Lowell Center for Sustainable Production
UNIVERSITY OF MASSACHUSETTS LOWELL

Update on Alternatives Assessment Under Reach

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** If you would like to ask a question or comment during this webinar please type your question in the Q&A box located in the control panel.*

Purpose of this call

- REACh requires alternatives assessment as part of the Authorisation process and in the context of restrictions proposals
- Dozens of assessments have now been completed as part of both sections of REACh
- A number of lessons can be taken to inform substitution efforts moving forward

Speakers

- Sanna Henrichson, European Chemicals Agency, Socio-economic analyst

Webinar Discussion Instructions

- Due to the number of participants on the Webinar, all lines will be muted.
- If you have a question or comment, please type it in the “Questions” box located in the control panel
- All questions will be answered at the end of the presentations.

Update on alternative assessment under REACH

Webinar

14 March 2016

Sanna Henrichson
Socio-economic analyst
Risk Management Implementation Unit
European Chemicals Agency

Outline

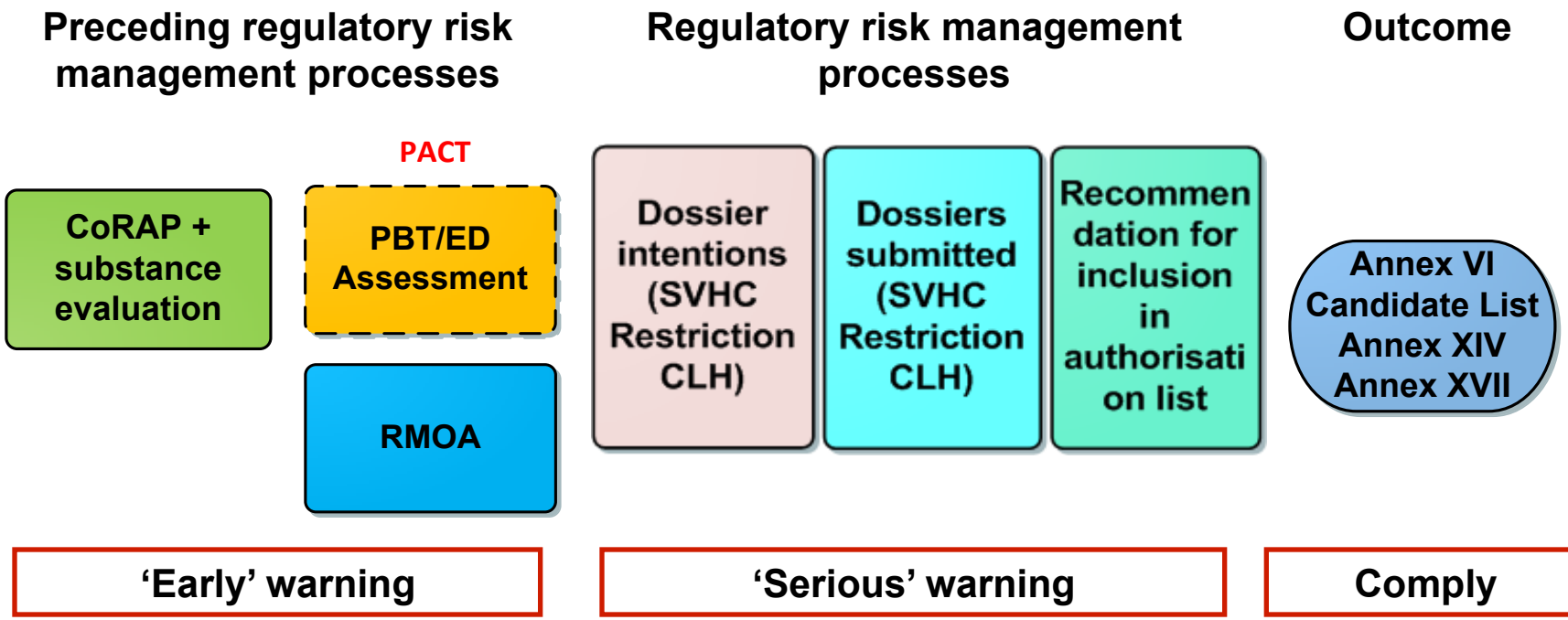
- REACH and substitution
- Analysis of alternatives in applications for authorisation
- Experiences so far
- Developing the science of analysis of alternatives
- Take home

REACH and substitution

REACH, CLP and substitution

- REACH and CLP promote substitution activities by their very design
- They provide a suite of tools that will push companies to search for and move to safer alternatives
  - directly (e.g. Restriction, Authorisation)
  - indirectly (e.g. CLP, Registration, eSDS, communication along supply chain)
- Increased accountability of downstream users and better public information will create a strong demand for substitutes
- Developing new and safer chemicals will also stimulate innovation and will hence support the competitiveness of the European industry

Regulatory Risk Management activities encourage substitution



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

Authorisation and substitution

- Candidate List of substances of very high concern: strong signal for substitution and legal obligations
- Authorisation list (Annex XIV): second signal
- Allows companies to apply for an authorisation for a continued (or new) use of an SVHC
- Applications for authorisation: require analysis of alternatives
- Public consultation on alternatives + 'trialogue'
- Authorisation subject to time-limited review → pressure to substitute

Aim of Authorisation

Authorisation aims to ensure that:

- the risks from substances of very high concern are properly controlled and
- that these substances are progressively substituted by alternative substances or technologies
  - where these are economically and technically viable whilst
  - ensuring the good functioning of the internal market

