REACH

Interpretation guidelines

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AeroSpace and Defence
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Table of contents

1/ Forward

Since the entry into force of REACH (Registration, Evaluation and Authorisation and Restriction of Chemicals) Regulation on 1 June 2007, most industrial sectors have now rallied to inform the different actors in their supply chain of the key points and associated issues of this regulation.

From 2007, the European aerospace industry has established interpretation guides and set up appropriate training. These efforts informed the industrial network of the main obligations and timelines through a dedicated organization (REACH Implementation Working Group later called RIWG) within ASD. This exchange of good practices and sharing of tools have undoubtedly helped mitigate the administrative and financial impact generated by this regulation, and aided compliance with these obligations.

Today, thanks to valuable experience gained, the REACH Implementation Working Group is ready to propose a new edition of the REACH Interpretation guidelines, paying particular attention to the specific needs of the aerospace industry and providing recommendations to make the implementation of REACH easier. This document is intended to a useful guide for the implementation of REACH, providing the user with various approaches without replacing the texts to which one should refer in his own compliance process.

The aerospace industry has a long tradition of traceability as part of its imperative safety requirements which must always be satisfied. This experience must be used and extended to include the traceability of hazardous substances throughout the product life cycle and the gradual elimination of the most hazardous substances. We hope that this document will provide readers with sufficient information to help implement these legal requirements and enable the business continuity of our industry.

2/ Executive Summary

The European regulation EC1907/2006 also known as REACH, which stands for «Registration Evaluation, Authorization and Restriction of Chemicals», is the European regulation which came into force on 1 June 2007 with the purpose of managing all chemicals manufactured, imported or used within the European Union. This regulation aims at reducing impacts to human health and to the environment, but is also intended to enhance the competitiveness of the chemical industry in the European Union.

REACH is impacting any company manufacturing, importing or using chemical substances on their own or contained in mixtures/articles. If your company uses chemicals or mixtures, manufactures products or distributes products/chemicals, then you must take into account the provisions of REACH to operate legally within the European Union, and consider what action needs to be taken to maintain supply.

Responsibility for chemical safety assessment now lies with the substance manufacturers and importers. The legislation requires compulsory sharing of data in order to minimise animal testing. This will result in a better understanding of risk for the 30,000 most frequently used substances throughout their life cycle and could gradually lead to the withdrawal from the market of the substances of highest concern. Use of some substances may now be subject to a legally binding authorisation process where they meet the criteria for being Substances of Very High Concern.

A change in the classification and labelling of all chemical substances and mixtures is taking place with the international adoption of the Globally Harmonised System (GHS), now introduced as the CLP (Classification, Labelling and Packaging of substances and mixtures) regulation in Europe.

The authority responsible for implementing and monitoring this system is the ECHA (European Chemicals Agency), which is based in Helsinki. The ECHA website is a rich and obviously reliable source of information on REACH and CLP, which is accessible at http://echa.europa.eu.

REACH is generating an unprecedented change in the conditions under which information is exchanged on substances, mixtures and articles, and in the distribution of responsibilities between the various actors all along the supply chain. All actors in a supply chain must now strengthen the traceability of the various substances they use, and mandatorily declare the use of Substances of Very high concern within their products according to the provisions of REACH.

Finally, and perhaps most importantly, REACH is creating an unprecedented threat of obsolescence. This arises from the regulatory obligations placed on upstream chemical producers, which affects commercial viability for continued supply, especially in low volume uses of chemicals such as in the Aerospace and Defence industry. These guidelines should help the reader navigate and manage these issues.

3/ Glossary and Definitions

3.1/ Glossary

CAS: Chemical Abstract Service

CBOM: Chemical Bill of Material

Cefic: European Chemical Industry Council

CMRs: Carcinogenic, Mutagenic or Toxic (for reproduction) Chemicals classified under Directive 67/548)

Consortia: A grouping of companies with similar interests, formed through a contractual agreement to minimise the costs of REACH. These groups have no legal standing in REACH, but are formed by companies to help share costs and data required for Registration or Authorisation.

CoRAP: Community Rolling Action Plan

(http://echa.europa.eu/web/guest/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan)

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DNEL: Derived No-Effect Level. *This is the level of exposure to a substance to which humans may be submitted.*

DU: Downstream Users

DUCC: Downstream Users of Chemicals Co-ordination group (http://www.ducc.eu/Home.aspx)

ECHA: European Chemicals Agency

EINECS: List of substances compiled in 1981 that today are considered "existing substances

See *http://esis.jrc.ec.europa.eu/index.php?PGM=ein*

ELINCS: European List of Notified Chemical Substances

See *http://esis.jrc.ec.europa.eu/index.php?PGM=eli*

Endocrine disrupters: Substances of very high concern that mimic or inhibit the effects of hormones.

GD: (ECHA) Guidance Document

GHS: the UN's Globally Harmonised System of Classification and Labelling

IUCLID: International Uniform Chemical Information Database

IUPAC: International Union for Pure Applied Chemistry

See *http://www.iupac.org/*

PBT: Persistent, Bio-accumulative and Toxic

Polymers: large molecules consisting of repeated chemical units (monomers)

POPs: Persistent Organic Pollutants

PPORD: Product and Process Oriented Research and Development

R&T: Research and Technology

SDS: Safety Data Sheet - tool for information transfer for all dangerous substances

SEA: Socio-economic analysis

SIEF: Substance Information Exchange Forum. *Groupings of all companies registering the same substance*

SVHC: Substance of Very High Concern

vPvB: Very Persistent, Very Bio-accumulative

3.2/ Definitions

The definitions here below are provided from article 3 of REACH for the purposes of this regulation.

1. Actors in the supply chain: means all manufacturers and/or importers and/or downstream users in a supply chain.

2. Agency: means the European Chemicals Agency as established by this Regulation.

3. Alloy: means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.

4. 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.

An article may in turn be made up of an assembly of articles; according to this definition, metal sheets, bearings, engines, cars or aircraft are considered to be articles. Please note that sometimes it is difficult to determine whether something is an article or mixture.

This definition is based on the advice communicated by the commission legal service.

5. Competent authority: means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation.

6. 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.

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

8. Exposure scenario: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

9. Full study report: means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed

10. Identified use: means a use of a substance on its own or in a mixture, or a use of 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.

11. Import: means the physical introduction into the customs territory of the Community.

12. Importer: means any natural or legal person established within the Community who is responsible for import.

13. 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):

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

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

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

14. Manufacturer: means any natural or legal person established within the Community who manufactures a substance within the Community.

15. Manufacturing: means production or extraction of substances in the natural state.

16. Mixture: means a mixture or solution composed of two or more substances.

17. 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.

18. Not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities.

19. Notified substance: means a substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC.

20. Per year: means per calendar year, 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 basis of the average production or import volumes for the three preceding calendar years.

21. Phase-in substance: means a substance which meets at least one of the following criteria:

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

(b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004 or on 1 January 2007, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the

entry into force of this regulation, provided the manufacturer or importer has documentary evidence of this;

(c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004 or on 1 January 2007, by the manufacturer or importer before the entry into force of this Regulation and it was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC in the version of Article 8(1) resulting from the amendment effected by Directive 79/831/EEC, but it does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this, including proof that the substance was placed on the market by any manufacturer or importer between 18 September 1981 and 31 October 1993 inclusive.

22. 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.

23. 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.

24. Producer of an article: means any natural or legal person who makes or assembles an article within the Community.

25. Product and process orientated research and development: 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.

26. Recipient of a substance or a mixture: means a downstream user or a distributor being supplied with a substance or a mixture.

27. Recipient of an article: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers.

28. Registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance.

29. Registrant's own use: means an industrial or professional use by the registrant.

30. Restriction: means any condition for or prohibition of the manufacture, use or placing on the market.

31. Robust study summary: means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independ-

ent assessment of the study minimising the need to consult the full study report.

32. Scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year.

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

34. SME: means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises.

35. Study summary: means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study.

36. 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.

A substance is characterised by an IUPAC chemical name and a CAS number.

Examples: Methanal (Formaldehyde) - CAS No 50-00-0

Nickel metal - CAS No 7440-02-0

Tetrachloroethylene (Perchlorethylene) - CAS No 127-18-4

37. substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means.

38. Supplier of a substance: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture.

39. 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.

40. 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.

41. 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.

4/ REACH and the Aerospace, Defence and Security sector

Being a major industrial sector in Europe, REACH has and will to continue to have a significant impact on the Aerospace Defence and Security sector. Our sector has indeed many specific characteristics, leading to major issues on our way to complying with REACH.

These specific issues are:

- Very low volume consumption of chemicals compared to consumer use and other industry sectors;
- Low production series and long production timelines for single platform and total production runs;
- International certification process (any change must be certified);
- The need to keep the products in operational conditions over their long life cycle (>30 years);
- Supply chains which are both international and highly complex, holding stock for long periods of time, re-sale and re-use of second hand assets;
- Manufacture of highly complex articles;
- Some substances, including some SVHC's, are absolutely critical to ensure aircraft safety (e.g. chromates for anti-corrosion protection).
- Repair and overhaul may only be undertaken by approved organisations in accordance with controlled and approved design data

Therefore, it is expected that the consequences associated with the implementation of REACH will be significantly higher than for other sectors.

Our sector concerns are:

- Business and supply chain disruption due to:
  - Non-registration of substances or non coverage of use;
  - Non-authorization of substance uses;
- Administration and flow of data to be exchanged throughout the supply chain, whilst ensuring compliance as well as consistent treatment for Defence and Security sector,
- Additional R&T costs, in particular linked to the development/qualification of alternatives and the adaptation of processes to match safety requirements.

It is expected that REACH will lead to a significant reorganization of the chemical supply chain along with additional and significant administrative and R&T costs.

For more information on the impacts of REACH on the Aerospace, Defence and Security business, please refer to the dedicated ASD document entitled "*REACH Main concerns resulting from the implementation of REACH within the Aerospace Defence and Security business*", available on the ASD website at:

http://www.asd-europe.org/fileadmin/user_upload/Client_documents/ASD_Contents/7_CROSS-FUNCTIONS/7.4_Environment/REACH_14.pdf

5/ REACH main obligations

REACH comprises three steps:

- Compulsory **registration** of all substances to which it applies (see below)
- **evaluation** of the inherent properties of these substances,
- **authorisation** or restriction.

Strengthening the communication of information throughout the supply chain is also a requirement of REACH.

As a general rule, REACH applies to all substances:

on their own; contained in mixtures; or contained in articles.

Potentially included therefore are all "ingredients", raw materials, components, alloys, etc.

The provisions to be implemented in order to comply vary according to the hazardous properties, your role in the supply chain and the quantities of the substance manufactured or placed on the market in the European Union.

However, this regulation does not apply to:

- radioactive substances;
- substances subject to customs control that are not intended to remain in the European Union and are not processed or treated;
- non-isolated intermediates;
- the transport of dangerous substances by rail, road, inland waterway, sea or air;
- waste, unless it is reused or recycled as a new product; and
- whenever this is necessary to preserve the interests of the Defence of a Member State, in accordance with any defence exemption provided by individual member states.

You are impacted by REACH if you are dependent on chemicals in your supply chain or product manufacture, but you may also be concerned by some of the REACH obligations depending on the chemical content of your products and your role in the supply chain.

i Several gateways exist for entering the REACH system, amongst which are:

The minimum threshold above which the registration for a manufactured or imported substance applies is set at one tonne per year accumulated per legal entity;

Substances subject to authorisation are included whatever their quantity (see chapter VI).

i For defence exemptions please refer to chapter 10 “Defence exemption” of this document.

5.1/ Registration

5.1.1/ Who must register?

There are two possible cases:

- Substances on their own or contained in mixtures: manufacturers or importers of substances/mixtures must register the substances if manufactured or imported in quantities of more than one tonne per year*;
- Substances contained in articles: producers or importers of articles must register each substance:
  - ◊ present in these articles in quantities greater than or equal to one tonne per year*;
  - ◊ and intended to be released under normal or reasonably foreseeable conditions of use;
  - ◊ and if the substance has not already been registered for this use.

*Average estimated over the previous 3 calendar years (Art. 3 (30) and chapter 2.2.6.5 of the "Registration" Guidance document).

It is not always clear whether a substance in an article is 'intended to be released', whether a substance is part of a 'mixture in a container' or whether it is not an intentional release, but merely inevitable.

This procedure is applicable to each legal entity.

Example: the subsidiaries of any given company that each import more than one tonne of a substance a year must each register that substance.

For further details, please refer to your national helpdesk.

If a subsidiary legal entity purchases a substance in quantities greater than 1 tonne per year from outside Europe under its own name, and separately to the parent company, then it needs to register that substance itself.

If the parent company also imports the substance, then it will need to also register the substance.

Organisationally, it can be the same individuals that do the administration, but two registration dossiers have to be submitted, and two fees have to be paid.

"No data, no market" principle"

Substances above 1 tonne per annum that have not been registered where required cannot be manufactured or placed on the market in the EEA.

Some substances do not have EINECS or ELINCS numbers and therefore cannot benefit from phase-in and have not already been registered. These substances, and all future new substances, have to go through an INQUIRY process with ECHA prior to Registration to allow data sharing with other Registrants. Details of this process are available at: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/inquiry

5.1.2/ Registration procedure

This is an administrative procedure for submitting a declaration to the European Chemicals Agency supported by a technical dossier whose content and complexity vary according to the quantity and hazardous properties of the substance (article 10).

All companies that are obliged to register the same substance are strongly advised to make a joint registration to minimise duplication of effort or animal testing. For this purpose, the various registrants are automatically put in contact with each other by a Substance Information Exchange Forum (SIEF). One Registrant takes a Lead Registrant role; all other registrants use the core data from the Lead Registrant and register after the Lead Registrant. The Lead Registrant is consequently expected to register before other registrants in the same SIEF.

The SIEF will need a Consortium agreement to determine and agree cost sharing and data sharing obligations between joint registrants. Later registrants of the same substance would need to purchase a "Letter of Access" from the SIEF to gain access to the Lead Registrant data and contribute to the sharing of costs. Due to administrative costs, letters of access are more expensive than being an original member of the SIEF consortium.

Manufacturers based outside the European Union may appoint a natural or legal person established in the European Union to accomplish, as an Only Representative, taking responsibility for Registration in place of Importers. Suppliers of imported mixtures are most likely to appoint Only Representatives to preserve commercial confidentiality of mixture constituents.

Companies that purchase supplies from outside the European Union are advised to encourage their non-European suppliers to appoint such an Only Representative. If none is appointed, the Purchaser may have Registration obligations as an importer.

5.1.3/ The case of polymers

The registration requirement does not apply to polymers.

All manufacturers or importers of a polymer must submit a request for registration to the Agency for the monomer substance(s) or any other substances that have not yet been registered by an actor situated upstream in the supply chain if both the following conditions are met:

- the polymer contains 2 % weight by weight or more of that or those monomer or other substances;

  and

- the total quantity of that or those monomer or other substances totals one tonne or more per year.

For further guidance refer to the ECHA Guidance for monomers and polymers.

The requirement to register monomers of polymers applies to all monomers that have not been registered. In the case of polymers, monomers are subject to registration as are any incorporated additives.

5.1.4/ Substances not subject to registration

5.1.4.1/ Already registered substances

Substances notified under legislation Directive 67/548/EEC (ELINCS), are regarded as already registered. ECHA granted them a registration number by 1 December 2008.

This type of notification is made with respect to a named entity and this article therefore applies only to those who have made a notification. All other manufacturers or importers of the substance must register it.

5.1.4.2/ Non-Isolated Intermediates

These are substances created in a chemical process, subsequently converted to other substances, but never extracted from the process before conversion. These are entirely outside the scope of REACH.

5.1.4.3/ Exempted substances

The following substances are exempted from registration (as well as from the "Downstream users" and "Evaluation" titles):

- The substances listed in annex IV because sufficient information is available to consider that they represent a minimal risk. *Examples: Carbon Dioxide, Argon, Nitrogen, Glucose, Ascorbic Acid.*
- The substances listed in annex V. These are principally:
  - ◊ Products of unintentional chemical reactions due to environmental factors, or of intentional chemical reactions in processes when they are not manufactured, imported or put on the market;
  - ◊ Minerals, ores, ore concentrates, crude oil and natural gas;
  - ◊ Other substances occurring in nature or elemental substances, unless it:
    - * is classified as dangerous in Regulation EC 1272/2008;
    - * persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or ;
    - * has been on the Candidate List for over 2 years;
- results from a chemical reaction occurring upon end use of other substances, mixtures or articles and which are not then manufactured, imported or placed on the market.

  Example: a substance formed by a reaction between other substances in the manufacture of a mixture within Europe, and not extracted from that mixture for sale need not be registered, even if it is declared on the Safety Data Sheet!

5.1.4.4/ Research and Development Use

Scientific Research and Development use is out of the scope of registration under REACH. Substances manufactured in Europe or imported for Product and Process Oriented Research and Development activity purposes can be exempted from registration for a period of 5 years.

5.1.4.5/ Isolated Intermediates

Intermediates which are isolated from the chemical process and subsequently transformed into another substance, and are categorised into 2 types:

- On-Site Isolated Intermediates (OSII): Extracted and subsequently transformed within the same site;
- Transported Isolated Intermediates (TII): Extracted and then transported to another location, and subsequently transformed.

Isolated Intermediates are subject to reduced registration obligations, provided that they are rigorously contained through technical means through its entire lifecycle, including for manufacture, sampling, maintenance and cleaning - referred to as “Strictly Controlled Conditions".

For Transported Isolated intermediates, Strictly Controlled Conditions must be confirmed by all users of the substance. If Strictly Controlled Conditions cannot be proven then a full registration dossier is required.

5.1.4.6/ Substances in articles

According to REACH an article is defined as **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**. Nevertheless, in certain cases, the boundary between a mixture and an article remains difficult to determine, and reference should be made to the ECHA Guidance on Substances in articles for clarification.

With respect to metals, bars, blanks (punched out, machined, stamped), films and filaments, thin foils and ribbons, forgings, thick sheets, pipes and tubes (cast, without welding and welded), tube and pipe connections, sheet and strip (coated or otherwise), stamped parts, machine-wire and wire, sintered parts (finished or otherwise) are articles.

5.1.4.6.1/ Case where a substance present in articles must be registered

Pursuant to article 7.1 of the Regulation, any producer or importer of articles must register a substance present in these articles if **all** the following conditions are met:

a) The substance is present in those articles in quantities of more than a total of 1 tonne per year per producer or importer;

and,

b) The substance is intended to be released under normal or reasonably foreseeable conditions of use;

and,

c) The substance has not already been registered for that use. When that substance is present in quantities greater than 10 tonnes per year, the producer or importer is required to produce a Chemical Safety Report (see chapter IV).

Article 7.1 means that from 2008 the producer or importer of an article preregisters the substance that meets criteria a) and b).

Example:

The producer is aware that criteria a) and b) are met.

Assume that the substance in question is present in his articles at a total quantity of 8 tonnes/year: he is potentially required therefore to register in 2018 (date for quantities comprised between 1 and 100 t).

In order to benefit from not having to register until 2018, he must have preregistered the substance between June and November 2008.

In 2018, he will only have to register if his use has not already been covered by a registration made earlier (2010 or 2013) by someone else.

The term intentional release is used when the answer to the following question is "yes":

Is the release of a substance/preparation in normal and reasonably foreseeable use of an article desired because it is necessary in order to allow the article to fulfil a certain function?

