

REACH – Overview and Timelines

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REACH – an overview

- **European Union's Registration, Evaluation and Authorization of Chemicals (REACH) provides a major redrafting of European chemicals policies**
- **Proposed by the European Commission in 2003 and enacted as a Regulation in December, 2006**
- **REACH drives the generation and collection of hazard data, while minimizing duplicate efforts and animal testing**
- **Came into force June 1, 2007**



REACH: Scope

- **Covers some 30,000 substances manufactured or imported into any of the European Union countries in quantities of 1 ton or more per year**
- **Exemptions:**
 - medicinal products, food additives
 - polymers
 - pesticides and biocides
 - ores, fuels, cements
 - chemicals in research labs



The EU Registration, Evaluation and Authorization of Chemicals (REACH) proposal

- Coordinated European response to limits of existing approaches
- Ensure greater supply chain sharing of information and risk management measures
- Applies to manufacturers and importers of chemicals but also to chemicals in products (not the actual foreign production processes)
- Ensure control (including substitution) of chemicals of high concern
- Result of years of discussion and negotiation.



REACH –in force 1 June 2007

- **Single coherent system for new (non phase-in) and existing (phase-in) chemicals**
- **Elements:**
 - **Registration** of substances ≥ 1 tonne/yr (staggered deadlines)
 - More **information and better communication** through the supply chain
 - **Evaluation** of some substances by European Chemicals Agency (MS support for substance evaluation)
 - **Authorisation** only for ‘Substances of Very High Concern’ (SVHC)
 - **Restrictions** - the safety net
 - **Agency** to manage system
- **Focus on priorities:**
 - high volumes (early deadline)
 - greatest concern (CMRs and high volume R50/53 early)
 - Establishes new European Chemicals Agency (ECHA)

A Tiered Approach

REACH

Substances: A chemical substance and its compounds in the natural state or obtained by any manufacturing process. For example: chemicals, metals, etc.

Preparations: A mixture of solution composed of two or more substances. The function is more determined by the chemical composition than by its shape, surface or the design. For example: Paints, Resins, Alloys, etc.

Article: An object which during

Pre-registration

- **By November 30, 2008 all manufacturers or importers of 1 ton or more per year must notify the new European Chemicals Agency in Helsinki**
- **Information:**
 - **identification of registrant**
 - **substance name**
 - **annual volume**
 - **deadline for registration**
- **Agency publishes list of information on website to facilitate all potential registrants of the same substance cooperating, through membership of a Substance Information Exchange Forum (SIEF).**



Importance of pre-registration?

- **First duty under REACH**
- **Vital to ensuring non-duplicative registrations – ie the challenge of correct chemical identification**
- **Have to ensure substances which are supplied to you are registered to reduce threat of withdrawal**
- **If you do not pre-register you cannot take advantage of the phase-in (tiered) registration deadlines and will have to register immediately**
- **For a chemical user this could mean supply shortages so should ensure pre-registration of substances you use**
- **Should also examine importance of substance and alternatives.**



Another immediate requirement – updated Safety Data Sheets

- As of June 1, 2007 SDSs must be provided for all PBT and vPvB substances and preparations containing more than 0.1%
- SDSs must include exposure scenarios if prepared up the supply chain
- Slight change in format of an SDS
- Should have plan in place to update as soon as possible.



Registration

- Any substance manufactured in, or imported into, the EU in quantities > 1 t/yr must be registered
 - Each substance per manufacturer/importer
 - All M/I of the same substance are required to cooperate to provide a single hazard data set per substance
- Goal is flexibility in information requirements – use of structure activity, etc. and minimization of testing
- A notification process
- Includes substances in preparations or articles
- Already listed non-phase-in in substances automatically registered
- Amount of information & schedule for registration tiered by volume (10, 100, 1000 t/yr) and level of concern
- Costs to be determined in 2007.



