Evaluation under REACH

Visit of Ministry of Environment and of Institute of Environment and Renewable Natural Resources of Brazil

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Directorate E

Outline

- Introduction
- Dossier evaluation
  - Compliance check
  - Testing proposal examination
- Substance evaluation
- Conclusions

Evaluation: management system

- Directorate of Evaluation
  - Director: Leena Ylä-Mononen
- 3 Evaluation Units
  - Heads of Units: Wim De Coen (E1), Claudio Carlon (E2), Watze de Wolf (E3)
- 15 Dossier Evaluation Groups (DEGs)
- Co-operation with Directorates A (Communications), B (Legal Affairs and MSC-Secretariat), C (Substance Identity, QSAR), D (Exposure Assessment & Risk Management)

Evaluation under REACH

- **Pre-registration**
- **Data sharing**
- **Registration**

Industry provides information

ECHA
EUROPEAN CHEMICALS AGENCY

MSs

- **Evaluation**
  - **Dossier evaluation**
  - **Substance evaluation**

ECHA and MS-CAs control and request for further info

- **Classification & labelling**
- **Authorisation**
- **Restriction**

COM, with support of ECHA and MS-CAs, applies community wide risk management instruments

What is evaluation? (1)

Provide confidence that industry is meeting obligations

Prevent unnecessary animal testing

Build up information basis for eventual risk management measures at EU level

ECHA EUROPEAN CHEMICALS AGENCY

MSCAs

Dossier evaluation

Substance evaluation

Check test proposals

Compliance check

Examine any information on a substance

Output, e.g.:

- accept/reject a testing proposal
- request information, because the dossier is not compliant
- request information to clarify potential risks

What is evaluation ? (2)

Dossier evaluation

- ECHA evaluates:
  - testing proposals, *all of them*! (Art. 40)
  - compliance of dossiers, *at minimum 5% per tonnage band* (Art. 41)

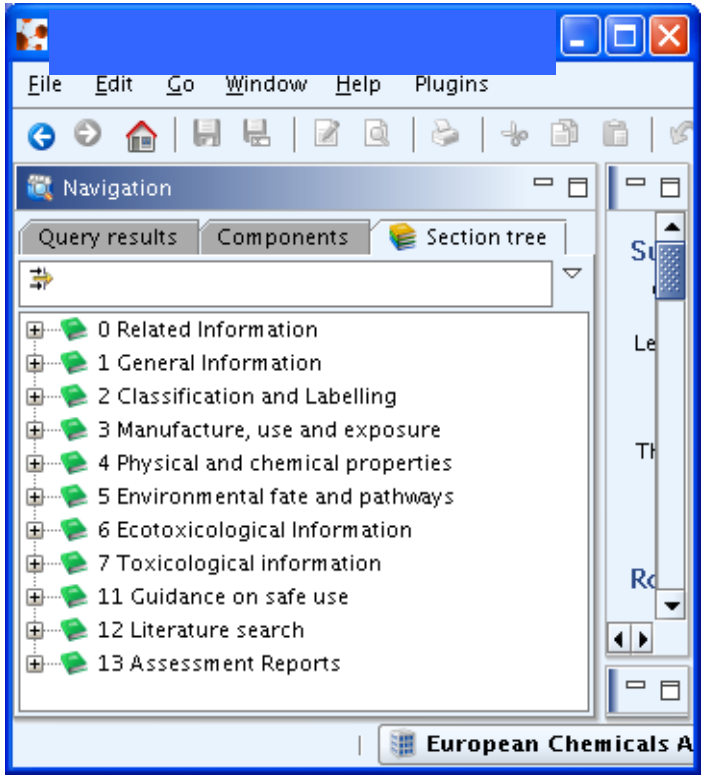
Substance evaluation

- MSCAs evaluate:
  - *selected* substances
  - Community Rolling action plan (CoRAP)-list (ECHA) (Art. 44)
  - Selection criteria (Art. 44): risk-based priority setting:
    - Hazard
    - Exposure
    - Aggregated tonnage

Dossier Evaluation:

Compliance check

Aims of the Compliance Check



- To check whether the information requirements are fulfilled in the registration dossiers
- To promote the quality of registrations
- ! Main instrument to request missing information, if information requirements are not addressed (=non-compliance)

When will the Agency perform a Compliance Check?

