

REACH Authorisation

Application for authorisation: Key issues for applicants and outlook for 2013

Workshop on Airworthiness and
REACH Authorisation

Cologne

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Outline

- Key issues for applicants
 - Pros and cons of joint applications
 - Relationship between the Analysis of Alternatives and SEA
 - Public consultation: broad information on uses, information from third parties
 - How RAC and SEAC evaluate the applications
- Outlook for 2013

Two steps in authorisation

- Step 1: Identification of Substances of Very High Concern and inclusion in the Authorisation List
 - Candidate list (SVHC)
 - Authorisation list (Annex XIV)
- Step 2: Applying for authorisation
 - Topic of today

Pros of joint applications

- For the preparation of the dossier
 - Broader range of experience/expertise, cost sharing
 - Better coverage of supply chains specificities
- For the submission of the dossier
 - Reduced fee per applicant
 - Simultaneous evaluation by the Committees of several [applicant-substance-use] combinations

Cons of joint applications

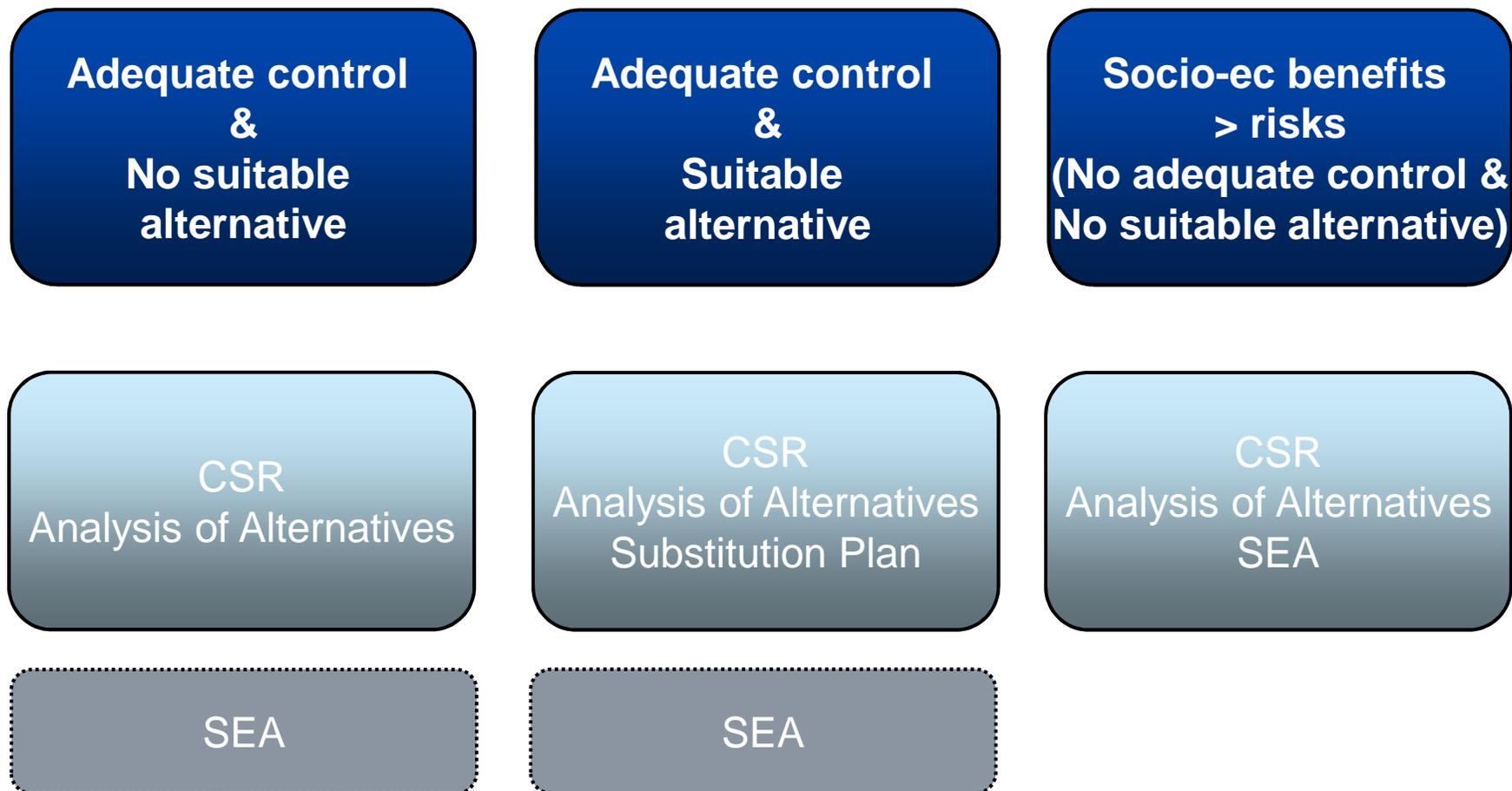
- Coordination: Difficulties to gather (confidential) information, set contractual and financial arrangements
- Complex or unfocussed applications with many [applicant-substance-use] combinations
- Confidential information likely to be shared between all co-applicants
- Competition law?

