

Chemicals risk management and Critical Raw Materials under REACH and CLP

Joint Raw Materials Supply Group and
ECHA information session on
Critical Raw Materials and REACH

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Outline

- Purpose of the presentation
- REACH and CLP Regulation
- REACH, CLP and Critical Raw materials – state of play
- Authorisation process
 - Aim of Authorisation
 - Authorisation process
- Identification and prioritisation of SVHCs (Jan-Karel Kwisthout)
- Application for authorisation
- Summary
- Issues for discussion

Purpose

- To clarify how REACH and CLP regulations work
- How they relate to the use of critical raw materials
- How the Authorisation Title of REACH works and relates to critical raw materials

REACH and CLP Regulation





ECHA, REACH and CLP

- **ECHA** established on 1 June 2007
- **REACH** Regulation entry into operation June 2008
 - **R**egistration of chemicals [“substances”]
 - **E**valuation of selected registered substances
 - **A**uthorisation of (certain) Chemicals
 - **R**estriction of (certain) **C**hemicals
- **CLP** Regulation applies from 1 Dec 2010
 - **C**lassification, **L**abelling and **P**ackaging of substances and mixtures
 - Implementation of agreed UN-wide system
 - Transitional period 2010-2015: both classification systems used

Aims of REACH and CLP

- Ensure a high level of protection of human health and the environment
- Promote alternatives to animal testing
- Ensure the free circulation of substances (mixtures and certain articles/under CLP) on the internal market
- Enhance competitiveness and innovation



Institutional setup

- **ECHA** is an independent EU agency with committees;
 - Member States (representatives from Member States)
 - Risk Assessment (independent experts)
 - Socio-economic Analysis (independent experts)The Forum for Exchange of Information on Enforcement (representatives of Member States)
- **European Commission** is responsible for decisions (based on opinions), updating REACH, CLP and Fee Regulations, asking ECHA to carry out different tasks
 - identifying substances subject to authorisation, granting authorisations, etc.
- **European Parliament** and **Council** have a specific role in comitology process and in updating the legislation (co-decision)

EU Decision making

- **Co-decision**
 - Includes European Parliament and the Council (Member States) in decision making.
 - REACH was the product of extensive co-decision process
- **Comitology**
 - Implementing powers attributed to the Commission with Council (and Parliament's scrutiny)
 - Regulatory committee with scrutiny: must allow the Council and the European Parliament to carry out a check prior to the adoption of measures of general scope
 - Regulatory committee: responsible when the implementing measures related to legislation applicable in the whole of the European Union
 - For example:
 - REACH Annexes XIV (authorisation) and XVII (restrictions) can be amended by comitology through the regulatory procedure with scrutiny.
 - Applications for authorisation decided without scrutiny.

REACH and CLP – main processes and actors



Pre-registration
Data sharing
Registration
Self-classification

Facilitated by ECHA, industry gathers information and ensures management of risks
Duty to communicate in supply chain



