EU Legislation on chemicals in products, in particular Reach Information requirements, Restrictions and Authorisation

Eva Sandberg

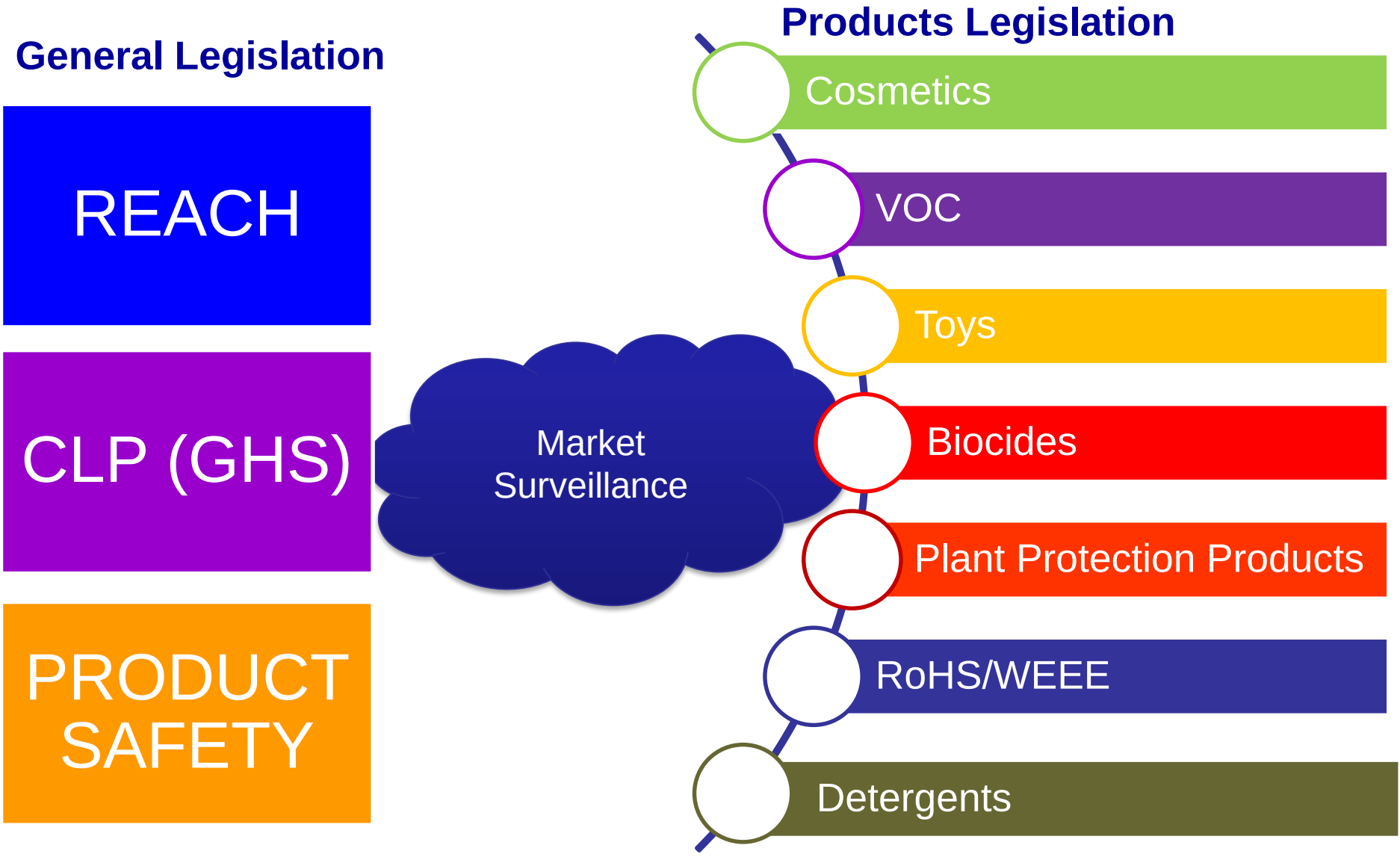
International Secretariat

Swedish Chemicals Agency

KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

EU Member States

EU Chemicals Related Legislation



KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

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

KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Registration, Evaluation and Authorisation of Chemicals

