publications/guides/reach.htm>.



Example on how to use the matrix:

A company has production plants in and outside Europe. For their European production, they are using substances, preparations and articles from different sources:

- European suppliers
- Non European suppliers
- Own plants outside Europe

Taking into consideration this simple example, the company would have the following roles under REACH*1:

- Article producer in the EU
(In their own plant)
- Article importer into the EU
(From their plant outside Europe)
- Downstream User of preparations
(From a European supplier)
- Importer of preparations into the EU
(Only in case that supplier has no Only Representative in EU)
- Downstream User of substances
(From a European supplier)
- Importer of substances into the EU
(Only in case that supplier has no Only Representative in EU)

NOTE

A Company might have more than just one role under REACH. An Article manufacturer, for example, can also be a Downstream User or Importer of Substances or Preparations. Therefore, it is recommended to first check your roles under REACH and then to find out what information will be required. More guidance may be necessary to determine if you are an Importer/ Producer/DU, etc.

Especially for inventories related to articles, the Automotive Industry in general has already established several tools to be compliant with other obligations (ELV, RRR, etc.). It is of course recommended to use those tools (see Guidelines 8 & 9).

*1) Within REACH, the role of a "Downstream User of Articles" does not exist; rather "Recipient of Articles" is the applicable term

*1) "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 Guideline 8)." →

*2) Modification to Orgalime REACH Guide, pages 20, paragraphs "Which substances are intended to be released from an article that the company produces" and "Which substances are intended to be released from an article that the company imports?". For original, please see <http://www.orgalime.org/publications/guides/reach.htm>."



4.4 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^{*1}, following the same regime as substances intended to be released from an article produced in the EU (see Guideline 7). Registration procedures for such imported substances may be carried out by:

- Import a substance on its own/in preparations in quantities of 1 tonne and above per year/ importer; (...)*²
- Import a substance on its own/in preparations in quantities of 1 tonne and above per year/ importer, to be supplied to customer together with an article.
- Import an article intentionally releasing a substance and the substance is present in articles in quantities of 1 tonne and above per year/ importer.

NOTE

"• The supply of substances/preparations/articles from EU Member States to other EU Member States are not considered imports.

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, companies (for every one of their importing 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:

- 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, or Norway (which are members of the EEA, but are not members of the EU) would not be considered imports.
- If a global acting company manufactures outside the EU a substance on its own, preparations or articles intentionally releasing substances 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 and join the related Substance Information Exchange Forum (SIEF). Joint submission of data by multiple registrants is possible (Article 11 REACH). Joint submission of most of the data is required by the "One-Substance-One-Registration" (OSOR). In most cases, it is not optional (see RIP 3.4)
- "• 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."



An “Importer” is any natural or legal person established within the Community who is responsible for import (Article 3(11) REACH). Import means the physical introduction into the customs territory of the Community (Article 3(10) REACH). By contrast, the “Exporter” ships substances, preparations, and articles into the EU Community and is not established in the EU as a legal entity.

As an Exporter, non-EU companies have no formal obligations under REACH. Based on contracts and other business relationships, exporters may be required to provide substance information to the importer or their “Only Representative” (see Flowchart 5 and additional text below) to aid in fulfilling the REACH registration obligations. Alternatively, non-EU suppliers in the automotive supply chain may be asked by their EU customers to appoint an “Only Representative” and assume the responsibility for registration. See recommendation below.

Substances on their own or in preparations that are imported from outside the EU must be registered following the same rules as substances manufactured in the EU (see Flowchart 1). Companies that import substances and preparations from outside the EU are not considered “Downstream Users” of those substances and preparations, but Importers, and must comply with the Importer’s obligations under REACH. EU Importers must fulfil the REACH registration obligation and join the related Substance Information Exchange Forum

(SIEF). They will need information provided by their suppliers and/or must purchase the required data in the SIEF. Importer obligations appear in various sections of this AIG, and are summarized in Flowchart 6.

NOTE

All “Phase-in” substances must be pre-registered by 1 December 2008 by the Importer, the “Only Representative” of a non-EU manufacturer, or both. Failure to pre-register a substance, substances in preparations, or substances intentionally released from articles may result in one of the following:

- 1.) The substance, preparation, or article may no longer be imported into the EU;
- 2.) The substances must be fully registered immediately, prior to importing into the EU.

If the substance is not pre-registered, the registration phase-in period no longer applies. This may result in a disruption in the supply chain.

In addition, the importer must also comply with all authorization and notification requirements for substances, preparations, and articles designated as or containing Substances of Very High Concern (SVHC). (See Flowcharts 2 and 4).



Automotive Industry recommendation for Exporters:

Collecting the relevant data required for REACH registration is very time consuming and costly. This is especially true for companies that import substances and preparations that are produced outside of the EU Community. They must gather the necessary data required to register the substance from the substance suppliers. Every attempt should be made to use substances that are already registered. Importing companies prefer to cooperate with non-European companies that have already established an “Only Representative” in Europe. It is suggested that registration is pushed as far upstream in the supply chain as possible to make the most effective use of technical information and to avoid duplication. (The substance manufacturer is the furthest upstream in the supply chain; the automotive OEM is the furthest downstream.)

Consequently, the major recommendation of the AIG to the non-European suppliers providing products to EU customers is to establish an “Only Representative” within the EU (i.e., for the Exporter to assume the obligations of an Importer). Regrettably, this first priority cannot always be adopted. If, for example, suppliers choose or are not able to establish an “Only Representative” in the EU, further options may be considered and prioritised as follows:

➡ Priority 1

Ask non-EU supplier to establish an “Only Representative” and to register

➡ Priority 2

Change suppliers or substitute the substance / preparation

➡ Priority 3

Assume registration responsibilities, as importer, using required technical data provided by the non-EU supplier, or ask a service provider to act on your behalf

The order of the Priorities, especially Priorities 2 and 3, is not fixed, but depends on company-specific policies and strategies.

When an “Only Representative” submits a registration, a copy of the letter of the non-EU manufacturer(s) officially assigning the Only Representative is also required. For phase-in substances, the “Only Representative” must also pre-register the substance and will subsequently become a participant of the Information Exchange Forum (SIEF).

Moreover, an “Only Representative” will have to keep all available up-to-date information on quantities imported, the list of EU customers of the exporters he represents, as well as information on the supply of the latest update of the Safety Data Sheet (SDS). The non-EU manufacturer must inform all of the EU importers in the same supply chain that he has appointed a representative in the EU as his “Only Representative”, who then becomes legally responsible for the registration. Nevertheless, it can be anticipated that in most cases, it will be the non-EU exporter who will provide the “Only Representative” with all necessary data for his dossier. If a non-EU manufacturer decides to change his “Only Representative”, the newly appointed “Only Representative” can, in agreement with the former “Only Representative”, update the registration dossier by changing the registrant identity, and if necessary, any other issues (e.g. change of tonnage band) (Article 8 REACH).

It is possible that an “Only Representative” is named for all legally incorporated or registered entities of an importing company. In such cases, the legal entity taking over the role of an “Only Representative” will carry out the pre-registration/registration for all other parts of the organisation. These will then assume the status of “Downstream Users” under REACH.



4.5 Guideline 5: Communication obligations along the supply chain

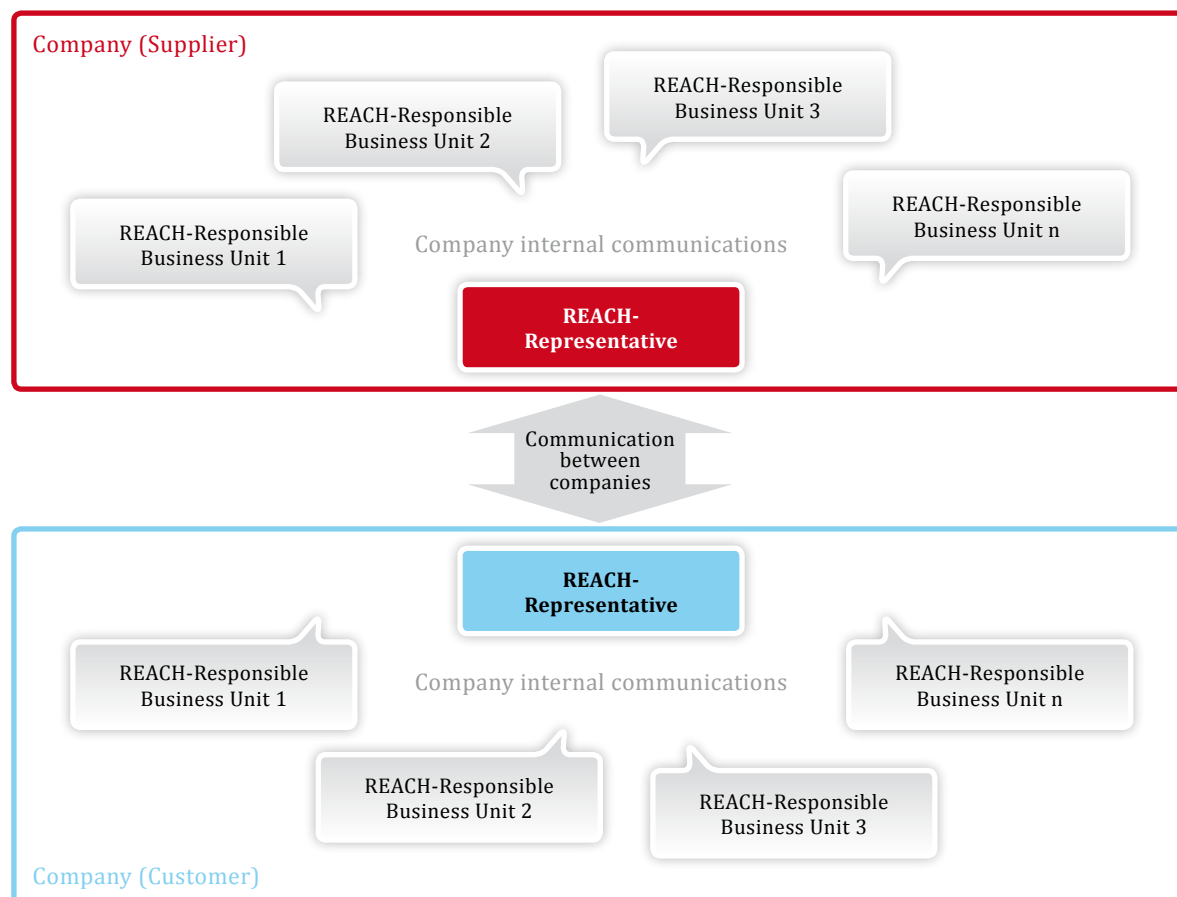
"In order to secure a continued supply of a substance on its own/in preparations for their use(s), Downstream Users (hereafter called "DU"), have to check whether the supplier will support their use(s) and include them in the substance registration dossier to be submitted to the Agency. DU may only use 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 him 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 the supply chain

Under REACH, communication is required between the legal entities of each company. As one company very often has many different legal entities, communication can be difficult to manage. Therefore, it is recommended to appoint one REACH representative within each company to be the central contact point and take responsibility for managing the internal company communication for all legal entities.



*“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).**”*

To protect intellectual property rights it is recommended for the Downstream User not to explain the use in too much detail.

“DU” should therefore:

- *As a first step, identify the substances and preparations used in their industrial processes (see Guideline 3).*
- *As a second step, ask their suppliers whether they intend to pre-register/register the 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)*¹. 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 scenarios*² covering their use(s)” as informed by declaration of intent request letter (see Step 3 of AIG 8-step compliance schedule). “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 proactive 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).*

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 or finding an alternative substance if at all possible;*
- *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 Guideline 6).*

**1) 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.*

**2) 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 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.
- Whether 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 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

Guideline 9), which would come in addition to the communication requirements outlined in the present guideline. Reference to Article 33 of REACH and its communication requirements.

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 State's competent authority or the Agency (Article 36 REACH).

If DU is using substances of very high concern, authorisation procedures might also apply (see 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 suppliers*1."*

For more details, please check

Title IV, Title V, Annex VI n°6 REACH

RIP 3.2, RIP 3.5, RIP 3.8"

Additional considerations

For suppliers or distributors with only a small number of customers, it is possible to communicate by letter or questionnaire. However, most suppliers (and distributors) within the Automotive Industry have significantly more complex supply chains with a large number of customers of different sizes. For these companies, there is a great deal of concern that using a questionnaire in this format to harmonise data gathering could result in an unmanageable administrative burden.

In order to simplify communication along the supply chain, different institutions are working on IT-tools. As the development is still ongoing, it is currently not possible to recommend one of those for the special purpose of the Automotive Industry (AI). The TF REACH will observe and evaluate the solutions in the future and finally make a recommendation, which will be published in a future version of this Guideline with the objective of having a single common communication tool in the AI.

It is strongly recommended that Downstream Users check the available data to find out whether their use of a substance is covered in the registration (even if they are not legally required to do so) in order to avoid substance or supplier loss. Following are two possible ways of accomplishing this:

- Collect SDS for ALL substances & preparations in the production process:

Impacts:

- The registration numbers as well as all registered uses are included in the SDS, once the revised SDS has been issued after registration by the registrant. This can be as late as 2018. As the process of SDS-

handling is usually well established in European companies it would be easy to check in the received data whether the use is covered or not.

- Once a SDS is received, the recipient has - independent of the potential risk of a substance or preparation - the obligation to apply the therein mentioned Risk Management Measures (Article 37(5a) REACH) and to fulfil the communication obligations which could lead to unnecessary burden.

- According to Article 32(1a) REACH, any supplier of preparations and substances who does not have to supply a safety data sheet in accordance with Article 31 shall provide the recipient with the registration number(s) referred to in Article 20(3), if available. This information could also be used to check whether the use is identified.

Impacts:

- You will only get SDSs and need to apply the related obligations if the requirements under Article 31(1) REACH are fulfilled.
- The investigation work is more complicated because the registration number must first be collected, which could be available as late as 2018, and second it must be used for further investigations.