- The Agency may perform a compliance check of any registration dossier
- Some priority setting is suggested in the legislation:
  - Dossiers where information is submitted separately (opting-out of joint submission)
  - Dossiers [1, 10t], not fully falling under Annex VII (not fulfilling the criteria of Annex III)
  - Substance is on Community Rolling Action Plan (Substance Evaluation)
- Random selection
- Concern-driven selection

What is checked for compliance?

That:

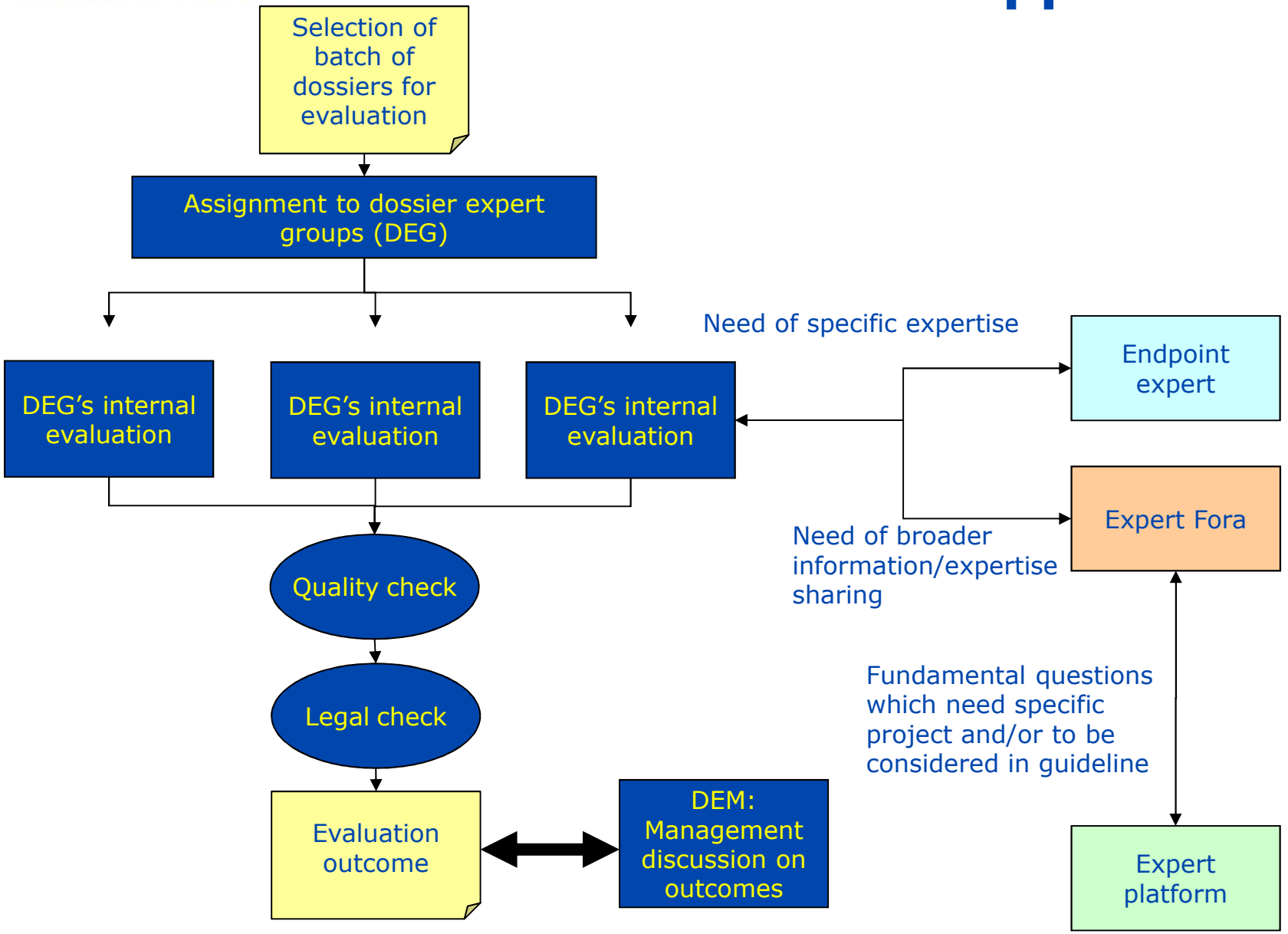
1. **Information in the technical dossier(s)** complies with the requirements of Art. 10, 12 and 13 and with Annexes III, VI to X;

