

Registration of Existing Substances

Registration requirements

Requirements on physical, chemical, toxicological and eco-toxicological information in relation to annual production / import volume per supplier:

≥ 1 t/a	≥ 10 t/a	≥ 100 t/a	≥ 1000 t/a
Technical dossier	Technical dossier	Technical dossier	Technical dossier
	Chemical safety report	Chemical safety report	Chemical safety report
		Suggestions for additional tests	Suggestions for additional tests

Registration deadlines

Deadlines for registrations depend on the one hand on the hazard potential of the substances and on the other hand on their production or import volume.

- Substances that do not have a particularly high hazard potential and are produced annually in amounts of 1,000 metric tons or more need to be registered in 2010.
- Similar substances produced in annual volumes of up to 100 metric tons can wait until 2018.
- For substances with CMR properties at amounts > 1 metric ton/year and for those requiring labeling with R50/53 at amounts > 100 metric tons/year, the dossiers have also to be submitted by December 1, 2010.

The required data for the chemicals must be submitted electronically to the European Chemicals Agency (ECHA) in Helsinki.

These deadlines are only granted by the ECHA, however, if the relevant chemicals have been pre-registered in the period from June 1 to November 30, 2008.

In the course of the evaluation of a registration, the Agency will scrutinize the data in the registration dossier to determine if and if so, which additional data still need to be supplied.

Saltigo has already completed the pre-registration of all of its substances (raw materials, intermediates and sales products) that it could clearly identify as requiring such.

Registration of New Substances / PPORD **(From the RSC brochure: A brief guide to REACH)**

“After 1 June 2008, substances manufactured in or imported into the EU for the purpose of product and process oriented research and development (PPORD) in cooperation with listed customers and in quantities limited to the above purpose are exempt from the general obligation to register for a period of five years.

PPORD includes any scientific development of a product, or the further development of a substance on its own or in preparations or in articles, in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance.

The manufacturer can apply for the PPORD to be extended for another five years, if justified, or another ten years if a pharmaceutical.

The manufacturer/ importer will have to supply the following information to ECHA:

- Manufacturer/importer identity
- Substance identity
- Quantities involved (overall manufactured / imported quantities in tons per registrant per year in the calendar year of the registration)
- Classification and labeling (where information on classification and labeling is not available, reasons for such lack of information should be given)
- Customer involved in the research (names and addresses)”

Saltigo will work with you, our customers, to ensure timely and complete PPORD filing and management for your project.