Guidance for the Navigator

June 2007

LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

PREFACE

This Guidance Document contains all the guidance available to help the user to answer the different questions of the Navigator. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) lead by the European Commission services, involving all stakeholders: Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.html). Further guidance documents will be published on this website when they are finalised or updated.

CONTENTS

1 SCOPE ISSUES

1.1 Radio-active substances

Radio-active substances are substances that contain one or more radionuclides of which the activity or concentration cannot be disregarded as far as radiation protection is concerned. In other words, they are substances which give off such a degree of radiation that there is a need to protect people and the environment against that radiation.

Radio-active substances were already exempted from notification under Directive 67/548/EEC on classification, packaging and labelling of dangerous substances, and the REACH Regulation exempts them from its application altogether. The reason for this exemption is that there is specific legislation applicable to them, so that there is no need to apply the REACH Regulation in addition.

Legal reference: Article 2 (1) (a)

If substances (on their own, in a preparation or in an article) in temporary storage, in transit, in a free zone or in a free warehouse on the EU territory are only transiting through the EU and remain under customs supervision while waiting to leave the EU, they are not subject to the provisions of the REACH Regulation.

Importers of substances meant to leave the EU again, who wish to rely on the exemption from REACH are therefore advised to ensure that the substances, while on the EU territory, meet all the following conditions:

- the substances are put in a free zone or free warehouse as defined under customs legislation or placed under another relevant customs procedure (transit procedure, temporary storage),
- the substances are kept under supervision of the customs authorities, and
- the substances do not undergo any form of treatment or processing (including formulation, consumption, filling into containers, transfer from one container to another, mixing or production of an article) during their stay in the EU. For that purpose a free zone or a free warehouse on the EU territory is regarded as being part of the EU.

In the case of doubt, it is recommended to contact the customs authorities, who can provide more detailed clarification on the possible customs regimes established by Regulation (EEC) No 2913/92 on community customs code which may be applied to substances merely passing through the EU.

Legal reference: Article 2 (1) (b)

1.2 Substances under customs supervision

If substances (on their own, in a preparation or in an article) in temporary storage, in transit, in a free zone or in a free warehouse on the EU territory are only transiting through the EU and remain under customs supervision while waiting to leave the EU, they are not subject to the provisions of the REACH Regulation.

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In the case of doubt, it is recommended to contact the customs authorities, who can provide more detailed clarification on the possible customs regimes established by Regulation (EEC) No 2913/92 on community customs code which may be applied to substances merely passing through the EU.

Legal reference: Article 2 (1) (b)

1.3 Substances used in the interest of defence and covered by National exemptions

The REACH Regulation allows individual Member States to exempt certain substances (on their own, in a preparation or in an article) from the application of REACH, in the interests of defence.

It should be noted that this exemption will only apply once a Member State has taken a formal measure, in accordance with its national legal system, to exempt certain specific substances from REACH. The exemption will, naturally, only apply within the territory of the Member State having fixed the exemption.

At the time of writing this guidance, no Member States had fixed an exemption in the interests of defence. It can be expected that Member States who decide on such an exemption will inform their suppliers concerned; however, if in doubt, manufacturers, importers and producers of preparations or articles which are used by Member State military forces or authorities in a defence context, are advised to contact those forces or authorities to check if an exemption was granted which may cover their substance, preparation or article.

Legal reference: Article 2 (3)

1.4 Waste

Waste is any substance or object which the holder discards, or intends or is required to discard. This may be waste from households (e.g. newspapers or clothes, food, cans or bottles) or from professionals or industry (e.g. tires, slag, window frames that are discarded).

The REACH Regulation does not exempt waste from its provisions, but clarifies that waste is not a substance, a preparation or an article within the meaning of REACH. This is because when the holder discards, intends or is required to discard something, it loses its status as a substance, preparation or article which is used by its holder for a specific purpose. For practical purposes, this clarification can be considered as an exemption for waste from the REACH requirements. Note that when a Chemical Safety Assessment is required, this must include the whole lifecycle of the substance including the waste stage (cf. *Annex I, 0.7 and 5.1.1*). If necessary to manage risks from chemical substances, recommended waste management measures have to be communicated through the supply chain via SDSs (heading 13). However, waste treatment is not a downstream use under REACH and waste treatment operators will not receive SDSs on how to handle the substance during the waste phase. As long as residues from waste treatment operations are waste, i.e. that they

are disposed of (e.g., landfilled or stored in salt mines), they do not fall under REACH. Residues which are recovered as any other substances or preparations fall under REACH.

It is important to note that once waste is recovered and in this recovery process another substance, preparation or article is produced, the REACH rules will in principle apply again, as they would to any other substance, preparation or article manufactured, produced or imported in the EU. In specific cases, where a substance which has already been registered is recovered, an exemption from the registration obligation may apply.

Legal reference: Article 2 (2)

1.5 Non isolated intermediates

A non-isolated intermediate is 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.

Non-isolated intermediates falling within the above definition are not covered by REACH.

Note however that quantities of the same substance may be used in other operations or under other conditions, which implies that those quantities cannot be regarded as "non-isolated intermediate". Only the quantities of the substance used under the conditions qualifying it as a "non-isolated intermediate" are exempted from REACH. For the remaining quantities, the relevant requirements under REACH must be fulfilled.

Legal references: Article 2 (1) (c), Article 3 (15) (a)

1.6 Transport of substances

The REACH Regulation exempts from its provisions the carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air. Please note that for all activities (manufacture, import, use) related to the concerned substances other than the transport, the REACH requirements apply (unless covered by another exemption).

EU transport legislation (for example, Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road, and relevant amendments) already regulates the safety conditions of transport of dangerous substances by various means of transport and thus such transport is exempted from the provisions of the REACH Regulation.

Legal reference: Article 2 (1) (d)

1.7 Food or feedingstuffs

When a substance is used in food for humans or feeding stuffs for animals in accordance with the Food Safety Regulation (EC) No 178/2002, the substance does not have to be registered.

The Food Safety Regulation already requires that food for humans cannot be placed on the market unless it is safe, i.e. not injurious to human health and fit for human consumption. Similarly, feed for animals is not to be placed on the market or fed to food-producing animals unless it is safe, i.e. not having an adverse effect on human or animal health and not making the food derived from food-producing animals unsafe for humans. Moreover, for food additives, food flavourings, feeding stuffs additives and animal nutrition, specific pieces of Community legislation already create a system for authorisation of substances for those particular uses. Therefore, registration under REACH would have little added value.

Accordingly, it is in the interest of manufacturers and importers of substances which may be put to food - or feeding stuffs-related uses to be aware if their own legal entity or their clients actually use the substance in food or feeding stuffs in accordance with the Food Safety Regulation, since in that case they will not have to register this use or obtain authorisations, at least for the quantities of the substance which are used in this way. Thus, if a downstream user makes such a use known to his supplier in accordance with *Article 37(2)*, he should be advised to consult the Food Safety Regulation.

Note however that quantities of the same substance may be used for other uses than food and feeding stuffs, so those quantities are not exempted. Only the quantities of the substance used in food and feeding stuffs are exempted from the registration obligation under REACH.

Example:

A manufacturer manufactures 100 tonnes of sulphuric acid in year X. 50 tonnes are used to produce foodstuffs in accordance with the Food Safety Regulation, 50 tonnes are used for the formulation of a non-food preparation. The 50 tonnes used for the formulation of the non-food preparation will be subject to the registration provisions of the REACH Regulation and can, if their properties warrant so, be made subject to authorisation, while the 50 tonnes used to produce foodstuffs are exempted from registration, evaluation and authorisation.

Legal references: Article 2 (5) (b), Article 2 (6) (d)

1.7.1 Specific provision on information in the supply chain for preparations consisting of food and feeding stuff

There is no need to comply with the REACH obligation to provide information in the supply chain for preparations which are food or feedingstuffs (in accordance with the Food Safety Regulation (EC) No 178/2002) intended for the final user. This is because the Food Safety Regulation already provides what information has to be given to users.

Legal references: Article 2 (6) (d) .

1.8 Medicinal products

When a substance is used in a medicinal product within the scope of

- either Regulation (EC) No 726/2004 on Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

- or Directive 2001/82/EC on the Community code relating to veterinary medicinal products

- or Directive 2001/83/EC on the Community code for medicinal products for human use

the substance does not have to be registered under the REACH Regulation for that use.

Accordingly, it is in the interest of manufacturers and importers of substances which may be put to pharmaceutical-related uses to be aware if their own legal entity or their clients actually use the substance to produce pharmaceuticals covered by this legislation, since in that case they will not have to register or obtain authorisations, at least for the quantities of the substance used in this way.

The exemption does not distinguish between active or non-active ingredients as it applies to any substance "used in medicinal products". Excipients used in medicinal products are therefore also exempted from registration.

Note however that quantities of the same substance may be used for other uses than pharmaceuticals, so those quantities are not exempted. Only the quantities of the substance used in medicinal products are exempted from the registration obligation and REACH authorisation.

Example:

A manufacturer manufactures 100 tonnes of salicylic acid in year X. 50 tonnes are used to produce medicinal products within the scope of Directive 2001/83/EC on the Community code relating to medicinal products for human use, 50 tonnes are used for the formulation of a non-medicinal preparation. The 50 tonnes used for the formulation of the non-medicinal preparation will be subject to the registration provisions and can, if their properties warrant so, be made subject to authorisation, while the 50 tonnes used to produce medicinal products are exempted from registration, evaluation and authorisation.

Legal references: Article 2 (5) (a), Article 2 (6) (a)

1.8.1 Specific provision on information in the supply chain for preparations consisting of medicinal products:

There is no need to comply with the REACH obligation to provide information in the supply chain for medicinal products for human or veterinary use (as covered by either the Regulation (EC) No 726/2004 on Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, or Directive 2001/82/EC on the Community code relating to veterinary medicinal products, or Directive 2001/83/EC on the Community code for medicinal products for human use) intended for the final user. The specific Community legislation on medicinal products already provides what information has to be given, for example on labels or packaging leaflets.

Legal references: . Article 2 (6) (a) .

1.9 Annex IV and V

Annex IV contains a list of substances exempted from the obligation to register.
Annex V describes types of substances that are exempted from the obligation to register.

1.9.1 Substances included in Annex IV

Annex IV currently lists 68 substances for which it is understood that sufficient information is available to consider them as causing minimum risk to human health and the environment. These substances are typically of natural origin and the list of exempted substances includes, for example, corn oil and nitrogen (N_2). Substances included in *Annex IV* are exempted from the registration provisions.

The list is largely based on the exemptions from Regulation (EC) No 793/93 on risk evaluation of existing substances, but more substances were added. The registration exemption applies to the substance as such, not to a particular use.

The Commission is required, by 1 June 2008, to review this Annex and, if appropriate, propose amendments to it. As this provision may lead to the inclusion of additional substances into Annex IV or the exclusion of substances from it, manufacturers and importers are advised to regularly check the list of substances in *Annex IV*. In the Navigator, a search engine has been implemented to help the user check whether his substance is listed in *Annex IV*.

1.9.2 Substances covered by Annex V

Annex V currently lists nine broad categories of substances for which registration is deemed inappropriate or unnecessary. They are exempted from the registration and evaluation provisions, but not necessarily from authorisation or restrictions. Check whether your substance is covered by one of the categories on this list.

The registration exemption applies to the substances as such, provided however that they meet the conditions for the exemption which are given in the particular category of *Annex V*. For example, for hydrates or hydrated ions, copper (II) sulphate pentahydrate formed by association of copper (II) sulphate with water, will not require registration by its manufacturer provided the copper (II) sulphate was registered (or exempted) from registration.

The Commission is required, by 1 June 2008, to review this Annex and, if appropriate, propose amendments to the Annex. As this provision may lead to the inclusion of additional categories or substances into *Annex V* or the exclusion of categories from it, manufacturers and importers are advised to regularly check the list.

ANNEX V

EXEMPTIONS FROM THE OBLIGATION TO REGISTER

IN ACCORDANCE WITH ARTICLE 2(7)(b)

1. Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.
2. Substances which result from a chemical reaction that occurs incidental to storage of another substance, preparation or article.
3. Substances which result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported

or placed on the market.

4. Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:

   (a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or

   (b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.

5. By-products, unless they are imported or placed on the market themselves.

6. Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.

7. The following substances which occur in nature, if they are not chemically modified.

   Minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal, coke.

8. Substances occurring in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC.

9. Basic elemental substances for which hazards and risks are already well known:

   hydrogen, oxygen, noble gases (argon, helium, neon, xenon), nitrogen.

Legal references: Article 2 (7) (a) and (b), Annex IV, Annex V .

1.10 Recycled or recovered substance already registered

The REACH Regulation exempts from registration substances which are registered and recovered in the Community, provided a number of conditions are met. Recycling is a form of recovery and therefore covered by this exemption.

Recovery is defined in EU law (Waste Framework Directive 2006/12/EC (Article 1(f)) as one of the operations included in the following list:

- Use principally as a fuel or other means to generate energy
- Solvent reclamation/regeneration
- Recycling/reclamation of organic substances which are not used as solvents (including composting and other biological transformation processes)
- Recycling/reclamation of metals and metal compounds
- Recycling/reclamation of other inorganic materials
- Regeneration of acids or bases

- Recovery of components used for pollution abatement
- Recovery of components from catalysts
- Oil re-refining or other reuses of oil
- Land treatment resulting in benefit to agriculture or ecological improvement
- Use of wastes obtained from any of the operations numbered 1 to 10
- Exchange of wastes for submission to any of the operations numbered 1 to 11
- Storage of wastes pending any of the operations numbered 1 to 12 (excluding temporary storage, pending collection, on the site where it is produced)

The REACH Regulation sets conditions which have to be respected in order to benefit from the exemption, as follows:

(1) The recovered substance must have been registered. This means that if, for some reason, the substance has not been registered at manufacturing or import stage the recovered substance has to be registered following the recovery operation before being put to a new use.

On the other hand, the person who performs the recovery should check whether an exemption applies to the recovered substance. If an exemption applies which frees the recovered substance from the registration obligation, then that exemption can of course be invoked.

(2) The substance already registered must be the same, i.e. have the same chemical identity and properties, as the substance being recovered. For example, if the substance itself was modified in the recovery then the recovered substance has to be registered.

(3) The legal entity who did the recovery must ensure that information on the registered substance is available to it, and that information must comply with the rules on information provision in the supply chain.

This means that the person who did the recovery must have obtained one of the following:

- a safety data sheet, as required by *Article 31 (1) or (3)*, on the registered substance,
- other information sufficient to enable users to take protection measures, as required by *Article 31 (4)*, for the registered substance, or
- an information package comprising the status of the registered substance under the authorisation part of REACH, any applicable restrictions under REACH, other information necessary to allow appropriate risk management measures and the registration number, as required by *Article 32 (1)*.

Companies undertaking recovery operations and wishing to avail themselves from this exemption are advised to ensure as much as possible that the information on the registered substance which was put together to comply with the REACH Regulation, is available to them as well, as otherwise they will have to register the recovered substance.

It is worth noting that this exemption does not require that the substance has been registered by an actor in the same supply chain. Therefore, it is sufficient that a registration was filed for the substance, either by a registrant in the same supply chain or by a registrant in another supply chain.

Note that if the recycled substance is a phase-in substance, it is recommended that the recycler pre-registers that substance in order to benefit from the transitional provisions laid down in Article 23 and eventually be later on exempted from the registration requirements if another pre-registrant registers the substance.

Legal reference: Article 2 (7) (d)

1.11 Re-imported substance

The registration obligation of *Article 6* applies to manufacturers and importers of a substance, on its own or included in a preparation. However, in cases where a substance is first manufactured in the EU, then exported – for example, to be formulated into a preparation – and then brought back into the EU again – for example, to be marketed or for further processing – this could lead to a double registration obligation if it happens within the same supply chain: first at the stage of original manufacture, by the original manufacturer, and a second time at the stage of import back into the Community, by a re-importer down in the same supply chain (who may or may not be the original manufacturer). Therefore, substances which have been registered, exported and then re-imported are exempted from registration and evaluation under certain conditions.

The following conditions must be fulfilled to benefit from this exemption:

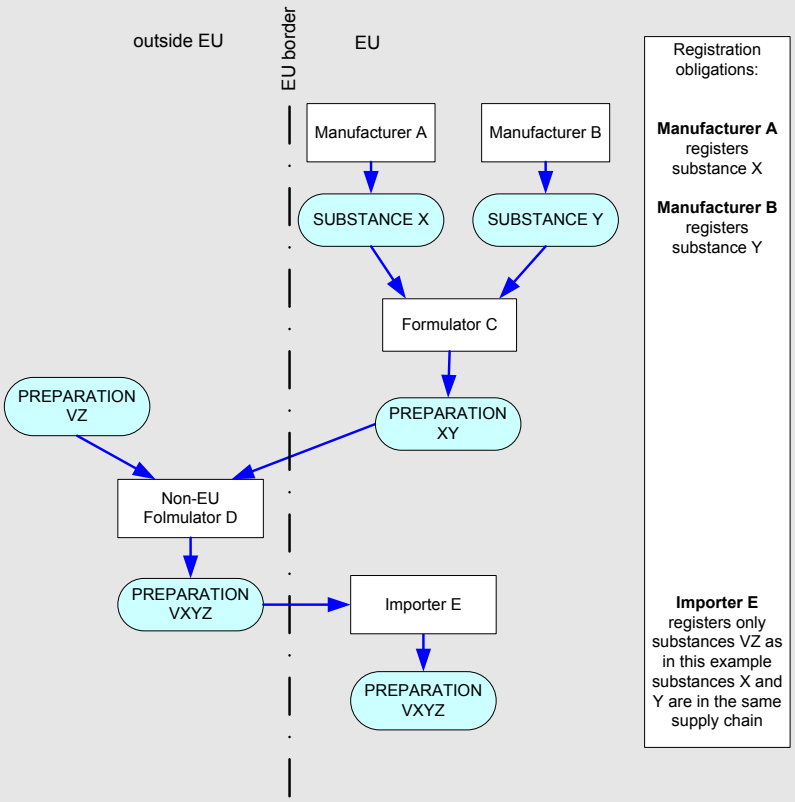
(1) The substance must have been registered before it was exported from the Community. This means that if, for some reason, the substance was not registered at the manufacturing stage, the substance has to be registered upon re-import.

(2) The substance already registered and exported must be the same, i.e. have the same chemical identity and properties, as the substance being re-imported, on its own or in a preparation. For example, if the exported substance itself was modified outside the EU and therefore it is not the same substance which is now being re-imported, the re-imported substance has to be registered.

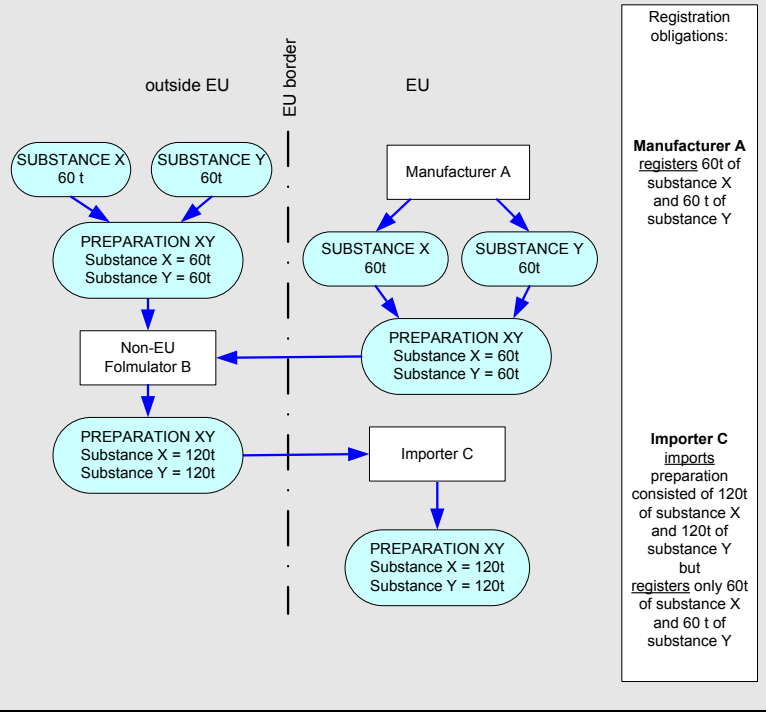
Again, the reason is clear: if the substance does not have the same chemical identity, it has not yet been registered (the registration information will be different), and therefore there will not be duplication of registrations. Note that the re-importer has to be able to prove that the substance is still the same. For more details on substance identification see the Guidance on substance identification.

(3) The substance must not only be the same, i.e. have the same chemical identity and properties, but it must actually be the same batches of the substance which are exported from and re-imported back to the Community (whether or not processed). This is meant by the requirement that the re-importer is "in the same supply chain".

Example (1):



Example (2):



(4) The re-importer must have been provided with information on the exported substance, and that information must comply with the rules of REACH on information provision in the supply chain.

This means that the re-importer must have been supplied with one of the following:

- a **safety data sheet**, as required by *Article 31 (1) or (3)*,
- other information sufficient to enable users to take protection measures, as required by *Article 31 (4)*, or
- an information package comprising the status of the substance under the authorisation, any applicable restrictions, other information necessary to allow appropriate risk management measures and the registration number, as required by *Article 32 (1)*.

Note that the re-importer has to be able to prove that he was provided with one of these pieces of information.

If the re-importer can avail himself of the exemption, he will be considered as a downstream user. Therefore, he is advised to check what downstream user obligations are applicable to him.

Note that the re-import exemption is not available if the substance is being re-imported in articles.

Legal reference: Article 2 (7) (c)

1.12 Polymer

A polymer is 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.

In accordance with REACH (Article 3(5)), a polymer is defined as a substance meeting the following criteria:

(a) Over 50 percent of the weight for that substance consists of polymer molecules (see definition below); and,

(b) The amount of polymer molecules presenting the same molecular weight must be less than 50 weight percent of the substance.

In the context of this definition:

- A "**polymer molecule**" is a molecule that contains a sequence of at least 3 monomer units, which are covalently bound to at least one other monomer unit or other reactant.
- *A "**monomer unit**" means the reacted form of a monomer substance in a polymer* (for the identification of the monomeric unit(s) in the chemical structure of the polymer, the mechanism of polymer formation may for instance be taken into consideration).
- A "**sequence**" is a continuous string of monomer units within the molecule that are covalently bonded to one another and are uninterrupted by units other than monomer units. This continuous string of monomer units can possibly follow any network within the polymer structure.

- "**Other reactant**" refers to a molecule that can be linked to one or more sequences of monomer units but which cannot be regarded as a monomer under the relevant reaction conditions used for the polymer formation process.

These definitions are exemplified in the following example.

Example : Example illustrating the definition of a polymer

To illustrate the definitions, let us consider a polymer forming reaction taking place when ethylene oxide is reacted with phenol.

Figure 1 represents the different molecules susceptible to be formed upon completion of this ethoxylation-type of polymerisation reaction.

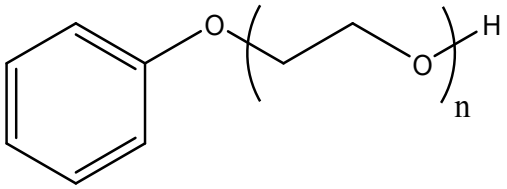


Figure 1: ethoxylated phenol (n is an integer, n≥1)

The **monomer unit** is in this case the opened epoxide -(CH_2-CH_2-O)-

Phenol acts as the initiator of the ethoxylation reaction, and shall be regarded as an "**other reactant**" since it cannot react with either itself or an opened epoxide.

The molecule depicted in **Figure 1** would therefore qualify for the definition of "**polymer molecule**" whenever n≥3.

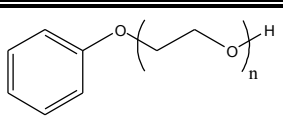
The ethoxylated phenol substance thus manufactured shall be regarded as a **polymer** if both following conditions are met:

(a) Over 50 weight percent of the substance consists of polymer molecules, i.e. molecules depicted in figure 2 and for which n≥3)

(b) None of the polymer molecules having the same molecular weight represent 50 weight percent or more of the substance.

In **Table 1** three different compositions of the ethoxylated phenol substance are considered. For each example, the weight percent of every molecule present in the substance is reported.

Table 1 Molecular composition of 3 examples of ethoxylated phenol substances.

	**Example 1**	**Example 2**	**Example 3**
n=1	0%	40%	5%
n=2	10%	20%	10%
n=3	85%	15%	20%
n=4	5%	12%	30%
n=5	0%	8%	20%
n=6	0%	5%	10%
n=7	0%	0%	5%
Sum	100%	100%	100%

In Example 1, the substance consists of 10% ethoxylated phenol with n=2, 85% with n=3 and 5% with n=4. Since this substance comprises 85 weight percent of the same polymer molecule (n=3), it does therefore not meet the definition of polymer. Therefore, it should be considered as a standard substance.

In Example 2, only 15+12+8+5=40 weight percent of the substance consists of polymer molecules, i.e. molecules for which n≥3). For this reason, example 2 does not qualify for the criteria of polymer definition either. Therefore it should also be considered as a standard substance.

Example 3 meets the definition of a polymer since 20+30+20+10+5=85 weight percent of the substance consists of polymer molecules (i.e. molecules for which n≥3),and none of the different constituent are present at concentrations above 50 weight percent, each constituent having a different molecular weight.

