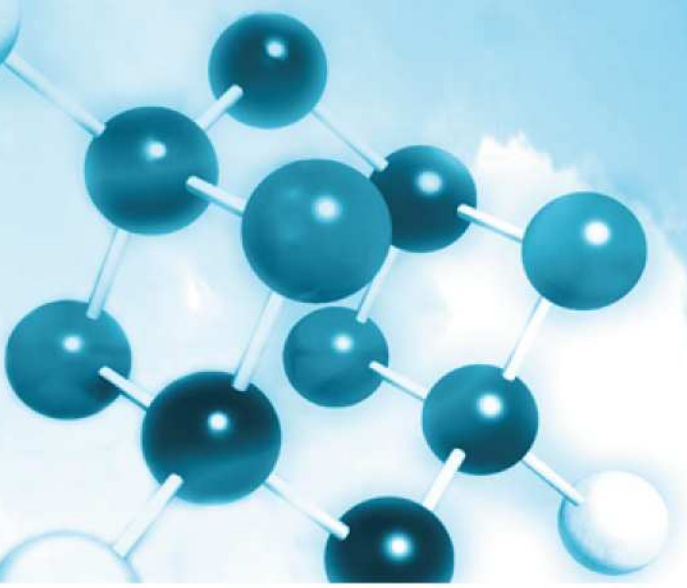

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REACH Fact Sheet

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Substance Evaluation

The REACH Regulation contains a specific process for substance evaluation. Its aim is to clarify whether the uses of a chemical substance poses a risk to human health or the environment.

Substance evaluation is one of the three types of evaluation processes under REACH. The other two are testing proposal examination and compliance checks, which together are also known as dossier evaluation.

WHAT ARE THE SPECIFIC FEATURES OF SUBSTANCE EVALUATION?

There are four major differences between substance evaluation and dossier evaluation:

1. The substance evaluation process is **triggered as a result of risk-based concerns**. Under dossier evaluation all testing proposals must be examined, whereas compliance checks can be based on specific criteria for dossier selection and random selection.
2. If it turns out in a dossier evaluation that a registration dossier does not fulfil the standard information requirements of the REACH Regulation for its relevant tonnage band, ECHA can take a decision requiring the registrant to provide this missing information; under substance evaluation such **requests can go beyond these standard REACH information requirements.**
3. Substance evaluation may **involve an assessment of all registration dossiers from all registrants specific to the same substance** as well as an assessment of any **other sources of information** available, while dossier evaluation involves the assessment of a specific registration dossier.
4. **Substance evaluation is carried out by the Member States,** while the European Chemicals Agency (ECHA) evaluates dossiers under dossier evaluation. ECHA has a co-ordination role in the substance evaluation process and it remunerates the Member States for the task.

REACH

WHICH SUBSTANCES WILL BE EVALUATED?

For substances for which the registration data is already sufficient to conclude that a risk does or does not exist, substance evaluation is not needed.

Substance evaluation can be useful for **substances triggering initial concerns for human health or the environment**. Such substances will be prioritised for substance evaluation if it is expected that by requesting and receiving further information the initial concern will be confirmed, validated, eliminated or marginalised so that a conclusion can be drawn as to whether further action is necessary.

The selection and eventual **prioritisation of substances for evaluation** is made according to risk-based criteria, which include:

- **Hazard** information (for instance structural similarity of the substance to known substances of concern or to substances which are persistent and liable to bio-accumulate),
- **Exposure** information regarding people and the environment,
- **Tonnage,** including the aggregated tonnage of the registrations submitted by several registrants.

These criteria are further refined in collaboration with the Member States and published by ECHA.

Member States can also propose substances based on other specific risk-based concerns as they find appropriate and necessary.

Prioritised substances will then be listed in a Community Rolling Action Plan (CoRAP).

HOW IS THE COMMUNITY ROLLING ACTION PLAN ESTABLISHED?

