Community Rolling Action Plan (CoRAP) and substance evaluation process

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Key messages

Substance Evaluation

- Substance Evaluation (SEv) complements the scope of Compliance Check (CCH): CCH may be performed in preparation of SEv

- SEv allows further information to be requested 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 only the first step to performing 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 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

Evaluation under REACH

- Pre-registration
- Data sharing
- Registration

Industry provides information (including on risk management measures)

ECHA

- 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 MSCAs, implements community wide regulatory risk management measures

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 for 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

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 (I)

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

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

Combination of hazard and exposure criteria:

- e.g. suspected PBTs/vPvBs, endocrine disruptors, CMRs, sensitisers
- 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

First CoRAP:

- published on ECHA's website on 29 Feb 2012,
- contains 90 substances (36 for 2012; 23 for 2013; 31 for 2014)

CoRAP update under development:

- it will include substances for 2015;
- revision and additional substances for 2013-14

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,
- Adoption and publication of CoRAP (update)

evaluation outcomes and follow up

SEv evaluation process:

- If further information is needed, MSCAs have to prepare a draft decision within 12 months from the CoRAP publication date

- Decisional process similar to dossier evaluation. All registrants of the same substance will have 30 days in which to make comments: Coordination is recommended!

Final conclusions:

- (1) concern clarified and no action needed, e.g. no concern or (new) risk management measures indicated by registrants are sufficient

- (2) concern confirmed and possible need for regulatory management measures (to be considered under e.g. authorisation/restriction processes)

CONCLUDING REMARKS

- SEv is an important instrument to increase information on chemicals
- Inclusion in the CoRAP is just the start of an evaluation process
- Requests of comments and final requests of information require coordination among registrants of the same substance. The first draft decisions may be issued in autumn 2012
- ECHA aims at making the process very transparent

Thank you.

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