It should be highlighted that polymers may be synthesised not only from the polymerisation of monomers, but also from other processes such as the chemical post-modification of polymer substances. Examples of such post-modification reactions include polymer curing, polymer functionalisation via grafting, and controlled polymer degradation such as visbreaking.

Whenever it is not scientifically possible to establish whether the substance falls under the definition of polymer or identify the chemical structure of the monomer units or any other unit as well as their concentration in the substance, the substance can be regarded as a UVCB substance, i.e. substance of Unknown or Variable composition, Complex reaction products or Biological material (see Guidance on substance identification).

Legal references: Article 3 (5), Article 6 (3).

1.13 Monomers

REACH defines a **monomer** as *a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process* (Article 3(6)). In other words, it is a substance which, under the polymerisation reaction, is converted into a repeating unit of the polymer sequence. Substances exclusively involved in the catalysis, initiation or termination of the polymer reaction are not monomers. Any monomer is therefore by definition an intermediate. Nonetheless,

the specific provisions for the registration of intermediates under REACH do not apply to monomers.

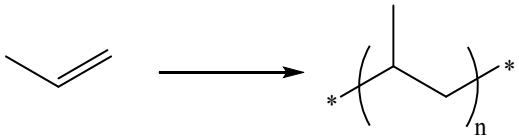
For applications outside the scope of polymerisation, the same substance is not regarded as a monomer. If it is used as an intermediate, it might fulfil the conditions to benefit from the specific provisions for the registration of intermediates under REACH (see the Guidance for intermediates). Otherwise, it will have to follow all REACH requirements for a "normal substance" with registration requirements in accordance with Title 2 (cf. Guidance on registration).

An illustration of the definition of monomer is provided in following example

Example to illustrate the Monomer definition: the propylene case

Propylene is to be considered as a monomer under REACH when it is used for the purpose of polymerisation process such as polypropylene manufacture, as illustrated in **Figure 3**:

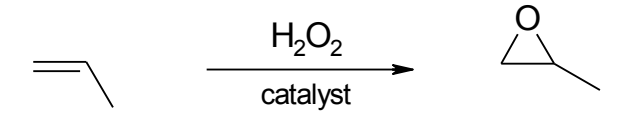
Figure 2: Propylene polymerisation



Propylene Polypropylene

Propylene may also be used for the manufacture of propylene oxide, for instance according to a catalytic epoxidation reaction with hydrogen peroxide. The reaction is illustrated in **Figure 3**. For this application, propylene is in fact an intermediate but is not regarded as a monomer.

Figure 3: Propylene epoxidation reaction



propylene propylene oxide

Another example of application for propylene is its utilisation as fuel gas in certain industrial processes. In this specific case, propylene is not regarded as an intermediate or as a monomer.

Manufacturers or importers of monomers have to register their monomers in accordance with the normal registration obligation laid down in Article 6 of REACH. Although monomers are by definition intermediates, these substances cannot be registered in accordance with the provisions which normally apply to on-site isolated or transported intermediates (Article 6(2)) (note however that the provisions of Articles 17 and 18 apply for the other substances used in the manufacture of the polymer, provided those other substances meet the conditions of those Articles (see the Guidance for intermediates)

If a natural or legal person manufactures or imports a substance to be used both as a monomer and as non-monomeric intermediate, he needs to submit one "standard" registration dossier according to Article 10. If part of the tonnage manufactured or imported is for a use as non-monomeric intermediate and is handled under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirement of the registration dossier. Nevertheless the use as intermediate should be documented in the dossier, including the volume manufactured or

imported for this purpose. For instance, if a manufacturer manufactures 11 tonnes/year of a substance, of which 2 tonnes/year are for use as monomer and the remaining 9tonnes/year is a non-monomeric intermediate handled under strictly controlled conditions, the registration information requirement for that substance is based on the 2 tonnes/year.

Monomers are by definition intermediates. These substances therefore cannot be subject to authorisation under REACH for the use as monomers in polymerisation reactions.

The manufacturer or importer of a monomer substance has otherwise the same obligations under REACH as for any standard substance: general rules on restriction, information down the supply chain and classification and labelling shall therefore apply.

Legal references: Article 2 (8), Article 3 (6), Article 6 (2) and (3).

1.14 Active substance for use in biocides

Active substances for use in biocidal products are regarded as registered as biocidal products and their active ingredients are covered by Directive 98/8/EC (Biocidal Products Directive). To benefit from the exemption, several conditions have to be fulfilled:

(1) the substance must be an active substance for use in a biocidal product.

An active substance in the context of biocides is a substance or micro-organism including a virus or a fungus having general or specific action on or against harmful organisms. A biocidal product may be composed of only one active substance, without co-formulants, or it may be a preparation including one or more active substances.

(2) the substance must be included in one of the following:

- Annex I to Directive 98/8/EC – this is the list of active substances which are authorised for use in biocidal products; it is regularly updated and manufacturers and importers are advised to check the latest version.
- Annex IA to Directive 98/8/EC – this is the list of active substances which are authorised for use in low-risk biocidal products; it is regularly updated and manufacturers and importers are advised to check the latest version.
- Annex IB to Directive 98/8/EC – this is the list of basic substances which are authorised for use as biocidal products; it is regularly updated and manufacturers and importers are advised to check the latest version. Basic substances are substances which only have a minor use as a biocide and which are not directly marketed for that biocidal use.
- Regulation (EC) No 2032/2003 – this regulation lists active substances which were already on the market on 14 May 2000 and for which information was submitted with a view to including them in the Commission's review programme of active substances for use in biocidal products. However, once a decision is taken for one of the active substances on the lists of Regulation (EC) No 2032/2003 not to include it into Annex I, IA or IB, the active substance loses the exemption and must be registered, since its manufacturer will not have submitted the required information to allow full assessment under Directive 98/8/EC. Decisions not to include active substances, which are on the lists of Regulation (EC) 2032/2003, into Annex I, IA or IB of Directive 98/8/EC will be published in the Official Journal of the European Union and may take the form of a Commission Decision or a Commission Regulation. They can be accessed on http://ec.europa.eu/environment/biocides/annexi_and_ia.htm.

Note however that only the quantities of the active substance for use in biocidal products are exempted from the registration obligation. If they are used in another non-biocidal product, they are not exempted. It means that in the case when a manufacturer who manufactures only for the purpose of biocides puts the same substance on the market but for other purposes (not exempted from registration) he has to prepare a full registration dossier, including all relevant information including, if fulfilling conditions, the Chemical Safety Report (CSR).

Example:

A manufacturer manufactured 100 tonnes of quaternary ammonium compounds in year X. 50 tonnes are used as active substances in biocides (e.g. wood preservatives) and the active substance is included in one of the acts mentioned under (2) above, the other 50 tonnes are used as surfactants in cleaning products. The latter use is within the scope of REACH and has to be registered; the former use is exempted from registration.

The Agency has been charged with including the information submitted in the framework of Directive 98/8/EC, which is equivalent to registration dossier data, into its databases. This is to ensure that this data can be valorised where appropriate. Note that although these substances are considered registered for the use in biocides, there is no need for companies to update the dossier.

Finally, use of substances in biocides is exempted from authorisation as they are already being authorised for biocidal use under Directive 98/8/EC.

Legal references: Article 15 (2), Article 16, Article 56 (4) (b)

1.15 Active substance for use in plant protection products

REACH does not exempt active substances and co-formulants for use in plant protection products (pesticides) from registration, but provides that they are regarded as registered under REACH, Active substances and co-formulants for use in plant protection products (pesticides) are regarded as registered as the plant protection products and their active ingredients and co-formulants are covered by Directive 91/414/EEC (Directive on plant protection products) and in principle undergo a thorough assessment, on the basis of already submitted substantial information, before they can be placed on the market. To benefit from the exemption, several conditions have to be fulfilled:

(1) the substance must be either an active substance or a co-formulant for use in a plant protection product.

An active substance in the context of plant protection products is a substance or micro-organism, including a virus, having general or specific action against harmful organisms or on plants, parts of plants or plant products. A plant protection product may be composed of only one active substance, without co-formulants, or it may be a preparation including one or more active substances.

A co-formulant in the context of plant protection products is a non-active substance in a plant protection product which is a preparation.

Therefore, it appears that all substances contained in plant protection products are eligible for the exemption. However, since only active substances can meet condition (2) below, only active substances can qualify for the exemption.

(2) the substance must be included in one of the following:

- Annex I to Directive 91/414 – this is the list of active substances which are authorised for use in plant protection products; it is regularly updated and manufacturers and importers are advised to check the latest version (information can be found on http://ec.europa.eu/food/plant/protection/evaluation/legal_en.htm).

- Regulation (EEC) No 3600/92 – this regulation lists 90 active substances which were already on the market on 26 July 1993 and which were the first ones to be identified for assessment with a view to being authorised and included into Annex I to Directive 91/414/EEC.

- Regulation (EC) No 703/2001 – this regulation lists a further 63 active substances which were already on the market on 26 July 1993 and for which their producers wished to secure inclusion into Annex I of Directive 91/414/EEC and which were thus identified for assessment.

- Regulation (EC) No 1490/2002 - this regulation lists a further 161 active substances which were already on the market on 26 July 1991 and for which their producers wished to secure inclusion into Annex I of Directive 91/414/EEC and which were thus identified for assessment.

- Decision 2003/565/EC – this decision lists further active substances and micro-organisms already on the market on 26 July 2003 for which the assessment period was extended.

- a Commission decision on the completeness of the dossier submitted pursuant to Article 6 (3) of Directive 91/414/EEC – such decisions are taken in respect of active substances which were not yet on the market on 26 July 1991 but for which an application for inclusion into Annex I of Directive 91/414/EEC was submitted and deemed admissible. They concern the admissibility of applications filed by individual legal entities and are therefore not published in the Official Journal, but notified to the legal entities concerned. Accordingly, relevant operators will be aware of decisions of interest to them.

Note however that quantities of the same active substance may be used for other uses than plant protection products, so those quantities are not exempted. Only the quantities of the active substance for use in plant protection products are exempted from the registration obligation. If they are used in another product, they are not exempted. It means that in the case when a manufacturer who manufactures only for the purpose of biocides puts the same substance on the market but for other purposes (not exempted from registration) he has to prepare a full registration dossier, including all relevant information including, if fulfilling conditions, the Chemical Safety Report (CSR).

Example:

A manufacturer manufactured 100 tonnes of copper sulphate in year X. 50 tonnes are used as active substances in pesticides and the active substance is included in one of the acts mentioned under (2) above, the other 50 tonnes are used for another use. The latter use is within the scope of REACH and has to be registered; the former use is exempted from registration.

The Agency has been charged with including the information submitted in the framework of Directive 91/414/EEC, which is equivalent to registration dossier data, into its databases. This is to ensure that this data can be valorised where appropriate. Note that although these substances are considered registered for the use in pesticides, there is no need for companies to update the dossier.

Finally, use of substances in plant protection products is exempted from authorisation.

Legal references: Article 15 (1), Article 16, Article 56 (4) (a)

1.16 Cosmetics

A cosmetic product is a substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good conditions. Examples of cosmetic products are deodorant, toothpaste, soap, make-up, shaving cream, suntan lotion and hair lacquer.

For companies manufacturing or handling either substances to be used in cosmetic products or preparations that are cosmetic products, a number of exemptions apply:

Substances for use in cosmetic products have to be registered, but the chemical safety report (CSR) does not have to consider the human health risks related to that use, as those risks have already been considered in establishing lists of approved substances under the Cosmetics Directive. The possible risk to the environment still has to be considered.

There is no obligation to provide a safety data sheet on cosmetic preparations in their finished state or other special information to customers for the purposes of REACH.

No authorisation application needs to be filed for the use of a substance in cosmetic products if the substance is subjected to authorisation because it is carcinogenic, mutagenic or toxic to reproduction or because there are probable serious effects to human health giving rise to an equivalent concern. The Directive on cosmetic products already extensively addresses these human health effects. This means in practice that when a substance in included in Annex XIV due to the fact that it is carcinogenic, mutagenic, or toxic to reproduction or because there are probably serious effects to human health giving rise to an equivalent concern, the use of such substances in cosmetic products will be automatically exempted from the authorisation requirement.

Similarly, if a substance is restricted because of human health risks, the restriction will not apply for the use of the substance in cosmetic products.

Legal references: Article 2 (6) (b), Article 14 (5) (b), Article 56 (5) (a) and Article 67 (2).

1.17 Medical devices

The REACH provisions regarding information in the supply chain do not apply to preparations which are medical devices in the finished state, intended for the final user, which are invasive or used in direct physical contact with the human body, in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection as Directive 1999/45/EC.

Legal references: Article 2 (6) (c).

The risks to human health arising from the use of a substance in medical devices regulated by Directives 90/385/EEC, 93/42/EEC or 98/79/EC shall not be considered when applying for authorisations or granting them under REACH.

Legal references: Article 60(2) and 62(6).

2 LEGAL STATUS OF THE SUBSTANCE

2.1 Notified substances according to Directive 67/548/EEC

Directive 67/548/EEC introduced a notification requirement for **so-called new substances**, which were substances not appearing on the European Inventory of Existing Commercial Chemical Substances (EINECS). The EINECS list contains, in principle, all substances on the Community market on 18 September 1981.

Notifications made in accordance with Directive 67/548/EEC contain a lot of the technical dossier information which the REACH Regulation aims to have assembled by registrants through the registration requirement. This is the reason why such notifications are regarded as registrations. The Agency is instructed to assign registration numbers to notifications considered as registrations. It must do so by 1 December 2008.

Legal entities are therefore advised to check whether they submitted a notification for their substance to a Member State competent authority in accordance with the national legislation implementing Directive 67/548/EEC. If this is the case, they have an official notification number on file which was allocated by the Member State competent authority. The substance will in that case also appear on the European List of Notified Chemical Substances (ELINCS).

Notification under Directive 67/548/EC was only required if a substance was placed on the EU market or imported into the EU. If a substance was merely manufactured in the EU, but not placed on the market, a notification would not have been made. These substances will have to be registered under REACH.

Moreover, legal entities must also check which tonnage range was covered by their notification. Notification of substances was required starting at 10 kg per year per manufacturer, and the tonnage thresholds after that were 100 kg per year or 500 kg in total, 1 tonne per year or 5 tonnes in total, 10 tonnes per year or 50 tonnes in total, 100 tonnes per year or 500 tonnes in total, and 1000 tonnes per year or 5000 tonnes in total. Registration dossier for those substances which are regarded as registered should be updated as soon as the manufactured/imported quantity reaches the next tonnage threshold under *Article 12* (10, 100 or 1000 tons). This update should not only contain the information required by REACH which corresponds to that higher tonnage threshold, but also any information which corresponds to lower tonnage thresholds but which was not yet submitted. This means that if the annual quantity reaches 10 tonnes, a Chemical Safety Report will have to be prepared. On the other hand, since a notification at 10 kg or 100 kg per year is regarded to be a registration, and registration under REACH applies as of 1 tonne per year, the first update to submit additional information will only be due when the 1 tonne threshold is reached. For more details on registration update see section 4 of the Guidance on registration and section 9 of the Guidance on registration.

Registrants of notified substances will also have to comply with all other REACH requirements and provisions: for example, when submitting their update they will have to prepare a Chemical Safety Report and to prepare Exposure Scenarios to attach to t heir Safety Data Sheet when relevant.

Please note that a notification under Directive 67/548/EC is nominal so that only the notifier benefits from being considered registered; any other parties manufacturing or importing the substance but who have not notified it, must register, unless there is another exemption that applies to them.

Legal reference: Article 24

2.2 Phase in substances

The REACH Regulation creates a special transition regime for substances which, under certain conditions, were already being manufactured or placed on the market before the entry into force of the REACH Regulation on 1st June 2007 and were not notified according to Directive 67/548/EEC. For these substances, the registration can be submitted within deadlines foreseen by the REACH Regulation.

Such substances are called "**phase-in substances**", because they are being subjected to the registration system in different phases over time, rather than immediately in one go.

A precondition is that the phase-in substance is being pre-registered within between the 1st June 2008 and the 1st December 2008.

Phase-in substances are substances which fall under at least one of the following criteria:

- *The substance is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) (Article 3 (20)(a)).* The EINECS list contains, in principle, all substances on the Community market on 18 September 1981. These are the so-called "existing substances". The full and exhaustive list is accessible at http://ecb.jrc.it/esis/. Note that the list has been "frozen" and no more substances can be added to it or removed from it. Note that the list has been "frozen" and no more substances can be added to it or removed from it.

- The substance was manufactured in any of the current Member States of the EU (except Bulgaria and Romania), at least once after 31 May 1992, without being placed on the EU market by the manufacturer or importer, provided that the manufacturer or importer has documentary evidence of this. Such documentary evidence can be, for example, order sheets, stock lists, or any other documents which can be undoubtedly traced back to a date after 31 May 1992. If the substance was placed on the market, it would normally have been notified under Directive 67/548/EEC and in that case it will be considered as registered.

- The substance was placed on the market in any of the current Member States of the EU before 1 June 2007 by the manufacturer or importer, and is a so-called "no-longer polymer". A NLP is a substance which was placed on the EU market between 18 September 1981 and 31 October 1993 inclusive, was considered as notified under Article 8 (1) of the 6th amendment of Directive 67/54/EEC (and hence did not have to be notified under that Directive), but which does not meet the REACH definition of a polymer (which is the same as the polymer definition introduced by the 7th amendment of Directive 67/548/EEC). Also in this case, the manufacturer or importer must have documentary evidence that he placed the substance on the market in the relevant territory and that it was considered as NLP (and as such considered as notified under Article 8 (1) of the 6th amendment). Such documentary evidence can be, for example, order sheets, stock lists, labels, safety data sheets, or any other documents which can be undoubtedly traced back to a date between 18 September 1981 and 31 October 1993 inclusive. A non-exhaustive list of NLPs is accessible at http://ecb.jrc.it/esis; note that it only serves information purposes.

Please note that the transitional regime for phase-in substances also applies to on-site and transported isolated intermediates as well as to substances in articles which need to be registered.

Note also that manufacturers and importers of phase-in substances who do not pre-register on time will not be able to benefit from the transitional regime provided for in *Article 23.* Consequently, they will have to register their substance before continuing their manufacture or import as for any non phase-in substances , at latest on the 1st December 2008.

Legal references: Article 3 (20), Article 23, Article 28 (1).

3 ROLE IDENTIFICATION: MANUFACTURER, IMPORTER, PRODUCERS OF ARTICLES

The REACH legislation makes a distinction between several **roles in the supply chain** of substances on their own, in preparations or in articles, connected to the activities of a company. The obligations you have to fulfil depend on your role.

Identify here the role(s) you have for the substance for which you are running the Navigator session. Note that a company can have different roles for different substance, e.g. when formulating a preparation, if some of the substances are obtained from a supplier in the EU and some are imported by the company from a country outside the EU (cf. below on the European Economic Area), then you are a downstream user for some of the substances and an importer for the other substances. Even for a given substance, a company can have more than one role: e.g. a manufacturer can also use the substance he manufactures to formulate a preparation or produce an article.

You have to decide if you are **a manufacturer** or **an importer** of a substance on its own, in a preparation or in an article, or not. In case you are a manufacturer and/or importer but you also have another role, you should answer **YES**. If this is the case you might have additional obligations, for example as a downstream user when communicating in the supply chain, to your manufacturer or importer obligations only. When relevant the navigator will warn you about this issue.

If you are a non-EU company, you have formally no obligations under REACH. Nevertheless to facilitate your exportation towards EU you can help your EU customers to prepare their registration dossiers and eventually appoint an "only representative".

Are you a manufacturer?

A manufacturer under REACH means any natural or legal person established within the European Community who manufactures a substance within the Community.

Manufacturing means production or extraction of substances in the natural state. It is a case by case decision to establish which steps of the synthesis of the end product lead to substances which need to be registered (e.g. different purification or distillation steps).

Customs boundaries for Manufacture and Import:

Iceland, Liechtenstein, Norway and Switzerland are members of the **European Free Trade Agreement** (EFTA). The EFTA Convention established a free trade area among its Member States in 1960. Iceland, Liechtenstein and Norway entered into the Agreement on the **European Economic Area** (EEA) in 1992, which entered into force in 1994. Therefore, the EEA is composed of Iceland, Liechtenstein, Norway and the 27 EU Member States.

As soon as REACH is implemented by the EEA EFTA-States (which means EFTA States covered by EEA agreement), imports from Norway, Iceland and Liechtenstein will be considered as intra-Community trade for the purposes of REACH. EFTA is preparing a proposal for an EEA Joint Committee Decision, incorporating the Regulation and establishing the conditions for the EEA EFTA participation in the EU Chemicals Agency. EFTA is targeting to have the Regulation incorporated by 1 June 2008.

As soon as REACH is ratified in the EEA EFTA-States a supplier in the EEA EFTA-States will have to register the substance as a manufacturer under REACH with all associated obligations like any other manufacturer within the EU.

> **Examples:**
>
> A formulator purchasing his substances in Germany or Iceland will be considered as a Downstream User.
>
> A formulator purchasing his substances in Switzerland or Japan will be considered as an Importer.

Are you an importer?

An importer means any natural or legal person established within the Community who is responsible for import (Article 3(11)).

Import: means the physical introduction into the customs territory of the Community (Article 3(10)). In other words, all substances on their own, in preparations or in articles manufactured or produced outside the European Community and put in the European market are considered as imported

What are the boundaries for importation?

The **customs territory** of the Community can be found below.

As soon as REACH is ratified in the EEA EFTA-States, an EU importer of a substance from an EEA country will not be required to register the substance under REACH and will simply be regarded as a downstream user.

Importers of a substance from Switzerland (a non EU country belonging to EFTA but not to EEA) will have the same obligations under REACH as any other importer.

Only representative

If a non-EU manufacturer decides to appoint an "only representative" in the EU, this only representative will take over all obligations as an importer according to Article 8 (2). This means that you, as an importer, will not have to register your substance, even if you are importing it from a non-EU manufacturer. Instead you will be considered as a downstream user, and you will have to inform the only representative about your use and in return you will receive instructions on safe use. If you had already registered the substance, you will have to withdraw the registration (or update the file to reduce the registered quantity, in case you still import the substance from other non-EU manufacturers).

When your supplier (a non EU manufacturer or formulator) has designated an "only representative", not being you, you should answer **NO** to the question.

If you are appointed by a non-EU manufacturer to act as an "only representative" you should answer **YES** to the question.

Moreover you should answered **YES** to the question if you are importing the substance and no "only representative" was appointed.

What is an "only representative"?

According to Article 8(1) "*A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or*

produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title".

When the registration is submitted by an "only representative" he will have to enclose a copy(ies) of the letter(s) of the non-EU manufacturer(s) officially assigning him as a "only representative". For phase-in substances the "only representative" will also have to pre-register the substance and will subsequently become participant of the Substance Information Exchange Forum (SIEF) (see Guidance on data sharing).

Moreover, an "only representative" will have to keep available and up-to-date information on quantities imported, the list of EU customers of the exporter he represents, as well as information on the supply of the latest update of the safety data sheet. The non-EU manufacturer has to inform all the EU importers in the same supply chain that he has appointed an EU representative as his "only representative".

The only representative is legally responsible for his registration. Nevertheless, it can be anticipated that in most cases, it will be the non-EU exporter who will provide him with all necessary data for his dossier.

Example:

- A manufacturer of a substance who uses the manufactured substance himself is a manufacturer and downstream user. He has a duty to register each substance manufactured in quantities of 1 tonne or more per year, unless exemptions apply, and will have to include information on his own use(s) and any identified uses of his customers in his registration.

- An importer of a preparation has to register those substances which are present in the imported preparation in quantities of 1 tonne or more per year, unless exemptions apply. He will have to include information in his registration on the identified use(s) of the substance(s) in the preparation. There is no obligation for importers of preparations to register the preparations themselves; indeed preparations cannot be registered.

Example of when registration is NOT needed:

- Any person, who is using substances which he has not manufactured or imported, is a downstream user and has no obligation to register these substances.

- An importer of a substance, a preparation or an article, from a non-EU company who has appointed an "only representative" will be considered as a downstream user and therefore does not need to register.

An "only representative" needs to have sufficient background in the practical handling of substances and the information related to them.

Regarding the establishment of the number of registrations and the data requirements for an only representative, several situations can be distinguished:

- you act as an "only representative" for a single non-EU manufacturer who exports a substance to the EU via several EU importers. In this case you will have to submit one registration for the full imported tonnage;

- you act as an "only representative" for several non-EU manufacturers who export the same substance to the EU via one or several EU importers. The issue will be clarified by the Commission services as soon as possible.

If you are appointed as "only representative", your non-EU manufacturer has to inform all the EU importers in the same supply chain that he has appointed you as his “only representative”. These EU importers have to fulfil downstream users' obligations under REACH.

