Lowell Center for Sustainable Production
UNIVERSITY OF MASSACHUSETTS LOWELL

Alternatives Assessment 125 Webinar:

Alternatives Assessments Under REACH: Lessons Learned

FEBRUARY 26, 2015

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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.*

Goals

- Continuing education and dialog

- To advance the practice of alternatives assessment for informed substitution across federal, state, and local agencies through networking, sharing of experiences, development of common approaches, tools, datasets and frameworks, and creation of a community of practice.

Purpose of this call

- The European Union and its Member States have a long history in chemical substitution efforts in occupational and environmental settings.
- REACH requires that companies seeking authorizations for Substances of Very High Concern conduct alternatives assessments as a pre-condition of continued use while exploring suitable alternatives.
- This webinar examines the experience of the European Chemicals Agency (ECHA) with the alternatives assessment process to date and provides perspectives from a company preparing alternatives assessment and a European non-governmental advocacy organization on the process.

International Symposium on Alternatives Assessment

Advancing Science & Practice

NATCHER CONFERENCE CENTER | BETHESDA, MD | MARCH 5–6, 2015

Organized by The Lowell Center for Sustainable Production at UMASS Lowell

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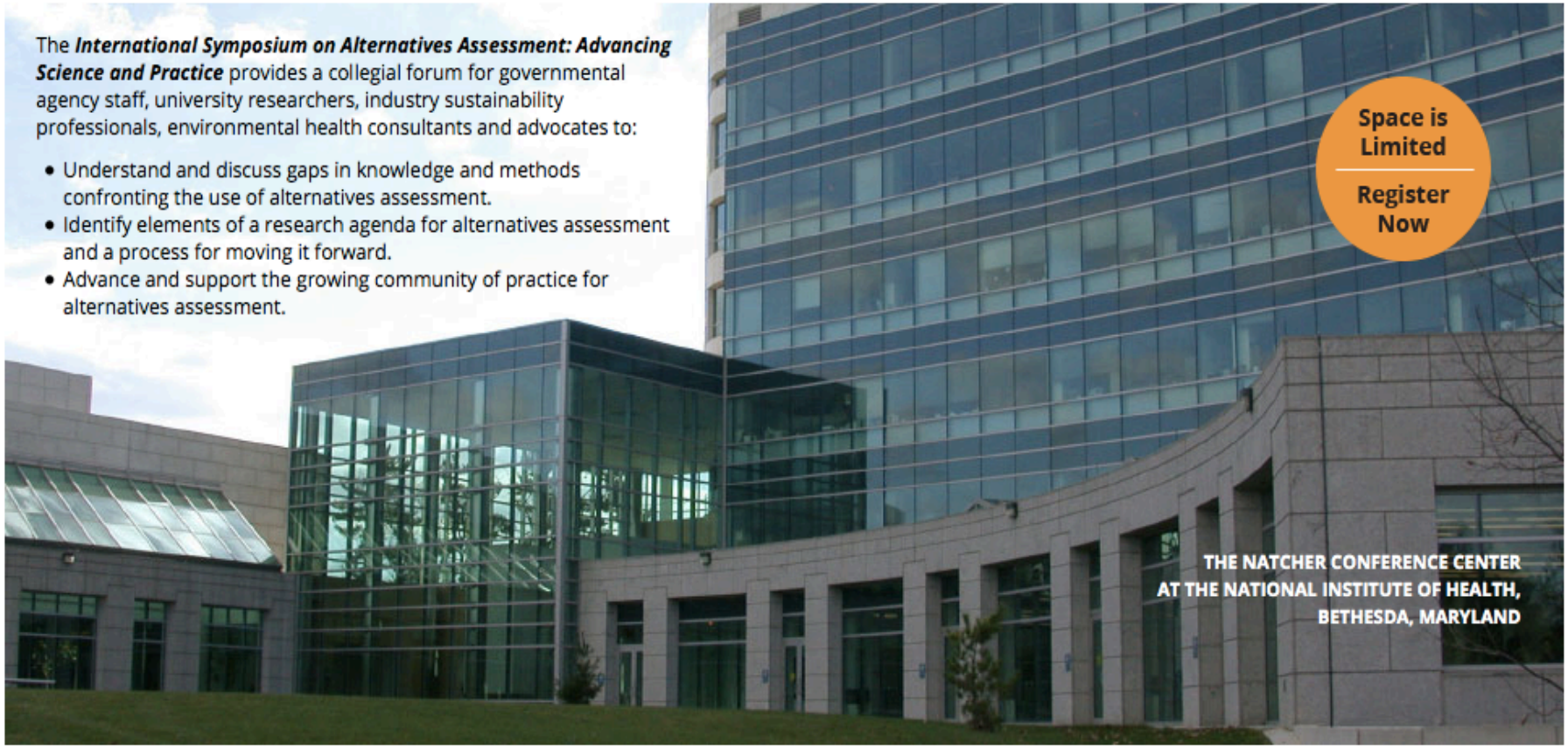
The ***International Symposium on Alternatives Assessment: Advancing Science and Practice*** provides a collegial forum for governmental agency staff, university researchers, industry sustainability professionals, environmental health consultants and advocates to:

- Understand and discuss gaps in knowledge and methods confronting the use of alternatives assessment.
- Identify elements of a research agenda for alternatives assessment and a process for moving it forward.
- Advance and support the growing community of practice for alternatives assessment.



To view program and to register visit: www.saferalternatives.org

Speakers

Theirry Nicot and Denis Mottet, European Chemicals Agency

Julius Waller, EPPA

Tatiana Santos, European Environment Bureau

Discussion Questions

- What are the key lessons learned by ECHA in undertaking some of the first regulatory alternatives assessments globally?
- What are the strengths/weaknesses of the assessments received to date?
- What improvements can be made to the process so that it more effectively stimulates informed substitution?

Authorization consultations

- http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations
- http://echa.europa.eu/view-article/-/journal_content/title/conference-on-lessons-learned-on-applications-for-authorisation

Webinar Discussion Instructions

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- Due to the number of participants on the Webinar, all lines will be muted.
- If you wish to ask a question, please type your question in the Q&A box located in the drop down control panel at the top of the screen.
- All questions will be answered at the end of the presentations.

Analysis of alternatives under REACH Authorisation

Webinar

26 February 2015

Thierry Nicot / Denis Mottet
Risk Management Implementation Unit
ECHA

Outline

- Introduction
  - REACH, CLP regulation, ECHA, and substitution

- Applications for Authorisations and Analysis of Alternatives: lessons learnt from the first AfAs

REACH, CLP regulation, ECHA, and substitution

How ECHA contributes to promote substitution?

- ECHA does not carry out direct substitution work or give direct advice
- ECHA's task is to make REACH and CLP work to ensure safe use of chemicals and promote substitution:
  - Dissemination of information on registered/notified substances
  - Support implementation of effective risk management advice in the supply-chain
  - Support authorities in identifying problematic substances that need regulatory action
  - Promote active participation of third parties in public consultations
- Industry is the actor actually substituting

REACH, CLP and substitution

- REACH and CLP promote substitution activities by their very design
- They provide a set of tools that will push companies to move to safer alternatives
  - indirectly (e.g. CLP, Registration, eSDS, communication along supply chain)
  - directly (e.g. Restriction, Authorisation)

