Evaluation: lessons learnt 2013

Ninth Stakeholders' Day

21 May 2014

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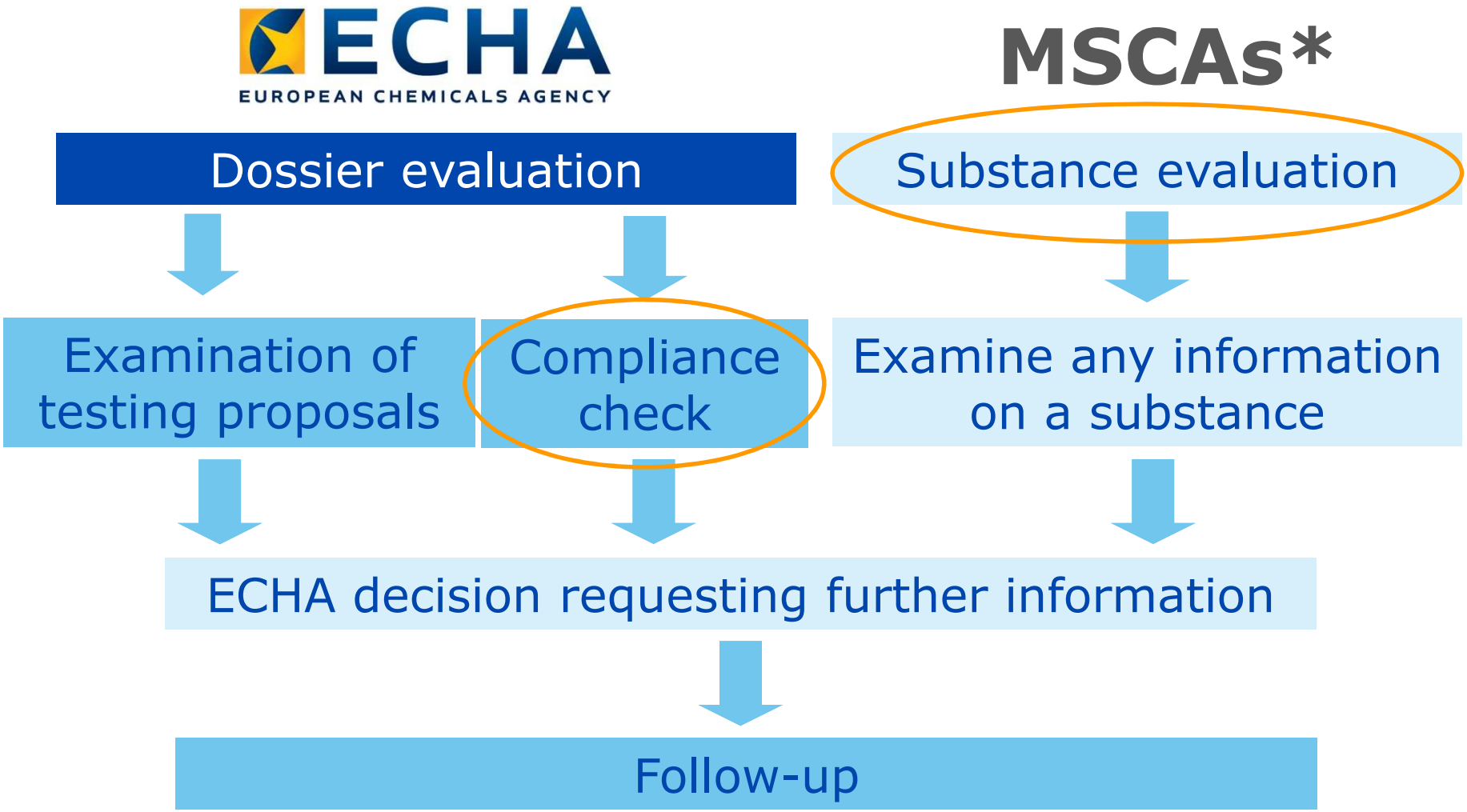
European Chemicals Agency

Evaluation 2013 – what was new?

