MINUTES
INFORMATIONAL MEETING
INTERNATIONAL CADMIUM ASSOCIATION
Wednesday, April 25, 2007– 10:00 AM

King & Spalding, LLP – Conference Room F (2nd Floor)
1700 Pennsylvania Avenue, N.W., Washington DC 20006 USA

1. CALL TO ORDER

The meeting was called to order at 10:01 AM by its Chairman, Graham White of Considar Metal Marketing, Inc. The following persons were in attendance:

REPRESENTATIVE	MEMBER COMPANY
Tim Pugh	Black & Decker Corporation
Graham White, Chairman	Considar Metal Marketing, Inc.
Al Hardies	INMETCO

STAFF AND GUESTS	ORGANIZATION
Hodayah Finman	U.S. Department of State
Randy Wentsel	U.S. Environmental Protection Agency
Jane Luxton	King & Spalding, LLP
Khouane Ditthavong	King & Spalding, LLP
Astrid Voigt	International Zinc Association
George Vary	American Zinc Association
Christian Canoo	International Cadmium Association
Hugh Morrow	International Cadmium Association

An attendance roster was circulated for each attendee to sign. The Chairman asked Hugh Morrow to serve as the Secretary Pro-Tempore to record the Minutes of the General Assembly. The Chairman then asked each attendee to introduce himself / herself.

2. REGULATORY AFFAIRS AND MARKET UPDATES

As an informational meeting, this meeting consisted of a series of presentations updating regulatory affairs in Europe, North America, and at the International Level. A short market update was also presented before lunch. After lunch, Hodayah Finman of the U.S. Department of State made a presentation on the U.S. Government's position on the UNEP Heavy Metals Program. Khouane Ditthavong of King & Spalding discussed the activities of the North American Metals Council (NAMC) for which King & Spalding serves as the Secretariat. Randy Wentsel of the U.S. Environmental Protection Agency's Office of Research & Development made a presentation on EPA's new Metals Framework, while Christian Canoo of IZA-ICdA summarized issues related to the EU's recently enacted REACH legislation.

Annex I contains the presentation made by Dr. Christian Canoo with an update of European Regulatory Affairs. Annex II presents Hugh Morrow's update on North American and International Regulatory Affairs. Annex III summarizes the latest report on the status of the cadmium market. Annex IV presents the information given by Hodayah Finman of the U.S. Department of State while Annex V is the presentation given by Khouane Ditthavong of King & Spalding on the activities of the NAMC. Annex VI contains the presentation made by Randy Wentsel on the new EPA Metals Framework, while Annex VII is the presentation made by Dr. Christian Canoo on the EU REACH legislation. An additional background document on REACH is also attached in Annex VII for the information of ICdA Members.

3. NEXT GENERAL ASSEMBLY OF MEMBERS

The Chairman announced that the next General Assembly of Members of the International Cadmium Association would tentatively be held on Thursday, October 11, 2007 in London, UK during London Metals Exchange Week.

Respectfully Submitted,	Approved,
Hugh Morrow Secretary, Pro-Tempore	Graham White Chairman

ANNEX I

EU-Regulatory files

Status review

Informational meeting –
Washington, 25 April 2007

1

Main EU Regulatory files currently on the agenda

- Risk Assessment & Risk Reduction Strategy :
- Water framework Directive :
  - and daughter directive on Environmental Quality Standards (EQS)
- IPPC Directive & BREF-notes:
  - Integrated Pollution Prevention & Control (IPPC)
  - Best Available Technologies Reference Notes (BREF)
- REACH :
  - Will be discussed in the afternoon

2

I- Risk Assessment (RA) & Risk Reduction Strategy (RRS)

RA-conclusions are essentially targeting the Human Health

- In the Environmental RA, a conclusion (iii)-Risks identified- is reached for following compartments:
  - The local surface water at 5 production/processing sites
  - The regional terrestrial ecosystem is at potential risk in one region (UK)
  - The secondary poisoning to mammals (Cd concentrations in soils) is at potential risk in one region (UK)

  A conclusion (i) –additional studies required- is drawn for Cd-ecotoxicity in very soft waters

- In the Human Health RA, a conclusion (iii) is reached:
  - For Cd oxide:
    - ✓ Risk to workers
    - ✓ Man indirectly exposed via the Environment
  - For Cd metal:
    - ✓ Risks to consumers from using Cd-containing brazing sticks

I- The Risk Reduction strategy meeting is planned for May 10th 2007

- Occupational :
  - Requesting the definition of harmonized EU OEL's by the SCOEL (Scientific Committee for Occupational Exposure limits)
  - Making reference to good practice as developed in the Industry Guidance document

  Current Q/A from some member states: What about binding measures ? Commitment ?

- General population :
  - Fertilisers
  - Smokers

  Current Q/A from some Member States: Quid further Restrictions on use ??

We are still in close contact with the belgian rapporteur + Ecolas to prepare that meeting

I – RRS > We would like to steer the discussions with the belgian rapporteur as follows

- Occupational :
  - Guidance document + commitment
  - Showing occupational records (EU-wide, sector-wide):
  - Showing the start-up of the "Bone study"
  - Request for advise of SCOEL on usefulness of OEL's
- General population :
  - Fertilisers
  - Smokers
  - Current directives are already in place: WEEE, ROHS, BD, ELV,

II - Water framework Directive

- Objective :

To reach a good status of surface waters and groundwaters by 2015

- Surface waters = inland, transitional, coastal waters
- Good ecological status for
  - ✓ Biological elements (composition and abundance of aquatic flora, invertebrate and fish fauna, phytoplancton biomass)
  - ✓ Physico-chemical elements (t°, O_2, nutrients, pollutants,…)
- Good chemical status
  - ✓ Compliance with the standards (EQS: Environmental Quality Standards)

- Through a management by River basin
  - River basin management plan (RBMP) to be published by member states in 2009
  - Revised every 6 years
  - Based on regular monitoring

- Priority list of substances (annex X) :
  - To be monitored, of which "Priority Hazardous substances" , i.e. Cd, for which emissions should cease as of 2015

III – IPPC & BREF-notes

- BREF-notes
  - of Non Ferrous Metals are to be revised in 2007-2008 :
  - wish-lists on articles to be revised are going to be compiled by the Joint Research Center (JRC) in Sevilla
  - Kick-off meeting in September
- Follow-up through member's network
  - Zn plants with Cd extraction &refinery
  - Battery-manufacturer's plants
  - Recycler's plants

Regulatory Affairs Report North American and International Activities

International Cadmium Association
Informational Meeting

King & Spalding, LLP – 2nd Floor Conference Room
1700 Pennsylvania Avenue, N.W., Washington DC 20006
April 25, 2007

North American Cadmium Issues

- U.S. EPA Development of Metals Assessment Framework
- U.S. EPA Toxic Release Inventory (TRI) Lead Rule
- NAFTA CEC SMOC Action Plan
- U.S. EPA IRIS Cadmium Assessment
- USA State Programs on Cadmium

US EPA Framework for Metals Risk Assessment

- EPA Released Final on March 8, 2007
- Report EPA 120/R-07/001 Available at www.epa.gov/osa/metalsframework
- "Inorganic metals & metal compounds have unique characteristics that should be considered when assessing their risks."

US EPA Framework for Metals Risk Assessment

- Applicable to All Metals
- BAF/BCF Not Appropriate for the Ranking of Metals, Emphasizes BLM
- Includes Language on Human Health Bioaccumulation but Recognizes the Importance of Metal Form, Specific Organ or Tissue, and Metal's Kinetics

US EPA Framework for Metals Risk Assessment

- Recognizes Naturally Occurring Levels of Metals (Effect on Some Regulations)
- Recognizes Essentiality of Metals
- Emphasizes the Importance of the Metallic Form (species, particle size)
- Acknowledges Bioavailability for Assessing Hazard and Risk of Metals

U.S. EPA Toxic Release Inventory (TRI) Lead Rule

- District of Columbia Court Ruled That EPA Was Not Required to Follow Methodology in Establishing Lead TRI Reporting Threshold
- With Release of Metals Framework, TRI Office Will Reconsider Metals Regulations
- At February 27 Meeting, TRI Chief Rebecca Moser Said TRI Office is "Cross-Walking" MF with TRI Methods to Assess and Classify
- Activity Will Include Re-Examination of Pb TRI Rule Which is Based on PBT Concepts

NAFTA CEC Sound Management of Chemicals (SMOC) Action Plan

- **NAFTA CEC SMOC Working Group Meeting in Monterrey, Mexico, April 18-19, 2007**
- **Work on Four Proposed Concept Areas under** *Puebla Priority Strategy to 2020*
- **Reduce the Risk from Chemicals of Concern to North America: Hg and Several POPs**
- **Develop and Implement Sustainable Regional Approach to Monitoring / Biomonitoring and Assessment of Toxic Chemicals. Emphasis on Mexico.**

NAFTA CEC Sound Management of Chemicals (SMOC) Action Plan

- **Improve Environmental Performance through a Sector Approach to Sound Management of Toxic Substances.**
- **Establish a Foundation for Chemicals Management across North America. Emphasis on Upgrading Mexico's Programs.**
- **EPA Looking for Industry Input and Case Histories of Voluntary Initiatives**
- **EPA Minimized Concern over New Chemicals Being Added to Programs**

U.S. EPA Integrated Risk Information System (IRIS)

- EPA Database Contains Scientific Levels of Potential Adverse Human Health Effects
- Update Started in February 2003
- Literature Search Completed in July 2003
- First Draft Started in February 2006
- Draft Completion Expected in April 2008
- Final Report Expected in September 2009
- Many Opportunities for ICdA Comments

USA State Programs on Cadmium and Products

- Legislation to Lower Cadmium Product Use
  - Labeling, Purchasing Preferences, Few Bans
- Required Establishment and Financing of Cadmium Product Collection and Recycling
  - NiCd Batteries and Electrical / Electronic Waste
- Emissions, Air and Water Quality Standards
  - Labeling, RfD, Disposal Restrictions, Concentration Limits
  - Complete Listing in ATSDR Cadmium Profile

International Cadmium Programs

- UNECE LRTAP Heavy Metals
- UNEP Heavy Metals Program
- IFCS Program on Heavy Metals
- OECD Guidance Manual on ESM of Waste
- WHO / FAO JECFA PTWI for Cd

UNECE LRTAP Heavy Metals Protocol

- Entered into Force 29 December 2003
- Applies to Long-Range Transboundary Air Emissions of Pb, Cd & Hg
- Applies BAT to Reduce HM Emissions of Selected Industries from 1990 Base
- Existing Product Restrictions
  - Pb in Gasoline; Hg in Batteries; None Cd
- Sufficiency & Effectiveness Review

UNECE LRTAP Heavy Metals Protocol

- S & E Review Completed in 2006
- No Specific Wording on Products and Indirect Emissions was Included
- 2007 Task Force on Heavy Metals
  - Options for Further HM Reductions
  - Health & Ecosystem Benefits of Lower Heavy Metal Emissions
  - Other Approaches than Critical Loads

UNEP Heavy Metals Program

- "Scientific Review" on Cadmium by Danish Consultant Prepared in 2006
- Review Strongly Criticized by Industry and Several Governments
- Review Expresses Nordic Viewpoint and is Highly Specific to EU Data
- IFCS Supports Scientific Review and Calls for Global Programs on Hg,Pb,Cd
- UNEP Governing Council Meeting Held in Nairobi, Kenya in February 2007 to Consider Actions on HM Programs

UNEP Heavy Metals Program

- UNEP GC Acknowledges "Data and Information Gaps" in Reviews, and Requests Action to Fill Those Gaps
- However, In Deference to IFCS, GC Notes Situations in Third World
- Encourages Governments and Others to Reduce Cadmium Risks Throughout the Whole Life Cycle
- Requests Inventory of Existing Risk Management Measures for Cadmium

UNEP Heavy Metals Program

- Next Steps are Unclear
- No Subsequent Working Group Meetings Have Been Announced
- ICdA, ILZRO, ICMM Are All Involved with the UNEP HM Working Group
- USA and Canada Are Very Supportive of Cadmium Industry's Position
- USA and Canada Would Also Like to Minimize or Eliminate the Political Participation of IFCS

IFCS Proposed Program on Heavy Metals

- "Health and Environmental Concerns Asociated with Heavy Metals: Global Need for Further Action?"
- 25 Sept 2006 during IFCS Forum V
- Organized by Switzerland with Emphasis on Developing Nations
- 12 Case Studies Presented and Cadmium Working Group Discussion

IFCS Proposed Program on Heavy Metals

- IFCS "Budapest Statement" for Global Legally Binding Programs for Hg,Pb,Cd
- Norway and Switzerland Proposed Global Action on Hg,Pb,Cd at UNEP GC
- IFCS Forum Standing Committee (FSC) Looking at Cadmium for Forum VI
- LDAI and ICMM are Involved
- Forum VI: September 13-19, 2008 in Dakar, Senegal or Nairobi, Kenya

OECD Guidance Manual on ESM of Wastes

- Drafted to Help Implement Previous OECD Recommendation (Non-Binding)
- 11 Recommendations and 6 Core Performance Elements (CPEs)
- Addresses Hazardous, Non-Hazardous Wastes and Recyclables
- Covers Disposal & Recovery Activities
- Recent Changes of Concern to USA

WHO / FAO JECFA PTWI For Cadmium

- PTWI Held at 7 μg/kg-bw/wk at 2003 and 2005 JECFA Meetings
- EU Risk Assessment and Nordic Reviews Trying to Suggest Much Lower Levels
- Current Intake Levels Range = 0.7 to 2.8 μg/kg-bw/wk (10% - 40% PTWI)
- JECFA Requests Data on Cd in Rice, Wheat, Potatoes, Leafy Vegetables, Molluscs & National Food Cadmium Consumption Data

Cadmium Market Report

International Cadmium Association
Informational Meeting

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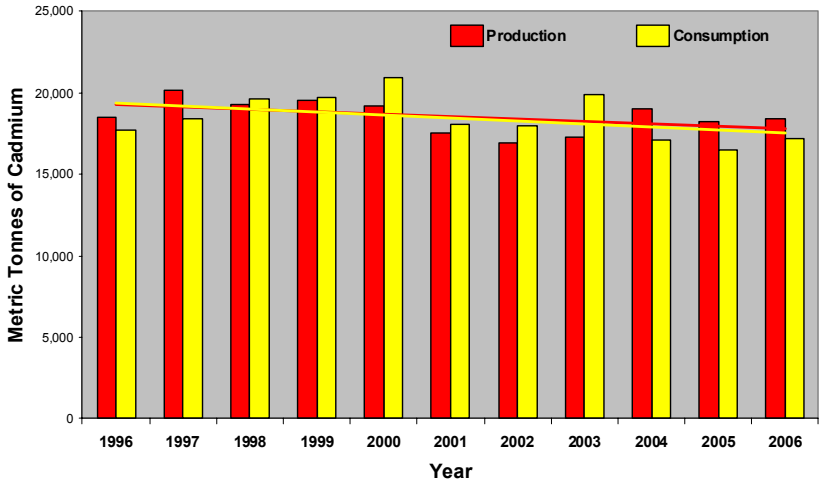
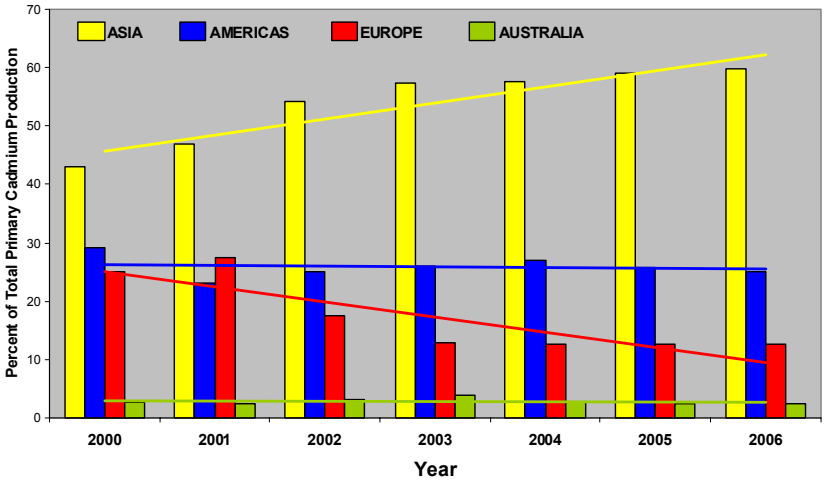
Wednesday, April 25, 2007

