

REACH

Interpretation guidelines



This document aims to provide a general and simplified explanation of the mechanisms and main provisions relative to complying with the EU REACH regulation.

The document has been created for engineering manufacturers of articles, particularly for suppliers into the automotive and aviation industries. Inevitably some nuances have been overlooked in order to help manufacturing businesses understand the general implications of the regulation. It should not be used as a substitute for the applicable rules as they are described in regulation (CE) No 1907/2006 and other applicable texts.

The authors cannot be held responsible for the consequences of any extensive or inappropriate use made of the content of this document and are advised to seek independent legal opinion on specific scenarios for their own businesses.

The authors of this document have based their interpretation on the documents available at the time of writing. Some of these references may be modified, in particular through the REACH Implementation Projects. Users are therefore encouraged to check for later versions of this guide.

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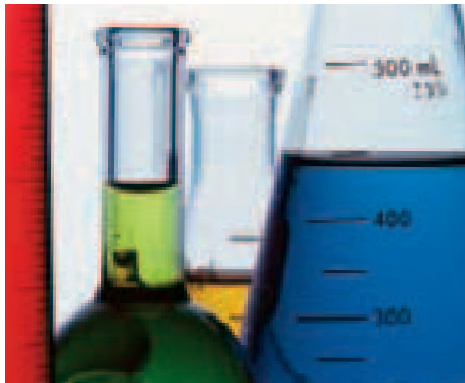
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The **European REACH regulation (Registration, Evaluation and Authorisation of Chemicals)** comes into force on 1 June 2007 with a gradual introduction of the obligations through to 2018.



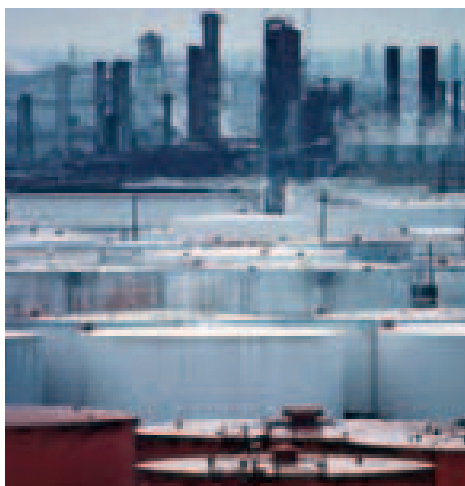
If your company is a manufacturer, importer or user of chemical **substances** on their own, or contained in preparations (i.e. in a solid, liquid or gaseous mixture of chemical substances) or in the products you make (these are called "articles" in REACH), you must take into account the new provisions of **REACH** to be permitted to continue to operate legally within the European Union.

REACH will generate unprecedented changes in the way information on the substances is exchanged and in the distribution of responsibilities between the various actors all along the **supply chain**. Each actor will have to strengthen the trace-ability of each of the different substances that are used and incorporated into products.

REACH requires the **compulsory registration** of all substances that are sold, imported, manufactured or used in quantities exceeding one tonne per year (per legal entity).

Data on the hazardous nature of the substances and their uses must be collected with the responsibility now falling on industrial manufacturers and users (and no longer on the Member States as was the case with the previous system). The **sharing of data is compulsory** in order to minimise the number of tests required. Routes of exposure have to be identified, and recommended risk management measures have to be given to downstream users.

This will result in a reduction in risk for the 30,000 most frequently used substances throughout their life cycle and will gradually lead to the withdrawal from the market of substances of highest concern.



A **European Chemicals Agency** based in Helsinki will be responsible for implementing and monitoring this new system. The agency will evaluate the information provided by companies, which will result in the most hazardous substances becoming candidates for authorisation or restriction.

Furthermore, a change in the **classification and labelling** of all chemical substances and preparations is expected with the gradual adoption of the Globally Harmonised System (GHS).

Most manufacturing businesses in the automotive, aviation or similar engineering manufacturing industries, will be downstream users in REACH and will have obligations to provide information. Businesses could also be importers of chemicals, metals and other substances, but are unlikely to manufacture their own chemicals.

This document is a reference and interpretation guide specifically intended for manufacturing companies working in the mechanical, aeronautical and automotive sectors. It aims to highlight the main obligations of the new REACH system and to help companies prepare for significant deadlines that will have to be met in order to ensure business continuity. It attempts to provide simple recommendations and links to the various sources of additional information in order to assist with practical implementation.

Glossary

CAS: Chemical Abstract Service

CMR: Carcinogenic, Mutagenic and toxic for Reproduction

CSR/CSA: Chemical Safety Report & Chemical Safety Assessment

DNEL: Derived no effect level. The point below which the hazardous substance is considered not to harm health

EINECS: European Inventory of Existing Chemical Substances

ELINCS: European List of Notified Chemical Substances

European Union: in this document, this term refers to all the EU member States and some other countries that will be implementing REACH and will be considered to be 'inside the EU' – namely Iceland and Norway. Note that Switzerland is outside the EU for the purposes of REACH.

GHS: Globally Harmonised System for the classification and labelling of dangerous substances and preparations

IUCLID: International Uniform Chemical Information Database

IUPAC: International Union of Pure and Applied Chemistry

Legal Person: In this document "Legal Person" refers to the legal entities e.g. a company with a legal status

Only Representative: The legal person registered in the EU, who is representing a non-EU company, thereby allowing them to comply with REACH in their own right.

OSOR: One Substance One Registration

PBT: Persistent, Bioaccumulative and Toxic

PNEC: predicted no effect concentration: The predicted level below which the substance is expected to have no effect

RIP: REACH Implementation Projects. The European Chemicals Bureau (ECB) is responsible for developing the technical guidelines and IT tools required for putting REACH in place and for its satisfactory operation. These activities are carried out in cooperation with the member States, industry and the non-governmental organisations in the form of RIPs

SDS: Safety Data Sheet

SIEF: Substance Information Exchange Forums

SVHC: Substance of Very High Concern

vPvB: Very Persistent and very Bioaccumulative

References

Regulation (EC) N° 1907/2006 of the European Parliament and of the Council of 18 December 2006
http://eur-lex.europa.eu/LexUriServ/site/fr/oj/2006/l_396/l_39620061230fr00010849.pdf

Directive N° 2006/121/CE of the European Parliament and of the Council of 18 December 2006 modifying Directive 67/548/CEE of the Council
<http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2006:396:SOM:FR:HTML>

Directive N° 67/548/CEE of the Council of 27 June 1967

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31967L0548:FR:HTML>

Directive 1999/45/CE of the European Parliament and of the Council of 31 May 1999

http://eur-lex.europa.eu/LexUriServ/site/fr/oj/1999/l_200/l_20019990730fr00010068.pdf

REACH Implementation Projects: these are working groups whose task is to draw up the guidelines required for the implementation of the regulation, associating the Commission and the actors concerned. These documents will not have regulatory status.

- RIP 1: REACH process Description: Development of a detailed description of the REACH processes

- RIP 2: REACH-IT: Development of the IT system set up to support REACH implementation

- RIP 3: Guidance documents: Development of guidance documents for industry

- RIP 4: Guidance documents: Development of guidance documents for authorities

- RIP 5: Setting up the pre-Agency

- RIP 6: Setting up the Agency

- RIP 7: Preparing the Commission for REACH

<http://ecb.jrc.it/reach/rip/>

Website of the European Commission

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

http://europa.eu/pol/enter/index_en.htm

www.reach-compliance.eu

Websites for Germany

REACH Helpdesk: Federal Institute for Occupational Safety and Health (BAuA – Bundesanstalt für Arbeitsschutz und Arbeitsmedizin)

http://www.baua.de/de/Themen-von-A-Z/REACH-Helpdesk/REACH-Helpdesk.html_nnn=true

<http://www.bdli.de>

The Federation of German Industries (BDI) (BDI-REACH-HELPDESK)

<http://reach.bdi.info/index.htm>

Websites for Italy

www.federchimica.it

Websites for France

BERPC (in charge of the "Help Desk" in France)

<http://www.berpc.fr/>

Websites for United Kingdom

HSE (in charge of the "Help Desk" in the UK)

<http://www.hse.gov.uk/>

Email: ukreachca@hse.gsi.gov.uk

Websites for Sweden

Association of Swedish Engineering Industries

http://www.teknikforetagen.se/templates/index_en_1122.aspx

Association of Swedish Defence Industries (FIF)

http://www.defind.se/index_eng.html

Swedish Chemicals Agency (KemI)

http://www.kemi.se/default_550.aspx

Article: 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, bolts, bearings, engines, cars or aircraft are considered to be articles. A cleaning product is not considered to be an article when taken as a whole: its packaging is an article; its content is a preparation.

Supplier of an article: any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market.

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

Distributor: any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.

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

Non-isolated intermediate: an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place.

Monomer: 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.

Polymer: a substance consisting of molecules characterised by the sequence of one or more types of monomer units (reacted form of a monomer substance in a polymer) and distributed over a range of molecular weights.

Preparation: a mixture or solution composed of two or more substances. A paint or resin made up of several substances is a preparation. Composite materials, alloys, lubricants, paints, varnishes, adhesives, etc. are preparations.

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

Exposure scenario: 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.

Substance: 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 a CAS number, and an IUPAC chemical name.
- Examples: Methanal (Formaldehyde) - CAS N° 50-00-0.
Nickel metal - CAS N° 7440-02-0
Tetrachloroethylene (Perchloroethylene) - CAS: 127-18-4

Phase-in substance:

a substance which meets at least one of the following criteria:

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

Notified substance: *a so-called ELINCS substance, for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/CEE. These substances have a 'notification number'.*

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

Natural or legal person: This is the individual or legal entity (the legal company). Some legal entities may cover several business units, and some businesses may contain several legal entities. Each Joint Venture company or wholly-owned subsidiary company (e.g. a limited company) will have their own legal identity in law. They must comply with REACH separately to the main legal entity (the holding company). It is allowable for companies to collect the data needed and organise for REACH at a corporate / group / central entity level, but the reporting output to the REACH agency (ECHA) has to be per legal entity.

