AUTOMOTIVE INDUSTRY GUIDELINE ON

REACH

VERSION 3.0

The Automotive Industry Guideline is developed by:

ACEA European Automobile Manufacturers Association

ICAMA

JAMA Japan Automobile Manufacturers Association, Inc.

CLEPA European Association of Automotive Suppliers

VDA Verband der Automobilindustrie

BIL Sweden

AIAG Automotive Industry Action Group

Comité des Constructeurs Français d'Automobiles

SMMT DRIVING THE MOTOR INDUSTRY

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EXECUTIVE SUMMARY

The European REACH Regulation[1] came into force on 1 June 2007 and affects all industries. It requires immediate and ongoing action from the OEMs and suppliers. Under REACH, Substances of Very High Concern (SVHC) may require authorisation and substances which place unacceptable risk on human health or the environment may be restricted. Compliance with the REACH Regulation is mandatory for companies doing business in the EEA (and for businesses with customers or subsidiaries do business in the EEA).

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

Since the publication of the Automotive Industry Guideline (AIG) on REACH Version 2.1 in May 2008 the REACH process has passed some important milestones such as pre-registration, the first publication of a Candidate List (hereinafter CL) with SVHC, Annex XIV Authorisation List and most importantly the first registration deadline at the end of 2010. Having accumulated a wealth of experience through the cooperation in the Task Force and in the light of upcoming processes which include authorisation of use, notification of CL substances in articles and communication due to the steadily increasing CL, it was felt that an update of the AIG would be helpful for vehicle manufacturers and the automotive industry supply chain.

Whereas in the past industry had been concerned about how to cope with REACH in a timely manner, it now can face upcoming duties with confidence that tasks can be adequately managed. The automotive industry appreciates the efforts made in the supply chain in finding substitutes for SVHC which better protect human health and the environment along the supply chain, at our facilities and dealerships and last but not least our customers.

Key messages

- REACH imposes different obligations for each role the sector performs: as a Downstream User of substances (e.g. magnesium) and mixtures (e.g. engine oil), a producer of articles (e.g. vehicle, engine, bumper manufactured in the EEA), or an importer of articles/mixtures/substances (from outside EEA). The flowcharts in Chapter 4 will help you determine what your obligations are and direct you to the appropriate section of the AIG where you can find guidance on what to do next.
- Depending on the role(s) they perform in REACH, companies should have an inventory of the substances/mixtures/articles they use. This will help to assess their obligations and next steps.
- Downstream users expect their uses of a substance to be registered up the supply chain.
- The AIG makes the recommendation that non-EEA suppliers appoint an Only Representative in the EEA which takes on the importer responsibilities, instead of each of their customers duplicating the importer role (see Chapter 5.4).
- To fulfil their REACH obligations, the entire supply chain needs to communicate data, uses, control measures for safe use, etc. (see Chapter 5.5 and the standard REACH awareness letter in Annex B).
- Each actor in the supply chain should appoint a REACH representative and develop a strategic action plan to ensure compliance and minimise the business risks posed by REACH.
- The sector has considered whether any substance releases from articles are considered to be intended releases for the purposes of REACH and our conclusions are set out in Chapter 5.8.
- Chapter 6 of the AIG summarises the main obligations and recommendations for the AI response to REACH. It identifies the tools available to help, along with a timeline for each activity. These activities are broadly grouped into the 5-step compliance schedule under the headings of raising awareness, developing a substance inventory, declaration of intent (three steps), SVHC and risk management measures and uses.

- The Chapters 5 and 6 describe the different processes around supply chain communication, including the SDS/eSDS requirements with a focus on DU. This chapter is followed by information about CLP and the notification duties.

The AIG is a living document which will be updated in light of guidance and the practical experience gained by TF-REACH members when tackling the different REACH processes.

[1] Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation (and Restriction) of Chemicals

Disclaimer

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

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

7 July 2011


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FOREWORD: ABOUT THIS GUIDELINE

The Registration, Evaluation, Authorisation (and Restriction) of Chemicals (REACH) Regulation (EC) No 1907/2006 entered into force on 1 June 2007 and affects all industries. As the automotive industry is made up of vehicle manufacturers and many tiers of the supply chain, it has several roles under REACH which are all linked to different obligations (see Chapter 5). In preparation for REACH, the major vehicle manufacturers, represented by the associations ACEA, JAMA, KAMA, the European Association of Automotive Suppliers (CLEPA) and the Automotive Industry Action Group (AIAG) formed a task force on REACH (TF-REACH[2]). The task force aims to establish a common schedule and external communication strategy which will harmonise the sector's REACH implementation process.

The TF-REACH 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. Positions adopted in this guide are based on consensus between all task force members, not on a majority voting system.

This guide will be a living document and will be modified according to the future revisions of REACH. It will also be updated with the release of the European Chemical Agency (ECHA) Guidance Documents (formerly RIPs) and the practical experiences gained by members of the different associations during REACH implementation.

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

This guide will reference the legal text of REACH and the CLP Regulation. The REACH Regulation (EC) No 1907/2006 and Directive 2006/121/EC amending Directive 67/548/EEC were published in the Official Journal on 30 December 2006 and in the corrected text version dated 29 May 2007. The legal text can be found at;

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF and
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF

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

The structure and main content of the previous Automotive Industry Guideline followed the first version of the Orgalime REACH Guide entitled "A Practical Guide For Downstream Users, Article Producers and Article Importers" (May 2007).
Much of the structure has been retained along with the main content of the previous Automotive Industry Guideline and therefore of the first version of the Orgalime REACH Guide. However, the latest developments of the Orgalime Guide have not been reflected in this document. The present Guideline takes into account the work of the automotive industry. For readability reasons, this version does not anymore include indicators "Text in Italics" showing the Orgalime origin although this can be still found in the previous document (AIG V2.1).

Comments and updates of the Automotive Industry Guideline on REACH

This version, and future updates of the Automotive Industry Guideline on REACH, will be available to download free of charge at http://www.acea.be/reach. Comments and suggestions for improving the guideline are welcome, via the secretary to TF-REACH under reach@acea.be or to the association of which you are a member (see Annex A). A list of changes comparing the current and previous version of the AIG can be found in Annex F of this guideline.

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

CHAPTER 1: INTRODUCTION – REACH AND THE AUTOMOTIVE INDUSTRY

This Introduction explains why the automotive industry needs such guidelines but will not give a complete overview of "What is REACH?"

The REACH Regulation was adopted into European Union (EU) law in December 2006 and came into force on 1 June 2007. As an EC regulation, it automatically becomes law in each Member State, so it does not need transposition in the same way as a directive. However, each Member State is obliged to enforce REACH under consideration of the individual national legislation scheme.

REACH Realities

- REACH is **not** just a chemical industry issue as it impacts producers or importers of articles.
- REACH is **not** only an EU-based company issue.
- REACH is **not** only an issue for environmental, health and safety specialists.
- Companies that do not comply with REACH will have no market. REACH poses a threat to any company doing business in the EEA (and businesses with customers or suppliers who do business in the EEA).
- Business continuity can be adversely impacted by REACH and supply chains can be disrupted.
- Companies that understand the business implications and impacts of REACH and develop strategic action plans will gain competitive edge over those that do not.
- Substitutions need to be phased-in with product development programmes to minimise 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 within the internal market while enhancing competitiveness and innovation" (Article 1.1 REACH).

The main objectives of REACH are therefore:

- To reduce the risk from chemicals to humans and the environment and to reduce animal testing.
- To encourage substitution of specific dangerous substances, listed in REACH Annex XIV and XVII.
- To require authorisation for use or restriction of the substances mentioned in Annex XIV and XVII

To accomplish these realities and to fulfil the aims and objectives, REACH requires action from the Automotive OEMs and suppliers immediately and in the future.

When registration is considered, one has to be assured that all business relevant substances on their own or in mixtures are or will be registered for your specific use by a supplier. For non-EEA suppliers it is **highly recommended** to appoint an OR in the EEA to take on the responsibilities of an importer. In this case, non-EEA suppliers can continue to deliver into the EEA without each of their customers becoming importers under REACH.

As well as registration, REACH includes a number of other obligations that require the automotive industry, to adopt processes and tools already in existence as well as the implementation of new practices.

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 mixture and in articles, but there are exemptions for radioactive substances, non-isolated intermediates, substances used during transportation, and waste (Article 2 REACH). These are covered by other existing regulations. Member States may also grant exemption for substances used in the interest of defence.

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

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

The automotive industry includes producers of articles (e.g. car, engine, bumper), importers of articles (e.g. screw from China), importers of mixtures (e.g. engine oil from USA) and importers of substances (e.g. elemental Magnesium from Australia). Article producers and article importers have specific obligations under REACH, in particular the registration of substances intended to be released from articles and the communication/notification to downstream users and ECHA of CL substances present in the article under certain conditions. Under REACH it is not required to register or to notify ECHA of substances in articles if they are already registered for that use. However, the presence of CL substances must be communicated to downstream users in this case.

NOTE

- Companies that import substances or mixtures from outside the EEA are no longer considered to be downstream users but Importers and have to comply with the Importer's obligations under REACH.
- Companies that produce articles that intentionally release substances are not acting as downstream users and may have registration obligations if this use has not been already registered.
- Substances or mixtures that were originally produced (and the registration has been completed) in the EEA and which have been re-imported to the EEA are considered as being registered.

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

In addition to these registration and notification obligations, REACH built on legislation regarding restriction, classification and labelling of dangerous substances that were amended in 2008. The Classification, Labelling and Packaging Regulation (CLP Regulation (EC) No 1272/2008[4]) as the European implementation of the United Nations (UN) Globally Harmonised System for Classification and Labelling of Chemicals (GHS) is leading to further adaptations of REACH that are also impacting the automotive industry, e.g. with additional obligations in regard to notification and safety data sheets.

REACH Review

Article 138(6) REACH calls on the Commission to carry out a review by 1 June 2012 to assess whether or not to amend the scope of REACH to avoid overlaps with other relevant Community provisions. On the basis of such review, the Commission may, if appropriate, present a legislative proposal.

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

[4] For more information see: http://ec.europa.eu/enterprise/reach/ghs_en.htm

CHAPTER 2: MAIN DEFINITIONS
2.1 Glossary of Terms

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

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

Article
means "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition" (Article 3.3 REACH).
Example: Vehicle, airbags, engine, seat, generator, wiper, steel coil or steel slab, windscreen, headlamp, screw, bolt, brake pads or linings.
Borderline cases:
Articles or articles with an integral substance/mixture: e.g. batteries, touch-up paint sticks, liquid tyre repair kit.
Combination of an article (functioning as a container or a carrier material) and a substance mixture: e.g. cleaning agents in cans, engine oil in cans, spray can with paint, desiccant bags.

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

Competent authority
means "the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation" (Article 3.19 REACH).

Consumer
means any natural person who is acting primarily for purposes which are not related to his or her trade, business or profession.

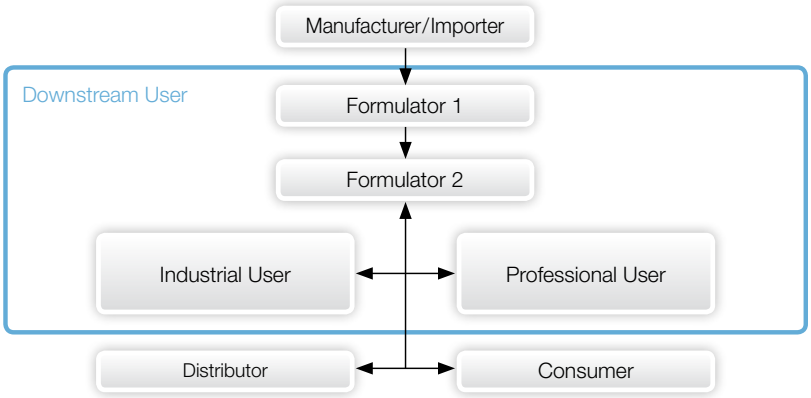
Dangerous substance
is the term used for substances which meet the criteria as being dangerous according to Directive 67/548/EEC (on the classification, packaging and labelling of dangerous substances, so-called "DSD"). Annex I therein gives the list of dangerous substances classified according to the categories specified in Article 2.2 (a–h). In addition, vPvB & PBT.

Derived No-Effect Level (DNEL)
is the level of exposure to a substance above which humans should not be exposed. According to Annex 1 REACH manufacturers and importers of chemical substances are required to calculate DNELs as part of their Chemical Safety Assessment (CSA) for any chemicals used in quantities of 10 tonnes or more per year. The DNEL is to be published in the manufacturer's Chemical Safety Report (CSR) and, for hazard communication, in an extended Safety Data Sheet.

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 mixture, 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 mixture, 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) REACH shall be regarded as a Downstream User" (Article 3.13 REACH)."

NOTE
If you manufacture articles only by assembling other articles (sub-components) without using substances or mixtures, you are not considered a downstream user (of chemicals) under REACH.



Picture 2.1.1 Downstream User Definition

Environmental Release Categories (ERCs)

represent certain activity categories linked to a set of conservative environmental parameters to be used in exposure prediction tools like ECETOC TRA. They represent "worst case" release conditions for each category for a first (TIER I) approach to exposure prediction, risk characterisation (e.g. by comparing to a substance's PNECs) and calculation of the maximum tonnages that can be safely used.

European Economic Area (EEA)

Iceland, Liechtenstein and Norway entered into the Agreement with the EU on the European Economic Area (EEA) in 1992 which, entered into force in 1994. Therefore, the EEA is composed of Iceland, Liechtenstein, Norway and the 27 EU Member States.

Exporter

means any natural or legal person established outside the Community who is responsible for exporting goods into the EEA. Even if the term "Exporter" is not used in the REACH legal text it is important in the AIG (see also the definition for Importers).

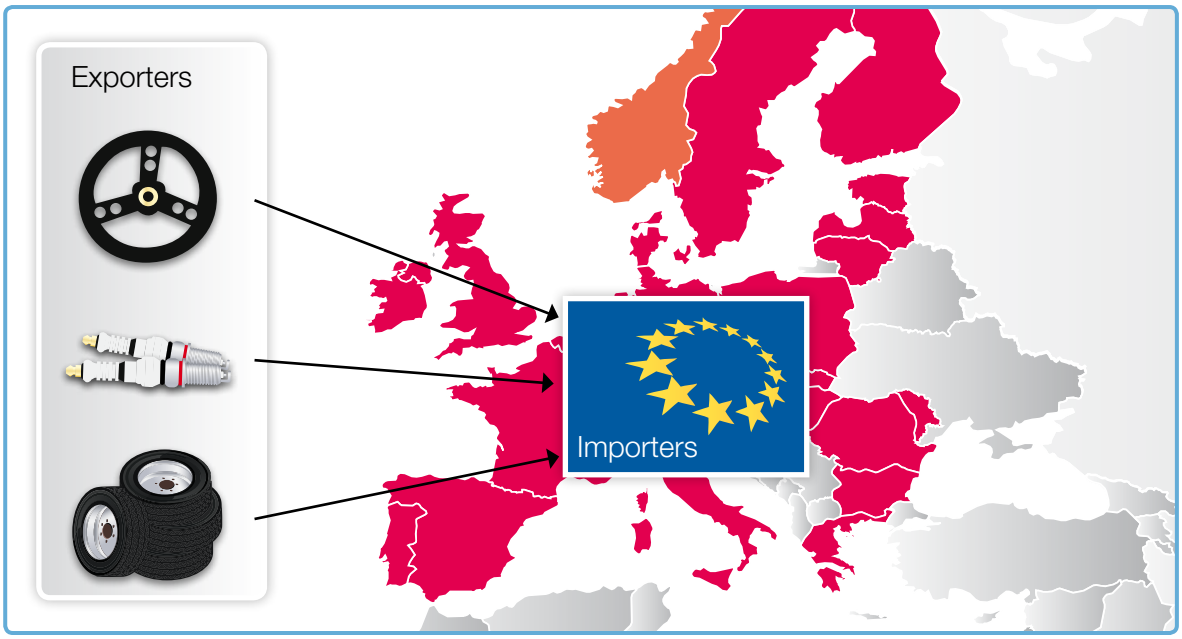
Exposure scenario

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 exposure to 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).

Generic Exposure Scenario (GES)

This term is not defined in the legal REACH text. In the context of the current ECHA Guidance, a Generic Exposure Scenario means an exposure scenario covering the typical conditions of use for a substance in the corresponding sectors of industry[5]. A Generic Exposure Scenario may be defined as a single Exposure Scenario that describes the relevant Operational Conditions (OC) and Risk Management Measures (RMM) for the typical use conditions relevant to operations for a Downstream User sector, in particular small and medium-sized enterprises. This means that the Generic Exposure Scenarios supporting the substance are oriented towards the areas of application of the substance. Thus Downstream Users only have to select the Generic Exposure Scenarios relevant to the sector for which it is intended and for which the use is supported. (Guidance on information requirements and chemical safety assessment)

[5] Beside Exposure Scenarios for substances, the ECHA guidance document also describes Exposure Scenarios for mixtures. However, according to the legal REACH text, there are no exposure scenarios for mixtures. The automotive industry therefore decided not to put "mixtures" into this definition. For further information and explanation please visit AIG Chapter 5.5.



Picture 2.1.2 Importers Definition
Iceland, Liechtenstein and Norway (which are members of the European Economic Area but not European Union Member) had implemented REACH so that substances supplied from these countries are not considered imports.
Please consider Q51 of AIG Annex D for further information.

Guidance document

(formerly named RIP – REACH Implementation Project) provides guidance on the REACH processes and methods, to be used by industry and authorities to facilitate the implementation of REACH by describing good practice on how to fulfil the obligations. These documents have been developed with the participation of stakeholders from Industry, Member States and NGOs. Please note that the Guidance Documents are not legally binding. http://guidance.echa.europa.eu/guidance_en.htm

Hazardous substance

is the term used for substances which meet the criteria as being hazardous according to Regulation (EC) No 1272/2008 (on classification, labelling and packaging of substances and mixtures, so-called "CLP"). Annex I, parts 2 to 5, therein describe the criteria making a substance hazardous.

Identified use

means "a use of a substance on its own or in a mixture, 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 OR has the same status under REACH as an Importer.

Intended to be released

means that the release of the substance is deliberately planned and has a specific function for the article which is not the main function of the object, but an additional attribute. If a release is incidental, this is not an intended release. In cases where an intended release of substances is the main function of an object, it is to be regarded as a container with substances/mixtures inside but not an article.
Basic criterion: Does the Article still work without the release? If yes, the release is not intended.
A list of automotive industry specific examples of intended release is given in Chapter 5.7.
A release is not considered to be an intended release in the following cases:

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

Intermediate

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

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

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

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

Legal entity

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

Manufacturer

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

Example: ethanol manufacturer, copper manufacturer

Manufacturing

means "production or extraction of substances in the natural state" (Article 3.8. REACH).

Mixture

means "a mixture or solution composed of two or more substances". This term was changed from "preparation" (Article 3.2 REACH) due to implementation of CLP Regulation into REACH (CLP Article 2.8, (EC)1272/2008).

Example: Paint, lubricant, adhesive, windshield-washer fluid, engine oil, a metallic alloy (e. g. steel, brass; Article 3.41 REACH and Guidance for Articles)

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).

Nanomaterials

Although there is currently no definition of nanomaterials included in the present REACH Regulation (EC) 1907/2006, REACH applies to man-made "manufactured nanomaterials". Document CA-59-2008 rev.1 of the Commission clearly stipulates: "There are no provisions in REACH referring specifically to nanomaterials. However, REACH deals with substances, in whatever size, shape or physical state. Substances at the nanoscale are therefore covered by REACH and its provisions apply. It thus follows that under REACH manufacturers, importers and DU's have to ensure that their nanomaterials do not adversely affect human health or the environment". Document CA-59-2008 rev.1, that has been endorsed by the Competent Authorities with a view to its publication on the Commission's website and that has been published on http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf contains useful information for companies in the automotive chain that today already have to deal with nanomaterials under REACH.

Non phase-in substance

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

Notified substance

means "a substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC" (Article 3.21 REACH). Notified substances have an ELINCS number.

Only Representative

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

Persistant Organic Pollutant (POP)

is a chemical substance that persists in the environment, bioaccumulates through the food chain and poses a risk of causing adverse effects to human health and the environment falling under the UNECE and Stockholm Convention on POPs.

POP and PBT substances are carbon-based chemicals that resist degradation in the environment and accumulate in the tissues of living organisms, where they can produce undesirable effects on human health or the environment at certain exposure levels. POPs, specifically, are PBT substances likely to be transported and deposited long distances from their original source".

Whereas REACH deals with vPvB and PBT, officially recognised POPs are regulated in the EU by Regulation (EC) No 850/2004 of 29 April 2004 and its later amendments (such as Regulation (EU) No 757/2010 and (EU) No 756/2010 of 24 August 2010). Because REACH cannot weaken international Conventions and other existing EU legislation, REACH Authorisation cannot be granted for a substance that has been officially classified as a POP under Regulation (EC) No 850/2004 or one of its later amendments.

Reference is made to POPs in Article 61.6 of REACH where it states "If a use of a substance is subsequently prohibited or otherwise restricted in Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants, the Commission shall withdraw the authorisation for that use". If an exemption is granted under the Convention that will be included in Regulation 850/2004.

Per Year

means per calendar year.

Phase-in substance

means "a substance which meets at least one of the following criteria"

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

NOTE

EINECS
(European Inventory of Existing Commercial Chemical Substances)
is a list of substances, excluding polymers, which had been commercially available in the EU from 1 January 1971 to 18 September 1981. Their identifying number was called "EINECS number" and is now called "EC-number". There are currently 100,204 entries.

ELINCS
(European List of Notified Chemical Substances)
is a list of substances having become commercially available after 18 September 1981. They were already notified under Article 8(1) of Directive 67/548/EEC amended by Directive 79/831/EEC and their identifying number is called "ELINCS number". Such substances have an official notification number (ELINCS) mainly starting with digit "4". These ELINCS substances are considered registered

under REACH. The final edition of ELINCS (2009) is comprehensive and contains 8433 notifications, representing 5292 substances in total.
Both lists are accessible via:
http://ecb.jrc.ec.europa.eu/esis

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).

