

What applicants need to know about technical equivalence and chemical similarity

Chemical similarity check

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Sanna Airaksinen

Substance Identification and Data Sharing Unit

European Chemicals Agency



Outline

- What is a chemical similarity check (CSC)?
- Chemical similarity check vs. technical equivalence
- Application types
- Application procedure
- Requirements and assessment of CSC
- Key messages

**What is CSC and how does
it differ from technical
equivalence?**



What is a chemical similarity check?

- CSC is a voluntary service provided by ECHA to facilitate the implementation of BPR
 - ECHA Management Board Decision 31/2013:

"an assessment similar to technical equivalence assessment described in Article 54 of Regulation (EU) No 528/2012, but performed **solely on the substance identity and chemical composition** of a substance with the aim of establishing its **similarity as regards the chemical composition** of a second substance."
- Same type of assessment as for technical equivalence Tier I
- Intended for active substances for which there is no decision on approval adopted

CSC
VS.
TE

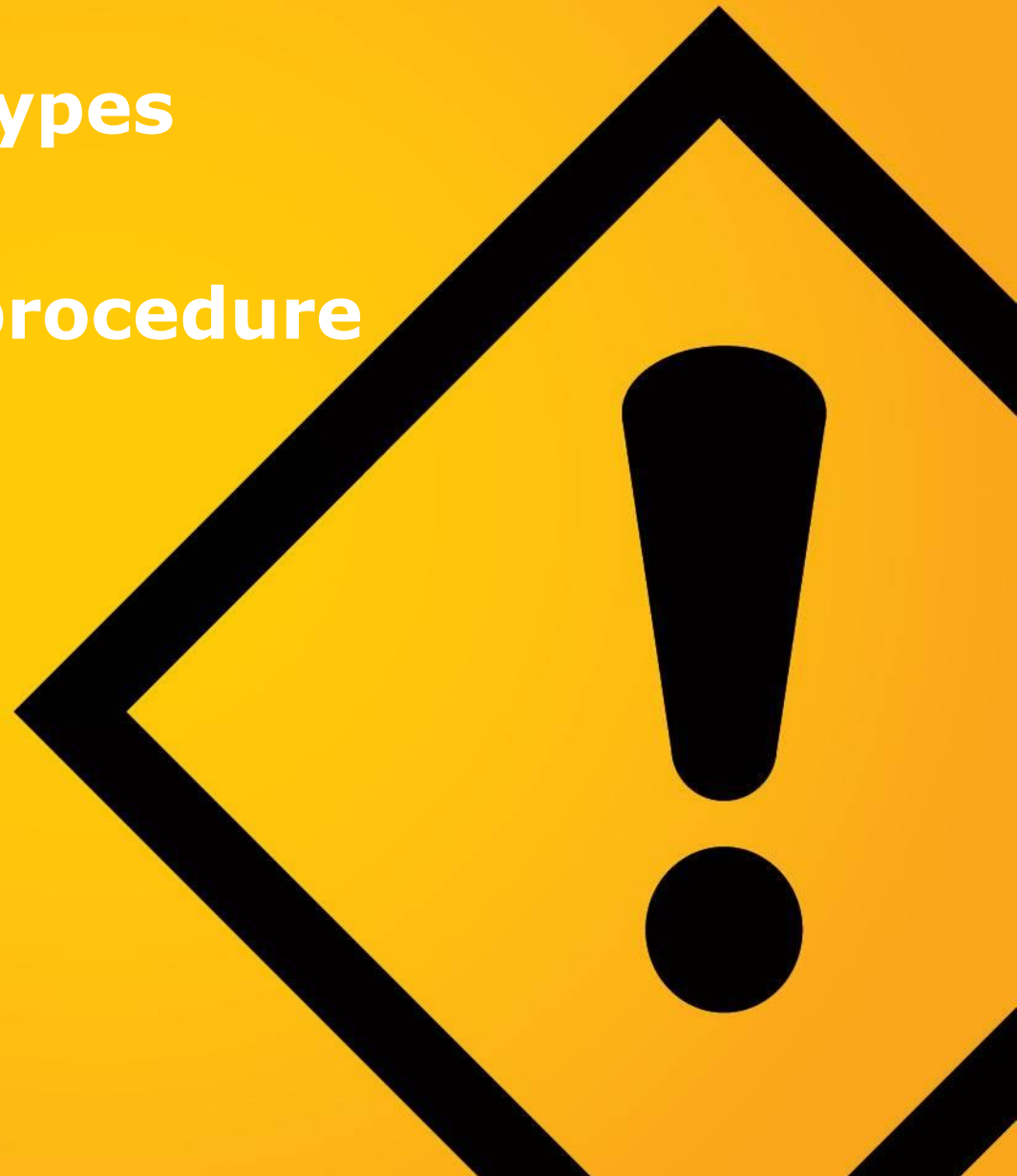
	Technical equivalence assessment	Chemical similarity check
Basis	Article 54 of the BPR	ECHA Management Board Decision 31/2013 ⁵ , Article 15 of the BPR Fee Regulation
Legal requirement	Mandatory to include a decision of TE assessment for biocidal product authorisation applications in cases when the active substance is considered a substance from a source different from the reference source.	Voluntary
Intended for	Active substances for which there is a Commission decision on approval	Active substances for which there is no Commission decision on approval
Application types	Tier I applications Tier II applications	Individual application: comparison of one source of an active substance to an active substance which has been submitted for evaluation under the BPR or BPD Joint applications: comparison of several sources of the same AS
Scope of assessment	Substance composition and hazard profile: Tier I: Substance identity and chemical composition (including analytical information) Tier II: Substance identity and chemical composition (including analytical information) and the (eco)toxicological profile	Substance identity and chemical composition (including analytical information)