Intentional release therefore depends on the intention of the article's producer and is deliberately planned. Furthermore, it contributes to a specific function of the article which is often not its main function (added value).

Example: perfume diffuser in a car, packaging that gives off anti-corrosion products

In the case where intentional release is the article's main function, this usually concerns a substance/preparation in a container.

Example.: fire extinguisher, cleaning towelette

In certain situations, the release is not considered to be intentional:

- release of "impurities" during an article's manufacturing process;
- release during the use or maintenance of an article with a view to improving the quality or safety of the product, the released substances not contributing to the article's main function:

Example: rinsing of textiles

- release as an inevitable secondary effect

Example: wear on tyres, brake pads…

- release of substances formed during any type of chemical reaction:

Example: release of ozone by photocopiers, release of substances during chemical reactions caused by accident or incorrect use

- accidental release or during incorrect use.

The normal conditions of use are associated with the article's main function. They are often described in the operating manual or user's instructions. These conditions may be different for industrial companies and the end consumers.

The reasonably foreseeable conditions of use are not planned by the producer or importer of

the article, but may arise because of the article's shape, surface or design.

> **Example:** high-probability accidents (e.g. breaking of a fragile container), uses suggested by the article's function or appearance, more frequent utilisation than initially expected.

In the case of professional and industrial uses, the following conditions cannot be considered to be reasonably foreseeable:

- uses clearly and specifically excluded by the article's producer or importer;
- uses that are clearly not recommended due to the article's design and/or warning labels;
- clearly inappropriate use.

5.1.4.6.2/ How to calculate the quantities provided for by Art. 7.1 a)

A company imports three articles A, B and C, each containing 60 tonnes of a given substance X.

Article A will not release substance X during its lifetime.

Article B will release 40 tonnes (out of the 60 initially contained in the article) under reasonable and foreseeable conditions of use, and article C 10 tonnes (out of the 60 tonnes).

The company will therefore have to register the sum of all the amounts of substance X contained in articles B and C (both the quantities released and those not released), that is to say 120 tonnes.

5.1.5/ Content of the registration dossier

The registrant must complete a technical dossier which includes a range of information, clearly detailed in the ECHA guidance on registration.

This includes in particular:

- the identity of the manufacturers or importers;
- the identity of the substance;
- information on the manufacture and the use(s) made of the substance;
- the classification and labelling of the substance;
- guidance on safe use of the substance;
- the study summaries regarding the information derived from the application of annexes VII to XI (relative to the requirements in the area of standard information for manufactured or imported substances in quantities of one tonne or more, 10 tonnes or more, or 100 tonnes or more);
- a request as to which of the information in article 119(2) the manufacturer or importer considers should not be made available on the Internet, with in particular the commercial reasons.

Furthermore, the registrant must draw up a chemical safety report for all substances subject to registration, for quantities of 10 tonnes or more per year per registrant. The chemical safety report is intended to help identify the hazards and facilitate their subsequent control. It contains the CSA, either for each substance, or for a group of substances. The CSA includes assessments of the hazards for human health; the physicochemical hazards; the environmental hazards; and the PBT and vPvB aspects.

The Chemical Safety Report prepared by the registrant needs to cover all known 'uses' of a substance within his supply chain, from cradle to grave. In REACH, 'use' is a very broad term and includes original synthesis, storage and transport right through to application and methods of disposal.

Any data shall be entered and the registration or notification dossiers shall be prepared using the IUCLID 5 software or on-line via REACH-IT (See http://iuclid.echa.europa.eu/).

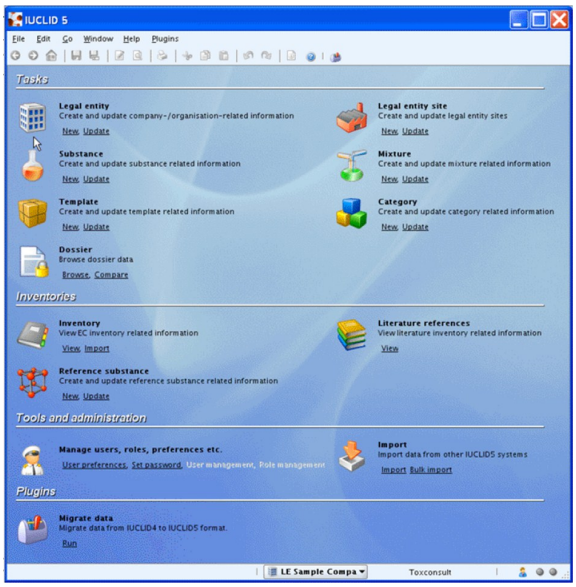


Figure 3: IUCLID 5 software home page

5.1.6/ Registration implications for the Downstream User (see also section 5.6).

The uses covered by the chemical safety report have to be stated on the extended Safety Data Sheet produced by the registrant.

Uses not covered by the Registrant may be acceptable if:

- The use and exposure is broadly inside the conditions, due to a lower risk or similar use (such as “brushing” where “spraying” or “rollering” was Registered”); or
- The user uses less than a tonne per year of the substance or mixture, and ECHA is notified within 6 months; or
- The substance or mixture is being used for Process or Product Oriented Research and Development, and ECHA and ECHA is notified within 6 months of first use.

If Uses not covered do not fulfil one of these, the user will have to undertake one of the following:

- A Downstream User Chemical Safety Report within 12 months of receipt of the substance Registration number through the Safety Data Sheet, and notify ECHA within 6 months (this may be the preferred solution for highly confidential process applications);
- Persuade the Registrant to update the registration dossier to include the missing uses;
- Implement changes to use and risk management measures to align with those registered;
- Discontinue use.

The impact and timescales of these options differ greatly.

Getting the Registrant to update the dossier and Safety Data Sheet may benefit your suppliers as well as your own company. The Registrant may only refuse to do this on grounds of health or environmental protection.

It is in the interests of downstream users to ensure that their uses will be Registered by their up-stream supply chain, as soon as possible. *See guidance to downstream users on this topic http://echa.europa.eu/documents/10162/13634/du_en.pdf.*

Guidance on Chemical Safety Reports is available on the ECHA web-site. Section D of the guidance explains how uses relate to exposure scenarios and end point tests.

The 'Guidance on Information Requirements and Chemical Safety Assessment Section R12' contains the Use Descriptor System, which is used by registrants to classify uses.

See http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

See guidance to downstream users on this topic.

5.1.7/ Fees

Any request for registration must be accompanied by the required fee.

5.1.8/ Supply Chain Continuity Concerns

Registration is a costly burden for Manufacturers and Importers. There are 3 components to the costs for this:

- The (shared) costs for data searches, test data and chemical safety reports – avoidable for Isolated Intermediates under Strictly Controlled Conditions
- SIEF Consortium management costs
- ECHA fees (€64 to €33,201 depending on volume range and company size)

The total cost for Registration may be typically between €20,000 and €1,000,000, depending on the quantity of data required, tonnage and other factors.

Some potential Registrants may not register at all if the market is not big enough, or limit the Registration costs through limiting supply to Isolated Intermediate with Strictly Controlled Conditions.

5.1.8.1/ Ensuring Supply Continuity and Use Coverage in Registration

18-12 Months before each Registration Milestone

- provide use information as high up the supply chain as possible. Use the DUCC user template if possible, to reduce upstream supplier administration burden. Use data may be accepted after this timescale, though there is no legal obligation to do so. Registrants have a right to ignore uses also if there is a safety or environmental concern from the proposed uses.

See use and exposure information at http://www.ducc.eu/Activities.aspx

The Authorities may want to see evidence of this if help is required with supply chain continuity later.

12 – 6 Months before each Registration Milestone

- ask suppliers to confirm (with sub-tiers if necessary) that supply will continue irrespective of potential Registration requirements;
- resolve problems or seek new sources if a problem seems likely – note this may

require a financial contribution towards registration costs;

- consider whether it is possible to substitute to prevent business disruption.

6 – 0 Months before each Registration Milestone

- pre-stock any substances or mixtures still at risk – 6 to 12 months of stock is advised, but do consider shelf life;
- consider the Director's Contact Group solutions on the ECHA web-site, in particular number 21, which can be used to continue supply with a new Importer, with only partial Registration – this can buy time; *See* *http://echa.europa.eu/web/guest/about-us/partners-and-networks/directors-contact-group*
- if all else fails initially contact your trade association, followed by the MS CA helpdesk or ECHA helpdesk for advice, this also applies after the deadline.

Use of substances and mixtures in stock after the initial placing on the Market or import into Europe is allowable after the applicable Registration date.

This is a valuable risk mitigation measure. Stock may be held at any point in the supply chain downstream of the Manufacturer or Importer if purchased prior to the Registration date.

5.1.9/ Registration milestones

31 May 2017: 3rd Late pre-registration period ends on 31 May 2017 for substances to be registered by 31 May 2018. Downstream users should notify their uses to the suppliers at the latest by this date.

31 May 2018: 3rd and final registration deadline for phase-in substances manufactured in the Community or imported in quantities of 1 tonne or more per year per manufacturer or per importer at least once after 1 June 2007.

5.2/ Evaluation

This is the ECHA's monitoring tool. Since one of the key goals of REACH is to have a better understanding of the hazards and a better control of the risks with respect to dangerous substances, an evaluation process - for registration dossiers - has been put in place.

3 types of evaluation have been defined by the regulation:

- Dossier evaluation;
- Substance evaluation;
- Evaluation of intermediate.

5.2.1/ Dossier evaluation

The evaluation of the registration dossier includes:

- examination of the test proposals submitted by the manufacturers and importers ;
- verification of the compliance of the registration dossiers.

ECHA automatically checks the completeness of each registration dossier. The ECHA will then check at least 5% of the registrations per tonnage band in greater depth.

As a priority, ECHA selects dossiers for evaluation using four sets of criteria:

- random selection;
- criteria set out in the REACH Regulation (e.g. substance mentioned in the Community rolling action plan);
- other concern driven criteria;
- testing proposal with unclear identity of the substance registered.

5.2.2/ Substance evaluation

The substance evaluation process aims to clarify possible risk of the use of a substance.

The first step of the Substance evaluation is the establishment by ECHA of a list of substances (CoRAP) to be evaluated for a three-year period.

These priority substances are chosen according to a risk-based approach (hazard, exposure and tonnage, including the aggregated tonnage of the same substance from multiple registrations.)

ECHA adopted the first plan on 29 February 2012 (90 substances): http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table.

ECHA will present annually to the Member States, on 28 February at the latest, draft updates of the CoRAP.

Member States will carry out the evaluation, under the supervision of the ECHA responsible for its coordination. From the publication of the CoRAP, designated Member States have one year to evaluate the substance.

In case the evaluation concludes that the risks are not sufficiently under control with the measures already in place, it may lead to the proposal of EU-wide risk management measures such as restrictions, identification of SVHC, harmonised classification or other actions outside the scope of REACH.

5.2.3/ Evaluation of intermediates

Isolated intermediates remaining on the site that are used under strictly controlled conditions are not subject to a dossier evaluation or to a substance evaluation.

However, if there is any risk, the authority of the Member State upon whose territory the site is located may ask the registrant to send additional information on the risk that has been identified, or recommend risk reduction measures.

5.2.4/ Publication of the information relative to evaluation

No later than 28 February of each year, the ECHA will publish a report on its website on the progress made during the past year regarding evaluation. This report will include, in particular, recommendations to potential registrants in order to improve the quality of future registrations.

See the latest reports at: http://echa.europa.eu/web/guest/regulations/REACH/evaluation.

5.3/ Authorisation

Note: This section is extracted from Industry Guidance-REACH Authorisation Guidance for Downstream Users. Users are recommended to check the Cefic website for subsequent updates:

http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/REACH-Authorisation-Guidance-for-Downstream-Users.pdf

Any Substance considered to be of Very High Concern (SVHC) pursuant to Article 57 of the REACH Regulation might be introduced in the "Candidate List". From this list, substances with very high health and/or environmental concerns will be prioritised for inclusion in Annex XIV of REACH. Once the European Commission (following the comitology procedure) has included the substance on the list given in Annex XIV of REACH and the defined sunset date has passed, the substance cannot be placed on the market for a use or used without the prior authorisation of the European Commission unless that use is exempt from authorisation.

REACH authorisation is a new, complex and expensive process;

- *The regulation encourages change and the development of safer alternatives.*
- *Authorisation is granted for a limited period, after which the applicant may re-apply.*
- *It is clear that the quality of the application for authorisation (strength and simplicity) is key to the success of that application –and, depending on the substance and the particular applicant, the Socio-Economic Analysis (SEA) and Analysis of Alternatives (AoA) are very important.*

Authorisation aims to:

- guarantee that the risks relative to substances of very high concern are properly controlled throughout their life cycle, and
- promote the progressive replacement of these substances by other substances or by the implementation of new technologies if and when these are economically and technically available and feasible.

In the authorisation process, it is not substances as such that require authorisation, but the uses of those substances. Therefore, any use of a SVHC included in Annex XIV that is not authorised or exempt from authorisation is prohibited after the sunset date.

In the EEA, placing an Annex XIV substance on the market after the sunset date is subject to authorisation which is company-specific, supply chain-specific and use-specific.

5.3.1/ Which substances are affected?

Authorisation relates to substances of very high concern, as defined in the REACH Regulation, Article 57 (a) to (f), i.e.:

- substances which are CMRs categories 1A and 1B (CLP Regulation)
- Persistent, Bioaccumulative and Toxic substances (PBT)
- very Persistent and very Bioaccumulative substances (vPvB)
- substances identified on a case by case basis whose health and environmental effects give rise to an equivalent level of concern to those above (for instance such substances may be substances having endocrine disrupting properties or having PBT/vPvB properties without fulfilling the PBT/ vPvB criteria set out in Annex XIII of REACH).

The European Chemical Agency (ECHA) publishes on its website the list of substances identified as SVHC in the so-called "Candidate List" (CL). This CL is a "living document", typically updated twice per year, with new substances being added each time.

Substances recommended by ECHA to the Commission, for potential inclusion in Annex XIV are selected from this CL. Annex XIV is the list of substances subject to authorisation.

Alternatively, a restriction can also be proposed for SVHC substances.

Link to ECHA Recommendation:

http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list

i *Examples of substances without a threshold that were recommended for inclusion on Annex XIV at the time of publication (2012) and that are known to be used in many industries include Chromium Trioxide, Sodium Dichromate, Potassium Dichromate, Trichloroethylene, Dichloroethane and MDA. Further details on the categories of substances that require authorisation can be found on ECHA's website*

5.3.2/ What is the impact of substances of very high concern (SVHCs) on article producers?

1. Notification of SVHCs in articles within 6 months after inclusion of a substance on the CL

According to Article 7(2) of the REACH Regulation (EC) No 1907/2006, producers and importers of articles have to notify to ECHA if the substance listed on the candidate list is present in their articles above 1tonne/year and in a concentration > 0.1% w/w. If the use of the SVHC in articles has already been covered in the registration dossier, or if no exposure to human or environment can be foreseen from that use, no notification by the article producer/importer needs to be submitted to ECHA.

http://echa.europa.eu/en/web/guest/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles

2. Communication of SVHCs in articles immediately after inclusion on the CL

According to Article 33(1) and (2) of REACH, any supplier of an article containing a substance meeting the SVHC criteria in a concentration above 0.1% w/w shall provide:

1) the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article, including, as a minimum, the name of the substance.

2) the consumer (on his request) with sufficient information, available to the supplier, to allow safe use of the article, as minimum the name of the substance. The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

3. SVHC on the authorisation list (Annex XIV):

For imported articles, the substances listed in Annex XIV that are an integral part of articles (as defined in Article 3(3) of the REACH Regulation) will not require an application for **authorisation**. However, substances in imported articles can still be subject to a **restriction**.

For articles produced in the EEA (European Economic Area), the substances listed in Annex XIV that are:

1) an integral part of these articles will require an application for authorisation if the intention is to use the substance (in this case, use means incorporate it into the article) after the sunset date, unless an exemption applies to that (category of) use. This application can be submitted by the article producer or by the upstream supplier which has decided to cover the article producer's use in their application for authorisation.

2) used in the production process of the article but not included in the final article, will require an application for authorization covering the whole manufacturing process of the article.

Note: The use of the **article** containing an Annex XIV substance is not a use of a substance requiring an authorisation; however the article service life and its end of life shall be assessed in the exposure scenarios (Chemical Safety Report) provided in the application for authorisation covering the use of the **substance.**

Where articles are produced in the EEA before the sunset date and held in stock;

- *There is a need to apply for the use of a substance but not for the use of articles containing the substance. Therefore, authorisation is not required when assembling parts of articles.*
- *The whole life cycle (including the article service life) shall be covered in the CSR provided in the application for authorisation covering the substance use.*
- *Articles (or parts of articles) in stock produced in the EEA before the sunset date can be supplied after the sunset date.*
- *Communication obligations remain for substances listed on the CL contained in articles at more than 0.1%weight/weight*

5.3.3/ What is the authorisation procedure?

Examples of substances without a threshold that were recommended for inclusion on Annex XIV at the time of publication (2012) and that are known to be used in many industries include Chromium Trioxide, Sodium Dichromate, Potassium Dichromate, Trichloroethylene, Dichloroethane and MDA. Further details on the categories of substances that require authorisation can be found on ECHA's website

The authorisation may be granted or not. The ECHA Committees form an opinion which is sent to the Commission for decision-making.

An application for authorisation may include a request for the length of time of continued use. However, the Commission decides on the time-limited review period.

If an authorisation application is denied, applicants can lodge an appeal against the adverse decision of the Commission before the European Court of Justice (in Luxembourg).

The authorisation may be reviewed or suspended by the Commission at any time, if information regarding possible replacement substances becomes available or the circumstances of the authorisation have changed.

Timeline

The timeline for the authorisation process is very tightly controlled so it is necessary to take into consideration the time submission window period when defining your business strategy. ECHA has to receive the payment of the fees before the latest application date in order to ensure market continuity after the sunset date and before Commission's final decision.

Every applicant submitting a dossier after the latest application date has to stop using the substance after the sunset date until authorisation has been granted. On the other hand applicants, who have submitted an application before the latest application deadline specified in Annex XIV but have not yet received a decision, can still use the substance after the sunset date.

In order to clarify regulatory and procedural issues related to the application for authorisation, as well as the wording published for the public consultation on alternatives, the applicant may use the opportunity to meet ECHA during the pre-submission information session (PSIS); One session per applicant, requested to ECHA no later than 8 months before the submission is foreseen.

Hereafter, the timeline indicates the commenting period for stakeholders available from the publication of the Annex XV SVHC dossier until the decision given by the European Commission on the application for authorisation. **All supporting information must be provided ONLY during the three public consultation periods** shown in Figures 1-4. It is strongly recommended that Downstream Users **use the opportunity to comment**. The information as described in the following table should be included in the comments. Downstream users can comment for example that some specific uses shall be exempt from authorisation or some uses need a longer review period. **Don't miss it!**

Deadlines must be respected.

