



REACH:

Registration, Evaluation,
Authorization, (and Restriction)
of Chemicals

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An Introduction to REACH

- History
- The four basic elements of REACH
- Registration
 - Data requirements
 - Chemical safety assessment
- Evaluation, Authorization, and Restriction
- Substances in commercial articles
- Nanomaterials

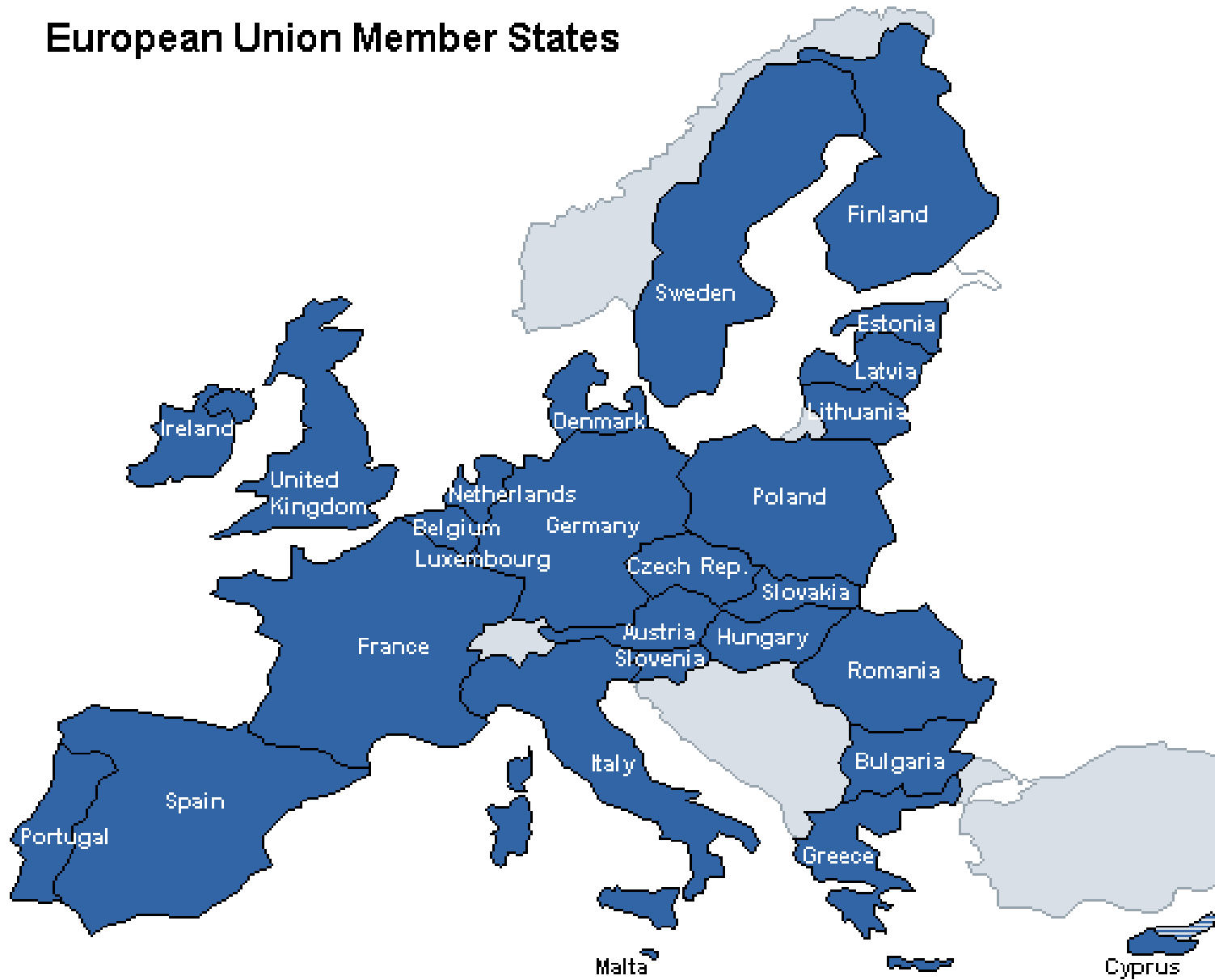


A Brief History of REACH

- April 1998: Regulators meeting in UK express concern about current mechanisms for regulation of chemicals industry
- November 1998: European Commission publishes a report on the efficacy of the four main regulatory elements
- June 1999: Environment Council calls on Commission to submit a policy document for a new regulatory framework by the end of 2000
- February 2001: EC publishes the White Paper outlining REACH
- 2001-2002: Development of Regulation with stakeholder input
- October 29 2003: Publication of full REACH proposal by EC
- December 18 2006: REACH adopted by Parliament and Council Regulation 1907/2006 (co-decision process)
- June 1 2007: REACH entered into force
- June 1 2008: REACH deadlines began