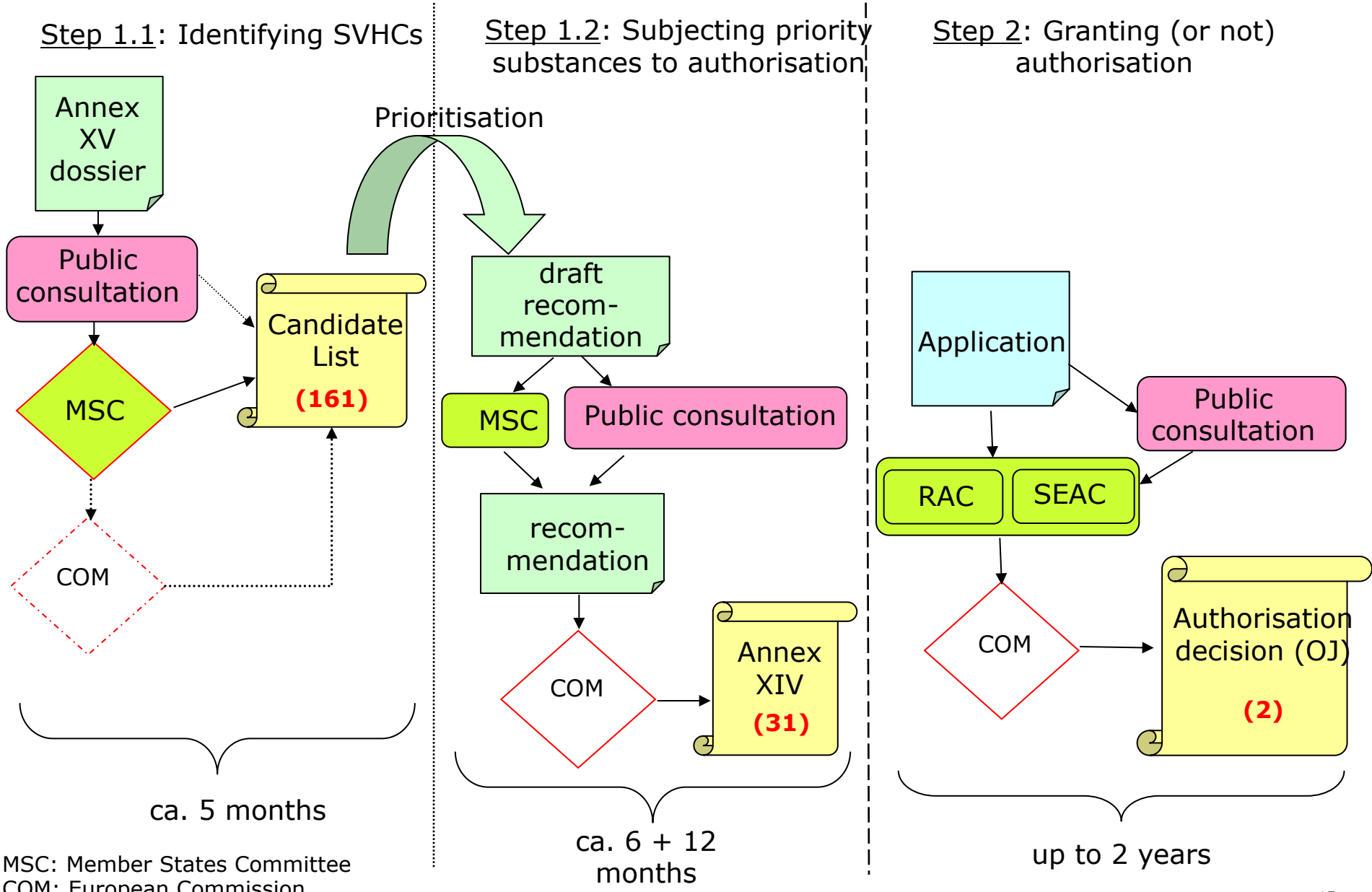
- Increased accountability of downstream users and better public information will create a strong demand for substitutes
- Developing new and safer chemicals will also stimulate innovation and support the competitiveness of the European industry

Authorisation

Aim is 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

The authorisation overall procedure



MSC: Member States Committee
COM: European Commission

Authorisation

- Candidate List of substances of very high concern (SHVC): 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
- AfA: requires analysis of alternatives
- Public consultation on alternatives + trialogue
- Subject to time-limited review → pressure to substitute

Applications for Authorisations and Analysis of Alternatives: lessons learnt from the first AfAs