ECHA / Commission	Third party
Notice that Annex XV dossier has been prepared placed on ECHA website (Article 59(4))	Comments invited from interested parties within specified time period (Article 59(4))
Substance placed on candidate list, recommendations for priority substances published on ECHA's website (Article 59(10))	Comments invited from interested parties, in particular on uses that should be exempted within 3 month time period (Article 58(4))
Substance placed on Annex XIV, applicant applies for authorisation, ECHA publishes information on broad uses on website (Article 64(2))	Information on alternatives invited from third parties within a specified time period (Article 64(2))
ECHA may request further information from third parties (Article 64(3))	Interested parties may still provide information on alternatives to ECHA (Article 61(2))
Granting of authorisation (Article 60)	
Review of authorisation (Article 61)	Comments invited from interested parties (Article 61, 64(2))

An authorisation dossier should include information provided by **all actors of the supply chain**.

- Application may be submitted by the manufacturers, importers, DUs or ORs
- Therefore, **communication** in the entire supply chain is important.
- All actors need to consider the level of involvement they may need in the authorisation process.

For instance, communication ensures the producer is aware that a DU is willing to support authorisation and thus keep the chemical on the market.

Figure1. "Candidate List" timeline: selection of substances for the "Candidate list".

From submission of the Annex XV dossier till inclusion in the CL, it takes approx. 5 to 10 months.

Figure2. Prioritisation timeline: substances selected by ECHA from the CL to enter Annex XIV

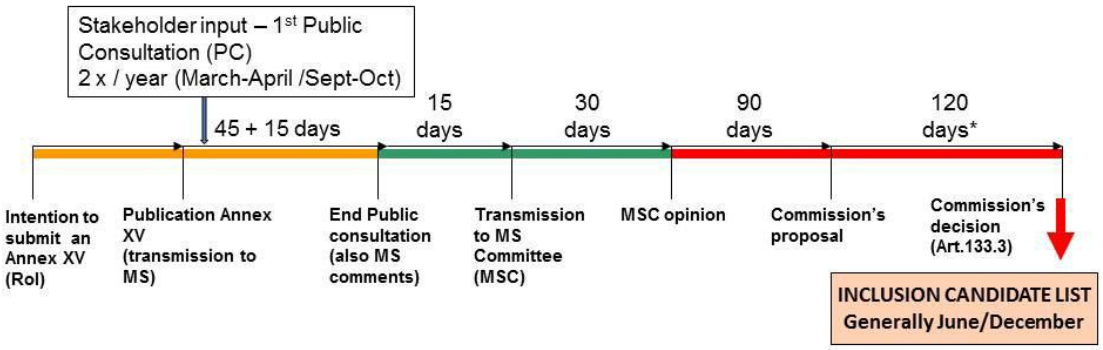
From the ECHA draft recommendation till inclusion in Annex XIV, it takes approx. 14 months.

Figure3. Application for authorisation submission window timeline: Time to submit your application

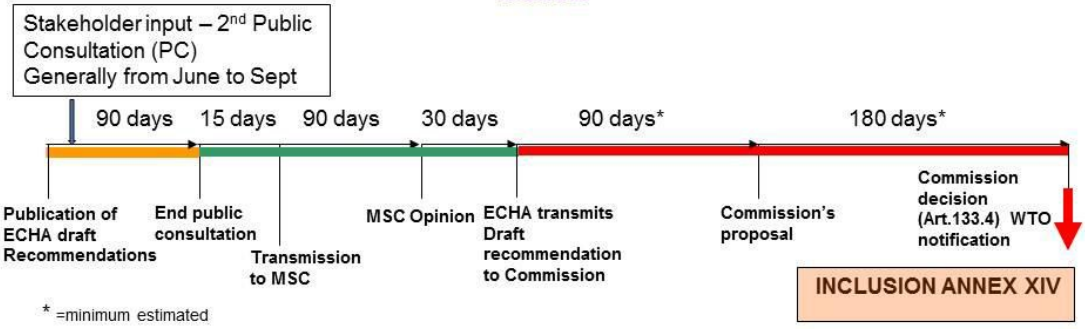
From notification till latest application date, it takes approximately 11 months.

Figure4. Authorisation granted or refused: Timeline for the evaluation and granting of the authorisation. From application submission till Commission final decision, takes up to 2 years.

1- Candidate List: From submission AXV dossier till inclusion in the CL about 5-10 months



2 - Prioritization: From ECHA draft recommendation till inclusion in Annex XIV about 14 months



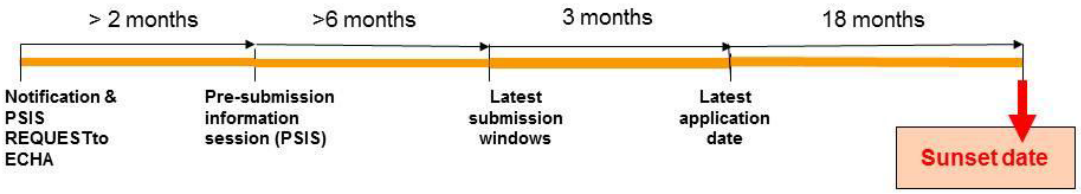
Note on the first step: SVHC proposal

- There are 2 public consultations/year on SVHC proposals (generally one in March-April, then in Sept-Oct).
- If a general agreement is reached at the MSC, the substance goes directly (or not) to the "Candidate List" without any input from the Commission. => inclusion after 5 months is possible. If a single Member State disagrees on the opinion, the Commission will decide and inclusion of the substance into the "Candidate List" may take longer.
- Final inclusion on the "Candidate List" generally happens twice a year (in June and December).

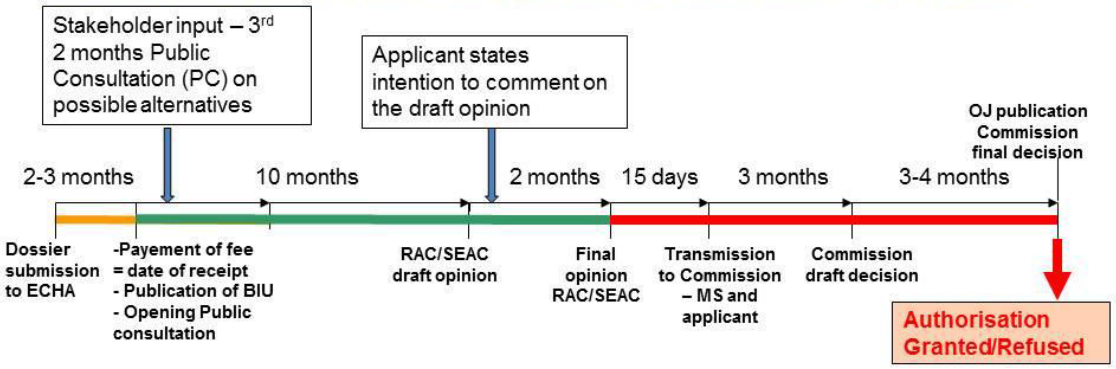
Note on the second step: recommendation

- Public consultation for recommendation for inclusion in Annex XIV generally takes place from June to September.
- In case of no unanimous agreement

3 - AfA Submission windows: From notification till Latest application date = at least 11 months



4 - Authorisation granted or not: From application till COM decision = up to 2 years



5.3.4/ Who can apply for an authorisation?

The requests for authorisation may be submitted by:

- the manufacturers or importers of the substances
- the downstream users, which may include formulators as well as end-users of the substance on its own or in a mixture and producers of articles
- the Only Representative (OR)
- any combination of these.

An application for authorisation can be submitted:

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

Depending on the complexity of the supply chain, it is highly recommended;

- *To enter into contact with all actors involved (suppliers, customers, etc…)*
- *To determine who has the best knowledge on the use of the substance and have them apply. This must be based on company specific internal business decision. It could be the M/I/DU or OR.*
- *Once decided, ensure the applicant has all the information needed to cover your use and those of your DUs.*

A manufacturer/Importer or a non-Community manufacturer represented by an "only representative" may only sell the substance for a given use if he and the use are covered by a granted authorisation. Authorisation obtained by M/I/OR or by an immediate DU.

DUs may only use an authorised substance if the authorisation is granted to a company further up their supply chain and their uses are covered.

In cases where a downstream user uses the substance on the basis of the authorisation granted to his supplier, the downstream user shall notify ECHA within three months of the first supply of the substance (Art. 66(1)).

If none of the companies in the supply chain holds an authorisation, all users must cease use immediately after the sunset date until such time as they find another duly authorised supplier.

The downstream or end-user, the chemical manufacturer or any other actor in the supply chain can seek a joint authorisation for a substance. Therefore, the users will need to ensure that the use(s) of their supply chain are covered as well as their own.

In a joint application, some documents regarding the Socio-Economic Analysis (hereinafter SEA) and the Analysis of Alternatives (hereinafter AoA) will probably contain sensitive and individual commercial data that cannot be exchanged between competitors. Nevertheless SEA and AoA need to be as complete and meaningful as possible. A careful assessment and drafting of the Broad Information on Uses (BIU) statement by the applicant can provide good guidance for the detail of the AoA and SEA.

In any case, when multiple applicants are preparing applications partially or completely together, it is recommended that applicants provide a clear set of assessment reports per combination of applicant-use-substance i.e. one CSR/ES, one AoA, one SP, and one SEA is developed for each combination. This information shall be clearly identified in the IUCLID dossier (see Dossier Submission Manual – 22: How to prepare and submit an AfA using IUCLID 5)

http://echa.europa.eu/documents/10162/13653/data_submission_manual_22_application_authorisation_iuclid5_en.pdf

Strict measures have to be adopted in order to be compliant with Competition law (refer to Cefic document on do's and don'ts – competition law) **and to protect Confidential Business Information (CBI).** http://www.cefic.org/Documents/IndustrySupport/Cefic%20REACH%20AUT%20Competition%20DO%20-%20DONT%20first%20edition%20DEC%2010.pdf) or http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/

*An authorisation granted to a **Manufacturer or Importer** of a substance could cover throughout the complete supply chain, all known uses specified in the AfA.*

*An authorisation granted to a **Formulator** could cover throughout his complete supply chain all known uses of the mixture identified specifically in the AfA.*

*An authorisation granted to a **Producer of articles** using the substance could cover his own use, and could also cover the placing on the market of the substance by his immediate supplier. Such an authorisation seems to be very limited in benefit but might be useful for simple cases where a unique use is confidential.*

*An authorisation granted to a **downstream user** of the substance covers that use and that of his customers down his supply chain. This authorisation could also cover the placing on the market of the substance by the downstream user's immediate actor(s) supplied up his supply chain (i.e. manufacturers, importers or formulators from which the DU purchase the substance directly or via distributors), but no further up the supply chain. Therefore if the immediate supplied actor is the manufacturer or importer of the substance, that would cover the supply chain but if not, the upstream supply chain is not covered by the authorisation.*

***Distributors** are not users or DUs according to REACH Regulation-Art 3(13). There are not entitled to apply for an authorisation.*

5.3.5/ When and how can the downstream user contribute to the authorisation process?

At each step, for each public consultation, the most effective method for commenting is via your industry sector groups, your trade association, at both national and European levels. They will consolidate inputs from their member companies to submit to the authorities during the public consultation. The earlier they receive this information the more effective it will be.

1. When the substance is included in the Registry of Intentions:

The authorisation procedure begins when a Member State or the European Chemicals Agency (on behalf of the European Commission) uses the possibility to publicly announce their intention to prepare an Annex XV dossier for identification of a SVHC via the Registry of Intentions. This publication allows stakeholders to start preparing their application for authorisation and business strategy.

http://echa.europa.eu/addressing-chemicals-of-concern/registry-of-intentions

At this stage, REACH does not foresee an official process for industry to interact directly with ECHA. However, it is possible to provide relevant input via Member States or consultants of Member States who prepare the Annex XV dossier. *Providing information at this stage may lighten regulatory work on the substance or even prevent the proposal for the candidate list or indicate availability/ development of other most relevant risk management option.*

Companies should start gathering information on e.g. SEA and AoA to help and guide them on business strategy decision.

2. When submission of an Annex XV dossier identifying SVHCs is published:

Once the Annex XV dossier has been published on the ECHA website, the downstream user has a **period of 45 days** to comment (Public Consultation Period). There are 2 public consultations (hereinafter PC) per year on SVHC proposals (generally one in March-April and one in September-October). Comments to the Agency usually relates to the identification of the substance as SVHC. Information on the uses of the substances (including data on tonnages per use and exposures or

releases resulting from these uses), on the availability of safer alternative substances and techniques and the structure of supply chains is also welcome. ECHA will however rather consider this information when recommending SVHCs in the "Candidate List" for inclusion in the authorisation list (Annex XIV).

More information is available at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

3. When the "Candidate List (CL) is published:

It is not possible to intervene but legal obligations need to be fulfilled (Article 33, Communication and Article 7(2), Notification).

DUs are advised to monitor the information on ECHA website to check the biannual CL update.

4. When the substance is proposed for prioritisation:

Indication of the substances on the candidate list to be included as a priority in Annex XIV.

The Agency will publish the list of priority substances on its website, proposed to be included in Annex XIV (Article 58(3)). Downstream users may submit their comments over **a three-month period** (Article 58(4)).

After that time, based on the comments received, the Member State Committee will prepare an independent recommendation for ECHA and they (ECHA) will prepare the opinion and transfer a final recommendation to the European Commission. The European Commission will finally decide according to the comitology procedure whether or not to include substances in Annex XIV, which exemptions should be granted and what should be the sunset date.

5. When the substances is included in Annex XIV:

No possibility to intervene on the process but at this point producers and users of Annex XIV substances must decide whether or not to make an application for authorisation for an/each individual use of the substance.

In addition there are further opportunities to comment during the process:

6. When an application is submitted:

- As an applicant, keep in contact with ECHA and the Commission.
- As a third party, comments on possible alternatives may be submitted during the public consultation on alternatives which is based on broad information on uses (BIU) that follows the submission of an application (Article 64(2)).

7. When authorisation is granted:

- As an applicant, keep the contact with ECHA and the Commission even after authorisation is granted
- As a third party, comments on possible alternatives may be submitted at any time.

How to define the authorisation strategy?

1. Produce an inventory for all substances and uses in your business (check the SDS)

2. Check the list of uses already exempted in Annex XIV, if any.

http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf

3. Compare and highlight those substances used against the Registry of Intentions, Candidate list

and Annex XIV. Substances included in the Candidate List will appear in the SDS of your suppliers after 6 months of inclusion on the Candidate List. Check the SDS.

4. Assess the importance of the substances for your business (e.g. potential risk of supply chain disruption) and evaluate potential counter measures

5. Identify the actors within your supply chain.

6. Contact the suppliers (particularly the manufacturer/importer of the substance or mixture) to ascertain if they are considering substitutes or the development of alternatives.

7. Identify as much as possible who in the supply chain will be applying for an authorisation.

8. Contact the consortium or any working group on authorisation.

9. Decide on your own substance strategy i.e. authorisation, substitution (or exemption) and how it fits with your sourcing/supply chain strategy.

- *Do not forget that an application for authorisation requires a lot of data, including some which may be available to registrants, manufacturers or other actors in the supply chain but not directly to the downstream user or end-user of a substance.*

- *Some relevant information can be extracted from the Chemical Safety Report and are related to the threshold/non-threshold status, the DNELs and DMELs. It is highly recommended that all applicants use the same references to avoid choosing different authorisation route or using different DNEL references to proof adequate control.*
- *However, depending on the length and transparency of the supply chain, information on the precise conditions of use and information on potential alternatives are often better known by the downstream users.*

- *Collecting and generating data (e.g. for use in the Socio-economic Analysis (SEA)) is resource and time consuming and costly. Joint application can be considered if combined actions provide benefits and are in line with CBI concerns and legal constrains. (refer to Cefic documents -do's and don't – competition law).*
- *As the application must be submitted at least 21 months (18+3 to define the BiU and pay the fees) before the sunset date, and a SEA takes about 1 year to put together; gathering all data needed for the dossier will take a minimum of 2 years.*
- *Starting your SEA early is essential and should be part of the corporate/company decision-making process on whether to apply for authorisation or not.*

Two kinds of authorisation dossiers may be submitted

There are two ways to build an authorisation dossier depending of the recognition of a threshold concentration for the substance:

- For the threshold substances, by demonstrating that the risk from the use of this substance is adequately controlled throughout its life cycle (Article 60(2))
- For the non-threshold substances, by demonstrating that benefit is outweighing the risk. Meaning that the socio-economic advantages prevail over the risks to human health or the environment arising from the use of the substance, and that there are no appropriate replacement substances or technologies (Article 60(4))

For the SEA route, it is **mandatory** to demonstrate that socio-economic benefits outweigh the risks. Whereas for the adequate control route a socio-economic analysis (SEA) is **recommended** to be included in the application (see Appendix 1 of REACH for details on socio-economic analysis and dossier content).

5.3.6/ Time limited authorisations (Review)

Authorisations are granted until a specific date by which the holder of the authorisation will have to resubmit an application (i.e. a review report). Review dates are set **on a case-by-case basis** and are driven by the information provided by the applicant, in particular the substitution plan and the analysis of alternatives.

To renew an authorisation, a **revised report must be sent to ECHA by the holder** at least **18 months** before the expiry date of the time limited review period defined in the authorisation decision.

This review report will then be processed and the authorisation may in certain circumstances be renewed.

The Commission may decide to withdraw, suspend or modify the authorisation **at any time** for the reasons below:

- if the circumstances have changed since the initial request was made (health or environmental hazard or socio-economic impact)
- if new information on possible replacement substances becomes available
- in the case of a serious and imminent risk for human health or the environment
- If an environmental quality standard is breached
- Uses of a substance that are subsequently prohibited or otherwise restricted under the Persistent Organic Pollutant Regulation (EC) No 850/2004 (hereinafter POPs Reg.) must be withdrawn from authorisation (for those uses). See Art 61.6 of REACH. If a substance is going to be banned with possible (time limited) exemptions under the POPs Reg. it should only be included in Annex XIV for the exempted uses.

The only route for appeal is the existing one for challenging decisions of the European Commission via the European Court of Justice

5.3.7/ Authorisation exemption

The downstream users may request exemptions for their use(s) when the Agency publishes the list of substances recommended for authorisation on its website (Article 58(4) REACH). Check the publication of the ECHA's Annex XIV draft recommendations. The deadline for submitting this request is 3 months after publication.

Authorisation covers all the stages of the life cycle of a substance for a specific use. It is therefore not possible to get an exemption based on when a substance is exempted under other legislation and where only one stage of the life cycle is taken into consideration (e.g. only the production process). However, if a piece of legislation is prohibiting the use of substances in end products and if this prohibition has an impact throughout the complete life cycle (e.g. end-of-life legislation like ROHS or ELV), an exemption for this particular use might be worth to be considered. But at this stage, exemptions remain an open issue; more clarifications would be welcome in a following document.

Exemptions are most likely where the risk is properly controlled for specific uses, on the basis of other existing Community legislation (Article 58(2) REACH), or where it is based on Scientific Research, or Product/Process Oriented Research and Development (PPORD) (Article 56(3) REACH), ECHA and the EC presently state that such reference legislation must be substance specific.

Intermediates (but not catalysts) are exempt from authorisation for a specific applicant for as long the use fully complies with the definition of intermediates. A rejection of the intermediate status would automatically imply a need for a granted authorisation to pursue activities with this substance.

Based upon the knowledge existing in many industries today, an authorisation strategy relying on exemption is at risk of failure.

ECHA have provided a document listing generic exemptions from authorisation:

http://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf.

5.3.8/ Duties of downstream users (DUs) regarding authorisation

1. Once authorisation is granted, DUs shall notify the ECHA within three months from first time receiving the substance if this substance is used in accordance with the authorisation granted for that use (Article 66(1) REACH).