2. **Adaptations** of the standard information requirements in the technical dossier(s) comply with Annexes VII to XI;

3. **Chemical Safety Assessment (CSA) and Chemical safety Report (CSR)** comply with Annex I and that the proposed **Risk Management Measures (RMM)** are adequate;

4. **Explanations** for separate submission from other registrants have an objective basis

DEGs & support

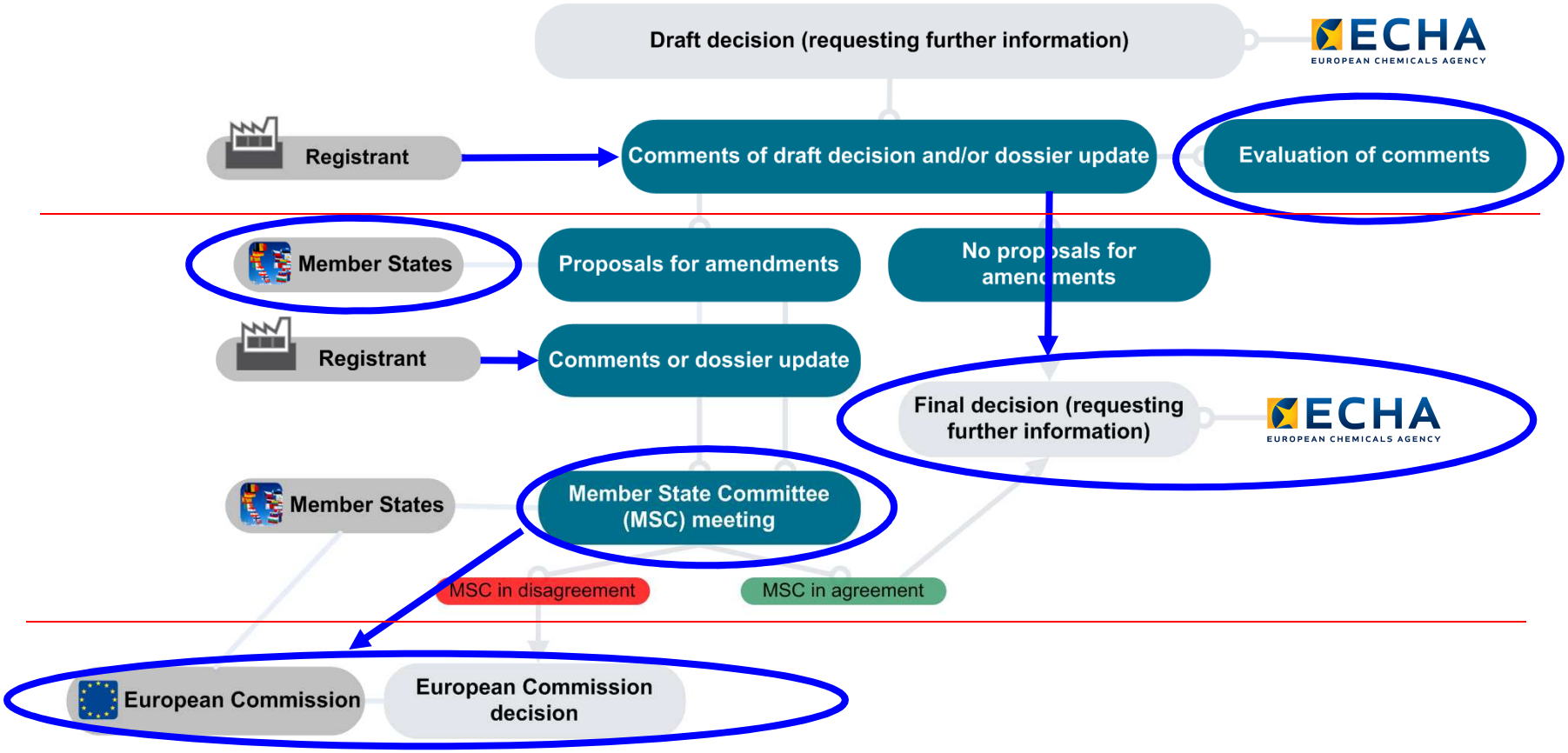


Possible outcomes of Compliance Check

- Conclusion document: no communication, internal document

- Communication to the registrant
  - Draft decision: request to provide information to make the dossier compliant + deadline for submitting further data
    - Legally binding
    - Communicated to the Member States
  - Quality Observation letter: observations, invitation to the registrant to improve the quality of the dossier
    - Not legally binding, but a follow-up process is in place
    - Communicated to MS

Evaluation – the mechanics



Follow-up of ECHA Decision

Registrant submits an updated dossier prior to the deadline set:

a) Examination by ECHA
- The update of the dossier is in line with the requests for further information
- The update of the dossier is found to be not in line with the request or the results are not taken into account in risk assessment: follow up action has to be decided
- Informing Commission and MSCAs of the conclusions

b) Possible further EU-wide follow up
- MSCAs/ECHA: Inclusion in Community Rolling Action Plan for Substance Evaluation
- MSCA: Annex XV dossier for authorisation
- MSCA: Annex XV dossier for restriction
- MSCA: C&L proposal

If no submission by the Registrant → MS enforcement matter

Dossier Evaluation:

Testing proposal examination

Aims of testing proposal examination (TPE)

- To stimulate and support industry towards efficient testing
- To conduct testing only if needed, in particular vertebrate animal testing

When a testing proposal?

Required by REACH Annexes IX and X:

- Registrants identify a data gap and cannot otherwise fulfil the REACH information requirements;
- Additional testing is triggered by risk, e.g.:
  - available information of the substance is inconclusive;
  - further investigation is needed

ECHA's tasks

Art. 40: the Agency shall evaluate any testing proposal in a registration or DU report

Deadlines:

- for non phase-in substances: 180 days after receipt
- for phase-in substances:
  - by 1 Dec 2012 (if received by 1 Dec 2010; >1000 tpa, CMR…)
  - by 1 Jun 2016 (if received by 1 Jun 2013; 100-1000 tpa)
  - by 1 Jun 2022 (if received by 1 Jun 2018; 1-100 tpa)

How to evaluate testing proposals?

Is the testing proposal justified?

- Is the test requested by Annexes IX-X?
- Is all available information considered?
- What impact on risk characterization, C&L or PBT/vPvB?
- Information received from the 3rd parties during public consultation should be considered

Is the testing proposal adequate?

- Is the proposed test method reliable and relevant?
- Is there a need to modify/adapt the test protocol?
- Is further testing needed?