Article 2

As a general rule, the REACH regulation applies to all **substances...**

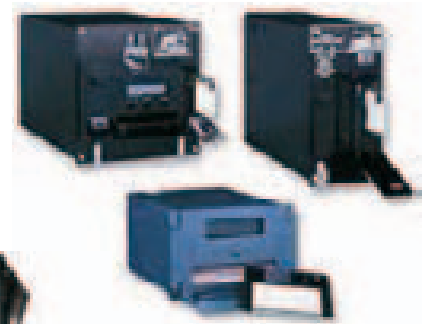
on their own;



or contained in preparations (mixture of at least two chemical substances without the formation of new substances);



or **contained in articles.**



All "ingredients", raw materials, consumables, components, alloys (and their constituents), etc. are therefore potentially included.

The provisions to be implemented vary according to the **hazardous properties** and the **quantities** of the substance manufactured or placed on the market in the European Union.

Two keys for
entering the REACH
system



The minimum threshold above which the provisions for a manufactured or imported substance apply is set at one tonne per year accumulated per legal person.¹

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

(1) See definition

The Regulation does not apply to:

- radioactive substances (if covered by EURATOM);
- substances subject to customs control that are not intended to remain in the European Union and are not processed or transformed;
- non-isolated intermediates;
- the transport of dangerous substances by rail, road, inland waterway, sea or air;
- waste (as covered by waste directives);
- nano-materials
- Specific substances, whenever this is necessary to preserve the interests of the Defence of a Member State (if an exemption has been agreed with the relevant defence agency).

Article 2.3



Member States may make provisions to exempt certain substances from REACH in the interests of defence. Defence product suppliers will need to ask national Defence Agencies for these substances to be exempted for their applications.

Articles 23 and 28

See
PRE-REGISTRATION sheet
in annex 2 of this
document

REACH requires all substances manufactured/imported in the EU over 1 tonne per year to be registered. To help ease this process a pre-registration process has been established.

Principle

Using pre-registration, producers and importers of substances can **benefit from a phased registration timetable that will run between 2010 and 2018** depending on the nature of those substances and the quantities manufactured and/or imported (see figure 1).

i The pre-registration phase, which is voluntary, only lasts from 1 June to 30 November 2008.

Substances that are not pre-registered will not be able to benefit from the phased registration timetable (called the transitional regime). These substances will need to be registered immediately or will be illegal to supply.

Imported ELINCS substances ('Notified Substances') are **ALREADY** registered - no pre-registration is required

Substances eligible for pre-registration

These are the **substances that can benefit from a transitional regime**. These are essentially:

- EINECS substances;
- substances manufactured in the European Union, but not placed on the market by the manufacturer or importer (at least once) since June 1992;

Substances benefiting from a transitional regime

- EINECS substances
- Substances manufactured in the European Union, but not placed on the market by the manufacturer or importer at least once since June 1992.

Substances that do not benefit from a transitional regime

- "New" substances, i.e. manufactured for the first time after the introduction of REACH
- Substances that have not been pre-registered.

"Catch-up" measures for "newcomers"

Consider the case that your company makes a substance that is eligible as a phase-in substance but the current production is less than 1 tonne per year. If production increases to more than a tonne per year **after 1 December 2008** and **before** the transitional regime ends, the company can still participate as a phase-in substance as long as they notify the agency and join the relevant 'substance information exchange forum' (SIEF), which are explained more fully later. If this were not the case, the company would have to register immediately, as would be the case for a non phase-in substance.

Article 28.6

Who is responsible for pre-registration?

Responsibility lies with **the legal person that is obliged to register the substance** (see chapter IV).

"The potential registrant" is the manufacturer or importer of a substance or the producer/importer of an article (this applies only in the case where the article contains one or more substances that are intended to be released under normal or reasonably foreseeable conditions of use, see chapter VIII).

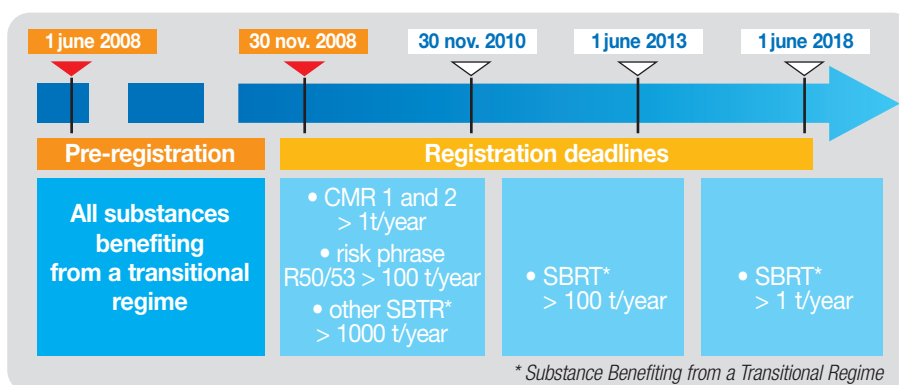


Figure 1: Registration deadlines for substances benefiting from a transitional regime

Manufacturers and importers of substances/preparations and the producers of articles (where there is an intended release of a substance from the article) must pre-register their substances. Failure to do so could result in placing products on the market illegally, or the products will have to be withdrawn until the full registration dossier is complete. Pre-registration gives companies time to prepare their registration dossiers.

i Most engineering manufacturing companies are downstream users of chemicals/alloys/raw materials rather than manufacturers of chemicals. Engineering manufacturers will make 'articles' as defined in REACH. Downstream users are advised to remind their suppliers of the importance of pre-registration.

Caution: pre-registration is not a commitment to make a registration at a later time and does not guarantee the continued supply of the substance.

As a manufacturer of 'articles', it is essential to check whether the substances in articles are 'intended for release' in normal or reasonably foreseeable conditions of use at any point in their life cycle (including disposal). Such substances will have to be pre-registered by the downstream user, if the supplier is not already pre-registering them for that use.

The list of pre-registered substances will be published on the Agency's website on 1 January 2009 at the latest. If a substance does not appear on the list published by the Agency, the downstream user may notify the Agency of the use of the substance, so that the potential registrants can be informed

Article 28.5

Articles 25 and 29

The data exchange system

Pre-registration allows the producers and importers of any given chemical substance to:

- take part in substance information exchange forums (SIEFs);
- share information on the data required to write the dossiers;
- reach agreement on the classification and labelling of the substances;
- reduce the registration costs by sharing them;
- limit the tests on vertebrate animals.

Information to be provided

- the name of the substance along with its EINECS and CAS numbers if they are available;
- the name and address of the producer or importer;
- the planned registration deadline;
- and the tonnage band.

See PURCHASING sheets in annex 2 of this document

Who must register?

There are two possible cases:

- **Manufacturers** or **importers** of substances on their own or contained in preparations must register the substances manufactured or imported in quantities of **more than one tonne per year**;
- **Producers** or **importers** of articles in which substances are contained must register each substance:
 - present in 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.

i *Substances that are intended to be released have to be registered. The conditions of intentional release include both normal and reasonably foreseeable conditions of use.*

For example, combustion products from an accidental fire, are NOT intentional releases and do not have to be registered.

The release of an extinguishant is an intentional release, and the substances in the extinguishant do have to be registered.

However, there is a clause in Article 7(5) that could require combustion products to be registered, if they are hazardous.

For example, Welding gives rise to the unintended release of fume. This is not an intentional release, but the substances being released from the article could be hazardous. If the fume contains substances that are considered hazardous by the Agency, then the Agency may require the substances in the Article to be registered under Article 7(5).

This procedure is applicable to **each legal person**.

Careful attention should be given to the legal structure of the Company to ensure the registration is applied at the appropriate level.

i *Not all subsidiary companies are necessarily a 'Legal Person' in REACH. All companies that are legally separate from a holding company (such as wholly owned or part-owned subsidiaries with a separately registered legal name) must comply in their own right.*

"No data, no market" principle

i *The substances concerned that have not been registered cannot be manufactured or placed on the market in the European Union.*

Articles containing hazardous substances, that have not been registered, have to be notified to the agency.

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 can create a **joint registration**. The Regulation encourages joint submissions from consortia of companies (OSOR principle: One Substance, One Registration). Consortia and other companies registering the same substance will automatically be put in contact with each other by the European Chemicals Agency by means of 'substance information exchange forums' SIEFs. The purpose of these exchanges is to spread the burden of registration and evaluation and to share the costs and reduce the number of tests on animals.

Article 11

Registrants can opt out of the SIEF and pay for their registration separately, but they will still be obliged to share animal testing data and to minimise animal testing.

Article 4

For **confidentiality** reasons, it is possible to appoint a third party representative to accomplish the procedures requiring consultations with other manufacturers and importers. In this case, the identity of the person who has appointed a representative is not divulged by the Agency to the other members of the exchange forum.

Article 8



Manufacturers based outside the European Union may appoint a natural or legal person established in the European Union to accomplish, on his behalf as an **only representative**, the obligations incumbent on the importers.

Companies that purchase supplies from outside the European Union are advised to encourage their non-European suppliers to appoint such a representative (if none is appointed, they will have to assume the importer's obligations).

Notified substances

New substances (ELINCS), called notified substances in the sense of Directive 67/548/CEE, are regarded as **already being registered**. The Agency will grant them a registration number by **1 December 2008** at the latest.

Article 24

Polymers

The registration requirement does not apply to polymers.

However, 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.

Article 6.3

Substances not subject to registration

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

- The **substances listed in annex IV of the REACH regulation** as sufficient information is available to consider that they represent a minimal risk.

