Implementation of the Rotterdam Convention in the European Union

European Commission
DG Environment

Contents

- Legislation
- Who does what in the EU
- Chemicals
- Provisions on exports
- Controls
- Monitoring and reporting

The Regulation

Regulation (EC) No 689/2008 of the European Parliament and of the Council concerning the export and import of dangerous chemicals

implements the Rotterdam Convention in the European Union

(published in the Official Journal of the European Union, L 204, 31.7.2008, p. 1-35)

The Regulation

- Includes the list of chemicals subject to the Regulation in Annex I
- Annex I is amended regularly following changes in the EU legislation on various groups of chemicals (e.g. pesticides).
- All amendments are reflected in the EDEXIM database (edexim.jrc.ec.europa.eu).

Annex V (Banned - link to Stockholm Convention)

environment

Who does what in the EU

The European Commission

- is the common Designated (National) Authority (DNA) for the EU, working in close co-operation with the Member States' DNA
- manages the database EDEXIM (edexim.jrc.ec.europa.eu)
- forwards export notifications to importing countries
- establishes PIC notifications in consultation with and also on behalf of the Member States
- represents the EU at international level

environment

Who does what in the EU

Member States

- Each Member State has a Designated National Authority (DNA) responsible for implementation
  e.g. processing of export notifications
- Exporting Member State manages requests for explicit consent, i.e.
  - forwards the request to the importing country
  - handles replies received from importing countries
  - deals with the application of waivers
- Customs do export and import controls

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Chemicals

The Regulation covers:

- Chemicals that are banned or severely restricted (BOSR) in the European Union
- Chemicals that are listed in Annex III to the Rotterdam Convention

➢ Please note: the Regulation establishes subcategories of "convention use categories" so as to cover more chemicals, e.g. the category "pesticides" is divided in 2 subcategories: (1) pesticide in the group of plant protection products and (2) other pesticide including biocides.

→ usados em casa → tratados preserv. madeira

environment

Chemicals

The Regulation differentiates 3 categories of chemicals:

- Chemicals banned or severely restricted (BOSR) in a subcategory of a convention use category (Annex I Part 1)
- Chemicals banned or severely restricted (BOSR) in a convention use category (Annex I Part 2)
- Chemicals included in Annex III of the Convention (Annex I Part 3)

→ pesticides
→ industrie
na lei deles
→ Eles separam em subcategorias de uns daquelas que estão dentro da PIC

environment

Provisions on exports

Lists of chemicals and related obligations:

- Chemicals subject to export notification: Annex I Part 1 (BOSR within the EU in at least a use subcategory; about 150 chemicals)
- Chemicals subject to the explicit consent procedure: Annex I Part 2 (BOSR within the EU in a Convention use category; about 55)
- Chemicals subject to the PIC procedure: Annex I Part 3 = Annex III of the Rotterdam Convention (40 chemicals)

➢ The lists of chemicals are available on EDEXIM

→ Ex: nonylphenol...

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Composto falado pela Maria (caso complicado)
- pesticide
- sterilization medical advices

Shell get the request (very particular case).

Provisions on exports

The export notification

- Applies to chemicals in Part I of Annex I exported to any country and irrespective of the use
- Annual notification by each exporter before the first export of a chemical
- DNA checks notification and forwards it to the European Commission after approval
- European Commission sends notification to the DNA of the importing country
- Notifications are processed on EDEXIM

environment

all countries, não só os que são parte (mas quem não é parte não é obrigado a responder... notificam mas não esperam a resposta).

Provisions on exports

The explicit consent procedure applies to

- all chemicals that are banned or severely restricted (BOSR) in the EU in a convention use category (Annex I Part 2)
- all PIC chemicals for which no import decision from the importing country is published (Annex I Part 3)

➡ The procedure requires the explicit consent of the importing country before the export can take place and is managed by the exporter's DNA, in cooperation with the European Commission

environment

Provisions on imports

- The European Commission adopts decisions to establish EU import responses for chemicals subject to PIC procedure on basis of existing EU legislation.
- If necessary, consideration of EU measures to deal with risks presented by chemicals concerned on the basis of the DGD distributed by the Secretariat.
- European Commission receives export notifications from third countries and informs Member States and publishes them on EDEXIM.

environment

E se o membro tem uma legisl. específica?
Eu nunca vi um membro que tenha uma legisl + restritiva

Controls

- Member States designate authorities such as DNAs and customs that are responsible for controlling and monitoring exports and imports of chemicals listed in Annex I
- Targeted and co-ordinated control of compliance, with regular reporting by Member States

Tools for the control of exports

- Reference Identification Number (RIN)
- Customs declaration
- EDEXIM (European Database Export Import of Dangerous Chemicals)
- TARIC (Integrated Community Tariff) database - flagging for custom officers who then can check in EDEXIM database

Customs tem seus próprios database...

Status do RIN — not allowed / allowed

The Reference Identification Number (RIN)

- is assigned for each export of a chemical in Annex I upon introduction of the notification in EDEXIM,
- will be activated if all requirements are met,
- has to be provided on the customs declaration,
- is used by custom officers for checking the approval status of the export in EDEXIM database.

A swap to EACH export chemical (unique number)

→ Alguns membros requerem uma taxa... depende de cada país.

Monitoring and Reporting

Exporters and importers are requested to:

- provide the designated national authorities of the Member States with annual reports on the quantities of chemicals listed in Annex I that were exported or imported

environment

Monitoring and Reporting

Member States are requested to:

- report regularly to the Commission on the operation of procedures
- provide the Commission each year with aggregated information on export and import of chemicals based on the data received from exporters and importers

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The new Regulation

Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals

will implement the Rotterdam Convention in the European Union as of 1 March 2014

(published in the Official Journal of the European Union, L 201, 27.7.2012, p. 60)

environment

ainda não implementada

não haverão mudanças dramáticas

mudanças: apoia envolvem a ECHA.

The new Regulation (main changes)

Regulation (EU) No 649/2012 assigns certain administrative and technical tasks to the European Chemicals Agency (ECHA):

- Processing and dispatch of EU export notifications
- Handling of export notifications received from other countries
- Management of the database on export and import of hazardous chemicals

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More information

Implementation, legal aspects and chemicals:

http://ec.europa.eu/environment/chemicals/pic/index.htm

http://edexim.jrc.ec.europa.eu

as of 1 March 2014

http://echa.europa.eu

environment

fineb ...

Julien: Reach

Risk assessment: industry ?

How to identify the substances? = discussar atual

main point: TER INFOS

5% dos DOSSIÊS serão avaliados ... (nº dos substances).

