

An Overview of REACH

Chemical Control in the European Union

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REACH PURPOSE



Based on shifting the burden of proof
it is up to manufacturers, importers and
downstream users to ensure that they
manufacture, place on the market or use
such substances that do not adversely
affect human health or the environment.
Its provisions are underpinned by the
precautionary principle.

WHAT IS REACH?



- **Registration, Evaluation and Authorizations of Chemicals**
- Replace current EU chemicals legislation
- Create a European Chemicals Agency
- 3 versions: 2003 Commission Text; Dec. 19, 2005 Compromise Council Text; and Nov. 17, 2005 European Parliament (EP) First Reading Amendments.

WHO WILL BE IMPACTED



- All companies producing, importing and using chemicals in the EU and beyond
 - Extends beyond industrial chemicals
- Non-European companies that ship products into the EU
 - EU customers may draw foreign suppliers requiring testing, data and/or other registration assistance as a condition of purchasing that supplier's chemical(s)
 - Specialty chemicals supplied for use in complex formulations?

MAJOR ELEMENTS OF REACH



- Hazard-oriented assessment of chemical substances
- Burden shifted to industry -- most industrial chemicals to be supported by data and risk assessment dossiers (No Data, No Market)
- No distinction between existing & new substances
- Covers Manufacture and Importation of chemical substances and not just “placing on the market”
- Risk communication through the supply chain based on Safety Data Sheets (SDS) & Chemical Safety Reports (CSR)

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OVERALL SCOPE OF REACH



- Few exclusions in Commission Text
- Several exemptions from the REACH requirements. Different at Registration, Authorization, Restrictions
- Provisions are complex and spread throughout the text
- Exemptions are one topic where significant changes are proposed by Parliament & Council

EXCLUSIONS FROM OVERALL SCOPE OF REACH



Commission	Parliament	Council
<ul style="list-style-type: none">● <i>Radioactive substances</i>● <i>Substances under customs supervision</i>● <i>Non-isolated intermediates</i>	<ul style="list-style-type: none">● <i>Radioactive substances</i>● <i>Substances under customs supervision</i>● <i>Non-isolated intermediates</i>● <i>Waste (75/442)</i>● <i>Food (178/2002)</i>● <i>Flavorings (88/388)</i>● <i>Substances in tobacco (2001/37)</i>● <i>Substances in batteries (91/157)</i>	<ul style="list-style-type: none">● <i>Radioactive substances</i>● <i>Substances under customs supervision</i>● <i>Non-isolated intermediates</i>● <i>Waste (75/442)</i>● <i>Carriage of goods by road, air, water</i>● <i>Member States exemptions for defense interests</i>

COMPETENT AUTHORITIES FOR REACH: A COMPLEX STRUCTURE



- The European Chemicals Agency (Helsinki, Finland)
 - Major role in all REACH processes
- The Member States Competent Authorities
 - Retain major powers at Evaluation
 - Right of initiative for substance evaluations, Nomination of substances subject to Authorization, and Restrictions
- The European Commission
 - Final decision power at Evaluation, Authorization and Restrictions

COMPONENTS OF REACH



- First Leg: Registration
- Second Leg: Evaluation
- Third Leg: Authorization
- Fourth Leg: Restrictions
- Administrative & Other Elements
- Substantive Annexes

FIRST LEG: REGISTRATION



- Registration of all substances above 1 ton/year unless exempted
 - New and around 30,000 existing substances
- Includes substances in preparations and in articles (like US)
- Manufactured or imported into the EU (today only marketed)
- Registration is company specific
- Covers “identified uses”
 - Too risky or M/I decides not to supply for that use
- **THUS:** Downstream users need to ensure specific uses are registered

EXEMPTIONS FROM REGISTRATION



- Less than 1 ton/year per Manufacturer/Importer
- Exported and re-imported into the EU
 - Must be the same substance
 - Required safety information provided on exported substances
- Polymers (subject to the 2% rule for unregistered monomers/substances)
- Annex II Exemptions:
 - Listed Low Risk Substances
 - Generally food and food-related materials and common gases (EP – Adds many food oils; foods; common inorganics (i.e. NaCl, potash); cellulose pulp)

