REACH and other European Chemicals Legislation – An Overview

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Outline

- REACH and its background
- The CLP Regulation
- Other parts of EU legislation


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Guyane (F)
Suriname
Brasil
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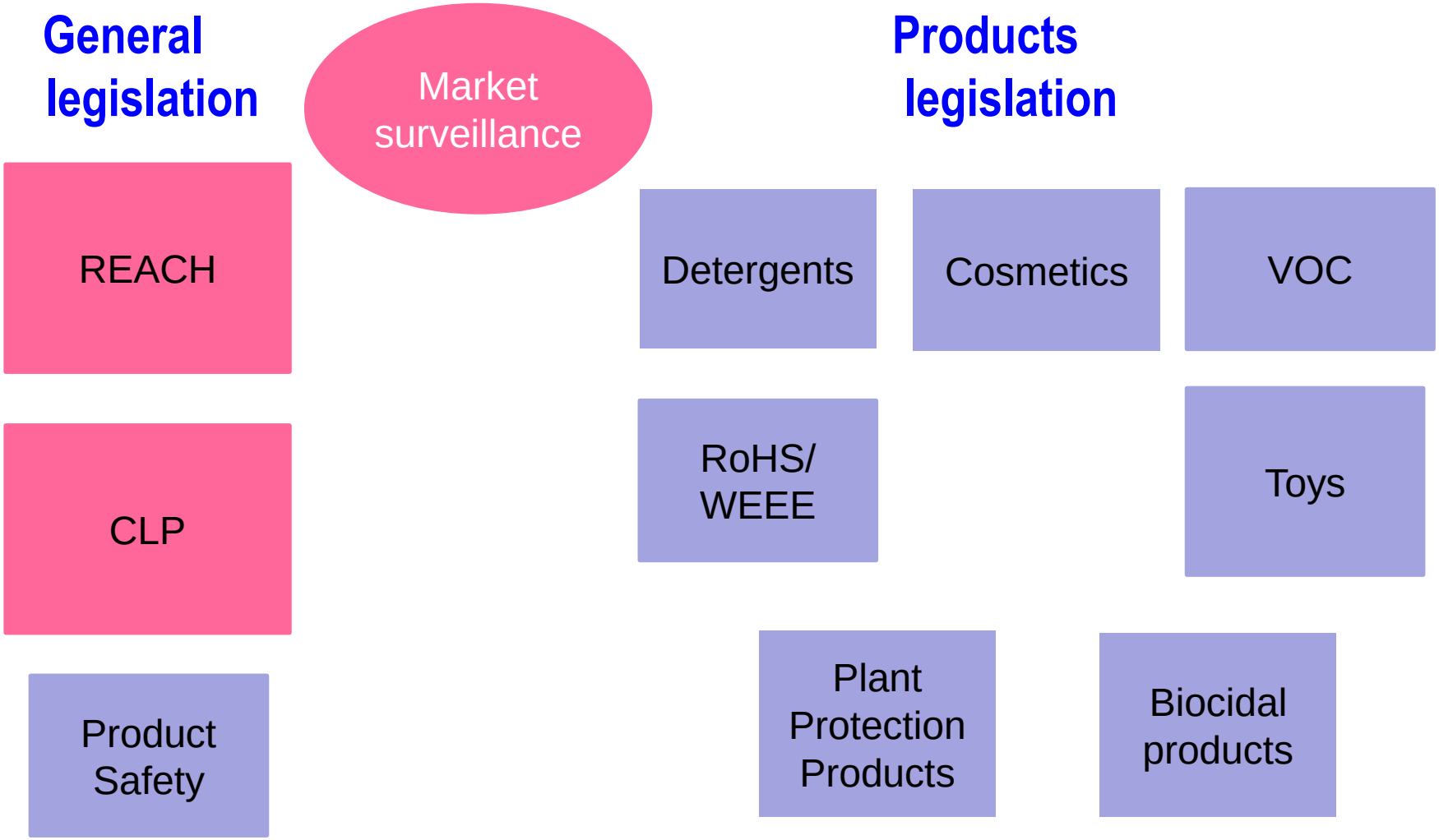
El Djazaïr
Tounis
Malta
Κύπρος Kypros Kıbrıs
Libnan

EU Chemicals legislation



REACH

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency

Entered into force 1 June 2007 and was fully applicable 1 June 2008

Before REACH

4 EU legislative instruments:

- Directive 67/548: notification of new chemicals, classification & labelling of dangerous chemicals
- Directive 76/769: Restrictions of marketing & use of certain dangerous substances & preparations
- Directive 88/379: classification and labelling of dangerous preparations (mixtures)
- Regulation 793/93: evaluation and control of risks of existing substances

REACH: Why?

