Guidance on Pre-registration

1.0 Introduction

Pre-registration is the process whereby Manufacturers, producers/importers of articles with an intended release and Importers of „phase-in substances" have to submit a brief set of information to ECHA in order to benefit from the extended registration deadlines. This guideline provides additional information on the pre-registration process for phase-in substances.

2.0 Pre-registration- Basic knowledge

2.1 Who can pre-register

Each natural and legal person who would be required to register a phase-in substance after 1 June 2008 may pre-register that substance. These persons include:

- Manufacturers and Importers of phase-in substances on their own or in preparations in quantities of 1 tonne or more per year, including intermediates;
- Producers and Importers of articles containing substances intended to be released under normal or reasonably foreseeable conditions of use and present in those articles in quantities of 1 tonne or more per year;
- "Only-representatives" of non-EU Manufacturers where the substance(s) will be imported in quantities of 1 tonne or more per year.

Non-EU Manufacturers* include natural or legal persons who:

- Manufacture a substance on its own, in preparations or in articles that is imported into the Community; or
- Formulate a preparation that is imported (by an EU Importer) into the Community; or
- Produce an article containing substances intended to be released that is imported (by an EU Importer) into the Community.

* **Note:** Non-EU Manufacturers cannot pre-register/register directly the substances that are exported in the EU; either registration is done by Importers or, alternatively, non-EU Manufacturers may be represented by a natural or legal person located in the EU territory, the "Only Representative".

2.2 Only Representatives

Only Representatives are natural or legal persons appointed by non-EU Manufacturers to fulfill the obligations of Importers. Only natural or legal persons: **(i) established in the EU and, (ii) having sufficient background in the practical handling of substances** and the information related to them, may be appointed as Only Representatives. When an Only Representative is appointed, the non-EU manufacturer has the obligation to inform the Importer(s) within the same supply chain (the - direct and indirect - customers of the non-EU Manufacturers) of the appointment. Following such communication the Only Representative takes up the role of the EU Importers, fulfils their registration obligations. He also has to keep available and up-to-date information on quantities imported and customers sold to (including their uses), as well as all information required to meet the obligation to communicate information down the supply chain. When an Only Representative is appointed for one or more substance(s), he becomes responsible for the volume of this/these substance(s) manufactured by this non-EU manufacturer and exported into the EU. An Only Representative can represent several non-EU manufacturers of a substance. When an Only Representative is appointed, the Importer(s) will have the status of downstream user and will have to comply with the applicable obligations under REACH.

2.3 Legal entity

When a phase-in substance is manufactured, imported or used in the production of an article by several EU legal entities belonging to the same company group, each legal entity has to pre-register separately. **Pre-registration must be done by each legal entity that is required to register.** This means that if a holding company is composed of different legal entities in Europe, each legal entity must pre-register the phase-in substances that they produce or import. Manufacturing sites that do not have legal personality are not required to pre-register because they do not have the obligation to register.

2.4 Manufacturers and Importers of substances below 1 tonne per year

Manufacturers and Importers of phase-in substances or article producers and importers containing phase-in substances in quantities of less than 1 tonne per year **do not need to pre-register** (as registration is not required). However, they can do so based on their intention to manufacture or import the substance in quantities of 1 tonne or more in the future. It is important to note that companies that exceed the 1 tonne threshold after 1 December 2008 are still entitled to pre-register if they (on their own or via the use of a Third Party Representative) submit the relevant information to ECHA within 6 months from the date where the 1 tonne threshold is first exceeded and provided this is at least one year before the relevant (extended) registration deadline.

2.5 Benefits of pre-registration

i. Pre-registration allows Potential Registrants to benefit from extended registration deadlines. For so-called phase-in substances, REACH provides for a phase-in scheme with staggered registration deadlines depending on the tonnage band and hazards of the substance, more specifically:

Table 1 Deadline for registration of phase-in substances

Substance properties/Yearly Volume	Deadline for registration of phase-in substances
• R ≧1 tpa • R 50-53 ≧100 tpa • Other substances ≧1000 tpa	**30 November 2010**
• Other substances ≧100 tpa	**31 May 2013**
• Other substances ≧1 tpa	**31 May 2018**

ii. Pre-registration also gives companies additional time to organize the collection and selection of available data, the sharing of existing data, and the collective generation of missing information.

