AUTOMOTIVE INDUSTRY GUIDELINE ON

REACH

VERSION 4.0

THE AUTOMOTIVE INDUSTRY GUIDELINE IS DEVELOPED BY:

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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 their suppliers. Under REACH, Substances of Very High Concern (SVHCs) 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 doing 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 3.1 in June 2012 the REACH process has passed some important milestones such as the continuous growth of the Candidate List (hereinafter CL) and the Annex XIV Authorisation List. Also the term "article" has been redefined by the EU Court of Justice. Furthermore under authorisation first sunset dates have passed and applications for authorisation have been granted to industry. Also experience was gained from the first and second registration deadlines. 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 another update of the AIG would be helpful for vehicle manufacturers and the automotive industry supply chain to benefit from this broad experience.

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 SVHCs 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/complex objects (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 (DUs) 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 (OR) 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.

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

- Chapter 6 of the AIG summarises the main obligations and recommendations for the AI response to REACH along with a timeline for each activity. These activities are broadly grouped into the 5-step REACH compliance schedule (see Annex C) 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/Ext-SDS requirements with a focus on DU. This chapter is followed by information about CLP and the notification duties.

This Guideline 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.

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 EU 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 the EU antitrust laws.

13 June 2018


» COMPLIANCE

The Registration, Evaluation, Authorisation (and Restriction) of Chemicals (REACH) Regulation (EC) No 1907/2006 entered into force on the 1st of 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, AIAG, BIL, CLEPA, JAMA, KAMA, and VDA 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 Guideline are based on consensus between all Task Force members, not on a majority voting system.

This Guideline 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 Chemicals Agency (ECHA) Guidance Documents 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 Guideline 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 including all implementing legislation can be found at: https://echa.europa.eu/regulations/reach/legislation.

This Guideline should be used in conjunction with the current REACH Regulation and ECHA guidance documents in order to understand the specific legal obligations of each member (actor) in the automotive industry supply chain.

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 this 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 this Guideline can be found in Annex T of this Guideline.

Updates that are agreed by the TF-REACH after the publication of the latest version of the AIG-REACH will be collected and published in the meantime in Annex S to this Guideline.

[2] See Annex A, "Associations supporting the Task Force REACH (TF-REACH)" 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[3] was adopted into European Community (EC) 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 an EU or EC 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 should follow the ACEA sustainable substitution criteria (see Annex 0) and 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" (Art. 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 their 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 adapt 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 mixtures and in articles, but there are exemptions for radioactive substances, non-isolated intermediates, substances used during transportation, and waste (Art. 2 REACH). These are covered by other existing regulations. Member States may also grant exemptions for substances used in the interest of defence.

Under REACH, manufacturers and importers have a duty to register 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 substances 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

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

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 and importers of articles (e.g. screw, fastener) or complex objects (e.g. car, engine, bumper), 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 for which 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 (SVHCs) 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 builds on the legislation regarding restriction, classification and labelling of dangerous substances that was 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 as well as to harmonised substance classifications fulfilling the criteria of Art. 57 REACH which defines a Substance of Very High Concern (SVHC).

REACH Review

Art. 138 REACH calls on the Commission to carry out different reviews to assess whether or not to amend the scope of REACH e.g. with regard to the scope of Art. 33, of Chemical Safety Assessments, of registration duties for polymers, of the PBT/vPvB Criteria, etc. On the basis of such a review, the Commission may, if appropriate, present a legislative proposal.

[4] For more information see: https://ec.europa.eu/growth/sectors/chemicals/classification-labelling_en

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" (Art. 3.17 REACH).

Article
means "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition" (Art. 3.3 REACH).

NOTE

Articles and complex objects

After REACH came into force, there was disagreement among the EU Member State Competent Authorities on how to interpret the obligations of Art. 7. (Notification) and Art. 33 (Communication) as to whether complex objects that are made of two or more components are themselves "articles", or whether "article" only refers to the individual components.

An important judgment by the European Court of Justice (ECJ) on this question concluded: "… there is no need to draw a distinction … between the situation of articles incorporated as a component of a complex product and that of articles present in an isolated manner." (ECJ Case C 106/14 Judgment, 10 September 2015)

In other words, the term "article" is now taken to mean a simple object in isolation (e.g. a bolt), or that same simple object when it is part of a complex object (e.g. a bolt used as a component in an engine). This principle is often referred to as "Once An Article, Always An Article", or "OAA" and applies according to our understanding not only to Art. 33 (Communication) or 7.2 (Notification) but to the whole REACH Regulation (e.g. including the Annex XVII Restrictions).

Although in practice the word "article" is still commonly used for vehicles themselves, or for complex vehicle parts such as headlamps or engines, after the ECJ judgment, these are no longer understood to be covered by the REACH definition of "articles", and are more correctly referred to as "complex objects" or "complex products".

For clarity, this Guideline uses the following terms:

1. "Article" as a simple object in isolation
2. "Complex object" when referring to an assembly of two or more articles.

We understand that this article definition applies to the complete REACH regulation.

Borderline cases

When an article or complex object contains an integral substance or mixture, a determination must be made as to whether the object is more correctly classed as an article or as a substance/mixture in a container. Examples according to TF-REACH understanding are shown below.

Article	Steel coil, screw, bolt, pin of a resistor
Complex objects (with integrated substance/mixture)	Airbag module, engine (containing oil), battery (high-voltage for electric vehicle, or lead-acid type)
Complex objects	Vehicle, seat, wiper assembly, headlamp, resistor, printed circuit board assembly (PCBA)
Substance/mixture in a container (which should be regarded as a separate article/ complex object)	Touch-up paint sticks, liquid tyre repair kit, cleaning agents in cans, engine oil in cans, spray can with aerosol paint spray, desiccant bags
Substance/mixture	Steel ingot, engine oil, adhesive, brake fluid

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

Community
when used in the REACH text, means the European Union (EU), previously known as the European Community (EC), and refers to the Member States of the EU. In practice the EEA countries are also covered wherever the REACH Regulation or this Guideline refer to the "Community".

Competent authority

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

Complex object

is not defined in the REACH Regulation, but is the term used by ECHA to refer to an assembly of two or more articles, whether joined mechanically or chemically, and is used in this Guideline in preference to the term "Complex Product", which is the term used by the European Court of Justice (see "Article" above). The term "very complex object" is used in by ECHA, but this is not well defined and the requirements are identical to those for complex objects, so the term "very complex object" is not used further in this Guideline.

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 Art. 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 (Ext-SDS).

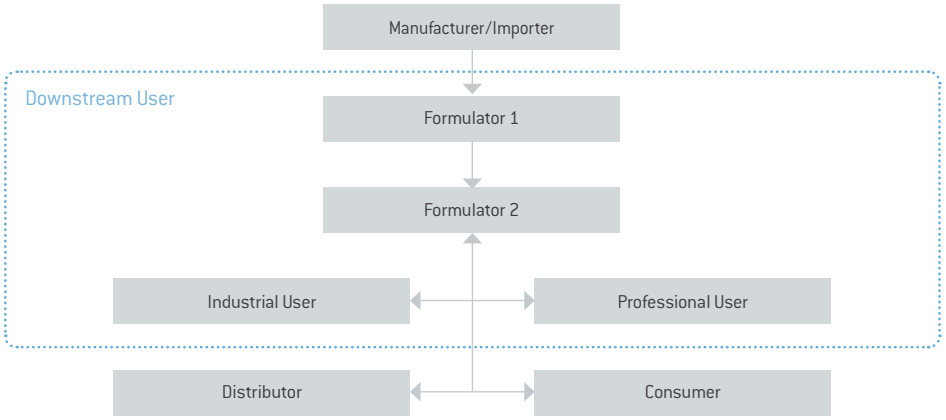
Distributor

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" (Art. 3.14 REACH).

Downstream user (DU)

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 Art. 2.7.c REACH shall be regarded as a downstream user" (Art. 3.13 REACH).

> NOTE
> If you manufacture complex objects only by assembling other complex objects and/or articles (sub-components) without using substances or mixtures, you are not considered a downstream user (of substances) 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 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 this Guideline (see also the definition for importer).

Exposure scenario (ES)

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" (Art. 3.37 REACH).

Extended safety data sheet (Ext-SDS)

The basic SDS comprises 16 sections (Annex II REACH). An extended safety data sheet is a basic SDS that has one or more exposure scenarios (ESs) added, either by integrating into the 16 sections as appropriate, or added as an annex to the basic SDS. Exposure scenario(s) for mixtures do not exist, because mixtures are not themselves subject to REACH registration and no chemical safety report is legally required for them. However, SDSs for mixtures may have attached "Safe Use Mixtures Information" (SUMI), in which the ES information of several ingredients is consolidated. In the following chapters, wherever Ext-SDSs or ESs are mentioned, they can also be understood to include SUMIs where applicable for mixtures.

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 (see ECHA Guidance on information requirements and chemical safety assessment).

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. They can be found at https://echa.europa.eu/guidance-documents

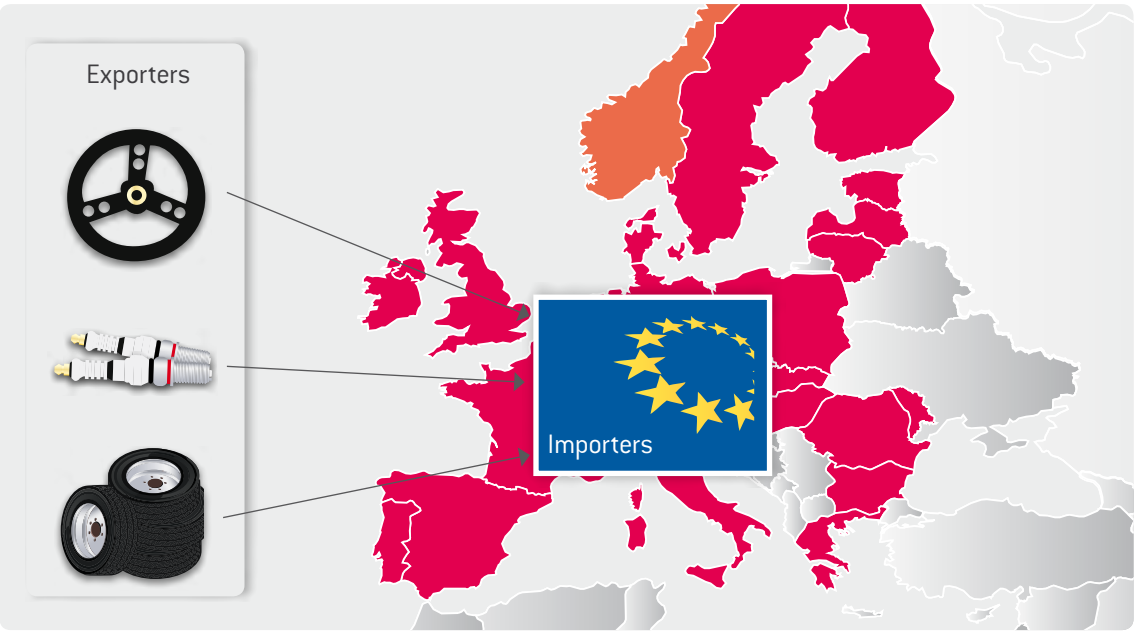
Hazardous substance

is the term used for a substance that meets 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" (Art. 3.26 REACH).

[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 see Chapter 5.6.



Picture 2.1.2 Importers Definition
Iceland, Liechtenstein and Norway (which are members of the European Economic Area but not European Union Member; Switzerland should be considered as an exporter) had implemented REACH so that substances supplied from these countries are not considered imports.

Import

means "the physical introduction into the customs territory of the Community" (Art. 3.10 REACH).

Importer

means "any natural or legal person established within the Community who is responsible for import" (Art. 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 its main. 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 as an article with intended release of a substance/mixture.

A list of automotive industry specific examples of intended release is given in Chapter 5.8.

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.
- 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"): (Art. 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.

Latest application date

date by when the application for authorisation has to be sent to ECHA at the latest to ensure that the substance is allowed to be used if the sunset date passed and the decision on authorisation is still pending; usually 18 months before the sunset date.

Legacy (spare) parts

means non-current vehicle components whose original supplier has ceased trading due to liquidation or bankruptcy and therefore no longer exists as a legal entity. In this instance there is no data available on the materials or specifications involved, and no entity to approach to obtain this information. Frequently, these parts have been subject to an all-time buy that was arranged before the supplier disappeared.

Legal entity

means any individual, partnership, proprietorship, corporation, association or other organisation 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" (Art. 3.9 REACH).

Manufacturing

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

Mixture

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

Example: Paint, lubricant, adhesive, windshield-washer fluid, engine oil, steel or brass alloy

(Art. 3.41 REACH and ECHA Guidance on requirements for substances in 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" (Art. 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 DUs have to ensure that their nanomaterials do not adversely affect human health or the environment". It is recommended to check the official EU Commission web site for further information at the following address: http://ec.europa.eu/environment/chemicals/nanotech/index_en.htm.

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 placed on the market prior to the entry into force of REACH.

Notified substance

means "a substance for which a notification[6] has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC" (Art. 3.21 REACH). Notified substances have an ELINCS number.

Only Representative (OR)

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 (Art. 8.1 REACH). The Only Representative can represent

[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.

one or several manufacturers, formulators, or producers of articles outside the EEA and exporting to the EEA.

Per year

means per calendar year.

Persistent 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, the POP Regulation generally takes precedence over REACH. REACH authorisation therefore 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 Art. 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.

Similarly, once a substance is added to the EU POP Regulation, restrictions under REACH Annex XVII on that substance and all its granted exemptions will be superseded by the related obligations of the POP Regulation. This may result in more stringent obligations, for example through the loss of exemptions.

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 Art. 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 (Art. 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 01 January 1971 to 18 September 1981. Their identifying number was called "EINECS number" and is now called "EC-number".

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 Art. 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.

Both lists are accessible via: https://echa.europa.eu/information-on-chemicals/ec-inventory

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" (Art. 3.12 REACH).

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

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" (Art. 3.5. REACH).

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 (surfactants) that have neither an EC nor an NLP number. Therefore dummy EC numbers were allocated to them starting with "600". https://echa.europa.eu/information-on-chemicals/ec-inventory

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.

Printed circuit board assembly (PCBA)

is a printed circuit board (PCB) populated with mounted and/or interconnected electronic components. (A PCB is a printed board used to mechanically support electronic components, and providing both electrical point to point connections and printed components in a predetermined arrangement, using conductive pathways, or traces, e.g. etched from copper sheets laminated onto a non-conductive substrate.)

Producer of an article

means "any natural or legal person who makes or assembles an article within the Community" (Art. 3.4 REACH).

Example: Vehicle manufacturer, parts manufacturer (e.g. engine, component, bolt).

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" (Art. 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" (Art. 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 or buys regular vehicles for company fleet use. 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.

Registrant

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

Registrant's own use

means "an industrial or professional use by the registrant" (Art. 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, i.e. 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 (Art. 2.7.c REACH, Guidance on Registration, item 1.6.4.6)

Repair as produced

means ACEA, JAMA, KAMA, CLEPA position in the context of REACH regulation for authorisation procedure on the basis of the "repair as produced" principle as exempted under End-of-Life Vehicle Directive 2000/53/EC (i.e. all new material restrictions in the ELV Directive have a "repair as produced" exemption for spare parts that were not originally designed to be compliant with the new material restrictions). Substances for spare parts that are manufactured after the sunset date, and which are used for vehicles that ceased production before the sunset date, should be exempted from the provisions of Art. 56 REACH.

Safety data sheet (SDS)

means the document defined in Annex II REACH, which is intended under REACH and other European legislation to be the primary means of transmitting data about chemical hazards along the supply chain.

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" (Art. 3.23 REACH).

Site

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

Specific environmental release categories (SpERC)

are required for obtaining more realistic Tier 1 emission estimates for substance uses in the chemical industry and its downstream users than those provided by ERCs.

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" (Art. 3.1 REACH). Example: methane, hydrocarbons, sulphuric acid, ethanol, calcium carbonate, silicon dioxide, elemental metals such as copper and 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 Art. 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 Art. 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" (Art. 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" (Art. 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 utilisation" (Art. 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" (Art. 3.38 REACH).

2.2 Acronyms & Initialisms

ACEA
European Automobile Manufacturers Association

AfA
Application for Authorisation

AI
Automotive Industry

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 (or CLS)
Substance 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 Chemicals Agency

ECJ
European Court of Justice

EDAS
Electronic data exchange of safety data sheets (superseded by SDSComXML)

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)

ERC
Environmental Release Categories

ES
Exposure Scenario

Ext-SDS
Extended Safety Data Sheet (see also SDS)

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

GHS
Globally Harmonised System for classification and labelling of chemicals https://ec.europa.eu/growth/sectors/chemicals/classification-labelling_en

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

OSA
Once An Article, Always An Article
(see also Chapter 2.1. "Article")

OC
Operational Conditions

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

OR
Only Representative

OSOR
One Substance, One Registration

PBT
Persistent, Bio-accumulative and Toxic

PCBA
Printed Circuit Board Assembly

PNEC
Predicted No Effect Concentration

PPORD
Product and Process Oriented Research and Development

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

RMM
Risk Management Measures

RMO
Risk Management Option

RMOA
Risk Management Option Analysis

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

SDS
Safety Data Sheet (see also Ext-SDS)

SDSComXML
It is an interface for structured data exchange on XML format basis.

SIEF
Substance Information Exchange Forum

SMMT
Society of Motor Manufacturers and Traders, UK

SpERC
Specific Environmental Release Categories

SUMI
Safe Use Mixtures Information

SVHC
Substance of Very High Concern

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 (Art. 7.2 REACH) which were included into the CL before 1st December 2010.
- ECHA will accept notification before the 1st of June 2011.
- Warning: Information requirements to downstream users (Art. 33 REACH) apply as of inclusion on the CL

As of 1 June 2011

- Notification of substances in articles 6 months after they have been included in the CL (Art. 7.8 REACH).