Important: Information that is not required under REACH might be required by other legal obligations (e.g. Health and Safety).

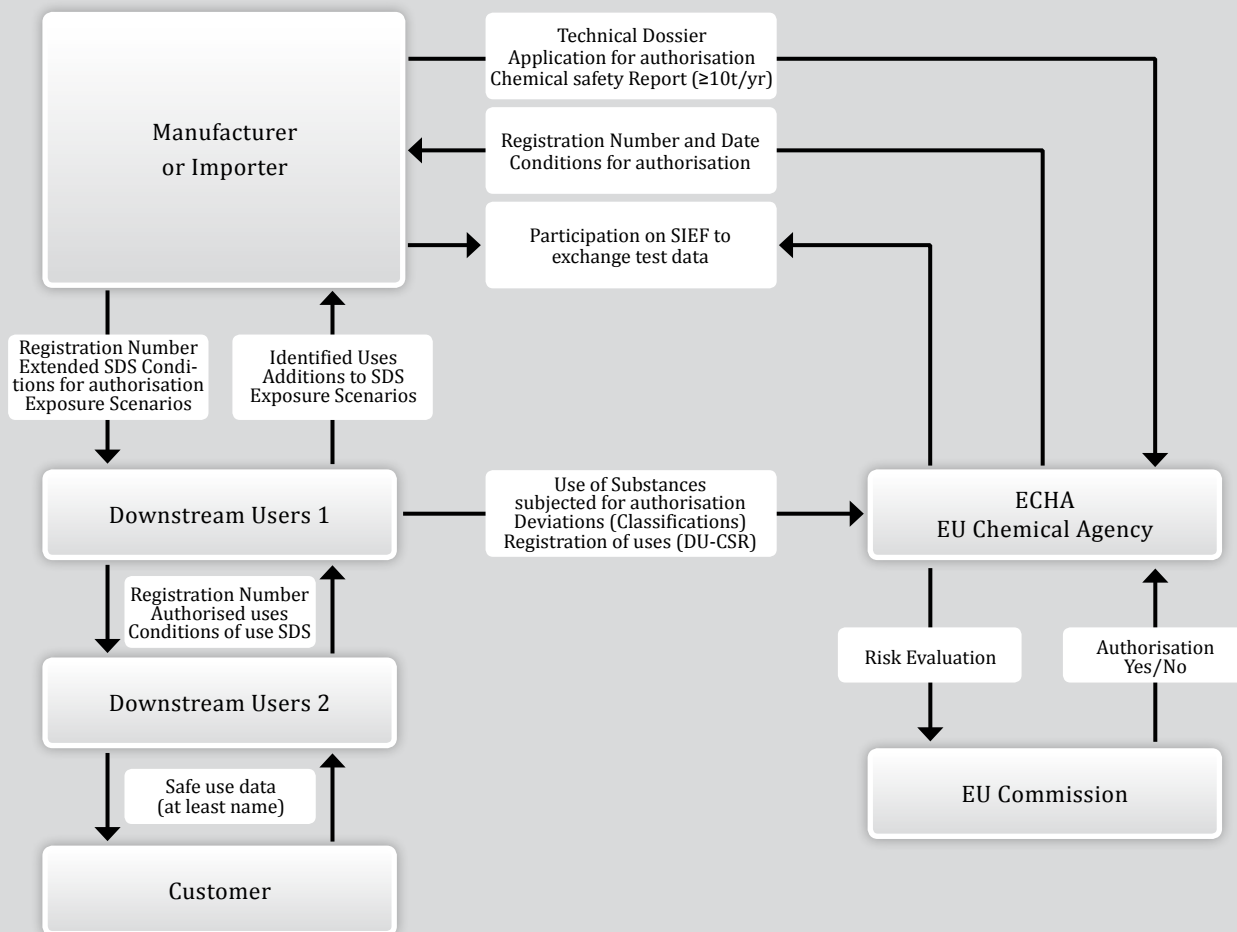
NOTE

The TF-REACH is of the opinion that one common IT-standard for exchanging SDSs (e.g. the EDAS-Format) is useful to simplify communication up and down the supply chain.

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



Principle of Communication



4.6 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 the Automotive Industry 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 Guideline 5)" (...)*1*

If you use dangerous substances and preparations as a Downstream User, you will receive Safety Data Sheets (SDSs), which under REACH may have one or more exposure scenarios attached. An exposure scenario describes how a substance or a preparation can be safely used and the risk management measures (RMM) which should be applied to control risk to humans or the environment. If you receive an exposure scenario, you must check whether your current use is covered and whether you comply with the conditions described in the exposure scenario. If you use a substance or preparation outside the conditions described in the exposure scenario, or if your use is not covered by the exposure scenario, you have several options:

- You may make your use/use conditions known to your supplier so that the supplier can prepare an exposure scenario covering your use conditions.
- You may change your conditions of use so that they comply with the supplier's exposure scenario.
- You may find another supplier who provides an exposure scenario covering your conditions of use.
- You may prepare your own chemical safety report.
- You may find an alternative substance, preparation or process and discontinue using the substance/preparation in question.

"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, DUs 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 they 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 "*

*1) Addition to Orgalime REACH Guide, pages 20, paragraphs "Which substances are intended to be released from an article that the company produces" & "Which substances are intended to be released from an article that the company imports?". For original, please see <http://www.orgalime.org/publications/guides/reach.htm>."



4.7 Guideline 7: Registration of Substances in Articles

"Both EU producers and importers of automotive 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 of the following conditions apply:

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

EU producers should check if their suppliers have already registered the substance intended to be released.

The global Automotive Industry has identified the following listed examples, once assembled onto a vehicle, as the currently identified articles that intentionally release substances under normal or reasonably foreseeable conditions of use:

- Fragrance dispensers,
- Fire extinguishers systems,
- Windshield-washer fluid reservoirs,
- Compressed gases from pyrotechnic devices.

Please note that although a pyrotechnic device with compressed gas is listed as an article with substances that intentionally release when assembled onto a vehicle, basic elemental substances for which hazards and risks are already well known (hydrogen, oxygen, noble gases, nitrogen) are exempted from registration, per Annex V (9) of the REACH regulation. Registration may be required if other substances or preparations are utilized.

These same articles, if imported on their own (i.e. not assembled onto the vehicle) would be considered containers with preparations, and would therefore be subject to the registration obligations associated with preparations in containers.

As a general rule, the term 'intended to be released' implies that a certain function or quality of an article is connected to the release of a substance or preparation.

Thus, all substance releases which occur because of aging of articles, because of wear and tear or as a result of accidents, are not intended releases (From RIP 3.8).

The global Automotive Industry supports the position of the Federation of European Manufacturers of Friction Materials that states that brake linings are articles with no intended release of substances. The Automotive Industry also supports the position of the Association of the Pyrotechnics Industry (VPI) and the manufacturers of automotive pyrotechnic products that the chemical products of the pyrotechnic reaction are exempt from REACH registration requirements under Annex V (3) upon deployment, since the chemicals are consumed in the reaction.

Preparations such as, but not limited to: brake, transmission, and steering fluids, greases, and lubricants that are in or on automotive articles are integral to the function of those articles, and are therefore considered to be an integral part of the article. They would, therefore, NOT require pre-registration and registration if contained in or on imported articles.*¹ These same substances in preparations, however, require pre-registration and registration if imported on their own.

Please keep in mind that the Automotive Industry may also produce or import other non-vehicle related articles that are subject to REACH requirements. These may include items such as tools, machinery, equipment, and packaging. Although these are all considered articles and are not expected to intentionally release substances under normal or foreseeable conditions of use, the SVHC contained therein must still be monitored and tracked.

*1) FEMFM Federation of European Manufacturers of Friction Materials stated clearly that brake linings are articles with no intended release of substances. Concerning a wrong example in RIP 3.8, FEMFM has sent a complaint to the EC, Unit REACH G1 in December 2006. It was confirmed by the EC to consider this objection in the next review in 2007.



In cases where EU REACH regulatory interpretation is vague or non-existent, the global Automotive Industry has established these positions. Although they may be used as guidance, these positions should not be considered legal opinion, and each company is advised to determine the appropriate position it will assume to meet its corporate and REACH regulatory requirements.

If a supplier becomes aware of other automotive articles that they consider to contain substances intended to be released under normal or reasonably foreseeable conditions of use that are not listed here, please contact rm@acea.be with details and for discussion with other global Automotive Industry representatives on further potential actions as determined.

Substances intended to be released under normal or reasonably foreseeable conditions of use from the above-mentioned automotive articles must be pre-registered in order to benefit from the registration transition periods (REACH Article 28). 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).

Furthermore, a substance intended to be released from an article should be registered according to the same timelines as those that apply to substances on their own or in preparations (REACH Article 23).

A registration (Article 7.1) is obligatory only for those substances in articles meeting the following conditions:

- The substance is intended to be released from the article during normal and reasonable foreseeable conditions of use
- The total amount of the substance present in all articles exceeds 1 tonne per year per producer or importer
- The substance has not yet been registered for the use (article 7(6) exemption does not apply)

"Timelines to register substances:

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 (inclusive)	<p>From 1 June 2008 until 30 November 2010 for:</p> <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. <p>From 1 June 2008 until 31 May 2013 for:</p> <ul style="list-style-type: none"> • Other substances in quantities of 100 tonnes and above per year. <p>From 1 June 2008 until 31 May 2018 for:</p> <ul style="list-style-type: none"> • Other substances in quantities of 1 tonne and above per year.



"Fees"

Fees required for the registration of substances in articles will be specified in a EC'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. "

In October 2007, a first draft of a commission regulation 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) was published under

http://www.euractiv.com/31/images/Commission%20draft%20REACH%20fees_tcm31-168130.pdf

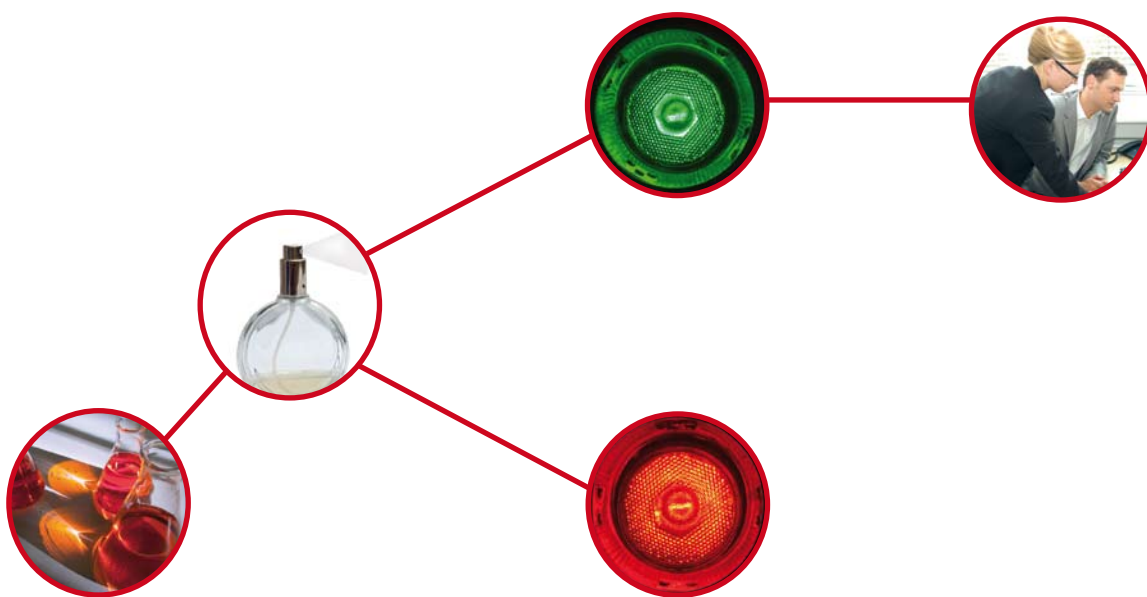
NOTE

"Article producers/importers should pay attention note 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 Guideline). "*

For more details, please check: Articles 6, 7, 23, 28; RIP 3.8

See flow chart 3.



4.8 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, and 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 Guideline 9).

For more details, please check Articles 7, 57, 59 REACH; RIP 3.8”



4.9. Guideline 9: Communication requirements for substances in articles

Communication requirements are already present in existing legislation applying to the Automotive Industry, such as in Directive 2001/95/EEC on General Product Safety or 2004/418/EC on the determination of guidelines for manufacturers and dealers when reporting hazardous consumer products to Member States.

*“Article 33 REACH further requires that the supplier of an article (see definition in section 2.1) 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 to the consumer 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 Guideline 10).
[...]*1*

Additional considerations

Summary of the most important obligations under REACH for communication and notification obligations for substances in articles and recommended strategy for an Automotive Industry:

1. Article 33.1

Supplier to inform article recipient if article contains SVHC

2. Article 33.2

Upon request by a consumer, any supplier of an article containing a SVHC shall provide the consumer with sufficient information to allow safe use of the article.

3. Article 7.2

Notification to the Agency of SVHCs by the importer/producer*2

4. Article 7.3

Notification is not necessary if exposure can be excluded*³ in normal use (incl. disposal). In this case the producer or importer shall supply appropriate instructions to the recipient of the article.

5. Article 7.4

Information which **only** has to be communicated by the article producer/importer to the Agency if there is exposure to SVHC under normal conditions.

6. Article 7.5

The Agency can require a producer or importer to register any substance in an article if there is a substance release.

By taking into consideration those six obligations, the following basic strategy for the Automotive Industry is recommended:

- 1, 2 Use the Substance Reporting Systems (e.g. IMDS, MACSI) already established for reporting purposes. The prerequisite for correct substance reporting is a continuously updated SVHC-list (e.g. GADSL). In case of new SVHC, an update of the reported substance information is necessary.
- For those companies that do not have an IT-tool available, alternative methods can be used to collect the necessary data.

