Content of Applications for Authorisation

and

Update on Restrictions

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Evgenia Stoyanova
ECHA – Risk Management Implementation

Presentation Scope

- Content of Authorisation Applications
  - Requirements
  - Main elements
  - Further information
- Update on Restrictions
  - Restrictions currently in the process
  - Upcoming restriction dossiers

Content of Authorisation Applications

Content requirements

- To provide the needed information to decision-makers in order to be granted an authorisation to use or to place on the market for a use a substance listed on Annex XIV
  - Information needs
    - Opinion elements (Art. 64)
    - Decision criteria (Art. 60)

Authorisation Decision

- Risks are adequately controlled ⇒ CSR, (SP)

OR

- Socio-economic benefits outweigh risk ⇒ SEA, CSR

AND

- No suitable alternative substances or technologies ⇒ AofA

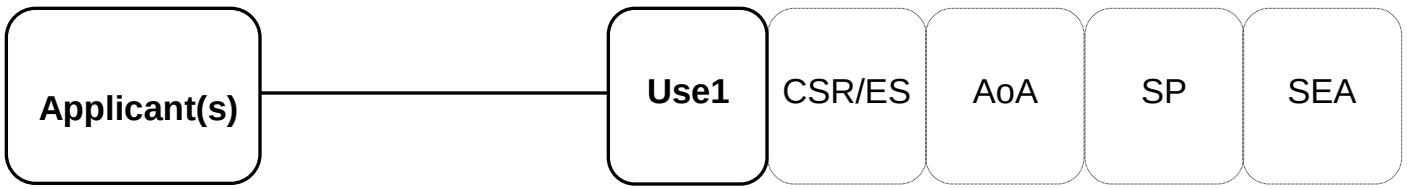
- In addition:
  - Conditions => CSR, AofA, SEA, SP
  - Monitoring arrangements => CSR
  - Review period => CSR, AofA, SEA, SP

Application Content

- Main elements – Art. 62 of REACH
  - Basis for conformity check
    - Art. 64.2 – performed by RAC/SEAC
      - Substance identity
      - Applicants
      - Uses applied for
      - Chemical Safety Report
      - Analysis of Alternatives
      - Substitution Plan
  - Additional elements
    - Art. 62.5
      - Socio-Economic Analysis
      - Justification for not considering certain risks to HH & Env
- Administrative elements
  - Application form (including Broad information on uses)
  - Concordance table

Uses Applied for

- Definition of uses for which authorisation is sought
  - Use descriptor system (IUCLID Sec.3.5), reference to ES
  - Detailed description of each use applied for (IUCLID Sec.3.10)
- Authorisation granted by use => Use-oriented dataset approach



- Consistent definition
  - Conformity check issue
- Can be confidential
- Scope – *How to develop the description on uses in the context of Authorisation*, ECHA 2011

Broad information on uses

- Non-confidential equivalent to Uses applied for
- Published on ECHA's website for public consultation on alternatives (Art. 64.2)
- Collected information from 3rd parties is considered by RAC/SEAC in their opinion on the availability and suitability of alternatives
- Must be meaningful for public consultation purposes

⇒Impact on assessment of AofA

⇒Impact on number of requests for clarification from RAC/SEAC

Broad information on uses

- Applicant's proposal to be considered by ECHA
  - Discussed during pre-submission information sessions (optional)
  - Draft in application (web)form (optional)
    - Potential revisions by ECHA
    - Applicant given 1 opportunity to comment on the amended draft
    - Final decision by ECHA

Chemical Safety Report

- Purpose:
  - To assess the risks to human health and the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV

⇒ Essential for concluding whether:

  - risks are adequately controlled in accordance with section 6.4 of Annex I

  OR

  - minimisation of emissions and exposures as far as possible, and to show that the likelihood of adverse effects is reduced

⇒ Impact on:

  - Conditions
  - Monitoring arrangements
  - Review period

CSR for Authorisation

- Mandatory assessment report – conformity check
  - Reference to own report submitted for registration
    - Current CSR
    - Revised CSR:
      - To refine the ES
      - Applying only for some of the uses of the substance
  - New CSR or Permission to refer to a CSR of a previous applicant

