How SEAs have affected the opinions of SEAC

Workshop on SEA in AfA and restrictions under REACH

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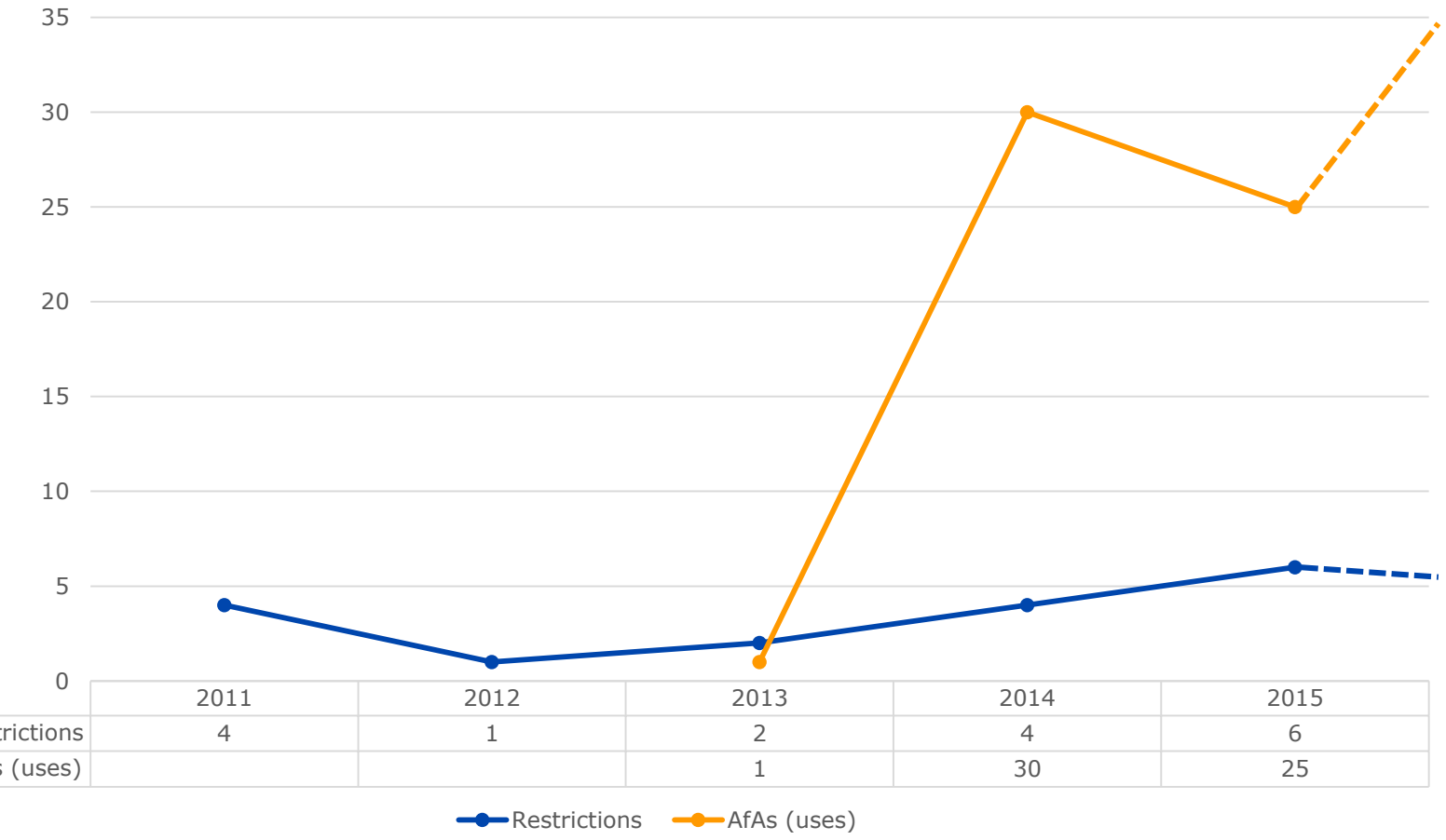
Outline

- Opinion-making process
- How SEAC evaluates SEAs
  - Interaction with RAC
  - Examples of past cases
- Limits of benefit-cost analysis
- Current challenges
- Concluding remarks

Why bother with SEA?

- REACH Regulation: Socio-economic analysis (SEA) *may* be included in restriction proposal or application for authorisation (AfA)
- SEAC *will* form an opinion on:
  - „the socio-economic impact" (restriction, Art. 71)
  - „the socio-economic factors" (AfA, Art. 64 (4) (b))
- Opportunity for dossier submitter or applicant to make their case that restriction/authorisation is socio-economically justified
  - SEA included in all dossiers so far

SEAC opinions adopted until 2015



	2011	2012	2013	2014	2015
Restrictions	4	1	2	4	6
AfAs (uses)			1	30	25

Opinion-making process

Restriction

- Conformity check
- 6 month public consultation on dossier
- within ~9 months: SEAC draft opinion
- 2 month public consultation on SEAC draft opinion
- within 12 months: final opinon