European Union Member States





Chemicals Manufacturing in The EU

- Chemicals industry
 - Germany (26%)
 - France (17%)
 - The United Kingdom (14%)
 - Italy (12%)
- Produces 31% of the world's chemicals (US = 28%)



Goals of the REACH Regulation

- Toxicity and exposure information on commercial chemicals
- Foster innovation in development of substitutes for dangerous substances
- Enhance competitiveness of EU chemicals sector
- Centralize and harmonize classification systems (CLP Regulation)
- Reduce liability for manufacturers and importers of chemicals
- Reduce need for animal testing
- Reduce duplication in testing
- Provide information on hazard to the public
- Alleviate disease associated with exposure to chemicals

The Four Pillars of REACH

Registration



>1 tpa

Evaluation



Dossier
Substance

Authorization



Candidate
Alternatives

Restriction



POPs



What must be registered?

- Substances manufactured or imported in quantities > 1 tpa
- Substances on their own or in preparations
- Monomers
- Substances in articles

- Exemptions
 - Polymers*
 - Medicinal products
 - Foodstuffs
 - Annex IV (eg glucose, corn oil, CO₂), Annex V (eg ores, hydrogen, by-products)
 - Radioactive substances, wastes
 - Product and process orientated R & D (PPORD)
 - BUT be careful



Who has to register?

- Manufacturers
- Importers
- Producers and importers of articles
- “Only representatives”
 - Representative for a manufacturer, formulator or article producer outside the EU
- Each legal entity*



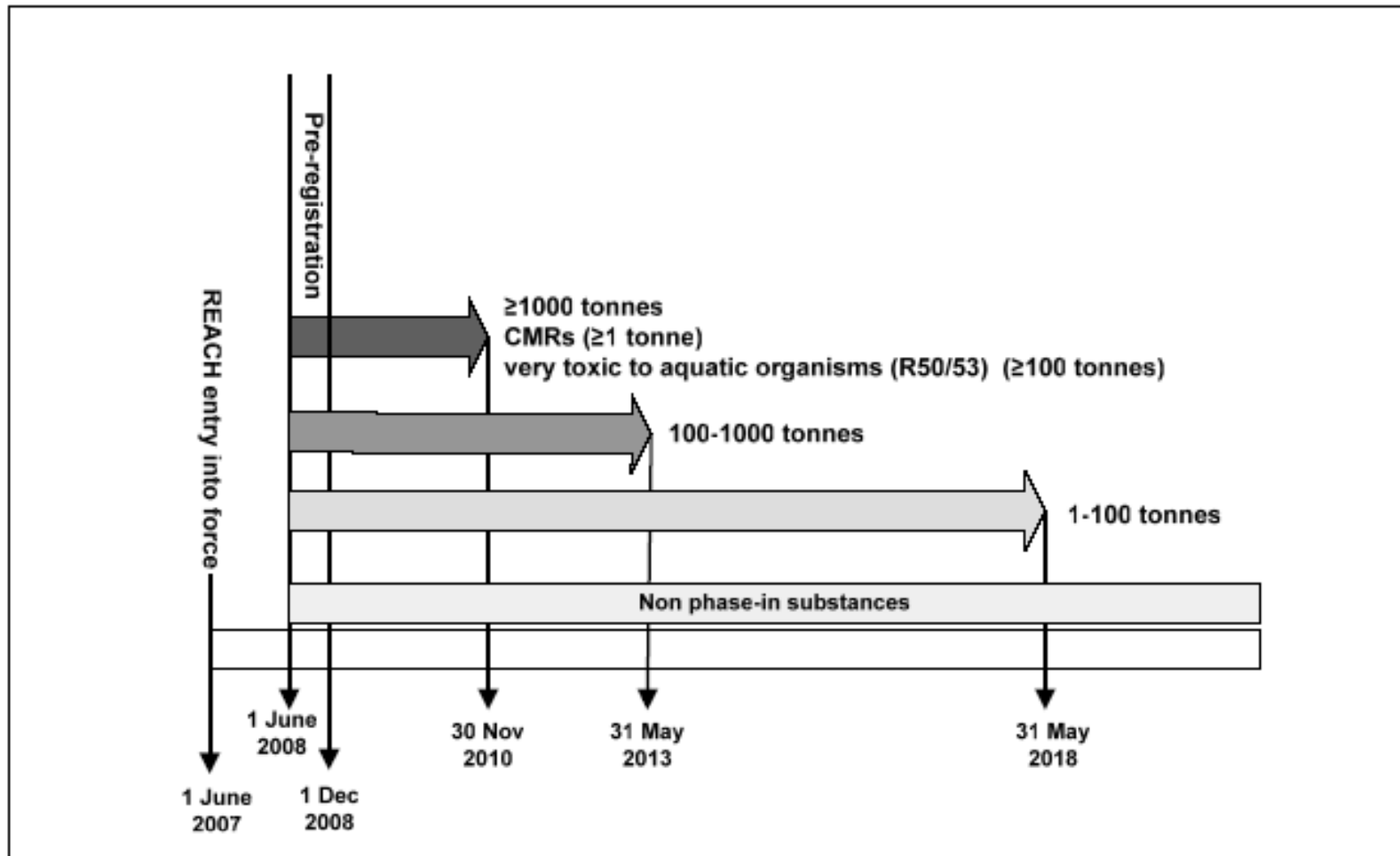
What are the deadlines?