Limited knowledge about possible negative effects for humans and the environment of the vast majority of chemicals

Shortcomings of previous chemicals legislation:

- **No obligation for risk assessment** for existing chemicals unless prioritised
- **Data gaps**: 86% of HPVs less than base data set
- **Slow and resources intensive** processes
- **Burden of proof** on public authorities
- **Downstream Users** stayed out of the picture, actual uses of chemicals unknown
- **Administrative and regulatory burden** prevented innovation
- **Over 40 single legal acts** prior to REACH - simplification needed under one piece of legislation

Solution:

A New EU Chemicals Policy

Registration, Evaluation

and

Authorisation of Chemicals

REACH

REACH – aim

Main objectives:

to ensure a high level of protection of the human health and the environment […] while enhancing competitiveness and innovation…

Five principles:

- shift of responsibilities from public authorities towards industry (shift of burden of proof)
- "duty of care"
- "no data, no market"
- a strong European CHemicals Agency (ECHA)
- special attention to SMEs

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REACH: Main features

A Single Coherent System for new (non phase-in) and existing (phase-in, in EINECS) substances

- New registration requirements for old substances.
- Data sharing as a general principle.
- Industry to generate information about substances and adopt risk management measures.
- Increased obligations to transmit information down the supply chain.
- New authorisation procedure

❖**Focus on priorities:**

❖ High volume chemicals (greatest likely exposure) register first

❖ Greatest concern chemicals (CMR and R50/53) register first

REACH: Key elements

- **R**egistration of chemicals
- **E**valuation of some registered chemicals
- **A**uthorisation of (some) **Ch**emicals
- Restriction of (some) **Ch**emicals

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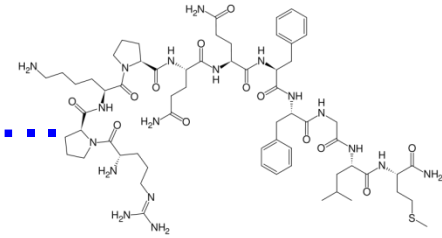
What Must Be Registered?



- Registration only concerns substances…..
- .....on their own, in preparations or in articles
- Mixtures and articles themselves are not registered

