

REACH Compliance

(Registration, Evaluation, Restriction and Authorization of Chemicals)

New EU Legislation



GE imagination at work

REACH Overview

Registration of all substances manufactured in the EU or imported into the EU above 1 tonne/year

Authorization of substances of very high concern (SVHCs) (severe pressure to use “safer substitute”)

Notification of SVHCs in articles above 0.1% w/w to Agency and **information** on SVHCs in articles above 0.1% w/w down the supply chain

Restriction of certain SVHCs

EU Chemical Agency (in Helsinki, Finland) to manage REACH in coordination w/ national chemical agencies

The provisions of REACH will enter into force progressively from 1 June 2007.



REACH...Overview

- Covers the manufacture, import, and use of chemical substances, in preparations, and in articles (finished products).
- Will regulate existing & new chemical substances...No Grandfathering.
- Final legislation went into effect **June 1, 2007**. Phase-in compliance deadlines begin to run in 2008.
- Commission expects 30-50% of the specialty chemicals to go off the market.
- Product critical substances (Chrome, Lead, Mercury, Beryllium, Nickel) at risk of being restricted to authorized uses.
- No use in manufacturing w/o confirmed Registration or Authorization.
- EU Commission estimates \$18-23B of implementation cost.



Registration Overview

Central data-base of chemicals and intended uses managed by EU Chemicals Agency

Accessible to users and the public

Registration deadlines for phase-in substances*

- Above 1000 tonnes and all CMRs (carcinogenic, mutagenic, reprotoxic) cat. 1 & 2 and R50/53 above 100 tonnes: **1 November 2010**
- Above 100 tonnes: **1 June 2013**
- Above 1 tonnes: **1 June 2018**
- New substances: register within 60 days (after entry into force)

***11 year phase-in only available to substances that have been pre-registered!**



Registration and Notification Obligations

	Substance	Preparation	Article
Definition	Chemical element and its compounds in the natural state or obtained by any manufacturing process.	Mixture or solution composed of two or more substances.	Object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.
Duties of Manufacturer or Importer	Registration before production or importation > 1 t/y.	Registration of substances in preparations before importation > 1 t/y.	<p><u>Registration</u> required of any substance <i>intended to be released</i> from articles > 1 t/y. <u>Notification</u> required if article contains substances of very high concern above 0.1% and 1t/y.</p> <p><u>Information</u> to recipient (or final consumer) if article contains substances of very high concern above 0.1%.</p>
Duties of Downstream User	Inform supplier of use <u>or</u> prepare own Chemical Safety Report and inform Agency.	Inform supplier of use of substances <u>or</u> prepare own Chemical Safety Report and inform Agency.	<p>No registration or notification duties towards Agency.</p> <p><u>Information</u> to recipient (or final consumer) if article contains substances of very high concern above 0.1%.</p>



Authorization* Overview

- Substances of very high concern (SVHC) (est. 1500-3000):
 - CMRs cat. 1&2 (Carcinogenic, mutagenic, reprotoxic)
 - PBTs (Persistent, Bioaccumulative, Toxic)
 - vPvBs (very Persistent, very Bioaccumulative)
 - Substances of “equivalent concern” (for example endocrine disruptors, sensitizers)

Authorization Overview (continued)

- SVHCs will be identified on a “candidate list”, will be prioritized and then progressively authorized as resources allow (25-30/year)

Commission grants authorizations if applicants demonstrate:

- Adequate Control (only CMRs with threshold safety levels),
or
- Socioeconomic benefits are greater than the risk and no substitutes exist (non-threshold CMRs, PBTs, vPvBs)
- If substitutes exist a substitution plan always has to be submitted.

