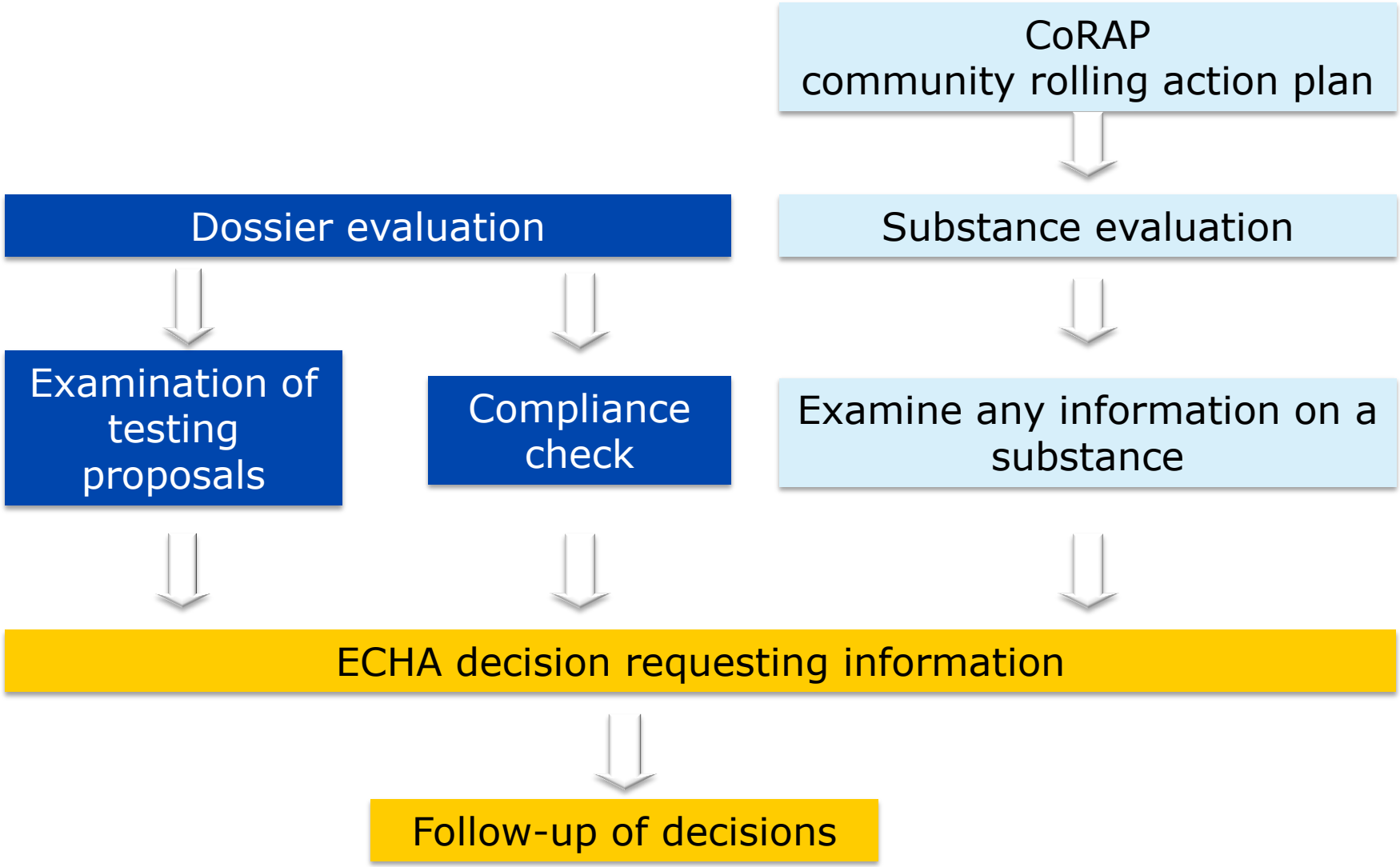
Dossier and substance evaluation: quality of dossiers

REACH Information and Experience Exchange Forum (RIEF I)

20 June 2013

Claudio Carlon
Head of Unit Evaluation
European Chemicals Agency

Evaluation: overview



Substance evaluation vs CCH

	Compliance check (CCH)	Substance evaluation (Sev)
Objective (Why)	•To ensure compliance with the standard information requirements	•To verify the suspected risks
How	•Request for information to fulfil standard requirements	•Request for information needed to clarify the risks
What	•Registration dossiers	•Substances (all registration dossiers) included in CoRAP
Who	•ECHA	•Member State Competent Authorities