- Phase-in substances (must be pre-registered)
 - Listed in EINECS, or NLP
- Phase-in deadlines:
 - **1 Dec 2010**: M/I 1000+ tpa, CMR substances, R50/53 substances
 - 1 June 2013: 100+ tpa
 - 1 June 2018: 1+ tpa
- Non phase-in substances
 - “need to be registered before they can be manufactured, imported, or placed on the market in the EU”
 - Inquiry dossier



What are the deadlines?

Figure 3





The Registration Dossier

- Technical dossier
 - Always required
 - Data requirements
 - IUCLID 5 format

- Chemical safety report
 - Documentation of chemical safety assessments
 - Required for substances M/I 10+ tpa
 - Primary outcome is an exposure scenario with risk management measures



Registration: Info Requirements

- Physicochemical characteristics
- Toxicological properties
- Ecotoxicological properties
- Many exceptions and adaptations to each
- Exposure-based waiving (EBW)
- Alternative methods
- Data-sharing and availability through other sources



Registration: Info Requirements

- Based on tonnage of substance manufactured or imported
 - Annex VII: Info Requirements for 1+ tpa
 - Annex VIII: Info Requirements for 10+ tpa
 - Annex IX: Info Requirements for 100+ tpa*
 - Annex X: Info Requirements for 1000+ tpa*

 - Annex VI: Specifics on rest of technical dossier
 - Annex XI: Adaptation of standard testing regime
- Guidance on Information Requirements and Chemical Safety Assessment
- REACH Test Methods Regulation



dose toxicity, (6) reproductive or developmental toxicity, (7) mutagenicity and carcinogenicity, (8) aquatic toxicity, (9) degradation and biodegradation, (10) bioconcentration and bioaccumulation (and long-term toxicity to birds), (11) effects on terrestrial organisms, and (12) toxicokinetics (ECHA, 2008d, 2008e, 2008f). The primary goal of the SIEF mechanism is to allow companies to share available data on the properties of each substance, so as to save costs and avoid unnecessary testing. To that end, the SIEFs will first gather all existing information (publicly available data as well as industry-generated data that have not previously been public), consider the scope and amount of information required to complete a registration dossier, and identify any gaps in their available information (ECHA, 2007b). Publicly available data may be obtained through several avenues, including commercial databases, the OECD HPV Chemicals Program, and the peer-reviewed literature (Anderson et al., 2000; Wright, 2001). Data may also be available from within the SIEF from companies who hold data on substances, but don't actually manufacture them (i.e., "data holders"). For data generated by members of the SIEF, a cost-sharing mechanism will be devised among the

Table 2a. Information requirements for physicochemical properties of substances manufactured or imported in tonnage bands mandated by REACH.