Outline

- New procedural aspects in 2013
- Substance evaluation
  - Status
  - Interaction with Member State competent authorities
- Dossier evaluation
- Recommendations
  - Interaction with ECHA
  - Adaptations
- More information

Evaluation Processes



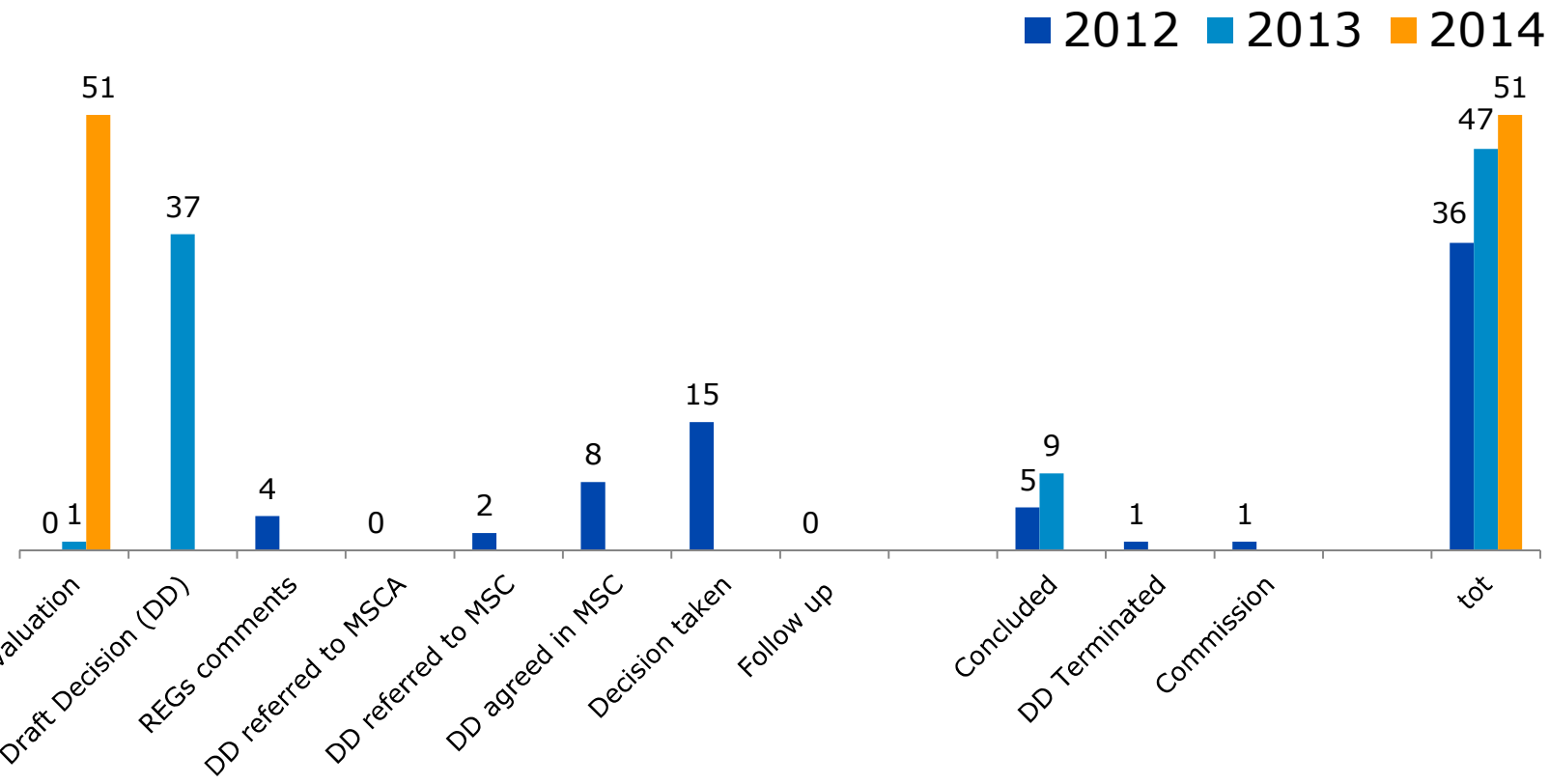
* MSCA = Member State Competent Authority

New procedural aspects in 2013

- Substance evaluation
  - Community rolling action plan (CoRAP) 2014
  - First ECHA decisions taken
- Dossier evaluation
  - Compliance check 5% target reached for 2010 dossiers
  - More checks on chemical safety reports
  - ECHA decisions taken on testing proposals
  - Decision follow-up and enforcement

