

European Photo and Imaging Association¹

EPIA REACH Guidance Document II: The Pre-registration of substances as required by REACH²

REACH provides an extended time period for the registration of phase-in substances which have been pre-registered. Any Manufacturer/Importer (M/I) of a phase-in substance in quantities of ≥ 1 t/y who intends to register this substance under REACH should therefore pre-register.

All substances of the Inventory List³ that are imported or manufactured will belong to one of the following categories (see also the flow scheme in appendix 1):

1. The substance is listed on EINECS
2. The substance is a 'no longer polymer' (NLP) that was placed on the market between 1995 and 2004
3. The substance was manufactured but not placed on the market during the last 15 years (examples: intermediates; substances that were made for export from the EU only)
4. The substance was notified as a "new chemical" in accordance with DIR 67/548/EEC (an ELINCS substance)
5. None of the above (such as new substances made or imported in quantities below 10 kg per year)

Substances that belong to one of the categories 1, 2, 3 are **phase-in substances (article 3.20)** for which an immediate registration, after REACH comes into effect, is not required, provided that such substances are pre-registered (article 28). The registration periods related to the substance properties and/or annual quantities for phase-in substances **which have been pre-registered** are given in the table below **(article 23)**.

Substance properties and/or annual amounts	Registration period for phase-in substances
- CMR ⁴ (≥ 1 t/y) - R 50-53 ⁵ (≥ 100 t/y) - ≥ 1000 t/y	1 December 2010
≥ 100 t/y	1 June 2013
≥ 1 t/y	1 June 2018

When a phase-in substance is not pre-registered, the registration has to be done without delay when Title II "Registration of Substances" applies to phase-in substances **(article 28.3)**, which is 12 months after REACH comes into force **(article 140)**.

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).

³ See the EPIA Guidance document I "Inventory List".

⁴ Classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC.

⁵ Classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50-53) in accordance with Directive 67/548/EEC.

Important notes:

Pre-registration of phase-in substances will only be possible within a limited time period of six months, starting 12 months after REACH enters into force and ending 18 months after REACH enters into force (**article 28.2**), thus allowing only a 6-month period for the actual pre-registration process. Pre-registration will be possible between June 1st and December 1st, 2008.

1. When a phase-in substance is introduced by a Manufacturer or Importer after the pre-registration deadline has expired, it will still be possible to make use of the extended registration periods given in the table above. Such a newly introduced phase-in substance must be pre-registered within 6 months after its introduction and no later than 12 months before a relevant deadline is reached (example: a non-hazardous phase-in substance that is introduced 2 years after REACH has come into effect and which will be used in 250 tons per year quantities will have to be registered at the latest 4 years later, provided that pre-registration is done within 6 months) (**article 28.6**).
2. When a phase-in substance is manufactured or imported in quantities <1 t/y, pre-registration is not required. However, a pre-registration will be required within 6 months after reaching the 1 t/y tonnage band for that substance to still make use of the registration period of 11 years after REACH has entered into force (**article 28.6**).
3. When use is made of categories 2 or 3 (NLP or not placed on the market during the last 15 years), supporting documents must be available (**article 3.20 (b) and (c)**).
4. When a phase-in substance is manufactured or imported by several legal entities in the EU belonging to the same company-group, each legal entity involved needs to do a pre-registration separately, either by themselves or by their representative (**article 8**).
5. A non-phase-in substance that is notified in accordance with Directive 67/548/EEC (ELINCS substance) is regarded as registered and therefore a pre-registration is not required (**article 24.1**).
However, if the quantity manufactured or imported per Manufacturer or Importer reaches the next tonnage threshold, the additional required information corresponding to that tonnage threshold, as well as to all the lower tonnage thresholds, shall be submitted (**article 24.2**).
6. Substances <1 t/y do not require pre-registration or registration. However see also note 3 above (**article 23**).
7. Non-phase-in substances and substances not regarded as registered have to be registered without delay when Title II "Registration of Substances" applies, i.e. 12 months after REACH enters into force (**article 141.2**). As mentioned before, the same applies to phase-in substances that are not pre-registered (**article 28.3**) within the time window for pre-registration (between 12 and 18 months after EIF) (**article 28.2**). Thus, if there is no intention to pre-register a phase-in substance, registration is required without delay 12 months after EIF, even though the possibility to pre-register any phase-in substance runs until 18 months after EIF.
8. It should be noted that pre-registration only affects the *timing* of registration, i.e. the actual registration will still need to be done at some point after the pre-registration. Also pre-registration does not affect the other form of reporting, i.e. notifications, which still need to be met according to the legislation requirements.

How to select pre-registration candidate substances?

Candidate substances for pre-registration are all the phase-in substances from the Inventory List⁶ that require registration, i.e. the substances from the Inventory List belonging to any of the categories 1, 2, 3 described in the introduction above that are manufactured or imported in quantities >1 t/y (**article 28.1**).

Guidance on how to obtain the registration candidates from the Inventory List is given in the referenced EPIA guidance document.