Annex XIV: precisam ter AUTORIZAÇÃO (14 atualmente)

Candidate list: in the future used be subject of authorization
→ precisam de notificação

→ Comitology procedure

Dossier: like a check list ... if its there and it is make sense.

Substance evaluation:

Reach IT.

CLP = Silvain (GHS)

Starting point of a lot of other legislations

1967 = 1º leg for the environment

Council = represents the member states

Excludes cosmetic, veterinary, medications, food, feed

includes PPP and Biocides

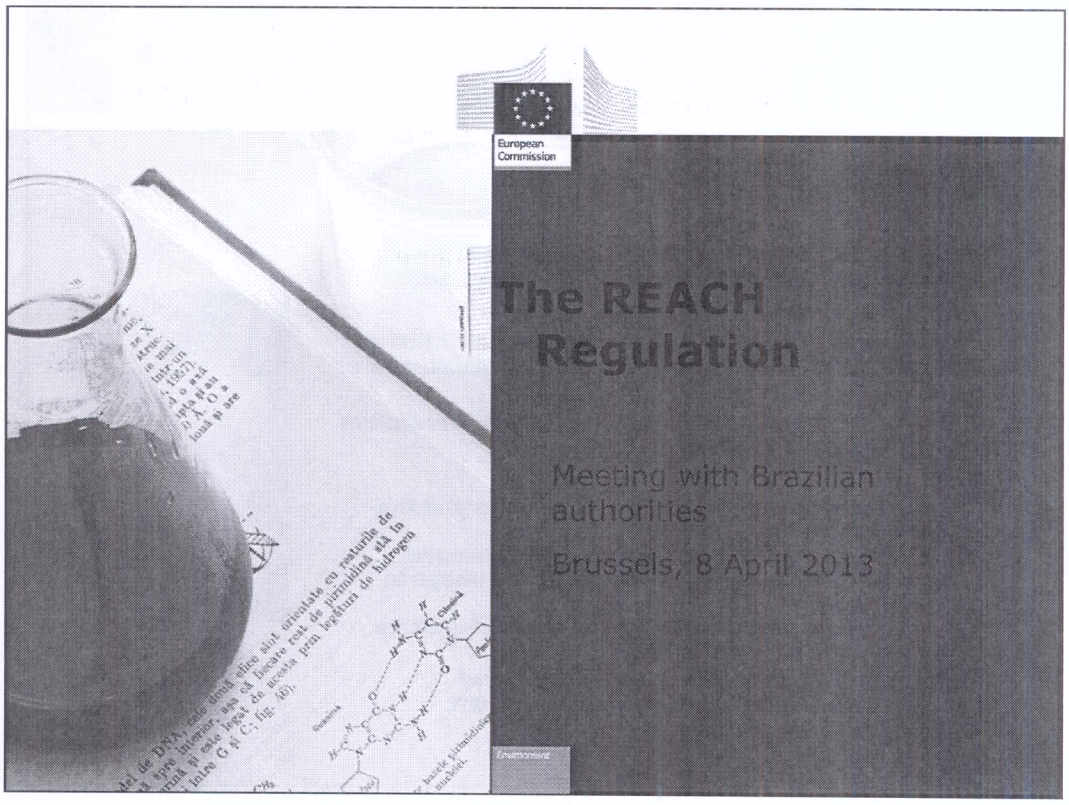
→ GHS = HAZARD based (do not consider exposure). ← • físico dum
• saúde
• environ

to environment = focused on AQUATIC

→ not 1 harmonized system for mixtures: (gradmente é baseia na class. f da subst que tá na mistura)

Biocide:

http: guidance.echa.europa.eu/docs


European Commission
The REACH Regulation
Meeting with Brazilian authorities
Brussels, 8 April 2013
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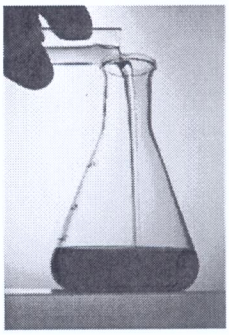
What is REACH?

- ***Regulation (EC) 1907/2006 on the Registration, Evaluation and the Authorisation of Chemicals***
- ***Entry into force - 1 June 2007***
- ***Scope: manufacture, import, placing on market and use of substances (on their own, in mixtures or in articles)***
- ***Excluded from scope: food, cosmetics, medicinal products, medical devices, waste.***
- ***Goals:***
  - **Improving health and safety of workers and the general public.**
  - **Environmental protection – avoiding chemical contamination of air, water, soil and damage to biodiversity**
  - **Maintaining a competitive/innovative chemicals industry**
- ***To manage registration, evaluation and authorisation: a new agency; the European Chemicals Agency (ECHA)***



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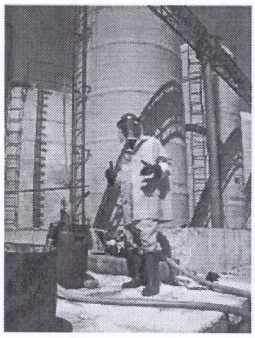
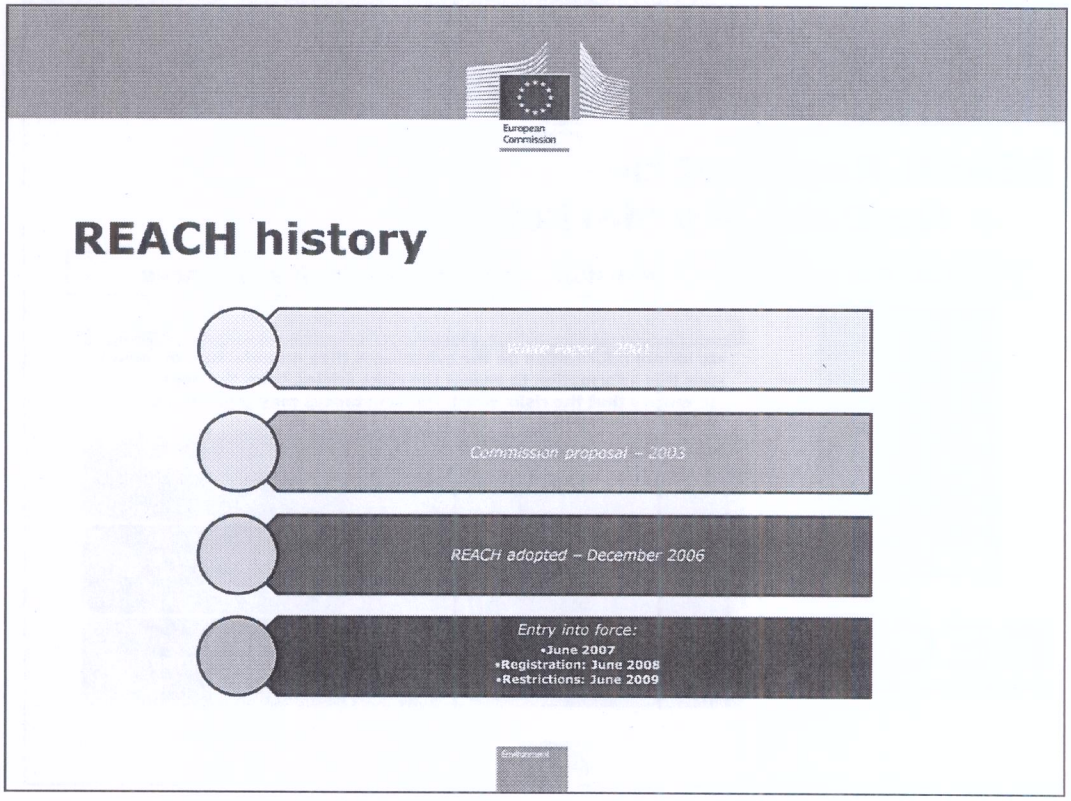
Why did we need REACH?