REACH Evaluation
Substance evaluation

Status of cases - 2012-2014



Community rolling action plan 2014-16

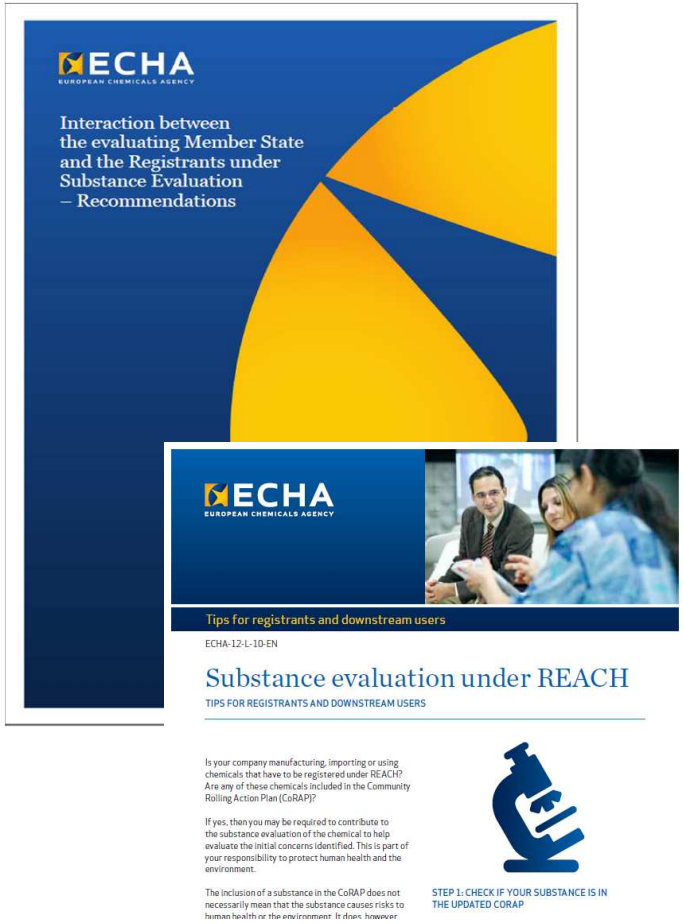
- **CoRAP** update published 26 March 2016:
  - 2012: 36 substances
  - 2013: 47 substances
  - 2014: 51 substances (50 entries)
  - 2015: 48 substances (plan)
  - 2016: 21 substances (plan)

- http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

Interaction with the Member State

- Agreement seeking starts before a draft decision is sent
- One contact point for registrants
- Leaflet on *Substance evaluation under REACH – Tips for registrants and downstream uses*
- *Interaction between the evaluating Member State and the registrants under substance evaluation – recommendations*

