

Automotive Industry

Guideline on REACH

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CLEPA
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VDA

Verband der
Automobilindustrie

Contents

Foreword: About this guide	3
Chapter 1 - Introduction: REACH and the Automotive Industry	4
Chapter 2: Main Definitions and Acronyms	6
2.1: Main Definitions	6
2.2: Acronyms	10
Chapter 3. "Important dates and deadlines to remember"	12
Chapter 4: How to comply with REACH - a step-by-step process	14
4.1. REACH Flow chart 1	15
4.2. REACH Flow chart 2	16
4.3. REACH Flow chart 3	17
4.4. REACH Flow chart 4	18
Chapter 5: Guidelines	19
5.1 Guideline 1: Roles in the supply chain	19
5.2 Guideline 2: Scope and Exemptions	21
5.3 Guideline 3: Substance Inventory	23
5.4 Guideline 4: Imports of substances/preparations/articles	25
5.5. Guideline 5: Communication obligations along the supply chain	26
5.6. Guideline 6: Downstream user chemical safety report and reporting to the Agency	30
5.7 Guideline 7: Registrations of substances in Articles	31
5.8. Guideline 8: Notification of substances in articles	33
5.9. Guideline 9: Communication requirements for substances in articles	34
5.10. Guideline 10: Authorisation procedures	36
5.11 Guideline 11: List of REACH Implementation Projects	39
5.12. Guideline 12: Helpdesks and Information tools	40
5.13 Guideline 13: Industry-run helpdesks and Guidance	41
Chapter 6: Summary of main obligations and recommendations for the Automotive Industry. 42	
Chapter 7: Frequently Asked Questions (FAQ)	44
Annex A: About Task Force REACH (TF-REACH)	49
Annex B: Awareness-Letter	50

Legal notice

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 Automotive Industry experts from all over Europe 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 Automotive Industry will not accept any liability regarding the contents of this document or arising from its use.

Foreword: About this guide

The new European "REACH Regulation" affects all industries, including the Automotive Industry (AI). As the Automotive Industry is made up of vehicle manufacturers and several 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) and the automotive supply chain (CLEPA) 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 developed along the time line of REACH implementation. It has to be updated with regard to the outcomes of the REACH Implementation Projects (RIPs) and the practical experiences we will gain during REACH implementation.

Our Automotive Industry guideline (AIG) is intended to provide practical help to downstream users using substances and/or preparations and 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 however not 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 to the legal text of REACH. REACH stands for **Registration, Evaluation, Authorisation (and Restriction) of Chemicals**. 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 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>

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>. 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 such modifications brought to the Orgalime Guide via this Automotive Industry Guideline represent the position of Automotive Industry in Europe but do not necessarily reflect the position of Orgalime industries. For Orgalime positions, please consult 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 free of charge at 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 involved, please contact the most appropriate association/the association of which you are a member (see Annex A).

^{*} See Annex A for a full list of TF-REACH member organisations and the companies they represent.

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 EC REACH Regulation* was adopted into 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 that a Directive would. 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. Pre-registration of substances intended to be released from articles, or substances in preparations imported on their own or in articles is to 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 – 2018, depending on tonnage. Without Pre-registration, substances have to be registered immediately. Pre-registration is free of charge and very simple, requiring only basic information.

Of further importance under REACH is the option for non-EU suppliers of appointing an only representative in the EU which will take-on the responsibilities of an importer. Taking advantage this option, non-EU suppliers can continue deliver into the EU without making each of their customer's importers under REACH.

REACH Myths

- REACH is a chemical industry issue
- REACH is an EU-based company issue
- REACH is an issue only for environment 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 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
- Need to phase substitutions with product development programs 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, environment and reduce animal testing
- To encourage substitution of unsafe substances
- Substances of high concern require authorisation or may be restricted

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 during transportation and wastes. 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

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

manufacturer/importer), 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 the registration.

To fulfil these obligations the whole supply chain needs to communicate (data, uses, 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 minimize the business risks posed by REACH

The Automotive Industry is a producer of articles (e.g. car, engine, bumper) but may also be an importer of articles (e.g. screw from China) or an importer of preparations (e.g. engine oil from USA) or substances (e.g. 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 notification of substances of very high concern present in the article under certain conditions. Under the REACH regime it is not required to register or notify substances in articles if they are already registered for that use. When importing substances or preparations from outside EU, you are no longer considered to be a downstream user but an Importer and you have to comply with the importer's obligations under REACH.

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 liable for authorisation) and have then been included in REACH Annex XIV (list of substances subject to authorisation). This authorisation procedure may have restrict the availability of a substance to the market. As a remark, we should note 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 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^{*}.

^{*} 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 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).
- **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; Break 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 as preparations in containers (borderline cases)
- **Candidate list:** List of substances of very high concern for potential inclusion in Annex XIV REACH, which itself lists substances subject to authorisation (Article 59 REACH). The establishment of the candidate list is subject to specific procedures described in Article 59 REACH.
- **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).
- **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).
- **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 is also considered as an Importer.

- **Intended to be released under normal or reasonably foreseeable conditions of use:** means “that the release is essential for the sufficient function of the article” (without the release the article would not work properly)

Derived out of Article 3.3: Definition of an article and the conclusion of the sub-CWG for borderline cases under Rip 3.8

Examples:

- Release of ink from felt tip pens (function = writing, requires the release of the ink from the pen), release of detergents from cleaning wipes for glasses (function = cleaning, the release of detergents contributes to the cleaning function of the wipes).
- 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 machine Release of particles or wear debris from tyres or rubber belts, or brake-linings and –discs or carbon brushes, etc.

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

- **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) 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
- **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 above), that is, a substance which was not manufactured or 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).
- **Phase-in substance:** means “a substance which meets at least one of the following criteria”
a) It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

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

- **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, an alloy (e.g. steel, brass; Article 3.41)
- **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, system manufacturer (e.g. engine plant, component plant, bolt manufacturer)
- **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 3.34 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, metals (e.g. copper, aluminium)** (detailed information on Identification and Naming of Substances in REACH can be found in RIP 3.10).
- **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, toxic for reproduction according to Directive 67/547/EEC (“CMR-substances”) category 1 or 2.
 - (b) Substances which are persistent, bioaccumulative and toxic according to Annex XIII REACH (“PBT-substances”).
 - (c) Substances which are very persistent and very bioaccumulative according to Annex XIII REACH (“vPvB-substances”).
 - (d) Substances which have endocrine disrupting, persistent, bioaccumulative and toxic or very persistent and very bioaccumulative properties, which give rise to an equivalent level of concern to those of other substances listed in points (a-c) and which are identified on a case-by-case basis in accordance with the procedures set out in Article 59 REACH.
- **Sunset date:** means “the date(s) from which the placing on the market or the use of the substance shall be prohibited unless an authorisation is granted which should take into account, where appropriate, the production cycle specified for that use” (Article 58.1 REACH).
- **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).