2012

By 31 May 2012

- DU to make their use(s) known (in writing) to the substance supplier in order to make it an identified use (Art. 37.3 REACH)

As of 1 December 2012

- The use of the new CLP safety data sheet format is obligatory for substances.

2013

By 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 (Art. 23.2 REACH).
- Safety data sheets for registered substances must be extended with exposure scenarios for all identified uses (Art. 14 REACH).

2015

As of 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

By 31 May 2017

- DU to make their uses known in writing to the substance supplier in order to make them identified uses (Art. 37.3 REACH)

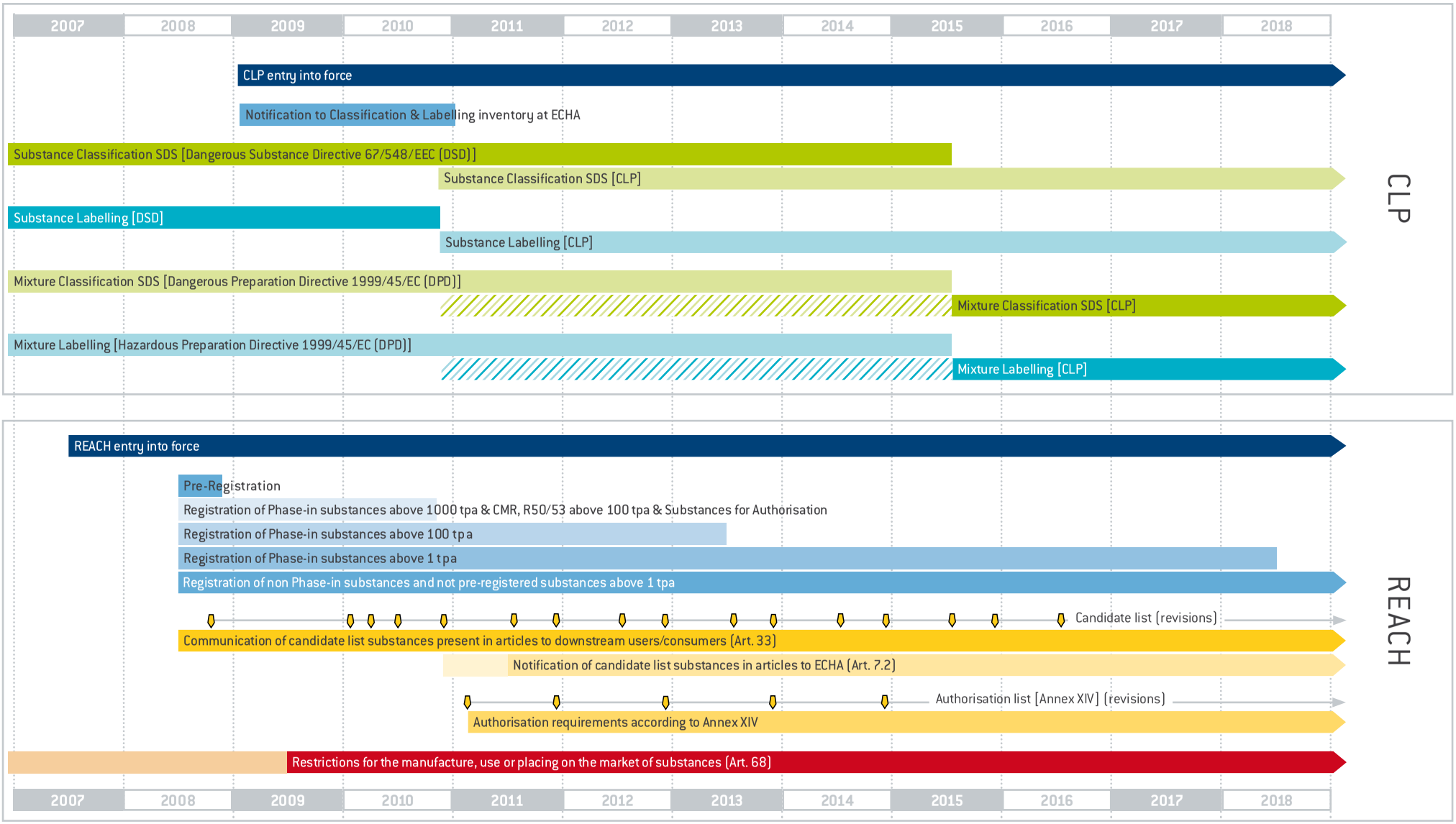
As of 1 June 2017

- End of transition period for mixtures in warehouses with pre-CLP labelling.

2018

By 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 (Art. 23.3 REACH).
- Safety data sheets for registered substances must be extended with exposure scenarios for all identified uses (Art. 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 Authorisation
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)
Authorisation list [Annex XIV] (revisions)
Authorisation requirements according to Annex XIV
Restrictions for the manufacture, use or placing on the market of substances (Art. 68)
REACH


0
20
40
60
80
100
% REACH
COMPLIANCE
8

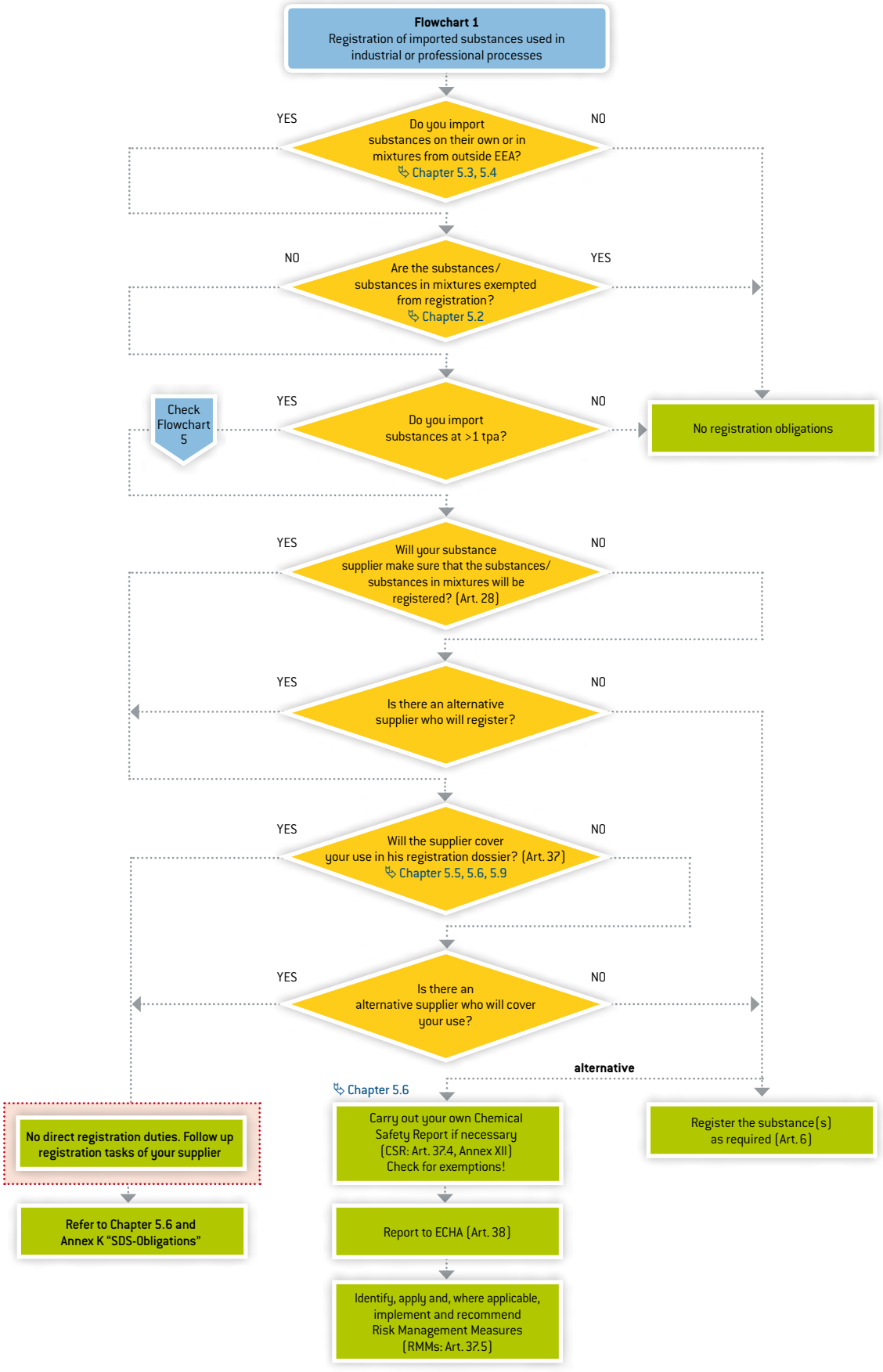
CHAPTER 4:
REACH COMPLIANCE - A STEP-BY-STEP PROCESS

The following flowcharts have been constructed to help companies determine what their obligations are under REACH. Flowcharts 1 to 9 should be viewed as complimenting each other. Where such guidelines exist, references to them have been integrated in the flowcharts and the AIG 5-step REACH compliance schedule (Chapter 6).

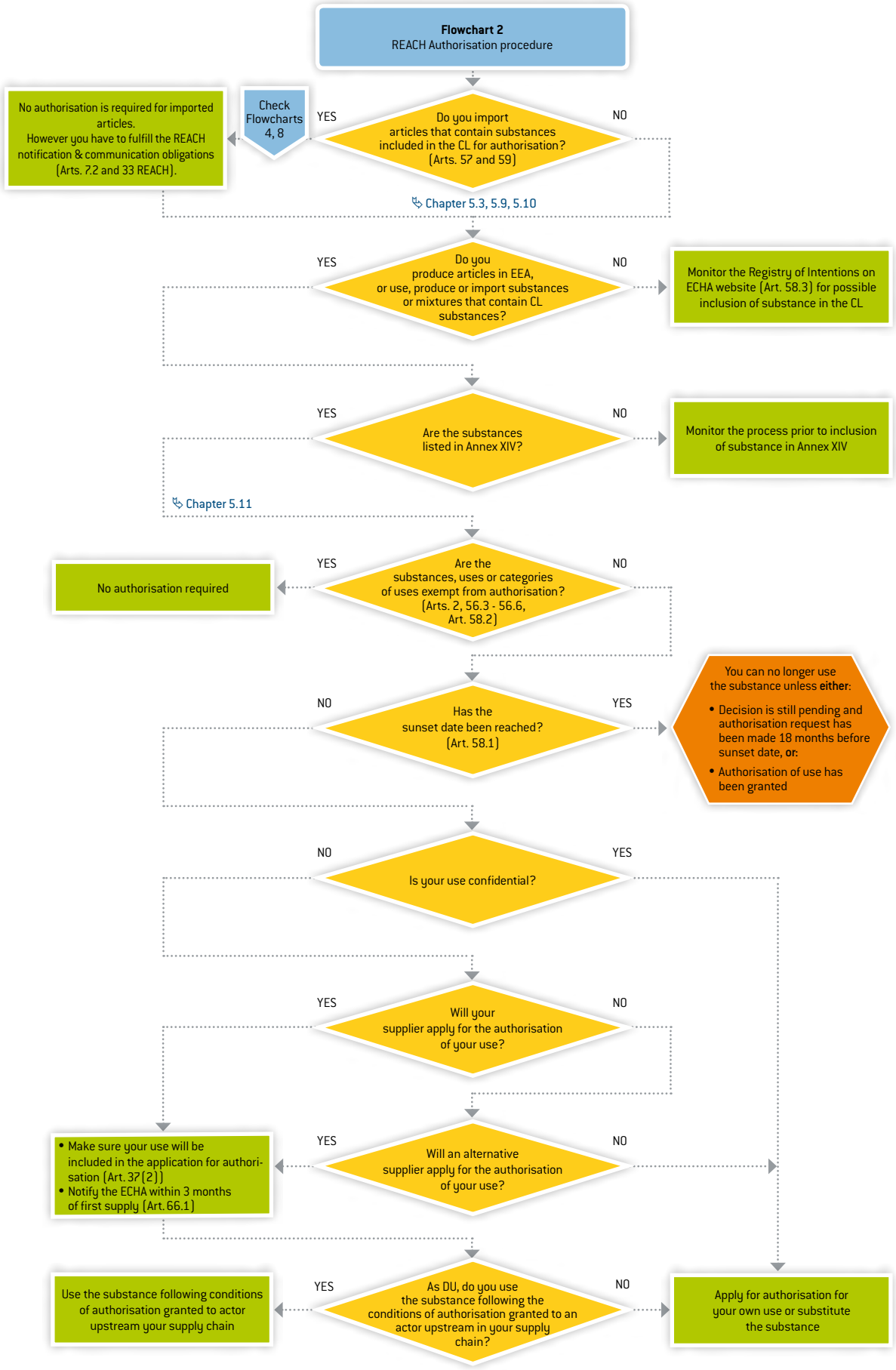
For the following REACH tasks, a flowchart has been developed. To directly jump into a specific subject, you can click on one of them in the list below:

4.0 Flowchart navigator

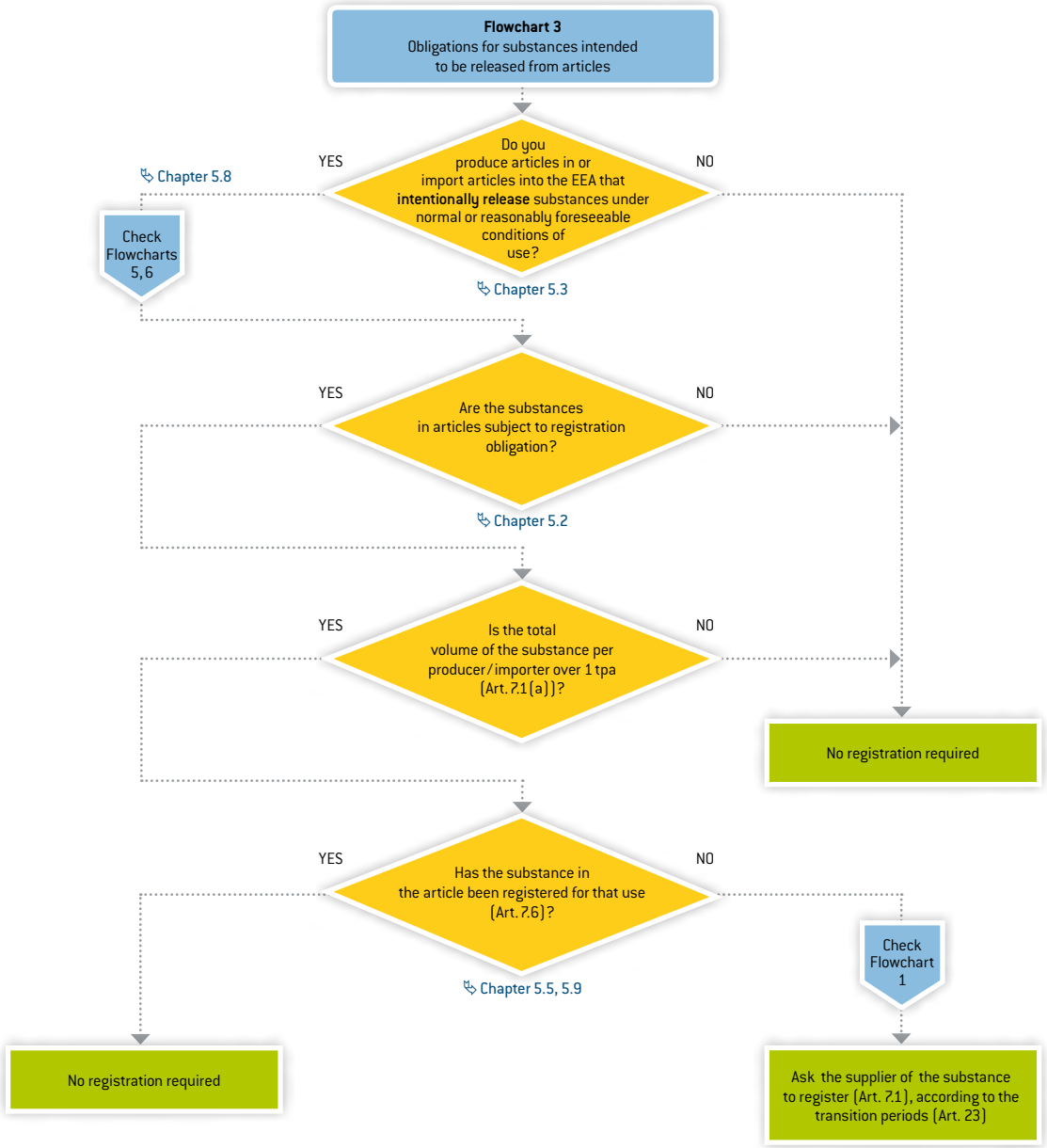
4.1 Registration of substances/substances in mixtures used in industrial (including engineering) processes



