Feedback from ECHA on dossier and substance evaluation

REACH Implementation Workshop X

13 December 2011

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ECHA – Evaluation Unit I

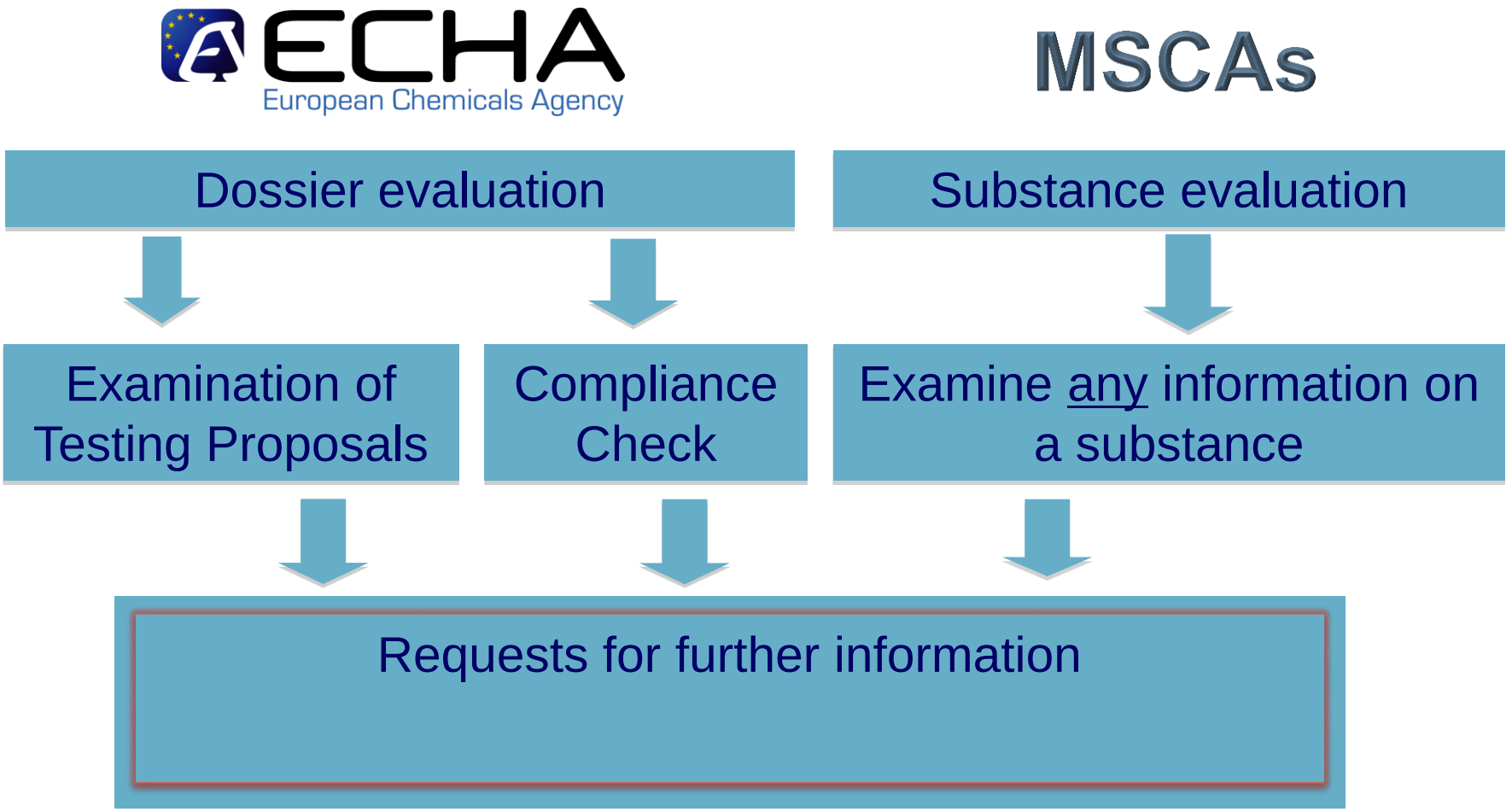
Overview

- Directorate of Evaluation
- Dossier evaluation
  - Compliance check & Testing proposals evaluation
  - Process, status, forecast and feedback
  - Feedback one-generation toxicity study (EOGRTS; OECD 443)
  - Bonus tip
- Substance evaluation
  - Process overview: CoRAP and Evaluation phase
  - Status overview
  - Recommendations
- Key messages and useful publications

