# European Perspective on Alternatives Assessment — Recent Actions

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# Outline

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   - REACH and CLP regulations and ECHA
2. Alternatives analysis requirements under REACH
3. Lessons learnt from recent actions
   - experience on authorization and restrictions
   - implications going forward
4. What is needed in the future?
5. Opportunities for greater international collaboration
6. Take home

# 1. Introduction

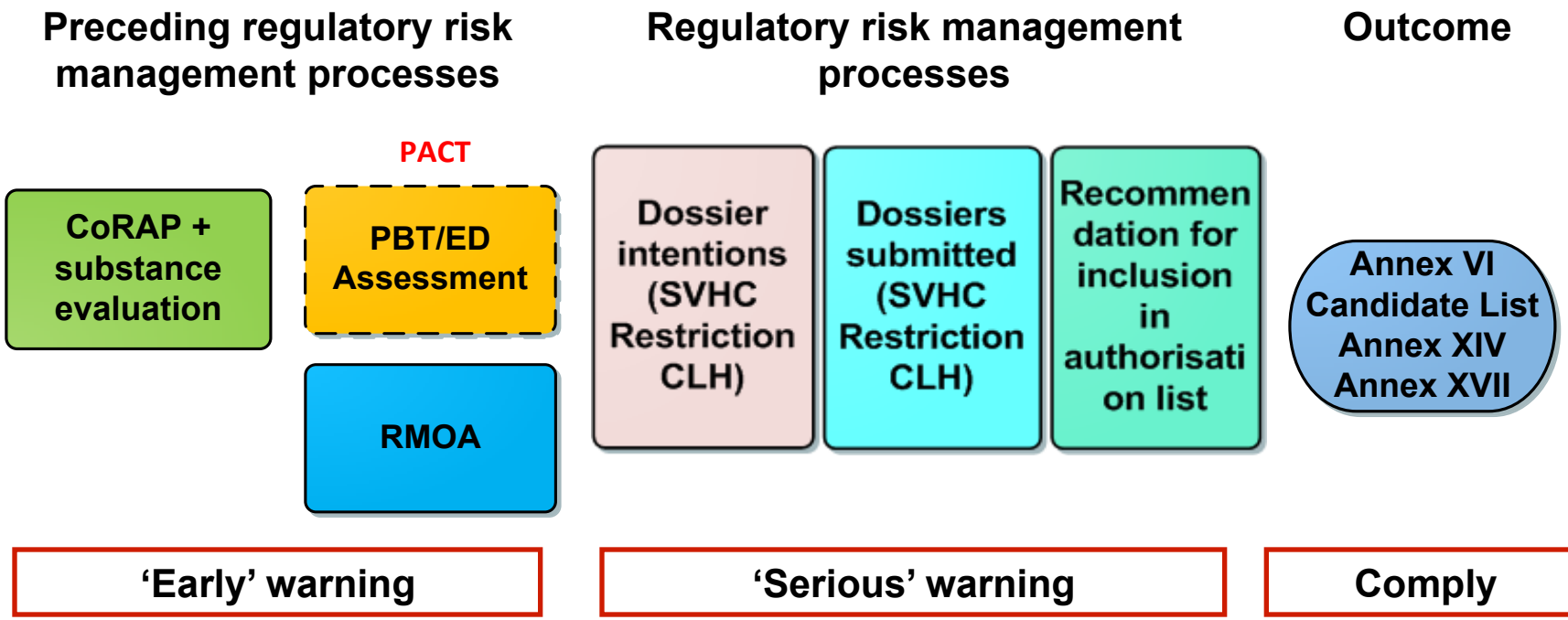
- Registration, Evaluation and Authorisation of Chemicals (REACH) requires companies to Register and evaluate chemicals
  - "no registration, no market"
  - ECHA evaluates registration dossier, Member States can evaluate "substances"
- Several ways of managing the risks
  1. Classification, Labelling and Packaging (**CLP**) Regulation
  2. Authorisation process under REACH for Substances of Very High Concern (**SVHC**)
  3. Restriction process under REACH
  4. Other European Union wide legislation (not here), eg
  - POPs Regulation, Workers' protection legislation, Industrial Emissions Directive
  - Vehicle type approval directive (e.g. Vehicle air conditioner refrigerant has to have Global Warming Potential under 150: HFC-134a cannot be used in the EU)
- EU regulations are compatible with World Trade Organisation
  - They affect also US producers that export to the EU (but even in the US)