iii. Pre-registration provides the basis to make existing information on substances e.g. non-testing information, substance to substance read-across, data from testing accessible to those who need the information for registration

Pre-registration is free of charge and does not establish any obligation to maintain production or import of substances. However, please note that a company who pre-registered will be part of a Substance Information Exchange Forum (SIEF) until 1June 2018 and may need to actively participate to the SIEF activities. In addition pre-registrant may have financial obligations in relation to its substance. Parties sharing data must make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. In general, it is recommended that an agreement on cost sharing is reached prior to the disclosure of available information by participants.

2.6 Deadline for Pre-registration

Pre-registration information has to be submitted to ECHA between 1 June 2008 and 1 December 2008 (inclusive).

2.7 What if the deadline for pre-registration is not met?

If a company fails (or does not wish) to pre-register within the applicable deadline (i.e. in most cases 1 December 2008), it will have to suspend its activities involving the substances concerned and register them without delay. In addition it should be remembered that in this case the registrant will also have to

inquire at the ECHA if a registration for the substance has been made. All manufacturing, placing on the market and use of such substances between the start of the pre-registration deadline (i.e. in most cases 1 June 2008) and the date of suspension of activities may be subject to penalties according to national law. This also means that the downstream uses of these substances may be at risk. Activities involving the substances concerned can then only be resumed three weeks after the submission date of the a complete registration dossier.

2.8 Is it possible to pre-register after December 2008?

If any company manufacturing or importing phase-in substances in quantities of 1 tonne or more for the first time, after 1 December 2008 she can still benefit from the extended registration deadlines if she pre-register:

- At the latest six months after manufacturing or importing exceeds the one-tonne threshold; and
- At least 12 months before the relevant deadline for registration.

Manufacture or import for the first time, refers to the first time after the entry into force of REACH (1 June 2007).