Information requirement	Tonnage band	Annex
State of substance at 20°C and 101.3 kPa	1	VII
Melting/freezing point	1	VII
Boiling point	1	VII
Relative density	1	VII
Vapor pressure	1	VII
Surface tension	1	VII
Water solubility	1	VII
Partition coefficient <i>n</i> -octanol/water	1	VII
Flashpoint	1	VII
Flammability	1	VII
Explosive properties	1	VII
Self-ignition temperature	1	VII
Oxidizing properties	1	VII
Granulometry	1	VII
Stability in organic solvents	100	IX
Dissociation constant	100	IX
Viscosity	100	IX

Table 2b. Toxicological information requirements for substances manufactured or imported in tonnage bands mandated by REACH.

Information requirement	Tonnage band	Annex
<i>Skin irritation or corrosion</i>		
Assessment of acid or alkaline reserve	1	VII
In vitro study for skin corrosion	1	VII
In vitro study for skin irritation	1	VII
In vivo skin irritation	10	VIII
<i>Eye irritation</i>		
Assessment of acid or alkaline reserve	1	VII
In vitro study for eye irritation	1	VII
In vivo eye irritation	10	VIII
<i>Skin sensitization</i>		
In vivo testing (LLNA)	1	VII
<i>Mutagenicity</i>		
In vitro gene mutation study in bacteria	1	VII
In vitro cytogenetic study in mammalian cells or in vitro micronucleus assay	10	VIII
In vitro gene mutation study in mammalian cells	10	VIII
In vivo somatic cell genotoxicity*	100	IX
In vivo somatic cell genotoxicity*	1000	X
<i>Acute toxicity</i>		
By oral route	1	VII
By inhalation	10	VIII
By dermal route	10	VIII
<i>Repeated dose toxicity</i>		
Short-term repeated dose toxicity study (28 days), one species, male and female	10, 100	VIII, IX
Subchronic toxicity study (90-day), one species, rodent, male and female	100	IX
Long-term repeated dose toxicity study (≥12 months)*	1000	X
<i>Reproductive toxicity</i>		
Screening for reproductive/developmental toxicity, one species	10	VIII
Prenatal developmental toxicity study, one species	100	IX
Two-generation study, one species, male and female	100, 1000	IX, X
Developmental toxicity study, one species	1000	X
<i>Toxicokinetics</i>		
Assessment of the toxicokinetic behavior of the substance	10	VIII
<i>Carcinogenicity</i>		
	1000	X



Table 2c. Ecotoxicological information requirements for substances manufactured or imported in tonnage bands mandated by REACH.

Information requirement	Tonnage band	Annex
<i>Aquatic toxicity</i>		
Short term toxicity testing on invertebrates	0001	VII
Growth inhibition study on aquatic plants	1	VII
Short-term toxicity testing on fish	10	VIII
Activated sludge respiration inhibition testing	10	VIII
Long-term toxicity testing on invertebrates	100	IX
Long-term toxicity testing on fish	100	IX
Fish early life stage (FELS) toxicity test	100	IX
Fish short-term toxicity test on embryo and sac-fry stages	100	IX
Fish, juvenile growth test	100	IX
<i>Degradation</i>		
Ready biodegradability	1	VII
Hydrolysis as a function of pH	10	VIII
Simulation testing on ultimate degradation in surface water	100	IX
Soil simulation testing	100	IX
Sediment simulation testing	100	IX
Identification of degradation products	100	IX
Further biodegradation study	1000	X
<i>Fate and behavior in the environment</i>		
Adsorption/desorption screening	10	VIII
Bioaccumulation in aquatic species, preferably fish	100	IX
Further information on absorption/desorption	100	IX
Further information on environmental fate and behavior	1000	X
<i>Effects on terrestrial organisms</i>		
Short-term toxicity to invertebrates	100	IX
Effects on soil micro-organisms	100	IX
Short-term toxicity to plants	100	IX
Long-term toxicity testing on invertebrates	1000	X
Long-term toxicity testing on plants	1000	X
Long-term toxicity to sediment microorganisms	1000	X
Long-term reproductive toxicity to birds	1000	X



Where does the data come from?

- Data-sharing with other potential registrants (SIEF)
- In-house studies
- Published literature
- Databases
- “Read-across” i.e., non-testing approaches
- Evaluation of data quality for suitability under REACH
 - Completeness and adequacy
 - Reliability: Klimisch et al., 1997



How is the data applied?