Data gaps	• **86% of High Production Volume Chemicals have less than base set data**
Burden of proof was on public authorities	• **Risk assessment procedure too slow**
Downstream Users not involved	• **Actual uses of chemicals remain unknown**
System inefficient	• **Myriad of directives and regulations**
Administrative burden for new chemicals	• **Prevented innovation**

Solutions brought by REACH

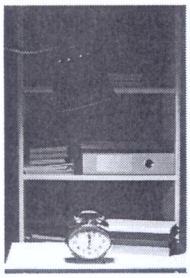
Data gaps:	•Registration and creation of data bank
Burden of proof was on public authorities	•Now on industry
Downstream Users not involved	•Information about safe use will be passed on "up and down" the supply chain
System inefficient	•REACH (and CLP) incorporate and streamline legacy of earlier legislation
Administrative burden for new chemicals	•No registration duty for low volume chemicals


European Commission
REACH history
Commission proposal – 2003
REACH adopted – December 2006
Entry into force:
•June 2007
•Registration: June 2008
•Restrictions: June 2009
Environment

European Commission

REACH Registration
« No Data, No Market »

AIM: Ensure industry adequately manages risks from substances



ECHA
EUROPEAN CHEMICALS AGENCY

Manufacturers and importers of substances need

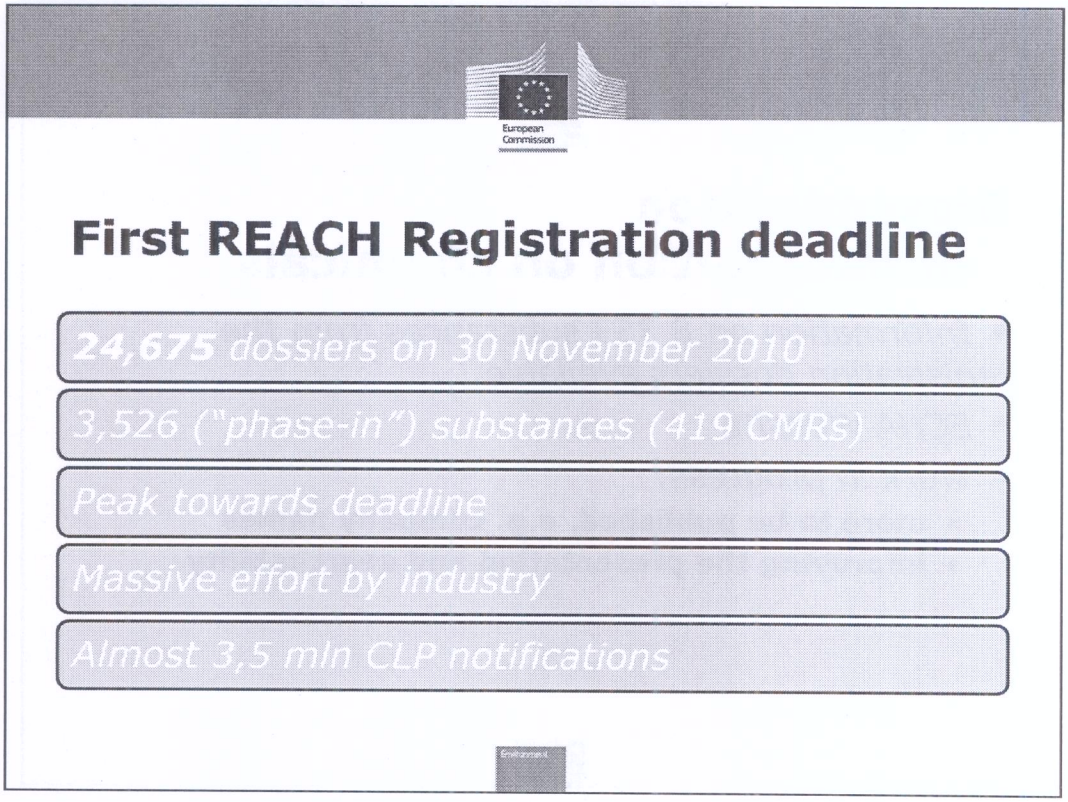
- **to obtain information on the substances they manufacture or import**
- **use this information to assess the risks arising from the uses**
- **to ensure that the risks which the substances may present are properly managed.**

Without registration, they cannot place the substance on the market

Two next registration deadlines for lower volumes: 2013 and 2018

In addition, since 1 June 2011, all SVHCs above a concentration limit of 0.1% w/w and present above 1 tonne per year must be notified to the Agency .

Environment

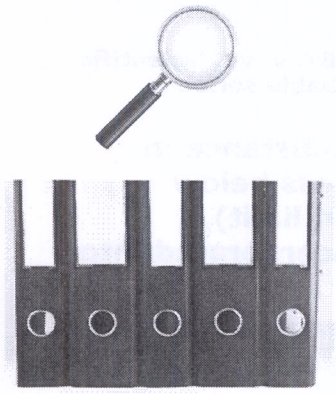

European Commission
First REACH Registration deadline
24,675 dossiers on 30 November 2010
3,526 ("phase-in") substances (419 CMRs)
Peak towards deadline
Massive effort by industry
Almost 3,5 mln CLP notifications
Environment

Dissemination of information on chemicals

- *Information on 8 353 substances from the registration dossiers available*
- *ECHA Website*
- *Work in progress:*
  - **more to be published, e.g. company names**
  - **improving the presentation and searchability**

European Commission

Evaluation



Compliance check

- Dossiers evaluation (at least 5% and potentially more through "targeted" compliance check)
- Priority setting: concern (3/4) and random selection (1/4)
- Dossiers quality: substances ID; endpoints, bad read across