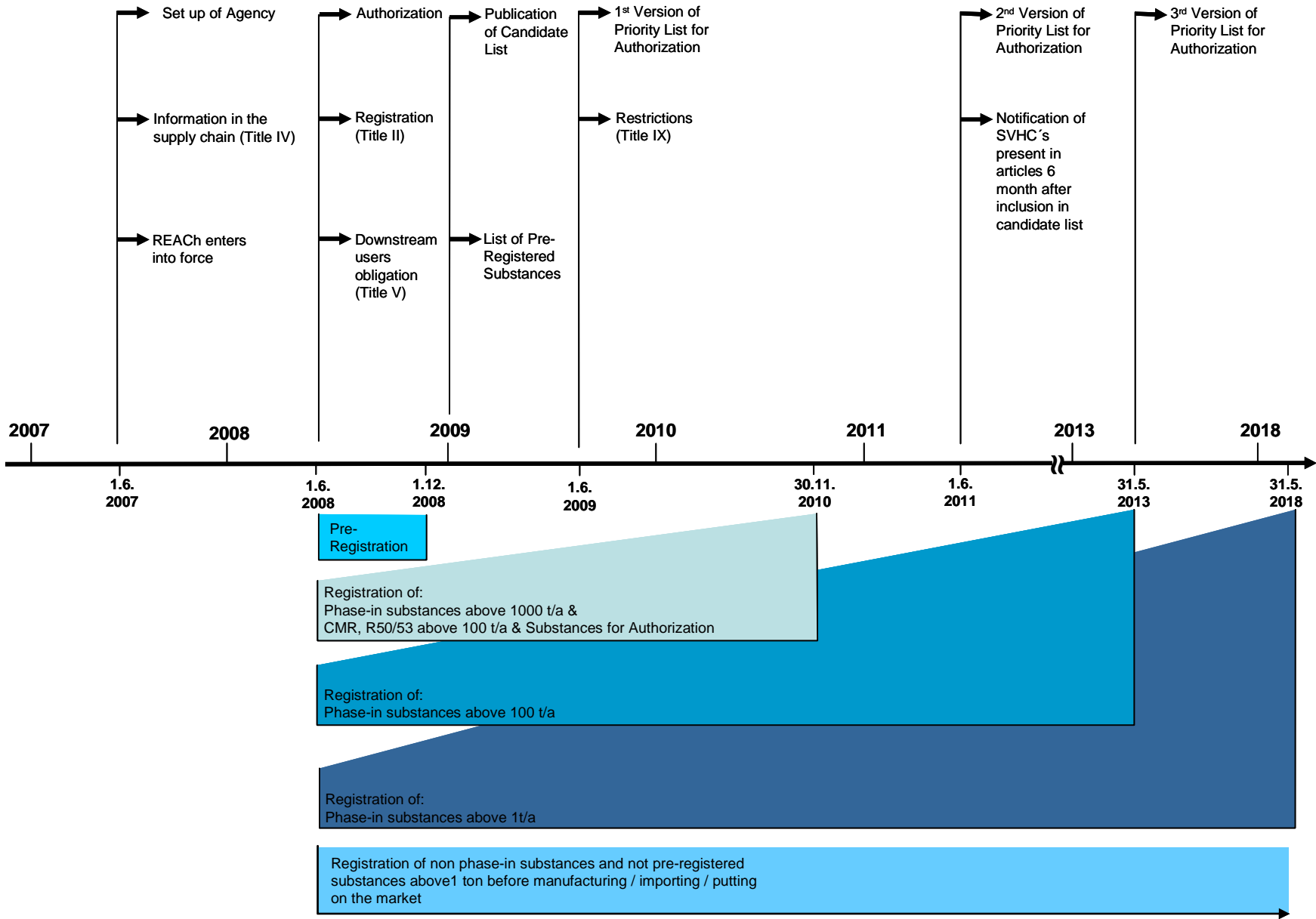
2.2: Acronyms

- ACEA: European Automobile Manufacturers Association
- 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 Harmonized System for classification and labelling of chemicals. http://ec.europa.eu/enterprise/reach/ghs_en.htm
- IMDS: International Material Data System. See <http://www.mdsystem.com/>
- IUCLID: International Uniform Chemical Information Database
- JAMA: Japan Automobile Manufacturers Association, Inc.
- KAMA: Korean Automobile Manufacturers' Association
- MACSI: PSA-System Déclaration des données de composition masses et matières des pièces
- 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 European Commission 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 (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	<ul style="list-style-type: none"> Pre-registration of phase-in substances on their own, in preparation 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 article imported for first time and containing a phase-in substance requiring registration (Article 28.6 REACH).
1 June 2008	<ul style="list-style-type: none"> Registration of non phase-in substances on their own, in preparations or 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 By 1 June 2009	<ul style="list-style-type: none"> Publication on Agency website of pre-registered phase-in substances with first envisaged registration deadline (Article 28.4 REACH). First recommendation for a priority list of substances for authorisation to be issued by the Agency (Article 58.3 REACH). Title VIII REACH “Restrictions” applies – repeal of Directive 76/769/EEC.
2010	
From 1 June 2008 until 30 November 2010	<ul style="list-style-type: none"> Registration of: <ul style="list-style-type: none"> - Substances classified as “CMR”, category 1 and 2 in quantities of 1 tonne/year and above per manufacturer/importer. - Substances classified as very toxic to aquatic organisms (R50/53) in quantities of 100 tonnes/year and above per manufacturer/importer. - Other substances on their own, in preparations or 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).
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).

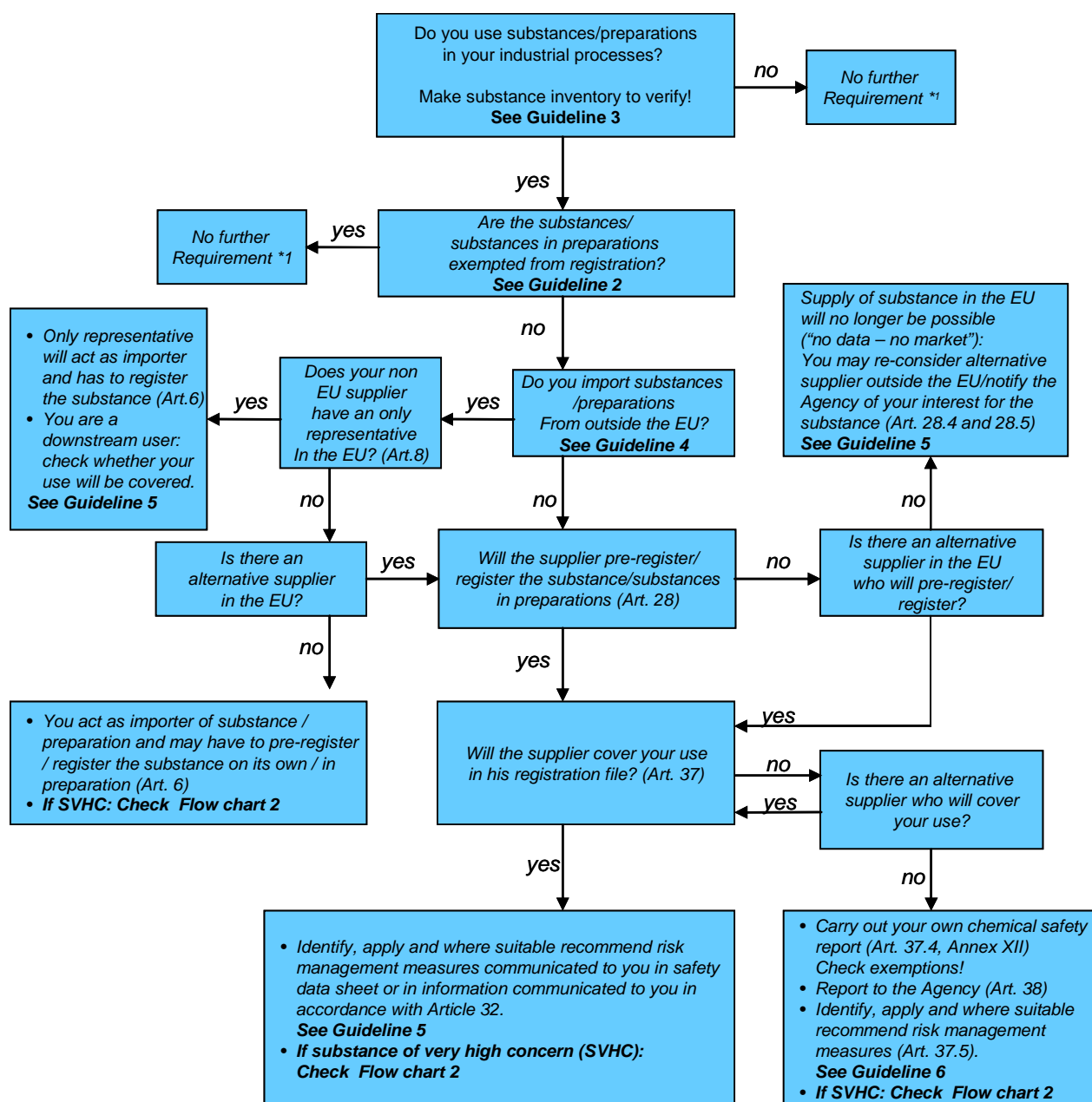


Chapter 4: How to comply with REACH - a step-by-step process

The following flow charts have been constructed to help companies to determine what their obligations are under REACH. Flow charts 1 to 4 should be viewed as complimenting 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 10 Step Process Chart (Chapter 6).