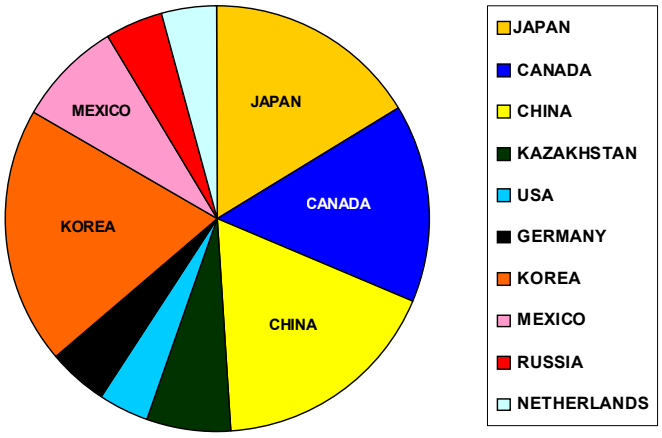
Primary Cadmium Production and Consumption, 1996 - 2006



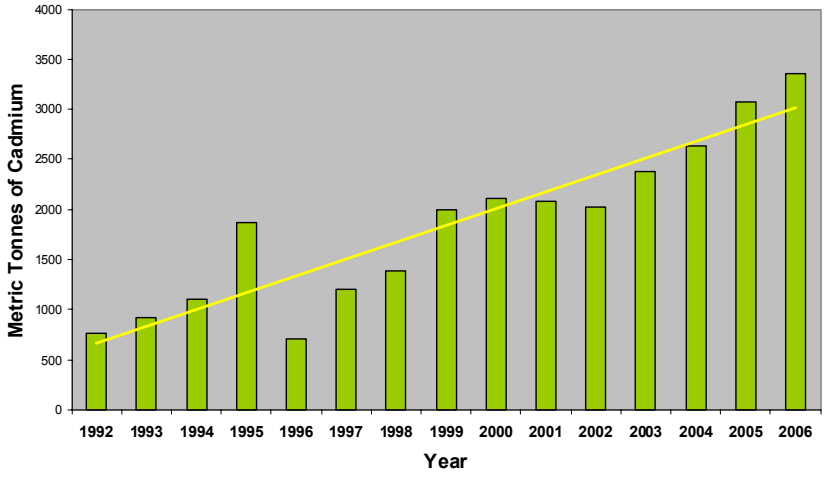
Geographical Trends in Primary Cadmium Production



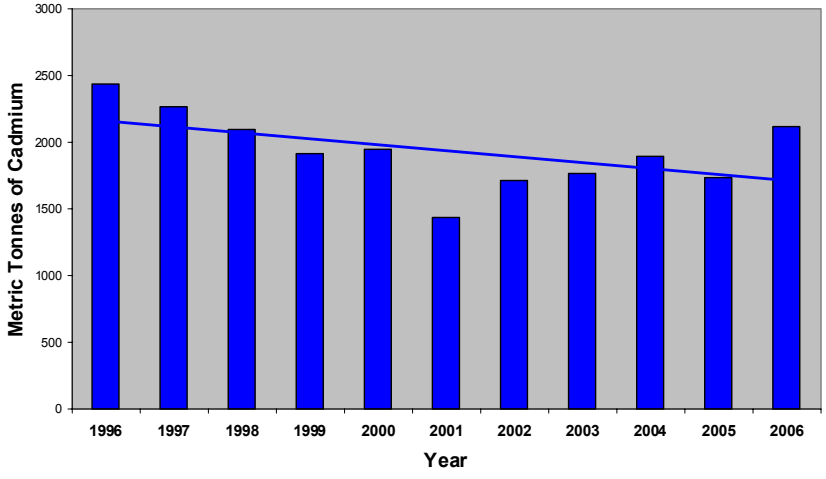
2006 Cadmium Production by Country



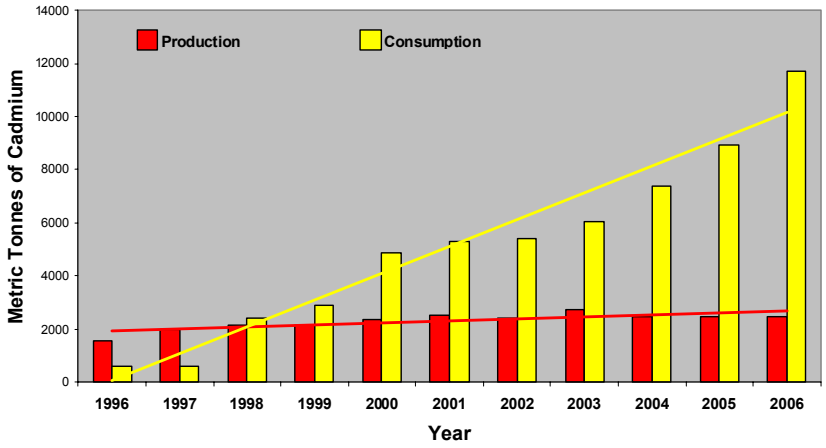
Korean Cadmium Production, 1992-2006



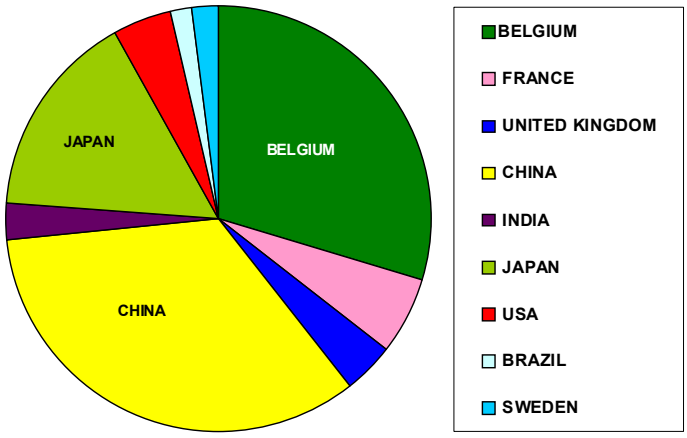
Canadian Cadmium Production, 1996-2006



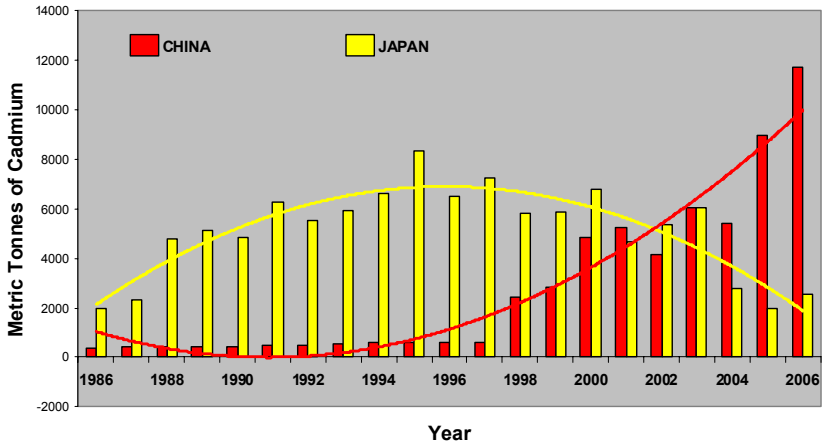
Chinese Cadmium Production and Consumption, 1996-2006



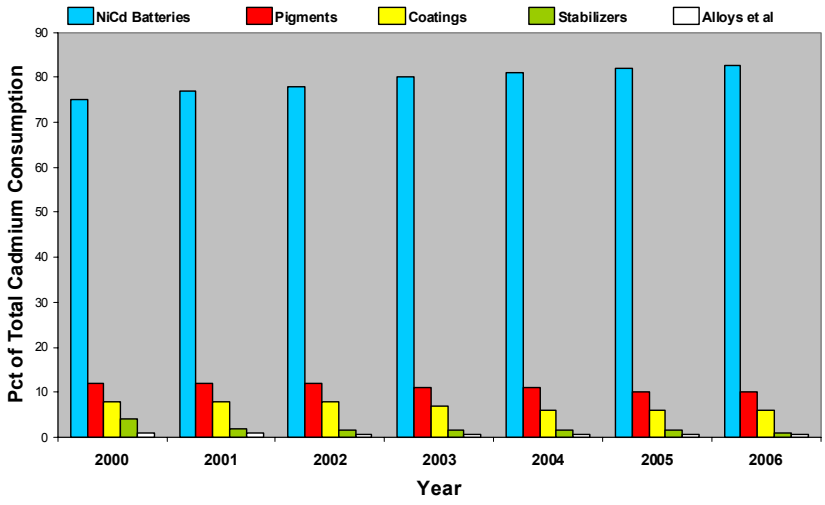
2006 Cadmium Consumption by Country



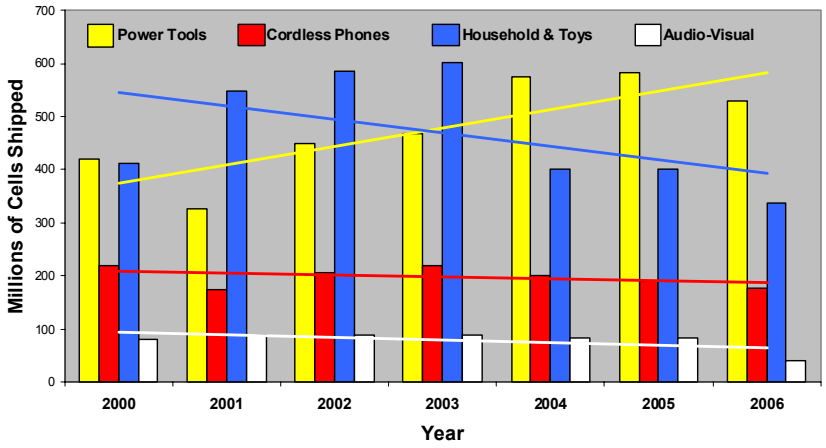
Japanese and Chinese Cadmium Consumption, 1986-2006



Trends in Cadmium Consumption Patterns



Worldwide Consumer NiCd Shipments
(Takeshita - 2003, 2004, 2005, 2006, 2007)



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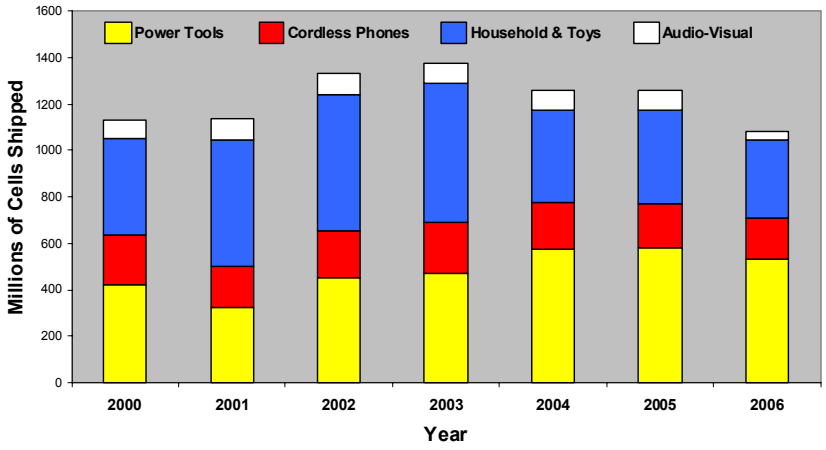
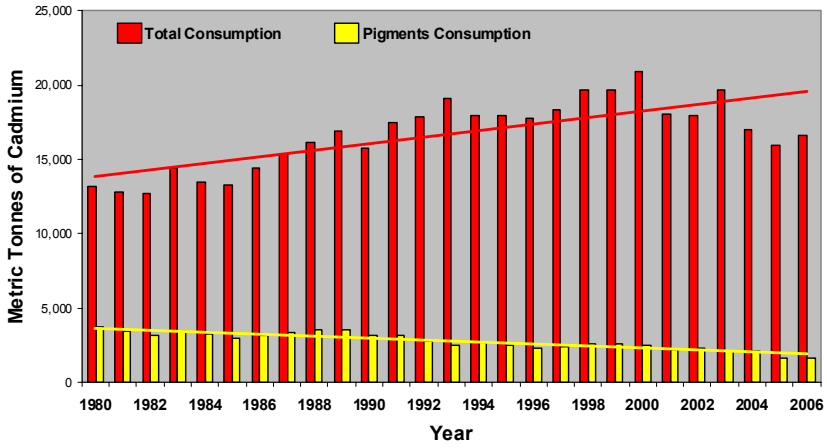
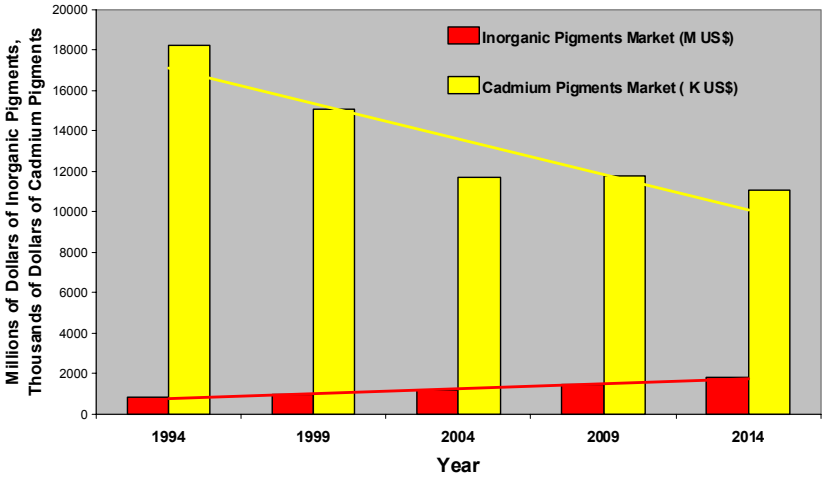