Examples: CO₂, Argon, Nitrogen, graphite, sugars, vegetable oils, fatty acid, lecithins, etc.

The **substances listed in annex V of the REACH regulation**. This essentially concerns:

- products of unintentional chemical reactions due to environmental factors, or intentional chemical reactions in processes when they are not manufactured, imported or put on the market;
- substances occurring in nature or elemental substances if they are not chemically modified.

Example: when preparing a surface treatment bath, the mixture of two or more substances makes it possible to create a new substance.

These two annexes will be revised by technical committees by **1 June 2008** at the latest.

Isolated intermediates that remain on the site and are transported are exempted from chapter I of title II on registration except with regard to articles 8 and 9 and of title VII on Authorisation.

Article 9

Product and process oriented research and development (PPORD)

Substances manufactured in the European Union or imported for research and development activity purposes and manufactured in quantities of more than a tonne are exempted from registration for a period of 5 years.

To benefit from this, the developers of PPORD need to notify the agency as soon as usage exceeds one tonne per year.

Content of the registration dossier

The registrant must complete a **technical dossier** that includes all the relevant information that he has at his disposal, whether it is of a physicochemical, toxicological or ecotoxicological nature, specifically:

- the identity of the manufacturers or importers;
- the identity of the substance;
- the identity of manufacturer(s)/importer(s);
- information on the manufacture and the use(s) made of the substance;
- the classification and labelling;
- guidance on safe use of the substance;
- the study summaries regarding the information derived from the application of annexes VII to XI of the REACH regulation (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 in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

Articles 10 and 12

Article 14

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 chemical safety assessment, either for each substance, or for a group of substances. The chemical safety assessment includes:

- an assessment of the hazards for human health;
- an assessment of the physicochemical hazards;
- an assessment of the environmental hazards;
- an assessment of the PBT and vPvB aspects.

If the assessment proves that the substance is dangerous or meets the criteria for being a PBT or vPvB substance, then exposure scenarios have to be produced for each use of the substance, together with risk management measures for each scenario.

The general provisions relative to submitting a chemical safety report are given in annex I of the Regulation.

The data shall be entered and the registration or notification dossiers shall be prepared using the **IUCLID 5 software** developed by the European Chemicals Bureau (see figure 2).



Figure 2: IUCLID 5 software home page

Title IX

Fee

Any request for registration must be accompanied by the required fee as stipulated in title IX of the REACH regulation.

The registrant must pay the whole fee if he makes the declaration on its own. He will benefit from a reduction of one third of the fee if he is a member of a consortium of companies, or of 25% if an SME².

The fees will be defined in a regulation of the Commission to be adopted by 1 June 2008 at the latest.

There will be three categories, depending on the quantities: 10-100 t, 100-1.000 t, and more than 1.000 t. For substances produced in quantities of less than 10 t/year, the fee will not be required when the registration dossier includes all of the information stipulated in annex VII.

(2) Refers to EU definition

Title VI
(Articles 40 to 54)

This is the Agency's **control tool**. One of the key goals of REACH is to significantly improve the control of dangerous substances through a comprehensive evaluation process.

Articles 40 to 43

Dossier evaluation

The evaluation of the registration dossier includes an examination of the **test proposals** made by the manufacturers and importers and a verification of the **conformity** of the registrations.

Article 41.5

The Agency automatically checks the completeness of each registration dossier electronically. The Agency will then check 5% of the registrations per tonnage band in greater depth, by hand.

As a priority, the Agency checks registration dossiers that meet at least one of the following criteria:

- part of the information that it contains has not been submitted jointly via the SIEF;
- there is a non-conformity in the submission;
- it concerns a substance mentioned in the Community rolling action plan (see below).

Priority will also be given to test proposals for the substances that give the most cause for concern.

Substance evaluation

Article 44

The Agency will draw up a **Community rolling action plan** for a three-year period that will indicate which substances must be evaluated each year. These priority substances will be chosen according to a **hazard-based approach**.

The first draft of the rolling action plan will be presented by the Agency to the Member States on **1 December 2011** at the latest. Furthermore, the Agency will present annually to the Member States, on **28 February** at the latest, draft updates of the rolling action plan.

The evaluation will be carried out by the Member States under the responsibility of the Agency, which is responsible for its coordination.

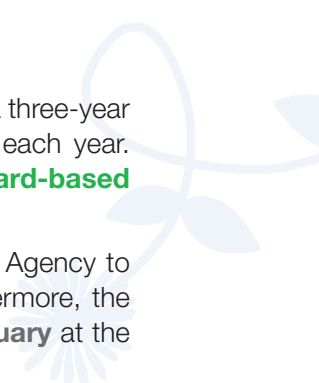
There is nothing in the Regulation indicating how many substances will be evaluated each year.

Evaluation of intermediates

Article 49

The 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 hazard, the authority of the State over the territory on which the site is located may ask the registrant to transmit additional information on the hazard that has been identified or recommend hazard reduction measures.



Rights of the registrants and downstream users

The registrants or downstream users can submit their remarks within **30 days** following receipt of the Agency's decision regarding the test proposals, the conformity of the registrations, and the results of the evaluation. The Agency forwards them to the authority of the concerned State.



All remarks received are taken into account and consequently may modify the draft decision.

Publication of the information relative to evaluation

No later than **28 February** of each year, the Agency 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.

Title VII

See
AUTHORISATION sheets
in annex 2
of this document

Any substance considered to be of **very high concern** (SVHC) pursuant to articles 57 and 58 must not be used, manufactured or imported without the prior **authorisation** of the Agency once it has been included on a list given in **annex XIV of the REACH regulation**.

This represents a major change from the system that has been in place in the European Union until now, which will come to an end on 1 June 2007.

Principle governing the management of dangerous substances and preparations regulation **before REACH:**

Everything that has not been banned is authorised

Principle governing the management of dangerous substances and preparations regulation **with REACH:**

Any use of a substance of very high concern included in annex XIV of the REACH regulation that is not authorised is prohibited



It is not substances as such that are authorised, but particular uses of those substances.

Article 55

Goals of authorisation

- guarantee that the **risks** relative to substances of very high concern are **properly controlled** throughout their life cycle;
- ensure that these substances are **progressively replaced** by other substances or by the implementation of new technologies when they are economically and technically available and viable.

Note: the definition of the term "properly controlled" is given in section 6.4 of annex II of the REACH regulation: for each exposure scenario, the risk for people and the environment can be considered to be properly controlled during the substance's life cycle if:

- the estimated exposure levels do not exceed the relevant derived no effect level (DNEL) or predicted no effect concentration (PNEC)
- and
- the probability and seriousness of an event occurring because of the substance's physicochemical properties are negligible.
 - For example, steel manufacturers will wish to prove that the risk posed by nickel in stainless steel is negligible because the available nickel at the surface of the steel is extremely low.

Obligations arising from a request for authorisation

Analyse the availability of alternative options and examine the risks that they include along with their technical and economic feasibility.

Which substances are concerned?

Authorisation relates to substances of **very high concern**:

- Category 1 and 2 CMR substances;
- Persistent, Bioaccumulative and Toxic substances (PBT);
- very Bioaccumulative and very Persistent (vBvP) substances;
- substances with endocrine disrupting properties.

The Agency will make its first recommendation concerning substances of very high concern to be included as a priority in annex XIV of the REACH regulation no later than 1 June 2009. The Agency will make other recommendations every two years at least with a view to including other substances in annex XIV of the REACH regulation.

The substances included in Annex XIV of the REACH regulation are classified in two distinct groups depending on whether it is possible to control the risk properly (substances with a danger threshold) or impossible to control it (substances without a danger threshold).

The authorisation procedure

i *The authorisation procedure is independent from the registration procedure. Substances already considered dangerous and known to meet the criteria can be subject to authorisation, regardless of their registration status.*

Authorisation is required without any minimum threshold for the quantity manufactured or imported.

Authorisation applies to substances on their own, in preparations or within articles, and regardless as to whether they are intended for release or not.

Member states will identify candidate substances for authorisation. The Agency will prioritise these substances according to guidelines from REACH implementation projects 4.3 and 4.5. The recommendation to require authorisation for a substance will then be made by the Agency, and issued by the European Commission.

REGISTRATION

Timetable introduced gradually according to the quantities manufactured, imported or used each year (subject to pre-registration).

AUTHORISATION

Authorisation is necessary for any use and is independent **from the quantity of the substance used**. Established on a case-by-case basis and for a time-limited period.

i *The authorisation is granted for a time-limited period on a case by case basis. Authorisations will only be granted if a substitution plan is in place*

The authorisation may be revised or suspended at any time. This is most likely to happen if information regarding viable replacement substances is made available.

There are two ways to apply for an authorisation

- By demonstrating that the **risk** from the use of this substance is **properly controlled** throughout its life cycle (article 60.2);
- By demonstrating that the **socio-economic advantages** provide a greater benefit than the risks from the use of the substance for human health or the environment and that there **are no appropriate replacement substances or technologies** (article 60.4, 60.5).

i Substances classified as CMR cat. 1 and 2 without a threshold, PBT, vPvB and substances with endocrine disrupting properties, must have a socio-economic case for an authorisation to be considered.

Article 62

Who can apply for an authorisation?

The requests for authorisation may be submitted by:

- the **manufacturers** or **importers** of the substances;
- the **downstream users**.

i A downstream user must only use a substance subject to authorisation if the conditions of the authorisation granted to a company situated further up the supply chain are met. The user has three months to notify the Agency.

If none of the companies in his supply chain holds an authorisation, the user is advised to find another duly authorised supplier, failing which, the user will have to seek the authorisation.

It is possible to apply for a joint authorisation, covering several sites and several businesses, if it relates to the same use (s) for a substance.