4.1. REACH Flow chart 1

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



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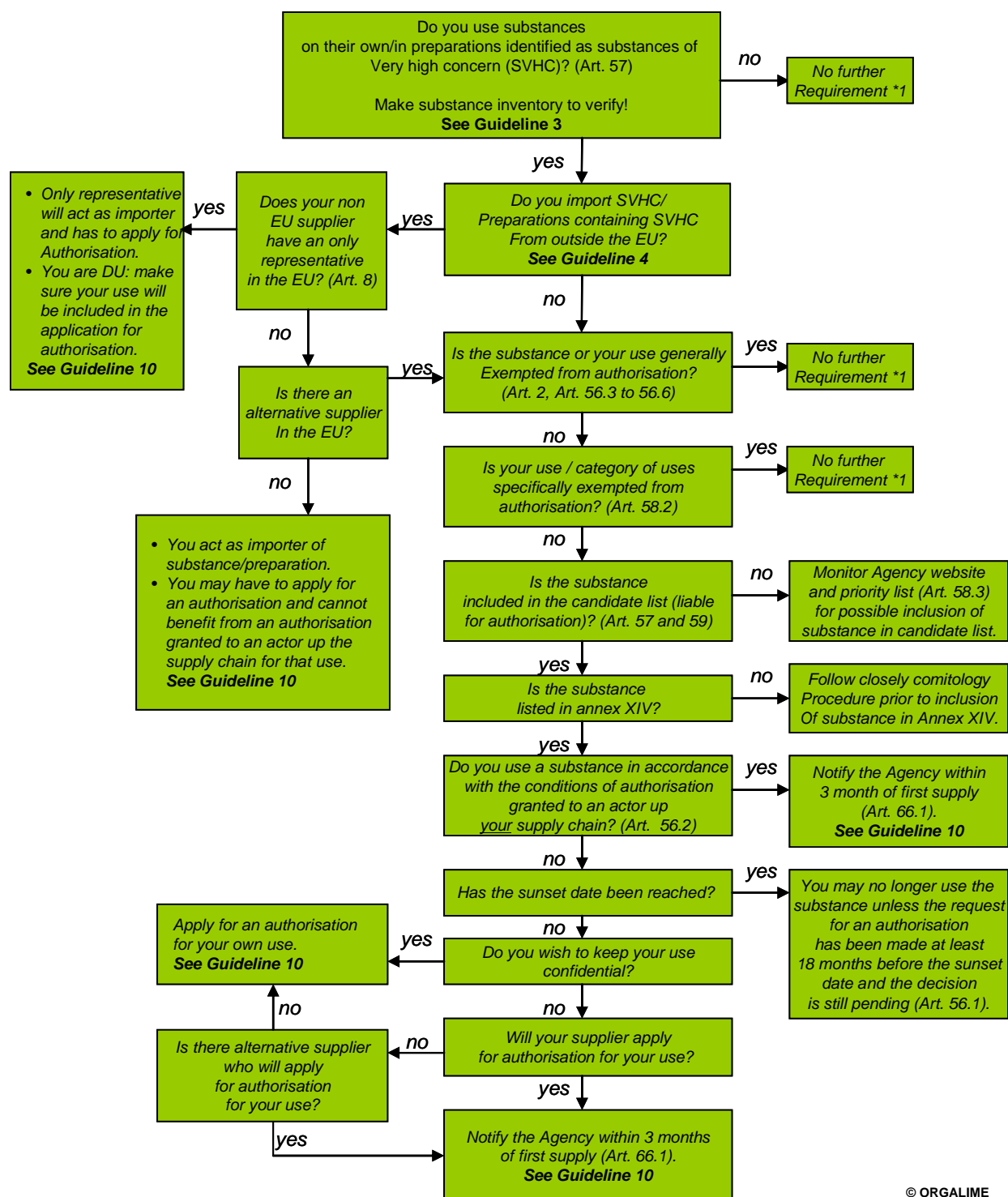
*1 Only for this Flow chart; Check also Flow charts 2, 3 and 4 for further possible obligations.

RECOMMENDATIONS:

- **Start your substance inventory NOW.**
- **Start communicating with suppliers EARLY:** to ensure continuous supply of a substance, be PRO-ACTIVE, don't wait until the supplier has registered the substance you are using in processes to start communicating!
- **Make sure the substance you use will be pre-registered.** In case the substance you use has not been pre-registered, you have the possibility to notify the Agency of your interest in that substance. The Agency shall publish on its website the name of that substance and, on request, provide your contact details to a potential registrant (Article 28.5 Reach). Transition periods for registration will however not be allowed.

4.2. REACH Flow chart 2

REACH authorisation procedures



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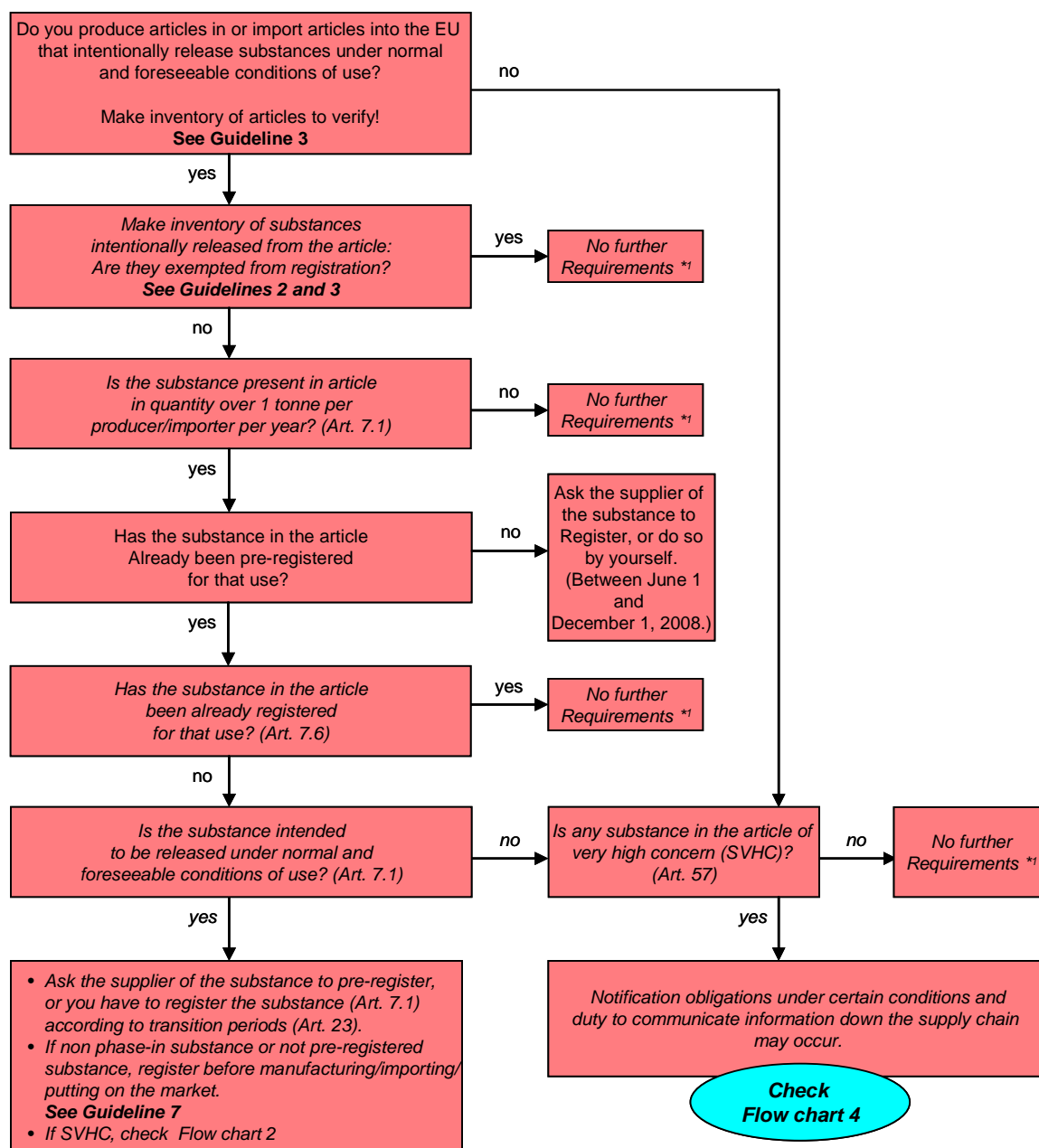
*1 Only for this Flow chart; Check also Flow charts 1, 3 and 4 for further possible obligations.

