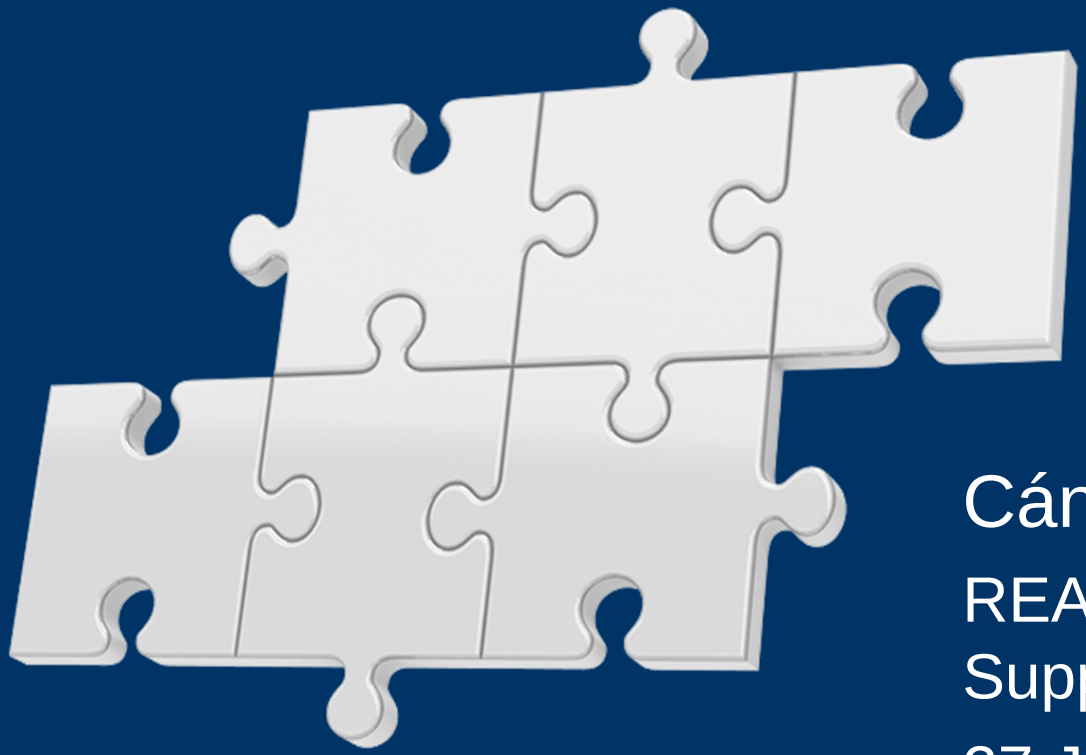

Cándido García Molyneux

REACH: Legal Implications & Supply Chain Strategies

27 June 2012

REACH and other EU Environmental and Health Safety Legislation

Outline

1. Introduction
2. Links between REACH/CLP Procedures and other EU rules
3. Possible Conflicts

- How does REACH/CLP fit with other EU environmental and health safety rules?

Introduction

"The benefits of the REACH system are twofold: risks to human health will be reduced and environmental quality will be improved through the better and earlier identification of the properties of chemical substances and through the improved framework for the registration, assessment, and authorisation of chemical substances"

Communication by Mr. Liikanen and Ms. Wallstrom, "Chemicals-Orientation Paper" (1 Apr. 2003)

Introduction

Links and spill overs between REACH/CLP and other EU vertical/ horizontal regulatory regimes

- Cosmetics
- Medical Devices
- RoHS
- Toys
- Detergents
- Fertilizers
- Biocides
- Food contact materials
- Food
- Product Safety
- Water
- Waste
- …other