The process of establishing the CoRAP consists of several steps:

1. **Identification** of CoRAP candidate substances by ECHA and the Member States;
2. **Preliminary draft CoRAP** - prioritised list of candidate CoRAP substances, which is the result of ranking the identified substances;
3. **Draft CoRAP**, following comments and confirmation/expression of interest by Member States to evaluate a substance;
4. **Consultation with the Member States** and **opinion of the Member State Committee** on the draft CoRAP. During this consultation process substances may be added or removed from the list;
5. **Adoption and publication** of CoRAP by ECHA.

ECHA will finalise the first draft CoRAP by 1 December 2011 and intends to adopt the final one by 28 February 2012.

The rolling nature of the plan means that the list will be updated annually following the same procedure as for its establishment. ECHA will submit a draft of the update to the Member States by 28 February each year. The first update is foreseen for 2013.

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WHAT WILL BE INCLUDED IN THE ACTION PLAN?

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 CoRAP list will include:

- **Names of the substances** to be evaluated, and
- **Names of the Member States responsible for the evaluation** of each substance.

Member States are required to evaluate and if necessary prepare a draft decision requesting further information within 12 months from the date of publication of the CoRAP for substances to be evaluated that year.

WHAT IF MY SUBSTANCE IS INCLUDED IN THE ROLLING ACTION PLAN?

The inclusion of a substance in the CoRAP list does not in itself have any legal impact on the registrant. 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.

The decisions made under substance evaluation are legally binding requests for further information which are addressed to the registrants of that substance. However, it is possible for the evaluation to conclude that there is no need to request any further information from the registrants.

In accordance with the legislation, registrants that are directly affected by a substance evaluation procedure are formally consulted at the stage of a draft decision prior to a final decision being taken.

WHAT IS THE SUBSTANCE EVALUATION PROCESS?

From the date of publication of the CoRAP list, the evaluating Member State has for those substances to be evaluated in that year 12 months to consider the need for further information to clarify the concern and to prepare the request in the form of a draft decision.

As all the Member States will be preparing draft decisions, ECHA will monitor the draft decisions to ensure a harmonised approach for all evaluation cases.

The decision-making process is essentially the same as for dossier evaluation:

- The draft decision is sent to the other Member States for proposals for amendments.

- In cases where Member States do not propose any amendments, ECHA takes the decision as notified to the Member States without involvement of the Member State Committee.

- In cases where ECHA receives proposals for amendments to the draft decision from the other Member States, it forwards the draft decision to the Committee and to the registrants for comments.

- If the Committee reaches unanimous agreement, ECHA takes the decision accordingly.

- If unanimous agreement cannot be reached in the Committee, the European Commission takes the decision after consulting a Committee and following the advisory procedure.

- After the adoption of the decision, the registrants shall, within the timelines specified in the decision, submit the requested information by updating their registration dossiers.

The responsible Member State will examine any new information in the updated registration and, if needed as a follow up, draft a further appropriate decision within another 12 months of the information being submitted.

If the evaluation is finalised without a draft decision (i.e. meaning that no further information is needed after all), the evaluating Member State also needs to notify ECHA of that outcome within 12 months.

WHAT HAPPENS AFTER SUBSTANCE EVALUATION?

Substance evaluation will normally result in a request for further information from the registrants of the substance. The registrants must submit the required information within the deadline specified in the final decision.

Once the newly-provided information has been assessed, the responsible Member State completes the evaluation and considers whether and how to use the information obtained for the purposes of Community level risk management measures. 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.

As a further follow-up of the substance evaluation, Member States may decide to:

- Propose EU-wide risk management measures (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
- Impose national actions.

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 Classification, Labelling and Packaging Regulations, 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.

FOR FURTHER INFORMATION:

Visit the evaluation section of the ECHA website:

http://echa.europa.eu/reach/evaluation_en.asp

The REACH Regulation EC1907/2006

http://echa.europa.eu/legislation/reach_legislation_en.asp