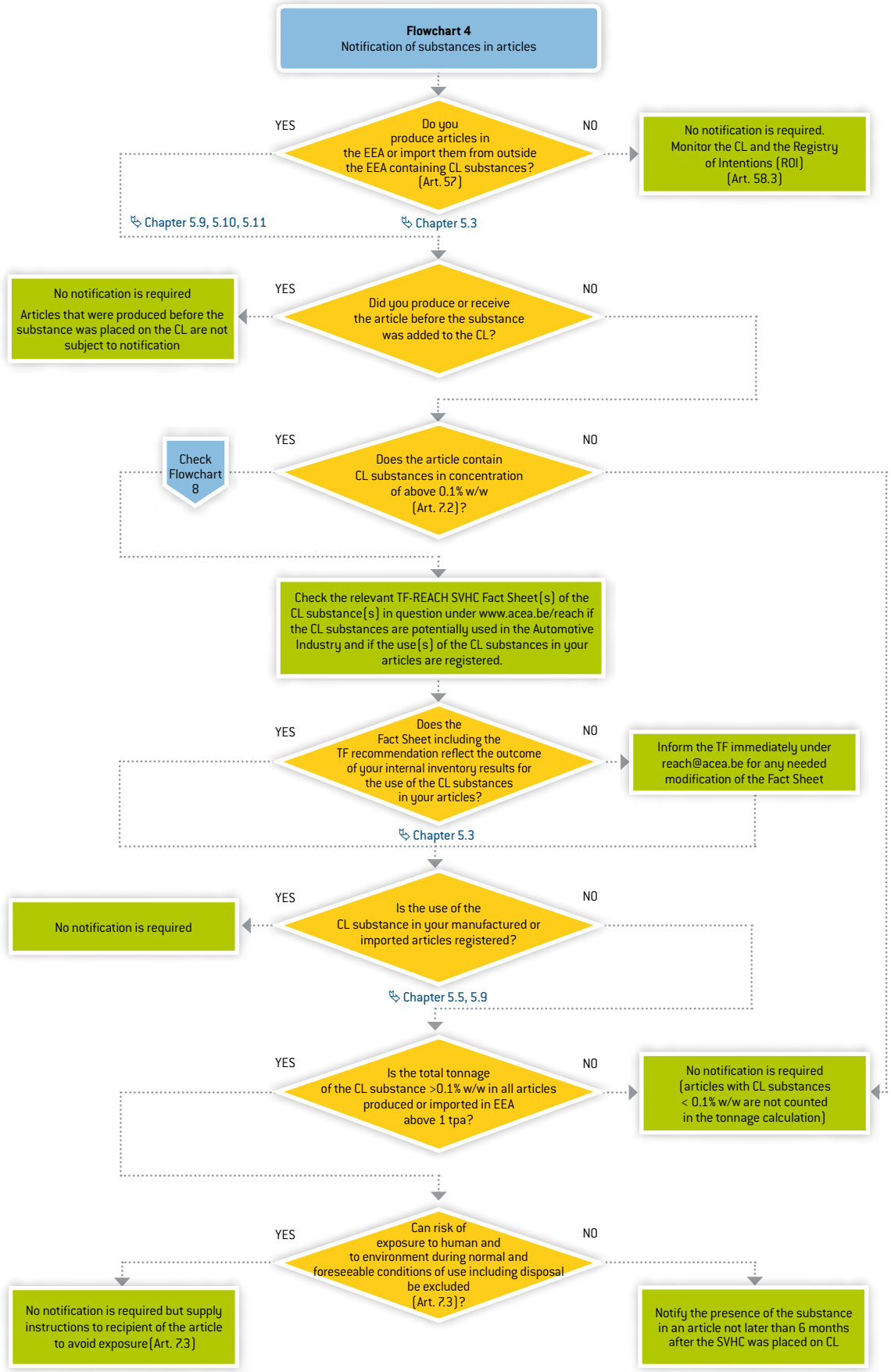
4.2 REACH authorisation procedures



4.3 Registration of substances intended to be released from articles

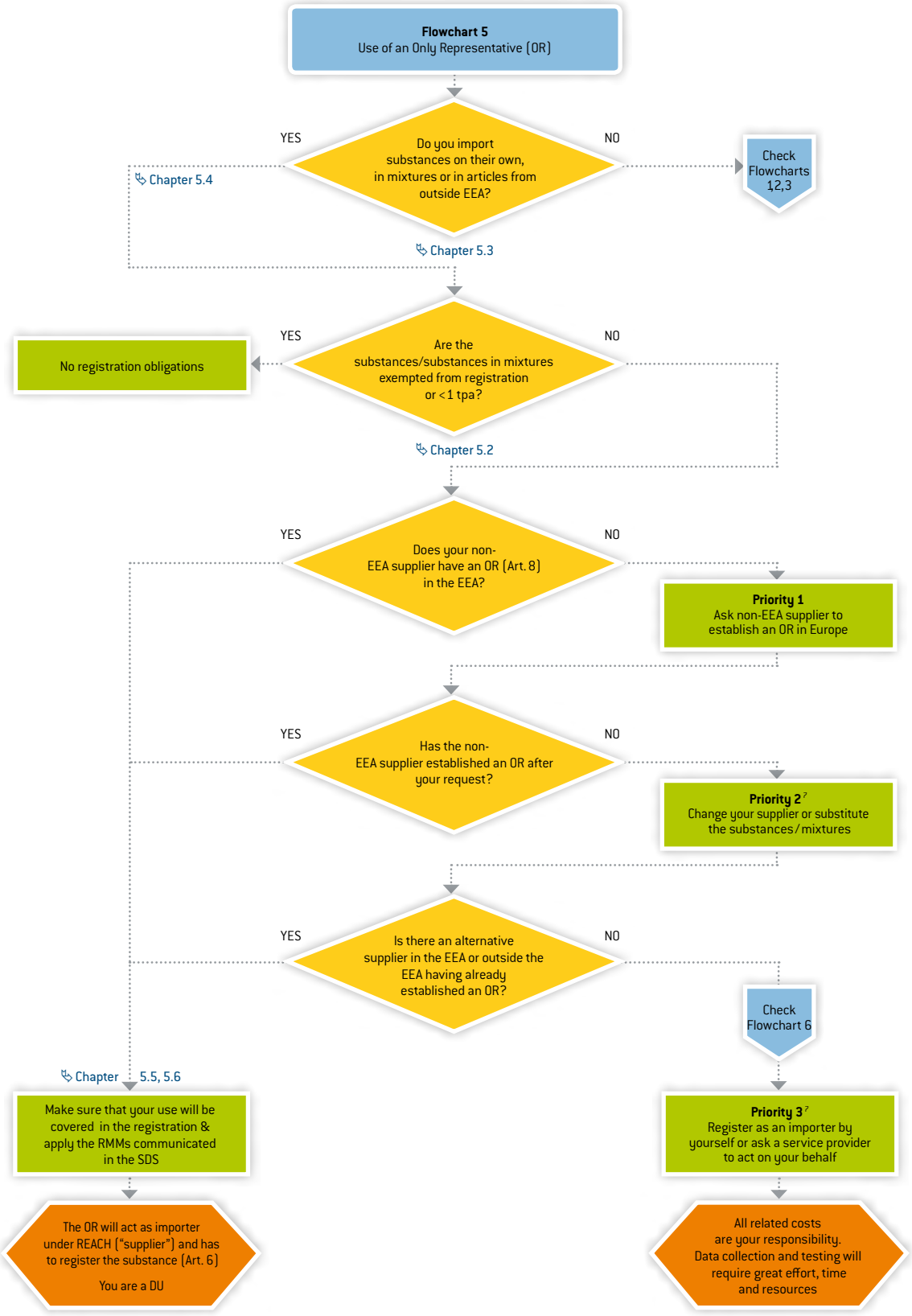


4.4 REACH notification of substances in articles



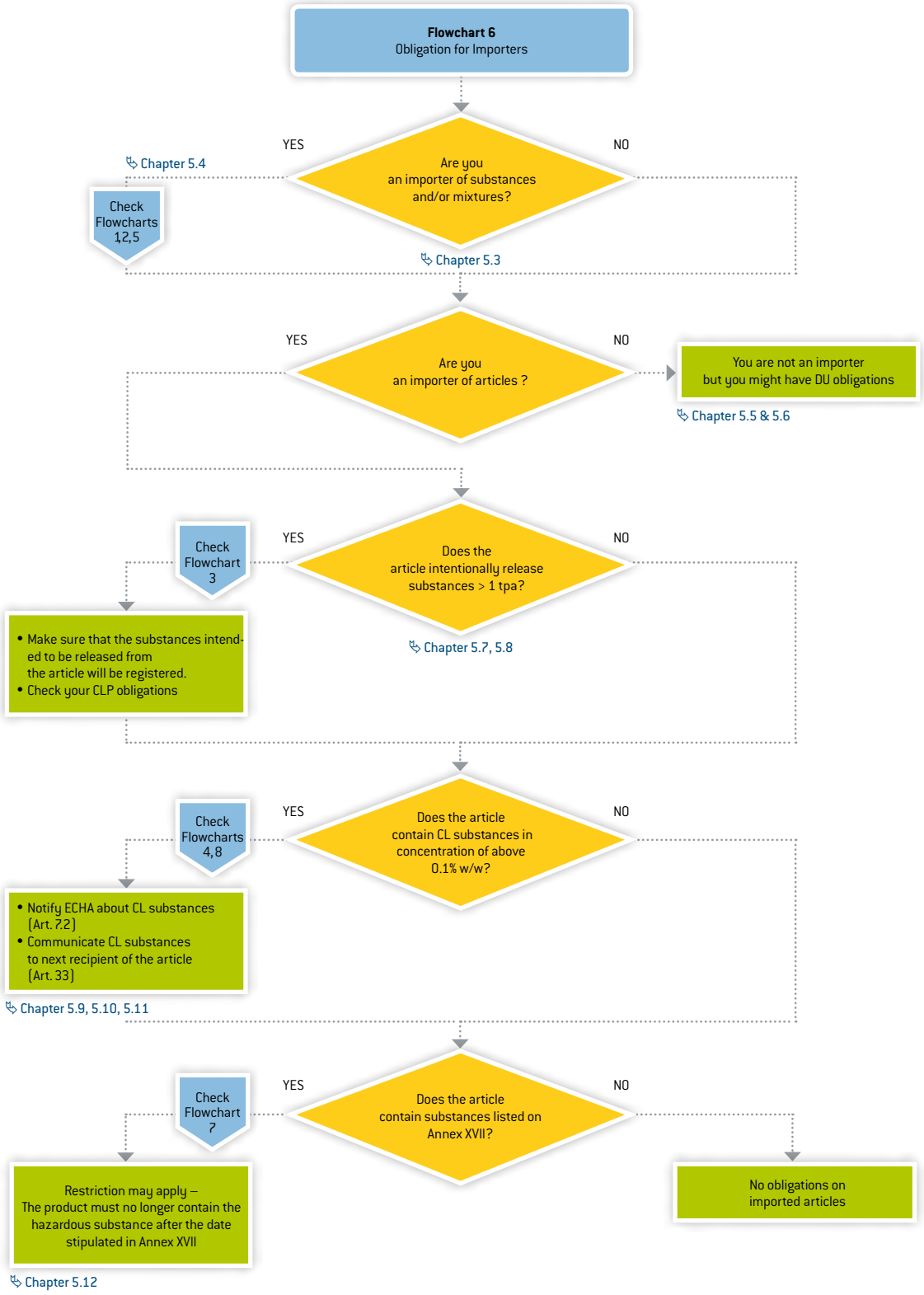
Working assumptions: see AIG Chapeter 5.9 "Notification of CL Substances in Articles"

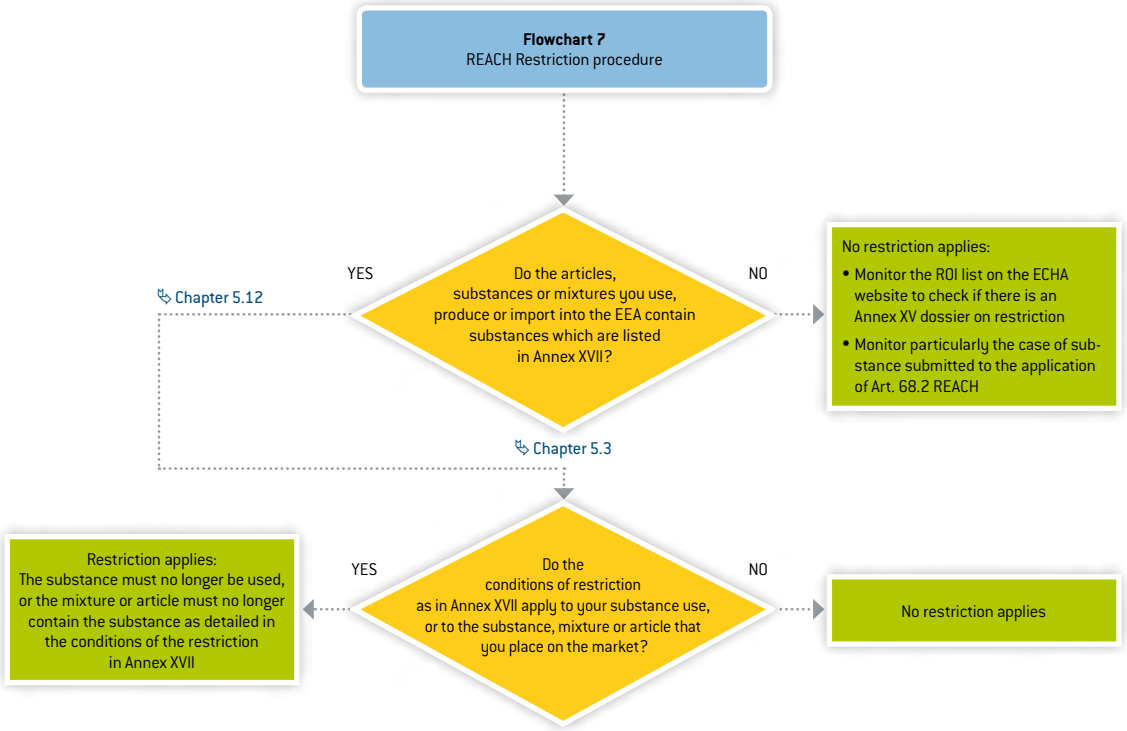
4.5 Use of the Only Representative



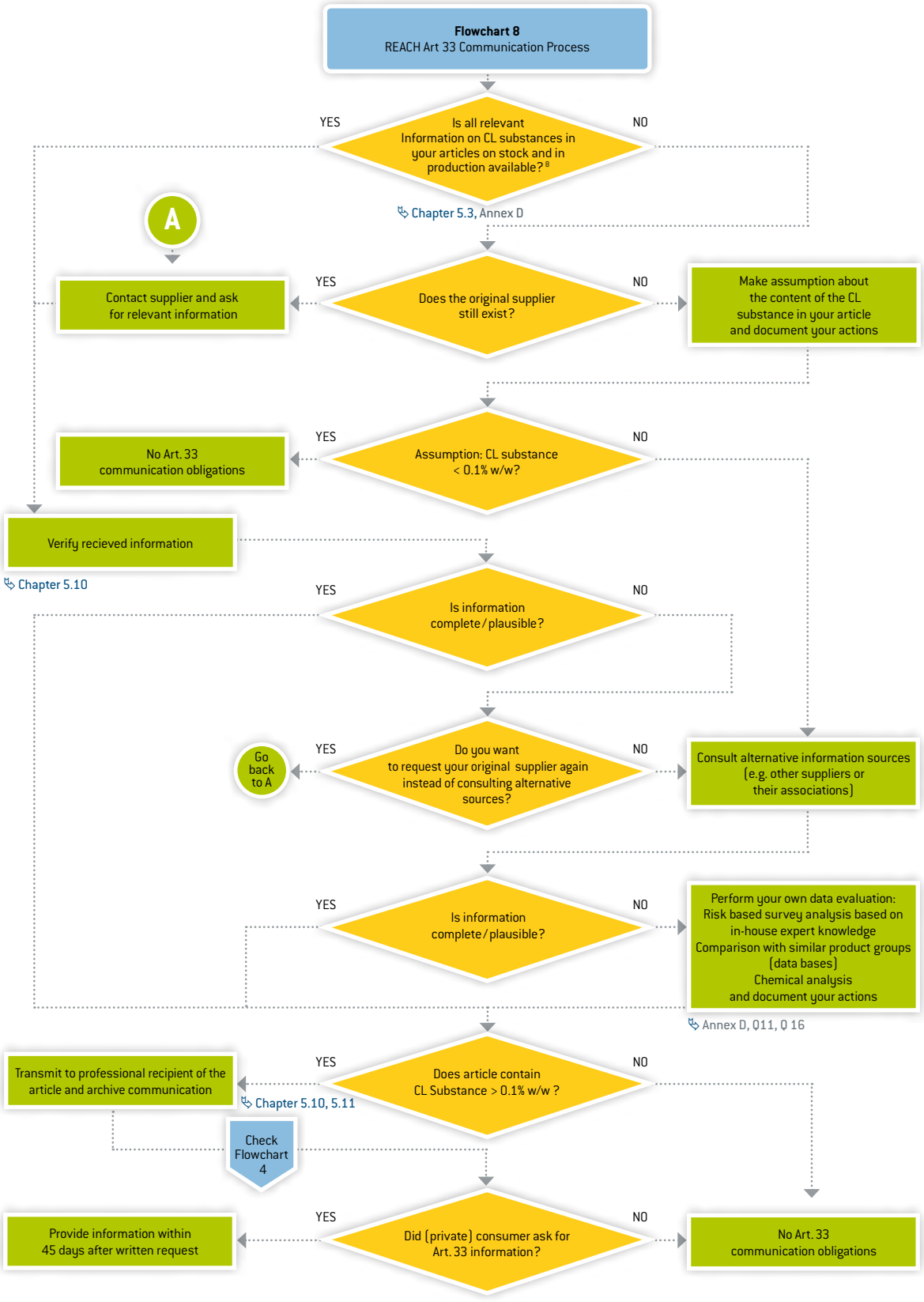
7 The order especially of Priority 2 & 3 is not fixed but depends on the company-specific policies and strategies.