Up to industry to decide

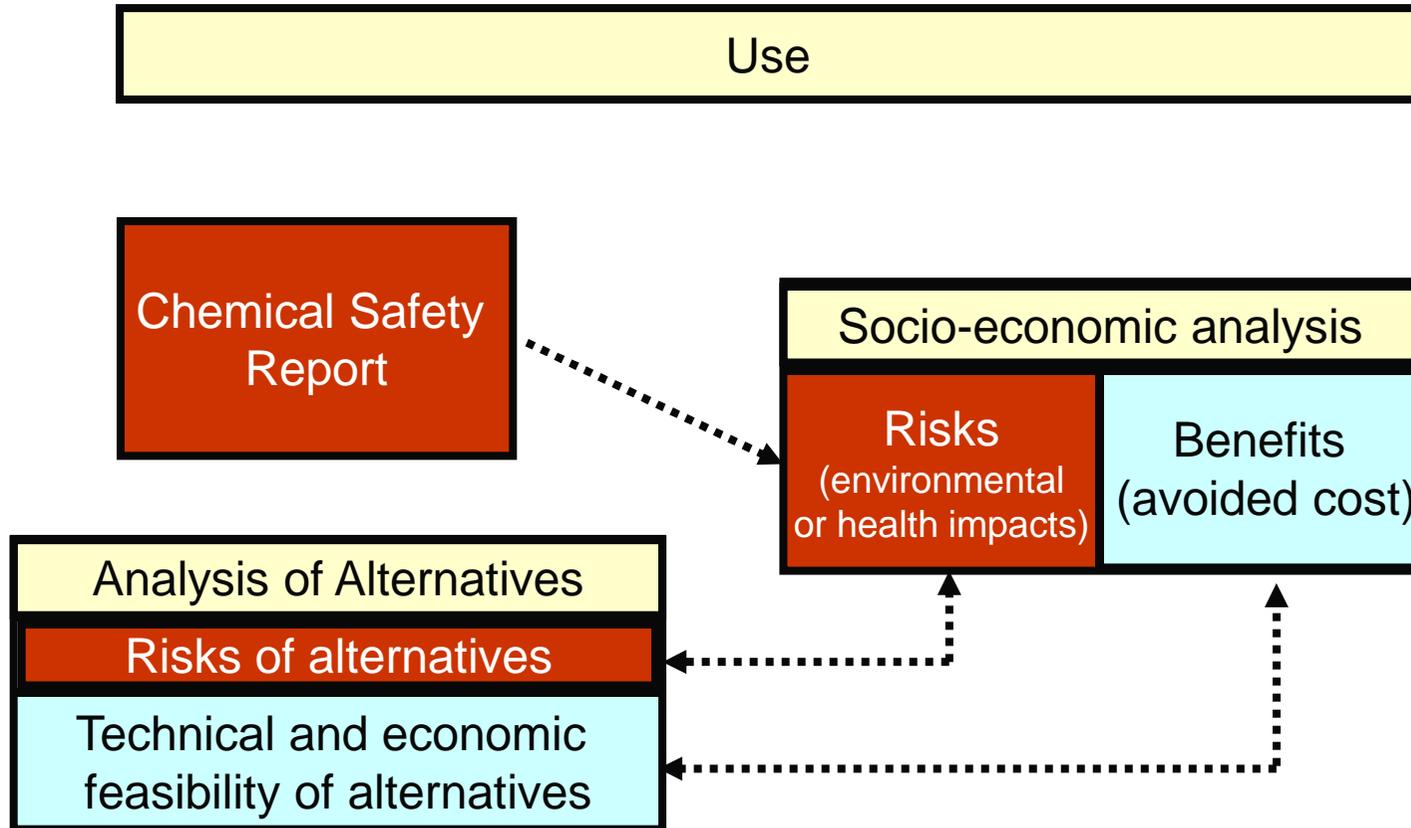
- What (confidential) information to include in the application
- Prepare common and specific parts
- Submit jointly or separately

