

Chemicals Management System

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Agenda

- Introduction
- REACH Requirements
- Chemicals Management System
- Database
- Q&A

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Introduction

REACH = **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals

- Regulation (EC) no. 1907/2006

Involved parties

- Manufacturers / Importers / Downstream users in EU
- European Chemical Agency (ECHA)
- Competent Authorities
- Suppliers / Traders / Manufacturers outside EU
- Only representative

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Introduction

- Substance
 - a chemical element or its compounds in the natural state or by obtained any manufacturing process
 - include any additive necessary to preserve its stability and any impurity deriving from the process used
 - exclude any solvent which may be separated without affecting the stability of the substance or changing its composition

Introduction

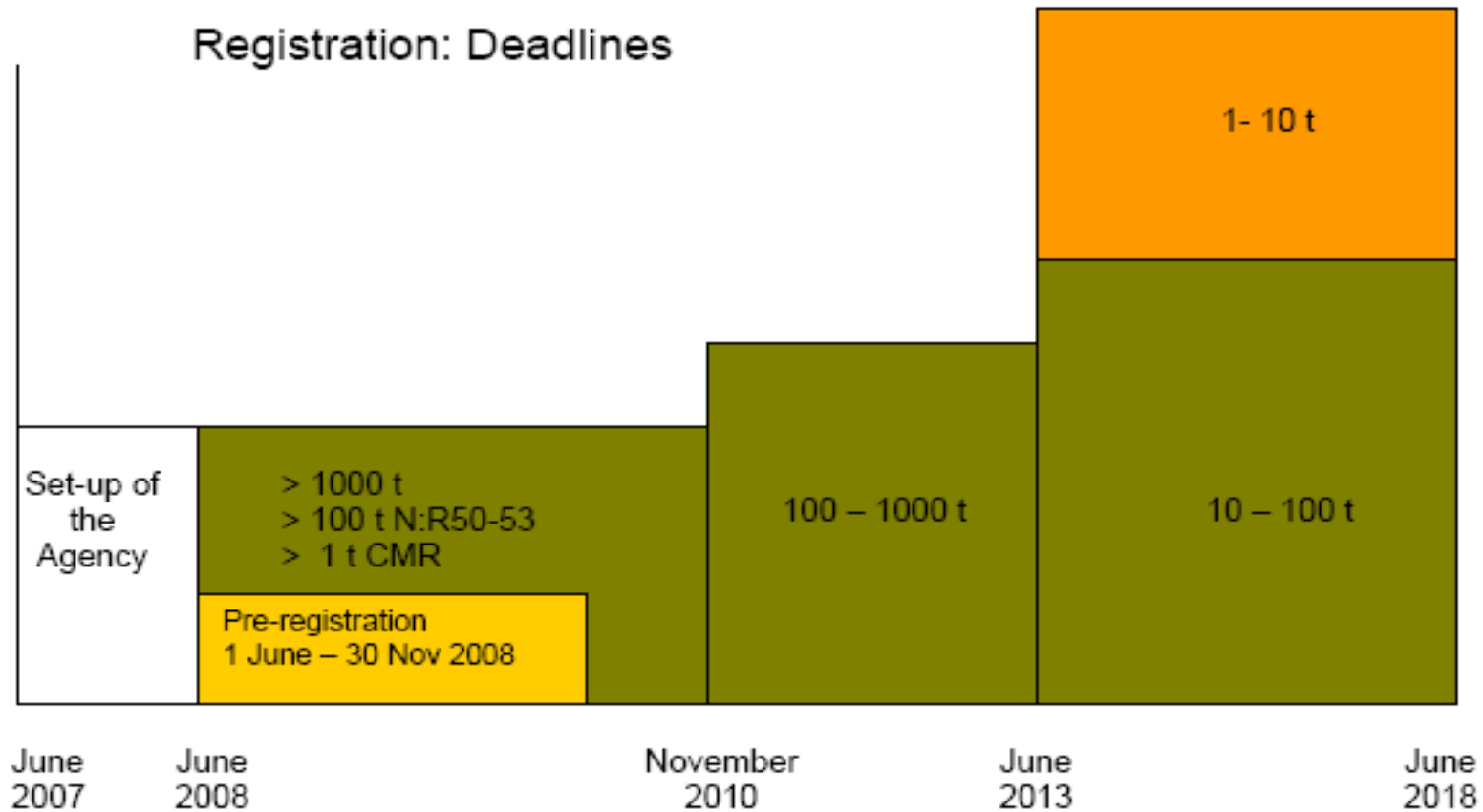
- Preparation
 - a mixture or solution composed of two or more substances
- Article
 - an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition

Introduction

Exemptions:

- Waste, medicinal products, food or feeding stuff
- Interest of defence
- Polymers (except monomers)
- Minerals (with exceptions)
- Low risk substances, e.g. water, CO₂
- Product and process oriented research and development
- Details in Annex IV and Annex V

