ECHA
EUROPEAN CHEMICALS AGENCY

REACH

Factsheet

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Follow up to dossier evaluation decisions

Dossier evaluation is designed to produce further information on registrations, which do not yet comply with REACH requirements. The examination of the dossier updates following a dossier evaluation decision is the final step of dossier evaluation. Firstly, it is to ensure that the compliance with the issues addressed by the dossier evaluation decision is achieved by the registrant. Secondly, it is to identify and possibly address issues arising from the new information submitted.

The compliance check, initiated by ECHA, and the testing proposal examination, initiated by the registrant, may lead to decisions requesting further information by a deadline. ECHA expects to receive the information requested at the latest by the deadline set in a registration dossier update. The Agency will examine any information submitted in consequence of a dossier evaluation decision. Once the dossier evaluation is completed, ECHA notifies the Commission and Member State competent authorities of the information obtained and conclusions made.

PROCESS

ECHA starts the follow-up step of the dossier evaluation process when the deadline set in the dossier evaluation decision has expired.

ECHA investigates if the information requested in the decision is provided in the latest dossier update. ECHA's dossier evaluation decisions – in order to be enforceable – foresee specific methods and specifications for how information requirements should be fulfilled. For example, in cases where a registrant has provided a study in response to an ECHA decision, ECHA inter alia establishes whether the study has been performed according to the specified test method, with the requested substance, and whether a proper (robust) study summary has been provided. ECHA also checks whether conclusions of the registrant based on the new information are reasonable.

Once it has been established, whether the information requested has been provided or not, the outcome is recorded in the appropriate outcome documents.

OUTCOME

If the registrant updates its dossier with information that is assessed by the ECHA Secretariat to comply with the information required in the Agency's decision, an Article 42(2) notification is sent to the MSCA concerned and to the European Commission informing them of this fact. If the registrant deviated from the information requested in the decision, but still ensured compliance with the relevant requirements of the REACH Regulation by an alternative method or another adaptation argument (e.g. test not technically possible), ECHA will consider the deviation from the request as acceptable (see also the section "reminder for registrants" for the documentation needed in such cases).

If no update is received or the update is assessed as inadequate for any of the requests in the Agency's decision, a "statement of non-compliance following a dossier evaluation decision" is sent to the Member State concerned and the registrant. This is a documentation of the ECHA Secretariat's assessment that a registrant did not comply within the deadline set with one or more of the information requests in this decision. The statement is a communication package consisting of a notification letter addressing the legal background and the assessment that the information request was partly or not fulfilled, an attachment with the scientific facts, the original notification and decision, and any relevant communication with the registrant after the decision was submitted. The Article 42(2) notification is kept on hold until all requests of the decision have been satisfactorily addressed by the registrant.

If the registrant complies with the Agency's decision but other concerns regarding the same information requirement are identified by the registrant or the Agency, the Agency may issue a new dossier evaluation decision pursuant to Article 42(1) of the REACH Regulation.

In addition, if an update is received that complies with the Agency's decision but new concerns with other information requirements are identified as a result of the information received, the Agency may open a new compliance check procedure on the basis of Article 41 of the REACH Regulation.

MEMBER STATE ACTIONS

The follow-up step in the dossier evaluation process forms one of the interfaces between ECHA, the Member State competent authorities (MSCAs) and the national enforcement authorities (NEAs), respectively.

The Article 42(2) notification informs the Member States and the Commission of the results of the dossier evaluation. MSCAs may use this new information for the purposes of other REACH or CLP processes (i.e. substance evaluation, authorisation, restriction, or harmonised classification and labelling).

The enforcement responsibility is attributed solely to the Member States (REACH Title XIV). If the issue(s) covered by a decision are not addressed by the deadline, ECHA informs the Member States of this fact through a "statement of non-compliance following a dossier evaluation decision". Its purpose

is to support national enforcement actions and therefore it is addressed to the relevant NEA and to the MSCA. The national authorities are asked to address the issues identified by ECHA in their own competence and, if found appropriate, to adopt enforcement measures. The registrant receives a copy so that all actors have the same starting point.

Once the case has been handed over to the national authorities, ECHA expects that any further communication on the case will be between the Member State authorities and the registrant. A communication system has been set up to allow ECHA and the Member States to exchange information on such cases. This allows ECHA to plan the examination of dossier udpates in the appropriate time once the missing information has been provided in a dossier update.

COMMUNICATION WITH REGISTRANTS AFTER ADOPTION OF A DOSSIER EVALUATION DECISION

Unless an appeal is filed, a legally binding decision is in place and ECHA's possible actions in such cases are limited.

Where registrants seek clarification on their obligations pursuant to the decision, such help can be provided by ECHA in the form of contextual guidance useful for the execution of the decision. The ECHA Helpdesk should be contacted for such cases and concrete questions should be posed. The decision content cannot be changed by ECHA.

In some cases, registrants would like to discuss whether the way they want to fulfil the information requirements is acceptable (e.g. by using general or specific adaptations). ECHA cannot provide advice or comments on any alternative strategies or approaches that the registrant considers to use to fulfil the request in the decision. As mentioned, the ECHA Secretariat only starts its assessment as to whether a registration dossier complied with the information requests in the decision when the deadline has passed, and based on the latest version of the registration dossier.

In some cases, registrants ask ECHA to postpone the deadline for various reasons. ECHA does not have the authority to alter the deadline specified in the decision since that deadline has been agreed unanimously by the Member States. Furthermore, the REACH Regulation does not provide for the

postponement of the deadline of a decision on dossier evaluation.

Once a "statement of non-compliance following a dossier evaluation decision" has been sent, the registrant should communicate with the national authorities.

REMINDERS FOR REGISTRANTS

Registrants must submit the information requested in a dossier evaluation decision as soon as they receive that new information (Article 22(1)) and at the latest by the deadline set. If the decision requests the generation of new hazard information, the information submitted should also comply with Article 10 of the REACH Regulation (submission of (robust) study summaries). The update of the dossier should also include any changes to the registration dossier that are in light of this new information required pursuant to REACH (e.g. with regard to classification and labelling, the chemical safety report, or submission of testing proposals).

Registrants may, under their own responsibility and risk, decide to fulfil the information requirements in an alternative way than requested in the decision. Thus, notwithstanding the dossier evaluation decision, registrants may seek to fulfil the information gap identified by ECHA in the dossier evaluation decision by providing justified adaptations of the standard information requirements. For instance, they might predict the results of the requested study by using information from a structurally similar substance (read-across). The use of such adaptations to the standard information requirements must fulfil the rules outlined in Annexes VI to X and/or the general rules in Annex XI. Any adaptation needs to be accompanied by sound scientific reasoning and documented comprehensively and transparently. If these conditions are not met, the adaptation would not be accepted by ECHA and a "statement of non-compliance following a dossier evaluation decision" would be issued.

If registrants encounter difficulties in submitting the requested information in due time, they are encouraged to update their registration dossier at the latest by the given deadline and, if necessary, include any relevant explanations and proof concerning the status and timing of pending information requirements so that these explanations can be considered by the relevant national enforcement authorities.

MORE INFORMATION

Evaluation and its steps
http://echa.europa.eu/regulations/reach/evaluation/steps

Procedure on dossier evaluation
http://echa.europa.eu/documents/10162/13607/procedure_dossier_evaluation_20110329_en.pdf

ECHA Helpdesk
http://echa.europa.eu/support/helpdesks/echa-helpdesk

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