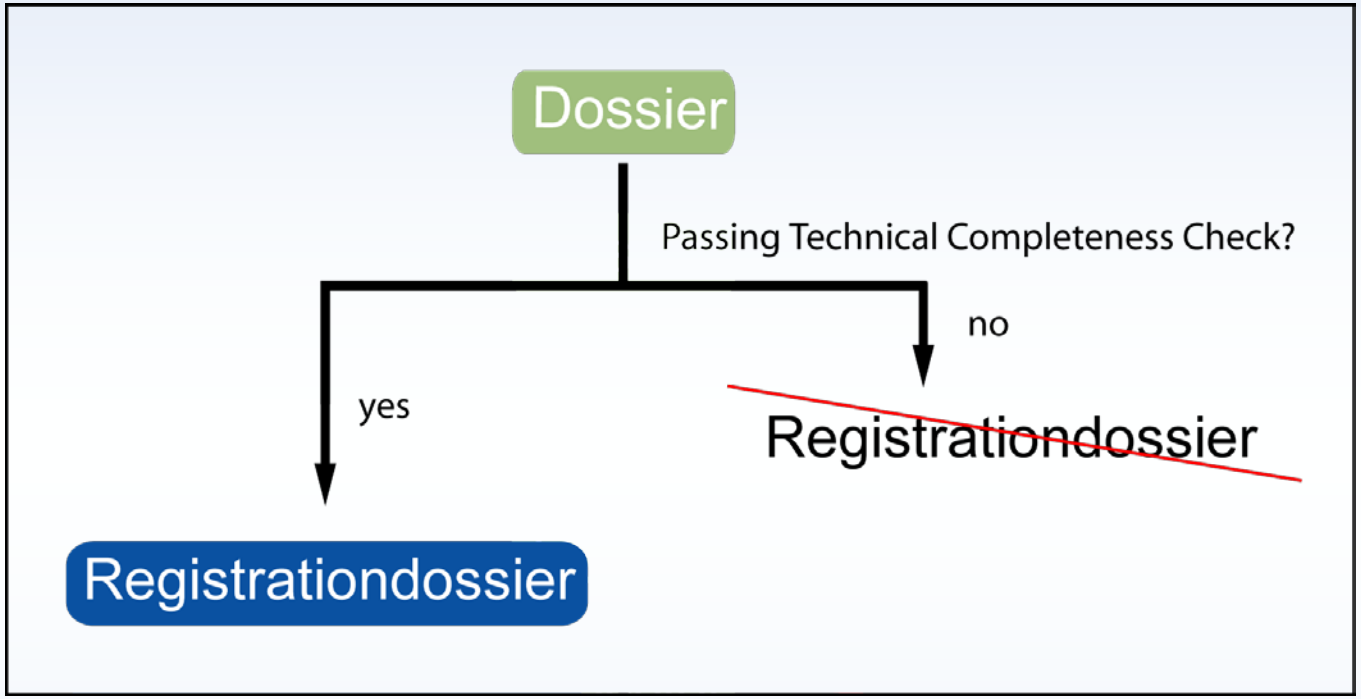
Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