Registration Requirement



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Registration Requirement

- Substances and Substances in Preparation
 - usage > 1 tonne per producer or importer per year and
- Substances in articles
 - are intended to be released under normal and reasonably foreseeable conditions of use
 - usage > 1 tonne per producer or importer per year and
- Pre-registration for phase-in substances (EINECS)

Registration Requirement

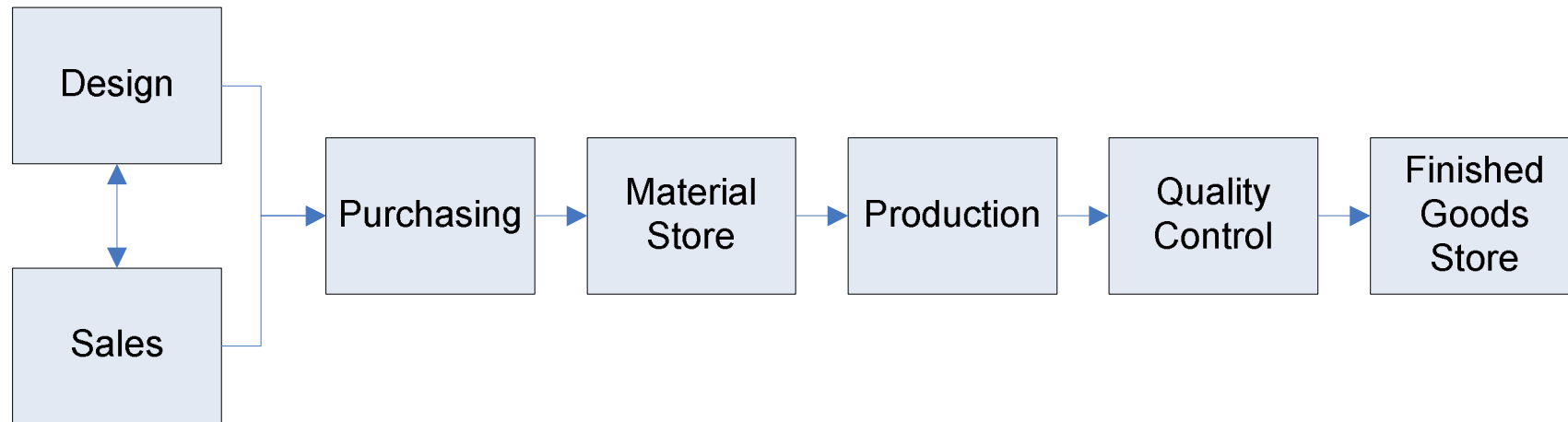
- Substances > 10 tonnes / year
 - Chemical Safety Report
 - Human health hazard assessment
 - Physicochemical hazard assessment
 - Environmental hazard assessment
 - PBT & vPvB assessment
 - Recommend the control in Safety Data Sheet

Notification Requirement

- Notify the Agency
 - CMR Cat 1 or 2 / PBT / vPvB or those of equivalent concern
 - > 1 tonne per producer or importer per year
 - > 0.1% weight by weight (w/w)
- Except where exposure to humans or the environment can be excluded during normal or reasonably foreseeable conditions.
- ECHA decides the need for registration if release of substance poses a risk to human health or the environment

Chemicals Management System

Typical manufacturing processes



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Chemicals Management System

- Design
 - Conduct new substance evaluation
 - Prepare substance specification
 - Prepare bill of materials and bill of substances
 - Arrange registration of new substances or those exceed 1 tonne per year usage
 - Find alternative source of substances for substitution
 - Prepare Chemical Safety Report for those substances exceeding 10 tonnes per year usage

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Chemicals Management System

- Sales
 - Review if any new substance required by customer
 - Check if usage of substance is higher than objectives or pre-defined volume
 - Negotiate any substitution of substance
- Purchasing
 - Collect MSDS / ingredient of substances
 - Find alternative source of substance for substitution
 - Specify compliance requirements of purchased goods

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Chemicals Management System

- Production
 - Produce products according to BOM and BOS
 - Notify Engineer for any change in use of substance
 - Provide information on usage of substance
 - Provide clear identification of substances
 - Ensure no mix up of substances and finished products
- Quality Control
 - Accept substance only when specification is available
 - Perform in-process control to ensure measurement of volume of substance is performed

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Chemicals Management System

- Warehouse
 - Provide clear identification of substances and products
 - Ensure no mix up of substances
 - Only products built for EU orders can be shipped to EU
- System Requirements
 - Policy and Objectives
 - Internal Audit and Supplier Audit
 - Corrective and Preventive Action
 - Management Review

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Database

- Substance Specification
 - Ingredient of substance
 - Technical dossier
 - Materials Safety Data Sheet
 - Chemical Safety Report
- List of exemptions
- List of substance of very high concern

Database

- Bill of Substance
 - Substance description
 - CAS no. / EINECS no.
 - Intended to be released
 - % weight by weight
 - Substance of very high concern
- Substance Usage Report

Q&A



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