

European Photo and Imaging Association¹

EPIA REACH Guidance Document I: Inventory List

Overview

Meeting the REACH² obligations, including

- ⇒ Registration of substances as such or in preparations (article 6)
- ⇒ Registration of substances intended to be released from articles (article 7.1)
- ⇒ Notification of substances of very high concern (SVHC) in articles (article 7.2 and article 33)
- ⇒ Notification of the Classification and Labelling (C&L) of substances meeting the criteria of DIR 67/548/EC (article 112/113)

starts with making an adequate inventory list, containing adequate information for the identified substances involved.

As not all information is required for all obligations, subsequent layers of information can be added for selected parts of the list in view of the different REACH requirements.

In this Guidance Document, the REACH requirements and their scope are explained in view of the preparation of an adequate and practical Inventory List.

I. Obligations under REACH for Substances and Preparations within the Imaging Industry

The REACH legislation will affect the registration of both individual substances and substances in preparations in the following way:

- **If you manufacture a substance within the EU or import a substance from a manufacturer outside the EU** you have to register the substance, taking into account provisions on exemptions/exclusions and deadlines for registration of phase-in substances. In the case of phase-in substances (**article 3.20**) we recommend to pre-register in order to benefit from the extended time window for registration (see separate EPIA Guidance Document II “The Pre-registration of substances as required by REACH”).
 - **Note that special provisions exist for manufactured substances that fulfil the definition of intermediates (article 3.15)** excluding monomers. So-called

¹ EPIA represents photo imaging companies and European national associations of photo imaging companies. The membership includes the major manufacturers of photographic products and the major national associations CIPHO (Chemieverband Imaging und Photo e.V.), PIC (Photo Imaging Council) and Federchimica.

² REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

“non isolated intermediates” are exempt from registration, whereas reduced registration requirements apply to “on-site isolated intermediates” (**article 17**) and to “transported isolated intermediates” (**article 18**).

- **If you manufacture a preparation within the EU or import a preparation from a manufacturer outside the EU** each substance in the preparation is subject to registration by the Manufacturer/Importer at the origin of the European supply chain if the amount of the substance exceeds 1 t/a (per legal entity). If multiple preparations are manufactured or imported, the amounts of the same substance need to be aggregated to determine the tonnage band for registration. Registration is required taking into account exemptions/exclusions and deadlines for registration of phase-in substances. In the case of phase-in substances we recommend to pre-register in order to benefit from the extended time window for registration (see EPIA Guidance Document II “The Pre-registration of substances as required by REACH”).
 - **Note that substances in preparations include “reaction products”:** in the case of formation of a reaction product (via chemical reactions during the manufacturing or via in-situ reaction), that reaction product is in itself a manufactured substance and will need to be registered.
- **If you are a downstream user, you have no registration obligations under REACH.** In case you buy a substance or a preparation from a Manufacturer, Importer or Distributor located in the EU, you are a downstream user. The substance or the individual substances in the preparation have to be registered by the Manufacturer/Importer at the origin of the European supply chain, if the 1 t/a threshold is exceeded.
 - **Note however that action is required in case this registration does not cover your usage (or your use and exposure category)**

