RoHS Overview

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EU Knows How to Regulate

- Battery Directives
- Ecodesign of Energy Using Products Directive (EuP)
- End of Life Vehicle Directive (ELV)
- Waste Electrical & Electronic Equipment Directive (WEEE)
- **Restriction of Hazardous Substances Directive (RoHS)**
- **Registration Evaluation and Authorization of Chemicals (REACH)**


Why RoHS?

Protect environment & recycling personnel in disposal

EU RoHS - In the Beginning

- Eliminated 6 hazardous substances from electrical and electronic equipment (EEE) by July 1, 2006
  - Prohibited in-scope products from being placed in EU market if “RoHS 6” substances present
- “RoHS 6”:
  - Lead, Mercury, Cadmium,
  - Hexavalent chromium,
  - Polybrominated diphenyl ethers (PBDE)
  - Polybrominated diphenyls (PBB)
- Producers to demonstrate compliance to enforcement authorities upon request
- No formal certification, declaration or labeling system attesting compliance

EU RoHS In the Beginning

RoHS applies to the following low voltage electrical and electronic devices, i.e. less than 1000V a.c. or less than 1500V d.c., listed in appendix 1A to directive 2002/96/EC on WEEE.

1. Large household appliances
2. Small household appliances
3. IT and telecommunications equipment
4. Consumer equipment
5. Lighting equipment
6. Electrical and electronic tools (with the exception of large-scale stationary industrial tools)
7. Toys, leisure and sports equipment

10. Automatic dispensers

Electric light bulbs, and

Luminaires in households.

EU RoHS In the Beginning

- Out of scope:
  - Equipment solely for military and national security purposes
  - Medical devices (WEEE category 8)
  - Monitoring and control instruments (WEEE category 9)
  - Aircraft equipment and fixed installations, such as a radio in an aircraft
  - Large-scale, stationary industrial tools
  - Equipment covered by other waste directives such as cars (ELV)
  - Spare parts for repair and re-use (includes upgrades) of EEE placed on the market before July 1, 2006

RoHS Reviews

Article 6 of the RoHS Directive requires periodic review in consultation with stakeholders to address required updates to the scope of the directive including the equipment covered and the substances restricted.

The consultations set specifically:

- To address the inclusion of Category 8 & 9 (medical devices, and monitoring & control equipment).
- To amend the list of restricted substances based on the emergence of new scientific.

RoHS Reviews

October 2007 - Study on hazardous substances in electrical and electronic equipment, not regulated by the RoHS Directive."

- Öko-Institut
- Investigation on other hazardous substances or materials used in electrical and electronic equipment, how they are managed currently as well as possible substitutes and the sustainability (environmental, economic, social) characteristics of these other hazardous substances and possible substitutes.

December 2007 - Study for the simplification for RoHS/WEEE

- Arcadis (formerly Ecolas)
- Analysis of the impacts of the RoHS Directive on the economy and the environment and to compare the ROHS approach with other approaches used outside of the EU, highlighting advantages and disadvantages. Formulate proposals to revise the Directive with a view to improving its cost-effectiveness.

Öko-Institut initially requested information on 46 substances Examples:

Antimony trioxide	PVC	Bisphenol A (4,4'-Isopropylidendiphenol)
Antimony compounds	PCBs - Polychlorinated Biphenyls	Diethylhexylphthalate (DEHP)
Arsenic/arsenic compounds	PCT - Polychlorinated Terphenyls	Butylbenzylphthalate (BBP)
Arsenic trioxide	Gallium arsenide	Dibutylphthalate (DBP)
Beryllium metal	Selenium	Dioctylphthalate (DOP)
Beryllium oxide (BeO)	Thallium	Dimethylformamide (DMF)
Cobalt oxide	Tributyl Tin (TBT) compounds	Short-chained chlorinated paraffins
Cobalt	Formaldehyde	Brominated flame retardants
Nickel and certain Ni compounds	Vanadium pentoxide	Medium-chained chlorinated paraffins

In their draft report, Öko-Institut recommended 8 substances be considered for future addition to RoHS

1. Tetrabromo bisphenol A (TBBP-A)
2. Hexabromocyclododecane (HBCDD)
3. Bis (2-ethylhexyl) phthalate (DEHP)
4. Butylbenzylphthalate (BBP)
5. Dibutylphthalate (DBP)
6. Medium-chained chlorinated paraffins (MCCP)
   (Alkanes, C14-17, chloro)
7. Short-chained chlorinated paraffins (SCCP)
   (Alkanes, C10-13, chloro)
8. Nonylphenol/Nonylphenol ethoxylates

RoHS Review

- Respondents: 26 industry associations 14 individual companies, 8 material producers/associations, 6 Member States, 2 NGOs