Producer of an article

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

Polymer

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

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

NOTE
So-called "no-longer polymers" (NLP) do also exist. Polymers were not reportable in the past and therefore not included in EINECS. In the 7th amendment (92/32/EEC) to Directive 67/548/EEC the term polymer was further defined with the consequence that some substances ceased being considered as polymers (i.e. no-longer polymers). The NLP list had been created showing substances having been on the EU market between 18 September 1981 and 31 October 1993 (fulfilling the requirement that they were considered to be polymers under the reporting rules for EINECS but are no longer considered to be polymers as from the 92/32/EEC). The no-longer polymer list contains only substances not included in EINECS. The list is not exhaustive. Please note in this connection that the notification to the NLP list was on a voluntary basis and since there were not many registrants making use of this there are many tensides that do neither have an EC nor an NLP number. Therefore dummy EC numbers were allocated to them starting with "600".
http://ecb.jrc.ec.europa.eu/esis

Predicted No Effect Concentration (PNEC)

means the concentration of a substance below which adverse effects in the environmental compartment of concern are not expected to occur.

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 mixtures or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance" (Article 3.22 REACH).

Recipient of an article

means "an industrial or professional user, or a distributor, being supplied with an article but does not include consumers" (Article 3.35 REACH).

NOTE
In the automotive industry, customers can be consumers or recipients of an article. The customer is considered a consumer, if he or she buys a regular vehicle which will not be used for any professional business. On the other hand, the customer is regarded as a recipient of an article if he or she buys a commercial vehicle like a taxi or truck. When spare parts are sold , customers can be also of both types, consumers or professional users. When selling spare parts for commercial vehicles the customer is generally regarded as recipient of an article and not a consumer.

[6] Notification under former Directive 67/548/EEC (Directive on Classification, Labelling & Packaging of dangerous substances). There is no link to the REACH or CLP notification.

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).

Re-import
means where a substance is first manufactured in the EEA, then exported (e.g. to be formulated into a mixture) and then brought back into the EEA again (e.g. to be marketed or for further processing). Such re-imports are exempted from registration under the following conditions:

- the substance must have been registered before it was exported from the EEA
- the substance already registered and exported must be the same, ie must have the same chemical identity and properties as the substance being re-imported on its own or in mixture (the re-importer has to be able to prove that the substance is still the same)
- Re-importer must have been provided with information on the exported substance (Article 2.7c REACH, Guidance on Registration, item 1.6.4.6)

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).

Specific Environmental Release Categories (SpERC)
are required for obtaining more realistic 1 tier emission estimates for substance uses in the chemical industry and its downstream users than those provided by ERCs.

Site
means "a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared"
(Article 3.16 REACH).

Substance
means "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition" (Article 3.1 REACH).
Example: methane, hydrocarbons, sulphuric acid, ethanol, calcium carbonate, silicon dioxide, elemental metals (e.g. copper, aluminium)
(Detailed information on identification and naming of Substances in REACH can be found in the "Guidance for identification and naming of substances under REACH").

Substances of very high concern (SVHC)
The following substances are considered of very high concern according to Article 57 REACH:

a) Substances meeting the criteria for classification as carcinogenic, mutagenic, or toxic for reproduction according to Directive 67/548/EEC ("CMR-substances") category 1a or 1b.
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 EEA market and the use of the substance is no longer allowed unless an authorisation has been granted for the specific use. The substance-specific sunset date is specified in Annex XIV REACH.

Supplier of a substance or a mixture
means "any manufacturer, importer, Downstream User or distributor placing on the market a substance, on its own or in a mixture, or a mixture"
(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 & Initialisms

ACEA
European Automobile Manufacturers Association

AIAG
Automotive Industry Action Group

AIG
Automotive Industry Guideline on REACH

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

CEFIC
European Chemical Industry Council (Conseil Européen de l'Industrie Chimique)

CLEPA
European Association of Automotive Suppliers

CLP
Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

CL-Substance
Substances added to the Candidate List for Authorisation or Annex XIV REACH

CMR
Carcinogenic, Mutagenic, Toxic for Reproduction

CSR
Chemical Safety Report

DNEL
Derived No Effect Level

DU
Downstream User

ECHA
European Chemical Agency

EDAS
Electronic data exchange of safety data sheets. It is an interface for structured data exchange on XML format basis.

EEA
European Economic Area

EINECS
European Inventory of Existing Commercial Chemical Substances

ELINCS
European List of Notified Chemical Substances

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

EPER
European Pollutant Emission Register
www.eper.ec.europa.eu/eper

ERC
Environmental Release Categories

ES
Exposure Scenario

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

GES
Generic Exposure Scenario

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

IMDS
International Material Data System
See http://www.mdsystem.com

IUCLID
International Uniform Chemical Information Database

JAMA
Japan Automobile Manufacturers Association, Inc.

KAMA
Korea Automobile Manufacturers Association

MACSI
Material Composition Information System
(PSA system for material declaration)

NGO
Non-Governmental Organisation

OC
Operational Conditions

OEM
Original Equipment Manufacturer
(Here in most cases the vehicle manufacturer)

OSOR
One Substance, One Registration

OR
Only Representative

ORGALIME
The European Engineering Industries Association

PBT
Persistent, Bio-accumulative and Toxic

PNEC
Predicted No Effect Concentration

PPORD
Product and Process Oriented Research and Development

PRTR
Pollution Release and Transfer Register

REACH
Registration, Evaluation, Authorisation (and Restriction) of Chemicals

RMM
Risk Management Measures

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

SDS
Safety Data Sheet – eSDS: extended Safety Data Sheet

SIEF
Substance Information Exchange Forum

SMMT
Society of Motor Manufacturers and Traders, UK

SpERC
Specific Environmental Release Categories

SVHC
Substance of Very High Concern

TARIC
Tarif intégré des Communautés européennes (Integrated Community Taxation & Customs Tariff) is designed to show the various rules applying to specific products when imported into the EU.

TGD
Technical Guidance Document
(Resulting documents from a RIP)

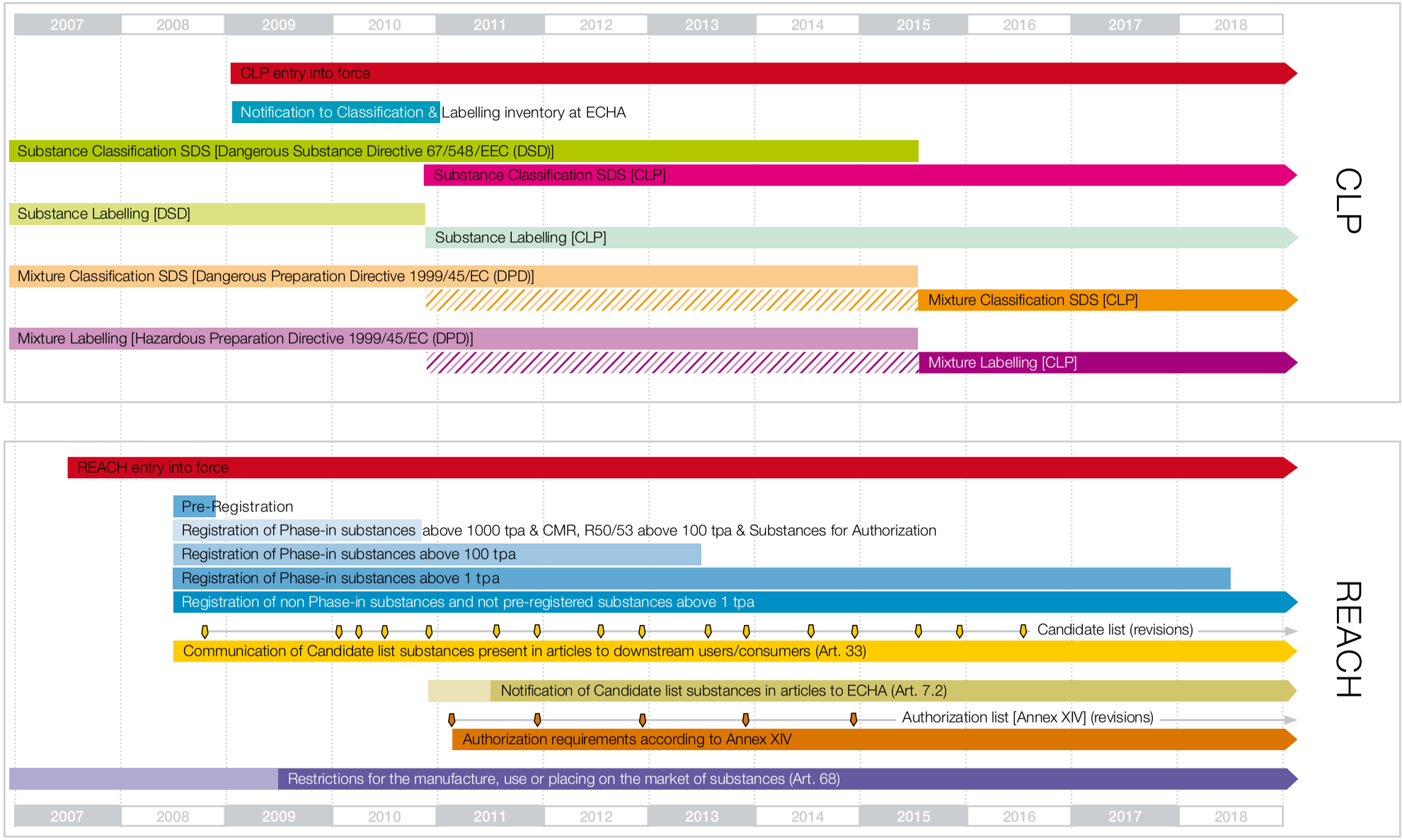
TPA
Tonnes per annum

VDA
German Automotive Industry Association

vPvB
very Persistent and very Bioaccumulative

CHAPTER 3: IMPORTANT DATES AND DEADLINES TO REMEMBER

2011	
By 1 June 2011	• Notification of substances in articles (Article 7.2 REACH) which were included into the CL before 1 December 2010. • ECHA will accept notification before 1 June 2011. Warning: Information requirements to downstream users (Article 33 REACH) apply as of inclusion on the CL
As from 1 June 2011	• Notification of substances in articles 6 months after they have been included in the CL (Article 7.8 REACH).
2012	
Until 31 May 2012	• DU to make their use(s) known (in writing) to the substance supplier in order to make it an identified use (Article 37.3 REACH)
As of 1 December 2012	• The use of the new CLP safety data sheet format is obligatory for substances.
2013	
Until 31 May 2013	• Registration of substances on their own, in mixtures or intended to be released from articles in quantities of 100-1000 tpa per manufacturer/importer (Article 23.2 REACH). • Safety data sheets for registered substances shall be extended with exposure scenarios for all identified uses (Article 14 REACH).
2015	
As 1 June 2015	• New CLP labelling and safety data sheet format is obligatory for mixtures. • Directives 67/548/EWG and 1999/45/EG are withdrawn.
2017	
Until 31 May 2017	• DU to make their use(s) known in writing to the substance supplier in order to make it an identified use (Article 37.3 REACH)
As of 1 June 2017	• End of transition period for mixtures in warehouses with old CLP labelling.
2018	
Until 31 May 2018	• Registration of substances on their own, in mixtures or intended to be released from articles in quantities of 1-100 tpa per manufacturer/importer (Article 23.3 REACH). • Safety data sheets for registered substances shall be extended with exposure scenarios for all identified uses (Article 14 REACH).


2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
CLP entry into force
Notification to Classification & Labelling inventory at ECHA
Substance Classification SDS [Dangerous Substance Directive 67/548/EEC (DSD)]
Substance Classification SDS [CLP]
Substance Labelling [DSD]
Substance Labelling [CLP]
Mixture Classification SDS [Dangerous Preparation Directive 1999/45/EC (DPD)]
Mixture Classification SDS [CLP]
Mixture Labelling [Hazardous Preparation Directive 1999/45/EC (DPD)]
Mixture Labelling [CLP]
CLP
REACH entry into force
Pre-Registration
Registration of Phase-in substances above 1000 tpa & CMR, R50/53 above 100 tpa & Substances for Authorization
Registration of Phase-in substances above 100 tpa
Registration of Phase-in substances above 1 tpa
Registration of non Phase-in substances and not pre-registered substances above 1 tpa
Candidate list (revisions)
Communication of Candidate list substances present in articles to downstream users/consumers (Art. 33)
Notification of Candidate list substances in articles to ECHA (Art. 7.2)
Authorization list [Annex XIV] (revisions)
Authorization requirements according to Annex XIV
Restrictions for the manufacture, use or placing on the market of substances (Art. 68)
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
REACH

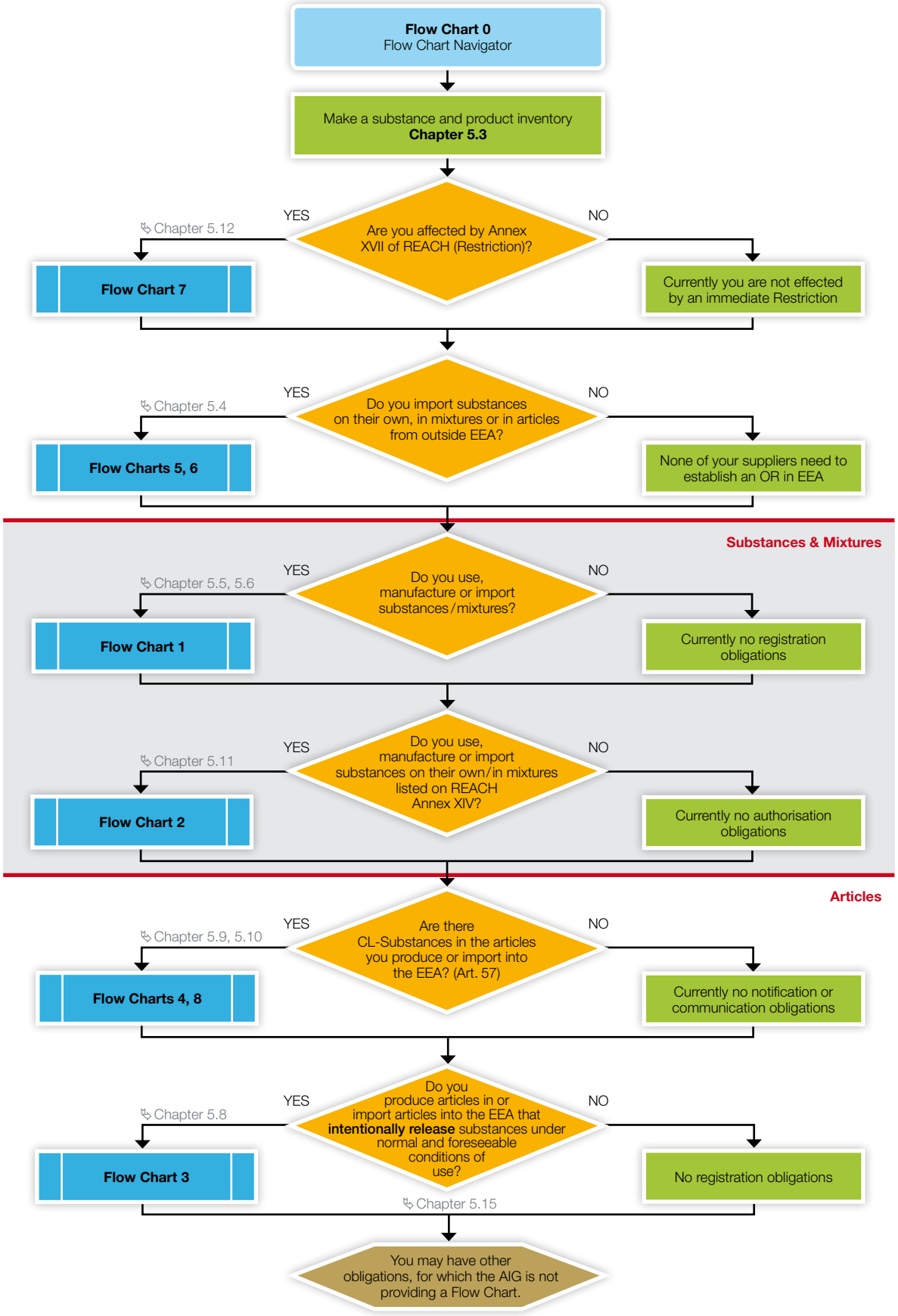

Destination:
REACH Compliance

CHAPTER 4: REACH COMPLIANCE – A STEP-BY-STEP PROCESS

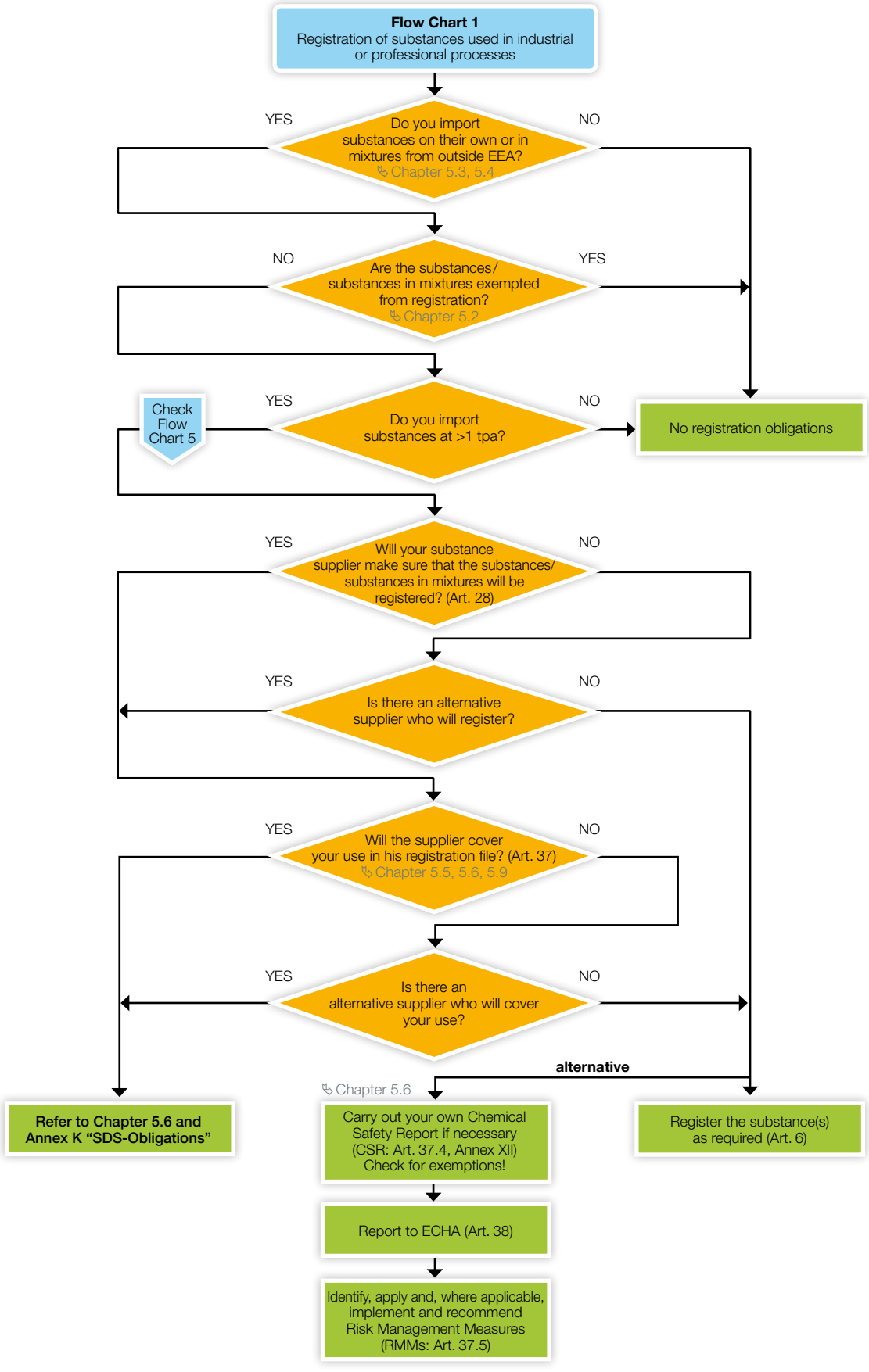
The following flow charts have been constructed to help companies determine what their obligations are under REACH. Flow charts 1 to 8 should be viewed as complimenting each other. Where such guidelines exist, references to them have been integrated in the flow charts and the AIG 5 step compliance schedule (Chapter 6).