Directorate of Evaluation

- Directorate Evaluation with three evaluation units
- 19 Administrative support staff
- 71 scientific staff
  - Various scientific disciplines: Toxicology, ecotoxicology, physico-chemistry, etc.
- Contributions from several other units:
  - E.g. Substance Identity Team, Computational assessment, RMM…
  - Other expert groups contributing to evaluation process (e.g. in relation to PBTs, Exposure assessment, C&L, nano's etc)

Evaluation Overview



Dossier Evaluation: compliance check process

Evaluation type	ECHA questions	ECHA examination conclusions	Numbers and timelines
Compliance Check (CCH)	Information requirements adequately fulfilled? Adaptations adequately justified?	Article 41(3) draft decision: •Request further information Other outcomes: •Quality Observation Letter – indicates elements to be improved •No further action	Select at least 5% of total received for each tonnage band •draft decision within 12 months of start CCH

- Detailed process description on webpage (http://www.echa.europa.eu/reach/evaluation/evaluation_process_en.asp)

Dossier Evaluation: compliance check status

- Since 1 june 2008 - present: 271 CCH Concluded
  - Draft/final decision: formal request for further information (231)
  - Quality observation letter: request for improving quality (59)
  - No administrative action/terminated (54)

- During 2011: 166 CCH concluded (end of Nov ’11 status)
  - Often in relation to Substance identity (SID) issues
  - In case SID is unclear, CCH is initiated to clarify and request further information, before concluding on Testing proposal

Dossier Evaluation: compliance check forecast 2012

- CCH needed as a minimum on 5% of dossiers per tonnage band ➔ 2010 registration deadline = approx. 1100 CCH

- For 2012 ECHA foresees to conclude on 250 CCH

- CCH selection based on concern/random ratio of 75/25
  - Potential for targeting areas of concern (targeted CCH): special attention may be paid to specific endpoints or information requirements
  - Targeted CCH could cover only parts of your dossier
    - In a worst case scenario this could result in consecutive draft decisions for same dossier, but targeting different endpoints

- CCH needs to ensure that quality of submitted dossiers is sufficient; currently there is significant room for improvement

Dossier Evaluation: compliance check feedback (i)

- Identity of the registered substance – describe it clearly
- Adaptation to the standard information requirements
  - must meet the conditions set out in Annex XI or in column 2 of Annexes VII – X of REACH Regulation;
  - sufficient justification for any adaptation should be provided;
- Robust study summaries: sufficient level of detail required to allow an independent assessment of information provided
- Classification and labelling: in line with the hazards identified or harmonized classification and labelling
- Testing proposal
  - submit for tests required under Annex IX and X before undertaking it
  - performing testing without an approving ECHA decision may lead to enforcement actions.

Dossier Evaluation: compliance check feedback (ii)

- Check consistency
  - Between CSR and IUCLID file
  - Between different parts of the CSR
- Always provide justifications for
  - Omission or modification of a standard CSR element (see REACH Annex I)
  - Deviations from guidance documents
- Qualitative assessment and justifications are not just statements
  - Detailed reasoning and supporting data are required
- Ensure transparency
  - Give details on model assumptions, versions, input parameters
- Use of Chesar and QSAR toolbox is recommended

Dossier Evaluation: testing proposal evaluation process

Evaluation type	ECHA questions	ECHA examination conclusions	Numbers and timelines
Testing Proposal Examination (TPE)	Proposed test adequate and justified? Unnecessary animal testing avoided?	Article 40(3) draft decision: •Accept testing •Reject testing •Change test conditions •Request additional testing	All testing proposals •non phase-in: draft decision in 6 months •phase-in submitted by 1 Dec 2010: draft decision by 1 Dec 2012

- Detailed process description on webpage (http://www.echa.europa.eu/reach/evaluation/evaluation_process_en.asp)

Dossier Evaluation: testing proposal evaluation status

- 573 Testing proposals (TP) need to be concluded by 1 December 2012
- Third party consultations for 430 dossiers with TP for vertebrate testing
  - Batchwise processing - will be ended by end of 2011
  - Relevant scientifically valid information related to hazard properties of substance required ➔ often hypothetical testing strategies, hence testing needs are not often changed
  - publication of ECHA responses on third party feedback on ECHA's website ➔ improved contributions over time
- Since 1 june 2008 - present: 271 TP Concluded
- During 2011: 183 TP concluded (end of Nov '11 status)