II. Inventory List

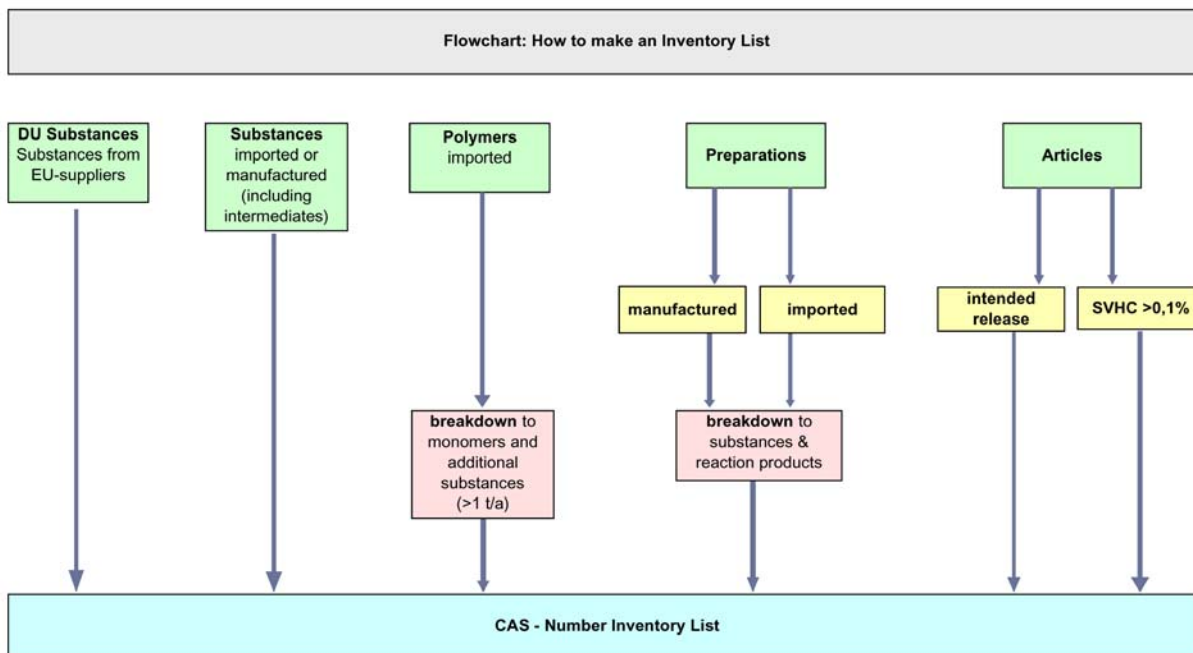
In view of the requirements described in the previous sections, REACH affects all European Imaging Industry companies, either as Manufacturer/Importer (Registrant), as Downstream User or in both capacities.

EPIA advises each Imaging company to prepare an inventory list of all the chemical substances used within the company, involving all the legal entities in the EU belonging to the same company-group, and to keep it carefully updated.

The following flowchart gives an overview of which substances need to be included in the Inventory List.

As an explanation for each of the different entries, the REACH requirement(s) justifying its inclusion is subsequently given.

Flowchart 1: How to make an Inventory List



Explanations:

1. DU Substances

EPIA recommends including all substances for which you are a Downstream User, without any limit in weight, because you have to verify if the registration by the M/I covers your DU usage or your use and exposure category, and take appropriate action if your use is not covered (**article 37.2**).

Further guidance on necessary steps is given in flowchart 2.

Relevant articles are given below:

Article 37: Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures

2. Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a preparation with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.

2. Substances imported or manufactured

EPIA recommends including all imported or manufactured substances (including intermediates of manufactured substances) without any limit in weight because of the following obligations:

- a) above 1 t/year** you have to register the substance in order to fulfill Article 6.1.
Note that special provisions exist for manufactured substances that fulfill the definition of intermediates (**article 3.15**). So-called “non isolated intermediates” are exempt from registration, whereas reduced registration requirements apply to “on-site isolated intermediates” (**article 17**) and to “transported isolated intermediates” (**article 18**).
Further guidance on necessary steps is given in flowcharts 2 and 3.
- b) below 1 t/year** you may have to notify the Agency in order to fulfill Article 113.
Further guidance is given in flowchart 4.

Relevant articles are given below:

a) above 1 t/year

Article 6: General obligation to register substances on their own or in preparations

1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency.

Article 17: Registration of on-site isolated intermediates

1. Any manufacturer of an on-site isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to the Agency for the on-site isolated intermediate.