Introduction

REACH

CLP

WORK SAFETY

WASTE FRAMEWORK DIRECTIVE

PACKAGING

ELV

BATTERIES

RoHS

PESTICIDES

BIOCIDES

MEDICINES

MEDICAL DEVICES

COSMETICS

FOOD

TOYS

WATER FRAMEWORK DIRECTIVE

PRIORITY SUBSTANCES

Different REACH/CLP Procedures

- Notification and Harmonized Classification (CLP)
- Registration
- Substance Evaluation
- Identification of SVHCs – Candidate List
  - Cat. 1A and 1B CMRs, PBTs, vPvBs, equivalent concern
- Authorization
  - Does not apply to substances “in” articles
  - Marketing and use
- Restrictions
  - “Unacceptable risk” that needs to be addressed on a EU basis
  - Fast track for Cat. 1A and 1B and CMRs
  - Manufacture, marketing and use
  - Also applies to substances “in” articles

Examples of Links Between REACH/CLP Procedures and Other Legislation

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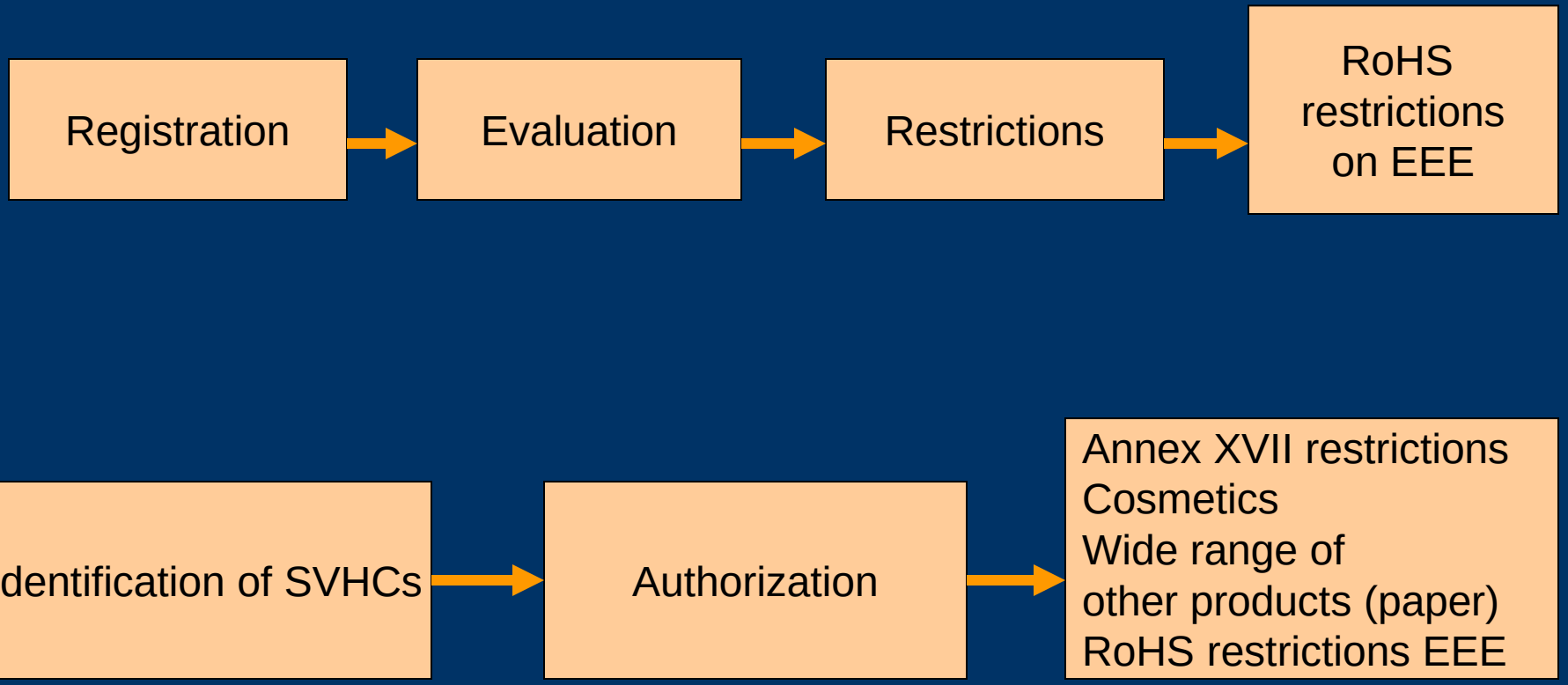
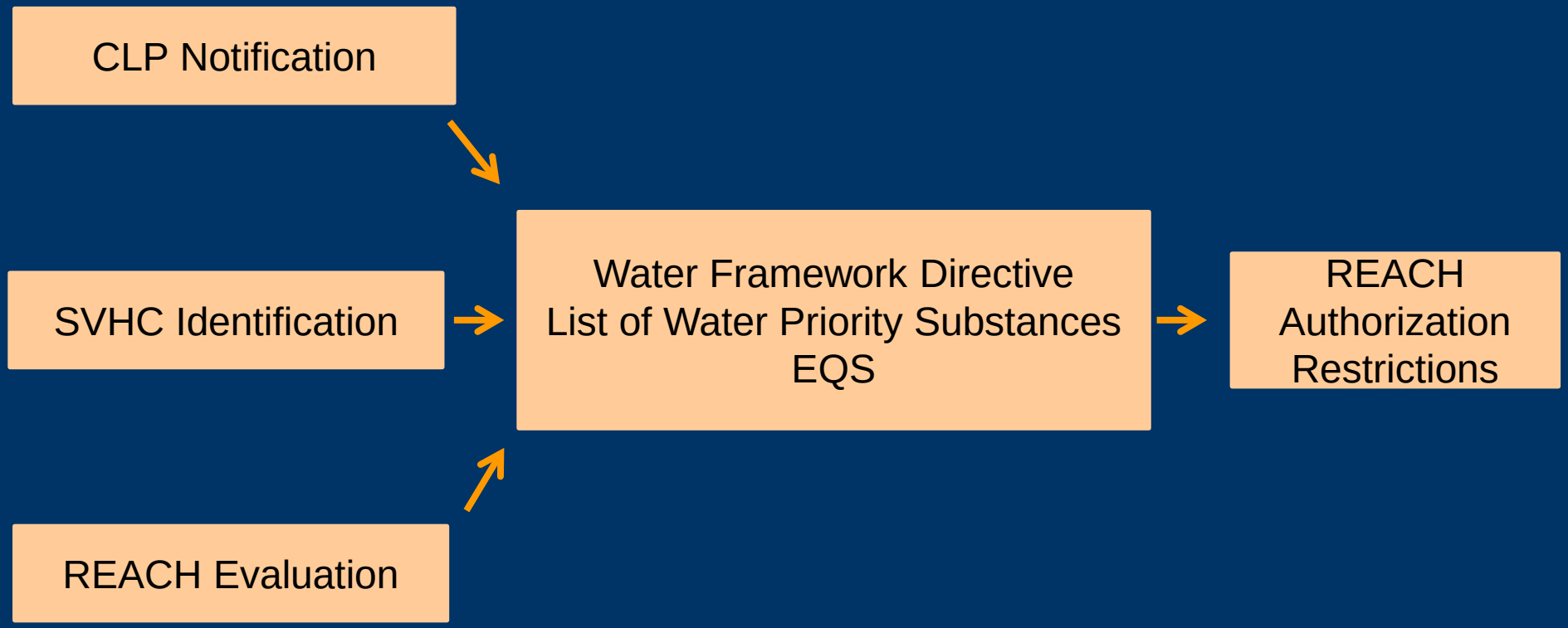


Examples of Links Between REACH/CLP Procedures and Other Legislation



REACH – RoHS (2011/65)

Rules REACH-RoHS

- RoHS – emphasis on "environmentally sound recovery and disposal of waste EEE"
- "Annexes [to RoHS] should be reviewed periodically to take into account, inter alia Annex XIV and XVII to [REACH Regulation]"
- "[RoHS] Directive shall apply without prejudice to the requirements of [REACH Regulation]"
- Exemptions for specific applications may be granted under RoHS if they do "not weaken the environmental protection afforded by [REACH Regulation]"

Issues

- ✓ REACH Annex XVII marketing and use restrictions
  - No exemption can be given under RoHS
- ✓ Substance benefits from a RoHS exemption
  - Can it still be subject to REACH Authorization?
- ✓ Use of substance does not obtain a REACH authorization
  - Can it still obtain a RoHS exemption?
- ✓ Use of substance authorized under REACH
  - Can it be restricted under ROHS?