Testing proposal examination

Substance evaluation

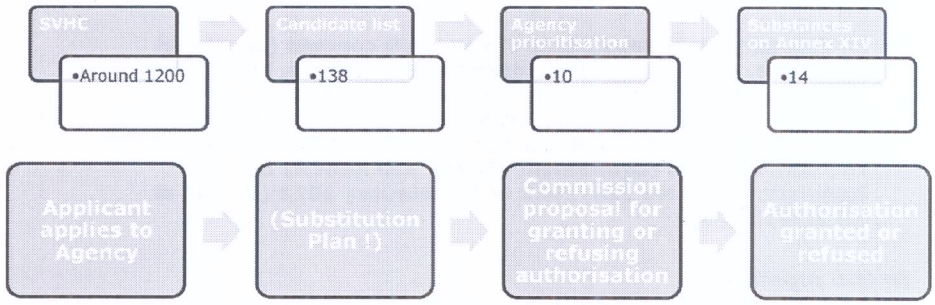
- Aim: verification whether a substance constitutes risk
- Community Rolling Action Plan (CoRAP)
- MS - ECHA colaboration
- 50 evaluations in 2012, 100 per year thereafter

REACH Authorisation

AIM: Ensure risks from substances of very high concern (SVHC) are properly controlled and <u>eventually substituted.</u>

- ***Applies to***
  - **SVHC (CMR, PBT, vPvB, 'scientific evidence of probable serious effects')**
  - **Substance, substance in mixture (unless below concentration limit), substance incorporated into an article.**
- ***Substance cannot be used unless authorised***

Authorisation



- *Goal: All relevant known SVHC by 2020*
- *Bi-annual updates of candidate list*
- *See http://echa.europa.eu/web/guest/candidate-list-table*

Candidate list as of now

- *Latest publications in EU Official Journal*
  - **In February eight substances of very high concern (diisobutyl phthalate, diarsenic trioxide, diarsenic pentaoxide, lead chromate, lead sulfochromate yellow, lead chromate molybdate sulfate red, tris (2-chloroethyl) phosphate and 2,4 dinitrotoluene) were added to the list of substances subject to the authorisation requirement (Annex XIV REACH) by Regulation (EU) No 125/2012 of 14 February 2012 (OJ L41 of 15.2.2012, p.1).**
- *In the pipeline*
  - **A draft Commission regulation will be submitted to the comitology procedure in November for adoption. The draft regulation proposes to include eight additional substances of very high concern in Annex XIV REACH (trichloroethylene, chromium trioxide, acids generated from chromium trioxide, sodium dichromate, potassium dichromate, ammonium dichromate, potassium chromate and sodium chromate).**

Restrictions

AIM: act as safety net, limit the use of certain toxic chemicals

- *Can apply to any substance for which it is considered that*
  - **manufacture**
  - **placing on the market**
  - **use**

  poses a risk to human health or environment that is not controlled
- *Existing restrictions carried over from pre-REACH legislation*
- *Can be initiated by Member State or Commission*
- *Agency Committees examine risk and socio-economic aspects*
- *Restrictions are decided by Commission, taking into account opinions of ECHA committees and in agreement with MS (Comitology).*
- *60 restrictions are listed in REACH banning or setting conditions for the use of certain substances*

Proposals for new restrictions

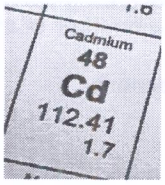
- ***Under REACH, Member States can maintain restrictions that are more than stringent than REACH only until 1 June 2013;***

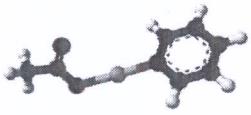
- ***More stringent chemical restrictions that are within the scope of REACH have to be introduced through an Annex XV Dossier;***

- ***Proposal may be introduced by ECHA and Member States on request of the Commission***

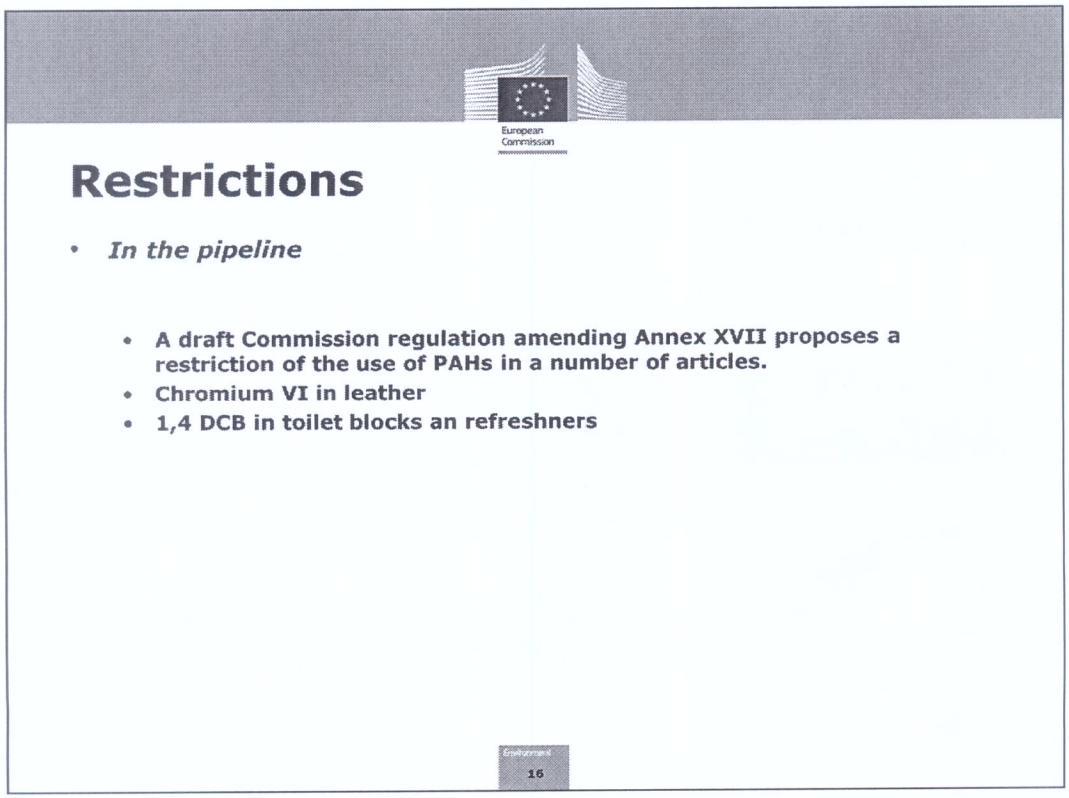
- ***Restrictions adopted through comitology***