More information on the “only representative” (submission of a registration; change of “only representative”) can be found in section 1.5.2 of the Guidance on registration

The **customs territory** of the Community:

- Austria,
- Bulgaria,
- Belgium,
- Denmark, except the Faroe Islands and Greenland,
- Germany, except the Island of Heligoland and the territory of Buesingen,
- Greece,
- Finland (including the Åland Islands),
- France (including Monaco and the overseas departments Guadeloupe, French-Guiana, Martinique and Réunion), except the overseas territories and Saint-Pierre and Miquelon and Mayotte,
- Ireland,
- Italy, except the municipalities of Livigno and Campione d'Italia and the national waters of Lake Lugano which are between the bank and the political frontier of the area between Ponte Tresa and Porto Ceresio,
- Luxembourg,
- The Netherlands in Europe,
- Portugal,
- Spain, except Ceuta and Melilla,
- Sweden,
- The United Kingdom of Great Britain and Northern Ireland and the Channel Islands and the Isle of Man.
- The Czech Republic,
- Estonia,
- Cyprus,
- Latvia,
- Lithuania,
- Hungary,
- Malta,
- Poland,

- Romania
- Slovenia,
- The Slovak Republic.

The customs territory of the Community includes the territorial waters, the inland maritime waters and the airspace of the Member States and the territory of the Principality of Monaco, except for the territorial waters, the inland maritime waters and the airspace of those territories which are not part of the customs territory of the Community as listed above.

4 DOWNSTREAM USERS ROLE IDENTIFICATION

More guidance can be found in the Guidance for Downstream Users.

4.1 Distributors

You are a distributor if you store and place on the market substances, on their own or in (a) preparation(s), without using them, e.g. you are not re-filling into other containers. In this process you may re-brand the product. Note that if you purchase from outside the EU, you are an importer.

Retailers, re-branders and storage providers have same obligations as distributors.

4.2 End users

You are an end user if you use the substance on its own or in a preparation in your industrial or professional activities without supplying them to customers.

Small downstream users, e.g. workshops, craftsmen and service providers have in principles same obligations as industrial users

4.3 Formulators

Formulators are actors in the supply chain that mix substances and/or preparations into a preparation. The preparations may be intended for use in further formulation steps, for industrial or other professional use, or for consumer use. Some formulators work under contract with another actor (Contract Formulator) without having access to the know-how and details of the preparation and even without owning ingredients or the final preparation.

Re-filling and re-packaging is considered a use under REACH and you therefore have same obligations as other downstream users that use and supply substances or preparations to further professional use downstream.

5 SUBSTANCES AND PREPARATIONS

Substance means a chemical element and its compounds. The term substance includes both substances obtained by a chemical manufacturing process (for example formaldehyde or methanol) and substances in their natural state (for example dried lavender heads). The term substance also includes its additives and impurities where these are part of its manufacturing process, but excludes

any solvent which can be separated without affecting the stability of the substance or changing its composition. Detailed guidance on substances and substance identity can be found in the Guidance on substance identification where the distinction is made between the three following types of substances: mono-constituent substances, multi-constituent substances and UVCB substances.

- A mono-constituent substance is a substance, defined by its quantitative composition, in which one main constituent is present to at least 80% (w/w).
- A multi-constituent substance is a substance, defined by its quantitative composition, in which more than one main constituent is present in a concentration ≥ 10% (w/w) and < 80% (w/w). A multi-constituent substance is the result of a chemical reaction in a manufacturing process. A multi-constituent substance is named as a reaction mass of two or more main constituents.
- A UVCB substance (substances of **U**nknown or **V**ariable composition, **C**omplex reaction products or **B**iological materials) cannot be sufficiently identified by its chemical composition, because: the number of constituents is relatively large and/or the composition is, to a significant part, unknown and/or the variability of composition is relatively large or poorly predictable. As a consequence, UVCB substances require other types of information for their identification, in addition to what is known about their chemical composition.

Preparation means a mixture or solution composed of two or more substances (Article 3(2)). Typical examples of preparations include paints, varnishes, inks. Preparations can contain several substances. Preparations are not the same as multi-constituents substances. The difference between preparation and multi-constituent substance is that a preparation is gained by blending of two or more substances without any chemical reaction occurring, whereas a multi-constituent substance is the result of a chemical reaction. REACH obligations apply individually to each of those substances depending on whether the individual substances are within the scope of REACH. Within the Globally Harmonised System for classification and labelling (GHS), a preparation is named a "mixture"1.

6 SUBSTANCE IN ARTICLE

Guidance on this topic is actually being developed within the REACH Implementation Project 3.8 for the development of Guidance for articles.

As a consequence, the appropriate guidance on this issue is not yet available but will be available soon.

7 USE OF THE SUBSTANCE

If you manufacture or import your substance for the purpose of **PPORD**, you can benefit from a registration exemption by notifying your substance as PPORD. Some guidance on PPORD definition is given below.

If your substance is exclusively a non isolated intermediate, you should have stated that in the first question of the Navigator so go back to question one. Otherwise you might have specific

1 Definition in GHS: “Mixture means a mixture or solution of two or more substances which do not react”

obligations if your substance is used as an **isolated intermediate**. If the use as intermediate is within Product and Processes Oriented Research and Development you should only click on PPORD and not on intermediate, as the exemptions you can benefit from under PPORD should cover the use as an intermediate. Some guidance on Intermediates definitions is given below.

What are the consequences of your choices in your Navigator session?

All chemical substances which are not solely used for the purpose of PPORD, as intermediates, as active substances for use in biocidal products or as active substances or co-formulant for use in plant protection product will have to fulfil the "standard obligations" described in REACH. As a consequence, if you tick the "**other uses**" box you will be directed to the "general" questions and obligations, regardless whether you also clicked on "PPORD" and/or "Intermediate". The only difference in terms of tasks between the situation where you only manufacture or import the substance for "other uses" and the situation where you manufacture or import the substance for "other uses" and for PPORD, is that you will have the choice to either register your substance and cover all your uses into one registration, or register your substance and cover only the uses which are for PPORD in this registration and make a separate PPORD notification for the use as PPORD. Further guidance on these issues can be found in:

- section 1.6.2 of the Guidance on registration
- Guidance for PPORD
- Guidance for intermediates

7.1 Research and Development or PPORD

7.1.1 Definitions

Scientific research and development means *any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year* (Article 3(23)).

Product and process oriented research and development (PPORD) is defined as *any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance* (Article 3 (22)).

Any scientific development on a substance consisting of, for example, campaign(s) for the scaling-up or improvement of a production process in a pilot plant or in the full-scale production, or the investigation of the fields of applications for that substance, falls under the definition of PPORD irrespective of the tonnage involved.

Examples of PPORD activities include:

- Development and testing of a new process for the manufacture of a substance, as for instance when testing a new catalyst, when changing raw materials or when optimising control or manufacturing parameters for improved quality, implying for instance innovative equipment or significant changes in the mass and heat transfer conditions.

- Testing of a new intermediate for the synthesis of a substance for instance in the manufacturing of an active pharmaceutical ingredient (API);
- Development and testing of a new application for a substance; for example the feasibility for use in a new preparation.

7.1.2 Considerations before making a PPORD notification

Prior to an eventual submission of a PPORD notification for a substance to the Agency, the potential PPORD notifier needs to figure out whether the activity he carries out alone or in cooperation with listed customers is within the scope of the definition of product and process oriented research and development (Article 3(22)).

In addition, it is important to figure out, based on the hazardous properties of the substance and the conditions of manufacture and use, whether the substance is effectively handled in reasonably controlled conditions for the protection of human health and the environment. In particular it is useful to take the following considerations into account:

1. Is the substance effectively manufactured and used for the purpose of PPORD?
    - What are the objectives of the research program?
    - What is the scale of the program: who will be exposed to the substance (workers, selected customers?
2. What are the conditions for the manufacture, use and disposal of the substance?
    - What is the process (including batch sizes, identification of any potential losses (e.g. process emissions to waste water, reactor washings and residual material left in containers))
    - Information regarding any treatment of wastes and waste disposal practices for all potential waste streams.
    - Guidance on risk management measures and use description is available in the Guidance on the Chemical Safety Report
    - What is the research program?
    - Description of the program including timelines and quantities used

It should be reminded that the Agency may impose some conditions as described in the Guidance for PPORD and that these should also be taken into account. The above considerations should make it easier for the PPORD notifier and his listed customers to comply with most of the conditions that the Agency may impose.

7.2 Isolated Intermediates

A specific Guidance for intermediates is available.

7.2.1 Definition of intermediates

REACH defines an **intermediate** as a *substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance(s)* (Article 3 (15)). Therefore intermediates should not be present in the final manufactured substance (except possibly as an impurity).

Different types of intermediates are defined under REACH:

- Non-isolated intermediates
- Isolated intermediates
  - On-site (non transported) isolated intermediates
  - Transported isolated intermediates

A non-isolated intermediate is 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 pipework 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* (*Article 3 (15)(a)*).

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 (Article 3 (15)(b)).*

A site means *a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared (Article 3(16)).*

A transported isolated intermediate is *an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites (Article 3 (15)(c)).*

Depending on the identified intermediates different obligations and information requirements apply.

The lifecycle of an isolated intermediate begins with its manufacture (in practical terms, with its removal from the manufacturing process). This lifecycle ends with the use of the substance in the synthesis process for the manufacture of another substance.

Residues of the isolated intermediate, which are not transformed into another substance in a manufacturing process, will be typically discarded or disposed of as waste and channelled into waste management when not recycled as a non-isolated or isolated intermediate. Consequently, they no longer fall in the scope of REACH. Where residues of the intermediate are found in the synthesised substance, they are covered – as an impurity - by the registration and evaluation of that other substance.

7.2.2 Strictly controlled conditions

This guidance can also be found in the section 2.1 of the Guidance for intermediates.

Strictly controlled conditions

For both on-site and transported isolated intermediates the possibility to provide a reduced set of information for their registration applies when:

- *For on-site isolated intermediates, the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle (Article 17(3)).*
- *For transported isolated intermediates, the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under strictly controlled conditions* detailed in *Article18(4)*. For transported isolated intermediates that are manufactured in the EU the strictly controlled conditions shall apply both to the manufacture and use of the substance (on both EU and non-EU sites in case of the use).

Therefore, in order to benefit from the reduced registration requirements the registrants have to first assess if their intermediates are handled under strictly controlled conditions on the sites of manufacture and uses. When filling his registration dossier using IUCLID[2]5 the registrant must report if the substance is manufactured and used under strictly controlled conditions or not and can provide the confirmation of this.

To assess if the intermediate is manufactured and used under strictly controlled conditions during its whole lifecycle, the registrant should evaluate if the following conditions, as detailed in *Article 18(4)*, are in place:

(a) *the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;* (see chapter 2.1.1)

(b) procedural and control technologies shall be used that minimise emission and any resulting exposure; (see chapter 2.1.2)

(c) only properly trained and authorised personnel handle the substance; (see chapter 2.1.3)

(d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;

(e) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures; (see chapter 2.1.4)

(f) substance-handling procedures are well documented and strictly supervised by the site operator.

The definition of strict control in *Article 18(4)* for transported isolated on-site intermediates can be used as a working basis for isolated on-site intermediates also. *Article 18(4)* provides a wider definition of strict control than *Article 17(3)* which is limited to criteria (a) and (b) of the above list. This does not mean that criteria (c) to (f) cannot also be appropriate criteria to determine strict control also for on-site isolated intermediates. This definition covers both: (i) normal operating conditions and (ii) non-routine operational circumstances such as maintenance and incidents.

For both types of intermediates, on the basis of the assessment and description of the conditions under which the substance is manufactured and/or handled on site(s) of both the manufacturer and the user in case of transported intermediates, the registrant has two possibilities:

[2] International Uniform Chemical Information Database

- Submit a registration dossier containing the limited set of data requested for intermediates, provided that he concludes that the substance is manufactured and used under strictly controlled conditions.
- Submit a full registration dossier as described in *Article 10*, if he is not able to conclude that the substance is manufactured and used under strictly controlled conditions.

Strictly controlled conditions should be seen as a combination of technical measures that are underpinned by management systems. This approach to managing human health and environmental risks aligns with and acknowledges the existing regulatory obligations that impact on manufacturers of substances (e.g. control of accidents under Directive 96/82/EC3, Integrated Pollution Prevention and Control under Directive 96/61/EC4, occupational protection under the Chemical Agents Directive 98/24/EC5). This approach includes training, process controls, management systems, monitoring, personal protective equipment (PPE) where combinations of 'hardware' and 'software' measures (using, in some cases, a hierarchy of preferences) strictly control risks. However it should be kept in mind that the use of PPE, for example, should not have a prime role when determining whether workplace exposures to an intermediate are strictly controlled as the use of such measures alone generally cannot equate to strictly controlled conditions. It is recognised that PPE should be recommended and used especially in relation to sampling, maintenance and repair.

A full explanation of the strictly controlled conditions in place is not required in the registration dossier, however the assessment of the use(s) of any substance (or group of similar substances) as an intermediate(s) should be documented within a company in order to show the adequacy of the measures as authorities may request such information which then must be made available. Where relevant, documentation for compliance with other legislative frameworks can also be referred to.

The documentation may include:

- justification for the assignment of use as an intermediate to the substance, including customers' statements if a transported isolated intermediate;
- the relevant operating conditions;
- the risk management measures implemented in the company and recommended to external customers; and
- the corresponding exposure considerations;
- reference or derivation of any relevant threshold value (e.g. Derived No Effect Levels (DNELs), Predicted No Effect Concentrations (PNECs)) including the relevant physico-chemical, toxicological and ecotoxicological data, including data from substance grouping where available.

The details of the risk management measures applied and recommended to the user, which reflect the strictly controlled conditions, should be included in the registration dossier. Existing legislative frameworks or industry standards can be used when documenting the risk management.

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[3] Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances.

[4] Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control

[5] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work.

To facilitate the process for assessing whether strict control is achieved, Appendix 1 presents an indicative and non-exhaustive list of issues that could be considered. This approach is only intended as a user-friendly tool to document the process of assessing the conditions of strict control. The actual process behind answering the questions involves considerable analyses by relevant people (e.g. site managers, engineers). Although transported isolated intermediates require communication through the supply chain for confirmation that strictly controlled conditions are achieved, the process for documenting strict control does not require the interchange of information that could be seen to constitute confidential business information (e.g. fine detail of process technology and/or engineering, etc).

An example of a general format to document how the substance is manufactured and used in strictly controlled conditions is also proposed in Appendix 2. This should contain information and justification on the relevant issues raised in Appendix 1. Please also note that any information produced for the purpose of other pieces of legislation (e.g. worker protection legislation) can of course be used as an element to demonstrate strictly controlled conditions.

1. Rigorous containment of the substance

Rigorous containment is the combination of technical and procedural measures that ensure that exposure (whether to man or the environment) is reduced so that risks are strictly controlled. It is applicable to handling intermediates at any scale.

In every case, the successful management of risk is central to the concept of rigorous containment: when no hazard and risk information is available, then intermediates have to be treated as hazardous substances, with the accompanying need to ensure (and demonstrate) that emissions and exposure are minimised. When information on hazard is available for an intermediate, then the intermediate will be handled under appropriate conditions that ensure that any risks rising from handling the substance are strictly managed. Consequently, the way that rigorous containment can be achieved may vary according to the knowledge of an intermediate's physicochemical and hazard properties.

The intermediate needs to be rigorously contained by technical means during its whole life cycle which includes the manufacture, the isolation of the intermediate out of the reaction mixture, if necessary further purification steps (e.g., distillation, re-crystallisation, filtration), cleaning and maintenance, sampling, analysis, loading and unloading of equipment/vessels, waste disposal/purification and storage, and the use in synthesis.

To be able to confirm and document in-house the rigorous containment of the substance, the registrant should characterise the processes during its whole life-cycle and equipment used to characterise the level of containment taking into account the properties of the substance.

The description of these technical means and conditions should allow the identification of potential exposure of workers and the environment to the substance. One way to do this is to assure the necessary level of leakproofness of the different functional elements (pressurised vessels, seals, sacks, containers, drums, etc.) involved during the different steps of the whole process such as manufacture, transfer (filling, emptying, etc.) or sampling of the substance when potential emission could be expected to the workplace or the environment.

For example, isolated intermediate packaging and containers should only remain open for short periods during equipment filling and emptying (via hose lines, pipe joints), during sampling (transfer from one container to another container via closed sampler) and when performing cleaning and maintenance. Consideration should be given to the transfer and management of the isolated intermediate in bulk through pipelines and dedicated bulk storage facilities. Containers or equipment open for any extended period of time should have suitable measures in place, which will

be consistent with the characteristics and properties of the intermediate, e.g. efficient exhaust ventilation, to prevent any significant release of the substance into the immediate surroundings from the container. For companies operating batch processes in discontinuous equipment there may be other considerations, but the risk management adopted in these companies must also identify a suitable combination of technical measures.

Examples of technical measures that could be implemented in order to ensure rigorous containment are given in examples 2 to 3 for workers and environmental protection in different industrial sectors. Those examples are in no way binding or exhaustive but illustrate the types of measures that can be applied.

Example 1 Pharmaceutical industry: examples of technical measures for workers and environmental protection.

Wherever possible, design containment is implemented to prevent exposure of the worker. The design and selection of control technologies and equipment is based upon a set of performance based criteria. The selection of control measures that aim to control and prevent emissions at source are prioritised. Examples of technical measures may include:

- Transfers using direct coupling and closed systems, also selected use of unidirectionalised air flow booths. . Examples include:
  - Engineered Airflow Device
  - Ventilated enclosures e.g. laminar flow/powder containment booth
  - Vertical process trains
  - Special valving such as split butterfly valves
  - Vacuum transfer
  - Intermediate bulk containers
- Totally enclosed processes; transfers using direct coupling; barrier/isolator technology. Examples include:
  - Isolation technology e.g. isolators
  - Intermediate bulk containers with split butterfly values
  - Soft Wall Isolators (Glove bags)
  - Alpha Beta Rapid Transfer systems on enclosures
  - Specialised Vacuum transfer systems

Emissions and exposures of the environment are controlled by technical measures.

Examples of technical measures to control emissions to the environment may include:

- Waste gas incineration: complete destruction of waste gases at high temperatures () for a specified minimum residence time, as calculated by an engineer
- Condenser – low temperature devices through which waste vapours are sent causing them to liquefy and be collected.
- Scrubber – number of types available. Usually packed columns around which an appropriate scrubbing solution circulates, as specified by an engineer. The waste vapours from a process and/or area are passed through the scrubber causing the fumes to be trapped in the scrubbing solution. The waste scrubber solution is then disposed of by incineration.
- Hepa-filter – a filter designed to trap small particles. The general air from an area or a piece of equipment passes through the filter before discharge to atmosphere. The contaminated filter is then disposed of by incineration.
- WWTP – a wastewater treatment plant is a biological system to which the aqueous wastestreams from a process and washing/cleaning solutions are sent. Microbes in the WWTP break down the organic constituents of the wastestreams to CO2 and water before discharge into the environment.
- Cryogenic treatment is a very low temperature condenser which traps all the condensable materials as a liquid or a solid. This liquid or solid is then disposed of by incineration.

Example 2 Petrochemical Industry: example of technical measures for workers and environmental protection.

Bulk petrochemical intermediates will invariably be handled in a chemical plant of a high integrity that is designed to minimise potential for emissions to air and water. Typical examples of control measures and systems in place to deliver such strictly controlled conditions include:

- Enclosed transfers designed to prevent leaks e.g. self-draining transfer lines
- High integrity methods of material loading and unloading (e.g dry lock couplings, vapour capture and recovery)
- Plant designed to facilitate the draining and flushing of plant equipment items prior to maintenance, with recycle and/or suitable disposal of wastes
- High integrity (low emission) valve packings and flange seals
- In-line process controls and/or contained systems for process sampling
- Low emission pumps e.g. canned, magnetic, mechanical seals
- Routine monitoring and inspection for leaks to reduce fugitive emissions

Example 3 Fine chemicals industry: examples of technical measures for workers and environmental protection.

Handling intermediates in batch fine chemicals facilities will require that the plant engineering and systems are designed to minimise potential for emissions to air and water. Typical examples of control measures and systems which might be encountered to deliver such strictly controlled conditions include:

- Material transfers via enclosed systems (e.g. semi-bulk containers such as IBCs)
- Enclosed and vented charging systems (e.g. bag slitters with integral package disposal)
- Discharging arrangements designed to minimise emissions (e.g. into drums/kegs via pneumatic filling heads and continuous liners; vented booths with exhaust scrubbing)
- Plant designed to facilitate the draining and flushing (and detoxification) of equipment items prior to maintenance
- Maximal use made of automated process control systems to minimise manual interventions
- Contained process sample systems (e.g. vented cabinets or sample bombs)

If the information available to determine whether the substance is rigorously contained during manufacture, use and handling, is not sufficient, then reliable model calculations and/or monitoring data could also be used to assess the exposure of workers or the environment to the substance.

Product-based containment procedures depend on the form and use of the substance, e.g. some degree of containment is inherent in a liquid or a pasty substance with a very low vapour pressure or a solid that does not release dust in repacking/decanting or processing activities. Where a substance is in a matrix used for synthesis (e.g. masterbatch, glass, plastic), containment depends on the potential migration of the substance from the matrix.

2. Procedural and control technologies to minimise emission and any resulting exposure

Any significant release of the substance into the wider environment should be prevented through containment procedures, such as suitable physical barriers (e.g. bunds) and/or chemical barriers (e.g. membranes). Operations on site should be managed in order to ensure containment within the site premises wherever possible, including accident prevention, as specified under the section entitled Management Systems.

An additional way to minimise emissions and resulting exposure is to apply procedural and control technologies when emissions have been identified. Such technologies allow to still consider the substance to be rigorously contained. For example, in case of emissions to waste water (including during cleaning and maintenance processes), it will be considered that the substance is rigorously contained if the registrant can prove that techniques are used to minimise the emissions by, for example, incinerating the waste water or extracting the intermediate from it. The same applies to emissions to air or disposal of wastes where procedural and control technologies are used to minimise potential exposure of humans and environment. The efficiency of any methods applied to minimise emissions and resulting exposure should be described and documented in-house. Furthermore the details of these methods (e.g. efficiency) must be included and described in the registration dossier. The documentation and description of methods applied can be based on the company's IPPC licence or permit, as long as sufficient and adequate documentation of the compliance with the conditions of the permit are available, and demonstrate rigorous containment of the substance.

Following an assessment of containment, the selection and use of further risk management measures, equipment standards and safety procedures will vary considerably across industry and be dependent on the process and on the physico-chemical properties and the hazard of the substance, when sufficiently well known.

3. Handling of the substance by trained personnel

In order to minimise emissions and any resulting exposure, it is important that only trained and authorised personnel handle the substance (*Article 18(4)(c)*). As a minimum, the registrant should take care that the workers who handle intermediates are provided with:

- training and information on appropriate precautions, working procedures during the malfunctioning of the process and in accidental situations, and actions to be taken in order to safeguard themselves and other workers at the workplace.
- access to a safety data sheet (SDS), which includes information on the hazardous properties of the substance, such as its identity, the risks to safety and health, relevant occupational exposure limit values (EU and national ones) and other relevant legislative provisions.

These procedures should apply to all personnel handling the substance including during cleaning and maintenance works.

4. Cases of accident and where waste is generated

There must be procedural and/or control technologies in place that are used in cases of accidents and in cases where waste is generated (*Article 18(4)(e)*). In this, the clarifications according to the Directive 96/82/EC on the control of major-accident hazards involving dangerous substances and the Directive 94/9/EC concerning equipment and protective systems intended for use in potentially explosive atmospheres might usefully be consulted.

5. Management System

Management systems are good options to ensure the proper application of risk management measures. A management system should include the relevant operational procedures to ensure that

control measures are indeed applied[6]. Such a system may also define management responsibilities, authorisation procedures (e.g. for maintenance or opening of equipment, inspection and auditing requirements etc).

On any given site, a management system should contain reference to procedures for accident prevention and response. It may be appropriate to link this system to operational engineering control systems. In case of a transported intermediate, the various parties involved (supplier and customer) each will need a management system in order to ensure rigorous containment and controlled conditions over the life cycle of the intermediate.

Legal reference: Article 17 and Article18

8 TONNAGE ISSUES

Guidance on how to calculate the total tonnage relevant for one manufacturer or importer of a substance or articles and/or producer of articles is given below as well as guidance on how to calculate the tonnage in case of exemptions to the "normal" registration obligations which might influence the calculation of the total tonnage for registration.

8.1 How to calculate total tonnage?

Addition of the volumes

Each legal entity manufacturing or importing a substance is required to submit its own registration. The tonnage covered by a registration corresponds to the full tonnage manufacturer or imported by the legal entity.

For the calculation of the yearly tonnage it is necessary to sum up all volumes of the substance that are intended to be manufactured and imported by the given registrant and that are not exempted from registration. This means, for example, that if a substance is imported in several preparations, the volumes of the substance in each preparation (calculated using the amount of the substance present in these preparations) will have to be added.

In the case that the same registrant manufactures and/or imports the same substance at different sites which belong to the same legal entity, then the volume of substance to be registered is the total of the volumes of the substance manufactured and/or imported at the different sites, because the sites are not separate legal entities.

Moreover, if a substance manufactured by a single non EU-manufacturer is imported in several articles from which it is intended to be released, the potential registrant needs to sum up all volumes of the substance present in those articles. For this purpose, he needs to count only those articles from which the substance is intended to be released. Whenever a substance is intended to be released from an article, the whole amount present in that article needs to be counted and not only the amount intended to be released.