- Classification and labeling
- Determination of persistent, bioaccumulative, and toxic (PBT) status
- Determination of very persistent, very bioaccumulative (vPvB) status
- **Risk assessment in the Chemical Safety Assessments**
- Application of risk management measures

- Downstream communication
- Determination of risk to human health and the environment



Chemical Safety Report

- Goal: Assess and document risks arising from substances, and how these risks are managed
- CSAs address all identified uses of the substance
 - The substance on its own, in a preparation, in an article
 - The entire life-cycle of the substance, including disposal
 - Should consider exposure to same substance from other suppliers
- CSAs are based on information from the Technical Dossier



Chemical Safety Assessment

- 1) Human health hazard assessment (DNEL)
- 2) Human health hazard assessment for physicochemical properties
- 3) Environmental hazard assessment (PNEC)
- 4) PBT and vPvB assessment

If substance can be classified as dangerous, then CSA must also include:

- 5) Exposure assessment
- 6) Risk characterization



Exposure Scenarios

- A description of real-life conditions under which humans or the environment may be exposed to a substance
 - Operational conditions, risk management, inherent properties, local conditions
 - Should include maintenance tasks, other reasonably foreseeable conditions of use (e.g., consumer products)
 - MUST describe risk management measures
 - Library of RMMs, efficiency information
- Iterative process (“tentative” vs. “final” ES)



Dossier Evaluation

- Compliance check (5% or more)
 - Information requirements fulfilled
 - Adaptation of info requirements acceptable
 - CSR complies with Annex I
 - EChA can request information within 12 months
 - Notify MS-CA of outcome

- Testing Proposals
 - Priority to PBT, vPvB, CMR, 100+ tpa
 - Proposals published on Agency website – third parties invited to submit information that addresses issue



Substance Evaluation

- Member states develop risk-based prioritization scheme
 - Hazard info, exposure info, tonnage

- Community rolling action plan for substance evaluation
 - Developed by EChA, with suggestions from MS
 - Which substances to be evaluated each year (3 year window) and which CA will perform evaluation
 - MS-CA can demand new information (possibly outside of Annexes VII to X) – 12 months to respond, then 12 months to evaluate new info

Authorization

- Goal: Control risks arising from SVHC and encourage substitution (chemical or technological)
 - Mandatory substitution eliminated from final Regulation – activists, industry
- Candidate list for authorization
 - NGO participation
 - Airbus
- What gets on the candidate list?
 - CMR 1 and 2, PBT, vPvB, EDCs, other



Restriction

- Annex XVII currently contains
 - PCBs (transformers etc., replaced at end-of-life)
 - Vinyl chloride (as a propellant)
 - Benzene (in toys >5 mg/kg or in preparations $>0.1\%$, okay in motor fuels and some industrial processes)
 - Asbestos (end-of-life provision)
 - PBBs (all uses restricted)
 - Arsenic (Some CCA, all anti-fouling uses restricted)
 - Pentachlorophenol (except for industrial)
 - Cadmium (in paint or as colorant)
 - Nickel (in earrings with migration limit, other jewelry)
 - Creosote, chloroform, PBDEs, PAHs in tires, phthalates, etc.



Articles and REACH

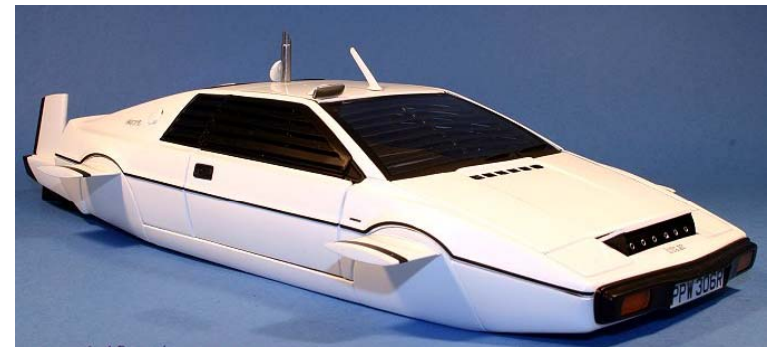
- Definition of articles

- Potential obligations under REACH
 - Registration
 - Notification
 - Communication
 - Authorization
 - Restriction

- Borderline cases

What is an article?