German Competent Authority – Dossier Evaluation work

Dortmund, 10. April 2013

Dr. Dana Rühl
Federal Office for Chemicals/Authorisation of Biocides

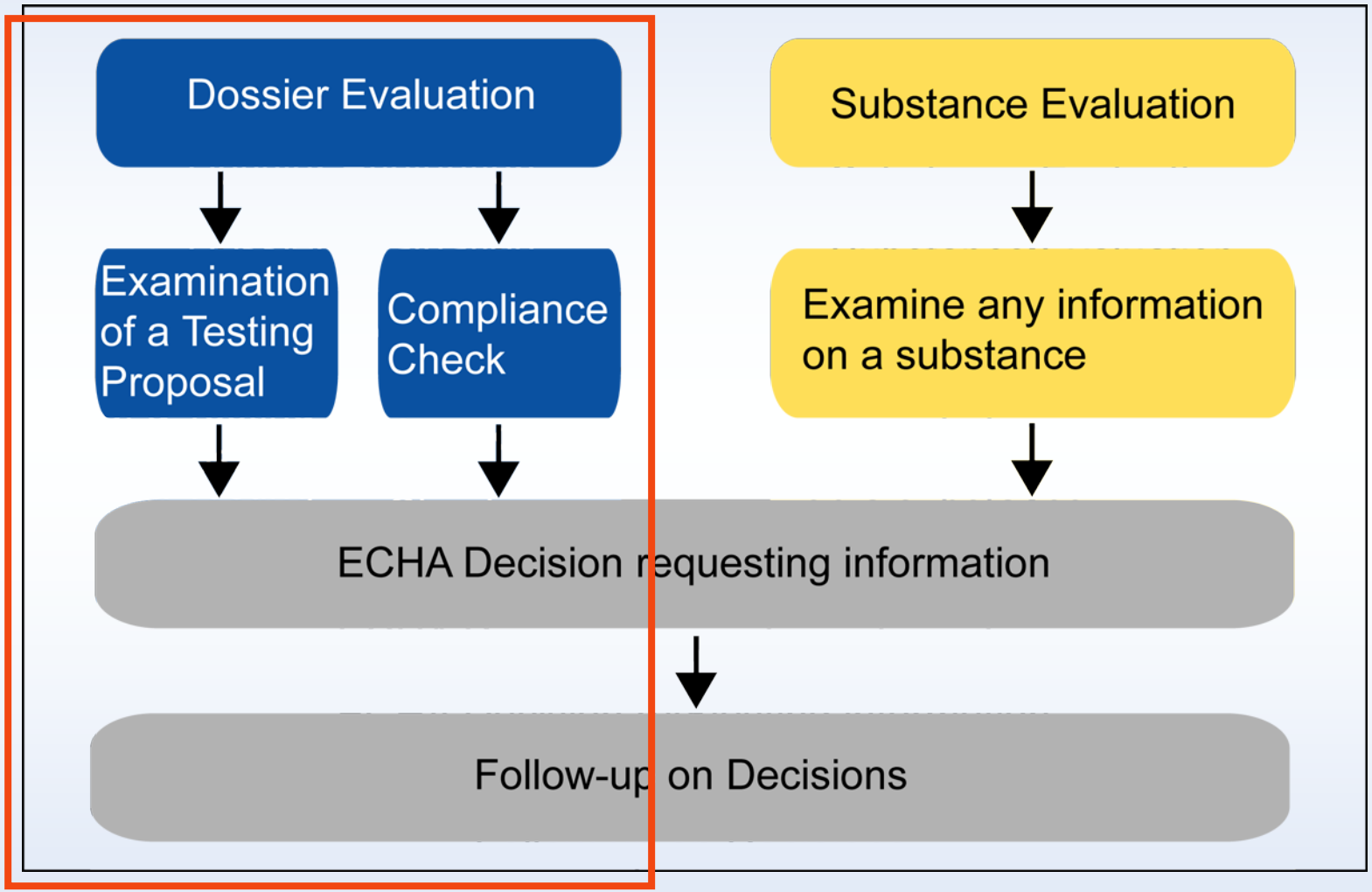
Registration



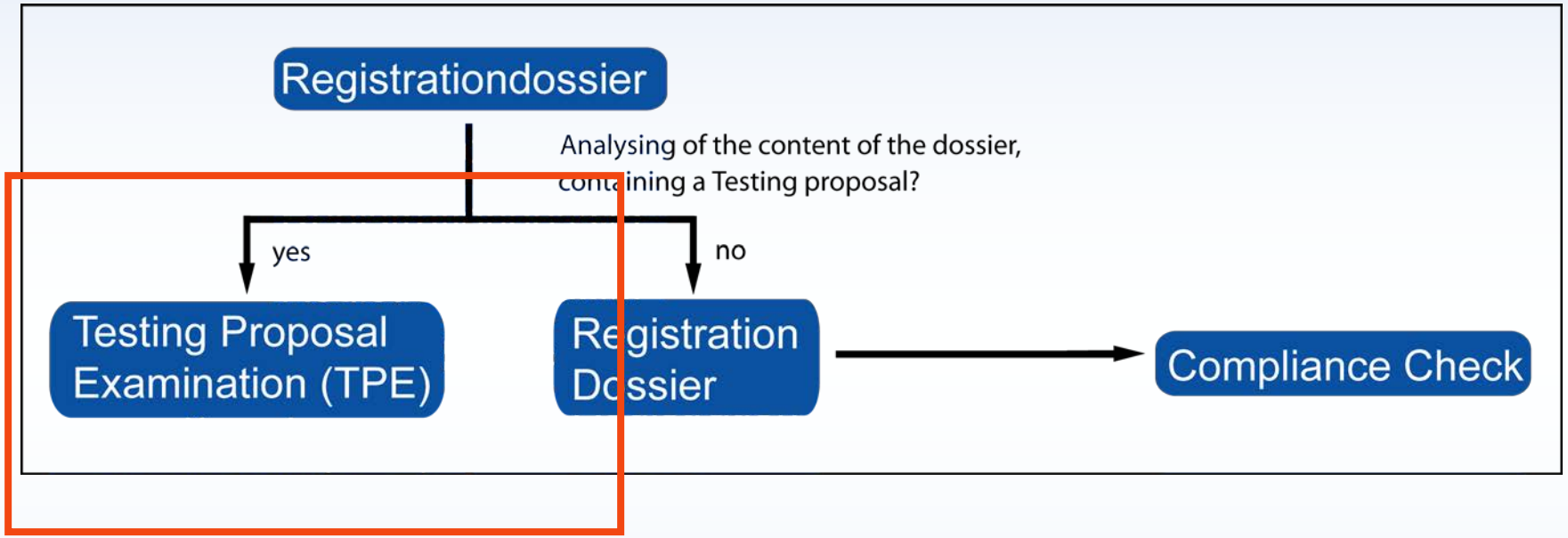
Dossiers have to pass the Technical Completeness Check to gain a registration number.