Authorisation exemption

i Exemptions from the authorisation process will be by exception as they will apply only to substances with thresholds and for which the risk can be properly controlled. The majority of substances of very high concern should be considered as not having a threshold.

However, if the risk is properly controlled, the downstream users may request exemptions for their uses when the Agency publishes the list of substances for which an authorisation is being sought on its website. The deadline for submitting this request is 3 months after the substance has been put on this list.

Content of the dossier to be sent to the Agency

All dossiers must contain:

- The identity of the substance(s);
- The name and contact details of the person(s) submitting the request;
- The use(s) for which the authorisation is being requested;
- The chemical safety report;
- The analysis of the replacement solutions, examining the risks as well as their technical and economic feasibility.

In the case of a request for an authorisation based on the socio-economic advantages provided by the use of this substance or if a substitute has been identified, the dossier must also contain:

- a substitution plan with an action timetable
- a socio-economic analysis

Article 61

Revising authorisations

The authorisations granted are only valid until the expiry date (sunset date) fixed **on a case-by-case basis**.

To renew an authorisation, a **revised report must be sent to the Chemical Agency by the holder** at least **18 months** before the authorisation expires.

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 has been made available;
- in the case of a serious and imminent risk for human health or the environment;
- if an environmental quality standard has been breached by the holder of the authorisation.

Title IX

Fees

The fee stipulated in title IX of the REACH regulation must accompany all requests for registration.

In all cases a reduced fee is set for SMEs.

Title VIII
and Annex XVII
of the REACH
regulation

The restriction system in REACH **extends what already existed in previous regulations**. Annex XVII of the Regulation carries over the restrictions that existed in Directive 76/769/CEE.

From now on, the Commission or a Member State may submit restriction proposals relative to the manufacturing, placing on the market or use of a substance.

The restriction procedure makes it possible to keep a "safety net" for controlling the risks that have not been taken into account elsewhere in REACH.

The restriction may apply to a substance on its own or contained in an article or preparation.

Examples:

Toluene CAS N° 108-88-3: Shall not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0,1 % by mass in adhesives and spray paints intended for sale to the general public.

Trichlorobenzene CAS N° 120-82-1: Shall not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0,1 % by mass for all uses except: as an intermediate of synthesis, or as a process solvent in closed chemical applications for chlorination reactions, or in the manufacture of 1,3,5-trinitro-2,4,6-triaminobenzene (TATB).

Article 67.3

Until **1 June 2013**, a Member State may maintain existing stricter restrictions concerning annex XVII applicable to the manufacturing, placing on the market or use of a substance.

The Commission will publish an inventory of these restrictions by **1 June 2009** at the latest.

Article 7
and RIP 3.8

See ARTICLES
sheets in annex 2
of this document

Article 3.3

Definition

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**.



The purpose of RIP 3.8 is to define the boundary between preparation and article (examples of cases under discussion: steel strip, parts made of glass, etc.).

Case where a substance present in articles must be registered

Article 7.1

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**.

*The definition of "intended to be released" is not yet clearly defined. However when a substance is released in the normal condition of use of the article, and essential for its function it is considered as an intended release e.g. ink in a cartridge.

When this substance is present in quantities greater than **10 t/year**, the producer or importer is required to produce the **chemical safety report** (see chapter IV of this document).

As such the producer or importer of articles should be encouraged to pre-register the substance that meets criteria a) and b) in 2008 (see chapter 3 of this document).

Example:

A company identifies that criteria a) and b) are met for a substance, whilst assessing substances for REACH during 2007.

The substance in question (non CMR) is present in several articles. When totalled, the quantity of the substance is 8 tonnes/year: Therefore the phase-in registration deadline is in 2018 (date for quantities comprised between 1 and 100 t).

In order to benefit from the phase-in and not have to register until 2018, the company must pre-register the substance between June and November 2008.

Following pre-registration, the company will be kept informed about the progress of the work of the SIEF, which will be driven by manufacturers (or importers) making >1000 tonnes/year.

In 2018, the company will have access to all the work previously generated by the SIEF. The company will only have to add to the registration dossier, information on uses (their own, and uses downstream in their supply chain) that have not already been covered by a registration made earlier (2010 or 2013) by someone else.

Article 7.2

Conditions when the presence of a substance of very high concern in an article must be notified

If an article contains one or more of the substances of very high concern included on the "candidate list" of substances (published on the Agency's website), then this/these substance(s) must be notified to the Agency pursuant to article 7.2 if all the following conditions are met:

- the substance is present in these articles in quantities totalling **more than 1 tonne per producer or importer 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 and including disposal*;

AND,

- the substance has not already been registered for that use

*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.

The obligation to notify applies as from **1 June 2011**. Whenever a substance is added to the "candidate list", a period of **six months** is allowed for the notification for that substance.

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

Article 7.7

Article 33

1 *The obligation to inform the agency of the presence of substances on the candidate list applies to everything supplied after 1 June 2011.*

This information is expected to be kept up to date for all products sold after this date.

For example, if an article is sold in June 2011, and the candidate list has 30 new substances added to it in 2020, the notification information must be updated for the product that was sold in June 2011, if it is still operating. However, the company is given 6 months in which to comply.

Conditions where the supplier of articles must transmit information on the composition of the article

Any supplier of articles (producer, importer, distributor) containing a substance on the **candidate list** and identified with a **concentration higher than 0.1% weight by weight**, must submit:

- to the article's end-user: the "sufficient information available to him to allow safe use of the article". This information must include, as a minimum, the name of that substance (art. 33.1).
- to the consumer who asks for it: "sufficient information available to him to allow safe use of the article". This information must include, as a minimum, the name of that substance. The relevant information must be provided free of charge within **45 days** of receipt of the request (art. 33.2).

This obligation will come into force on the date the Agency publishes the list of substances that are "candidates for authorisation" established pursuant to article 59.1, and only for the substances given on that list.

i *The obligation to inform the agency of the presence of substances on the candidate list that are within articles, applies once the candidate list starts to be populated.*

It is understood that products supplied before 1 June 2007 cannot be 'articles' because it is before the introduction of REACH. However, all products sold after this date are either preparations or articles and have to comply.

The candidate list will change regularly, and so the information provided to customers has to be kept up to date. If the customer sells the product (bought after 1 June 2007) to a third party, then the information has to be supplied to the third party free of charge.

There is no concept of 'second hand' product, or 'legacy' product in REACH. When a second hand product is sold, the same information requirements will apply. For products first sold before 1 June 2007, the owner is obliged to provide information when they sell the product as second-hand



Title IV

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 a 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.

Safety Data Sheets are not required for dangerous substances in articles, because this is covered in article 33.

Goal of the Safety Data Sheet

The SDS is a tool that is used to transmit 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: each company that is a downstream user of substances needs to check its own country's current laws and regulations for the control of chemical risk in the workplace and in particular for CMRs. It is likely that REACH will add to existing requirements.

Article 31.6 and annex II

Compulsory content of the SDS

SDSs must conform to a "compilation guide" which is included in annex II of the Regulation.



Content of the Safety Data Sheet

- 1 Substance/preparation/company identification
- 2 Identification of the hazards
- 3 Composition/information on ingredients
- 4 First- aid measures
- 5 Fire-fighting 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



- Exposure scenarios (main elements of the chemical safety report: CSR)
- Use categories

Article 31

Section 1 of the SDS includes the registration number along with the uses covered by the SDS.

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**.

i Therefore, more substances and preparations will need to have a SDS than previously.
Note that alloys are considered 'special preparations' in REACH (REACH Annex II), and therefore will require safety data sheets.

Coherence between the SDS and the chemical safety assessment (exposure scenarios 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 "relevant exposure scenarios" to the SDS. There are cases when a downstream user has to create a chemical safety report – see section X. The exposure scenarios describe the operating conditions, hazard management measures and the substance use recommendations. The substance's complete life cycle must be taken into account.

Article 32

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 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 on any restriction that may have been imposed.

Registration numbers and authorisation details will not be available on 1 June 2007, however restrictions can still apply.

Article 34

Other information and communication obligations 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 on the appropriate nature of the risk management measures identified in the 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 transmit this information to the actor or distributor situated immediately above them in the supply chain.

This should result in updated exposure scenarios being created and flowed back down to users.

Article 35

Access to information for workers

Employers must grant their workers and their representative's access to adequate hazard and risk management information 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 already exists in law for many Member States, including French Labour Law and UK Law via the Control of Substances Hazardous to Health.

Article 36

Obligation to keep information

Manufacturers, importers and downstream users 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.

Title V

New obligations are imposed on downstream users of substances and preparations.

They require far greater communication between the various actors in the supply chain (down and upstream).

Each downstream user has to check the conditions under which the substances are used and check with suppliers if the conditions of use are covered by the registration or authorisation processes.

If the conditions of use are not covered, the downstream user has two options:

1. to pass the corresponding information related to their conditions of use to their suppliers.
2. to cover their conditions of use by their own assessment (refer to the flowchart in annex of this document and legal articles).

- In this way, the downstream users are expected to contribute to assessing the chemical safety of substances.

What is a downstream user?

Article 3.13

According to the Regulation, a **downstream user** is *any natural or legal person established within the [European Union], other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities.*

Distributors or consumers are not downstream users.

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

Articles 37.1 and .2

When a downstream user receives an SDS containing the registration number(s) of a substance, the downstream user can check whether their 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, a "brief general description" of the use with a view to making it an identified use, which will be covered by an exposure scenario appended to the SDS by the supplier.

The supplier must 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.

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

Article 37.4

A Chemical Safety Report (described in chapter IV) must be created by a downstream user if the use of the substance/preparation is not covered by the SDS (unless covered by the derogations described in the next point). This requirement will arise if:

- The downstream user **does not inform the supplier** of a specific use which represents a departure from the conditions described in the SDS's exposure scenario (for reasons of confidentiality or quite simply because the user has forgotten to inform the supplier);
- When the downstream user has given the supplier all the information for an "identified use" and the **supplier advises against it**. The supplier must then "immediately inform the Agency and the downstream user in writing of the reasons for that decision" (these reasons must be related to the protection of

human health or the environment). The supplier may nevertheless sell the substance to the downstream user, but with this unadvised use included in the SDS (or equivalent of the SDS for substances that are not dangerous).

