Task Force on the Workability of Applications for Authorisation

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Report of activities undertaken in 2016

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1. Background

The task force was established following CARACAL-15 (8-9 July 2014), where the Commission proposed a way forward for a workable application for authorisation process. Since then the task force has been working with the overall objective of:

- assisting on technical and practical aspects in the development of the streamlined application for authorisation approach for all cases in general; and
- assisting on technical and practical aspects in the development of a possible "Authorisation implementing act" in selected special cases.

The task force consists of representatives from the Commission, the Committee for Risk Assessment (RAC), the Committee for Socio-economic Analysis (SEAC), the ECHA Secretariat and a number of Member State Competent Authorities (MSCAs)[1].

The report on the task force's activities in 2014-15 and objectives for work for 2016-17 provides further information about the background and the working method of the task force.

2. Deliverables of the task force

In 2016, the task force has held three face-to-face meetings and four WebEx meetings. The main focus of the task force in 2016 has been to support ECHA in the development of a guide for applicants with practical advice on developing an application strategy and preparing the various assessment reports necessary in an application for an authorisation i.e. CSR, AoA and SEA. The task force also gave advice on the preparation of a note on the review report of an authorisation. These two deliverables are described in more detail below.

Furthermore, the task force gave contributions to the Workshop on Socio-economic analysis in applications for authorisation and restriction under REACH that was organised in Brussels on 29 June 2016.

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[1] Member State Competent Authorities currently represented in the task force are Belgium, Denmark, France, Germany, the Netherlands, Sweden and the United Kingdom.

2.1 How to apply for authorisation – a step-by-step guide

Background: As part of the efforts to clarify and streamline the application for authorisation process, ECHA and the task force identified a need to develop a guide with practical advice on how to prepare a 'fit-for-purpose' application for authorisation. It was agreed that the guide would be partly based on feedback to be collected from past applicants and stakeholders. It would also incorporate the experience from the Committees' work in evaluating applications for authorisation.

Outcome: In the spring of 2016, ECHA collected feedback and suggestions for the content of the guide from past applicants and other stakeholders. Based on this feedback, ECHA, with the help of the task force, identified the key issues that practical advice was needed on. Common themes within the feedback were, in particular, considerations for the application strategy, how to demonstrate that data are representative and defining an appropriate scope for the use description. Many applicants and stakeholders requested that the advice would be supported by real examples from previous applications.

With the help of the task force, ECHA developed a draft version of the guide during the summer of 2016. During the autumn of 2016 a series of targeted consultations were undertaken to refine the content of the guide, including with RAC, SEAC, previous and likely future applicants, industry associations and, finally, the task force. The feedback received from these various consultations was very useful in ensuring that the final content was as relevant, and practical, as possible. After a final consultation with the Commission services, ECHA published version 1 of the guide on its website, titled "How to apply for authorisation", on 19 December 2016.

The guide will be updated from time to time in the future as further experience is gained in the evaluation of applications and in response to any improvements in the implementation of the application process. The first update is likely to take place in spring 2017 to include the implications of the Commission's implementing act for use of Annex XIV substances in low quantities.

2.2 Review phase of authorisation

Background: According to Article 61(1) of the REACH Regulation, a granted authorisation is valid until the Commission decides to amend or withdraw it in the context of a review, provided that the authorisation holder submits a review report at least 18 months before the expiry of the review period. ECHA will receive the first review reports in the summer of 2017. There was therefore a need to clarify what should be included in the review reports and how ECHA's committees will give opinions on them.

Outcome: With the help of the task force and the Commission services ECHA prepared a note outlining the approach to be taken when a review report is submitted. Specifically, the note clarified to what extent the review process and the elements of the review report

are identical to an application for authorisation and what would be different or new. Following a consultation in RAC and SEAC, the note on the review report of an authorisation was published in September 2016. The approach is also outlined in the guide on How to apply for authorisation.