REACH – RoHS (2011/65)

- RoHS exempts medical devices until 2014
- RoHS - 0,1% for Pb, Hg, Chromium VI, PBBs, PBDEs, and 0,01 Cd
  - per "***homogenous material***"
- Compare with "For obligations according to [REACH] Article 7(2) and 33 to apply, the concentration of this SVHC has to exceed 0.1% (w/w) in the entire article" (ECHA Guidance 2011)

45.	Diphenylether, octabromo derivative $C_{12}H_2Br_8O$	1. Shall not be placed on the market, or used: — as a substance, — as a constituent of other substances, or in mixtures, in concentrations greater than 0,1 % by weight. 2. Articles shall not be placed on the market if they, or flame-retardant parts thereof, contain this substance in concentrations greater than 0,1 % by weight. 3. By way of derogation, paragraph 2 shall not apply: — to articles that were in use in the Community before 15 August 2004, — to electrical and electronic equipment within the scope of Directive 2002/95/EC.

REACH/CLP and Medicines

- MA for human medicines may not be denied for environmental reasons
- REACH registration, evaluation, authorization do not apply to substances used in medicinal products
- CLP obligations (including notification) apply to active medicinal substances in bulk
- REACH Annex XVII restrictions may apply to medicinal products
  - And medicinal substances could still be subject to restrictions deriving from water rules (and other applicable environmental legislation)

REACH and Testing of Cosmetics

Article 18 Cosmetics Reg.

Prohibits

1. Placing on the market of cosmetic products that "in order to meet the requirements of [Cosmetics Regulation]" has been subject to [vertebrate] animal testing using a method other than a validated alternative method
2. Placing on the market of cosmetic products with ingredients that "in order to meet the requirements of the [Cosmetics Regulation]" have been subject to [vertebrate] animal testing using a method other than a validated alternative method
3. Performance of [vertebrate] animal testing of cosmetic products in the EU "in order to meet the requirements of the [Cosmetics Regulation]"

REACH Rules

1. REACH Regulation applies "without prejudice to [Cosmetics Regulation] as regards testing involving vertebrate animals" "within the scope of [the Cosmetics Regulation]"
2. Substances used in cosmetic products are subject to REACH registration and testing requirements
   - CSA need not take into account health risks of use of substance in cosmetic products
3. Rules on data sharing and testing proposals

REACH and Waste

- Waste is not a substance, mixture or article under REACH (Art. 2(2))
- Materials that are recovered are no longer waste
  - "manufactured" and subject to REACH
- Recovered substances are not subject to registration, downstream users and evaluation if: (i) recovery in the EU, (ii) recovered substance is the same as that already registered (by any third party), and (iii) recovery facility has SDS or Art. 32 information on the substance
  - SDS, SVHC information, Authorization and Restrictions apply
- Several materials that are recycled/recovered are listed in Annex IV or V as exempted from registration (cellulose pulp, certain glasses and metals)
  - "Impurities"
- EoW – recycler/recoverer becomes REACH manufacturer

Different Concentration Limits Benzene

Annex XVII REACH

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
5. Benzene CAS No 71-43-2 EC No 200-753-7	1. Shall not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg (0,0005 %) of the weight of the toy or part of toy. 2. Toys and parts of toys not complying with paragraph 1 shall not be placed on the market.