For the following REACH tasks, a flowchart has been developed. To directly jump into a specific subject, you can click on one of them in the list below:

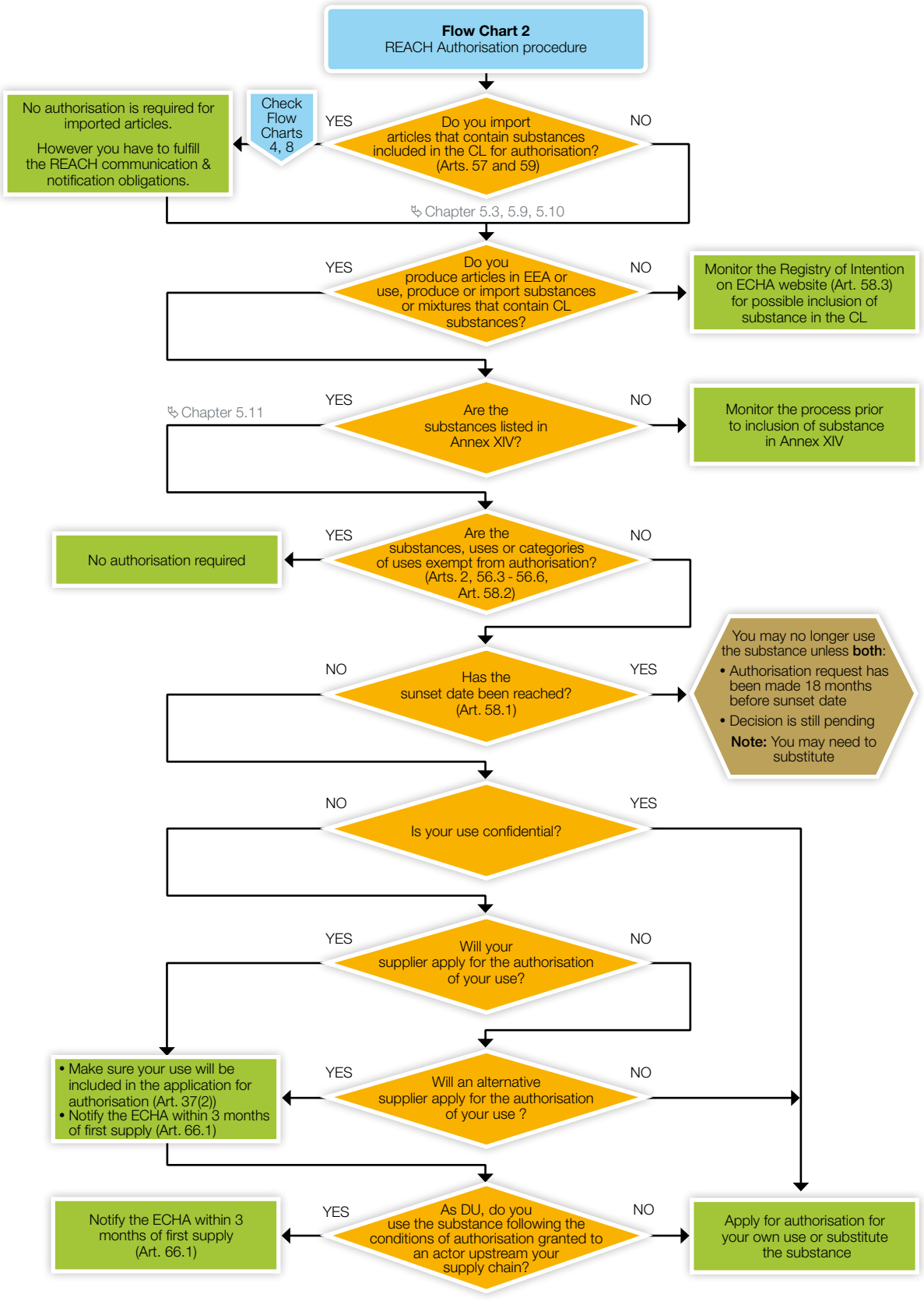
4.0 Flow Chart Navigator



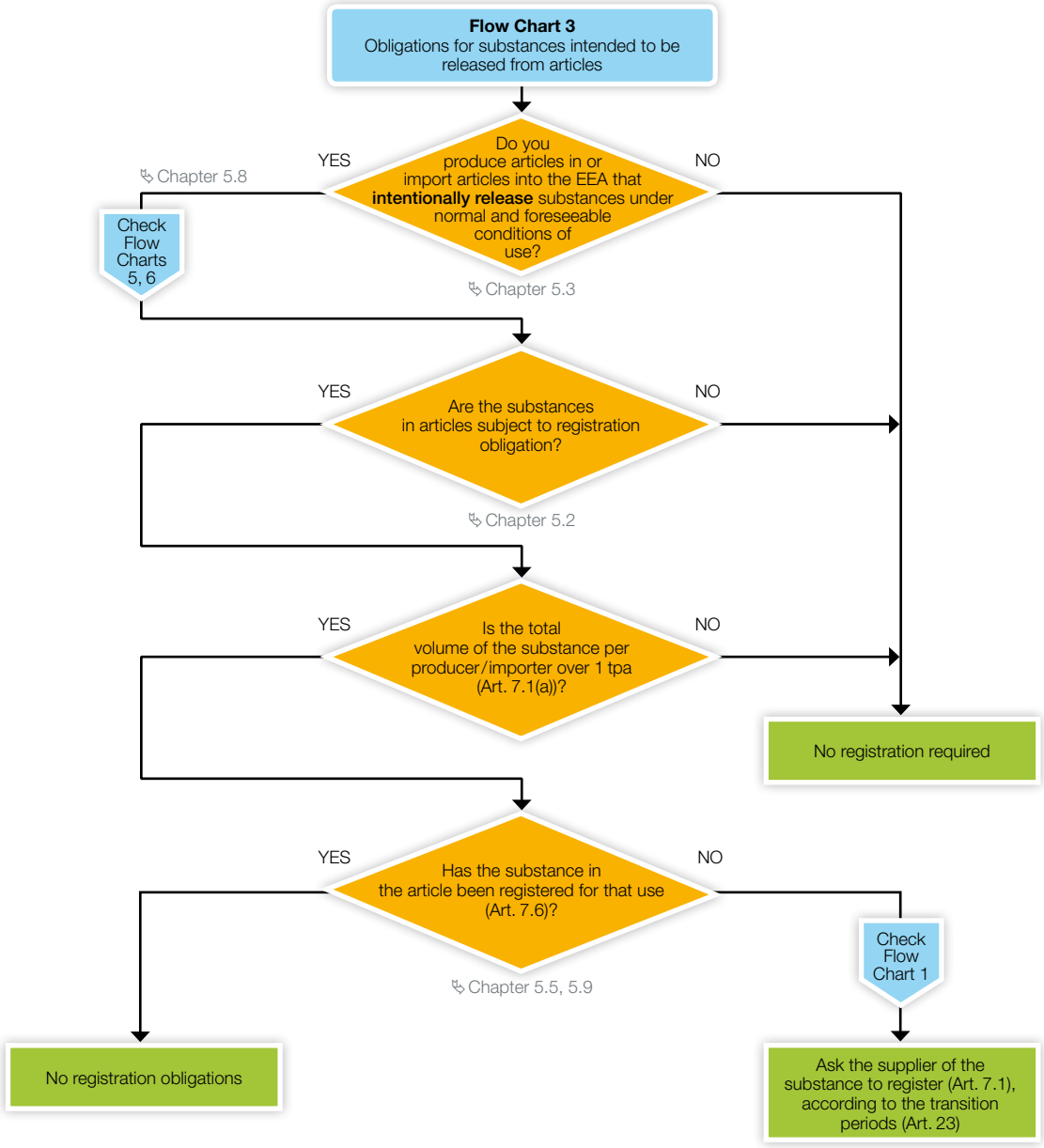
4.1 Registration of Substances/Substances in Mixtures used in Industrial (including Engineering) Processes



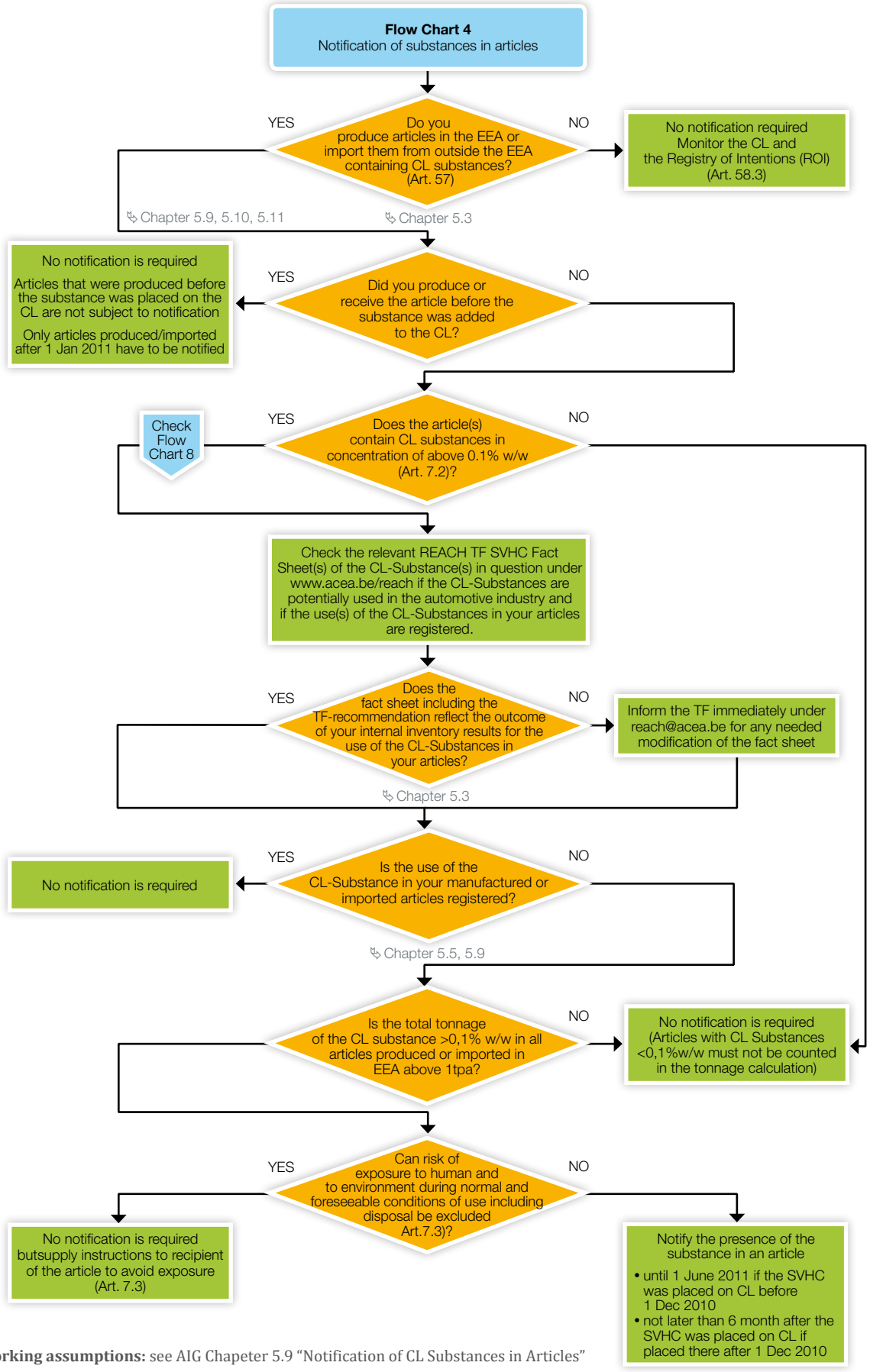
4.2 REACH Authorisation Procedures



4.3 Registration of Substances intended to be released from Articles

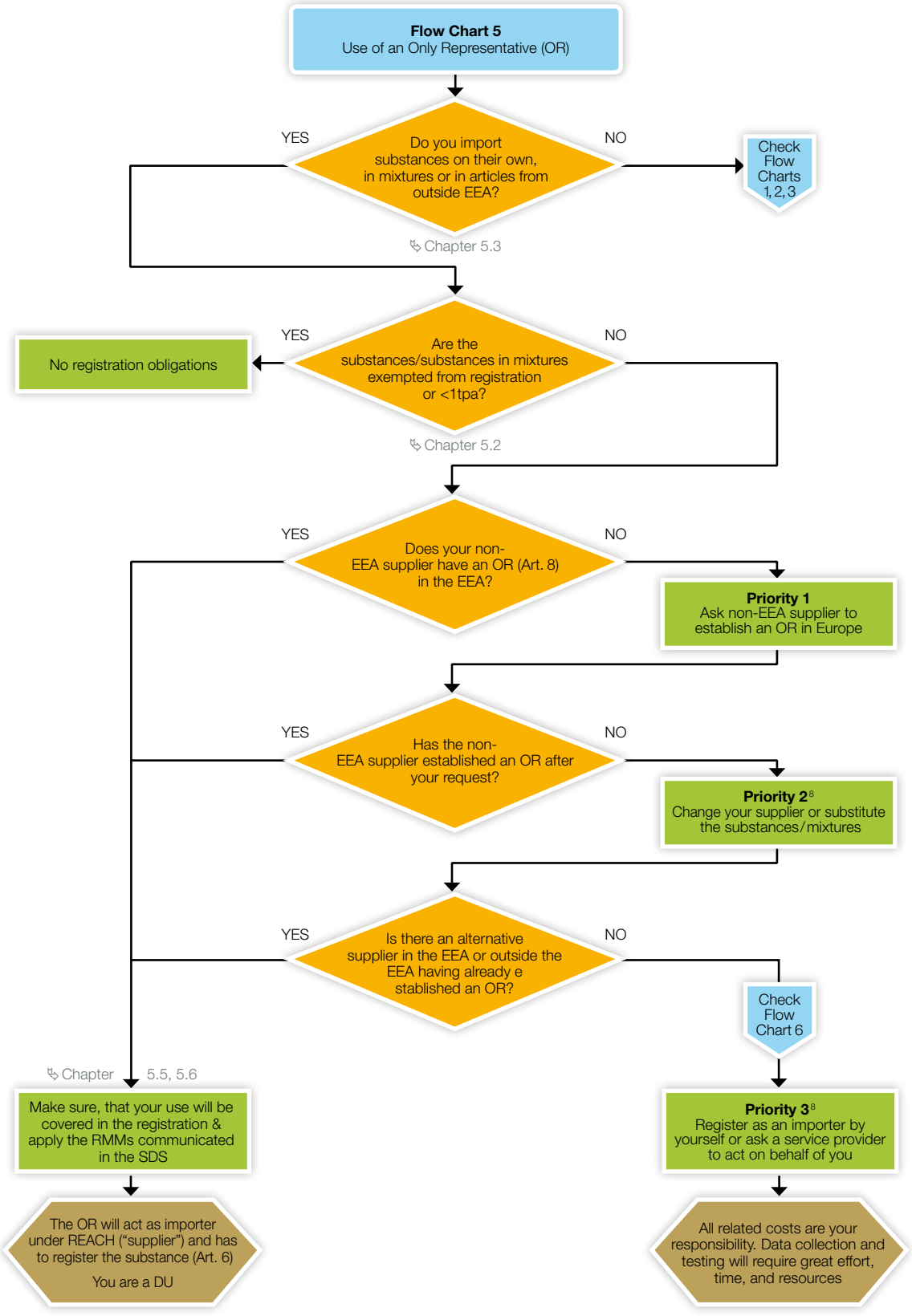


4.4 REACH Notification of Substances in Articles



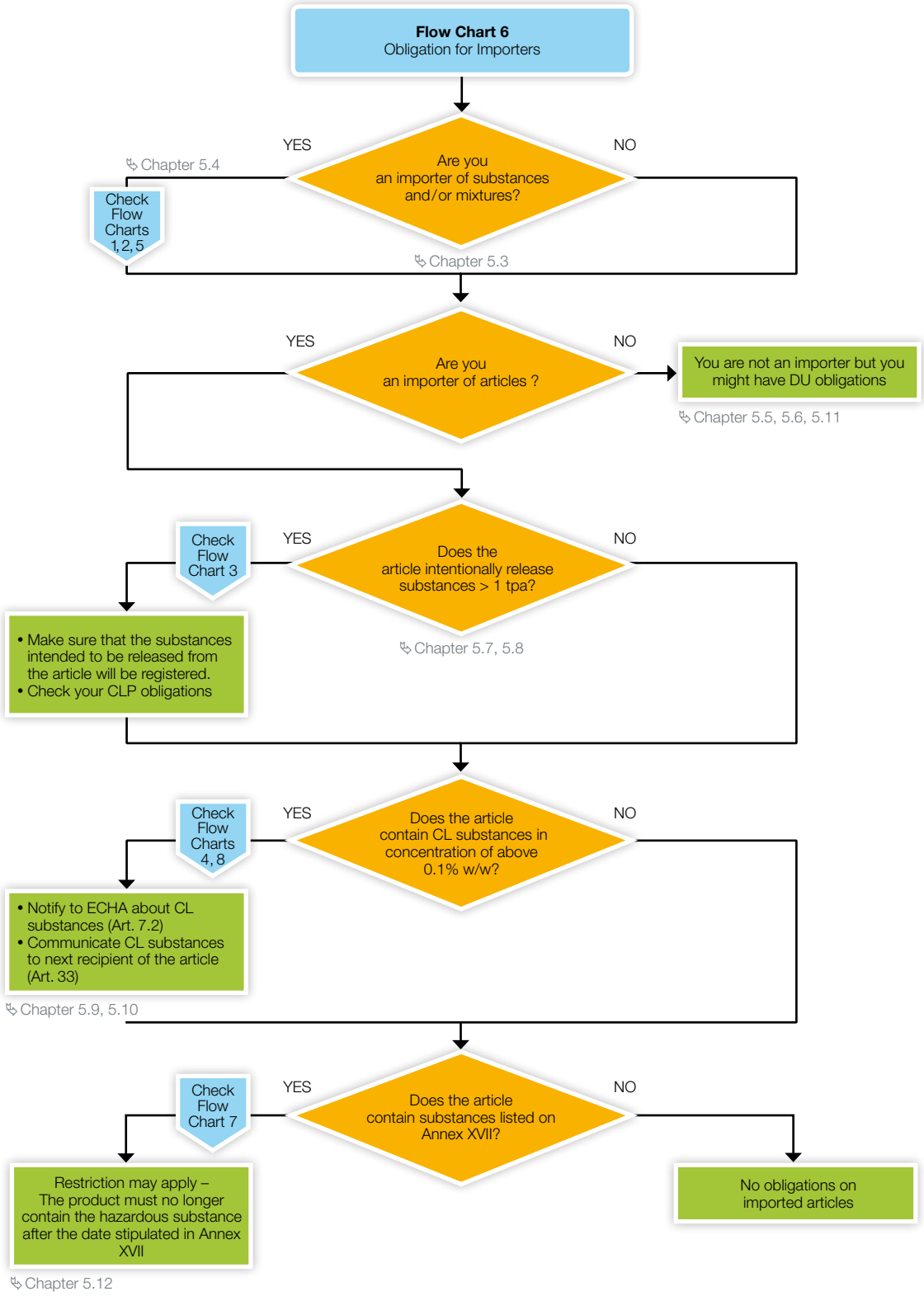
Working assumptions: see AIG Chapeter 5.9 "Notification of CL Substances in Articles"

4.5 Use of the Only Representative

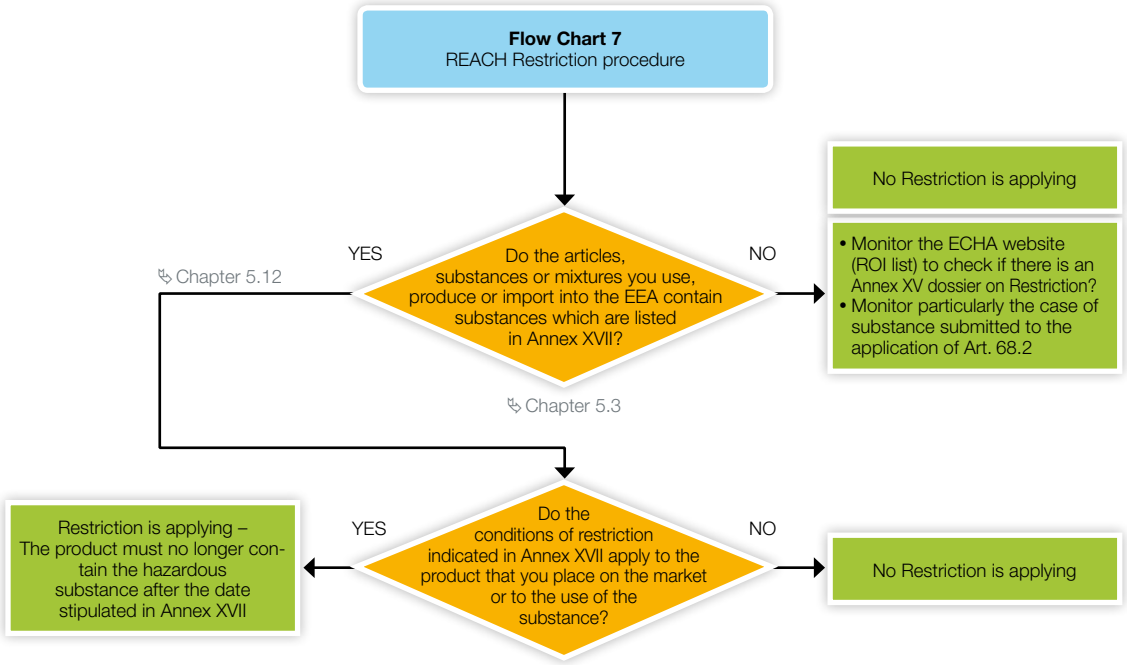


[8] The order especially of Priority 2 & 3 is not fix but depends on the company specific policies and strategies.