RECOMMENDATIONS:

- Please be aware that authorisation may cause substance withdrawal from the market.
- Application for authorisation must include an analysis of alternatives (Article 62.4 REACH). Please consider Article 62.4 REACH at an early stage, especially if the use of the substance is critical to your processes.

4.3. REACH Flow chart 3

Registration of substances intended to be released from articles



*1 Only for this Flow chart; Check also Flow charts 1, 2 and 4 for further possible obligations.

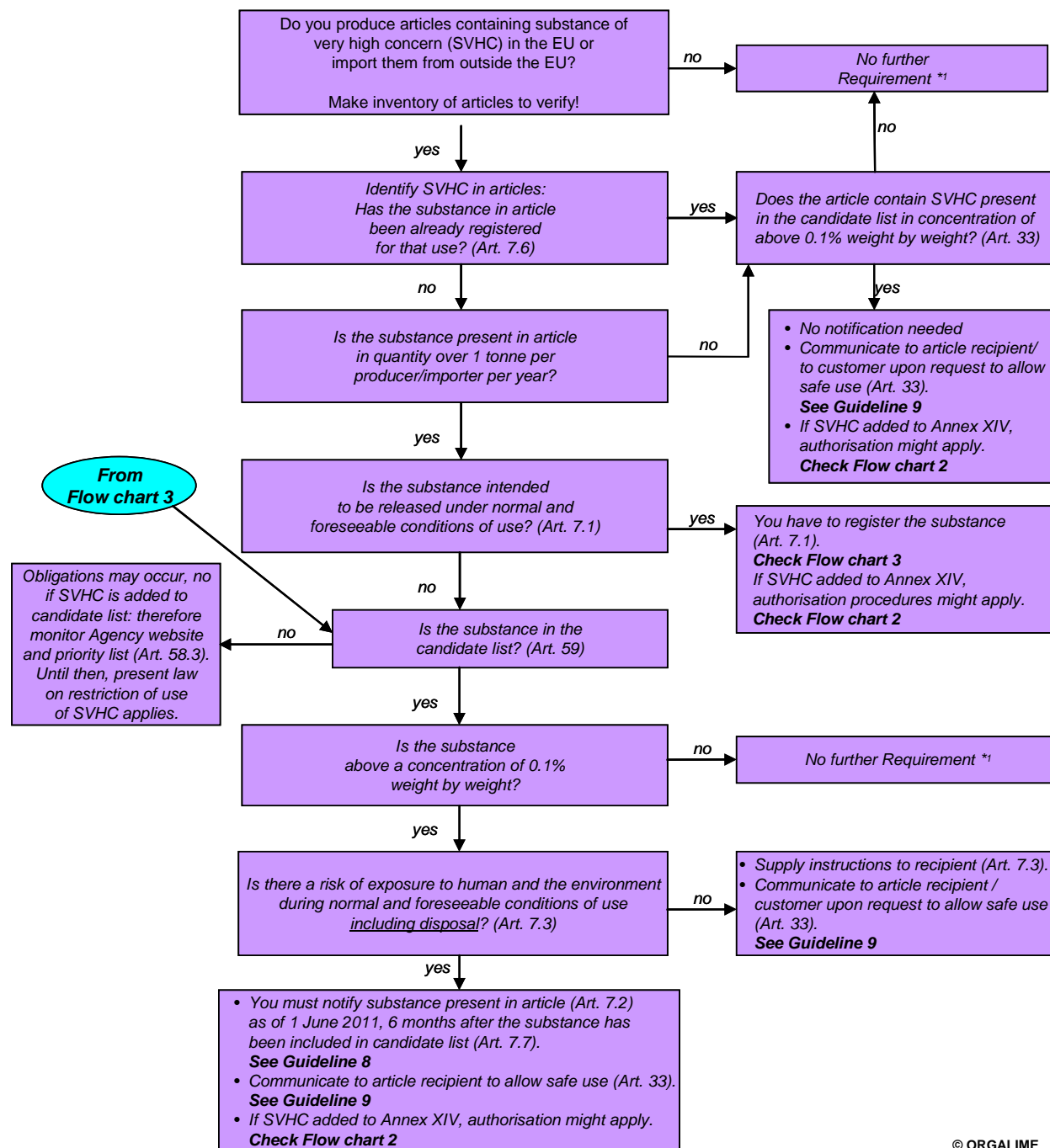
RECOMMENDATIONS:

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

- If the substance that requires registration is considered as a substance delivered in a container, be registered according to Article 6 REACH. Please note that the container itself may require registration according to Article 3.3 REACH.
- If the substance to be registered is considered as a substance in an article, the substance according to Article 7.1 REACH.

4.4. REACH Flow chart 4

Notification of substances in articles and obligation to communicate information



*1 Only for this Flow chart; Check also Flow charts 1, 2 and 3 for further possible obligations.

RECOMMENDATIONS

- According to Article 7.2 REACH, the **calculation of the 0.1% w/w concentration refers to the article**, not at the level of the homogeneous material.
- Please be aware that according to Article 7.5 REACH, **the Agency may require you to register the SVHC under certain conditions.**

Chapter 5: Guidelines

5.1 Guideline 1: Roles in the supply chain

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

Downstream user: means “any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user” (Article 3.13 REACH).

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

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

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

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

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

NOTE:

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

Manufacturer of substances/preparations	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)
Use substances/preparations supplied by an EU supplier	In this case companies bear the obligations of downstream users	See Guideline 5
Import substance/preparations from outside the EU	in this case, companies bear the obligations of importers, if there is no EU “only representative” (that is exclusive representative) of the non EU chemicals supplier appointed	See 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, 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^o 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”

5.2 Guideline 2: Scope and Exemptions

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

However, REACH does not apply to:

- Radioactive substances ([Directive 96/29/EURATOM](#)).
- Substances on their own, in preparations or in articles subject to customs supervision and which are in temporary storage for re-exportation or in transit.
- Non-isolated intermediates.
- The carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air.
- Certain substances on their own, in preparations or in articles exempted by Member States in the interests of defence.
- Waste, which as defined in [Directive 2006/12/EC](#) (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).

“...”^{*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, issues 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>.”