Article 18: Registration of transported isolated intermediates

1. Any manufacturer or importer of a transported isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.

b) below 1 t/year

Article 113: Obligation to notify the Agency

1. Any manufacturer, producer of articles or importer, or group of manufacturers or producers of articles or importers, who place on the market a substance within the scope of Article 112, shall notify to the Agency the following information in order for it to be included in the inventory in accordance with Article 114, unless submitted as part of the registration:

- (a) the identity(ies) of the manufacturer(s), producer(s) of articles or importer(s) responsible for placing the substance(s) on the market as specified in section 1 of Annex VI;
- (b) the identity of the substance(s) as specified in sections 2.1 to 2.3.4 of Annex VI;
- (c) the hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;
- (d) the hazard label for the substance(s), resulting from the application of Article 23(c) to (f), of Directive 67/548/EEC;
- (e) specific concentration limits, where applicable, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.

2. Where the obligation under paragraph 1 results in different entries on the inventory for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory.
3. The information listed in paragraph 1 shall be updated by the notifier(s) whenever:
 - (a) any new scientific or technical information is generated which results in a change to the classification and labelling of the substance;
 - (b) notifiers and registrants of differing entries for a single substance come to an agreed entry in accordance with paragraph 2.

The scope is described in Article 112:

Article 112

This Title (Title XI: Classification and Labelling Inventory) shall apply to:

- (a) substances subject to registration;
- (b) substances 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.

Note that there is no weight limit like >1 t/year for such substances or preparations!

3. Imported Polymers

Based upon the REACH requirements laid down in Article 6.3, EPIA recommends considering all imported polymers. A breakdown to their monomers and other chemically bound substances making up 2 % (w/w) or more of the polymer should be made, where these are present in amounts above 1 t/year, for inclusion in the Inventory List.

The relevant article 6.3 is given below:

Article 6: General obligation to register substances on their own or in preparations

3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:
 - (a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);
 - (b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

4. Manufactured or imported Preparations

EPIA recommends considering all imported or manufactured preparations, without any limit in weight, and to make a breakdown to their individual substances for inclusion in the Inventory List, thereby considering the formation of in situ reaction products, because of the following obligations for substances present in imported or manufactured preparations:

- | | |
|--------------------------|--|
| a) above 1 t/year | you have to register the substance in order to fulfill Article 6.1.
Further guidance on necessary steps is given in flowcharts 2 and 3. |
| b) below 1 t/year | you may have to notify the Agency in order to fulfill Article 113.
Further guidance is given in flowchart 4. |

Relevant articles are given above, in section 2 “Substances imported or manufactured”.

Note on Reaction Products:

If two or more ingredients of a preparation react with each other, the reaction products formed are regarded as ingredients of the preparation. The reaction products are calculated according to current chemical knowledge. A matrix of the most common reactions between the ingredients of photographic processing solutions is attached to the Code of Practice of the EPIA. Only those reactions which occur during the production of the preparation are considered.

If there is more than one reaction possible the sequence of the reactions is carried out in the order of the pKa and pKb values.

5. Articles

Based upon the REACH requirements laid down in Article 7.1 (registration), 7.2 and 7.3 (notification), Article 33 (communication down the supply chain) and Article 112/113 (notification of the C&L of intentionally released hazardous substances), EPIA recommends considering all imported or manufactured articles. A breakdown to substances intended to be released from the articles and to SVHC appearing on the so called candidate list (Article 59) should be made, where these are present in concentrations >0.1 % (w/w). These should be included in the Inventory List.

The relevant provisions on Substances in Articles are summarized below:

- Registration of substances intended to be released from articles (**article 7.1**): only for >1 t/year
- Notification of the C&L of substances that meet the criteria of DIR 67/548/EC (**article 112/113**): without weight limit but only if intentionally released
- Notification of substances of very high concern (SVHC) in articles included in the so called candidate list (**article 7.2**) only for >1 t/year and only when >0.1 % (w/w) where exposure to humans or the environment cannot be excluded (**article 7.3**)
- Duty to communicate information down the supply chain on substances of very high concern (SVHC) in articles (**article 33**): no weight limit but only when >0.1 % (w/w)

Or presented in an alternative way:

a) above 1 t/year

- you have to register the substance if there is an intentional release (**article 7.1**).
- you have to notify to the Agency any SVHC that is present on the candidate list (**article 59**), if it is present in a concentration >0.1 % (w/w) and exposure to humans and the environment cannot be excluded (**article 7.2 and 7.3**).

b) below 1 t/year

- you have to notify the C&L to the Agency if there is intentional release and the substance meets the criteria of DIR 67/548/EC (**article 113**).
- you have to communicate information down the supply chain on any SVHC that is present on the candidate list (**article 59**), if it is present in a concentration >0.1% (w/w) (**article 33**).