REACH

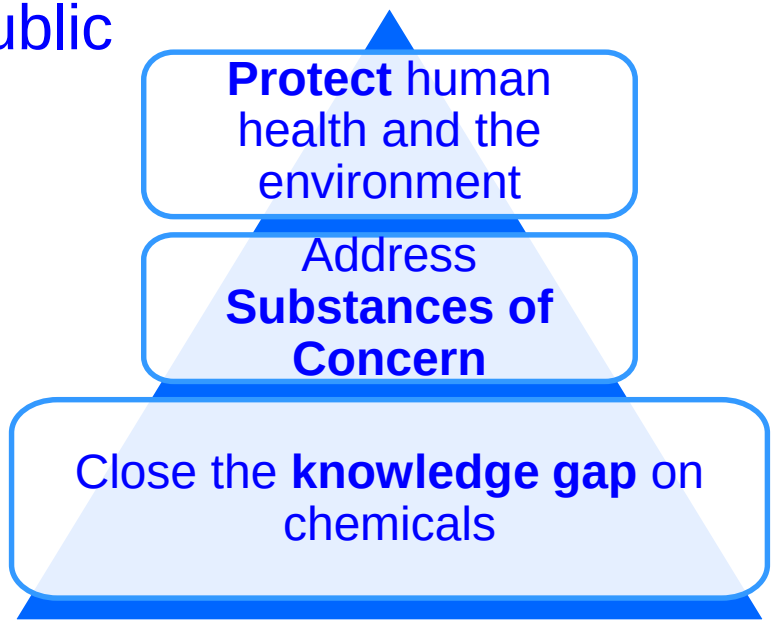
Products vs Article

- EU definitions in REACH
  - Products = Chemical substances and mixtures
  - Articles = Form defines function

REACH – aim and objectives

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



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:**

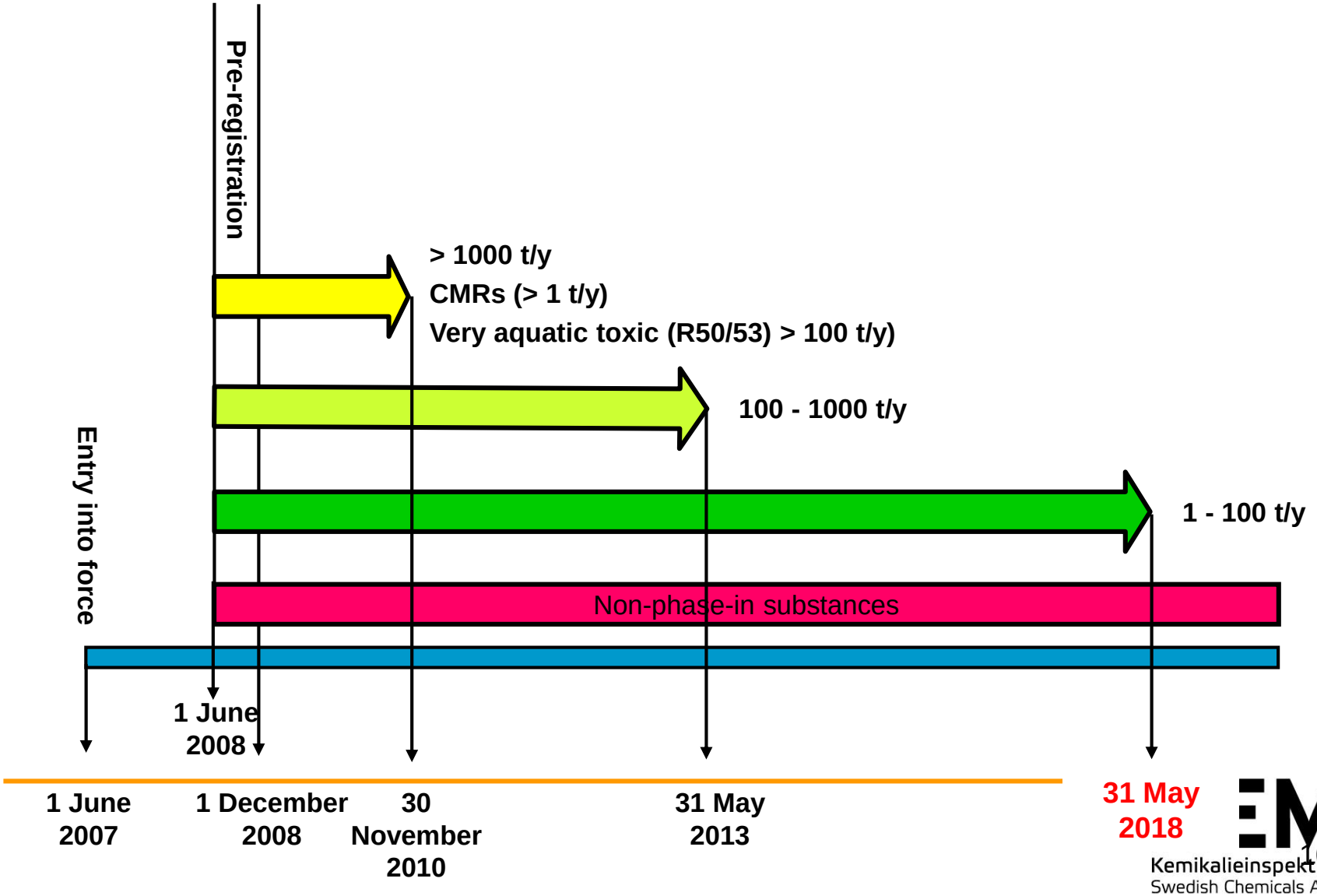
❖ High volume chemicals (greatest likely exposure) register first