Member States

Evaluation
– Dossier evaluation
– Substance evaluation

ECHA and MSCAs control and request for further info

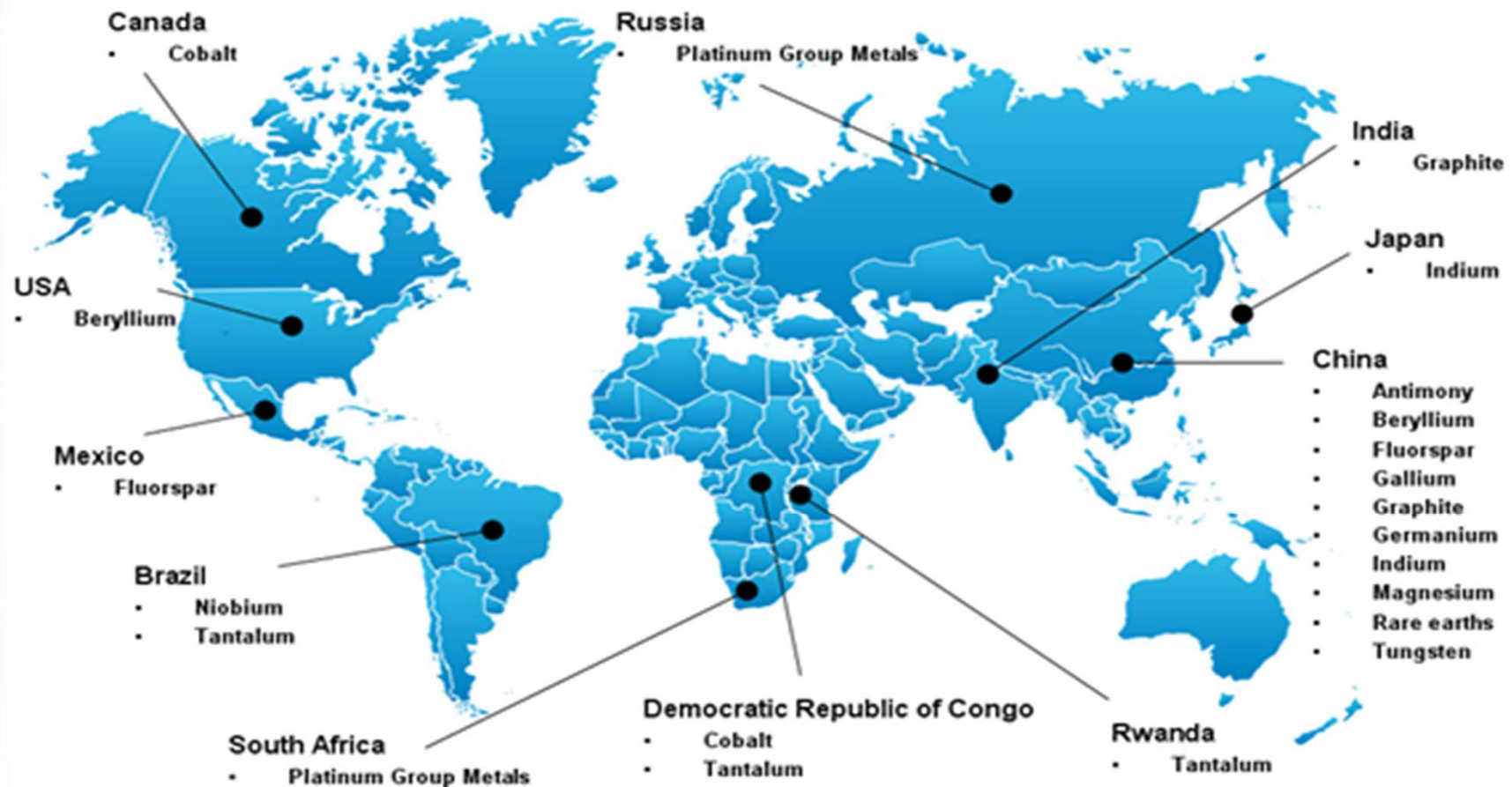


Authorisation
Restriction
Harmonised Classification, Labelling and Packaging

Commission, with support of ECHA and MSCAs, applies community wide risk management measures

REACH, CLP and CRITICAL RAW MATERIALS – State of play

Production concentration of critical raw mineral materials



REACH and Critical Raw Materials: Example

- Nine of critical raw materials are registered
Antimony (Sb), Beryllium (Be), Cobalt (Co), Graphite Magnesium (Mg), Niobium (Nb), Cerium (Ce), Neodymium (Nd), Tungsten (W)
- Three classified Hazard e.g. Beryllium statement
 - Acute Tox. 3 * H301
 - Skin Irritant 2 H315
 - Skin Sensitiser 1 H317
 - Eye Irritant 2 H319
 - Acute Tox. 2 * H330
 - STOT SE 3 H335
 - STOT RE 1 H372
 - Carcinogen 1B H350**
(H350: May cause cancer)
- Self classifications are also important to be considered, as the triggered risk management measures would apply to all users
- Identification of a substance as SVHC is based on intrinsic properties (CMR, PBT, vPvB or equivalent concern)