The text of relevant articles is given below:

Article 7: Registration and notification of substances in articles

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

- (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
- (b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

Article 7: Registration and notification of substances in articles

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

- (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
- (b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

Article 7: Registration and notification of substances in articles

3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

Article 33: Duty to communicate information on substances in articles

1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

Article 113: Obligation to notify the Agency

See above, under "2. Substances imported or manufactured"

More details and flowcharts regarding the issue of Substances in Articles are given in a dedicated EPIA Guidance Document "EPIA REACH Guidance Document III - Substances in Articles of the Imaging Industry".

6. Result

The Inventory List worked out as described in Flowchart 1 and according to the explanatory notes given above in points 1 to 5 will help to find out for which substances your company has obligations regarding registration and notification as well as supply chain information. EPIA advises keeping this Inventory List carefully updated.

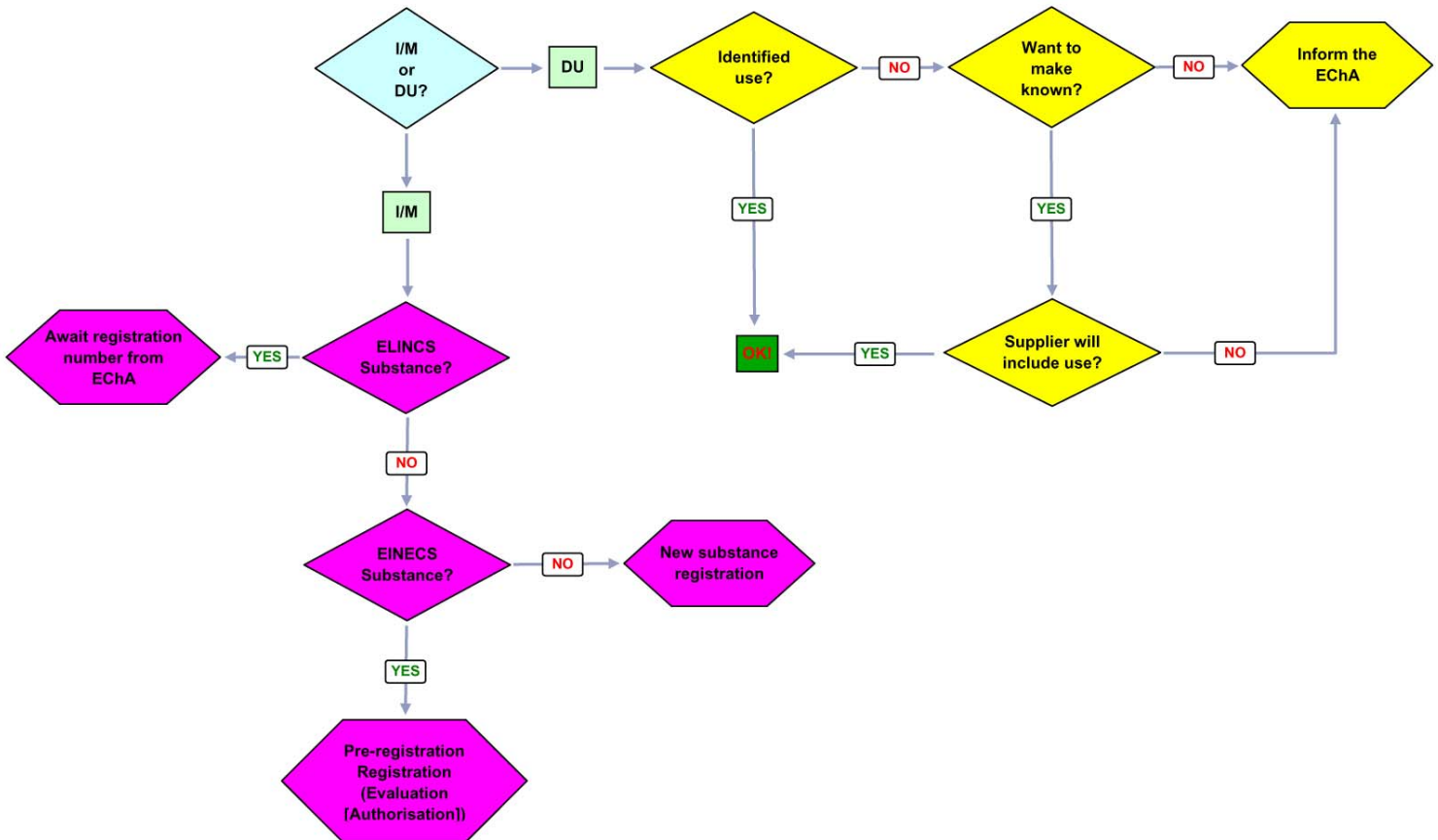
In order to facilitate complying with the REACH obligations, EPIA furthermore recommends that the Inventory List holds the following additional information for the substances on the List, independent of the quantities involved:

As not all information is required for all obligations, subsequent layers of information can be added for selected parts of the list in view of the different REACH requirements.

- Substance Code and Substance Name,
- CAS, EINECS, ELINCS, Other
- Type of substance (end product / isolated intermediate / transported intermediate / NLP (no longer polymer) / exported only / polymer / excluded substance),
- Manufacturer, Importer, Downstream-User,
- Supplier and alternative Supplier(s),
- Supplier location and alternative Supplier(s) location (EU or non EU),
- Amount purchased from each supplier,
- Classification, R-Phrases,
- SVHC (substances of very high concern; included in the candidate list)
- Source (substance / polymer / preparation / article)
- Name of the legal entity in the EU where used

III. Basic Determination of the Substance Role

Flowchart 2: REACH requirements depending on the Substance Role

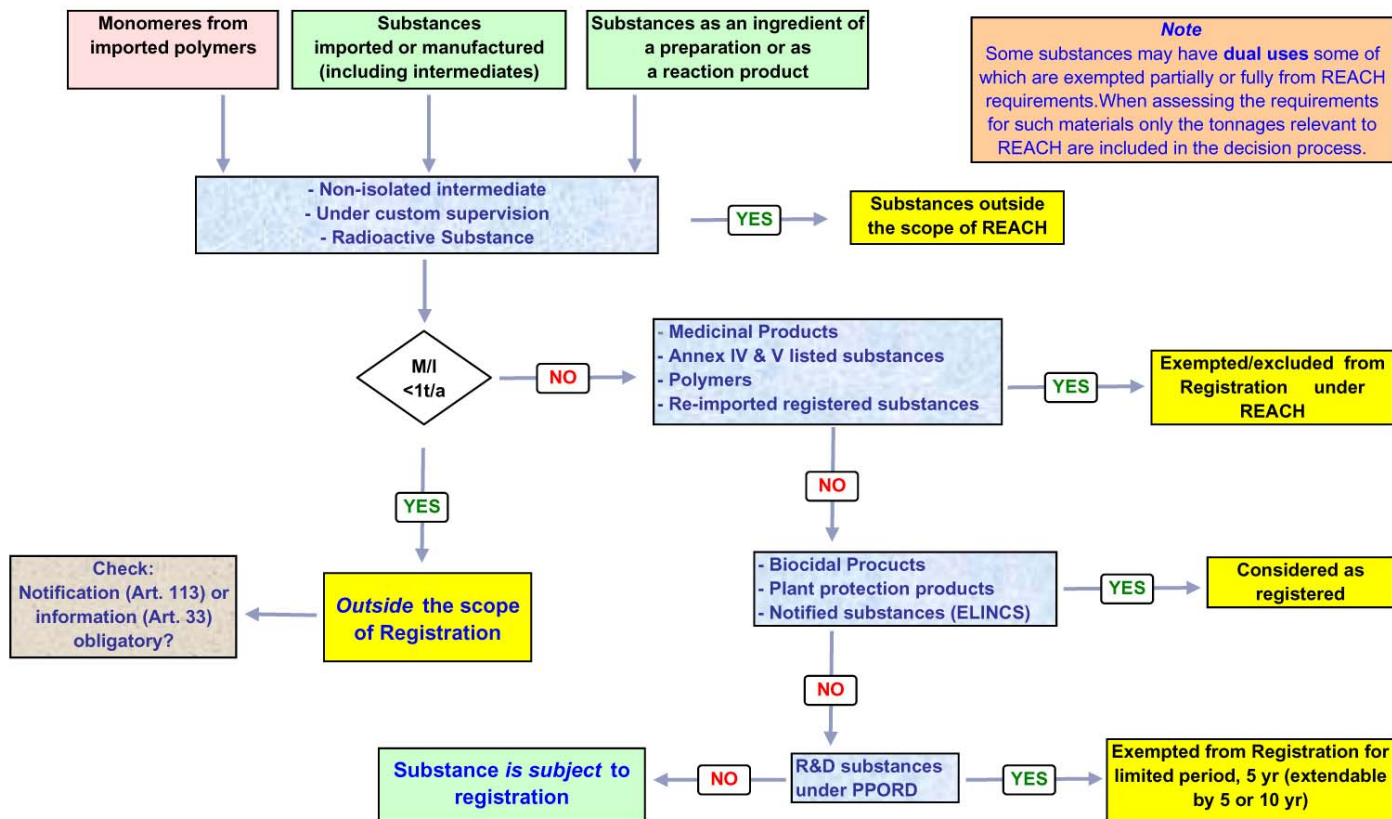


For each substance, first it has to be determined if Manufacturer/Importer (M/I) or Downstream User (DU) obligations have to be fulfilled. If M/I, you have to carry out a registration if indicated (according to the following flowchart, 'Registration requirements under REACH'). As a DU, you have to check if your use is already identified (included in the supplier's SDS) or, if not, if you want to make it known or not.