Multi-annual WP 2012 - 2014

- Expects to handle about 600 dossiers/year.
- 1 December 2012 deadline for TPs submitted by the first registration deadline of 30 November 2010; 571 dossiers with 1184 individual TPs. 436 draft decisions were issued.
- 2013 priority, to conclude the up to 1000 compliance checks necessary to achieve the 5% target.
- 2014 target is to achieve good progress in the evaluation of testing proposals submitted by the 2013 deadline.

Substance Evaluation

Substance evaluation

Aim

- Clarification of a concern for human health or environment by requiring registrants to provide additional information

Who performs the evaluation?

- Member States' competent authorities (MS-CAs)

Decisions

- Requests for further information

What substances?

- Community Rolling Action Plan (CoRAP)

Substance evaluation vs CCH

	Substance evaluation (SEv)	Compliance check (CCH)
Objective (Why)	To verify the suspected risks	To ensure compliance with the standard information requirements
How	Request for information needed to clarify the risks	Request for information to fulfil standard requirements
What	Substances (all registration dossiers) included in CoRAP	Registration dossiers
Who	Member State Competent Authorities	ECHA
	Interlinked and complementary **(a CCH can be performed in preparation of SEv)**	

Role of MSCAs, Registrants and ECHA

- The Competent Authorities of the Member States (MSCA) evaluate the substances
- Registrants may be requested to update dossiers with further information
- ECHA coordinates the selection of substances to be evaluated (Community Rolling Action Plan) and the substance evaluation process in order to ensure a harmonised approach.

N.B. Any request of information will be proposed by the evaluating MSCA, but eventually made by ECHA

Community Rolling Action Plan (CoRAP)

Duration

- Covers three years

What is it?

- List of substances to evaluate in each of the next three years, evaluating Member States and initial concerns
- Substance specific justification documents published (from 2013)

Consequences of inclusion into CoRAP

- No legal impact for the Registrant
- Substances listed in the first year need to be evaluated within 12 months from the publication of the CoRAP
- Evaluation of substances listed for the 2nd and the 3rd year only starts from the publication of CoRAP updates in that year. They may be revised.

CoRAP – selection criteria

Selection criteria based on risk [Art. 44(1) REACH]

General criteria refined in collaboration with MSCAs and published on ECHA website.

Combination of hazard and exposure criteria:

- e.g. suspected PBTs/vPvBs, endocrine disruptors, CMRs, sensitizers
- e.g. wide dispersive use, consumer use, aggregated tonnage

According to Art. 45(5) MSs can notify substances based on any risk concern

CoRAP development and adoption in collaboration with MSCAs

Annual stepwise process:

- Selection of CoRAP candidate substances (IT based selection + expert verification),
- Consideration of regulatory effectiveness of CoRAP inclusion,
- Tentative distribution among evaluating MSCAs,
- Draft CoRAP publication, submission to MS Committee for opinion (October)
- Adoption and publication of CoRAP (update; March)

CoRAP publication

CoRAP 2012-2014	CoRAP 2013-2015
Published 29 Feb 2012	Published 20 March 2013
Contains 90 substances: • 36 for 2012; • 23 for 2013; • 31 for 2014	Contains 115 substances: • 46 for 2013; • 46 for 2014; • 23 for 2015
17 Member States evaluated substances	21 Member State will evaluated substances