Authorisation process

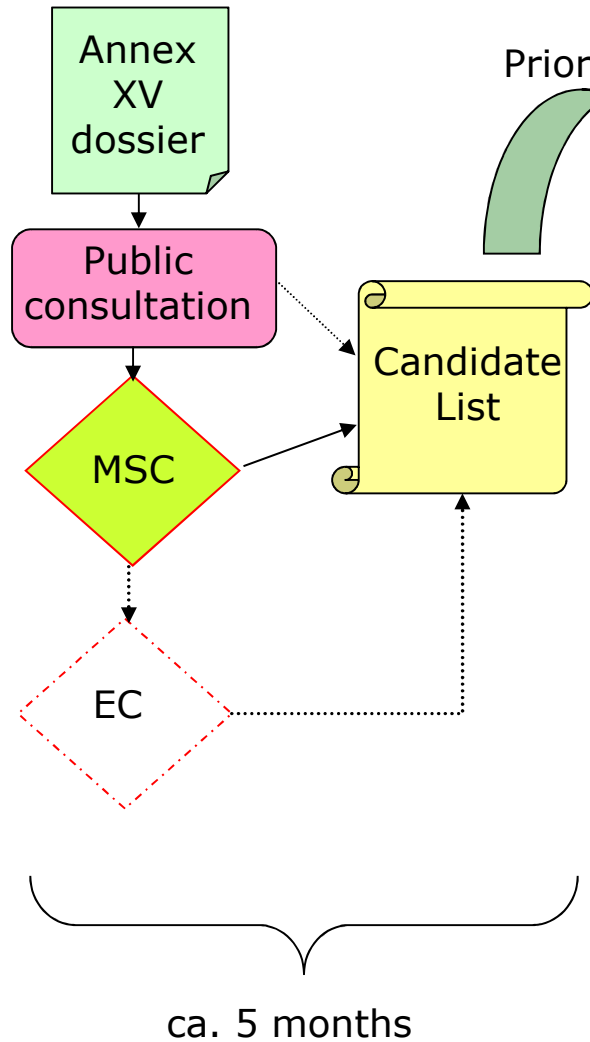


Aim of the Authorisation Title

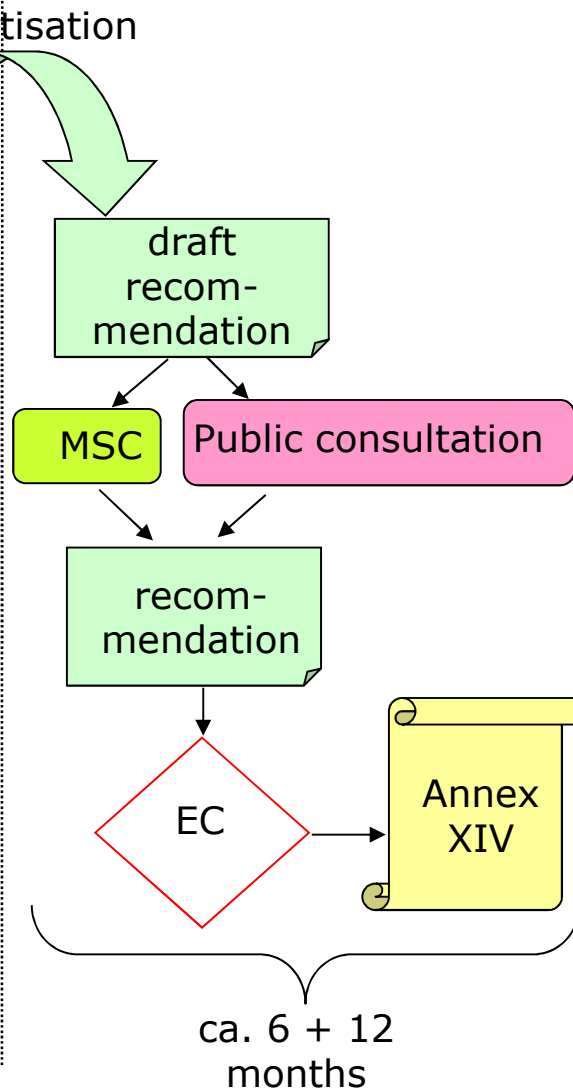
- Assure that the risks from Substances of Very High Concern (SVHC) are properly controlled and that these substances are progressively replaced by suitable alternatives while ensuring the good functioning of the EU internal market.
- SVHCs are:
 - Carcinogenic, Mutagenic or Toxic for reproduction (CMR) category 1A or 1B
 - Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB)
 - Substance of equivalent level of concern