Example:

If a company X imports three articles A, B, and C with 60 tonnes of the substance present in

[6] In practice management systems include the structure to respond to accidents and demonstrate compliance with relevant occupational and environmental legislation and/or standards.

each but:

- in article A, the substance is not intended to be released
- in article B, 40 out of 60 tonnes are released under normal conditions
- in article C 10 out of 60 tonnes are released under normal conditions

the company X will need to register the total volume of the substance in article B and C: 120 tonnes, i.e. in the 100-1000 tonnes band.

Calculation of the amount of substance in a preparation or in articles

Specific situations may occur for substances present in preparations of in articles:

Amount of a substance in a preparation

In order to be able to calculate the amount of a substance in a preparation, the total volume of the preparation is multiplied by the fraction of the constituent substance. This value can for example be obtained from the safety datasheet of the preparation. When only a range of concentrations of a substance in a preparation is available then the maximum volume of the substance is calculated using the highest possible content of that substance in the preparation. Without more precise information on the composition, this volume should be used for the purpose of registration.

Amount of a substance in an article

In the case of articles which contain a substance that is intended to be released under normal or reasonably foreseeable conditions of use, then:

- If the weight by weight content of that substance is known, then this value is multiplied by the total mass of the produced and/or imported article; or
- If the weight of substance per unit article is known then this value is multiplied by the total number of imported articles.

More detailed guidance can be found in Guidance for articles.

Calculations of yearly tonnage for phase-in and non phase-in substances

There are different rules to be applied on how to calculate a yearly tonnage for the registration dossier for phase-in and non phase-in substances (see *Article 3(30)*).

Tonnage for **non phase-in substances** in the registration dossier

The volume of a non-phase-in substance to be reported in a registration dossier is the estimated quantity that is expected to be manufactured and/or imported in the calendar year (1 January – 31 December) of registration (see *Article 3(30)*). The definition of non phase-in substances can be found in the section 1.7.1.2 of the Guidance on registration.

Calculation of the tonnage for the registration of **phase in-substances** that have been pre-registered

The definition of **phase-in substance** can be found in section 1.7.1.1 of the Guidance on registration.

In the case of a phase-in substance that has been imported or manufactured for at least three consecutive years, the quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years (see *Article 3(30)*). If the substance has

not been manufactured or imported for 3 consecutive years then the calendar year tonnage should be used.

This provision has been put in place to avoid situations where a sudden increase in demand would lead to the impossibility to comply with the registration obligations. This value is to be used for the purpose of pre-registration as well as for registration. The highest yearly tonnage calculated after 1 June 2007 determines the deadline for registration.

Examples are available in section 1.6.2.4 of the Guidance on registration.

8.2 Calculation of the tonnage in case of exemptions

In principle a registrant needs to calculate total volume of the substance he manufactures or imports and based on that decide whether the registration must be submitted and within which tonnage band. However if certain **exemptions to registration** apply to the specific substance, the potential registrant does not need to include those quantities in his calculation to determine the volume he has to register.

- Some substances or specific uses of some substances are totally exempted to registration. These exemptions to registration can be found in section 1.6.3 of the Guidance on registration.

Example 1: When a use is exempted from registration

If a company manufactures a substance to be used in a medicinal product, it does not need to register the substance for that use. However, this company or its customers may at the same time make other uses of the same substance. To determine its registration obligation under REACH, it must count the quantities for the other uses. E.g., company A is a manufacturer manufacturing 120 tonnes of magnesium hydroxide in year X. 70 tonnes are used in medicinal products and 50 tonnes are used for the formulation of a preparation. The 50 tonnes used for the formulation of the preparation will be subject to the provisions of the REACH Regulation, while the 70 tonnes used in medicinal products are exempted from registration under REACH Regulation. As the total tonnage to be counted for registration purposes is 50 tonnes, the company must register in the 10-100 tonnes band.

- Substances manufactured or imported for the purpose of Product **and Process Orientated** Research **and Development (PPORD)** can also be exempted from registration under certain conditions (see Guidance for PPORD) as long as a PPORD notification is submitted to the European Chemicals Agency and any conditions set by the Agency are fulfilled (see *Article 9*).

Example 2: Tonnage to consider for the registration dossier in case of PPORD use

If a company manufactures 11 t/a of a substance, of which 2.0 t/a are for PPORD, the registration obligation is defined by the 9.0 t/a, i.e. the information requirements in *Annex VIII* do not pertain.

- Manufacturers or importers of **isolated intermediates** can, under certain conditions (see Guidance for intermediates) submit a registration dossier containing a limited set of information (see *Article 17* and *18*).

When a substance is manufactured or imported for several of these uses (for PPORD, as intermediate and for other uses) the registrant has the possibility to submit:

- one notification dossier for the use under PPORD
- one registration dossier covering both the use as isolated intermediate and the other uses. If the manufacture or use(s) as intermediate are not under strictly controlled conditions, then the manufacturer or importer needs to submit a "standard" registration dossier according to *Article 10*. If part of the tonnage manufactured or imported is for uses as intermediate under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirement of the registration dossier. Nevertheless the use as intermediate should be documented in the dossier, including the volume manufactured or imported for this purpose.

Example 3 Tonnage to consider for the registration dossier

A company manufactures 2300 tonnes of substance A, of which 1700 tonnes are used as intermediate in strictly controlled conditions. This company will submit a registration dossier for substance A, where the volume of the remaining 600 tonnes not used as intermediate is used to determine the information requirements. This means that the information requirements for 100-1000t substances will be used as a basis for this dossier. The fact that the substance is also used as an intermediate should be indicated in the dossier and the volume of 1700 tonnes used as intermediates will also need to be documented in the dossier.

9 CLASSIFICATION AND LABELLING

9.1 Does the substance meet the criteria for classification as dangerous ?

Explanations on **classification and labelling** are given below.
Guidance on how to find out whether your substance or preparation is dangerous for human health and/or the environment and/or has dangerous physical chemical properties can also be found below.

As a manufacturer or importer of a substance or preparation, you **have to consider classification of** your substance in accordance with Article 4 to **Directive 67/548/EEC**, as most recently amended by **Directive 92/32/EEC**, and your preparation in accordance with **Directive 1999/45/EC**. The properties that are considered as dangerous (physico-chemical properties, health hazards and environmental hazards) are listed in Article 2(2) of Directive 92/32/EEC and are the following:

Physico-chemical properties:

explosive

oxidising

extremely flammable

highly Flammable

flammable

Health hazards:

very toxic

toxic

harmful

corrosive

irritant

sensitising: to skin and respiratory tract

carcinogenic

mutagenic

toxic for reproduction

Environmental hazards:

dangerous for the environment

Under REACH (article 112) a classification and labelling inventory will be created which will contain the classification and labelling for all the substances which are placed on the market and are:

a) subject to registration (i.e. manufactured or imported above 1 tonne per year) or,

b) within the scope of Article 1 of Directive 67/548/EEC, which meet the criteria for classification as dangerous in accordance with that Directive, and which are placed on the market either on their own, or in a preparation above the concentration limits specified in Directive 1999/45/EC, where relevant, which results in the classification of the preparation as dangerous.

Therefore, this classification and labelling inventory, publicly accessible, will contain all classification and labelling made by industry.

In addition, Annex I to Directive 67/548/EEC as last updated with **Directive 2004/73/EC** (the 29th Adaptation to Technical Progress) contains all dangerous substances for which a harmonised classification and labelling has been agreed in the EU. A possibility for harmonisation of Classification and Labelling is also foreseen under REACH, and substances with such a harmonised classification and labelling will continue being added to Annex I to Directive 67/548/EEC.

How to find out whether your substance or preparation is dangerous for human health and/or the environment and/or has dangerous physical chemical properties?

To be able to determine whether or not your substance or preparation is dangerous and therefore subject to classification and labelling under Directive 67/548/EEC you need to:

1) Look in Annex I to Directive 67/548/EEC, containing all dangerous substances for which there is a harmonised classification and labelling in the EU. This can be done at the following website: http://ecb.jrc.it/classification-labelling/, where you can search the classification and labelling database. Published and legally binding classifications can be found in the 'classlab' database and recommendations for classification can be found in the 'workclab' database. When your substance is listed in Annex I to Directive 67/548/EEC, you are obliged to classify and label your substance accordingly.

When your substance is not listed on Annex I and has not (yet) been evaluated, you need to:

2) Gather test and non-test data for physico-chemical properties, toxicological properties and environmental fate and effect properties of the substance. Guidance on Gathering all existing available information is available in the section 8.1.3.1 of the Guidance on registration.

3) Interpret the available information for the substance or the preparation.

4) Determine the hazard classification of your substance on basis of the test and non-test results in accordance with Article 4 (See Directive 92/32/EEC) and the classification and labelling criteria laid down in Annex VI to Directive 67/548/EEC, as last amended by **Directive 2001/59/EC** OR

   Determine the hazard classification of your preparation on basis of the test and non-test results in accordance with Article 4 to **Directive 1999/45/EC** and the classification and labelling criteria laid down in Annex VI to Directive 67/548/EEC, as last amended by **Directive 2001/59/EC**. Your preparation is also considered dangerous when it contains a dangerous substance which exceeds a certain concentration limit in the preparation, depending on the toxicological properties of the substance. For health and environmental hazards, general concentration limits, above which a preparation is considered as dangerous, are provided in Annexes II and III parts B to **Directive 1999/45/EC.**

   You could consult the Classification and Labelling Inventory to figure out whether your substance has already been classified by another party and, if yes, what was the proposed classification.

All references to classification and labelling terminology, criteria and Directives are going to be amended as soon as the new EU Regulation, implementing the Globally Harmonised System for classification and labelling, is entering into force. This is foreseen to happen in 2008.

9.2 Is your substance CMR Category 1 or 2 or classified as N R50/53?

Phase-in substances that are manufactured or imported in quantities reaching 1000 tonnes or more per year, as well as substances classified as Carcinogenic, Mutagenic or Reprotoxic (CMR) category 1 or 2, manufactured or imported in quantities reaching 1 tonne per year and substances that are classified as N R50/53 and manufactured or imported in quantities reaching 100 tonnes per year have to be registered by the 1st December 2010.

Carcinogenic, Mutagenic and Reprotoxic substances can be placed in 3 categories (1, 2 and 3) in accordance with the classification and labelling criteria of Annex VI(4.2) to Directive 67/548/EEC, as last updated with **Directive 2001/59/EC**. You must control whether the criteria for any of the two more serious categories (i.e. category 1 or 2) are fulfilled. Category 1 is for all three end-points defined as a substance known from human experience to have these effects, and Category 2 should be considered as a human carcinogen, mutagen or reprotoxic substance based on animal data.

N; R50/53 indicates that the substance is very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment. Criteria for classification for this environmental hazard can be found in Annex VI(5.2) to Directive 67/548/EEC, as last updated with Directive 2001/59/EC. You must control whether the criteria are fulfilled for you substance.

All references to classification and labelling terminology, criteria and Directives are going to be amended as soon as the new EU Regulation, implementing Globally Harmonised System for classification and labelling, is entering into force. This is foreseen to happen in 2008.

The following criteria are extracted from Directive 2001/59/EC. It does not correspond to the full text, but only refers to the parts relevant for the classification as CMR cat 1 or 2.

4. CLASSIFICATION ON THE BASIS OF SPECIFIC EFFECTS ON HUMAN HEALTH

4.2.1. Carcinogenic substances

For the purpose of classification and labelling, and having regard to the current state of knowledge, such substances are divided into three categories:

Category 1

Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

Category 2

Substances which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:

- appropriate long-term animal studies,
- other relevant information.

Category 3

Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in Category 2.

Comments regarding the categorisation of carcinogenic substances

The placing of a substance into Category 1 is done on the basis of epidemiological data; placing into Categories 2 and 3 is based primarily on animal experiments.

For classification as a Category 2 carcinogen either positive results in two animal species should be available or clear positive evidence in one species, together with supporting evidence such as genotoxicity data, metabolic or biochemical studies, induction of benign tumours, structural relationship with other known carcinogens, or data from epidemiological studies suggesting an association.

4.2.2. Mutagenic substances

Category 1

Substances known to be mutagenic to man.

There is sufficient evidence to establish a causal association between human exposure to a substance and heritable genetic damage.

Category 2

Substances which should be regarded as if they are mutagenic to man.

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of heritable genetic damage, generally on the basis of:

- appropriate animal studies,
- other relevant information.

Category 3

Substances which cause concern for man owing to possible mutagenic effects. There is evidence from appropriate mutagenicity studies, but this is insufficient to place the substance in Category 2.

Comments regarding the categorisation of mutagenic substances

Definition of terms:

A mutation is a permanent change in the amount or structure of the genetic material in an organism, resulting in a change of the phenotypic characteristics of the organism. The alterations may involve a single gene, a block of genes, or a whole chromosome. Effects involving single genes may be a consequence of effects on single DNA bases (point mutations) or of large changes, including deletions, within the gene. Effects on whole chromosomes may involve structural or numerical changes. A mutation in the germ cells in sexually reproducing organisms may be transmitted to the offspring. A mutagen is an agent that gives rise to an enhanced occurrence of mutations.

It should be noted that substances are classified as mutagens with specific reference to inherited genetic damage. However, the type of results leading to classification of chemicals in Category 3: 'induction of genetically relevant events in somatic cells`, is generally also regarded as an alert for possible carcinogenic activity.

Method development for mutagenicity testing is an ongoing process. For many new tests no standardised protocols and evaluation criteria are presently available. For the evaluation of mutagenicity data the quality of the test performance and the degree of validation of the test method have to be considered.

Category 1

To place a substance in Category 1, positive evidence from human mutation epidemiology studies will be needed. Examples of such substances are not known to date. It is recognised that it is extremely difficult to obtain reliable information from studies on the incidence of mutations in human populations, or on possible increases in their frequencies.

Category 2

To place a substance in Category 2, positive results are needed from assays showing (a) mutagenic effects, or (b) other cellular interactions relevant to mutagenicity, in germ cells of mammals in vivo, or (c) mutagenic effects in somatic cells of mammals in vivo in combination with clear evidence that the substance or a relevant metabolite reaches the germ cells.

With respect to placement in Category 2, at present the following methods are appropriate:

2 (a) in vivo germ cell mutagenicity assays:

- specific locus mutation test,

- heritable translocation test,
- dominant lethal mutation test.

These assays actually demonstrate the appearance of affected progeny or a defect in the developing embryo.

2 (b) in vivo assays showing relevant interaction with germ cells (usually DNA):

- assays for chromosomal abnormalities, as detected by cytogenetic analysis, including aneuploidy, caused by malsegregation of chromosomes,
- test for sister chromatid exchanges (SCEs),
- test for unscheduled DNA synthesis (UDS),
- assay of (covalent) binding of mutagen to germ cell DNA,
- assaying other kinds of DNA damage.

These assays provide evidence of a more or less indirect nature. Positive results in these assays would normally be supported by positive results from in vivo somatic cell mutagenicity assays, in mammals or in man (see under Category 3, preferably methods as under 3 (a)).

2 (c) in vivo assays showing mutagenic effects in somatic cells of mammals (see under 3 (a)), in combination with toxicokinetic methods, or other methodologies capable of demonstrating that the compound or a relevant metabolite reaches the germ cells.

For 2 (b) and 2 (c), positive results from host-mediated assays or the demonstration of unequivocal effects in in vitro assays can be considered as supporting evidence.

4.2.3. Substances toxic to reproduction

Category 1:

Substances known to impair fertility in humans

There is sufficient evidence to establish a causal relationship between human exposure to the substance and impaired fertility.

Substances known to cause developmental toxicity in humans

There is sufficient evidence to establish a causal relationship between human exposure to the substance and subsequent developmental toxic effects in the progeny.

Category 2

Substances which should be regarded as if they impair fertility in humans

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in impaired fertility on the basis of:

- clear evidence in animal studies of impaired fertility in the absence of toxic effects, or, evidence of impaired fertility occurring at around the same dose levels as other toxic effects

but which is not a secondary non-specific consequence of the other toxic effects,

- other relevant information.

Substances which should be regarded as if they cause developmental toxicity to humans

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in developmental toxicity, generally on the basis of:

- clear results in appropriate animal studies where effects have been observed in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of the other toxic effects,
- other relevant information.

Substances which cause concern for humans owing to possible developmental toxic effects

Generally on the basis of:

- results in appropriate animal studies which provide sufficient evidence to cause a strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of the other toxic effects, but where the evidence is insufficient to place the substance in Category 2,
- other relevant information.

Category 3

Substances which cause concern for human fertility

Generally on the basis of:

- results in appropriate animal studies which provide sufficient evidence to cause a strong suspicion of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occuring at around the same dose levels as other toxic effects, but which is not a secondary non-specific consequence of the other toxic effects, but where the evidence is insufficient to place the substance in Category 2,
- other relevant information.

Substances which cause concern for humans owing to possible developmental toxic effects

Generally on the basis of:

- results in appropriate animal studies which provide sufficient evidence to cause a strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of the other toxic effects, but where the evidence is insufficient to place the substance in Category 2,

other relevant information.

Comments regarding the categorisation of substances toxic to reproduction

Reproductive toxicity includes impairment of male and female reproductive functions or capacity and the induction of non-inheritable harmful effects on the progeny. This may be classified under

two main headings of 1. Effects on male or female fertility; 2. Developmental toxicity.

Effects on male or female fertility, includes adverse effects on libido, sexual behaviour, any aspect of spermatogenesis or oogenesis, or on hormonal activity or physiological response which would interfere with the capacity to fertilise, fertilisation itself or the development of the fertilised ovum up to and including implantation.

Developmental toxicity, is taken in its widest sense to include any effect interfering with normal development, both before and after birth. It includes effects induced or manifested prenatally as well as those manifested postnatally. This includes embrytoxic/fetotoxic effects such as reduced body weight, growth and developmental retardation, organ toxicity, death, abortion, structural defects (teratogenic effects), functional defects, peri-postnatal defects, and impaired postnatal mental or physical development up to and including normal pubertal development.

Classification of chemicals as toxic to reproduction is intended to be used for chemicals which have an intrinsic or specific property to produce such toxic effects. Chemicals should not be classified as toxic to reproduction where such effects are solely produced as a non-specific secondary consequence of other toxic effects. Chemicals of most concern are those which are toxic to reproduction at exposure levels which do not produce other signs of toxicity.

The placing of a compound in Category 1 for effects on fertility and/or developmental toxicity is done on the basis of epidemiological data. Placing into Categories 2 or 3 is done primarily on the basis of animal data. Data from in vitro studies, or studies on avian eggs, are regarded as 'supportive evidence' and would only exceptionally lead to classification in the absence of in vivo data.

In common with most other types of toxic effect, substances demonstrating reproductive toxicity will be expected to have a threshold below which adverse effects would not be demonstrated. Even when clear effects have been demonstrated in animal studies the relevance for humans may be doubtful because of the doses administered, for example, where effects have been demonstrated only at high doses, or where marked toxicokinetic differences exist, or the route of administration is inappropriate. For these or similar reasons it may be that classification in Category 3, or even no classification, will be warranted.

Annex V to the Directive specifies a limit test in the case of substances of low toxicity. If a dose level of at least 1000 mg/kg orally produces no evidence of effects toxic to reproduction, studies at other dose levels may not be considered necessary. If data are available from studies carried out with doses higher than the above limit dose, this data must be evaluated together with other relevant data. Under normal circumstances it is considered that effects seen only at doses in excess of the limit dose would not necessarily lead to classification as 'Toxic to reproduction`.

EFFECTS ON FERTILITY

For the classification of a substance into Category 2 for impaired fertility, there should normally be clear evidence in one animal species, with supporting evidence on mechanism of action or site of action, or chemical relationship to other known anti-fertility agents or other information from humans which would lead to the conclusion that effects would be likely to be seen in humans. Where there are studies in only one species without other relevant supporting evidence then classification in Category 3 may be appropriate.

Since impaired fertility may occur as a non-specific accompaniment to severe generalised toxicity or where there is severe inanition, classification into Category 2 should only be made where there is evidence that there is some degree of specificity of toxicity for the reproductive system. If it was

demonstrated that impaired fertility in animal studies was due to failure to mate, then for classification into Category 2, it would normally be necessary to have evidence on the mechanism of action in order to interpret whether any adverse effect such as alteration in pattern of hormonal release would be likely to occur in humans.

DEVELOPMENTAL TOXICITY

For classification into Category 2 there should be clear evidence of adverse effects in well conducted studies in one or more species. Since adverse effects in pregnancy or postnatally may result as a secondary consequence of maternal toxicity, reduced food or water intake, maternal stress, lack of maternal care, specific dietary deficiencies, poor animal husbandry, intercurrent infections, and so on, it is important that the effects observed should occur in well conducted studies and at dose levels which are not associated with marked maternal toxicity. The route of exposure is also important. In particular, the injection of irritant material intraperitoneally may result in local damage to the uterus and its contents, and the results of such studies must be interpreted with caution and on their own would not normally lead to classification.

The following criteria are extracted from Directive 2001/59/EC. It does not correspond to the full text, but only refers to the parts relevant for the classification as N, R50/53

5.2. Criteria for classification, indication of danger, choice of risk phrases

5.2.1. Aquatic environment

5.2.1.1. Substances shall be classified as dangerous for the environment and assigned the symbol 'N' and the appropriate indication of danger, and assigned risk phrases in accordance with the following criteria:

R50 Very toxic to aquatic organisms

Acute toxicity: 96 hr LC50 (for fish) < 1 mg/l

or 48 hr EC50 (for Daphnia) < 1 mg/l

or 72 hr IC50 (for algae) < 1 mg/l

and

R53 May cause long-term adverse effects in the aquatic environment

the substance is not readily degradable, or

the log Pow (log octanol/water partition coefficient) > 3.0 (unless the experimentally determined BCF < 100).

10 PBT, VPVB

In case your substance on its own or in a preparation does not meet the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC (see previous question for further guidance), you will still have to prepare a Safety Data Sheet in accordance with Article 31 of REACH if it is PBT or vPvB.

How to figure out whether your substance is PBT or vPvB in accordance with the criteria set in Annex XIII?

Annex XIII lists the criteria for the identification of PBT and vPvB.

If you are manufacturing or importing the substance at more than 10 tonnes per year, a PBT/vPvB assessment is required except if you are exempted from registration under REACH. In this assessment you will figure out, while preparing your registration dossier whether your substance is PBT or not. Guidance on how to perform a PBT assessment will be available in the Guidance on the Chemical Safety Report.

If you do not have to perform a PBT, vPvB assessment then you will have to identify the data you have that characterise these properties for your substance. Guidance on Gathering all existing available information is available in the section 8.1.3 of the Guidance on registration.

Based on this information you should figure out whether the criteria of Annex XIII are fulfilled. The Guidance on the Chemical Safety Report can be of help for that purpose.

ANNEX XIII

CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES

This Annex lays down the criteria for the identification of:
(i) persistent, bioaccumulative and toxic substances (PBT-substances), and
(ii) very persistent and very bioaccumulative substances (vPvB-substances).
A substance is identified as a PBT substance if it fulfils the criteria in Sections 1.1, 1.2 and 1.3. A substance is identified as a vPvB substance if it fulfils the criteria in Sections 2.1 and 2.2. This annex shall not apply to inorganic substances, but shall apply to organo-metals.

1. PBT-substances

A substance that fulfils all three of the criteria of the sections below is a PBT substance.

1.1. Persistence

A substance fulfils the persistence criterion (P-) when:
- the half-life in marine water is higher than 60 days, or
- the half-life in fresh- or estuarine water is higher than 40 days, or
- the half-life in marine sediment is higher than 180 days, or
- the half-life in fresh- or estuarine water sediment is higher than 120 days, or
- the half-life in soil is higher than 120 days.

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.

1.2. Bioaccumulation

A substance fulfils the bioaccumulation criterion (B-) when:
- the bioconcentration factor (BCF) is higher than 2 000.

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

1.3. Toxicity

A substance fulfils the toxicity criterion (T-) when:
- the long-term no-observed effect concentration (Noec) for marine or freshwater

organisms is less than 0,01 mg/l, or
– the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or
– there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

2. vPvB – substances

A substance that fulfils the criteria of the sections below is a vPvB substance.

2.1. Persistence

A substance fulfils the very persistence criterion (vP-) when:
– the half-life in marine, fresh- or estuarine water is higher than 60 days, or
– the half-life in marine, fresh- or estuarine water sediment is higher than 180 days, or
– the half-life in soil is higher than 180.

2.2. Bioaccumulation

A substance fulfils the very bioaccumulative criterion (vB-) when:
the bioconcentration factor is greater than 5 000.

11 PLACING OF THE SUBSTANCE ON THE MARKET

Article 3(11) of REACH defines: *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*;

"Third parties" should be viewed as other legal persons; thus a transfer between two companies, even if they belong to the same group, is included, while transfer between two factories operated by the same company is not. Transfers between employees of the same company are not included where the employees act on behalf of the employer, not independently.

In the view of the Commission's Services this definition covers all transfers of control, not only those which are accompanied by transfer of ownership. Transfer to a processor, for instance, is therefore covered by the definition. This view is supported, in particular, by the use of the phrase "making available" as an alternative to "supplying", which implies an intent to cover transactions which do not involve a transfer of ownership.

Holding in stock by the manufacturer, producer of an article or importer should not be considered to constitute a "placing on the market".

Export and transport of substances

Where the transfer of a substance takes place before export from a Member State, this constitutes a placing on the market within the Community.

Where the manufacturer exports directly or where the transfer of control takes place while the goods are already undergoing a custom transit procedure, there is no "placing on the market" within the Community.

