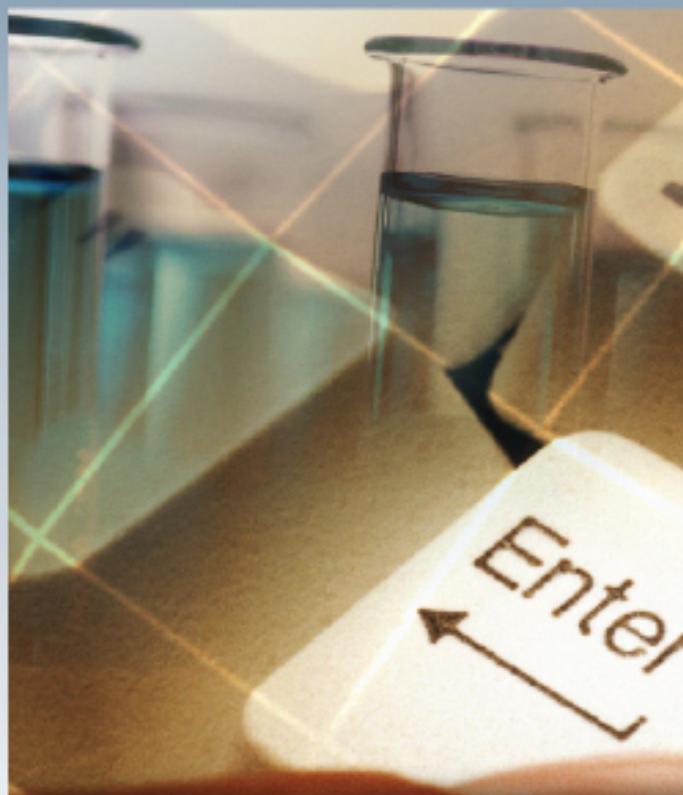


## Questions and answers regarding CoRAP (Community Rolling Action Plan) and Substance Evaluation



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## ***Questions and answers regarding CoRAP (Community Rolling Action Plan) and Substance Evaluation***

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## 1. What is Substance Evaluation?

Substance Evaluation is an integral part of the REACH implementation. It aims to clarify whether a substance which has been identified as potential concern, poses an actual risk for the health and/or environment. To clarify the risks the registrants may be asked for more information on the substance. Substance evaluation shall be carried out by the Member States whilst ECHA coordinates the procedure. The substances to be evaluated annually are listed in the CoRAP (Community Rolling Action Plan).

## 2. Which Member State will evaluate my substance?

Member States may volunteer to evaluate a substance. Two Member States may also decide to make a joint evaluation. However, in all cases only one Member State will be designated as the responsible Member State for the evaluation. Final allocation of the substances to the Member States will be decided with the adoption of the final CoRAP by ECHA, based on the opinion of the Member State Committee (MSC) on the draft CoRAP. Thus, this information will be available upon publication of the final CoRAP.

## 3. Why is my substance on the draft CoRAP list? What criteria have been used?

The REACH Regulation Article 44(1) provides the general criteria for substances to be selected for substance evaluation. The legal text defines that prioritisation shall be on a risk-based approach. According to Article 44(1):“(...) the criteria shall consider:

- (a) hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;*
- (b) exposure information;*
- (c) tonnage, including aggregated tonnage from the registrations submitted by several registrants.”*

The criteria have been refined by ECHA in cooperation with the Member States and are published on ECHA's website: **Selection criteria to prioritise substances for Substance Evaluation (2011 CoRAP selection criteria)**

[http://echa.europa.eu/doc/reach/evaluation/background\\_doc\\_criteria\\_ed\\_32\\_2011.pdf](http://echa.europa.eu/doc/reach/evaluation/background_doc_criteria_ed_32_2011.pdf)

These criteria are applied in the initial step of the identification of substances with potential concerns. A further ranking process takes into consideration whether the substances are already subject to regulatory measures and the effectiveness of the substance evaluation to clarify the concern by requesting further information on the substance. Thus, meeting the risk-based criteria alone does not automatically mean an inclusion of the substance in the CoRAP.

