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Workshop on Substance Evaluation
Helsinki, 23-24 May 2011

Summary Proceedings

On 23-24 May 2011, the European Chemicals Agency (ECHA) hosted a workshop on substance evaluation. This document provides a concise summary of the topics discussed and the major conclusions reached during the workshop.

Substance evaluation is a concern-driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. The evaluation is conducted by the Member States while the coordination of the process falls under ECHA's responsibility. The main objective of the workshop was for the representatives from the Member State Competent Authorities (MSCAs), the European Commission and ECHA to build a consensus view and to, as far as possible, agree on the most efficient process for substance evaluation.

The workshop addressed the following topics:

- Preliminary experience from the selection and prioritisation of substances for the first Community Rolling Action Plan (CoRAP);
- The procedure for substance evaluation, including organisational aspects and the role of ECHA and the Member States;
- The follow-up to substance evaluation and its link with the identification of risk management options;
- The format and content of the outcome documentation to be prepared by the Member States during the substance evaluation process;
- Capacity-building and collaboration on scientific, legal and technical issues;
- Communication between ECHA and the Member States, and to external audiences.

On the first day of the workshop, the discussion was initiated by presentations given by Member States and ECHA on the topics listed above. On the second day, the same topics were discussed in break-out groups, followed by a conclusive plenary session. Based on the conclusions reached and the ideas proposed for future consideration, the workshop represents a major step forward in the process of substance evaluation. A summary of the conclusions is given below.

1. Selection and priorisation of substances for CoRAP

The first step in the substance evaluation process is the establishment of a list of substances subject to evaluation, the Community Rolling Action Plan (CoRAP). This list will cover a period of three years and be updated each year.

At the workshop on prioritisation criteria in October 2010, ECHA presented a proposal for criteria to be used for the establishment of the first CoRAP in accordance with REACH Art. 44. The initial ECHA proposal has thereafter been amended according to the recommendations made during the October 2010 workshop and based on written comments provided by the Member States. The participants of the May 2011 workshop supported the use of the refined criteria. Following the workshop, the selection criteria were adopted as a decision by ECHA's Executive Director and published on the ECHA website (http://www.echa.europa.eu/reach/evaluation_en.asp). The workshop participants agreed that the CoRAP selection criteria and their application should be refined in the coming years, as ECHA and the Member States will have gained experience with the first substance evaluations and IT approaches for the selection and prioritisation activity will have further developed. During the second half of 2011, ECHA will develop the draft CoRAP based on the candidate substances identified by the Member States and ECHA, taking into account expressions of interest by Member States to evaluate specific substances.

2. Substance evaluation procedure

As outlined in the REACH Regulation, the evaluating MSCA has twelve months from the publication of the CoRAP to consider the need for further information and prepare a request in the form of a draft decision. The final decision will be taken by ECHA following the procedure as provided for by REACH. After the adoption of the decision, the registrant(s) will have to submit the requested information to ECHA, within the timelines specified in the decision.

The workshop discussed administrative, legal and scientific aspects of the substance evaluation process. These included ECHA's task to monitor substance evaluation draft decisions in order to ensure a harmonised approach in decision making, practical aspects in relation to requesting available information from registrants upon the start of substance evaluation, and the possibilities of aiming the substance evaluation at issues and endpoints of particular interest, as opposed to generic evaluation activities. The workshop participants also discussed the transfer of funds to MSCAs conducting substance evaluation. While conclusions were reached on most issues, some others are requiring further legal consideration.

3. Follow-up of substance evaluation

After completing the substance evaluation, the responsible MSCA shall consider whether there is a need to follow up any identified concerns and propose how to use the information obtained within other REACH processes or under other Community or national legislation. At the workshop, the discussion focused on practical and procedural aspects, and in particular on the timeframe in which the MSCA should come to a conclusion, as this is not explicitly specified by the legal text.

4. Outcome documentation

In relation to the substance evaluation process, the workshop participants discussed the use of generic templates and formats for the outcome documentation. The purpose of these documents would be to ensure the maximum transparency of the substance evaluation process, to enable the construction of information databases, and to ensure interaction between substance evaluation and other processes under REACH. The formats and content of the templates including their use as proposed by ECHA were, on the whole, supported. ECHA will take on board proposals presented during the workshop and submit new templates to the Member States for further written comments in order to have them ready for use by the start of the process in 2012.

5. Capacity-building and collaboration

Discussions during the workshop confirmed that building up the capacity of MSCAs to conduct substance evaluation is of high priority. ECHA will therefore provide training and advice for MSCA staff on legal, scientific and IT-related issues. To facilitate collaboration between Member State Competent Authorities, appropriate platforms for discussion and communication will be set up when needed.

6. External communication

Following a request at the October 2010 workshop, ECHA developed and presented a communication strategy on substance evaluation, to the MSCA representatives. In order to inform stakeholders, industry and the public a fact sheet was published on the ECHA website in April. Furthermore, to promote the transparency of the process, the names of the substances included in the draft CoRAP and the non-confidential decisions on further information from substance evaluation will be made available to the public. It was evident from the discussions at the workshop that the participants showed an interest in how to maintain the benefits of efficient external communication while continuing to ensure the protection of confidential data.