AfA

- Conformity check
- 2 month public consul-tation on alternatives
- Trialogue
- within 10 months: draft opinion
- 2 month commenting possibility for applicant
- within ~14 months: final opinon

Opinions of SEAC

- Basis for the opinion: Dossier (all relevant parts), info submitted by third parties, other available information
  - Some info used in the opinion may not be found in the public dossier (e.g. confidential data, applicant‘s answers to requests for additional information)
- Opinion documents published by ECHA comprise preamble, opinion and justification
  - Important to read the document as a whole
  - Justification contains RAC, SEAC and joint sections
- Most opinions adopted by consensus
  - Lively debate on methodological issues but usually agreement on core conclusions and recommendations
  - Minority positions (if any) are published

Role of SEA

Restriction

- Comparison of reduced health or environmental risks (benefits) and costs of restriction
- May be used by dossier submitter to demonstrate that the restriction is "proportional to the risk" (Annex XV (3) (i))

AfA

- Comparison of benefits and monetised health or environmental risks (costs) of continued use
- May be used by applicant to demonstrate that the „socio-economic benefits outweigh the risk" (Art. 60 (4))

How does SEAC evaluate SEAs?

- Tasks of the rapporteurs: Reviewing the dossier, presenting the case to SEAC, drafting the opinion
  - Plenary discussion(s) and written commenting round(s)
  - Support and quality assurance by ECHA Secretariat
- Key steps of the evaluation
  - Check the appropriateness of the methods
  - Verify that all relevant impacts have been included
  - Scrutinise the data and the assumptions made
  - Check the calculations and the conclusions drawn
  - Verify robustness of conclusions against uncertainties