EXEMPTIONS FROM REGISTRATION (cont)



- Annex III Exemptions:
 - Incidental Substances (Environmental degradates, storage-related incidental substances and end-use related substances)
 - By-products, unless imported or placed on the market in their own right
 - Hydrates of registered substances
 - Naturally-occurring substances not chemically modified, unless dangerous under Directive 67/548/EC

THE REGISTRATION PROCEDURE



- Dossier to the European Chemicals Agency
- Completeness check (not a conformity check) within 3 weeks
- If no news within 3 weeks, right to market
- Reject incomplete registrations that are not cured by deadlines set by Agency (subject to appeal)

THE REGISTRATION PROCEDURE (cont.)

- The Agency provides a registration number and a registration date (same as submission date)
- Information maintained on data base
- “No registration: no market”
- Duty to update Registration (change in status, composition, quantities, new uses, new C&L, etc.)

COMMON INFORMATION FOR ALL REGISTRATIONS -- OSOR (ANNEX IV)



- Classification and labelling
- Guidance on safe use from SDS
- Summaries or robust study summaries of available data
- Statement as to whether existing data has been reviewed by a competent technical “assessor”
- Proposals for testing
- Individual M/I Submissions of C&L/data summaries/testing proposals, if joint submission: (1) disproportionately costly, (2) discloses CBI, (3) M/I disagrees with lead registrant

INFORMATION/DATA REQUIREMENTS FOR REGISTRATION



- TECHNICAL DOSSIER
 - Common information for all registrations
 - Depending on tonnage
- CHEMICAL SAFETY REPORTS (CSR)
 - Required at >10 t/yr (EP: > 1 t/yr)
 - Portions to be communicated with SDS down the supply chain
 - CSR is a Risk Assessment (RA) and Risk Management (RM) Plan
 - Must Include All Identified Uses

INFORMATION/DATA REQUIREMENTS FOR REGISTRATION



- CHEMICAL SAFETY REPORTS (CSR)
 - Must consider use of the substance on its own (incl. major impurities and additives), in preparations, or in articles
 - Exemptions for trace components in preparations
 - Can be based on related substances or group of substances, if justified
 - If substance is Classified or PBT/vPvB must include exposure assessment and risk characterization
 - Duty to update CSR

REGISTRATION TIME TABLE – PRE-REGISTRATION



- New Substances – Effective date 12 months implementation
- Phase-in Substances
 - 3, 6 and 11 years phase-in, depending upon volume and intrinsic properties
 - Must be pre-registered
 - Identity and other initial information
 - Different proposals on the Registration timetable and pre-registration by Council and Parliament

REGISTRATION OF PHASE IN SUBSTANCES



	Commission	EP and Council
Phase 1: 3 Years	CMR 1 and 2 Substances > 1000 tons	Same + R50/53 substances > 100 tons
Phase 2: 6 Years	Substances > 100 tons	Same + R50/53 substances > 1 ton (Only EP)
Phase 3: 11 Years	Substances > 1 ton	Same

REACH PROVISIONS ON DOWNSTREAM USERS



- Tell suppliers uses.
 - DU provide info to allow M/I to develop exposure scenario (ES)
 - Or perform CSA and separately notify
- DU has choice
 - Follow supplier's ES
 - Incl. Risk management methods (RMMs)
 - Develop own ES.
 - Prepare SDS and include ES
- If product contains ingredients suppliers do not support through REACH, DU will be unable to continue to sell a product into the EU

- Information on intrinsic properties of substances and > 10 years from Registration freely available
- Other information < 10 years:
 - Sharing of data and cost
 - Different rules for non-phase-in and phase-in substances
- Formation of consortia mandated to allow industry to share data and costs and avoid duplicative animal testing
- Different views on data sharing in Parliament and Council

SECOND LEG: EVALUATION



- Two types of Evaluations:
- Registration Dossier Evaluations:
 - Compliance checks
 - Review of testing proposals to prevent unnecessary animal testing (Annexes VII and VIII) with priority given to high risk/ high volume substances
 - Substance Evaluations to clarify suspicions of risk by requesting further data on certain types of substances
- The ECA does the evaluations
 - under Council Text M perform core scientific work