Article 38.2

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 the classification for a substance is different from that of the supplier.

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

Article 37.4

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 preparation;
- the supplier is not obliged to establish a Chemical Safety Report;
- The substance or preparation is used in a total quantity of less than 1 tonne per year*;
- The downstream user implements or recommends an exposure scenario that implements the same or more onerous risk controls over those given the exposure scenario given in the SDS;
- the substance is present in a preparation at a concentration lower than the concentrations indicated in article 14, paragraph 2 (concentration limits given in various earlier directives for hazardous substances, or if there are no stricter concentrations for the substance, at least 0.1% w/w);
- the downstream user uses the substance for the purpose of research and development activities*

*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;
- if the downstream user's classification of a substance is different from that of the supplier.

Application of downstream user obligations

Article 39

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 the interest of downstream users to pass information up the supply chain, if use and exposure category recommendations have been made.

A **European Chemicals Agency (ECHA)** is 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 will be based in Helsinki (Finland).

It will be **inaugurated on 1 June 2007, and be operational on 1 June 2008**. Meanwhile, the European Chemicals Bureau (ECB) will continue to implement the current regulations on new and existing substances.

Composition

The European Chemicals Agency will be comprised of:

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

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;

Annex 1 : Structure of the regulation

TITLE I	General issues
TITLE II	Registration of substances
TITLE III	Data sharing and avoidance of unnecessary testing
TITLE IV	Information in the supply chain
TITLE V	Downstream users
TITLE VI	Evaluation
TITLE VII	Authorisation
TITLE VIII	Restrictions on the manufacturing, placing on the market and use of certain dangerous substances and preparations
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
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 manufactured or imported in quantities of 1 tonne or more
ANNEX VIII	Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more
ANNEX IX	Standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more
ANNEX X	Standard information requirements for substances manufactured or imported in quantities of 1000 tonnes 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
ANNEX XIII	Criteria for the identification of persistent, bioaccumulable and toxic substances, and very persistent and very bioaccumulable 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



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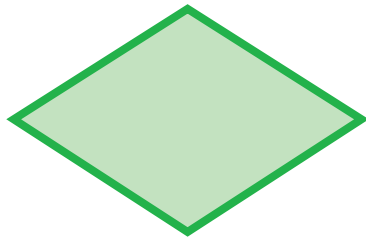
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How to read these flowcharts

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

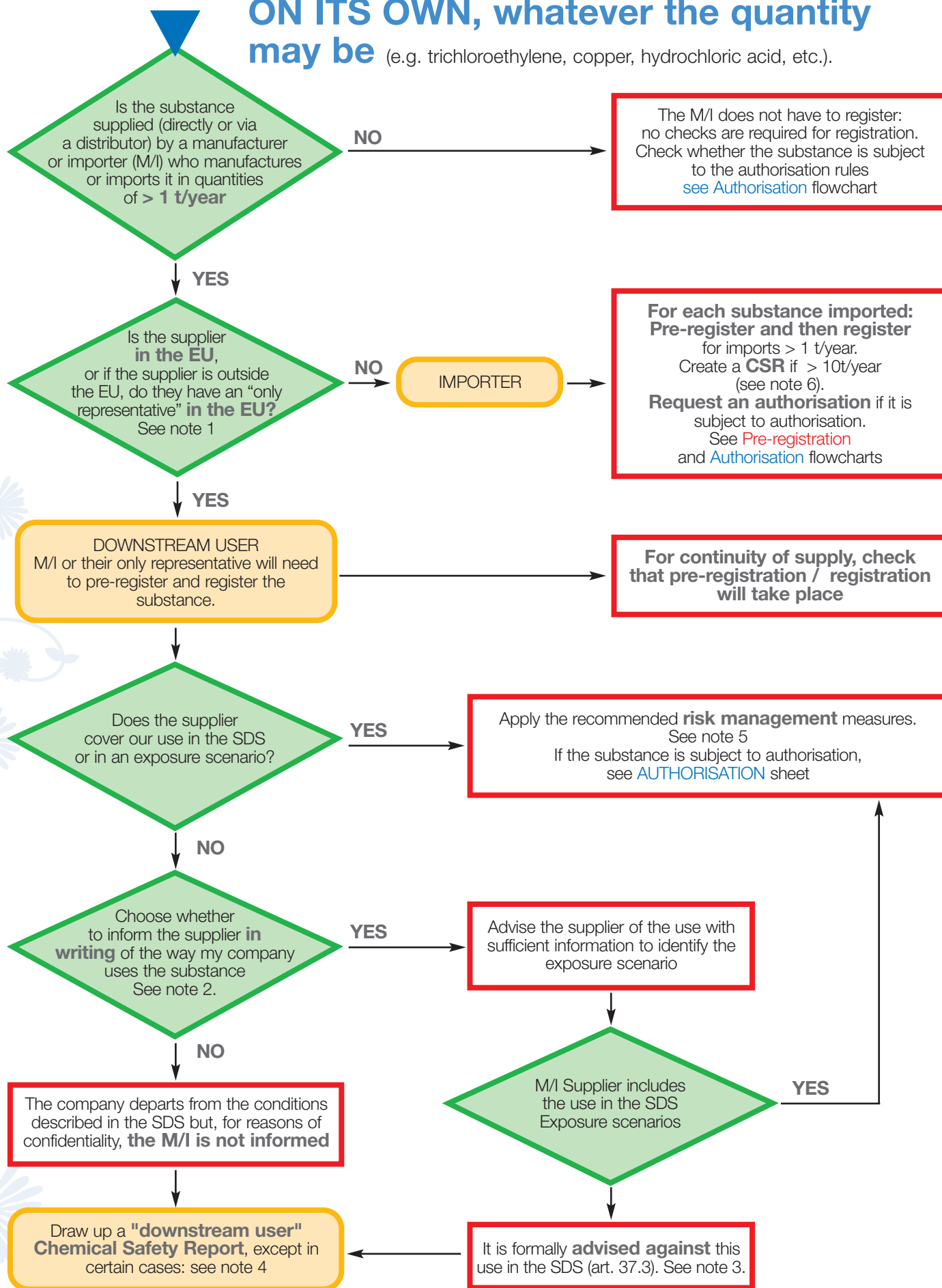


Information

The black arrows link the boxes to each other. They may indicate a flow of information or data, a piece of advice, a regulatory obligation, etc.

PURCHASING Flowchart 1

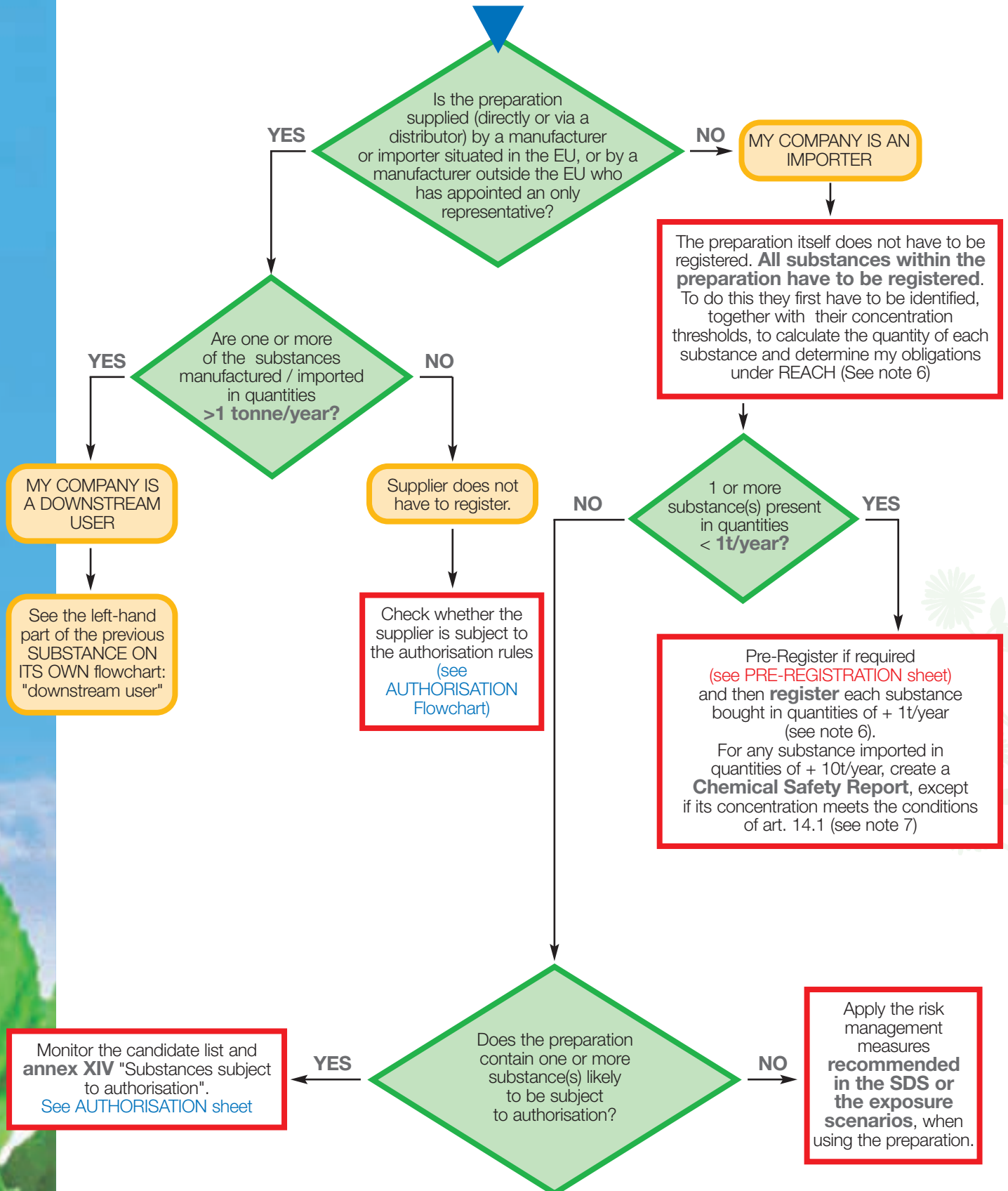
My company purchases a **SUBSTANCE ON ITS OWN**, whatever the quantity may be (e.g. trichloroethylene, copper, hydrochloric acid, etc.).