Registrant
Member States
ECHA

Evaluation


Dossier Evaluation
Substance Evaluation
Examination of a Testing Proposal
Compliance Check
Examine any information on a substance
ECHA Decision requesting information
Follow-up on Decisions
Registrant
Member States
ECHA

Evaluation



- if no study for one endpoint (from Annex IX and X) is available – the Registrant has to propose a Test
- all submitted and accepted Dossiers are checked if they contain a proposed test
- any TPE has to be evaluated by ECHA

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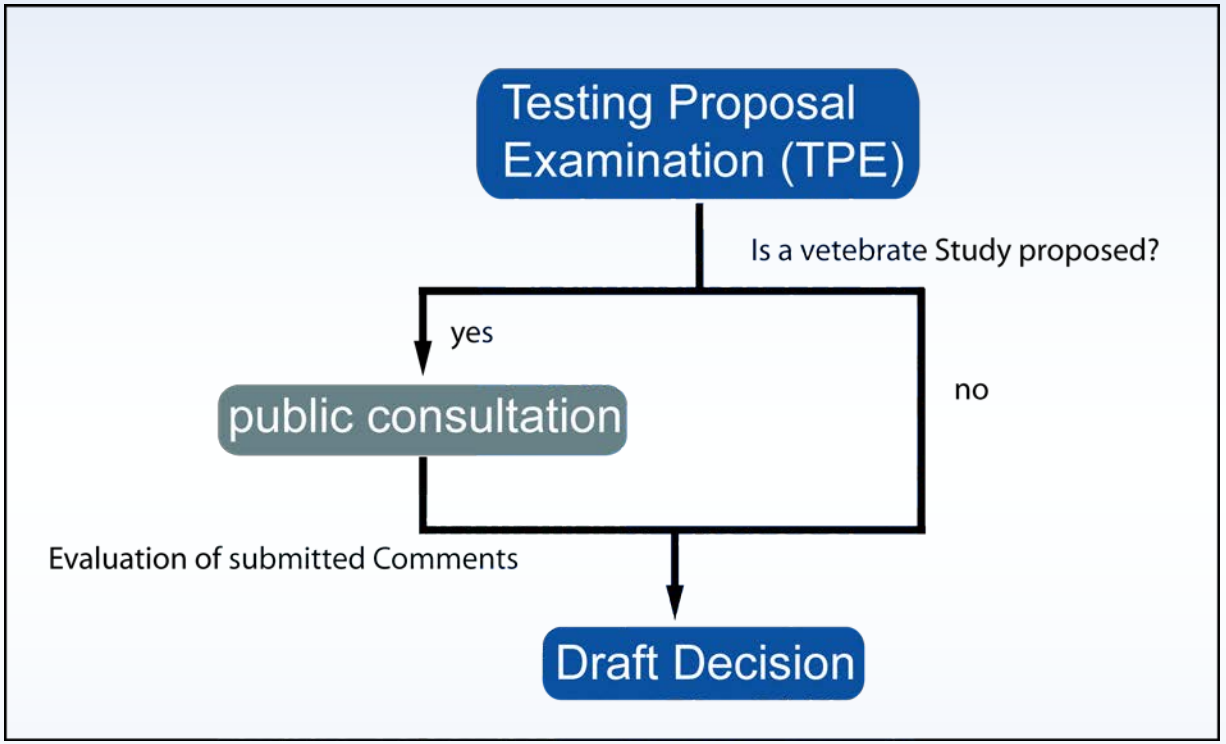
Evaluation - Testing Proposal Examination



- all animal studies – Third party consultation of 45 days
- after this generation of a Draft Decision – ECHA can support Registrant choice, can reject the proposed study, or propose another study