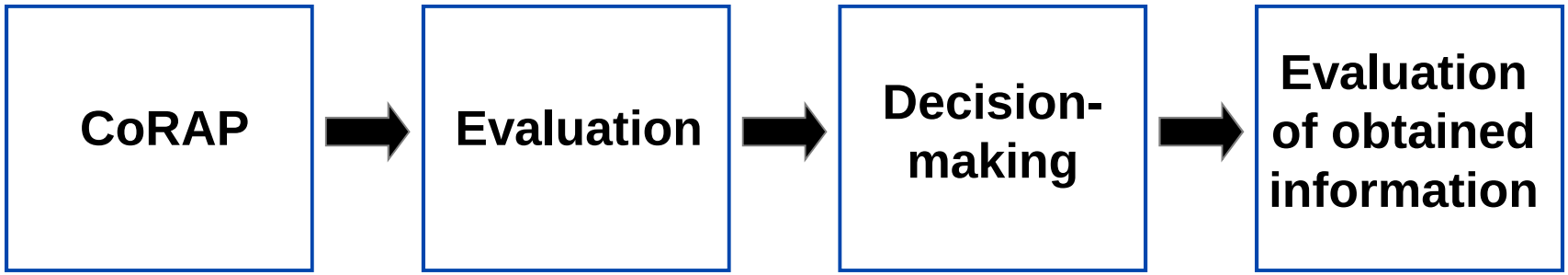
Complementary part to the CoRAP

- On 5 Sept 2012 ECHA published the list of pending evaluations originating from the previous legislation (NONS and ESR) that are regarded as included in the CoRAP.

- No new substances will enter to the complementary part of the CoRAP, the work will be just completed

- http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/transitional-measures