By following that recommendation, the main tasks are achieved:

- Complete Inventory of SVHCs in Articles*⁴
- Evaluation of potential exposure of humans or the environment

From RIP 3.8 (Draft): "Appropriate instructions should be supplied to the recipient of an article containing SVHC in concentrations above 0.1% (w/w). The information should be sufficient *to allow safe use* and disposal of the article and should include as a minimum the *name of the substance*."

The information needed by the recipient could be adjusted to the type of the intended use of the article and the user, e.g. industrial or professional user. The purpose of the information is to ensure safe use, i.e. to

limit the risk associated with the use of the article. The level of the knowledge of the recipient should be decisive for the formulation and design of the instruction. For industrial users, additional information could be part of the information requirements stated in Annex VI of REACH "Guidance on safe use":

3. Based on the inventory, cases requiring notification can be identified and actions defined.
4. To avoid release of critical substances to the environment, the disposal of vehicles is regulated in the ELV-Directive 2000/53/EC. All European car manufacturers have to fulfil those obligations. Consequently, exposure during vehicle treatment can be excluded. In other words, the notification obligation for the article "Vehicle" is unlikely. This may differ for sub-components or after-sales parts. Provide appropriate instructions to the recipient of the article.
5. In the Automotive Industry, an exposure from articles (also during exposure) is unlikely (see results of 1, 2). No systematic data collection is necessary, but remedial data gathering is recommended in cases of exposure.
6. Based on the inventory, cases for registration can be identified and actions defined.

These recommendations will be finalised when RIPs are finalised.

*1) Modification to Orgalime REACH Guide, pages 20, paragraphs "Which substances are intended to be released from an article that the company produces" & "Which substances are intended to be released from an article that the company imports?".

For original, please see <http://www.orgalime.org/publications/guides/reach.htm>.

*2) Also to be considered: tonnage (>1t/year) and threshold (0.1% w/w)

*3) Guidance on checking if exposure can be excluded during normal or reasonably foreseeable conditions of use is given in RIP 3.8 (Guidance On Requirements For Substances In Articles, due in autumn 2007, see <http://ecb.jrc.it/reach/rip> for more information).

*4) Data are only available for Articles which are used in the vehicle but not for Articles used for the production process (welding machines...).



4.10 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 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, which 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 REACH ^{*1} (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 the 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).

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).

^{*1}) 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 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 making 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 socioeconomic 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

Article 64

Title VII REACH

RIP 3.5, RIP 3.7, RIP 3.9”

ADDITIONAL NOTE FOR THE AUTOMOTIVE INDUSTRY

- DUs should be prepared for a potential restriction and substitution of substances and should outline related strategies.
- Following the results of the substances inventory, it is recommended to identify potential critical substances
- If necessary, data to support authorisation for your use should be gathered.



4.11 Guideline 11: List of REACH Implementation Projects

“REACH Implementation Projects (RIPs) are technical guidance documents and IT-tools developed for the Agency, industry and the authorities by the EC in collaboration with stakeholders. RIPs tackle seven main areas and a number of sub-projects, which are outlined below.”

NOTE

- RIP guidance documents are subject to change and are not legally binding.
- Of main importance for the AI are the RIPs 1 to 3. Guidance from RIP 4 to 8 do not have direct relevance.

RIP 1	REACH Process Description	project running
RIP 2	REACH-IT	project running
RIP 3	Technical Guidance and Tools for Industry RIP 3.1 Registration RIP 3.2 Preparing Chemical Safety Report (CSR) RIP 3.2-1A Technical Guidance Document (TGD) on preparing the CSR (Scoping) RIP 3.2-1B TGD on preparing the CSR (Draft CSA) RIP 3.2-2 TGD on preparing the CSR RIP 3.3 Information requirements on intrinsic properties of a substance RIP 3.3-1 TGD on information requirements (Scoping) RIP 3.3-2 TGD on information requirements RIP 3.4 Data sharing (pre-registration) TGD on data sharing RIP 3.5 Downstream User requirements RIP 3.5-1 TGD on Downstream User requirements RIP 3.5-2 TGD on Downstream User requirements RIP 3.6 Guidance on classification and labelling under GHS RIP 3.7 Guidance on preparing an authorization application RIP 3.8 Guidance on fulfilling the registration requirements for substances in articles RIP 3.9 Carrying out a socio-economic analysis RIP 3.9-1 Preliminary study on Socio-Economic Analysis RIP 3.9-2 Guidance on carrying out a socio-economic analysis RIP 3.10 TDG on identification and naming of substance	project finalized preliminary project finalised preliminary project finalised project running preliminary project finalised project finalised project running preliminary study finalised project running project running project running project finalised, currently under review; it will be updated finalised project running project finalised
RIP 4	Technical Guidance and tools for authorities RIP 4.1 Dossier evaluation RIP 4.2 Substance evaluation RIP 4.3 Inclusion of substances in Annex XIV RIP 4.4 TGD on the preparation of Annex XV dossiers RIP 4.5 Priority setting for evaluation	project finalised project finalised project running project finalised project running
RIP 5, 6	Setting up the agency	project running
RIP 7	Preparation of the new tasks of the Commission	
RIP 8	Agency Standard operation procedures	

Overall guidance package

An overview of RIPS can be found under <http://ecb.jrc.it/reach/rip>. To facilitate the accessibility to the guidance RIPs 1, 2, 3 and 4, a web application has been developed. The “REACH-Navigator” helps industry to determine

its obligations under REACH and find the appropriate guidance on how to fulfil these obligations. The navigator and further information can be found on the ECHA website under: http://reach.jrc.it/navigator_en.htm

4.12 Guideline 12: Helpdesks and Information tools

This selection of web addresses from helpdesks and information sources is intended to identify additional help when this guideline does not provide the answer. Inclusion of a source in this list does not mean that the TF REACH or Automotive Industry agrees to all of the content and its interpretation of REACH may differ from that of the Automotive Industry.

The “European Chemicals Agency” ECHA found at: http://ec.europa.eu/echa/reach_en.html

Content:

- **About REACH:** This section provides you with an overview of the Regulation. It lets you get started with REACH processes, chemicals covered, methods and tools used and parties involved (Actors under REACH). http://reach.jrc.it/about_reach_en.htm
- **Navigator:** The Navigator is an interactive tool that provides answers to questions companies may have on their substance and what they need to do under REACH. <http://reach.jrc.it>
- **Guidance:** REACH guidance documents provide supplementary information to the legal text. They cover all technical aspects of REACH. These documents have been produced with the assistance and endorsement of the Member States authorities, the EC and industry. Therefore, companies should use the guidance documents as the primary source of information when they need advice on how to fulfil their REACH duties. http://reach.jrc.it/guidance_en.htm
- **Software tools for REACH:** To assist with chemical data management and registration submission under REACH, two software tools will be available: REACH-IT and IUCLID5. http://ec.europa.eu/echa/reach/software_en.html
- **Frequently Asked Questions (FAQs):** If you have a question, the quickest way for you to get an answer may be the database of Frequently Asked Questions. http://ec.europa.eu/echa/reach/faq_en.html

- **Helpdesks:** The Agency helpdesk assists companies with questions relating to their registrations of chemical substances. Each Member State provides REACH helpdesk services to all interested parties in their country. These helpdesks are operating in a network that will harmonise the answers to ensure consistent support to companies across Europe. IUCLID helpdesk assists registered users of the software. http://ec.europa.eu/echa/reach/helpdesk_en.html

REACH.startpagina.nl: This “website of websites” gives a good overview about the different websites and helpdesks from several nations and organizations. It provides links to legal texts, news about REACH, and related websites regarding chemicals information: <http://reach.startpagina.nl>

This selection will be updated as necessary as new reference material and guidelines become available.



4.13 Guideline 13: Industry-run helpdesks and Guidance

This selection of web addresses from helpdesks and information sources is intended to identify additional help when this guideline does not provide the answer to your question. Inclusion of a source in this list does not mean that the TF REACH or Automotive Industry agrees with all of the content, and its interpretation of REACH may differ from that of the Automotive Industry.

German Industry (BDI):

This site contains a “one pager” on all aspects of REACH and its different chapters. Language: German
<http://reach.bdi.info>

European Chemical Industry Council (CEFIC):

“REACHCentrum” is the new professional services body established by CEFIC.
<http://www.reachcentrum.eu>

Danish Industry (DI):

The Confederation of Danish Industries (DI) has established a helpdesk to assist Danish companies in meeting their REACH obligations and to help them comply with the new chemical legislation. (Danish language with basics in English).
www.reach-klarbesked.dk

UK Chemical Industry:

“REACHReady” is a wholly-owned subsidiary of the Chemical Industries Association (CIA) in the UK.
<http://www.reachready.co.uk>

Greece Industry Association:

(in Greek language)
http://www.haci.gr/english/index_en.htm

Austrian Chemicals Industry (FCIO):

(German language)
<http://reach.fcio.at>

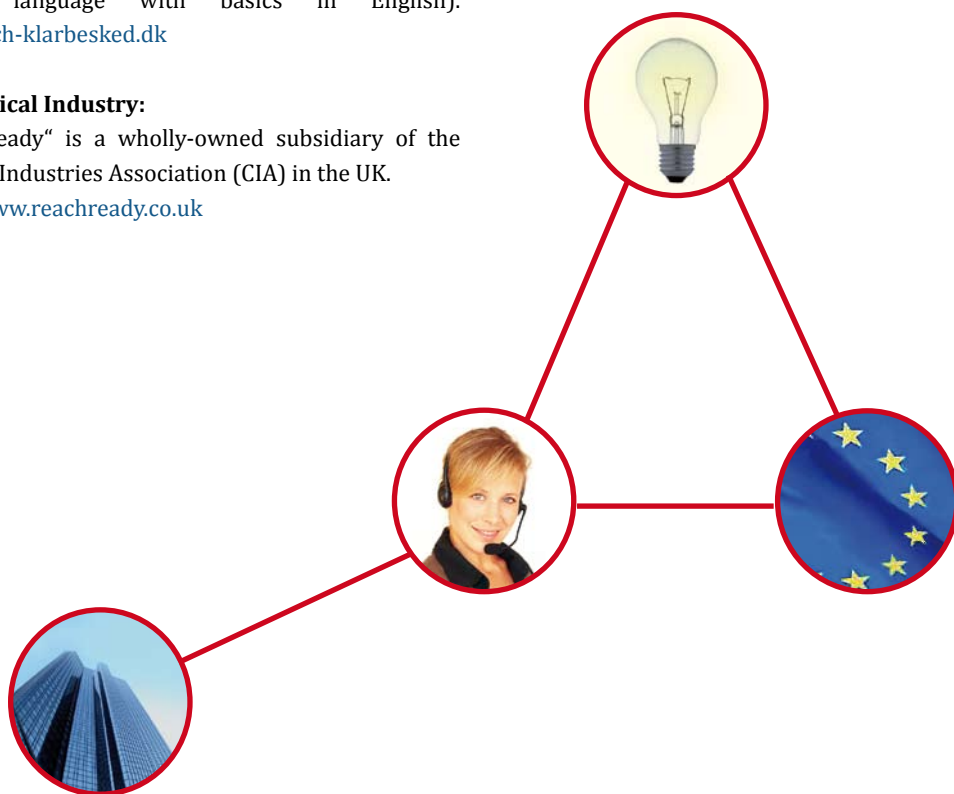
Aero SME:

is a joint activity of ASD, AeroSpace and Defence Industries Association of Europe, and the EC
<http://www.asd-europe.org/Content/Default.asp?PageID=41>

ORGALIME:

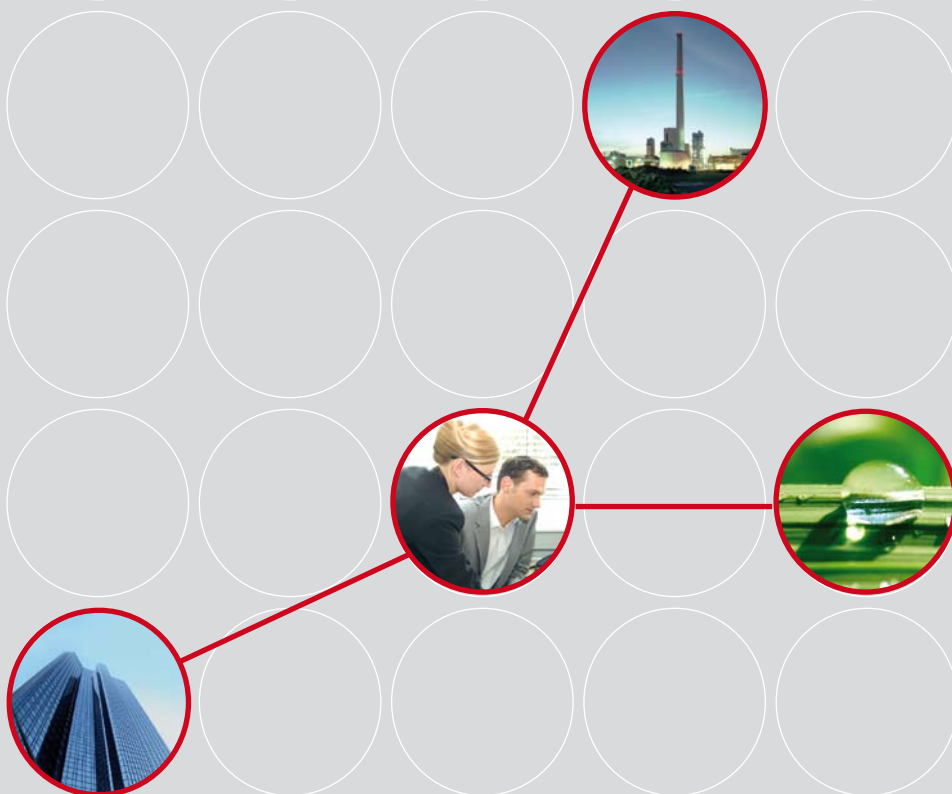
is the European Engineering Industries Association
<http://www.orgalime.org>

This selection will be updated as necessary.