Implications of placing a substance on the market under REACH

If the substance is placed on the market and is classified as dangerous or is PBT or vPvB (meeting the criteria in Annex XIII) or is included in the candidate list for Annex XIV inclusion (list of substances subject to authorisation), a Safety Data Sheet should be provided to the recipient of the

substance, according to Article 31. If no SDS has to be provided to the recipient of the substance, information according to Article 32, still needs to be provided.

The classification and labelling of all substances put on the market shall be notified by manufacturers or importers if these substances are either subject to registration or meeting the criteria for classification as dangerous.

12 AUTHORISATION

12.1 Substances on the candidate list of substances for eventual inclusion in annex XIV (established in accordance with Article 59)

You will also have to prepare a Safety Data Sheet in accordance with Article 31 of REACH if your substance is included in the Candidate list of substances for eventual inclusion in Annex XIV (substances subject to authorisation) established in accordance with Article 59(1)

How to figure out whether your substance is included in the list established in accordance with Article 59(1)?

The list referred to is the list of substances that are candidates for eventual inclusion in Annex XIV (list of substances subject to authorisation).

Guidance on how to identify whether your substance is included in that list will be updated once this list is created.

It will be nevertheless very important to check this candidate list regularly, in particular if your substance meets the following criteria of Article 57:

(a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;

(b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;

(c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;

(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;

(f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

More guidance on such substances can be found in the Guidance on identification of SVHC.

12.2 Is the substance listed in Annex XIV (list of substances subject to authorisation)?

According to Article 58(3), the Agency shall make its first recommendation of priority substances to be included in Annex XIV (list of substances subject to authorisation) by 1st June 2009.

The Navigator and the Guidance will be revised at that point in time.

If you are only a distributor, your supplier should normally take care that the substance is authorised. As a consequence, you should not care about authorisation obligations.

It will be nevertheless very important to check Annex XIV regularly, in particular if your substance meets the following criteria of Article 57:

(a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;

(b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;

(c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;

(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;

(f) substances - such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) - for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

More guidance on such substances can be found in the Guidance on identification of SVHC.

12.3 Are all your uses of the substance exempted from authorisation?

According to Article 58(3), the Agency shall make its first recommendation of priority substances to be included in Annex XIV (list of substances subject to authorisation) by 1st June 2009.

The Navigator and the Guidance will be revised at that point in time.

For substances in articles, only the incorporation of the substance in the article can be made subject to authorisation. Therefore substances in imported articles are in any case not subject to authorisation.

12.4 Do you hold an authorisation for all your uses subject to authorisation ?

According to Article 58(3), the Agency shall make its first recommendation of priority substances to be included in Annex XIV (list of substances subject to authorisation) by 1st June 2009.

The Navigator and the Guidance will be revised at that point in time.

13 RESTRICTIONS

13.1 Is the substance listed in Annex XVII (list of restrictions)?

Annex XVII contains the "restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles".

13.2 Is one or several of your uses of the substance described in Annex XVII and is therefore subject to restriction?

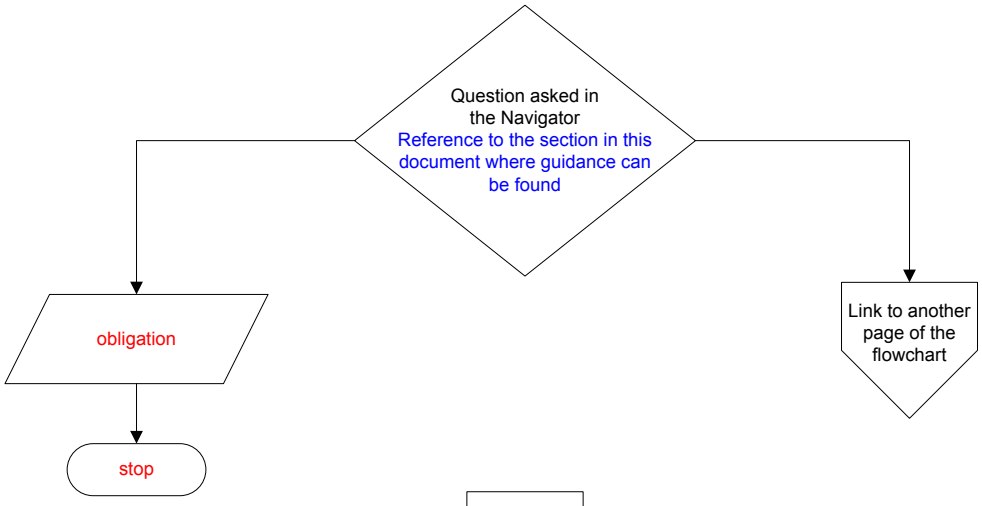
Once you have identified that your substance is included in Annex XVII you have to identify whether your use is covered by the conditions of the restriction.

If you are only a distributor your supplier should already be complying with the restriction and as a consequence you should answer NO to this question.

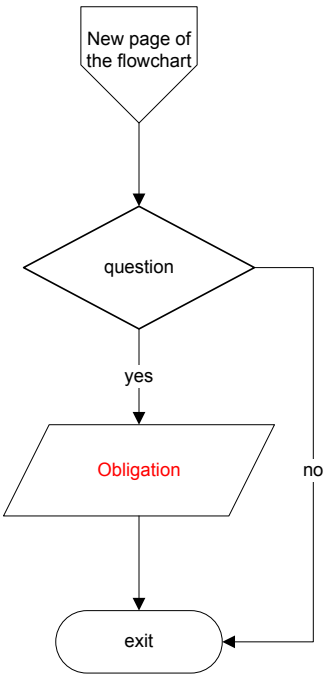
APPENDIX 1: FLOWCHARTS OF THE ALGORITHM OF THE NAVIGATOR

Explanations

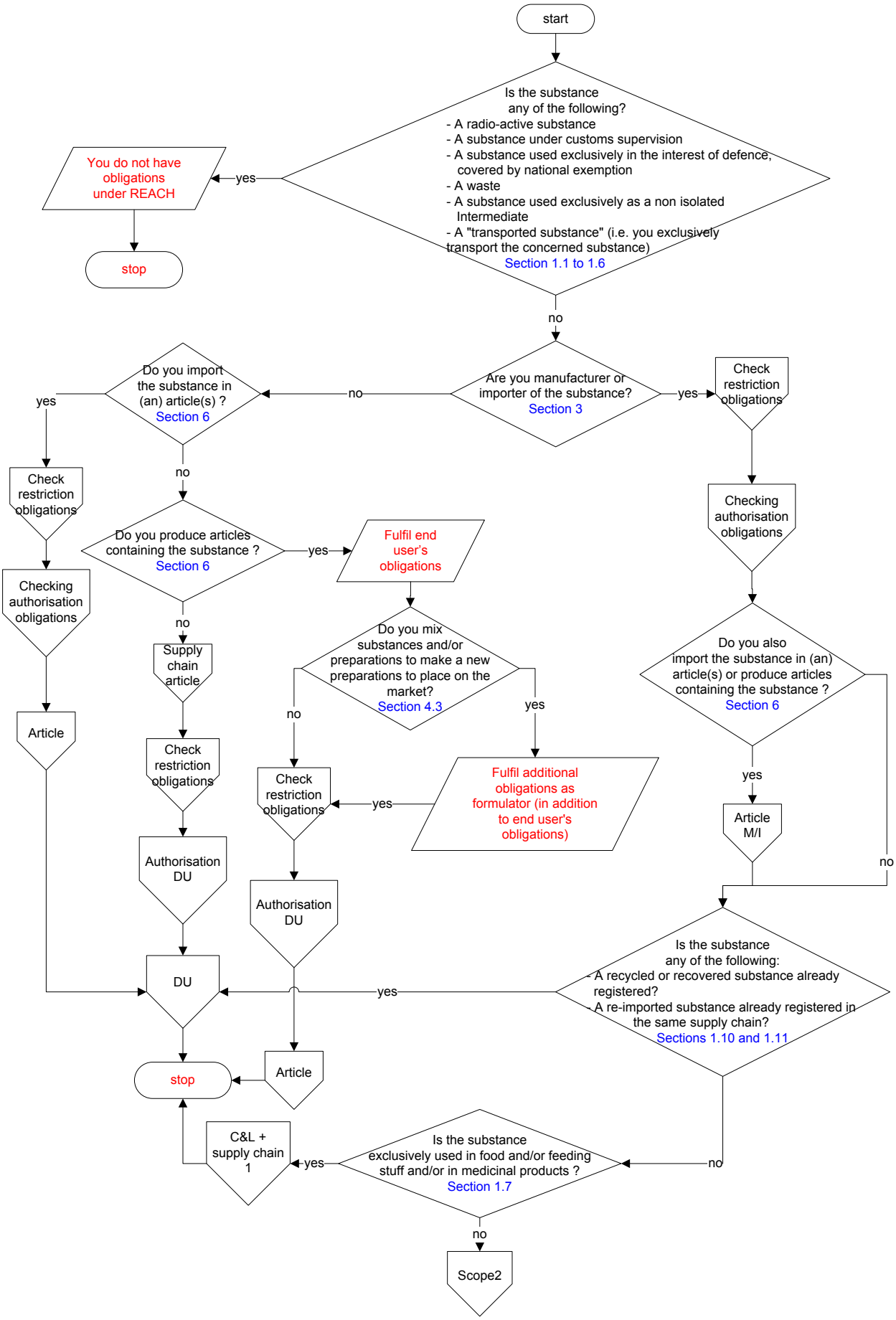
These flowcharts are provided for transparency to describe the algorithm used by the Navigator and to help the user in finding the appropriate guidance in this document.

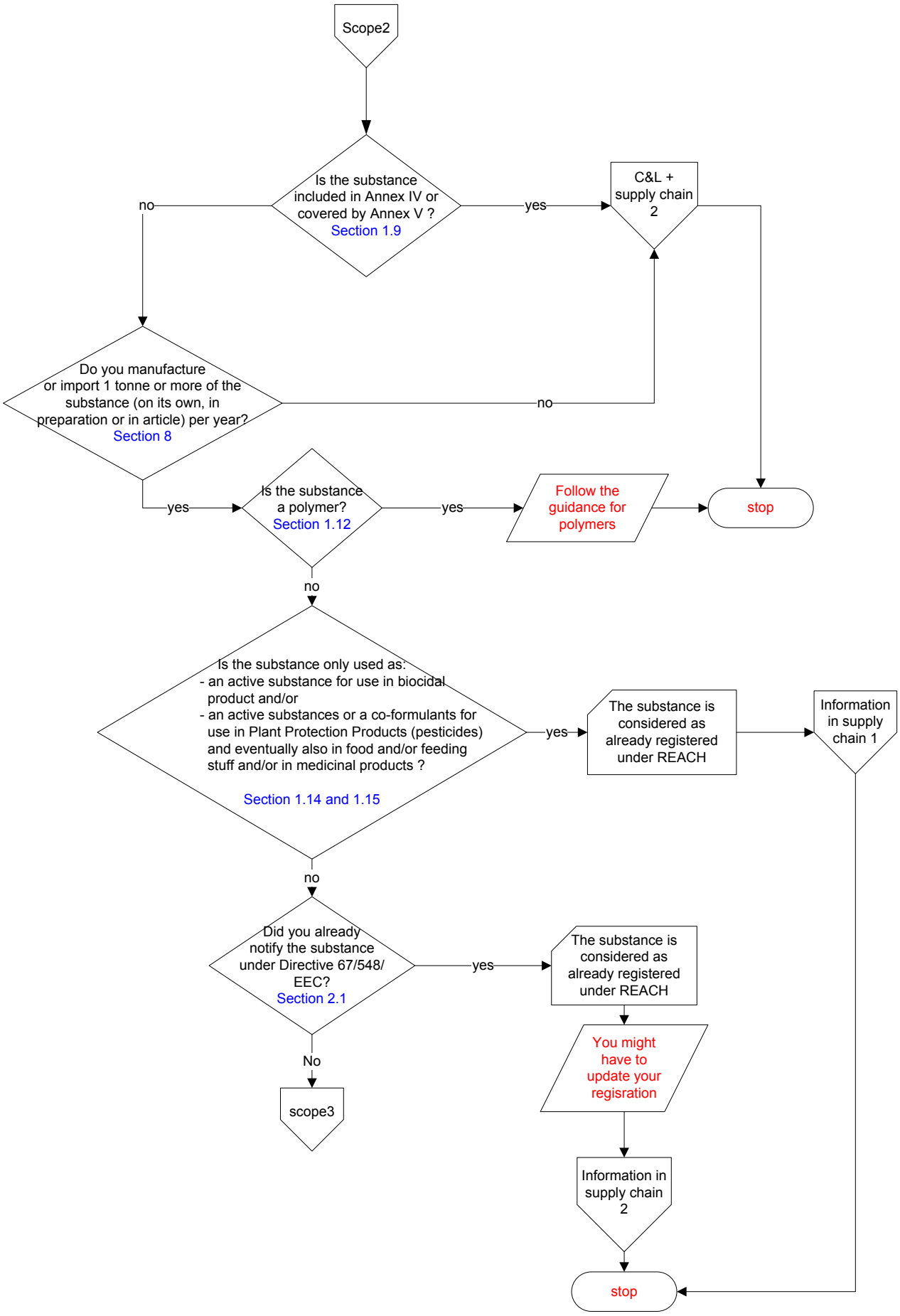


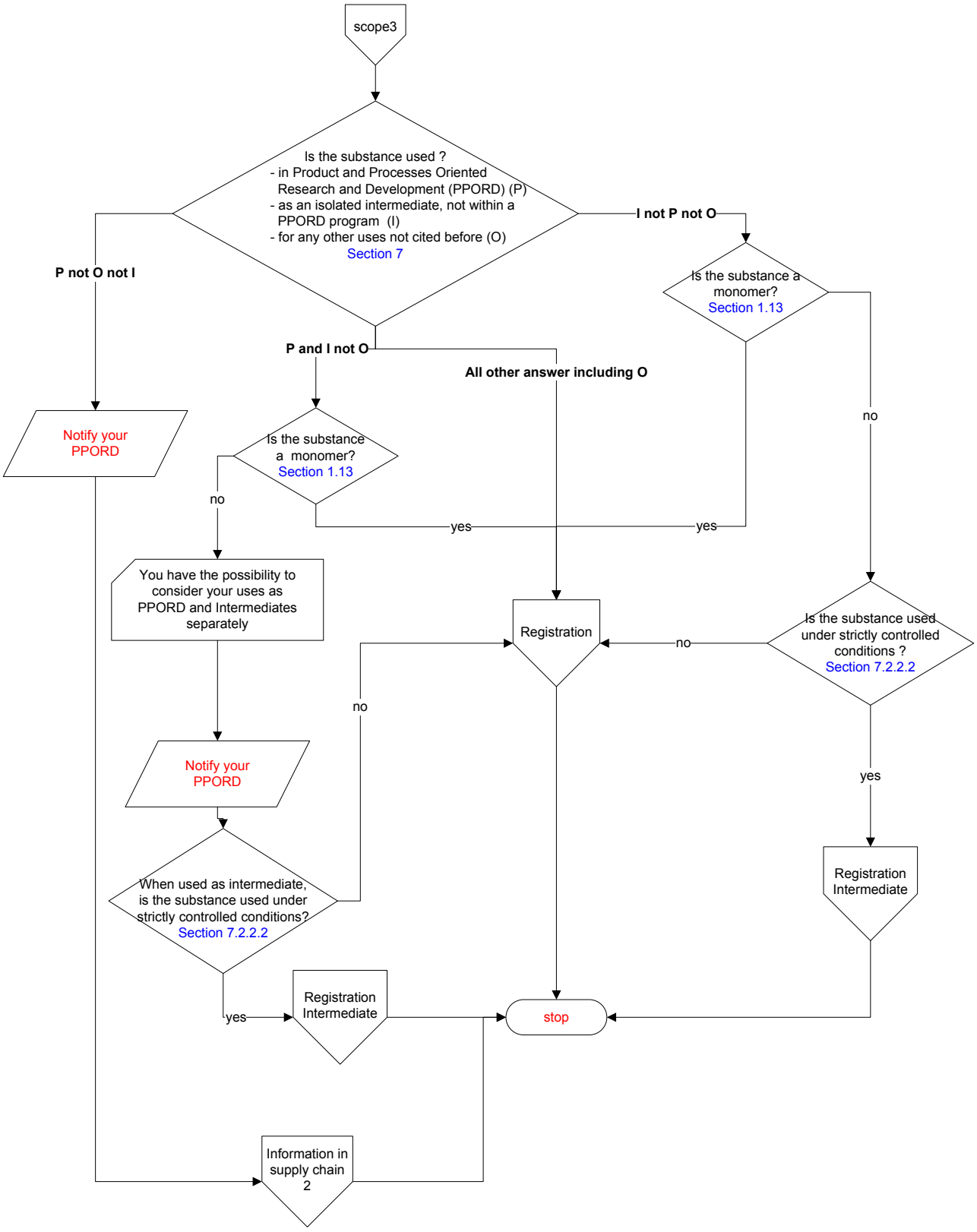
"Stop" means that no further question will be asked to the user.

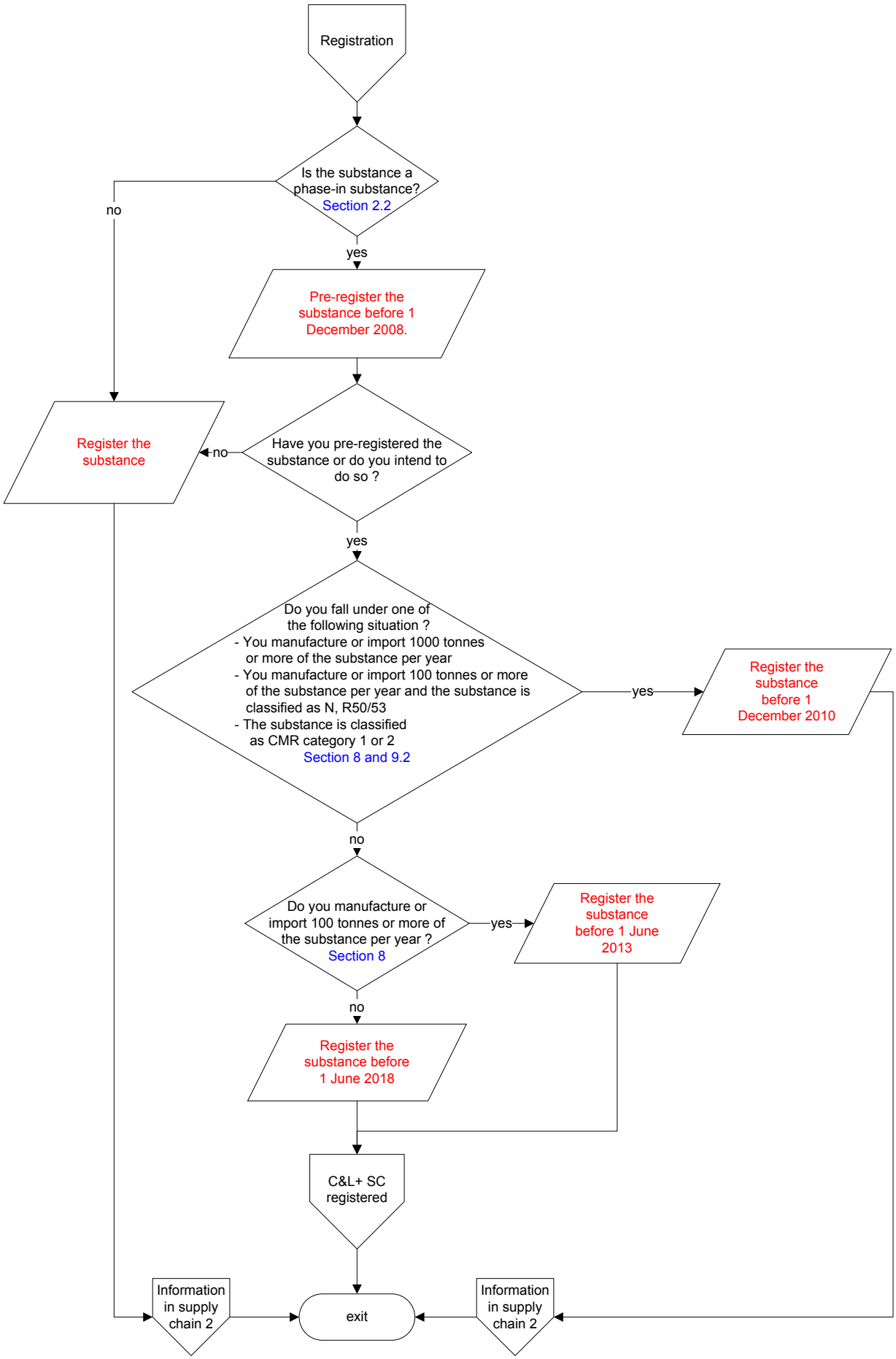


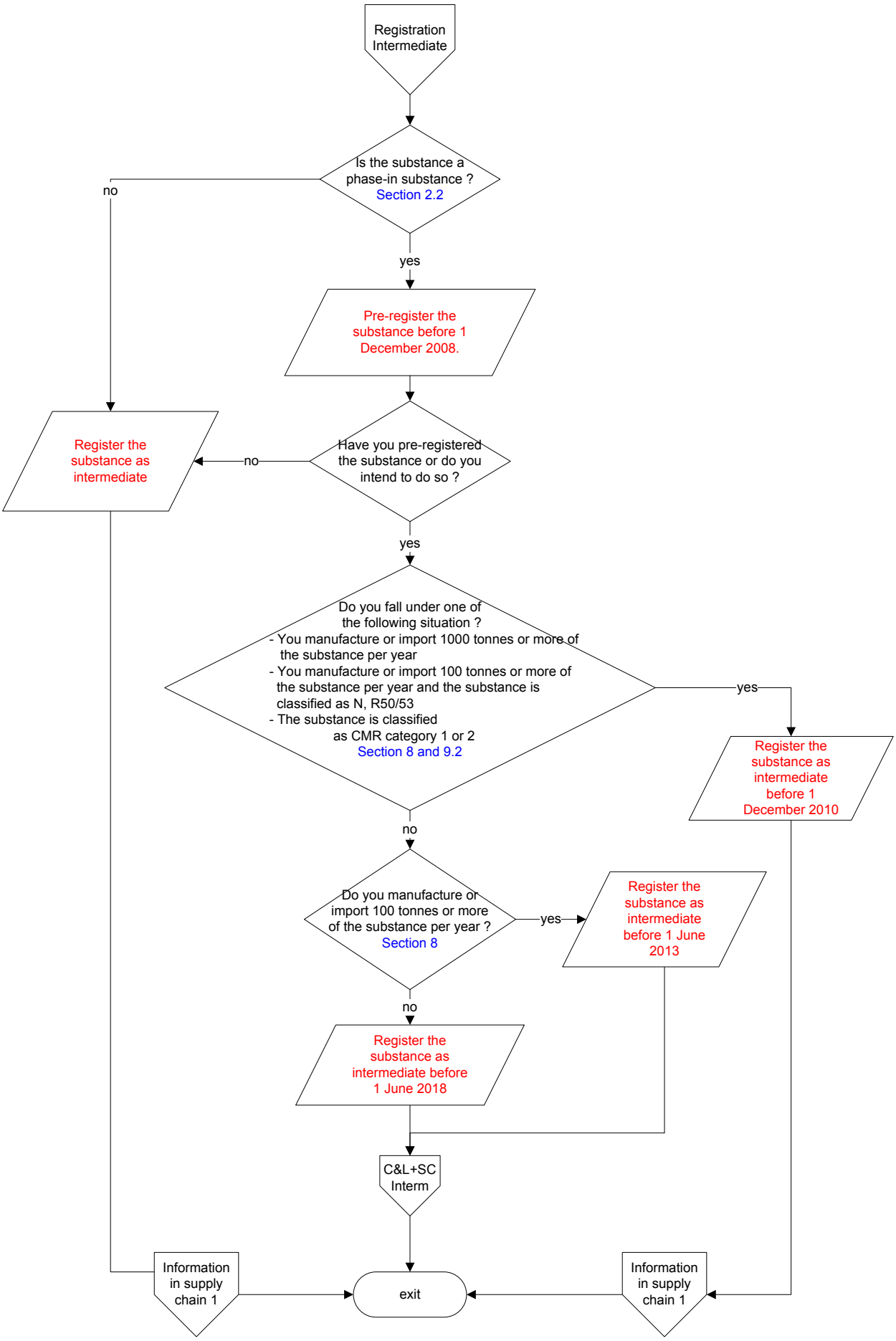
"Exit" means that the user has finalised his route in this flowchart and should come back to and continue with the previous flowchart (the one that has directed him here).