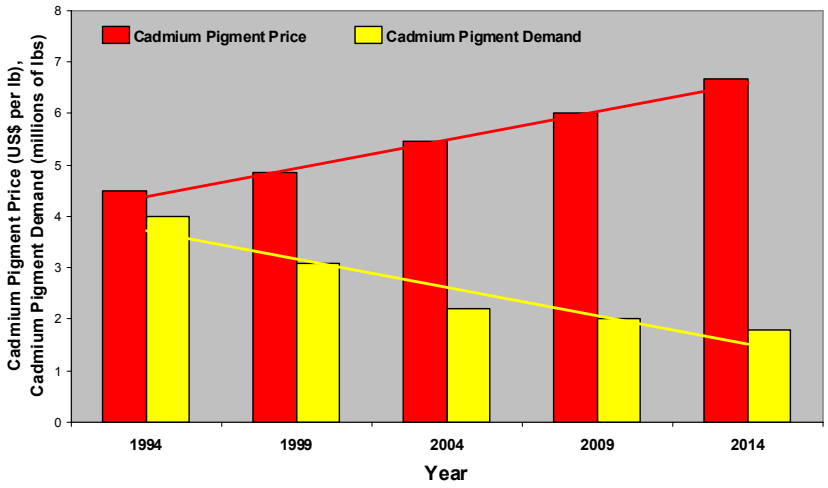
Cadmium Pigment Consumption vs. Total Cadmium Consumption, 1980-2006



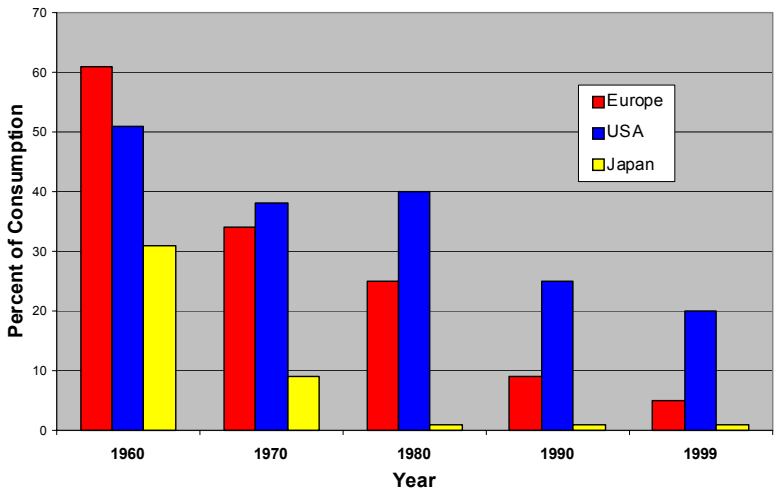
Freedonia Forecast of Cadmium Pigments Market



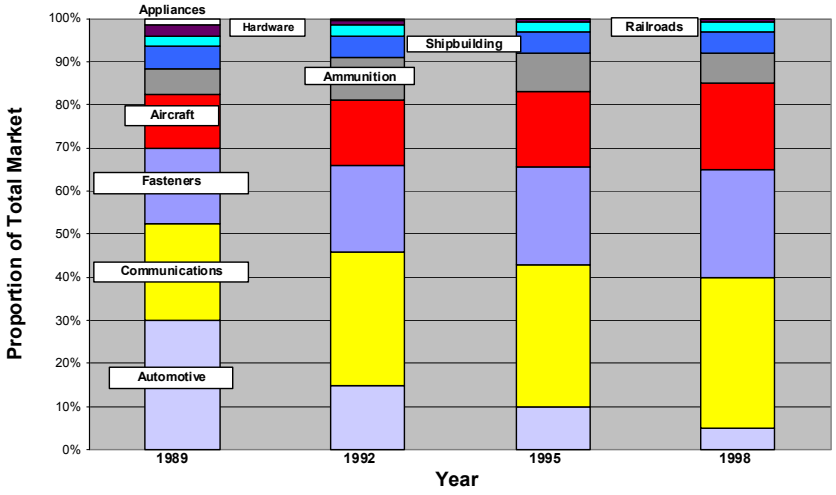
Freedonia Forecast of Cadmium Pigment Price and Demand



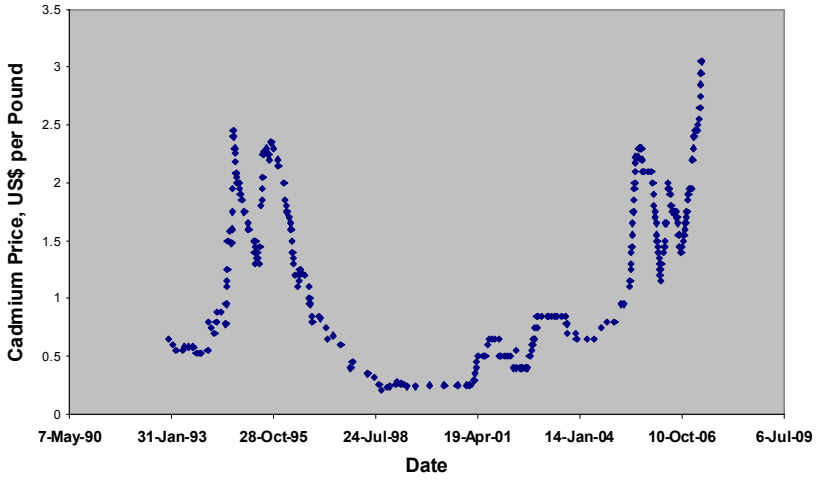
Geographical Cadmium Coating Markets, 1960 - 1999



USA Cadmium Coatings Market



Metal Bulletin 99.99% Cadmium Price, 1993-2007



U.S. Views on the UNEP Heavy Metals Program

Hodayah Finman
Department of State
Presentation to the International Cadmium Association
Informational Meeting
April 25, 2007

Direction from Governing Council

- Every two years the Governing Council (GC) to the United Nations Environment Program (UNEP) meets in Nairobi
- The GC provides direction to UNEP and provides opportunity for policy level discussions
- GC decisions in 2005 and 2007 take up the issue of cadmium during larger discussions on mercury

GC Decision 23/9

"Requests the Executive Director to undertake a review of scientific information, focusing especially on long-range environmental transport, to inform future discussions on the need for global action in relation to lead and cadmium"

Study on Cadmium

- UNEP Chemicals developed a study on cadmium and review process
- USG view: report to focus on long-range environmental transport
- Report may be found at UNEP website: http://www.chem.unep.ch/Pb_and_Cd/SR/Files/Interim_reviews/UNEP_Cadmium_review_Interim_Oct2006.pdf

Study Process

- UNEP consultant developed study
- Two rounds of comments from the Lead/Cadmium Working Group
- WG then met 18 to 22 September 2006 to develop key findings and provide additional comments on study document
- WG composed of governments, industry, and environmental/health experts

Magnitude of Cadmium Emissions

- Global anthropogenic emissions estimated at 2,983 tonnes in the mid-1990's, newer estimates not available
- Available data indicate anthropogenic emissions decreased by an average of about 50 per cent from 1990 to 2003 in developed countries
- Adequate data are not available to evaluate trends in developing countries. The

LRET Show Minimal Concern

- Cadmium is subject to atmospheric transport and may be transported on local, national, regional or intercontinental scales, depending on various factors, including, for both natural and anthropogenic sources, particle size, the height of emission outlets and meteorology.
- Because it has a relatively short residence time in the atmosphere (days or weeks), however, this metal is mainly transported over local, national or regional distances.
- Based on the relatively scarce specific evidence available, cadmium is considered to be subject to a certain degree of long-range air transport on an intercontinental scale. Intercontinental transport is, however, expected to make only a minor contribution to cadmium levels in regions affected by other, local emitting sources

Human Health

- Food accounts for approximately 90 per cent in the general, non-smoking population
- Cadmium in crops is due to the uptake of cadmium from soils and the rate of uptake is influenced by factors such as soil pH, salinity, humus content, crop species and varieties and the presence of other elements (e.g., zinc)
- Less than 10 per cent of the total exposures among general populations occur due to inhalation of low levels of cadmium in ambient air and through drinking water

But Data Gaps…

- Exposure assessments and use and release inventories
- Hemispheric modelling
- Assessment of the extent of risks
- Relative contribution of anthropogenic sources
- Data on accidental spills from mine tailings
- Cadmium disposal in developing countries
- Transport by rivers to marine environments
- Global flow of cadmium in products

Status of Reports

- Interim Documents
  - Reports themselves
  - Data gaps
- Key findings finalized

Governing Council 24

- State Department held series of consultations in advance of GC
- At GC significant momentum on mercury action, while lead & cadmium less clear
- Norway/Switzerland maintain LRET a concern with lead & cadmium

GC Decision 24/3

- *Acknowledges* the data and information gaps identified in the United Nations Environment Programme Interim Scientific Reviews on Lead and Cadmium and that further action is needed to fill those data and information gaps, taking into account the specific situation of developing countries and countries with economies in transition;
- *Requests* the Executive Director to provide available information on lead and cadmium to address the data and information gaps identified in the Interim Reviews and to compile an inventory of existing risk management measures

GC Decision 24/3: Mercury

- Re-endorse UNEP Mercury Partnerships
- Identified mercury priorities
- Ad-hoc Open Ended Working Group (AHOWEG) to meet twice before GC 25

Next Steps

- Existing Data to UNEP
- UNEP to make available
- USG stakeholder consultations for AHOWEG

Any Questions?

Further Information:

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Finmanhh@state.gov

KING & SPALDING

North American Metals Council – Current Activities

Khouane Ditthavong

April 25, 2007

NAMC Members

Afton Chemical
American Iron & Steel Institute
American Zinc Association
ASARCO, Inc.
Association of Battery Recyclers
Battery Council International
*Copper Development Association
Edison Electric Institute
Ethyl Corporation
Horsehead Corporation
International Manganese Institute
Kennecott Utah Copper
*Mining Association of Canada
*National Mining Association
Newmont Mining Corporation
*Nickel Institute
*Noranda, Inc./Falconbridge Ltd.
*Phelps Dodge Corporation
Photo Marketing Association
*Rio Tinto
Society of Glass & Ceramic Decorators
Sporting Arms & Ammunition Mfgs.
Teck Cominco
The Aluminum Association
*The Doe Run Company
The Fertilizer Institute
Treated Wood Council
Umicore USA, Inc.

**Steering Committee Member*

Metals Framework

- On March 8, 2007, EPA released its final Framework for Metals Risk Assessment, EPA 120/R-07/001, available at www.epa.gov/osa/metalsframework
- EPA scientific offices used a comprehensive, inclusive scientific process to develop this set of guiding principles for metals
- EPA upheld key "fundamental truths," advocated by NAMC, that must be addressed in metals risk assessments
- Result represents an outstanding example of government and industry working together to recognize critical scientific principles. NAMC considers this a success.

Metals Framework (cont'd)

- "Fundamental truths" include:
  - The essential difference between metals and organic chemicals
  - The inappropriateness of using BAF/BCF for ranking metals
  - The need to consider metals speciation and bioavailability
  - The role of background levels of metals in the environment
  - The fact that some metals are essential elements

Metals Framework (cont'd)

- NAMC is monitoring the effect the new Framework is having on EPA regulations
  - Trade press reports indicate uncertainty among EPA officials over whether EPA can continue to defend the use of PBT criteria for metals
  - Reexamination of the TRI Lead Rule's reliance on a PBT classification of lead is underway
- NAMC successfully convinced the Washington State Department of Ecology that it is inappropriate to classify Cd and Pb as "PBT substances"

Metals Framework (cont'd)

- NAMC is exploring other scientific and policy venues to leverage the Framework findings

REACH

- On December 13, 2006, the EU Parliament formally voted to enact REACH effective June 1, 2007
- Training and implementation are key challenges for the North American metals industry, and NAMC plans to host:
  - A June conference call to discuss basic timelines and requirements
  - A more detailed one-day workshop focusing on impacts on North American metals industry in August or September

UNEP Governing Council

- Extensive discussion on possible regulation of Hg, Cd, and Pb going into the February UNEP meeting in Nairobi
- NAMC's role:
  - Coordination with U.S. and Canadian Governments
  - Liaison with international metals industry meeting participants (John Atherton, Bill Adams, Joe Pollara)
  - Close coordination with Hugh Morrow among others

UNEP Governing Council (cont'd)

- Key outcomes included:
  - Action on Cd/Pb limited to gathering additional data
    - Cd/Pb whitepaper on hold pending data collection
  - Continuing with partnerships for Hg, with progress review at interim working group meetings (*e.g.*, Summer 2007) and next UNEP Governing Council meeting (2009)
  - Option to review "other chemicals of global concern" not incorporated
  - No specific product use bans or phase-outs were adopted

UNEP Governing Council (cont'd)

- ICMM Mercury Workgroup is exploring partnership opportunities on artisanal gold mining and Chinese metal smelter mercury emissions
- NAMC and CMM are playing a facilitating role

SAICM

- Individual member countries are developing national action plans, and regional implementation efforts are moving forward
  - One commentator noted developing countries are looking for funding; developed countries are looking for ways to keep control; and the EU is looking for ways to expand its REACH legislation
- In North America, NACEC SMOC is carrying the SAICM portfolio
  - Meeting scheduled for Spring 2007 will focus on harmonizing Canadian, U.S., and Mexican environmental standards and facilitating environmental regulation in Mexico

SAICM (cont'd)

- Metals, particularly Hg, Cd, and Pb, have been cited as priority areas for SAICM
  - Some proponents favor using SAICM as a vehicle for international regulation of metals

Other Issues of Concern

- *Globally Harmonized System* – effort is tied to REACH; potential impact on MSDSs
- *Canadian Domestic Substances List (DSL)* - Canada is evaluating its DSL to prioritize substances based on their PBT categorization and potential for human exposure; some metal compounds appear on the list
  - NAMC is coordinating with Canadian industry to ensure coverage of metals and related chemicals of concern as they come under evaluation

Other Issues of Concern

- *Nanotechnology* – Increasing regulatory interest affecting metals industry
  - NTP has announced its intention to study gold and silver nanoscale materials
  - Nanosilver has received regulatory attention for its use in antibacterial applications (FIFRA)
  - Applications not yet targeted by regulators include nanoscale zinc oxide and titanium dioxide used in sunscreens, but NGOs are interested
  - NAMC workshop on metal nanotechnology issues is in the early planning stages

Other Issues of Concern

- *OECD Council's Decision on the Control of Transboundary Movements of Wastes Destined for Recovery Operations* - draft revisions to OECD's decision and guidance include new procedures for movement of "green-listed" wastes (*i.e.*, wastes deemed to pose no or negligible risk) contaminated with other hazardous wastes
  - U.S. is concerned that OECD has not provided enough lead time to evaluate the provisions before asking for a vote
  - NAMC is coordinating comments on the new procedures and other aspects of the proposed revisions

Framework for Metals Risk Assessment

Randy Wentsel and Anne Fairbrother
U.S. Environmental Protection Agency
Office of Research and Development
April 25, 2007

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Background

- There has been considerable interest in the Agency's assessments on metals and metal compounds
  - recent events surrounding promulgation of the Toxics Release Inventory (TRI) lead rulemaking
  - development of the Agency's Waste Minimization Prioritization Tool

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Background

- The Agency therefore initiated a process
  - to address issues associated with metals
  - will provide opportunities for external input, peer review and cross-Agency involvement
  - that assigned responsibility to the Science Policy Council with technical support from the Risk Assessment Forum

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Basis for Stakeholder Challenge to the PBT Framework as Applied to Metals

- BCFs for metals vary with species, environmental conditions, generally show an inverse relationship with concentration and are not a predictor of toxicity
  - unlike organics with high BCFs, metals do not biomagnify up the food chain
  - only metals that that biotransform to organo-forms will biomagnify
    - mercury, selenium
  - most organisms have evolved mechanisms to regulate (excrete/store) metals.

