

REACH-Role Of Registrants

Recital 19

Therefore, the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration should require them to submit a dossier containing all this information to the Agency. Registered substances should be allowed to circulate on the internal market.

REACH-Role Of Registrants 1

Definitions (Article 3)

Registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;

Manufacturer: means any natural or legal person established within the Community who manufactures a substance within the Community;

Importer: means any natural or legal person established within the Community who is responsible for import;

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Pre-registration (Article 28)

- Duty to pre-register within a time-slot of 12-18 months(June - December 2008) after the enforcement of REACH;
- Pre-registered substances can apply transitional periods for the further registration;
- The list of pre-registered substances will be published in the internet and forms the basis for Substance Information Exchange Fora (SIEF).

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Pre-registration (Article 28)

Information required:

- name of the substance as specified in section 2 of Annex VI, including its EINECS and CAS number or, if not available, any other identity codes;
- name and address and the name of the contact person
- the envisaged deadline for the registration and the tonnage band;
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Pre-registration (Article 28)

- The Agency will publish a list of pre-registered substances by 1 January 2009
- After the publication of the list a downstream user of a substance not appearing on the list may notify the Agency of his interest in the substance, his contact details and the details of his current supplier.

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Substance Information Exchange Fora (Article 29)

- All potential registrants, downstream users and third parties who have submitted information to the Agency in accordance with Article 28,for the same phase-in substance, or registrants who have submitted a registration for that phase-in substance before the deadline.....shall be participants in a substance information exchange forum (SIEF).

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Substance Information Exchange Fora (Article 29)

- The aim of each SIEF shall be to:
 - (a) facilitate, for the purposes of registration, the exchange of informationbetween potential registrants, thereby avoiding the duplication of studies; and
 - (b) agree classification and labelling where there is a difference in the classification and labelling of the substance between potential registrants.

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Pre-registration (Article 28)

Very Important

If pre-registration is not completed on time,

- Manufacturers and importers will not be able to produce and supply
- Downstream users will have no supply.

REACH-Role Of Registrants Registration

Manufacturers and importers of more than 1 tonne per year must submit a technical dossier to the agency including,

- Identity of the manufacturer(s) or importer(s)
- Identity of the substance
- Information on the manufacture and use(s) of the substance
- Classification and labelling of the substance
- Guidance on safe use of the substance
- Study summaries
- Proposals for testing

REACH-Role Of Registrants

Registration

Additionally, manufacturers and importers of more than 10 tonnes tonne per year must submit a chemical safety report (CSR) to the agency including,

- Human health hazard assessment
- Environmental hazard assessment

REACH-Role Of Registrants

Registration

Additionally, manufacturers and importers of substances with hazardous properties* must submit,

- An exposure assessment including Exposure Scenarios
- A risk characterisation

* As defined in the Substances Directive 67/548/EEC

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Definition: Exposure Scenario

- the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

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Joint submission of data by multiple registrants

(Article 11)

- When a substance is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration the following shall apply.

.....the information specifiedand any relevantshall first be submitted by the one registrant acting with the agreement of the other assenting registrant(s) (... "the lead registrant").

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Downstream Users Obligations

A Downstream User has to check, if

- his intended use for the substance is included in the registration
- the exposure scenario described in the SDS fulfils his needs,

In case of discrepancies he has to inform his supplier.

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Registration costs Euros (Up to date?)

Tonnage Category	Full Base Fee	Consortium Participants	SMEs	SMEs Consortium
1-10	1200	800	900	500
10-100	3250	2200	2450	1400
100-1000	8850	5900	6600	3700
>1000	24000	16000	18000	10100

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REACH and Parts Makers March 2007

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Time is short!

Latest registration for

- 1000 tonnes/annum
- 100 tonnes/annum dangerous for the environment
- 1 tonne/annum CMR categories 1 & 2

Is 1st. December 2010

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Remember!

NO DATA, NO MARKET!

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