PURCHASING Flowchart 2

I am purchasing a PREPARATION, whatever the quantity may be

(lubricant, alloy, paint, surface treatment solution)



Notes for the PURCHASING A SUBSTANCE and PURCHASING A PREPARATION 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, 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. Norway, Iceland and Liechtenstein will be considered WITHIN the EU for REACH (these countries will also apply the regulation), and Switzerland is OUTSIDE the EU.

Note 2. Identified use

When a company receives an SDS accompanied by one or more registration numbers (registration made by the manufacturer/importer*) the user can check whether the use is listed amongst the "identified uses" on the SDS. If that is not the case, the downstream user 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.

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

** The user company will receive these numbers between 2010 and 2018. This is because amongst its suppliers it will have manufacturers/importers who will have to register in 2010, others in 2013 and others in 2018.*

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. When this occurs, the manufacturer/importer must inform the relevant downstream user, and the Agency. The manufacturer/importer must include this "unadvised use" in the Safety Data Sheet (point 16). The manufacturer / importer must update the SDS or other risk management information, before the substance/preparation is next supplied.

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

- Principle:

Art. 37.4 states that if a use is not covered by an exposure scenario appended to the Safety Data Sheet, then the downstream user must

create a Chemical Safety Report (CSR) described in annex XII of the Regulation. This "downstream user" CSR contains less data than the CSR created by the manufacturer or importer, but the requirements are still considerable.

> It is recommended that businesses collaborate with others that have the same uses for a substance in order to spread the costs.

The downstream user must also tell the Agency that they have prepared a CSR (art. 38.2) and provide basic information about the use and the relevant substance registration(s).

- Derogations:

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

- a) the substance or preparation does not require an SDS
- b) the immediate upstream supplier was not obliged to create a Chemical Safety Report
- c) **The substance or preparation is used in a total quantity of less than 1 t/year***
- d) **The user will implement risk management measures at least equivalent to one recommended in the SDS**
- e) the substance is present in a preparation at a concentration lower than the concentrations indicated in article 14.2
- f) The substance is being used for product and process R&D activities, provided that the risks for human health and the environment are properly controlled, and provided that the agency has been notified with basic information about the use, 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.

Your company will have twelve months following the receipt of the registration number (notified by the supplier in the SDS), in which to inform the supplier of your company's use of the substance.

Note 6. Identifying substances in preparations

An importer may import several preparations containing the same substance. For each preparation, the total annual quantity of each substance has to be estimated (% of substance in preparation X mass of preparation bought per annum, averaged over the last 3 years). This has to be summed together with the amount of the same substance within all other preparations, with sufficient accuracy to identify which tonnage band the substance will fall into. This in turn will identify the expected date of registration, if it is a phase-in substance (see pre-registration flowchart).

Note 7. Chemical Safety Report that must be established by the importer of a substance or preparation

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 nature).

When the substance is contained in a preparation, 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:

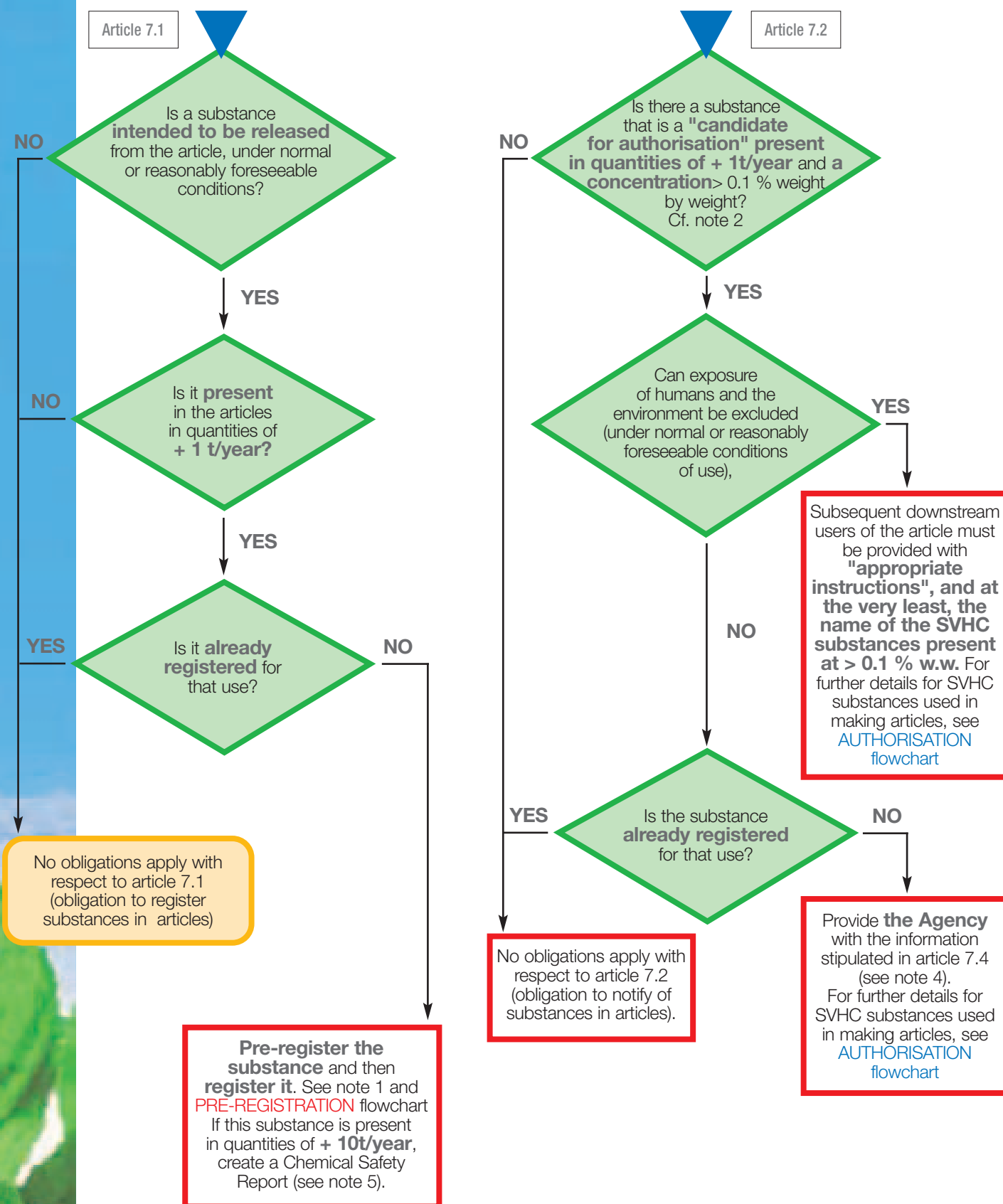
- a) the applicable concentrations, defined in the table in article 3, paragraph 3, of Directive 1999/45/CE;
- b) the concentration limits given in annex I of Directive 67/548/CEE;
- c) the concentration limits given in annex II, part B, of Directive 1999/45/CE; the concentration limits given in annex III, part B, of Directive 1999/45/CE;
- e) the concentration limits mentioned in an agreed entry in the classification and labelling inventory established pursuant to title XI of the Regulation;
- f) 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 preparation, it is possible to create a CSR for each substance on its own, or for the preparation as a whole (art. 31.2).