Speciation and bioavailability are more meaningful than persistence when evaluating hazard potential

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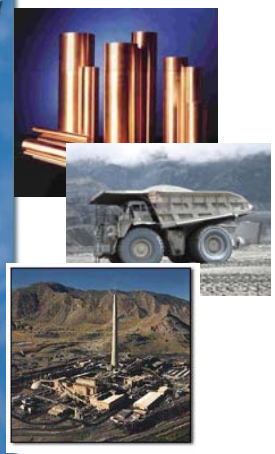
Metals Framework

Charge:



- Develop a comprehensive framework that could be the basis of future Agency actions
- Provide a consistent set of basic principles to be considered in assessing risks posed by inorganic metals
- Identify available methods, models, and approaches for use in metals assessments

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Programmatic Challenges

Difficult to develop a single approach for all programs based on available science

- Programs conduct different levels of assessment, e.g., hazard assessment/ ranking, national level, and site specific
- Programs have different ways of dealing with the unique features of metals due to:
  - statutory requirements and assessment goals
  - availability of exposure and effects data
  - degrees of conservatism
  - ways of dealing with uncertainties

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Collaboration

- Involved national and international experts in two workshops and five issue papers that supported the development of the document
- We were active with MERAG in Europe attending workshops and reviewing documents
- Active in Canadian Metals in the Human Environment Research Network
- Co-sponsored a SETAC workshop on metals issues

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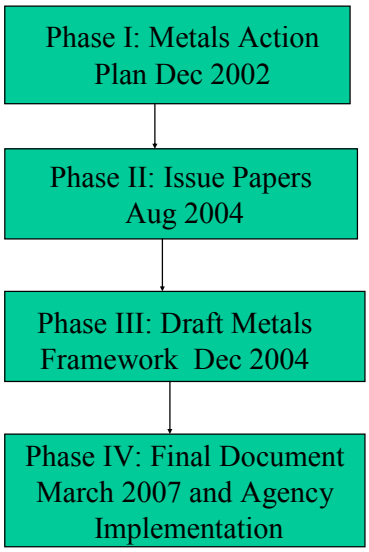

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Purpose

- Present key guiding principles based on the unique attributes of metals
- Describe how metals-specific attributes and principles may then be applied in the context of existing EPA risk assessment guidance and practices
- Outline key metal principles and how they should be considered in existing human health and ecological risk assessment practices
- Foster consistency across EPA programs and regions

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Principles

- Metals are naturally occurring constituents in the environment and vary in concentrations across geographic regions.
- All environmental media have naturally occurring mixtures of metals, and metals often are introduced into the environment as mixtures.
- Some metals are essential for maintaining proper health of humans, animals, plants, and microorganisms.

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Principles

- **Unlike organic chemicals, metals are neither created nor destroyed by biological or chemical processes**
  - **They can transform from one species to another (valence states) and can convert them between inorganic and organic forms.**
- **The absorption, distribution, transformation, and excretion of a metal (toxicokinetics) within an organism depends on**
  - **the metal**
  - **the form of the metal or metal compound**
  - **the organism's ability to regulate and/or store the metal.**

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Science Policy Issues

- **Incorporation of Bioavailability**
- **Limited use of BAF/BCF**
- **Application of RDA**
- **Environmental Chemistry**
- **Human Health**
- **Ecological**

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Bioavailability Issues

- Bioavailability of metals and the associated risk vary widely according to the physical, chemical, and biological conditions under which an organism is exposed.
- Bioavailability should be explicitly incorporated into all risk assessments
- Assumptions should be clearly articulated
  - in situations where data or models are insufficient to address bioavailability rigorously

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BAF/BCF Issues

- Certain metal compounds are known to bioaccumulate in tissues and this bioaccumulation can be related to their toxicity.
- The latest scientific data on bioaccumulation do not currently support the use of bioconcentration factor (BCF) or bioaccumulation factor (BAF) values when applied as generic threshold criteria for the hazard potential of inorganic metals

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BAF/BCF Issues

- Single value BAF/BCFs hold the most value for site-specific assessments
  - extrapolation across different exposure conditions is minimized
- For regional and national assessments, BAF/BCFs should be expressed as a function of media chemistry and metal concentration for particular species (or closely related organisms)
- Bioaccumulation of metals is the net accumulation of a metal in the tissue of interest or the whole organism that results from *all environmental exposure media*, including air, water, solid phases (i.e., soil, sediment), and diet, and that represents a net mass balance between uptake and elimination of the metal (SAB, 2006)

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RFD and RDA Issues

- RFDs should not be below RDAs
- Essentiality should be viewed as part of the overall dose-response relationship for those metals shown to be essential
- Zinc IRIS document is an example

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Environmental Chemistry

- Metal speciation affects metal behavior in environmental media
- pH and redox potential affect speciation
- Kd values
  - limited use of single values
- Aging of metals in media reduces bioavailability
- Metal sorption behavior affects bioavailability

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Human Health

- The organ or tissue in which metal toxicity occurs may differ from the organ or tissue(s) in which the metal bioaccumulates and may be affected by the metal's kinetics
  - target organs may differ by species, mainly owing to differences in absorption, distribution, and excretion.
- Both the exposure route and the form of a metal can affect the metal's carcinogenic potential and its noncancer effects
- Sensitivity to metals varies with age, sex, pregnancy status, nutritional status, and genetics

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Human Health

- Metals attached to small airborne particles are of primary importance for inhalation exposures.
- Adverse nutritional effects can occur if essential metals are not available in sufficient amounts
  - increases the vulnerability of humans to other stressors, including those associated with other metals.
- Because the diets of humans and other animals are diverse, there may be wide variability in the dietary intake of some metals (e.g., in seafood)
  - results in temporal, geographic or cultural variability of responses

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Ecological

- Background levels refers to those concentrations of metals that derive from natural as well as anthropogenic sources that are not the focus of the risk assessment
  - metal concentrations vary widely over space and time owing to differences in geology, hydrology, anthropogenic and natural loads from “nontarget” sources, and other factors
- For aquatic organisms, routes of exposure include absorption across (or in some cases adsorption to) respiratory organs, dermal absorption, sediment ingestion, and food ingestion
- For terrestrial organisms, routes of exposure include binding to roots, foliar uptake, dermal absorption, food, water, and soil ingestion, or inhalation.

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Ecological

- For most metals, the free ionic form is most responsible for toxicity
- Free-ion activity models are useful for establishing relative toxicity among metals in different media
- Sediment toxicity is reduced by acid volatile sulfides, organic carbon and other factors that bind free ions and decrease bioavailability
- Soil toxicity is affected by pH, CEC, and % organic matter
- Inorganic metal compounds rarely biomagnify across three or more trophic levels
- Effects addition models are a useful first approximation of acute toxicity of metal mixtures

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Assessment Questions

- Principles are translated into assessment questions to assist in their consideration
- Questions drafted for phases of risk assessment

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Web Sites

- **Metals Framework, March, 2007**
  http://www.epa.gov/osa/metalsframework/
- **Issue papers August 2004**

  http://cfpub2.epa.gov/ncea/cfm/recordisplay.cfm?deid=86119

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Core Technical Panel

Co-leads: **Anne Fairbrother ORD/NHEERL**
Randy Wentsel ORD

Steering Committee:

Keith Sappington	**ORD/NCEA**
Bill Wood	**ORD/RAF**
Steve Devito	**OEI/OIAA**
Alec McBride	**OSWER/OSW**
Dave Mount	**ORD/NHEERL**

REACH

The new EU regulation on Chemical Substances

Informational meeting –
Washington, 25 April 2007

What is REACH ?

- REACH is the Regulation for **R**egistration, **E**valuation, **A**uthorisation & Restriction of **Ch**emicals
- It enters into force on 1st June 2007, and will:
  - streamline and improve the former legislative framework on Chemicals (40 pieces of legislation will be repealed)
  - place greater responsibility on Industry to manage the risks associated with chemicals for health and environment
- The set objectives are to:
  - Improve the protection of human health and the environment from potential risks posed by chemicals
  - Enhance competitiveness of EU chemicals industry
  - Promote alternative methods for assessment of hazards of substances
  - Ensure the free circulation of substances on the internal EU market

REACH time-line

- June 1st 2007
  - Enforcement of REACH
- till December 1st 2008
  - Pre-registration by legal entities of their portfolio of Phase-in substances
- In the course of 2009
  - Call of SIEF's by the Agency
  - Issuance of the first Priority-list for Authorisation
- till December 1st 2010
  - Registration of Phase-in substances:
    - ✓ > 1000 t/y : all
    - ✓ > 100 t/y : harmful to the environment
    - ✓ > 1 t/y : CMR's substances (cat. 1 & 2)
- till December 1st 2011
  - Notification of substances in Articles (if in the first authorisation list)
- till December 1st 2012
  - Timing for examination of testing proposals by the Agency for Registration-files received by Dec. 2010

Any Cadmium or Cd-compound producer/importer in Europe will have to register the Cd-substance(s)

- The pre-Registration will have to occur between June-December 2008 :
  - Per legal entity
  - Limited information on substances intended to be registered, tonnage b
  - ...

Common elements need to be prepared consistently

- The Registration will have to occur between June-December 2010 :
  - Per legal entity, individual, specific part
  - And a common part of the dossier:
    - ✓ Hazard characteristics
    - ✓ Classification
    - ✓ CSR + Σ ES's
  - ...

Common elements need to be prepared consistently

- When applicable (priority listed – Cd ?) an Authorisation dossier will be filed simultaneously with the Registration :
  - Showing that risks are controlled
  - Presenting a potential substitution plan (or Socio Economic Assessment – SEA)

Consortium formation might help producers/importers of similar substances to comply with REACH obligations

- The purpose of the Consortium might be minimal to meet the compulsory requirements under REACH (SIEF's: Shared Information Exchange Forum):
  - ✓ Sharing results of Vertebrate Animal Studies (VAS)
  - ✓ Agreeing on Classification of the substance(s) under consideration
- The purpose and mandate of the Consortium might be extended and include :
  - ✓ Compiling and assess available data
  - ✓ Preparing robust data summaries
  - ✓ Addressing technical issues
  - ✓ Developing read-across approach to use surrogate data
  - ✓ Conducting modelling to assess opportunities for exposure-based waivers
  - ✓ Preparing testing proposal for non-animal testing and contract for it, if necessary
  - ✓ Developing uniform classification
  - ✓ Preparing jointly Exposure Scenario's (ES's), Chemical Safety Reports (CSR's) and guidance for uses
- The scope of the Consortium can be limited to one substance or include several related substances, leading to an organisation of the Consortium in 2 or 3 Product-groups, e.g. :
  - ✓ Metal production
  - ✓ Metal compounds production
  - ✓ Intermediates / by-products

The preliminary tasks in Consortium formation include, a.o.

- The definition of the market players and mass-flows of the substance(s)
- The identification of the potential members of the Consortium for Registration, Authorisation or Notification
- The identification of the potential substances to be included :
  - ✓ Related substances > allowing read-across
  - ✓ Similar Exposure scenario's

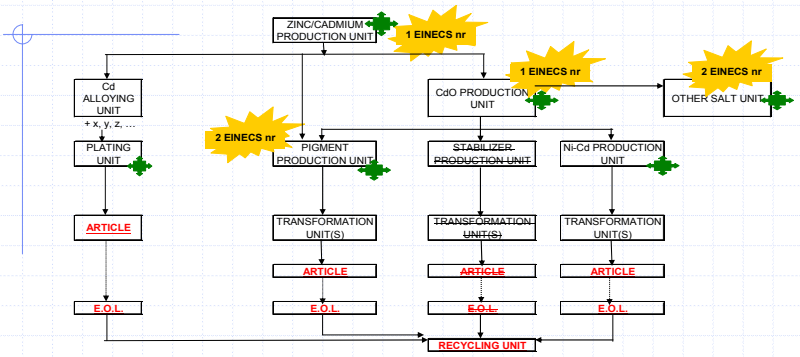
What are the candidate-substances to be taken into account in the Cd Consortium ?

- ESIS –data base (European Substances Identification System):
  - 215 EINECS numbers related to Cd compounds
- H/LPV-data base:
  - 5 EINECS numbers related to Zn compounds currently registered as High Volume (>1000 t) produced/imported substances by 115 legal entities; Cd-pigments (at least 2 EINECS) need to be added to the list
- Scope of the Cd- consortium :
  - Under discussion

What are the candidate-substances to be taken into account in the Cd Consortium ?

Cadmium metal	IN	OUT
Cd	231-152-8	
Cd-dust		
Cd- alloys		
Cadmium compounds		
CdO	215-146-2	Cd-carboxilate(s)
CdSO4		Cd-organo-compounds
Cd(NO3)2		
Cd-S-Se (> reds)	235-758-3	
Cd-Zn-S (> Yellows)	232-466-8	
CdS	245-147-8	
Cadmium Intermediates		
Flue dust, Pb-manufact., Cd-rich	285-554-3	
Leach residues, Cd-contg. dust	305-417-4	
Leach residues, Cd-Cu cement ppt	293-311-8	

Exposure scenario's requirements along the supply chain



= by-products, intermediates

Sludges	Einecs
Flue dusts	Einecs
Leach-residues	Einecs
Slags	Einecs
Cements	Einecs
Drosses	Einecs
Ashes	Einecs

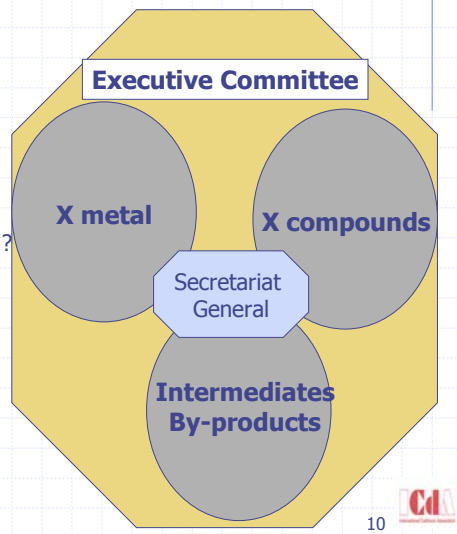
Cd = ~6 ES's

CdO = ~6 ES's

By-products =~10

The structuring of the Consortium will depend on the negotiations on the purpose, on the scope, but also on

- Membership: Association-members and non-members
- Adhesion rules: what about late entrants ? … free-riders ?
- Rights & duties: Ownership of data ? Confidentiality ?
- Budget & membership fees:
- Legal structure:
- Timing: June 2007 ?