4.6 Obligations for importers



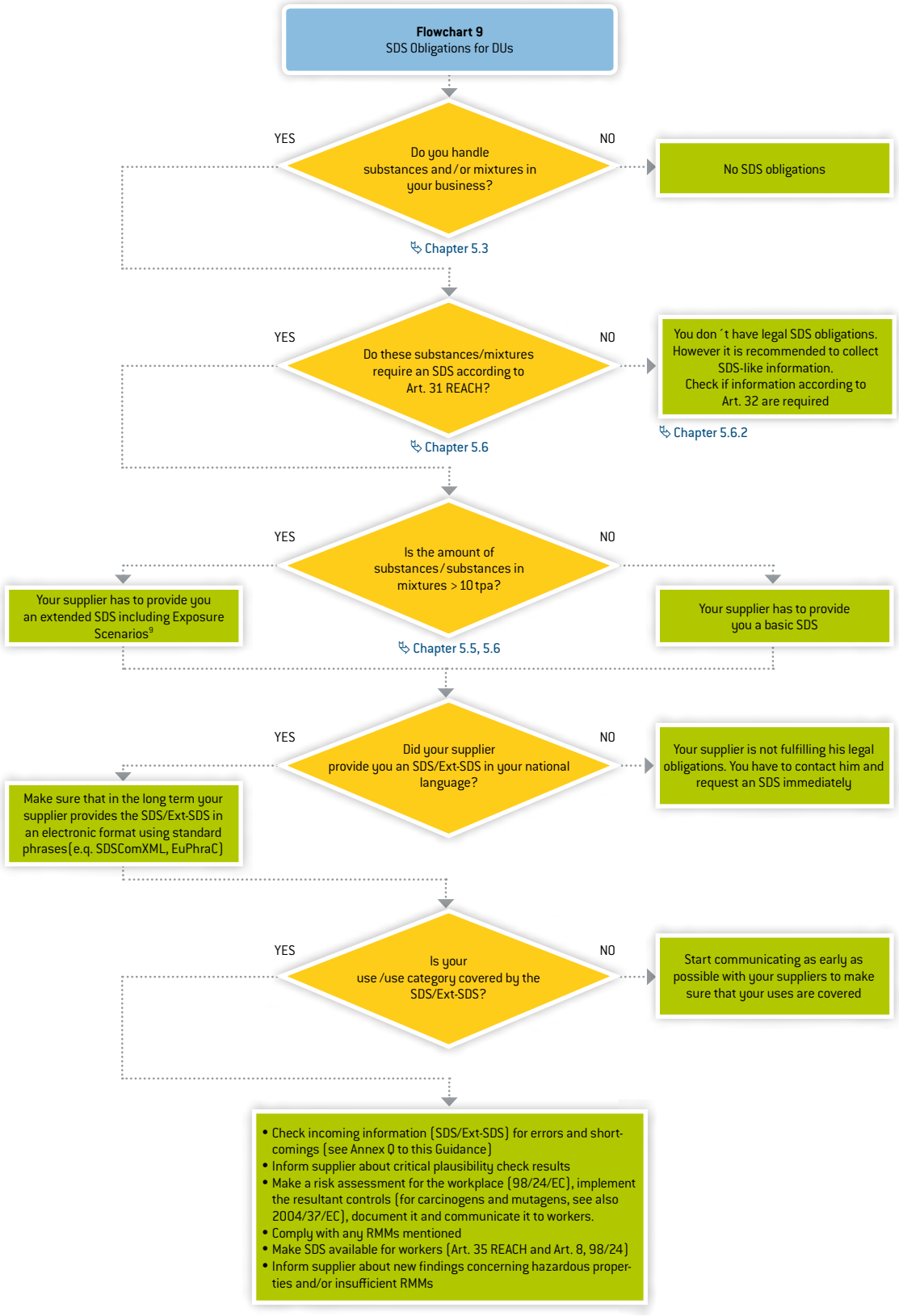

Flowchart 7
REACH Restriction procedure
Do the articles, substances or mixtures you use, produce or import into the EEA contain substances which are listed in Annex XVII?
YES
NO
Chapter 5.12
No restriction applies:
• Monitor the ROI list on the ECHA website to check if there is an Annex XV dossier on restriction
• Monitor particularly the case of substance submitted to the application of Art. 68.2 REACH
Chapter 5.3
Do the conditions of restriction as in Annex XVII apply to your substance use, or to the substance, mixture or article that you place on the market?
YES
NO
Restriction applies:
The substance must no longer be used, or the mixture or article must no longer contain the substance as detailed in the conditions of the restriction in Annex XVII
No restriction applies

4.8 REACH Art. 33 communication



[8]
- Information on CL substance > 0.1 % w/w should be delivered automatically by your supplier (e.g. IMDS Material Data Sheet)
- For in-house manufactured parts the same information has to be available

4.9 SDS obligations for DUs



[9] Please note that exposure scenarios only exist for substances, not for mixtures, but you may receive a Safe-Use Mixtures Information (SUMI) for the mixture or scenarios for the individual ingredients of the mixture

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 have 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/Flowchart 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 "OR" 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 "OR" of the non-EEA supplier appointed. If no intentional release, importers still bear the obligations of DUs	See Chapters 5.8, 5.9, 5.10

Table 5.1.1 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 no 4 REACH). Further exemptions from registration of substances resulting from a chemical reaction that 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 remain 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 Art. 3 REACH. These provisions 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, since this is not a substance, mixture or article within the meaning of Art. 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) do 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 Art. 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 must in this case notify certain information to ECHA (Art. 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 Art. 8 and 9 REACH. They are also exempted from authorisation (Art. 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 (Art. 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 residual monomer content.

For exemptions from authorisation, please refer to Chapter 5.11.

For more details, please refer to:
Art. 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 articles. 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 5.6).
  An efficient way to collect data is to request suppliers to deliver SDSs/Ext-SDSs (or SDS-like documents) for all substances and mixtures, regardless 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 substances/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, are SDSs/Ext-SDSs are available/not available?**
  For hazardous substances/mixtures that fulfil certain criteria, the supplier has to provide SDSs/Ext-SDSs. If you have received such SDSs/Ext-SDSs, 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 5.6)

- **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 5.8).

- **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**
  - Art. 57 REACH (SVHCs)
  - Art. 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 (Art. 7.2 REACH: See Chapter 5.9), Communication (Art. 33 REACH: See Chapter 5.10), Authorisation (Art. 56 REACH, Annex XIV: See Chapter 5.11) and Restriction (Art. 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 Art. 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			
Mixtures 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 5.3.1 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[10]:

- 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
  (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 5.9 & 5.10).

[10] 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" (Art. 3.10 REACH). The importer is further defined as any natural or legal person established within the Community who is responsible for the import" (Art. 3.11 REACH). Substances on their own, in mixtures and in articles that 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 5.8). 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":
Art. 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 DUs 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 (Art. 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 Art. 56 REACH). See Chapter 5.11.
- Import articles with CL substances included above 0.1% w/w, to be supplied to the next recipient in the EEA (communication according to Art. 33 REACH). See Chapter 5.10.
- Import articles with CL Substances included above 0.1% w/w and exceeding 1 tonne per year per importer (notification requirement according to Art. 7 REACH). See Chapter 5.9.
- 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 Art. 7.1 REACH). See also Chapter 5.8.
- Provide SDSs/Ext-SDSs 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 mixture 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 that requires an SDS/Ext-SDS have the responsibility for its contents, even though they may not have prepared the SDS/Ext-SDS themselves. See Chapter 5.6.2

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 a substance either on its own, in a mixture or in an article 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 (Art. 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 exporters, 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 Guideline, 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 this Guideline 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.

- **Priority1**: Ask non-EEA supplier to establish an OR and to register
- **Priority2**: Change suppliers or substitute the substance/mixture
- **Priority3**: 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, and information on the supply of the latest update of the SDS/Ext-SDS. 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 who 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) (Art. 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, which 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 (Art. 7.2 REACH), communication (Art. 33 REACH), authorisation (Art. 56 REACH), SDS obligations (Art. 31 REACH), etc.)


IMPORT

5.5 Downstream user obligations according to REACH Title V

In REACH Title V (Art. 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 downstream users" provides assistance with all tasks.
Table 5 of the guidance document provides an overview in regard to possible obligations related to different roles.
In Chapters 3 and 4 of the guidance document, 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 registered 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 Ext-SDS. Such Ext-SDS 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 basic 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 > 10tpa: Ext-SDS including Use Descriptors (detailed information)

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

NOTE
DUs are obliged to understand the REACH communication tools (e.g. SDS/Ext-SDS, use descriptors, exposure scenarios etc.). Thus, it is highly recommended that DUs learn how to read the information in the SDS/Ext-SDS 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 identified uses. 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 must 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 (Art. 37.2 REACH) if necessary.

The deadline for this feedback communication was 1 year before the relevant registration deadline.
For any new registration after May 2018 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 Art. 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 ECHA and the downstream user with the reason(s) for that decision in writing (Art. 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 5.6.3 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) that needs only to be checked for completeness i.e. that 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 (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:

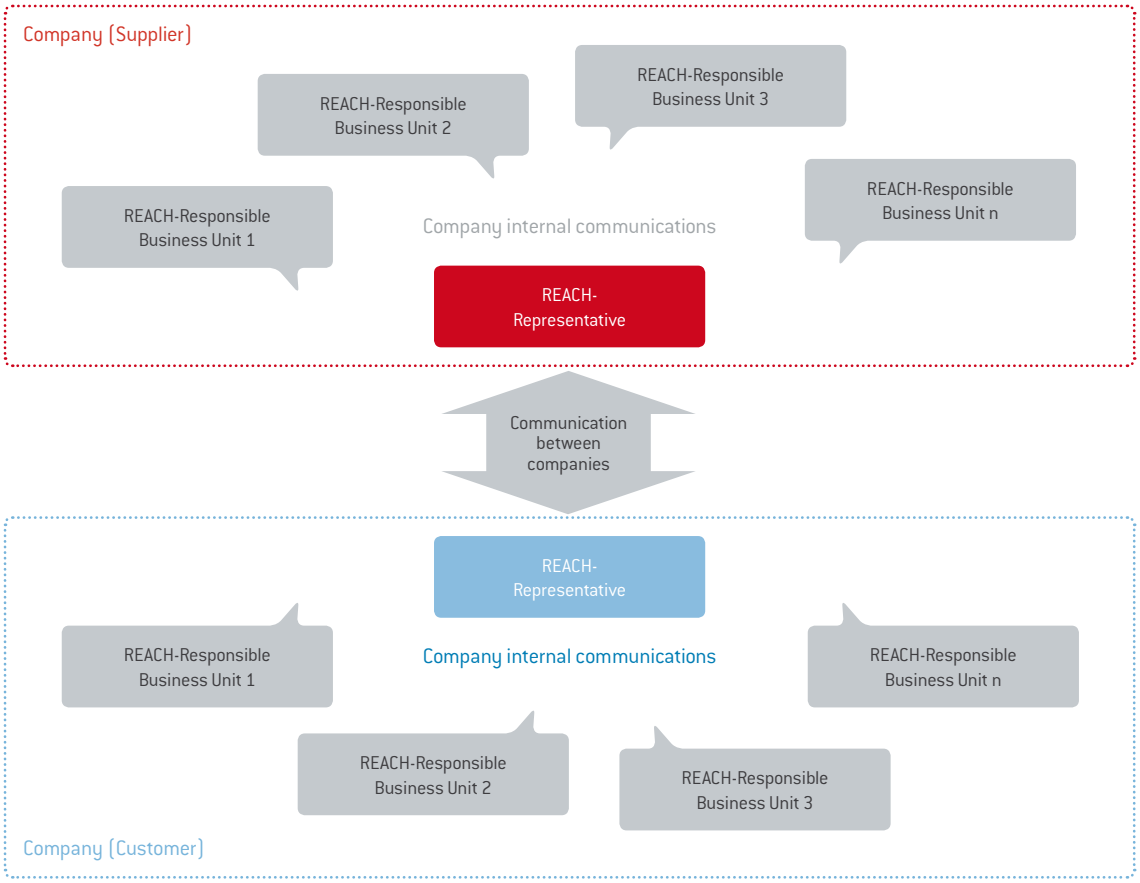
- As a first step, identify the substances and substances in mixtures used in their industrial processes (see Chapter 5.3).
- As a second step, if the supplier intends to carry out registration procedures, ask whether the supplier has already established use and exposure scenarios covering their use(s).
- DU may also check SDSs/Ext-SDSs 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 proactive 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 soon 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 Ext-SDS.

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 5.5.2.1 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 any of the following criteria:

- classification as hazardous according to CLP;
- persistent, bioaccumulative and toxic (PBT) according to REACH Annex VIII;
- very persistent and very bioaccumulative (vPvB) according to REACH Annex VIII;
- included in the CL for authorisation for any other reason; or
- under certain conditions some mixtures which do not meet the criteria for classification as hazardous (Art. 31.3 REACH).

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

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

NOTE
The automotive industry recommends using the standard phrases provided by 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 Art. 31.7 REACH, registrants and users that had to prepare a CSR must place the relevant exposure scenario(s) into an annex of the SDS which then becomes an Ext-SDS. A DU has to take into consideration relevant exposure information received from suppliers when compiling his Ext-SDS.

The SDS is intended for professional DUs 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.

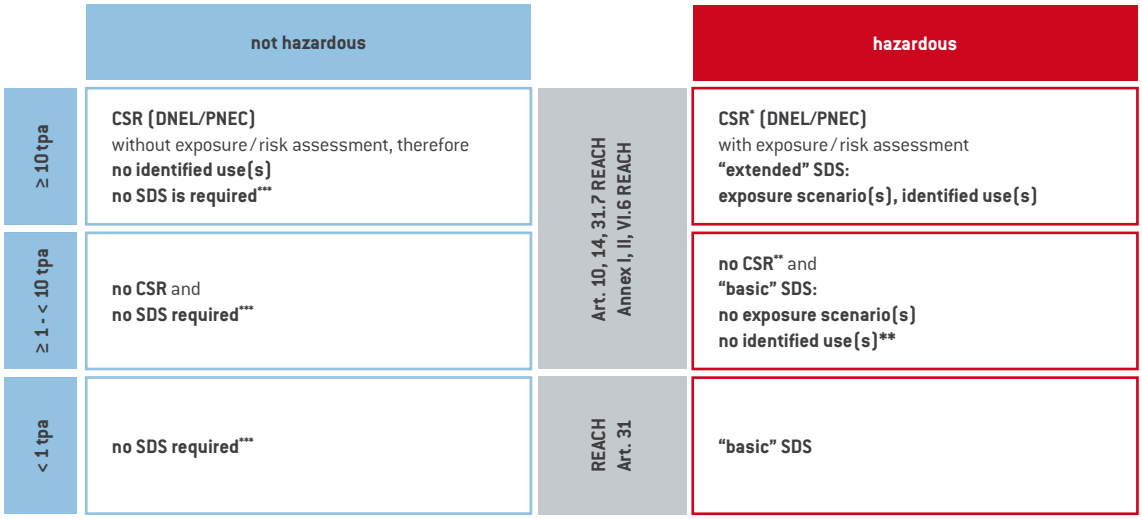
Any updated information on authorisation, restriction or risk management measures must be made available by the supplier to all former recipients to whom they have supplied the substance or mixture within the 12 preceding months. It should be made available free of charge, on paper or preferably electronically. Any updates following registration must 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 (Art. 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 P:



Picture 5.6.1 Overview about the registration and communication requirements for a substance

* 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.

** Information according to Art. 10 REACH and in addition according to Annex VI (6) i.e. exposure related information (use and exposure categories).

*** 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 Art. 32 REACH might have to be communicated along the supply chain.

5.6.1 DU OBLIGATIONS FOR AN SDS

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

Upon receipt of an SDS/Ext-SDS, 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 (Art. 31.5 REACH) can the SDS be in another language[11]. It should be noted that it is for the recipient Member State to provide otherwise.
- Whether an exposure scenario (ES) or safe use mixtures information (SUMI) is attached to the Ext-SDS and whether it corresponds to the DU's use of the product.
- Whether the information mentioned in the SDS/Ext-SDS 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/Ext-SDS 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 Art. 38.4 REACH the DU must 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 Art. 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.

See Annex Q to this Guideline for more details.

[11] Source: ECHA Guidance on the compilation of safety data sheets.

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

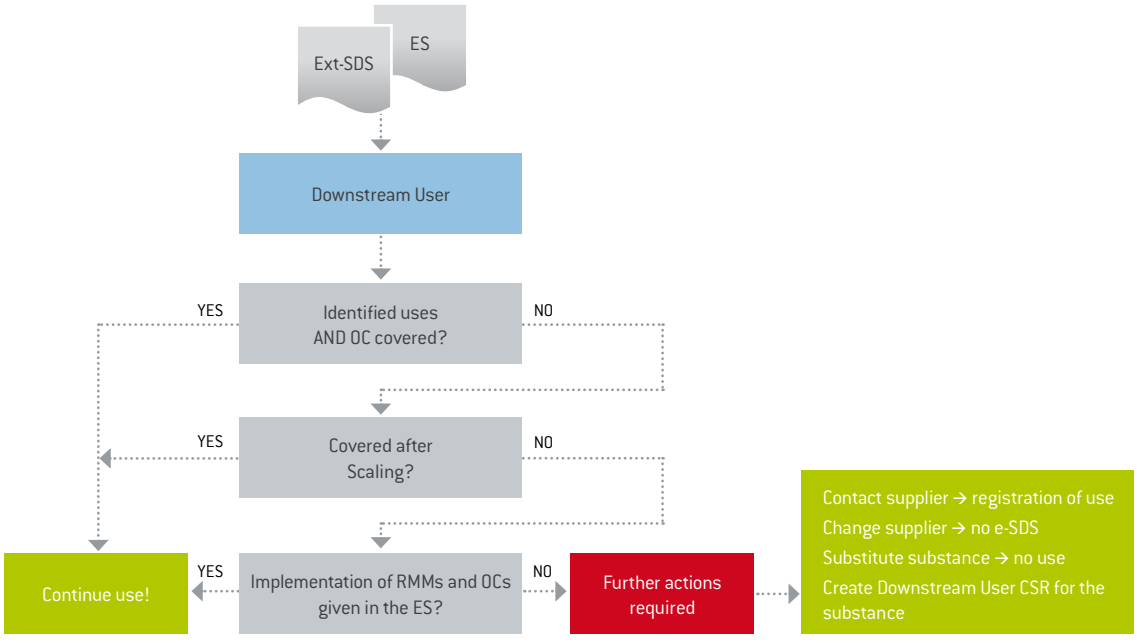
Option 1

For all hazardous substances that are manufactured or imported by a single legal entity at above 10 tpa (for example technical gases like ammonia or solvents like isopropanol) the DU will receive an Ext-SDS for the substance. Ext-SDSs mainly differ from "basic" SDSs 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 Ext-SDS, he has to check whether the current use is covered and whether his workplace and environmental risk assessment and the RMMs 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).
- DU may prepare a CSR according to Art. 37.4 REACH and notify ECHA of the additional use(s) as described in Art. 38.1 REACH. Note that the DU does not have to prepare a CSR if his use is less than 1 tpa (Art. 37.4.c REACH), but in this case he needs to notify ECHA that he is taking advantage of this exception (Art. 38.1.b 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 5.6.1.1 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 Ext-SDS 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 that 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 Ext-SDS only. There may be a possibility that identified uses appear to be covered in such an Ext-SDS 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[12]). In those cases the obligations according to REACH Title V have to be considered.

