

Substance Evaluation and CoRAP

*What should every registrant know
about Substance Evaluation?*

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Webinar

Substance Evaluation (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 in performing an evaluation and NOT a judgment on the actual risk
- The initial concern will not limit the scope of the evaluation (other concerns can be found and addressed)
- If your substance is included in the CoRAP, you should coordinate with other registrants of the same substance and prepare to handle requests for comments and final requests for information



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

**Industry provides information
(including on
risk management measures)**



- **Dossier evaluation**

**ECHA checks for compliance
and requests for further info**

MSs

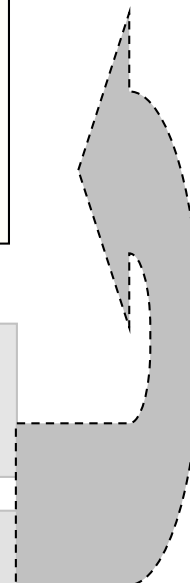
- **Substance evaluation**

**MSCAs verify the risk
and request for further info**



**Classification &
labelling
Authorisation
Restriction**

**COM,
with support of ECHA and MS-CAs,
implements community wide regulatory
risk management measures**

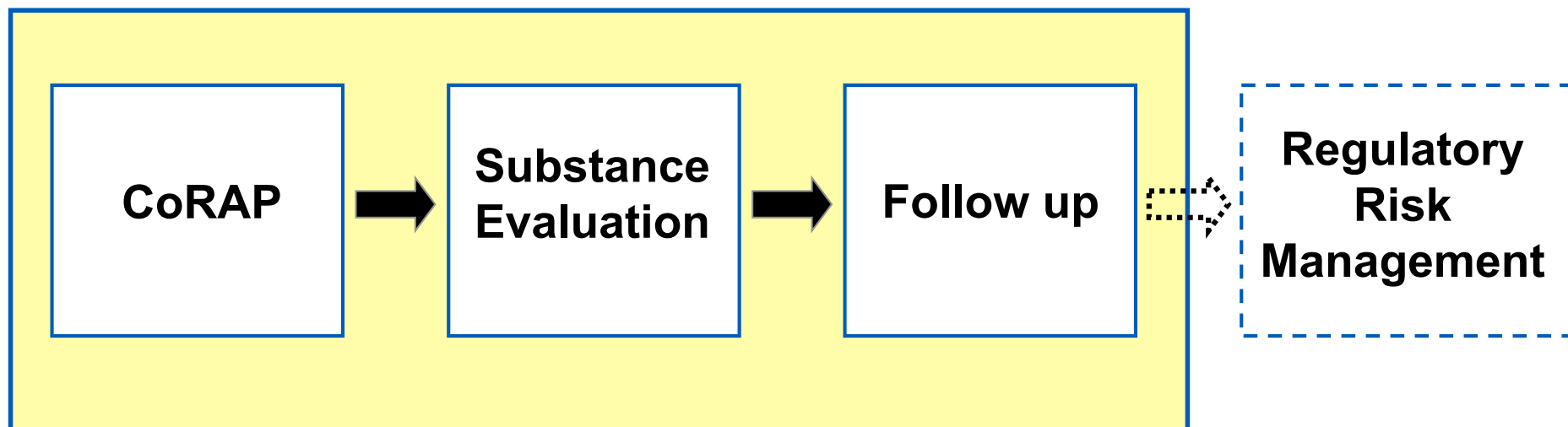


	Substance evaluation (SEv)	Compliance check (CCH)
Objective (Why)	To verify the suspected risks	To ensure compliance with the standard information requirements
How	Request for information needed to clarify the risks	Request for information to fulfil standard requirements
What	Substances (all registration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

