Ministry of Infrastructure and the Environment

Chemicals Risk Management and Critical Raw Materials

Within Reach

A Member State's perspective from the Netherlands

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Dutch policy aims and objectives for REACH

- Achieving International policy targets on sustainability for manufacturing and use of chemicals
- **Making REACH** work as part of **green growth**
- Continuity, reliability and predictability are essential
- REACH is as good as the quality of registration dossiers.
- Continued need for all actors to co-operate
- Reduction of costs and bureaucracy where possible
- Remain output oriented and make achievements visible

- What about Critical Raw Materials?

Dutch Policy on Critical Raw Materials

http://ec.europa.eu/enterprise/policies/raw-materials/documents/index_en.htm#h2-5

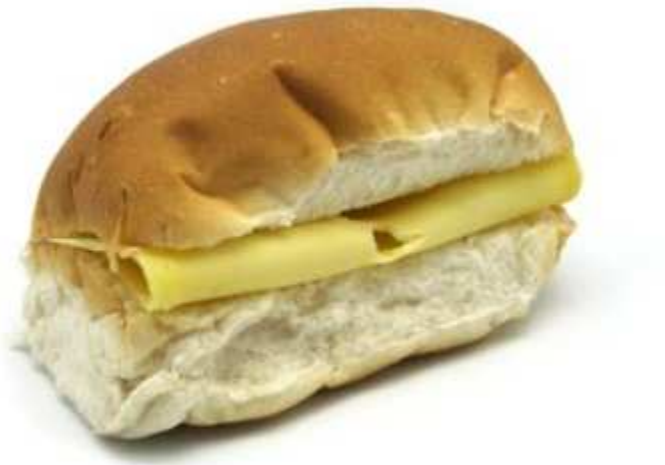
Three agendas

1. Supply, demand and scarcity in a Global Multipolar Economy
2. Sustainability
   - Secure an increase supply and improve sustainability of supply
   - Limit demand and where possible improve sustainability thereof
3. Improve sustainability and efficiency of Raw Materials consumption