Downstream Users can use suppliers' authorization

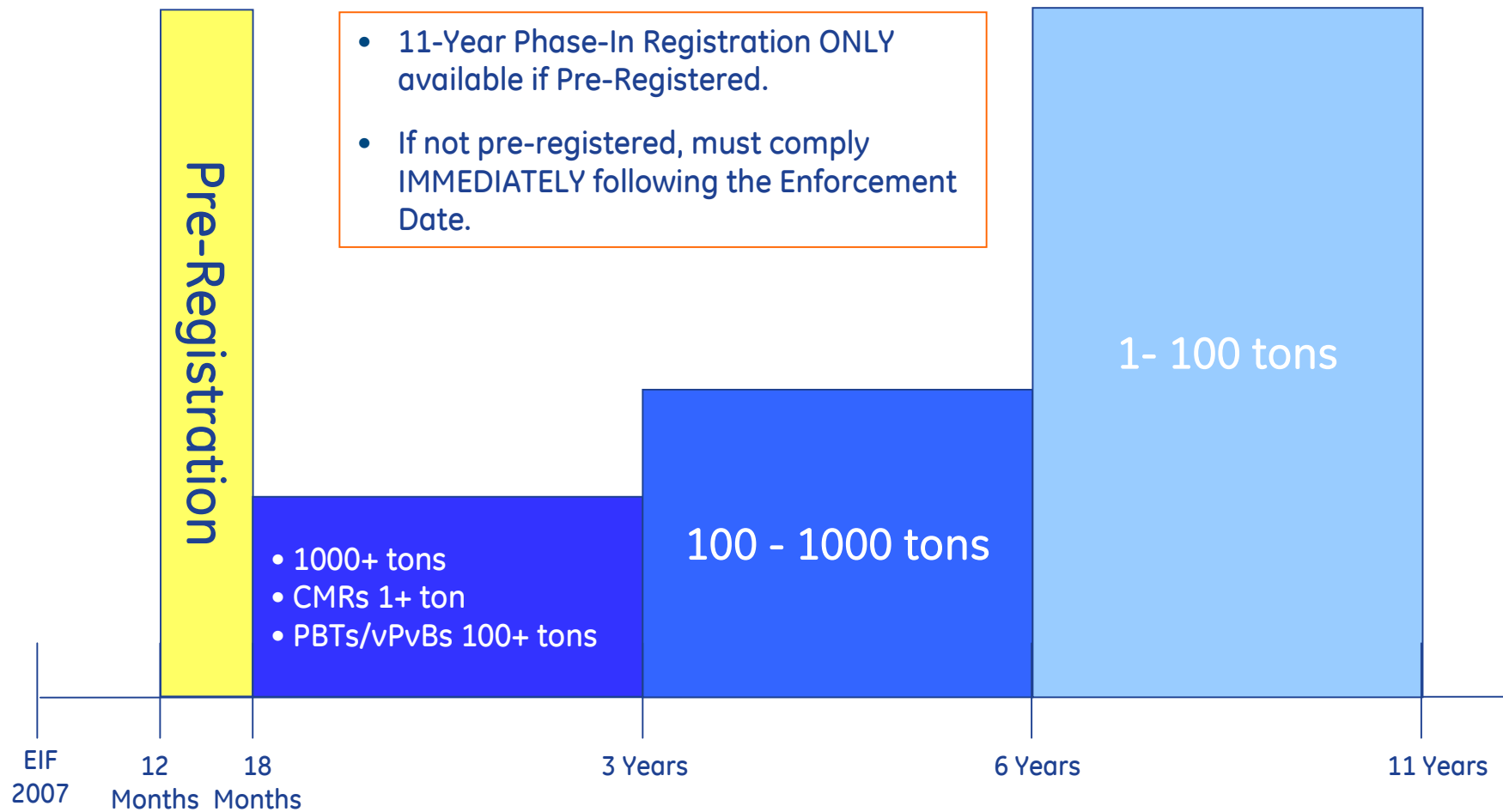
Obligations for Article Manufacturers/Importers (M/I) and Suppliers

1. M/I: pre-register and register substances in your article that are intended to be released **from 1 June 2008** (Article 7.1 of REACH)
2. M/I: notify Agency of substances of very high concern above 0.1% and above 1t/y in article **from 1 June 2011** (Article 7.2 of REACH)
3. Suppliers: inform recipient and consumer of substances of very high concern above 0.1% in article **from first publication of "candidate list"** (Article 33 of REACH)

"Substances of very high concern" (SVHCs) will be defined through the "Candidate List" (Articles 59 and 57 of REACH). **The first "Candidate List" is expected to come out between 1 June 2008 and 1 June 2009.**



REACH...Pre-Registration



Enforcement Date - 2008



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CMR - Carcinogenic, Mutagenic, Toxic for Reproduction

PBT - Persistent, Bioaccumulative and Toxic substance

vPvB - very Persistent and very Bioaccumulative substance

REACH...Registration

- **Each Chemical M/I must register ALL substances > 1 ton/yr manufactured or imported to EU.**
 - Must include all substances included in a preparation
 - Registration must cover all identified uses.
 - If Manufacturer / Supplier can not comply, GE Aviation must...
 - Change Supplier(s)
 - Change Product(s)
 - Register on Supplier(s)' Behalf
- **Finished Articles may Require either Registration or Notification:**
 - Registration if any substance intended to be released from articles > 1 t/y.
 - Notification if article contains specific substances of very high concern above 0.1% and 1t/y
- Downstream User (DU) must make a use known to his supplier *or* Keep his use confidential and prepare his own CSR (Chemical Safety Report).
- Registration is Complex and Costly.
- Must join "Substance Information Exchange Forum" (SIEF) for that substance for data sharing purposes. May elect not to join the joint registration. Must be completed immediately following Phase-In Registration.



REACH...Authorization & Restriction

- All substances as such, in preparations, or in articles can be subject to Restrictions, irrespective of volume
- Agency will “Authorize” the use of certain Substance of Very High Concern (SVHC) (as found on the Restricted List) based on
 - Applicant’s demonstration of adequate control or
 - Applicant’s demonstration that socioeconomic benefits is greater than the risk and no substitutes exist
- Authorization designed to force substitution.
- Downstream User just make notifications for any substances when using suppliers’ “authorized” chemical substance.