COMPLIANCE CHECKS



- ANY Registration Dossier may be reviewed for compliance (5% of total dossiers for each tonnage band to be checked)
 - In addition to the “completeness check”.
 - Meets data requirements
 - justification of waivers
- No time limit to start, but 12 months to complete
- ECA may request additional information from Registrant to correct the Dossier –
 - National enforcement action also possible

THIRD LEG: AUTHORIZATION

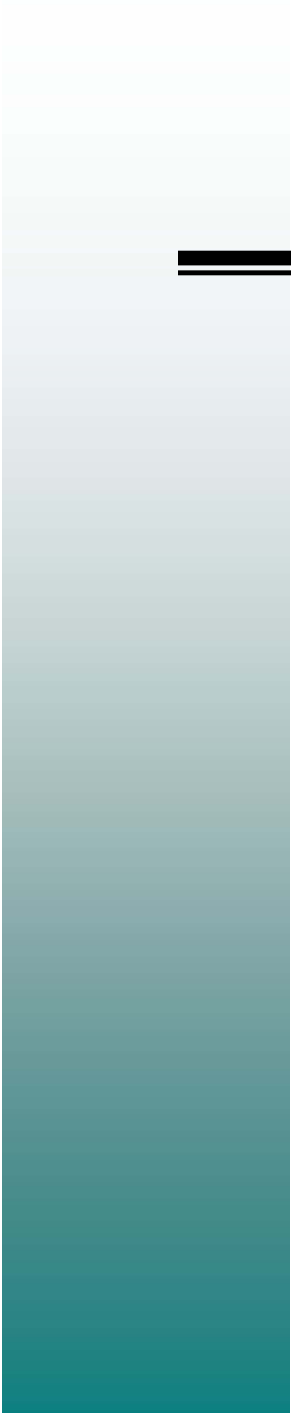


- Pre-market approval (Authorization) for “Substances of Very High Concern” (SVHC)
 - Based on hazard properties
 - Council/EP envision candidate list
- Authorization based on risk and socio-economic assessments, takes into account available substitutes
- Use-specific, company-specific and limited in time (EP = 5 yr term; Council : case-by-case)
- Purpose is to phase-out the use of most SVHC
 - prohibition of SVHC is the rule, authorization the exception

SUBSTANCES OF VERY HIGH CONCERN



- Carcinogenic Substances, Cat. 1 & 2
- Mutagenic Substances, Cat. 1 & 2
- Reprotoxic Substances, Cat. 1 & 2
- Persistent, Bioaccumulative & Toxic Substances - PBTs.
- Very Persistent, Very Bioaccumulative Substances - vPvBs
- Substances identified on a case-by-case as causing serious, irreversible effects to humans or the environment which are “equivalent” to those listed above (e.g. endocrine disruptors)
 - Council and EP criteria are more relaxed



FOURTH LEG: RESTRICTIONS



- The “safety net” of REACH
- Permits Community-wide legislative-type restrictions/bans
 - On the use of substances that present “unacceptable risks”
 - In preparations or in articles
- Current restrictions will be transferred
- New process for new restrictions
- No fundamental changes brought by Council/ Parliament

LIKELY IMPLEMENTATION STATUS



- Council's common position adopted June 27, 2006 and sent to Parliament for second reading.
- Parliament likely to amend, then sent to Council and Commission.
 - Could be adopted as is or sent to Conciliation Committee to reconcile positions in a joint text.
 - Parliament could still reject joint text by absolute majority but this is extremely unlikely.
- **REACH is expected to be implemented in the Spring of 2007**

PREPARING FOR REACH



- To be prepared for REACH, you must:
 - Understand REACH
 - Audit your product portfolio to identify applicable REACH requirements and specific impact
 - Adopt a strategy and action plan
 - Prepare communications up and down the supply chain

- REACH audit:
 - A Product Review: each substance, preparation and article produced in or imported into the EU
 - A Strategic Analysis: review product-specific information to set priorities, strategies, competencies, allocations of resources, timing and costs,
- Adopt a REACH Action Plan

For more information

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