Split of the workload for coming months in 2 WG and a steering committee

- WG1- Legal aspects: drafting the consortium agreement
- WG2 -Technical aspects:
  - Define the scope of substances to be considered in the Consortium
  - Assessment of the available data
  - Assessment of the data-gaps
- Steering Committee: to balance the inputs from the 2 WG's and to give orientation to progress in the negotiations
  >> monthly meeting (tel. conference + web-meeting)

Scheduled Meetings

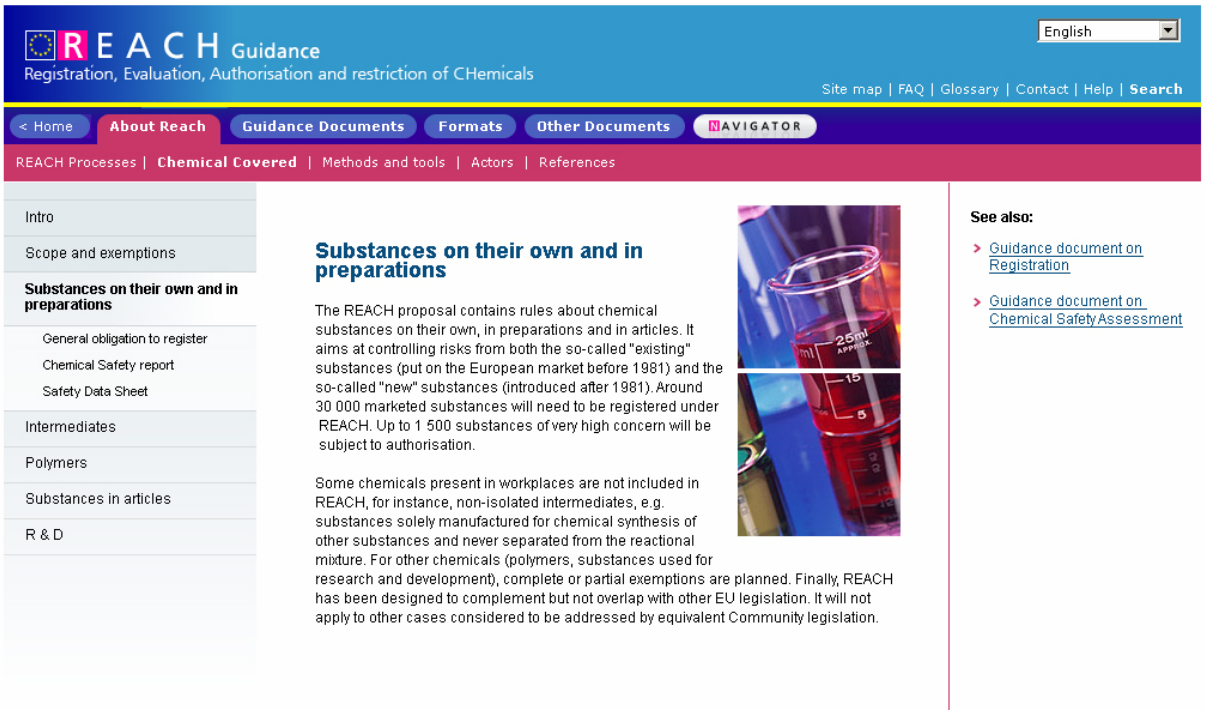
- May 3 , 2007:
  - 10:00 – 15:30_> WG Technical & Scientific matters
  - 15:30 – 19:00_> WG Legal & Administrative matters + Dinner
- May 23, 2007:
  - 15:00 – 16:30 > Steering Committee (Web / conference call ?)
- June 21, 2007:
  - 15:00 – 16:30 > Steering Committee (Web / conference call ?)
- End of June target > Kick-off meeting of the Cd-Consortium

“About REACH”: detailed description of REACH

Short introductory note:

This draft is intended to facilitate the discussion within the Commission services on the content of start pages on REACH for the overall guidance package. It might be slightly different from the text which is displayed on http://194.185.30.169/reach_site/about_reach_en.htm, as the web-version has not been updated with final minor changes. Nevertheless it is recommended to have first a look at the web-version of this text. The start pages are foreseen to be addressed to people with very little or no knowledge on REACH.

For each page, a “see also” section need to be developed which will direct the user to the relevant guidance documents on the topic and relevant terms from the glossary. This has not yet been finalised but is an important feature of these pages.



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WHAT IS REACH?

REACH is the Regulation for **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals. It entered into force on 1st June 2007 to streamline and improve the former legislative framework on chemicals of the European Union (EU). REACH places greater responsibility on industry to manage the risks that chemicals may pose to the health and the environment.

In principle REACH applies to all chemicals: not only chemicals used in industrial processes but also in our day-to-day life, for example in cleaning products, paints and in articles intended for consumer use such as clothes, furniture and electrical appliances.

Objectives

The aims of REACH are to:

- Improve the protection of human health and the environment from the risks that can be posed by chemicals
- Enhance the competitiveness of the EU chemicals industry, a key sector for the economy of the EU.
- Promote alternative methods for the assessment of hazards of substances
- Ensure the free circulation of substances on the internal market of the European Union

REACH replaces about 40 pieces of legislation with a streamlined and improved single Regulation. Other legislation regulating chemicals (e.g. on cosmetics, detergents) or related legislation (e.g. on health and safety of workers handling chemicals, product safety, construction products) not replaced by REACH will continue to apply. REACH has been designed not to overlap or conflict with the other chemical legislation.

How will REACH work?

REACH makes industry bear most responsibilities to manage the risks posed by chemicals and provide appropriate safety information to their users.

In parallel, it foresees that the European Union can take additional measures on highly dangerous substances, where there is a need for complementing action at EU level.

REACH also creates the European Chemicals Agency (ECHA) with a central coordination and implementation role in the overall process.

All manufacturers and importers of chemicals must identify and manage risks linked to the substances they manufacture and market. For substances produced or imported in quantities exceeding 1 tonne/year per company, manufacturers and importers need to demonstrate that they have appropriately done so by means of a registration dossier, which shall be submitted to the Agency.

Once the registration dossier has been received, the Agency may check that it is compliant with the Regulation and shall evaluate testing proposals to ensure that the assessment of the chemical substances will not result in unnecessary testing, especially on animals.

Where appropriate, authorities may also select substances for a broader substance evaluation to further investigate substances of concern.

REACH also foresees an authorisation system aiming to ensure that substances of very high concern are adequately controlled, and progressively substituted by safer substances or technologies or only used where there is an overall benefit for society of using the substance. These substances will be prioritised and included in an Annex of the Regulation. Industry will have to submit applications to the Agency on authorisation for the continued use of these substances. In addition,

EU authorities may impose restrictions on the manufacture, use or placing on the market of substances causing an unacceptable risk to human health or the environment.

Manufacturers and importers must provide their downstream users with the risk information they need to use the substance safely. This will be done via the classification and labelling system and Safety Data Sheets (SDS), where needed.

Substances can be exempted from all or a part of the obligations under REACH. These exemptions are not described in detail in this part of the web-site (About REACH). More information on exemptions can be found when using the navigator. Users are strongly advised to use the navigator to find out if their substance is covered by an exemption under REACH.

Will there be guidance to fulfil REACH obligations?

Guidance has been developed over the past few years for industry and the authorities for a smooth implementation of REACH. The guidance documents were drafted and discussed within projects lead by the European Commission services, involving all stakeholders: Industry, Member States, non-governmental organisations and the European Commission. Finalised guidance documents can be found on this website. Further guidance documents will be published on this website as they are finalised.

Competent Authorities have established national helpdesks to provide advice to industry on their obligations and how to fulfil their obligations under REACH, in particular in relation to registration.

Disclaimer: the "About REACH" webpages aim at facilitating the dissemination of information about the REACH Regulation. Neither the Commission nor any person acting on behalf of the Commission is responsible for the use which might be made on the following information.

1 REACH PROCESSES

Pre-registration

Manufacturers and importers must pre-register substances that are already on the EU market (so-called phase-in substances), if they want to benefit from transitional arrangements that allow registering them at a later stage. Pre-registration also enables registrants to share data with other registrants and avoid carrying out redundant tests. The pre-registration period is limited from 1 June 2008 to 1 December 2008.

Registration

REACH requires manufacturers and importers of chemical substances (≥ 1 tonne/year) to obtain information on the physicochemical, health and environmental properties of their substances and use it to determine how these substances can be used safely.

Each manufacturer and importer must submit a registration dossier documenting the data and assessments to the Agency.

Evaluation

The Agency will perform dossier evaluation to assess testing proposals made by the registrant or to check that the registration dossiers comply with the requirements. The Agency will also co-ordinate substance evaluation, which will be conducted by the Member States to investigate chemicals of concern.

Authorisation

Authorisation may be required for some substances of very high concern that are prioritised and included in Annex XIV.

Companies applying for authorisation will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits from their use outweigh the risks.

Applicants will also have to investigate the possibility of substituting theses substances with safer alternatives or technologies, and prepare substitution plans, if appropriate.

Restriction

The European Union can impose restrictions and prohibit or set conditions for the manufacture, placing on the market or use of certain dangerous substances when unacceptable risks to humans or the environment have been identified.

Classification and labelling inventory

A classification and labelling inventory will be developed from notifications submitted by industry on substances classified as dangerous (including those below 1 tonne/year) and from information on classification and labelling included in registration dossiers.

Communication in the supply chain

Suppliers of substances must pass on information on the health, safety and environmental properties and safe use of their chemicals to their downstream users (via a Safety Data Sheet or other means). Downstream users may only use substances classified as dangerous or which are persistent, bioaccumulative and toxic (PBT and vPvB) if they apply risk management measures identified on the basis of exposure scenarios for their use.

See also: PBT; vPvB; SVHC, phase in substances

1.1 Pre-registration

After entry into force of REACH, manufacturing and import of substances in quantities ≥ 1 tonne per year can only take place if the substance is registered. However, for phase-in substances a transitional arrangement has been made. In order to benefit from this transitional arrangement a manufacturer or importer has to pre-register their substances between 1 June 2008 and 1 December 2008.

Pre-registration allows companies to continue manufacturing and importing their phase-in substances for several years until the registration deadline is reached.

The objective of pre-registration is to facilitate sharing of data between registrants, where possible, in order to reduce unnecessary testing, especially on vertebrate animals, and to decrease costs for the industry.

A list of all pre-registered substances will be published on the website of the Agency by 1 January 2009. This list will facilitate the identification of potential registrants of the same substance for the purpose of data sharing.

For pre-registration, the potential registrant needs to submit to the Agency only basic information on the produced or imported substance. This information must comprise the registrant's name and contact details, the substance name, the envisaged registration dead-line and the tonnage band within which he produces or imports the substance.

If a manufacturer or importer fails to pre-register a phase-in substance, he will need to register it before continuing manufacture or import.

See also: RIP 3.1; phase-in substance

1.2 Data-sharing

REACH foresees the sharing of data between registrants to keep testing on vertebrate animals to the necessary minimum and to reduce the related costs for industry. For phase-in substances, a system is established to help registrants finding other registrants with whom they can share data and to get an overview of which of the studies requested for registration are already available. Pre-registrants of the same phase-in substance are required to share existing vertebrate animal test data and they should agree on the generation of new test data within a Substance Information Exchange Forum (SIEF). Other information on the properties of substances must be shared on the request of a potential registrant. There might be also data holders, who have no registration obligations under REACH who can, however, submit data for the pre-registered substances which are published by the Agency by 1 January 2009 and will hence also be part of the SIEF.

See also: RIP 3.4; phase-in substance; non phase-in substance; SIEF

1.3 Registration

Manufacturers and importers of substances have a general obligation to submit a registration to the Agency for each substance manufactured or imported in quantities of 1 tonne or more per year per company (legal entity).

This obligation applies to substances as such and, in the case of import, also to substances in preparations. A special registration regime applies for substances in articles (e.g. manufactured goods such as cars, textiles, electronic chips). However, certain substances are exempted from registration under REACH (see chemicals covered).

Failure to register means that the substance cannot be manufactured or imported.

Registration timelines

The phase-in substances (substances which have long been on the EU market) and the non-phase-in substances have **different timelines** for registration under REACH.

Substances, which have not previously been placed on the EU market (non phase-in substances), and phase-in substances which have not been pre-registered, must be registered before marketing can take place.

For phase-in substances, which are manufactured or imported in a quantity of 1 tonne or more per year and which have been pre-registered, the registration provisions will be applied in a stepwise way to facilitate the transition to REACH. Substances manufactured or imported in quantities of 1000 tonnes or more per year as well as certain substances of very high concern (Carcinogenic, Mutagenic or Reprotoxic substances category 1 and 2 (CMR cat 1 and 2)) and substances classified as very toxic to aquatic organisms (R50/53) manufactured or imported in quantities of 100 tonnes or more per year will have to be registered before 1 December 2010, while substances manufactured or imported in lower volumes will have to be registered before 1 June 2013 (100 – 1000 tonnes/year) or 1 June 2018 (1 – 100 tonnes/year).

Similar obligations were in place before REACH for certain substances, e.g. substances notified under the former chemicals legislation for new substances. These substances are considered as already registered under REACH. However, such registrations will need to be updated as appropriate if new circumstances arise, e.g. if production or import is increased to a higher tonnage band or if new information becomes available.

Content of the registration dossier

Manufacturers and importers of substances will need to gather information on the environmental and health properties of their substances, assess the risks arising from the uses of their substances and ensure that these risks are properly managed. To demonstrate that this has been done, manufacturers and importers need to submit:

- a **technical dossier**, for substances in quantities of 1 tonne or more per year,
  and, in addition,
- a **chemical safety report**, for substances in quantities of 10 tonnes or more per year.

The **technical dossier** contains information on the properties, uses, the classification of a substance as well as guidance on safe use. The information required to determine the properties of the substances varies according to the tonnage in which the substance is manufactured or imported. The higher the tonnage the more information on the intrinsic properties of the chemical is required. The information requirements are set out in the annexes VI to XI of the Regulation. REACH foresees data sharing between registrants to gather the required information.

For substances manufactured or imported in quantities starting at 10 tonnes, the chemical safety report (CSR) documents the hazards and classification of the substance and the assessment as to whether the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB).

If the substance is classified as dangerous or is PBT or vPvB, then an exposure assessment and risk characterisation shall be performed to demonstrate that the risks are adequately controlled. This exposure assessment is done using exposure scenarios for each use of the substance.

Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.

Process for the registration

Dossier submission

The registration dossier has to be submitted electronically, using IUCLID 5 format.

Registrants must pay a fee for submitting a dossier.

Registrants must update their registration as appropriate, e.g. if the production or import increases to a higher tonnage band or on the basis of new information that require to modify the dossier.

In cases where a substance is manufactured or imported by more than one company, they are required to jointly submit information on the hazardous properties of the substance and its classification. If registrants agree they can also submit a joint chemical safety report.

Dossier completeness check

The Agency is responsible for managing all registration dossiers. It will perform a simple electronic completeness check at the dossier submission stage (the quality of the information submitted may be checked at a later stage).

If the Agency does not indicate otherwise within 3 weeks of the registration, the registrant may begin (for non-phase-in substances) or continue (for phase-in substances) to manufacture or import the substance.

However, a positive completeness check does not imply any form of approval of the registration dossier or use of the substance from the Agency.

See also: RIP 3.1; PBT; vPvB

1.4 Evaluation

The Agency and the Member States Competent Authorities will carry out different types of evaluations to determine the need for further information on the registered substance.

In **dossier evaluation** the Agency will pick out some registration dossiers to check if all requested information has been made available by the registration and is adequately reported (compliance check). Furthermore, all proposals to test substances will be scrutinized by the Agency to prevent unnecessary animal testing, i.e. the repetition of existing tests and poor quality tests.