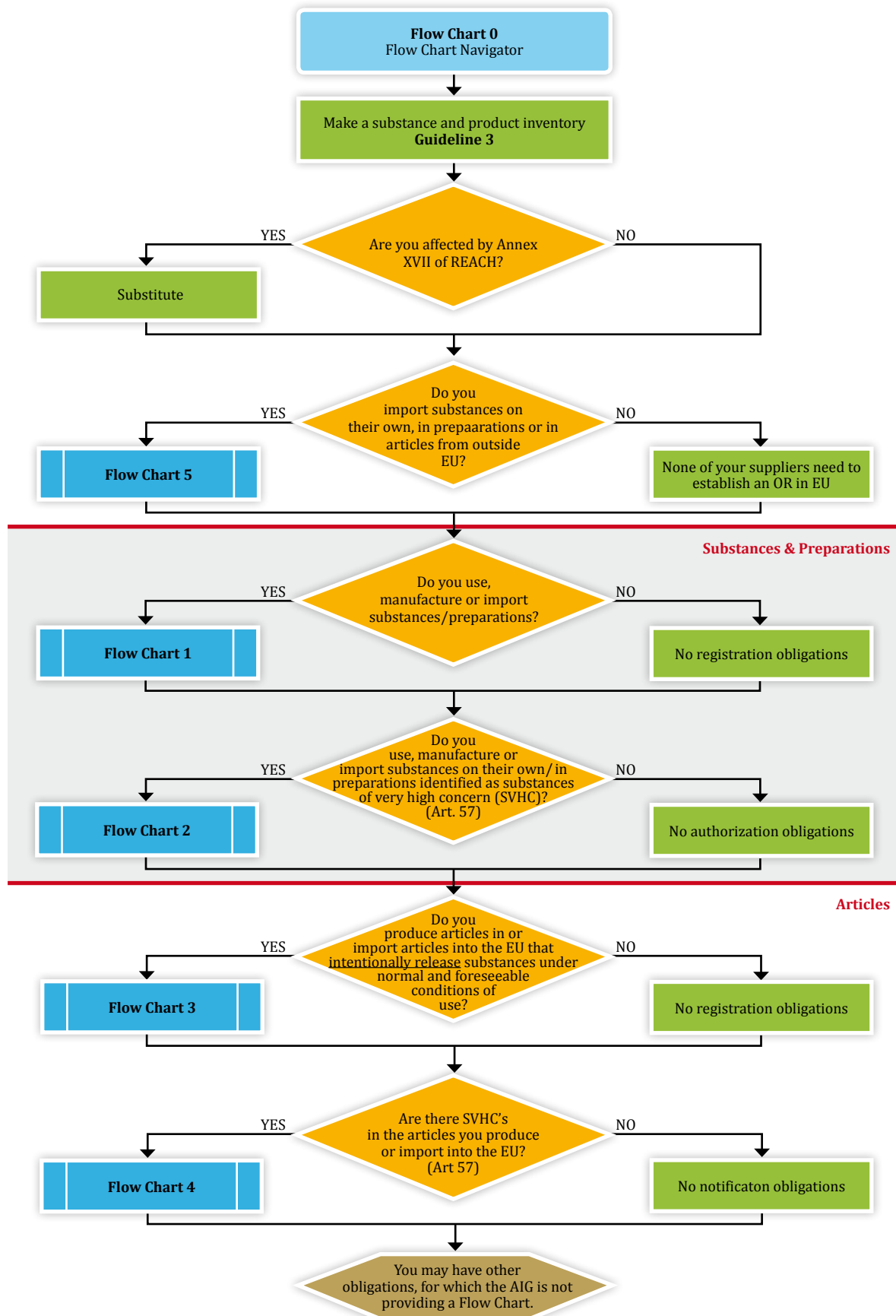
CHAPTER 5: REACH compliance - a step-by-step process

The following flow charts have been constructed to help companies determine what their obligations are under REACH. Flow charts 1 to 4 should be viewed as complementing each other. For more information on the step-by-step process, refer to Chapter 5 of this guideline. Where such guidelines exist, references to them have been integrated in the flow charts and the AIG 8 step compliance schedule (Chapter 6).



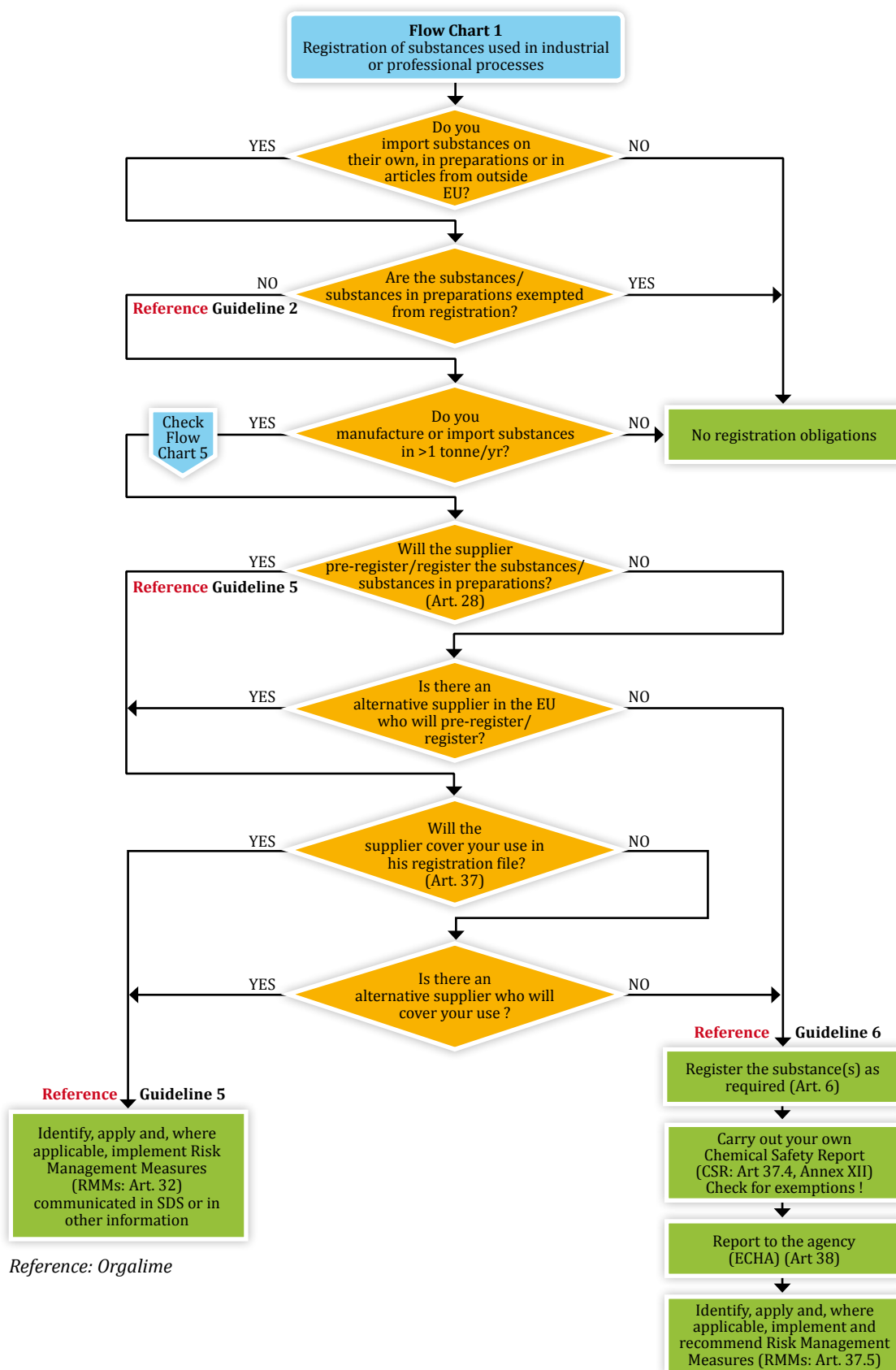
5.0 REACH Flow Chart 0 Flow Chart Navigator

47



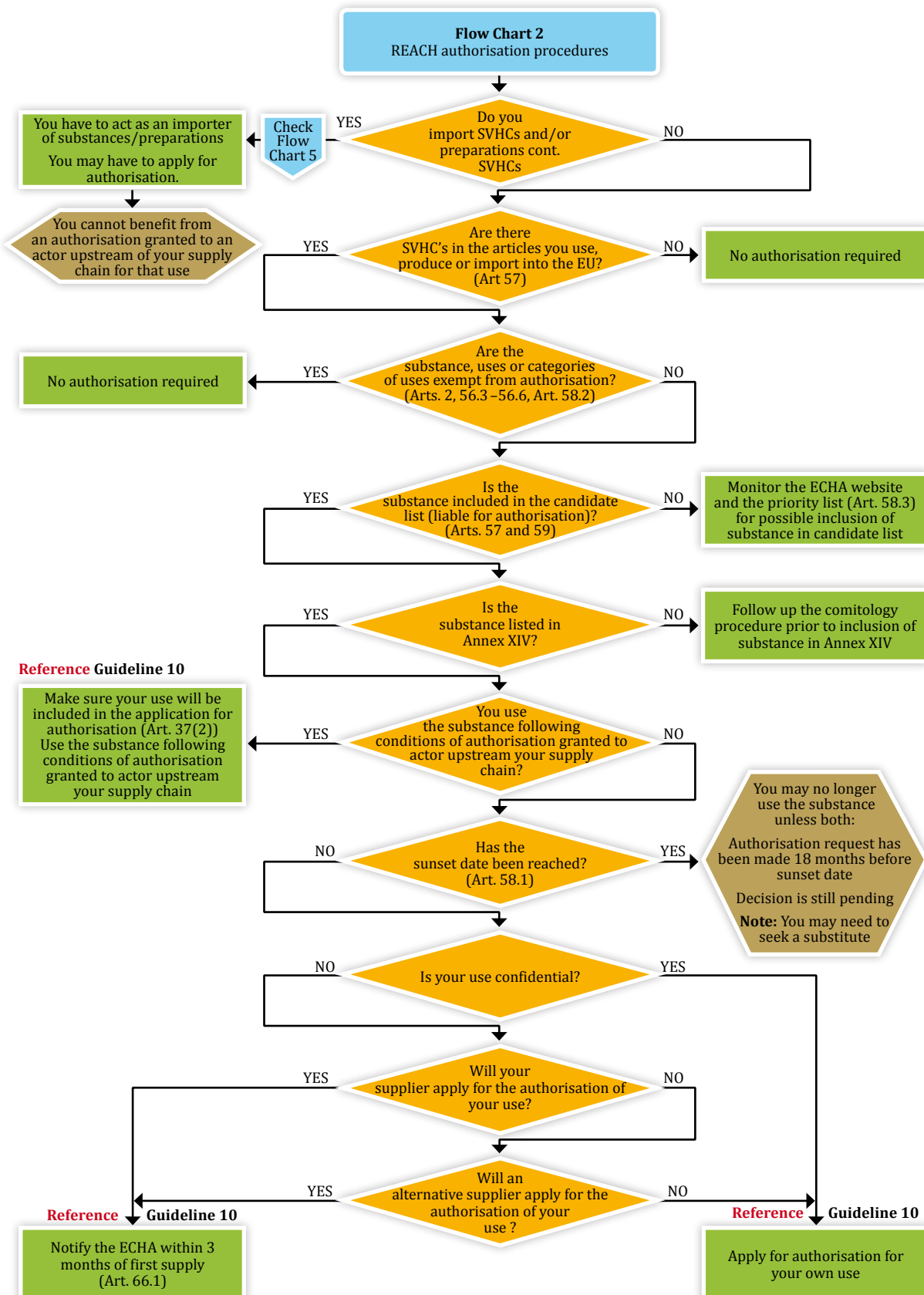
5.1 REACH Flow Chart 1

Registration of substances/substances in preparations used in industrial (including engineering) processes