Different Concentration Limits Benzene

Toys Directive

3. Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

4. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 3 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:

(a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;

(b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2);

(c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

That decision may be taken if the following conditions are met:

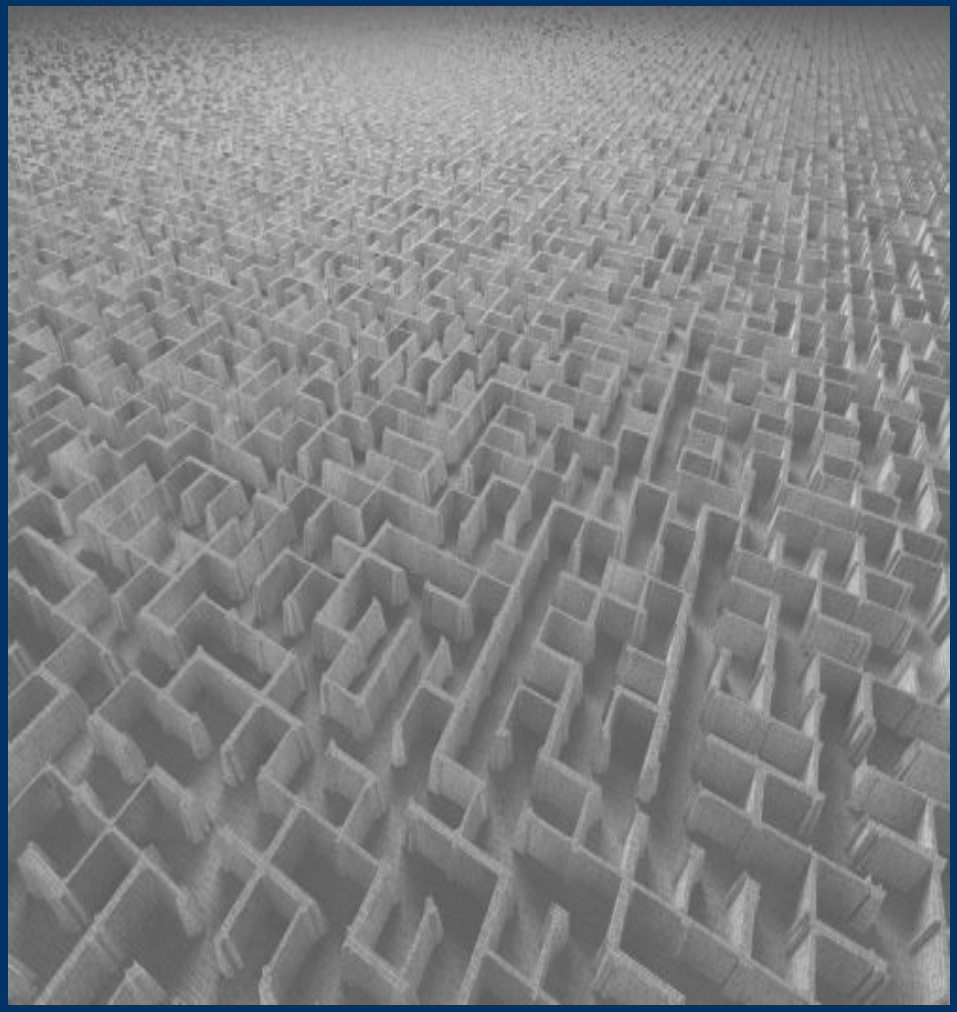
(i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;

(ii) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and

(iii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years from the date that a decision in accordance with Article 46(3) was taken.

Recommendations



1. Think in advance
2. Consider how different rules could affect your products
3. Identify key substances and risks

Dr. Cándido García Molyneux
Covington & Burling LLP
44 Avenue des Arts
1040 Brussels Belgium
+32.2.549.5261
cgarciamolyneux@cov.com

Cándido García Molyneux is a Spanish of counsel in the Brussels office of Covington & Burling LLP. His practice focuses on EU environmental law and food and drug law. He advises clients on legal issues concerning environmental product regulation, chemical law, waste management, climate change, renewable energies, and energy efficiency.
Dr. García Molyneux holds a PhD in Law from the European University Institute, an LLM from the University of Georgetown, and a Law Degree from the Autonomous University of Madrid. He is a lecturer on EU environmental law and policy at the College of Europe.