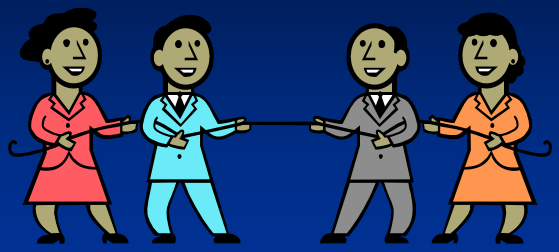
RoHS Review

General support for:

- Including medical devices and control and monitoring equipment in scope
- Strengthening market surveillance
- No new marking for RoHS compliance
- Maintaining exemption mechanism and stakeholder consultation requirement

RoHS Review

Conflicting positions:



- **Industry:** extend deadlines (some as long as 2018) & exemptions for Cat 8 & 9; **NGOs**: rapid inclusion, restricted exemptions
- **Industry**: don't add new substances, use REACH; **Member State, NGOs**: add to RoHS
- **Industry**: broader criteria for granting exemptions; several **Member States and NGOs**: What are you smoking?

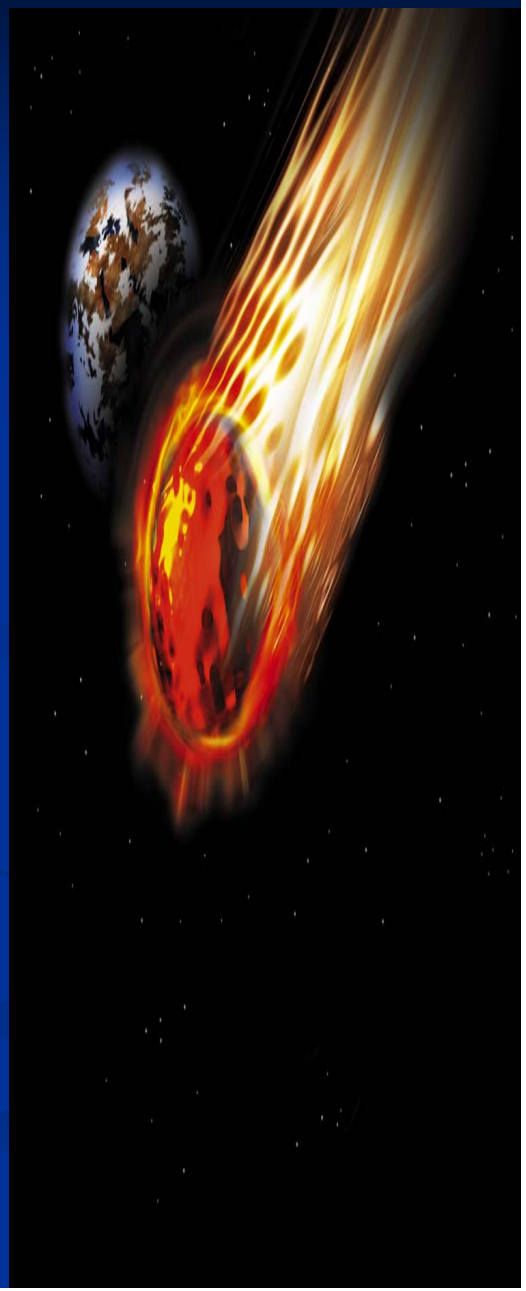
NGOs and Member States are highly influential!

EU RoHS—Timetable to 2010

- The European Commission has delayed its publication of draft legislation reviewing the WEEE and RoHS Directives, planned for September 2008. The drafts will not be published until later in 2008 (Nov. or Dec.)
- Final stakeholder review (options, scope)
- Final options before submittal to EU Council and Parliament (date: est. early 2009)
- Negotiations in EU Council and Parliament (2009)
- Publish revised RoHS Directive (2010)
- RoHS entry into force (early 2012, at earliest)

EU RoHS—Impacts

- Global electronics industry implementation impact estimates $32 Billion.
- Model for RoHS legislation worldwide
- Affects global supply chain.
- Future uncertainty.
- Potential scope changes: restricted substances, product scope, exemptions, exceptions.



Is this town big enough for the both of us?

- “Competition” between RoHS and REACH as preferred chemical management tool

Estimated cost

If RoHS cost the industry $1 dollar then…

Reach will cost the industry $12

REACH Overview

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REACH

Registration

Evaluation

Authorization

of

Chemicals

Waking up to REACH!

Registration Evaluation Authorization of Chemicals

EU & Chemicals?

A Major Producer:

- The EU produces 29% of the world's chemicals the largest chemical industry in the world

A Major Market:

- Currently 25 countries, around 450 million people (the US population is 275 million)
- The EU is setting global standards on the Environment
- Control of the production and use of chemicals is controlled at the EU level and not within individual Member States

The REACH Vision...