- Only substances manufactured/imported over 1 ton/year

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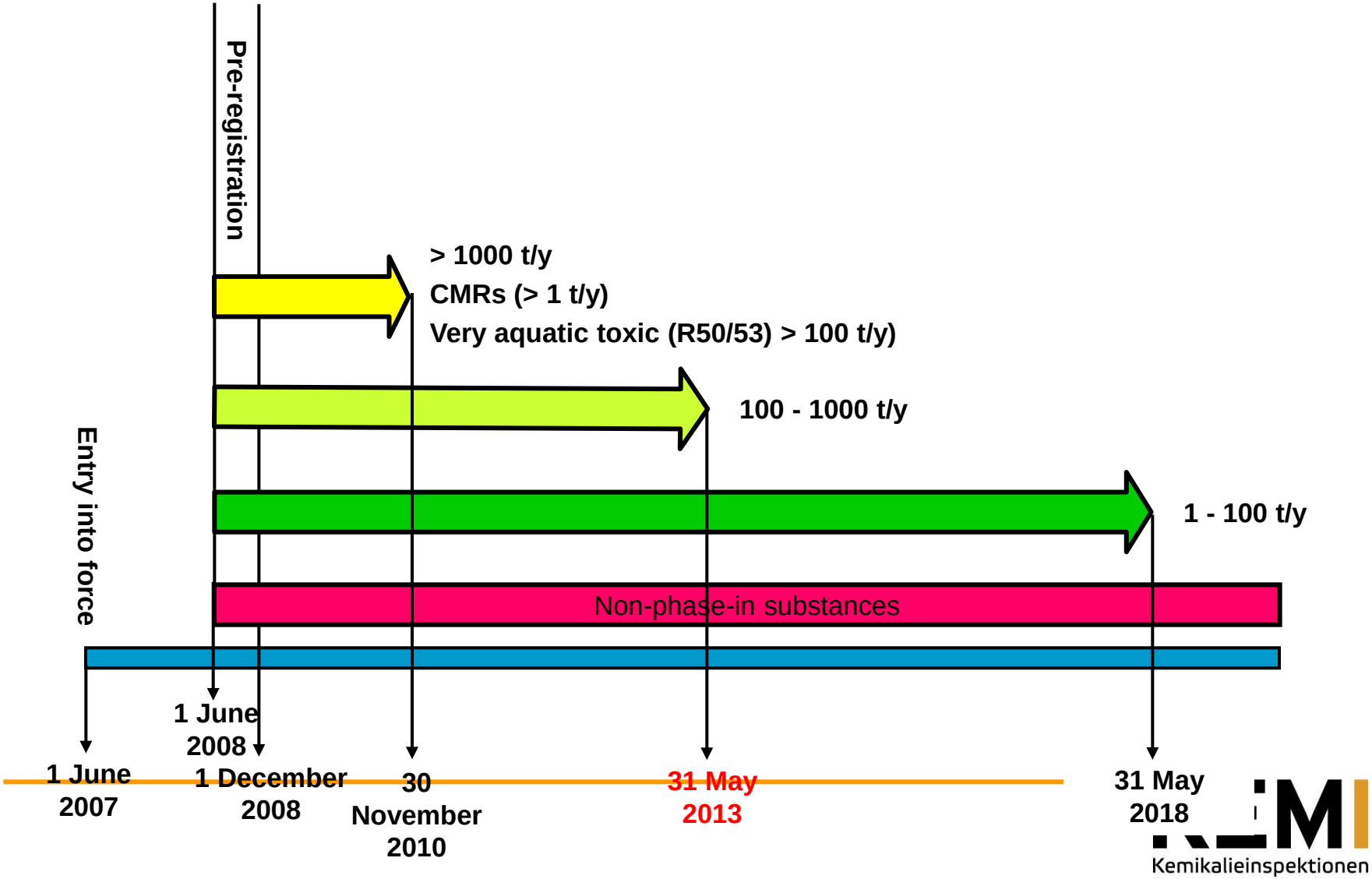
Registration
WHEN?



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Evaluation Objectives

- Dossier evaluation
  - Avoiding unnecessary testing.
  - Ensuring that industry meets its obligations.
- Substance evaluation
  - Gathering further information for substances that may present a risk for human health or the environment.

REACH – Authorisation

- Scope: substances of very high concern (SVHC)
  - CMR 1 and 2, PBT, vPvB, 'scientific evidence of probable serious effects'
- Substance cannot be used (including imported) unless authorised for specific uses and if
  - risks are adequately controlled
  - and/or socio-economic benefits outweigh risk
- Prioritised - Substances progressively authorised (as resources allow)

Ultimate objective: substitute SVHC by less hazardous substances or technologies

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Authorisation - steps

1: Identification of Substances of very high concern

2: **Inclusion in Candidate list**

3: Draft Recommendation on Priority substances for authorisation

4: Commenting period (3 months)

5: ECHA Recommendation to Commission

6: Commission decision = inclusion in Annex XIV

- application date
- sunset date (≥18 months later)

First application period ongoing

Information obligations – Candidate list

From the **date of inclusion** on the Candidate list of a SVHC, any supplier of an article which contains substances on the Candidate List in a concentration above 0.1% (w/w) **has to provide sufficient information**, available to the supplier,

- to the recipients (professional and industrial users, distributors) and
- on request, to a consumer - free of charge - within 45 days of the receipt of the request

This information must ensure safe use of the article including as a minimum the name of the substance

Currently 155 substances on the Candidate list

Restrictions

- May be applied to:
  - manufacture, use and placing on the market
  - a substance on its own, in a preparation or in an article
- When:
  - an unacceptable risk to human health or the environment
  - the risk needs to be addressed on a Community-wide basis
- Restrictions will be included in Annex XVII
  - takes over existing restrictions of Directive 76/769/EC

REACH's reach

In the EU

- Every manufacturer and importer
- Every downstream user of substances
- Every citizen

Worldwide

- Every manufacturer (more or less)
- Ultimately every citizen

Information down the Supply Chain - Objectives

- To ensure dissemination of information about properties of substances.
  - Safer use of the substances.
  - Ability of manufacturers and suppliers to develop appropriate risk reduction measures.