- Link to Analysis of Alternatives
  - “risks arising from the intrinsic properties specified in Annex XIV” vs. all risks

Analysis of Alternatives

- Mandatory assessment report – conformity check
- REACH objective:
  - Progressive replacement of SVHCs by suitable alternatives where these are economically and technically feasible

⇒Conclusion on whether there are suitable and available alternatives

⇒Impact on:

  - Review period, conditions, and monitoring arrangements

AofA for Authorisation

- Steps:
  - Identify possible alternatives (for each use applied for)
  - Identify relevant R&D that is appropriate for the analysis
  - Determine suitability and availability of alternatives:
    - Suitability:
      - Risks of alternatives
      - Technical feasibility for the applicant
      - Economic feasibility for the applicant
    - Availability
  - Determine actions and timescales that may be required to make possible alternatives suitable and available for the applicant

Substitution Plan

- Mandatory assessment report, when AofA shows availability of suitable alternatives – conformity check
- Purpose:
  - to present the applicant's commitment to take the actions needed to substitute the Annex XIV substance with a suitable alternative within a specified timetable

⇒Conclusion on the review period

⇒For adequate control route (Art. 60.2)

(SEA route – benefits exceed risk and no suitable alternatives)

Socio-Economic Analysis

- Analysis of socio-economic impacts is practically a must for
  - Non-threshold CMRs as well as PBTs and vPvBs

⇒ Conclusion on whether the socio-economic benefits of continued use outweigh the risk to HH or ENV

- Also useful for threshold substances for which adequate control of risks cannot be demonstrated
  - applicant may decide to use both reasoning
    - e.g. if RAC considers that risks are not adequately controlled the applicant could have analysed that the benefits > risks
  - in support of review period argumentation

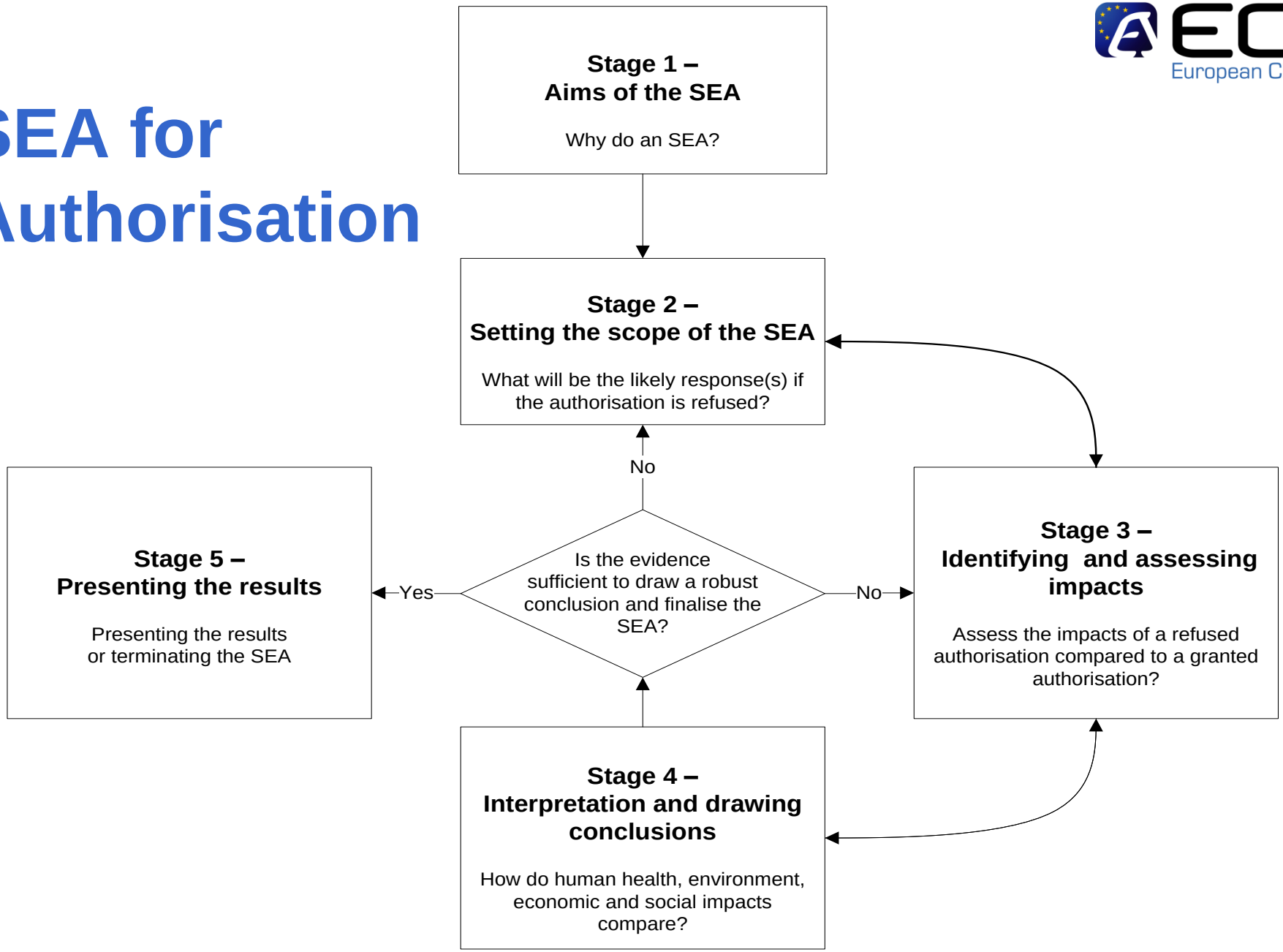
⇒ Impact on:
  - review period, conditions, and monitoring arrangements