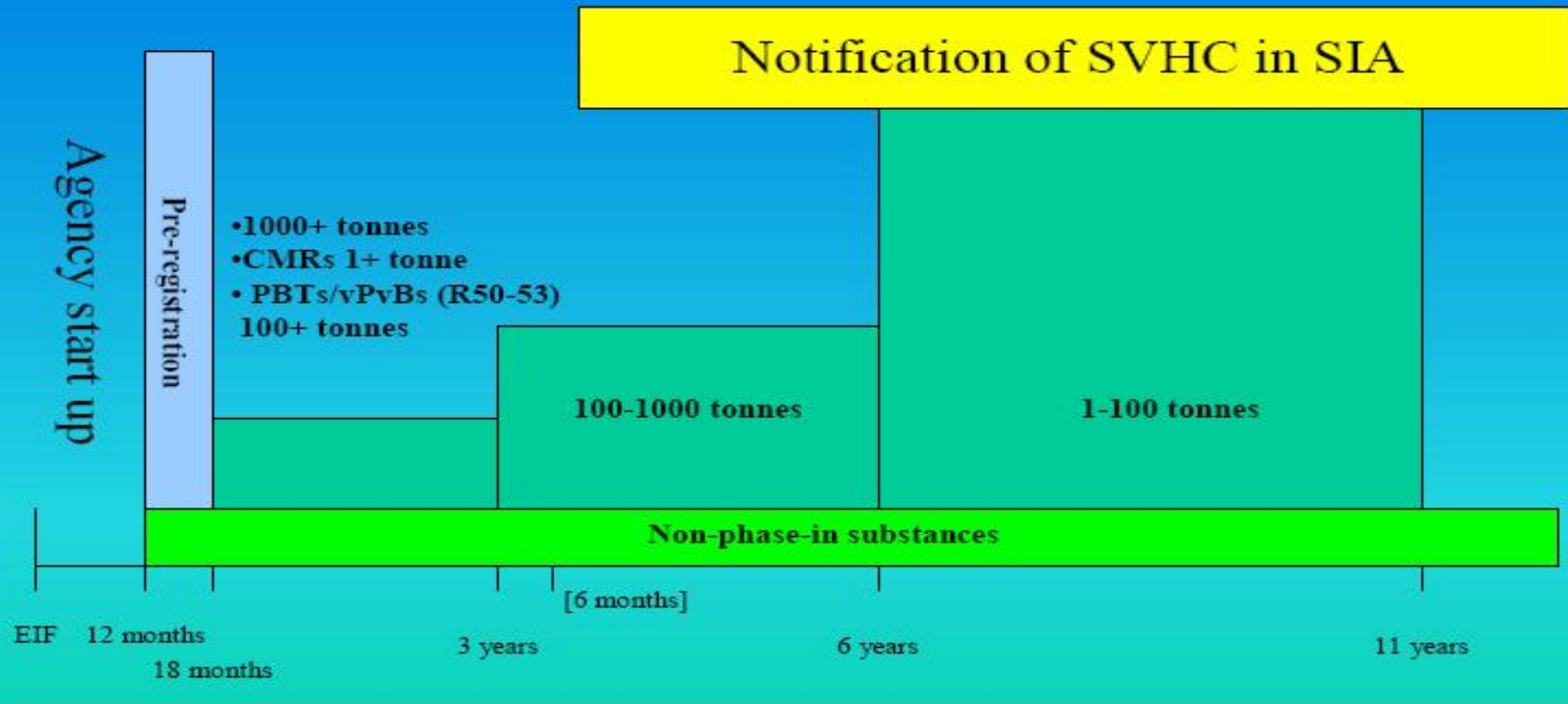
Information Requirements for Registration

TECHNICAL DOSSIER

- **Common information for all registrations**
 - **technical data on the registrant, identification of the substance, physio-chemical properties, manufacture and use and guidance on safe use**
 - **Robust summaries of test data (studies) (rules for non-test data)**
 - **Proposed classification and labelling**
- **Testing Depending on tonnage thresholds**
 - **> 1 t/yr ⇒ Annex VII (non-phase in and high concern) but lower concern just available data and physiochemical properties**
 - **> 10 t/yr ⇒ As above + Annex VIII**
 - **> 100 t/yr ⇒ As above + proposals for Annex IX**
 - **> 1000 t/yr As above + proposals for testing Annex X**



REACH – (Pre) Registration Timeline



“Registration” of *substances, substances in preparations, substances in articles.*

“Registration” on basis of “tonnages”, “SVHC or not”, “phase-in or not”.