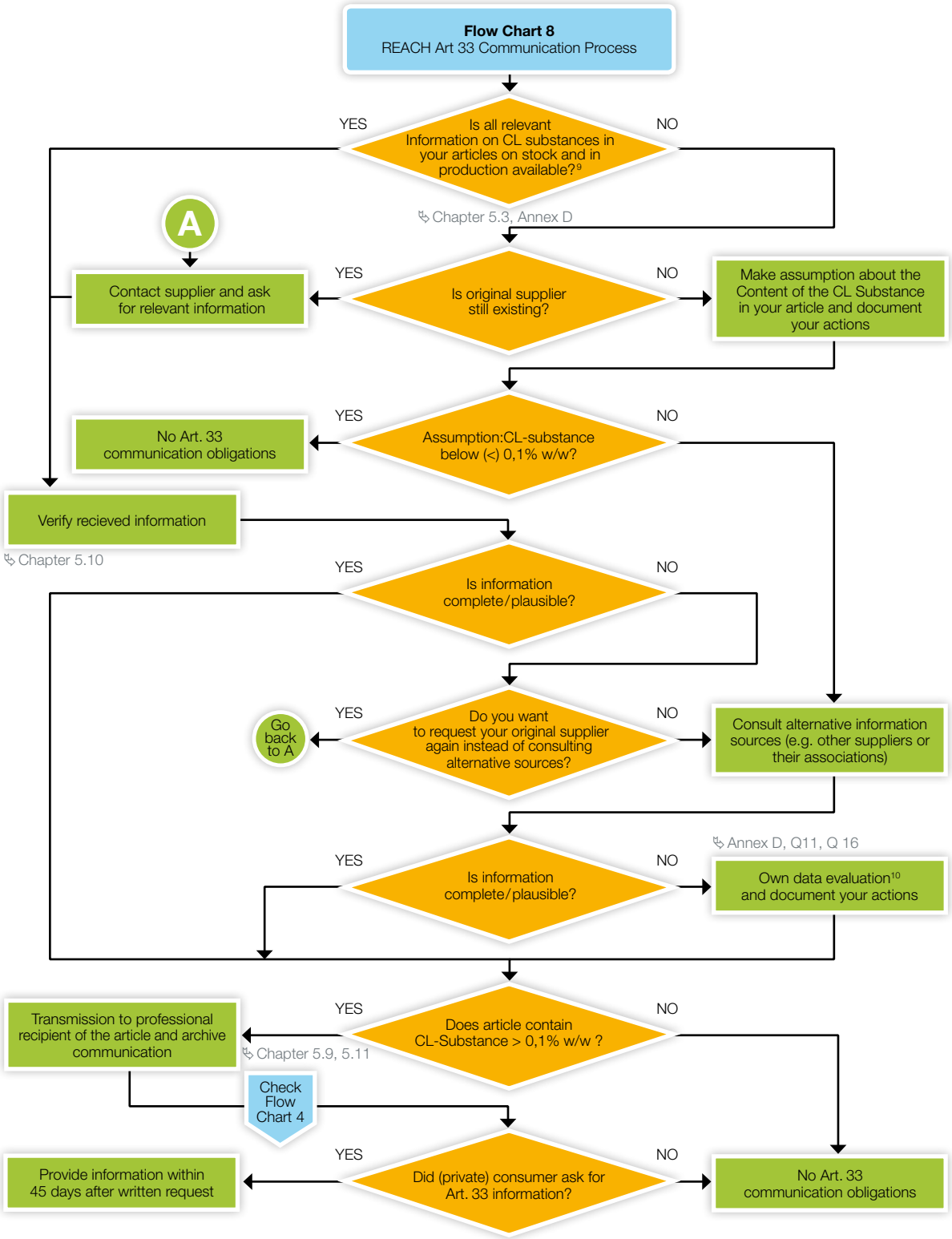
4.6 Obligations for Importers



4.7 REACH Restriction



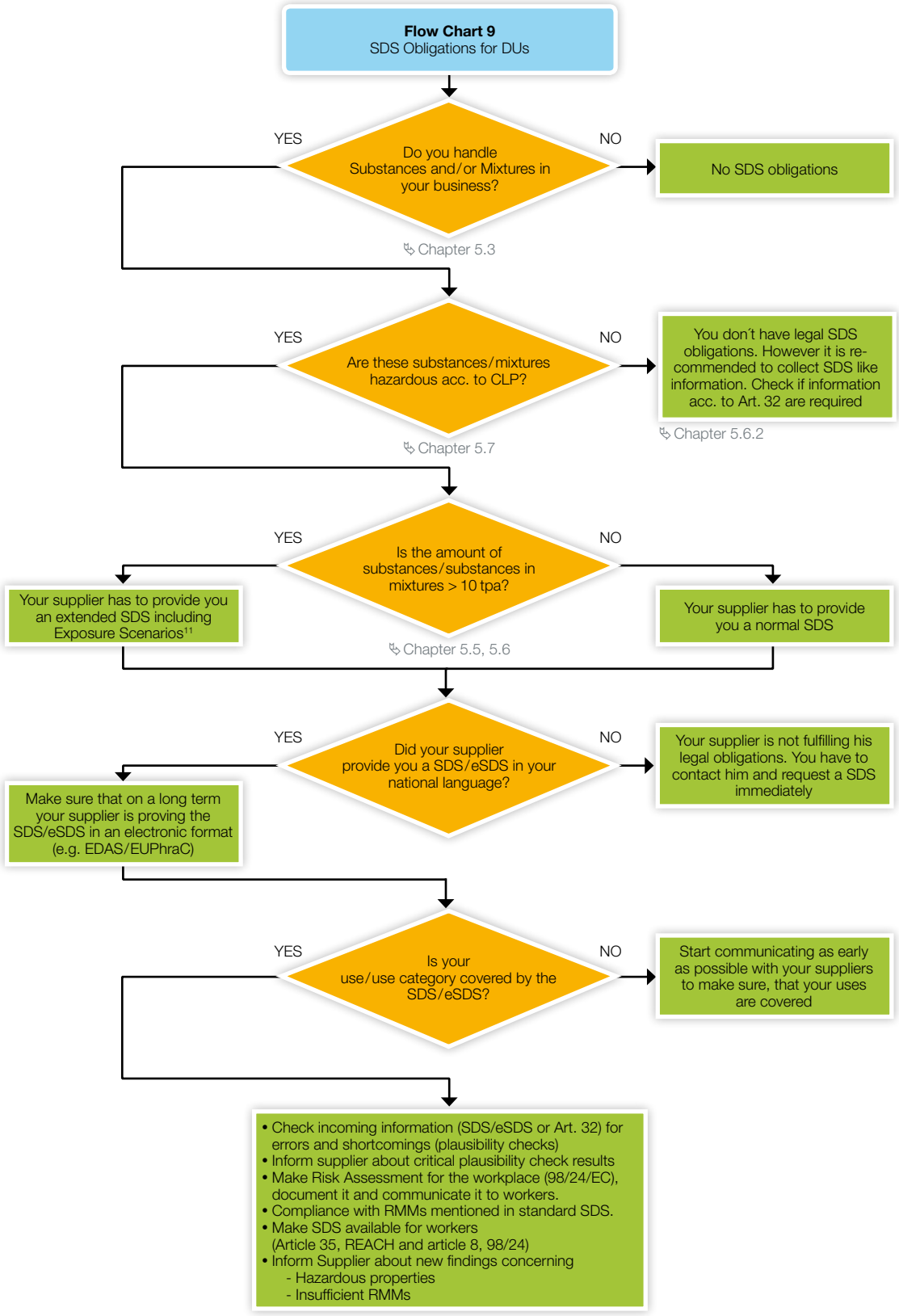
4.8 REACH Article 33 Communication



9 ● Information on CL-substance > 0.1% w/w should be delivered automatically by your supplier with the article (e.g. IMDS Material Data Sheet)
● For in house manufactured parts the same information has to be available

10 ● Risk based survey analysis based on in-house expert knowledge
● Comparison with similar product groups (data bases)
● Ultima ratio: chemical analysis

4.9 SDS Obligations for DUs



[11] Please note that exposure scenario only exist for substances not for mixtures, but you may receive a consolidated safety assessment for the mixtures.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CHAPTER 5: AUTOMOTIVE SECTOR ADVICE
5.1 Roles in the Supply Chain

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

- Downstream user
- Exporter
- Manufacturer
- Importer
- Producer of articles
- Recipient of articles
- Supplier of articles

For further explanation, please check Chapter 2.1 "Main Definitions"

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

Manufacture substances	In this case companies bear the obligations of a manufacturer (e.g. pre-registration/registration needs to be done by this company)	Partly covered by Chapter 5.4/Flow Chart 1
Formulate (Manufacture) Mixtures	In this case companies bear the obligations of DUs	See Chapter 5.5
Use substances/mixtures supplied by an EEA supplier	In this case companies bear the obligations of DUs	See Chapter 5.5
Import substances/mixtures from outside the EEA	In this case, companies bear the obligations of importers, if there is no EEA "ORs" of the non EEA chemicals supplier appointed	See Chapter 5.4
Produce articles	In this case, companies bear the obligations of article producers	See Chapters 5.7, 5.8, 5.9
Import articles from outside the EEA	In this case, and if an intended release occurs companies bear the obligations of substance importers, if there is no EEA "ORs" of the non EEA supplier appointed. If no intentional release, the importer still bears the obligations of DUs	See Chapters 5.7, 5.8, 5.9

Table 4.1.1 Roles under REACH

It is important to note for downstream users that substances that may result from a chemical reaction acting upon the end use of other substances, mixtures or articles and which are not themselves manufactured, imported or placed on the market, are exempt from registration (Annex V n°4 REACH). Further exemptions to register substances resulting from a chemical reaction which may be of relevance to downstream users, are listed in Annex V REACH.

In cases where the article producer/importer subcontracts a certain treatment of the article to a second company (e.g. for surface treatment), the 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.

5.2 REACH Scope and Exemptions

The REACH Regulation lays down provisions on substances and mixtures within the meaning of Article 3 REACH. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles and to the placing on the market of mixtures.

Scope

However, REACH does not apply to:

- Radioactive substances Directive 96/29/Euratom
- Substances on their own, in mixtures 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 mixtures by rail, road, inland waterway, sea or air.
- Certain substances on their own, in mixtures or in articles exempted by Member States in the interests of defence.
- Waste, as defined in **Directive 2008/12/EC** is not a substance, mixture or article within the meaning of Article 3 REACH.

Exemptions

REACH applies without prejudice to:

- Community workplace legislation including Directives 89/391/EEC, 98/24/EC and 2004/37/EC
- Community environment legislation including Directives 96/61/EC and 2000/60/EC

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

Tonnage:
Substances on their own, in mixtures or in articles (where there is an intended release under normal or reasonably foreseeable conditions of use) manufactured or imported below 1 tonne per manufacturer/importer per year are exempted from registration (Title II REACH).

N.B. The tonnage limit does not apply to authorisation, restriction, classification and labelling or safety data sheet requirements.

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 of REACH as amended by Regulation (EC) No 987/2008 Annex I and II.
- Re-imported substances on their own or in mixtures, **already registered**.
- Substances, on their own, in mixtures or in articles, already registered and resulting from a waste recovery process (consult the "Guidance on waste and recovered substances" published by ECHA).

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 (EEC) No 3600/92, Regulation (EC) No 703/2001, (Regulation (EC) No 1490/2002, Decision 2003/565/EC and biocidal products only Directive 98/8/EC and Regulation (EC) No 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 a manufacturer or importer or producer of articles are exempted from Articles 5, 6, 7, 17, 18 and 21 of Title II REACH (registration) for a period of five years. ECHA may prolong the five years to ten years for certain substances and uses. The manufacturer, importer or producer of articles shall in this case notify certain information to ECHA (Article 9 REACH).

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

Polymers:
Polymers are exempted from registration and evaluation but may still be subject to authorisation and restrictions.
However, manufacturers or importers of a polymer must submit a registration to ECHA for the monomer substances or any other substances that have not already been registered by an actor up the supply chain under certain conditions (Article 6.3 REACH).

e.g. Vinyl chloride monomer (VCM) must be registered for producing PVC. The polymer PVC is exempted from registration but may be restricted for specific uses depending on the residue monomer content.

NOTE
The scope of REACH will be reviewed in 2012

For exemptions from authorisation, please refer to Chapter 5.10

For more details, please refer to
Articles 1, 2, 6, 9, 138.4, 138.6 REACH

5.3 Substance Inventory

A key step for downstream users to comply with the REACH and CLP Regulation is to have a full understanding of what substances/mixtures the company uses or imports either on their own or in an article. Establishing a substance inventory will allow the company to determine:

- **Which substances/mixtures the company purchases from a European supplier and for what purpose they are used?**
  You may contact the chemicals supplier to ensure that the substance/mixture will continue to be supplied and that the company's use will be covered in the substance registration dossier, in the Chemical Safety Report and in an exposure scenario (see Chapter 5.5)."
  An efficient way of data collection is to request suppliers to deliver SDS/eSDS (or an SDS-like document) for all substances and mixtures, independent of whether they are hazardous or not.

- **Which substances/mixtures the company imports from outside Europe?**
  Unless an "OR of a non-Community manufacturer, 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 registration of those substance/substances in mixtures. These cases may not be obvious: for example, if you import a lubricant from a non-EEA 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/mixture (see Chapter 5.4). "

- **For which substances/mixtures the company purchases, SDS/eSDS are available/not available?**
  For hazardous substances/mixtures that are fulfilling certain criteria, the supplier has to provide SDS/eSDS. If you have received such SDS/eSDS, you may have to fulfil several obligations to be REACH compliant. This may have an impact on both your production process and your products. (see Chapter 5.5)

- **Which substances are intended to be released from an article that the company produces in the EEA?**
  If you produce articles in the EEA, intentionally releasing substances, without this substance having been pre-registered/registered by an actor up the supply chain, you will be obliged to register the substances released under certain conditions (see Chapter 5.7).

- **Which substances are intended to be released from an article that the company imports?**
  If no OR of a non-Community manufacturer has been appointed, you are obliged to do late pre-registration or registration of the substances intentionally released from the article that you import.

- **Which imported substances/mixtures are dangerous according to**
  - Article 57 REACH (SVHCs)
  - Article 67 REACH (Restriction)
  - CLP Regulation
  - Regulation (EC) No 552/2009 amending REACH in regard to Annex XVII

  Identify substances in the substance inventory which are classified as hazardous under CLP and which are present in a mixture above the concentration limits specified in Annex I of CLP or as specified in Annex XVII of REACH.

- **Which articles contain Dangerous Substances?**
  You need to know this information to be able to fulfil your REACH obligations on Notification (Article 7.2 REACH: See Chapter 5.9), Communication (Article 33 REACH: See Chapter 5.10), Authorisation (Article 56 REACH, Annex XIV: See Chapter 5.11) and Restriction (Article 67 REACH, Annex XVII: See Chapter 5.12)

- **Depending on your role under REACH, you need to collect the following key information in order to determine your REACH obligations (if any):**
  - Substance/mixture name (supplier's proprietary name, if any)
  - Chemical name
  - CAS number (if any)
  - EC number (if any)
  - REACH registration number if available (starting with "01" for registered substances or "05" for pre-registered substances)
  - INDEX number or CLP Reference number for dangerous substances (also < 1 tpa) according to Article 18 CLP (product identifier)

- Amount of substances imported into or used in the EEA per year (kg)
- Supplier name and address (responsible individual for each supplier)
- Is it imported by you?
- Is the substance identified as of very high concern? If yes, is it already on the CL or does it already have an authorisation number?
- Is the substance critical for your business?

- **Possible further information you may add to your substance inventory is:**
  - Have you contacted the supplier about registration for your use?
  - Is there a confidentiality issue regarding specific uses?
  - Is the substance already pre-registered/registered?
  - Will the substance/mixture continue to be available for purchase?
  - Is the substance on the CL, on Annex XIV (Authorisation List) or on Annex XVII (Restriction List)?
  - Can the substance be substituted (if it is likely to be withdrawn in future)?
  - If you need to produce a data package for registration and/or notification to the CLP Inventory, what data is necessary?
  - Who else supplies the substance or mixture?

Additional considerations:
Please note that the level of detail 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:

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

Table 4.3.1 Data for Inventory

Example on how to use the matrix:

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

- EEA suppliers
- Non EEA suppliers
- Own plants outside EEA

Taking into consideration this simple example, the company would have the following roles under REACH[12]:

- Article producer in the EEA
  (In their own plant)
- Article importer into the EEA
  (From their plant outside the EEA)
- Downstream user of mixtures
  (From an EEA supplier)
- Importer of mixtures into the EEA
  (Only in case that supplier has no Only Representative in the EEA)
- Downstream user of substances
  (From an EEA supplier)
- Importer of substances into the EEA
  (Only in case that supplier has no Only Representative in the EEA)

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 mixtures. Therefore, it is recommended to first check your roles under REACH and then to find out what information will be required. More guidance may be necessary to determine if you are an Importer/producer/DU, etc.

Especially for inventories related to articles, the automotive industry in general has already established several tools to be compliant with other obligations (ELV, RRR, etc.). It is of course recommended to use those tools (see Chapters 5.8 and 5.9).

[12] Within REACH, the role of a "Downstream User of Articles" does not exist; rather "Recipient of Articles" is the applicable term.

5.4 Imports of Substances/Mixtures/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, in mixtures and in articles which, are imported from outside the EEA underlay different obligations under REACH (Registration, Notification, Communication, Authorisation), following the same rules as if manufactured/supplied in the EEA. e.g. registration is required for substances intended to be released from an imported article, following the same regime as substances intended to be released from an article produced in the EEA (see Chapter 5.7). REACH procedures for an imported substance on its own, in mixtures or in articles may be carried out by:

The "OR 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 mixtures or in articles, formulates a mixture or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community as an OR to fulfil all the obligations of the importer.

If an OR is appointed, the EEA importers of the same supply chain, whether they are affiliated to the non-EEA supplying company or not, are regarded as a DU and do not need to carry out the affected REACH requirements. The OR of the non-community manufacturer has the legal responsibility to comply with all relevant obligations under REACH and must be based in the EEA (Article 8.2 REACH).

In the absence of an OR appointed in the EEA, companies (for each of their importing legally incorporated or registered entities) importing the substance or mixtures or article into the Community market **are regarded as importers and are responsible for carrying out all REACH relevant obligations** whether they:

- Import a substance (included in Annex XIV) on its own (authorisation obligation according to Article 56 REACH). See Chapter 5.10
- Import articles with CL substances included above 0.1% w/w, to be supplied to the next recipient in the EEA (communication according to Article 33 REACH). See Chapter 5.9.
- Import articles with CL Substances included above 0.1% w/w and exceeding 1 tonne per year per importer (notification requirement according to Article 7 REACH). See Chapter 5.8
- Import an article intentionally releasing a substance and the substance is present in articles in quantities of 1 tonne or above per year per importer (registration obligation according to Article 7.1 REACH). See also Chapter 5.7
- Provide SDS/eSDS of imported substances or mixtures to their next recipient. The initial responsibility for drawing up the safety data sheet falls to the manufacturer or importer, who should anticipate, so far as it is reasonably practicable, the uses to which the substance or preparation may be put. Actors further down the supply chain should also provide a safety data sheet, drawing on, checking the adequacy of and adding to, the information provided by their suppliers to cater for the specific needs of their customers. In all cases, suppliers of a substance or a mixture which requires a SDS/eSDS have the responsibility for its contents, even though they may not have prepared the SDS/eSDS themselves. See Chapter 5.5.2

NOTE

- "The supply of substances/mixtures and articles from EEA Member States to other EEA Member States are not considered imports.
- If a globally operating company manufactures either a substance on its own, mixtures or articles outside the EEA that intentionally releases substances and then imports it again via its own European affiliates into the EEA, 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 EEA, has to register the substance and join the related Substance Information Exchange Forum (SIEF). Joint submission of data by multiple registrants is possible (Article 11 REACH). Joint submission of most of the data is required by the "One-Substance-One-Registration" (OSOR) principle.
- "When importing an identical substance from different suppliers in different countries outside the EEA, it is not necessary for the EEA importer to carry out repetitive registrations for each supplier. The importer may instead register per substance imported, provided that the substance is identical."

By contrast to the importer, the "Exporter" ships substances, mixtures, and articles into the EEA Community and is not established in the EEA as a legal entity.

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

EEA Importers must fulfil the REACH registration obligation and join the related Substance Information Exchange Forum (SIEF). They will need information provided by their suppliers and/or must purchase the required data through the SIEF. Importer obligations appear in various sections of this AIG, and are summarised in Flowchart 6.

Automotive Industry Recommendation

Registration

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

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

- **Priority 1**
  Ask non-EEA supplier to establish an OR and to register
- **Priority 2**
  Change suppliers or substitute the substance/mixture
- **Priority 3**
  Assume registration responsibilities as importer using required technical data provided by the non-EEA supplier or ask a service provider to act on your behalf

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

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

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

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

NOTE

The OR obligations are not limited to registration duties only but include all other obligations of manufacturers/importers (e.g. notification (Article 7.2 REACH), communication (Article 33 REACH, authorisation (Article 56 REACH), SDS obligations (Article 31 REACH), etc)

5.5 Downstream User Obligations according to REACH, Title V

In REACH Title V (Article 37 to 39) the DU has the right to make his use known to his suppliers. The supplier has the duty to evaluate the use and to provide information back to the DU on whether or not the use can be supported as an identified use. If the use is not supported, the DU has several options to continue using the substance. Certain deadlines have to be respected for the communications between DU and supplier. In addition, there are also obligations for DUs to report information to ECHA under special conditions.

The ECHA guidance for DUs provides assistance with all tasks. Table 5 of the guidance document (ECHA 2008, chapter 2.5.5, P. 25) provides an overview in regard to possible obligations related to different roles. In Chapters 3 and 4 of the ECHA guidance for DUs, recommendations are given on how a DU can prepare for REACH and what is to be done when a DU receives new information.

NOTE
All obligations under Title V of REACH are limited to substances or substances in mixtures which are hazardous according to CLP. Refer to Title V of REACH for more information.

5.5.1 DOWNSTREAM COMMUNICATION OF THE USES

In order to secure a continued supply of a hazardous substance on its own or in a mixture a DU has to check whether the supplier will support their use(s) by including them in the substance registration dossier.

Any use of a substance by a DU outside the supported uses is not allowed. If DUs are not sure if their supplier is aware of their use, it is in the interest of DUs to communicate early with suppliers with the view of having their use(s) included in the supplier's registration dossier.

For hazardous substances >10 tpa, the supported uses are communicated through the ES in the eSDS. Such eSDS will be issued once the registrant has made his registration. The registration deadline depends on the hazard classification of the substance and its volume per manufacturer/importer. For hazardous substances between 1-10 tpa the use is communicated via a normal SDS where only general use categories are included.

NOTE
There are two different ways to communicate identified uses under REACH:
- For hazardous substances between 1-10 tpa: SDS including general use categories (only reduced information)
- For hazardous substances >10 tpa: eSDS including Use Descriptors (detailed information)

Non-hazardous substances or mixtures without hazardous ingredients do not require a SDS and therefore have no use restrictions. In this case an ES is not provided to DU.

5.5.2 UPSTREAM COMMUNICATION OF USES

If a DU identifies a new hazard of a substance or a substance in a mixture, the supplier has to be informed in order to enable the appropriate risk assessment to be performed. The purpose is to cover the hazards in an update of his registration dossier and to communicate down the supply chain the appropriate Risk Management Measures (RMM).

NOTE
DUs are obliged to understand the REACH communication tools (e.g. SDS/eSDS, use descriptors, exposure scenarios etc.). Thus, it is highly recommended that DUs learn how to read the information in the SDS / eSDS including the use descriptors.
In order to be able to compare the suppliers' exposure scenarios, DUs should prepare their own ESs for their use conditions, using the Use Descriptors as described in the ECHA Guidelines.

DUs may assist in the preparation of a registration. They have the right to make known in writing (on paper or electronically) their use(s) to the supplier

so that they become an identified use. A DU can also provide a system of brief general descriptions of uses that can be used as a minimum to identify such uses to the supplier. In making the use(s) known, DUs shall provide sufficient information to allow the supplier to prepare an exposure scenario/use and exposure category that can be included in the chemical safety assessment (Article 37(2) REACH) if necessary.

The deadline for this feedback communication is 1 year before registration has to be carried out by the manufacturer. Other deadlines are as follows;

- 31 May 2012: deadline for communication of the identified uses to the upstream user of substances which have to be registered by 1 June 2013.
- 31 May 2017: deadline for communication of the identified uses to the upstream user of substances which have to be registered by 1 June 2018.

Therefore it is strongly advised that DUs start communicating as early as possible with their suppliers.

If a DU makes a formal request in writing to a supplier to have the use(s) of a substance included and the supplier, after having assessed the use in accordance with Article 14 REACH, is unable to include it as an identified use (for reasons of protection of human health or the environment), the supplier must without delay provide the ECHA and the downstream user with the reason(s) for that decision in writing. (Article 37.3 REACH).

For suppliers or distributors with only a small number of customers, it is possible to communicate by letter. 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 letters could result in an unmanageable administrative burden. The use of electronic exchange of information is recommended. (see also Chapter 5.6.4 of this guideline).

NOTE

Vehicle manufacturers and tier one suppliers in general will not respond to company specific questionnaires in regard to exposure scenarios, but require a pre-populated spreadsheet (preferably the DUCC UseR template and/or CEFIC template) which need only to be checked for completeness i.e. that your identified uses are covered.
Suppliers of substances or substances in mixtures are urged to contact the appropriate association for the substance in question, to make sure that their use becomes an identified use in the generic exposure scenario. (For further details see Annex L3 "Automotive Industry Recommendation on Exposure Scenarios")

To protect intellectual property rights it is recommended that the DU explains the use in general terms. Nevertheless in special cases it may be useful to communicate in detail with the supplier to make sure that all conditions of use and/or risk management measures are covered by the exposure scenario.