5.3 Guideline 3: Substance Inventory

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

- **Which substances/preparations the company purchases and for what purpose they are used:**
You may then contact the chemicals supplier to ensure that the substance/preparation will continue to be supplied (supported by pre-registration of the substance on its own or in preparations) and that the company's use will be covered in the substance registration dossier (see Guideline 5).
- **Which substances/preparations the company imports:**
Unless an “only representative of a non-Community manufacturer” (that is, an exclusive representative), who will take over the obligations as an importer, has been appointed, you will have to comply with REACH obligations as an importer. This may result in the obligation to go through pre- and full registration of 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 generate the data package for registration in order to be allowed to continue to supply that substance/preparation (see Guideline 4).
- **Which substances are intended to be released from an article that the company produces?**
*If you produce articles intentionally releasing substances, you will be obliged to register the substances released under certain conditions (see Guideline 7). **For substances present in the article, you will have to identify whether they are of very high concern.** Under certain conditions, you will have to notify the Agency for such substances (see Guideline 8).*
- **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 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).*

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

Possible further information you may add to your inventory is:

- Have you contacted the supplier about registration for your use?
- Is there a confidentiality issue regarding specific uses?
- Will the substance be pre-registered/registered? When?
- Will the substance/preparation continue to be available for purchase?
- Is the substance on the candidate list?
- Can it be substituted (if it is likely to be withdrawn in future)?
- If you need to produce data package for registration, what data is necessary?
- Who else supplies the substance or preparation, and can you form a consortium?
- Who are your downstream users and what use do they use the substance for? “

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:

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

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, first checking your roles under REACH and then to check the needed information to be gathered.
- Especially for inventories related to articles, the Automotive Industry in general has already established several tools to be compliant with other obligations (ELV, RRR ...). It is of course recommended to use those (see Guidelines 8 & 9)

*¹: Within REACH the role of a "Downstream User of Articles" does not exist. However, there are certain obligations for that role. Therefore it has been added to that matrix a "Recipient of articles" and his information needs.

5.4 Guideline 4: Imports of substances/preparations/articles

“Import under REACH means “the physical introduction into the customs territory of the Community” (Article 3.10 REACH). The importer is further defined as “any natural or legal person established within the Community who is responsible for the import” (Article 3.11 REACH). Substances on their own or in preparation which are imported from outside the EU have to be registered, following the same rules as substances manufactured in the EU. Registration is also required for substances intended to be released from an imported article⁴, 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:

The “only representative of a non-Community manufacturer”: Article 8.1 REACH foresees that “a natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under Title II. The representative shall also comply with all other obligations of importers under this Regulation”.

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

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

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

NOTE:

- The supply of substances/preparations/articles from EU Member States to other EU Member States are not considered as imports.
- Negotiations are currently taking place to have REACH included in the European Economic Area (EEA) Agreement before pre-registration starts, so that substances supplied from Iceland, Liechtenstein, Norway (which are members of the EEA, but are not members of the EU) would not be considered as imports.
- If a global acting company manufactures a substance on its own, preparations or articles intentionally releasing substances outside the EU and imports it via its own European affiliates into the EU, the latter are the importers. Each individual legal entity (that is a commercial country organisation or each distribution centre for finished products of a global company) importing from their parent company or from any other company located outside the EU, has to register the substance. Joint submission of data by multiple registrants is possible (Article 11 REACH).
- When importing an identical substance from different suppliers in different countries outside the EU, is it not necessary for the EU importer to carry out repetitive registrations for each supplier. The importer may instead register per substance imported, provided that the substance is identical.”

⁴ “In case of the import or the producing of an article containing substances of very high concern, the article producer or importer has to notify the Agency under certain conditions. According to Article 7.5 REACH, the Agency may also decide that the article producer/importer has to register that substance (see Guideline 8).”

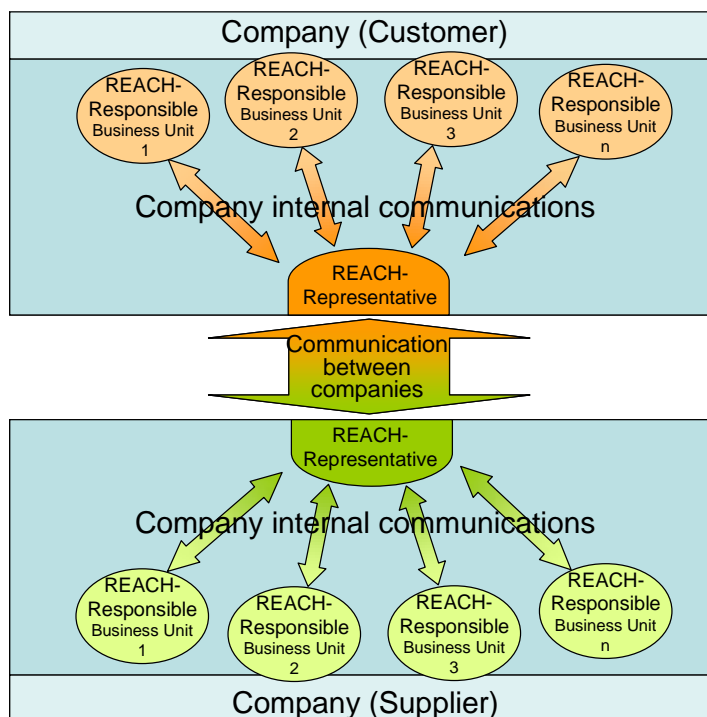
5.5. Guideline 5: Communication obligations along the supply chain

*“In order to secure a continued supply of a substance on its own/in preparations for their use(s), downstream users (hereafter called “DU”), have to check whether the supplier will support their use(s) and include them in the substance registration dossier to be submitted to the Agency. DU may only use substances on their own/in preparations which have been registered for their use(s) after the registration deadline has passed. It is therefore in the interest of DU to **communicate early** with their suppliers with view to having their use(s) included in the supplier’s registration dossier.*

The supplier might be a downstream user, which, in turn, may decide either to carry out a registration by 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, the 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 responsible 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).

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 substance/substances in preparations that they supply. If the supplier does not intend to pre-register a phase-in substance, DU may look for an alternative supplier, who would pre-register the substance. Pre-registration will only be possible between 1 June 2008 and 1 December 2008. The Agency shall, by 1 January 2009, publish a list of pre-registered substances and the first envisaged registration deadline (Article 28.4 REACH)⁵. If a phase-in substance is not pre-registered, no transition periods for registration will be allowed and the substance will have to be registered before the supplier can continue manufacturing, importing or putting the substance on the market. This situation may have consequences on the continuity of the supply of the substance to DU.
- As third step, if the supplier intends to carry out registration procedures, ask whether the supplier has already established use and exposure categories/exposure scenarios⁶ covering their use(s). DU may also check safety data sheets (SDS) provided to them to see whether their uses are already covered in these. If the supplier has not elaborated a use and exposure category/exposure scenario yet, DU may take a pro-active role and provide their supplier with information to develop an exposure scenario/use and exposure category in order to ensure that their uses will be covered.

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

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

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

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

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

Any updated information on authorisation, restriction, risk management measures, registration number must be made available by the supplier to all former recipients, having received the substance or preparation the 12 preceding months free of charge, on paper or electronically (Article 32 REACH).

⁵ "DU of a certain substance, which does not appear on this list of pre-registered substances, have the possibility to notify the Agency of their interest in that substance. The Agency shall publish on its website the name of that substance and on request provide details of DU to a potential registrant (Article 28.5 REACH), who would however not be able to rely on registration transition periods for that substance. Despite this provision, it is in the DU's interest to make sure that the substances they use are pre-registered in due time.

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

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.*

Further DU obligations

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

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

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

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

DU, as well as manufacturers, importers and distributors shall keep the information on REACH available for at least 10 years after they have last used, imported, supplied or manufactured the substance or preparation. This information shall be made available without delay and upon request to Member States competent authority or the Agency (Article 36 REACH).