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Assessment Reports: Possible Packages



CSR, AoA and SEA



Analysis of alternatives template

- List of possible alternatives
- Description of efforts made to identify possible alternatives
- Research and development
- Data searches
- Consultations
- Alternative 1: Substance ID and properties/Description of technique
- **Technical feasibility**
- **Economic feasibility**
- **Availability**
- **Reduction in overall risk**

Socio-economic analysis template

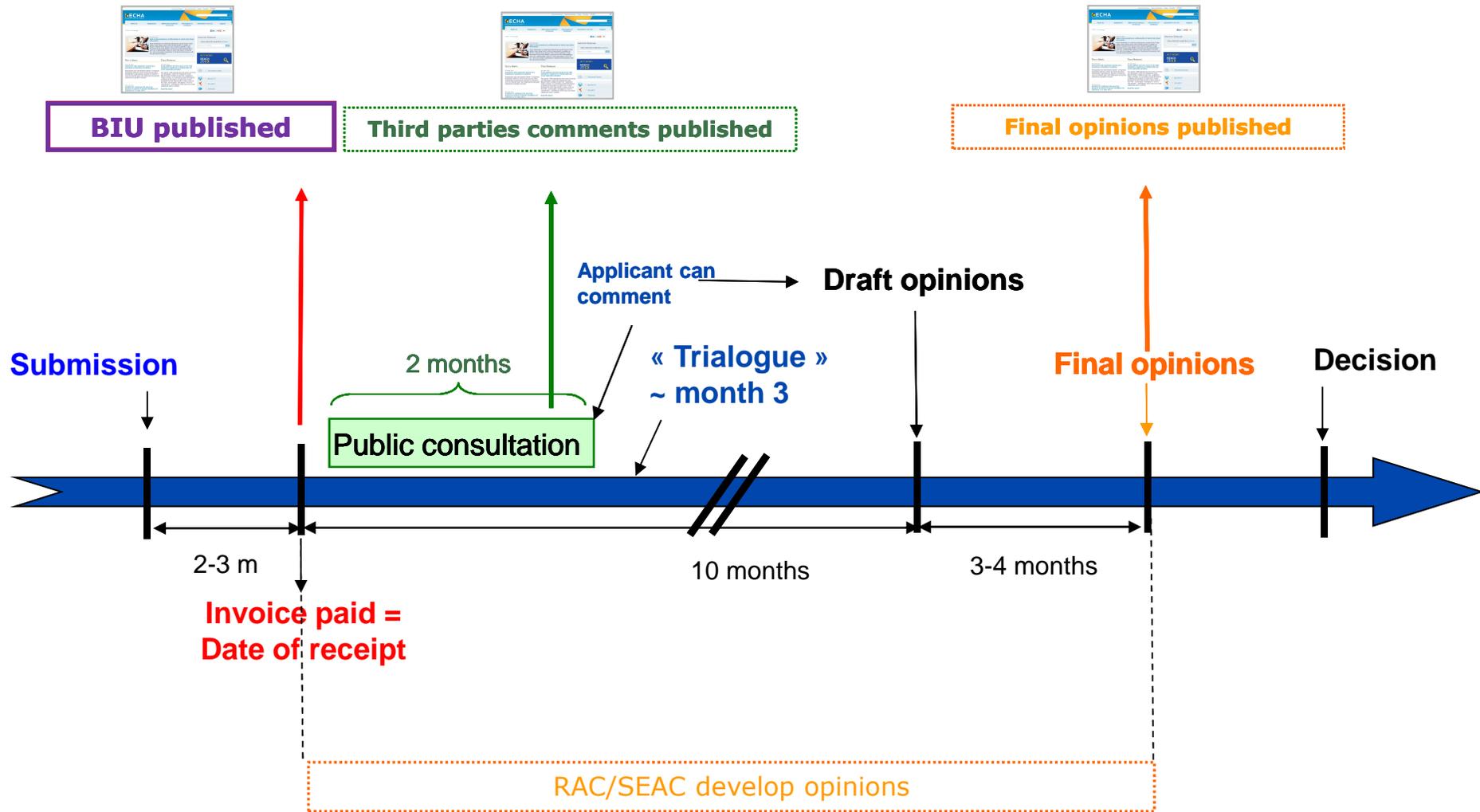
- Definition of “applied for use” scenario
- Definition of “non-use” scenario
- **Human health and environmental impacts**
- **Economic impacts**
- Social impacts
- Wider economic impacts
- Comparison of impacts
- Distributional impacts
- Uncertainty analysis