DU should therefore:

- As a first step, identify the substances and substances in mixtures used in their industrial processes (see Chapter 5.3).
- As a second step, if the supplier intends to carry out registration procedures, ask whether the supplier has already established use and exposure scenarios covering their use(s).
- DU may also check SDS/eSDS provided to them to see whether their uses and all conditions of use/RMMs are already covered (see next Chapters 5.6.1 and 5.6.2). If the supplier has not elaborated a use and exposure scenario, a DU may take a pro-active role and provide their supplier with information to develop an exposure scenario/use in order to ensure that their uses will be covered.

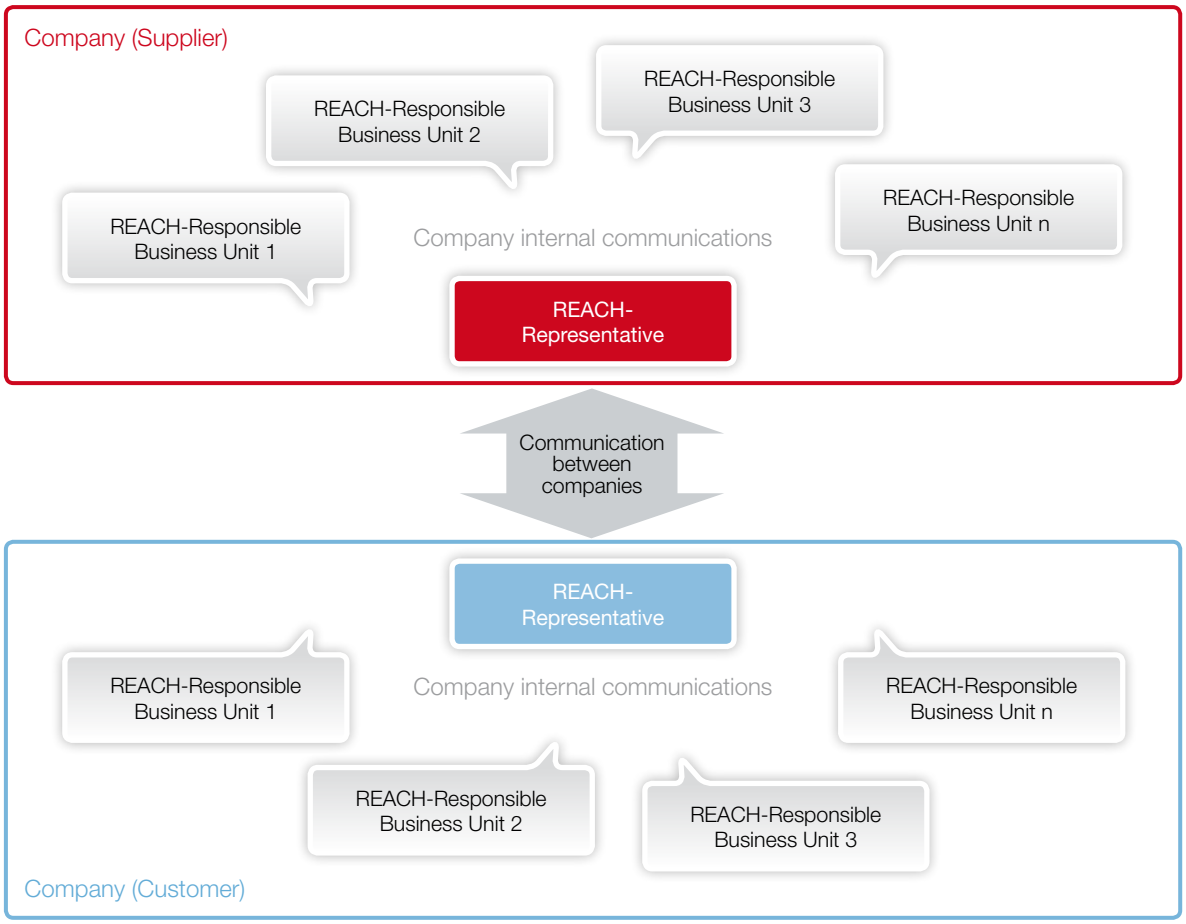
NOTE

The use of a substance on its own or in a mixture by DUs within the automotive industry should be covered in the supplier's registration dossier so that the use becomes an identified use.
DUs must check as early as possible, whether or not their supplier will effectively support their use(s) in order to ensure continuous supply of the substance/substance in mixture.
This check can be done for hazardous substances manufactured above 10 tpa by reading the eSDS (see Chapter 5.6.3).

It is in the DUs interest to make sure that the substances they use will be registered in time to avoid possible disruption. The consequence of being put in contact with a would-be-registrant could influence a company's business case and therefore the purchasing department must be involved. Even if a substance is pre-registered a DU cannot rely on a registration being made for that substance.

How to communicate with the supply chain

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



Picture 4.5.2.1 Recommendation for REACH Communications

5.6 Safety Data Sheet and DU Obligations (REACH Compliance Check)

SDSs have been a well-accepted and effective method for the provision of information to DUs in regard to chemical substances and mixtures in the EEA. They have been made an integral part of the system of REACH.

The SDS provides a mechanism for transmitting appropriate safety information on substances and mixtures which meet the criteria for classification as hazardous, persistent, bioaccumulative and toxic or very persistent and very bioaccumulative or are included in the CL for authorisation for any other reason and under certain conditions some mixtures which do not meet the criteria for classification as hazardous (Article 31.3 REACH).

NOTE
According to Art. 31, REACH, a SDS is not required for articles. However according to Art. 13 of the Pyrotechnic Directive 2007/23/EC, a SDS is currently required for pyrotechnic articles as used in vehicles and supplied to professional users. However, the Directive 2007/23/EC is currently under revision.

The SDS/eSDS includes information from the relevant Chemical Safety Report (CSR) if one exists. The information provided in the SDS/eSDS shall be consistent with the information in the CSR as well as with the registration dossier. Usually a SDS/eSDS is created by using pre-defined phrases.

NOTE
An example of a source of standard phrases is the European Phrase Catalogue (EUPhraC), which is available free of charge in German and English. This catalogue contains phrases in a well-structured form which have been shown to be useful in SDSs. The catalogue is being updated continuously and is available at: www.euphrac.eu

In addition, according to Article 31.7 REACH, registrants and users that had to prepare a CSR shall place the relevant exposure scenario(s) into an Annex of the SDS which then becomes an eSDS. A DU has to take into consideration relevant exposure information received from suppliers when compiling his eSDS.

The SDS is intended for professional DU in order to provide the information necessary to use the substance or mixture safely. It is an essential document for providing data with particular relevance to the protection of human health and the environment.

Any updated information on authorisation, restriction or risk management measures must be made available by the supplier to all former recipients to whom they have supplied the substance or mixture within the 12 preceding months. It should be made available free of charge, on paper or preferably electronically. Any updates following registration shall include the registration number. However, the existence of a registration number does not trigger an update of the SDS.

Also for non-hazardous substances communication duties have to be fulfilled (Article 32 REACH). Here the supplier has to provide information on:

- Whether the substance is subject to authorisation and details (e.g. authorisation number, special provisions) 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. In case information has to be given for one of the above reasons, the registration number has to be provided if available

In general there is a difference between the information the registrant (i.e. manufacturer or importer) has to provide to ECHA and the information he has to communicate along the supply chain (with or without SDS) to the DU.
The following picture provides an overview of the registration and communication requirements for a substance along the supply chain. A more detailed overview is provided in Annex K:

	not hazardous		hazardous
≥ 10 tpa	**CSR (DNEL/PNEC)** without exposure/risk assessment, therefore **no identified use(s)** **no SDS is required**[15]	REACH Article 10, 14, 31.7 Annex I, II, VI (6)	**CSR**[13] **(DNEL/PNEC)** with exposure/risk assessment **"extended" SDS:** **exposure scenario(s), identified use(s)**
≥ 1 - > 10 tpa	**no CSR** and **no SDS required**[15]		**no CSR**[14] and **"normal" SDS:** **no exposure scenario(s)** **no identified use(s)**[14]
< 1 tpa	**no SDS required**[15]	REACH Art. 31	**"normal" SDS**

Picture 4.6.1 overview about the registration and communication requirements for a substance

[13] CSR contains in addition exposure scenario(s) **and** an exposure/risk assessment.
The exposure scenario(s) have to be delivered to the next supply chain member as SDS attachments.
[14] Information according to Article 10 REACH and in addition according to Annex VI (6) i.e. exposure related information (use and exposure categories).
[15] SDS is required for PBT/vPvB substances or endocrine disruptors which do not meet the criteria of CLP. If no SDS is required, information according to Article 32 REACH (without format proposal) might have to be communicated along the supply chain.

5.6.1 DU OBLIGATIONS FOR A SDS

Under normal conditions a SDS/eSDS has to be provided automatically. However in case the DU does not receive a SDS/eSDS from the supplier he should check whether a SDS is required for the substance or mixture. In such cases, he may ask the supplier for the SDS/eSDS which then has to be provided immediately (see Chapter 5.6.2).

Upon receipt of a SDS/eSDS, the DU should check:

- Whether the SDS is supplied in the official language of the Member State(s) where the substance or mixture is placed on the market. Only when the Member State(s) concerned provide(s) otherwise (Article 31.5 REACH) can the SDS be in another language[16]. It should be noted that it is for the recipient Member State to provide otherwise.
- Whether an exposure scenario (ES) is attached to the eSDS and whether it corresponds to the DUs use of the product.
- Whether the information mentioned in the SDS/eSDS is sufficient for workplace and environmental risk assessment.

Due to workplace safety obligations, the DU should make a short general plausibility check of the SDS/eSDS content. In particular attention should be paid to the following:

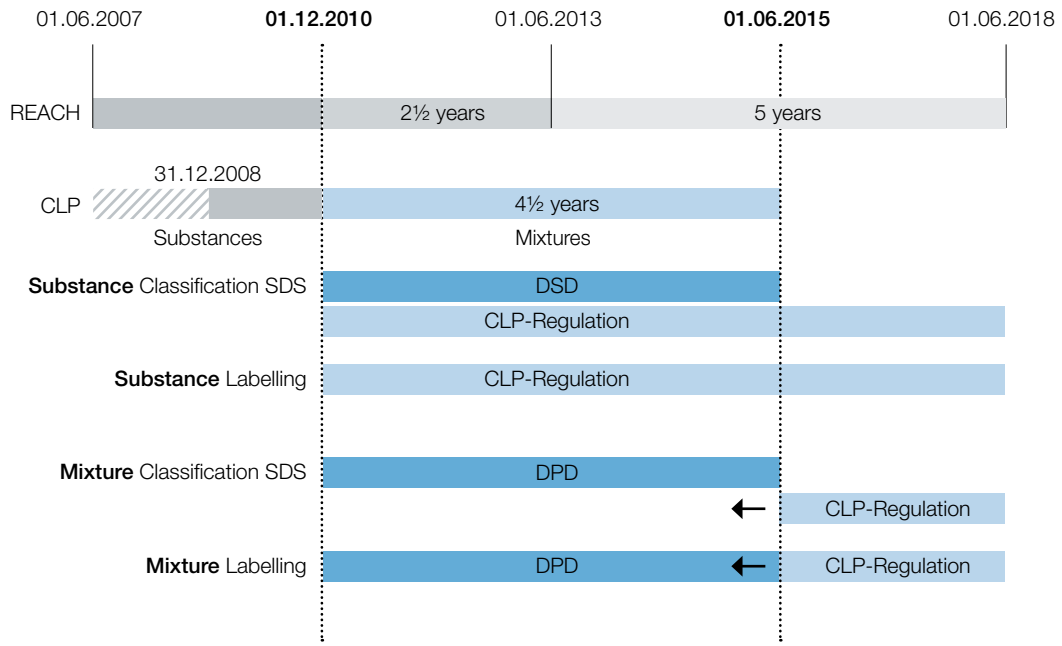
- Classification (including transport classification). If further information is needed, contact your supplier.

> **NOTE**
> according to Article 38.4 REACH the DU shall report to ECHA if the classification of a substance is different to that of the supplier.

- Consistency between information given in sections 9, 11 and 12 and the classification.
- Appropriateness of the RMM: according to Article 34 REACH, the DU needs to report back to the supplier if they are inappropriate.
- Any other available and relevant information about the substance that is necessary to enable appropriate RMMs to be identified and applied.

NOTE

DUs should be aware that REACH & CLP are providing transitional periods for SDS until 2017. Within these periods, DUs may receive different formats of SDS.



DSD = Dangerous Substance Directive 67/548/EEC | DPD = Dangerous Preparation Directive 1999/45/EC

Picture 4.6.1.1 Transition periods according to REACH & CLP

In most cases DUs will receive the following kind of SDS (Article 31 REACH):

1. For all hazardous substances above 10 tpa (for example technical gases like ammonia or solvents like isopropanol) the DU will receive an eSDS for the substance. eSDS mainly differ from "normal" SDS by having exposure scenario(s) attached as an annex, relevant identified uses in section 1 and DNEL/PNEC values in section 8.

   Related DU obligations:

   If a DU receives an eSDS, he has to check whether the current use is covered **and** whether his workplace and environmental risk assessment and the RMM are covered by the attached exposure scenario as well as the operational conditions described therein.

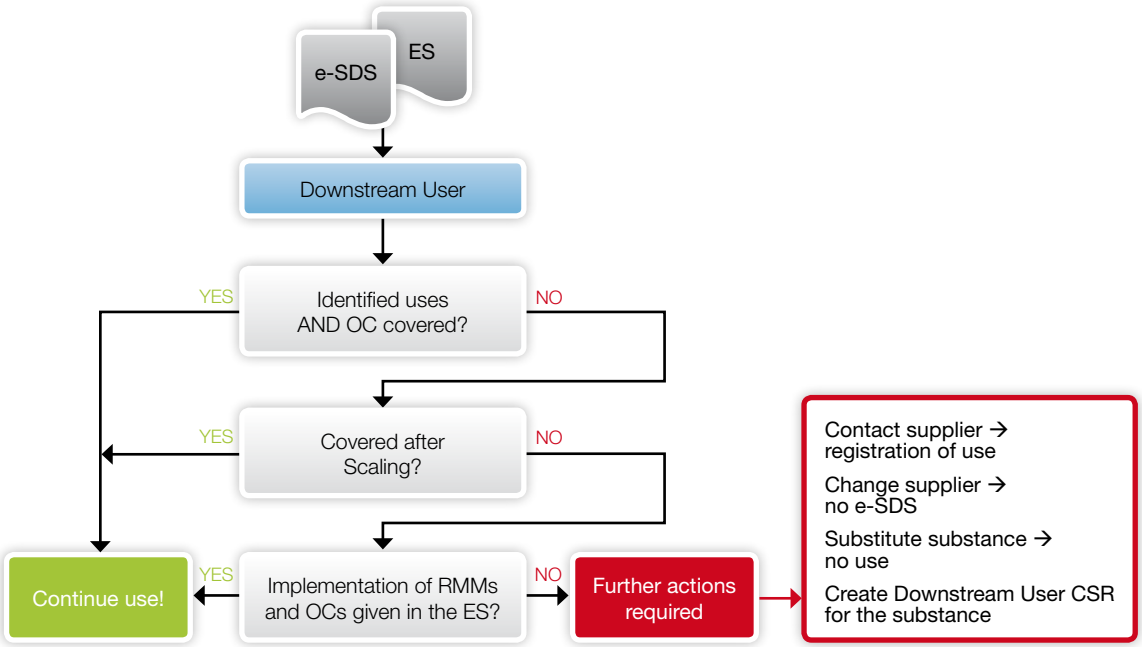
   If a DU uses substances (e.g. formulating a mixture) outside the conditions described in the exposure scenario, or if the uses are not covered, or for any use(s) the registrant advises against, he has several options:

   - DU may make the use/use conditions known to his supplier so that the supplier can prepare an exposure scenario covering them.
   - DU may change the conditions of use or modify the variable scaling parameters within the ES (scaling) so that they are covered by the supplier's exposure scenario.
   - DU may find another supplier who provides an exposure scenario covering the particular use(s) and conditions of use(s).
   - A CSR may be prepared by the DU according to

[16] Source: Draft Guidance on the compilation of safety data sheets

Article 37.4 REACH **and** notification made to ECHA for the additional use(s) as described in Article 38.1 REACH.

- DU may implement the conditions of use as described in the ES/use by modifying his production process
- DU may find an alternative substance or process if possible and discontinue using the substance in question (substitution).



Picture 4.6.1.2 Exposure Scenarios and Communication in the Supply Chains

Source: REACH Practical Guide on Exposure Assessment and Communication in the Supply Chains Part II: Exposure Scenarios and Communication in the Supply Chains, Figure 5, modified by automotive industry. "Further actions" are options which can be chosen by the downstream user as alternatives or in parallel.

NOTE

The eSDS will include the relevant exposure scenarios as attachments for the identified uses for which the substance was registered.
An exposure scenario generally describes how a substance can be safely used under the given operational conditions of use and which risk management measures (RMM) should be applied to control risk to humans or the environment. Exposure scenarios must be compiled by the registrant, as part of the registration dossier, for certain substances on their own or in mixtures, which are imported/manufactured in quantities over 10 tpa and hazardous according to CLP.

Please consider that in principle identified uses described with the use descriptor system in ES are provided in the eSDS only. There may be a possibility that identified uses appear to be covered in such an eSDS but the conditions of use and risk management measures are different from those in your own processes, because they are mainly estimated by using worst case ES estimation tools (e.g. ECETOC-TRA). In those cases the obligations according to REACH Title V have to be considered.

2. For mixtures containing hazardous substances ≥10 tpa (e.g. coatings), two kinds of SDS are legally possible (2a or 2b below). A third option was developed by the chemical industry (2c):

   a) A "normal" SDS for the mixture without any ES attachment and where all RMMs for safe handling are included in the main body. For general information around SDS: see also Chapter 5.6.2 of this guideline.

   NOTE
   This is the recommended option for communication of SDS for mixtures. Even if no ES is contained in the SDS as an annex, the DU must still consider the specifications given in sections 1-16 of the SDS.

   b) A SDS for the mixture where all relevant ES of the registered hazardous substances ≥10 tpa are attached ("SDS book").
   If the DU receives such a SDS it has the obligation to check substance-wise all attached ES to see whether the uses and the conditions of use (OC) are covered (REACH compliance check).

   NOTE
   Automotive industry recommendation that even if option 2b is legally correct to ask your supplier to submit a consolidated SDS describing the risk of the whole mixture in the main body of the SDS (see point 2a) instead of providing a "SDS book" in order to avoid unnecessary administrative work.

   c) A SDS with a "consolidated exposure scenario for the mixture", developed by the chemical industry.

   Because the DU duties of REACH Title V are related to substances and substances in mixtures only but not to the mixture itself, the duties resulting from a "consolidated exposure scenario for mixtures" are not equivalent to those resulting from an exposure scenario for substances. DUs may consider the information obtained from such a consolidated exposure scenario for a mixture for their own workplace and environmental risk assessment, especially in those cases where no national workplace exposure limit value or environmental relevant threshold or technical equipment approval conditions are yet available.

   NOTE
   Exposure scenario(s) for mixtures do not exist, because mixtures are not subject of registration and no safety report is legally required for them (see attachment: position paper of the EU commission dated 28. April 2006. Quote: "Finally, the Council has in its Common Position decided to delete Annex Ib (Chemical Safety Assessments for Preparations) given that the scientific methodology underpinning this Annex is still being developed"). Special substances may be regarded as mixtures under CLP and REACH (multi-consistent substances and/or complex substances, alloys etc.). For these "substances" a CSR may be reasonable.

Further DU information obligations around SDS, ES and Article 32 REACH

The DU must compare the RMM in a risk assessment with the recommended risk management measures, as indicated in the SDS communicated or supplied in accordance with Article 32 REACH. Any differences can lead to further obligations.

According to Article 34 REACH any actor in the supply chain of a substance or a mixture also has the obligation to communicate to the next actor up the supply chain, if:

- New information on hazardous properties is discovered, regardless of the use.
- Any other information is discovered that might call into question the appropriateness of the RMM identified in the SDS supplied, and this shall be communicated for identified uses (Article 34 REACH).

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

[17] http://www.ecetoc.org/tra

Generally the DUs, as well as manufacturers, importers and distributors shall keep the information gathered for the purpose of fulfilling their duties under REACH available for a period of at least 10 years. This information shall be made available without delay and upon request to Member States´ competent authority or ECHA. (Article 36 REACH).

NOTE 1
Information that is not required under REACH might be required by other legal obligations (e.g. CLP, other Health and Safety regulations etc.).

NOTE 2
The DU may communicate with their supplier by means of use and ES, especially if it is deemed necessary to:

- protect confidential data.
- avoid an own DU CSR and to report to the ECHA, which requires expertise and may be costly, besides being time consuming.
- communicate with each of their suppliers, even if they supply the same substances/mixtures to him.

Practical information on communication in the supply chain/use is not thoroughly explained in the REACH Regulation. Further information is given in the following industry guidance documents:
http://REACH.bdi.info
http://cefic.org/en/reach-for-industries-libraries.html
http://guidance.echa.europa.eu/guidance_en.htm

5.6.2 COLLECTION OF SDS

REACH does not provide other information sources on the registration of uses apart from via a SDS. But as registration of substances ≥10 tpa has to include the identified use information has DUs have to make sure that their uses are included in the registration to guarantee business continuity. It is therefore strongly recommended that DUs check the available data to find out whether their use of a substance and the corresponding operational conditions of use are covered in the registration in order to avoid substance or supplier loss. Below are three possible ways to accomplish this:

Option 1

Ask for identified uses according to the DUCC template

Advantages:

- DU will see whether the identified uses are covered by the use descriptors and can react in time to make these uses known to the supplier.
- There are no resulting DU obligations such as under the following option.
- The information is available independent from the SDS.

Disadvantages:

- Difficult handling of the DUCC template
- Information is often incomplete and cannot be used for worker or environmental protection
- At a later stage, information will become redundant because the SDS has to be collected anyway.

Option 2

Collect SDS for ALL supplied substances & mixtures (not only for hazardous):

Advantages:

- The registration numbers as well as all registered uses are included in the SDS, once the revised SDS has been issued after registration. This can be as late as 2018. As the process of SDS handling is usually well established in most companies it would be possible to check in the received SDS whether the uses are covered.
- The collected information is also the basis for a substance inventory, necessary to fulfil obligations on workplace and environmental protection.
- No unstructured Article 32 REACH-based information is necessary as it is already covered in the SDS.