“Registration” after 3 1/2 year (> 1000 t/j) , 6 year (100-1000 t/j), 11 year (1-100 t/j).

“Notification” of Substances of Very High Concern (SVCH) in articles



Substances in Articles

- **Substances intended to be released from articles, and present above 1 tonne per M/I per year, are subject to the same registration requirements and deadlines as for substances on their own or in preparations**
- **Importers need provide a notification only to the ECHA if the article contains a substance of very high concern (SVHC) and it is not intended to be released.**
- **The ECHA may request the registration of a notified substance in an article if it poses a risk to human health or the environment.**



Most recent info on SIA's

- May 2007 Memo from European Commission concern about requirements for SVHC's >0.1% (whole article or parts of it?) - borderline cases
- Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition.
- Therefore, if the object merely acts as a container/carrier material to deliver a substance/preparation (such as a spray can with a preparation in it, a printer cartridge, a pen, a cleaning tissue containing chemicals, ink in a printed ribbon or on carbon paper etc.) then it is a substance/preparation in a container. It is then the substance/preparation that matters most, even though the container can have a specific shape. The content is emptied and the container discarded or reused separately. Such substances/preparations will be subject to registration under Article 6.
- If the substance is an [integral] part of the article, then the substance can either be intended to be released or not intended to be released. In both cases the substance is considered a substance in an article in the sense of Article 7. The article with any remaining substance is discarded together at the end of life.



Chemical Safety Report (>10 t/year)

- List hazards of all identified uses (by users and projected)
- Chemical Safety Assessments must include:
 - human health hazard assessments
 - environmental hazard assessments
 - PBT and vPvB assessments
 - and , if the substance is high hazard (or PBT/vPvB), then
 - exposure assessment for specific uses
 - risk characterization
- Exposure scenarios are sets of conditions that describe how substances should be manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends to control exposures of humans and the environment.
- The exposure scenarios must include the appropriate risk management measures that, when properly implemented, ensure that the risks from the uses of the substance are adequately controlled.



Downstream Users (DU)

- **Manufacturer/importer CSR to cover all uses identified by downstream users. Goal is upstream/downstream communication**
- **DU has two options: (1) supplier carrying out assessment, or (2) for confidentiality reasons doing own assessment.**
- **If using suppliers' CSR just have to:**
 - **implement supplier's risk management for identified uses**
- **If conducting own CSR will have to:**
 - **perform assessments only for 'unidentified uses' (using supplier hazard information)**
 - **inform Agency of 'unidentified uses'**
- **Suppliers of articles have to provide information to the recipients of these articles (not including consumers) on substances in them which are SVHC and present above 0.1% (weight by weight) to allow their safe use (the minimum information to be provided is the name of the SVHC).**



REACH: Registration

- Phased in by annual volume category over 11 years
- Register 'non-phase-in' (new) substances or non-pre-registered phase-in substances at ≥ 1 t.p.a. before manufacture or import from 1 June 2008.

Tons/year	>1000 tons, CMRs, vPvBs, PBTs	100-1000 tons	10-100 tons	1-10 tons
Deadline	3-1/2 years	6 years	11 years	11 years
Est. Number of firms	2,600	2,800	4,600	20,000
Chemical Safety Report	Yes	Yes	Yes	No



Classification and Labeling Inventory

- For now current classification and labeling requirements taken further by REACH by requiring:
 - those placing on the market dangerous substances (on their own or in preparations above certain concentration limits) or
 - M/I, or producers and importers of articles containing substances, that are subject to Registration
- to submit the classification and labelling information on the substances to the ECHA. This information will be entered into a publicly available inventory.
- The inventory ensures that hazard classifications and labeling of all dangerous substances manufactured in, or imported into, the EU are available to all.
- Industry will be required to submit all its classifications to the Agency, to be included in the inventory, by 30 November 2010.
- Draft proposals to implement the GHS in the EU with final proposal in 2007