Option 2

For mixtures (e.g. coatings) containing hazardous substances that are manufactured or imported by a single legal entity at above ≥ 10 tpa, two kinds of SDS are legally possible (2a or 2b below). A third option was developed by industry experts (2c):

a) A "basic" SDS for the mixture without any ES attachment and where all RMMs for safe handling are included in the main body.

NOTE

This is the recommended option for communication of SDSs 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) An SDS for the mixture where all relevant ES of the registered hazardous substances ≥ 10 tpa are attached ("SDS book"). If the DU receives such an SDS, he has the obligation to check each 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) or to attach a SUMI (see point 2c below) instead of providing an "SDS book" in order to avoid unnecessary administrative work.

c) An SDS with attached "Safe Use Mixtures Information" (SUMI), as developed by industry experts.

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 SUMI are not equivalent to those resulting from an exposure scenario for substances. DUs should consider the information obtained from such a SUMI 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 to registration and no chemical safety report is legally required for them (see Annex L23 - "Position Paper of the Automotive Industry in regard to exposure scenarios for mixtures/extended SDS for mixtures"). However, see point 2c above.

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 Art. 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 Art. 32 REACH. Any differences can lead to further obligations.

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

According to Art. 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 must be communicated for identified uses (Art. 34 REACH).

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

Generally the DUs, as well as manufacturers, importers and distributors must keep the information gathered for the purpose of fulfilling their duties under REACH available for a period of at least 10 years. This information must be made available without delay and upon request to Member State's Competent Authority or ECHA (Art. 36 REACH).

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

Practical information on communication in the supply chain/use is not thoroughly explained in the REACH Regulation. Further information is given in the following guidance documents:
https://echa.europa.eu/guidance-documents/guidance-on-reach

5.6.2 COLLECTION OF SDS

REACH does not provide other information sources on the registration of uses apart from via an SDS, but as registration of substances ≥10 tpa has to include the identified use information, DUs have to make sure that their uses are included in the registration, in order 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 "UseR template". (http://www.ducc.eu/publications.aspx)

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 independently of 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 SDSs 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 Art. 32 REACH-based information is necessary as it is already covered in the SDS.

Disadvantages:

- Once an SDS is received, the recipient has, independently of the potential risk of a substance or mixture, the obligation to apply the RMMs mentioned therein (Art. 37.5.a REACH) and to fulfil the communication obligations which could lead to additional burden on the receiver side.
- As a consequence of Art. 34 REACH, a DU is obliged to make a short general plausibility check (see Annex Q to this Guideline) 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 an 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 SDSs for all substances & mixtures where legally required plus SDS-like information 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

To minimise the administrative burden and therewith costs, it is essential to switch to a paperless SDS communication between manufacturers, importers and downstream users. In order to achieve this, the automotive industry recommends SDSComXML for the basic SDS, which is the evolution of the former EDAS format.

The automotive industry supports the implementation of SDSComXML interfaces into environmental, health and safety IT systems, and implementation of the systems into the whole supply chain.

See "Position Paper: Automotive Industry usage of SDSComXML for the electronic exchange of Safety Data Sheets"

5.6.4 UPDATE OF SDS

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

Suppliers must 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 the SDS once a substance has been added to the CL for authorisation.

The new, dated version of the SDS, identified by 'Revision: (date)', must 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 must include the registration number.

Although there are industry recommendations available on when a change in an 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 (Art. 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 on the ECHA website.

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

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

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 a case he can, after agreement with the other importers, submit a notification jointly for all importers.

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 Art. 6.3 REACH), and small tonnages (< 1 tpa) of hazardous substances.

Art. 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

For further information see the following links:
https://echa.europa.eu/web/guest/regulations/clp/cl-inventory/notification-to-the-cl-inventory
http://echa.europa.eu/documents/10162/13643/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 Art. 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 (Art. 7.6 REACH exemption).

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. brake linings, tyres; leakage of lubricant used to reduce the friction between two moving parts (see "Guidance on requirements for substances in articles" on the ECHA website). This substance release could be subject to Art. 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:

1. the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
2. ECHA has grounds for suspecting that:

a) the substance is released from the articles, and
b) the release of the substance from the articles presents a risk to human health or the environment.

Exemption according to Art. 7.6 REACH: This registration obligation does not apply for substances already registered for that use or substances otherwise exempted, e.g. water (please refer to Chapter 5.2 of this Guideline). Therefore EEA producers should check if their suppliers have already registered the substance intended to be released.

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 "Pyrotechnic devices that release compressed gases", the above mentioned examples 1-3, if imported on their own (i.e. not assembled onto the vehicle) would be considered mixtures in containers, 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 Art. 6 REACH, unless already done so by the upstream supplier.

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**.

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 (Art. 23 REACH, AIG Chapter 3).

Fees

Fees required for the registration of substances in articles are specified in the Regulation (EC) No 864/2015 (amending Regulation (EC) 340/2008).

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

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

5.9 Notification of CL substances in articles

General requirement and exemptions

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

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

Notification is not required in either of the following conditions:

- The substance has already been registered for that use by a member of any supply chain (Art. 7.6 REACH); or,
- 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 (Art. 7.3 REACH).

The details of these general requirement and exemptions are given in the following sections.

Who must make the notification?

The notification of a CL substance in an article, assuming the conditions are met, must be made by either:

- The EEA producer of the article who combines the substance into the article (e.g. produces polymer parts by injection moulding of a polymer resin that includes a CL substance); or
- The importer of the article, on its own or within a complex object, from a non-EEA producer.

It follows that any customer of an EEA supplier of an article does not need to notify, as the duty to notify falls only on EEA producers or importers of articles (ECJ Case C 106/14 Judgment, 10 September 2015).

Examples

- Company A, based in the EEA, imports Article A, on its own or within a complex object, from a non-EEA producer and that same Article A contains a CL substance above the 0.1% w/w threshold and 1 tpa yearly tonnage.

» Notification is required by Company A.

- Company A supplies Company B with Article A, and Company B assembles this same Article A within the EEA into a Complex Object B and the 0.1% w/w threshold and 1 tpa are still exceeded.

» No further notification is required by Company B.

- Company C buys Article A on its own from EEA-based Company A; Company C does not know whether Article A is originally produced in the EEA or imported from a non-EEA producer.

» No notification of Article A is required by Company C, since Company C can assume that Company A has fulfilled its notification duties for Article A.

- Company C coats Article A with a paint which contains a CL substance to make a coated Article C. When the paint is cured, the CL substance exceeds the 0.1% w/w threshold (based on the whole weight of the coated Article C) and the 1 tpa.

» Notification is required by Company C only for the CL substance in the coating (cured paint).

Calculation of the 0.1% w/w threshold

According to a 2015 judgment of the European Court of Justice, the calculation of the concentration threshold "0.1% w/w" for both Art. 7.2 notification and Art. 33 communication (see Chapter 5.10) must follow the "OSA" principle; i.e. the calculation must be done by reference to the weight of the CL substance in each article in isolation, or in each article when part of a complex object (see Chapter 2.1, "Article", and Annex N to this Guideline).

The practical impact of the OSA principle for articles containing CL substance above the concentration threshold is summarised in the following table:

	EEA in-house production of article/complex object	Purchased article/complex object from EEA supplier	Article/complex object from non-EEA production (purchased or in-house)
Information source	Information received from the Material suppliers	Information received from suppliers of article or complex object	Information received from suppliers of article or complex object
Information Duty from suppliers	Suppliers have: • the legal duty to inform us via SDS (Art. 31) or otherwise (Art. 32) • the contractual duty via IMDS	Suppliers have: • the legal duty to inform us (Art. 33.1) • the contractual duty via IMDS	Suppliers have: • no legal duty • the contractual duty to inform us via IMDS
Notification (Art. 7.2)	Basis for the 1 tpa threshold calculation: • each article that is self-produced	No Notification required	Basis for the 1 tpa threshold calculation: • each article contained in the imported complex object
Communication (Art. 33)	Duty to communicate further down the chain of: • each article that is self-produced and placed on the marketd	Duty to communicate further down the chain of: • each article contained in the purchased complex object that is placed on the market	Duty to communicate further down the chain of: • each article contained in the imported complex object that is placed on the market

Table 5.9.1 Summary of obligations under the ECJ Judgement

Example

- A CL Substance S is an ingredient of a plastic clip, which itself is an article within a wiper assembly, which is imported by Company D:
  - Weight of substance S = 0.005g per clip
  - Weight of clip = 0.5g (two clips per wiper assembly)
  - Weight of wiper assembly = 20g
- Percentage substance in each clip = 1.0%
- Percentage substance in each wiper assembly = 0.05%

» Conclusion: the substance threshold calculation must be made with respect to the weight of the CL substance within the article (clip) alone, and so in this case the substance threshold of 0.1% w/w is exceeded, and so notification may be required (if the 1 tpa substance threshold is also exceeded).

Calculation of the 1 tpa threshold

The definition of "per year" in the legal text (Art. 3.30 REACH) which is copied into the definition section of this Guideline, means per calendar year, but does not explicitly state that it applies to substances on their own, in mixtures or in articles as other parts of the legal text do.

Furthermore, Art. 3.30 REACH states "… unless stated otherwise, for phase in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the average production or import volumes for the three preceding calendar years." and therefore applies to substances imported/manufactured as such and has nothing to do with notification of CL substances 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.

Having given due consideration to the term "per year" and whether it should apply to notification, we reached the conclusion that in the case of notification the "per year" starts from when the substance is included in the CL for authorisation. In case the 1 tpa threshold is not reached during the remainder of the calendar year when the substance appeared on the CL for authorisation, the calculation should start again on 1st January of the following year. 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 calendar year following the introduction of the substance on the CL due to the tonnage not being tripped, the situation should be monitored as the tonnage threshold may be exceeded in subsequent calendar years when production/import of articles containing the substance increases.

Example

A substance is added to the CL on 1st June 2012. The company importing or producing articles containing this substance will have to start investigating and calculating from that point in time until the end of that calendar year and not from the beginning of 2012. The tonnage of the substance is considered to be zero on 1st June 2012 and again on the 1st January 2013. The tonnage calculation needs to be done for each calendar year that you produce/import articles following the inclusion of the substance on the CL, but only if there is an increase in production/import volumes (of articles containing the substance) after the first tonnage calculation. A notification is only required once per substance per legal entity.

NOTE

Aggregation of substance notifications

According to the OSA principle of calculating which substances exceed the 0.1% w/w threshold in complex objects, the same substance could be present above the threshold in multiple different articles within an imported complex object. Likewise, it follows that the same type of component (i.e. the same type of substance use) can be present multiple times within that same complex object. However, notification needs to be made only once per substance per legal entity, and so it follows that the annual tonnage, and any resulting substance notifications, should be aggregated according to all uses that are not registered uses.

Example

- Company A, based in the EEA, imports a complex object which contains the same CL substance, "Substance A", in multiple articles as follows:

Article	Description	Use of Substance A	Annual imported tonnage for Company A
A	PVC O-Ring	Plasticiser for PVC	0.6 tpa
B	PVC Seal	Plasticiser for PVC	0.7 tpa
C	Coated metal bracket	Coating aid	1.4 tpa
D	HDPE Clip	Processing aid for HDPE	0.3 tpa

For the purposes of this example, it is assumed that three of the above CL substance uses are not already registered.

» Company A must make one notification for Substance A covering the three uses: plasticiser for PVC; coating aid; and processing aid.

Exemption: Substance already registered (Art. 7.6 REACH)

If you wish to rely on the exemption for a substance that has already been registered for your use, the registration does not need to have been done by an actor of your supply chain, but could have been made by any other manufacturer or importer of the CL substance. For articles produced in or imported into the EEA, it is necessary to confirm that the use of the substance in the article is supported by the registration in order to avoid the notification obligation.

A substance is considered to have already been registered for a particular use, if two conditions are fulfilled:

- The substance in question is the same as a substance that has already been registered; and,
- The use in question is the same as one of the uses described in a registration of this substance that was already made.

Step 1: Check sameness of substance identity
The first step in the process is to ensure that the substance in question is the same as a substance that has already been registered. Comparing names and EINECS or CAS numbers of both substances may not always be sufficient (see Chapter 5, "Criteria for checking if substances are the same", in ECHA's "Guidance for identification and naming of substances under REACH and CLP", https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf).

Step 2: Check sameness of registered uses
A potential notifier of a substance in articles must check if the use of the substance in his articles is the same as one of the uses described in a registration of this substance that was already made. For this he has to describe the function of the substance in the article. Normally the function of a substance would include a verb e.g. 'soften' (in the case of a phthalate (plasticiser)) but as the registration dossiers and the dissemination data do not include this, it is necessary to draw a conclusion from the noun e.g. plasticiser. The process by which the substance is included in the articles, and into which type of article, should also be described.
Comparing your use with a description of use based only on the use descriptor system will not be sufficient to conclude on the sameness of two uses for the purpose of establishing whether an exemption on the basis of Art. 7.6 applies. Thus, the "article category" (which is generally a very broad description often referring only to the material) will not be detailed enough (see Chapter 3.3.1 of ECHA's "Guidance on requirements for substances in articles" https://echa.europa.eu/documents/10162/23036412/articles_en.pdf). Therefore, the use in question has to be described in more detail than just by using elements of the use descriptor system.

The published information that a substance has been registered for use in the Article Category "Plastic articles" does not necessarily mean the registration is made to cover all plastic articles. It could mean that use of the substance in production of some specific plastic articles is covered and described in the registration, while other plastic articles are not covered and assessed. The uses of two very different plastic articles may lead to very different exposures to humans and the environment. If the exposure related to the use of your article is not adequately assessed in a registration dossier, it cannot be considered a registered use.

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. See also Chapter 5.9.1 for reference to the relevant automotive industry substance notification factsheets. Efforts to make contact with these bodies can prove to be difficult in practice as business confidentiality considerations may thwart the disclosure of the required information. It is recommended that any such correspondence is recorded.

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 once a substance is included in the CL (see chapter 5.3).

Example

on how to check that your use of a CL substance is covered by an already made registration using the case of DEHP in electric wires and cable:

1. Check whether DEHP has already been registered.
a) Go to the ECHA website by following the link: https://echa.europa.eu/information-on-chemicals/registered-substances
b) Check registration status for DEHP by entering the CAS number 117-81-7.
RESULT: full registration dossier data available

2. Check that the substance in question is the same as the substance that has already been registered, at least by comparing names and EINECS or CAS numbers of both substances.

3. Check if the type of article is covered in the registration dossier. In this example you must check for "electric wires and cable", covering also its synonyms, e.g. wiring loom, wiring harness, cable assembly, wiring assembly, etc. This information is not available on the registered substance list disseminated on the ECHA website and must be obtained by other means, e.g. from the lead registrant, consortium, association, internet etc. After receiving requested information from the above mentioned additional sources, check for "electric wires and cable". If this covers your article category you are covered by the already made registration.

Suppose 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).

1. Check the sector of use (SU) of electric wires and cable. The registration dossier for DEHP specifies "Consumer uses: Private households (=general public = consumers)". If this covers your Sector of Use you are covered by the already made registration, AND

2. Check the product category (PC) in the registration dossier. For electric wires and cable the product category is "Polymer preparations and compounds". If this covers your product category you are covered by the already made registration, AND

3. Check the exposure release category (ERC) included in the registration dossier. In the case of the articles electric wires and cables, the exposure release categories are:

   - "Low release of substances included into or onto articles and materials during their service life in outdoor use, such as metal, wooden and plastic construction and building materials (gutters, drains, frames, etc.)" (ERC10a)

   - "Substances included into or onto articles and materials with high or intended release during their service life from outdoor use. Such as tyres, treated wooden products, treated textile and fabric like sun blinds and parasols and furniture, zinc anodes in commercial shipping and pleasure craft, and brake pads in trucks or cars. This also includes releases from the article matrix as a result of processing by workers. These are processes typically related to PROC 21, 24, 25, for example: Sanding of buildings (bridges, facades) or vehicles (ships)" (ERC11a)

If your exposure release category is the same, then you are covered by the already made registration of the substance.

4. Confirm that 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 confirm that no uses advised against your scope of use are listed.

b) If no applicable restrictions are listed, you are covered by the already made registration.

NOTE

Action if use is not covered
Should you find your use is not covered by an already made registration, 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.

5. **Conclusion:** If you consider that the example above covers your uses of DEHP in electric wires and cable, no notification is necessary. The conclusion obtained and the considerations that led to it should be well documented in order to be able to demonstrate REACH compliance towards authorities when required.

NOTE

Action if not certain your use is registered

- Incorporation of a substance in an article is a "use". However, the placing on the market of an article containing a specified substance is not a use of that substance.
- Packaging is either an article or a complex object made of articles, and so the presence of a CL substance in packaging may need to be notified if it exceeds the 0.1% w/w limit and the 1 tpa threshold.
- Other promotional point of sale or marketing materials you may distribute in the course of your business are also considered as articles, and so the presence of a CL substance again needs to be considered.
  If you were checking the registration of the use as described in this chapter but you are still not certain that your specific use is already registered, you should consider your own notification.

Please refer to the factsheet on notification for each substance on the CL (see Chapter 5.9.1).