2. Holders of an authorisation, as well as DUs referred to in Article 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. This shall be done without delay once the authorisation number has been made publicly available in accordance with Article 64(9) REACH. Where a substance is subject to authorisation it must also be mentioned in section 15.1 of the SDS.

If you are submitting an application for authorisation, there are limitations on what can be included. Please refer to the recommendations and tips below.

When an application for authorisation is made for your own use, make sure the substance manufacturer intends to provide you with the substance in the long term.

5.3.9/ List of recommendations for DUs and tips for authorisation

- Produce an inventory of all substances and uses in your business (check the Safety Data Sheet (SDS)).
- Compare and highlight those substances used by your company against the Registry of Intentions, "Candidate list" and Annex XIV. (CL is generally updated in June and December).
- Assess the importance of the substances for your business (e.g. potential risk of supply chain disruption) and evaluate potential counter measures.
- Evaluate the costs and benefits to your business, industry, economy.
- Identify the actors within your supply chain.
- Contact the suppliers (particularly the manufacturer/importer of the substance or mixture) to ascertain if they are considering substitutes or the development of alternatives. R
- Identify who in your supply chain will be applying for an authorisation.
- Decide on your own substance strategy i.e. authorisation, substitution (or exemption) and how it fits with your sourcing/supply chain strategy.
- When a substance enters the "Candidate List", as DU, provide information on your use showing there is no risk handling this threshold substance. For non-threshold substance, a demonstration of no exposure may ensure to avoid prioritisation.
- Do not miss the public consultation period. All information has to be provided during the fixed time period.
- Investigate whether to limit your use of the targeted substances. Using potential alternatives should be carried out with the agreement of both customers and suppliers (fulfilling e.g. the technical/quality requirements).
- If you use an Annex XIV substance to produce an article, communicate your use upstream and check if your supplier has achieved an authorisation application number. If not, consider making your own application for authorisation of use.
- An authorisation application submitted by a DU can only cover the DU's uses, the uses of "his" downstream supply chain (i.e. your customers, their customers etc), and only the "placing on the market of the substance" by his immediate supplier (i.e. one level up his supply chain). A DU cannot cover other use up his supply chain.
- When determining the date to submit your application, don't forget to consider the three months period between the submission of the application and the official date of receipt (payment of the fee received and opening of the public consultation). Therefore it is recommended to submit your dossier at least 21 (18+3) months before the sunset date.

- Substitution of substances falling under the scope of authorisation (listed on the "Candidate List" and fulfilling the criteria for prioritisation) is recommended for new developments if technically and economically feasible. Consider the hazard profile of the replacement substance in your assessment.
- For existing products, if production of this product containing the targeted substance is going to cease prior to the sunset date, substitution will not be necessary for that use.
- For existing products, if production is going to continue after the sunset date, you will need to consider substitution of the substance requiring authorisation unless an authorisation for this specific use was obtained.
- Consider the contractual requirements between you and your supplier. You may want your supplier to inform you about their intentions to authorise or substitute the Annex XIV substance.
- Once authorisation is granted the review period may, in principle, be suspended at any time.
- As flexible strategy is needed in your business, do not entirely rely on the review period mentioned in the Commission's final decision.

5.4/ Restrictions

Restrictions in REACH are used to either:

- Control or eliminate risks that cannot be managed through the Registration, or Authorisation process,

  or to

- Target specific risk controls for particular uses or practices.

REACH Restrictions may concern Articles as well as substances on their own or in Mixtures. The actual scope of the Restriction is, however, defined by the wording in Annex XVII, which may be very broad or narrow in scope. Restrictions are documented in REACH Annex XVII. Many restrictions pre-existed REACH, through carry over from other legislation such as Directive 76/769/EEC.

A Restriction is the only means in REACH by which a risk from a hazardous substance in imported articles can be eliminated by prohibition.

Examples: The first example targets the use and sale including import of articles, but not the manufacture, use or sale of the substance. The risk relates to wearing the clothing.

- Tris (2,3 dibromopropyl) phosphate

  Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.

  Articles not complying with paragraph 1 shall not be placed on the market.

The second example targets the use and supply of brazing filler, but not Articles containing the material. The risk relates to fumes from the brazing process.

- Cadmium (part of...)

  Shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight.

  Brazing fillers shall not be placed on the market if the concentration of cadmium (expressed as Cd metal) is equal to or greater than 0,01 % by weight..

  In this case Aerospace and Defence applications have derogation in Annex XVII, Entry 23, Condition of restriction paragraph 9.

Read the wording of a Restriction and the legislation introducing it carefully to understand the Restriction scope.

A substance may appear in both Annex XIV (Authorisation) and Annex XVII (Restrictions) if import or use of Articles containing the substance is considered to pose a risk to human health or the environment. This would normally be considered after the Annex XIV sunset date.

5.4.1/ Restrictions Process

The restriction system in REACH extends what already existed in previous regulations. Annex XVII of the regulation carries over the restrictions existing in Directive 76/769/CEE and has been added to regularly since REACH became law.

The process for implementation of new restrictions is:

1. A new Restriction is proposed by the Commission or a member state, using an Annex XV dossier.
2. After conformity checks, ECHA publishes the Restriction proposal on the ECHA website Registry of Intent, and informs substance Registrants of this.
3. Public consultation - Stakeholders must submit comments within 6 months of publication, including socio-economic impacts, advantages and drawbacks of the proposal.
4. ECHA publishes their opinion accounting for comments received, which may take up to 6 months. This time includes a 60 day opportunity for interested parties to comment on the draft opinion.
5. The Commission drafts an amendment to Annex XVII.
6. The Commission submits the proposed amendment to the Member State Committee for agreement, using qualified majority voting.

Each Restriction will have a date at which it comes into effect. This date should be accounted for in any comments submitted during public consultation.

5.4.2/ Restriction Risks

Restrictions are contained in Annex XVII of the regulation. These are often application specific for example the restriction on the use of Poly Aromatic Cyclic Hydro-Carbon oils in road tyres. Proposals for additions to Annex XVII are publicised via the ECHA and Commissions websites. Once a proposal has been published, the specific details of the proposal will need to be reviewed to determine if they apply. If the proposed restrictions do apply then the CBOM can be consulted to determine the affected products.

5.5/ Communication of information throughout the supply chain

Communication with all relevant stakeholders is key to REACH compliance and the minimisation of potential risks to your business. Whilst the REACH regulation mandates the exchange of certain information, relying on this may put your business at risk, therefore a more proactive approach is recommended. The following sections provide guidance on how you can minimise this risk by actively communicating information up and down your supply chain, ensuring you have systems in place to respond to Customer and Consumer requests and ensuring internal systems ensure compliance with the extended Safety Data Sheet.

5.5.1/ Conditions under which the presence of a substance of very high concern in an article must be notified

An importer or producer of articles must notify to the Agency the presence of substances of very high concern included on the list of substances that are "candidates for authorisation" (published on the Agency's website), if all the following conditions are met:

- the substance is present in these articles in quantities totalling more than 1 tonne per year*; and,
- the substance is present in these articles in a concentration higher than 0.1% weight by weight; and,
- the producer or importer cannot exclude the exposure of humans and the environment under normal or reasonably foreseeable conditions of use, throughout the life cycle including disposal and by all possible means of exposure**; and,
- the substance has not already been registered for that use

* All the articles produced and/or imported must be taken into consideration

** In the case where the producer or importer can exclude this exposure, he no longer has to make any notification, but must provide appropriate instructions for the article's end-user. However, it will not always be easy to demonstrate that such exposure can be excluded.

Within the context of applying articles 7.2 and 33, the 0.1% weight by weight threshold applies to the produced or imported article in its entirety and not to the homogeneous materials or parts of articles, as may be the case with other legislation.

If the article being placed on the market is a whole aircraft, then the whole aircraft is the article that the declaration must be made for. If the article being placed on the market is a spare part, then the spare part is the article that the declaration must be made for.

Note: Note: this is based on the current advice of the Commission Legal Service

Whenever a substance is added to the "candidate list", a period of **six months** is allowed for the notification for that substance.

There is no obligation for declarations or notifications for articles sold prior to a substance being added to the candidate list.

The elements making up the information to be notified are given in point 4 of article 7.

5.5.2/ Conditions under which the supplier of articles must supply information on the composition of the article

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

- The substance is identified as of very high concern (SVHC) and included in the Candidate List
- The substance is present in the article in a concentration above 0,1 % weight by weight
- The Candidate List is available on the ECHA website (See http://echa.europa.eu/web/guest/candidate-list-table) and will normally be updated twice a year (in January and June) when substances have been identified as meeting the criteria to be considered as SVHC.
- The information has to be provided automatically to the business-to-business recipient of the article. The same information requirements exist also in cases of consumer requests in which case this information should be provided, free of charge, within 45 days of receipt of the request.

The 0.1% threshold weight by weight applies to the produced or imported article in its entirety in accordance with the Commission Legal service, and not to sub-components of articles.

Note: some EU States want this rule to be examined again in the future.

This obligation will come into force on the date of publication of the candidate list. It concerns the articles placed on the market after it was published. There is no standard format imposed for notifying this information. It may be submitted in various ways and in different formats (for example in user manuals or on labels). Furthermore, the content and the level of detail must be defined case by case according to the uses, exposures and risks specific to the end-user or consumer. So, professional users and consumers may not be provided with the same information. However, the International Aerospace Environment Group (IAEG) is developing an Aerospace industry standard expected to be published as an update to SAE9535 sometime in 2014. This standard will help reduce repetitive redeclaration burden every time the Candidate List is updated as well as helping to identify obsolescence issues and Authorisation requirements.

5.5.3/ Where to obtain information on the presence of substances of very high concern ?

When SVHC communication (Article 33) may be required for a purchased article, the following steps should be taken sequentially, with escalation to the next level only in cases where the preceding step failed to yield satisfactory results:

- Survey suppliers for all purchased articles, mixtures and substances to determine the presence of any SVHCs. A quality check of the data must be conducted after suppliers submit a response. If the submitted data does not pass a quality assurance check, a request for re-submittal should be initiated to fill any gaps and/or remedy any inaccuracies. If after these follow-up activities, suppliers are unable or unwilling to provide sufficient data, then the process can proceed to step 2.
- Engage internal resources to fill in any data gaps remaining after step 1 activities. Drawings, materials specifications, Bills of Material and other sources may provide substance information for products if the knowledge exists within your company. If the data is unavailable internally, proceed to step 3.
- If specific data is not available from suppliers or from internal records, then esti-

mates based on available analogous sources of data can be used to generate the needed data points. For example, comparable parts from comparable suppliers may be used as references to quantify the percentages of SVHCs and/or weight of parts. This approach should be used with caution and applied only in instances where the appropriateness of the comparisons is well known. If this data is unavailable, proceed to step 4.

- If SVHC data cannot be unmasked by any of the above methods, then the last resort is to test parts for the presence of SVHCs via laboratory methods. If this approach must be used it is sufficient to confirm that the presence of all SVHCs is less than 0.1% (w/w). If the concentration of any SVHC exceeds 0.1% (w/w) it is necessary to determine the precise quantity of SVHC in the article.
- via the information on the restrictions on the use of those substances;
- by means of the chemical analysis of the substances in the articles (but this approach is highly complex).
- After the final aggregation of total SVHCs occurs per article utilizing the methods addressed above, and if any SVHC exceeds the 0.1% (w/w) REACH Communication threshold, a final check should be conducted to verify this exceeding value before any paperwork is generated and submitted to requester. It is possible that substances incorporated into an article are diminished via various in-house processes and thus will be less than the 0.1% (w/w) threshold after these processes occur. In addition, the requirement applies to the product placed on the market; so a part shipped as part of a larger article may not exceed the threshold when aggregated to the entire article; but the part shipped separately as a spare may exceed the threshold.

There are a number of lists in the public domain that attempt to identify substances of very high concern.

In addition to Annex XIV, the 'candidate List' and the 'Registry of Intentions', the official CoRAP specifies the substances that are to be evaluated over a period of three years.

The following key messages of the requirement can be summarised as follows:

- Legacy parts are within the scope
- Packaging is an article, so the presence of a Candidate List substance needs to be communicated
- There is no exemption from this obligation possible and the obligation applies regardless of quantity
- Information must be forwarded directly after a substance has been included in the Candidate List, or the supplier becomes aware of it.
- No particular information is necessary to allow safe use of the article other than name of the substance in question has to be communicated, but suppliers should be aware of "Duty of Care" considerations relating to product safety, and any other legal requirements.
- The substance name to be communicated is the one appearing on the Candidate List for authorisation
- A supplier can not comply with this obligation just by referring the consumer to his own supplier, or the producer of the articles.

The obligations also apply to articles which were produced or imported before the substance was included in the Candidate List and are supplied after the inclusion. Thus, the date of supply of the article is the relevant date.

5.5.4/ Gathering of information in the Supply Chain

5.5.4.1/ Background

This section addresses the issues that businesses may wish to consider in order to manage the risks of supply chain discontinuation, disruption, or change that arise as a consequence of the regulation.

One of the likely scenarios that arises as a result of the introduction of REACH on to the global supply chain is that substances are withdrawn from the market either in their entirety or for specific uses. These substances may be contained in the product or used in the process for their manufacture but not contained within the product. E.g. a degreasing solvent may be key to achieving the desired functional performance of a product but it does not remain in the delivered product.

The REACH processes which give rise to substance obsolescence are known, which does allow for planning. The 4 key processes are:

- Registration
- Evaluation
- Authorisation
- Restriction

In addition, one of the consequences of REACH has been to cause chemical suppliers and formulators to critically evaluate their product ranges and their commercial viability. This has resulted in some products being withdrawn from the market or re-formulated without any direct regulatory action on the substances concerned.

Individual businesses will have their own approach to risk management. The information provided here is to aid businesses in obtaining information from the supply chain and formulating appropriate strategies to manage the risks.

5.5.4.2/ The Nature of Products

Coupled with these processes there are typically 2 broad groups of product risk within the sector:

- Goods of a company's own design / Intellectual Property
- Goods of 3rd party design / Intellectual Property

These are supplemented by substances used during manufacture that are not contained in the final product. In attempting to identify and manage the risks it is helpful to be clear in which group the potential business risk originates. This will have bearing on the ability to access information to enable risk management.

5.5.4.3/ The Chemical Bill of Material

In order to identify where business risk may arise compiling a Chemical Bill of Material (CBOM) for each product is a useful starting point. This can be approached in a number of ways:

- Review of drawings and specifications.
- Placement of a specific contractual requirement upon suppliers.
- Adoption of an available standard

  Some work is currently being developed within the frame of standardisation bodies and IAEG. See http://www.iaeg.com on this matter.
- Information relating to legal obligations. E.g. REACH Article 33.

Once compiled a business can then consult the CBOM to determine where risks may arise as a

result of each of the processes that exist with REACH.

5.5.4.4/ Supplier Relationships

The aim should be to establish constructive relationships with suppliers in regard to sharing risk information and associated mitigation actions. In addressing the supply chain continuity risk which results from REACH businesses should consider: the magnitude of the risk against the effort required for managing the risk; the level of information needed in terms of the quantity and quality required; the nature of current contracts; risks such as obsolescence; inclusive continuity of supply conditions; notifications for last time buys.

There are some practical realities in obtaining information from the supply chain that are likely to be encountered. It can be difficult to obtain information beyond the 1st tier of suppliers due to the lack of a formal contractual relationship at that level and that information relating to substances and mixtures is easier to obtain within the EU/EEA due to the obligation to provide Safety Data Sheets.

5.5.4.5/ Further Help

The ASD REACH Implementation Working Group or the relevant trade association in the country of operation may be able to provide some further guidance.

5.5.5/ Communicating information

In determining what information should be considered for communication by the article supplier other than the name of the substance, the following need to be considered:

- Customer contract requirements;
- what the downstream life-cycle stages of the article are up to final disposal (transport, storage, uses);
- what the potential routes of exposure are during each of these life-cycle stages what the hazards of the SVHC are for human health and the environment;
- what types of exposure control / personal protection measures are likely to be appropriate during each of the life-cycle stages in order for the handling of the article to be considered safe.

These considerations are required in order to identify any risks arising from the SVHC in the article, and thus determine which information has to be provided to the user, in addition to the name of the SVHC, in order for him to control these risks.

5.5.5.1/ Format of the information

The most appropriate format for the information may also vary, depending on the content and the addressee of the information. Standard answering letters might be a suitable medium to inform consumers, whereas a professional user might be better informed through separate use instructions.

Possible formats could for example be:

- Contract requirements
- modification of existing documents, such as instructions for use and packaging
- information on labels
- link to a website with up-to-date information
- standard communication formats developed by industry sector associations

The chosen format must ensure that the information is readily available to the recipient of the article or the consumer, taking into account the particular situation of use, and who within

the receiving company needs ready access to such information

It is the Intent of the IAEG to improve data flow for Articles, and standardise and minimise burden through an Industry standard.

5.5.5.2/ Information to be exchanged within the supply chain - Substances/Mixtures

The key element in the REACH system for communicating information relative to substances is the Safety Data Sheet (SDS).

Certain items of information must nevertheless be provided to the various actors even in the absence of an SDS (art. 32).

The Safety Data Sheet must be written in the official language of the Member State in which the dangerous substances and preparations are placed on the market.

5.5.5.2.1 / Goal of the Safety Data Sheet

The SDS is a tool that is used to convey the appropriate safety information on the classified substances and preparations to the users immediately downstream. The goal is to allow employers to determine whether dangerous chemical agents are present in the workplace and evaluate any risk for the health and safety of workers resulting from their use.

Reminder: EU law contains a number of provisions related to the protection of the health and safety of workers from the risks related to chemical agents at work. These require that relevant assessments and information is provided to those who may come into contact with the substance. These directives have been translated into national regulations by each member state.

5.5.5.2.2/ Compulsory content of the SDS

SDSs must conform to a "compilation guide" which is included in annex II of the Regulation. (as amended by COMMISSION REGULATION (EU) No 453/2010)

Content of the Safety Data Sheet

1 Substance/company identification
2 Identification of the hazards
3 Composition
4 First-aid measures
5 Firefighting measures
6 Accidental release measures
7 Handling and storage
8 Exposure controls / personal protection
9 Physical and chemical properties
10 Stability and reactivity
11 Toxicological information
12 Ecological information
13 Disposal considerations
14 Transport information
15 Regulatory information
16 Other information

+Annexes

- **Exposure scenarios (main elements of the CSR)**
- **Use categories**

Section 1 includes the registration number along with the uses covered by the SDS. The uses which the supplier advises against and why shall, where applicable, be stated.

5.5.5.2.3 / Who must provide an SDS?

The supplier of a substance or preparation must provide the user of the substance or preparation with an SDS in a greater number of situations than in the past:

- when the substance is a dangerous substance or preparation;
- when the substance is Persistent, Bioaccumulative or Toxic (PBT) ;
- or very Persistent and very Bioaccumulative (vPvB);
- or when it is included in the list of substances that are candidates for authorisation.

The application area therefore changes partially with respect to the previous regulation.

The supplier must provide the up-to-date SDS in the REACH format from 1 June 2007.

5.5.5.2.4/ Coherence between the SDS and the chemical safety assessment (exposure scenario appended to the SDS)

The information contained in the SDS must correspond to the information contained in the substance's chemical safety assessment when this assessment was made by the manufacturer or importer (quantity > 10t/year).