If a substance is suspected to pose a risk to human health or the environment, the Agency will include that substance on a list for "**substance evaluation**". For each substance on this list, one Member State will evaluate in more detail whether further information is needed and in that case the registrant(s) will be requested to provide such information. Substance evaluation may lead to the following conclusions:

- action needs to be taken under the restrictions or authorisation procedures
- classification and labelling needs harmonising
- information needs to be given to other authorities to take appropriate action under other legislation E.g.: If during substance evaluation information on risk management measures becomes available that might have an impact on permit conditions, this information should be handed over to the authorities dealing with this legislation.

See also: RIP 4.1/4.2

1.5 Authorisation

Substances of very high concern will be gradually included in Annex XIV of the REACH Regulation. Once included in that Annex, they cannot be placed on the market or used unless the company is granted an authorisation for a specific use.

Substances of very high concern

Substances of very high concern include substances which are:

- Carcinogenic, Mutagenic or toxic to Reproduction (CMR) classified in category 1 or 2,
- Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to the criteria in Annex XIII of the REACH Regulation, and/or
- identified from scientific evidence as causing probable serious effects to humans or the environment equivalent to those above on a case and on the basis of scientific evidence, such as endocrine disrupters.

Why and how do they need to be regulated?

These substances have hazardous properties of very high concern. It is essential to regulate them because the effects they can have on humans and the environment are very serious and often irreversible. There is no tonnage threshold for a substance to be subject to authorisation.

The authorisation mechanism consists in an in-depth assessment, whose outcome is then thoroughly discussed before appropriate decisions are taken.

How will the authorisation process look like in practice?

The authorisation process consists of four steps. Industry has obligations in the third step. However, all interested parties have the opportunity to provide input in steps 1 and 2.

Step 1: Identification of substances of very high concern (by authorities)

Substances of very high concern can be identified on the basis of the criteria previously described. This will be done by Member State authorities or the Agency (on behalf of the European Commission) by preparing a dossier in accordance with Annex XV. Interested parties can comment on substances for which a dossier has been prepared. The outcome of this identification process is a list of identified substances, which are candidates for prioritization (the "candidate list"). The list will be published by the Agency, probably not before end 2008.

Step 2: Prioritisation process (by authorities)

The substances on the candidate list are then prioritised to determine which ones should be subject to authorisation. Interested parties are invited to submit comments during this process. At the end of the prioritization process, the following decisions are taken:

- whether or not the substance is subject to authorisation;
- which uses of the included substances will not need authorisation (e.g. because sufficient controls established by other legislation are already in place);
- the "sunset date" by when a substance can no more be used without authorisation.

Step 3: Applications for authorisation (by industry)

Applications for authorisation need to be made within the set deadlines for each use that is not exempted from the authorisation requirement. They must include among others:

- a chemical safety report covering risks related to those properties that caused the substance to be included in authorisation system (unless already submitted as part of the registration)

- an analysis of possible alternative substances or technologies including, where appropriate, information on research and development foreseen or already in progress to develop such alternatives.

If an applicant's chemicals safety report demonstrates adequate control of risks, and the analysis of alternatives reveals that a there is a suitable alternative, the applicant must submit a substitution plan, explaining how and when he intends to replace the substance by the alternative. A suitable alternative is an alternative that results in reduction of overall risks and is technically and economically feasible for the applicant.

In cases where the applicant is not able to demonstrate adequate control of risks and where no suitable alternative exists, he needs to include in his application a socio-economic analysis.

A fee has to be paid for each application.

For all applications, the Agency will provide expert opinions. The applicant can comment on these opinions.

Step 4: Granting of authorisations (by the European Commission)

Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. The "adequate control route" does not apply for substances for which it is not possible to determine thresholds and substances with PBT or vPvB properties.

If the risk is not adequately controlled, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substances or technologies.

Downstream users may only use such substances for uses which have been authorised.

For this they must either:

- obtain the substance from a company that was granted an authorisation for that use. They must stay within the conditions of that authorisation. Such downstream users must notify the Agency that they are using an authorised substance.
- apply themselves for authorisations for their own uses.

Reviews

All authorisations will be reviewed after a certain time-limit which will be set on a case-by-case basis.

See also: RIP 3.7; RIP 4.3; RIP 4.4; endocrine disrupters; sunset date

1.6 Restrictions

REACH foresees a restriction process to regulate the manufacture, placing on the market or use of certain substances within the EU territory if they pose an unacceptable risk to health or the environment. Such activities may be limited or even banned, if necessary. The restriction is designed as a "safety net" to manage risks that are not addressed by the other REACH processes.

Any substance on its own, in a preparation or in an article may be subject to restrictions if it is demonstrated that risks need to be addressed on a Community-wide basis.

Restrictions of a substance can apply to all uses or to specific uses.

All uses of a restricted substance which are not specifically restricted are allowed under REACH unless they are subject to authorisation, or other Community or national legislation regulating their use.

There is no tonnage threshold for a substance to be subject to restriction.

Proposals for restrictions will be prepared by Member States or by the Agency on request of the Commission in the form of an Annex XV dossier.

The Annex XV dossier should demonstrate that there is a risk to human health or the environment that needs to be addressed at Community level and should identify the most appropriate set of risk reduction measures.

Interested parties will have an opportunity to comment and the Agency will provide opinions on any proposed restriction.

Deadlines for the decision-making process have been included in REACH in order to speed up the restriction procedure.

Annex XVII of the REACH Regulation contains the list of all restricted substances, specifying which uses are restricted. The existing restrictions set out in the Marketing and Use Directive (76/769/EEC), e.g. the ban on asbestos and restrictions on the uses of certain azo-dyes, were carried over to REACH.

See also: **RIP 4.4**

1.7 Classification and Labelling

A requirement for industry to classify and label dangerous substances and preparations according to standard criteria has long been a feature of the EU chemicals legislation.

REACH builds on this existing legislation but does not contain the criteria nor the obligations relating to classification and labelling. These are currently laid down in the classification and labelling section of Directive 67/548/EEC and the dangerous preparations Directive 1999/45/EC. REACH refers to this classification and labelling system, until it is in future replaced by a separate regulation (GHS).

REACH also specifies the obligations for substances and preparation classified as dangerous, such as making a Safety Data Sheet available or conducting an exposure and risk assessment during the course of a chemical safety assessment.

To ensure that hazard classifications (and consequent labelling) of all dangerous substances manufactured in or imported into the EU are transparent, industry will be required to submit all its classifications to the Agency at the latest by 1 December 2010. The Agency will then include them in a **classification and labelling inventory** in the form of a database accessible via internet.

This transparency will highlight divergences between classifications of the same substance and thereby create pressure to remove them over time through co-operation between notifiers and registrants or by an EU harmonised classification.

The harmonisation of EU classifications will especially be conducted for substances that are carcinogenic, mutagenic or toxic to the reproduction and respiratory sensitisers. It is nevertheless also possible to harmonise the classification and labelling of other substances if justified at EU level. Member States can make such proposals to harmonise the classification of a substance by submitting an Annex XV dossier.

The classification system is undergoing major revisions. In view of the extensive global trade in chemicals and the aim to ensure safe use, transport and disposal, an internationally-harmonised approach to classification and labelling has been developed by the United Nations (Globally Harmonised System for classification and labelling of chemicals, GHS). A planned regulation will implement the GHS in the EU. In order to facilitate its implementation, the timing of the obligations will as far as possible be aligned with the relevant deadlines in the REACH Regulation.

See also: RIP 4.4; SVHC

1.8 Communication in the supply chain

REACH foresees communication in the supply chain in two directions:

1. Communication down the supply chain (from suppliers to customers)

REACH requires that manufacturers and importers of a substance on its own or in a preparation to communicate how they can be used safely for humans and environment.

The main vehicle for this communication down the supply chain is the Safety Data Sheet (SDS).

The manufacturer, importer or downstream user will prepare the SDS according to a similar principle as he did before REACH came into force. The main difference is that when required, the SDS will also have an annex including exposure scenarios specifying the conditions under which the substance or preparation can be used safely, for uses that have been identified. The quality of the SDSs is expected to improve due to REACH as more information will be available as a result of the registration process.

If an SDS is not required, the supplier shall still communicate key risk information about the substance, in particular stating if the substance is subject to authorisation or restriction, together with any other available and relevant information to enable appropriate risk management.

Furthermore, suppliers of articles shall inform their customers about substances of very high concern contained in concentrations above 0.1%. Also consumers can request such information.

Distributors are not considered as downstream users under REACH but should pass on information received from their suppliers to their customers to ensure they can use the substance or preparation safely.

2. Communication upstream (from customers to suppliers)

Upstream communication by an actor in the supply chain is mandatory in a number of situations. This includes the communication of new information on the hazardous properties that become available as well as of information that may call into question the appropriateness of the risk management measures recommended by the supplier. Distributors have a general obligation to pass on information received to the next actor in the supply chain.

Downstream users have a right to make their use known to the supplier and in doing so shall provide sufficient information to prepare an exposure scenario. This upstream communication will play an important role when a registrant will prepare a chemical safety report, including exposure scenarios if required, as a part of the registration dossier. The manufacturers and importers often do not know what the substance is used for, and how it is used, and therefore need to collect such information from customers in order to assess how risks can be adequately controlled for the different identified uses. The downstream users have on the other hand the detailed knowledge on their uses and also an interest in having these covered by the suppliers' exposure scenarios thus being able to continue the use and receiving relevant information on how to control possible risks.

See also: RIP 3.5; SVHC

1.9 Enforcement

Enforcement of REACH towards companies is a task for the Member States.

They shall maintain a system of official controls and inspections and set effective, proportionate and dissuasive penalties in national legislation.

In order to co-ordinate the enforcement of REACH, a Forum for Exchange of Information ("Forum") will be established within the Agency.

2 CHEMICALS COVERED

REACH applies to the manufacture, placing on the market or use of substances on their own, in preparations or in articles and to the placing on the market of preparations. REACH follows a substance based approach: the obligations do not directly apply to preparations and articles (with the exemption of the requirements for Safety Data Sheets and exposure scenarios, which also apply to preparations) but to the substances contained in them.

REACH applies to all substances with a few exemptions: Radioactive substances, substances under customs supervision, the transport of substances and non-isolated intermediates are not covered under REACH. Waste is also specifically exempted. A number of other substances are exempted from parts of the provisions of REACH, where other equivalent legislation applies (for example substances used in medicinal products).

Polymers are for the time being exempted from registration.

Special rules apply for substances used for research and development and for the registration of isolated intermediates.

Detailed information on exemptions for other substances can be found by using the navigator on this web-site.

See also: RIP 3.1

2.1 Substances on their own and in preparations

The concept of REACH is based on substances. Most obligations refer to substances, whether on their own, in preparations or in articles.

A substance is defined as a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

If two or more substances are mixed together forming a mixture or a solution, the term "preparation" is used.

For each substance, manufactured or imported in quantities of 1 tonne or more per year, there is a general obligation for manufacturers and importers to submit a registration to the Agency. This also applies to substances manufactured or imported as part of a preparation.

Downstream users formulating preparations are required to classify and label the preparation and, where needed, prepare Safety Data Sheets for those preparations. Under certain circumstances, formulators are also required to prepare exposure scenarios for their preparations.

See also RIP 3.10

2.2 Substances in articles

For substances in articles, a special regime applies regarding registration and notification under REACH.

An article is the legal term under REACH for any object that has been given a specific shape, surface or design so that it can be used for a specific purpose (e.g. manufactured goods such as cars, textiles, electronic chips).

REACH requires all substances that are intended to be released from articles during normal and reasonably foreseeable conditions of use to be registered according to the normal rules, if they are produced or imported in quantities exceeding 1 tonne/year per producer or importer.

In addition, all substances included in a 'candidate list', which are present in articles above a concentration limit of 0.1% weight by weight and above 1 tonne per year must be notified to the Agency.

Such notification is not required, however, when exposure to humans and environment can be excluded during normal conditions of use, including disposal. In such case safety instructions should be provided.

A notification of a substance in an article consists of sending a dossier to the Agency containing the identity of the notifier, the identity of the substance, its classification and labelling, a brief description of its use and the tonnage range.

As a safety net, the Agency can require a registration of a substance in an article at any time if it considers that the release of the substance poses a risk to human health or the environment.

See also: RIP 3.8

2.3 Intermediates

Intermediates are substances that are meant to be consumed or transformed into another substance and therefore are not intended to be present in the final manufactured substance.

Substances which are not intentionally removed from the equipment in which the chemical processing takes place are called **non-isolated intermediates** and are **excluded** from REACH.

For certain isolated intermediates, a "light" registration can apply, whereby REACH only requires some specified risk information to be submitted to the Agency:

- **On-site isolated intermediates** (intermediates that remain on the site on which they are used) have to be registered.

  However, lighter information requirements apply if they are used under strictly controlled conditions. The registrant must only submit:

  - the hazard classification
  - any information on the properties of the substance that is already available to him, and
  - information on the risk management measures applied, or recommended.

  A chemical safety assessment is not required.

  They are not subject to authorisation but may be subject to limited substance evaluation by Member States.

- **Transported isolated intermediates** (intermediates transported between sites under controlled conditions) have to be registered.

  Lighter information requirements apply if they are used and transported under strictly controlled conditions.

  If more than 1000 tonnes of an intermediate are transported under controlled conditions, the registration dossier needs to include information listed in Annex VII of the REACH Regulation, since the risk of exposure is potentially higher.

  A chemical safety assessment is not required.

  They are not subject to authorisation but may be subject to dossier and substance evaluation.

Monomers have to be registered as any other substance, even if they are used as intermediates. The lighter rules on intermediates do not apply to them.

See also: Guidance on intermediates; Guidance on polymers

2.4 Polymers

Polymers are substances whose structure results mainly from the repetition of low molar mass units (monomers). Plastics are examples of polymers.

In view of the potentially large number of polymer registrations and given that most of them pose a limited risk because of their nature, polymers are exempted from registration and evaluation to preserve workability and to focus resources on substances of more concern.

However, polymers may still be subject to authorisation and restriction.

Nevertheless, manufacturers and importers of polymers must submit a registration to the Agency for the non-registered monomer substance(s) or other non-registered substance(s) if both the following conditions are met:

(a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s);

(b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

Monomers used as on-site isolated intermediates or transported isolated intermediates have to be registered as any other substance and the lighter rules on intermediates do not apply to them. This is necessary because the polymers resulting from the use of monomers are not subject to registration.

See also: Guidance on polymers;

2.5 Research and Development (R&D)

To support industry's capacity for innovation, one of the objectives of REACH is to promote research and development. This results in a number of exemptions from the obligations under REACH.

Scientific research and development under REACH means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume below 1 tonne per year.

A substance being used solely for such research and development is exempted from registration, and, in most cases, also from authorisation and restrictions processes.

Substances used for **product and process orientated research and development (PPORD)** will receive exemption from registration if they are notified to the Agency.

The notifier must pay a fee to the Agency when applying for this.

This exemption can be for up to 5 years and applies only to the quantity of substance being used for PPORD and to a limited number of specified customers. The Agency may extend the exemption period for up to a further 5 years (or 10 years in case of medicinal products or substances not put on the market) upon request, as long as this can be justified by the programme of research and development presented by the applicant.

The Agency will check the completeness of the information supplied by the notifier.

The Agency could decide to impose conditions to ensure that the substance will be handled only by staff of listed customers in reasonably controlled conditions and will not be made available to the general public and that remaining quantities will be re-collected for disposal after the exemption period.