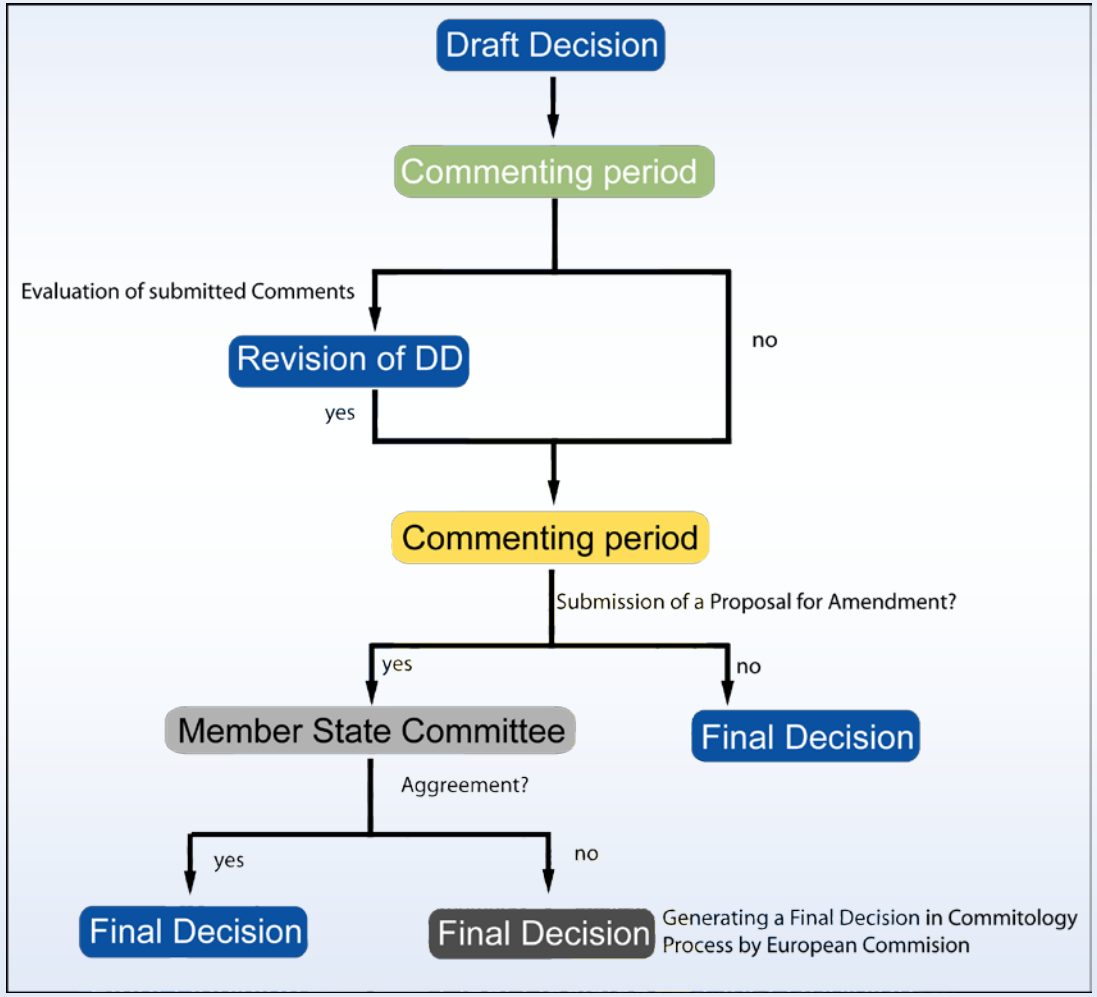
Registrant
Member States
ECHA

Evaluation - Testing Proposal Examination – Overview

Period for evaluation of all Testing Proposals (TP) of Dossiers > 1000 tons/year (1.12.2010) was 1. December 2012

- 571 Dossiers containing 1.184 TP to different endpoints
- 445 Dossiers containing 770 TP for vertebrate studies