SEA for Authorisation

- Analysis of negative and positive impacts of:
  - "Applied for use" scenario: applicant/its DUs can continue using the substance for specific uses

  vs.
  - "Non use" scenarios: authorisation is refused: substance cannot be used
- Impacts considered:
  - human health, environmental, economic
  - social, wider economic, distributional
- Benefits of authorisation:
  - reduced costs to the applicant, other actors in the supply chain (incl. consumers) and society as whole
- Costs of authorisation:
  - negative human health or environmental impacts
- Perspective – society as a whole

SEA for Authorisation

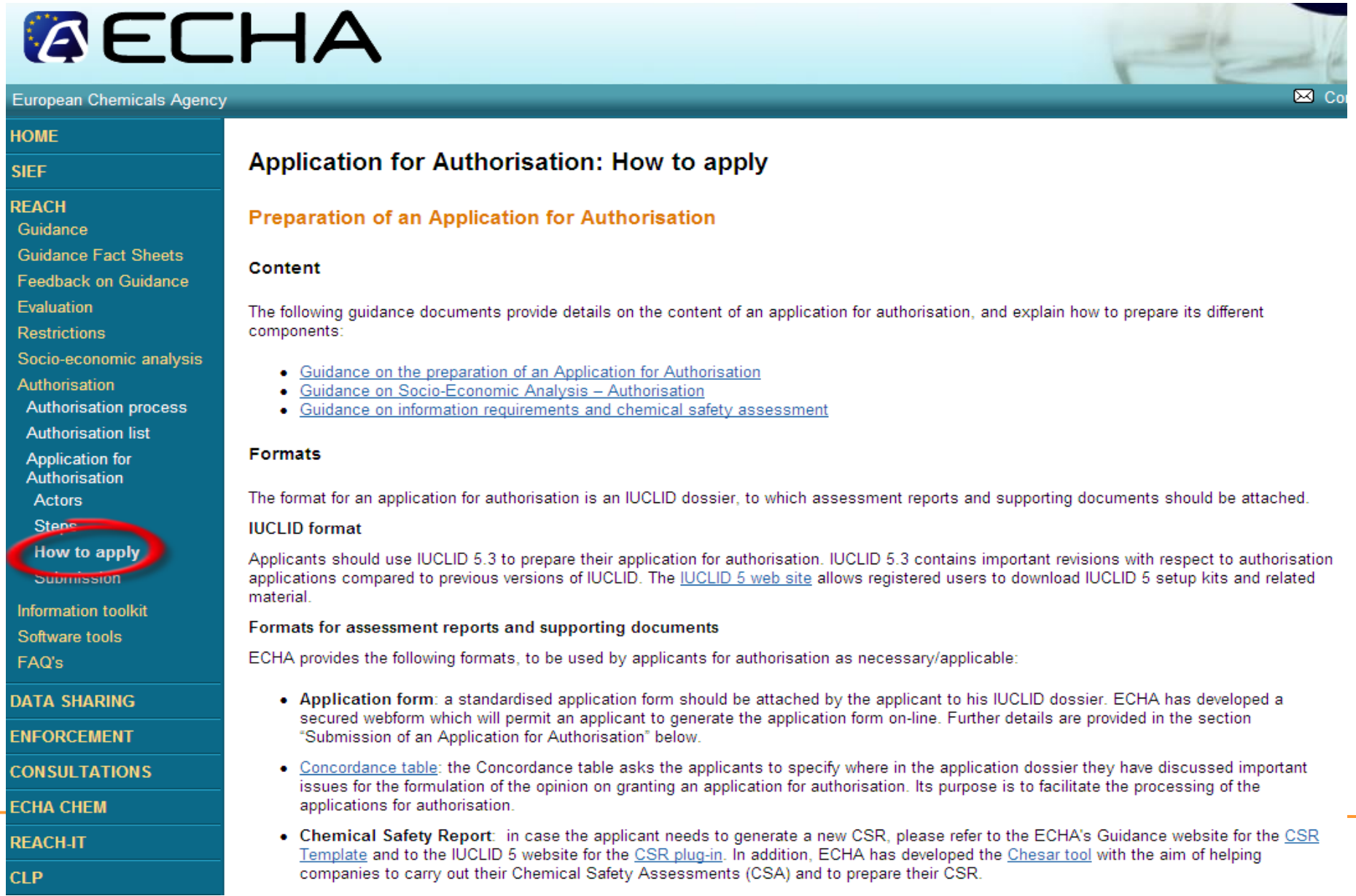


Possible application packages

Adequate control & No suitable alternative	Adequate control & Suitable alternative	Socio-ec benefits > risks (No adequate control & No suitable alternative)
Threshold substances	Threshold substances	Threshold & Non-threshold substances
CSR Analysis of Alternatives SEA Substance & Applicant info	CSR Analysis of Alternatives Substitution Plan SEA Substance & Applicant info	CSR Analysis of Alternatives SEA Substance & Applicant info

Resources: ECHA website

http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application/authorisation_how_en.asp



Applications for Authorisation

- Pre-notify
  - echa_application_for_authorisation@echa.europa.eu

- Pre-submission information sessions with applicants