Any actor in the supply chain who has to draw up a chemical safety report must append the "corresponding exposure scenarios" to the SDS. The scenarios describe the operating conditions, hazard management measures and the substance use recommendations. The substance's complete life cycle must be taken into account.

5.5.5.2.5/ Obligations when an SDS is not required

For substances and preparations not subject to an SDS, the suppliers must nevertheless provide a certain amount of information to the end-user at the latest at the time of the first delivery (of the substance on its own or in a preparation) that follows the entry into force of the Regulation, i.e. 1 June 2007.

This information should contain:

- the registration number(s) (as soon as it (they) are available);
- a "declaration" indicating whether the substance is subject to authorisation;
- details regarding any authorisation granted or refused in the supply chain concerned;
- details of any restriction that may have been imposed.

5.5.5.3/ Other information and communication obligations

5.5.5.3.1/ Duty to communicate information up the supply chain

When a downstream user obtains new information on dangerous properties or any other information that could raise doubts as to the suitability of the risk management measures identified in a Safety Data Sheet that he has been supplied with, he must pass this information on

to the actor immediately above him in the supply chain.

Distributors pass this information to the actor or distributor situated immediately above them in the supply chain.

5.5.5.3.2/ Information access for workers

Employers must grant their workers and their representatives access to information supplied when an SDS is required (article 31) and when an SDS is not required (article 32). This information concerns the substances or preparations that these workers use or to which they may be exposed.

This provision reinforces the requirements of other a number of other EU directives which have been transposed into member state legislation.

5.5.5.3.3/ Obligation to keep information

Manufacturers, importers, downstream users and distributors, must keep the information they have collected for at least 10 years after the date on which they manufactured, imported, supplied or used the substance for the last time, in order to comply with the requirements of REACH.

5.6 Downstream users

New obligations now fall upon downstream users of substances and mixtures.

These obligations demand far greater communication between the various actors in the supply chain (down and upstream) to:

- enable information related to their types of use of substances to get back to those who supply these substances (manufacturers, importers....);
- contribute to assessing the chemical safety of substances.

5.6.1/ What is a downstream user?

According to the Regulation, a downstream user is any natural or legal entity established within the [European Union], 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.

Distributors or consumers are not downstream users. Refillers, however, are considered to be downstream users.

Distributors have an obligation to pass on relevant exposure scenarios and use the relevant information in the safety data sheet received when compiling their own safety data sheet. Furthermore distributors shall provide customers with the information that is supplied to him in accordance with Article 32 of REACH regulation.

5.6.2/ What information must the downstream user pass up to the supplier and why?

When a downstream user receives an SDS containing the registration number(s) of the substances concerned, the downstream user can check whether his use is listed amongst the "identified uses" in section 1 of the SDS. If this is not the case, the downstream user has twelve months from receipt of the SDS in which to send the supplier, should he so decide, a "brief general description" of his use with a view to making it an identified use, which will be covered by an exposure scenario appended to the SDS.

The supplier should pass the information up to the immediately higher actor, and so on up to the manufacturer/importer. The user must provide "sufficient information" to make it possible to establish an exposure scenario.

5.6.3/ What options does the downstream user have when his use does not correspond to an exposure scenario given in the SDS?

There is no standard answer to this, each decision being taken case by case. The options the user must consider are as follows:

- inform his supplier of the use he makes of the substance/mixture and "persuade" him to make it one of the identified uses,
- adapt his procedures to make them comply with the exposure scenario,
- replace it with an alternative substance/mixture whose exposure scenario complies with the company's conditions of use;
- find a substance/mixture that is not subject to an exposure scenario,
- find a supplier who has provided an exposure scenario covering his use.

If none of the above is possible, the downstream user draws up his own report on chemical safety, unless he can benefit from one of the exemptions listed below.

A downstream user is obliged to inform his supplier if he has new information on the hazard of the substance or mixture, or if he believes that the risk management advice provided is not appropriate.

5.6.4/ When must the downstream user draw up a Chemical Safety Report?

A Chemical Safety Report (described in Annex I and Annex XII) must be created by a downstream user if the use of the substance/mixture is not covered by the SDS Exposure Scenarios (unless covered by the dispensations described in the next section). This requirement may arise in the following situations:

- when the downstream user does not inform the supplier of a specific use and unanticipated exposure scenario;
- when the downstream user has given the Registrant all the information for an "identified use" and the supplier advises against it. The Registrant must then "immediately inform the Agency and the downstream user in writing of the reasons for that decision".

Furthermore, the downstream user must submit the information stipulated in article 38(2) to the Agency:

- the company contact details;
- the registration number;
- the identity of the substance and of the manufacturer, importer or other supplier, a general description of use;
- a proposal for additional tests on vertebrate animals if considered necessary.

The downstream user must inform the Agency if his classification for a substance is different from that of his Registrant.

5.6.5/ Case where the downstream user does not have to draw up a Chemical Safety Report even though his use is not covered by the SDS

The downstream user does not have to draw up a Chemical Safety Report if:

- an SDS does not have to be appended to the substance or mixture;
- the Registrant is not obliged to establish a Chemical Safety Report (for example due to Manufacture or Import below 10t pa);
- the substance or mixture is used in a total quantity of less than 1 tonne per year*;
- the downstream user implements an exposure scenario that contains as a minimum one of the exposure scenarios given to him in the SDS;
- the substance is present in a mixture at a concentration lower than the concentrations indicated in article 14, paragraph 2,
- he uses the substance for the purpose of PPORD[1].

* the user must notify ECHA that he is relying on this exemption within 6 months of receiving a registration number on an SDS which has exposure scenarios attached.

[1]In this case the user must nevertheless pass on the information stipulated in article 38(2) to the Agency:

the company contact details;

the registration number;

the identity of the substance and of the manufacturer, importer or other supplier, a general description of use;

a proposal for additional tests on vertebrate animals if considered necessary;

his classification of the substance if it is different from that of his supplier.

5.6.6/ Case of Mixture formulators

Within the context of information exchanges organised by REACH, formulators must inform their customers of the hazards and utilisation conditions relative to their mixtures and provide appropriate risk management measures (article 31 and 32 of the regulation). In particular, they must:

- select the most appropriate exposure scenarios, utilisation conditions and risk management measures;
- complete the information, write the suitable exposure scenarios and provide them to downstream users.

5.6.7/ Execution of downstream user obligations

Downstream users must comply with the requirements relative to chemical safety evaluation no later than 12 months after receipt of a registration number (which is notified to them by their suppliers in the SDS).

Downstream users must comply with the requirements relative to the communication of information no later than 6 months after receipt of a registration number. It is in their interest to pass on information if use and exposure category recommendations have been made.

5.6.8/ Case where the user uses a substance subject to authorisation

Downstream users who use a substance in accordance with an authorisation issued by an actor in their supply chain must send a notification to the Agency within three months of the first delivery of the substance.

The holders of an authorisation, as well as the downstream users of an authorised substance who incorporate the substance in a mixture must include the authorisation number on the label.

6/ Administrative bodies and stakeholders organisation

Administrative bodies are spread over different levels, from European level to national enforcement agencies and local authorities. See organisational chart in annex 12.3 for more details.

6.1/ The European Chemicals Agency (ECHA)

A European Chemicals Agency (ECHA) has been established for managing and implementing the technical, scientific and administrative aspects of the REACH regulation.

It will provide the Member States and European institutions with the "best possible scientific and technical advice on questions relating to chemicals which fall within its remit" (article 77). The Agency is based in Helsinki (Finland).

It was inaugurated on 1st June 2007 and became operational on 1st June 2008.

6.1.1/ Composition

The European Chemicals Agency comprises:

- a Management Board
- an Executive Director
- a Risk Assessment Committee
- a Socio-economic Analysis Committee
- a Member State Committee
- an Information Exchange Forum
- a Board of Appeal (all appeals are suspensive)
- a Secretariat

6.1.2/ Tasks

The tasks assigned to the Agency are detailed in article 77, the main ones being:

- managing the registration process;
- managing the dossier evaluation process;
- coordinating the substance evaluation process;
- putting in place the databases and keeping them up-to-date;
- providing advice and assistance;
- providing technical support;

6.2/ Enforcement agencies

The Enforcement of REACH is a responsibility carried out by national authorities. It is important to remember that ECHA has no enforcement responsibility and only provides support by hosting the Forum for Exchange for Information on Enforcement.

The national authorities include:

- France: Ministry of Ecology, Energy, Sustainable Development and the Sea.
- United-Kingdom: Health and Safety Executive (HSE), Health and Safety Executive for Northern Ireland (HSENI), the Environment Agency (EA), the Scottish Environment Protection Agency (SEPA), the Northern Ireland Environment Agency (NIEA), the Department of Energy and Climate Change (DECC), various local authorities.
- Germany: Federal Institute for Occupational Safety and Health, various regional

enforcement authorities.

- Spain: The Ministry of Environment and Rural and Marine Affairs, The Ministry of Health, Social Politics and Equality
- Belgium: Health and Environment Inspection, Labour Inspection, Regional governments
- Sweden: The Swedish Chemicals Agency (KEMI), The Swedish Work Environment Authority, Customs authorities, Local and regional authorities.
- Etc.

A full list of enforcement authorities can be found on the ECHA website until the page entitled 'National Inspectorates': http://echa.europa.eu/web/guest/regulations/enforcement/national-inspectorates

6.3/ Trade associations

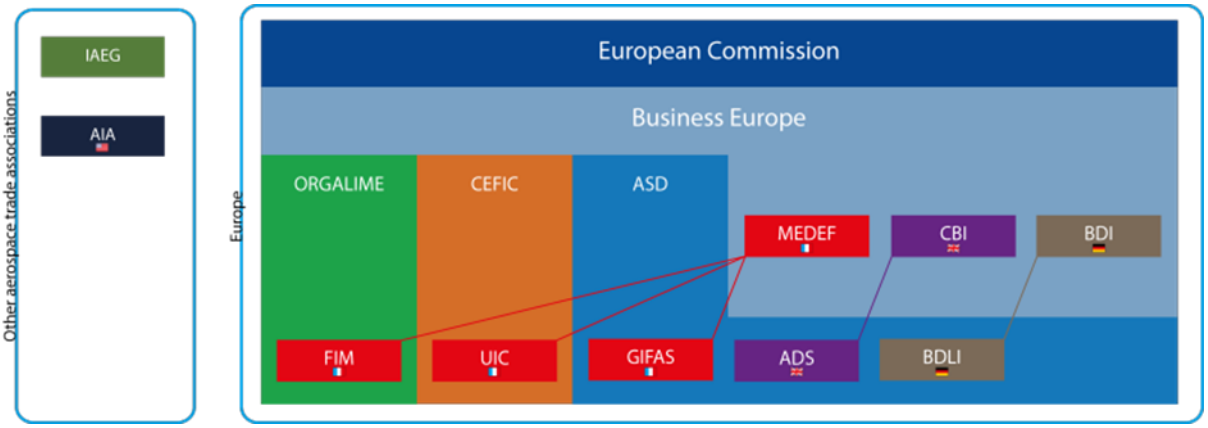
In order to coordinate all sectoral actions and ensure a proper and coherent interface is in place with regards to the different national and European institutions, several trade associations have put in place working groups dedicated to REACH. A trans-sector group has now taken the lead of coordination for the aerospace (ASD), automotive (ACEA), mechanical engineering (ORGALIME), trading and retailers (Eurocommerce) together with various upstream sectors such as Chemicals (Cefic).

At national level, REACH groups have been established in a number of countries such as France (GIFAS), Germany (BDLI) and the UK (ADS). Coordination of policy direction and interfaces with European authorities is managed through the ASD RIWG.

Coordination and exchange of views between trade associations representing different actors in the supply chain, and between industry sectors takes place at both national and European level. At European Level these are managed through the ASD RIWG.

More recently and at international level, close relationships have been developed with the AIA (American Aerospace Industries Association), and workshops are regularly co-organised to exchange on these topics.

Additionally a global coordination at international level has been put in place with the creation of the IAEG (International Aerospace Environmental Group), which aims at the standardisation of the aerospace supply chain and the mitigation of administrative constraints coming in particular from the enforcement of REACH (http://www.iaeg.com/).



6.4/ Standardisation bodies

Several initiatives have been engaged in order to make even more coherent the various approaches in use to take REACH into account within the different sectors and in particular in the Aerospace, Space, Defence and security sector. Within the frame of respectively the IEC (International Electrotechnical) TC111 committee and the ITU (international Telecommunication Union) SG5 committee, in line with the ISO (international standardisation organisation) TC207 committee, a set of standards have been issued along with a database and formats.

A dedicated working group formed through the SAE (Society of Automotive Engineers) E1 committee has produced two standards respectively published under SAE and ASD (STAN TR9536/ TR3535) for declarable substance list and material declaration forms.

Taking into account the difficulties faced to implement these standards, the International Aerospace Environmental Group has been established with the charge of proposing relevant standardisation approach for the whole aerospace business. Today, IAEG counts 11 founding members and numerous members have now joined (http://www.iaeg.com/). It is intended that IAEG will produce some standardised tools together with an update to the SAE/ASD standard 9535 to support a consistent declared reporting of chemicals for the whole supply chain as well as the development of alternative chemicals for those considered and prioritized as critical.

Figure: International standardisation bodies organisation

7/ Fines and penalties, consequences of REACH non compliance

Article 126 of REACH regulation states that:

> *"**Member States** shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than 1 December 2008 and shall notify it without delay of any subsequent amendment affecting them."*

The penalties in each country were summarised in a report published by the European Commission in 2010 which can be found at: http://ec.europa.eu/environment/chemicals/reach/enforcement_en.htm

Conclusion: Important differences between the **severity** of the penalties (i.e. UK: unlimited fines under the procedure of "conviction on indictment" and Spain: €1,2 Millions) and the **system** of penalties (difference between administrative and criminal penalties) can be seen in the differing MS legislation introduced to comply with REACH.

Strong co-operation and co-ordination aspect between the different controls authorities of the Member State should be anticipated by Industry Sectors.

8/ Defence exemptions

8.1/ Background

The REACH regulation (Article 2) provides that "Member States may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a mixture or in an article, where necessary in the interests of defence."

There are a number of areas where defence exemptions may be required:

- The Protection of state secrets,
- Development of new military technology,
- US equipment/technology that is subject to regulation such as International Traffic in Arms Regulations (ITAR) or Export Administration Regulations (EAR).

8.2/ Defence Interests

Generally, state secrets can only be shared with appropriately cleared individuals. Any information sent to the European Chemicals Agency (ECHA) cannot be sent to identified, security cleared, individuals. Although disclosure of information by ECHA is governed by EU Regulation 1049/2001, which does have provision for protecting state security, it would appear impossible to comply with national security requirements and notify ECHA of any use of a substance that is classified.

It is important to understand that industry has to comply with REACH. So, without an exemption, there are circumstances where a business may find itself with conflicting requirements of having to provide data to ECHA and to control the disclosure of the same information under other national or international laws. In such scenarios businesses should seek further guidance from their defence ministry and seek confirmation with the supplier of the materiel of concern that the controls on information disclosure are valid. It may be that the necessary approvals or licences to disclose the information required by REACH can be granted.

8.3/ Availability of Defence Exemptions

The availability of a Defence Exemption is dependent upon the respective Member State taking measures to implement the exemption within that state. This means that the processes to be followed to claim a defence exemption are likely to differ from Member State to Member State and that mutual recognition of an exemption granted in another Member State may not occur automatically. This is important to note for collaborative Projects or Projects that have a supply chain that flows through the EU/EEA.

The majority of EU/EEA Member States participate in the European Defence Agency (EDA) which is a voluntary organisation for the co-operation of defence ministries across the EU/EEA. The EDA publishes the defence exemption processes of those Member States that make them available to the EDA on its website (http://www.eda.europa.eu/REACH/). However, there is no obligation for Member States to provide their processes for publication through the EDA. As new information becomes available from Member States, EDA will update their website.

It is likely that any application for a defence exemption will receive rigorous scrutiny as part of its approval process to ensure that it meets the criteria specifies by the authority(-ies) responsible for granting the exemption.

8.4/ Supply Chain

A Defence Exemption does not guarantee supply of the exempted products, so it is recommended that any business seeking a defence exemption keeps in close communication with its supply chain to ensure that the products remain available.

Where a business is benefiting from a defence exemption higher up in the supply chain (e.g. an

exemption obtained by a prime contractor) it is recommended:

- that the Business ensures that it is explicitly named on any exemption paperwork, and
- that the Business hold copies of the exemption paperwork.

8.5/ Multi-National Projects

Projects with multi-national partners are not uncommon in this sector. Where these involve one or more EU member states there will probably be a requirement to flow Defence Exemptions end to end across project supply and delivery chains. This will need discussion with the Defence Agencies in the Member States where manufacturing is planned to take place.

8.6/ Business Management

In addition to the administrative aspects and uncertainty of obtaining a defence exemption, Businesses also need to account for the resources required to obtain and maintain such exemptions when compiling bid estimates, risk logs, dependencies and assumptions lists.

9/ Obsolescence and supply chain disruption risk management

One of the major consequences of the REACH regulation will be the obsolescence of substances and mixtures. The causes can be :

- inclusion of a substance in the authorization process
- decision by the manufacturer of a substance not to register a substance, mainly because its business case does not support the cost and burden of the registration dossier.
- production stoppage or change of composition of a mixture because a substance is planned to become obsolescent (anticipation by the formulator).
- non-European formulators of mixtures may need to register many substances, and may view this to be not commercially viable.

Some experience can be obtained from the management of obsolescence of electronic components, in which the standard practice is a mix between a purely reactive process and an anticipative one. The risk of obsolescence of substances and mixtures can be assessed, and in many cases, REACH provides identifiable time-scales to anticipate potential last manufacture dates.

In general, the root cause of an obsolescence of a mixture being an obsolescence of a substance, the knowledge of the composition of the mixtures in use in the entity, allows the implementation of an anticipative process on mixtures. For this purpose a systematic analysis of the Safety Data Sheet is necessary for collecting the composition of the mixtures.

A decision to cease the production of some mixtures or substances may be announced by the supplier some months in advance. It is therefore recommended that a systematic process for collecting and flowing down such announcements is put in place within the legal entity so that the different actors have sufficient time to react to it : purchasing for the placement of a stockpiling last Purchase Order, Engineering for studying the potential alternatives, etc.

10/ Classification, Labelling and Packaging (CLP regulation)

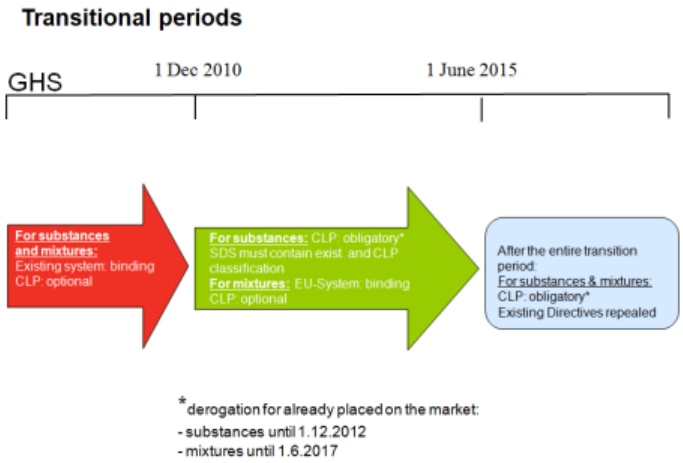
Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances, mixtures, amending and repealing Directives 67/548/EEC (Dangerous Substances Directive) and 1999/45/EC (Dangerous Mixtures Directive), and amending Regulation (EC) No 1907/2006 (REACH) affects all EU/EEA manufacturing industries, including aerospace & defence.