Authorisation: Overall procedure

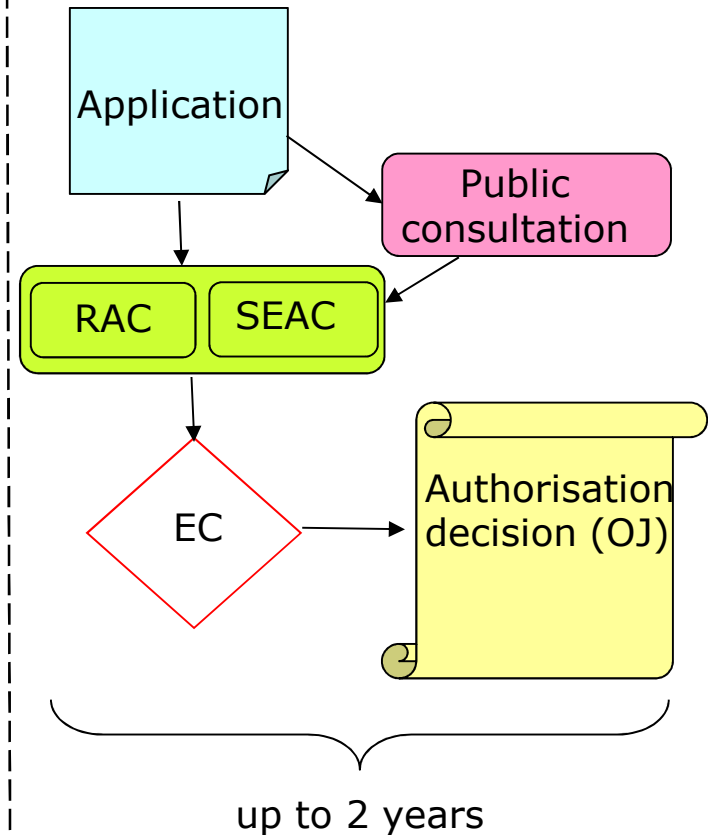
Step 1.1: Identifying SVHCs



Step 1.2: Subjecting priority substances to authorisation



Step 2: Granting (or not) authorisation



Purpose and content of Authorisation (1/2)

	Authorisation steps		
	Inclusion in the Candidate List	Prioritisation	Authorisation decision
Purpose	Enhance substitution	Enhance substitution	Enhance substitution Ensure proper control of risks
Decision on	Which substances can be subject to authorisation	When substances on Candidate List will be subject to authorisation	Whether a use can continue after the sunset date
Basis	Art 57	Art 58(3)	Art 62 (and 60)
Who provides information	MS or Commission (ECHA) based on REACH/CLP information	ECHA, based on REACH/CLP information	Applicant

Purpose and content of Authorisation (2/2)

	Authorisation steps		
	Inclusion in the Candidate List	Prioritisation	Authorisation decision
Aspects considered	Substance specific - Intrinsic properties	Substance specific - All potential uses of the substance	Use and applicant specific - Control of risks - Availability of suitable alternatives - Socio-economic consequences
Decision by	ECHA – MSC – Commission, (no comments – unanimous agreement – no agreement)	ECHA considering views of MSC (Recommendation: ECHA- MSC opinion; Decision on inclusion in Annex XIV by Commission)	Commission, taking into account RAC and SEAC opinions

MSC = Member State Committee **RAC = Risk Assessment Committee**
SEAC = Socio-economic Analysis Committee

Role of public consultation

	Identification of SVHCs	Recommendation for inclusion in the Authorisation List	Applications for authorisation
Type of information requested during the public consultation	<ul style="list-style-type: none"> • Identity of the substance • Intrinsic properties relevant for the identification* • Additionally, information on uses, exposures and alternatives 	<ul style="list-style-type: none"> • Uses and volumes used • Complexity of the supply chain • views on the transitional arrangements and possible exemptions 	Alternative substances or technologies to the use(s) applied for <ul style="list-style-type: none"> • Risks of alternatives • Technical feasibility and costs of alternatives
When will the public consultation take place?	Twice per year (45 days in March-April and September-October)	Once a year (90 days in June-September)	Quarterly (8 weeks in March, June, August and December)

*unless identification is based on harmonised classification and labelling and cannot be challenged in this context

Identification and prioritisation of SVHC

(Jan-Karel Kwisthout)



Application for Authorisation(AfA)



Purpose

- Allow the continued use of an SVHC, if
 - The risks are adequately controlled, or
 - The benefits of continued use are higher than the risks and there are no suitable alternatives for the applicant