  - An opportunity for applicants to:
    - ask for clarifications on how to prepare and submit an application
    - give their preliminary views on a possible "*broad description of uses*" applied for

Key messages

- Begin your analysis early
- Consult available resources
  - guidance documents, manuals, website material, pre-submission information sessions

Update on Restrictions

Restrictions under consideration

- Dimethylfumarate in articles:
  - SEAC final opinion on adopted in June
- Lead in jewellery:
  - SEAC final opinion in September 2011
- 5 phenylmercury substances and mercury in measuring devices
  - RAC final opinion adopted/agreed in June 2011
  - SEAC draft opinion
    - Adopted/agreed in June 2011
    - Public consultation until Aug 16, 2011

Upcoming restriction dossiers

- 4 Phthalates
  - DEHP – Bis(2-ethylhexyl) phthalate
  - BBP – Benzyl butyl phthalate
  - DBP – Dibutyl phthalate
  - DIBP – Diisobutyl phthalate
    - To be resubmitted by Denmark in summer/autumn 2011
    - Combined effects of the 4 classified phthalates to human health (REP 1B) and emissions to indoor environment and direct exposure from certain articles

Further information

- Restrictions under consideration
  - http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp

- Registry of Intentions
  - http://echa.europa.eu/chem_data/reg_intentions_en.asp

Thank You