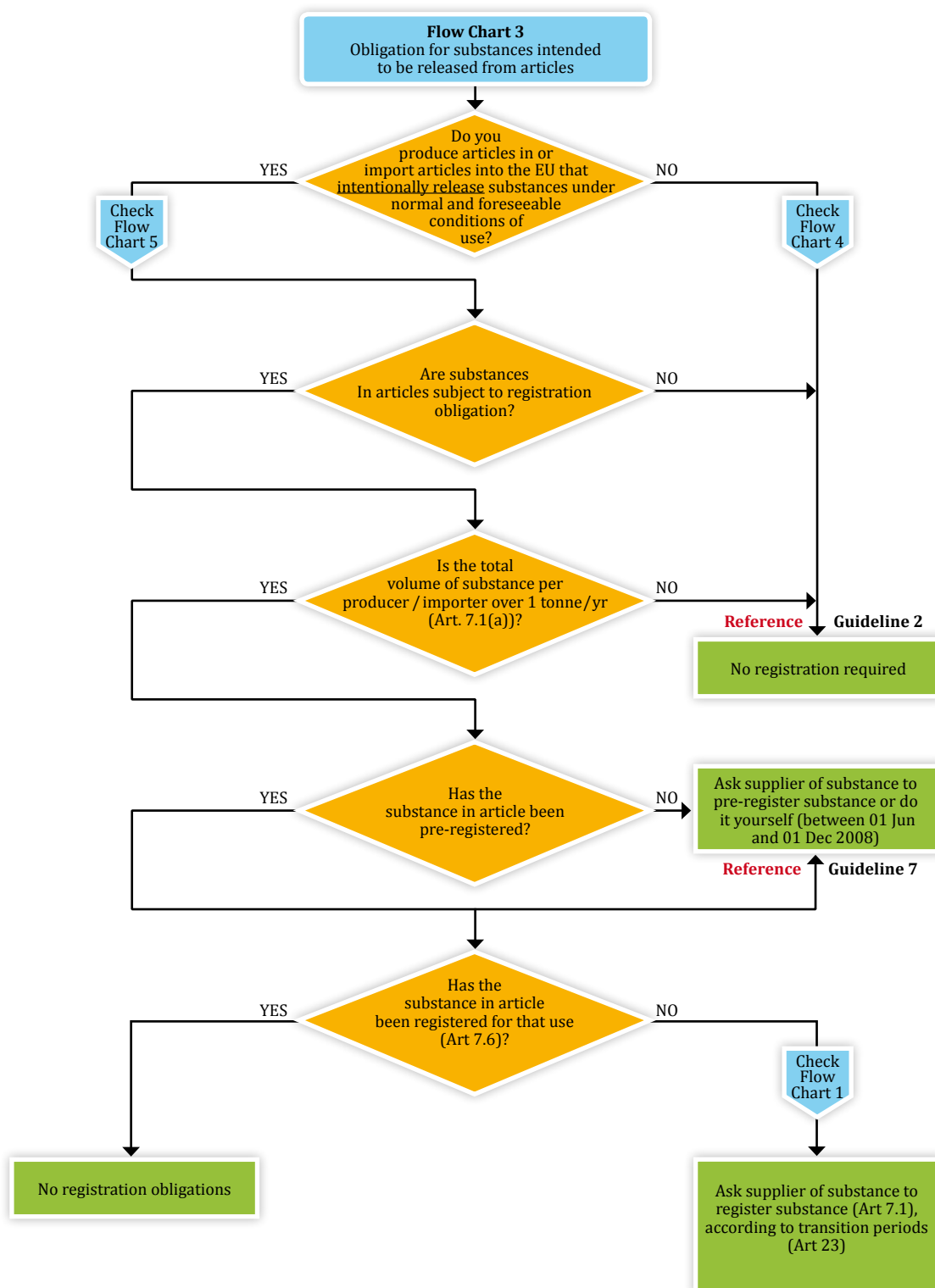
5.2 REACH Flow Chart 2

REACH authorisation procedures



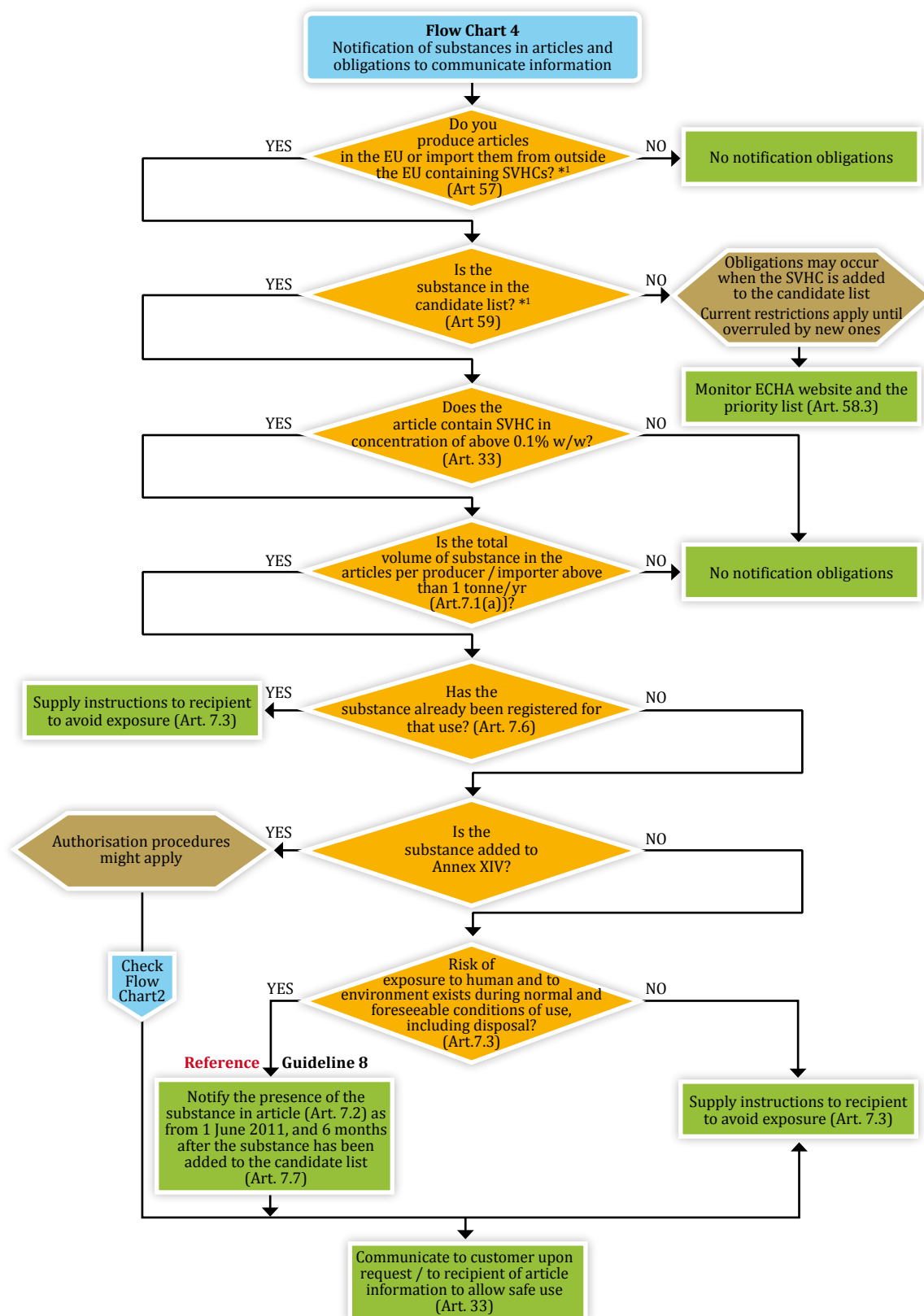
5.3 REACH Flow Chart 3

Registration of substances intended to be released from articles



5.4 REACH Flow Chart 4

Notification of substances in articles and obligation to communicate information

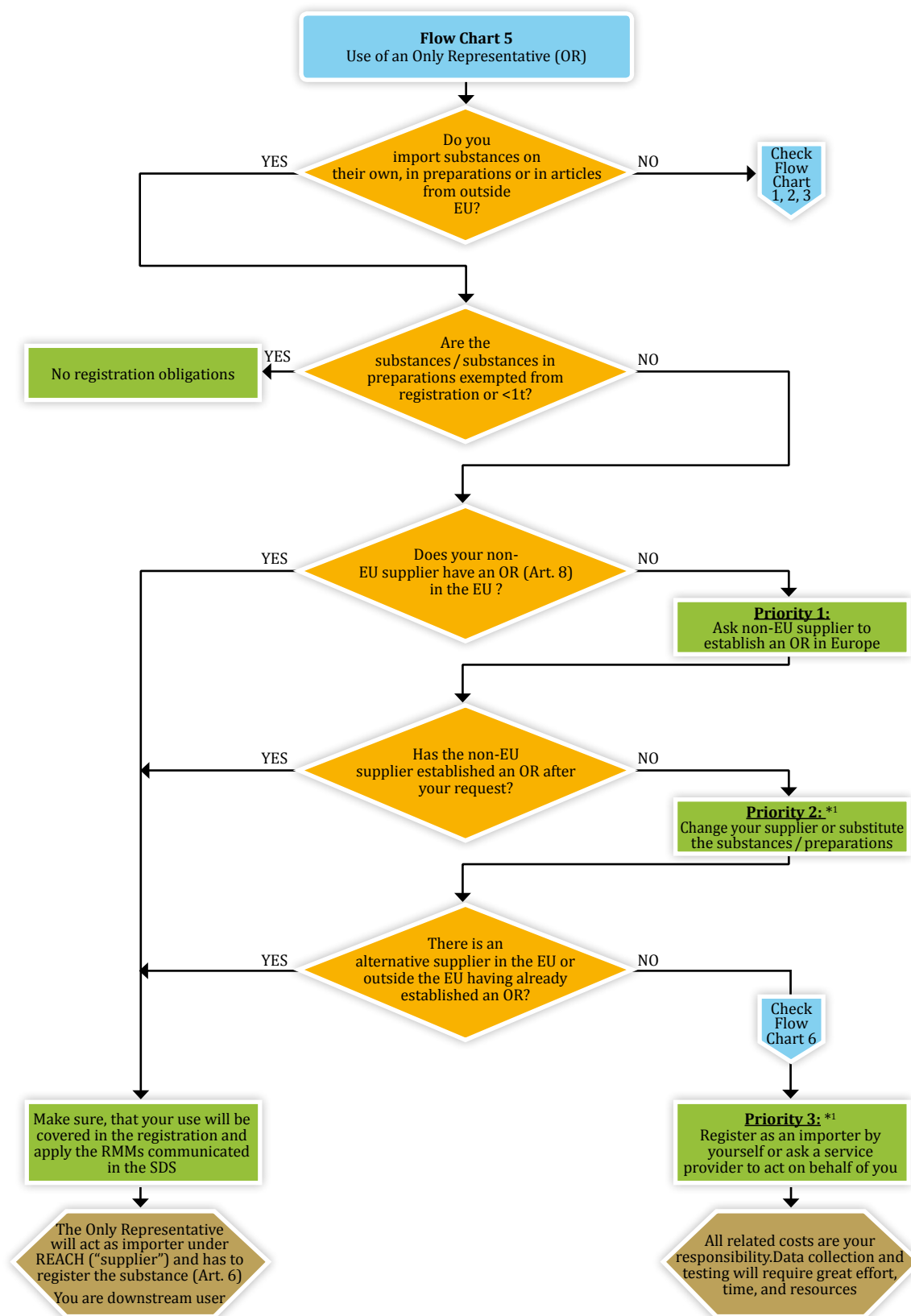


*1) Be aware that a formal list of EU designated SVHC's is not scheduled to be published until June 2009. Until there is an official list published, please use accepted industry listings of restricted substances or the working candidate list to determine if your materials may be SVHC's (Article 59)



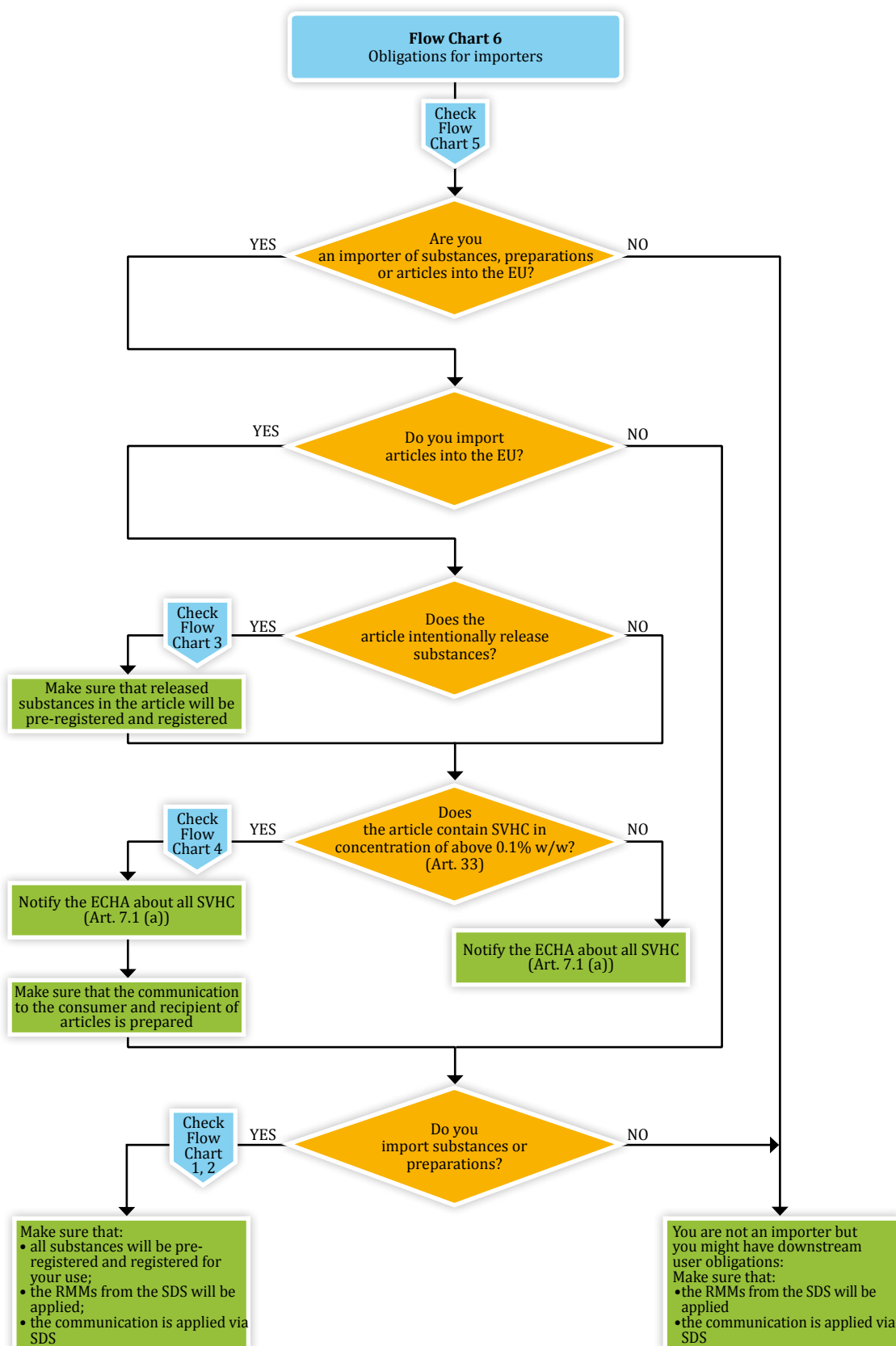
5.5 REACH Flow Chart 5

Use of an Only Representative (OR)



*1) The order especially of Priority 2 & 3 is not fix but depends on the company specific policies and strategies.