In summary, substances for which pre-registration needs to be considered are (**article 28.1**):

- substances manufactured and/or imported on their own (**article 6.1**)
- substances in imported preparations (**article 6.1**)
- substances in imported articles (**article 7.1**)
(under certain conditions: if the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year and the substance is intended to be released under normal or reasonably foreseeable conditions of use)
- substances in imported polymers such as monomers and additives (**article 6.3**)
(under certain conditions: if the monomer or additive is present >2 % weight by weight (w/w) in the form of monomeric units or chemically bound substances and if the total quantity of such monomer or additive makes up 1 tonne or more per year)
- on-site isolated intermediates (**article 17, article 19**)
- transported isolated intermediates (**article 18, article 19**)
- substances which have been synthesized at least once in the 15 years before the entry into force, but not placed on the market (**article 3.20**)
- No-Longer Polymers (**article 3.20**)

What information needs to be submitted for pre-registration? (**article 28.1**)

The Council common position requires the following information for pre-registration:

1. Substance identifiers, such as:
 - name(s) in the IUPAC nomenclature or other international chemical name(s)
 - other names (usual name, trade name, abbreviation)
 - EINECS or ELINCS number (if available and appropriate)
 - CAS name and CAS number (if available)
 - other identity code (if available, e.g. NLP number)
2. Identity of the potential registrant, including:
 - name and address of the potential registrant
 - name of the contact person
 - name and address of the representative where appropriate
3. Envisaged deadline for the registration/tonnage band
4. Name(s) of other substance(s) that may be helpful for grouping, read-across and (Q)SAR

⁶ See the EPIA Guidance document I "Inventory List".

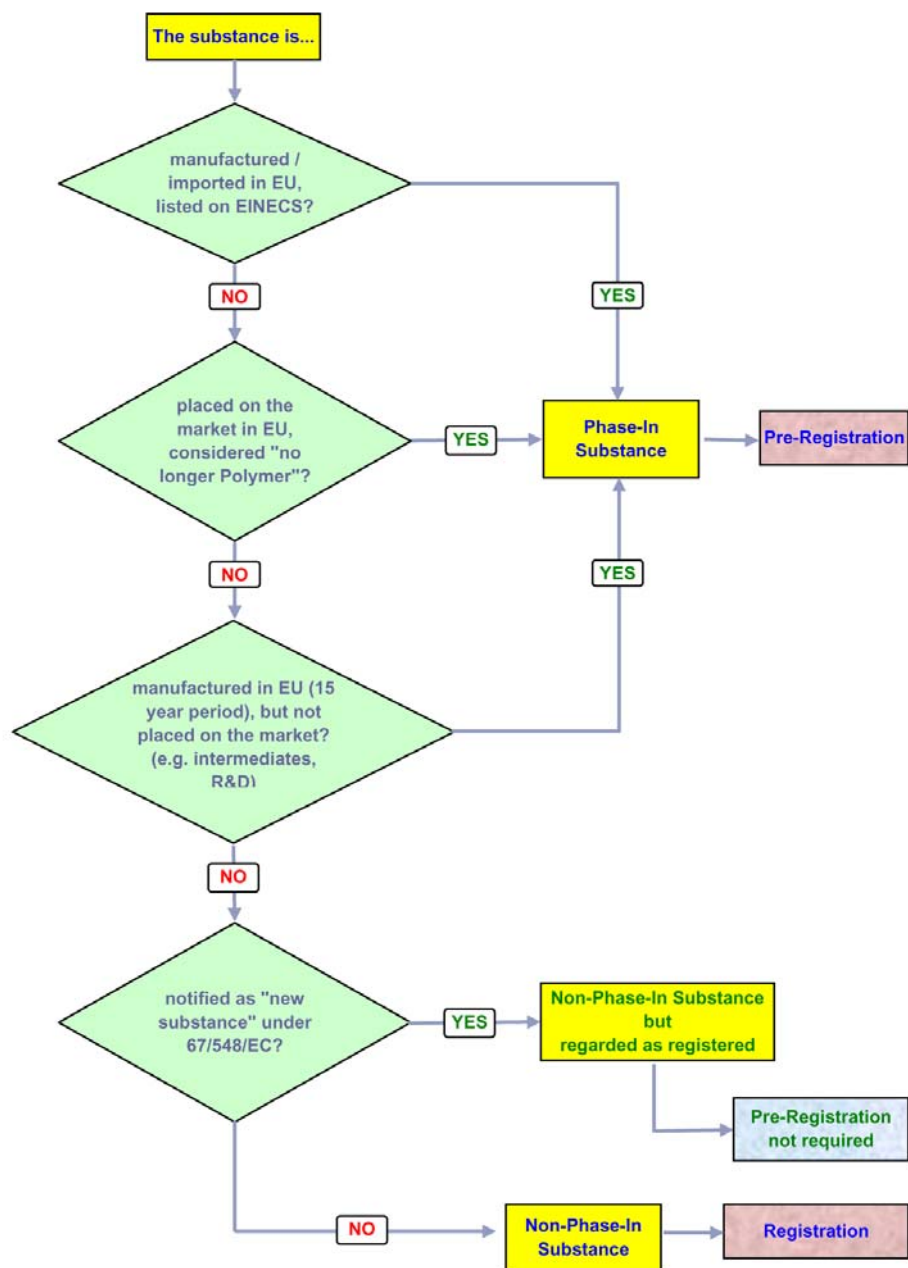
What to do after pre-registration?

After pre-registration the Agency will publish a list of all pre-registered substances (**article 28.4**). Pre-registrants of the same substance will be informed about participation in a SIEF⁷ for that substance (**article 29.1**). Manufacturers or Importers of a phase-in substance not required to be registered because the volume is <1 t/y can also participate in a SIEF for that substance when they have data available for the substance, provided they have pre-registered the substance (**article 28.7**). Also, downstream users can participate in a SIEF when they have data available for the substance concerned (**article 28.7**).

Additional guidance about the REACH requirements after pre-registration will be the subject of a future EPIA document.

⁷ SIEF: Substance Information Exchange Forum (**article 29, article 30**).

Appendix 1.



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.