Dossier Evaluation: testing proposal evaluation forecast 2012

- Remaining Testing proposals (TP) need to be concluded (approx 350 draft decisions)
  - Draft decision sent before 1 December 2012

- For a significant number of TPs the ongoing (targeted) CCH needs to be concluded first
  - CCH in relation to SID ➔ ECHA expects the updated dossier(s) with correct SID
  - Updated dossier forms the basis of new TP evaluation

Dossier Evaluation: testing proposal evaluation feedback

- Provide adequate Substance identity information
  - Registered substance
  - Test material

- In case of category/read across:
  - Provide thorough scientific justification on why you think this is appropriate
  - Consider legal text Annex X 1.5 of REACH
  - Strengthen your rationale for read-across
  - Do not apply “wishful” thinking nor general statements. Consider that “more information is better”

Feedback on OECD test method 443 (i)

- Extended One-Generation Toxicity Study (EOGRTS) was adopted as an OECD Test Guideline (number 443) on 28 July 2011.
  - In principle this new method may be suitable to fulfil current information requirement in Annexes IX and X 8.7.3 for a “two-generation reproductive toxicity study”.
- One draft decision for one testing proposal was referred to the Commission for decision making for the first time (MSC-19)
- Working group (MS, Commission, ECHA, Industry, NGO) was set up to develop scientific criteria for use of TG 443 under REACH.
- Currently there is general MSCA support for urgent adoption by EU Test Method Regulation (EC) No 440/2008.
- However, discussion on scientific criteria for triggering 2nd generation and legal basis still ongoing.

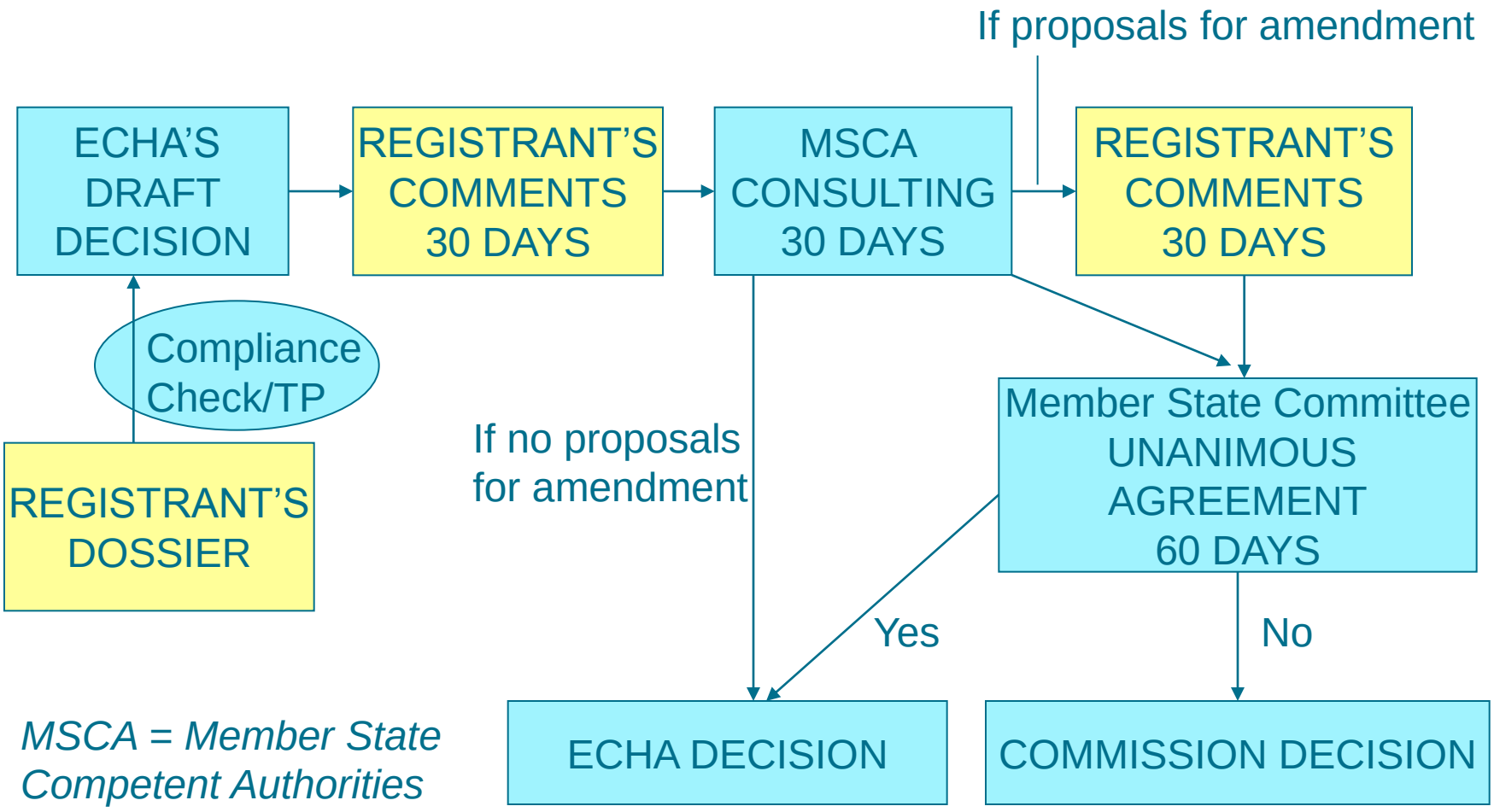
Feedback on OECD test method 433 (ii)