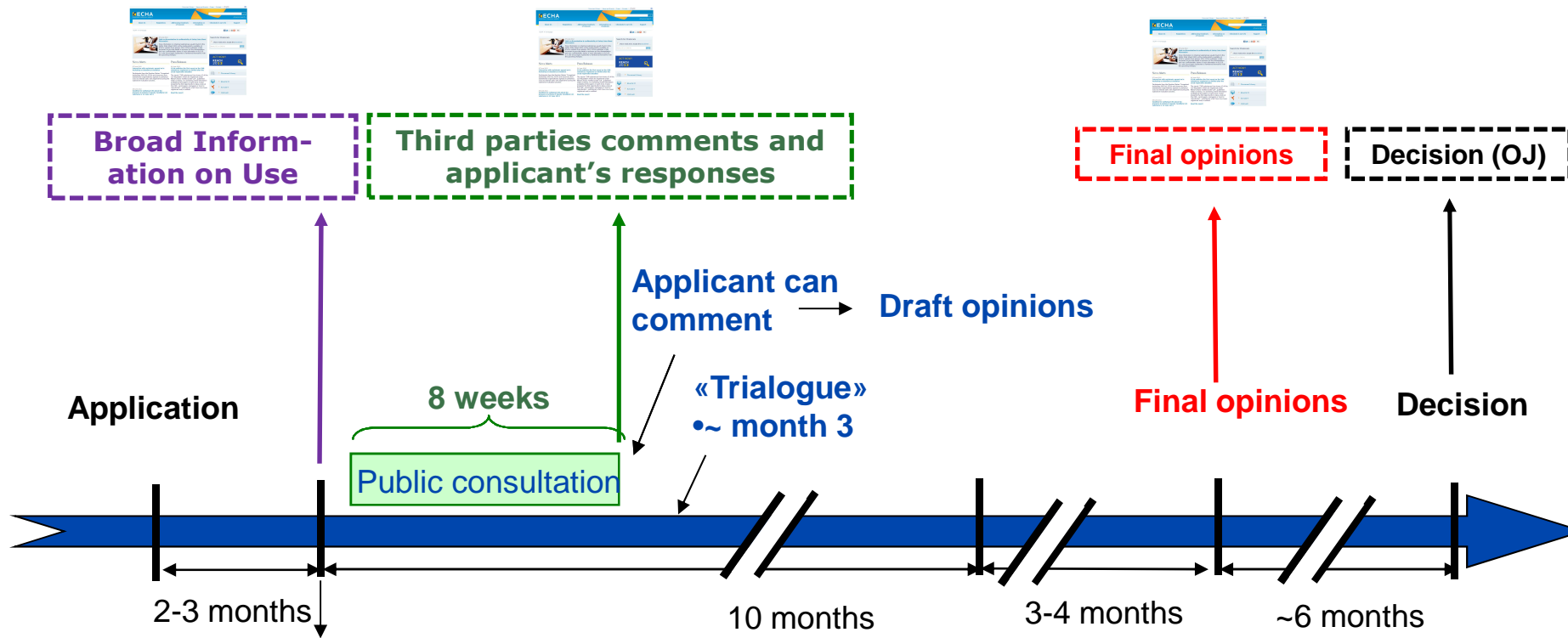
Obligations

- Application
 - from the manufacturer or the user of the substance
 - Exceptions: e.g. intermediate use
- Opinions of two scientific committees of ECHA
- Commission's decision
- Applicant to abide to the decision
 - Member States enforce
- If relevant, re-apply at the end of the "review period"

Critical information

- Description of use
 - Including how the substance is used (exposure scenario)
- Are risks adequately controlled
- If not, are the benefits of continued use higher than the (remaining) risks
 - ... and no suitable alternatives exist
- What about critical substances for certain uses?
 - An analysis of alternatives needs to be done
 - If this shows there are no alternatives available, the applicants are expected to have good arguments for continued use (based on Socio-economic analysis)
- Third parties give comments/information

Transparent, trustworthy and predictable process



**Invoice paid =
Date of receipt
(Art. 64(1))**

ECHA's committees develop opinions

Summary



Take home

- REACH Regulation replaced 40 directives and other legal instruments to modernise EU's chemicals regulation
- Main purpose is to protect human health and the environment and maintain the competitiveness of the EU economy
 - The purpose is not to "ban" the use of substances
- REACH runs smoothly
 - Commission's review confirmed this
- Current highlights
 - Second registration round has just ended; first applications for authorisation arriving; SVHC Roadmap to 2020 issued by the Commission
- Close institutional collaboration between ECHA and its Committees, the Commission, Member States (including Council) and the European Parliament
- Specific issues identified warranting clarification, eg.
 - Aviation, maritime transport, critical raw materials

Discussion points



Issues for discussion

1. If critical raw materials are substances*) these need to comply with the obligation of REACH
 - For instance: If a substance causes cancer it does so irrespective of its criticality as a raw material
 - If a substance is of very high concern (SVHC), it needs to comply as well
 - All titles are applicable
2. Business interests and socio-economic aspects are well taken into account in REACH
 - Applicants for authorisation for SVHC need to demonstrate that they risks are adequately controlled or that the benefits of continued use are greater than the (remaining) risks
 - First applications are arriving
3. Critical substances for certain uses?
 - If no alternatives available, the applicants are expected to have good arguments for continued use

*) in the meaning of the REACH Regulation

Thank you!

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