Statistics

Substance	Number of received AfAs (applicants)	Number of uses	RAC/SEAC opinions	Commission decisions
			Per use and applicant	
DEHP	**5** (7)	10	11	1
DBP	**2** (2)	4	4	1
[DEHP + DBP]	**1** (1)	3	3	-
Lead chromate Yellow + Red	**1** (1)	12	12	-
HBCDD	**1** (13)	2	26	-
Diarsenic trioxide	**4** (4)	5	5	-
Trichloroethylene	**13** (15)	19	2	-
Lead chromate	**1**(1)	1	-	-
Total	**28** (44)	**56**	**63**	**2**

Analysis of alternatives

Applicants for authorisation need to provide a solid analysis of alternatives with the following main elements:

- 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 of the identified
  - 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

Analysis of alternatives: what we have seen so far

- Many applicants had done a thorough job in AoA, but…
- Identification of alternatives
  - Data sources sometimes unclear
  - Some did not explain
    - how the short-list of alternatives was derived
    - if the function of Annex XIV substance could be replaced
    - why some ”sub-uses” could be substituted while others not
- Assessment of alternatives
  - Time and resources required to transition to an alternative could have been clearer in some applications
  - Analysis of commercially available alternatives sometimes missing
  - When Manufacturer or Importer applied, they sometimes failed to provide a clear analyse of the technical and economic feasibility for DUs.
  - Reduction of overall risk: analysis generally addressing only the hazards, and substances with equal or higher hazard not considered further

Public consultations on alternatives

- Large variety of comments:
  - from 0 to 400 per application
  - risks, alternatives and socio-economic factors
  - 'quality' and relevance
  - submitted by competitors, DUs, authorities/universities, NGOs… from EU, USA, Japan…
  - ECHA to improve awareness raising and instructions/formats to get focused and meaningful comments
- Public consultation useful to capture any potential alternative not assessed in the application
  - Together with trialogues, useful to challenge applicant's assessment
- "Interactive"
  - comments were made public already during the consultation
  - possibility for applicants to respond

Is substitution actually happening?

- Yes but difficult to quantify for ECHA!
- When substitution is happening ECHA does not necessarily know it, e.g.:
  - ECHA knows the tonnages currently on the market but cannot compare with the situation 10 years ago
  - A substance initially planned by industry to be registered as >1000T/y but actually registered as 10-100T/y : is it due to (partial) substitution or inaccurate planning?
  - Some registered uses might have been abandoned in practice but the registration dossier not (yet) updated
- Currently: more visibility at the AfA stage only

Some indicators that substitution happens

- Applications for authorisation:
  - no application received by ECHA for ~ 50% of substances in Annex XIV 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)
- Press articles/conferences/websites giving concrete examples of substitution
- Etc.

Promoting substitution further

- ECHA is willing to further work on, promote and monitor/analyse substitution activities
  - Website
  - Webinars
  - OECD working group…
- Encouraging industry networks to contribute to the information exchanges on alternatives (vie e.g. public consultation on alternatives)
- Monitoring/analysis of substitution activities

Main conclusions of the AfA conference

- The AfA process works and provide pressure on industry to substitute
- While dossier drafting maybe less complicated than suggested, the process is too burdensome for some cases
- Need for more specific advice on what a fit-for-purpose dossier looks like
- Transparent and predictable… but room for improvement
- Get the balance right between generic upstream AfAs and specific DU ones
- Is the ultimate aim of progressively replacing SVHCs with safer alternatives still sufficiently addressed?

Useful links

- All submitted Applications for Authorisation and ECHA's scientific opinions: http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations

- AfA conference on lessons learnt (10-11 February 2015)
  - Presentations: http://echa.europa.eu/view-article/-/journal_content/title/conference-on-lessons-learned-on-applications-for-authorisation.
  - Conclusions: http://echa.europa.eu/documents/10162/21825501/afa_201502_18_hansen_de_bruijn_en.pdf

ECHA
EUROPEAN CHEMICALS AGENCY

Thank You!