Evaluation - Testing Proposal Examination

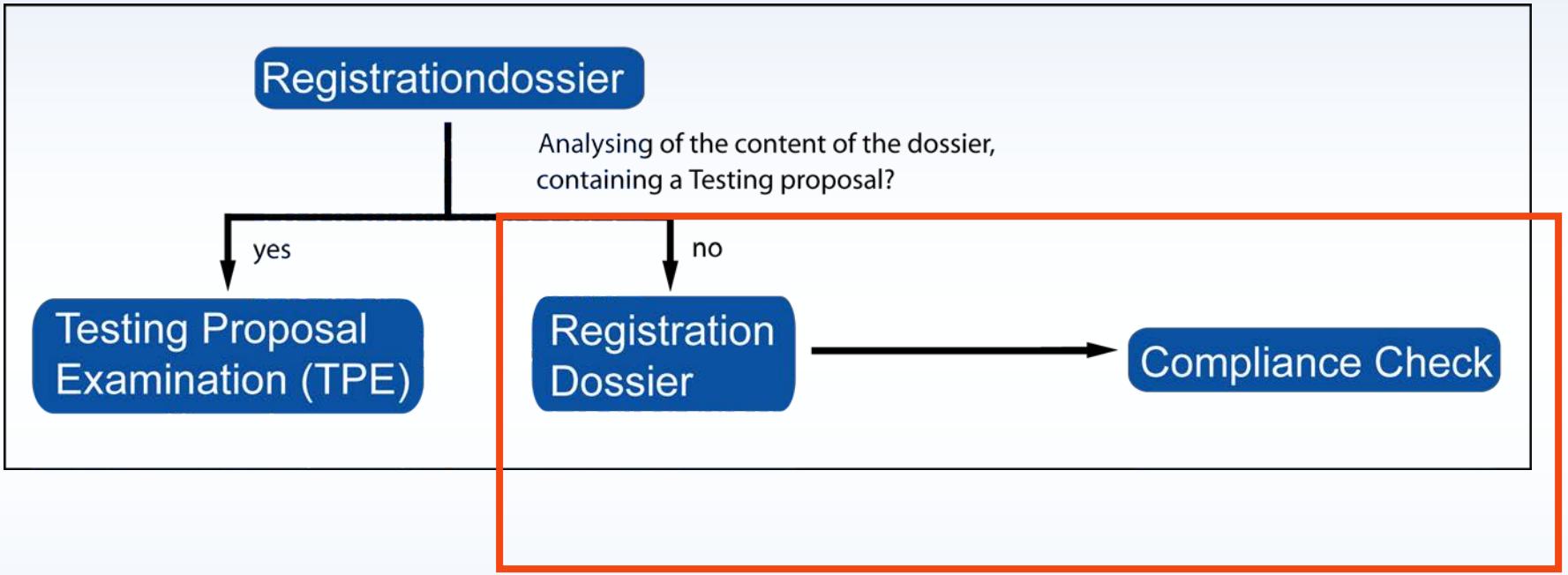


- Registrants commenting period as well commenting period of the Member States (MS) is 30 days

- If a MS decides to amend the Draft Decision it needs to be referred to the Member States Committee to seek for Agreement

Registrant
Member States
ECHA

Evaluation



- 5% of Dossiers of each tonnage band (> 1000 t/a; 100 – 1000 t/a and 1 -100 t/a) needs to be checked for compliance
- for 2010 Deadline around 900 Dossiers

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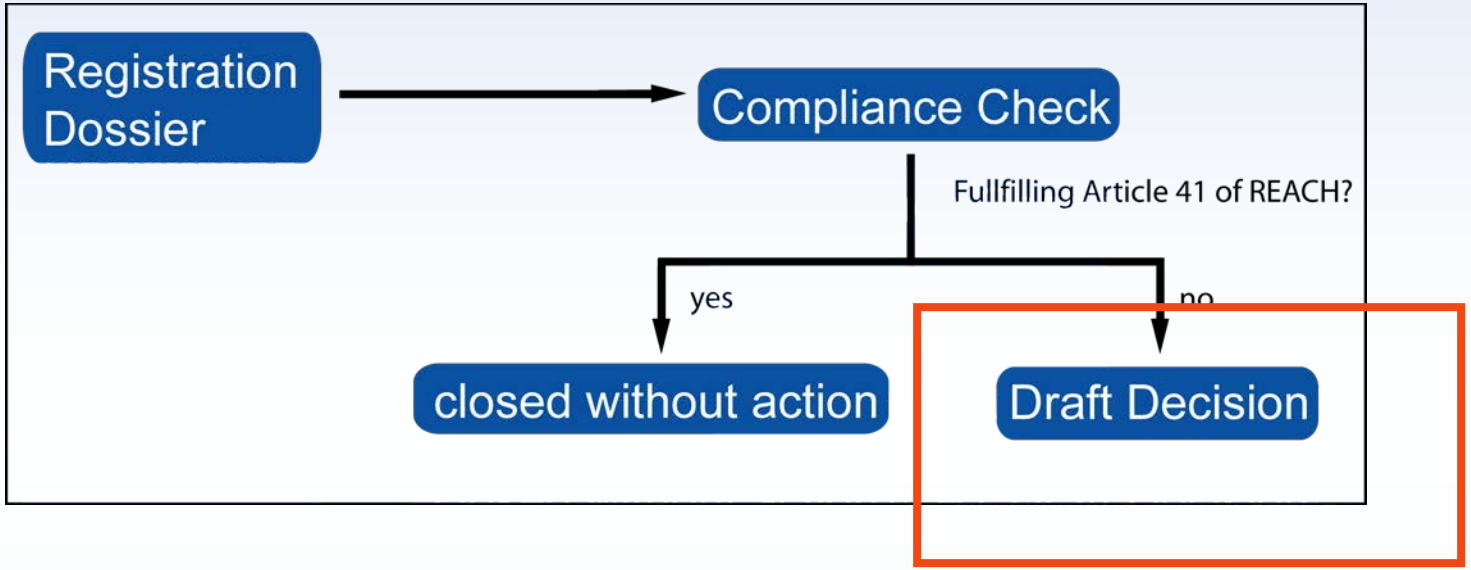
Evaluation - Compliance Check