Exemption: Substance exposure is excluded (Art. 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 evidence that one or more of the following applies:

- There are no emissions from the article, even during disposal;
- The substance is contained in the article by technical means, and there is an explanation of why the article is unlikely to be opened, broken, or lead to release of the substance;
- The substance is embedded in the matrix of the article, and there is 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;
- The substance remains fully immobile inside the article and does not migrate out or escape its confines (e.g. due to the inherent physicochemical properties of the substance, or a special coating of the article);
- The amount of substance released from the article is contained by technical means or directly destroyed (e.g. during thermal treatment of waste).

NOTE

Tips on notification

» AI recommendation is to avoid using the Art. 7.3 REACH exemption, since it will likely be more difficult and costly to demonstrate "no exposure" than to make a notification.

» ECHA may require a notifier to perform a registration of the notified substance under Art. 7.5 REACH, even if the general registration criteria are met in your case.

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

» Mixtures contained or integrated in an article or complex object are not covered by Art. 7.2.

» A notification needs only to be done once per substance per legal entity. 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 refer to ECHA's "Guidance on requirements for substances in articles" https://echa.europa.eu/documents/10162/23036412/articles_en.pdf.

» According to ECHA[13], in some cases the producer of complex objects 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 Candidate List, which is available on the ECHA website, includes substance datasets with some sections of the IUCLID file already filled in (substance identity, composition and classification information).

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 section 1.1);
- Identity of the notifier and role in the supply chain (IUCLID section 1.1);
- Identification of the substance, i.e. substance name, EC number, CAS number, type of substance and substance composition (IUCLID sections 1.1 and 1.2): this information is provided in the pre-filled substance dataset; the registration number of the CL substance, if available (IUCLID section 1.3);
- Classification of the CL substance according to the CLP criteria (IUCLID section 2.1): this information is provided in the pre-filled substance dataset;
- 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 section 3.2);
- Production site of the notifier, to be filled only by producers of articles, not by importers of articles (IUCLID section 3.3);
- Brief description of the use(s) of the substance(s) in the article (technical function) (IUCLID section 3.5) and of the uses of the article(s) (IUCLID section 3.4 and 3.5).

Further information on how to notify by using IUCLID can be found in the ECHA Manual "How to prepare a substance in articles notification" https://www.echa.europa.eu/documents/10162/22308542/manual_subs_in_art_notif_en.pdf

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

Timeline

- For an SVHC placed on the CL **before** 1 Dec 2010, notification had to be made to ECHA by 1 June 2011;
- For an SVHC included on the CL **after** 1 Dec 2010 notification is required no later than 6 months after the CL inclusion and after exceeding the 1 tpa threshold.

Working assumptions of the TF-REACH

- First notification prior to 1 June 2011 was made on the basis of the CL version of 1 Dec 2010.
- The tonnage has to be calculated for the calendar year after the calendar year in which 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 per substance per legal entity for all uses of the substance that are not registered uses.
- In case the 1 tpa is not reached during the year after the substance appeared on the CL for authorisation, the calculation starts again on January 1 following year, starting with "zero".
- According to Art. 7.7 REACH, the notifier has to notify within 6 months after a substance is published on the CL and the substance is present in those articles in quantities totalling over 1 tonne per legal entity (producer or importer) per year.
- Art. 7 notification has to be done only once per CL substance per substance per legal entity, not every year.
- If the tonnage range changes, the notification has to be updated.
- The quantities of the same CL substance in both imported and manufactured articles for the same legal entity have 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 calculated for the notification.

For more details on refer to Art. 7, 57 and 59 REACH and ECHA's "Guidance on requirements for substances in articles" (https://echa.europa.eu/documents/10162/23036412/articles_en.pdf).

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 4):

1. Collect data on CL substances in articles using the International Material Data System (IMDS) (see Annex N, "Data collection for 05A substance threshold calculation").

2. Identify which CL substances are present in the articles and complex objects that you manufacture or import.

3. Check which of those CL substances are present at above the 0.1% w/w threshold according to the 05A principle (see Annex N, "05A CL substance threshold calculation").

4. Identify the affected uses of those CL substances that are present above the threshold.

5. Refer to the substance factsheet on notification which can be found by following the link: http://www.acea.be/publications/article/reach-automotive-industry-factsheets; check if the uses are already understood to be registered.

> NOTE
> The notification factsheets only consider the typical uses of a substance in the industry as identified by the Task Force members, and are not guaranteed to cover all possible uses. It is therefore up to each user of the factsheets to ensure that their company's uses are covered by any registered uses. For additional information ask the relevant association/consortium/supplier or manufacturer.
> If all your uses are already registered, you have no notification obligations, proceed to step 8; otherwise, proceed to step 6 below.

6. Check which of the unregistered CL substances exceed the 1 tpa limit. Use the results of your REACH Inventory and only take into account in the calculation those parts that you produce or import.

7. Make the necessary notification(s) to ECHA.

8. Maintain documents that record the reasons for your decisions and actions.

NOTE

Import of complete vehicles: A first calculation should be done based on the master parts list (often known as the 150% bill of materials). If a substance exceeds 1 tpa for unregistered uses, make a more detailed evaluation based on the actual imported vehicles.

5.10 Communication requirements for CL substances in articles

General requirements

Art. 33 REACH requires that the supplier of an article (see definition in Chapter 2.1) communicates sufficient information to the recipient on CL substances to allow safe use of the article. As a minimum the name of the CL substance must be included; any available additional information should also be provided if relevant to safe use.

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

- The substance is identified as of very high concern according to Art. 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 at a concentration above 0.1% weight by weight (w/w), calculated according to the OSA principle.**

There are no exemptions to the Art. 33 communication duties if the above criteria are met; i.e. the duties apply even if the parts do not discharge substances into the environment, and the duties apply to any amount of CL substance, with no minimum tonnage threshold.

NOTE

Scope of Art. 33 Communication

- Legacy parts are within the scope of Art. 33 REACH (see Annex L7).
- Packaging is either an article or a complex object made of articles, and so the presence of a CL substance in packaging needs to be communicated if it exceeds the 0.1% w/w limit.
- Packaging which is only provided for transport and is given back by the customer is not affected by Art. 33.1.
- Other promotional point of sale or marketing materials you may distribute in the course of your business are also considered as articles, and so the presence of a CL substance again needs to be considered.
- Mixtures contained or integrated in an article or complex object are not covered by Art. 33.

Communication to professional customers (Art. 33.1 REACH)

For Art. 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 Art. 33.1 REACH can be summarised as follows:

- Professional customers are to be informed of CL substances automatically as soon as the substance has been included on the CL.
- Professional customers include (but are not limited to) dealerships, fleet management, company vehicle owners (who have bought the vehicle). A company vehicle driver who does not own the vehicle is not a professional customer.
- It would be sufficient to provide the customer with a direct link to the relevant information. An 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. This information should be updated in response to CL changes for articles or complex objects that remain in series production.

Communication to consumers (Art. 33.2 REACH)

Art. 33.2 REACH states that the requirement to communicate information on substances in articles must extend to any consumer upon request. The information must be provided to the consumer free of charge within 45 days of receipt of the request. The consumer in this case does not need to already be a recipient of the article in question. Also in practice, the "article" in question includes complex objects made up of multiple articles.

Provision of safe use information (Art. 33.1 & 33.2 REACH)

Where a CL substance in an article that you supply (either on its own or as part of a complex object, such as a vehicle or vehicle part) exceeds the 0.1% w/w threshold, you must ensure that you provide information available to you to ensure the safe use of the article in any subsequent life cycle phases.

To evaluate what safe use information may be required, you should typically consider:

- Manufacturing or assembly operations in the article's downstream supply chain;
- Use of the vehicle/part by a professional user or consumer;
- Maintenance and repair of the vehicle/part;
- Reuse, remanufacturing, recycling or disposal of the vehicle/part.

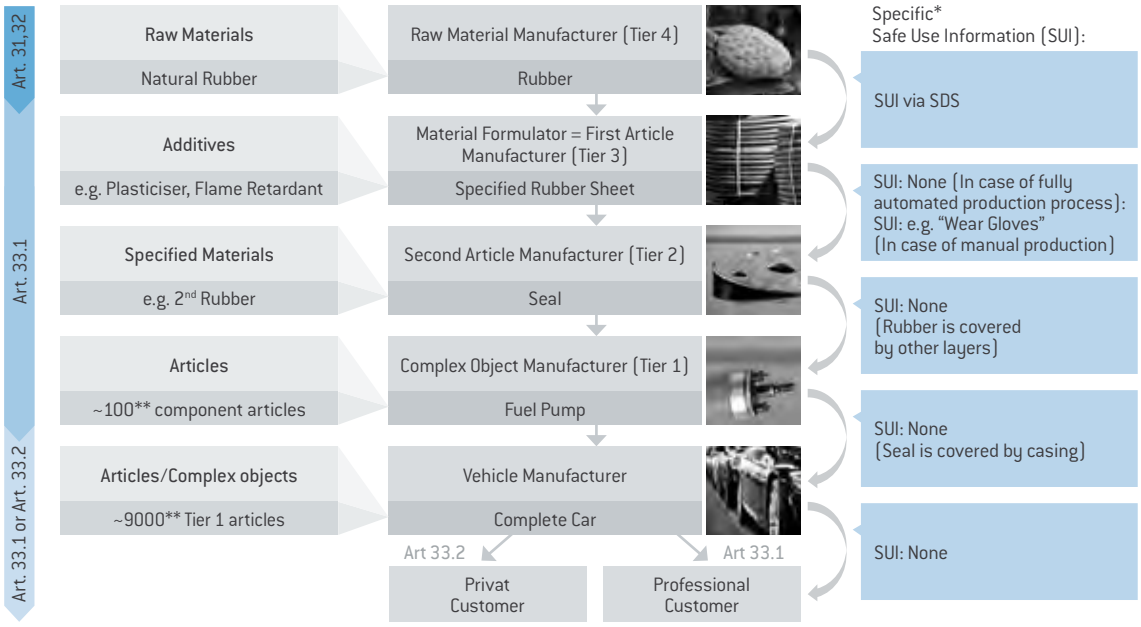
You should also consider what safe use information is available to you, including safe use information that may have been provided to you by your supplier, as well as information known to your technical experts and product safety specialists. You do not have to provide all the information that is available to you, but you do have to provide any of the available information that remains relevant to the safe use of the article that you place on the market.

Finally, you should take into account safe use information about the vehicle/part that you already make available to your customers, such as vehicle owner manuals, part service/repair instructions, and disposal/dismantling information.

It is up to each successive supplier who places a product on the market to determine if the existing product information is already sufficient to ensure safe use of the article that contains the CL substance, in which case reference should be made to the existing information, and then it is sufficient to provide the name of the CL substance in order to fulfil obligations under Art. 33 REACH. If further information is needed to ensure safe use, in any of the life cycle phases named above, then this information must be added in addition to the name of the CL substance.

The AI does not generally recommend providing the name or location of each article that contains a CL substance, since we consider that such information neither contributes to the effectiveness of the safe use information, nor is the component part name actually useful, since many component names are obscure and would not actually help to identify the affected article. An exception would be if additional specific safe use information were required, in which case the name of the article as well as its location in the complex object may be required to clearly identify that article for safe use.

The following diagram shows the flow of specific safe use information (SUI) down a simplified supply chain.



Picture 5.10.1: Example of specific safe use information (SUI) down a supply chain

* Specific SUI excludes the name of the CL substance, which must be provided in every case where a CL substance is present in the article above the threshold, and excludes general SUI for the article, which is provided whether or not a CL substance is present.

** Depends on the specific part or vehicle.

There is no required format for providing Art. 33 information, but the templates provided in Annex M1, M2 & M3 to this Guideline may prove useful for providing consistent and sufficient information.

When Art. 33 information is provided for a whole vehicle, it will not usually be feasible to provide that information for each vehicle configuration (i.e. by Vehicle Identification Number or VIN). Therefore the AI recommends providing the information in this case based on the master parts list (often known as the 150% bill of materials).

Where provided, Art. 33 safe use information should be made available in the local EEA language of the customer receiving the article. However, the AI does not believe that it will be necessary to translate the data collected via IMDS, except in the cases where specific safe use information is required for an article.

Where needed, safe use information may be provided by:

- Hard copy, for example by adding information sheets with the vehicle or parts when they are sold; or
- By electronic means, for example by providing a web site with the information directly accessible to your customers.

5.10.1 RECOMMENDATION FOR THE AUTOMOTIVE INDUSTRY

By taking into consideration all criteria, the following basic strategy for the automotive industry is recommended (refer to Flowchart 8):

1. Collect data on CL substances in articles using the International Material Data System "IMDS" (see Annex N, "Data collection for 05A substance threshold calculation").

2. Identify which CL substances are present in your articles and complex objects.

3. Check which of those CL substances are present at above the 0.1% w/w threshold according to the 05A principle (see Annex N, "05A CL substance threshold calculation").

4. For each CL substance above the threshold, identify existing safe use information covering the articles/complex objects that contain the CL substances, and evaluate if the existing SUI is sufficient to ensure safe use. The TF-REACH recommends communicating for vehicles based on the master parts list (i.e. the theoretical vehicle that contains all the options available).

5. For "risk article", i.e. those for which existing product information is not sufficient to ensure safe use, prepare specific Safe Use Information (SUI); for other "non-risk" cases, the substance name alone is sufficient SUI to meet Art. 33.1 and 33.2 requirements.

6. To meet Art. 33.1 REACH, assemble the required information (optionally following the format provided in Annex M1 to this Guideline), and provide automatically to the business-to-business recipient of the article/complex object.

7. To meet Art. 33.2 REACH, on request from a consumer, assemble the required information (optionally following the formats provided in Annex M2/M3 to this Guideline), and provide response to the consumer who made the request within 45 days.

8. Depending on the interpretation of the ECJ Judgement, the fulfilment of the requirements could lead to a disproportionate effort. To avoid unnecessary actions, it is recommended to consider the detailed recommendations and examples provided in Annex N that aim to apply the principle of proportionality according to Art. 5 of the Lisbon Treaty.

9. Maintain documents that record the reasons for your decisions and actions.

5.11 Authorisation procedure

The REACH Regulation sets up the authorisation procedure to permit a better management of the environmental and health risks associated with SVHCs and progressively replace those SVHCs with suitable alternative substances or technologies where these are economically and technically viable.

Substances fulfilling the criteria of Art. 57 REACH and on the CL will most likely be added to Annex XIV REACH.

Authorisation can be granted for specific uses by the European Commission on the basis of an Application for Authorisation (AfA) made to ECHA. When an authorisation is granted by the Commission, it is valid until amended or withdrawn, but it is subject to time-limited review, meaning authorisation holders are required to submit a review report.

The authorisation process involves 4 main steps:

Authorisation scope

Authorisation applies to the "use" of a substance (Art. 3.24 REACH, see Chapter 2.1), which means that authorisation applies to the Annex XIV substance when it is:

- Processed;
- Formulated or mixed;
- Consumed;
- Stored or kept (on its own or in a mixture);
- Treated;
- Filled into containers or transferred from one container to another;
- Incorporated into an article;
- Otherwise utilised.

Authorisation does not apply if the Annex XIV substance has already been incorporated into an article, i.e. if the substance has been used to produce articles, the substance as such is no longer "used" and no authorisation of use of the substance is required (see "Effect of authorisation on articles" below).

Exemptions to authorisation

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 (Art. 58.2 REACH).

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

The following uses are exempted (Art. 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 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 (Art. 2.8.b REACH).

Under specific conditions, the following uses are exempted (Art. 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) No1935/2004.

Further exemptions include the use of substances when they are present in mixtures (Art. 56.6 REACH):

- For PBT, vPvB or endocrine disrupting substances (Art. 57.d-f REACH), below a concentration limit of 0.1 % weight by weight.
- For all other substances, below the specific concentration limits according to the CLP Regulation (Art. 11.3 CLP).

See also further exemptions in Chapter 5.2.

Process for adding substances to Authorisation List (Annex XIV)

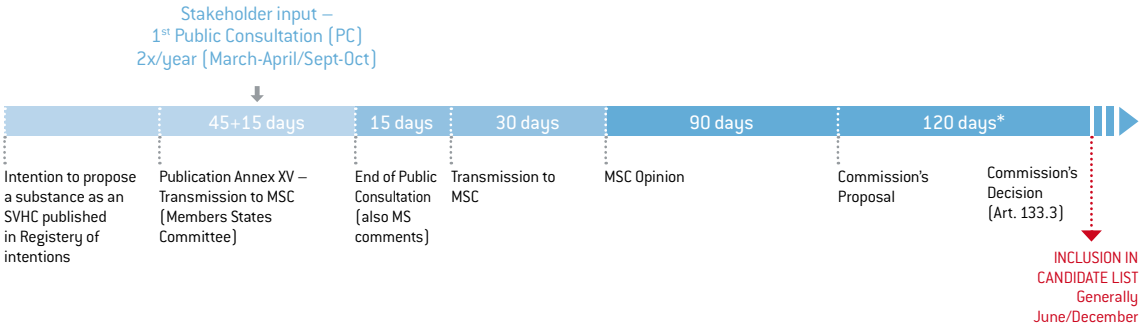
Below is a description of the process to add substances to the CL and their prioritisation, recommendation and inclusion in Annex XIV.

NOTE

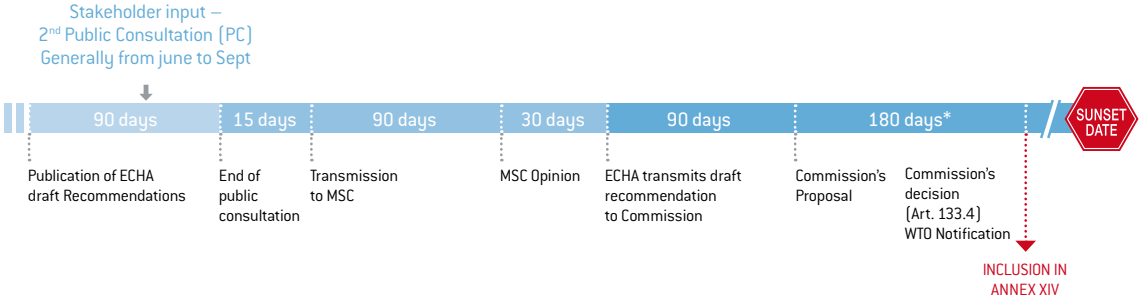
» The authorisation procedure is independent of the registration procedure.