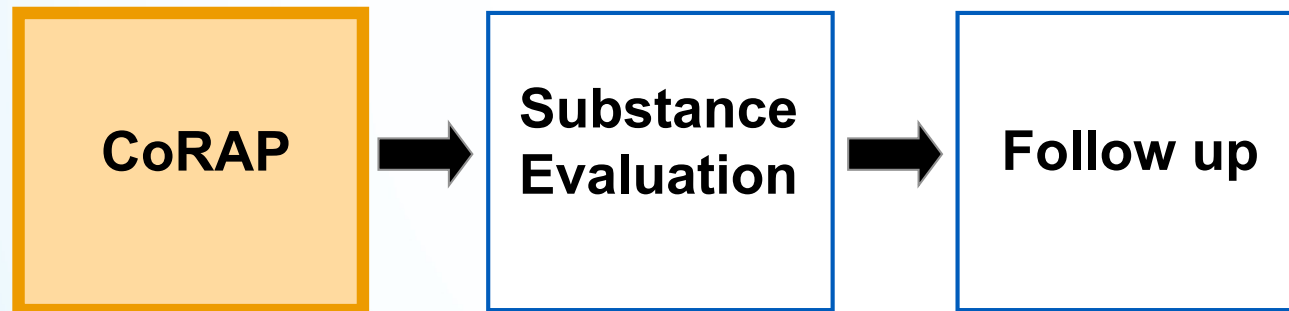
Role of MSCAs, Registrants and ECHA

- The competent authorities of the Member States (MSCAs) evaluate the substances
 - Registrants or downstream users (DUs) may be requested to provide further information.
(DUs, e.g. those submitting DU reports)
 - 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

Substance Evaluation process



Community Rolling Action Plan (CoRAP)



Community Rolling Action Plan (CoRAP)



What is it?

- List of substances which will be subject to Substance Evaluation in each of the next three years. It contains the substance name, evaluating Member States with contact details and information on initial concerns

Duration

- Covers three years at a time, is annually updated

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 second and third 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] as agreed and published in 2011.

General criteria refined in collaboration with Member State Competent Authorities 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) Member States can notify substances based on any risk concern.

[Selection criteria ECHA website:](http://echa.europa.eu/documents/10162/13628/background_doc_criteria_ed_32_2011_en.pdf)

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CoRAP development and adoption

Annual stepwise process in collaboration with MSCAs:

1. Selection of CoRAP candidate substances (IT-based selection + expert verification)
2. Consideration of regulatory effectiveness of CoRAP inclusion
3. Tentative distribution among volunteering MSCAs
4. Draft CoRAP publication, submission to MS Committee for opinion
5. Adoption and publication of CoRAP (update)

First CoRAP for years 2012-2014

- Published on ECHA website on 29 Feb 2012
- Contains 90 substances:
 - 36 for 2012;
 - 23 for 2013;
 - 31 for 2014.
- 20 Member States will evaluate substances listed in the first CoRAP

This document contains the first Community Rolling Action Plan (CoRAP), a list of 90 substances which are scheduled to be evaluated in years 2012-2014. Furthermore it contains the names of the evaluating Member States with contact details and the indication of the initial grounds for concern.

YEAR	MEMBER STATE *	EC NUMBER	CAS NUMBER	SUBSTANCE NAME **	INITIAL GROUNDS FOR CONCERN ***	Member State contact details ****
2012	France	200-262-8	56-23-5	carbon tetrachloride	Human health/CMR; Exposure/High exposure for workers, high aggregated tonnage	French Agency for Food, Environmental and Occupational Health Safety (ANSES) Department for Regulated Products (DPR) REACH-CLP Unit henri.bastos(at)anses.fr
2012	Poland	200-659-6	67-56-1	methanol	Human health/Suspected CMR; Exposure/High exposure for workers and the environment, wide dispersive use, consumer use	Bureau for Chemical Substances evaluation(at)chemikalia.gov.pl
2012	Italy	200-817-4	74-87-3	chloromethane	Human health/CMR; Suspected Endocrine Disruptor; Risk characterisation ratio close to 1 (human health)	Institute of Health 299 Viale Regina Elena 00161 ROME E-mail: leonello.attias(at)iss.it Tel.00390649902061
2012	Austria	200-849-9	75-21-8	ethylene oxide	Human health/CMR; Exposure/High aggregated tonnage	Umweltbundesamt GmbH Abteilung Chemikalien/ Department Chemicals Spittelauer Lände 5 1090 Wien Österreich/Austria T: +43-(0)1-313 04/5620 Stoffbewertung(at)umweltbundesamt.at
2012	Germany	201-245-8	80-05-7	4,4'-isopropylidenediphenol (Bisphenol A)	Suspected Endocrine Disruptor; Exposure/Wide dispersive use, consumer use, high aggregated tonnage	Ann Bambauer Federal Institute for Occupational Safety and Health Division 5 "Federal Office for Chemicals, Authorisation of Biocides" Friedrich-Henkel-Weg 1-25 44149 Dortmund E-mail: chemg(at)baua.bund.de