- according REACH Regulation - all standard information requirements were checked
- if shortcomings occur – addressing in a Draft Decision

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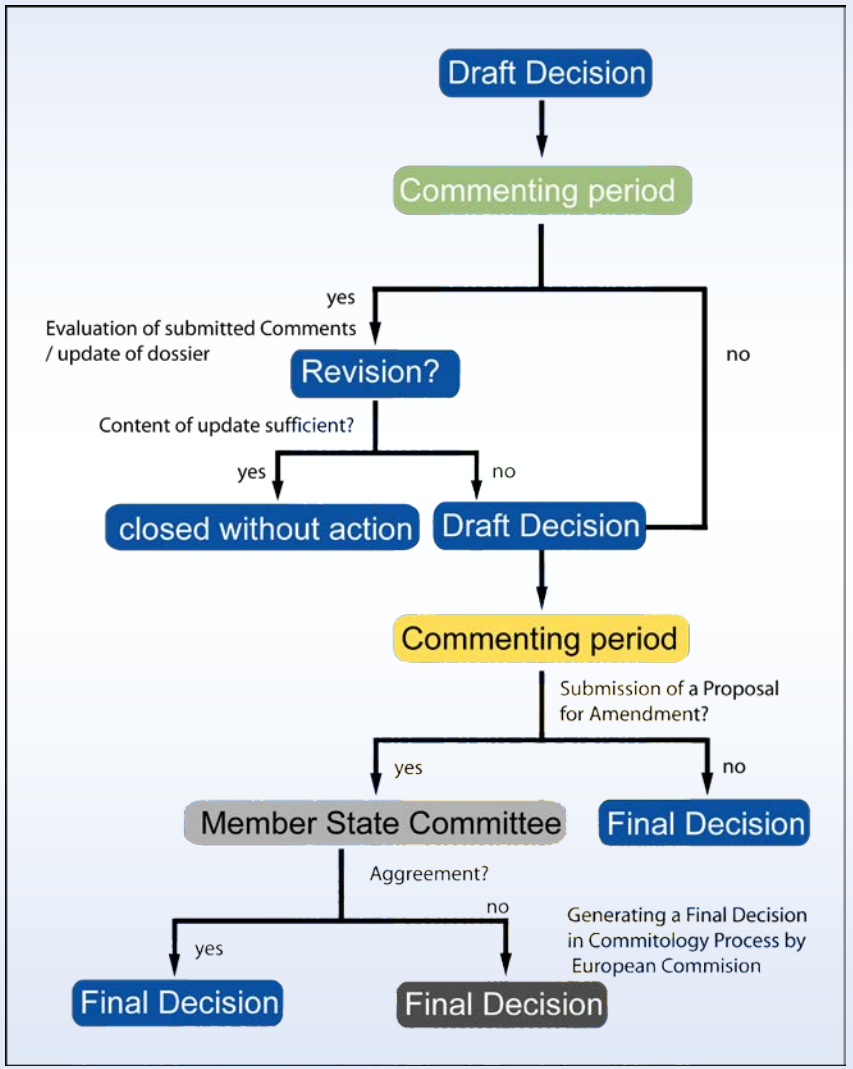
Evaluation - Compliance Check



- Registrants commenting period (30 d) to react on the draft decision
- Analysing submitted Comments can lead to close the compliance check
- commenting period of the Member States (MS) is 30 days
- If a MS decides to amend the Draft Decision it needs to be referred to the Member States Committee to seek for Agreement