When identifying substances subject to authorisation and restrictions, it will be specified if the requirement does not apply to PPORD and the maximum quantity exempted.

See also: Guidance for the notification of PPORD

3 ACTORS

There are three main types of actors involved in the REACH processes: Industry, Authorities and Third Parties.

Industry

The role of companies under REACH is determined by the activity they carry out with a substance. The following types of industry actors can be distinguished:

- **Manufacturers of substances:** means any natural or legal person established within the EU who manufactures a substance in one or more Member States. Manufacturing means production or extraction of substances in their natural state.
- **Producers of articles:** means any natural or legal person established within the EU who makes or assembles an article in one or more Member States.
- **Importers (of substances and articles):** means any natural or legal person established within the Community who is responsible for import. Importing means the physical introduction into the customs territory of the European Union.
- **Downstream Users** may be any industrial user of chemicals, whether formulators of preparations (e.g. paint producers) or users of chemicals such as oils or lubricants in other industrial processes or producers of manufactured articles such as electronic components.
- **Distributors** must pass on relevant information to their recipients.

All industry actors must respect restrictions rules and they can apply for authorisation if they wish to use substances of very high concern.

Companies dealing with chemicals may have more than one role. This can be in relation to a single substance or different substances they handle.

> **Example**: If a company uses a substance supplied by an EU manufacturer, it is a downstream user. If the same company also imports the same or any other substance, it is an importer at the same time.

In certain circumstances, companies may also appoint representatives under REACH to carry out certain obligations:

- **Third Party Representatives:** any manufacturer, importer, or where relevant, downstream user, may appoint a third party representative for certain tasks relating to data and cost sharing. The company nominating a representative retains full responsibility for complying with his obligations under REACH. The identity of a manufacturer or importer or downstream user who has appointed a representative will not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.
- **Only Representatives** are the appointees of non-EU manufacturers/producers of substances, preparations or articles whose products are imported into the EU. They carry out the obligations of importers of substances from those non-EU manufacturers. Importers in the same supply chain are in this case considered to be downstream users. The only representative must have a sufficient background in the practical handling of the non-EU supplier's substances and the information related to them. He must keep available up-to-date information on quantities imported and customers sold to as well as

information on the supply of the latest update of the Safety Data Sheet. As soon as REACH is implemented by the EEA EFTA-States, imports from Norway, Iceland and Liechtenstein will be considered as intra-Community trade for the purposes of REACH. Imports from Switzerland will be considered as imports from a third country. EFTA is preparing a proposal for an EEA Joint Committee Decision, incorporating the Regulation and establishing the conditions for the EEA EFTA participation in the Agency. The target date to have the Regulation incorporated is 1 June 2008. National transpositions will take place after that date.

Authorities under REACH

The authorities having obligations and rights in the REACH processes are the Agency (specifically set up for REACH), the Member States Competent Authorities and the European Commission.

The authorities carry out the evaluation, authorisation and restriction processes of REACH. In addition, the Agency and Member States will provide helpdesk assistance. Member States are responsible for enforcement under REACH.

Third Parties

Third parties under REACH include any private and public organization (e.g. private individuals, non-governmental organizations, companies providing input on dossiers they are not directly affected by, international organizations and non-EU countries).

Third parties do not have obligations under REACH but they may provide information to the Agency on substances and be part of a Substance Information Exchange Forum (SIEF).

3.1 Manufacturers and Importers

The vast majority of obligations under REACH apply to manufacturers and importers of substances in the EU.

The REACH processes relevant for manufactures and importers are:

Substance registration

Manufacturers and importers of substances must submit a registration to the Agency for each substance manufactured or imported in quantities of 1 tonne or above per year. Failure to register means that the substance cannot be manufactured or imported**.** Producers and importers of articles need to pre-register and register substances which are present in their articles in quantities over one tonne a year and if those substances are intended to be released (e.g. printing cartridges). For these cases, the same registration obligations as for manufacturers and importers of substances apply in analogy.

Registrants wishing to use the phase-in provisions will be required to pre-register to the Agency to permit sharing of available information (data sharing). Registrants will be required to share data gained by vertebrate animal testing.

Registrants are required to update their registrations on their own initiative as soon as the quantity of a substance reaches the next tonnage threshold and/or when relevant new information becomes available.

Notification obligations for articles

If an article contains a substance of very high concern (≥ 0.1% w/w) which has been placed on the candidate list for authorisation there is an obligation to notify the Agency. This requirement applies if the substance is present in the article produced or placed on the EU market in quantities of 1 tonne or more a year and exposure to humans or the environment cannot be excluded. The obligation will apply from 1 June 2011 at the earliest (or six months from the date the substance has been placed on the candidate list, in case the substance has not been on the list before 1 December 2010).

Classification and labelling inventory

Manufacturers and importers must notify to the Agency the classification and labelling of all substances subject to registration or classified as dangerous (Art. 1 of Directive 67/548/EEC) and placed on the EU market. The Agency will include the notified substances in the Classification and Labelling Inventory.

Information in the supply chain

REACH will replace the current Safety Data Sheets Directive. The SDS requirements and responsibilities for manufacturers and importers will remain and be extended by the requirement to convey information from any relevant chemical safety assessment.

When a chemical safety assessment is performed (substances placed on the market in quantities ≥ 10 tonnes per year by a manufacturer or importer), exposure scenarios must be developed for dangerous substances and PBT/vPvB substances. These exposure scenarios shall be placed in an annex to the Safety Data Sheet. The exposure scenarios contain a description of the risk management measures which the manufacturer or importer has implemented and recommends downstream users to implement. For this purpose, manufacturers or importers must assess all uses that are identified to them by their downstream users. If they decide not to support a particular use, they must justify this and notify the Agency and their downstream user.

Producers or importers of articles containing a substance of very high concern (≥ 0.1% w/w) which has been placed on the candidate list for authorisation must supply information on the safe use of those articles to industrial and professional users. To consumers this information must be provided on request. In addition, the same information obligations as for manufacturers and importers of substances apply in analogy for substances in articles intended to be released.

Substances subject to authorisation

An authorisation is required for uses and placing on the market of substances included in Annex XIV of the REACH Regulation. An authorisation can be requested by manufacturers, importers or downstream users on their own or in collaboration with other actors in the supply chain.

Applicants for authorisation have to demonstrate that the risks from their uses are adequately controlled or that the socio-economic benefits outweigh the risks, in cases where there are no suitable alternative substances or processes.

Substances subject to restriction

Manufacturers and importers and their customers must comply with the **restrictions** listed in Annex XVII of the REACH Regulation.

See also: RIP 3.1, RIP 3.2, RIP 3.7, RIP 3.8; PBT; vPvB

3.2 Downstream Users

Downstream user may be formulators of preparations (e.g. paints, glues, detergents, plastics or rubbers), users of chemicals (e.g. oils, lubricants, antifoams) in industrial processes, or producers of articles (e.g. electronic components, computers, toys or cars). Distributors and consumers are not regarded as downstream users under REACH. However, distributors must ensure safety information (e.g. a SDS) is provided with the substances they sell and pass on relevant information within the supply chain.

The REACH processes relevant for downstream users are:

Substance registration

Downstream users of substances do not have registration obligations. However, to get the relevant information, downstream users have the right to make their uses known to their suppliers, so that the suppliers can include these uses in their chemical safety assessments as "identified" uses or pass the request up the supply chain. In doing so, they provide sufficient information to allow their supplier to prepare an exposure scenario. Downstream users can give brief general descriptions of uses that can be used as a minimum to identify such uses to the supplier. They can also provide an exposure scenario describing their use to the supplier. The manufacturer is not obliged to supply a substance for a use that he considers he cannot support.

Downstream users must prepare their own chemical safety reports (including the development of exposure scenarios) for uses outside the conditions described in an exposure scenario included in the SDS supplied to them. This provision enables downstream users to keep their use(s) confidential from their supplier if they should wish to do so.

"Notification" obligations

A downstream user must report to the Agency:

- if he uses a substance outside the conditions described in the supplier's exposure scenario in quantities of more than 1 tonne per year;
- if he concludes (e.g. as an outcome of a chemical safety assessment) that the classification and labelling of his substance is different from that received by their supplier;
- if he uses an authorised substance (within 3 months of the first supply).

Information in the supply chain

Downstream users must communicate information on dangerous substances and preparations down the supply chain through SDSs. They must communicate information up the supply chain when they gain new information on hazardous properties of the substance or the appropriateness of risk management measures in the SDS supplied to them.

REACH will replace the current Safety Data Sheets Directive. The SDS requirements and responsibilities for downstream users who formulate preparations and supply them further down the supply chain will remain and be extended by the requirement to convey information from any relevant chemical safety assessment (in particular exposure scenarios).

In addition, downstream users may be supplied with additional safety information on the substances and/or preparations they purchase. They must follow this information and will also need to make sure that their customers have all the information necessary to use their products safely.

Substances subject to authorisation

Downstream users may use a substance for an authorised use provided they obtain the substance from a company that has received an authorisation for this use and they use it within the conditions laid out in that authorisation. The information on the uses covered by the authorisation and any applicable conditions must be provided by the supplier.

Alternatively, downstream users can apply for an authorisation for their own or customers' uses.

Substances subject to restriction

Downstream users and their customers must comply with the **restrictions** listed in Annex XVII of the REACH Regulation.

See also: RIP 3.5

3.3 European Chemicals Agency

REACH requires the set-up of a **E**uropean **Ch**emicals **A**gency (ECHA), in Helsinki as of 1 June 2007. The Agency will be operational on 1 June 2008. Its main tasks are to manage the registration process and carry out dossier evaluations. It will also co-ordinate the substance evaluation process and will take most of the decisions resulting from those evaluations.

Via its Committees for Risk Assessment and Socio-Economic Analysis the Agency will be able to provide expert opinions to the European Commission in the authorisation and restriction procedures.

Through its Member States Committee the Agency aims to reach agreement amongst Member States authorities on specific issues which require a harmonised approach across the EU. A Forum will coordinate the network of Member States authorities responsible for the enforcement of REACH.

ECHA will handle requests for exemptions from the registration requirement for product and process oriented research and development, and facilitates the sharing of animal test data at the pre-registration stage by enabling the formation of the Substance Information Exchange Forums (SIEFs).

The Agency will establish a Classification and Labelling Inventory and maintain it in an electronic database.

The Agency is also responsible for providing technical guidance and tools for the operation of REACH, especially to industry and Member States Competent Authorities. Furthermore, it supports the national helpdesk system that is foreseen to provide assistance to industry.

The Agency will make information available on its internet to stakeholders, including the general public, while preserving business confidentiality.

3.4 Member States Competent Authorities

Member States have to appoint one or more Competent Authorities for co-operation with the Agency and the European Commission and for carrying out their tasks under REACH.

An important task for Member States Competent Authorities will be to support industry in fulfilling their duties under REACH. Member States have to establish national helpdesk(s) to provide advice on responsibilities and obligations to manufacturers, importers and downstream users as well as any other interested party.

Member States will be represented in the Management Board as well as in the Committees and the Forum of the Agency.

Substance evaluation

The Competent Authorities of Member States can propose substances for substance evaluation. The evaluation will be carried out to clarify any potential risk to human health or the environment the substance may cause. Additional information may be requested from industry through substance evaluation.

Substances subject to authorisation or restrictions

A substance evaluation may lead authorities to the conclusion that a restriction or authorisation procedure needs to take place or that information needs to be passed on to other authorities responsible for relevant legislation.

For a follow-up action regarding authorisation and restriction, the Competent Authorities of a Member State may prepare an Annex XV dossier.

Enforcement

Member States are responsible for enforcement under REACH.

See also RIP 4.1/4.2; RIP 4.4

3.5 European Commission

The Commission has representatives in the Management Board of the Agency and may participate to the meetings of the Committees of the Agency. In addition to this operational role, it is responsible for reviews of the REACH Regulation. The Commission must propose and instigate implementation measures, e.g. fee regulation and testing methods. It will review the Annexes I (General provision for assessing substances and preparations), and IV and V (substances that are exempted from the scope of REACH) of the REACH Regulation by 1 June 2008.

The Commission will also provide guidance on some specific technical aspects of REACH (e.g. short description of uses).

Substances subject to authorisation or restrictions

The European Commission will have a key role in the authorisation and restriction processes. It will identify substances that are subject to authorisation, and grant authorisations. It will also issue decisions regarding restrictions.

3.6 Third parties

Third parties can be any private or public person or organization (e.g. private individuals, non-governmental organizations and companies), international organizations and non-EU countries. Third parties do not have obligations under REACH, but have certain rights to access information and submitting comments on substances.

These rights relate to:

Submitting information in the context of registration and evaluation (information requirements and testing)

Third parties holding information on substances may submit such information and become part of the Substance Information Exchange Fora (SIEFs) for the concerned substance. In this way, they can contribute to reducing the need for testing by registrants, take part in the operation of SIEFs and recover part of the costs they incurred for obtaining the relevant information.

In the framework of testing proposals involving tests on vertebrate animals, the Agency will publish relevant information on its website. Third parties may then submit scientifically valid information and studies that address the relevant substances and hazard end points within 45 days.

Third parties may also electronically submit information to the Agency relating to substances appearing on the list of pre-registered substances that is published by the Agency by 1 January 2009 on its website. The Agency will consider this information when checking and selecting dossiers for compliance after registration.

Submitting information in the context of authorisation

In the context of authorisation, specific dossiers and lists of substances are prepared during the various steps of identifying substances that will be subject to authorisation. Annex XV dossiers and the candidate list are published on the Agency website and all interested parties are invited to comment within a specified deadline.

When a request for authorisation for the use of a particular substance of very high concern has been submitted, the Agency will make broad information on these uses available on its website. In this context, third parties may submit information on alternative substances or technologies. This information will be considered by the Committee for Socio-economic analysis in delivering its opinions on authorisation applications.

Submitting information in the context of restrictions

In the context of restrictions, the Agency or the Member States prepare dossiers describing unacceptable risks where action on a community wide basis is needed (Annex XV dossiers). These dossiers will be published on the Agency's website, including the restrictions suggested. Interested parties will be invited to submit comments on dossiers and proposed restrictions as well as information in the context of socio-economic analysis. These comments and this information will be taken into account by the relevant committees when giving their opinions on the draft restriction. In addition the draft opinion of the Committee for Socio-Economic Analysis will be published on the Agency website and comments by interested parties will be invited.

4 METHODS AND TOOLS

The application of the REACH processes requires the use of several tools or methodologies, existing or developed for the purpose of REACH.

A **Chemical Safety Assessment** has to be performed for all substances manufactured and imported in quantities ≥10 tonnes/year to determine and demonstrate the safe use of a substance. The Chemical Safety Assessment has to be included in the Chemical Safety Report of the registration dossier.

Exposure scenarios are used to assess the exposure to chemicals of humans and the environment and to identify the appropriate risk management measures.

Classification and Labelling of substances involves an evaluation of the hazard of a substance or preparation and a communication of that hazard via a label. If a chemical meets certain criteria for classification, some obligations are triggered, for example a **Safety Data Sheet** should be provided to **downstream users** of the chemical.

Annex XV dossiers are the regulatory instruments for the Authorities (Member States or the Agency) to propose and justify:

- proposals for a substance to be included on the candidate list for authorisation,
- proposals for restrictions, and
- proposals for harmonisation of classification and labelling.