Who benefits from CSC?

- The check is beneficial to:
 - Alternative suppliers of active substances before they invest in a letter of access to the dossier of an active substance in order to be included in the list of approved suppliers under Article 95 of the BPR;
 - Prospective applicants seeking confirmation that different sources of the same active substance could be assessed jointly before they submit the application for approval of the active substance.

CSC application types

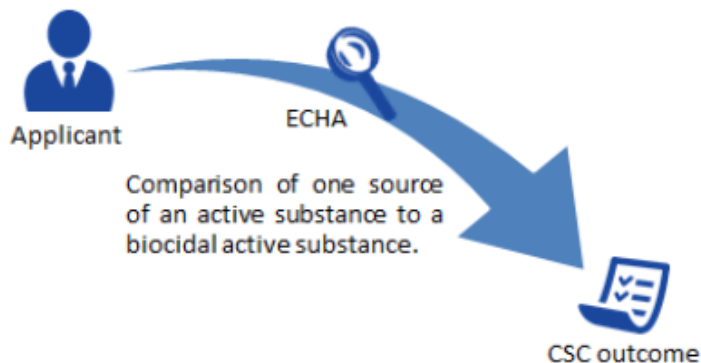
CSC application procedure



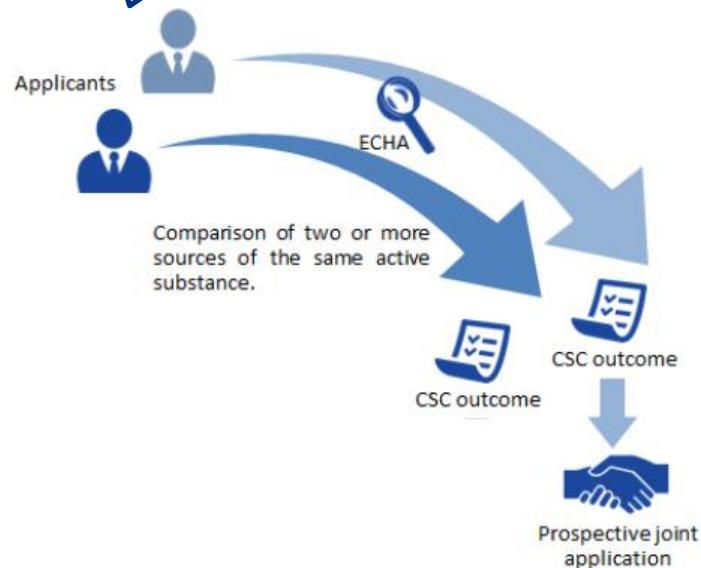
CSC application types

- Individual application
- Joint application

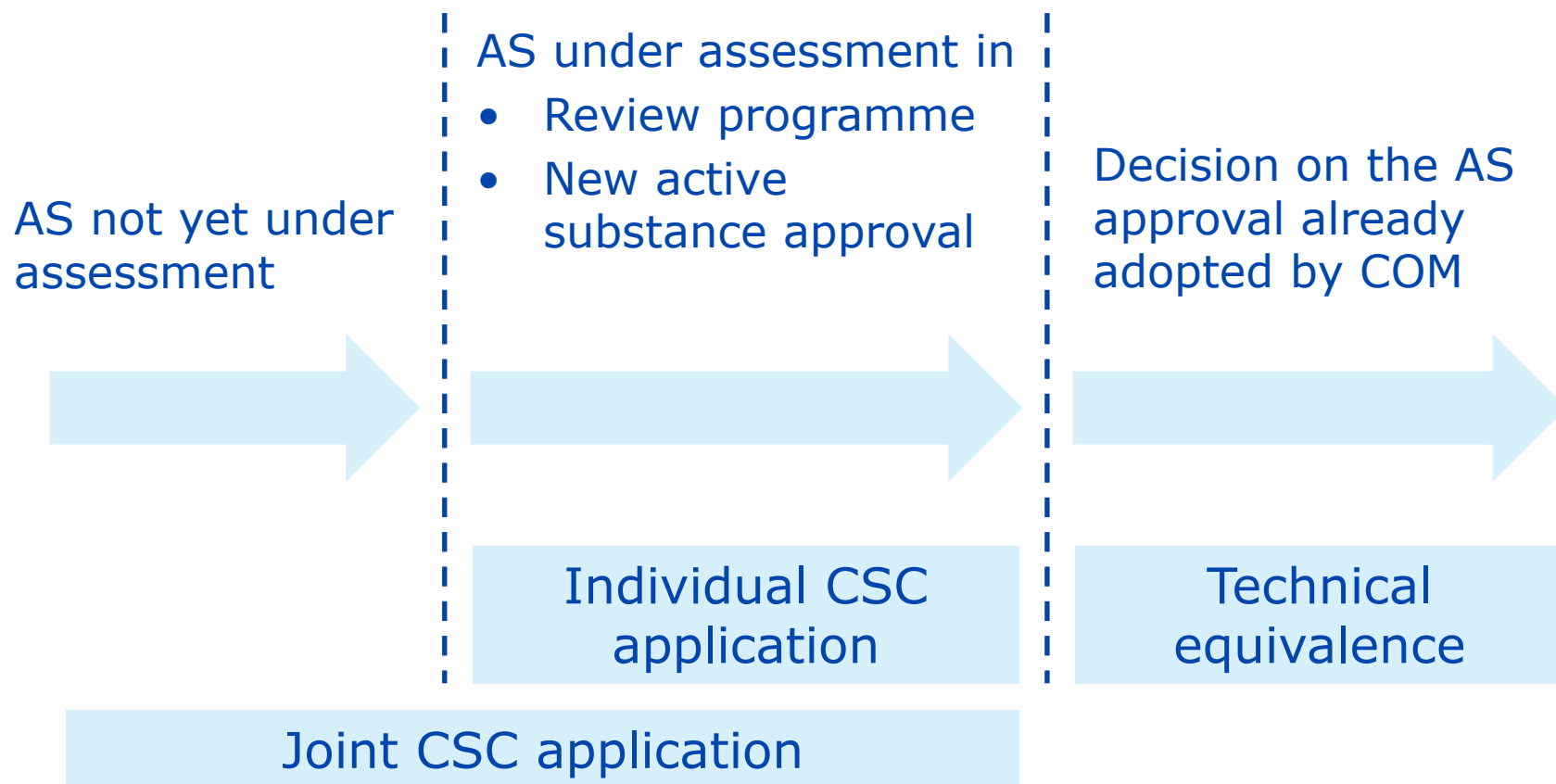
Is my active substance chemically similar to the active substance which is under assessment?