5.6 REACH Flow Chart 6 Obligations for importers



CHAPTER 6:

AIG 8 STEP COMPLIANCE SCHEDULE

Taking into consideration the results from the AIG Chapters 1-5, the following steps and tasks are recommended for the Automotive Industry to fulfil the obligations under REACH. As those obligations are the same for Tier-suppliers and vehicle manufacturers,

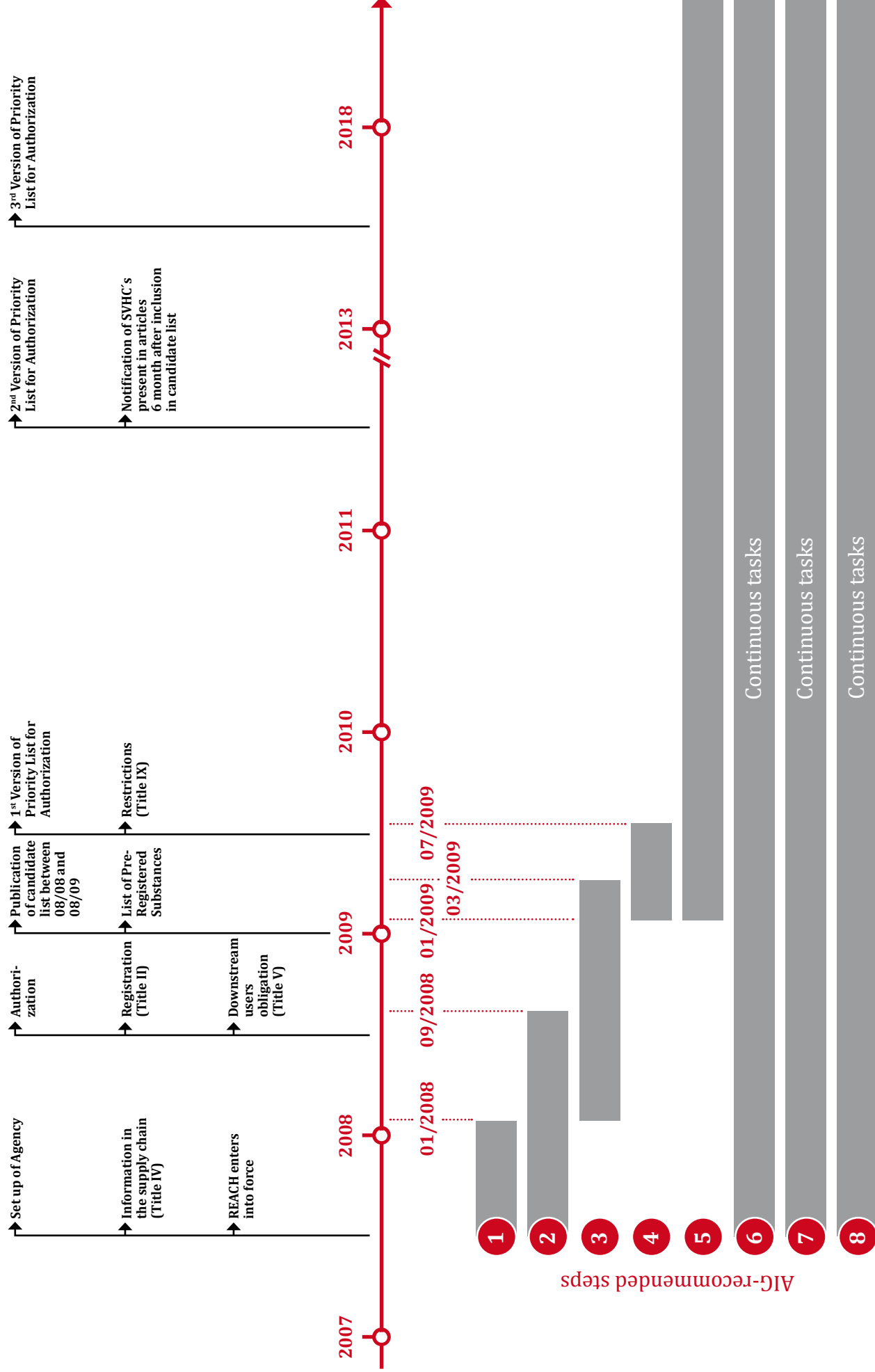
every company along the supply chain can proceed as recommended below. Please note that the AIG recommendations are general enough for company-specific interpretations. The related Excel file is available at <http://www.acea.be/reach>:

	Activities	Main Responsible	Supporter	Re-commended Tools	AIG Reference	Timing	
1	REACH AWARENESS						
	1.0	Request/define contact - data of REACH representative for your company and your suppliers			REACH-awareness letter	Annex B	
	1.1	Develop an internal team chaired by your company's REACH representative to provide overall steer					today - 01/08
	1.2	Identify own REACH Point of Contact responsible for external communications					today - 01/08
	1.3	Identify all own EU legal entities impacted by REACH					today - 01/08
	1.4	Sending out of REACH - awareness letter to all suppliers/Tracking of supplier responses					today - 01/08
	1.5	Identify the respective REACH representative of the suppliers					today - 02/08
1.6	Identify low, medium, high risk suppliers & define approach for handling each category			today - 02/08			
2	SUBSTANCE INVENTORY						
	2.0	Identify all substances, preparations and articles falling under REACH			Inventory	Guideline 3	
	2.1	Identify your roles under REACH (i.e. manufacturer, importer, downstream user)					today - 04/08
	2.2	Recommended data for inventories, depending on the different roles					today - 10/08
		• Which substances/preparations the company purchases from inside EU and for what purpose they are used?					today - 10/08
		• For which substances/preparations the company purchases, SDS are available/not available?					today - 10/08
		• Which substances/preparations the company imports and for what purpose they are used?				Guideline 4	today - 10/08
	2.3	Check whether article list is complete for your business			List of Articles	Guideline 7, 8	today - 06/08
	2.4	Define/Distinguish whether the substances are in an article (Registration acc. to Art. 7) or in a preparation in a container (Registration acc. to Art 6)					today - 10/08
	2.5	Which substances are intentionally released from an article that the company produces?					today - 10/08
2.6	Which substances are intentionally released from an article that the company imports?			today - 10/08			



Declaration of Intent							
3	3.0	Identify all substances which will NOT be pre-registered by a supplier			Declaration of intent request letter & Result of Inventory	Guideline 5 & Annex C	
	3.1	Send out letter to all of our suppliers requesting Declaration of Intent					01/08 - 06/08
	3.2	Tracking of supplier responses on Pre-Registration and reassess suppliers' risk category assigned in step 1.6					01/08 - 07/08
	3.3	Make sure that phase in substances are pre-registered by checking the pre-registration list published on 1 January 2009					01/09 - 04/09
	3.4	If substance is not included in the Pre-Registration list, DUs should seek a supplier that has Pre-Registered (ECHA can provide a list of alternative suppliers that have Pre-Registered, Art 28.5)					01/09 - 04/09
	3.5	Identify the respective REACH representative of the suppliers					01/08 - ~
4	4.0	Inform your supplier about your use of the substances/preparations			Company specific Communication & already established tools	Guideline 5	
	4.1	Start company-specific communication with your suppliers about your uses/Tracking of supplier responses					01/09 - 07/09
5	5.0	Identify all substances/preparations where there is NO intention to register them and for your use			Declaration of intent request letter & Result of Inventory	Guidelines 4, 6 & Annex C	
	5.1	(Send out letter to all of our suppliers requesting Declaration of Intent, see 3.1)					01/08 - 06/08
	5.2	Tracking of supplier responses on intention to register your uses					01/09 - ~
	5.3	If supplier does not intend to register, define your next steps/counter-measures and communicate these to customers					01/09 - ~
SVHCs							
6	6.0	Identify:			GADSL, Material Reporting Systems (IMDS, MACSI, etc.)	Guideline 8, 9, 10	
	6.1	Which articles & materials are likely to contain substances to be listed on the candidate list/ Annex XIV (potential candidate list-substances)					today - 12/08
	6.2	Assess potential risk of supply chain disruption and evaluate potential counter measures					today - ~
	6.3	Check if your identification of potential candidate list-substances is correct once the official candidate list is published					07/08 - ~
	6.4	Identify potential Substances of Very High Concern (candidate list-substances) in articles					07/08 - ~
	6.5	In your role as manufacturer or importer, Identify all substances in articles included in the candidate list subject to notification requirements under Art.7(2)					07/08 - ~
	6.6	Ensure safe use information is available for SVHC in articles in accordance with Article 33(1) and be prepared to provide the data to DU					07/08 - ~
	6.7	Ensure safe use information is available for SVHC in articles in accordance with Article 33(2) and be prepared to provide the data to consumer within 45 days of request.					07/08 - ~
	6.8	Notify ECHA of substances contained in articles in accordance with Article 7(2)					06/11 - 01/12
	6.9	Identify imported substances on the candidate list on their own or in preparations			Results of Inventories & Already existing internal processes	Guideline 3	07/08 - ~
	6.10	Identify Substances on the candidate list on their own or in preparations used in the EU production process					07/08 - ~
	6.11	Make sure, that the identified substances are authorized for your use (Authorisation: in case of Annex XIV inclusion)					07/09 - ~
Risk Management Measures							
7	7.0	Identify the Risk Management Measures in the SDS			Already existing internal processes	Guideline 5	
	7.1	In your role as Downstream User, apply the RMM's					today - ~
	7.2	In your role as manufacturer/importer, define the RMM's					today - ~
	7.3	Supply safety data sheets for substances and preparations in accordance with article 31 compiled in accordance with REACH Annex II including Chemical Safety Report (CSR) where needed					today - ~
8	8.0	Checking compliance with the Exposure Scenarios					
	8.1	Verify if the conditions of your use and your customers uses comply to the prescription of your supplier and if they do not, then re-contact your supplier to have them included.					today - ~





The chart below is based on the chart presented in Chapter 3. In addition, it highlights the recommended timing for the 8 steps, explained in the matrix above. The 1st “Candidate list” may be published by the end of August 2008.

ANNEX A:

ABOUT TASK FORCE REACH (TF-REACH)

Comments and suggestions for the authors are welcomed, via the Secretary to TF-REACH: rm@acea.be. However, to distribute the workload involved, please contact the association of which you are a member:

- **ACEA (European Automobile Manufacturers Association)**

Roman Meininghaus, rm@acea.be

ACEA represents the interests of the thirteen European car, truck and bus manufacturers: BMW, Renault, Porsche, Fiat, GM, Volvo, DAF, Scania, MAN, PSA, Ford, Chrysler LLC, and Volkswagen.

- **AIAG (Automotive Industry Action Group)**

REACH@AIAG.ORG

AIAG is a U.S. based not-for-profit organization where retailers, automakers, suppliers, and service providers work collaboratively to drive cost and complexity from the supply chain via global standards development and harmonized business practices.

- **CLEPA (European Association of Automotive Suppliers)**

Louis-Sylvain Ayrat, techsec@clepa.be

CLEPA represents around 70 of the world's most prominent suppliers for car parts, systems and modules. National trade associations and European sectorial associations from 15 countries represent more than 3,000 companies, employing more than three million people, covering all products and services within the automotive supply chain.

- **JAMA (Japan Automobile Manufacturers Association, Inc.)**

Serge Verdée, tca@jama-e.be

JAMA is a non-profit industry association currently comprised of fourteen manufacturers of passenger cars, trucks, buses and motorcycles in Japan: Daihatsu, Fuji Heavy Industries, Hino, Honda, Isuzu, Kawasaki, Mazda, Mitsubishi, Nissan, Suzuki, Toyota and Yamaha.

- **KAMA (Korea Automobile Manufacturers Association)**

Timo Unger, tunger@hyundai-europe.com

KAMA is an organization representing the major automakers in Korea. KAMA has been established to foster and develop the Korean auto industry and thereby contribute to sustainable growth of the national economy. Korea's 5 major automakers (Hyundai, Kia, GM Daewoo, Ssangyong, and RenaultSamsung), with a total of 120,000 employees, have joined the association. KAMA also organizes the Seoul Motor Show, which is the only international motor show in Korea accredited by OICA.

- **SMMT (The Society of Motor Manufacturers and Traders, UK)**

Robert Walker, rwalker@smmmt.co.uk

SMMT is the national association for the UK automotive industry, representing more than 500 member companies ranging from vehicle manufacturers, component and material suppliers to power train providers and design engineers. SMMT owns the British International Motor Show.

- **VDA (German Automotive Industry Association)**

Stefan Wöhrle, woehrl@vda.de

The members of VDA are companies that operate a plant in Germany for the industrial production of motor vehicles and their engines, trailers, special bodies and containers and vehicle parts and accessories. From these manufacturing sectors, about 580 companies with a total of 750,000 employees have joined the association. VDA organises, under its own auspices, the IAA International Motor Show.

The Task Force-REACH would like to express its sincere gratitude to Orgalime (The European Engineering Industries Association) for their co-operation during the preparation of this Automotive Industry Guideline, and for their kind permission to reproduce passages from the Orgalime Guide, *A Practical Guide for Downstream Users, Article Producers and Article Importers (May 2007)*.



ANNEX B: AWARENESS LETTER

As recommended as Step 1 (Chapter 6), a preliminary message should be sent out as soon as possible to promote awareness of REACH in the supply chain. An example has been developed and is provided below. It is recommended that this wording be used and that further information is not requested at this early stage. This document can be downloaded as a Microsoft Word file in the REACH section of the ACEA webpage <http://www.acea.be/reach>.

[COMPANY LETTER HEAD]

To CEO of all suppliers

[Date]

Subject: New European Union (EU) Regulation on Chemicals (REACH)

As of June 2007, the European **Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)** entered into force.