Substance Evaluation process



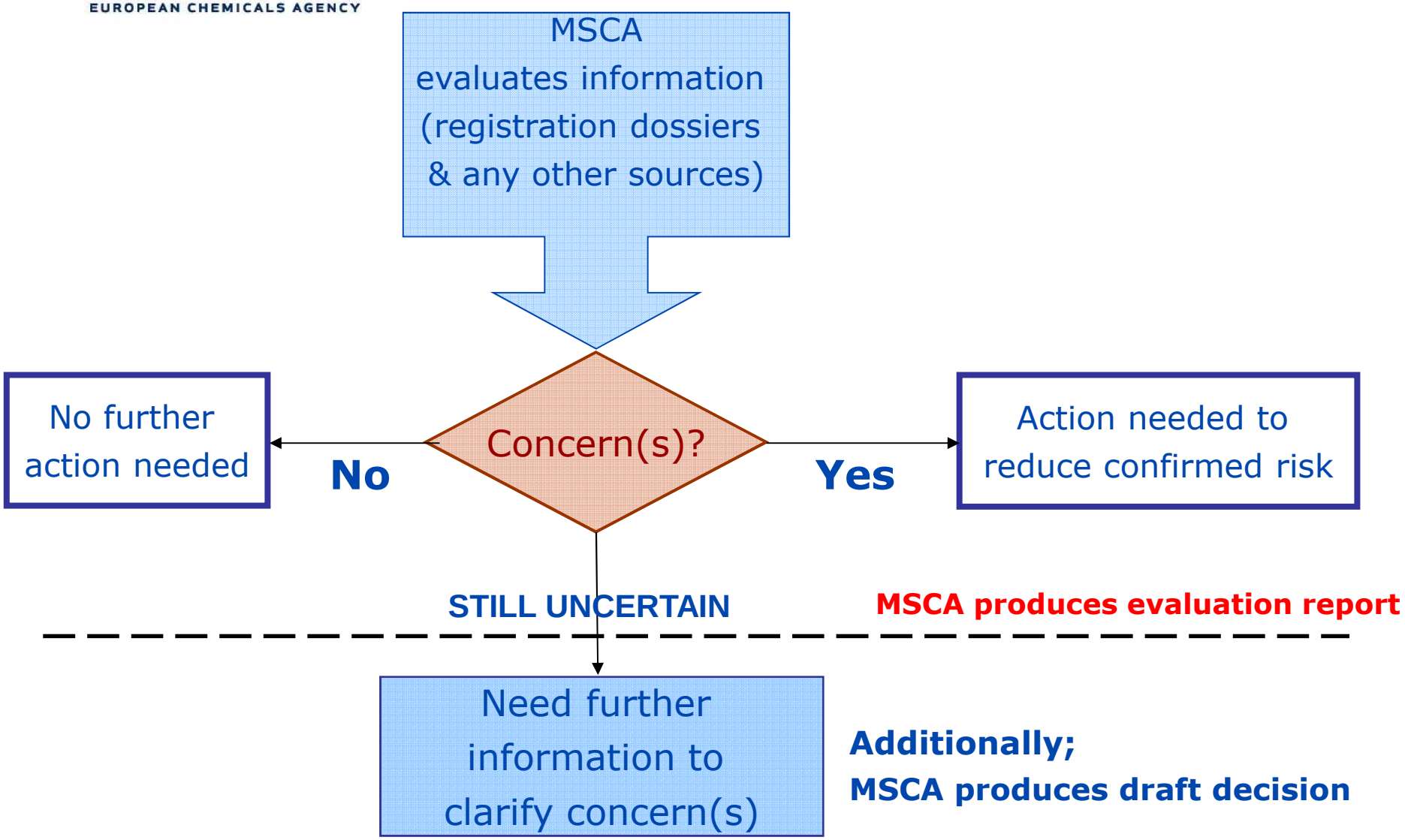
Substance Evaluation process

- Evaluation: from publication of CoRAP, evaluating MSCA has **12 months** for considering the need for further information and preparing request (draft decision).