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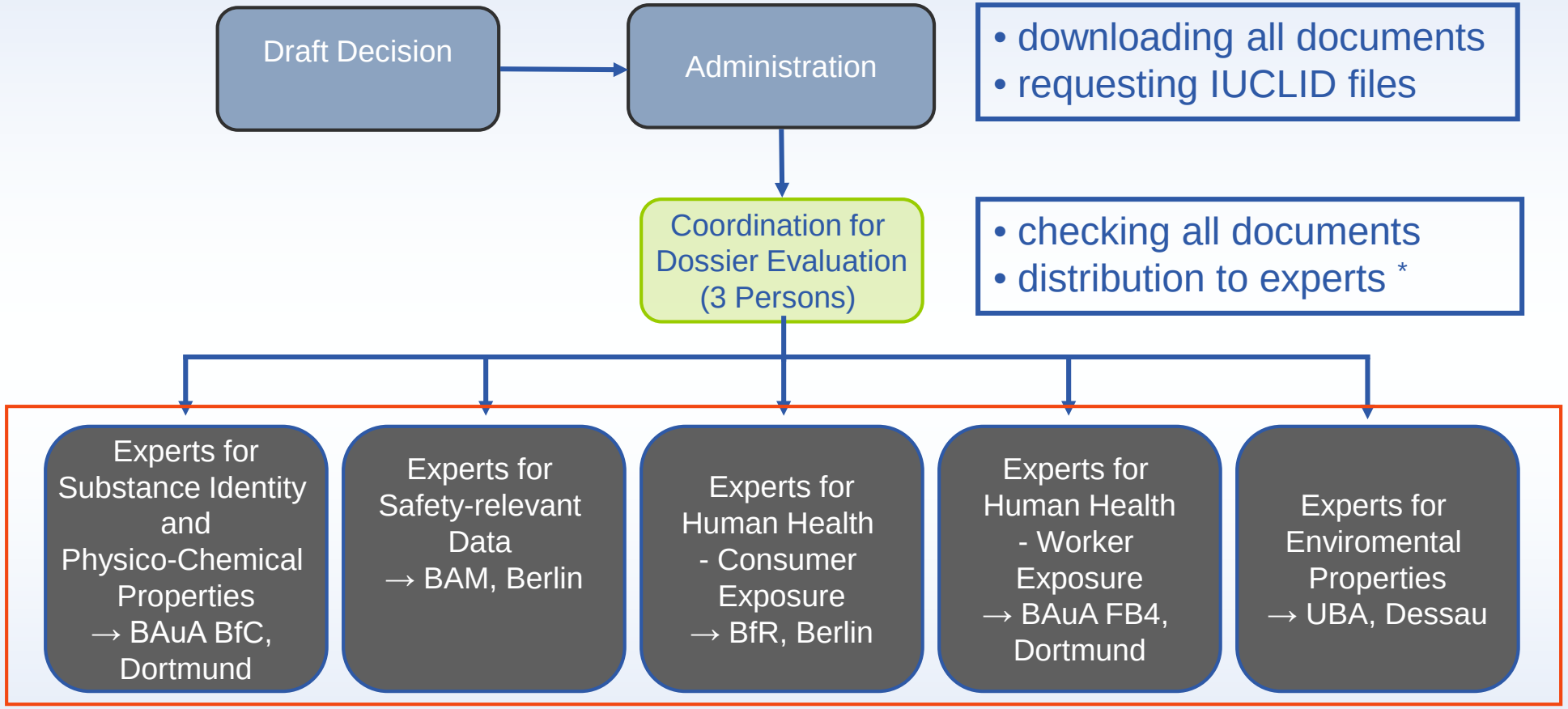
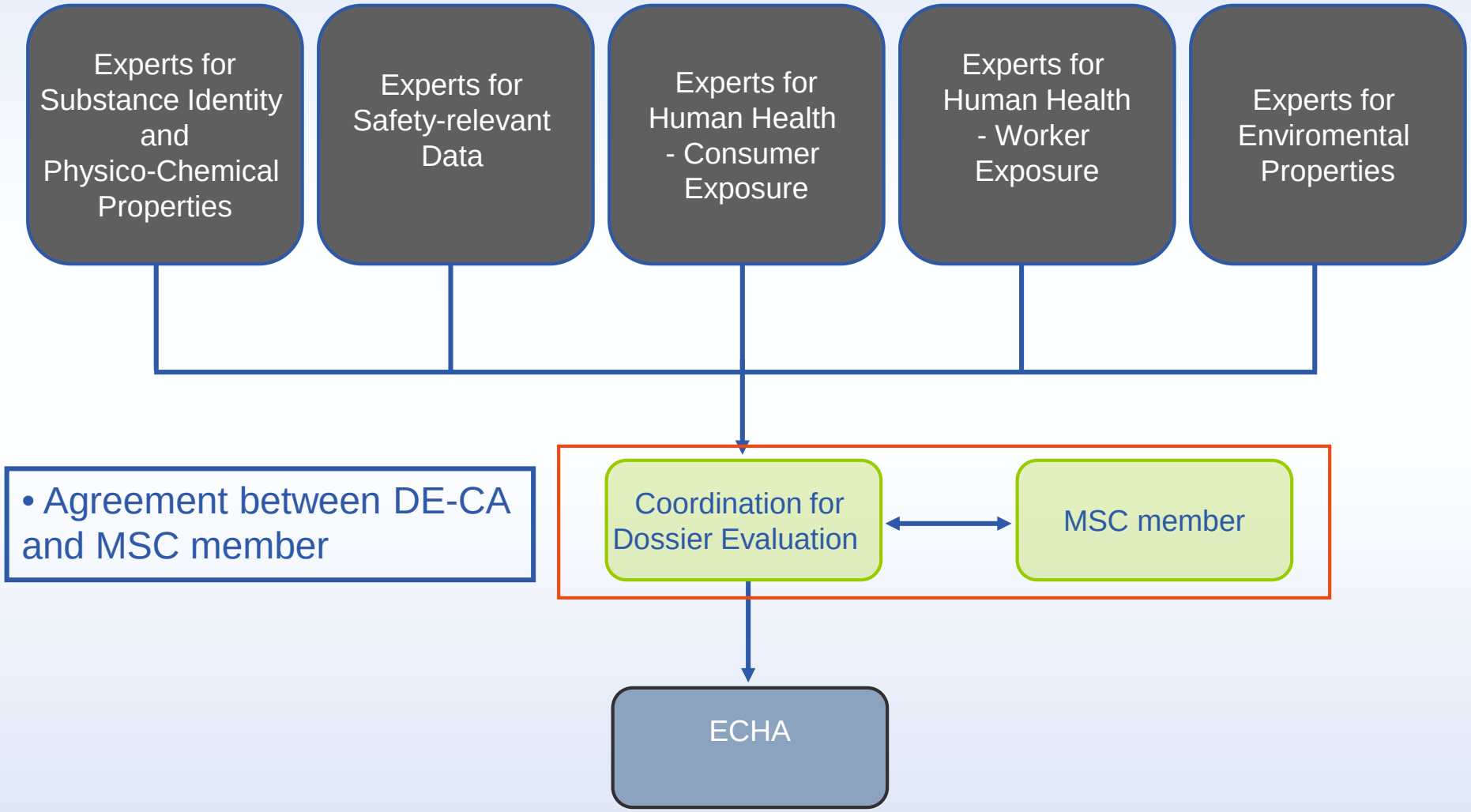
Workflow – DE-CA Commenting period [1]