Are our active substances chemically similar to each other?

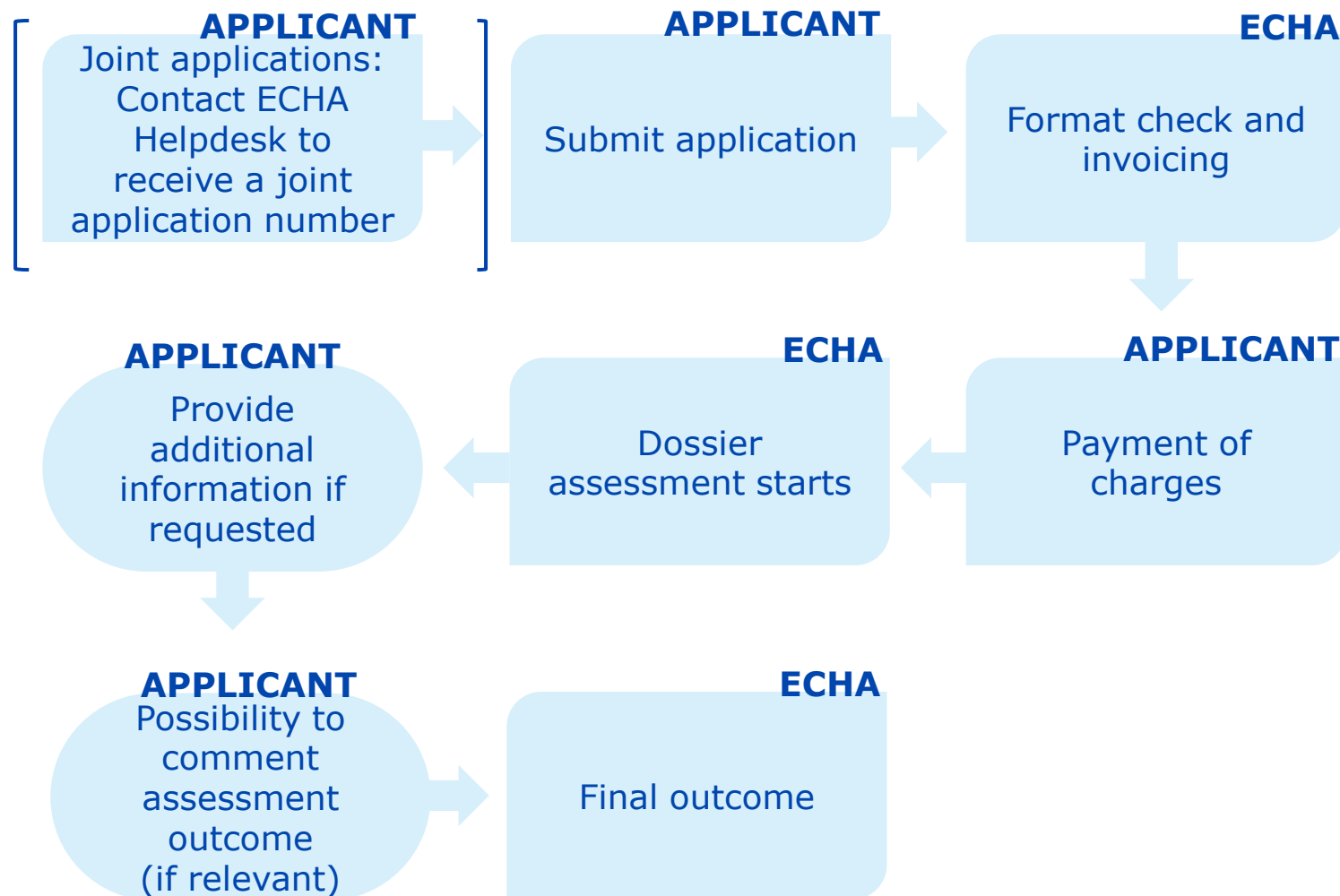


When to submit which application?



N.B.: CSC does not replace future TE assessment


Application procedure



CSC charges and target processing times

- The charge is based on the type of application and starts from 4 200 EUR
- The target processing time depends on the type of application and the available information; starts from 25 calendar days from the date when all necessary information is available to ECHA
- More information is available in Biocides Submission Manual 3b: Active substances Part B, Technical equivalence and Chemical similarity
<http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals>