Restrictions





- Mercury in measuring devices (OJ L 253 of 20.9.2012, p.1)
- Lead in Jewellery (OJ L 252 of 19.9.2012, p.4)
- Cadmium (OJ L 252 of 19.9.2012, p.1)
- Phenylmercury compounds ((OJ L 253 of 20.9.2012, p.5)


European Commission
Restrictions
In the pipeline
A draft Commission regulation amending Annex XVII proposes a restriction of the use of PAHs in a number of articles.
Chromium VI in leather
1,4 DCB in toilet blocks an refreshners
Environment
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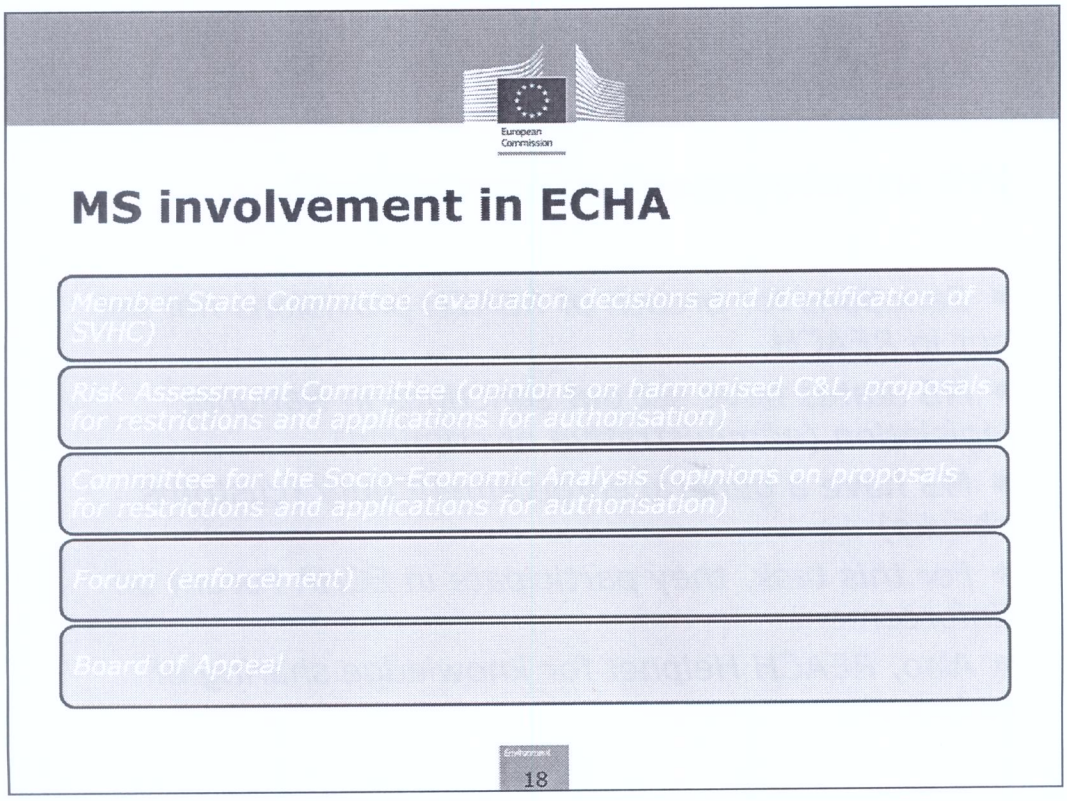
MS involvement enforcement

- *Sanctions for breach of REACH provisions not set out in REACH*
- *MS states have set out sanctions in National legislation (administrative or criminal)*
- *MS have a general enforcement duty (customs checks)*
- *For this task, they participate in ECHA Forum on Enforcement*
- *Also, REACH Helpnet for knowledge sharing of Helpdesks*


European Commission
MS involvement in ECHA
Member State Committee (evaluation decisions and identification of SVHC)
Risk Assessment Committee (opinions on harmonised C&L, proposals for restrictions and applications for authorisation)
Committee for the Socio-Economic Analysis (opinions on proposals for restrictions and applications for authorisation)
Forum (enforcement)
Board of Appeal
Environment
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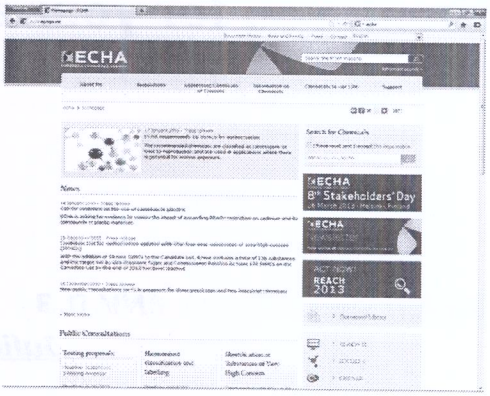
European Commission

European Chemicals Agency in Helsinki



Web address: http://echa.europa.eu

Thank you for your attention!

Julien De Cruz, DG ENV.D.3

Julien.DE-CRUZ@ec.europa.eu

European Commission

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Biocides: EU n° 528/2012 = New Joana...

Main obligations under the CLP Regulation and latest developments

Sylvain BINTEIN

GHS – Global Context

- Rio, ***1992*** – Chapter 19 of UNCED Agenda 21
- Development by IOMC, to end ***2001***
- UN CETDG/GHS – agreed Dec ***2002***
- UN ECOSOC – adopted July ***2003***
- Periodic Revisions: Rev. 1 ***2005***, Rev. 2 ***2007***, Rev. 3 ***2009***, Rev. 4 ***2011***
- WSSD, Johannesburg ***2002*** – operational by ***2008***

A Global System

GHS Status Worldwide – early 2011

activities | preparation | Implementation

CLP Regulation - Basics

Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of substances and mixtures (CLP)

- Entry into force 20 January 2009
- Transition periods: 1 December 2010 for substances
  1 June 2015 for mixtures

Scope

- substances and mixtures including C&L of Plant Protection Products and Biocides

Main features

- Self-classification
- Common rules within the EU on classification & labelling
- Classification and labelling Inventory (moved from REACH)