Its purpose is to implement internationally accepted definitions & criteria to identify the hazards of chemicals & communicate those hazards via labels & safety datasheets and align the EU/EEA system of chemical classification with the UN globally harmonised system (GHS).

CLP also establishes an inventory of all hazardous substances on the EU/EEA market:

- ECHA has established a database inventory which is populated from REACH Registration dossiers
- Manufacture or Import of a substance not already Registered must be Notified to ECHA, irrespective of quantity.
- A Harmonised list of hazardous substance Classifications are identified in the Annex VI of the CLP Regulation. Harmonised classifications must be used by all users, importers etc. for Classification, Labelling, Packaging as well as REACH Registration.
- Member States, ECHA or the Commission may seek harmonisation of classifications for substances not on this list. Such proposals are issued on the ECHA Web-0site Register of Intent, and are subject to Public Consultation.

A transitional phase exists currently whereby the both former (Dangerous Substances Directive & Dangerous Products Directive) & new (CLP) classification & labelling provisions can still apply. This transition phase ends on 1st June 2017 when mixtures already placed on the market prior to 2010 must complete transition. Post this date, all substances & mixtures will need to be classified and labelled in accordance with CLP (see below):



- **Substances** – to be classified & labelled until 1 Dec 2010 [article 61(1)] by existing Substances Directive 67/548/EEC
- **Mixtures** – (formerly preparations) to be classified & labelled until 1 June 2015 by existing Preparations Directive 1999/45/EC

Substances or Mixtures can be classified, labelled & packaged in accordance with CLP prior to the above dates in which case the provisions on labelling & packaging specified by the former Directives do not apply [article 61(2)]

Substances already classified & on market before 1 Dec 2010 need no reclassification or label-

ling until 1 Dec 2012 [article 61(4)]

Mixtures already classified & on market before 1 June 2015 need no reclassification or labelling until 1 Dec 2017

10.1/ Impact on Aerospace/Defence Industry

Once a substance or mixture has been appropriately classified & labelled under CLP, manufacturers, importers, downstream users, distributors of substances or mixtures, as well as producers and importers of certain specific articles (explosive articles which are subject to classification according to Part 2 of Annex I of CLP) should communicate the identified hazards of these substances or mixtures to other actors in the supply chain, including to consumers.

The EU aerospace industry supply chain is no exception and the benefits of a harmonised chemical classification & labelling system are recognised, as are the significant changes that actors in the aerospace and defence industry need to be aware of, namely:

- Pictograms & hazard statements on substance/mixture safety datasheets will change

- Substances & mixture classifications & labelling including packaging labelling may change, i.e. the hazardous properties of a substance/mixture may alter
- Industry accepted risk and safety phrases will also change to hazard and precautionary statements, i.e. R & S phrases will be phased out.
- Chemical transport rules must also be consistent
- Ensure those dealing with, handling, storing substances & mixtures (employees, subcontractors, possibly customers etc) know about changes from existing system to CLP with new hazard info/pictograms & packaging labelling requirements
- Obtain updated Safety Data Sheets from suppliers & review processes
- Inform production operatives using substances & mixtures
- Ensure that health & safety/environmental provisions such as Personal Protective Equipment or Local Exhaust Ventilation are suitable for manufacturing processes

and that associated risk assessments & chemicals assessments are amended as necessary

Any import of unregistered substances on their own or in mixtures may require Notification to ECHA within 1 month of first import, irrespective of import quantity. All potential import routes, such as Purchasing, Materials test laboratories (for research samples) will require awareness of this obligation.

Your obligations depend upon your role in the supply chain.

Suppliers may have one or more of these roles:

- Manufacturer of substances or mixtures
- Importer of substances or mixtures
- Producer of specific articles
- Downstream user, including formulator and re-importer
- Distributor, including retailer.

10.2/ Obligations of a downstream user

You should assemble and keep available all the information required for the purposes of classification and labelling under CLP for a period of at least 10 years after you have last supplied a substance or mixture.

10.3/ Impact of CLP on REACH Evaluation, Authorisation and Restriction, and Supply

New data coming from Registration processes or CLP Notifications, may prompt the need for evaluation of dossiers, additional testing etc, in particular where substances are classified in different ways by different actors.

If, as a result of such Evaluation there is a need for a Harmonised Classification, a conclusion may be reached that a substance is a Substance of Very High Concern, and may subsequently be placed on the Candidate List for Authorisation, or be subject to Restriction.

This is a natural part of the process of evaluating substances which are new to the market, or for which there is little testing data and would add to the pool of around 2000 substances already known to meet the Candidate List criteria.

Addition to this pool is made based on intrinsic properties. Further “promotion” to REACH Annex XIV (Authorisation) or Annex XVII (Restriction) requires other risk factors to be fulfilled, such as wide dispersive use or consumer exposure.

If a substance is given a Harmonised Classification of 1A or 1B for Carcinogenicity, Mutagenicity, or Repro-toxicity, then it is automatically restricted to use only by professional users in substances and mixtures. This has no direct (legal) impact to the Aerospace and Defence industry, but may impact the economics of substance manufacture and therefore may affect supply availability or prices.

TITLE I General issues

- Chapter 1 Aim, scope and application
- Chapter 2 Definitions and general provision

TITLE II Registration of substances

- Chapter 1 General obligation to register and information requirements
- Chapter 2 Substances regarded as being registered
- Chapter 3 Obligation to register and information requirements for certain types of isolated intermediates
- Chapter 4 Common provisions for all registrations
- Chapter 5 Transitional provisions applicable to phase-in substances and notified substances L 396/42 EN Official Journal of the European Union 30.12.2006

TITLE III Data sharing and avoidance of unnecessary testing

- Chapter 1 Objectives and general rules
- Chapter 2 Rules for non-phase-in substances and registrants of phase-in substances who have not pre-registered
- Chapter 3 Rules for phase-in-substances

TITLE IV Information in the supply chain

TITLE V Downstream users

TITLE VI Evaluation

- Chapter 1 Dossier evaluation
- Chapter 2 Substance evaluation
- Chapter 3 Evaluation of intermediates
- Chapter 4 Common provisions 30.12.2006 EN Official Journal of the European Union L 396/43

TITLE VII Authorisation

- Chapter 1 Authorisation requirement
- Chapter 2 Granting of authorisations
- Chapter 3 Authorisations in the supply chain

TITLE VIII Restriction on the manufacturing, placing on the market and use of certain dangerous substances and preparations

- Chapter 1 General issues
- Chapter 2 Restrictions process

TITLE IX Fees and charges

TITLE X Agency

TITLE XI Classification and labelling inventory

TITLE XII Information

TITLE XIII Competent authorities

TITLE XIV Enforcement

TITLE XV Transitional and final provisions *L 396/44 EN Official Journal of the European Union 30.12.2006*

ANNEX I General provisions for assessing substances and preparing chemical safety reports

ANNEX II Guide to the compilation of safety data sheets

ANNEX III Criteria for substances registered in quantities between 1 and 10 tonnes

ANNEX IV Exemptions from the obligation to register in accordance with article 2(7)(a)

ANNEX V Exemptions from the obligation to register in accordance with article 2(7)(b)

ANNEX VI Information requirements referred to in article 10

ANNEX VII Standard information requirements for substances requirements for substances manufactured or imported in quantities of 1 tonne or more *30.12.2006 EN Official Journal of the European Union L 396/45*

ANNEX VIII Standard information requirements for substances requirements for substances manufactured or imported in quantities of 10 tonne or more

ANNEX IX Standard information requirements for substances requirements for substances manufactured or imported in quantities of 100 tonne or more

ANNEX X Standard information requirements for substances requirements for substances manufactured or imported in quantities of 1000 tonne or more

ANNEX XI General rules for adaptation of the standard testing regime set out in annexes VII to X

ANNEX XII General provisions for downstream users to assess substances and prepare chemical safety reports *L 396/46 EN Official Journal of the European Union 30.12.2006*

ANNEX XIII Criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances

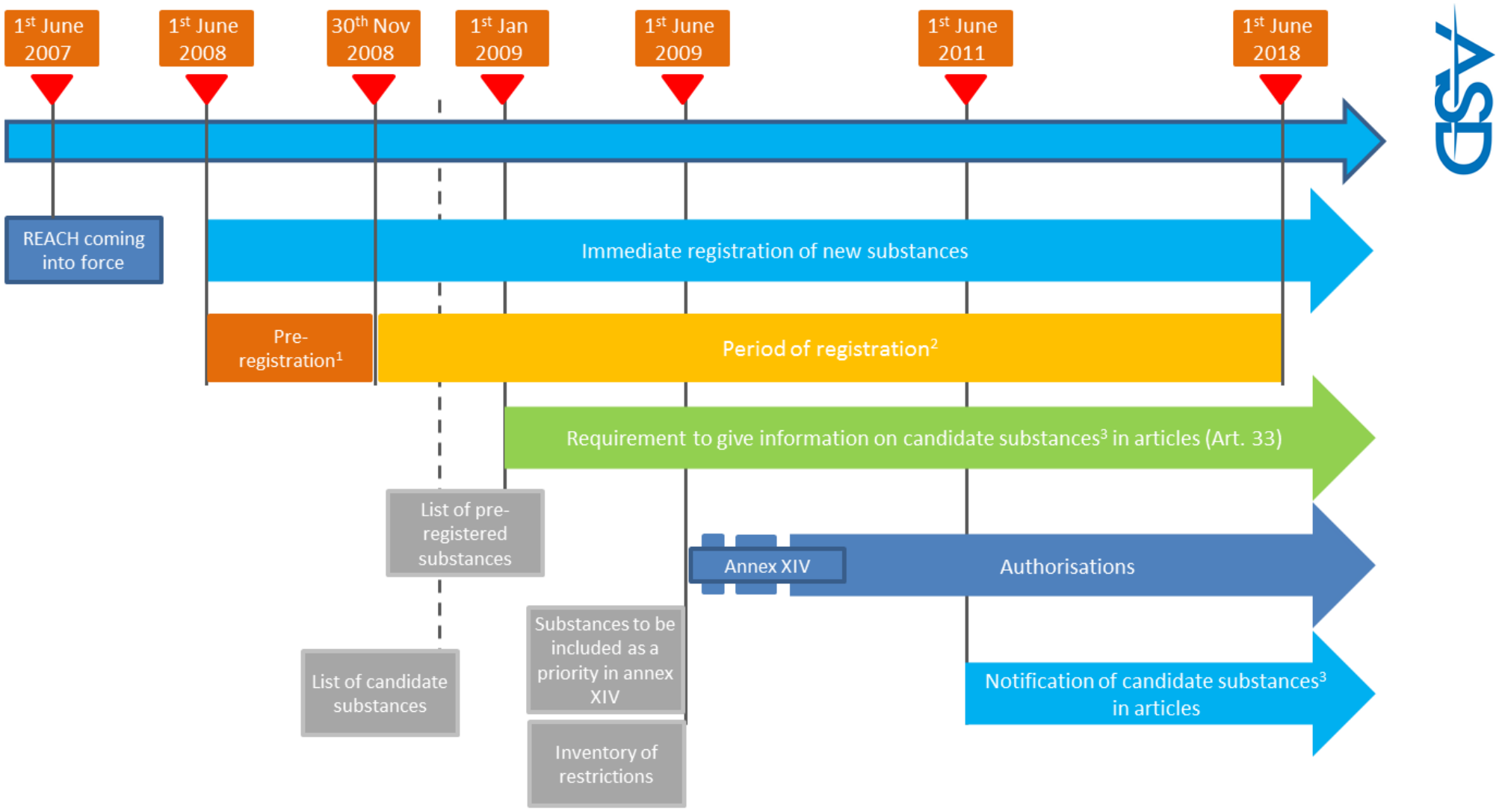
ANNEX XIV List of substances subject to authorisation

ANNEX XV Dossiers

ANNEX XVI Socio Economic Analysis

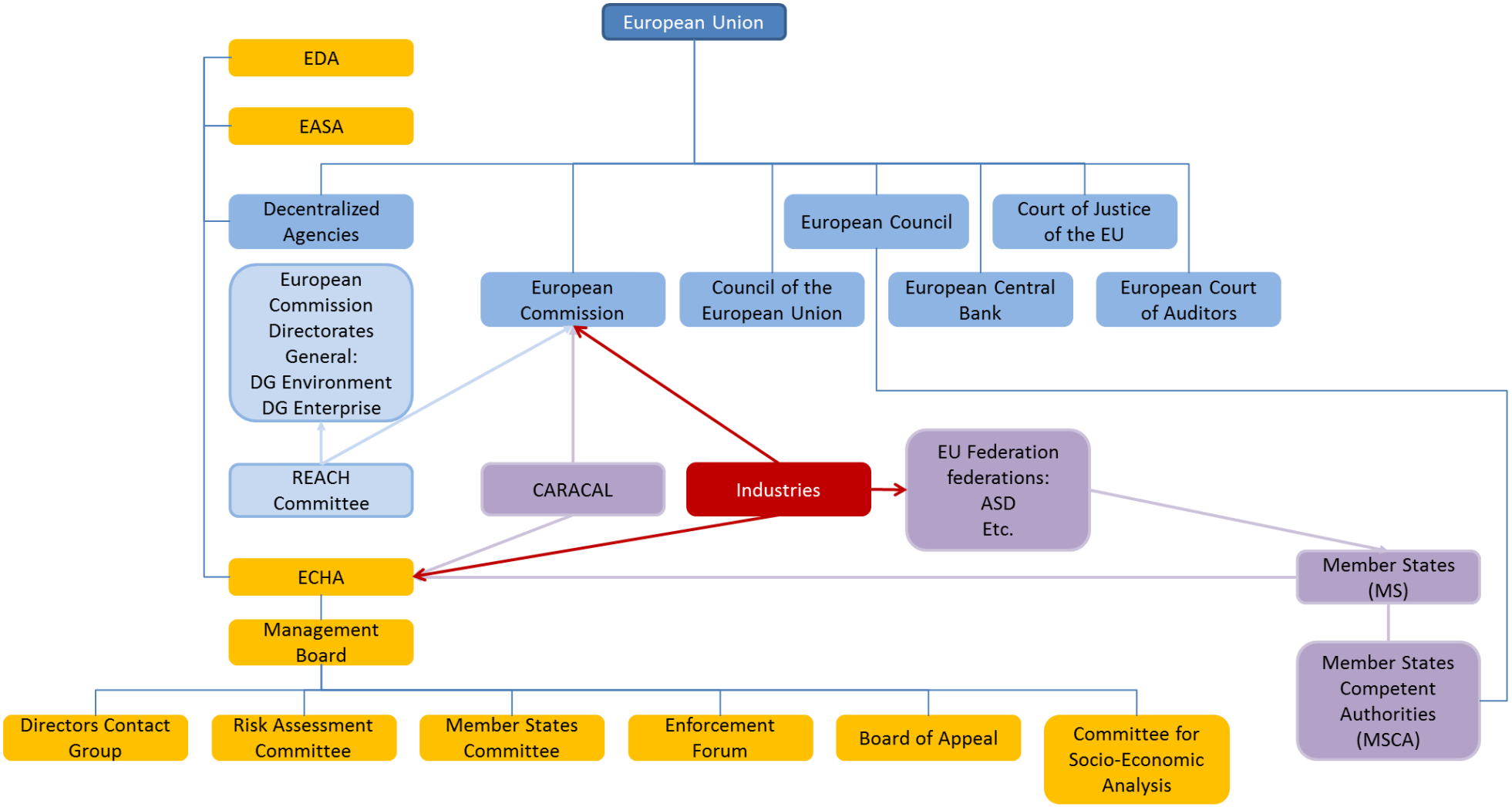
ANNEX XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles

11.2/ Annex 2 – REACH Timetable



[1] of existing substances *[2] for pre-registered existing substances* *[3] substances appearing on the list of substances which are candidates for authorisation (Art. 59)*

11.3/ Annex 3 - European Agencies

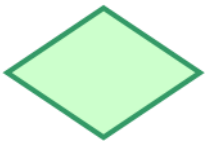


11.4.1/ How to read these flowcharts?

These flowcharts must be read from top to bottom and horizontally.

The symbol  represents the entry point to the flowchart.