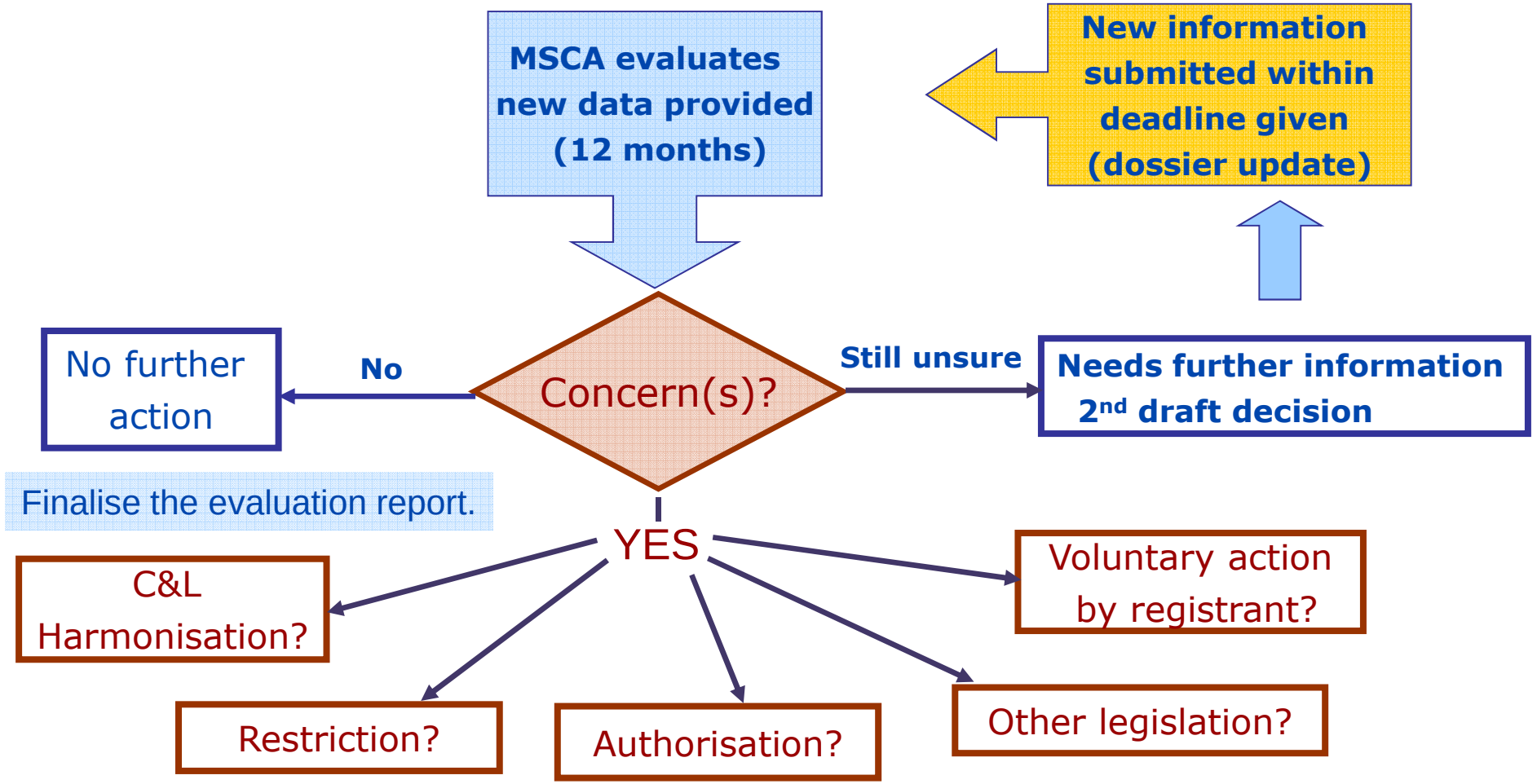
- After adoption of decision, registrant(s) shall within timelines specified in the decision submit requested information to ECHA by updating the registration dossier(s) with new data.