Disadvantages:

- Once a SDS is received, the recipient has, independent of the potential risk of a substance or mixture, the obligation to apply the RMMs mentioned therein (Article 37.5(a) REACH) and to fulfil the communication obligations which could lead to additional burden on the receiver side.
- According to Article 34 REACH a DU is obliged to make a short general plausibility check of the SDS content and to report upstream to his supplier if his own RMMs are deviating from those given in the SDS.
- In addition, once a SDS has been provided, the creator has the obligation to keep this SDS updated which could lead to additional burden on the creator and receiver side.

NOTE
As there is no legal obligation, you would have to put additional requirements into your supplier contracts/purchasing conditions.

Option 3

Collect SDS for all substances & mixtures where legally required plus SDS-like information also for those where no SDS is legally required.
In the case of substances and mixtures where no SDS is legally required ask your supplier for safety information, having the **same content and format** as the SDS but without naming it SDS.
Advantages:

- You fulfil the legal requirements and remain in the existing IT systems.
- See advantages of option 2 above.
- None of the above disadvantages apply

NOTE

» It is the recommendation of TF REACH to use Option 3 in order to collect all necessary information on the registration of substances on their own or in mixtures.

» As there is no legal obligation, you would have to put additional requirements into your supplier contracts/purchasing conditions.

5.6.3 EXCHANGE OF SDS

In order to simplify communication along the supply chain, different institutions are working on IT-tools. The chemical industry has developed a xml-based exchange format for ES (EsCOMxml). The TF REACH is observing and evaluating this solution and will finally make a recommendation. This will be published separately in a TF REACH communication paper. The objective is to have a common communication tool as open IT-standard which is combined with the EDAS Exchange Format for SDS.

NOTE
The TF REACH members have agreed upon the use of a common open IT-standard for exchanging a SDS. The automotive industry therefore supports the concept and further development of the EDAS standard and recommends their suppliers to implement an EDAS interface in their IT systems to simplify communication up and down the supply chain. (See Annex L6 “Position paper EDAS Final”)

5.6.4 UPDATE OF SDS

The conditions under which a SDS must be updated and re-issued are given in Article 31.9 REACH as follows:

Suppliers shall update the SDS without delay on the following occasions:
a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
b) once an authorisation has been granted or refused;
c) once a restriction has been imposed;
In addition it is also recommended to update SDS once a substance has been added to the CL for authorisation.

The new, dated version of the SDS, identified by ‘Revision: (date)’, shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or mixture within the preceding 12 months.

NOTE
Any updates following registration shall include the registration number.

Although there are industry recommendations available on when a change in a SDS is considered a “major” or a “minor” change, this terminology is not used in the REACH Regulation. Only the above mentioned changes (a to c) give rise to a legal obligation to provide updated versions to all recipients to whom the substance or mixture has been supplied within the preceding 12 months.

5.7 CLP Notification

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (hereinafter CLP) harmonises the provisions and criteria for the classification and labelling of substances and mixtures within the Community, taking into account the classification criteria and labelling rules of the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS). The CLP Regulation contributes to the UN GHS aim of describing and communicating the same hazards in the same way around the world.

If you are an EEA manufacturer of substances or an importer of substances on their own or in mixtures into the EEA, you might have an obligation to notify the classification and labelling to ECHA according to the requirements of Title 2 (Article 39 –42) CLP. The notified information will be entered into the publicly available C&L Inventory and the information will be visible to the public and is regulated in, Article 119 REACH.

The notification obligation to the C&L Inventory applies if a substance you import or manufacture is:

- > 1tpa and thus subject to Registration under REACH irrespective of whether or not the substance is hazardous (CLP).
- present in a mixture above the concentration limits specified in Annex I of CLP or as specified in Directive 1999/45/EC, where relevant, which results in the classification of the mixture as hazardous, and where the mixture is placed on the market.
- contained in articles where Article 7 REACH provides for their registration (check Chapter 5.8 for examples in the automotive industry).
- classified as hazardous under CLP and placed on the market **irrespective of the tonnage**.

NOTE
if your supplier has submitted a REACH registration dossier before 1 December 2010 which contains the classification according to CLP, then the C&L is considered to be already notified. In that case a separate notification would not be necessary.

A notification is **not** required if

- a manufacturer, importer or OR has already registered the substance **with the classification and labelling according to CLP** when its notification in line with Article 40(1) CLP is due. In particular, notification is not required for the importers covered by a registration that has already been done by an OR on **their behalf**. The OR can be made an importer by supplying him with a sample of the respective substances or mixtures so that he becomes responsible for the import, including the safe handling of the substance or mixture imported.

NOTE
Under CLP the role of an OR does not exist. Consequently the notification has to be made by importers that are physically importing the products. However, an OR can become an importer even with the import of a sample quantity. In such case he can, after agreement with the other importers, submit a notification jointly for all importers.

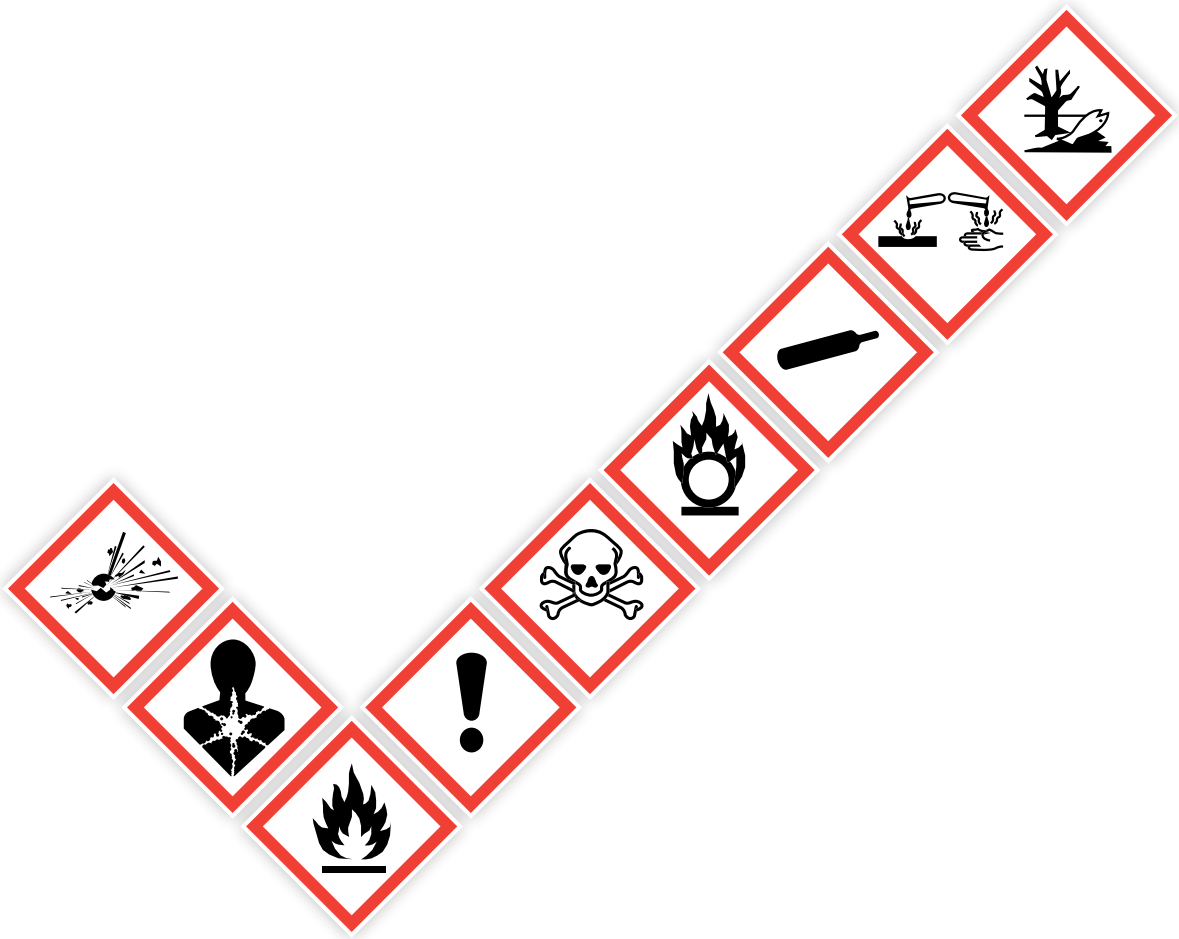
- the substance does not meet the criteria of CLP and is imported < 1 tpa.

NOTE
» Certain substances that are exempted from registration under REACH may well be subject to C&L notification. This includes, for example, active substances in biocides and plant protection products, polymers (if hazardous, see Article 6.3 REACH), and small tonnages (< 1 tpa) of hazardous substances.
» Article 39(b) CLP refers to all hazards. This includes notification of a substance classified for a particular physical hazard and contained in a mixture whenever the mixture is placed on the market and needs to be classified for a physical hazard due to the presence of that substance. It should be noted that the physical hazard class to which the mixture belongs could be different from that of the substance(s) causing the hazard. Expert judgment should be sought in case of doubt.

Timeline:

- General rule: Within one month from placing on the market
- Substances on the market on 1 December 2010 had to be notified by 3 January 2011

For further information see the following links:
http://echa.europa.eu/clp/inventory_notification_en.asp
http://echa.europa.eu/clp/inventory_notification/notification_who_en.asp
http://echa.europa.eu/doc/publications/practical_guides/pg_7_clp_notif_en.pdf
(ECHA Practical guide 7: How to notify substances in the Classification and Labelling Inventory).



5.8 Registration of Substances in Articles

A registration according to article 7.1 REACH is obligatory for EEA producers and importers of automotive articles from outside the EEA or the "OR of non EEA manufacturer" of articles for those substances in articles meeting all of the following conditions:

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

Exemption according to Article 7.6 REACH: This registration obligation does not apply for substances already registered for that use. Therefore EEA producers should check if their suppliers have already registered the substance intended to be released.

Examples

The global automotive industry has identified the following list of examples of articles that intentionally release substances after being assembled onto a vehicle, when normal use conditions apply:

1. Fragrance dispensers,
2. Fire extinguisher systems
   (excluding a hand held mobile fire extinguisher).
3. Windshield-washer fluid reservoirs,
4. Pyrotechnic devices that release compressed gases.
   Please note that although a pyrotechnic device with compressed gas is considered as an article with substances that intentionally release when activated in a vehicle, basic elemental substances for which hazards and risks are already well known (hydrogen, oxygen, noble gases, nitrogen) are exempt from registration, per Annex V (9) of the REACH regulation. Registration may be required if other substances or mixtures are utilised.

NOTE
The automotive industry supports the position of the Association of the Pyrotechnics Industry (VPI) and the manufacturers of automotive pyrotechnic products that the chemical products of the pyrotechnic reaction are exempt from REACH registration requirements under Annex V (3) upon deployment, since the chemicals are consumed in the reaction. See Annex L2 - Automotive Industry Pyrotechnic Position Paper"

Beside example 4 "Compressed gases for pyrotechnical devices", the above mentioned examples 1-3, if imported on their own (i.e. not assembled onto the vehicle) would be considered containers with mixtures, and would therefore be subject to the registration obligations associated with mixtures in containers. Beside portable fire extinguishers, the most prominent example for imported mixtures in containers without intentional release are tyre repair kits:

The kit is not part of the vehicle. Thus, there are no registration obligations acc. to Art 7.1, REACH. However, if you are importing it (even if in an imported vehicle) you are considered as an importer of a substance/mixture.

In such cases one should check the amount of imported substances in the sealant mixture. If the 1 tpa threshold is exceeded, either the OR or the company concerned will need to undertake a registration under Article 6 REACH, unless already done so by the upstream supplier. Alternatively, supply can be changed to an EU supplier so that you are not anymore an importer.

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

A release of substances is not considered to be an intended release if it is an unavoidable side effect of the functioning of the article, but the release does not contribute to the functioning of the article. Examples: wear and tear of materials under conditions of high friction, e.g. break linings, tyres; leakage of lubricant used to reduce the friction between two moving parts (see Guidance on requirements for substances in

articles). This substance release could be subject to Article 7.5 REACH where the ECHA could take decisions to require producers or importers of articles to submit a registration if all of the following conditions apply:

a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
b) ECHA has grounds for suspecting that:
   (i) the substance is released from the articles, and
   (ii) the release of the substance from the articles presents a risk to human health or the environment;
c) the substance is not subject to paragraph 1.

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

Please bear in mind that the automotive industry may also produce or import other non-vehicle related articles that are subject to REACH requirements. These may include items such as tools, machinery, equipment, and packaging that may fall under Article 7.1 REACH. It is recommended to check your product portfolio for such examples

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

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 mixtures (Article 23 REACH, AIG 3 Chapter 3).

Fees

Fees required for the registration of substances in articles are specified in the Regulation (EC) No 340/2008. 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.

The regulation is published in the Official Journal of the European Union (L 107/6 dated 17.4.2008):

NOTE
Article producers/importers should pay attention under which provision of the REACH Regulation the intentionally released substance/substance in mixtures under normal and reasonably foreseeable conditions of use 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 an article according to Article 3.3 REACH.

For more details, please refer to Articles 6, 7, 23, 28 REACH and ECHA Guidance on Requirements for Substances in Articles

5.9 Notification of CL Substances in Articles

Both producers of articles in the EEA and importers (or OR) of articles from outside the EEA must notify ECHA if the substance present in articles meets all of the following conditions in line with Article 7.2 REACH:

- The substance has been added to the CL for authorisation
- The substance present in articles is above a concentration of 0.1% w/w
- The substance is present in those articles where the concentration exceeds 0.1% w/w in quantities totalling over 1 tpa (per producer/importer)

NOTE

The definition of "per year" in the legal text (Art. 3.30) which is copied into the definition section of the AIG does not explicitly state that it applies to substances on their own, in mixtures or in articles. TF REACH is of the opinion that this provision was put in place to avoid situations where a sudden increase in demand would lead to legal entities being unable to comply with the registration obligations and as such has nothing to do with notification. Therefore, having given due consideration to the term "per year" and whether it should apply to notification, we reached the conclusion that the "per year" starts from when the substance is included in the CL for authorisation. The reason behind this decision is that companies will not have accumulated information about a CL substance being present in an article before the substance appears on the CL.
Should a notification not be necessary during the year following the introduction of the substance of the CL due to the tonnage not being tripped, the situation should be monitored as the tonnage threshold may be exceeded in a subsequent year when production/import of articles containing the substance increases.

Example

A substance is added to the CL on 1 June 2012. The company importing or producing articles containing this substance will have to start investigating and calculating from that point in time and not from the beginning of 2012. The tonnage of substance on 1 June 2012 is considered to be zero.

Notification is not required:

If the substance has already been registered for that use by a member of any supply chain (Article 7.6 REACH)

The registration needs **not** to be done by an actor of **your** supply chain but can be made by any other manufacturer or importer of the CL substance. For articles produced in or imported into the EEA it is necessary to check if the use of the substance in the article is supported by the registration so as to avoid the notification obligation. If you have an inventory for the articles that you produce or import, you may have information about the materials and the produced/imported volumes. This information will provide you with a first indication on whether a notification may be required.
The use of the affected CL substance must be in line with the "use descriptor" of the registered CL substance described on the ECHA webpage (see below). Due to the lack of clarification in the ECHA guidance documents this information might be considered insufficient or questionable. It is therefore strongly recommended to use other information sources on registered uses by contacting appropriate bodies, such as SIEFs, lead registrants, substance consortia and substance-responsible associations.

Efforts to make contact with these bodies can in practice prove to be difficult as business confidentiality considerations may thwart the disclosure of the required information. It is recommended that any such correspondence is recorded. It may be that the registration dossier published by ECHA specifies seemingly relevant uses e.g. manufacture of automobiles. In such cases, it is a judgement call whether notification is pursued relying solely on this information from the dossier.

NOTE

For DUs in the automotive industry, the Article Category (AC) has to be considered while checking the registration of uses. **The ACs are describing the type of article in which the substance is known to be included on its end use.**

Example

A PVC cable containing DEHP is used in a vehicle:
In this case the end use of DEHP is not the vehicle

(AC 1) to which the article "PVC Cable" has been attached. Instead it is the end use of the substance itself, which is the inclusion into the PVC cable. Therefore the AC might be e.g. rubber articles (AC 10) or plastic articles (AC 13).

Example for the use of DEHP in an article of the automotive industry:

1. Check whether DEHP has already been registered for use within a wiring harness in a vehicle
   a) Go to the ECHA website by following the link: http://apps.echa.europa.eu/registered/registered-sub.aspx
   b) Check registration status for DEHP by entering the CAS number 117-81-7;
   RESULT: full registration dossier data available

2. Check whether your use of DEHP in the article is an identified use:
   a) Click on view and go to chapter "Manufacture, Use & Exposure" and check whether the listed uses of the substance in the article are covering the end use of the substance while incorporated into the article "PVC cable".

   To do so, you may first check the article categories (ACs):
   For DEHP the AC 13: "Plastic articles" is mentioned. As DEHP has been used as plasticiser in the plastic part of the wiring harness it can be concluded that the use in PVC cable is covered!

   NOTE
   - Other ACs such as AC1: "Vehicles", AC5: "Fabrics, textiles & apparel" or AC10: "Rubber articles" are in this example not relevant because the end use of the substance is the plastic part "PVC cable" and not the vehicle, textile or rubber part.
   - The Article Category AC1 only has to be considered if the substance (here DEHP) or mixture containing the substance is directly incorporated into the vehicle (e.g. in lubricants, paints, etc.).
   - As a DU of DEHP and the SU and PROC Categories have also to be considered.

   b) If your are uncertain whether your uses are covered by the listed ACs the M/I or the DU of a substance is according to Chapter R.12 "Use Descriptor System" of the ECHA Guidance on "Information requirements and chemical safety assessment" under http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf allowed to identify a suitable article category by using a code (and the corresponding phrasing) from the TARIC system under: http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp.
   e.g. "plastics and articles thereof" the corresponding code would be 39.

   c) If the ACs do not cover your uses or if there is no AC mentioned at all, it does not automatically imply that your uses are not registered. In this case you have to check other use categories:
   Product category (PC): PC32: "Polymer preparations and compounds" **→OK (AI use is covered)!**
   Sector of use category (SU): SU12: "Manufacture of plastic products, incl. compounding and conversion" **→ OK (AI Use is covered)!**

3. Cross-check whether there are no restrictions on use(s) of DEHP in the article for your use:
   a) Click on details and go to chapter "Manufacture, Use & Exposure" and check whether no uses advised against your scope of use are listed.
   b) No restriction(s) listed **→ OK!**

   NOTE
   Should you find restrictions on your end use listed, you are recommended to take necessary action making sure your use is covered. Please refer to chapter 5.5 "Downstream User Obligations according to REACH, Title V" for options.

4. Conclusion:

No notification is necessary for DEHP in PVC cables!

NOTE

Incorporation of a substance in an article is a "use". However, the placing on the market of an article is not a use.

Please refer to the factsheet on notification for each substance on the CL which can be downloaded by following the link: www.acea.be/reach/publications/notification_factsheets

Notification is also not required 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).

Documentation for a notification exemption due to exclusion of human or environmental exposure to a CL-substance does not need to be submitted to ECHA but should be retained so that it can be presented to the enforcement authorities on request. A justification of an exemption to notify could include one or more of the following:

- Proof of no emissions from the article, even during disposal.
- The substance is contained in the article by technical means, and the rationale explaining why the article is unlikely to be opened or to break, leading to release of the substance, can be made available.
- The substance is embedded in the matrix of the article, a description of the stability of the article matrix and the bonds between the substance and the matrix during the different life cycle stages of the article.
- Proof exists that the substance remains fully immobile inside the article and does not migrate out from or escape its confines (e.g. due to the inherent physicochemical properties of the substance, or a special coating of the article).
- Proof that the amount of substance released from the article is contained by technical means or directly destroyed (e.g. during thermal treatment of waste).

NOTE

» It may be more difficult and costly to demonstrate "no exposure" than to make a notification.

» A notification is not required for a substance in articles which were produced or imported before the substance has been included on the CL for authorisation.

» A notification needs only to be done once. However, if your circumstances change e.g. in regard to a tonnage band change, an update of the original notification will be necessary.

» For more information on exposure-based exemption from notification please check the ECHA Guidance on requirements for substances in articles published in 2011.

The information to be included in the notification is described in Art. 7.4 REACH

- identity of the notifier (i.e. the producer or importer of articles), i.e. name, contact details (REACH-IT account and IUCLID 5 section 1.1);
- identity of the notifier and role in the supply chain (IUCLID 5 section 1.1);
- identification of the substance, i.e. substance name, EC number, CAS number, type of substance and substance composition (IUCLID 5 sections 1.1 and 1.2): this information is provided in the pre-filled substance dataset; the registration number of the SVHC substance, if available (IUCLID 5 section 1.3);
- classification of the SVHC substance according to the CLP criteria (IUCLID 5 section 2.1): this information is provided in the pre-filled substance dataset;
- the tonnage band of the substance contained in the article(s), i.e. 1-10 tpa, 10-100 tpa, 100-1000 tonnes or ≥1000 tpa (IUCLID 5 section 3.2);
- the production site of the notifier, to be filled only by producers of articles, not by importers of articles (IUCLID 5 section 3.3);
- a brief description of the use(s) of the substance(s) in the article (Technical function) (IUCLID 5 section 3.5) and of the uses of the article(s) (IUCLID 5 section 3.4 and 3.5)

NOTE

» According to ECHA[18], in some cases the producer of complex articles may not be aware of the technical function of the CL substance incorporated into an article. In which case an assumption has to be made by the notifier.

» The CL of SVHCs, which is available on the ECHA website, includes substance datasets with some sections of the IUCLID 5 file already filled in (substance identity, composition and classification information)

Timeline

Article 7.7 REACH states; From 1 June 2011 paragraphs 2, 3 and 4 of this Article shall apply 6 months after a substance is identified in accordance with Article 59(1) REACH. Legally, one is not required to notify anything until 1 June 2011. However, due to the way REACH has been drafted, for substances added to the CL before 1 December 2010, the 1 June 2011 start date is also the deadline for notification. This creates an impractical situation for both duty holders and ECHA and for this reason ECHA opened the notification facility before the deadline so that, whilst under no legal obligation, duty holders can choose to notify early if they wish. Hence the ECHA draft guidance document and alert state: for a SVHC placed on the CL **before** 1 Dec 2010 notification has to be made to ECHA by 1 June 2011; for a SVHC included on the CL **after** 1 Dec 2010 notification is required no later than 6 months after the inclusion.