According to Article 45(5) of the REACH Regulation, a Member State may notify ECHA of a substance, whenever it is in possession of information suggesting that the substance is a priority for evaluation. Thus the draft CoRAP contains also substances that have been proposed based on notifications from Member States.

Both hazard and exposure information (or a lack of it) is taken into consideration upon prioritising the substances. In the current first draft CoRAP with many substances, the initial concerns are generally related to potential PBT-properties, suspected endocrine disruption, or carcinogenic, mutagenic and reprotoxic properties in combination with wide dispersive or consumer use(s) and/or high tonnages. In general, the uses of these substances cover various areas and do not focus on any particular industrial, professional or consumer uses.

When the final CoRAP is published it will also contain a general indication of the reasons why the substance was prioritised and selected for substance evaluation.

#### 4. Are the criteria for selection fixed?

The CoRAP selection criteria and their application shall be refined in the coming years as ECHA and the Member States gain experience with the first substance evaluations. Also stakeholders will be given an opportunity to comment when the criteria will be revised.

#### 5. When will the final 1st CoRAP be adopted?

ECHA submitted the draft CoRAP to the Member State Competent Authorities and the ECHA Member State Committee in October 2011. Also the draft CoRAP was published on ECHA website to inform the stakeholders. The Committee is asked to prepare an opinion on the draft CoRAP in February 2012. On the basis of the Committee's opinion, ECHA will adopt the final CoRAP.

ECHA aims to adopt the final CoRAP by the end of February 2012 with the final CoRAP published on the ECHA website. The final CoRAP will indicate the Member State responsible for the evaluation of each substance and the initial reasons for concern.

#### 6. What happens after the final CoRAP is adopted?

From the publication of the final CoRAP, the respective Member States have one year to evaluate substances listed for 2012 and, where regarded as necessary, to prepare a draft decision for requesting further information to clarify the suspected risks. The evaluation of the substances listed for the second and third year only starts after the publication of the CoRAP update in 2013 and 2014 respectively.

#### 7. What is the outcome of substance evaluation?

If the evaluating Member State considers that further information is necessary to clarify a potential risk caused by the substance, it may draft a decision specifying the additional data requirements. The registrants of that substance will have an opportunity to provide comments on the draft decision. Such a draft decision will be reviewed and agreed by the other Member States and ECHA, and in the case of proposals for amendment also by the Member State Committee. After this procedure, ECHA will take the **final decision** in line with the agreement in the Member State Committee. If no unanimous agreement is reached by the Member State Committee, the decision will be taken by the European Commission. The decision will contain a deadline by which the registrants must submit the requested information. It may also be that **no further action or request for information** is needed because the risks are considered to be sufficiently under control with the measures already in place.

Once the registrant(s) submit the requested information, the responsible Member State has other twelve months to assess this information and to decide whether **a further request** for information is necessary or whether the evaluation can be concluded. In this latter case, the responsible Member State should consider whether and how to use the information obtained for the purposes of Community level risk management measures. The Member States may conclude:

- EU-wide risk management measures are necessary (e.g. EU wide restriction, EU-wide authorisation, EU-harmonised classification and labelling, occupational exposure limits, measures for the protection of the environment under the Water Framework Directive) or
- Actions at national level should be taken.

**The conclusion** can also be that the risks are sufficiently under control with the measures already in place. ECHA informs the Commission, the registrant and the other Member States about the conclusions.

The decisions on data requests and **evaluation reports** will be made publicly available once finalised. It should be noted that as the production of the information requested may take several years in some cases (e.g. in the case of long term studies and annual environmental monitoring) also finishing a final evaluation report may take several years from the adoption of the CoRAP.