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

REACH: Key elements

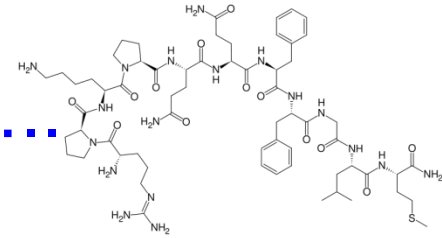
- **R**egistration of chemicals
- **E**valuation of some registered chemicals
- **A**uthorisation of (some) **Ch**emicals
- Restriction of (some) **Ch**emicals

Registration
WHEN?



Kemikalieinspektionen
Swedish Chemicals Agency

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

KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Information requirements (inherent properties)

- Physical-chemical properties (e.g. solubility, vapour pressure)
- Toxicity properties (e.g. acute toxicity, irritation, mutagenicity, carcinogenicity)
- Fate properties (e.g. (bio)degradation, partition coefficients)
- Ecotoxicity properties (e.g. toxicity to aquatic or terrestrial organisms)

Industry Role

Manufacturers & importers:

1. Obtain information on properties and **uses** of their substances
2. Use this knowledge to **ensure responsible and well-informed management of the risks of these substances**
   - apply parts of classification system which are appropriate
   - [If > 10 tonnes] performs Chemical Safety Assessment
   - [If > 10 tonnes & substance is PBT/vPvB or dangerous] implement Exposure Scenario
3. Send information to ECHA by deadline (registration dossier) and to users (extended Safety Data Sheet)

No formal acceptance - industry retain responsibility

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.

REACH – Authorisation

- Scope: substances of very high concern (SVHC)
  - CMR 1A and 1B, PBT, vPvB, 'scientific evidence of probable serious effects'
- Substances 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

Authorisation - steps

1: Identification of Substances of very high concern (SVHC)

- comments invited

2: Inclusion in Candidate list

3: Draft Recommendation on Priority substances for authorisation

- comments invited

4: ECHA Recommendation to Commission

5: Commission decision = inclusion in Annex XIV

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

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 handled on European Union level
- Restrictions will be included in Annex XVII
  - Companies are obliged to follow the restrictions