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

Compliance deadline

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

For more details, please check

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

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

Further comments to be considered for the Automotive Industry:

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 next version of this Guideline with the objective of having a single common communication tool in the AI.

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

“In principle, the use of a substance on its own/in preparations by 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).

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

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

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

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

In case DU carry out their own chemical safety report or rely on the tonnage exemption or the product and process oriented research exemption, DU also have to comply with reporting obligations to the Agency before starting or continuing with a use of a substance registered by an actor up the supply chain (Article 38 REACH). This must be done at the latest 6 months after receiving a registration number communicated to them by their supplier in a safety data sheet (Article 39.2 REACH).

For more details, please check

*Articles 37.4, 38, 39.2 Annex XII REACH
RIP 3.5 “*

5.7 Guideline 7: Registrations 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 the article is present in quantities totalling over 1 tonne per producer or importer per year (REACH Article 7.1).”*

The global Automotive Industry has identified that the only articles that intentionally release substances under normal or reasonably foreseeable conditions of use are:

- Fragrance dispensers,
- Fire extinguishers,
- Windshield-washer fluid (if imported in a vehicle),
- Compressed gases for pyrotechnic devices

Normal wear and tear of articles is NOT considered by the Automotive Industry an intentional release, but rather incidental releases. These include:

Particles or wear debris from tyres, rubber belts, friction materials (brake linings, clutch linings, etc.), brake discs, carbon brushes, brake and steering fluid, coolant, lubes and greases, sizes (stiffeners) from fabrics to improve its process ability, catalytic converters, DPF, pyrotechnic-substances contained within automotive pyrotechnic products, etc. (on deployment, all the pyrotechnic chemicals themselves are completely consumed in the reaction. The chemical products of the pyrotechnic reaction are exempt from REACH registration requirements under Annex V (3))

These are conclusions of the AI which do not necessarily follow the RIP 3.8 recommendations^{*1}.

If a supplier becomes aware of other automotive articles that they feel do also have 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).

Registration of substances intended to be released from articles is NOT required when:

- The definition of intended to be released under normal or reasonably foreseeable conditions of use in quantities >1 tone per producer or importer per year definition is not met, or
- The substance is exempt from registration, (see Guideline 2) or
- The substance has already been registered FOR THAT USE. (REACH Article 7.6).

^{*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 European Commission, Unit REACH G1 in December 2006. It was confirmed by the EC to consider this objection in the next review in 2007.

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	<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 European Commission’s Regulation by 1 June 2008. No fees are required for the registration of a substance between 1 and 10 tonnes where the registration dossier contains the full information specified in Annex VII REACH.

NOTE:

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

- If the substance that requires registration is considered as a substance delivered in a container, the substance has to be registered according to Article 6 REACH. Please note that the container itself may be considered as an article according to Article 3.3 REACH.
- If the substance to be registered is considered as a substance in an article, the substance requires registration according to Article 7.1 REACH (for the definition of an article, please see Chapter 2 of the Guideline). “

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

See flow chart 3.

5.8. Guideline 8: Notification of substances in articles

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

- The substance has been identified as of very high concern (Article 57 REACH), that is,
 - (a) The substance meets the criteria for classification as carcinogenic, mutagenic, 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”

5.9. 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).*
- *The REACH Regulation does not provide for a definition for “consumer” nor consider a consumer as an actor in the supply chain. “*

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

1. Article 33.1: Supplier to inform article recipient if article contains substances of very high concern (SVHC) ^{*1}
2. Article 33.2: On 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. ^{*1}
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 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: Already established Substance Reporting Systems (e.g. IMDS, MACSI) can be used. Prerequisite for a 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, not having an IT-tool available, alternative methods can be used to collect the necessary data.

By following that recommendation, the main tasks are done:

- Complete Inventory of SVHCs in Articles^{*3}
- Evaluation of potential exposure of humans or the environment
- 3: Based on the inventory, cases requiring notification can be identified and actions defined.
- 4: Provide appropriate instructions to the recipient of the article
- 5: As in the Automotive Industry an exposure from Articles 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 are incomplete, mainly because the related RIPs are not finalised. The remaining question to be answered is:

- What are “Appropriate Instructions” and how to collect them?
(For example, it is possible to include the information in the already existing systems. Other solutions are possible as well. This will be discussed further by the experts (cost-benefit-analysis). The final recommendation will be added to future versions of this Guideline.

^{*1} Minimum information for both is the name of that substance.

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

^{*3} Data are only available for Articles which are used in the vehicle but not for Articles used for the production process (welding machines ...).

5.10. Guideline 10: Authorisation procedures

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

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

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

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

NOTE:

- **DU may use a substance subject to authorisation provided that they use the substance in accordance with the conditions of authorisation granted to an actor up the supply chain for that use (Article 56.2 REACH).**
- *DU shall notify the Agency within three months of first supply of the substance if they use this substance in accordance with the authorisation granted for that use (Article 66.1 REACH).*
- *Uses and categories of uses may be exempted from authorisation if, on the basis of existing community legislation imposing minimum requirements related to the protection of human health and the environment for the use of the substance, the risk is properly controlled (Article 58.2 REACH). Use and exposure exempted, if any, and the conditions for such exemption, if any, shall be listed in Annex XIV REACH (Article 58.1 REACH).*

Exemptions to authorisation (see also further exemptions in 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 REACH⁸ (Article 59.9 REACH).

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

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

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

Application for authorisation

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

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

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).

⁸ Please note that Decision 1999/468/EC setting up Comitology rules, which is referenced in Article 133 REACH, has been amended by Council Decision 2006/512/EC of 17 July 2006, establishing a new regulatory procedure with scrutiny. In how far Decision 2006/512/EC will impact REACH, is unclear at this stage.

The application may include a socio-economic analysis and a justification for not considering risks to human health and the environments in specific cases (Article 62.5 REACH).

The application shall not include the risks to human health arising from the use of substances in medical devices regulated by (Directive 90/385/EEC), (Directive 93/42/EEC) and (Directive 98/79/EC) (Article 62.6 REACH).

Granting of an authorisation

The European Commission is responsible for taking the decisions on applications for authorisation. An authorisation will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled (see also Annex I section 6.4 REACH). The “adequate control route” does not apply for substances for which it is not possible to determine thresholds and substances with “PBT” or “vPvB” properties. If it cannot be demonstrated that the risk is adequately controlled, an authorisation may still be granted, if it is proven that the 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

Title VII REACH

RIP 3.5, RIP 3.7, RIP 3.9”

5.11 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 European Commission in collaboration with stakeholders. RIPs tackle seven main areas and a number of sub-projects, which are outlined below. “

NOTE:

RIP guidance documents are not legally binding.

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 (project finalized)

RIP 3.2: Preparing Chemical Safety Report (CSR)

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

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

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

RIP 3.3: Information requirements on intrinsic properties of a substance

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

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

RIP 3.4: Data sharing (pre-registration)

TGD on data sharing (project running)

RIP 3.5: Downstream user requirements

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

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

RIP 3.6: Guidance on classification and labelling under GHS (project running)

RIP 3.7: Guidance on preparing an authorization application (project running)

RIP 3.8: Guidance on fulfilling the registration requirements for substances in articles

Project finalised. Currently under review; it will be updated.

RIP 3.9: Carrying out a socio-economic analysis

RIP 3.9-1: Preliminary study on Socio-Economic Analysis (finalised)

RIP 3.9-2: Guidance on carrying out a socio-economic analysis (project running)

RIP 3.10: TDG on identification and naming of substance (project finalised)

RIP 4 Technical Guidance and tools for authorities

RIP 4.1: Dossier evaluation (project finalised)

RIP 4.2: Substance evaluation (project finalised)

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

RIP 4.4: TGD on the preparation of Annex XV dossiers (project finalised)

RIP 4.5: Priority setting for evaluation (project running)

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

RIP 7: Preparation of the new tasks of the Commission

RIP 8: Agency Standard operation procedures

Overall guidance package

To facilitate the accessibility to the guidance RIPs 1, 2, 3 and 4, a web application has been developed. The so called “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

5.12. Guideline 12: Helpdesks and Information tools

This selection of web addresses from helpdesks and information sources is intended to signpost additional help where 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 the Automotive Industry's.