- EU based manufacturers and importers to be responsible for assessing the health and environmental effects of every substance
- EU based manufacturers and importers to transmit information to downstream users
- Downstream users to apply risk management measures

The REACH Vision...

- Ensure risks are evaluated

  EVEN IF the chemical has been around for ages
  EVEN IF no-one has identified any problems with the chemical

- Applies the Precautionary Principle

- Substances of very high concern are properly controlled and that these substances are eventually substituted where economically and technically feasible

Have you been in touch with REACH?

Yes!

68% of European companies;
32% of them intensively.

65% of Asian companies;

45% of North American

PwC Study, 03/2008

Key Definitions

- *Substance* - a chemical element and its compounds in the natural state or obtained by any manufacturing process (REACH regulates substances)
- *Article* - an object which during production is given a specific shape, surface or design which determines its function to a greater degree than its chemical composition

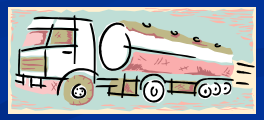
Key Definitions

- *Only Representative* - EU-based natural or legal person acting on behalf of a Non EU manufacturer fulfilling the duties of an importer.

  As of April 2008, the "Only Representative" will need to file a separate registration for each substance/legal entity it represents.

REACH Does Not Apply to:

- Radioactive substances
- Substances subject to customs control that are not intended to remain in the European Union and are not processed or transformed
- The transport of dangerous substances by rail, road, inland waterway, sea or air
- Non-recovered or non-recycled waste (as covered by waste directives)
- Specific substances, whenever this is necessary to preserve the interests of the Defense of a Member State *(if an exemption has been agreed with the relevant defense agency)*



Defense Exemption in REACH

- Defense exemptions are possible for substances, preparations and substances within articles.
- Each member state will administer this separately and set its own criteria for allowing exemptions. Some may have none.
- No expectation for a global defense exemption!



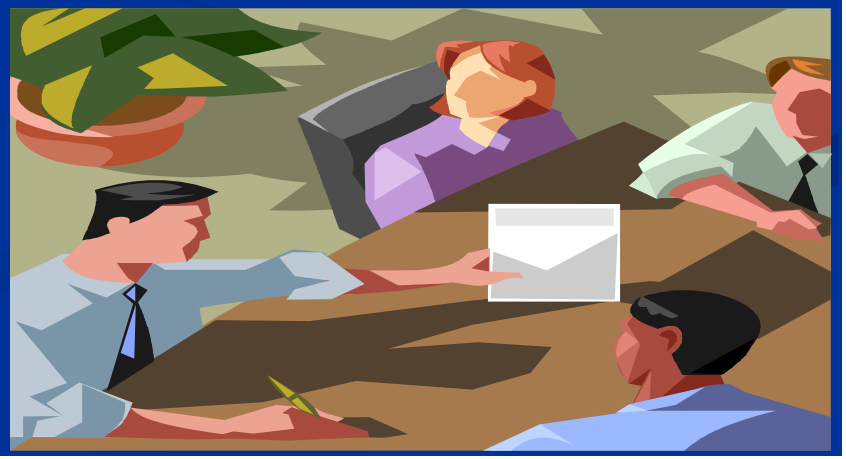
Pre-Registration

June 1 – December 1, 2008

Supply basic information on line

- Chemical name
- Company information
- Tonnage band (MT)

Allows for formation of consortiums to share costs and data.



Pre-Registration

- ECHA is scheduled to publish by Jan. 1, 2009, a list of pre-registered substances. This will include substance identification names, numbers, and registration deadlines.
- The agency also will set out information showing which companies have preregistered the same substance to facilitate forming the SIEFs.

Pre-Registration

- It is highly recommended by (almost everyone) to Pre- Register every substance)
  - Substances in articles that could be borderline
  - There are always **Changes** in interpretations

Registration – The Tonnage System

CMR R 50 / 53* all Phase in Substances (PIS)	⬅ 1 t/y ⬅ 100 t/y ⬅ 1000 t/y	within 3 years, i.e. by December 1 2010
all PISs	⬅ 100 t/y	within 6 years, i.e. by June 1, 2013
all PISs	⬅ 1 t/y	within 11 years, i.e. by June 1, 2018

*Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Registration Details

Toxicity testing results

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
Joint Research Centre

(Robust) study summaries (1)

- **Annexes VII to X**: from chapter 3 to chapter 7

1 General Substance Information
2 Manufacture, use and exposure

[redacted]

8 Preliminary: Effectiveness against target organisms
9 Guidance on safe use
10 Literature search
11 Assessment Reports

- Sub-chapters

5 Ecotoxicological Information
5.1 Aquatic toxicity
5.1.1 Short-term toxicity to fish
5.1.2 Long-term toxicity to fish
5.1.3 Short-term toxicity to aquatic invertebrates
5.1.4 Long-term toxicity to aquatic invertebrates
5.1.5 Toxicity to aquatic algae and cyanobacteria
5.1.6 Toxicity to aquatic plants other than algae
5.1.7 Toxicity to microorganisms
5.1.8 Toxicity to other aquatic organisms

Joint Research Centre

Registration Details

- How a substance (in a preparation or in an article) is manufactured or used during its life-cycle.
- How the manufacturer or importer or downstream user controls or recommends controlling exposure of humans and the environment.