Restrictions concerning chemicals in products/articles - examples

- Azodyes in textiles
- Phthalates in toys
- Asbestosis fibres
- Several flame retardants in textiles (PBB, phosphates)
- Benzene in toys
- Mercury in measuring devices
- Arsenic as wood preservative
- TBT as biocide

- Cd in PVC and other polymers
- Nickel & Lead in jewellery and accessories
- CMR-substances as such or in (chemical) mixtures intended for consumers
- NFE in textiles and leather
- Chrome VI in cement
- PAH in tyres

Preparing a decision

- Two ECHA committees preparing decisions for authorisations and restriction
  - RAC - Risk assessment committee
  - SEAC - Socio-economic assessment committee
- Experts in relevant fields nominated by Member States appointed by ECHA Management Board
- Applicants have to supply an risk assessment, alternatives analysis and a socio-economic analysis in their authorisation application if risks cannot be adequately controlled

Socio-economic analysis

- Is an integral part of the authorisation and the restriction processes
- Supports decision-making
- Its purpose is to describe the impact of choosing one course of action over another
- Needs to include an alternatives analysis
- Shall include both cost and benefits of options

To note: A negative effect for one company might be a positive effect for another

Socio-economic analysis - links

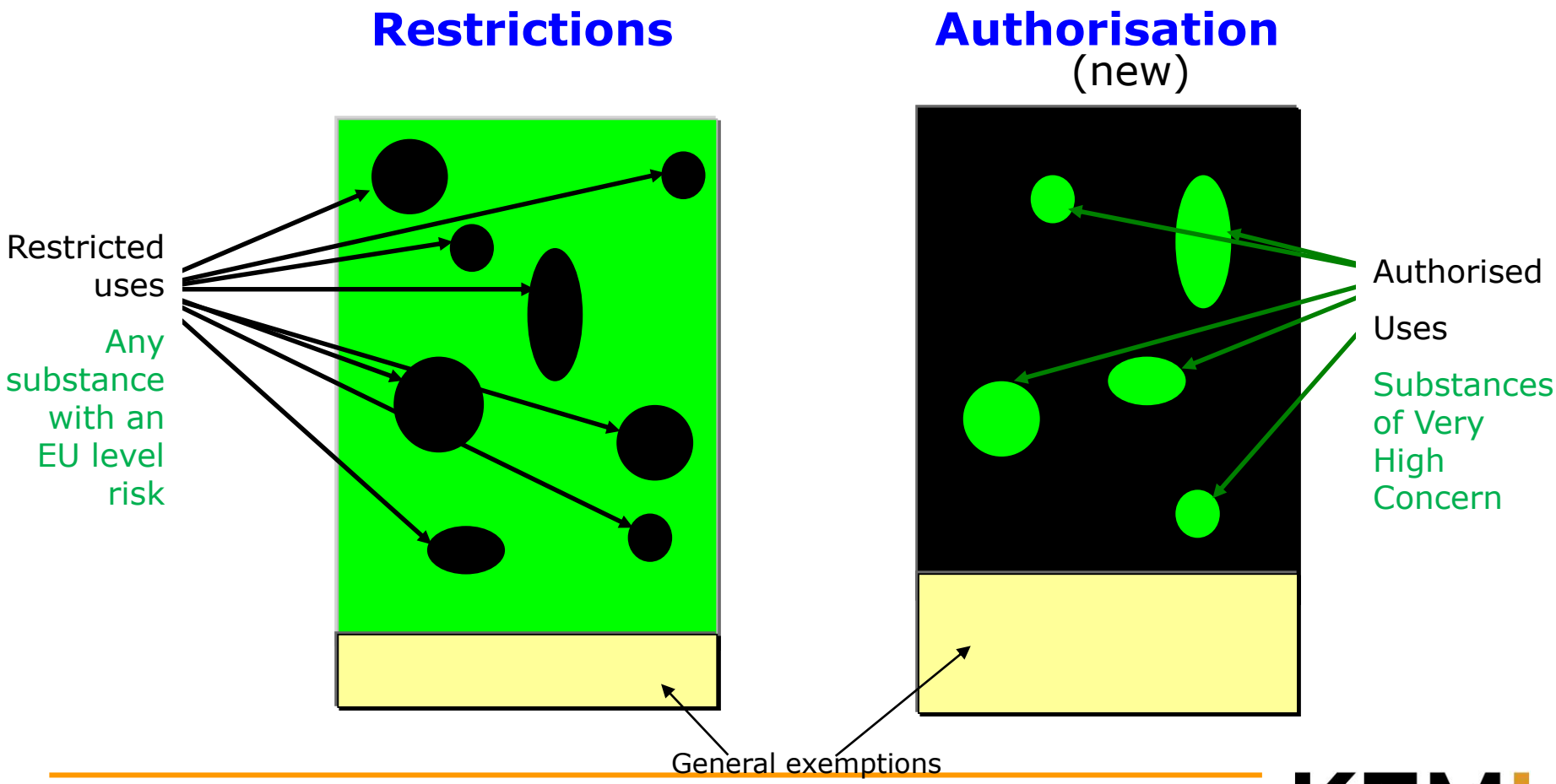
- EU-guidance at:

  http://echa.europa.eu/support/socio-economic-analysis-in-reach

- EU Commission Impact Assessment Guidelines:

  http://ec.europa.eu/smart-regulation/impact/commission_guidelines/commission_guidelines_en.htm

Difference between Restrictions & Authorisation



Information obligations – Articles and 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

The obligation applies to imported articles as well as those manufactured within the EU

Currently 163 substances on the Candidate list

Other Obligations for Substances in Articles

- Normal registration applies to substances in articles that are 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%

Substances of Potential Concern
Which road to take?

Authorisation or restriction?

- 2 different risk Management Options (RMO) in REACH
- Other options within or outside REACH

Biocides regulation

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

Requires:

- Approval of active substances
- Approval of final products
- Set rules for treated articles

Biocide-treated articles

- Articles may be intentionally treated with or contain one or more biocidal products to protect against the infestation of microorganisms or insects.
- The EU Biocidal Products Regulation (BPR) sets rules for the use of articles treated with, or intentionally incorporating, one or more biocidal products.
- According to the regulation, articles can only be treated with biocidal products containing **active substances approved in the EU.**
- Companies must also be ready to provide the consumers with information about the biocidal treatment of the article they are selling. If a consumer requests information about a treated article, the supplier must provide it free of charge within 45 days.

Biocide-treated articles

Labelling of treated articles

- Manufacturers and importers of treated articles need to ensure that products are labelled according to both the regulation on CLP (GHS) and the additional requirements defined by the Biocidal Products Regulation (BPR).
- BPR requires manufacturers and importers of treated to label treated articles when:
  - a claim that the treated article has biocidal properties is made
  - it is required in the conditions of the approval of the active substance contained in the biocidal product used to treat the article

Biocide-treated articles

- The labels need to be easily understandable and visible for consumers
  - it shall be clear, easy to read and still be legible during the entire period of use of the article, and shall contain the following information:
    - the fact that the article contains a biocidal product
    - the name of the active substance that is included
    - the purpose of the treatment, such as removing bad odour
    - relevant instructions for use and any essential precautionary measures
- if nanomaterial is included in the biocidal product, state its name.

Examples of articles that may have been treated with biocides

Type of article

shoes	refrigerators and freezers	cushions
kitchen utensils	different types of handles	shower hoses
cleaning materials	sportswear	drinking water filters
cleaning cloths	changing tables for babies	construction materials
vacuum cleaner bags	baths	exterior paints
knives	toothbrushes	coolants
food containers	mattresses	cutting fluids

Examples of active substances which can be found in a biocide-treated article

Substance	Properties
Boric acid	damage the testicles, reduce fertility and damage the foetus in several animal species
Copper	Very toxic to marine plants and animals, bioaccumulative;
Permethrin	Very toxic to marine plants and animals.
Silver	Suspected of giving rise to antibiotic resistance
Triclosan	Eye and skin irritant. Very toxic to marine plants and animals. Suspected of containing hormone-disrupting properties. Suspected of being able to give rise to antibiotic resistance.

Thank you!

Kemikalieinspektionen
Swedish Chemicals Agency