Requirements for CSC applications

- Applications submitted in R4BP 3 
 - Supporting document
 - Information requirements and assessment criteria are similar to technical equivalence Tier I
 - IUCLID dossier:
 - information on the substance identity
 - manufacturing process
 - chemical composition
 - analytical profile of five representative batches
 - description of the analytical method used for the determination of the substance
 - absorption spectra
- More information can be found in the “Biocides submission manual 3b” and the “Guidance on applications for technical equivalence”.



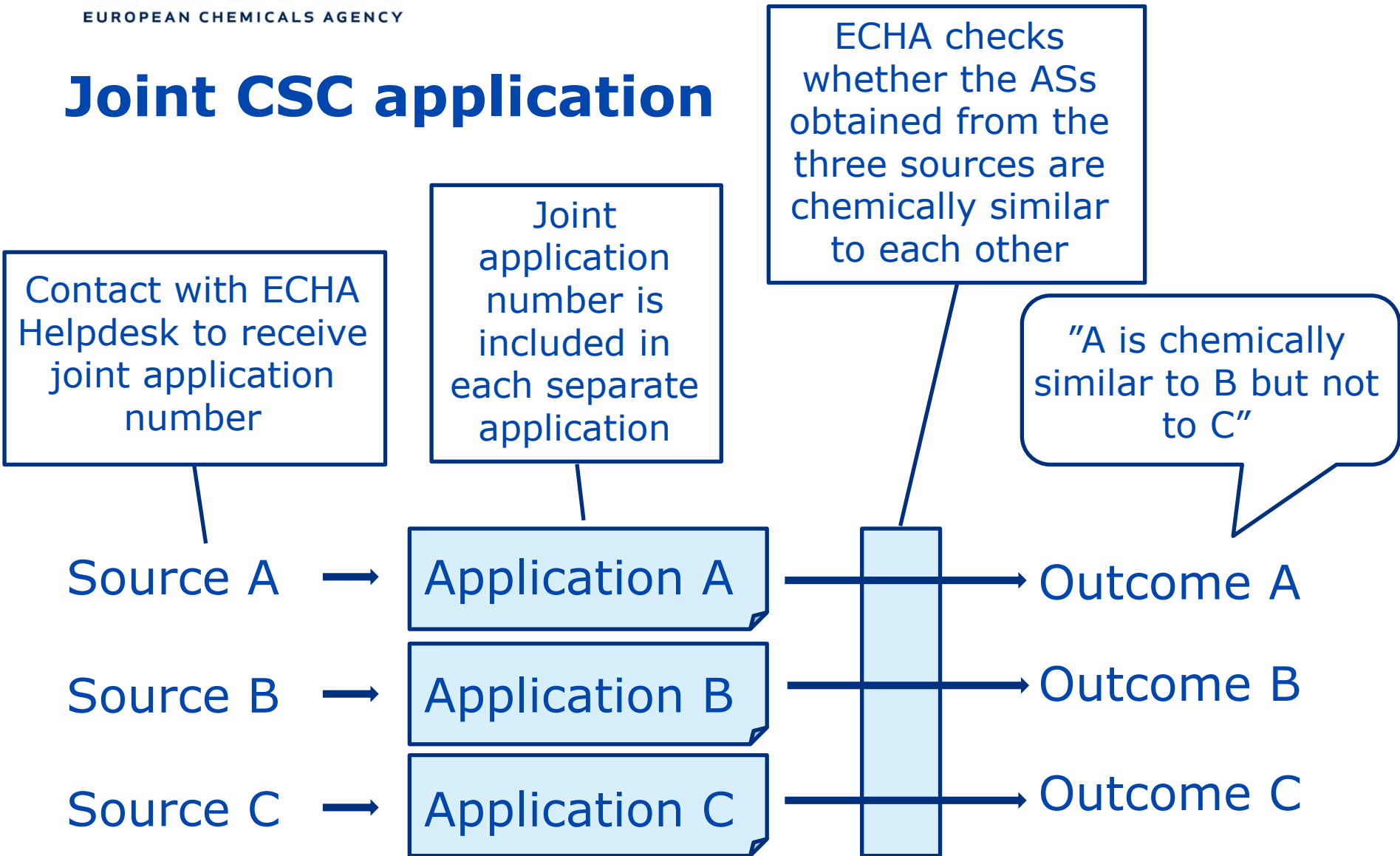
Individual CSC application (1)