# Risk Management in CLP and REACH

- Community Rolling Action Plan (CoRAP) and evaluation of 201 substances
  http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table
- Public Activities Coordination Tool (PACT) of SVHCs – currently 111 substances
  http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-implementation-plan/pact
- Registry of Intentions (48 CLH, 3 restriction and 173 SVHC entries)
  http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/registry-of-intentions
- Harmonized Classification (Annex VI) of 4180 entries*)
  http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/harmonised-classification-and-labelling/annex-vi-to-clp
- ECHA's Candidate List of 151 substances
  http://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles-table
- ECHA's Recommendations of 66 substances
  http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list
- EU's Authorisation List (Annex XIV) of 31 substances
  http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list
- ECHA received 28 applications for 56 uses, EU approved 2 applications for 2 uses
  http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/received-applications
- EU's Restrictions (Annex XVII) (105 entries)
  http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/restrictions/list-of-restrictions

*) 4430 unique harmonised substances and 89 open group entries

# Regulatory Risk Management activities encourage substitution




EU (European Commission with Member States and the Parliament) approves **Annexes**
ECHA publishes the **Candidate List**

# 2. Alternatives analysis requirements under REACH

- Requirements are gradual
  - Anticipatory
    - Registration (Chemical Safety Report)
    - Substance evaluation
    - PACT
    - Candidate List
    - Classification
  - Required from applicants, if they wish to continue to use a substance of very high concern
    - Authorisation
- Mandatory to use alternatives, if restricted
  - Required from EU Member States or ECHA

# 3.1 Lessons learnt: Authorization

- Conclusion of Lessons Learned conference of 10-11 February 2015: "Authorization system works"
- The system is new, all are learning
  - Applicants, ECHA (including its Committees on Socio-economic Analysis and Risk Assessment), the Commission, EU Member States and stakeholders (including NGOs)
- Applicants have done a thorough job
  - Analysis of technical and economic feasibility of alternatives with links to socio-economic impact of not getting an authorization
    - Some have done this in an excellent manner, some less so
    - All cases on ECHA's website (currently 28 applications for 56 uses)
- Risks have been reduced during the application process, e.g.
  - Sasol-Huntsman (Germany) (benchmarked on the US plants), Yara (France) improved the process
- Firm's preparation costs down considerably (>30%) from 2013

# 3.2 Lessons learnt: Restriction

- Restriction system itself is old but REACH changed the institutional setup
  - EU Member States or ECHA have to make a full analysis
  - New to many
- Member States and ECHA have analyzed the alternatives
  - Analysis of the technical and economic feasibility of alternatives and linked this to the socio-economic impact if a restriction takes place
    - Varied quality in the analysis
- ECHA will help EU Member States in dossier preparation
- **Ne**twork of **R**EACH **S**ocio-economic Analysis and **A**nalysis of Alternatives **P**ractitioners (NeRSAP)
  - A platform to exchange experience and learn from one another
  - Also open for firms and consultants

http://echa.europa.eu/support/socio-economic-analysis-in-reach/network-of-reach-sea-and-analysis-of-alternatives-practitioners

# 4. What is needed in the future?

- Better knowledge of alternative substances and techniques
  - Technical performance / indirect costs
  - Direct costs of substitution
  - Risks of Alternatives
  - ECHA facilitates (e.g. through NeRSAP)
- Better knowledge of substances used
  - Monitoring, if substitution works (ECHA works on this)
- Good incentives for efficient and affordable use of alternatives
  - Reduce market uncertainty
  - Competitive pressure: EU operates in an open market
  - In practice, make the application for authorisation process work in a "fit-for-purpose" manner

# 5. Opportunities for greater international collaboration

- Data sharing on chemical hazards and alternatives
  - Global Portal to information on Chemical Substances (eChem portal) http://www.echemportal.org/echemportal/participant/participantinfo.action?participantID=140
- Tools, methods and approaches
  - OECD Substitution of Harmful Chemicals (Toolbox, principles of alternative assessment) http://www.oecdsaatoolbox.org/Home/Index
- Events: seminars, webinars, teleconferences (ECHA-EPA)
- Provide input during public consultations
- Ensuring that risks are not shifted
  - Analysis of Alternatives and Socio-economic analysis look at the markets both in the EU and the world
  - WTO notifications of restrictions

# 6. Take home

- REACH Registration process gives incentives to substitute
  - Better information flow in the supply chain
- Classification and PBT assessment reinforces this
  - Substances and mixtures are restricted from consumers
- REACH Substance evaluation and PACT give ‘early’ warnings
- Adding a substance to the Candidate List gives a ‘serious’ warning
- Requiring REACH authorization creates the legal obligation to
  - make an analysis of alternatives and
  - demonstrate that an authorization is needed
  - 31 substances are on this list
- REACH Authorization system is working well
  - Substitution is not necessarily visible, though
  - To date 28 applications for 56 uses have been made
- EU Member States and ECHA carry out analysis of alternatives
  - For substance which are proposed to be restricted under REACH
- Many any other legislative acts in the EU require substitution

# Thank you!

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