Obligations for Substances in Articles

- Normal registration applies to substances in articles that are **intentionally** released from the article
- Notification by manufacturer/importer to ECHA of unregistered uses of Candidate List substances
- Supplier must provide information on safe use to article recipient (or to a consumer within 45 days of a request) for articles containing Candidate List substance at > 0.1%

Regulation on the Classification, labelling and packaging of substances and mixtures – CLP substances and mixtures including plant protection products and biocides (no tonnage thresholds) (EC regulation No 1272/08)

GHS

- Classification, Packaging and Labelling of substances
- Harmonised classification and self-classification of substances
- Classification and labelling inventory

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GHS - Global Context

- Rio, 1992 Chapter 19 of UNCED Agenda 21
- Development by IOMC up to 2001
- UN ECOSOC adopted July 2003, rev 3 2009
- WSSD, Johannesburg 2002 – operational by 2008

A Global Initiative

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GHS - Context

- GHS is **not legally binding** but agreed to implement at World Summit for Sustainable Development in 2002
- GHS provides common basis for classification and hazard communication for **transport** and **supply and use**
- GHS includes a **"building block"** approach to facilitate implementation => freedom to take up hazard classes and/or categories but **NO** change of criteria for classes/categories
- GHS will not be completely uniformly applied at first
- More similarity and improvement over time

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CLP Regulation - Principles

- Applies the general principles of the GHS
- Introduces the GHS criteria for data interpretation, classification and labelling
- Uses the GHS Building Block Approach and a few other options to adapt the system to EU needs
- Ensures consistency with transport rules
- Keeps the scope as close as possible to the previous EU system

Main roles and obligations of suppliers

- Classify:
  - before placing on the market
  - if REACH requires classification; e.g. on-site isolated intermediate
- Ensure appropriate labelling and packaging before placing on the market
  - Downstream users may use classification from supplier, provided no change of composition
  - Distributors: no obligation to classify; may use classification from supplier
- Cooperate with others in the supply chain for meeting requirements

Harmonised C&L

- Which types of substances
  - Carcinogenic, Mutagenic, Reprotoxic, respiratory sensitisers
  - Pesticidal & biocidal active substances
  - Others case-by-case
- Proposals may be submitted by
  - MSCAs
  - Industry (Manufacturers/Importers, Downstream Users)
- Decision by European Commission
- How many?
  - Estimated 90 proposals per year

C&L inventory

Classification and labelling inventory

- Obligation to notify the Agency
- Agreed entries among industry
- The classification and labelling inventory is publicly available at the ECHA website
  - Substances in Annex VI of CLP, i.e. harmonised C&L
  - Substances self-classified by manufacturers and importers

Further information

More information about CLP, how it works and available tools can be found on the website of the European Chemicals Agency in the Classification section at:

http://echa.europa.eu/classification_en.asp

Pesticides: Plant protection products and biocides

Directive on plant protection products (91/414/EEC)	Regulation on plant protection products (PPP) 1107/2009/EC

Regulation on biocidal products 582/2012/EU	Directive on biocides (98/8/EC)

Product Safety Directive 2001/95/EC

- Consumer products not covered by specific sector legislation
- Generic definition of safe product
- Not only chemical risks
- RAPEX, Rapid alert system

  (http://ec.europa.eu/consumers/safety/rapex/index_en.htm)

Examples of products legislation –

Detergents Regulation EC No 648/2004

RoHS/WEEE (Directive 2002/96/EC) – 2011/65/EU

Toys (Directive 2009/48/EC - 88/378/EEC)

Cosmetics (Directive 76/768/EEC - 1223/2009 /EC)

VOC (Directive 2004/42/EC)

Preventing accidents

Transport of Dangerous goods (2008/68/EC)

Flammables and explosives (93/15/EEC)

”Seveso II”(Directive 96/82/EC)

Implementing the Stockholm convention

REGULATION (EC) No 850/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC

Implementing the Rotterdam Convention

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

applicable from 1 March 2014

Thank you for the attention!

Questions?