To ensure support to all REACH processes, **Information Technology tools** have been developed to store and exchange information and data on chemicals: REACH IT, IUCLID5 and the Agency website.

4.1 Chemical Safety Assessment and Report

The purpose of the **Chemical Safety Assessment** (CSA) is to assess risks arising from the manufacture and/or use of a substance and to ensure that they are adequately controlled.

A CSA has to be performed by registrants for substances manufactured and imported in quantities starting at 10 tonnes per year and by downstream users if their uses are not addressed by their supplier.

The **Chemical Safety Report (CSR)** submitted to the Agency as part of the registration dossier must document the results of the CSA.

A CSA includes the following steps:

- human health hazard assessment: determination of the classification and labelling of the substance, derivation of no effect levels (DNELs)
- physicochemical hazard assessment: determination of the classification and labelling of the substance
- environmental hazard assessment: determination of the classification and labelling of the substance, derivation of predicted no effect concentrations (PNECs)
- Persistent, Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB) assessment (or substances of similar concern): comparison of the data on degradation, bioaccumulation and toxicity with the criteria available in Annex XIII of the REACH Regulation.

If the substance meets the criteria for classification as dangerous, or meets the PBT/vPvB criteria, the CSA shall also include:

- An **exposure assessment** for all identified and relevant uses of the substance and resulting life cycle steps, including the generation of exposure scenario(s).

  An exposure estimation of humans and the environmental compartments to the substance is performed from the conditions defined in the exposure scenarios.

- A **risk characterization** which is the final step in the chemical safety assessment

  The risk characterisation identifies if the risks arising from manufacture/import and uses of a substance are adequately controlled.

  It consists of a comparison of the derived no effect levels (DNELs) and predicted no effect concentrations (PNECs) with calculated exposure concentrations respectively to human and the environment.

The CSA is an iterative process: hazard assessment, exposure assessment and risk characterisation can be refined through the use of more precise information or improvement of measures taken until risks to human health or the environment are shown to be adequately controlled.

The output of the CSA will be exposure scenarios with operational conditions and risk management measures for adequate risk control.

Exposure scenarios have to be documented in the Chemical Safety Report (CSR) and communicated to the downstream users as annexes to the Safety Data Sheets.

It is also planned to develop an IT tool for the generation of exposure scenarios and their integration in chemical safety reports. For this purpose, the Commission plans to start an analysis and design study shortly. Results of this study should be available by early 2008.

Uses and life cycle stages covered

The company performing the CSA (manufacturer or importer, or downstream user performing his own CSA) has to assess all the identified uses, e.g.:

- own uses, e.g. in a production or formulation process, or storage
- uses which are made known to it by downstream user**s**

In addition, the assessment shall cover all life-cycle stages resulting from these uses, for example, the "use" of an article containing the substance (sometimes referred to as "service life") as well as the waste stage.

Any downstream user has the right to make a use known in writing to his supplier **with the aim of** making this an identified use. This will allow his supplier to include an exposure scenario for his particular use in the chemical safety assessment.

A downstream user may also decide to perform his own chemical safety assessment when his use is not covered under the exposure scenario developed by his supplier and then not attached to the Safety Data Sheet, or for any use his supplier advises against.

Exemptions

A chemical safety assessment does not need to be performed:

- for a substance present in a preparation at a concentration below the concentration limits that apply for the classification of substances in preparations;
- for on-site isolated intermediates or transported intermediates;
- for Product and Process Oriented Research and Development (R&D) even if produced at more than 10 tonnes per year;
- when the specific use of the substance is already regulated under more specific legislation (e.g. biocides, pesticides, pharmaceuticals)

For uses in food contact materials and cosmetics, the CSA need not address human health aspects because these are addressed under another legislation.

See also: RIP 3.2, RIP 3.6; PBT; vPvB; DNEL; PNEC

4.2 Exposure scenarios

Exposure scenarios must be prepared when a substance is manufactured or imported in quantities of 10 tonnes per year and above and classified as dangerous or as PBT/vPvB.

An exposure scenario is a set of conditions that describe how a substance (as such, in a preparation or in an article) is manufactured or used during its life-cycle and how the manufacturer or importer or downstream user controls or recommends controlling exposure of humans and the environment.

An exposure scenario must include the appropriate risk management measures and operational conditions that, when properly implemented, ensure that the risks from the uses of the substance are adequately controlled.

Exposure scenarios need to be developed to cover all "identified uses" which are the manufacturers', importers' or downstream users' own uses, and uses which are made known to the manufacturer or importer or downstream user by his downstream users and which the manufacturer or importer or downstream user includes in his assessment. In addition, all life-cycle stages resulting from these uses shall be covered by the assessment, including for example the 'use' of an article containing the substance (sometimes referred to as 'service life') as well as the waste stage.

Exposure scenarios are also a tool for communicating operational conditions of use and risk management conditions of use through the supply chain as relevant exposure scenarios will be annexed to the Safety Data Sheets that will be supplied to downstream users and distributors.

The development of an exposure scenario is an iterative process which is part of the CSA. Once the registrant or downstream user has identified the relevant uses of his chemical substance he may derive a tentative exposure scenario on the basis of a first set of defined operational conditions of use, risk management measures and local conditions. From this tentative exposure scenario the exposure can be estimated as well as the risk. If it is estimated that a risk might not be adequately controlled then further refinement of either the hazard assessment or of the exposure assessment, eventually including modifications of the operational conditions or risk management measures put in place and described in the exposure scenarios, might be needed until the risks to the environment and the human health are adequately controlled. The output of this iterative process will be the final exposure scenario which will be annexed to the Safety Data Sheet as described before.

4.3 Classification

Classification and Labelling includes the evaluation of the hazard of a substance or preparation in accordance with Directive 67/548/EEC (substances) and 1999/45/EC (preparations) and a communication of that hazard via the label.

This evaluation must be made for any substance or preparation manufactured, imported or placed on the EU market for any tonnage level.

The classification of the substance and preparations as being dangerous is based on one or several endpoints concerning physical-chemical properties, health or environmental effects.

Currently, substances can be classified according to the following 15 categories:

(a) explosive substances and preparations
(b) oxidising substances and preparations
(c) extremely flammable substances and preparations
(d) highly flammable substances and preparations
(e) flammable substances and preparations
(f) very toxic substances and preparations
(g) toxic substances and preparations
(h) harmful substances and preparations
(i) corrosive substances and preparations
(j) irritant substances and preparations
(k) sensitising substances and preparations
(l) carcinogenic substances and preparations
(m) mutagenic substances and preparations
(n) substances and preparations which are toxic for reproduction
(o) substances and preparations which are dangerous for the environment

Under REACH, any manufacturer or importer of a substance (regardless of quantity) will be required to submit all its classifications to the Agency, to be included in the Classification and Labelling Inventory. Classifications must be submitted by 1 December 2010 if the substance is put on the market and is either classified as dangerous (no tonnage threshold) or subject to registration.

The classification has to be included in all registration dossiers.

Classifications should also be communicated in the notifications which are required for substances for research and development (PPORD) and substances in articles.

The classification of a substance or preparation as being dangerous triggers certain obligations under REACH:

- A Safety Data Sheet has to be provided to the recipient of a substance or preparation with dangerous properties to communicate potential hazards and how to control related risks.
- Phase-in substances classified as CMR (category 1 or 2) and those classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment and produced or imported in quantities reaching 100 tonnes or more per year are substances of priority under REACH and will have to be registered at an earlier stage.

- The Chemical Safety Assessment (CSA) of a substance classified as dangerous has to include an exposure assessment and the risk characterisation for the substance, in addition to the hazard assessment.

- A larger data set is required for the registration of those phase-in substances in the tonnage band of 1 to 10 tonnes per year and likely to meet the criteria for carcinogenicity, mutagenicity or reproductive toxicity (category 1 or 2) or any classification for human health or environmental effects in combination with dispersive or diffuse use(s).

  The full data set for this tonnage band (Annex VII of the REACH Regulation) has to be provided for those substances, which includes information on human health and environmental endpoints. Only data on the physicochemical properties of the substance are requested for substances not expected to fulfil the above criteria,

It should be noted that many of these obligations are also true for substances that are PBT or vPvB.

See also: RIP 3.6; PBT; vPvB; endpoint

4.4 Safety Data Sheet

The communication requirements of REACH ensure that not only manufacturers and importers but also their downstream users have enough information to use chemical substances safely.

The main tool for information transfer is the well-established and familiar Safety Data Sheet.

The current duties and responsibilities for Safety Data Sheets remain, as the provisions of the Safety Data Sheets Directive (91/155/EEC) are carried over to REACH: the supplier must provide a Safety Data Sheet to his customer when supplying a dangerous substance or preparation.

However, under REACH a Safety Data Sheet must also be provided when supplying substances that are PBT or vPvB, or preparations containing such substances.

In addition, where exposure scenarios are developed as a result of conducting a Chemical Safety Assessment, they must be annexed to the Safety Data Sheet and thus be appropriately passed down the supply chain. By doing so, the supplier informs his customer about the risk management measures that are implemented or recommended for safe uses of the substance.

A Safety Data Sheet has to be supplied in the official languages of the Member States in which the substance or preparation is placed on the market.

The Safety Data Sheet must be updated if new data become available on hazards or data which may affect the risk management measures, if an authorisation is granted or refused, or if a restriction is imposed.

See also: RIP 3.5; PBT; vPvB

4.5 Annex XV Dossier

Annex XV dossiers are the regulatory instruments for the Authorities (Member States or the Agency) to propose and justify:

- a **harmonised classification and labelling** of substances as carcinogenic, mutagenic and or toxic to reproduction (CMR) and as respiratory sensitisers, or for any other endpoint if justification for action at Community level can be provided. Agreement on a dossier for harmonised classification and labelling will lead to the addition of the classification to Annex I of Directive 67/548/EEC.
- the **identification of CMR substances, PBT substances, vPvB substances or substances of an equivalent level of concern**. Agreement on the identification of a substance as a PBT, vPvB or of an equivalent level of concern means that it is a substance of very high concern and is to be included in the candidate list of substances for eventual inclusion in Annex XIV of the REACH Regulation, and through this be subject to authorisation. Substances with PBT or vPvB properties, wide dispersive use or high volumes will be priority substances for inclusion in Annex XIV.
- **restrictions** on the manufacture, placing on the market or use of substances within the Community. Agreement on proposed restrictions will lead to the addition of any agreed restrictions to Annex XVII of the REACH Regulation. Any subsequent manufacture, placing on the market or use of the substance has to comply with the conditions of the restrictions.

Annex XV of the REACH Regulation lays down general principles for preparing these three types of dossier.

See also: RIP 4.4; PBT; vPvB; SVHC

4.6 Socio Economic Analysis (SEA)

What is a SEA?

The purpose of a socio-economic analysis (SEA) is to evaluate what costs and benefits an action will create for society by comparing what will happen if this action is implemented as compared to the situation where the action is not implemented. The analysis typically attempts to include also the effects that are indirect or incompletely reflected by market transactions. The analysis can be used to better understand how the various costs and benefits are distributed over the various affected parties in society and whether a certain action is desirable from a societal point of view.

What is covered by a SEA?

A SEA shall ideally cover all relevant effects related to the introduction of such an action such as impacts on health and the environment and on the economy, (e.g. the costs to different actors in the supply chain and changes in consumer satisfaction), and social effects (e.g. on employment and labour quality). SEAs are for example often conducted to support the decision-making process for new infrastructure projects such as bridges. In that situation possible effects could include the socio-economic effects (e.g. the investment costs of building a bridge; time saved by those using the bridge and the resulting impacts on traffic and economic activity; the effect on employment in the short and in the long run; effects on human health and the environment such as changes in air pollution and the consequent health effects, impact on how the water flows, disruption of nature areas, etc.).

REACH and SEA

Under REACH, SEA arguments can be made in relation to the decision of whether or not to grant an authorisation for the use(s) of a substance and in relation to the decision whether or not to introduce a restriction.

Authorisation

When adequate control of risks cannot be demonstrated and when no suitable alternatives exist, the Commission decision of whether or not to grant an authorisation for uses of a substance will take into account whether the socio-economic benefits from continuing these uses outweigh the risks to human health and the environment. This decision will take into account the opinions of the Agency SEA and Risk Assessment Committees. The SEA Committee shall form an opinion on socio-economic factors in those cases where the authorisation applicant has included a SEA in his application. In doing so, information submitted by third parties and all other available information shall be taken into account.

Restrictions

The Commission decision whether or not to impose a restriction will take into account whether introducing a restriction causes a net benefit for society as a whole comparing on the one hand the net benefits to health and the environment and on the other hand the net costs to the involved supply chains and other parts of society. This decision shall take into account the opinions made by the Agency SEA and RA Committees. The SEA Committee shall take into account all available information, including a SEA being part of a restriction proposal (optional) from a Member State or the Agency and possible SEAs or inputs for one as provided by third parties.

See also: RIP 3.9; RIP 3.7; RIP 4.4

4.7 IT tools: REACH-IT and IUCLID 5

The REACH-IT system is a central system running in the data centre of the Agency. It enables all stakeholders (Agency, European Commission, Member State Competent Authorities, industry, NGOs, general public) to submit (mostly industry), retrieve, exchange, evaluate, further treat (mostly authorities) and view (general public) information on chemical substances.

REACH-IT consists of three main parts:

The industry homepage is addressed mainly to manufacturers, importers, and downstream users. This is the place where, amongst others, a company can pre-register or make inquiries on substances, submit registrations, download invoices and view the status of submitted registrations and payments. In addition, it will allow online preparation of certain types of dossier, e.g. PPORD notification, C&L notification, downstream user notification - users will have their private workspace where they can prepare dossiers.

The Authorities workflow is addressed to the Agency and Member States Competent Authorities staff. This part of REACH-IT support the communication between the Agency and the Member States Competent Authorities and enable them fulfilling their tasks under registration, evaluation, authorisation, restriction and classification and labelling of substances.

The dissemination website is addressed to the general public and makes available all non-confidential data on chemicals (e.g. physicochemical data, the results of toxicological and ecotoxicological studies, the classification and labelling inventory) as well as the information on the status of those chemicals.

IUCLID5 (International Uniform ChemicaL Information Database) is the tool for data collection related activities. In particular IUCLID5 enables to prepare a registration dossier as well as to prepare other types of dossiers (PPORD dossiers, C&L notifications, notifications of substances in articles, DU reports and Annex XV dossiers).

IUCLID5 is built using internationally harmonized formats for reporting data on chemicals that were prepared and accepted by many national and international regulatory authorities within the OECD.

The use of IUCLID by industry can be twofold:

Any company can use its local IUCLID5 installation to collect, store and maintain relevant data on its substances. Once all the data necessary for a dossier (be it a registration dossier, a notification of C&L or of substances in article, a DU report, etc.) are included into IUCLID, the user can automatically prepare its dossier ready for submission to the European Chemicals Agency. This way, the data which have been reported once in IUCLID can be used in several types of dossier, or when update of dossiers is requested.

- When the company decides to submit the dossier, it will do it via the Industry homepage of REACH IT where it will use the appropriate functionality to submit the dossier file.

IUCLID5 is provided free of charge to all stakeholders (companies, Member States, individuals, universities, research organisations etc.).