Restrictions under REACH

- Restrictions may limit or ban the manufacture, placing on the market or use of a substance
- Restriction proposed by Member States or ECHA
- Comprises an analysis of alternatives
- Similar elements to Analysis of Alternatives under applications for authorisation
- Depth of the analysis depends on the decision of the dossier submitter

Analysis of alternatives in applications for authorisation

Structure of an analysis of alternatives in AfA

- Analysis of substance function
- Annual tonnage
- Identification of possible alternatives
  - List of possible alternatives
  - Description of efforts made to identify possible alternatives
  - Research and development
  - Data searches & consultations
- Assessment of the suitability and availability
  - Substance ID and properties
  - Technical feasibility
  - Economic feasibility
  - Reduction of overall risk due to transition to the alternative
  - Availability
- Overall conclusions on suitability and availability of possible alternatives
  - Including required actions and timescales to make possible alternatives suitable and available

Tips for a good analysis of alternatives

- The analysis of the existing alternatives should be based on the applicant's context, in terms of technologies, markets etc.
- Descriptions of technical functions in Analysis of Alternatives should be concise and meaningful for non-experts
  - Consider a broad range of chemical and technological alternatives to identify best-in-class options to achieve the required function
- Briefly describe any shortlisting criteria and process
  - No need to list thousands of substances – importance of screening
  - Equally or more hazardous alternatives in general should not be shortlisted
  - Include alternative substances and technologies used by competitors
- The economic feasibility assessment can be based on typical costs within a sector. Detailed specifications for new plants are not required.
- Describe your substitution efforts to substantiate the requested review period

Experiences so far

Statistics on received applications

Substance	Number of received** AfAs	Number of uses	RAC-SEAC Draft opinions per use (per use and applicant)	RAC-SEAC Final opinions per use (per use and applicant)	Commission decision (per use and applicant)
Phthalates	8	17	17 (21)	17 (21)	5
Lead chromate pigments	1	12	12 (12)	12 (12)	
HBCDD	1	2	2 (26)	2 (26)	26
Diarsenic trioxide	4	5	5 (5)	5 (5)	5
Trichloroethylene	13	19	19 (21)	19 (21)	2
Lead chromate	1	1	1 (1)	1 (1)	
EDC	2	2	1 (1)	1(1)	
Chromium VI substances	29	47	2 (3)	2 (3)	
Diglyme	1	1			
Arsenic acid	1	1			
Total:	**61**	**107**	**59 (90)**	**59 (90)**	**38**

Status on 01/03/2016; ** Fee paid

Applications for authorisation

- New process – still learning
- It is working!
- Gives pressure to substitute
  - Recognises the trade-off between substituting and continuing using the substance
- Predictable
  - a well documented case will get an authorisation

Real cases of analysis of alternatives

- REACH brings real cases of analyses of alternatives (AoAs):

  Applications for authorisation: ~100 AoAs

  http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations

  Restrictions: ~18 AoAs

  http://echa.europa.eu/web/guest/previous-consultations-on-restriction-proposals

- One of the largest single source of AoA in the world
- Quality of analysis naturally varies
- ECHA highlighted a few examples of best practices of AoA and SEAs: http://echa.europa.eu/support/socio-economic-analysis-in-reach/examples-of-sea-and-analyses-of-alternatives

Indicators that substitution actually happens

- Applications for authorisation:
  - no application has been submitted for one third of Annex XIV substances with passed latest application dates
  - industry feedback that they will not apply because they found an alternative
  - ~ 50% of the received applications are ‘bridging applications’ (i.e. requesting time to switch to an identified alternative)

Meta-analysis of socio-economic benefits and risks

- Based on SEAC opinions adopted until January 2016 covering 30 uses of carcinogenic substances.
- Many applicants based assessment of socio-economic benefits on the costs that would arise if an alternative was adopted. Others claimed that refused authorisation would lead to shutdown or relocation of production.
- Risk was assessed in terms of the welfare burden stemming from human health impacts.

Results of meta-analysis

	Lower-bound estimate	Upper-bound estimate
Quantity of Annex XIV substances used per year	6 350 tonnes	8 330 tonnes
Benefits per year	325 million €	338 million €
Risks per year **…Monetised** **…Illustrative statistical cancer cases**	3.4 million € 2.9	6.6 million € 5.5
Net benefits per year	319 million €	335 million €
Benefit-risk ratio	49	98

Developing the science of analysis of alternatives

ECHA's current activities on substitution and AoA

- Project "Improving the Analysis of Alternatives and practical ways of promoting innovation and substitution in the EU" with University of Massachusetts Lowell
- Work on substitution and economic feasibility of alternatives
  - abatement costs
  - studies on cost & benefits of authorisation

At international level:

- OECD *ad hoc* Group on the Substitution of Harmful Chemicals: projects on analyses of alternatives
- "*Advancing alternative assessment*" research project of University of Massachusetts Lowell

Take home

- REACH Substance evaluation and PACT give ‘early’ warnings of substances of potential concern. Get prepared for substitution!
- REACH Authorisation works well
  - Builds up experience on assessment of alternatives
  - Substitution is not necessarily visible, though
- EU Member States and ECHA also carry out analysis of alternatives
  - For substance which are proposed to be restricted under REACH
- Over 100 AoAs available on ECHA’s website
- Public consultations on alternatives: input from experts in the use of the substance is very valuable and should be encouraged
- Identification of best practices in performing AoA under development

Thank you!

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Discussion

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Thank you for joining us!

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