REACH affects all industries, including the Automotive Industry (AI). As the AI is made up of vehicle manufacturers and many tiers of the supply chain, it has several roles and obligations under REACH. Action is required from the OEMs and suppliers, some immediately and some over the coming 11 years and beyond.

One of the requirements of REACH is that manufacturers and importers have a duty to register, for each legal entity, 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 exempt from registration. Registration requirements also apply to substance(s) intentionally released from articles under certain conditions, in which case the article producer/importer is responsible for the registration.

It is of key importance to take advantage of the pre-registration option in REACH. Pre-registration of substances on their own, in preparations, or substances intentionally released from articles will take place between 1 June and 1 December 2008. Taking advantage of pre-registration allows for a transitional period to the registration process and allows continued production and use of substances until 2010 to 2018, depending on annual tonnage. **Without pre-registration, substances have to be registered immediately. Without Registration, Substances can not be marketed in the EU. Pre-registration is free of charge and very simple, requiring only basic information.**

Please consider that:

- Companies that do not comply with REACH will have no market. REACH poses a threat to any company doing business in the EU (and businesses with customers who do business in the EU).
- Business continuity can be adversely impacted by REACH and supply chains can be disrupted.
- Companies that understand the business implications and impacts of REACH and develop strategic action plans will gain competitive edge over those that do not.

In order to be prepared for REACH, representatives of all the major vehicle manufacturers and the automotive supply chain around the world developed an "Automotive Industry Guideline on REACH" which can be used to get a quick overview of REACH, its requirements and the recommended actions arising. This guideline can be found at: www.acea.be/reach.

This "awareness" letter with some recommendations and requests for information is considered to be the start of the communication in the AI supply chain required by REACH. There is more to come.

Please respond with the information by [Date] requested in the attached Standard Communication along the Supply Chain document.

Regards

[COMPANY LETTER HEAD]

REACH: 1. Standard Communication Along the Supply Chain¹**Recommendation and Requests from Downstream User (Customer) to Suppliers regarding Pre-registration / Registration**

Concerning all products supplied to us are defined as Substances, Preparations or Articles according to the REACH terminology.

1. At this stage, we strongly recommend and expect that all substances, which require registration and are contained in the products you are supplying to us, will be pre-registered (between 1 June and 1 December 2008) by your company or by your upstream supplier.
2. At this stage, we also recommend and expect that all substances, which require registration and are contained in the products you are supplying to us, will be registered².
3. Regarding the substances that are contained in the product and require registration – please take note of the crucial REACH registration deadlines for those substances which are decisive for the product properties.
4. We expect that your business will take organisational measures to manage the implementation of the REACH regulation requirements including appointing an only representative in the EU if applicable.
5. If you do not intend to pre-register any substance that is currently in use, please get in contact with our REACH contact person. (See 8 below).
6. We expect that you will appoint a single point contact for your company covering all legal entities.
7. Your single point contact details.
Please provide full contact details for the person in your company responsible for REACH issues.
Name, company, telephone & fax number mailing address and email
8. Our single point contact details
Please find below the full contact details for the person in our company responsible for REACH issues.
Name, company, telephone & fax number, mailing address and email
9. Please provide your response and questions to:
Business/supply chain contacts to be inserted, if not the same as mentioned under no. 8

1) The information contained in this letter expresses only the intention of the requester and does not constitute a legally binding obligation. Whilst the information is provided in utmost good faith, no representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted for damages of any nature whatsoever resulting from the use of or reliance on the information

2) See section 5.7 of the Automotive Guideline on "Registrations of substances in articles"



ANNEX C:

DECLARATION OF INTENT REQUEST LETTER

[COMPANY LETTER HEAD]

To REACH contact person of all suppliers

[Date]

— **Subject: Request to clarify your intentions under REACH (EC Regulation on chemicals).**

Further to our awareness letter [dated], in which we informed you of the new European Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which entered into force on 1 June 2007, it is now time for you to clarify your intentions.

As we already explained in our awareness letter, REACH affects all industries. As the Automotive Industry (AI) is made up of vehicle manufacturers and many tiers of the supply chain, it has several roles and obligations under REACH. Action is required from the OEMs and suppliers, some immediately and some over the coming 11 years and beyond.

It is of key importance that all actors in the supply chain understand their duties and perform necessary actions in a timely manner in order to avoid supply chain disruption. A helpful planning tool is the Automotive Industry Guideline (AIG) on REACH, the second version (v2.0) of which was released in early 2008. The latest version of the AIG is available to download free of charge at: www.acea.be/reach. We would like to draw your attention to the fact that there are changes from the first version of the AIG, especially the 8-step compliance schedule (Chapter 6).

Please find enclosed a questionnaire based on the tasks recommended in the AIG compliance schedule. We kindly ask you to fill it in and reply as soon as possible, but not later than **30 June 2008** to [sender's REACH contact details]. In order to answer these questions, we expect that you will need to cascade them down your supply chain and receive the answers back by this date. The aim of this communication is to create a standardised response, which will minimise the duplication of effort when responding to each of your customers.

We are only asking you to confirm your intentions, so please consider this questionnaire a chance to further improve our business relationship. A late or incomplete response would raise concerns that our common legal responsibilities under REACH are at risk and may mean that we are forced to consider looking for an alternative supplier.

Please note that answering the attached questions does not mean that you are REACH compliant. However, in responding you will build confidence in our mutual ability to comply with REACH.

Regards



[COMPANY LETTER HEAD]

REACH: Standard Communication Along the Supply Chain¹**Declaration of intent for REACH implementation**

You may have different responses for different "products" supplied to us (which can be Substances, Preparations or Articles according to REACH terminology) and you may need to send a separate sheet for each category of products. Please tick the box(es) for the products covered by this sheet:

☐ Substances ☐ Preparations ☐ Articles

1. We (the supplier) confirm that we understand our obligations under REACH.
☐ Yes ☐ No
2. If our company is located outside the EU/EEA we will ensure that you, our customer, do not need to act as importer under REACH e.g. by nominating an only representative. We answer questions 3-8 on behalf of our importer/only representative.
☐ Yes ☐ No
3. The intention is that all substances in the products we supply to you, which require registration, will be pre-registered by us or an actor further up our supply chain.
☐ Yes (If yes, go to Q5) ☐ No
4. We will send a list of "products" supplied to you for which there are substances that are not intended to be pre-registered.
☐ Yes ☐ No
5. We confirm, or have confirmed with the actors in our supply chain, that the intention is to register for your use(s) the substances that we/they pre-register.
☐ Yes ☐ No
6. By 30 November 2008, we will send you a list of all "products" that contain substances likely to be included in the candidate list (see guidance and tools in step 6.1 of the AIG compliance schedule and REACH Article 57).
☐ Yes ☐ No ☐ None expected
7. We will send you a list of all "products" that contain substances on the candidate list within 45 days of its publication, or confirmation that there are none (see step 6.3 of the AIG compliance schedule and Article 57).
☐ Yes ☐ No
8. We will have a dialogue with you and our suppliers regarding safe use and risk management measures (RMMs) for the substances and preparations we supply to you.
☐ Yes ☐ No ☐ Not applicable

Further comments (use additional sheets if necessary).....

1) The information contained in this letter expresses only the intention of the respondent and does not constitute a legally binding obligation. Whilst the information is provided in utmost good faith, no representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted for damages of any nature whatsoever resulting from the use of or reliance on the information completeness or accuracy and no liability will be accepted for damages of any nature whatsoever resulting from the use of or reliance on the information



ANNEX D:

FREQUENTLY ASKED QUESTIONS (FAQ)

REACH general

Q1 What are the overall goals of the new chemicals regulation?

The two most important goals are to improve the protection of human health and the environment from the hazards of chemicals and to enhance the competitiveness of the EU chemicals industry. Enterprises that manufacture or import more than one tonne of a chemical substance per year will be required to register the chemical in a central database.

Q2 How does REACH provide for punishments / penalties / fines / imprisonment? Are they country-specific punishments or EU-wide punishments?

Penalties are country-specific and Member States will impose a penalty for non-compliance which will be effective, proportionate and dissuasive.

Q3 How will ECHA monitor REACH implementation?

ECHA will request reports about REACH implementation from member states. The national authorities will perform the implementation checks.

Q4 In the AIG it is stated that “substances listed in ELINCS are regarded as registered” per Article 24. Clearly, registration is not required from the person who notified the substance under Directive 67/548/EEC. Must others who use the ELINCS substance register it, or is it regarded as registered for them also?

ELINCS substances are regarded as registered only for companies who submitted the required information under Directive 67/548/EEC. The Agency will assign a registration number by 1 Dec. 2008. Source: Article 24(2) says “if the quantity of a notified substance...reaches the next tonnage threshold...additional required information...shall be submitted.” The concept of next tonnage threshold is only meaningful for those who submitted information for a particular tonnage threshold under Directive 67/548/EEC.

Q5 Are there different requirements to be introduced for Small and Medium Enterprises (SME)?

Small and medium-sized enterprises (SME) are a vital part of the EU chemicals industry; for that reason the Regulation has been made workable also for them (e.g. a lower registration fee). Since safety is a key concern regardless of company size, the REACH information requirements relate to production volumes, uses and properties of the chemicals, and not to turnover or the number of employees of the companies.

Q6 SME will face more difficulties in compliance with REACH administration than large-scale enterprises. How did the EC balance the different interests between the large-scale enterprises and SME?

For the most part, SME are more likely than other companies to be registering at the 1-10 t/y level. They will therefore benefit from the longest transition period and a lower registration fee will be required. The information requirements for these volumes are also light compared to the higher tonnages and no CSR needs to be developed.

Q7 What information network has been built for supply chains in Europe?

It is responsibility of the Industry to determine how to handle this.

Pre-registration and Registration

Q8 Is there a legal requirement to pre-register all substances?

There is no legal obligation for it, but pre-registration is strongly encouraged to gain the benefit of the extended registration deadlines.

Q9 What are the substances within articles that have to be registered?

Pursuant to Article 7(1) all substances in imported articles that meet the following two conditions must be registered under REACH: 1. the substance is present in the imported articles in quantities above 1 tonne per importer per year, and 2. the substance is intended to be released under normal or reasonably foreseeable conditions of use.

Q10 What happens if we, as a DU, find out after pre-registration has ended that our substance has not been pre-registered?

You can ask the ECHA to publish your name and substance on its website, which will enable potential registrants to contact you (REACH Article 28.5). The new potential supplier can pre-register it by sending the information described in REACH Article 28.1 within 6 months of first manufacture/import or use (REACH Article 28.6). Also, this information must be sent at least 12 months before the phase-in deadline. If the supplier is not manufacturing/importing it for the first time, they cannot benefit from the phase-in dates and must register it immediately in order to continue supplying it.

Q11 Which substances are exempt from registration?

Some substances are exempted from REACH altogether and so will not be subject to Registration, for example: radioactive substances, non-isolated intermediates, wastes, substances under customs supervision, and, if Member States so choose, substances necessary for the interests of defence. In the REACH regulation you will find a more comprehensive list of general exemptions within Article 2 and Annex V and more specific substance exemptions within Annex IV. Substances manufactured or imported in quantities less than 1 tonne per year do not need to be registered.

Q12 Is there an obligation to register steel or other alloys?

Alloys (including steel) are Preparations under REACH, albeit special ones where the properties of the Preparation do not always simply match the properties of the components. As Preparations, alloys do not have to be registered but their component metals must be registered if manufactured/imported in quantities greater than 1 tonne per year.

Q13 One of the registration requirements is “(a) the substance is present in those articles, in quantities totalling over 1 tonne per producer or importer per year.” We understand that

this 1 tonne is for each individual producer or importer. Is our understanding correct?

Yes, it is per producer or importer (legal entity).

Q14 Will each company that registers a substance receive a different registration number for it?

Yes, each company receives an individual registration number.

Q15 When is windscreen washer fluid considered a “preparation in a container” and when is it a “preparation within an article”?

When you import a car with windscreen washer fluid in it, then the fluid is a “preparation within an article, which is intended to be released”. When you import a barrel/bottle etc with windscreen washer fluid, it is a “preparation in a container.” In both cases, the substances within the windscreen washer fluid have to be registered for that use.

Q16 Is it right to think that the mechanism for registration and restriction of new chemicals is almost the same as the existing one?

Yes, substances put on the market after 1981 and compliant with the existing regime are seen as “REACH compliant”.

Q17 What substances should OEMs ensure for registration?

Each OEM must identify its role under REACH. If the company imports substances or substances in preparations then they have to register.

Authorisation / Notification and SVHC

Q18 Can the industry predict which substances may be subject to an authorisation? Are the criteria clear enough?

A The identification of the different groups of substances that may be subjected to authorisation is clearly defined. For CMR category 1 and 2 substances, the criteria have long been established in the present legislation (Directive 67/548), for PBT and vPvB substances the criteria are included in REACH Annex XIII. For any other substance there must be scientific evidence of probable serious effects to humans or the environment,



which give rise to an equivalent level of concern as CMRs category 1 and 2, PBTs or vPvBs.

To provide more certainty for industry, substances will be identified through an open process and the decision to include the substance in REACH Annex XIV will finally be taken by the Commission in accordance with the Comitology procedure. The process for such decisions is as follows:

Dossiers to identify a substance for the authorisation procedure will be prepared either by a Member State or by the Agency if requested by the Commission. All dossiers will be published and will be open for comments by interested parties. Substances identified as having any of the listed properties of very high concern will be included on a candidate list published by the Agency, within which the Agency indicates the substances that are on its work programme. The Agency then recommends substances to the Commission for inclusion in REACH Annex XIV. Priority will normally be given to substances with PBT or vPvB properties, with wide dispersive use or in high volumes. These priority substances may then finally be included in REACH Annex XIV.

Q19 Can applications for authorisation be submitted together?

Grouping of applications for authorisation is possible in REACH. Groups can be of: manufacturers, importers and DUs; substances; uses; or any combination of these groups. This is to enable costs to be minimised and the system to process applications rapidly.