Working assumptions

- First notification prior to 1 June 2011 is made on the basis of the CL version of 1 Dec 2010.
- The tonnage has to be calculated for the year after the substance appeared on the CL for authorisation.
- The notification of articles that contain a CL substance above a concentration of 0.1% w/w is triggered when 1 tpa is reached.
- According to Article 7.7 REACH the notifier has a 6 months window in which to notify after the inclusion of the substance in the CL for authorisation. In case the tonnage exceeds 1 tpa within this 6 months one has to notify on the due date. Otherwise one has to proceed collecting data till 1 tpa is exceeded and then notify.
- Art 7 notification has to be done only once (for 1 CL substance), not every year.
- If the tonnage range changes the notification has to be updated.
- The quantities of the same CL substance in both imported or manufactured articles for the same legal entity has to be summed up for the tonnage calculation.
- If only a part of the uses of a CL substance can be found registered the quantities of non-registered uses must be notified/calculated for the notification.
- The internal shipment between different legal entities (even within the same company) has to be considered.

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

- The substance is present in these articles in quantities over 1 tpa.
- ECHA has grounds for suspecting that the substance is released from the articles, and the release of the substance from the articles presents a risk to human health or the environment.
- The substance is not subject to registration according 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 sub-component weight.
If company A imports an article from a non-EEA producer and that same article contains a CL-substance above the threshold and yearly tonnage, then a notification is required by company A. If then a company B assembles this article into a complex article and the threshold and tonnage is still exceeded, a further notification is required. This means that one notification is required to be made by company A acting as an importer and another by company B because he is an EEA producer of an article and the criteria for notification are met.

For more details refer to Articles 7, 57 and 59 REACH and ECHA **"Guidance on requirements for substances in articles"**

[18] Information from audio conference with ECHA staff on 14 April 2011

5.9.1 Recommendation for the Automotive Industry

By taking into consideration all criteria, the following strategy for the automotive industry is recommended (refer to Flowchart 10):

1. Check which CL-Substances are relevant for your business
   a) Use results from the REACH TF SVHC Survey or of your internal investigations to evaluate the impact on your business
   b) Use data from substance reporting systems to check the 0.1 w/w threshold
   To get an overview about all CL-substances in your product portfolio, use the already established Substance Reporting Systems (e.g. IMDS, MACSI) of the automotive industry. The prerequisite for correct substance reporting is a continuously updated declarable substance list (e.g. GADSL http://www.gadsl.org) which contains those CL-substances and regulated substances from other countries being relevant for automotive articles. When new CL substances are added that impact the AI, an update of the GADSL list is undertaken by the responsible organisations. For those companies that do not have an IT-tool available, alternative methods can be used to collect the necessary data.

   By following the above recommendation, the main task is to complete an inventory of CL-substances in **all** articles produced and/or imported where the concentration of a CL substance is above 0.1% w/w. Packaging is considered an article.

   According to these inventory results, cases requiring notification can be identified and actions defined.

NOTE
According to the IMDS rules each user has to check his existing IMDS data whenever a new substance has been added to GADSL (e.g. new CL substances). In case a new GADSL substance is hidden in behind IMDS Joker, the user **has to** update his Material Data Sheet by uncovering this substance(s)!

   By using IMDS it is recommended to avoid the use of wildcards and instead to work with the "confidential substance" functionality.

2. Check if the CL substances have been registered by any supplier
   a) As official and reliable source use the ECHA database under: http://apps.echa.europa.eu/registered/registered-sub.aspx
   b) For additional information ask the relevant association/consortium/supplier or manufacturers

3. Check if the CL Substances are exceeding the 1tpa limit
   a) Use the results of your REACH Inventory and only take into account in the calculation those parts that you produce or import.

NOTE
- To simplify and justify your decision making process, use the substance factsheet on notification which can be found by following the link www.acea.be/reach/publications/notification_factsheets
- In any case, the reasons for your decisions have to be documented

5.10 Communication Requirements for CL 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. In general this means that goods supplied within our supply chain are considered safe.

Article 33 REACH further requires that the supplier of an article (see definition in Chapter 2.1) communicates information available on substances present in the article to the recipient in order to allow its safe use, including, as a minimum, **the name of that substance.**

Communication requirements apply to substances in articles meeting **all** of the following criteria:

- The substance is identified as of very high concern according to Article 57 & 59 REACH (see Chapter 2.1 "Main Definitions" for "SVHC") and **included in the CL** for authorisation
- **The substance is present in the article in a concentration above 0.1% weight by weight.**

For Article 33.1 REACH the information on CL-Substances contained in the article has to be provided automatically to the business-to-business recipient of the article. The following key messages of Article 33.1 REACH can be summarised as follows:

- Legacy parts are within the scope of Article 33.1 REACH
- Packaging is an article, so the presence of a CL-Substance needs to be communicated if it exceeds the 0.1% w/w limit
- Professional customers are to be notified of CL-Substances automatically
- Article 33.1 REACH affects the supply chain even if the parts do not discharge substances into the environment
- It is not sufficient to load all the data on the internet and leave it up customers to find this
- information. A DVD or online catalogue is normally used by the AI when spare parts, are purchased and CL-Substance information displayed next to the part number would be appropriate.
- Exemptions from the duties to communicate do not apply if total CL-Substances in articles are under 1 tonne per year

Article 33.2 of REACH states that the information requirement must extend to consumers upon request. The information must be provided to the consumer free of charge within 45 days of receipt of the request.

In cases where data is not available, a four-step approach is recommended;

- Ask your supplier (if still in business, if not, follow the next steps).
- Undertake a risk based survey type analysis based on your in- house knowledge to arrive at the most likely areas of CL-Substance existence
- Obtain robust and reliable data from similar product groups and then use those findings to infer upon articles where there is no information. This may be called "read across" process.
- As a last resort and in extreme circumstances, laboratory tests can be carried out. At present this is not foreseen as being necessary or appropriate.

If templates are considered helpful please refer to Annex M "Article 33 answer letters"

For more details on AI position regarding Article 33.1 REACH please refer to Annex D "Frequently Asked Questions (FAQ)" and here especially to the Questions 17 to 31.

5.10.1 Recommendation for the Automotive Industry

By taking into consideration all criteria, the following basic strategy for the automotive industry is recommended:

a) Use the Substance Reporting Systems (e.g. IMDS, MACSI) together with a continuously updated declarable substance list (e.g. GADSL). For those companies that do not have an IT-tool available, alternative methods can be used to collect the necessary data.

> **NOTE**
> According to the IMDS rules each user has to check his existing IMDS data whenever a new substance has been added to GADSL (e.g. new CL Substances). In case such a new GADSL substance is hidden behind an IMDS Joker, the user **has to update** his Material Data Sheet by uncovering this substance(s)!

b) By using IMDS it is recommended to avoid the use of wildcards and instead to work with the "confidential substance" functionality.

c) According to AI agreement for assembled parts, communication has to be done on the level of the part number.
As automotive parts are considered safe and information on safe use is given in the parts documentation (e.g. user or workshop manuals) it is in most cases sufficient to provide the name of the substance in order to fulfil obligations under Article 33 REACH.

5.11 Authorisation Procedure

Substances fulfilling the criteria of Article 58 REACH and on the CL will most likely be added to Annex XIV REACH.

In order to ensure "a high level of protection of human health and the environment", REACH Regulation sets up the Authorisation procedure to permit a better management of the risks associated with Annex XIV SVHCs and progressively replace those SVHCs with suitable alternative substances or technologies.

A manufacturer, importer, OR or DU needs an authorisation to place on the market or to use an SVHC on its own, in a mixture, or incorporated into an article which has been included in Annex XIV REACH.

However, using or placing the substance on the market subject to authorisation may continue as long as the so called "sunset date", has not been reached. The sunset date is the date after which the placing on the EEA market and the use of the substance is no longer allowed unless an authorisation has been granted for the specific 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 until a decision about the authorisation has been made (Article 58.1 REACH).

NOTE

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

» 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). As mentioned the "Guidance on the preparation of an application for authorisation" 2011/C 28/01, the term "use" is also defined via "Use Descriptors" system (refer to Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system)

» DUs shall notify the ECHA within three months of first supply of the substance if this substance is used in accordance with the authorisation granted for that use (Article 66.1 REACH).

Authorisation in the supply chain

If you are dealing with a substance included in Annex XIV there are additional obligations.

- Holders of an authorisation, as well as DUs referred to in Article 56(2) REACH including the substances in a mixture, shall include the authorisation number on the label before they place the substance or a mixture containing the substances on the market for an authorised use without prejudice to Directive 67/548/EEC and Directive 1999/45/EC. This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 64(9) REACH.

- DUs using a substance in accordance with Article 56(2) REACH shall notify the ECHA within three months of the first supply of the substance.

- ECHA shall establish and keep up to date a register of DUs who have made an application. ECHA must grant access to this register to the competent authorities of the Member States.

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).

Exemptions to authorisation

(see also further exemptions in Chapter 5.2)

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.
- On-site isolated intermediates and transported isolated intermediates (Article 2(8b) REACH).

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 mixtures (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, CLP which result in the classification of the mixture as dangerous.

NOTE

Authorisation requirements apply to the supply and use of an Annex XIV substance in the EEA (it is clearly stated that after the sunset date the substance can not be placed on the market or used).

It follows that if the substance has been used to produce articles, the substance as such is no longer used and it follows that no authorisation of use (of the substance) is required.

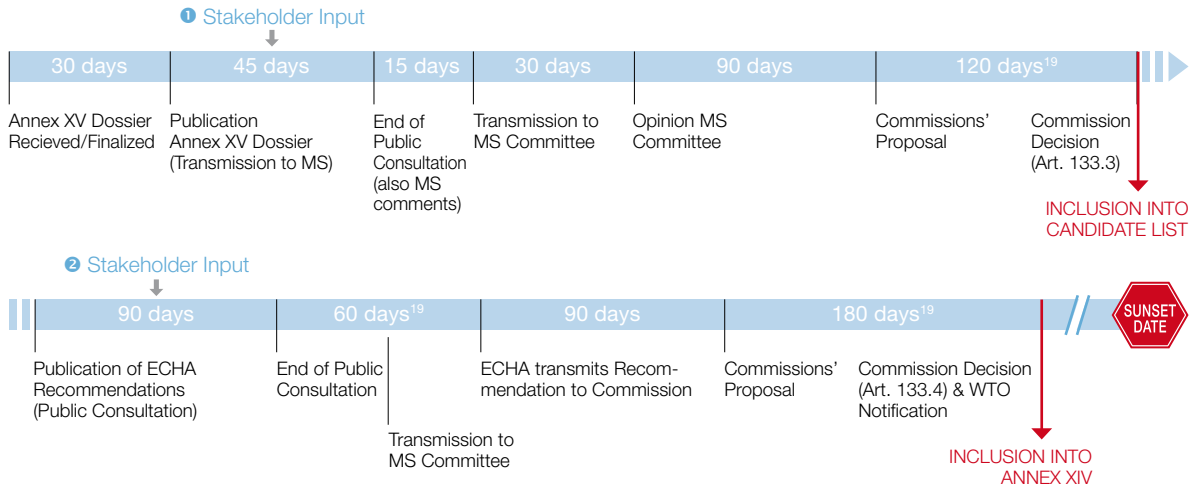
Articles produced in the EEA and held in stock after the relevant substance was included in Annex XIV but before the sunset date

» Authorisation of use of the substance must be sought by the producer who incorporates the Annex XIV substance into the article.

» No obligations for parts held in stock.

Articles in stock produced in the EEA before the sunset date can be supplied after the sunset date.

Articles produced outside the EEA with a Annex XIV substance can be imported into the EEA without authorisation of use.



[19] Minimum estimated

Picture 4.10.1 Main stages of the Authorisation process (Source: CEFIC)

The authorisation process provides two opportunities for stakeholder input.

❶ **First Stakeholder consultation:**
Before including a substance in the CL, the ECHA shall prepare a dossier in accordance with Annex XV REACH. ECHA shall publish a notice on its website that an Annex XV dossier has been prepared. ECHA shall invite all interested parties to submit comments within 45 days to the ECHA (Article 59.4 REACH).

❷ **Second Stakeholder consultation**:
Before ECHA sends its recommendation to the European Commission, it shall make it publicly available on its website. ECHA shall invite all interested parties to submit comments within three months of the publication, in particular on uses which should be exempted from the authorisation requirement (Article 58.2 REACH), before ECHA includes the substance in the Priority List.

NOTE
TF REACH has developed a process (see Annex N– "REACH-GADSL-IMDS FlowChart") which enables the automotive industry to provide in time an industry wide and consolidated input to the stakeholder consultations. Additionally it helps to keep the tools of the automotive industry (GADSL & IMDS) updated with the latest versions of the REACH lists on authorisation and restriction.

An important component of this whole process is the "REACH TF SVHC Survey" which helps to find out in which products SVHCs might be included and where substitutions may have to be started (see Chapter 6; Step 1.3 of the 5 Step compliance schedule and Annex I - How to use the REACH TF SVHC Survey V2_Final.pdf).

The whole process is based on cross company co-operation. However, participating company names are not disclosed. It is highly recommended to support this process and to give input to the survey. As IMDS is the main source for analysis, please make sure that your data is always up-to-date.

Review of an authorisation

The authorisation is regarded as valid until such time as the European Commission refuses to support the authorisation of use. A time-limited review period is not set out in the first publication of Annex XIV. However, if it is necessary to extend the authorisation of use an application must be made by the holder at least 18 months before the stated review date (see also Art. 61 REACH).

For more details, check: Article 64 - Title VII REACH

NOTE
- » DUs should be prepared in case an authorisation of use is not granted and a substitution of an Annex XIV substance is required. DUs should set out their strategy.
- » Following the results of the substances inventory, it is recommended to identify potential critical substances
- » If necessary, data to support authorisation for your use should be gathered.

Others documents on the subject
- Title VII Article 55 to 66 REACH
- ECHA Guidance on Annex XIV inclusion
- ECHA Guidance on identification of SVHCs
- ECHA Guidance on the preparation of an application for Authorisation January 2011
- ECHA Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system

Recommendation for the Automotive Industry

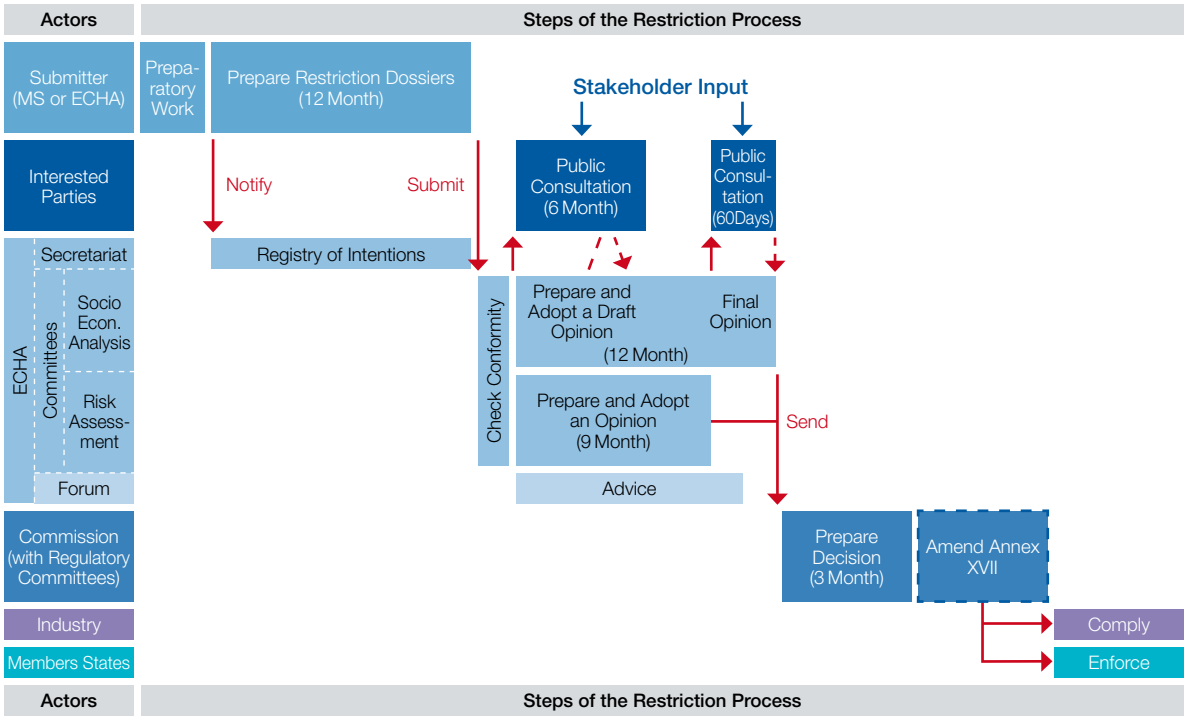
- Limit the use of substances included on the CL for authorisation while ensuring that the technical/quality requirements are met and the socio economic impact of substitutions has been taken into consideration. Thus, substitution must be carried out in agreement between customers and suppliers
- If you use a Annex XIV substance to produce an article make sure that the manufacturer/importer of the substance will authorise your use.
- Add to your supplier contract a clause that obligates the supplier to inform you about their intentions to authorise or substitute the Annex XIV substance.

5.12 Restriction Procedure

REACH foresees a restriction process to regulate the manufacture, placing on the market or use of certain substances if they pose an unacceptable risk to health or the environment. The restriction is designed as a "safety net" to manage risks that are not addressed by the other REACH processes.

Proposals for restrictions can be prepared by Member States or by ECHA on request of the Commission. The Restriction process is described in Title VIII of the REACH and Annex XVII of REACH lists all restricted substances and the conditions of their restrictions under REACH.

Overview on main steps of the Restriction process (Article 69 to 73 REACH), timeline and actors (source ECHA website).



Picture 4.11.1 Main stages of the Restriction process (Source: ECHA)

To facilitate open discussion and dialogue, Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC), ECHA organises public consultation on proposed restrictions. The consultation starts when the REACH Annex XV restriction report is published on the ECHA web page and is open for six months. Interested parties may comment on the proposed restriction and the Annex XV REACH restriction report.

Stakeholders are invited to comment on the Annex XV dossier. It is highly recommended to provide comments within the first three months of the consultation period in order to ensure your opinions and requests are considered by others.

According to Article 68.2 REACH, a substance on its own, in a mixture or in an article which meets the criteria for classification as CMR 1A or 1B, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII REACH shall be amended without following the complete procedure described below (Article 69 to 73 REACH shall not apply), particularly without consulting all interested parties (in accordance with the procedure referred to in Article 133(4) REACH).

Until 1 June 2013, a Member State may maintain any exis-ting and more stringent restrictions in relation to Annex XVII REACH on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. (REACH Title VIII-Chapter 1-Art. 67 REACH - Paragraph 3)

NOTE

Difference between Restriction and Authorisation Process:

The restriction and authorisation processes are related and can in practice have similar effect on the uses. However, they have different scope, the roles of actors differ and the procedures may have different cause. Authorisation can only address SVHCs on the CL as specified by Article 57(a-f) REACH whereas restrictions may be imposed on any substance where there is an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market., This can be addressed on a Community-wide basis (Article 68(1) REACH).

One main difference is that the import into the EEA of articles is not covered by the authorisation obligation (an article imported in EEA, containing a substance in Annex XIV REACH, is not concerned by Authorisation obligation) whereas the Restriction process can cover import of articles.

Substances for which all uses are prohibited under restriction procedure or under other Community legislation shall not be included in Annex XIV REACH or shall be removed from it (Article 58(7) REACH).

Generally, the restriction process is the preferred option in cases where it is justified to prohibit all uses of a substance or to ban some (well known) uses because of unacceptable risks for man or the environment.

Recommendation

Similar to the automotive industry processes for authorisation, the automotive industry is also using for restriction the REACH TF SVHC survey in order to generate an overview of the impact of possible restrictions on automotive business. It is thus recommended to give input to that survey in order to provide a representative overview.

Other documents on the subject

Title VIII Article 67 to 73 REACH

- ECHA Guidance on Annex XV for restrictions
- ECHA Guidance on Socio-Economic Analysis - Restrictions

5.13 REACH and Waste – Impact on the Automotive Industry

The definition of waste reads: "Waste shall mean any substance or object which the holder discards or intends or is required to discard" Article 3.1 Waste Framework Directive 2008/98/EC.

Waste as defined in the Waste Framework Directive is not considered a substance, mixture or article under REACH (Article 2.2 REACH). The reason for that is to ensure workability and to maintain the incentives for waste recycling and recovery (Recital 11 REACH). Consequently REACH requirements do not apply to waste. Nevertheless, this does not mean that waste is totally out of the scope of the Regulation.

According to REACH, manufacturers or importers of a substance, in mixtures or in articles, subject to registration are indeed obliged to take the waste life-cycle stage of the substance into account, where relevant, in particular to create exposure scenarios. That means they have to consider waste produced during the manufacturing and uses of substances. If relevant, waste produced during article manufacturing as well as waste linked to the end of article life containing substances may need to be considered.

As soon as a material ceases to be waste in a recovery process it has to comply with the REACH requirements - with a number of exemptions. Unfortunately at the time of writing there is no clear definition available when waste ceases to be waste with the exception of certain metal scraps (see Council Regulation (EU) No 333/2011 of 31 March 2011 establishing criteria determining when these certain types of scrap metal cease to be waste under Directive 2008/98/EC). Member States may decide on a case by case basis when waste ceases to be waste (Article 6.4 Waste Framework Directive) or criteria for the end of waste status will be developed for specific materials in the future.

Criteria for the defining of waste are given in Article 6.1 Waste Framework Directive:

a) the substance or object is commonly used for specific purposes
b) a market or demand exists for such a substance or object
c) the substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products and
d) the use of the substance or object will not lead to overall adverse environmental or human health impacts

According to Article 2.7(d) REACH, recovered materials can be exempt from registration, communication and evaluation, when the material

- is the same as a substance that has already been registered
- **and** sufficient safety information according to REACH Article 31 or 32 is available for this recovered substance.

That means for recovered material the manufacturer/importer has to ensure that the raw substances have already been registered and a SDS for substances or safety information shall be provided to customers for this recovered material.

Some recovery processes can also limit the obligations under REACH. This is the case for example if at the end of the recovery process, the recovered product can be considered an article. In that case, there is no need to register (except substances intentionally released from that article) since registration is only relevant to substances. But the manufacturer or the importer has to comply with other obligations like Article 33 if relevant.