- Therefore, Evaluation draft decisions will give registrants a choice of test method to use to address this standard information requirement:
  - two-generation reproductive toxicity study (test method: EU TM B.35/OECD TG 416) **OR**
  - OECD TG 443 including the extension of Cohort 1B to mate the F1 animals to produce the F2 generation which shall be kept until weaning. The conduct of this study should allow generation of data equivalent to the current EU TM B.35.
- Registrants are invited to indicate their preference during 30 day commenting period ➔ will be considered for final decision

Feedback on OECD test method 433 (iii)

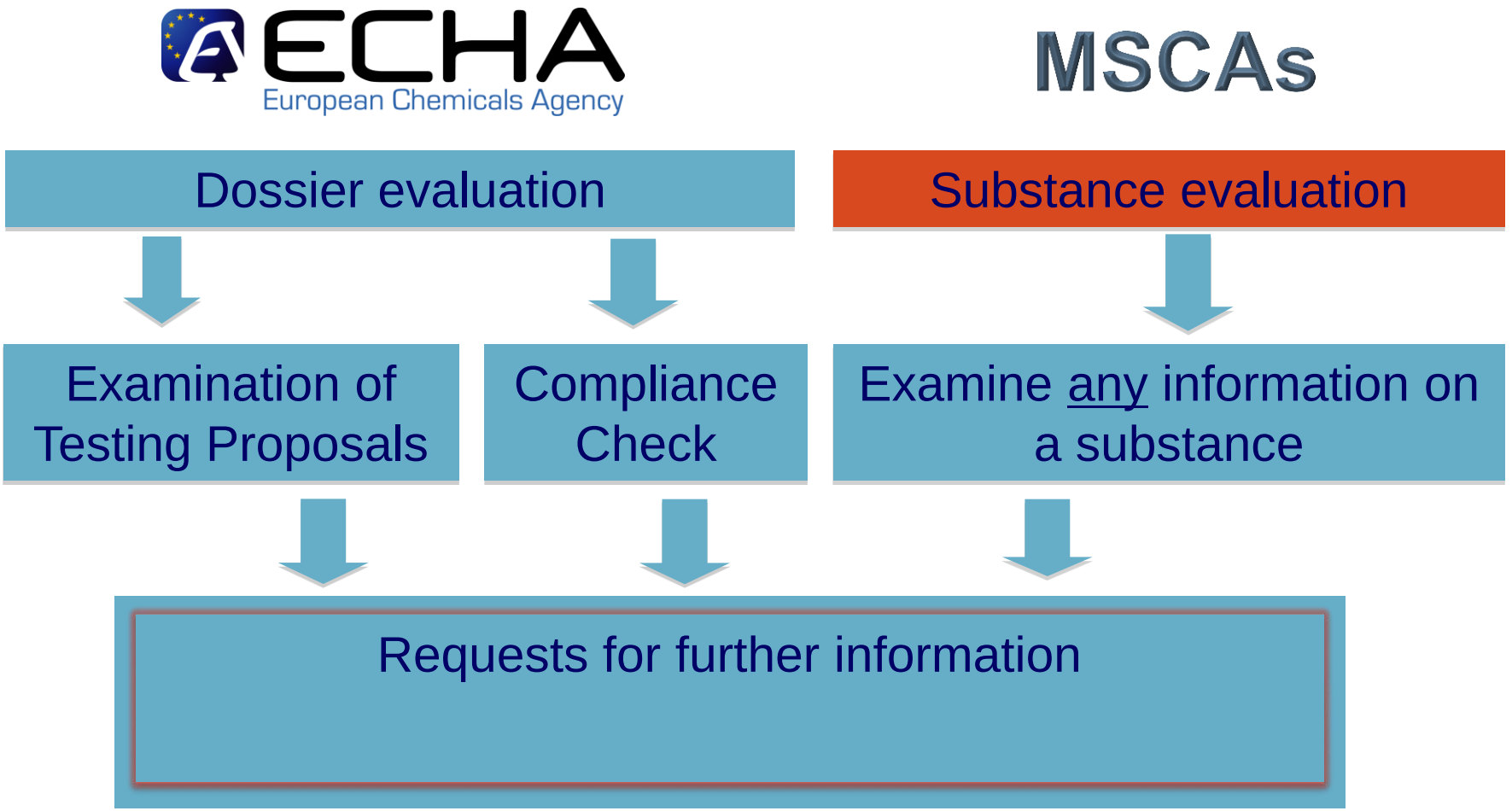
- There could be specific justifications indicating that it is not necessary to include second generation in EOGRTS
  - E.g. in a weight of evidence approach according to Annex XI, 1.2
  - It is the responsibility of registrant to present such arguments in TP
  - justifications must be scientifically sound and well documented
- In case MSC does not find unanimous agreement on this DD, a final decision on this endpoint may be put on hold, pending the outcome of the Committee procedure (art 133 of REACH)
- In case other tests for other endpoints have been proposed in the same dossier, the final decision will cover these other endpoints only ➔ no delay in testing, except for the “2-gen reproductive toxicity study”