ARTICLES flowchart 1

My company produces or imports articles

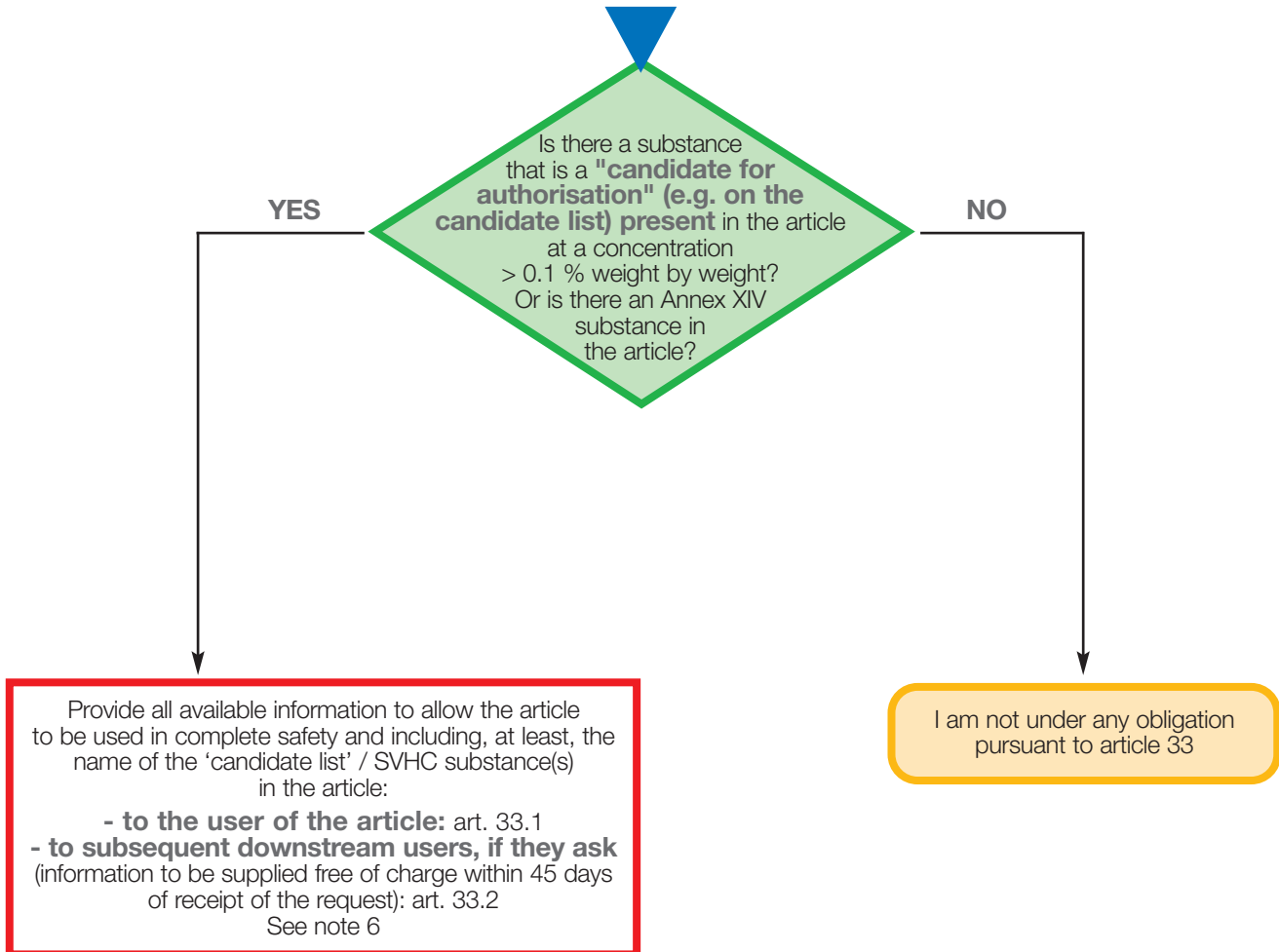
Two series of questions must be asked in succession



ARTICLES Flowchart 2

Downstream communication as a "supplier of articles"

(producer, importer, entity placing on the market)



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.

PREAMBLE

• Lack of clarity on obligations relating to substances in articles.

An article, in the REACH sense, is 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". Parts and components are therefore articles.

There are only two provisions (art. 7 and art. 33) in the Regulation that cover the obligations regarding the substances in articles. **There are still a large number of issues that need to be resolved:**

- on the basic definition of an article (is steel strip a solid preparation or an article? The European Commission has not yet reached its decision),
- on the calculation of the tonnage or concentration thresholds (should we consider the article as a whole, or each material? Do different part numbers represent different articles?),
- on the notion of "substance intended to be released under normal or reasonably foreseeable conditions of use".

Answers are expected in application guidelines written by the Commission and representatives of industry, RIP 3.8 (RIP for Reach Implementation Project).

• Optimistic presumption...

REACH presumes that all producers know all of the substances in all of the articles they produce or import. Some preparations used to manufacture articles or other preparations, can have variable constituents even if they conform to a specification. Therefore even two batches of the same standard material could lead to different obligations within REACH.

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 than or equal to a total of **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 a "candidate for authorisation" in an article, above certain concentration and tonnage thresholds (art. 7.2).

Amongst the substances said to be of "very high concern", the Agency will identify certain substances on a "candidate list for authorisation".

These candidate substances will then be included, or not, in annex XIV "Authorisation" (*this means: prohibited unless authorised*). An initial list will be drawn up by the Agency in 2008 or, at the latest, by 1 June 2009. Other recommendations will be added to this list every two years.

Note 3. Can exposure of humans and the environment be excluded (under normal or reasonably foreseeable conditions of use), including disposal?

If exposure can be proven to be prevented, then Article 7.3 states that the producer/importer does not have to provide the information to the Agency. The producer/importer still must provide "appropriate instructions" to the user of the article.

At present, no explanation is available defining exposure of human beings and of the environment, including disposal.

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 been registered
- **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 "intended to be released" present in quantities of > 10t/year, the producer or importer of articles must create the Chemical Safety Report (CSR) provided for in article 14 and described in annex I. The production of this report is expected to be time consuming and expensive.

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

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

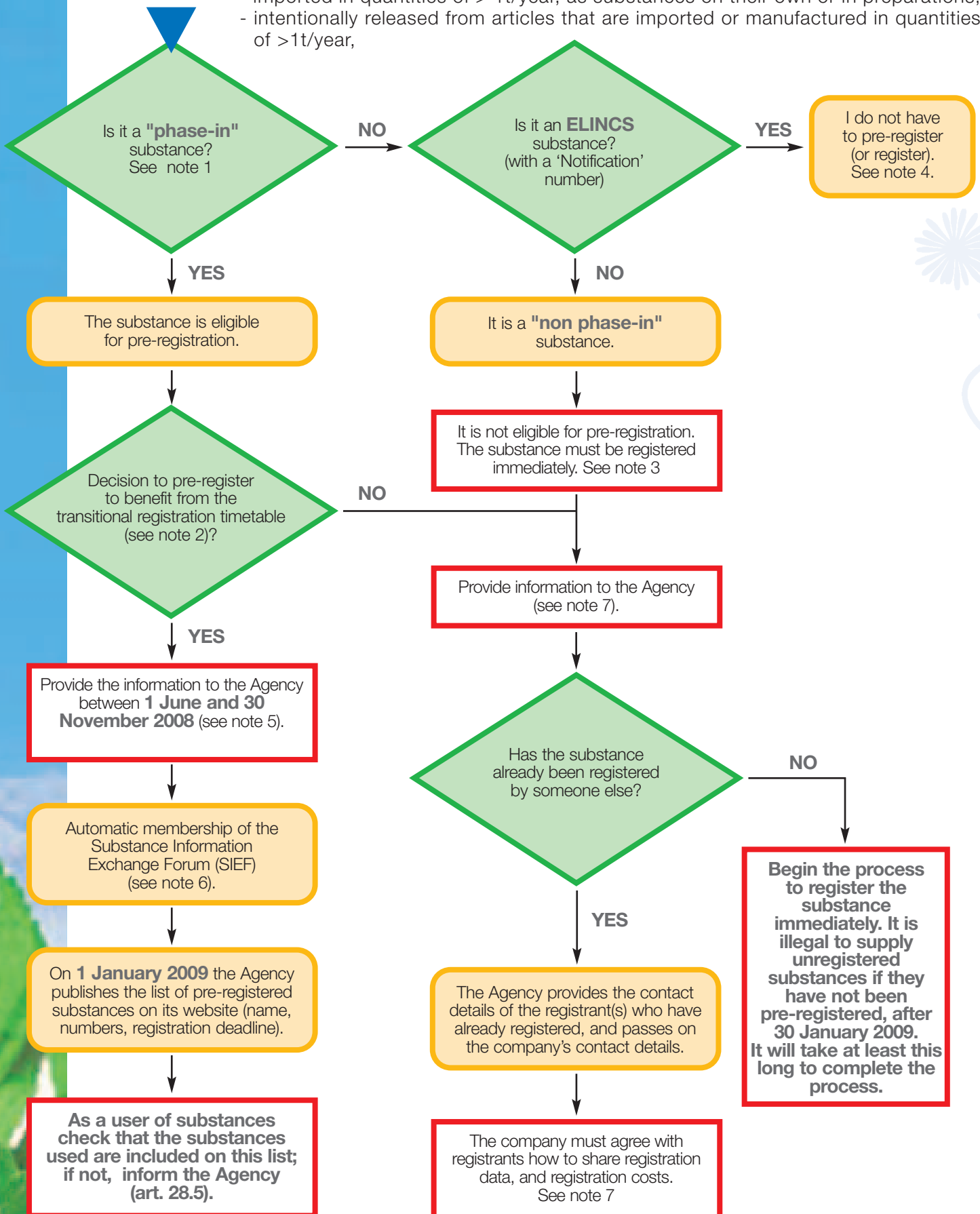
This communication of information is provided for in article 33. It applies once the 0.1 % concentration threshold is passed (the tonnage used/imported/manufactured is irrelevant). It applies to all "suppliers of articles", which includes the producer, importer, distributor or any other actor in the supply chain who places an article on the market.

It is required for any substance identified by the Agency as being a "candidate for authorisation" (see note 2). The obligation will come into force as soon as the list identifying this type of substance is issued by the Agency (2008 or, at the latest in June 2009).

PRE-REGISTRATION Flowchart

My company needs to pre-register substances that are:

- imported in quantities of > 1t/year, as substances on their own or in preparations,
- intentionally released from articles that are imported or manufactured in quantities of >1t/year,



Notes for the PRE-REGISTRATION Flowchart

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 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 that has 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 not often be the case.

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

Today, a very small number of substances are concerned since this concerns 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.

They 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 does not represent a great deal of information. 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 contacted; and if the registrant 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). Financing of the cost of the information to be provided at the time of 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 gives the procedures that their owner(s) share 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 SIEF, acting on behalf of the others (see art. 30.2).

Note 7. Procedure to be applied if it is decided to not pre-register a substance

On the face of it, we do not think that this will be a likely voluntary choice of the manufacturing companies concerned (but it could be a commercial strategy for certain manufacturers of substances and preparations, which will thus be "REACHed" before their competitors "REACH" theirs). However, in theory, the procedure described below will also apply to those who "forget" to pre-register.

The Agency is asked whether the substance has already been registered by another company. The request to the agency needs to contain the information defined in article 26.1.