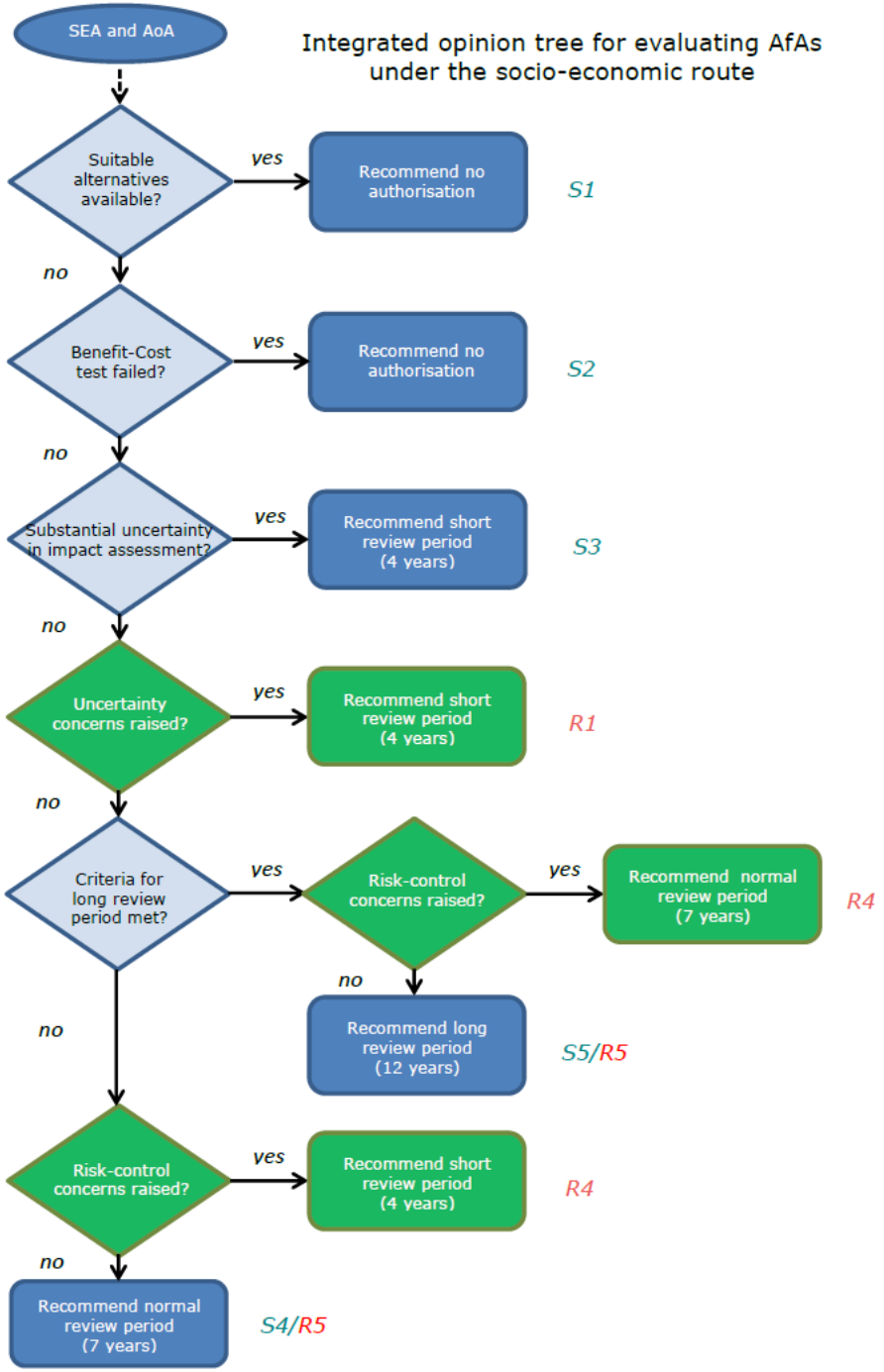
Interaction with RAC

- Close cooperation between RAC and SEAC rapporteurs throughout the opinion making process
- Bridge from risk to impact assessment still a challenge:
  - Reliable data on duration and frequency of worker tasks and number of exposed workers not always available
  - Exposure assessment models may come with high uncertainty (e.g. standard man via environment modelling)
- How to address remaining risks in AfAs?
  - RAC assesses exposure and risk management measures, recommends conditions to reduce the risks
  - Precise effect of conditions usually not known in advance, SEAC has to assess the impacts based on the available data
  - Careful coordination and presentation of opinions needed to make clear that RAC and SEAC are working with, not against each other

Opinion tree for recommending review periods

green: evaluation by RAC

blue: evaluation by SEAC



Examples from SEAC: Assessment of health impacts (restrictions)

- Chromium VI in leather articles
  - SEA based on assumptions on severity of chromium allergy
  - Consultations of RAC/SEAC with experts gave more insight
  - Result: SEAC was able to better understand the uncertainties and describe the benefits of the restriction in the opinion
- 1,4-dichlorobenzene in air fresheners and toilet blocks
  - Illustrative calculation of the human health cost of decreased lung functioning
  - RAC did not find the quantitative approach robust
  - SEAC did not take the monetised benefits into account
  - Based on other information, SEAC agreed with the dossier submitter about the proportionality of the restriction

Examples from SEAC: Assessment of non-use scenario (AfA)

- Use of trichloroethylene for the removal and recovery of resin from dyed cloth (applicant V)
  - Non-use scenario: Switch to a technically feasible alternative
  - Alternative not economically feasible, RAC said no risk reduction
  - Applicant had R&D plan to develop a less hazardous process
  - SEAC saw convincing case for a long review period
- Use of trichloroethylene in the manufacture of separators for lead-acid batteries (applicant M)
  - Non-use scenario: Complete shutdown (losses of profits, supplier revenues and jobs claimed by applicant, exceeding €150 million)
  - SEAC did not find non-use scenario credible (switching to alternative would be cheaper, approximately €10 million)
  - SEAC accepted the applicant's overall conclusion (at €10 million, benefits were still 1000 times higher than monetised risks)

What is a fit-for-purpose analysis?

- Benefit-cost analysis often used to underpin SEAs
- Benefit-cost ratio indicates the relationship between positive and negative consequences of a given course of action from a social welfare perspective
- In an ideal world: Possible to quantify and „monetise" all impacts and determine the socially optimal solution with mathematical precision
- In reality: Scientific uncertainty, information asymmetries, limited resources etc.
- Analysis can (and will) be imperfect but needs to be rigorous enough to reach a robust conclusion
  - Case with larger impact requires more thorough justification

Limits of benefit-cost analysis

- Benefit-cost ratio greater than 1 does not guarantee:
  - Coherence with wider policy objectives
  - Equitable distribution of benefits and costs
  - That all vulnerable groups are protected
  - That all important impacts are considered (quantification bias)
- Qualitative elements in SEAC opinions give context
  - Description of the impacts (HH, ENV, economic, social…)
  - Who is affected and how?
  - Which impacts have not been quantified?
- Benefit-cost ratio: formal criterion based on a well-developed and widely used scientific methodology
  - *Not* an overall policy recommendation to restrict/authorise

Current challenges

- Dossiers with very broad scope
  - Is the assessment performed consistent with the scope?
  - Suitability of alternatives and benefit-risk ratio may vary between use-scenarios within a broader use
  - Uncertainties are clearly pointed out by SEAC and taken into account in recommendations (e.g. review period, conditions)
- Public consultation
  - Restriction: High number of comments, conflicting views on need for exemptions, transition periods, limit values etc.
    - SEAC: Recommendation of derogations only if well justified
  - AfA: Limited number of comments even for broad upstream AfAs, often general statements but little specific info on alternatives

Concluding remarks

- Socio-economic analysis:
  - Both a science *and* an art
  - Steep learning curve for Member States, applicants and SEAC
  - Although not perfect, SEAs included in restriction and AfA dossiers have been invaluable for SEAC to be able to gain an understanding of the impacts of the cases
- Opinions of SEAC:
  - Provide an independent evaluation of the analysis presented by the dossier submitter or applicant
  - *Do not* preempt the decision making process
  - *Do* help to make the benefits and costs of implementing a restriction or granting an authorisation transparent

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