IV. Further Decision Trees

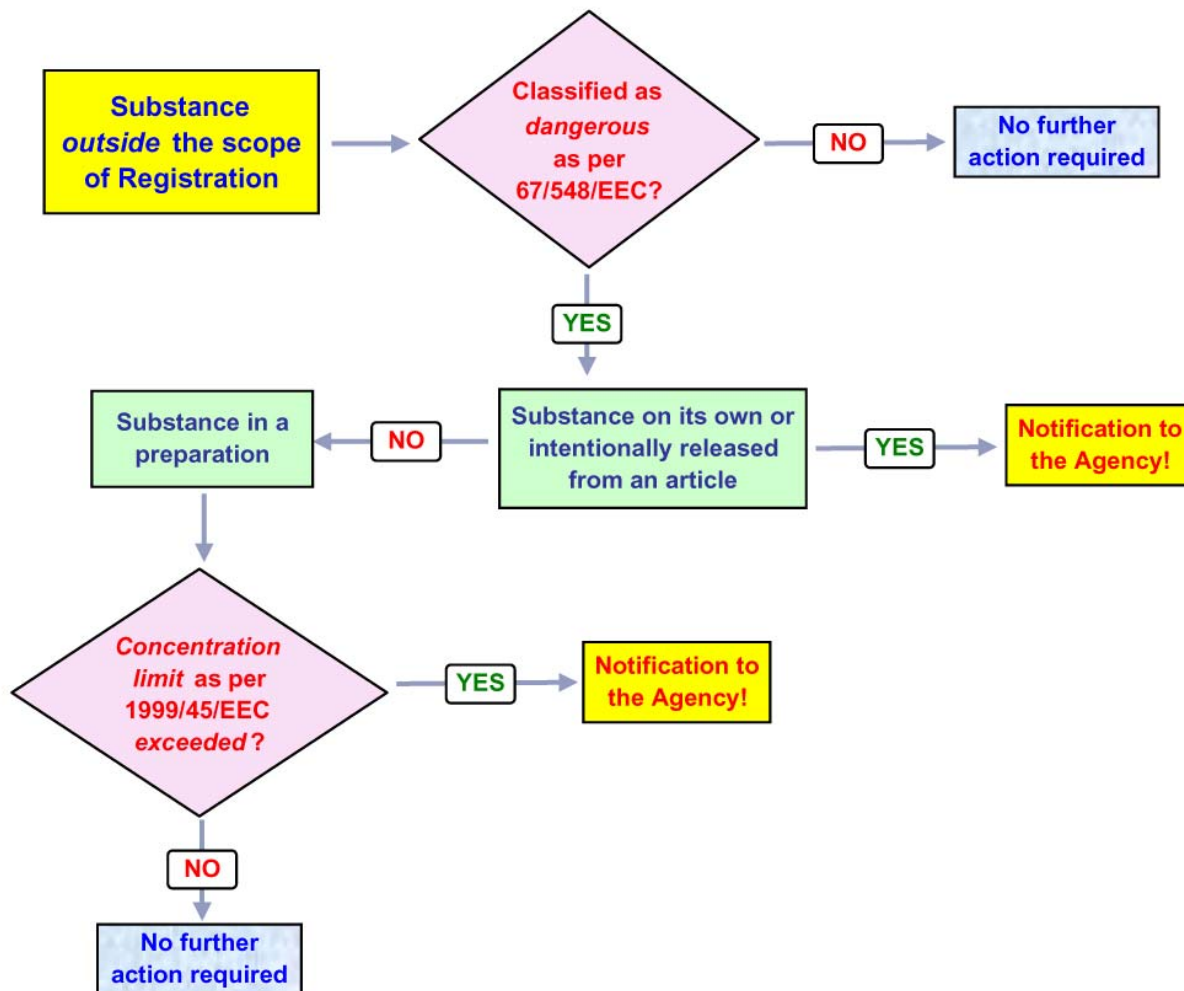
1. Registration

Flowchart 3: Registration requirements under REACH



2. Notification on Article 112/113

Flowchart 4: Notification of substances according to Article 113.



V. Substances Subject to Authorisation

It should be noted that substances with intrinsic properties of very high concern (SVHC) will have to be authorised, once such a substance is identified in Annex XIV.

Such substances of very high concern are:

- **CMRs category 1 and 2**
- **substances which are persistent, bioaccumulative and toxic (PBT)**
- **substances which are very persistent and very bioaccumulative (vPvB)**
- **other substances, such as endocrine disruptors, that present an equivalent level of concern to PBT or vPvB**

Substances to be authorised will be identified in **ANNEX XIV** along with a deadline for applications, and the date by which applications must be processed by the authorities.

To obtain an authorisation, a Manufacturer, Importer or Downstream user will have to demonstrate that the risk from the use of a substance can be adequately controlled or that the socio-economic benefits outweigh the risk. Authorisation decisions for uses for which the risks cannot adequately be controlled should take account of available information on alternative substances and processes that may replace the use. To focus efforts on aspects of highest concern, authorisations will only consider risks from the properties that led a substance being subjected to authorisation (e.g. if a carcinogen is also an irritant, the irritancy will not be considered).

Community-wide authorisations will be granted by the Commission after considering the recommendations of the Agency in all cases where the applicant places, or intends to place, the substance on the market.

To simplify and lighten the system, an authorisation will be valid for enterprises further down the supply chain as long as they abide by the conditions of the authorisation for the intended use and inform the Agency. Grouping of applications for authorisation is also possible, subject to justification by the applicant. Groups can be: Manufacturers, Importers and Downstream users; substances; uses; or any combination of these groups. This is to enable costs to be minimised and to enable the system to process applications rapidly.

Disclaimer

The present document was developed by experts from the photochemical industry to their best knowledge and judgement, but no liability whatsoever is accepted in respect of this document. The text of the REACH Regulation is decisive in all cases.