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 lets companies answer questions on their substance and quickly find out 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 European Commission 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 harmonize 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. Links to legal texts, news around REACH and related websites regarding chemicals information give a lot of information possibilities: <http://reach.startpagina.nl/>

This selection will be updated as necessary.

5.13 Guideline 13: Industry-run helpdesks and Guidance

This selection of web addresses from helpdesks and information sources is intended to signpost additional help where 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 the Automotive Industry's.

German Industry (BDI):

<http://reach.bdi.info/> contains "one pager" on all aspects of REACH and its different chapters.
Language: German

European Chemical Industry Council (CEFIC):

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

Danish Industry (DI):

www.reach-klarbesked.dk 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).

UK Chemical Industry:

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

Greece Industry Association:

<http://www.haci.gr/gr/reach2.htm> (in Greek language)

Netherland Chemical Industry (VNCI):

http://www.dzine-online.nl/client23/nb/nb600/batch717/reach_helpdesk_in_oprichting.html

Austrian Chemicals Industry (FCIO):

<http://reach.fcio.at/default.aspx?site=8&main=0&sub=0&content=0> (German language)

This selection will be updated as necessary.

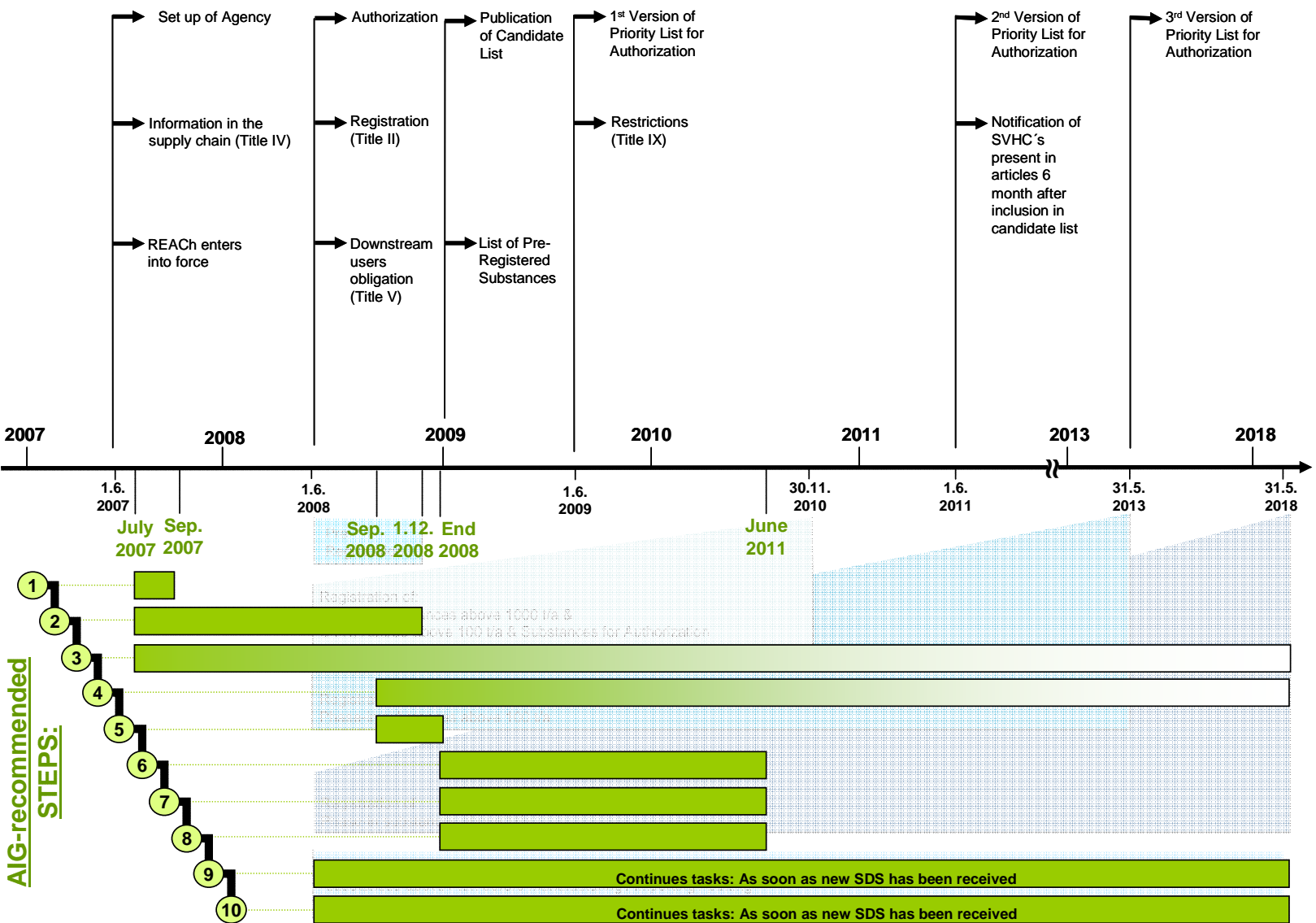
Chapter 6: Summary of main obligations and recommendations for the Automotive Industry

Taking into consideration the results from the AIG Chapters 1-5, the following steps and tasks are recommended to fulfil the obligations under REACH for the Automotive Industry. As those obligations are the same for Tier-suppliers as well as the vehicle manufacturers, every company along the supply chain can proceed as recommended below. Of course, the AIG recommendations are general enough to leave room for company-specific interpretations:

#	Which steps are necessary for a Downstream-User within the Automotive Industry (AI) to fulfil their REACH-obligations:	Main-Tasks	Recommended tools	Recommended Timing (Earliest starting date)	Recommended Timing (latest finish date)	Reference to AIG
1	Request/Define contact-data of REACH-representative for each company (customer & supplier)	- Identify the REACH representative (key contact) at each company - Recommend each legal entity for the company for which REACH is applicable - Recommend the REACH responsible for each applicable legal entity	Letter for REACH-awareness	July 07	Sep 07	Annex 1: Awareness letter
2	Identify all substances, preparations and articles falling under REACH	- Establish & complete inventories	Inventory		End of Pre-Registration Phase: 1-Dec-08	Guideline 3
3	Identify all Substances intended to be released... from Articles	- Make sure, that those substances are Registered for that use by the suppliers	List of articles were substances are intentionally released			Guideline 7
4	Identify all Substances / Preparations from inside EU OR which are imported from outside EU and have not already been registered for our use	- Make sure, that those substances are registered for that use by the suppliers	Declaration of Intent (Supplier has to confirm, that he will pre-register and has the intention to register. Supplier furthermore has to notify customer immediately if he will not register the substance for <u>the respective use</u>)	Sep 08 (During Pre-Registration Phase)	To be defined	Guideline 4 & 6
5	Identify all substances which will not be pre-registered by a supplier	- Make sure, that pre-registered	Use results of inventory		Jan 09 (after Pre-Reg-list is published)	Guideline 5
6	Identify SVHC's in Articles	- Make sure, that those substances are Registered/Authorized for the use by the suppliers (Authorisation: in case of Annex 14 inclusion)	GADSL, Material Reporting Systems (IMDS, others...)	End 08 (first candidate list is available) *1	June 2011 (start notification)	Guidelines 8, 9 & 10
7	Identify imported SVHC's		Adopt and adapt as necessary already existing internal processes.			
8	Identify SVHC's used in EU-production					
9	Identify the Risk Management Measures in the SDS	- Apply The RMM's	Adopt already existing internal processes (In the future, an IT-Tool will be available for communication up and down the supply chain.)	As soon as the new SDS has been received		Guideline 5
10	Check the conditions described in the Exposure Scenarios	- Verify the conditions for your use and your customers uses				Guideline 5

*1 A pre-analysis could be done by using already existing information (GADSL, Annex 17; Appendix I-IX of REACH)

The chart below is based on the chart, presented in Chapter 3. As additional information, it is highlighting the recommended timing for the 10-steps, explained in the matrix above.



