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Evaluation

Progress Report
2008



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1. INTRODUCTION

This report is required by Article 54 of the REACH Regulation (EC) No 1907/2006 and details the progress made by the European Chemicals Agency (Agency) in its evaluation tasks. As stated in Article 54, these reports should include recommendations to potential registrants in order to improve the quality of future registrations. This report covers progress made during the year 2008.

2. DESCRIPTION OF EVALUATION TASKS

2.1. Dossier evaluation

As soon as the registration dossier has passed the technical completeness check, the Agency:

1) will examine any registration dossier including a testing proposal ensuring that unnecessary animal tests and unnecessary costs are avoided and that test results are relevant for the chemical safety assessment process (Article 40 of the REACH Regulation), and

2) may check compliance of registration dossiers with the registration requirements (Article 41 of the REACH Regulation). The Agency may examine any registration dossier for compliance but shall select at least 5 % of the total number of registration dossiers received for each tonnage band for a compliance check.

2.2. Substance evaluation

Substance evaluation aims to clarify a concern that a given substance may pose a risk to human health or the environment. It consists of an evaluation of the information in all individual submitted registration dossiers for that substance and of other relevant information.

Substance evaluation is carried out by the Member State Competent Authorities (MSCAs) and the Agency coordinates the process. Substance evaluation will be started after adopting a Community Rolling Action Plan which lists the substances to be evaluated (Article 44 of the REACH Regulation). The Agency shall submit the first plan to the Member State Competent Authorities by 1 December 2011.

The REACH Regulation (Articles 135, 136(1) and 136(2)) contains transitional provisions for notified substances and existing substances covered by the previous legislation¹. For these substances, there are requirements from that legislation to provide further information. These information requirements are

¹ Directive 67/548/EEC and Existing Substances Regulation (EEC) No. 793/93

considered as decisions adopted in accordance with the REACH Regulation. Based on these provisions, MSCAs shall examine the new information and once their evaluation is completed, the MSCA shall inform the Agency of its conclusions and how to use the information obtained.

3. NUMBER OF EVALUATIONS CONDUCTED IN 2008

3.1 Testing proposals

No complete registration dossiers containing a testing proposal were received during 2008 and thus the Agency did not examine any dossiers for this purpose.

3.2 Compliance check

A relatively small number (94) of registration dossiers were submitted in 2008, of which only 10 passed the completeness check. The Agency started a compliance check for three dossiers and completed one of them. These three dossiers concerned the lowest tonnage band, 1 – 10 tonnes/year.

3.3 Substance evaluation

It was not possible to complete any of the examinations of new data for transitional substances, because industry still had time to submit the new information in accordance with deadlines from the previous legislation.

4. RECOMMENDATIONS TO POTENTIAL REGISTRANTS

As the Agency has examined only a small number of low tonnage band registration dossiers for compliance so far, it is not yet appropriate to make any recommendations to potential registrants at this point in time.

However registrants are reminded they should prepare their dossiers in accordance with the Data Submission Manuals. They should pay special attention to the manual 5 (How to Complete a Technical Dossier for Registrations and PPOD Notifications) to pass the technical completeness check. The manuals can be found at: http://echa.europa.eu/reachit/supp_docs_en.asp

The Agency anticipates providing recommendations in next year's report assuming that a larger number of registrations have been evaluated.

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