There are three different types of boxes:

 Decision gates, where the answer is "yes" or "no"

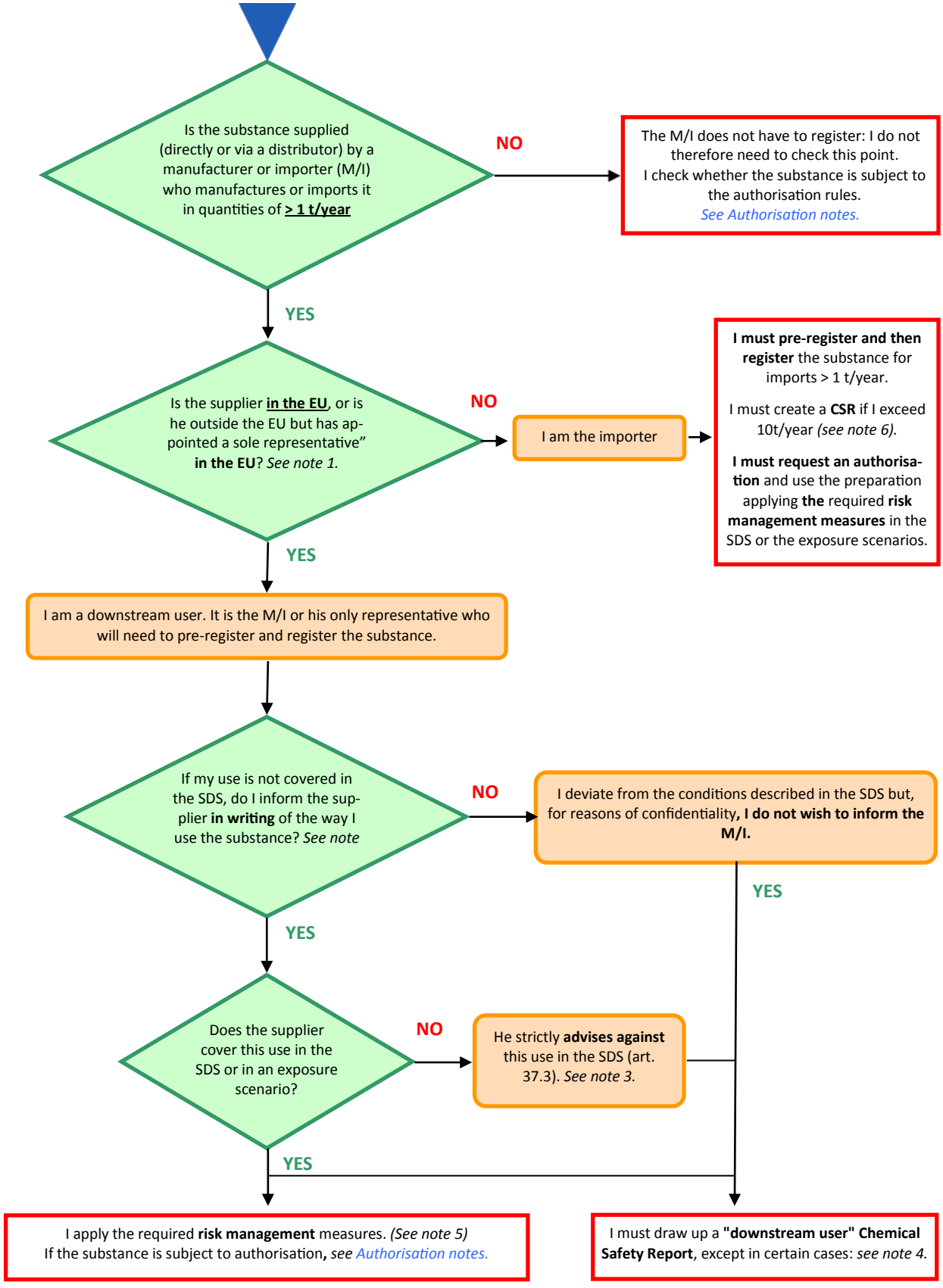
 Action

 Information

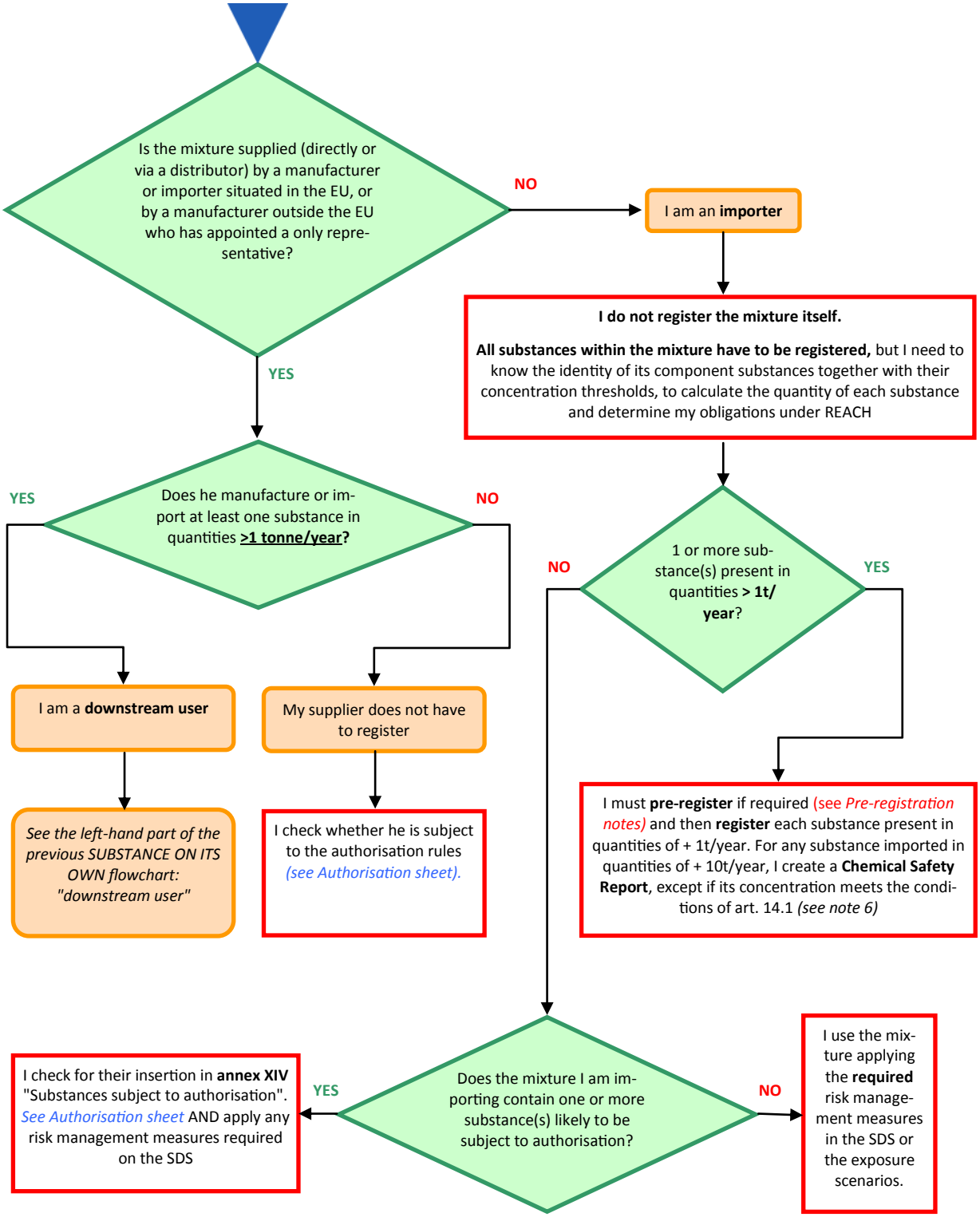
Black arrows link the different boxes to each other. They have no special significance and may indicate a flow of information or data, a piece of advice, a regulatory obligation, etc.

11.4.2/ Purchasing flowcharts

11.4.2.1/ Purchasing flowchart 1: I am purchasing a substance on its own, whatever the quantity may be



11.4.2.2/ Purchasing flowchart 2: I am purchasing a mixture on its own, whatever the quantity may be



11.4.2.2/ Notes for the purchasing of a substance and purchasing mixture flowcharts

Remark: in the flowcharts "I" corresponds to a legal entity: a company with three subsidiaries represents 4 distinct legal entities.

Note 1: Importation: reminder

By importation, we mean procurement from a country situated outside the European Union. For the record, the States of the European Union are:, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Rumania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

Certain countries (Iceland, Norway and Liechtenstein) are associated with the European Union within the context of the European Free-Trade Association (EFTA) and their position with respect to REACH depends upon signature of an agreement. For example Norway adopted the REACH regulation on 30th May 2008.

Note 2: Identified use

When the user receives an SDS accompanied by one or more registration numbers (registration made by the manufacturer/importer*) he can check whether his use is listed amongst the "identified uses" on the SDS. If that is not the case, he has twelve months from receipt of the SDS to provide a "brief general description" of the use, with a view to making it a use identified by the manufacturer/importer, which will be covered by an exposure scenario appended to the SDS.

He informs the supplier who must pass the information up to the actor immediately upstream, and so on up to the manufacturer/importer. He must provide a sufficient amount of information to make it possible to establish an exposure scenario. (Art. 37.1 and 37.2)

Note 3: Unadvisable use

Under the terms of article 37.3, the manufacturer or importer of the substance may advise against a use but only for reasons of protection of health or of the environment. He must inform the user who has communicated this use to him, and the Agency, in writing. He must include this "unadvised use" in the Safety Data Sheet (point 16). He must update the SDS, or any other information document where an SDS is not obligatory, before the substance is next supplied.

Note 4: Obligation to establish a "downstream user" chemical safety report: principle and exceptions

- Principle:

  Art. 37.4 states that a downstream user whose use is not covered by an exposure scenario appended to the Safety Data Sheet must create a Chemical Safety Report (usually referred to by the acronym CSR) as described in annex XII of the regulation. This "downstream user" CSR contains less data than the CSR required of the manufacturer or importer, but the requirements are still considerable.

  Clearly, in this case it is in the company's interests to collaborate on this measure with other companies that have the same use for a substance in order to spread the costs.

  The user must also convey information to the Agency (art. 38.2). But first, the user must check whether he can be exempted from these obligations.

- Exemptions:

  Article 37.4 gives six cases in which the user does not have to create a CSR:

a) if the substance or mixture is not the subject of an SDS;

b) if his supplier is not obliged to create a Chemical Safety Report;

c) if he uses the substance or mixture in a total quantity of less than 1 t/year*;

d) if he implements an exposure scenario at least equivalent to that recommended in the SDS;

e) if the substance is present in a mixture at a concentration lower than the concentrations indicated in article 14.2;

f) if he uses the substance for product and process R&D activities, provided that the risks for human health and the environment are properly controlled*.

* In that case, he must still provide the Agency with information as per article 38.2.

Note 5: Application timetable

The obligations to:

- draw up a Chemical Safety Report
- implement risk management measures

apply no later than twelve months following receipt of the registration number provided by the supplier in the SDS.

The possibility of informing the supplier of the use made of the substance remains open for twelve months following the receipt of the registration number notified by the supplier in the SDS.

Note 6: Chemical Safety Report that must be established by the importer of a substance or mixture

For any substance imported in quantities of + 10t/year, the manufacturer or importer must establish the Chemical Safety Report (CSR) stipulated in article 14 and described in annex I. The CSR contains an evaluation of the chemical safety (health hazards, physicochemical hazards, environmental hazards, persistent and bioaccumulative properties).

When the substance is contained in a mixture, art. 14.2 states that a CSR need not be created if the substance's concentration is lower than the lowest of the following levels:

a) the applicable concentrations, defined in the table in article 3, paragraph 3, of Directive 1999/45/CE;

b) the concentration limits given in annex I of Directive 67/548/CEE;

c) the concentration limits given in annex II, part B, of Directive 1999/45/CE; the concentration limits given in annex III, part B, of Directive 1999/45/CE;

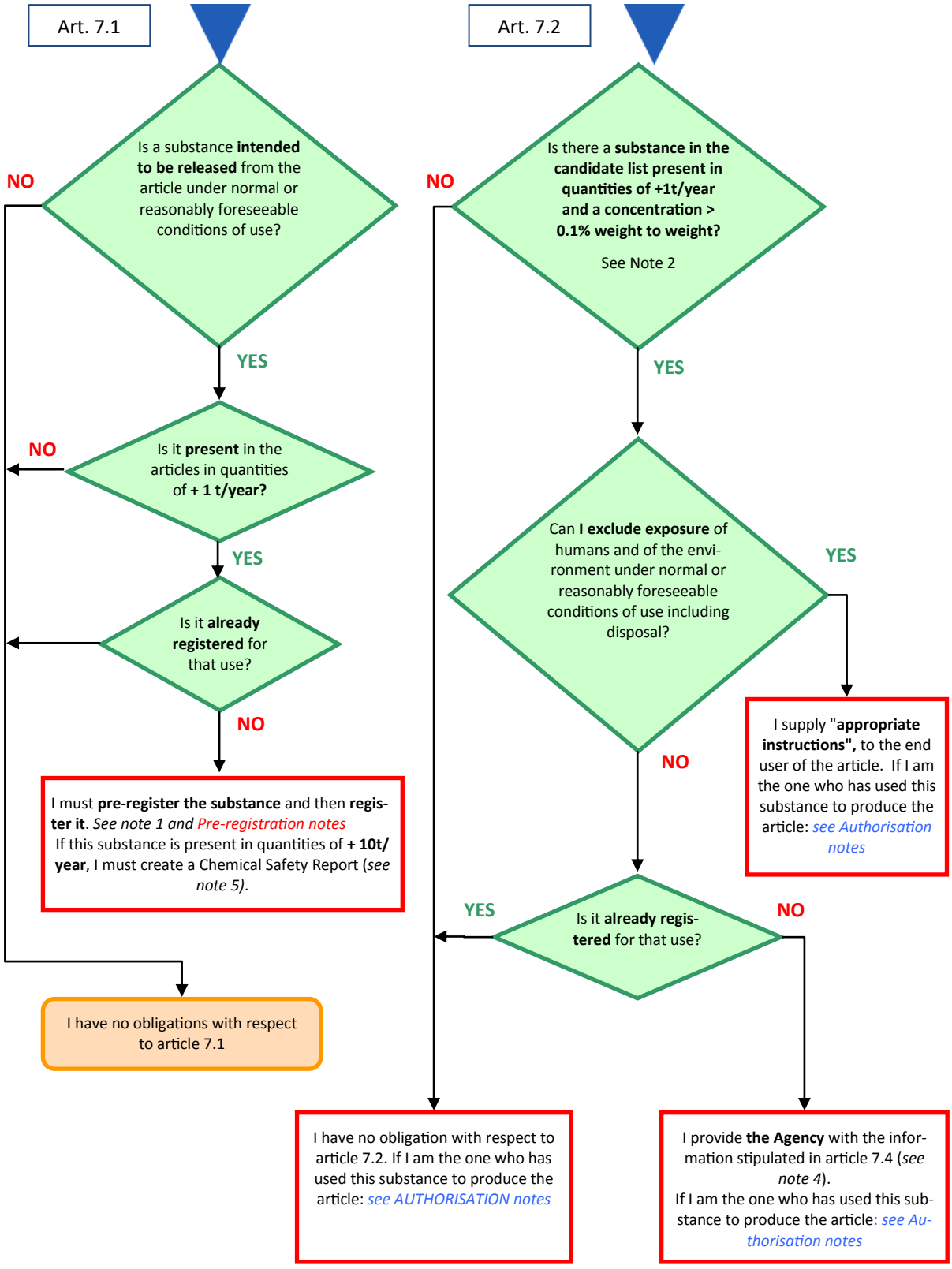
d) the concentration limits mentioned in an agreed entry in the classification and labelling inventory established pursuant to title XI of the Regulation;

e) 0.1 % weight by weight (w/w) if the substance meets the criteria laid down in annex XIII of the Regulation.

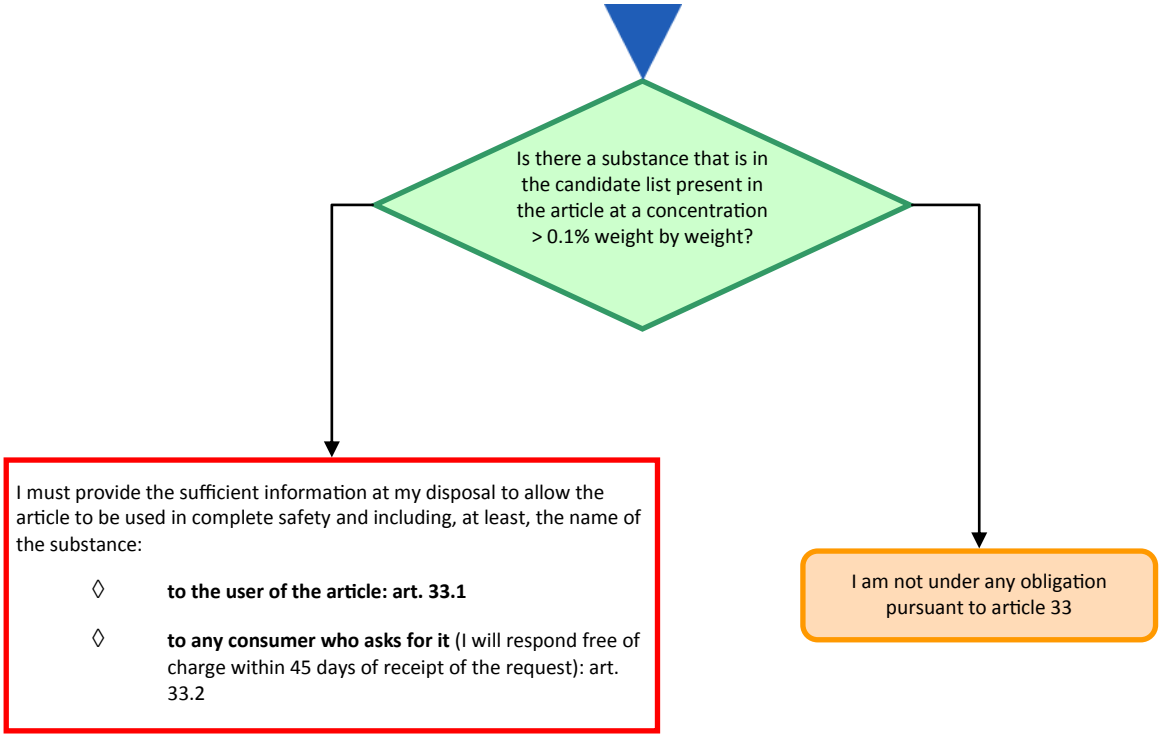
When creating the CSR for a mixture, there is a choice between evaluating the substance on its own, or evaluating the mixture as a whole (art. 31.2).

11.4.3/ Articles flowcharts

11.4.3.1/ Articles flowchart 1: I am producing or importing articles



11.4.3.2/ Articles flowchart 2: Downstream communication as a "supplier of articles"



11.4.3.3/ Notes for the articles flowcharts

Remark: In the flowcharts, "I" corresponds to a legal entity - a company with three subsidiaries represents 4 distinct legal entities.

To complement these notes, refer to the "Substances in articles" ECHA Guidance Document and, in this guide, to the “Deciding that the object is an article” flowchart.

Note 1: Possibility of an obligation to register for a substance "intended to be released" by the article.

Article 7.1 of the Regulation states that any producer or importer of articles must register a substance present in these articles if all the following conditions are met:

a) The substance is present in these articles in quantities greater in total than 1 t/year per producer or importer;

b) The substance is intended to be released under normal or reasonably foreseeable conditions of use;

c) The substance has not already been registered for that use.

Note 2: Presence of a substance that is in the candidate list in an article, above certain concentration and tonnage thresholds (art. 7.2).

Amongst the substances said to be of "very high concern" (meeting criteria of Article 57 which defines SVHCs), the Agency identifies certain ones on a "candidate list”, which is incremented with new substances (every 6 months). From that list, some substances for which risks measures should be taken might be incorporated within the Annex XIV for authorisation.

Note 3: Am I able to exclude exposure of humans and the environment under normal or reasonably foreseeable conditions of use, including disposal?

If the answer to this question is yes, Article 7.3 states that the producer/importer does not have to provide information to the Agency. The producer/importer must provide "appropriate instructions" to the user of the article.

It will not always be easy, however, to demonstrate that such exposure can be excluded, in particular when considering the full life cycle.

Note 4: Information to be provided to the Agency relative to article 7.2

This information must be provided:

- if a substance of very high concern is present in the articles in quantities above the stipulated thresholds
- and if that substance has not already been registered for that use
- or if the producer/importer cannot exclude exposure to that substance (see note 3).

Article 7.4 gives the list of information to be provided: identity of the producer, identity of the substance, its classification, a brief description of the use(s) made of the substance(s) contained in the article.

Entry into force of the obligation to notify: from 1 June 2011, then six months after a substance has been included on the above-mentioned list.

Note 5: Chemical Safety Report

For a substance "intentionally released" present in quantities of > 10t/year, the producer or importer of articles must create the (time-consuming and costly) Chemical Safety Report (CSR) provided for in article 14 and described in annex I.

The CSR includes a chemical safety evaluation (identifying the health hazards, physicochemical hazards, environmental hazards, persistent and bioaccumulative properties).

As indicated earlier, “releasing” articles are rare in our professions.

