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Substance Evaluation

The REACH Regulation contains a specific process for substance evaluation. Its aim is to clarify whether the manufacture or 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 examinations 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 for compliance checks any registration dossier can be selected.
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, the European Chemicals Agency (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 **involves 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 ECHA evaluates dossiers under dossier evaluation. ECHA has a coordinating role in the substance evaluation process and remunerates the Member States for the task.

WHICH SUBSTANCES WILL BE EVALUATED?

For substances for which the registration or other 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 that trigger 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, or eliminated 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 that 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 that they find appropriate and necessary.

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

WHAT IS INCLUDED IN THE COMMUNITY ROLLING ACTION PLAN??

The first CoRAP was adopted by ECHA on 29 February 2012. It covers a period of three years (2012-2014) and includes:

- **Names of the substances** to be evaluated
- An indication of the **initial concern** about the substances
- **Names of the Member States responsible for the evaluation** of each substance
- **The year** of evaluation

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 annually updated. In the update of the previous CoRAP, the second year's list becomes the list of the first year and a new list of substances for the third year is added. The evaluations on the original first year substances are either concluded or continued later when the new information is available.

HOW WILL THE PLAN BE UPDATED?

The CoRAP list will be updated annually following the same procedure as for its first establishment. This consists of several steps:

5. **Identification** of possible CoRAP candidate substances from the pool of registered substances by ECHA and the Member States;
6. **Preliminary draft CoRAP** - prioritised list of candidate CoRAP substances, which is the result of screening the identified substances;
7. **Draft CoRAP**, following comments and confirmation/expression of interest by Member States to evaluate a substance;
8. **Consultation with the Member States and opinion of the Member State Committee** on the draft CoRAP. As a result of this consultation process, substances may be added or removed from the list. ECHA also publishes the draft CoRAP on its website to inform the stakeholders of the progress made.
9. **Adoption and publication of the CoRAP** by ECHA.

REACH requires ECHA to submit a draft of the update to the Member States by 28 February each year. However, ECHA always plans to adopt the updated CoRAP by the end of February and thus the draft for it will be submitted already in October/November of the previous year. The first update will be adopted in 2013.

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

The inclusion of a substance in the CoRAP list does not in itself have any immediate legal impact on the registrant and does not necessarily mean that the substance causes risks to human health or the environment.

The evaluating Member State will assess whether it is necessary to require further information in order to clarify the potential risk. If it concludes so, a legally binding request for further information, which is addressed to the registrants of that substance will be issued. In case the evaluating

Member States can already conclude on the suspected risk on the basis of the available information, there is no need to request any further information from the registrants.

In accordance with the legislation, and similar to dossier evaluation, 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:

- First the draft decision is sent to the registrant(s) for comments.
- Then the draft decision is sent to the other Member States and ECHA for possible amendments.
- In cases where Member States and ECHA do not propose any amendments, ECHA takes the decision as notified to the Member States without the involvement of the Member State Committee.
- In cases where proposals for amendment are made to the draft decision, ECHA forwards the draft decision to the Committee and to the registrants for comments.
- If the Committee reaches a unanimous agreement, ECHA takes the decision accordingly.
- If a unanimous agreement cannot be reached in the Committee, the European Commission is responsible for taking the decision.

- 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, 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?

In many cases, substance evaluation is expected to 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 registrants and the other Member States about the conclusions.

The decisions on requests for further information and the evaluation reports of the Member States will be published on the ECHA website.

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.

Inclusion of a substance in the CoRAP does not directly lead to risk management actions. Thus, any proposed Community-wide actions will be subject to a separate regulatory 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 by the European Commission 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/evaluation>

The REACH Regulation EC (No) 1907/2006:

<http://echa.europa.eu/regulations/reach/legislation>

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