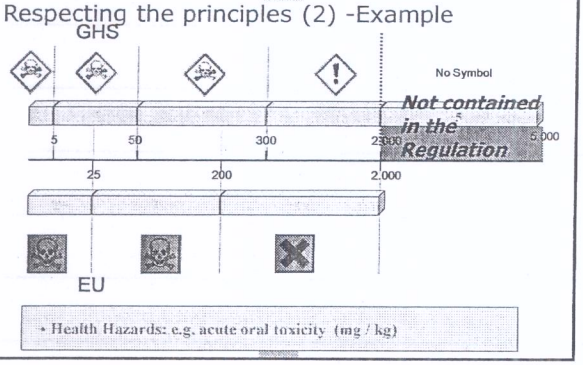
CLP Regulation- Principles

- Applies the general principles of the GHS
- Introduces the GHS criteria for data interpretation, classification and labelling
- Stays as close as possible to the GHS format and terminology (e.g."Mixtures" not "preparations")
- Ensures consistency with transport rules
- Uses the GHS Building Block Approach and a few other "optionalities" to adapt the system to EU needs
- Keeps the scope as close as possible to the previous EU system

Respecting the principles (1)

- **Takes up all GHS Hazard Classes**
- **Uses building block approach to omit categories not in old EU system**
  - Flammable liquids category 4
  - Acute Toxicity category 5
  - Skin corrosion / irritation category 3
  - Aspiration hazard category 2
  - Acute aquatic toxicity category 2 and 3

Respecting the principles (2) -Example



Respecting the principles (3)

- Maintains the current level of protection by including EU "left-overs" not yet covered by the GHS
  - **Ozone depletion (Annex I Part 5) – has been included in GHS Rev. 3**
  - **Additional labelling requirements in Annex II, e.g.**
    - EUH014 [R14] "reacts violently with water"
    - EUH066 [R66] "repeated exposure may cause skin dryness or cracking"
- Took over the current Annex I of Dir. 67/548/EEC (harmonised classification) – Annex I of Dir. 67/548/EEC is repealed

CLP Regulation - Overview

Legal text containing principles and general rules

- ***TITLE I - General Issues***
- ***TITLE II – Hazard Classification***
  - **Chapter 1 Identification and Examination of Information**
  - **Chapter 2 Evaluation of Hazard Information and Decision on Classification**
- ***TITLE III – Hazard Communication in Form of Labelling***
  - **Chapter 1 Content of the Label**
  - **Chapter 2 Application of Labels**
- ***TITLE IV - Packaging***
- ***TITLE V – Harmonisation of C&L of Substances and the C&L Inventory***
  - **Chapter 1 Establishing Harmonised Classification and Labelling of Substances**
  - **Chapter 2 Classification and Labelling Inventory**
- ***TITLE VI – Competent Authorities and Enforcement***
- ***TITLE VII – Common and Final Provisions***

CLP Regulation - Overview

- Annexes on technical details
  - Annex I: Classification and labelling requirements for hazardous substances and mixtures
  - Annex II: Special rules for labelling and packaging
  - Annex III: List of Hazard Statements
  - Annex IV: List of Precautionary Statements
  - Annex V: Pictograms
  - Annex VI: Harmonised List of Hazardous Substances
  - Annex VII: Translation Table for classification

CLP Regulation
Translation tables: examples

EU R-Phrase	GHS code	GHS hazard
R42	H334	Respiratory Sensitiser
R43	H317	Skin Sensitiser
Carc.Cat.2; R45	H350	Carcinogen Cat. 1B
Repr.Cat.2; R60	H360	Reproductive toxicant Cat. 1 B ("May damage fertility")
Repr.Cat.2; R61	H360	("May damage unborn child")

Main roles and obligations of suppliers

- Classify:
  - before placing on the market
  - if REACH requires classification; e.g. on-site isolated intermediate
- Respect harmonised classification (Annex VI) or self-classify
- Ensure appropriate Labelling and Packaging before placing on the market
- For purposes of C+L+P
  - Downstream users may use classification from supplier, provided no change of composition
  - Distributors: no obligation to classify; for purposes of L+P, may use classification from their supplier
- Cooperate with others in the supply chain for meeting requirements

Hazard communication: Labelling (Title III)



- Content of the label
  - Labelling elements
    - Product ID, hazard pictograms, signal words, hazard and precautionary statements, supplemental info, (supplier ID, quantity)
  - Use of languages
  - Updating information on labels
  - Derogations; use of alternative name for substances in mixtures
- Safety Data Sheets - Annex II REACH

Harmonisation of classification & labelling (Title V)

- Chapter 1 - Establishing harmonised classification and labelling of substances
  - for specific hazard classes or categories
    - CMRs
    - respiratory sensitisers
    - active substances in plant protection products and biocides
    - others: case-by-case if justified
  - Procedure to include a substance into Annex VI
    - started by public authorities or industry actor
    - opinion by RAC
    - decision by European Commission
  - Review of existing entry in Annex VI: can only be started by public authority – but initial proposal to authority can be made by supplier(s)

Harmonisation of classification & labelling (Title V)

Situation in January 2013:

- 66 dossiers completed => substances listed or to be listed in Annex VI if appropriate
- 120 dossiers under discussion
- 36 intentions in 'Registry of Intent'

Notification to C&L inventory (Title V)

- Chapter 2 – C&L inventory
  - "Any manufacturer or importer, or group of manufacturers or importers … who place on the market a substance … shall notify to the Agency …" (CLP, Art. 40(1))
  - Group of Manufacturers / Importers
    - Corporate company with different legal entities
    - Several companies with no specific links
    - SIEF
    - Joint Submission …

    that agree on a common C&L for the same substance

Notification to C&L inventory (Title V)

- Which substances:
- substances placed on the market on their own or in a mixture
  - subject to registration in accordance with REACH
  - or meeting classification criteria as hazardous; for substances in mixtures above concentration limit
    → Note! No tonnage trigger!
- Exemption: not required, if already submitted as part of the registration dossier, or if already notified by that notifier
- When: within one month after the substance is placed on the market on or after 1 Dec. 2010

Notification to C&L inventory – current situation

- **Status** at initial deadline of 3 Jan 2011:
  - 3 114 835 notifications submitted
  - 107 067 substances
- **Publication of the C & L Inventory** – first version on 13 February 2012 – latest update in January 2013
- **The C&L Platform** is a web-based discussion forum which allows notifiers to discuss the C&L of their substances and agree on appropriate classification

Guidance to CLP

- A short and industry-oriented guidance on basic features and procedures

  "Introductory guidance on CLP Regulation"
- Guidance on application of the CLP criteria, covers
  - general issues
  - physical, health and environmental hazards