Substance evaluation vs CCH

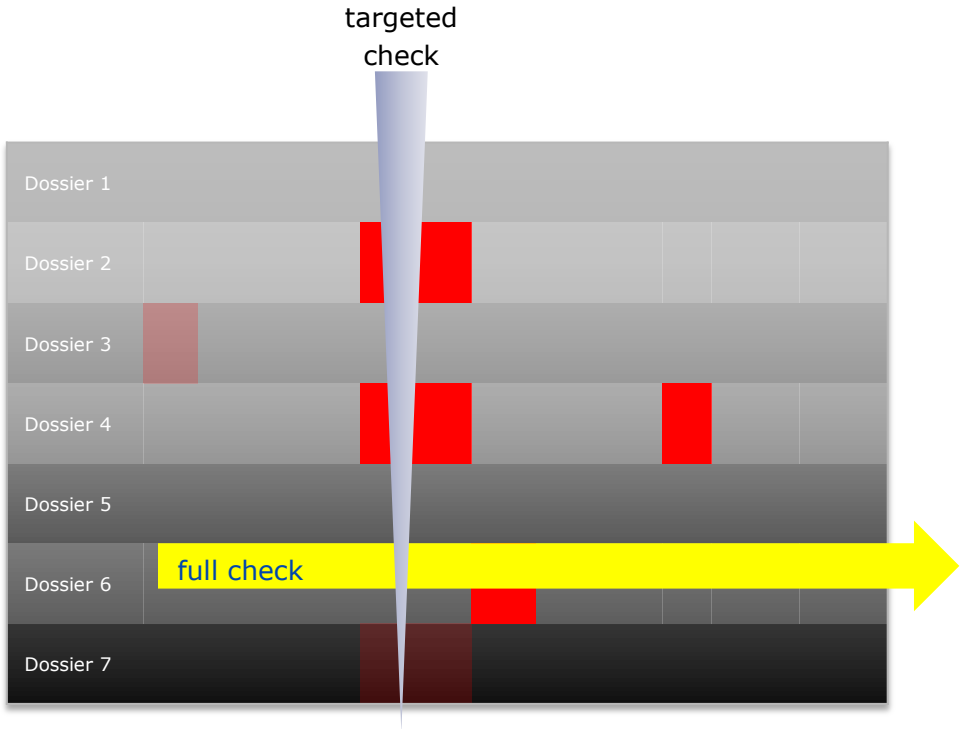
- They both deal with quality of dossiers and may lead to request of further information
- Interlinked and complementary
- A CCH can be performed prior SEv to ensure standard information is available by the time the evaluation starts

Compliance check:

- **what's new**
- **recommendations**

Targeted compliance checks

- Aimed at having **maximum impact on safe use** of chemicals
- ECHA will target compliance checks to specific dossier issues where safety matters



Targeted compliance checks to improve dossier quality

- ECHA scientists check dossiers more efficiently with data-mining tools
- **Poor entries will be caught**
- Complements other compliance check activities
- Most efficient use of ECHA evaluation resources

Evaluation progress report 2012

- Annual report
- On ECHA website
- Progress in our activities
- Information on common pitfalls
- **Recommendations for you**

- **N.B. in 2012 focus testing proposals; in 2013 focus on compliance checks**

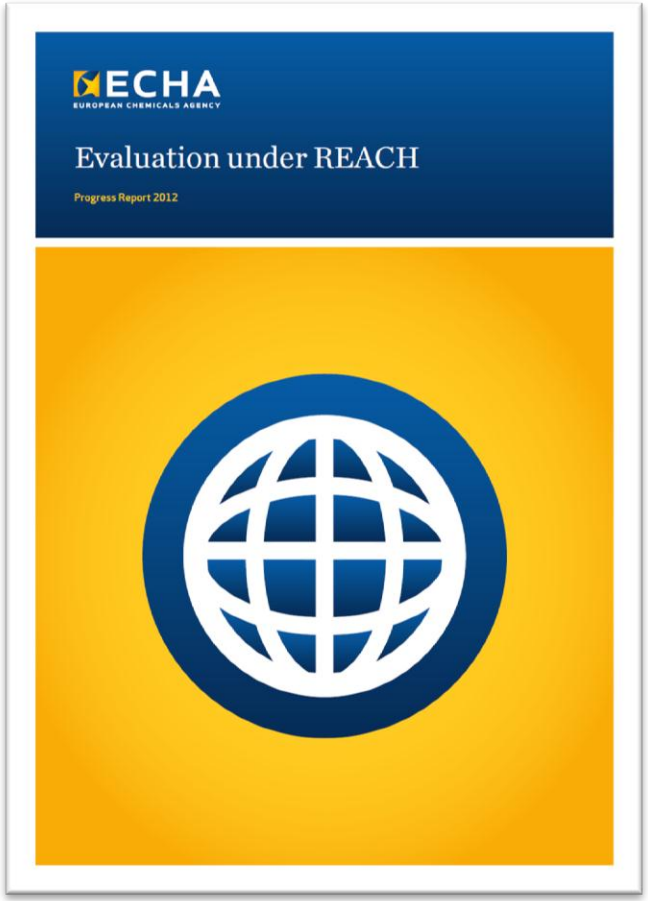


TABLE 7: INFORMATION REQUIRED BY ECHA DECISIONS TAKEN UNDER COMPLIANCE CHECK (2012)