Bonus tip: Use the formal and informal interaction possibilities



MSCA = Member State Competent Authorities

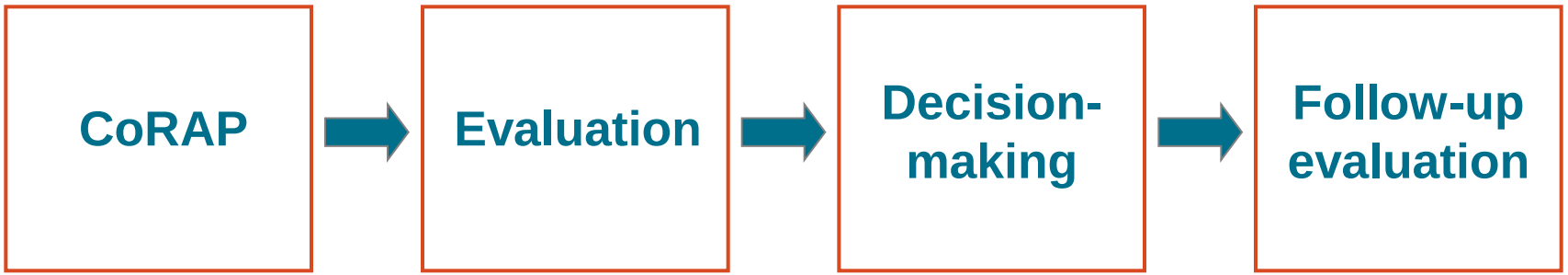
Evaluation Overview



Substance evaluation: aim

- To clarify whether substance constitutes risk to HH or ENV
- Potential formal outcome of substance evaluation:
  - request for further information to clarify risk
- Notification of evaluating MS to ECHA (report) in case no further information needs to be requested.
- If risk is already demonstrated, substance evaluation is not appropriate route.
- Other processes should be initiated instead by the respective actors (e.g. authorisation, harmonised classification and labelling, restrictions).