» There is no tonnage threshold for a substance to be subject to authorisation. Authorisation procedures therefore apply independently of any tonnage bands. This means that there are substances that require authorisation but do not require registration.

1 – Adding SVHCs to the Candidate List:
From submission of Annex XV dossier until inclusion in the CL about 5-10 months



2 – Prioritisation: From ECHA draft recommendations until inclusion in Annex XIV about 14 months



* minimum estimated

Picture 5.11.1

AfA submission windows

A manufacturer, importer, OR or DU (who may include formulators as well as end-users of the substances) can apply individually or in a group for an authorisation to place on the market or to use an Annex XIV substance on its own or in a mixture, or to incorporate the substance into an article.

An AfA can be submitted:

- for one or several uses
- for one substance or a group of (similar) substances

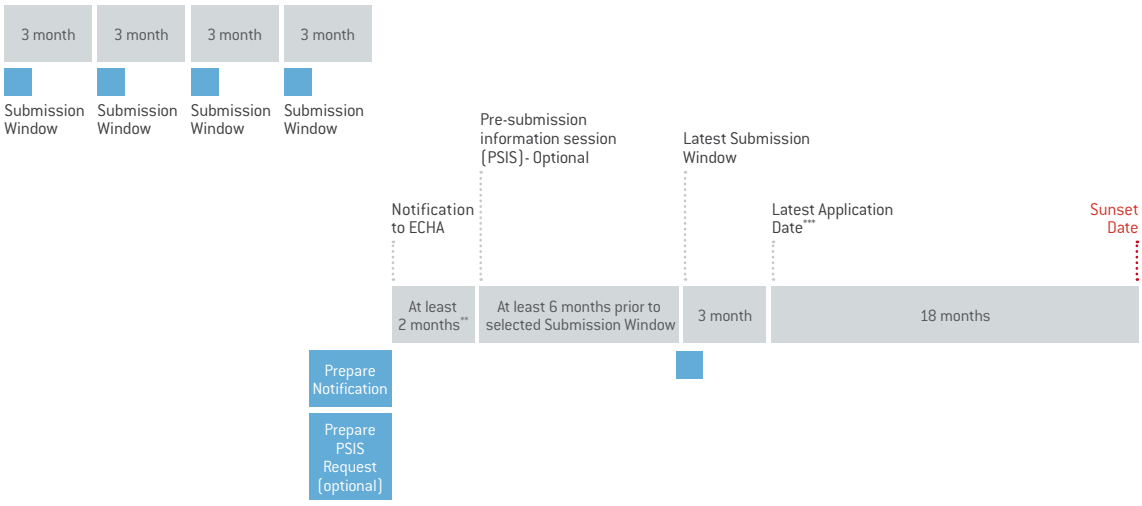
Using or placing the substance on the market subject to authorisation may continue as long as the so called "sunset date", has not been reached. The sunset date is the date after which the placing on the market and the use of the substance is no longer allowed unless an authorisation has been granted for the specific use. The sunset date is specified in Annex XIV.

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 (Art. 58.1 REACH).

It is possible to apply after the Latest Application Date (LAD), but it will be necessary to stop using/placing the substance on the market after the sunset date, until your AfA is granted by the Commission.

Notify ECHA, at the latest, eight months before you intend to submit an application for authorisation. When sending the notification, you should indicate the substance and provide a general description of the uses for which you will be seeking an authorisation. Send notification to: https://comments.echa.europa.eu/comments_cms/AfA_NotifyAndPresubmit.aspx

There are 'submission windows' for AfA that occur throughout the year. When applicants submit their applications within these windows, they ensure that their application will be processed within the shortest time possible. To ensure that the application is processed smoothly, it is recommended to submit the application in one of the windows before the latest submission window.



Picture 5.11.2: AfA Submission overview

* Submission windows have a 2 weeks period
** Notification has to be done at least 8 months prior to selected submission window
*** Official date of receipt (payment of the fee received and opening of the public consultation)

Individual or joint application

An application can be submitted by one applicant or a group of applicants, such as:

- By downstream user(s)
- By upstream actor(s)
- Or through a two-level application strategy involving both upstream actors (level 1) and downstream users (level 2)

Due to the possible complexity and technical issues of joint applications, ECHA recommends that you develop and submit a joint application when:

- all co-applicants of the group apply for all uses in the joint application for authorisation, and
- they have found an acceptable way to share all information provided in the application.

In complex cases, it may be preferable for each co-applicant to submit their own application separately.

Depending on the complexity of the supply chain, it is highly recommended to enter into discussions with all actors involved (suppliers, customers, etc.) and to determine the best approach for your case. Once decided, ensure that the applicant has all the information needed to cover your use and those of your DUs.

AfA preparation

There are two possible routes to apply for an authorisation to use an Annex XIV substance:

1. Adequate control route: by demonstrating that the risk from using the substance is adequately controlled, i.e. that the exposure is below the derived no-effect level (DNEL).
2. Socio-economic analysis route: by demonstrating that the socio-economic benefits of using the substance outweigh the risks and that there are no suitable alternative substances or technologies.

The information (assessment reports) required in an application will depend on whether you can demonstrate adequate control of the risks and whether there are suitable alternative substances or technologies available for the use you are applying for.

The basic information in the AfA includes:

- Identity of substance or substances covered by the application,
- Name and contact details of the person or persons making the application,
- Request for authorisation(s) for specific use(s),
- Chemical Safety Report(s),
- An analysis of the alternatives,
- Substitution plan.

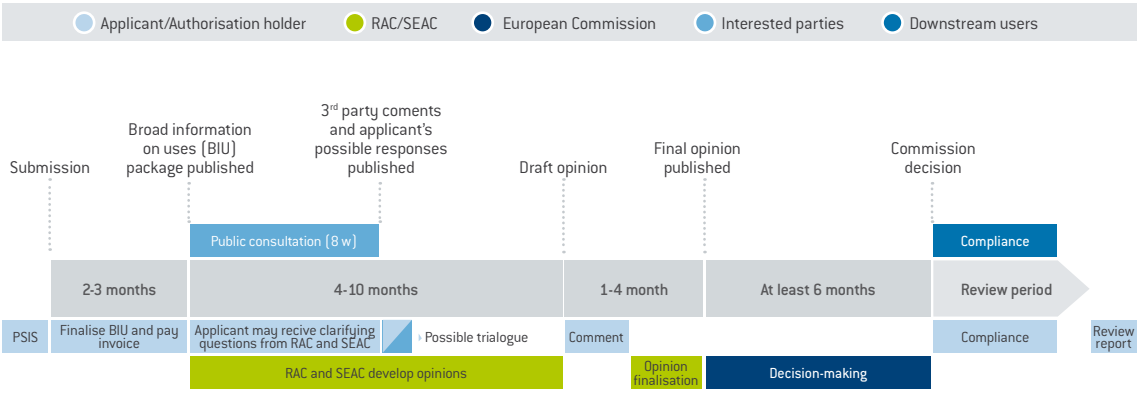
Depending on the route chosen for the AfA, other information may be included: A socio-economic analysis (SEA), a justification for not considering the risks to human health or environment (see ECHA Guidance on the preparation of an application for authorisation).

AfA submission and evaluation

ECHA's Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) develop an opinion on each use included in an application for authorisation. This opinion outlines the RAC and SEAC evaluation of an applicant's assessment reports and includes recommendations for any conditions or monitoring arrangements that could be included in an authorisation decision as well as a recommendation on the length of the time-limited review period, should an authorisation be granted for the use.

The RAC and SEAC opinion is based on the application, as well as any information received in the public consultation on possible alternatives. RAC and SEAC can request additional information from an applicant, which is also taken into account.

A 'trialogue meeting' may also be organised between the applicant, the Committees and third parties who have submitted information about potential alternatives in the public consultation.
The final decision to grant or not grant an authorisation is taken by the Commission after discussion with Member States in the REACH Committee. The decision-making process takes at least six months.



Picture 5.11.3: AfA Evaluation and Decision (Source: ECHA website - no longer posted)

Authorisation in the supply chain

A 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 (Art. 56.2 REACH).

Downstream user obligations for the use of Annex XIV substances

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 Art. 56.2 REACH including the substances in a mixture, must 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 in addition to any CLP-required labelling. This must be done without delay once the authorisation number has been made publicly available in accordance with Art. 64.9 REACH.

- DUs using a substance in accordance with Art. 56.2 REACH must notify the ECHA within three months of the first supply of the substance (Art. 66.1 REACH).
  - ECHA maintains a register of DUs who have made an application and grants access to this register to the competent authorities of the Member States.

Review period of an authorisation

The review period is set for each granted authorisation individually (i.e. 4, 7, 12 years).
The authorisation is regarded as valid until the end of the review period or until the European Commission withdraws the granted authorisation of use.

A time-limited review period is not set out in the first publication of Annex XIV. If it is necessary to extend the authorisation of use, the holder of the application has to apply for an extension of the review date at least 18 months before that date (see also Art. 61 REACH).

NOTE

» If the Commission makes the decision to deny the authorisation, you must stop all uses of the Annex XIV substance after the sunset date.
» That means that if the Commission decision to deny the authorisation is made after the sunset date, you must stop all non-authorised uses of the Annex XIV substance immediately.
» 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 substance inventory, it is recommended to identify potential critical substances
» If necessary, data to support authorisation for your use should be gathered.

	Candidate List inclusion	Prioritisation for the Authorisation List	AfA public consultation and trialogue
Type of information requested during the public consultation	Identity of the substance and intrinsic properties relevant for the identification (unless identification is based on harmonised classification and labelling and cannot be challenged in this context). Additionally, information on uses, exposure potential and alternatives	Confirmation on uses and volumes used; views on the transitional arrangements and possible exemptions.	Alternative substances or technologies to the use(s) applied for; risks, technical feasibility and costs of alternatives

Table 5.11.1: Type of information requested during the 3 main consultation steps within the authorisation procedure

Public consultations in the authorisation process

ECHA consults the public during 3 of the 4 steps for authorisation:

- Candidate List inclusion;
- Prioritisation for the Authorisation List; and
- AfA public consultation and trialogue.

ECHA encourages all interested parties to get involved and give their views.

The AI recommends that OEMs and/or their suppliers submit any comments for public consultations as early as possible via the relevant national or European trade associations, who can collect and combine the various proposals from their members and submit to the authorities under the name of the association.

During the 4th stage of authorisation process ("Evaluation of Applications"), our automotive industry experience (e.g. CrVI authorisation) shows that third parties not directly involved in the authorisation dossier submission can play a key role during public consultation.

NOTE

TF REACH has developed a process (see Annex J, "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 "Substance Impact Assessment Process" which helps to find out in which products and processes SVHCs might be included and where substitutions may have to be started (see Chapter 6; Step 1.3 of the 5 Step compliance schedule).

As IMDS is the main source for assessing the impact on articles, please make sure that your data is always up-to-date.

In order to assess the impact on the production processes, suppliers are invited to provide their relevant information into the impact assessment.

Effect of authorisation on articles

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

Articles that contain Annex XIV substances can be supplied after the sunset date if they were produced in the EEA before the sunset date and then held in stock.

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

Legacy spare parts

In order to avoid the premature obsolescence of articles that are no longer produced after the sunset dates, some substances included in Annex XIV need to be available for the production of spare parts for the repair of those articles, where those articles cannot function as intended without those spare parts, as well as where some Annex XIV substances are necessary for the repair of such articles.

To that end, the TF-REACH has produced a position paper on the need for exemptions from authorisation for legacy spare parts (see Annex L12), which in summary states:

- Applications for authorisation for the use of an Annex XIV substance for the production of such spare parts and for the repair of such articles should be simplified.
- The transitional arrangements applicable to the substances concerned by those uses should be extended in order to allow for the adoption of implementing measures for such simplified applications for authorisation.

As a result, the sunset dates for some substances have been extended for legacy spare parts.
Implementing measures for simplified applications for authorisation for the production of legacy spare parts are expected to start in 2018.

Others documents on the subject

- Title VII Art. 55 to 66 REACH
- ECHA List of Guidance Documents on REACH https://echa.europa.eu/guidance-documents/guidance-on-reach
- The Public Activities Coordination Tool (PACT) https://echa.europa.eu/status-and-purpose
- ECHA Guidance on identification of SVHCs https://echa.europa.eu/substances-of-very-high-concern-identification-explained
- ECHA How to apply for authorisation - a step-by-step guide for applicants https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842-4c90-7a1a-3e48-f5eaf3954676
- ECHA's online support pages on how to apply for authorisation provide a quick overview of the necessary steps from an applicant's point of view. https://echa.europa.eu/applying-for-authorisation
- The guidance on the preparation of an application for authorisation (ECHA, 2011a) provides information about the authorisation process and describes the main elements of an application for authorisation. https://echa.europa.eu/documents/10162/23036412/authorisation_application_en.pdf
- The guidance on the preparation of socio-economic analysis for authorisation (ECHA, 2011b) provides specific and detailed guidance on how to prepare a socio-economic analysis. https://echa.europa.eu/documents/10162/23036412/sea_authorisation_en.pdf
- The guidance on information requirements and chemical safety assessment provides guidance on how to prepare a CSR. https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
- "How to develop use descriptions in applications for authorisation" explains how the use(s) applied for presented in an application for authorisation should be developed and described. https://echa.europa.eu/documents/10162/13566/uses_description_in_auth_context_en.pdf

- ECHA has published over 80 Questions and Answers (Q&As) on the application for authorisation process. https://echa.europa.eu/de/support/qas-support/browse/-/qa/70Qx/view/scope/reach/authorisation
- Before submitting an application for authorisation, applicants can request a pre-submission information session (PSIS) with ECHA to ask questions regarding the regulatory and procedural aspects related to the application. https://comments.echa.europa.eu/comments_cms/AfA_NotifyAndPresubmit.aspx
- ECHA has also held several training seminars and workshops to clarify issues related to the application for authorisation process. The presentations and other material used in these events are available on ECHA's website. https://echa.europa.eu/support

Recommendation for the automotive industry

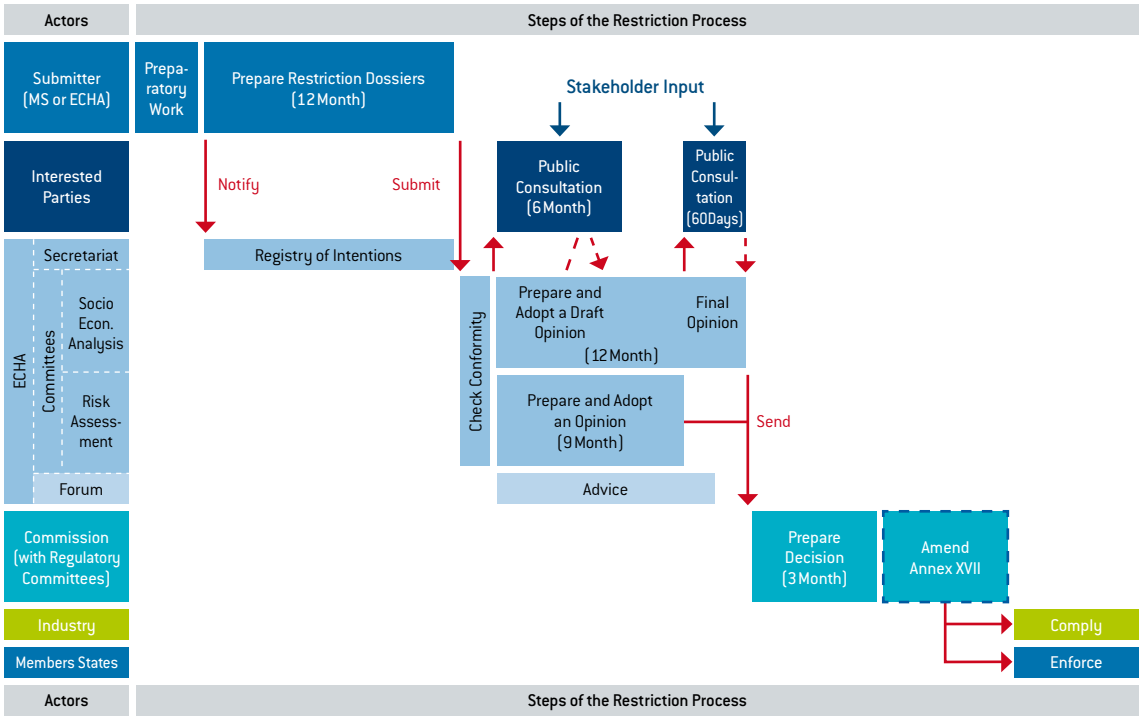
- Limit the use of substances included on the CL for authorisation, while ensuring that the technical/quality requirements are met and the socio economic impact of substitutions has been taken into consideration. Thus, substitution must be carried out in agreement between customers and suppliers.
- Take into account criteria for selecting suitable alternatives defined by Automotive Industry to carry out substitutions (see Annex 0, "Sustainable substitution criteria").
- If you use an Annex XIV substance to produce an article, make sure that your use of that substance is included in an AfA.
- Add to your supplier contract a clause that obligates the supplier to inform you about their intentions to apply for authorisation or to 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. Annex XVII of REACH lists all restricted substances and the conditions of their restrictions.

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



Picture 5.12.1 Main stages of the Restriction process

To facilitate open discussion and dialogue, 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. It is all the more important to pay attention to this restriction process and be involved in the consultation step for restrictions that could impact significantly the automotive industry because of the substances targeted, because of the interpretation of the restriction wording (e.g. "part thereof"), or because of specific ECHA guidance aiming at better defining the scope of the restriction.

According to Art. 68.2 REACH, for 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 will be amended without following the complete procedure described in Picture 5.11.1 above (Art. 69 to 73 REACH does not apply), and particularly without consulting all interested parties (in accordance with the procedure referred to in Art. 133.4 REACH). This may result in a shorter timeline for the restriction process and thus also reduce the time available to industry for any compliance actions.