Q20 Which are the substances within articles that require agency notification?

Pursuant to Article 7(2), SVHC listed on the candidate list for Annex XIV that meet the following two conditions must be notified under REACH: 1. the substance is present in the imported articles in quantities above 1 tonne per importer per year; and 2. the substance is present in the imported quantities above a concentration 0.1 % weight by weight.

Q21 How will notification work for DUs of substances under the product & process oriented research and development (PPORD) exemption?

The PPORD exemption from registration (Article 9) is for manufacturers and importers doing research, either by themselves or with listed customers. The substances for these uses do not require registration (and DU requirements do not apply because the supplier is not required to prepare a Chemical Safety Report) and would not be supplied to others in the supply chain for commercial purposes or to the general public at any time. However if the substance is used in quantities greater than 1 tonne per use per year, the DU must notify the Agency.

Q22 If a product contains more than 0.1% weight by weight (w/w) of SVHC, a manufacturer is liable to submit notification. Should 0.1% be calculated in terms of vehicle weight or component weight?

Always use the weight of the article manufactured in or imported into EU.

Q23 Could you be more specific about the expression "the substance is present in those articles above a concentration of 0.1% weight by weight?" Because a general automobile weights about 1,500 kg, 0.1 wt% of an automobile is 1.5 kg. It follows that substances used in an automobile should be controlled if the weight exceeds 1.5 kg. Is this understanding correct?

Yes, if a car is imported (the article in this case), this is correct for SVHC.

Q24 Manufacturers of final products are required to confirm that the use of SVHC contained in Articles (such as materials, parts, and subassemblies) has been authorized for a certain purpose. Suppose that substance X is a SVHC.

(Case 1) When a final product contains 2% (w/w) of substance X:

The article manufacturer/importer notifies the agency.



(Case 2) When a final product contains 0.05% (w/w) of SVHC substance X:

0.1% (w/w) is the threshold. If X is below 0.1% this obligation does not apply.

Q25 How is chemical control in REACH linked to waste control?

For all substances above 10 tonnes / year, a Chemical Safety Report (CSR) and a Chemical Safety Assessment (CSA) assessment have to be prepared. This risk assessment has to take into account all ways (including waste streams) in which the substance could contaminate the environment. "Waste" by itself is exempt from REACH and need not be registered.

Q26 We understand that REACH assumes that the European Chemicals Agency is responsible for the registration and assessment of chemicals. In which organizations are mechanisms for conveying information on substances contained in articles discussed?

The ECHA is the only agency registering substances. The agency will deliver IT tools for all registration and notification obligations.

Q27 What kind of SVHC do we need to take care of?
See Guideline 8.

Q28 Considering that supply chains spread beyond national boundaries, the implementation of REACH requires the cooperation of different countries. Does the EU have a plan to promote activities to raise awareness of REACH?

Each Member State has to establish "National help desks, these help desks will network together. Raising awareness is a task for industry and its associations. The responsibility for complying with REACH lies with the industry.

Q29 The "use" is the key to REACH. Some metals may serve as a catalysts when reduced to a fine powder but do not have oxidizing properties when used for decoration or plating. In this case, is it right to think that the metal must be registered as a "catalyst?"

The substance must be registered for the

appropriate "Use and Exposure Category" depending if it is used as a catalyst or alternatively for decoration or plating. RIPs will clarify this.

Q30 Is there a mechanism for conveying information on "use" to upstream suppliers? Shouldn't automobile industries in different countries share the recognition of "use?"

Communication within the supply chain is key for REACH compliance. The Automotive Industry, along with others, is building up networks. TF-REACH is an important part of this.

Q31 What does it cost to use the Reach-IT system (including IUCLID5)?

IUCLID 5 can be downloaded free of charge from the ECHA homepage, see Guideline 12.

Q32 Approximately how many substances are treated as SVHC?

The candidate list will be established toward the end of 2008; a rough estimate is 1000-2000 substances. From 2011 the REACH Annex XIV priority list will be updated at least every 2 years.

Q33 Will all SVHC substances be disclosed at one time?

Priority list for inclusion of the substances within REACH Annex XIV will be established and published for comments, so not all will be included at one time. It will be an ongoing process for years to come.

Q34 If a supply chain extends into more than one country, it may be difficult to collect sufficient information on the content of SVHC.

In light of this difficulty, sufficient time should be allowed for data collection. Start collecting the information you need now.

Response to REACH

Q35 We understand that chemical manufacturers are basically responsible for the registration of new and existing chemical compounds, and automobile manufacturers need only be concerned with preparations "intended to be



released.” What does the TF-REACH think about this point?

You must identify your roles and responsibilities under REACH. Use the AIG and / or consult the REACH Navigator under: http://reach.jrc.it/navigator_en.htm

Q36 We think that preparations “intended to be released” include brake pads (preparation) and windscreen washer fluid (preparation) in RIP 3.8. What is the TF-REACH opinion about this point?

This AIG makes it clear. We and the brake pad supplier organizations have the same opinion: brake pads are articles with no “intended releases”. The guideline includes the intended AI releases, see Chapter 5.7: Guideline 7 and RIP 3.8

Q37 If chemical constituents of materials for automobiles must be registered, upstream resin manufacturers should be requested to respond to the requirement. Does the TF-REACH request resin manufacturers to register those chemicals?

Roles and responsibilities are described under REACH. It is the task of the individual companies to make their suppliers aware, see this Guideline.

Q38 What do you think about legal compliance with REACH? Of course automobile manufacturers should respond in good faith. However, how do you check the contents of SVHC contained in articles that are difficult to check by data or by other means?

“Legal Compliance” is a need for each company in the supply chain. Your supplier has to inform you about SVHC in the products he delivers to you. You are obliged to deliver information about SVHC to your customer after you have received it from your supplier. There is no obligation for you to make chemical analyses if you have no information about non-compliance of your supplier.

Q39 How about parts purchased from outside the EU? How will you direct the suppliers to respond to REACH?

The obligations for importers are described in REACH and this AIG.

Q40 After the raw materials to be used in paints, rubber, adhesives, etc. are shipped by the chemical industry, suppliers might add more substances. How strictly should OEMs control these materials?

In general, all substances have to be registered, independent of when or who has added it to a product.

Q41 Shouldn't automobile industries in different countries share the recognition of exposure scenarios of substances “intended to be released?”

We share our experiences within the TF REACH.

Q42 Is there a plan to ask suppliers to pre-register their substances/preparations? If so, could you please tell us the expected period of pre-registration?

The pre registration period is 1st of June 2008-1st of December 2008. Proposals for an awareness letter and a declaration of intent are in this guide.

Q43 What are the obligations of a distributor?

A distributor has the obligation “not to interrupt” the information flow within the supply chain. He has to pass the information needed for REACH compliance up and down the supply chain. (REACH article 34)

Applicability of IMDS, GADSL etc.

Q44 Does TF-REACH consider using IMDS as a method for collecting information on SVHC contained in articles for REACH? Or does the TF-REACH have a plan to build another tool?

For companies already working with IMDS or other substance reporting systems, it makes sense to use those tools. The prerequisite would be an updated restricted-substance list (e.g. GADSL).



Q45 If IMDS is used for REACH, how is information on “use (purpose of use)” conveyed from DUs to upstream suppliers to meet the requirements of REACH?

IMDS could only be used for articles going into products. Further uses are currently not possible.

Q46 Most primary suppliers (Tier 1) are the only users of chemicals, and do not have complete information about the constituents of materials they deal in. There is a high probability that the requirements of REACH cannot be satisfied through cooperation with primary suppliers alone. What does the TF-REACH think about this point?

Communication must go through the whole supply chain, not just Tier1.

Q47 Does TF-REACH think that SVHC should be controlled or that the GADSL can be used?

TF REACH addressed this to GADSL team members. GADSL should cover SVHC in the future.

Q48 How can we set up a system for implementing REACH with respect to process materials (raw/ auxiliary material) in our EU manufacturing facilities?

If you follow Health, Safety, and Environmental legal requirements in Europe in your facility you will have enough information about your process materials and can make sure your suppliers/ importers are aware of REACH. Therefore we recommend using the pre-existing tools in your company.

Q49 Does this guideline cover the standard REACH implementation process for OEMs?

This is a recommendation for a standard REACH implementation process, but how the process will specifically work at the OEMs depends on so many Company specific factors that an honest answer cannot be given.

Q50 Is it necessary to inform your supplier if you are a DU and using a substance at less than 1 tonne per year?

Yes, because your supplier must note your usage on the SDS regardless of the tonnage.

Import of substances to the EU – Only Representative (OR)

Q51 What are the responsibilities of a non-EU company who has nominated an Only Representative?

Non-EU companies have no obligation under REACH. Compliance with REACH must be ensured by their EU-based importers (i.e. they have to register the substance, provide safety data sheets where necessary, etc.). In order to allow importers to fulfil their obligations, non-EU companies will however have to provide the necessary information on the substance to the importer.

If a non-EU company does not wish the importer to be responsible for obligations under REACH (e.g. if the non-EU company does not wish to disclose confidential information), it may appoint an Only Representative. In this case, the Only Representative takes over all obligations of the importers under REACH. (See also ECHA website and article 8 of REACH regulation.)

Q52 Are EFTA member states included in the scope of REACH?

Iceland, Liechtenstein, Norway and Switzerland are members of the European Free Trade Agreement (EFTA). The EFTA Convention established a free trade area among its Member States in 1960. Iceland, Liechtenstein and Norway entered into the Agreement on the European Economic Area (EEA) in 1992, which entered into force in 1994. Therefore, the EEA is composed of Iceland, Liechtenstein, Norway and the 27 EU Member States. As soon as REACH is implemented by the EEA EFTA-States (which means EFTA States covered by EEA agreement), imports from Norway, Iceland and Liechtenstein will be considered as intra-Community trade for the purposes of REACH. EFTA is preparing a proposal for an EEA Joint



Committee Decision, incorporating the Regulation and establishing the conditions for the EEA EFTA participation in the EU Chemicals Agency. EFTA is targeting to have the Regulation incorporated by 1 June 2008. Therefore, an importer of a substance from an EEA country would not be required to register the substance under REACH and would simply be regarded as a DU. However, his supplier in the EEA/EFTA States will have to register the substance as a manufacturer under REACH with all associated obligations like any other manufacturer within the EU. Importers of a substance from Switzerland (a non EU country belonging to EFTA but not to EEA) will have the same obligations under REACH as any other importer.

Examples: A formulator purchasing his substances in Germany or Iceland will be considered as a DU. A formulator purchasing his substances in Switzerland or Japan will be considered as an Importer.

Q53 When will Norway, Iceland and Liechtenstein bring REACH into force?

1 June 2008 is the estimated date.

Q54 What are "Appropriate Instructions" and how are they to be provided? Is it possible to include the information in the pre-existing systems?

Yes, but other solutions are possible as well.

Q55 Does the candidate list exist already?

No, not yet. This list has not yet been established. The Agency will publish and update this list on its website once it is available, near or after late 2008. The Agency shall make its first recommendation of priority substances selected from the candidate list to be included in Annex XIV by 1 June 2009. This list will be made available on the ECHA website. You can find more information on this issue in the Guidance on identification of SVHC and in the Guidance on Annex XIV inclusion on the ECHA website.

Q56 What about non-automotive products like machinery or tools which are exported into the EU?

The exporter has no obligation. Under REACH, the importer within the EU is responsible to fulfil

all requirements. The exporter has to deliver the information about SVHC. If this is not possible, the importer can ask the exporter to announce an "Only Representative" who will take over all duties under REACH.

Q57 What about packaging material included with the articles from outside EU?

If the packaging material becomes "waste" within the EU (not put on the market) it is exempted from REACH.

Q58 How will the new legislation ensure confidentiality of information with a public list of chemical substances?

The first list of substances that the Agency publishes will be the list of pre-registered substances. This list will be comprised of only the names of the substances and not the names of any company manufacturing or importing it. The purpose of this list is to give an overview of the substances that will be phased into REACH.

Q59 Is a waste treatment operator a DU under REACH?

The treatment of waste material itself is not a use of a substance or preparation and, therefore, the operator is not a DU under REACH.



To make using Version 2 of the Automotive Industry Guideline on REACH more user-friendly, the list below shows the key changes between this and Version 1 published in July 2007. Only the major changes are listed here. Modifications of grammar or wording without an impact on content are not considered in here.

Chapter	Changes
Executive Summary	One page explanation of REACH and AIG for your colleagues
Disclaimer	Additions regarding the anti-trust law
2	Some additional definitions (e.g. for Intended to be released, Only Representative, Legal entity, Exporter, Consumer etc.)
4	Was former Chapter 5
4.3	New matrix for inventories, depending on the different roles incl. examples
4.4	More detailed information about importers obligations and in addition new recommendations for exporters
4.5	Recommendations on how to collect information from the supply chain (e.g. by using Safety Data Sheets) and an explanation about the principle of communication
4.6	Additional information about Exposure Scenarios and how to act if your use is not covered
4.7	More detailed explanation about articles in the Automotive Industry, intentionally releasing substances
4.9	More detailed explanation about “appropriate instructions”
5	Was former Chapter 4
5.0	New Flow Chart: Flow Chart Navigator
5.1	Revised Flow Chart
5.2	Revised Flow Chart
5.3	Revised Flow Chart
5.4	Revised Flow Chart
5.5	New Flow Chart: Use of Only Representative
5.6	New Flow Chart: Obligations for Importers
6	Revised matrix: “10-Steps matrix” became the “8 steps compliance schedule” with more: detailed steps, new steps, realistic deadlines, explanations
Annex B	Minor modification of the REACH awareness letter (only wording, no content change)
Annex C	New “Declaration of intent request letter”
Annex D	The former chapter 7 now contains more Questions and Answers
Annex E	New Annex to track the changes between the AIG Versions





Task Force REACH is supported by:



CLEPA
European Association of
Automotive Suppliers



Verband der
Automobilindustrie