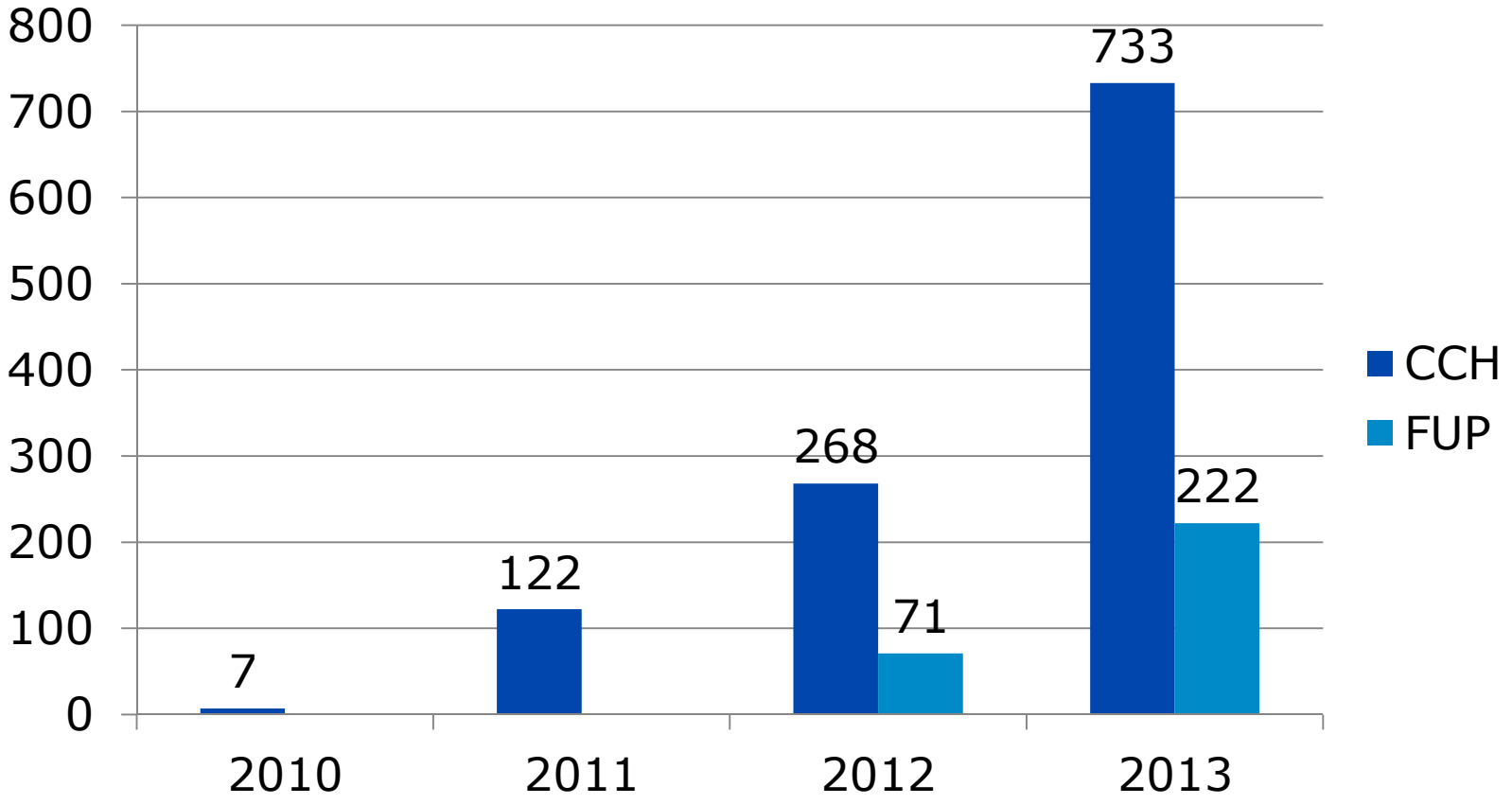
http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation



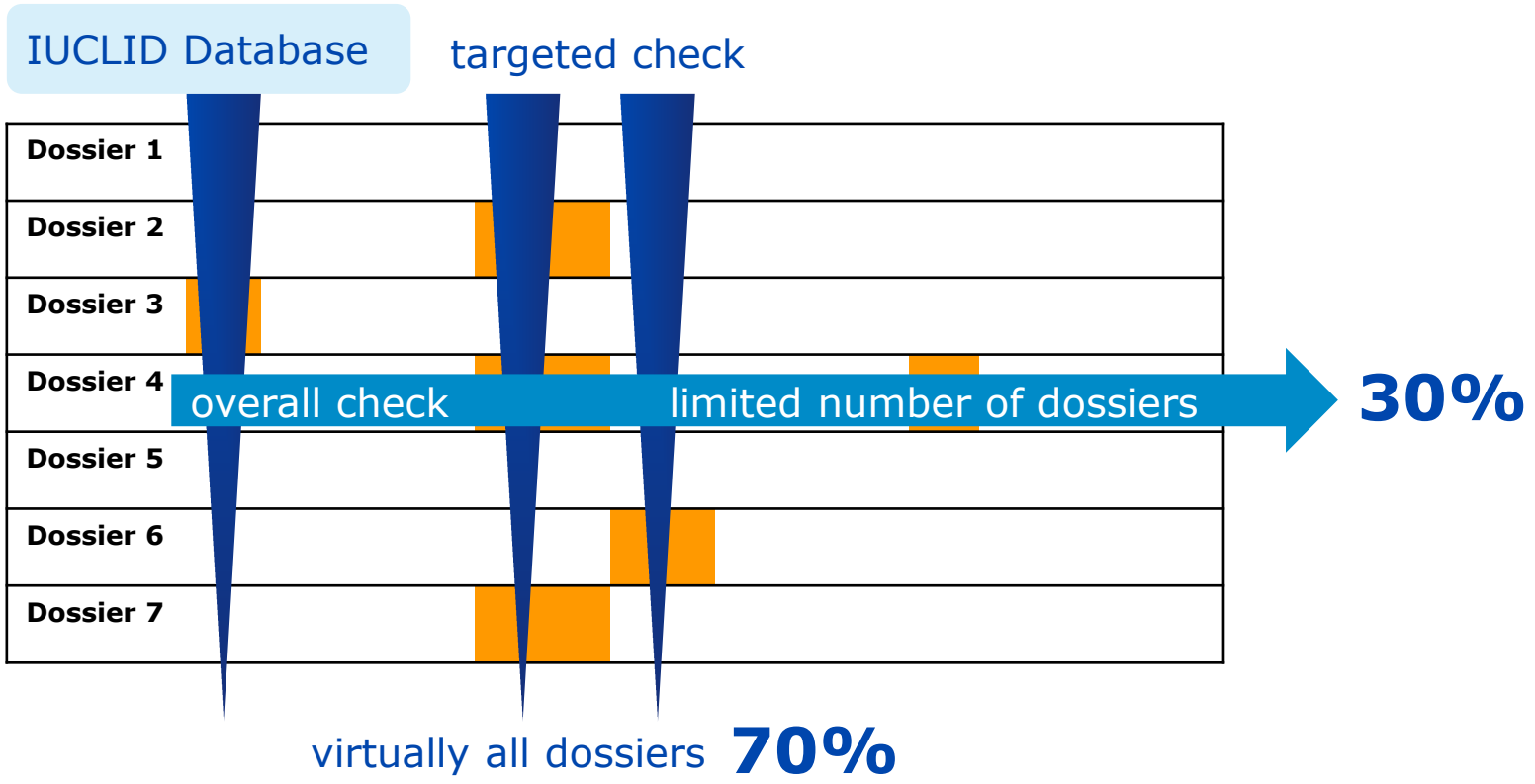
REACH Evaluation
Compliance check (CCH)