  "Guidance on the Application of the CLP Criteria"
- Published by ECHA:

  http://guidance.echa.europa.eu/docs/guidance_document/clp_en.htm

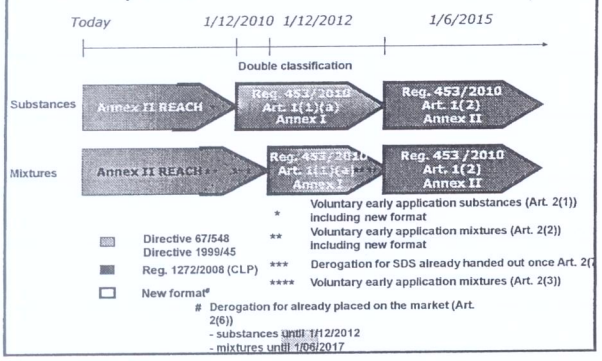
Hazard Communication: Safety Data Sheets (Annex II REACH)

- SDSs specified in Annex II to REACH
- Regulation (EU) No 453/2010 of 20 May 2010 revised Annex II to algin with UN GHS and CLP
- Key principles:
  - stays as close as possible to requirements laid down in Annex 4 to GHS
  - includes elements of version of Annex II to REACH which are essential or specific to REACH
  - includes transitional periods
  - two versions of Annex II, one effective 1 Dec 2010 and one 1 June 2015

SDS - key features of draft proposal

- Same 16 headings but new Sub-sections
- Registration number:
  - DU, distributors may omit part referring to registrant
  - Full number upon request for enforcement purposes
- Classification and label elements in section 2
  - Other regulatory information in section 15
- Old and new classification in parallel until 1 June 2015
  - Substances: both CLP & DSD classification in section 2
  - Mixtures: both DSD & CLP (if available) for substances in section 3
  - Earlier voluntary application possible

SDS - transitional period



Adopted implementing legislation

- 1st ATP to CLP: Regulation (EC) No 790/2009 of 10 August 2009 – added harmonised classifications from 30th and 31st ATP to Directive 67/548/EEC to Annex VI
- Regulation (EU) No 440/2010 of 21 May 2010 established fees for:
  - Requesting confidentiality of substance names in mixtures according to Article 24 (1)
  - Proposals from industry for proposing harmonised classification and labelling according to Article 37(1)
  - Significant reduction for SME's

Forthcoming amendments

2nd ATP (***Regulation (EC) No 286/211 of 10 March 2011***)

- Alignment with 3rd revision of the UN GHS:
  - Replace criteria for 'hazardous to the ozone layer'
  - Addition of chronic toxicity criteria for the aquatic environment
  - Strong or other sensitisers (skin and respiration)
    - distinction where data allows
    - sub-categories 1A and 1B
  - New combined hazard statements
  - New provisions for allocation of hazard statements and for the labelling of small packagings
- Some other clarifications and labelling provisions to protect indiviudals already sensitised to specific chemicals that may elicit a response at very low dose

Adopted and forthcoming amendments

- 3rd ATP (***Regulation (EU) No 618/212 of 10 July 2012***)
  - Inclusion of substances into Annex VI for which RAC opinions have been delivered already, where appropriate
- 4th ATP (by early 2013)
  - Alignment with 4th revision of UN GHS
    - modified criteria for 'explosives', 'flammable gases', 'flammable aerosols', 'oxidising gases', 'gases under pressure', 'unstable gases and mixtures'
    - Revision of some precautionary statements
    - Consolidate classification for all aerosols
    - Clarification for use of pictograms for substances 'corrosive to metals' but not 'corrosive to skin'
  - Labelling exemptions for packaging < 1ml and packaging < 10 ml

Forthcoming amendments

- **5th ATP *(mid 2013)***
  - **Inclusion of next batch of substances into Annex VI for which RAC opinions have been delivered by mid 2012, where found appropriate**
- **6th ATP *(mid 2014)***
  - **Inclusion of next batch of substances into Annex VI for which RAC opinions have been delivered by mid 2012, where found appropriate**
- **7th ATP *(early 2015)***
  - **Alignment with 5th revision of GHS**

Art. 45 (4) – Information to Poison Centres

- By 20 January 2012 Commission has to assess possibilities of harmonising information to be submitted to poison information centres (content and format)
- Similar work is ongoing for cosmetic products
- Two expert meetings with representatives from the European Association of Poison Centres and Clinical Toxicologists (EAPCCT) in 2010
- Stakeholder workshop on 24 November 2010
  - Broad consensus that it is possible and appropriate to harmonise the information to be submitted to poison centres
  - Broad consensus to develop a European product categorisation system
  - Broad consensus to use a common IT format for data submission
  - Further work necessary on:
    - Level of detail for the information concerning the composition of mixtures
    - Need for unique company identifier and/or unique product identifier
    - European database for submitting PIC notifications?
- *Two further meetings in 2011*

Art. 34 – ECHA to conduct a study on communication

- Understanding about how the general public perceives the new labelling
- Understanding of consumers' attitudes and behaviour – safe use
- Develop recommendations for a public information campaign
- A view on whether recommendations for amendments to Regulation are advisable or justified
- Questionnaire developed by outside consultant
- Eurobarometer Survey Nov – Dec 2010
- DG JRC conducts statistical and correlation analysis
- Reports expected in the coming months.

CLP and other EU legislation in addition to REACH

- ***"Downstream" legislation: SEVESO II, hazardous waste, ecolabel, workers' safety, pesticides & biocides, consumer products, etc.***
- ***More than 20 pieces of legislation refer to C&L***
- ***Amending downstream legislation***

Health and Safety at Work legislation

- *Six OSH downstream directives make reference to the EU C&L system*
  - *To define aspects of the scope of application*
- *Directives*
  - *Chemical Agents Directive 98/24/EC*
  - *Carcinogens and Mutagens Directive 2004/37/EC*
  - *Safety Signs Directive 92/58/EEC*
  - *Pregnant and Breastfeeding Workers Directive 92/85/EEC*
  - *Young People at Work Directive 94/33/EEC*
  - *Personal Work Equipment Directive 89/656/EEC*

New Regulation on Plant Protection Products

- *Regulation (EC) No 1107/2009 of 21 October 2009*
- *Aim: to ensure a high level of protection for human and animal health and the environment by using strict criteria for approval of substances*
- *Reg. provides that CMRs, endocrine disruptors, substances which are very persistent will not be approved, unless exposure to humans is proved negligible*
- *Substitution mechanism of more toxic pesticides by safer (including non-chemical) alternatives.*
- *Similar approach for biocides*