3.0 Practical steps for pre-registration

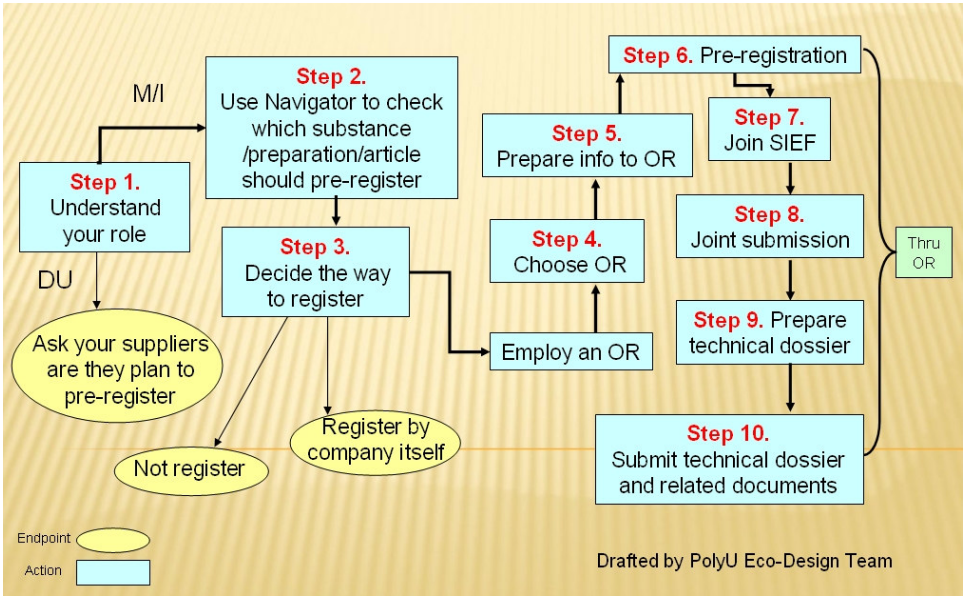

Figure 1 Holistic flowchart for (Pre-) registration processes

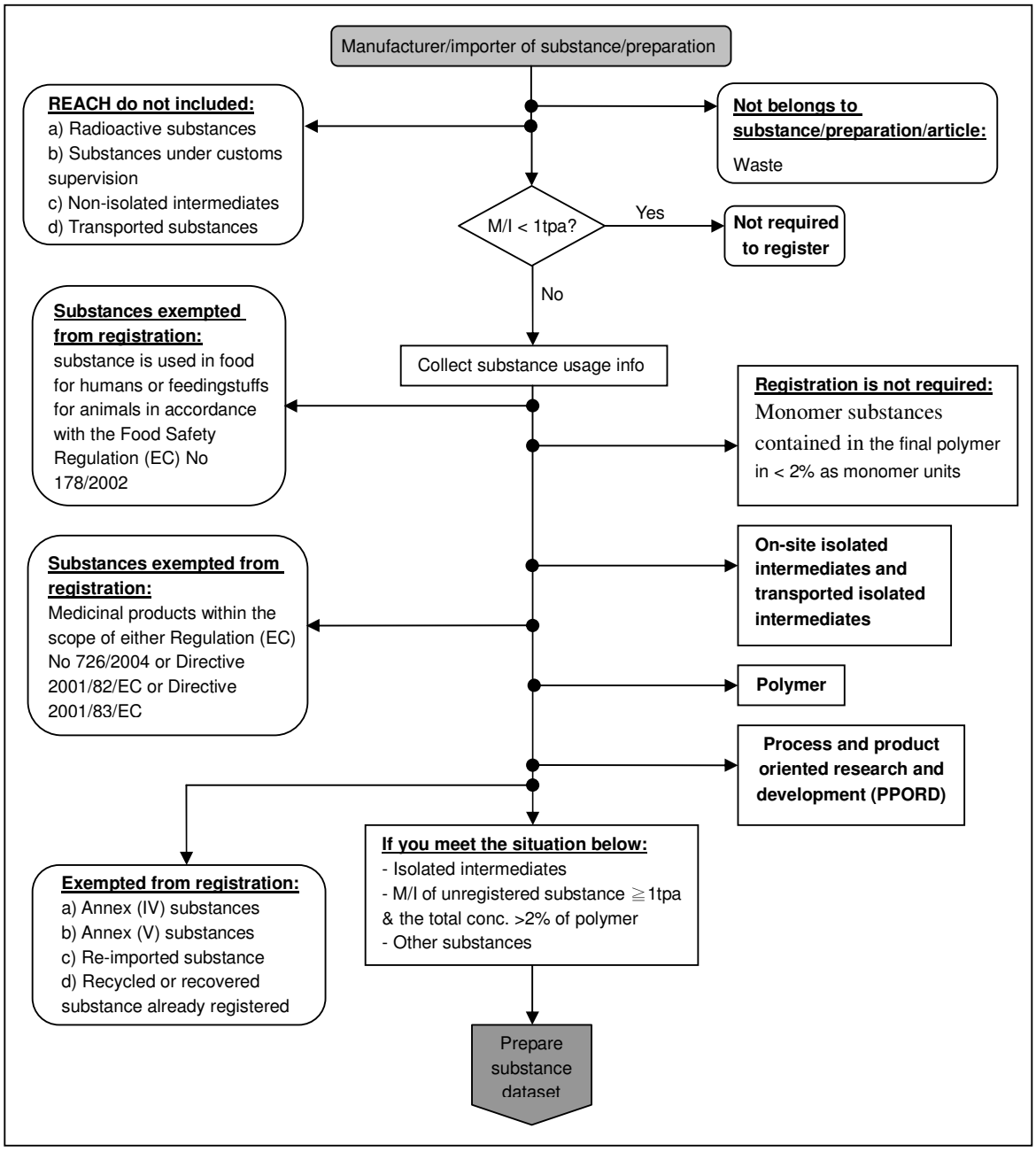

Figure 2: Check whether you have to pre-register your substance/preparation

Links to related material

REACH Regulation EC No 1907/2006

http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2007:136:SOM:EN:HTML

REACH guidance Documents

http://reach .jrc.it/guidance_en.htm

Guidance on data sharing

http://reach.jrc.it/docs/guidance_documents/data_sharing_en.htm

Guidance for substance identification and naming of substances under REACH

http://reach.jrc.it/docs/guidance_documents/substance_id_en.htm

ECHA website

http://echa.europa.eu

ECHA helpdesk

http://echa.europa.eu/reach/helpdesk_en.html