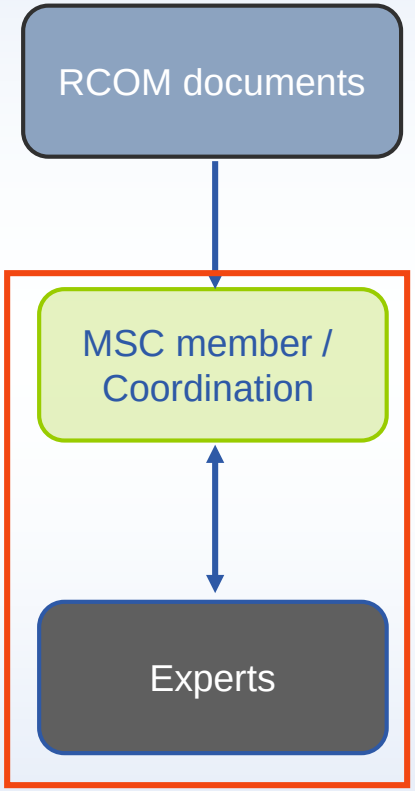


* TPE → participation of experts according to endpoints covered in DD
CCH → participation of all experts

Workflow – MSCA Commenting period [2]



Workflow – MSC



- Receiving of RCOM documents
  - Analyzing of the documents – involvement of experts
  - ECHAs response to DE-amendment is checked
  - analysing amendments from other MS
    - Support or reject amendment
  - Discussion between MSC member and experts
  - Development of DE-MSC opinion

Thank you for your attention!

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www.baua.de