Assessment of alternatives under REACH – a perspective from four applicants

EPPA's involvement in Alternatives assment

- Producers
  - ✓PY. 34 & PR.104 – AfA for DCC – SEA/AoA
    Use as pigment in coatings and plastics
- Downstream users
  - ✓As_2O_3 for Linxens : SEA/AoA
    Use as grain refiner in electroplating
  - ✓ As_2O_3 for Yara: SEA/AoA
    Use as processing aid in the absorbption and desorption of CO2 in the production of ammonia
  - Trichlorethylene: Roquette: SEA/AoA
    Use as processing aid in the enzymatic production of Beta-Cyclo dextrin for HPBCD excipient

Disclaimer

Main considerations for AoA as an applicant

REACH drives substitution but….

- AoA is basis of SEA non use scenario
- CMRs use already very penalising so remaining uses tend to have been analysed
- Application is made from the perspective of the applicant
- Thinking behind REACH AoA was simplistic, the world is more complex
- AoA essential in case control of risk cannot be demonstrated

Diarsenic trioxide as a grain refiner – straightforward AoA case of a DU

- Linxens France produces flexible micro-circuitry
- Catastrophic late stage failure of 3Y substitution drive
- Key technical aspects
  1. Allow 20 nm gold plating with less than 10% variance
  2. Should enhance wirebonding
  3. No discoloration c.q. secondary quality issues
  4. Time needed for qualification/testing
- Source of alternatives
  1. Max. 5 suppliers with ca. 12 options all proprietary
  2. Academic literature very limited
  3. All alternatives needed to be tested inhouse and refined to function for Linxens

Alternative assessment - simple

Why they fail to pass muster?

- 2 discarded based on literature (Thalium)
- 2-3 showed obvious incompatibilities with the current process
- Early testing showed unacceptable loss of quality in 5 cases
- All remaining alternatives had serious secondary quality issues and discoloration
- None achieved gold plating of <34nm (yet)
- For none lifetime quality warrantee could be assured

Issues?

- Proprietary supplier substances of partially unknown composition → risk comparison impossible
- Speeded age testing and contractual obligations to customers also eliminated a ‘quick fix’

PY. 34 and PR. 104 – alternatives assessment

The choice of any pigment for any use involves a compromise of some kind

Criteria:

- 7 major technical function aspects
- 8 major sustainability considerations
- 5 major economic factors

Additional complications

- Very long value chain – final link decides pigment
- Use definitions very complex
- Single substitute never possible

Alternatives assesment of pigments (50+)

General approach

1. Combination of quantitative and qualitative assessment
2. Technical criteria – *three strikes you're out*
3. Sustainability/availibility criteria – case by case qualitative assessment
4. Economic considerations – primarily used for SEA

Challenges

1. 450+ responses to public consultation – 250+ supportive and ca. 35 hostile – only 2 week response time
2. *'He said/she said'* trialogue debate with BASF
3. Anger in industry over outing of sustainability and quality issues of potential alternatives

Outcome

Alternatives cannot meet needs for the uses for which authorisation was applied for

Other typical complexities in AoA (1)

Trichloroethylene in BCD production:

- Enzymatic chemistry
  1. Empiric rather than "*research*" based
  2. All options tested in 2003/6 were duds
  3. Main literature/academic development stagnant
- Main alternative: toluene
  1. Explosive substance incompatible with production site
  2. Use would cause major change in environmental permit of 400ha site
- Non-use scenario: purchase BCD in China
  1. Incompatible with company CSR policy to transfer risk to other countries of known lower protection
  2. Serious residue issues in China relevant for pharma
  3. Pharmacopeia requires re-homologation of meds

Other typical complexities in AoA (2)

Diarsenic Trioxide in Ammonia production

- BREFS/BAT a great help (!)
- Conversion to alternative only possible during major installation halt
- Original choice for amines discarded for Potassium Vanadate
- Redesign build bridging period 3 years

DEHP producer application

- Exemption for medical use DEHP – however volume too low to keep a site open – added volume needed
- DEHP (for one applicant) is a by product of a main process – AoA completely different
- Alternatives likely to be classified soon

Q&A

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Substitution under REACH authorisation - NGOs view

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Senior policy officer - Chemicals and nanotechnology

The European Environmental Bureau (EEB)

Authorisation under REACH

Aims that ***SVHC are progressively replaced by suitable alternative substances or technologies***...