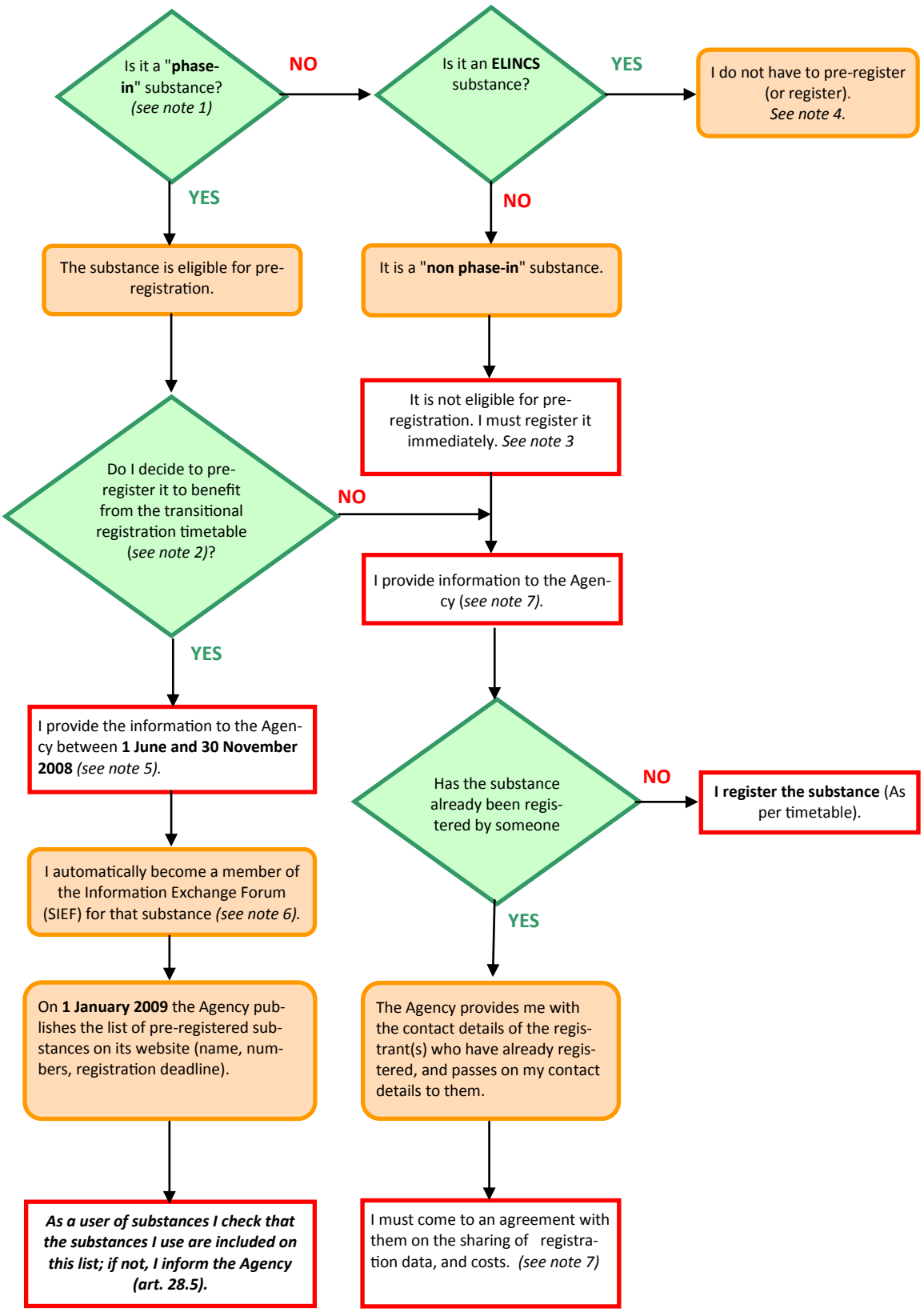
Note 6: Communication of information to the user of the article and the end consumer if he asks for it

This communication of information is provided for in article 33. It applies once the 0.1% by weight (total weight of the article) concentration threshold is passed (without tonnage threshold). It applies to all "suppliers of articles", which includes the producer, importer, distributor or any other actor in the supply chain who places an article on the market. It is required for any substance on the candidate list (see note 2).

Note 7: Clarification with regards to consumers

A consumer is a non commercial recipient of the article – Defence agencies and airlines are commercial recipients of articles and not consumers. Passengers of an aircraft - as they are not recipients of the aircraft - cannot be considered as consumers. However, a private pilot owning an aircraft would be a consumer.

11.4.4.1/ Pre-registration flowchart: I am able to pre-register a substance?



11.4.4.2/ Notes for the pre-registration flowchart 1: I am able to pre-register a substance?

Remark: in the flowcharts "I" corresponds to a legal entity: a company with three subsidiaries represents 4 distinct legal entities.

Note 1: "Phase in" substances that can be pre-registered to benefit from the registration timetable

These are the substances that meet one of the following criteria:

a) they are mentioned in the EINECS inventory (present on the market before September 1981),

b) or are manufactured in the Community or one of the countries that joined on 1 May 2004, but have not been placed on the market at least once in the last 15 years.

The inventory of 130,000 EINECS substances can be consulted on the website: http://ecb.jrc.it/existing-chemicals/. They have a numbering code comprised between 200-001-8 and 400-010-8.

Note 2: Transitional registration timetable

Pre-registering between June and December 2008 makes it possible to benefit from the transitional registration timetable, which is as follows:

- 2010 for substances manufactured or imported in quantities greater than 1000t/year, for category 1 or 2 CMR substances manufactured or imported in quantities greater than 1t/year, and for substances highly toxic for aquatic organisms (R50/53).
- 2013 for quantities comprised between 100t/year and 1000t/year
- 2018 for quantities comprised between 1t/year and 100t/year.

In the absence of pre-registration, the manufacturer or importer must register in 2008, which should happen only very occasionally.

Note 3: "Non phase-in" substance that must be registered in 2008.

Today, a very small number of substances are concerned since this applies to new substances in the sense of REACH (commercialised after this text has come into force) and the substances manufactured but not placed on the market before 1992. These substances are subject to articles 26 and 27.

Note 4: ELINCS substances that have not been pre-registered

Because these substances have already been very well evaluated, they are considered to be already registered: the Agency will grant them a registration number no later than 1 December 2008. They are subject to article 24 (see art. 24.2 in particular).

The list of 3,000 ELINCS substances can be consulted on the website: http://ecb.jrc.it/new-chemicals/

Their numbering code starts at 400-010-9.

Note 5: Information to be provided for pre-registration

This information is not very time-consuming to provide. Article 28 stipulates that each registrant must provide the Agency with the following information:

a) the name of the substance, its EINECS and CAS numbers or, if they are not available, any other identity code;

b) the registrant's name and address, along with the name of the person to be con-

tacted if he has appointed a representative as allowed for in article 4: the name and address of that representative;

c) the deadline envisaged for the registration and the quantity band;

d) and for substances that can be "grouped together" because of their structural similarity (annex XI, section 1.3 and 1.5): same information as in point a) above.

Note 6: Substance Information Exchange Forum (SIEF) and payment for the costs of information to be provided at registration.

A forum will be created for each substance, and will bring together all the "registrants" who have pre-registered the substance in question (art. 29). The purpose of a forum is to facilitate exchanges of information and data in order to avoid repeating studies unnecessarily.

If studies have already been carried out, article 30.1 sets out procedures so that their owner(s) may “share” them with the other registrants: the goal being to fix the costs of sharing in a fair and transparent way. If the owner of an existing study refuses to "share" it, alternative solutions are provided for in articles 30.3 and 30.4.

If, for an item of information required by REACH, there is no relevant study available, a single study will be carried out by one of the participants in the SIEF, acting on behalf of the others (see art. 30.2).

Note 7: Procedure to be applied if I decide not to pre-register a substance

I ask the Agency whether the substance has already been registered by another. My request is accompanied by the information defined in article 26.1.

The Agency will then inform me whether:

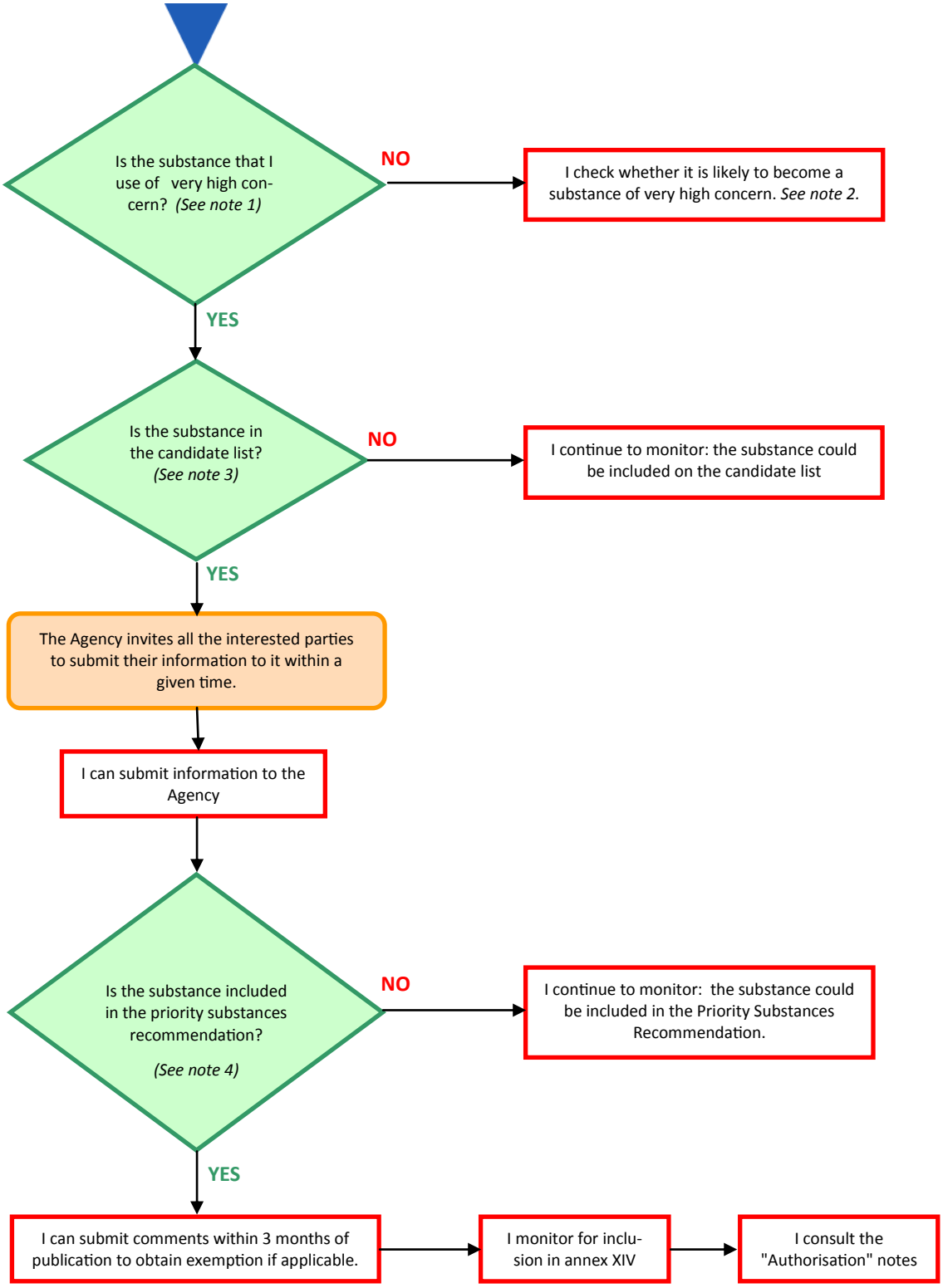
- the substance has not yet been registered: in that case I must register;
- it has already been registered by one or more earlier registrant(s); in which case the agency passes on to them my contact details and gives me their contact details. If the substance was registered less than twelve years earlier, article 27 sets out the procedures for "sharing" the data with the earlier registrant(s), the goal being to reach an agreement on a fair and transparent cost.

Note 8: Pre-registration of substances manufactured or imported for the first time after 31st December 2008, or which will be released intentionally by an article manufactured or imported for the first time after 31st December 2008.

Article 28.6 stipulates some "catch-up" provisions: it is possible to take advantage of the transitional timetable, provided the required information has been given to the Agency within six months of the first manufacture/importation (see note 4).

11.4.5/ Authorisation flowchart

11.4.5.1/ Authorisation flowchart 1: Monitoring



11.4.5.2/ Notes for the authorisation flowchart 1: Monitoring

Preamble

- The substances subject to authorisation will be listed in annex XIV.
- The authorisation procedure applies whatever the quantity.
- The authorisation associates a substance with a specified use of the substance.

Note 1: Substances of very high concern are (Art 57):

a) Category 1 or 2 CMRs (see Directive 67/548);

b) Persistent, Bioaccumulative and Toxic (PBT) substances (see Annex XIII);

c) Very Bioaccumulative and very Persistent (vBvP) substances (see Annex XIII);

d) Substances with endocrine disrupting properties or substances causing a level of concern equivalent to the substances indicated above.

Note 2: Substances that are likely become of very high concern (Art. 59.4)

The Commission and the Member States may submit a dossier to the Agency on a substance that it or they consider meets the "very high concern" criteria.

The Agency publishes opinions on these dossiers on its website.

All the interested parties can submit their information to the Agency within a given deadline.

Note 3: Candidate list

The list is published by the ECHA on its website.

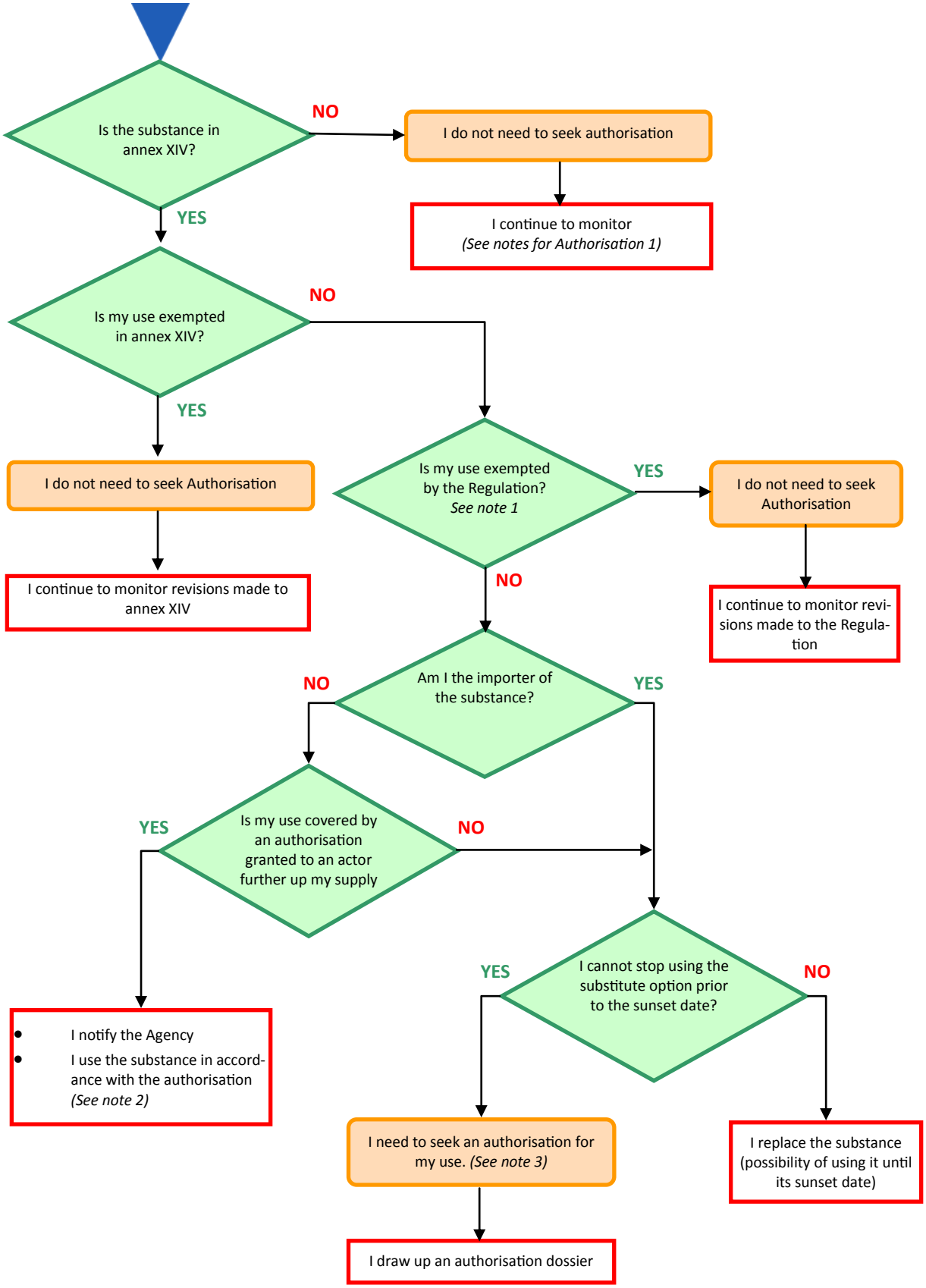
Note 4: The Agency's recommendation regarding the substances to be included as a priority in annex XIV (Art 58.3 & 58.4).

Priority is given to substances that have PBT or vPvB properties, or that have highly dispersive applications, or are produced in large quantities, for which risks management measures are deemed necessary within the EU.

The Annex XIV is issued as a formal corrigendum/modification of the EC regulation EC1907/2006.

All interested parties have 90-days in June-September in which to submit their comments regarding the uses that should be exempted.

11.4.5.3/ Authorisation flowchart 2: use of a substance subject to authorisation



11.4.5.4/ Notes for the authorisation flowchart 2: use of a substance subject to authorisation

Note 1: Uses exempted by the Regulation (Art. 56)

- Use of substances within the context of scientific research & development activities (< 1 tonne/year);
- Use of substances within the context of Product or Process Oriented Research & Development activities focussing on products and processes: annex XIV lists these exemptions and the maximum quantity that can benefit from them;
- Uses in biocide products that come within the scope of Directive 98/8/CE;
- Uses as fuels covered by Directive 98/70/CE of 13 October 1998 regarding the quality of petrol and diesel fuels;
- Uses as fuels and combustibles in mobile or fixed combustion installations consuming products derived from mineral oils, and uses as fuels and combustibles in closed systems;
- Uses in materials intended to enter into contact with foodstuffs, entering into the scope of Regulation (CE) No 1935/2004, there is an exemption for the substances that are subject to authorisation only because they have cat. 1 or 2 CMR properties, or because they have been identified per article 57, point f) (substances with endocrine disrupting properties or with an equivalent level of very high concern) only because of the hazards for human health.
- Uses of substances when they are contained in preparations:

  a) for PBT, vPvB substances, or substances with endocrine disrupting properties or with an equivalent level of very high concern: below a concentration limit of 0.1 % weight-by-weight (w/w);

  b) for all of the other substances, below the lowest concentration limits specified by Directive 1999/45/CE or annex I of Directive 67/548/CEE that give rise to the preparation being classified as dangerous.

Note 2: Notification (Art. 66) and labelling (Art.65)

- Notification: the downstream users that use a substance in compliance with an authorisation granted to an actor in their supply chain send a notification to the Agency within three months of the first delivery of the substance.
- Labelling: the holders of an authorisation and the downstream users of an authorised substance who include the substance in a preparation must mention the authorisation number on the label.

Note 3: Deadlines (Art 58.1.i & 58.1.ii)

When the Commission decides to include a substance of very high concern in annex XIV, it stipulates the transitional provisions, i.e:

- the "expiry date" (sunset date) after which it is prohibited to place the substance on the market and use it in a substance or mixture, unless an authorisation is granted;
- a date (at least 18 months before the sunset date), before which the Authorisation applicant must send his dossier if he wishes to continue to use the substance or place it on the market after the sunset date; these uses will continue to be authorised after the sunset date until a decision has been reached on the request for authorisation.