Strategic approaches and actions

- REACH & CLP are basic requirements and not impediments

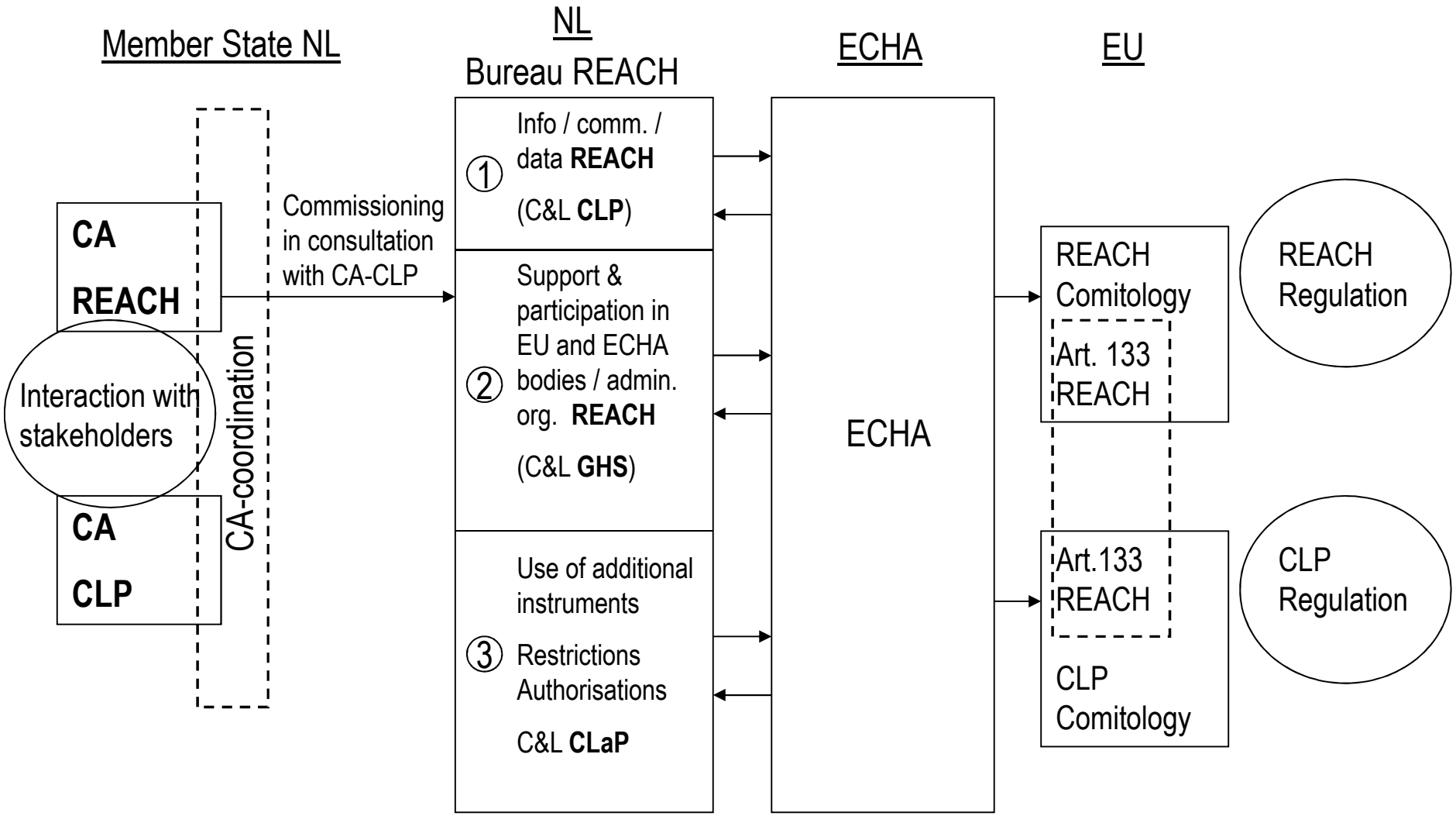
ECHA



Organisation in EU

Co-operation between
- EU Commission
- ECHA
- EU Member States
- Stakeholders

Organisation in NL for REACH and CLP



Regulatory relevance for Critical raw materials

- Classification, Labelling and Packaging (CLP)
  - CLH
- REACH
  - Restrictions
  - Evaluations
  - Roadmap SVHC
  - Authorisations

- Key issue is Identification and Priority Setting for SVHCs

Focus on Authorisation and SVHC Roadmap to 2020

- Critical Raw Materials are in REACH chemical substances to which regulatory schemes apply fully
- SVHC Roadmap
- Purpose and implementation
  - RMO-analysis
  - Candidate listing
  - Prioritisation
  - Decision making
  - Transparancy and Consultation
- Authorisation as explained by Matti Vainio.

Identification and Priority Setting of SVHCs

- 2010: Vice-President Tajani and Commissioner Potočnik publicly committed to "have a candidate list of 136 Substances of Very High Concern by the end of 2012 "
- Currently :138

  "have all relevant currently known SVHCs included in the candidate list by 2020"
- August 2012: Commissioners restated this commitment and underlined the will to continue working with Competent Authorities to develop a roadmap by the end of 2012
- Roadmap "should build on the RMO framework, setting out clear milestones, deliverables and division of work between the Commission, Member States and the European Chemicals Agency"

Roadmap and Implementation plan

- Council (Competitiveness 18-19 Feb; Environment 21 March)
- ECHA Workshop (17-18 April) towards implementation
- First draft implementation plan (juli 2013?) under construction

Key features

- Collaboration of all actors needed (Commission, ECHA and Member States) to make the implementation a success.
- **No numerical targets of substances that will be included in the candidate list**
- Developing a predictable and credible process to ensure the 2020 objective: defining a process or methodology, with clear deliverables, planning and share of responsibilities.

Predictability accountability and transparency

Communication recommended in all steps below

A. National or EU policy priorities
B. Informal data collection (screening)
C. RMO analysis
D. Policy intentions (incl. ROI)
E. Formal data collection and preparation of dossier
F. Submission of SVHC dossier
G. ECHA process of consultation and decision making
H. Start of prioritisation process
I. ECHA process of consultation and decision making
J. Comitology on inclusion in Annex IV

What is not a "relevant" SVHC by 2020?

Indications in the Roadmap:

- SVHC that is not registered is not a priority (some exceptions possible in the Roadmap, e.g. category approach)
- SVHC that has been registered as intermediate only is not a priority (but enforcement actions *(cf. intermediate) if appropriate and some exceptions possible in the Roadmap, e.g. category approach)*
- SVHC that fulfils the conditions of art. 69(1): if its use(s) pose(s) a risk to human health and environment that is not adequately controlled, a restriction process should be started (second step: SVHC for remaining uses)
- SVHC with (all) uses already regulated by specific EU legislation that provides a pressure for substitution or (all) uses exempted from the authorisation (see article 5, 56 or 60)

Role of the RMO

- The RMO is the key step in the process of defining the "relevance" of a substance
- It should be built on a screening exercise aimed at identifying substances that, on the basis of the registration dossiers, do not fulfil the first 2 criteria (registered + intermediates) (for example CMR substances used as intermediate only)
- The RMO assessment is made for listing substances resulting from such screening
- transparency / accountibility on RMO outcomes

Why this approach?