* 989 – 5.0%
1130 – 5.7%
19772 – 100%

Checking 5.7 % of the registration dossiers for compliance*



Dossier selection for evaluation



Positive trends in 2013:

Upon (draft) decision, registrants updated dossiers, and

- Improved adaptation justifications
  - Read-across and other predictions[1)]
- Individual registrants joining SIEFs
  - Sharing data
  - Elimination of unnecessary (animal) testing

1) e.g.: (**Q**uantitative) **S**tructure **A**ctivity **R**elationship - (**Q**)**SAR**

Accepted grouping approaches

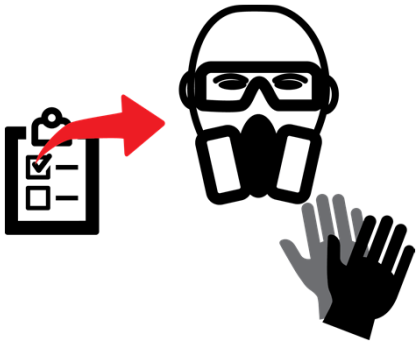
- Provided a clear and robust endpoint-specific read-across hypothesis,
- supported and justified the hypothesis with reliable scientific information,
- included all the supporting information in the dossier, and
- assessed the differences in composition between source and target substances

Recommendations to (future) registrants

- Integrate REACH compliance in your quality management system
- be proactive and keep your dossier up-to-date
- substantiate your reasoning when adapting the standard testing regime