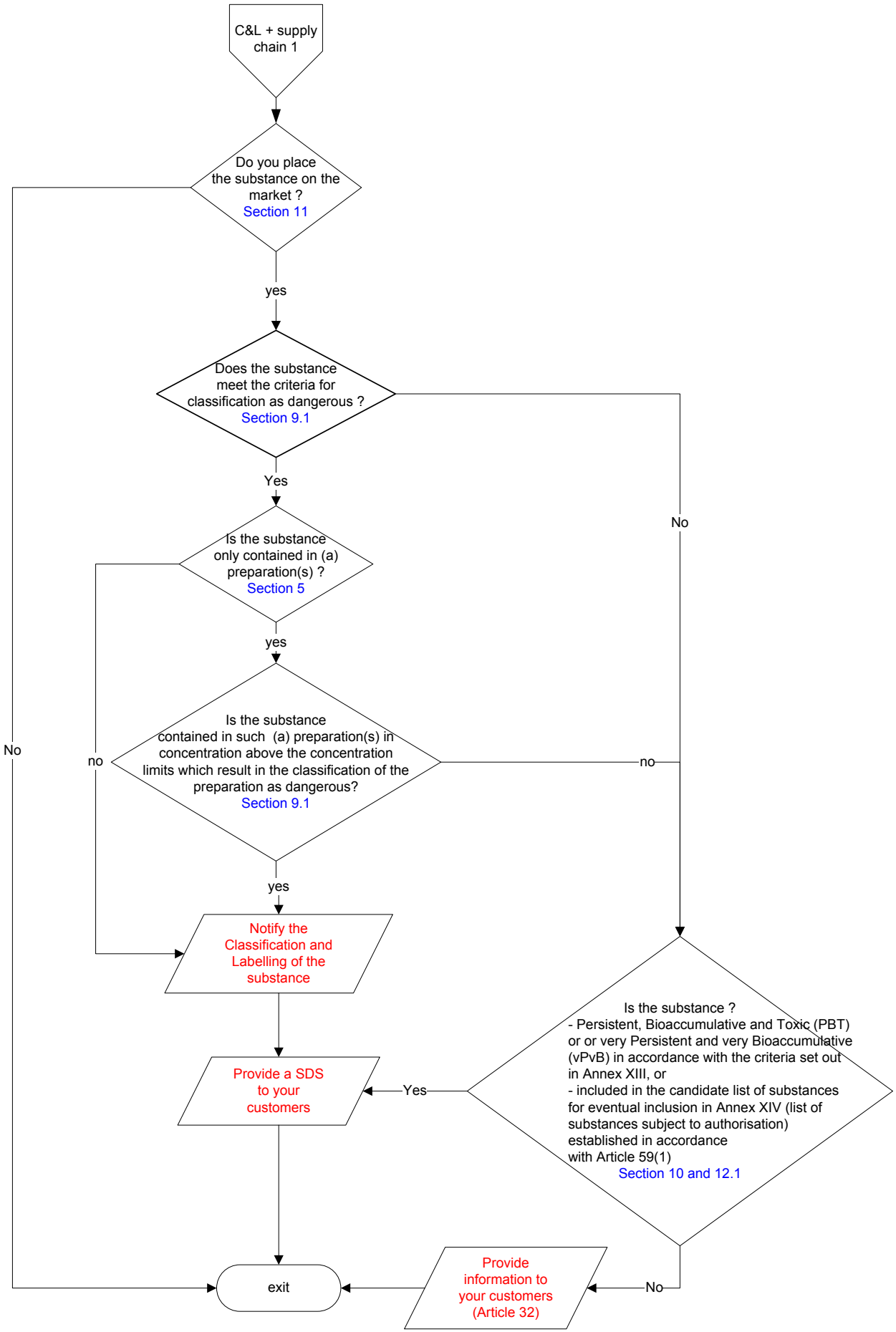

start
Is the substance any of the following?
- A radio-active substance
- A substance under customs supervision
- A substance used exclusively in the interest of defence, covered by national exemption
- A waste
- A substance used exclusively as a non isolated Intermediate
- A "transported substance" (i.e. you exclusively transport the concerned substance)
Section 1.1 to 1.6
yes
You do not have obligations under REACH
stop
no
Are you manufacturer or importer of the substance?
Section 3
yes
Check restriction obligations
Checking authorisation obligations
Do you also import the substance in (an) article(s) or produce articles containing the substance ?
Section 6
yes
Article M/I
no
no
Do you import the substance in (an) article(s) ?
Section 6
yes
Check restriction obligations
Checking authorisation obligations
Article
no
Do you produce articles containing the substance ?
Section 6
yes
Fulfil end user's obligations
Do you mix substances and/or preparations to make a new preparations to place on the market?
Section 4.3
no
Check restriction obligations
Authorisation DU
yes
Fulfil additional obligations as formulator (in addition to end user's obligations)
no
Supply chain article
Check restriction obligations
Authorisation DU
DU
yes
Is the substance any of the following:
- A recycled or recovered substance already registered?
- A re-imported substance already registered in the same supply chain?
Sections 1.10 and 1.11
stop
Article
C&L + supply chain 1
yes
Is the substance exclusively used in food and/or feeding stuff and/or in medicinal products ?
Section 1.7
no
Scope2

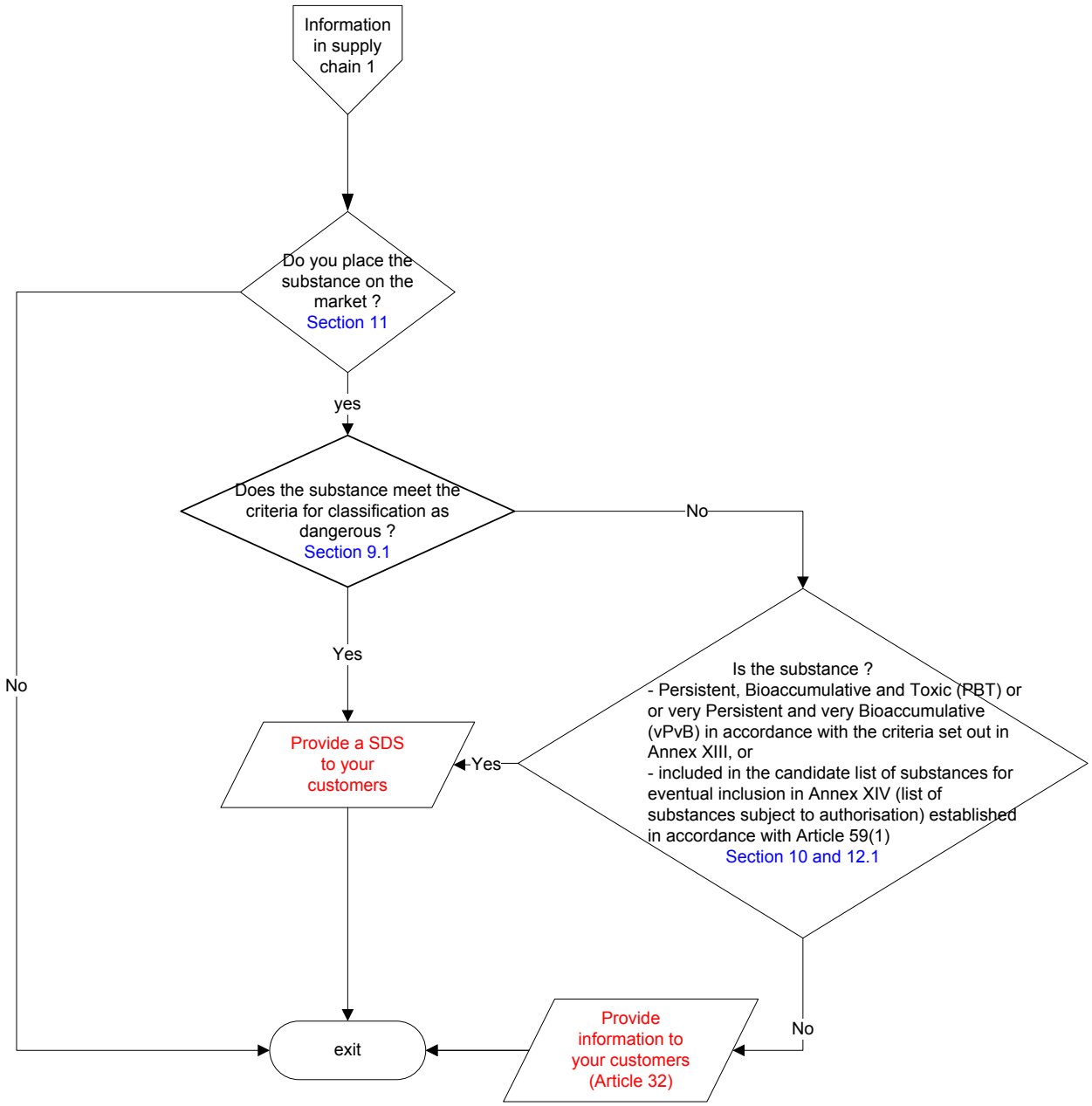

Scope2
Is the substance included in Annex IV or covered by Annex V ?
Section 1.9
no
yes
C&L + supply chain 2
Do you manufacture or import 1 tonne or more of the substance (on its own, in preparation or in article) per year?
Section 8
no
yes
Is the substance a polymer?
Section 1.12
yes
Follow the guidance for polymers
stop
no
Is the substance only used as:
- an active substance for use in biocidal product and/or
- an active substances or a co-formulants for use in Plant Protection Products (pesticides) and eventually also in food and/or feeding stuff and/or in medicinal products ?
Section 1.14 and 1.15
yes
The substance is considered as already registered under REACH
Information in supply chain 1
no
Did you already notify the substance under Directive 67/548/ EEC?
Section 2.1
yes
The substance is considered as already registered under REACH
You might have to update your regisration
Information in supply chain 2
No
scope3
stop

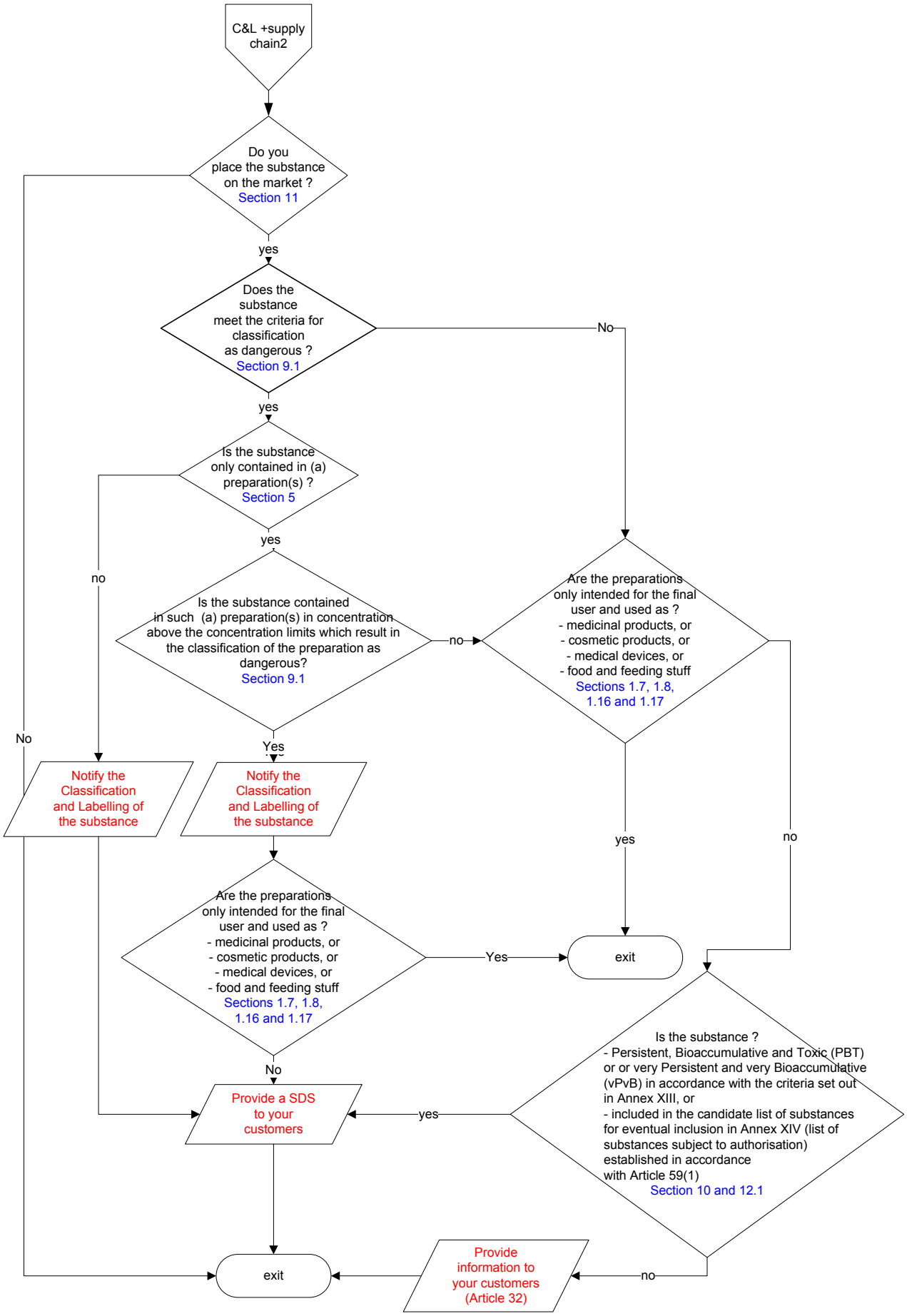

scope3
Is the substance used ?
- in Product and Processes Oriented Research and Development (PPORD) (P)
- as an isolated intermediate, not within a PPORD program (I)
- for any other uses not cited before (O)
Section 7
P not O not I
I not P not O
P and I not O
All other answer including O
Is the substance a monomer?
Section 1.13
Notify your PPORD
Is the substance a monomer?
Section 1.13
no
yes
yes
no
You have the possibility to consider your uses as PPORD and Intermediates separately
Registration
Is the substance used under strictly controlled conditions ?
Section 7.2.2.2
no
yes
Notify your PPORD
no
When used as intermediate, is the substance used under strictly controlled conditions?
Section 7.2.2.2
Registration Intermediate
yes
Registration Intermediate
stop
Information in supply chain 2

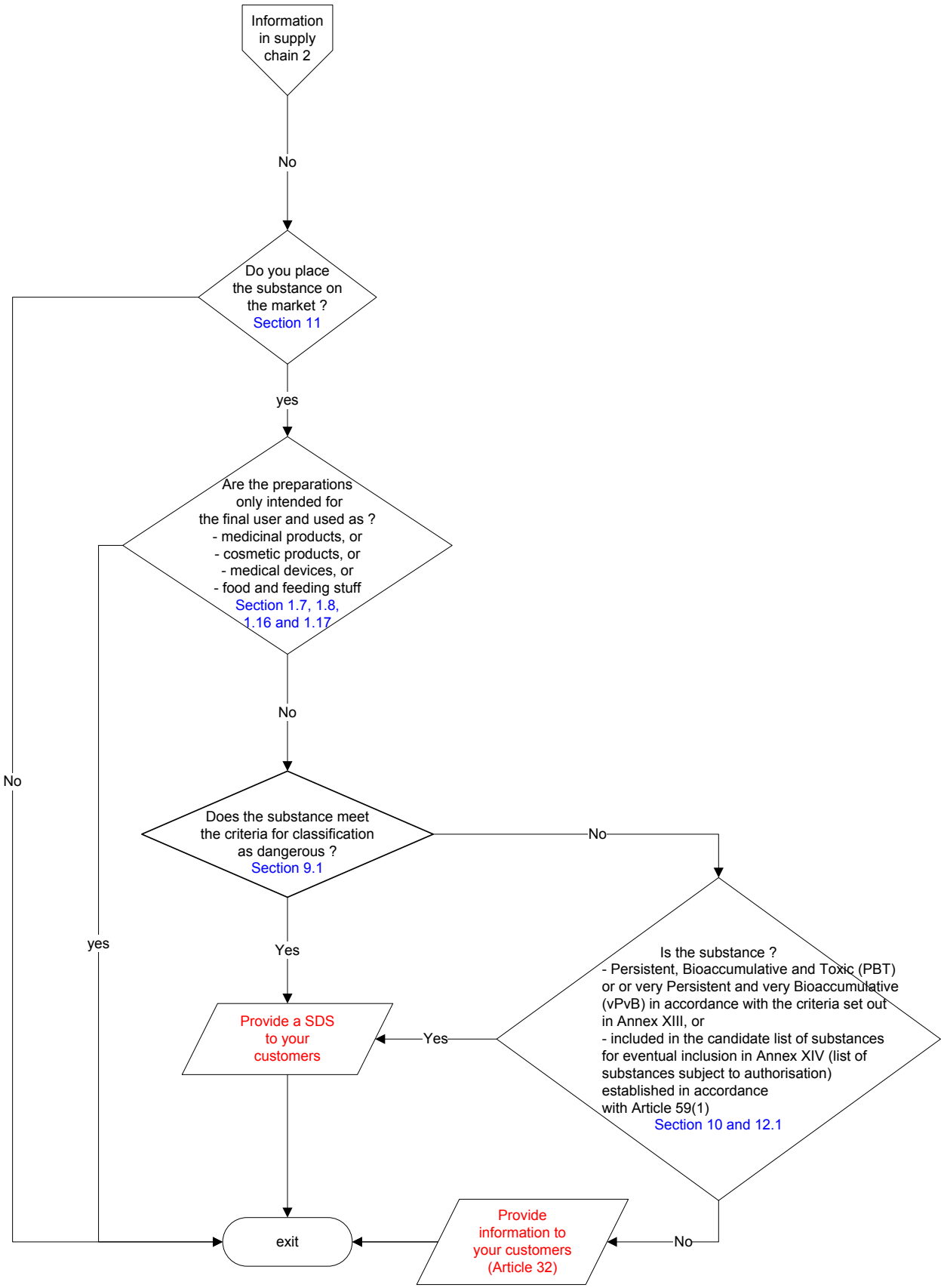

Registration
Is the substance a phase-in substance?
Section 2.2
no
yes
Pre-register the substance before 1 December 2008.
Have you pre-registered the substance or do you intend to do so ?
no
Register the substance
yes
Do you fall under one of the following situation ?
- You manufacture or import 1000 tonnes or more of the substance per year
- You manufacture or import 100 tonnes or more of the substance per year and the substance is classified as N, R50/53
- The substance is classified as CMR category 1 or 2
Section 8 and 9.2
yes
Register the substance before 1 December 2010
no
Do you manufacture or import 100 tonnes or more of the substance per year ?
Section 8
yes
Register the substance before 1 June 2013
no
Register the substance before 1 June 2018
C&L+ SC registered
Information in supply chain 2
exit
Information in supply chain 2

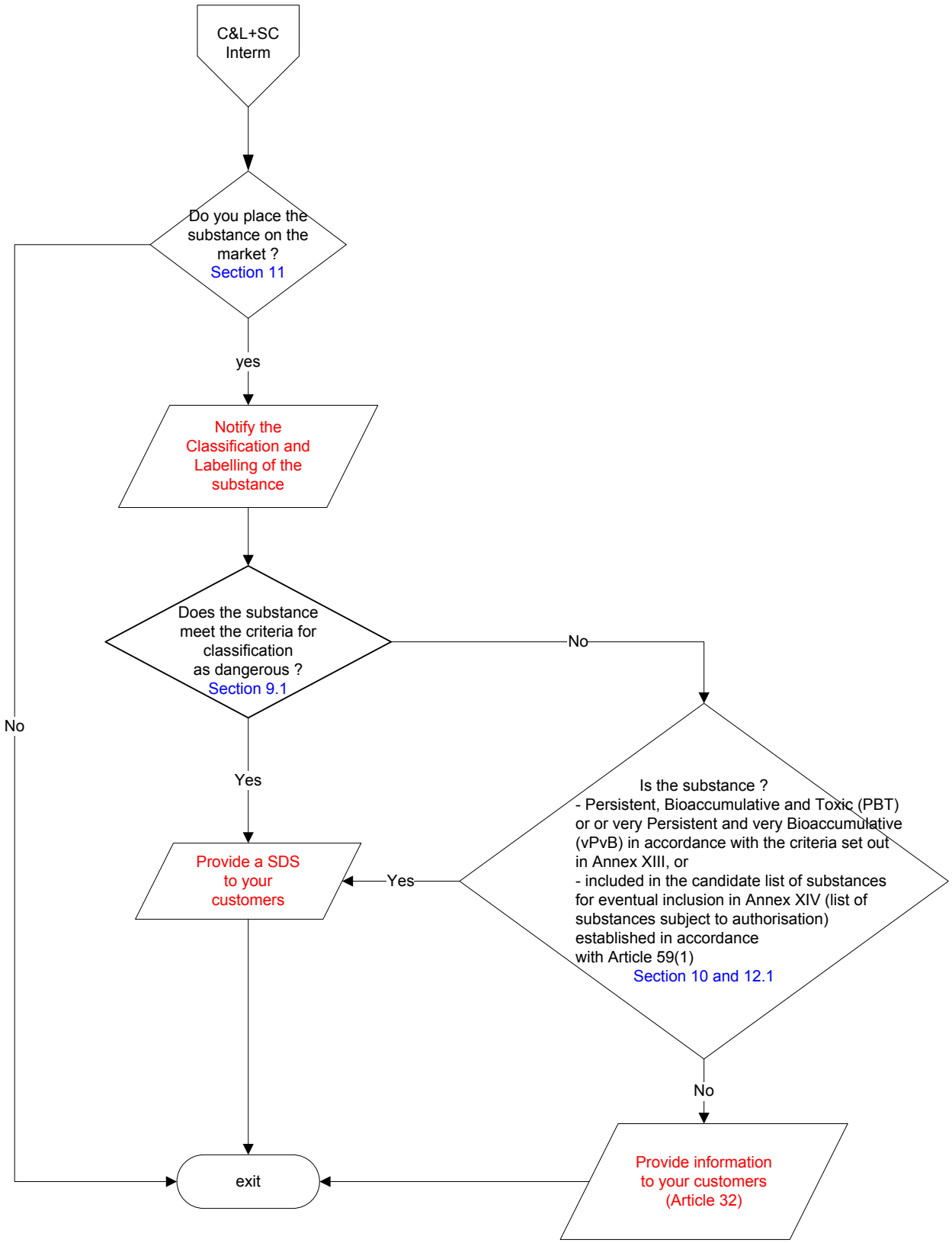

Registration Intermediate
Is the substance a phase-in substance ?
Section 2.2
no
yes
Pre-register the substance before 1 December 2008.
Have you pre-registered the substance or do you intend to do so ?
no
Register the substance as intermediate
yes
Do you fall under one of the following situation ?
- You manufacture or import 1000 tonnes or more of the substance per year
- You manufacture or import 100 tonnes or more of the substance per year and the substance is classified as N, R50/53
- The substance is classified as CMR category 1 or 2
Section 8 and 9.2
yes
Register the substance as intermediate before 1 December 2010
no
Do you manufacture or import 100 tonnes or more of the substance per year ?
Section 8
yes
Register the substance as intermediate before 1 June 2013
no
Register the substance as intermediate before 1 June 2018
C&L+SC Interm
Information in supply chain 1
exit
Information in supply chain 1

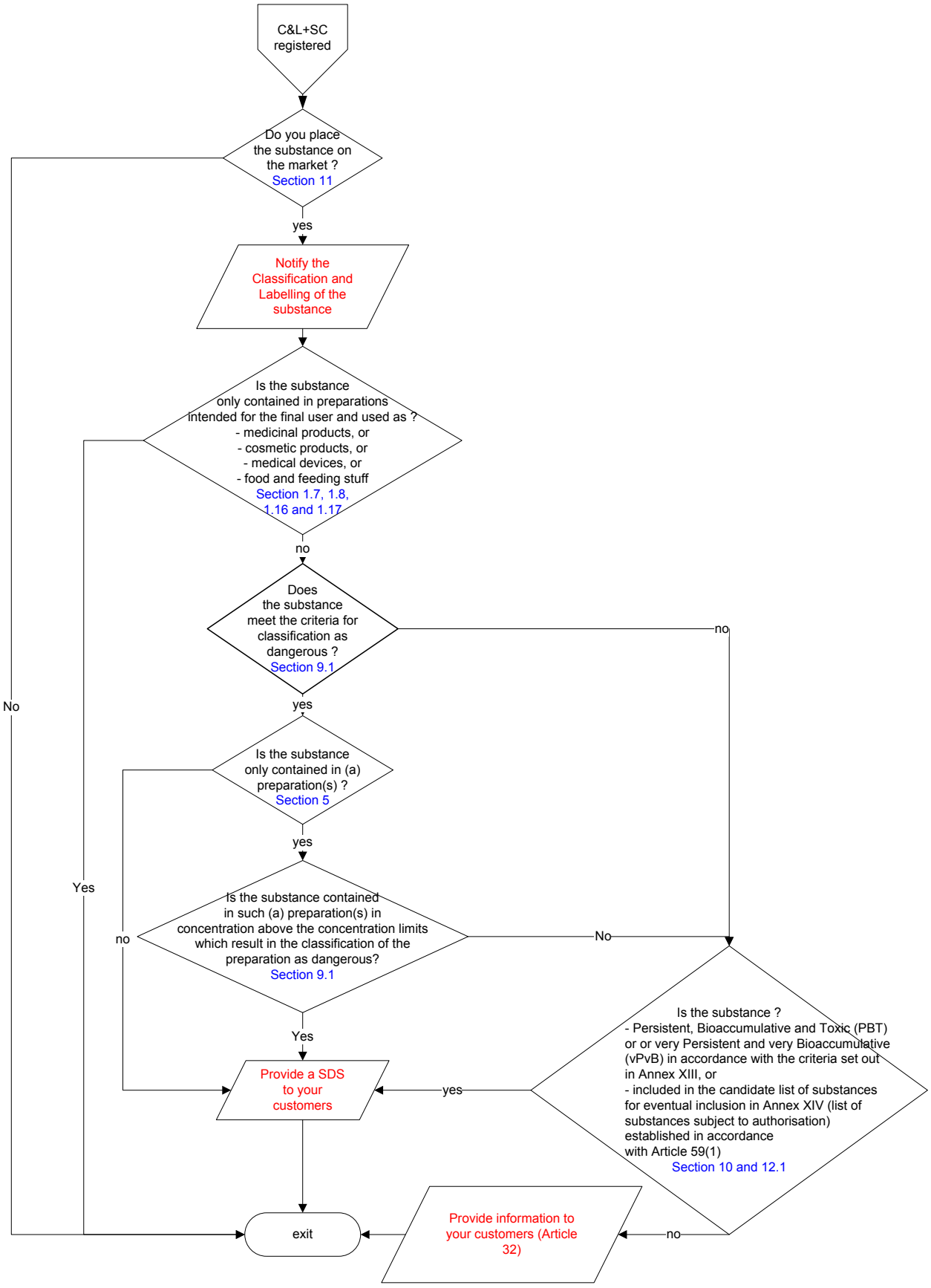

C&L + supply chain 1
Do you place the substance on the market ?
Section 11
No
yes
Does the substance meet the criteria for classification as dangerous ?
Section 9.1
No
Yes
Is the substance only contained in (a) preparation(s) ?
Section 5
yes
Is the substance contained in such (a) preparation(s) in concentration above the concentration limits which result in the classification of the preparation as dangerous?
Section 9.1
no
no
yes
Notify the Classification and Labelling of the substance
Provide a SDS to your customers
Yes
Is the substance ?
- Persistent, Bioaccumulative and Toxic (PBT) or or very Persistent and very Bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII, or
- included in the candidate list of substances for eventual inclusion in Annex XIV (list of substances subject to authorisation) established in accordance with Article 59(1)
Section 10 and 12.1
No
Provide information to your customers (Article 32)
exit