- 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)).

Evaluation and outcomes (12 months)



Follow up to Substance evaluation



The MSCA informs ECHA of its conclusions as to whether or how to use the information obtained **(Art. 48 – Follow-up).** ECHA informs the Commission, the Registrant and the other MSCAs.

Interaction with Registrant(s)

Formally – opportunity to comment on a draft decision
Value of a co-ordinated response from registrants

Informally – Registrant(s) can contact the MSs (details on the CoRAP)
– MS can contact registrant(s) (issues with submission of updates/pending studies)

Communication to the registrants and DU on how to act during SEv process

–A leaflet ”Tips for Registrants and DUs” under preparation

Work on-going on a harmonised policy across MS

Interaction between MS

Joint evaluations – collaboration between MS

Commenting – formally only on a draft decision
- no peer review of Sev reports

Information sharing – particularly when registrants are in another MS

Harmonised approach – workshops, commenting on documents

Interaction with ECHA

- **ECHA has a co-ordination role**
  - Ensuring a harmonised approach
  - Organising guidance, workshops, consistency screening of draft decisions, etc
  - Publication of outcome documents
- Specific **contact person in ECHA** allocated for each substance
- Preparation of the CoRAP
- Updating prioritisation criteria

Substance evaluation in 2012

- 36 substances evaluated
- Draft decisions prepared for 32 substances
- Evaluation of 4 substances concluded without sending a draft decision
  - Conclusion documents under preparation by MSs
- Substance evaluation in 2013:
  - Ongoing for 46 substances

Key messages

Substance Evaluation

- Substance Evaluation (SEv) complements the scope of Compliance Check (CCH): CCH may be performed in preparation of SEv
- SEv allows requesting further information on chemicals to clarify risk concerns. The information obtained should be considered by both industry and authorities for (regulatory) risk management

Community Rolling Action Plan (CoRAP)

- Inclusion in the Community Rolling Action Plan (CoRAP) is just the first step to perform an evaluation and NOT a preliminary judgment on the actual risk
- The initial concern will not limit the scope of the evaluation (other concerns can be found and addressed)
- If a substance is included in the CoRAP, industry should coordinate with other registrants of the same substance and prepare to handle requests for comments and final requests for information

Conclusions

Conclusions

- The safe use of substances starts under REACH with high quality registration dossiers (industry's responsibility)
- Through the process of Evaluation, ECHA and Member States are empowered to request additional information when essential data are missing, risk concerns need to be clarified
- ECHA also provides recommendations for registrants to improve the quality of dossiers
- Evaluation is the key process in achieving the ultimate aims of REACH – **a safer future for us all!**

Thank You.

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