Further recommendations

- The chemical safety report should **reflect the actual uses** and risks



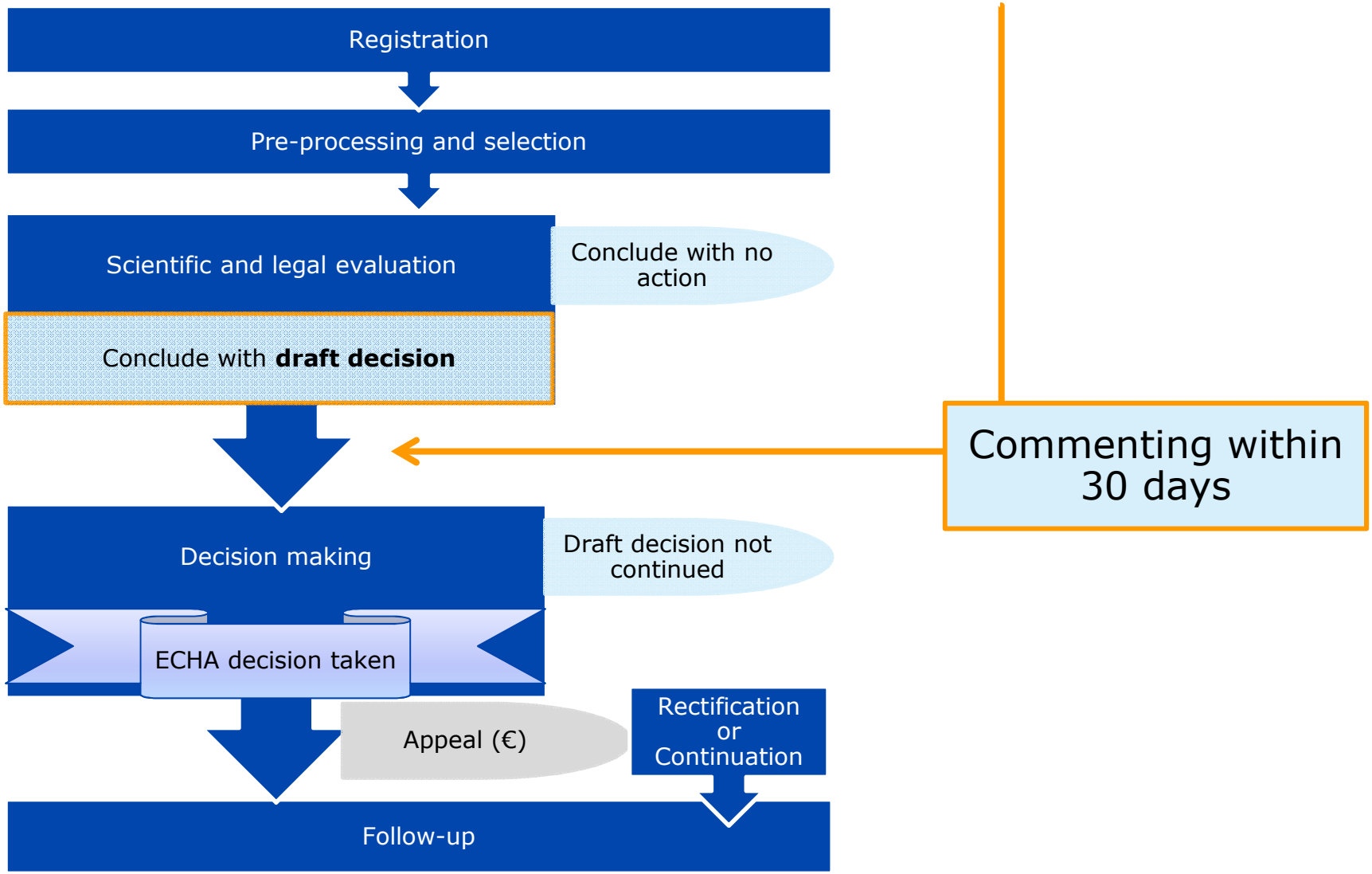
- **Watch the REACH-IT inbox**, so you can react immediately when you receive an ECHA communication

What if you get a draft decision?

Remember:

ECHA takes regulatory action to help you and your customers use chemical substances safely.

Registrant's part before a decision is taken



React when receiving the draft decision

- You have 30 days to give your views
- Keep talking in the substance information exchange forum (SIEF)
- You may be able to bring your dossier into compliance and avoid a decision
- Room for manoeuvre and timing gets tighter as the decision-making process rolls on

Adaptations

Use the available resources:

- REACH Guidance
- Read-across indicative example
- *Practical Guide 6*
- Annual Evaluation Report

Adapt according to REACH rules

- Explain <u>your</u> rationale behind the adaptation intention
- ECHA will help you to pinpoint remaining uncertainties

The Annual Evaluation Report:

http://echa.europa.eu/regulations/reach/evaluation

Contains recommendations, for example:

- PBT/vPvB[1] assessment
- Deriving No Effect Level
- Exposure scenarios
- Exposure assessment

1) **PBT** = **P**ersistent, **B**io-accumulative and **T**oxic
vPvB = **v**ery **P**ersistent and **v**ery **B**io-accumulative

Take home messages

- Regularly check your REACH-IT inbox and react to ECHA's communications
- Speak as a SIEF with one voice
- You are on track – continue the journey
- Integrate compliance in you quality system
- Use factual evidence for your positions
- Use the information provided on ECHA's website

Questions?

Ask your national helpdesk:

http://echa.europa.eu/support/helpdesks/national-helpdesks

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