Type of information required	No. of cases*
Exposure assessment and risk characterisation (Annex I)	15
Robust study summaries, hazard and exposure assessments, risk characterisation(Annex I)	4
Information regarding identification and verification of the composition of the substance (Annex VI, 2.)	44
Waste from production and use (Annex VI, 3.6)	1
C&L according to CLP Regulation (Annex VI, 4.)	2
Physicochemical properties (Annex VII)	3
Toxicological information (Annex VII)	4
Toxicological information (Annex VIII)	5
… of which: Screening for reproductive/developmental toxicity (Annex VIII, 8.7.1)	4
… of which: Toxicokinetic (Annex VIII, 8.8)	1
Physicochemical properties (Annex IX)	1
Sub-chronic toxicity study, 90-day (Annex IX, 8.6.2)	12
Prenatal developmental toxicity (Annex IX, 8.7.2)	11
Two-generation reproduction toxicity study (Annex IX and X, 8.7.3)**	2
Effects on terrestrial organisms (Annex IX, 9.4)	2
Mutagenicity (Annex X, 8.4)	1
Developmental toxicity study in the rabbit via the oral route (Annex X, 8.7.2)	7
Carcinogenicity study (Annex X, 8.9.1)	1
Effects on terrestrial organisms (Annex X, 9.4)	1
Justification for use of read-across	1
PBT assessment	1

ECHA
EUROPEAN CHEMICALS AGENCY

TABLE 9: QUALITY OF DOSSIERS: CASES CLOSED OR DECISION SENT TO THE REGISTRANT IN 2012

	Outcome type						Total
Reason for selection	Closed without action	Only QOBL	Closed after draft decision*	Decision taken without proposal of amendment: Article 51(3)	Decision taken after ECHA MSC agreement: Article 51(6)	Commission to take the decision: Article 51(7)	
Concern	11	1	0	7	14	0	33
Random	9	0	2	4	5	0	20
Intelligent selection tool	68	0	0	0	0	0	68
CCH targeted to SID	3	0	1	4	0	0	8
CCH targeted to SID, C&L and exposure	11	0	0	0	0	0	11
CCH triggered by Substance Evaluation Process	13	0	1	2	0	0	16
CCH triggered by TPE and targeted to SID	2	0	10	30	0	0	42
Total	**117**	**1**	**14**	**47**	**19**	**0**	**198**

* Cases closed after draft decision was sent to the registrant and the dossier being subsequently updated with the information required.

Recommendations - 1

- Identifying your substance clearly
- Many compliance checks currently targeted specifically on substance identity
- Making sure test material is representative
  - UVCBs – consistency in dossier and across registrants
  - Beware of the potential impact on your SIEF

Recommendations - 2

- Adapt information requirements correctly:
- *Read across & grouping:*
  - SID of source and target
  - Hypothesis: scientifically valid
  - Document and underpin your hypothesis
  - Illustrative examples

Recommendations - 3

- Making intelligent use of all available information
  - Report studies correctly
- Classification and labelling: consider self-classification in order to apply Column 2 of the Annexes
- Providing clear use and exposure information
  - Procs applied consistently (e.g. intermediates)

Substance evaluation Update & recommendations

CoRAP – community rolling action plan

- CoRAP update published on 20 March 2013 contains 115 substances for years 2013 (46), 2014 (46) and 2015 (23)
- On-going selection of substances for next CoRAP update in March 2014
- Inclusion in the CoRAP is just the first step to perform an evaluation and NOT a judgment on the actual risk
- 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
- The initial concern will not limit the scope of the evaluation (other concerns can be found and addressed)

What to do if my substance is in the CoRAP?

- you should coordinate with other registrants of the same substance and prepare to handle requests for comments (only 30 days) and final requests for information
- appoint one registrant as the coordinator
- make contact early with the evaluating Member State
- usually the evaluating Member State will contact the lead registrant and offer the opportunity to meet to discuss technical issues related to Substance Evaluation (in the beginning of the evaluation, in case registrant has not made contact).

Type of draft decisions for “2012” evaluations

- 36 substance evaluations started in 2012
- draft decisions for 32 substances; **170** information requests

Indicative distribution of requests		
Intrinsic properties	Environment	33%
	Human Health	23%
	Substance identity & physico-chemical properties	4%
CSR related requests	Exposure (worker, consumer, environment)	35%
	PBT, DNEL, PNEC, RCR	5%

General recommendation

Proactive in keeping the dossier compliant with REACH

- Understand your responsibility to ensure safe use
- Follow ECHA guidance in preparing the dossier
- Read the recommendations in ECHA's evaluation progress report **every year**
- Keep track of ECHA webinars
  - ECHA's **compliance check priorities**
  - Correct way of reporting study results

Proactive in keeping the dossier compliant with REACH

- **Spontaneously** update dossiers
- **Avoid waiting for a draft decision (DD)** (DDs are likely under CCH)
- If DD, you need to react quickly in formal decision-making process under REACH (30-day commenting period)
  - Draft decision points out how to bring your dossier into compliance
  - Informal communication may be offered in complicated cases
- If reaction is adequate, it is still possible to avoid a decision

ECHA
EUROPEAN CHEMICALS AGENCY

Thank you