- “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” (Article 3(3))





Articles and REACH

○ Registration

- Substances “intended to be released” >1 tpa

○ Notification

- Article contains SVHCs

○ Communication

- Downstream if SVHC >0.1% by weight

○ Authorization

- EU-based articles manufacturing

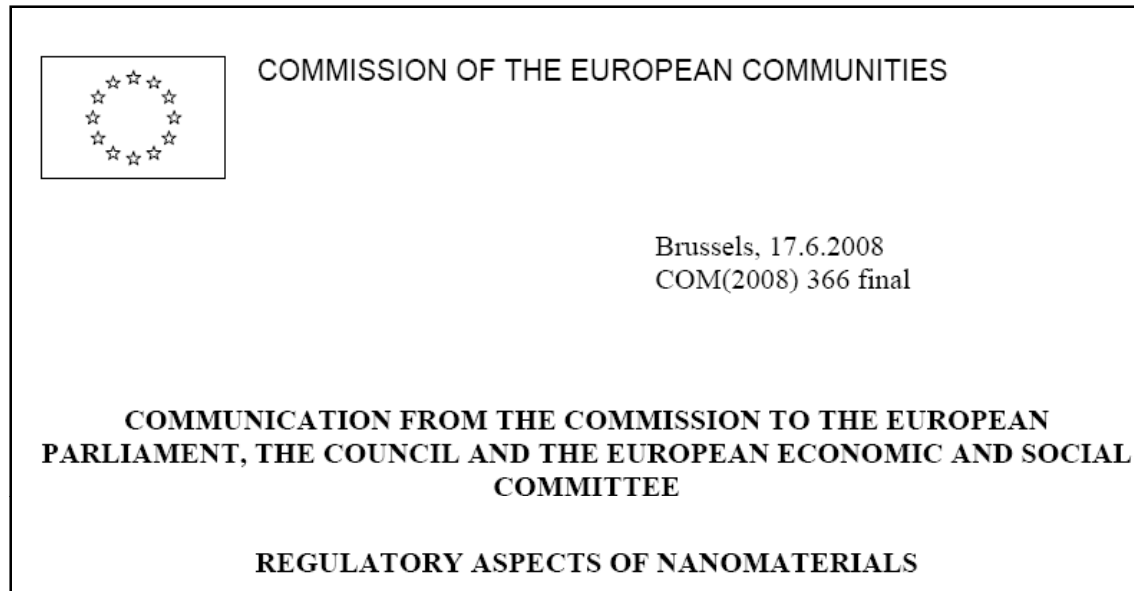
○ Restriction

- Substances in articles can be banned



Nanomaterials and REACH

- Several early theories regarding compliance
 - Articles?
 - Just bulk materials
- COM(2008) 366: Regulatory Aspects of Nanomaterials (6/17/2008)
- CA/59/2008 rev. 1: Nanomaterials in REACH (12/16/2008)
- CA/90/2009 Rev2: Classification, labelling, and packaging of nanomaterials in REACH and CLP (12/3/2009)



- “There are no provisions in REACH referring explicitly to nanomaterials. However, nanomaterials are covered by the ‘substance’ definition in REACH.”
- “Until specific test guidelines for nanomaterials exist, testing will have to be carried out according to already existing guidelines.”



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.6.2008
COM(2008) 366 final

**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL
COMMITTEE**

REGULATORY ASPECTS OF NANOMATERIALS

○ Research needed on:

- Data on toxic and eco-toxic effects as well as test methods to generate such data.
- Data on uses and exposures throughout the lifecycle of nanomaterials or products containing nanomaterials, as well as exposure assessment approaches.
- Characterization of nanomaterials, development of uniform standards and nomenclature, as well as analytical measurement techniques.
- For occupational health aspects, the effectiveness of a range of risk management measures including process enclosure, ventilation, personal protective equipment like respiratory protective equipment and gloves.



Nanomaterials and REACH

- Guidance document was expected in August 2010
 - RIP-oN
- Efforts of OECD and ISO
- For now, registration of nanomaterials go under bulk materials
 - Nano-specific properties, hazards, exposure scenarios, risks and management
 - Identification of the substance at issue



Other Resources

- The REACH Regulation
- The guidance documents
- Williams et al., Crit Rev Toxicol, 2009

- European Chemicals Agency website
 - REACH FAQ document from ECHA