## 8. What is the follow up of substance evaluation?

According to the conclusions of the substance evaluation, the follow up can be either no action or the implementation of the recommended actions, such as the proposal of EU wide risk management measures.

Any proposed Community-wide actions will be subject to a separate decision making process. For authorisation, restriction and/or harmonised classification under the REACH and the CLP Regulation, stakeholders are consulted at all relevant stages of the process and decisions are taken on the basis of the opinions adopted by the ECHA Committees.

## 9. What is the impact on my business?

The listing of a substance on the draft CoRAP does not in itself have any legal impact on the registrant and thus does not require any further action by the registrants. If the substance is included in the final CoRAP adopted by ECHA in February 2012, the registrants of substances listed for the year 2012 may expect to receive a draft decision requesting further information after the evaluation period of 12 months. At that point of time, the registrants will be given an opportunity to comment before any final decision to request further information is taken. The final decision will contain a deadline by which the additional information must be submitted.

On the other hand, if the evaluating Member State comes to the conclusion that no further information is necessary to clarify the risk, the substance evaluation process is concluded without a decision to request further information.

Inclusion of a substance in the CoRAP does not automatically mean that the substance poses a risk to human health or the environment, but rather that there is a concern that it

may pose a risk, which needs to be clarified (confirmed or dismissed). It also does not automatically trigger, for example, the restriction or authorisation process. However, the Member State responsible for the evaluation of a substance may consider these options once the evaluation is finished, if the risk is confirmed.

#### **10. Once adopted, is CoRAP fixed?**

The CoRAP list will cover a period of three years. The first CoRAP will thus include substances planned for evaluation in the years 2012, 2013 and 2014. The plan should be annually updated. ECHA will make a proposal for the annual update by 28 February. The next update will be in 2013. The rolling nature of the plan means that the list of prioritised substances included for evaluation during the second and the third year may change when the plan is updated (e.g. a substance on the first CoRAP for the years 2013 or 2014 may be dropped or new ones introduced) and that each year a new subsequent year is added.

#### **11. Are substances in the (draft) CoRAP going to be included in the Authorisation/Restriction processes?**

There is no direct link between the CoRAP and the Authorisation/Restriction process. While the inclusion in the CoRAP means that a substance is going to be evaluated by a Member State to clarify a potential risk by asking further information, the Restriction or Authorisation processes aim at controlling a known risk, which cannot be managed by other risk reduction measures.

#### **12. What is the added value of Substance Evaluation?**

Substance Evaluation may identify risks that could be otherwise missed. This process can further create additional value in respect of:

- Concerns that go beyond the control of the individual registrant, like regional risks or the potential additional risk caused by aggregated exposures of (sub)population or releases to the environment.
- The assessment of group of similar substances to predict cumulative effects and potentially increased risk levels from exposures to the different substances in the group.
- If considered scientifically necessary and proportionate the request for additional information can go beyond the standard information requirements in REACH.

#### **13. Where can I get more information on the CoRAP substances?**

Currently for 88 of the 91 substances, information is available on the ECHA website. This website contains non-confidential information on the properties and uses of the substances that have been retrieved from lead registrations for each substance. For the remaining three substances, it is expected that information on those will also be available on the dissemination site before the final CoRAP is adopted in February 2012.

## **For more information**

Dissemination portal

<http://apps.echa.europa.eu/registered/registered-sub.aspx>

ECHA guidance on Evaluation:

[http://guidance.echa.europa.eu/docs/guidance\\_document/evaluation\\_en.pdf](http://guidance.echa.europa.eu/docs/guidance_document/evaluation_en.pdf)

Substance Evaluation Fact Sheet:

[http://echa.europa.eu/doc/reach/substance\\_evaluation\\_fact\\_sheet\\_20110414\\_en.pdf](http://echa.europa.eu/doc/reach/substance_evaluation_fact_sheet_20110414_en.pdf)