- Application received by ECHA
- ECHA contacts the competent authority responsible for assessing the active substance to find out whether there are "temporary reference specifications" established for the active substance from the reference source
 - Yes → ECHA uses the temporary reference specifications from the competent authority for the assessment
 - No → ECHA derives temporary reference specifications for the assessment
 - This also determines the charge; the invoice is sent to the applicant after the contact with the competent authority; the assessment starts after the charges are received


Individual CSC application (2)

- The temporary reference specifications used in the CSC assessment may not be the same as the final specifications of the approved reference source
- CSC does not replace technical equivalence assessment, which is necessary for product authorisation

Joint CSC application



Joint CSC application (1)

- Contact with ECHA Helpdesk  [ECHA Helpdesk](#)
 - One applicant contacts ECHA Helpdesk on behalf of the group of applicants
 - Request is issued through the ECHA Helpdesk contact form (with topic of the question *Regulatory advice*) with information on the joint application and the active substance.
 - ECHA provides a 'joint application number' which needs to be included in the applications

Joint CSC application (2)

- **Each applicant in the group sends their own separate application** through R4BP 3:

- one source per application



> R4BP 3

- joint application number is included in the supporting document



Key messages

- Chemical similarity check focuses on the substance identity and chemical composition
- CSC is intended for active substances for which the decision on approval has not (yet) been adopted
- Two application types
 - Individual application
 - Joint application
- Requirements and assessment criteria are the same as for technical equivalence Tier I

Further information on CSC

- ECHA Management Board Decision 31/2013
http://echa.europa.eu/documents/10162/17287015/mb_decision_31_2013_bpr_chemical_similarity_check_en.pdf
- CSC webpages
- General page: <http://echa.europa.eu/regulations/biocidal-products-regulation/chemical-similarity-check-service>
- R4BP3: <http://echa.europa.eu/support/dossier-submission-tools/r4bp/chemical-similarity-check-service>
- Biocides Submission Manual 3b: Active substances Part B, Technical equivalence and Chemical similarity
- <http://echa.europa.eu/support/dossier-submission-tools/r4bp/biocides-submission-manuals>
- Guidance on applications for technical equivalence
- http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation?panel=guidance_applications_technical_equivalence
- Guidance on information requirements
- http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation?panel=guidance_information_requirements
- Guidance for identification and naming of substances under REACH and CLP: <http://echa.europa.eu/guidance-documents/guidance-on-reach>

Thank you

sanna.airaksinen@echa.europa.eu