NOTE

Difference between Restriction and Authorisation Process:

- » Under Authorisation, every use of a substance is prohibited if not explicitly allowed
- » Under Restriction every use of a substance is allowed if not explicitly prohibited

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 Art. 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 (Art. 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 may not be included in Annex XIV REACH or must be removed from it (Art. 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 human health or the environment.

Recommendation

- Similar to the Automotive Industry processes for authorisation, the automotive industry also uses for restriction the Impact Assessment Process in order to generate an overview of the impact of possible restrictions on automotive business. It is thus recommended to give input to that process in order to provide a representative overview.
- To understand the impact of a restriction on your business you may refer to the table developed by the REACH TF of all entries of Annex XVII which assesses their impact on the automotive industry (articles, production), see Annex K.

Other documents on the subject

Title VIII Art. 67 to 73 REACH

- ECHA Guidance on Annex XV for restrictions: https://echa.europa.eu/documents/10162/23036412/restriction_en.pdf
- ECHA Guidance on Socio-Economic Analysis-Restrictions: https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf
- The Public Activities Coordination Tool (PACT): https://echa.europa.eu/pact

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" (Art. 3.1 Waste Framework Directive, "WFD", 2008/98/EC).

Waste as defined in the WFD is not considered a substance, mixture or article under REACH (Art. 2.2[14] 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 stage of the life-cycle of substances into account, where relevant, in particular to create exposure scenarios or when assessing "safe use" under Art. 33 REACH (see also Chapter 5.10 "Communication Requirements for CL Substances in Articles"). That means they have to consider waste produced during the manufacturing and use phases 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 recycling or 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 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 (Art. 6.4 WFD[15]) or criteria for the end of waste status will be developed for specific materials in the future.

Criteria for defining when certain specified wastes cease to be wastes are given in Art 6.1 WFD. For example, in the authorisation decision on DEHP in recycled PVC it was concluded that recycled materials have ceased to be waste in accordance with the WFD.

According to Art. 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 Art. 31 or 32 is available for this recovered substance.

This means that, for recovered material, the manufacturer/importer has to ensure that the raw substances have already been registered and an SDS for hazardous substances or SDS-like safety information for non-hazardous substances must be available to the recovering company or organisation 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 Art. 33 if applicable.

Obligations on substances used in recycled or recovered materials, however, apply if the substances have been included into the REACH Authorisation list (see Chapter 5.11, "Authorisation procedure").

This requires recycling companies to undergo the authorisation process for the use of the substance in a recycled material that they would like to place on the EU market. An authorisation will only be granted if the applicant can prove that the benefits outweigh the risks and that safer alternatives are economically and technologically not feasible.

A first case on DEHP in recycled PVC has proven that the provision of such evidence is very difficult and heavily challenged.

[14] Art. 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)

[15] Where criteria have not been set at Union level in accordance with the procedure of the waste framework directive, Member States may establish detailed criteria on the application of the conditions including limit values for pollutants.

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 designed 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 desired flame retardant in PVC. In this case the constituent may fall under the registration obligation unless it has been registered before.

NOTE

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 Art. 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.

5.14 REACH enforcement

In accordance with Art. 126 REACH, each Member State has to appoint a Competent Authority (CA) and maintain an appropriate control system for enforcement. Member States were required to have an enforcement regime in place by 1 December 2008, which provides 'effective, proportionate and dissuasive' penalties for non-compliance.

Regarding enforcement, Member States, the European Chemicals Agency (ECHA) and the European Commission set up a "Forum for Exchange of Information on Enforcement", which coordinates harmonised enforcement projects and joint inspections.

For more information on the REACH enforcement projects, please visit the link to ECHA: https://echa.europa.eu/de/about-us/who-we-are/enforcement-forum/forum-enforcement-projects.
For details of REACH sanctions in the Member States, see Annex F.

Recommendations of the Automotive Industry resulting from REACH-EN-FORCE Projects

- 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/Ext-SDSs regarding their content consistency/plausibility and their structure (see Chapter 5.6.2). Check that method of working matches what is laid down in the SDS/Ext-SDS and the attached Exposure Scenarios.
- Make sure that your customers receive an SDS/Ext-SDS at first supply or every time there is a change in the SDS/Ext-SDS.
- Inform your customers of CL substances above 0.1% w/w in your articles (Art. 33 REACH Information obligation. Consider the new article definition according to the OSA principle (see Chapter 5.10 and Annex N).

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 when they need advice on how to fulfil their REACH duties.

NOTE

- REACH guidance documents are subject to change and are not legally binding.
- Although not legally binding, the guidance documents may also be used by national/local judiciary.

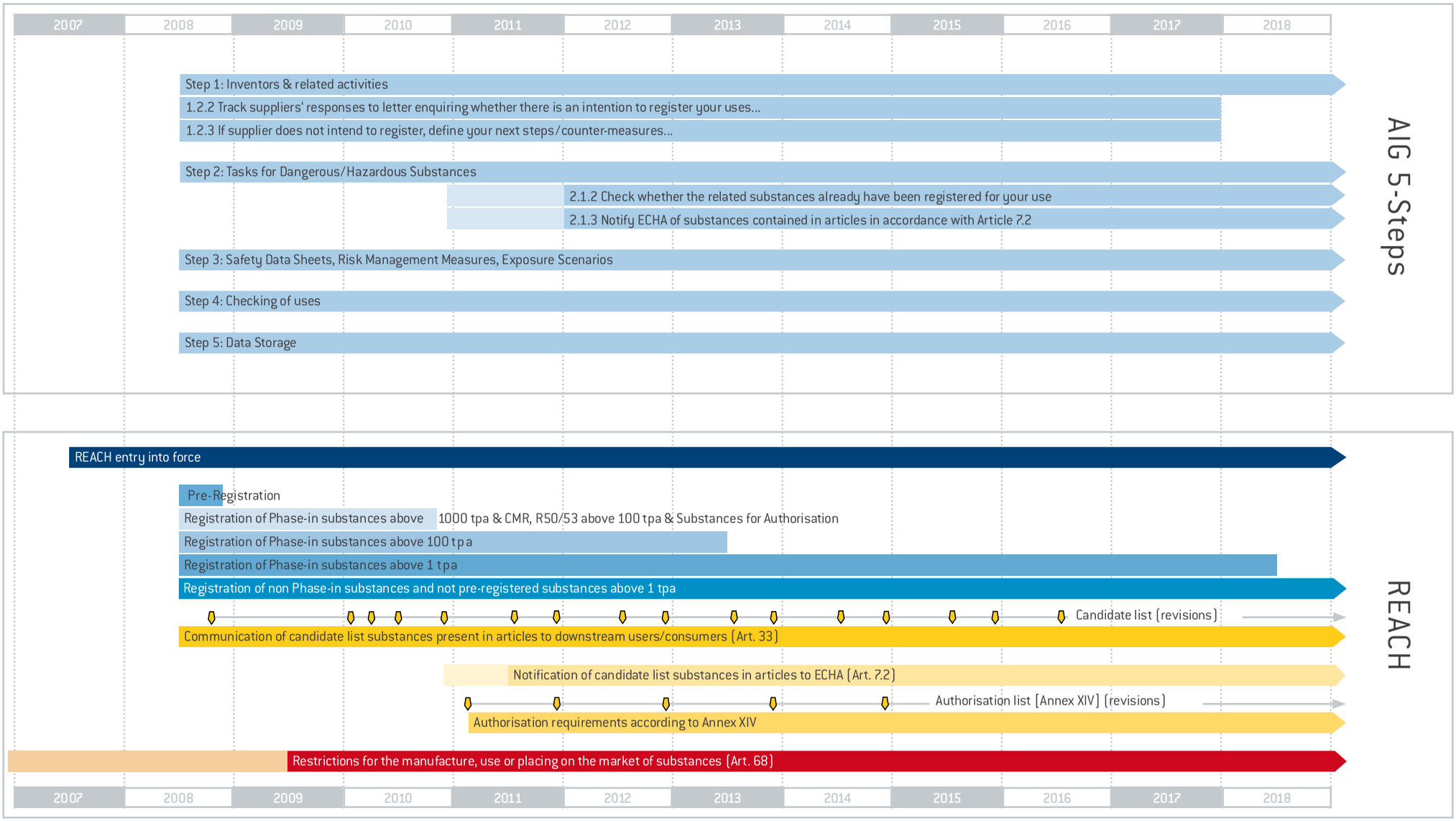
All of the finalised guidance documents are available on the ECHA website at: https://echa.europa.eu/guidance-documents/

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

CHAPTER 6: 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. Refer to Annex C "5-Step REACH compliance schedule" for a more detailed list in excel.

The chart on the right is based on the chart presented in Chapter 3.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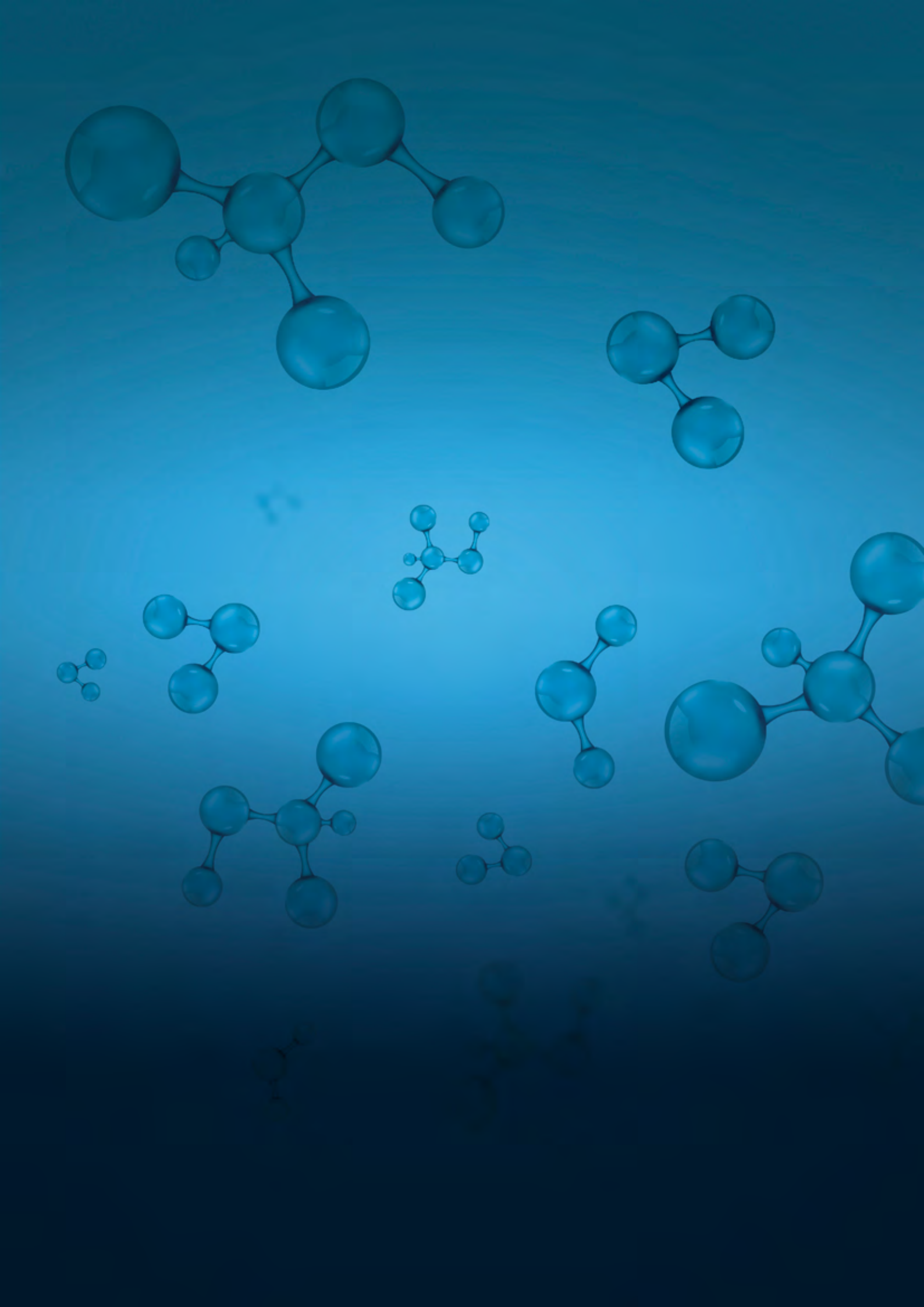
Step 1: Inventors & related activities
1.2.2 Track suppliers' responses to letter enquiring whether there is an intention to register your uses...
1.2.3 If supplier does not intend to register, define your next steps/counter-measures...
Step 2: Tasks for Dangerous/Hazardous Substances
2.1.2 Check whether 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
AIG 5-Steps
REACH entry into force
Pre-Registration
Registration of Phase-in substances above 1000 tpa & CMR, R50/53 above 100 tpa & Substances for Authorisation
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)
Authorisation list (Annex XIV) (revisions)
Authorisation requirements according to Annex XIV
Restrictions for the manufacture, use or placing on the market of substances (Art. 68)
REACH

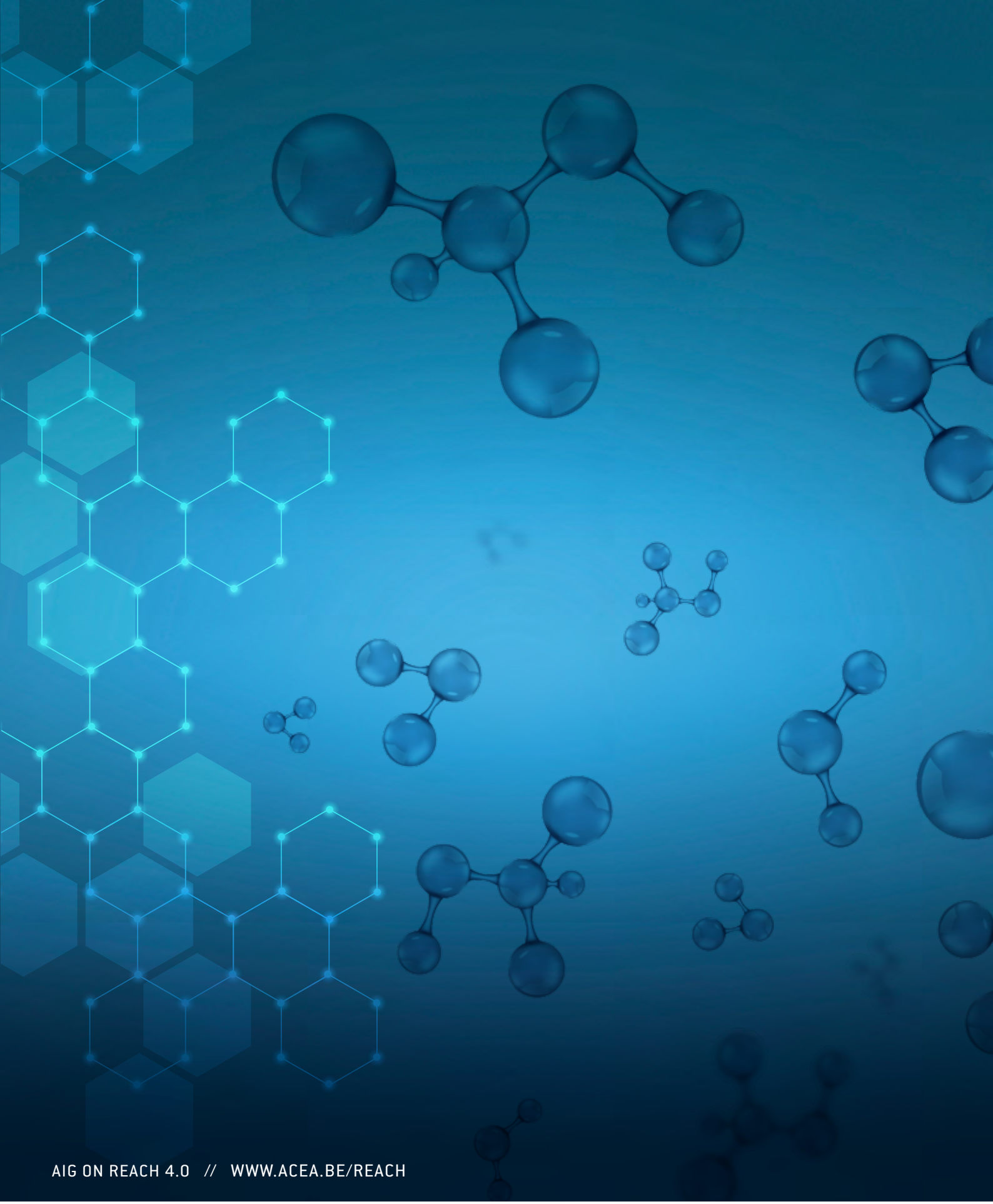
LIST OF ANNEXES

In its chapters, this Guideline refers 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 find a list of these documents. To download them, 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:	5-Steps Compliance Schedule.
Annex D:	Frequently Asked Questions (FAQ)
Annex E:	REACH - Supplier Risk Identification Matrix
Annex F:	REACH Sanctions in the Member States
Annex G:	Authority Helpdesks and Information Tools
Annex H:	Industry Helpdesks and Information Tools
Annex I:	REACH Substance Scrutiny – From PACT Onwards
Annex J:	REACH-GADSL-IMDS Flowchart
Annex K:	REACH Annex XVII Impact Evaluation List
Annex L:	Summary of Automotive Industry Position Papers & Communications
Annex M:	Art. 33 Answer Letters
Annex N:	Practical Application of the 05A Principle for CL Substances in Articles
Annex O:	Sustainable Substitution Criteria
Annex P:	SDS Obligations
Annex Q:	SDS Compliance Checks
Annex R:	History of Amendments to REACH Regulation
Annex S:	Addendum
Annex T:	List of Changes to AIG





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ACEA
European Automobile Manufacturers Association

CLEPA
European Association of Automotive Suppliers

JAMA
Japan Automobile Manufacturers Association, Inc.

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