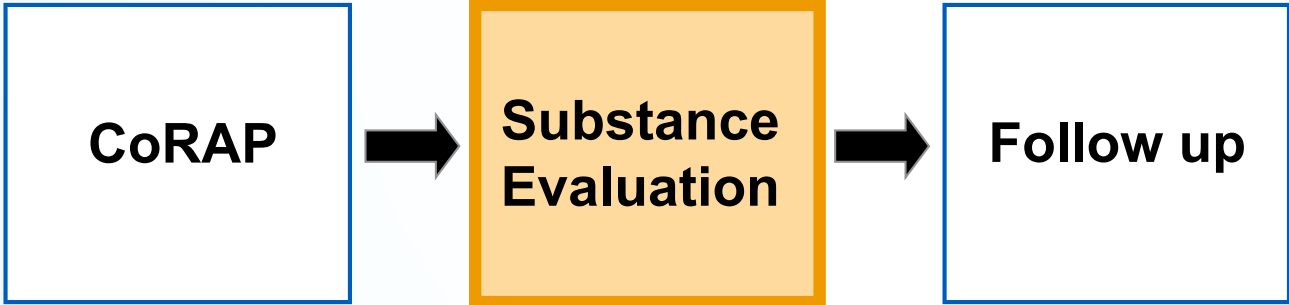
[CoRAP on ECHA website:](http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table)

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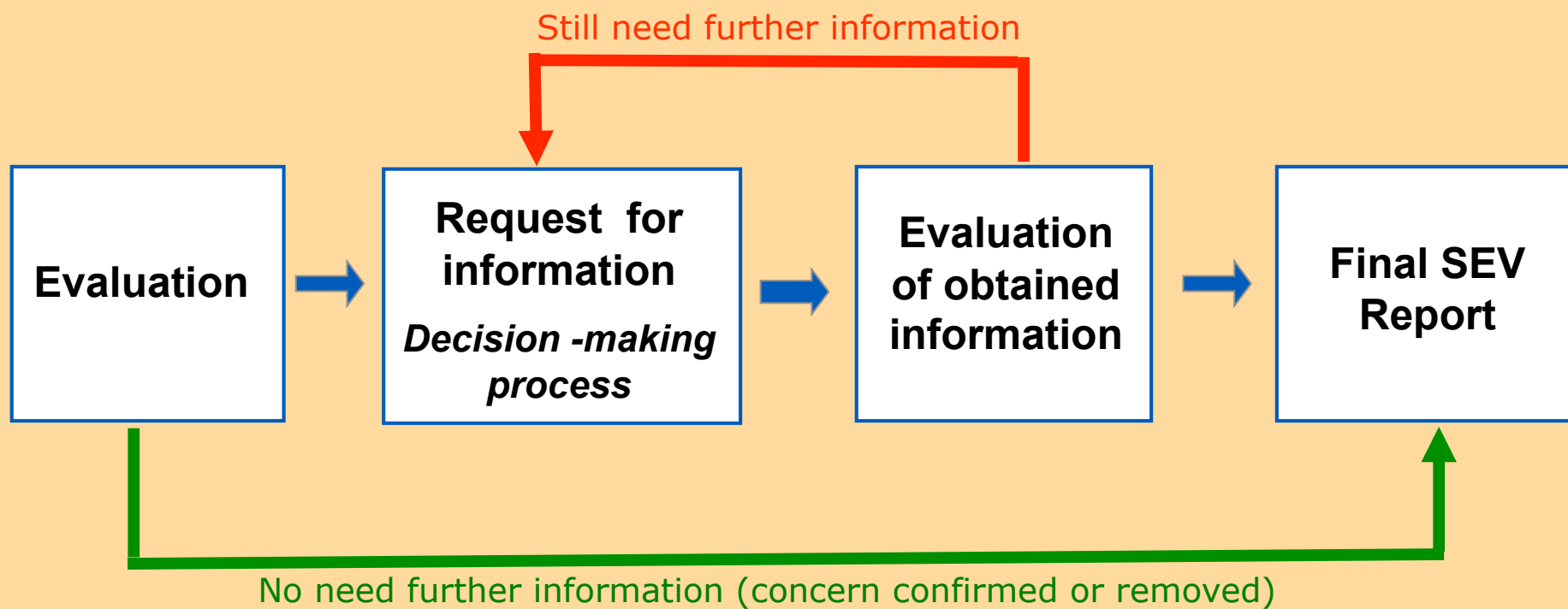
CoRAP update for years 2013-2015