REACH: Evaluation

- **Evaluations are conducted by the Member States**
- **Based on a “rolling plan” informed by substances of concern with a quota of 5% of Registrations per year**
- **Can lead to establishment of risk management/ restriction proposals**
- **There are 2 types of Evaluation**
 - **Dossier Evaluation**
 - a compliance check on the data
 - a review of testing protocols
 - **Substance Evaluation**
 - a check on validity of findings
 - a request for additional information or testing



Authorization

- **Substances of very high concern – CMRs, vPvBs, PBTs, and others of equivalent concern**
- **Manufacturers/importers must apply for authorization to continue use for each general use.**
- **Authorization can be given – time limited – if adequate control can be demonstrated**
- **If ‘adequate control’ cannot be demonstrated, or the ‘adequate control’ route is not available then a decision on authorising a use will take account of the risks posed by the substance, socio-economic impacts of authorising or not the use, possible alternatives and substitutes (substances and processes)**
- **Fed into system on a case by case basis as resources allow.**



Restrictions

- **Safety net to enable conditions (up to and including prohibition) to be placed on the manufacture, placing on the market or use of substances, on their own, in a preparation or in an article**
- **Member States develop proposals**
- **Existing restrictions carry over**



Getting Ready for REACH

- A huge undertaking
- Lots of details still to be worked out. Likely lots of uncertainty and flexibility in the beginning
- Agency still not set up
- Read the RIPs - <http://ecb.jrc.it/reach/rip/> - RIP 3.5 important for downstream users
- Keeping up to date with the legislation
http://ec.europa.eu/enterprise/reach/index_en.htm
- EU setting up NAVIGATOR system to answer questions.



RIPS projects

- **Finished projects**
 - **RIP 3.2-1A: Technical Guidance Document (TGD) on preparing the CSR (Scoping) & RIP 3.2-1B: TGD on preparing the CSR (Draft CSA)**
 - **RIP 3.3-1: TGD on information requirements (Scoping)**
 - **RIP 3.5-1: TGD on Downstream User requirements, preliminary study**
 - **RIP 3.9-1: Preliminary study on Socio-Economic Analysis**
 - **RIP 3.10: TGD on Identification and Naming of Substances in REACH**
 - **RIP 4.4: TGD on the preparation of Annex XV dossiers**
- **The projects are currently running or near completion:**
 - **RIP 3.1: Guidance on Registration**
 - **RIP 3.2-2: TGD on preparing the CSR**
 - **RIP 3.3-2: TGD on information requirements**
 - **RIP 3.4: TGD on data sharing**
 - **RIP 3.5-2: TGD on Downstream User requirements**
 - **RIP 3.7: Guidance on preparing an Authorisation Application**
 - **RIP 3.8: Guidance on fulfilling the requirements for articles**
 - **RIP 3.9-2: Guidance on carrying out a Socio-Economic Analysis**
 - **RIP 4.1/4.2 Guidance on Dossier/Substance evaluation**
 - **RIP 4.3/4.5: Guidance document on inclusion of substances in annex XIV and guidance document on priority setting for evaluation**



Steps for downstream users to prepare

- **1. Supply chain mapping**
 - Identify chemicals used – materials accounting – how chemicals are used and enter products
 - Identify suppliers
 - Identify substances needing pre-registration (ensuring these are included in pre-registration)
- **2. Identify vulnerable products**
 - Chemicals that might be withdrawn from supply chain
 - Chemicals of higher concern (and ensure inclusion in authorization if necessary_
 - Examine alternatives for chemicals of higher concern – suppliers, functionality, etc.



Steps for REACH preparation (cont)

- **3. Communicate with suppliers**
 - Provide information for exposure scenarios
 - Gather information on chemical toxicity/hazards
 - Gather information on alternatives
 - Need to ensure product level risk management guidelines proposed by manufacturer are implemented

- **4. Develop priorities/action plan**
 - Set priorities for REACH work
 - Which chemicals and uses pose the greatest risk (health and financial/social), provide the greatest opportunity for innovation, and are the easiest to work on immediately (short, medium, and long term)
 - Developing an action plan for the firm to address those chemicals and have processes for identifying new substances of concern (to address evolving risks).