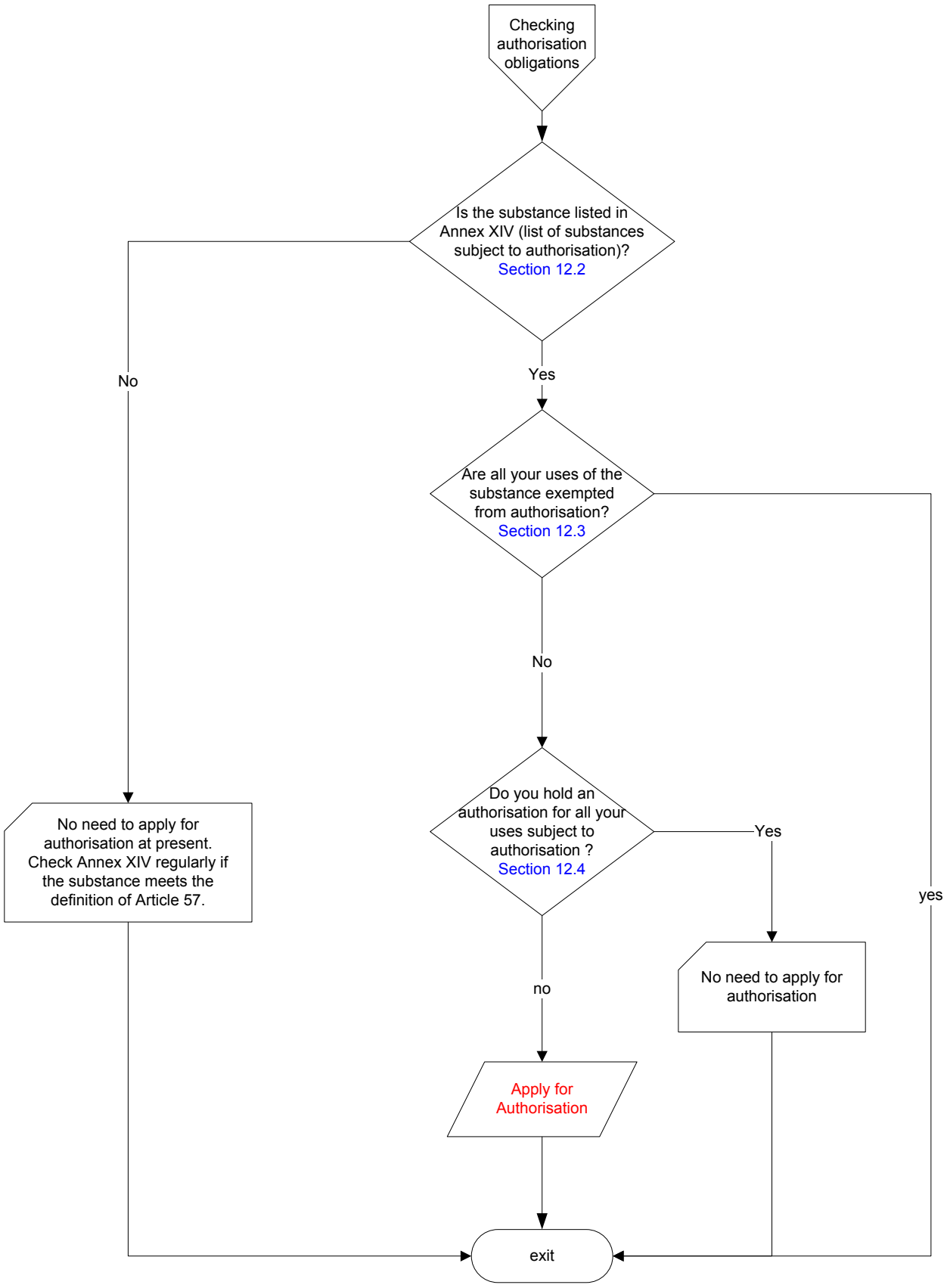

Information in supply chain 1
Do you place the substance on the market ?
Section 11
yes
No
Does the substance meet the criteria for classification as dangerous ?
Section 9.1
Yes
No
Is the substance ?
- Persistent, Bioaccumulative and Toxic (PBT) or or very Persistent and very Bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII, or
- included in the candidate list of substances for eventual inclusion in Annex XIV (list of substances subject to authorisation) established in accordance with Article 59(1)
Section 10 and 12.1
Yes
Provide a SDS to your customers
No
Provide information to your customers (Article 32)
exit

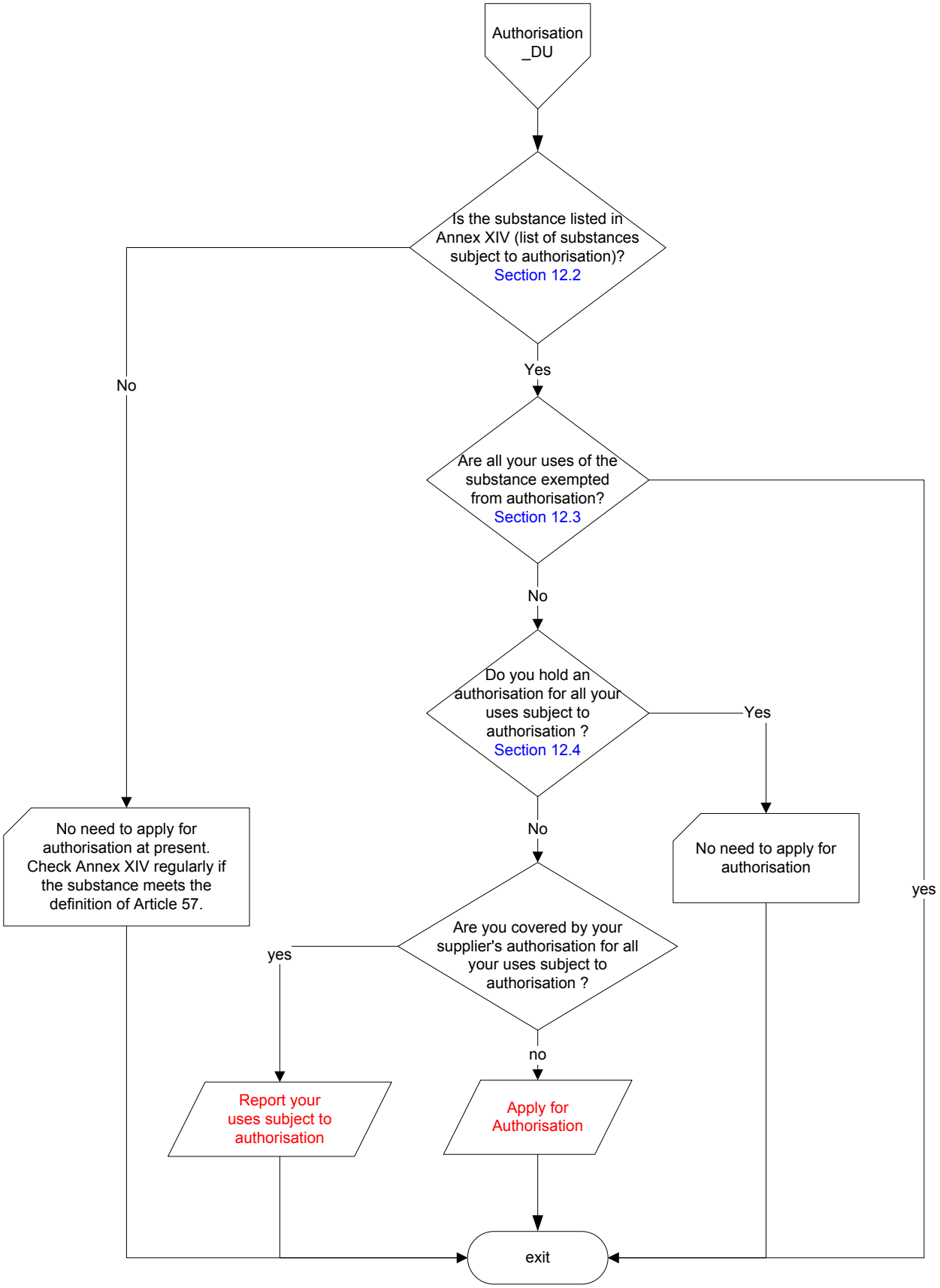

C&L +supply chain2
Do you place the substance on the market ? Section 11
yes
Does the substance meet the criteria for classification as dangerous ? Section 9.1
No
yes
Is the substance only contained in (a) preparation(s) ? Section 5
yes
no
Is the substance contained in such (a) preparation(s) in concentration above the concentration limits which result in the classification of the preparation as dangerous? Section 9.1
no
Are the preparations only intended for the final user and used as ?
- medicinal products, or
- cosmetic products, or
- medical devices, or
- food and feeding stuff
Sections 1.7, 1.8, 1.16 and 1.17
No
Yes
Notify the Classification and Labelling of the substance
Notify the Classification and Labelling of the substance
yes
no
Are the preparations only intended for the final user and used as ?
- medicinal products, or
- cosmetic products, or
- medical devices, or
- food and feeding stuff
Sections 1.7, 1.8, 1.16 and 1.17
Yes
exit
No
Provide a SDS to your customers
yes
Is the substance ?
- Persistent, Bioaccumulative and Toxic (PBT) or or very Persistent and very Bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII, or
- included in the candidate list of substances for eventual inclusion in Annex XIV (list of substances subject to authorisation) established in accordance with Article 59(1)
Section 10 and 12.1
exit
Provide information to your customers (Article 32)
no

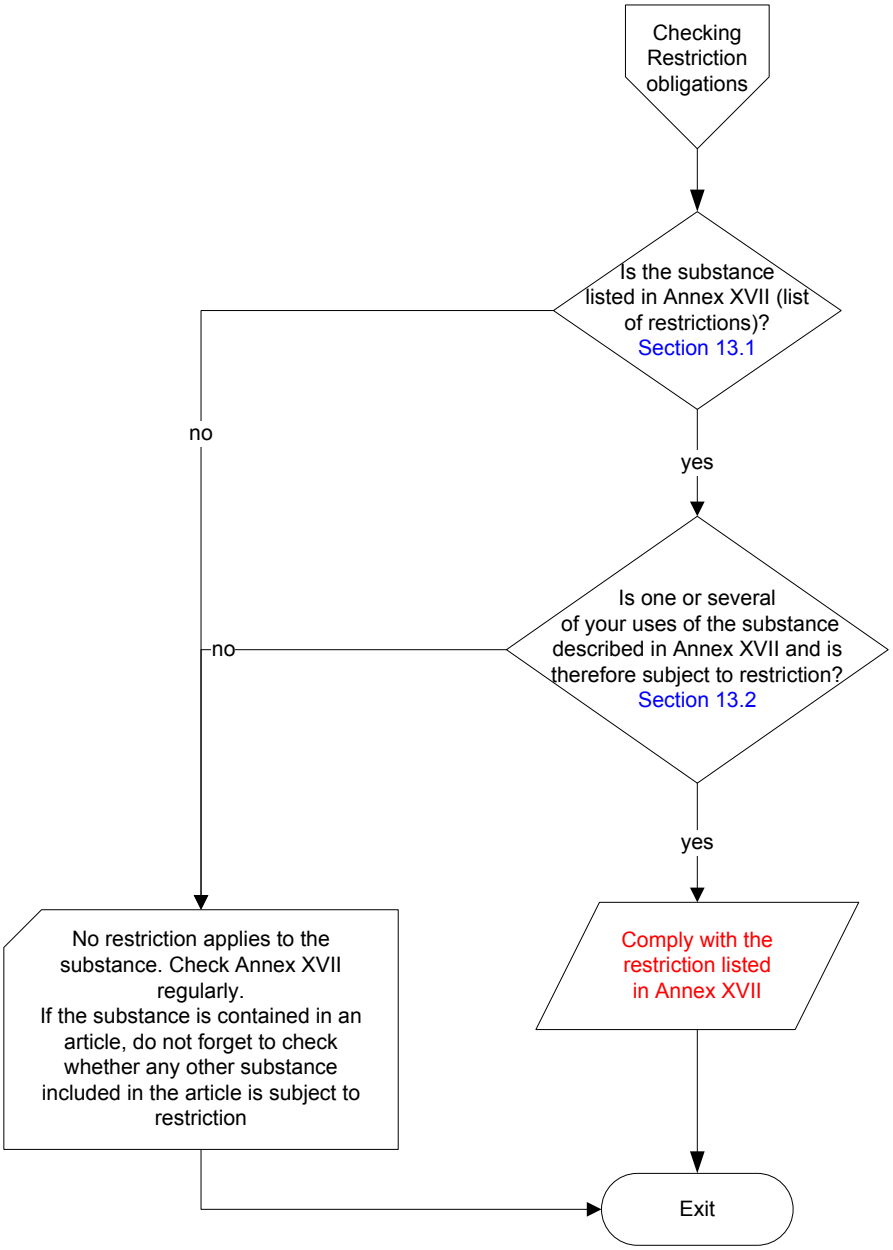

Information in supply chain 2
No
Do you place the substance on the market ?
Section 11
yes
Are the preparations only intended for the final user and used as ?
- medicinal products, or
- cosmetic products, or
- medical devices, or
- food and feeding stuff
Section 1.7, 1.8, 1.16 and 1.17
No
No
Does the substance meet the criteria for classification as dangerous ?
Section 9.1
No
yes
Yes
Is the substance ?
- Persistent, Bioaccumulative and Toxic (PBT) or or very Persistent and very Bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII, or
- included in the candidate list of substances for eventual inclusion in Annex XIV (list of substances subject to authorisation) established in accordance with Article 59(1)
Section 10 and 12.1
Provide a SDS to your customers
Yes
exit
Provide information to your customers (Article 32)
No

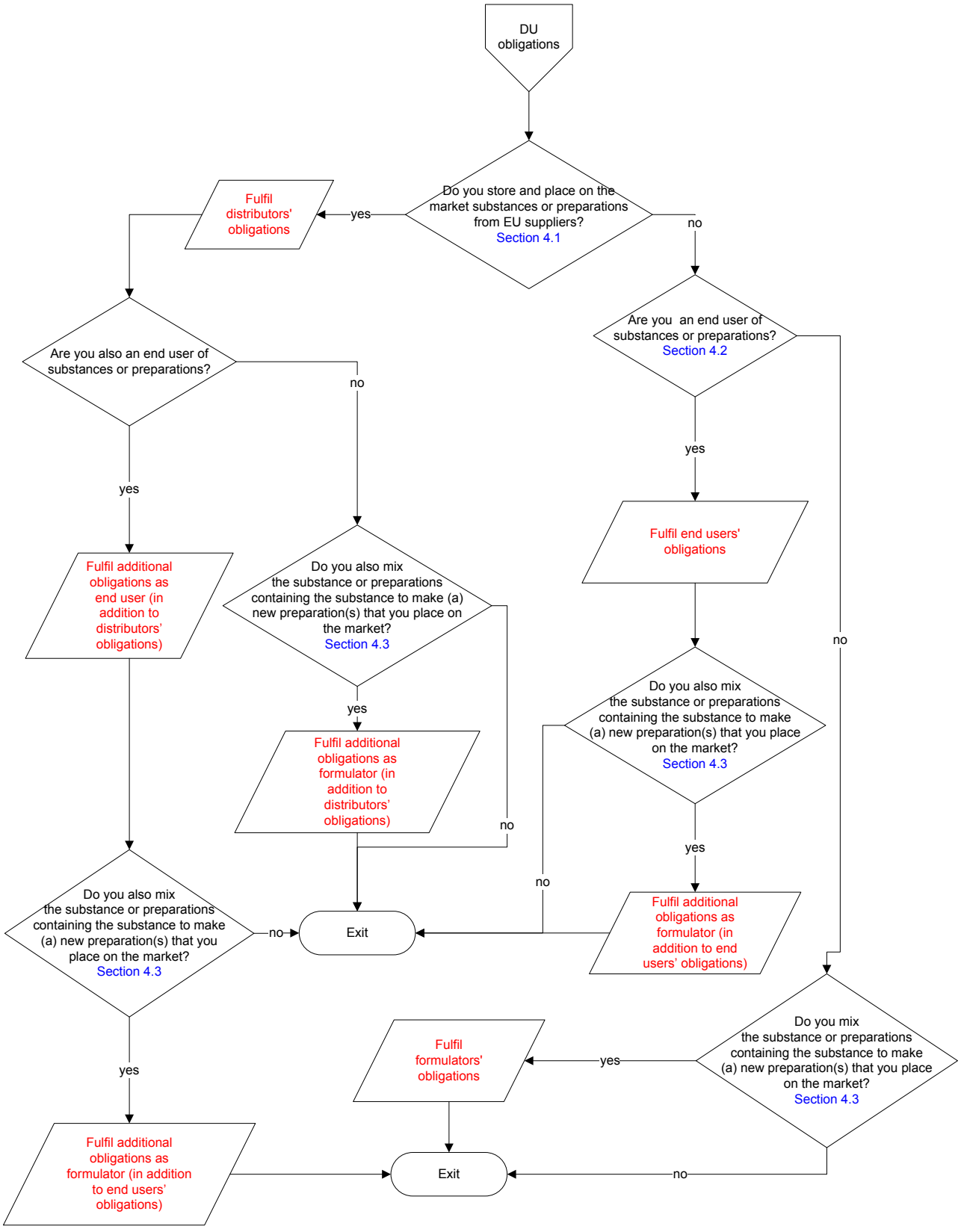

C&L+SC
Interm
Do you place the substance on the market ?
Section 11
yes
No
Notify the Classification and Labelling of the substance
Does the substance meet the criteria for classification as dangerous ?
Section 9.1
No
Yes
Is the substance ?
- Persistent, Bioaccumulative and Toxic (PBT) or or very Persistent and very Bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII, or
- included in the candidate list of substances for eventual inclusion in Annex XIV (list of substances subject to authorisation) established in accordance with Article 59(1)
Section 10 and 12.1
Yes
Provide a SDS to your customers
No
Provide information to your customers (Article 32)
exit

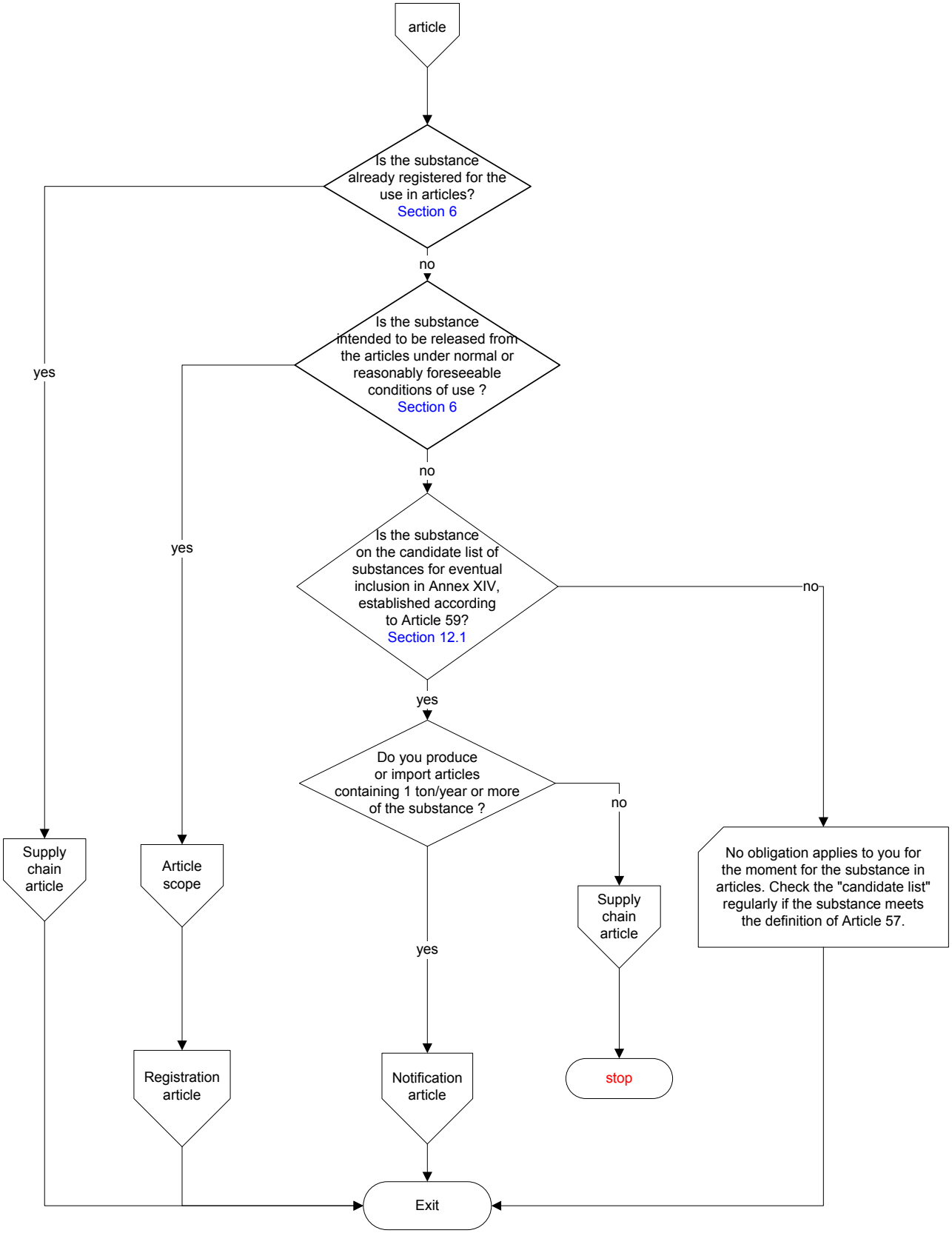

C&L+SC registered
Do you place the substance on the market ?
Section 11
yes
Notify the Classification and Labelling of the substance
Is the substance only contained in preparations intended for the final user and used as ?
- medicinal products, or
- cosmetic products, or
- medical devices, or
- food and feeding stuff
Section 1.7, 1.8, 1.16 and 1.17
no
Does the substance meet the criteria for classification as dangerous ?
Section 9.1
no
yes
No
Is the substance only contained in (a) preparation(s) ?
Section 5
yes
Yes
Is the substance contained in such (a) preparation(s) in concentration above the concentration limits which result in the classification of the preparation as dangerous?
Section 9.1
no
No
Yes
Provide a SDS to your customers
yes
Is the substance ?
- Persistent, Bioaccumulative and Toxic (PBT) or or very Persistent and very Bioaccumulative (vPvB) in accordance with the criteria set out in Annex XIII, or
- included in the candidate list of substances for eventual inclusion in Annex XIV (list of substances subject to authorisation) established in accordance with Article 59(1)
Section 10 and 12.1
exit
Provide information to your customers (Article 32)
no