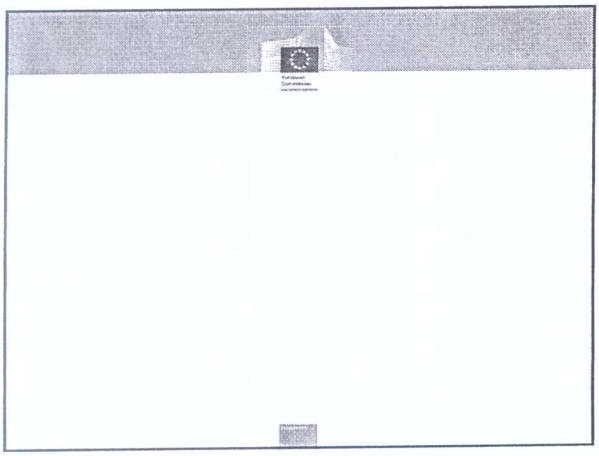
Consumer products legislation

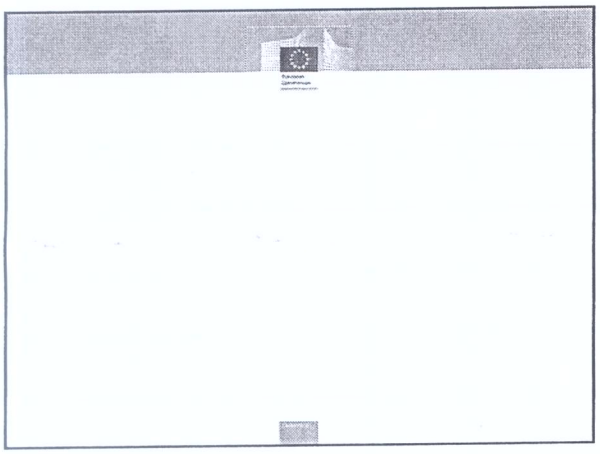
- *New Cosmetic Products Regulation: Regulation (EC) No 1223/2009*
  - ➢ *Art 15: use of CMRs (cat 1A, 1B and 2) prohibited in cosmetic products*
- *Safety of Toys Directive: Directive 2009/48/EC*
  - ➢ *CMRs (cat 1A, 1B and 2) are prohibited in toys, in components of toys or in micro-structurally distinct parts of toys*

Thank you!

For further information, please, consult the website:

http://ec.europa.eu/enterprise/sectors/chemicals/classification/index_en.htm
http://ec.europa.eu/environment/chemicals/ghs/index_en.htm
http://echa.europa.eu/home_en.asp





Biocidal products Regulation 'BPR'

Regulation (EU) No 528/2012

OJ L 167, 27.6.2012, p. 1

Environment

European Commission

Biocidal products

Chemicals supplied with the intention of controlling harmful organisms

Precise definition in Article 3(1)(a) of BPR

Examples:

- Disinfectants (for e.g. hands, drinking water, etc.);
- Preservatives (for e.g. wood, leather, etc.);
- Pest control products (against e.g. rats, insects, etc.)

List in Annex V to BPR

European Commission

Key features of BPR

Objective

- Facilitate the free movement of biocides on the EU market
- Protect health and the environment

Recital 3 of BPR

Instruments:

1. Assessment and approval of active substances

Articles 4-16 of BPR

2. Authorisation of products (usually mixtures)

Articles 17-52 of BPR

3. Requirements for all articles treated with biocides

Article 58 of BPR (Article 3(1)(a) of BPR)

1. Approval of active substances

Procedure

- A company submits a data "dossier" including a risk assessment

Article 7 of BPR

- The dossier is evaluated by an EU Member State

Article 8 of BPR

- Commission decides whether the substance can be approved

Article 9 of BPR

Consequence of substance approval:

- Products containing the active substance may be authorised

Article 19(1)(a) of BPR

2. Authorisation of biocidal products

Pre-condition for placing on the market (Exception: Transitional derogation for "existing active substances")
Article 17(1) of BPR (Article 89 of BPR)

Two types of authorisation:

- National authorisation with possible mutual recognition in other EU Member States

Articles 29-40 of BPR

- Union authorisation

Articles 41-46 of BPR

3. Articles treated with biocidal products

Scope: Articles and mixtures treated with or incorporating biocidal products

Definition in Article 3(1)(l) of BPR

Conditions for placing articles on the market:

- All active substances must have been approved

Article 58(2) of BPR

- Labelling requirement if biocidal properties are claimed, or if needed for human or environmental health safety

Article 58(3) and (4) of BPR

3. Treated articles subject to authorisation

Treated articles having primary biocidal function
Article 3(1)(a) of BPR

Same conditions for placing on the market as biocidal products, i.e. product authorisation

Concept to be developed, Commission can decide on interpretation
Article 3(3) of BPR

Implementing bodies

National competent authorities

- Decide whether to authorise products (***Articles 29-40 of BPR)***
- Check and report compliance (***Article 65 of BPR)***
- Participate in opinion forming and decision making through
    - **The Biocidal Products Committee ('BPC'; Article 75 of BPR)**
    - **The Standing Committee on biocidal products (Article 82 of BPR)**

European Chemicals Agency (ECHA)

- Form scientific opinions as basis for the decision making (BPC; ***Article 75 of BPR)***
- Establish and maintain the IT platform ('R4BP'; ***Article 76 of BPR)***
- Receive and process applications for substance approval and Union authorisation ***(Articles 7 and 43 of BPR)***

European Commission

- Take decisions on substance approval and Union authorisation (***Articles 9 and 44 of BPR)***
- Adopt implementing legislation

European Commission

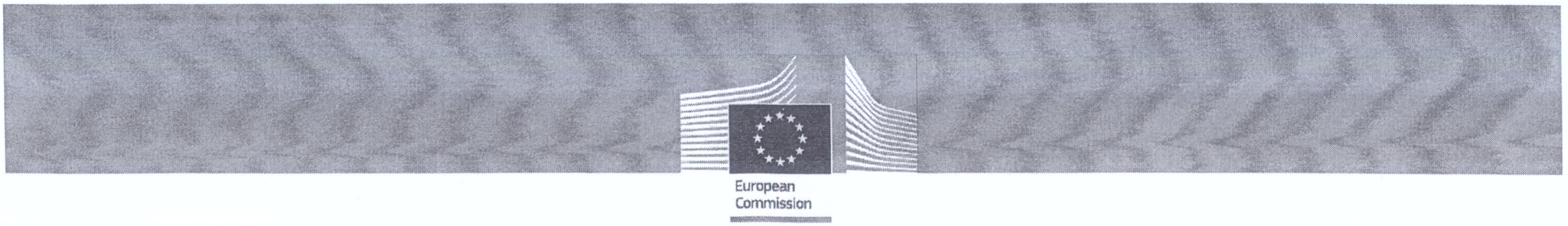
Key implementing legislation

Existing

Regulation 1451/2007 regarding the review of "existing active substances" (soon to be amended)

Upcoming

- Regulation on changes to authorised products
- Regulation on authorisation of "same products"
- Regulation on fees to ECHA



More information

http://ec.europa.eu/environment/biocides/index.htm

env-biocides@ec.europa.eu