AoA and SEA complement each other

- AoA more from applicant's point of view
- SEA more from society's point of view
- Interact
 - Helpful to prepare in an iterative manner
 - If separate, you may miss important aspects (e.g. resource availability)

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Overview of publication of information in the AfA process



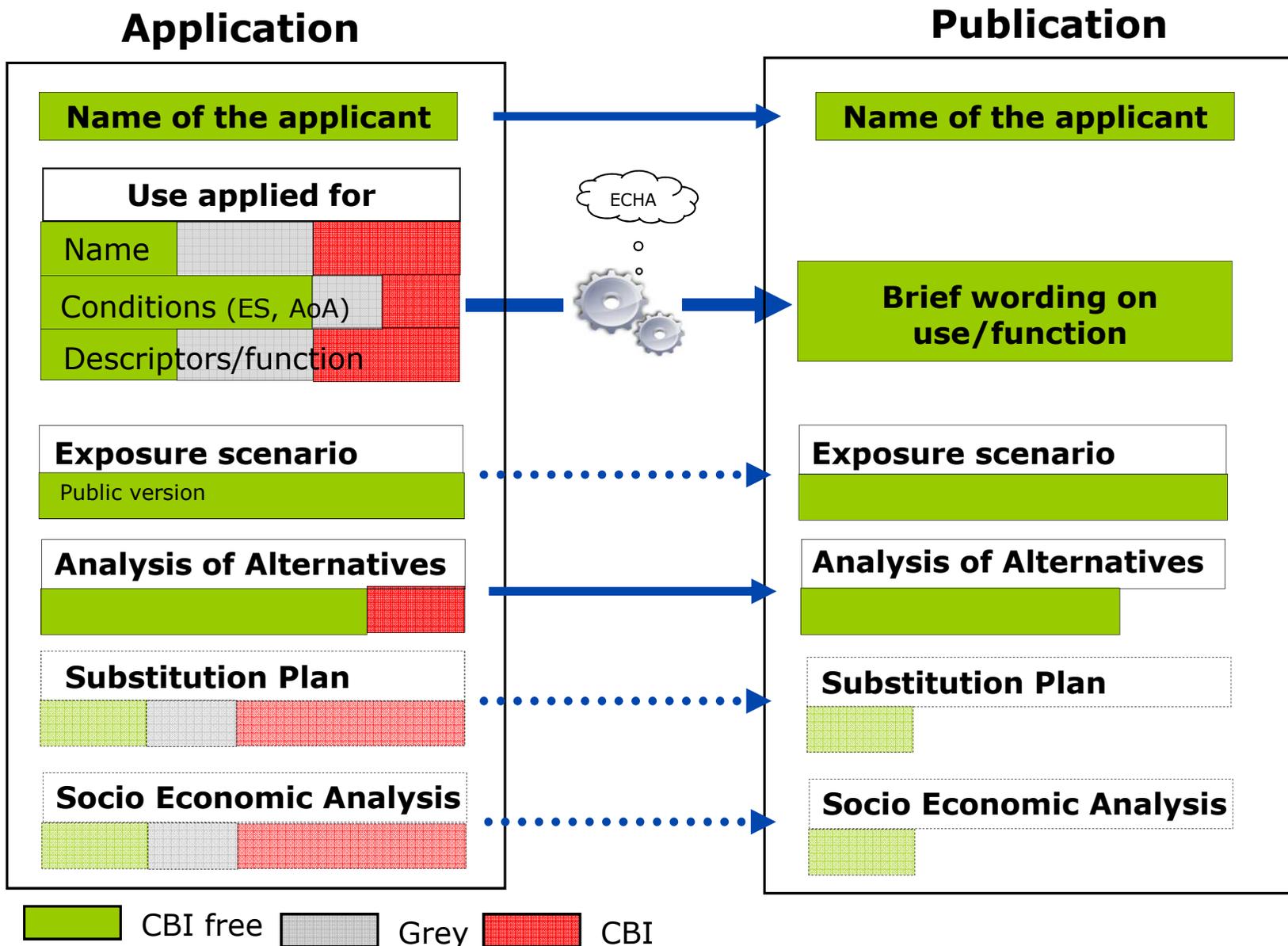
Broad Information on Uses (BIU)

- **Purpose**

- Information on uses for the public consultation on alternatives
- Enable third-parties to provide useful information
- Exact content developed in consultation with NGOs and Industry and communicated at the Stakeholders day in May 2012