Substance Evaluation: process overview



Community Rolling Action Plan

Substance evaluation: Status CoRAP development - 1

- First CoRAP development during 2010-2011
- Selection criteria (to be further refined for CoRAP 2013):
  - Hazard and risk related criteria
    - Suspected/Known PBT, endocrine disrupters, CMRs, sensitizers etc
  - Exposure related criteria
    - Wide dispersive use, Consumer use, exposure of sensitive subpopulations such as children, aggregated tonnage etc.
- Published on ECHA's website
  - http://www.echa.europa.eu/doc/reach/evaluation/corap_2011.pdf
- Based on these criteria ➔ multi-step interaction process with MSCA to generate candidate CoRAP substance into first draft CoRAP

Public version of the draft Community rolling action plan submitted to the Member State Competent Authorities and the Member State Committee

YEAR	EC NUMBER	CAS NUMBER	SUBSTANCE NAME*
2012	200-262-8	56-23-5	carbon tetrachloride
2012	200-659-6	67-56-1	methanol
2012	200-817-4	74-87-3	chloromethane
2012	200-849-9	75-21-8	ethylene oxide
2012	201-245-8	80-05-7	4,4'-isopropylidenediphenol
2012	201-289-8	80-54-6	2-(4-tert-butylbenzyl)propionaldehyde
2012	201-983-0	90-30-2	N-1-naphthylaniline
2012	202-046-9	91-17-8	decahydronaphthalene
2012	203-002-1	102-06-7	1,3-diphenylguanidine
2012	203-253-7	104-93-8	4-methylanisole
2012	203-625-9	108-88-3	Toluene
2012	203-777-6	110-54-3	n-hexane
2012	203-868-0	111-42-2	2,2'-Iminodiethanol
2012	203-956-9	112-30-1	decan-1-ol
2012	204-278-6	118-79-6	2,4,6-tribromophenol
2012	204-617-8	123-31-9	Hydroquinone
2012	204-800-2	126-73-8	Tributyl Phosphate
2012	205-288-3	137-30-4	ziram

Substance evaluation: Status CoRAP development - 2

- 3 years CoRAP
- Draft CoRAP submitted to MSC and MSs, 20th October (public version on ECHA web site)
- 91 substances in total
  - 36 in 2012
  - 24 in 2013
  - 31 in 2014
- Expected adoption by 28 February 2012
- Aim: clarify the concern, eventually by requesting further information. It is not a black list!

Substance evaluation: Evaluation phase

- Evaluation: from publication of CoRAP, evaluating MSCA has **12 months** for considering the need for further information and preparing request (draft decision).
- Decision making similar to Dossier Evaluation decisions
- After adoption of decision, registrant(s) shall within timelines specified in the decision submit requested information to ECHA by updating the registration dossier(s) with new data.
- Follow up evaluation: Following this, MSCA must examine any information received and, if needed, draft any further appropriate decision within another 12 months of the information being submitted (Article 46(3)).

Substance evaluation: Recommendations

- Is your substance is on the first formal CoRAP? Get prepared within your consortium!
- Substance evaluation final decisions will be generated within one year ➔ could result in further requests for information. Such as:
  - Testing requirements that go beyond the REACH standard information requirements
  - Exposure related information
- Be prepared to handle the incoming draft decisions and organise your commenting (same timelines as under Dossier Evaluation)

Key Messages for Registrants

- Whether you registered in 2010 or you are preparing your registrations for 2013: **do not consider your registration dossier as a final product**
  - Take a pro-active approach and update your dossiers when new information on hazards or uses becomes available
  - Take into account the recommendations in the Article 54 report
  - Do not await the outcome of potential compliance checks - improve the quality of the dossiers through updates on your own initiative.
  - Further compliance checks will be conducted and reporting on the results will improve the quality of the dossiers.

Relevant publications on Evaluation

- Evaluation under REACH – Progress Report 2010*
  - Yearly report according to Article 54
- Dedicated website section on evaluation
  http://www.echa.europa.eu/reach/evaluation_en.asp
- Factsheet Substance Evaluation
  Q&A on CoRAP (http://www.echa.europa.eu/doc/qa_corap.pdf)
- Practical Guides in general and especially nr 12: How to communicate with ECHA in Dossier Evaluation (!)*
- Article 117(3) report on implementation and use of non-animal test methods under REACH*

*See http://www.echa.europa.eu/publications_en.asp

Questions?