Note: PELs (Regulatory Limits are replaced with a DNEL (Derived No Effect Level) & PNEC (Predicted No Effect Concentration)

Downstream User

- A Downstream User has to check, if intended use for the substance is mentioned in the SDS and the exposure scenario described fulfils their needs.

- Downstream users to identify and apply risk management measures at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

Authorization

The aim is to ensure that the risks from substances of very high concern are properly controlled and eventually substitution is made when economically and technically viable.

This means that the use of such a substance on its own, in a preparation or incorporated in an article has been authorized and that it is not restricted.

An application for authorization must show that the risks are adequately controlled and that substitution is not possible.

Authorization

For **substances** (PBTs, vPvBs and CMRs for which a safe level cannot be defined), Authorization will only be given:

- If it can be shown that socio-economic benefits outweigh the risks to human health or the environment and
- There are no suitable alternative substances or technologies. In this case, the application must include a socio-economic analysis

Authorization

- All applications for Authorization must include an analysis of substitutes. If suitable alternatives exist, a substitution plan must be added. If not, information on R&D activities must be provided.
- Applications can be submitted by EU-based manufacturers, importers and downstream users.
- Must apply for Authorization for specific uses. All other non-authorized uses are prohibited. Authorizations are time-limited and have to be renewed on a case-by-case basis.

Inclusion in the candidate list

Agency and the Commission

Authorization

- Proposals for substances on the Candidate List to be made by Member States or by the Agency at the request of the Commission.

Member State Suggestions for Candidate list

Substance name	CAS number	EC number
Anthracene	120-12-7	204-371-1
4,4'- Diaminodiphenylmethane	101-77-9	202-974-4
Dibutyl phthalate	84-74-2	201-557-4
Cyclododecane	294-62-2	206-33-9
Cobalt dichloride	7546-79-9	231-589-4
Diarsenic pentaoxide	1303-28-2	215-116-9
Diarsenic trioxide	1327-53-3	215-481-4
Sodium dichromate, dihydrate	7789-12-0	
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	201-329-4
Bis (2-ethyl(hexyl)phthalate) (DEHP)	117-81-7	204-211-0
Hexabromocyclododecane (HBCDD)	25637-99-4	247-148-4
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	287-476-5
Bis(tributyltin)oxide	56-35-9	200-268-0
Lead hydrogen arsenate	7784-40-9	232-064-2
Triethyl arsenate	15606-95-8	427-700-2
Benzyl butyl phthalate	85-68-7	201-622-7

New Cost of Doing Business

Standard Fees for Registration

Tonnage band [t/a]	Individual Submission [€]	Joint Submission [€]
1 – 10	1,600	1,200
10 – 100	4,300	3,225
100 – 1,000	11,500	8,625
≥ 1,000	31,000	23,250

New Cost of Doing Business

Costs per tonnage band for data generation* [t/a]	[€]
1 - 10	31,000
10 - 100	225,000
100 – 1,000	400,000
> 1,000	500,000 – 2,000,000

REACH Impacts for DoD

Issues for DOD and Suppliers

- Legal role? (Importer, Non-EU entity)
- Authorization
  - Identifying specific uses
  - Preparing socio economic analysis
  - Delivering research plan for alternatives
  - Alternatives meet military specs?
- Forced to accept alternatives due to black listing?
  - Possible problems with availability of parts and materials?
    - ✓ e.g - EU Producers may not be able to use a substance in their manufacturing process
- Complicated and varying MOD requirements?

What can DOD and Suppliers do?

- Work together
- Identify strategic materials
- Propose defense exemptions for all allied states, especially those with installations
- Coordinate comment on proposed SVHCs and exemption of uses from Authorization
- Look for substitutes for non-strategic materials

Websites

- http://echa.europa.eu/home_en.asp (European Chemicals Bureau – best place to start)
- http://reach.jrc.it/guidance_en.htm (All ECHA Guidance documents)
- http://reach.jrc.it/navigator_en.htm (helpful tool)
- http://reach.jrc.it/docs/guidance_document/articles_en.pdf (Guidance on Articles)

We can make it to the finish line. It may not be fast

This is not an option