- It will consist of substances coming from the first CoRAP and newly allocated substances
- In mid-October 2012, the draft CoRAP update will be referred to the opinion of Member State Committee
- At the end of March 2013, the adoption and publication of the final CoRAP update for 2013-2015

Substance Evaluation



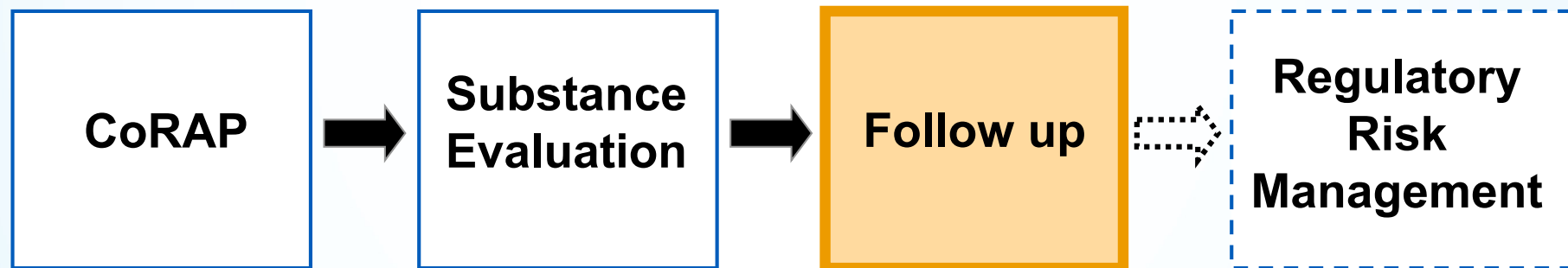
Substance Evaluation



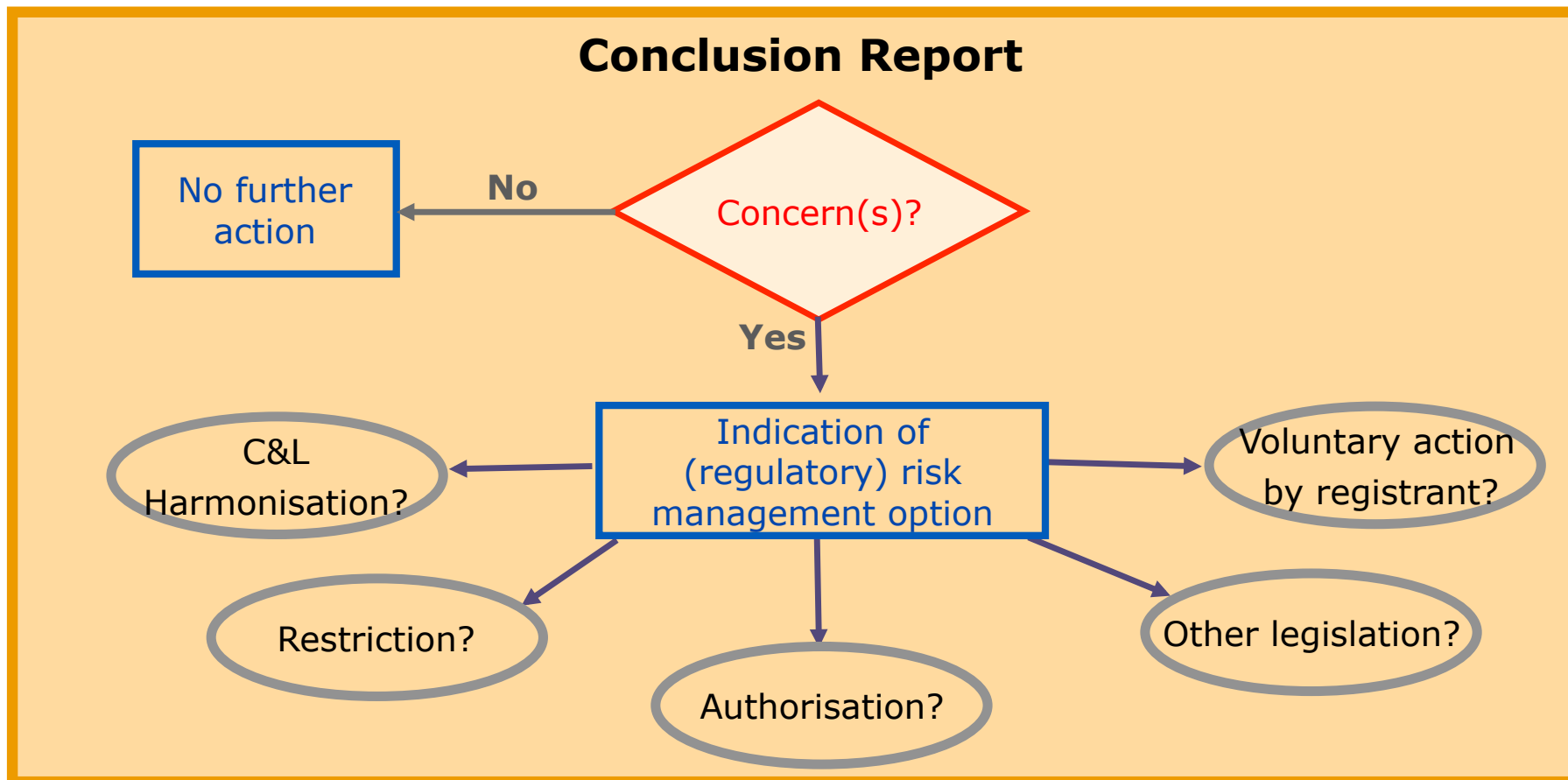
Substance Evaluation timing

- From publication of CoRAP, evaluating MSCA has **12 months** to consider the need for further information and preparing request (draft decision)
- Decision making includes **30 days** for registrants to comment. Tight deadline!
- After adoption of decision registrants shall, within **timelines specified in the decision**, submit requested information to ECHA by updating the registration dossiers with new data
- MSCAs 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))

Follow up to Substance Evaluation



Follow up to Substance evaluation



Ongoing Substance Evaluation

- 36 substances in CoRAP for 2012
- 28 February 2013, deadline for evaluating MSCAs to submit the draft decisions to ECHA

CONCLUDING REMARKS

- Inclusion in the CoRAP is just the start of an evaluation process
- SEv is an important instrument to increase information on chemicals
- Tight deadlines
- Coordination among registrants of the same substance is required

Thank you

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