NOTE
The fulfilment of this obligation is considered to be extremely difficult because in most cases the communication chain between the article producer and the recycler is disrupted. For further information please refer to Annex L7 "Position Paper Spare & Used Parts"

Another exemption covers substances unintentionally recovered in a process. That means if the process is to recover a material like a polymer that contains constituents, intentionally added or not, that are unintended for the recovered material, these constituents can be considered as impurities when they are below 20% w/w. In this case they do not require separate registration on their own. When the recovered material is intentionally selected for the presence of a certain constituent, the constituent is considered a separate substance even when below 20% w/w, for

example a flame retardant in PVC. It may fall under the registration obligation, unless it has been registered before.

NOTE
It must be stressed that even if there is no need to register "impurities", they have to be taken into account for exposure scenarios, SDSs and other risk assessments.

Substances of unknown or variable composition, complex reaction products or biological materials (UVCB substances) may be registered as a single substance under REACH, despite their variable composition, provided that the hazardous properties do not differ significantly and warrant the same classification (Recital 45 REACH). In that case, the manufacturer or importer cannot use the exemption according to Article 2.7(d) REACH.

Annex 1 of the ECHA Guidance on waste and recovered substances, Version 2 dated May 2010 lists particular streams of recovered materials, which may help when deciding whether or not to register a recovered material.

[20] Article 2.2 REACH refers to Directive 2006/12/EC which was repealed on 12 December 2010 and replaced by Directive 2008/98/EC (Waste Framework Directive)

5.14 REACH-EN-FORCE-1 and REACH-EN-FORCE-2 Projects

REACH-EN-FORCE-1 project

REACH-EN-FORCE-1 project was a joint inspection/enforcement project across EEA. Enforcement of REACH and CLP is a national responsibility. Therefore each member of the EEA must ensure that there is an official system of controls. In addition countries have to lay down legislation- specific penalties for non compliance which have to be effective, proportionate and dissuasive (Article 126 REACH). National inspectors checked:

- Pre-registrations
- Registrations
- Provisions for Safety Data Sheets (SDSs) – where applicable

The project gave a first impression of the level of compliance by manufacturers and importers (including ORs) with REACH in the EEA.

National coordinators have overseen the implementation of the project in each participating Member State and provided training for local inspectors.

REACH-EN-FORCE-2 Project

REACH-EN-FORCE-2 project is the second EEA-wide inspection/enforcement project that starts in summer 2011.

It will focus on:

- checking the compliance of DU duties and
- the communication in the supply chain

Previous results from REACH-EN-FORCE-1 project have shown that it is useful to focus more than before on the inspection of company internal information and control mechanisms. Under REACH-EN-FORCE-2 there are also inspections on Article 33 REACH compliance expected.

Recommendations of the Automotive Industry resulting from REACH-EN-FORCE-1 Project and REACH-EN-FORCE-2 Project

- Build up company internal and external information mechanisms with all your suppliers if not already done (see Chapter 5.5.1 “How to communicate with the supply chain”).
- Check company internal processes to ensure that you receive REACH compliant SDSs from all your suppliers e.g. by including a clause in your supplier contract.
- Ensure that you have a database or other storage system where you store all incoming SDSs and all other REACH relevant information (All SDSs for substances and mixtures have to be available in the language(s) of the EEA-Member State where they are put into circulation).
- Make sure, that all relevant information is stored and always available for at least 10 years after last manufacture/import/delivery.
- Check the received SDSs/eSDSs regarding their content consistency/plausibility and their structure (see Chapter 5.5.2). Check that method of working matches what is laid down in the SDS/eSDS and the attached Exposure Scenarios.
- make sure that your customers receive a SDS/eSDS at first supply or every time there is a change in the SDS/eSDS.
- Inform your customers of CL-substances above 0.1% w/w in your articles (Article 33 REACH Information obligation; see Chapter 5.9).
- Inform dealers that they have to take care of all modifications/parts they assemble to the vehicles that have not been delivered to them by the OEM.

Practical REACH-audit example of the automotive industry

An audit at an OEM Distribution Centre was carried out by a Member States Competent Authority. The warehouse of the OEM was inspected and two samples/products (glue and oil) were picked up during the tour through the warehouse. The representatives of the Competent Authority asked to see the related SDS and compared the information on the label with the information in the SDS. The inspectors recalculated the hazard classification and compared their results with the hazard pictogram and statement on the label of the product and it was found to be correct.

NOTE
It is not sufficient to solely place a SDS on a website but to actively provide the SDS to the customer.

5.15 List of ECHA Guidance Documents

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 State authorities, the European Commission, NGOs and industry. Therefore companies and authorities should use the guidance documents as the primary source of information when they need advice on how to fulfil their REACH duties.

NOTE
REACH Guidance documents are subject to change and are not legally binding.

All of the finalised Guidance Documents are available on the ECHA website at: http://guidance.echa.europa.eu/guidance_en.htm

ECHA is currently working on translating documents into all EEA languages. Also, contact your Member State REACH helpdesk for translations.

For further information see Annex G "Helpdesks and Information tools".

CHAPTER 6: AIG 5 STEP REACH COMPLIANCE SCHEDULE

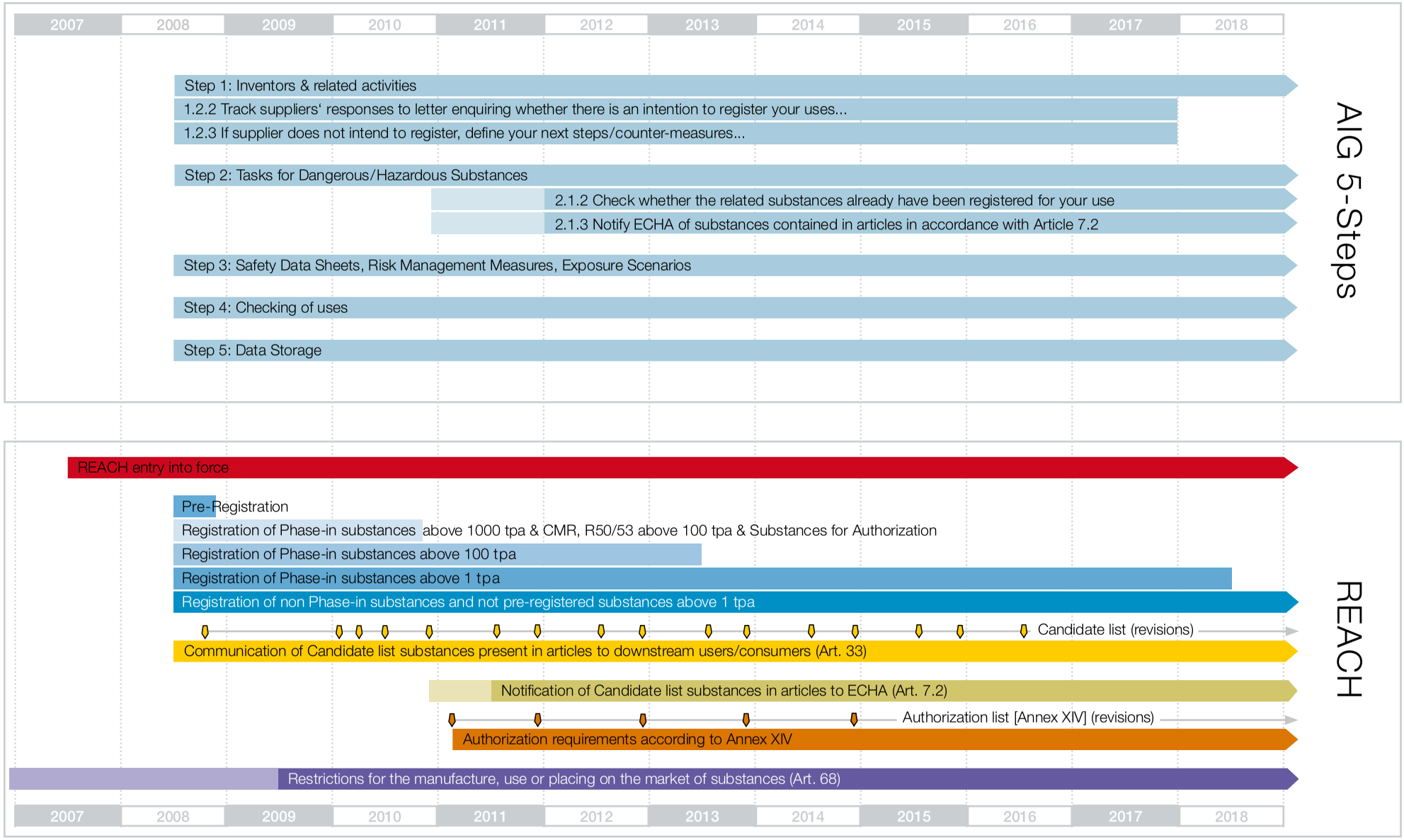
Taking into consideration the results from the AIG Chapters 1-5, the following steps and tasks are recommended for the automotive industry to fulfil the obligations under REACH. As those obligations are the same for suppliers to the automotive industry as well as vehicle manufacturers, indeed every company along the supply chain should proceed as recommended below. Please note that the AIG recommendations are general enough for company-specific interpretations. To get the related Excel file please check the list of Annexes below:

Step		Activities	Recommended Tools	AIG Reference	Timing
1		**General Identification**			
	1.0	General inventory and registration tracking	Declaration of intent request letter & Result of Inventory	Chapter 5.3 Annex C	
	1.1	Make inventory to identify all substances/mixtures you are purchasing within EEA or importing from outside EEA			01/08 - ~
		• Recommended data for inventories, depending on the different roles under REACH ◦ Which substances/mixtures the company purchases from inside EEA and for what purpose they are used? ◦ Which substances/mixtures the company imports from outside the EEA and for what purpose they are used? ◦ For which substances/mixtures the company purchases, SDS are available/not available? • Define/Distinguish whether the substances are in an article (Registration acc. to Art. 7) or in a mixture in a container (Registration acc. to Art. 6) • Which substances are intentionally released from an article that the company produces or imports?			
	1.2	Identify all substances/mixtures where there is NO intention to register them and for your use			01/08 - ~
	1.2.1	Send out letter to suppliers requesting Declaration of Intent			01/08 - ~
	1.2.2	Track suppliers' responses to letter enquiring whether there is an intention to register your uses. Archive records of correspondence.			01/08 - ~
		The major recommendation of the AIG is to ask the non-EEA suppliers to establish an OR within Europe. Regrettably this first priority can not always be adopted. If for example suppliers are not willing to or are unable to establish an OR in the EEA further options have to be considered and could be prioritised as follows: • Priority 1: Ask supplier to establish an OR and to register • Priority 2: Change your supplier or substitute the particular substance/mixture • Priority 3: Register by yourselves on behalf of your supplier or ask a service provider to act on behalf of you. The order especially of priority 2 & 3 is not fixed but depends on the company specific policies and strategies.			
	1.2.3	If supplier does not intend to register, define your next steps/counter-measures and communicate these to both customers & suppliers			01/08 - ~
		Identification of Dangerous/Hazardous substances			
	1.3	Identify Dangerous/Hazardous Substances	ECHA webside on ROI, TF REACH SVHC Survey, GADSL, Material Reporting Systems (IMDS, MACSI, etc.)	Chapters 4.2, 4.4, 4.7, 4,8, 5.7, 5.10, 5.11, 5.12. Annex I, N	
		A dangerous/hazardous substance is fulfilling at least one of the below criteria: • REACH Article 57 (SVHCs) • REACH Article 67 (Restriction) • CLP Regulation and/or the Dangerous Substance Directive			
	1.3.1	Determine which substances are likely to be listed on the current or future Candidate List/Annex XIV and/or Annex XVII by checking the Registry of Intentions (ROI)			10/08 - ~
		Regularly check the ROI under http://echa.europa.eu/chem_data/reg_int_tables/reg_int_curr_int_en.asp for new substance entries			
	1.3.2	Which articles & materials contain substances listed on the current CL/ Annex XIV and/or Annex XVII and on the ROI			10/08 - ~
		Screen your internal databases for the use of the listed dangerous substances. Existing substance reporting systems (e.g. IMDS, MACSI etc.) can be used for inventory. Prerequisite for correct substance reporting is a continuously updated list of declarable substances. When new SVHCs are added to the CL, an update of the reported substance information is necessary. Pre-Condition for compliance is that material reporting is completed!			

1	1.3.3	Provide results of your internal investigation via the TF REACH SVHC Survey to the TF REACH	ECHA webside on ROI, TF REACH SVHC Survey, GADSL, Material Reporting Systems (IMDS, MACSI, etc.)	Chapters 4.2, 4.4, 4.7, 4,8, 5.7, 5.10, 5.11, 5.12. Annex I, N	10/08 - ~
		• The survey is done on basis of the RoI • The survey as well as the relevant user manual can be downloaded under: www.acea.be/reach/publications/Guideline and Annex I. • Within 28 days the completed survey has to be submitted to: SVHC_SURVEY@gmx.de (only one selected person will have access to the address) The information will be treated as confidential. An anonymous summary of all feedbacks will be provided to all supporters • The participation is voluntary but recommendable as this information is needed to decide on further lobbying steps. Additionally it will help each individual company to decide on the impact on their business			
	1.3.4	Assess importance of the substance(s) for your business (e.g. potential risk of supply chain disruption) and evaluate potential counter measures			10/08 - ~
	1.3.5	Check if your identification of potential dangerous substances is correct once the official CL/Annex XIV/Annex XVII is published			10/08 - ~
		Tasks for Dangerous/Hazardous Substances			
2	2.0	Communication	GADSL, Material Reporting Systems (IMDS, MACSI, etc.) Company specific communication tools (e.g. Spare parts catalogue) Art 33.1 FAQ	Chapters 4.8, 5.10 Annex M, P	
	2.0.1	Ensure information is available for CL-substances in articles in accordance with Article 33.1 and proactively provide the data further down your supply chain (to your professional customer)			10/08 - ~
		Non EEA article suppliers do not have to fulfill the REACH obligation to **proactively** provide Art.33 information. The EEA importer therefore has the obligation to actively investigate the presence of CL-Substances included in the imported articles.			
	2.0.2	Ensure information is available for CL-substances in articles in accordance with Article 33.2 and be prepared to provide the data to consumer within 45 days of request.			10/08 - ~
	2.0.3	Ensure information is available for CL-substances in articles in your ware-houses/stocks and in the case of a vehicle manufacturer, to your distributor.			10/08 - ~
		To avoid unnecessary effort, (e.g physical testing of parts or establishing a complete inventory of your stock, check the TF REACH FAQ Document on Article 33 in Annex P			
	2.1	REACH Notification	ECHA webside on registered substances & Substance Fact Sheets	Chapters 4.4, 5.9	
	2.1.1	In your role as manufacturer or importer, identify all substances in articles included in the CL subject to notification requirements under Article 7.2			10/08 - ~
	2.1.2	Check whether the related substances already have been registered for your use			today - ~
		The registration needs not to be done by an actor of your supply chain but could also be made by any other manufacturer or importer of the CL-substance. The use of the affected CL substance must fit with the "use descriptor" of the registered CL substance. To check whether the substance in question has already been registered for your use go to the ECHA website under the following link: http://apps.echa.europa.eu/registered/registered-sub.aspx			
	2.1.3	Notify ECHA of substances contained in articles in accordance with Article 7.2			today - ~
	2.2	Authorisation	SDS management tools, company specific supplier communications	Chapters 4.2, 5.5, 5.6, 5.11	
	2.2.1	After publication/update of Annex XIV, check the sunset and latest application date for each relevant substance.			02/11 - ~
	2.2.2	After publication of Annex XIV: Contact your suppliers to make sure that an apropriate substitute is available or the identified substances (Step 2.0) will be authorised for your use			02/11 - ~
	2.2.3	Formulate company strategy in regard to substitution for relevant Annex XIV substances			02/11 - ~
		According to Art. 55 a substance has to be substituted if there is a suitable alternative available which is economically and technically viable. As Authorisation is also very expensive and will only be granted for a limited time. An option could be to start a substitution process when a substance has been placed in Annex XIV			
	2.2.4	After a substance has been included in Annex XIV: Contact your suppliers if you wish to authorise the use of the relevant substance or make an application yourself. Check SDS for the relevant substances to make sure that the identified substance has been authorised for your use.			02/11 - ~
	2.2.5	After the sunset date an Annex XIV substance cannot be used unless the authorisation of use has been granted unless the Commission has not yet adopted a decision and the application for authorisation of use was made before the final application date.			08/14 - ~

	2.3	Restriction	IMDS combined with In House Tools	Chapters 4.7, 5.12	
	2.3.1	After publication/update of Annex XVII, check whether the conditions of restriction are fulfilled in your process & product			06/07 - ~
	2.3.2	Start internal substitution process for Annex XVII substances if the restriction is relevant or reduce the substance below the stated theshold. Re-validation of the product will be necessary and a new Parts Approval Process (PPAP).			06/07 - ~
		Safety Data Sheets, Risk Management Measures, Exposure Scenarios			
	3.0	Safety Information Documents (Art 32 information, SDS or eSDS)	EDASx & EUPhraC, Already existing internal processes & in house tools	Chapters 4.9, 5.5, 5.6 Annex K, L6	
	3.1	Check safety information documents for errors and shortcomings (plausibility check)			06/07 - ~
	3.1.1	Check whether substances on their own or in mixtures imported or used in the EU production process are listed on the candidate list. See Art. 31.1 c).			10/08 - ~
	3.1.2	Inform Producer (Supplier of substances or mixtures) about critical check results and request an update of the document(s)			06/07 - ~
	3.2	Make Risk Assessment for the Workplace (98/24/EC) also under consideration of the Exposure Scenarios if applicable.			06/07 - ~
3		Exposure Scenarios as part of an extended SDS (eSDS) are available since end of the first registration deadline on 1.12.2010			
	3.2.1	Document the workplace risk assessment (article 4, 98/24)			06/07 - ~
	3.2.2	Communicate risk assessment results to worker (article 8, 98/24)			06/07 - ~
	3.3	Comply with the RMMs mentioned in the safety information documents			06/07 - ~
	3.3.1	Make available SDS for the workforce (Article 35, REACH and Article 8, 98/24)			06/07 - ~
	3.4	Inform supplier about new findings concerning: • Dangerous/Hazardous properties • Insufficient Risk Management Measures (RMMs)			06/07 - ~
	4.0	Checking of uses			
	4.1	Use the substance only as allowed in the extended Safety Data Sheets (eSDS)			06/07 - ~
	4.2	Verify ES if the conditions of your use and your customers uses comply to the prescription of your supplier (Identified Uses)			12/10 - ~
	4.2.1	Check the use descriptors provided in the eSDS with regard to your use			12/10 - ~
4	4.2.2	If your use is covered: No further action on identified uses. If your use is not covered check Chapter 5.5 & 5.6 for further guidance			12/10 - ~
		In order to avoid any discontinuity or disruption to supply of a substance on its own/ in mixtures for their use(s), DUs have to check whether the supplier will support their use(s) and include them in the substance registration dossier to be submitted to ECHA. DU may only use substances on their own/in mixtures 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 the view of having their use(s) included in the supplier's registration dossier. The supplier might be a DU, which, in turn, may decide either to carry out a registration by himself or to communicate the use(s) to his own supplier. The final actor of that chain is the manufacturer/importer or OR of a non Community manufacturer of the substance who may finally carry out the registration obligations.			
		Data Storage			
	5.0	Data Storage	Already existing internal processes & in house tools	Chapters 5.6, 5.15	
5	5.1	Assemble and keep available all the information required to carry out your REACH duties for a period of at least 10 years after the last manufacture, import, supply or use.			06/07 - ~
	5.1.1	Submit this information or make it available without delay upon request to any competent authority of the Member State where you are established or to the ECHA.			06/07 - ~

The chart below is based on the chart presented in Chapter 3. In addition, it highlights the recommended timing for the 5 steps, explained in the matrix above.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AIG 5-Steps
Step 1: Inventors & related activities
1.2.2 Track suppliers' responses to letter enquiring whether there is an intention to register your uses...
1.2.3 If supplier does not intend to register, define your next steps/counter-measures...
Step 2: Tasks for Dangerous/Hazardous Substances
2.1.2 Check whether the related substances already have been registered for your use
2.1.3 Notify ECHA of substances contained in articles in accordance with Article 7.2
Step 3: Safety Data Sheets, Risk Management Measures, Exposure Scenarios
Step 4: Checking of uses
Step 5: Data Storage
REACH
REACH entry into force
Pre-Registration
Registration of Phase-in substances above 1000 tpa & CMR, R50/53 above 100 tpa & Substances for Authorization
Registration of Phase-in substances above 100 tpa
Registration of Phase-in substances above 1 tpa
Registration of non Phase-in substances and not pre-registered substances above 1 tpa
Candidate list (revisions)
Communication of Candidate list substances present in articles to downstream users/consumers (Art. 33)
Notification of Candidate list substances in articles to ECHA (Art. 7.2)
Authorization list [Annex XIV] (revisions)
Authorization requirements according to Annex XIV
Restrictions for the manufacture, use or placing on the market of substances (Art. 68)
2007
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LIST OF ANNEXES

In its chapters, the AIG is referring to a number of additional documents that are useful for further clarification and may serve as tools to simplify the daily work.

Hereafter you will see a list of these documents. You will find these documents included in the zip file. To download it again, please click on www.acea.be/reach/publications/Guideline.

Annex A:	Associations supporting the Task Force REACH (TF-REACH)
Annex B:	Awareness letter
Annex C:	Declaration of intent request letter
Annex D:	Frequently Asked Questions (FAQ)
Annex E:	REACH - Supplier Risk Identification Matrix
Annex F:	List of changes
Annex G:	Authority Helpdesks and Information Tools
Annex H:	Industry Helpdesks and Information Tools
Annex I:	How to use the REACH TF SVHC Survey
Annex J:	REACH-EN-FORCE-2 projects
Annex K:	SDS matrix
Annex L:	Summary of Automotive Industry position papers & Communications
Annex M:	Art 33 answer letters
Annex N:	REACH-GADSL-IMDS Flow Chart
Annex O:	AIG 5 step compliance schedule in Excel
Annex P:	Article 33 FAQ

The Automotive Industry Guideline is developed by:

ACEA European Automobile Manufacturers Association

ICAMA

JAMA Japan Automobile Manufacturers Association, Inc.

CLEPA European Association of Automotive Suppliers

VDA Verband der Automobilindustrie

BIL Sweden

AIAG Automotive Industry Action Group

Comité des Constructeurs Français d'Automobiles

SMMT Driving the Motor Industry