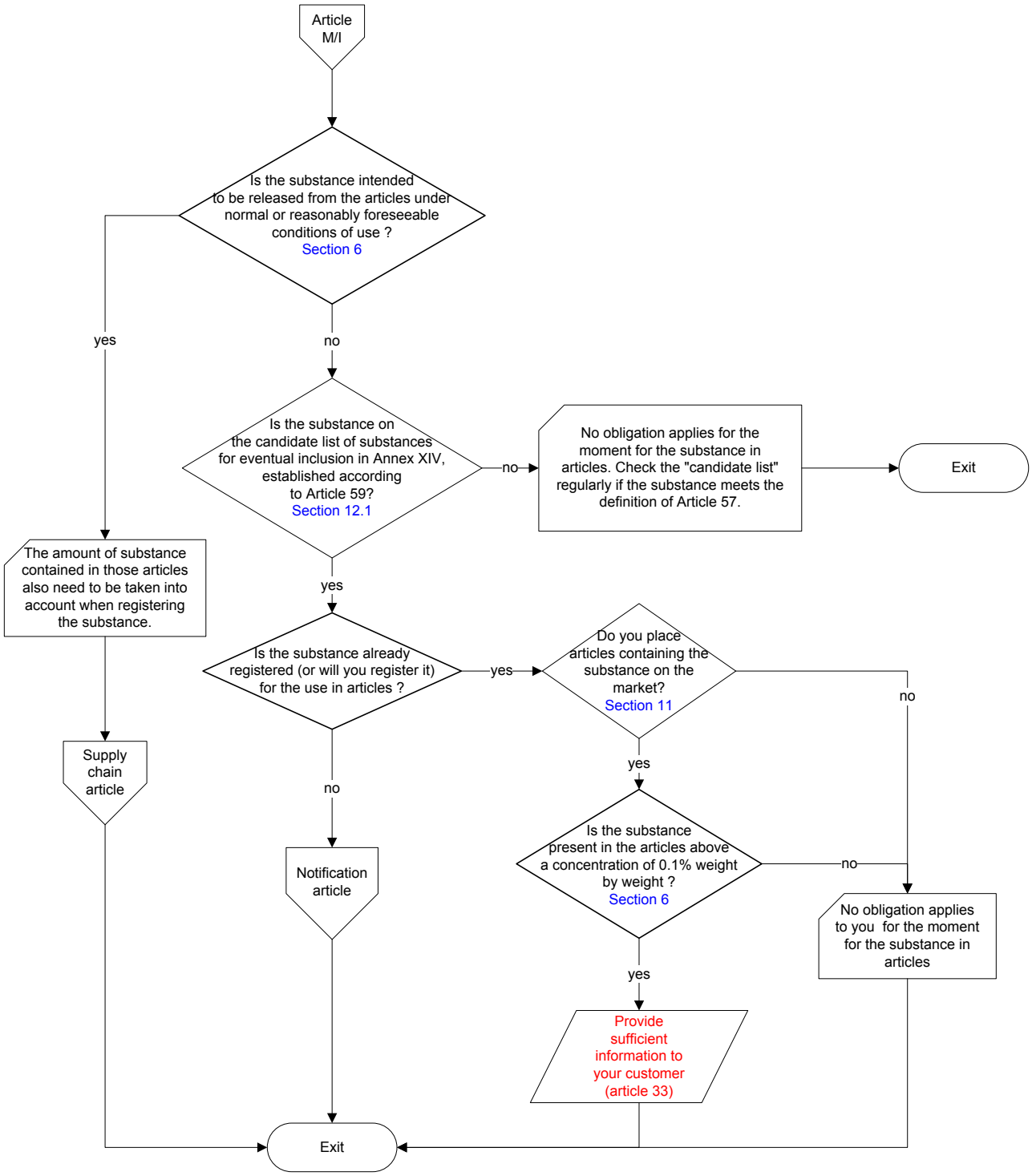

Checking authorisation obligations
Is the substance listed in Annex XIV (list of substances subject to authorisation)? Section 12.2
No
Yes
Are all your uses of the substance exempted from authorisation? Section 12.3
yes
No
Do you hold an authorisation for all your uses subject to authorisation ? Section 12.4
Yes
No need to apply for authorisation at present. Check Annex XIV regularly if the substance meets the definition of Article 57.
No need to apply for authorisation
no
Apply for Authorisation
exit

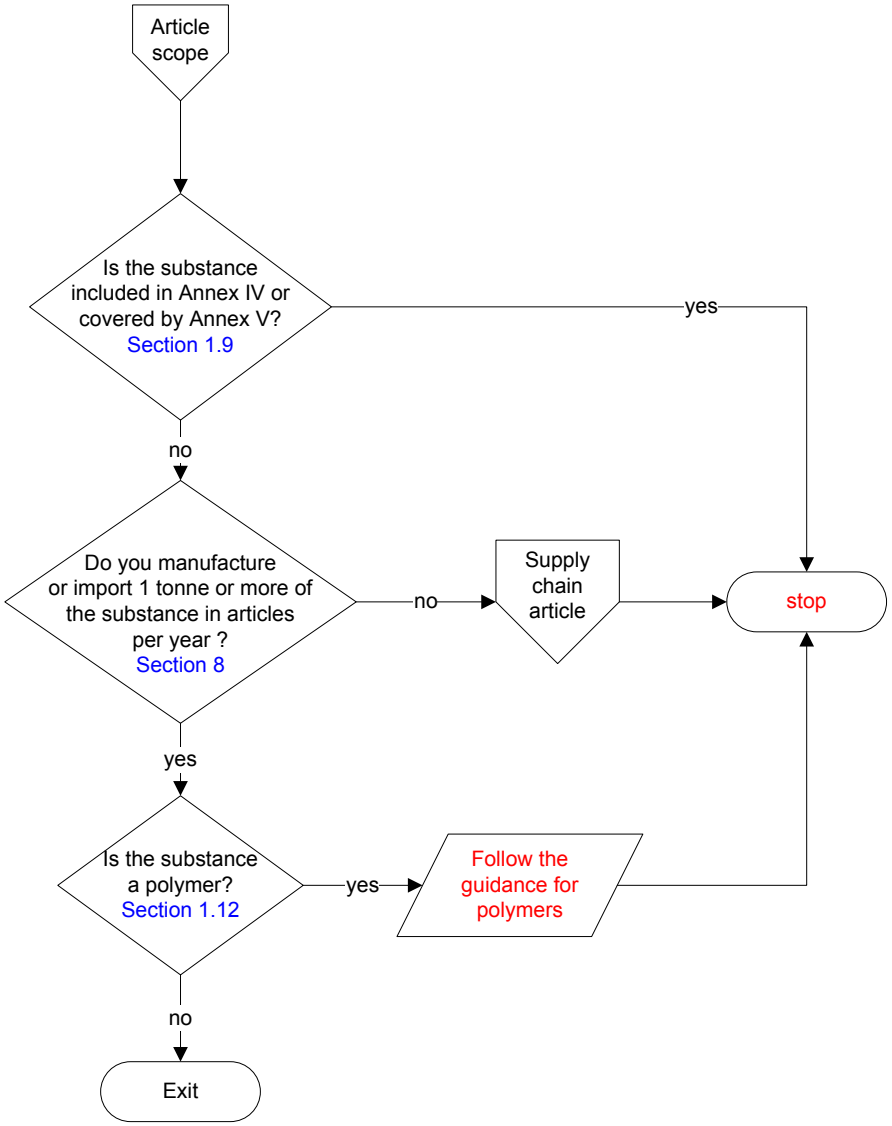

Authorisation _DU
Is the substance listed in Annex XIV (list of substances subject to authorisation)? Section 12.2
No
Yes
Are all your uses of the substance exempted from authorisation? Section 12.3
yes
No
Do you hold an authorisation for all your uses subject to authorisation ? Section 12.4
Yes
No need to apply for authorisation at present. Check Annex XIV regularly if the substance meets the definition of Article 57.
No need to apply for authorisation
No
Are you covered by your supplier's authorisation for all your uses subject to authorisation ?
yes
no
Report your uses subject to authorisation
Apply for Authorisation
exit

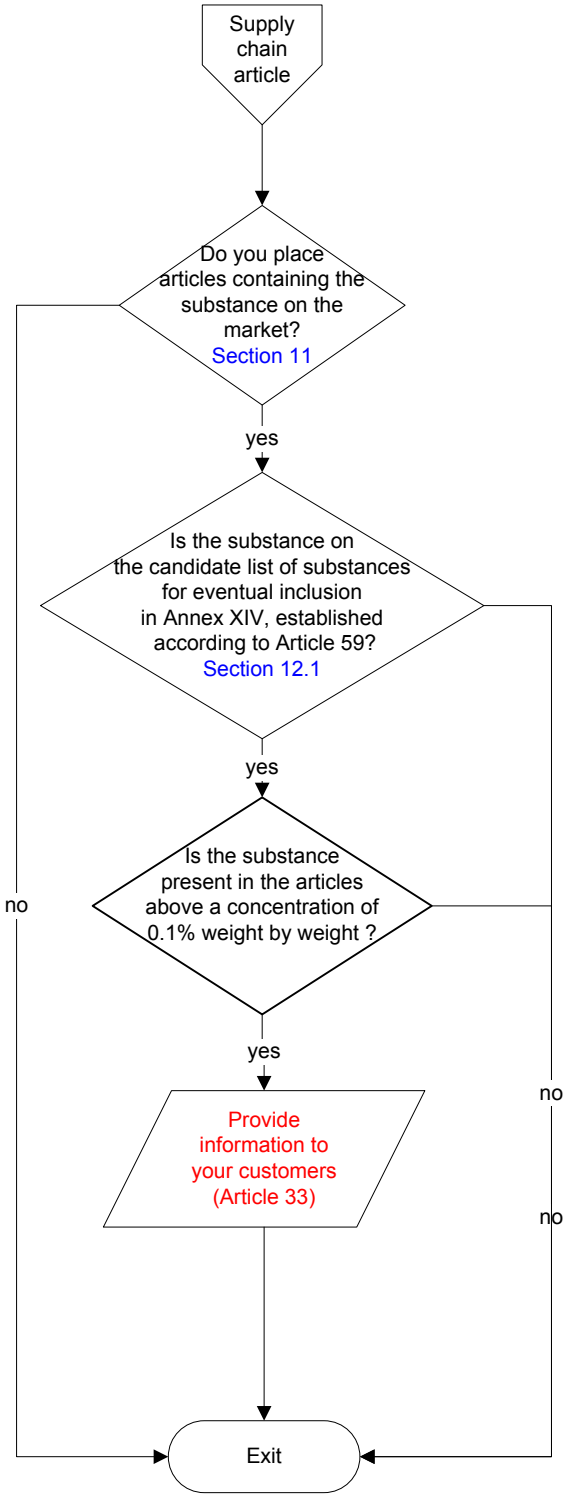

Checking Restriction obligations
Is the substance listed in Annex XVII (list of restrictions)? Section 13.1
no
yes
Is one or several of your uses of the substance described in Annex XVII and is therefore subject to restriction? Section 13.2
no
yes
No restriction applies to the substance. Check Annex XVII regularly.
If the substance is contained in an article, do not forget to check whether any other substance included in the article is subject to restriction
Comply with the restriction listed in Annex XVII
Exit

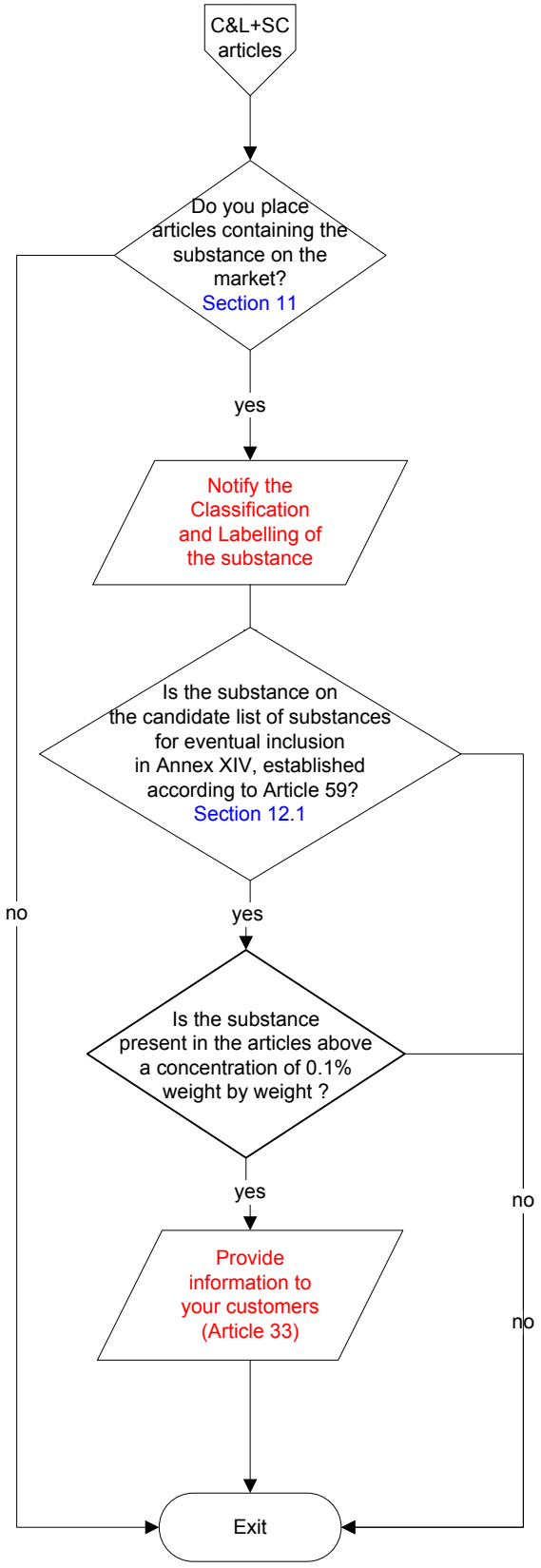

DU obligations
Do you store and place on the market substances or preparations from EU suppliers? Section 4.1
yes
Fulfil distributors' obligations
no
Are you also an end user of substances or preparations?
yes
Fulfil additional obligations as end user (in addition to distributors' obligations)
no
Do you also mix the substance or preparations containing the substance to make (a) new preparation(s) that you place on the market? Section 4.3
yes
Fulfil additional obligations as formulator (in addition to distributors' obligations)
no
Do you also mix the substance or preparations containing the substance to make (a) new preparation(s) that you place on the market? Section 4.3
no
Exit
yes
Fulfil additional obligations as formulator (in addition to end users' obligations)
Are you an end user of substances or preparations? Section 4.2
yes
Fulfil end users' obligations
Do you also mix the substance or preparations containing the substance to make (a) new preparation(s) that you place on the market? Section 4.3
no
yes
Fulfil additional obligations as formulator (in addition to end users' obligations)
no
Do you mix the substance or preparations containing the substance to make (a) new preparation(s) that you place on the market? Section 4.3
yes
Fulfil formulators' obligations
no
Exit

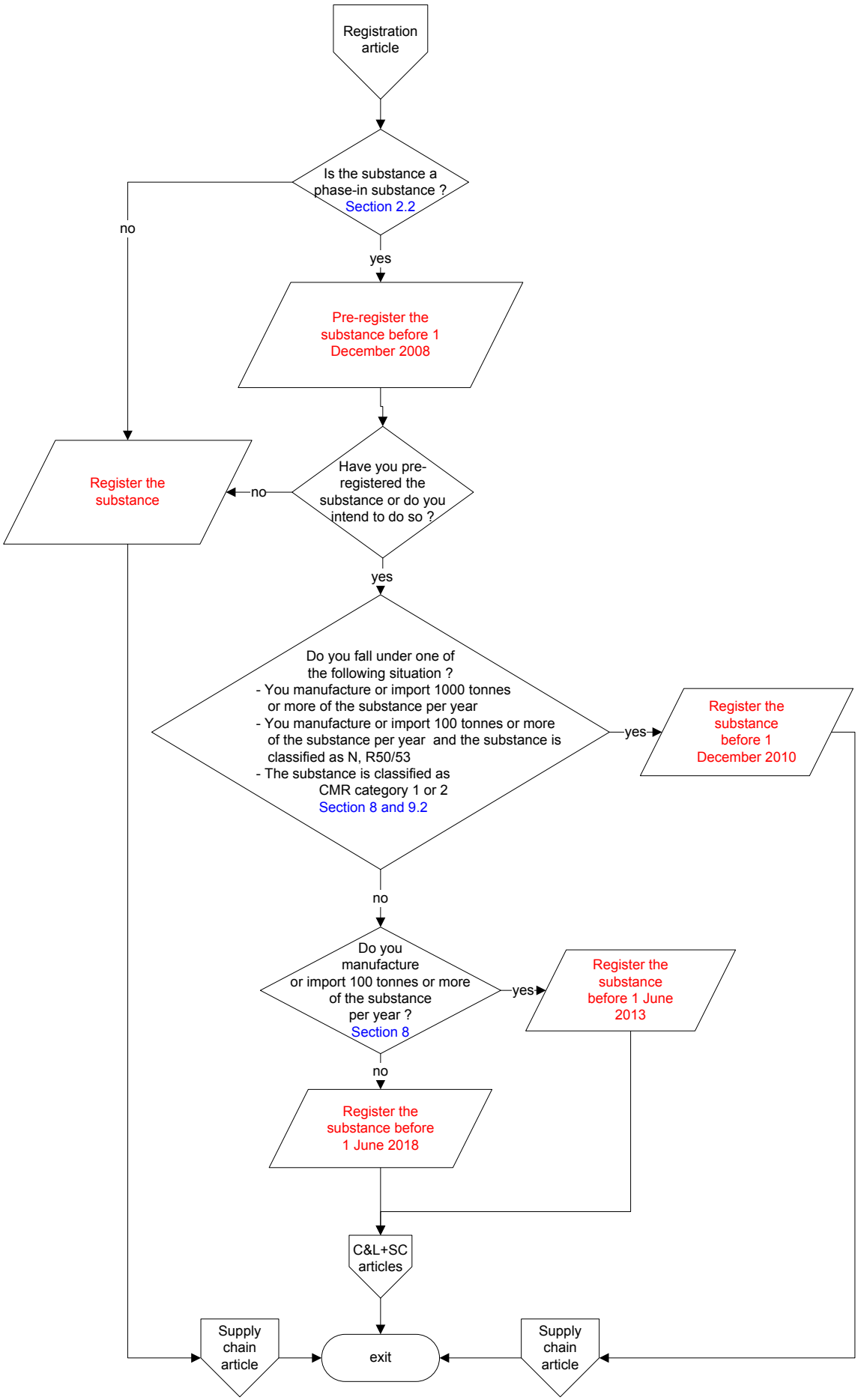

article
Is the substance already registered for the use in articles?
Section 6
yes
no
Is the substance intended to be released from the articles under normal or reasonably foreseeable conditions of use ?
Section 6
yes
no
Is the substance on the candidate list of substances for eventual inclusion in Annex XIV, established according to Article 59?
Section 12.1
yes
no
Do you produce or import articles containing 1 ton/year or more of the substance ?
yes
no
Supply chain article
Article scope
Supply chain article
No obligation applies to you for the moment for the substance in articles. Check the "candidate list" regularly if the substance meets the definition of Article 57.
Registration article
Notification article
stop
Exit

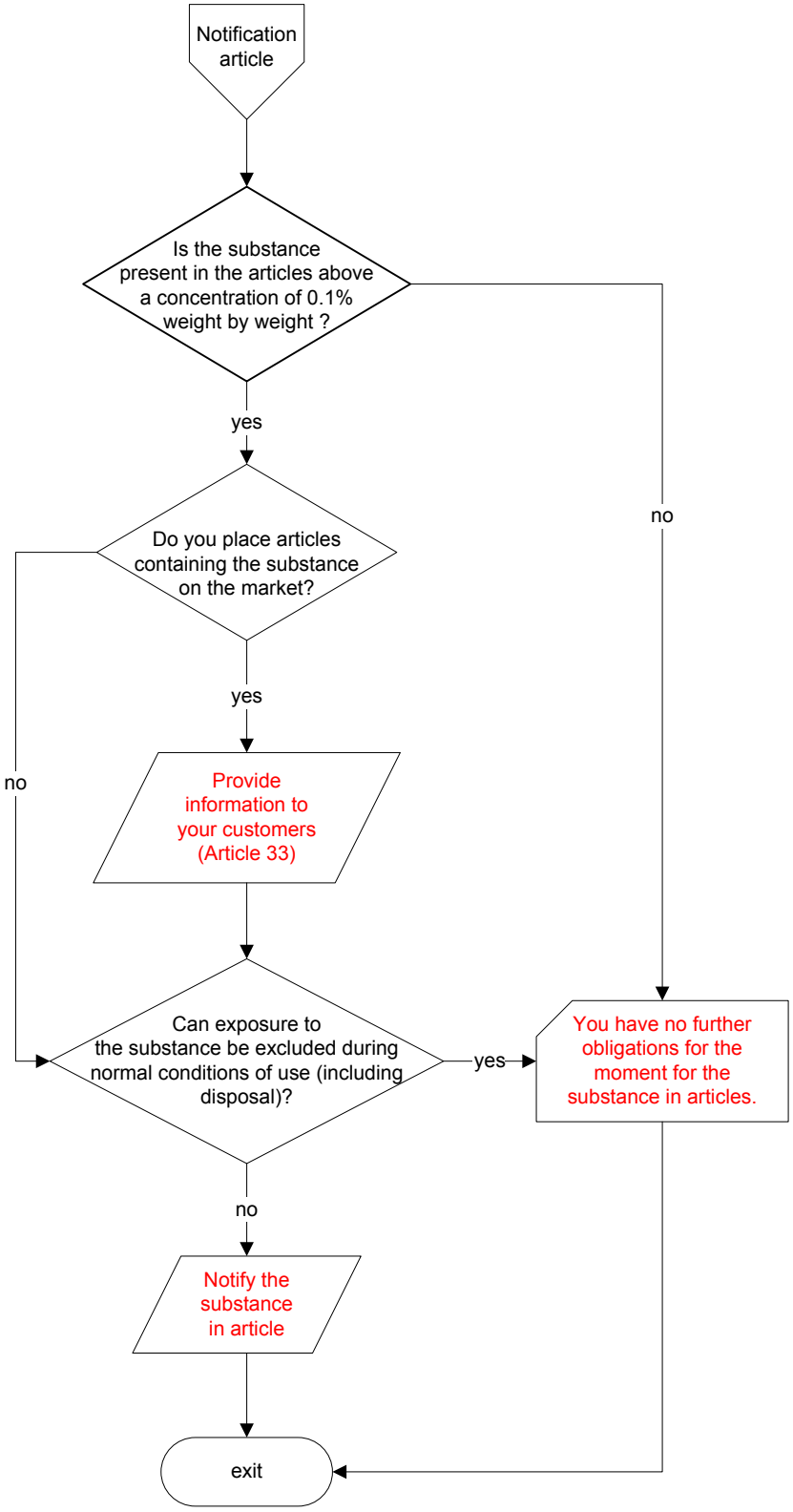

Article M/I
Is the substance intended to be released from the articles under normal or reasonably foreseeable conditions of use ?
Section 6
yes
no
Is the substance on the candidate list of substances for eventual inclusion in Annex XIV, established according to Article 59?
Section 12.1
no
No obligation applies for the moment for the substance in articles. Check the "candidate list" regularly if the substance meets the definition of Article 57.
Exit
The amount of substance contained in those articles also need to be taken into account when registering the substance.
yes
Is the substance already registered (or will you register it) for the use in articles ?
yes
Do you place articles containing the substance on the market?
Section 11
no
yes
Supply chain article
no
Notification article
Is the substance present in the articles above a concentration of 0.1% weight by weight ?
Section 6
no
yes
No obligation applies to you for the moment for the substance in articles
Provide sufficient information to your customer (article 33)
Exit


Article scope
Is the substance included in Annex IV or covered by Annex V? Section 1.9
yes
no
Do you manufacture or import 1 tonne or more of the substance in articles per year ? Section 8
no
Supply chain article
stop
yes
Is the substance a polymer? Section 1.12
yes
Follow the guidance for polymers
no
Exit


Supply chain article
Do you place articles containing the substance on the market?
Section 11
yes
Is the substance on the candidate list of substances for eventual inclusion in Annex XIV, established according to Article 59?
Section 12.1
yes
Is the substance present in the articles above a concentration of 0.1% weight by weight ?
yes
Provide information to your customers (Article 33)
no
no
no
Exit


C&L+SC articles
Do you place articles containing the substance on the market?
Section 11
yes
Notify the Classification and Labelling of the substance
Is the substance on the candidate list of substances for eventual inclusion in Annex XIV, established according to Article 59?
Section 12.1
no
yes
Is the substance present in the articles above a concentration of 0.1% weight by weight ?
yes
no
Provide information to your customers (Article 33)
no
Exit


Registration article
Is the substance a phase-in substance ? Section 2.2
no
yes
Pre-register the substance before 1 December 2008
Have you pre-registered the substance or do you intend to do so ?
no
Register the substance
yes
Do you fall under one of the following situation ?
- You manufacture or import 1000 tonnes or more of the substance per year
- You manufacture or import 100 tonnes or more of the substance per year and the substance is classified as N, R50/53
- The substance is classified as CMR category 1 or 2
Section 8 and 9.2
yes
Register the substance before 1 December 2010
no
Do you manufacture or import 100 tonnes or more of the substance per year ? Section 8
yes
Register the substance before 1 June 2013
no
Register the substance before 1 June 2018
C&L+SC articles
Supply chain article
exit
Supply chain article


Notification article
Is the substance present in the articles above a concentration of 0.1% weight by weight ?
yes
no
Do you place articles containing the substance on the market?
yes
no
Provide information to your customers (Article 33)
Can exposure to the substance be excluded during normal conditions of use (including disposal)?
yes
You have no further obligations for the moment for the substance in articles.
no
Notify the substance in article
exit