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LATER PRE-REGISTRATION

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PRE-REGISTRATION

Who can pre-register?

- **EU manufacturers**
- **EU importers**
- **Only Representatives on behalf of the Non European company**

What can be pre-registered?

- **Only "phase in substances" (with EINECS number)**

Notes:

1.- Control any exemptions if it is necessary (substances used in food, medicines or listed as exempts under REACH. Substances which are intermediates and are used to manufacture medicines or food).

2.- If a substance does not have EINECS, it has to go directly to registration, unless it is manufactured in the EU but not commercialized.

3.- The pre-registration is develop trough REACH-IT or IUCLID5 (ECHA platforms) and it is free.

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LATER PRE-REGISTER

Between 1 June and 1 December 2008 manufacturers and importers had the possibility to pre-register each existing (so-called phase-in) substance with the European Chemicals Agency. This allows companies to benefit from extended registration deadlines.

If an EU importer or your Only Representative has failed to meet the deadline for pre-registration, he does not benefit from the extended registration deadlines and will need to register the substance before importing it again into the EU market.

Phase-in substances which were not pre-registered but are imported for the first time into the EU after 1 December 2008 may benefit from the staggered registration timelines if the information requested for pre-registration is provided within 6 months of first import into the EU and no later than 12 months before the relevant registration deadline.

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Pre-registered substances would benefited from extended deadlines for registration

Substance properties/Yearly Volume	*Deadline for Registration of Phase-In Substances*
CMR[3] ≥ 1 t/y R 50-53[4] ≥ 100 t/y Other substances ≥ 1000 t/y	30 November 2010
Other substances ≥ *100 t/y*	31 May 2013
Other substances ≥ *1 t/y*	31 May 2018

Non phase-in substances that are commercialized in Europe in quantities above 1 tone/year will have to be registered as soon as possible because they will be illegally commercialized, this mean, that they will not in compliance with the European regulation and could be withdrawn from the market and the companies that use them, could be punished.

PRE-REGISTRATION CONSEQUENCES: SIEF

- As a result of pre-registration, the company (or OR) is placed in a specific database for the pre-registered substance, called SIEF to facilitate information exchange and to develop the registration dossier.
- This database lists all pre-registered companies of a substance and it is only accessible for those companies.
- There will be a SIEF for each pre-registered substance.

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SIEF OBJECTIVE

- The joint development of the registration dossier sharing information (one substance, one registration).
- It will be shared information in order to avoid studies duplication, in particular, studies on vertebrate animals.
- It will come to an agreement on the classification and labeling of the substance, required by December 2010.

CONSORTIUM

- SIEF participants may choose to join Consortium for a better cooperation. This is a strategic decision.
- The participation in a consortium is voluntary and generally implies a cost.

INTERMEDIATE SUBSTANCE

- If a substance is transformed into another substance by chemical synthesis, this substance could be considered an intermediate. If a substance is used directly, in a preparation or an article for another purpose, this substance can not be considered as an intermediate and will be under the usual registration requirements.

- There are less registration requirements for an intermediate substance than a non-intermediate substance, if strictly control and containment measures have been satisfied.

Conclusion:

- A substance (raw material or intermediate) that ends in a synthesis process could be considered an intermediate in REACH.
- A substance (raw material) that ends in a mixture or article, so it is not transformed into another substance, can not be an intermediate.

- Substances that may be considered intermediate and are marketed in Europe from a non-European company, are classified as " transported isolated intermediates.
- This means one substance is transformed into another through a synthesis process and it is manufactured in one place (for example, in a non-European) and transported to another places (for example, a company in the EU).

Thank you

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