- **Content**

- Public information related to the “use applied for”
- Disclose key information related to the use (conditions, function) and to the Analysis of Alternatives, Substitution Plan, Socio-economic analysis
- Trade-off between meaningfulness/level of detail and confidentiality
- Applicant proposes a non-confidential “brief wording”, ECHA assesses and publishes



Development of use descriptions

- The applicant should
 - use the use descriptor system, as appropriate
 - describe properly the function
 - refine original (generic) descriptions of uses
 - develop the scope of uses, AoA, SEA via an iterative process

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RAC's and SEAC's evaluation

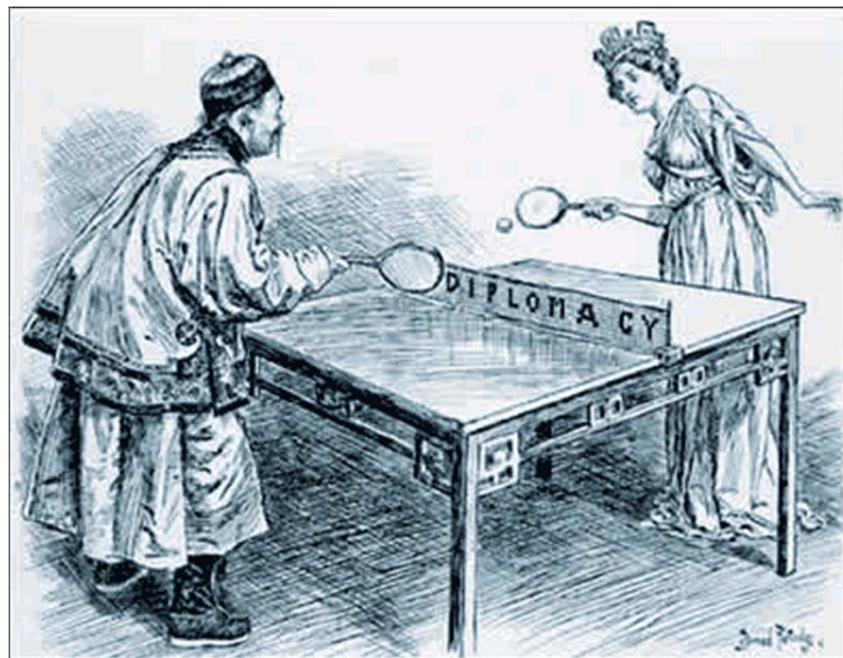
- Evaluate and validate information in applications:
 - Are methods appropriate and applied consistently?
 - Are conclusions logical?
 - Is evidence robust, is the scope correct?
 - Are all relevant issues included?
 - Are decisions not to include specific toxicological endpoints justified?
 - Are efforts in applicant's assessments proportionate given the importance of the application?
- Applicant's work is the basis for the evaluation
 - with information from public consultation

Evaluation of information from third party

- As the information from the applicant
 - If SEAC considers that the alternatives are technically **and** economically feasible
 - Important for RAC to consider the risks
- Applicant will have the possibility to respond
- 'Triologue' will be held between RAC and SEAC rapporteurs and the applicant
 - about month 3 after the receipt of the application
 - Not compulsory

Evaluation: summary

- Primary objective: Consistent opinions of high scientific quality to support the decision making of the European Commission
- Committees evaluate and validate information provided by applicants and third parties
- Several opportunities for applicants to communicate with Committees – but
 - Avoid ping-pong
 - Very difficult to make applications 'complete' during opinion making!



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Outlook for 2013

- Stakeholders
 - Collaboration with key stakeholders
 - Their role in public consultation, DUs, joint applications
 - Hold bilateral discussions (e.g. EASA, EMA, CEFIC, Eurometaux)
 - Participate in key events
 - See if templates can be further improved for streamlined opinion making
 - Two seminars on application for authorisation (February and June) and specific seminars with key stakeholders (e.g. EASA/ECHA workshop)
 - Creation of an EU-wide network of practitioners of Socio-economic analysis in chemicals risk management
 - Addressing specific issues of SMEs and DUs

Outlook for 2013 (cont.)

- Industry/applicants
 - Questions and Answers and instructions
 - Additional relevant information to ECHA's website
 - Up to 10 pre-submission information sessions & applications
 - "Dialogues"
- ECHA's scientific committees
 - Conformity check and opinion making started
 - Establish common understanding on key issues
 - Economic feasibility
 - Setting reference DNELs and dose-response curves

Thank You!