- Substitution may
  - take considerable time or its successfulness may be unpredictable
  - cause loss of certain services / functions provided by substances
  - be costly to part or whole supply chain or to society as a whole
- ➢ Candidate Listing and Annex XIV inclusion
  - ➢ Informs industries and allows it to prepare
  - ➢ Evens out the workload (authorities and industries)
- ➢ Authorisation application and granting system
  - ➢ allows continued use where justified
  - ➢ provides a mechanism to take costs (and level of risk) into account

  while placing the burden to justify the need for continued use on industry

Reasons for concern?

- Applications and decisions for authorisation fully consider:
  - Availability and viability of alternatives
  - Costs to the whole supply chain
- Why there still seem to be concerns by industry and authorities? .....uncertainty?

•lack of trust on how well the system will function

•how balanced will considerations be taken on board

  - ➢ First application for authorisation (AfA) cases crucial,
  - ➢ Concerns should reduce in near future

Taking into account...

- Societal and economic consequences can (obviously) be relevant for decision making
- The system is designed in such a manner that concerns are addressed in a way that respects
  - The objectives of REACH with regard to SVHCs
  - The design of authorisation process in Title VII and of other REACH processes
  - Reversed burden of proof
  - Principle of proportionality

Why an SVHC Roadmap?

- Relatively high number of substances (may) fulfil art 57 criteria and be ‘relevant’ (as defined in the Roadmap)
- Processing the substances (technical work) requires resources from authorities
- Substitution (and authorisation application) requires resources from industry
- Available resources do not allow all substances be included in one go

➢ Roadmap is to agree on priorities for the work: in which rough order to process (groups of) substances

Prioritisation

- All substances in the Candidate List are subject to prioritisation by ECHA and eventual inclusion in Annex XIV
- There may be reasons as to why substitution is not the wished outcome for a specific (groups of) substances
- Those substances should not be included in the Candidate List (not ‘relevant’)

➢ Roadmap is to enhance common understanding of the main principles: how and when we should include substances in the Candidate List

Prioritisation

ECHA prioritises substances from the Candidate List based on i.a.

- Rough proxy for exposure
- Volume within the scope of authorisation
- Indication that the uses 1) take place at several sites and 2) may result in not insignificant exposure (wide dispersive use)
- PBT/vPvB substances have higher priority
- Expected workload

Data used:

- Registration data
- Information from SVHC identification dossiers
- Public consultations

What prioritisation is not

≠ (Quantitative) Exposure Assessment

≠ Risk Assessment

≠ Assessment of Alternatives

≠ Socio-Economic Assessment

What it is

Recommendation which substances to be brought forward first!

REACH and Criticality

- Is it justified to perceive basics of Chemicals Management as regulatory risks?
- Some sectors may require specific clarifications (aviation, Critical Raw Materials, Maritime activities, oil and gas exploration, shale gas, bio-based economy)
- Incentive for sustainability and innovative solutions
- Incentive for circular economy, resource efficiency, recycling and sustainable use of scarce materials:
- REACH allows for doing justice to technical and/or socio-economic criticality provided that risks are
  - Adequately controlled
  - Managed appropriately and effectively

Future developments and challenges

- Need for more integral Waste/REACH strategy which goes above the individual substance or recycing perspective
- Inclusive policy making rather then exclusivity for specific areas
- No indications that REACH and CLP are impediments to innovation and green growth!
- Key Enabling Technologies are vital for EU but must be approached inclusively with REACH and CLP as pre-condition.

Continued

- Candidate listing and authorisation provisions have led to first effects towards substitution of SVHCs through the supply chain
- Need for further explanation of aims and functioning of different steps in the process to increase understanding and predictability
- Common understanding, acceptance and best use of the authorisation procedure is a key for this system to function as it was meant

To consider…….

- In as far Critical raw Materials are chemicals that fall within scope of REACH, the regulatory schemes apply fully and are basic preconditions for safe use.
- Being identified as SVHC ultimately aims for substitution but it's OK to apply for an authorisation
- The Analysis of Alternatives is to demonstrate what efforts have been made to assess potential for transition to alternatives
- REACH processes fully and adequately take into account criticality
- REACH/Authorisation is new for all parties (potential applicants, third parties and MSCA's and ECHA) so we are "learning by doing"
- Communication, pragmatism and sharing of experiences are key
- Being identified as SVHC, or even prioritised for authorisation should not hamper innovation and KETs, nor should it be detrimental to market developments and strategies.