REACH {Art. 55}.

- **MAIN TOOL FOR ELIMINATION/SUBSTITUTION OF SVHC**
- **Incentive for developing and using safer alternatives**
- **Authorizations should be an exception**
- **If granted: only for specific uses and for very limited time**

Authorisation process

- **ALL applications for authorization must submit an AoA** considering their risks and the technical and economic feasibility of substitution
- **Authorizations are time-limited** and would be accompanied by **substitution plan.**
- **Review period**: applicant shall submit an **update of any substitution plan**.
  - If risk is not adequately controlled, update of the SEA, AoA and SP.
  - If risk is adequately controlled: update CSR.

Furthermore: **Authorizations may be reviewed at any time** if:

- (a) **the circumstances of the original authorization have changed** so as to affect the risk to human health or the environment, or the socio-economic impact; or
- (b) **new information on possible substitutes becomes available**.

Gathering alternatives info

Transparent decision-making

Stakeholders invited to Committees plenary discussions

Public consultation on alternatives

Information on available alternatives is gathered

Trialogues

Interested parties invited to discuss with the applicant

NGOs analysis of the process

Is authorisation delivering? YES!

Applications not submitted for half of the substances included in Annex XIV with application deadline expired

Public consultations, have provided new information on alternatives not considered by applicants and showing the technical & economic feasibility of safer alternatives in the supply chain.

Substitution advancing for specific uses applied for

Improvements on risk management as a result of authorisation process: Applicants implementing RMM after deciding to submit applications. E.g. TCE (textiles) and As_2O_3 (ammonia).

Applications for authorisation

- **SCOPE:** use specific versus broad: bad quality of the information provided in applications for broad uses

SVHC	Nº uses and scope
DEHP	**6 broad** (PVC) + 3 specific
DBP	5 specific
Diarsenic trioxide	5 specific
Pigment yellow	**6 broad**
Pigment red	**6 broad**
HBCDD	**2 broad**
Trichloroethylene	**5 broad** + 17 specific

Chemical manufacturers applying for downstream users

Applications for authorisation

- **EXPOSURE:** not all downstream uses specifically described (broad use), exposure not sufficiently and correctly documented, risk not adequately calculated, lack real exposure data, mixture toxicity disregarded as well as other toxicological endpoints.

- **SOCIOECONOMIC ANALYSIS:** Limited information on benefits/costs for society, external costs/impacts not included

Applications for authorisation

ANALYSIS OF ALTERNATIVES:

- in general incomplete for upstream AfAs,
- no methodology is followed to implement in practice safer alternatives,
- not use-specific AoA (broad use),
- mainly drop-in chemical substitutes,
- too generic AoAs for specific DU uses that are covered by broad uses applied for,
- poor hazard assessment of alternatives: only 'official' classification info; other endpoints (e.g. EDC, neurotox) missing,
- assessment of costs of alternatives exaggerated,
- clear descriptions of substitution activities are lacking.

Recommendations to ECHA

- Encourage participation of interested 3rd parties;
- Provide guidance and technical support on how to implement safer alternatives
- Elaborate alternative assessment methodology
- Need to define “economic feasibility” of alternatives beyond ‘not more expensive’
- Better balance between costs for the applicant and external costs and frontrunners impacts associated with SVHC is needed

Conclusions

- Transition to safer alternatives should be encouraged, while increasing market opportunities for “green” companies and incentives for sustainable innovation
- ALL information on alternatives must be gathered in the process
- Downstream users play a key role (acceptability of alternatives, but also as drivers for innovation)
- Need for harmonised and comprehensive AoA methods
- Authorisations shouldn’t be granted for SVHC when alternatives are available!

Thank you for your attention!

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Discussion Questions

- What are the key lessons learned by ECHA in undertaking some of the first regulatory alternatives assessments globally?
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Next Webinar

May 2015

TBD