Chapter 7: Frequently Asked Questions (FAQ)

Pre registration

- Q1.** What happens if we, as a DU, find out after pre-registration has ended that our substance/use has not been pre-registered?
- A:** You can pre-register it after the pre-registration phase has ended, but you are required to send all the necessary information described in article 28 within 6 months of first manufacture/import or use. Also, this information has to be sent at least 12 months before the phase in deadline.

Registration

- Q2.** Which substances are exempt from registration?
- A:** 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 <1 tonne per year do not need to be registered.
- Q3.** Is there an obligation to register steel or other alloys?
- A:** 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 > 1 tonne per year.

Authorisation

- Q4.** 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 are long 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.

- Q5.** Can applications for authorisation be submitted together?
- A:** Grouping of applications for authorisation is possible in REACH. Groups can be of: manufacturers, importers and downstream users; substances; uses; or any combination of these groups. This is to enable costs to be minimised and the system to process applications rapidly.

Downstream users

Q6. How will notification work for downstream users of substances under the product & process oriented research (PPORD) exemption?

A: 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 Downstream User 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. However if the substance is used in quantities >1 tonne per use per year, the downstream user has to notify the Agency.

About the registration of substances in products (Article 7, Clause 1)

Q7. 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 and importer. Is our understanding correct?

A: Yes, it is per legal entity.

Q8. What is the definition of "article"?

A: See chapter 2 in this AIG

Q8a. What are the automotive products to which "intended to be released" applies?

A: See chapter 5.7 (Guideline 7)

Q9. When is windscreen washer fluid considered a "preparation in a container" and when is it a "preparation within an article"?

A: When you import a car with windscreen washer fluid in, 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.

Liability to notify substances in products (Article 7, Clause 2)

Q10. 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?

A: Always use the weight of the article manufactured in or imported to EU.

Q11. How is chemical control in REACH linked to waste control?

A: For all substances above 10 t /y a Chemical Safety Report and a risk 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 to be registered.

Q12. 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 weighs 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?

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

Q13. 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?

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

Q14. How does REACH provide for punishments/penalties/fines/imprisonment? Are they country-specific punishments or EU-wide punishments?

A: Penalties for non-compliance are country-specific. Only the Member States can punish their inhabitants.

Q15. 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?

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

Requests to manufacturers of final products

Q16. Manufacturers of final products are required to confirm that the use of substances of very high concern (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:

A: The article manufacturer/importer notifies the agency.

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

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

Registration and restriction of new chemicals

Q17. Is it right to think that the mechanism for registration and restriction of new chemicals is almost the same as the existing one?

A: Yes, substances put on the market after 1981 and compliant with the existing regime are seen as "REACH compliant".

Q18. 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?"

A: 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.

Q19. Is there a mechanism for conveying information on "use" to upstream suppliers? Shouldn't automobile industries in different countries share the recognition of "use?"

A: 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.

Q20. What does it cost to use the Reach-IT system (including IUCLID5)?

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

Substances of very high concern (SVHC)

Q21. About how many substances are treated as SVHC?

A: The candidate list will be established 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.

Q22. Will all SVHC substances be disclosed at one time?

A: 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.

Conveying information on the content of SVHC

Q23. What information network has been built for supply chains in Europe?

A: It is responsibility of the Industry how to handle this.

Q24. If a supply chain extends into more than one country, it may be difficult to collect sufficient information on the content of SVHC.

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

Response to REACH

Q25. We understand that chemical manufacturers are basically responsible for the registration of new and existing chemical compounds, and automobile manufacturers only have to care about preparations "intended to be released." What does the TF-REACH think about this point?

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

Q26. 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?

A: 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.

Q27. 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?

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

Q28. 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 substances of very high concern contained in articles that are difficult to check by data or by other means?

A: Not decided at today's date.

Q29. How about parts purchased from outside the EU? How will you direct the suppliers to respond to REACH?

A: The obligations for importers are described in REACH.

Q30. After the raw materials to be used in paints, rubber, adhesives, etc, were shipped by the chemical industry, suppliers might add more substances. How strictly should OEMs control these materials?

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

Q31. Shouldn't automobile industries in different countries share the recognition of exposure scenarios of substances "intended to be released?"

A: We share our experiences within the TF REACH.

Q32. 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?

A: The pre registration period is 1st of June 2008-1st of December 2008. A proposal for an awareness letter is in this guide.

Q33. What are the obligations of a distributor?

A: 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.

Q34. 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?

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

- Q35.** If IMDS is used for REACH, how is information on “use (purpose of use)” conveyed from downstream users to upstream suppliers to meet the requirements of REACH?
- A: IMDS could only be used for articles going into our products. Further uses are currently not possible.
- Q36.** Most primary suppliers (Tier 1) are 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?
- A: Communication must go through the whole supply chain, not with Tier1 alone.
- Q37.** Does TF-REACH think that SVHC should be controlled or that the GADSL can be used?
- A: TF REACH addressed this to GADSL team member. GADSL should cover SVHCs in the future.
- Q38.** What substances should OEMs ensure for registration?
- A: Each OEM has to identify their roles under REACH. If the company imports substances or substances in preparations then they have to register.
- Q39.** What kind of SVHC do we need to take care of?
- A: See Guideline 8.
- Q40.** How can we set up a system for implementing REACH with respect to process materials (raw / auxiliary material) in our EU manufacturing facilities?
- A: 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 your suppliers/importers aware of REACH. Therefore we recommend using the already existing tools in your company.
- Q41.** How will ECHA check up the REACH implementation, and what is the expected penalty?
- A: This is under investigation (RIP 4).
- Q42.** What is the basis for the 0.1% threshold?
- total article weight?
 - total sub part weight?
 - homogeneous material weight?
- A: In the regulation it is clearly stated article weight/weight (REACH Article 7.2).
- Q43.** Does this guideline cover the standard REACH implementation process for OEMs?
- A: That depends on so many Company specific factors that a clear recommendation cannot be given.
- Q44.** Is it necessary to inform your supplier if you are a DU and using a substance at less than 1 tonne per year?
- A: Yes, because your supplier must note your usage on the SDS regardless of the tonnage

Import of substances to the European Union – only representative

- Q45.** What are the responsibilities of a non-EU company who has nominated an only representative?
- A: 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)

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 spread the workload involved, please contact the most appropriate association/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, DaimlerChrysler, Volkswagen.
- CLEPA (European Association of Automotive Suppliers): Louis Sylvain AYRAL 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 (Korean Automobile Manufacturers' Association): Timo UNGER tunger@hyundai-europe.com
is an organization representing the major automakers in Korea. KAMA has been established to foster and develop Korean auto industry and thereby contribute to sustainable growth of the national economy. Korea's 5 major automakers (Hyundai, Kia, GM Daewoo, Ssangyong, 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 WÖHRL, mailto: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, below. It is recommended that this wording is used and that further information is not requested at this early stage. This document can be downloaded as an MS Word-file in the REACH-section of the ACEA webpage www.acea.be/REACH.

Date: To be added

To CEO of all suppliers

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. 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 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 as soon as you have the required information available.

Regards

COMPANY LETTER HEAD

REACH: 1. Standard Communication Along the Supply Chain¹

Jul-07

Recommendation and Requests from Downstream User (Customer) to Suppliers regarding Pre-registration / Registration

Concerning all products supplied to us which can be 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 **registered** ⁽²⁾
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 contact details 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”