The Agency will then inform my company whether:

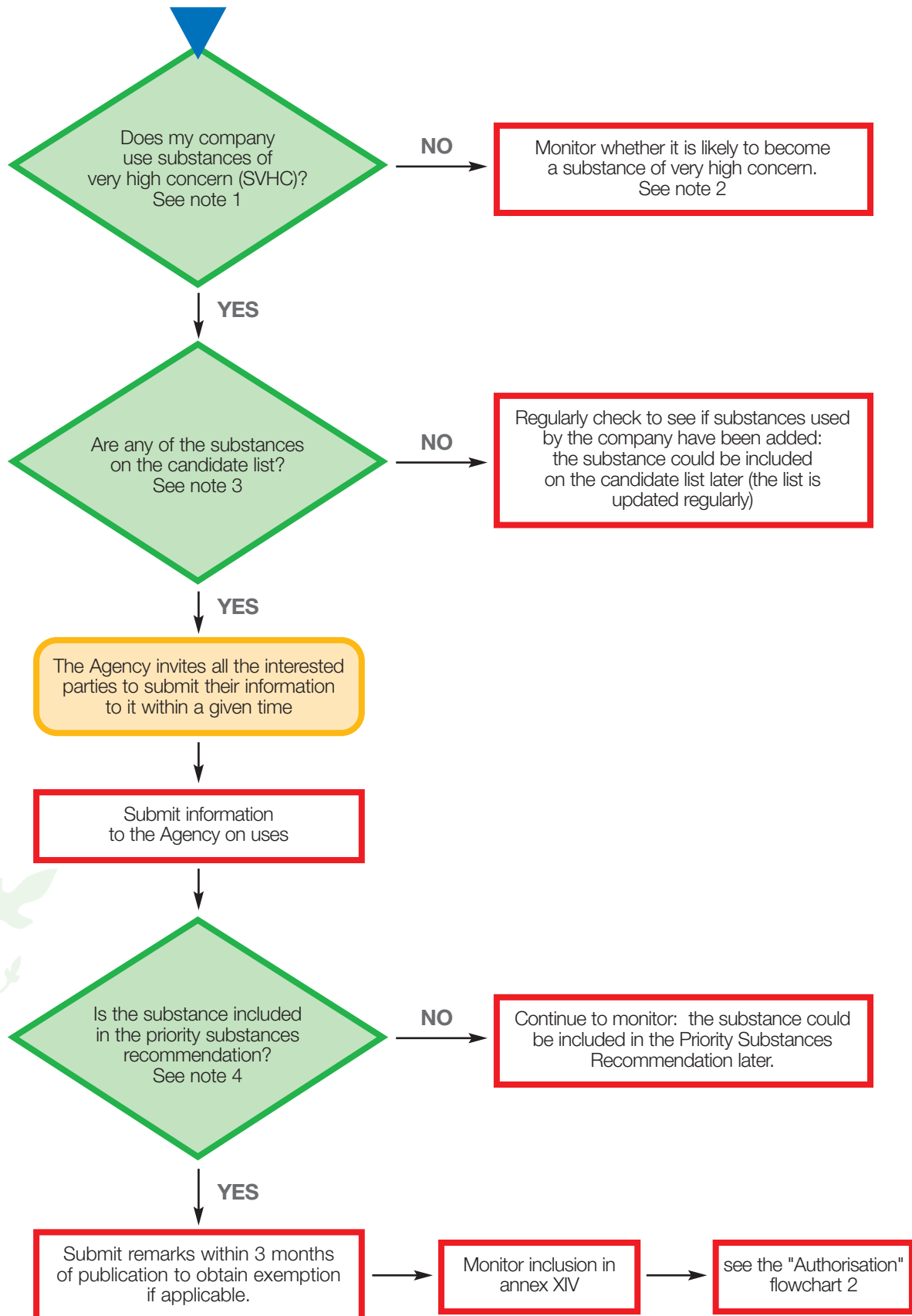
- the substance has not yet been registered: consequently my company must register.
- it has already been registered by one or more earlier registrant(s); in which case the agency passes on contact details to all parties. If the substance was registered less than twelve years earlier, article 27 organises 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: Pre-registration of substances manufactured or imported for the first time after 31 December 2008, or intended to be released by an article manufactured or imported for the first time after 31 December 2008.

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

AUTHORISATION FLOWCHART 1

Checking / Review



Notes for the AUTHORISATION flowchart 1 checking / review

Preamble

The substances subject to authorisation will be listed in annex XIV.

The authorisation procedure applies whatever the quantity.

The authorisation does not cover a substance, but identified uses of the substance.

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

- Category 1 or 2 Carcinogenic, Mutagenic or Toxic for Reproduction (CMR) substances (see Directive 67/548)
- Persistent, Bioaccumulative and Toxic (PBT) substances (see Annex XIII)
- very Bioaccumulative and very Persistent (vBvP) substances (see Annex XIII)
- 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 a substance 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 dossier on its website.

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

We can assume that the Cat. 3 CMRs will, in all likelihood, be considered candidate substances (e.g. formalin).

Note 3. List of candidate substances, that is to say the list of Substances identified with a view to being included eventually in annex XIV (Art. 59 & 83.3)

The list will be published by the Agency on its website (see point 6.1.1 of the Commission's FAQ – February 2007).

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

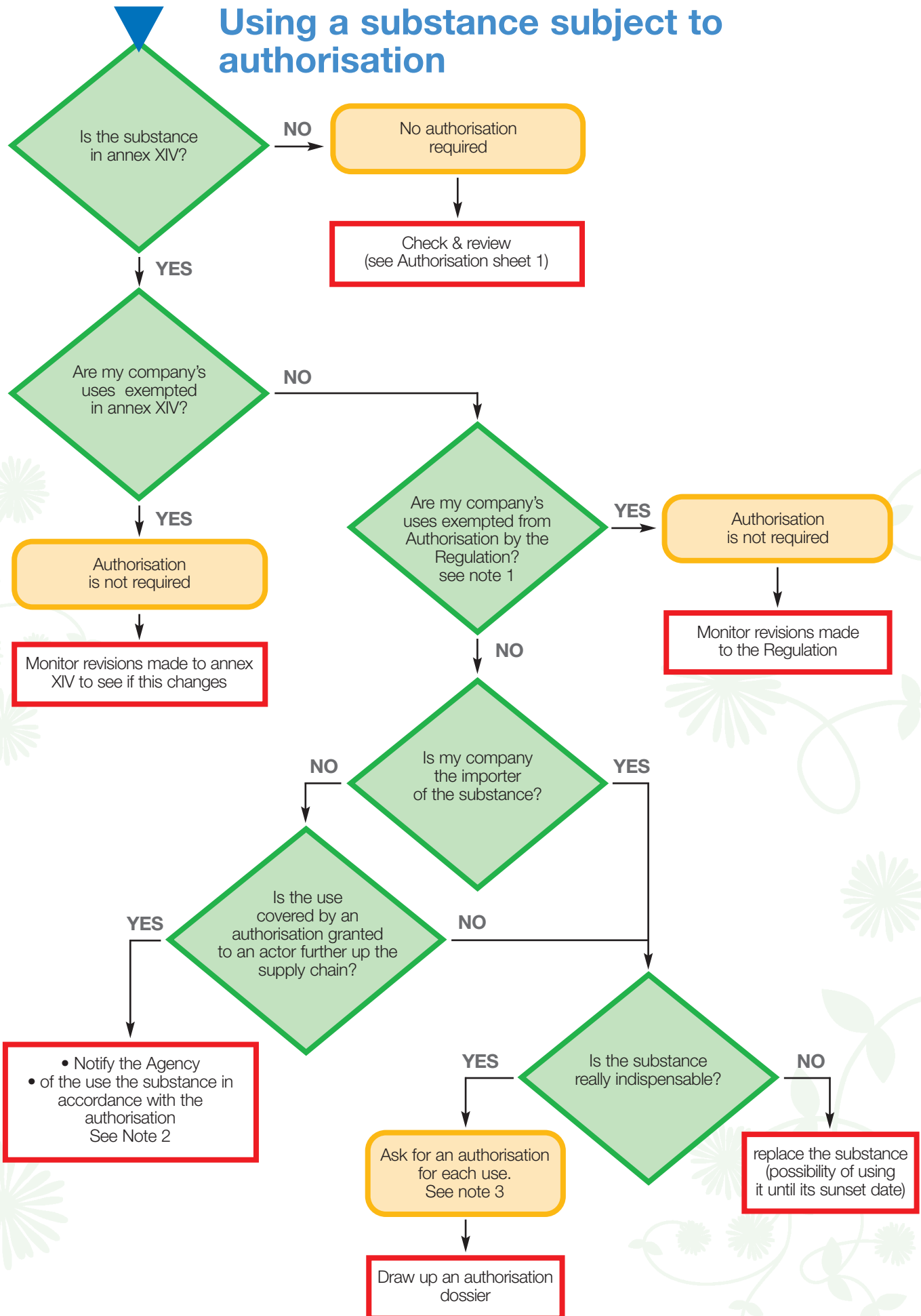
The Agency will make its first recommendation no later than 1 June 2009. It will publish it on its website.

The priority is given to the substances that have PBT or vPvB properties, or that have highly dispersive applications, or products in large quantities.

All the interested parties have 3 months in which to submit their remarks regarding the uses that should be exempted and why.

AUTHORISATION flowchart 2

Using a substance subject to authorisation



Notes for the AUTHORISATION flowchart 2

Using a substance subject to authorisation

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

- Use of substances in the framework of scientific research & development activities (< 1 tonne/year)
- Use of substances in the framework of 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) N° 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) from which it is prohibited to place the substance on the market and use it, except if an authorisation is granted;

a date (at least 18 months **before the sunset date**), **before which each registrant must send its request if it 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.**



