Task Force on the Workability of Applications for Authorisation

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2017

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Report of activities undertaken in 2017 and work plan for 2018

Task Force on the Workability of Applications for Authorisation: Report of activities undertaken in 2017 and work plan for 2018

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A. Report of activities in 2017

1. Background

The task force was established following CARACAL-15 (8-9 July 2014), where the European 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 European 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 as well as the report of the AfA task force 2016 provide further information about the background and the previous activities of the task force.

2. Deliverables of the task force

In 2017, the task force held two WebEx meetings. In preparation for the Stock-taking conference on the implementation of REACH authorisation, a group of task force members formed a conference organising committee. The conference organising committee held one face-to-face meeting and four WebEx meetings.

In addition to the stock-taking conference, the task force has contributed to the update of the guide on how to develop the description of uses in the context of authorisation as

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

well as the ongoing update of the application and opinion formats. These deliverables are described in more detail below.

2.1 Stock-taking conference on the implementation of REACH authorisation

Background: The task force had previously committed to assist ECHA and the European Commission in organising a conference after the majority of the chromates applications had been through the opinion-development phase. The purpose of the conference was to take stock of the evolution and achievements of the authorisation process in terms of the progression of substitution, proper control of risks and cost-effectiveness. It would also serve as a follow-up to the Workshop on Streamlining applications for authorisation held in Brussels on 17 November 2015 and the 'Lessons Learnt' conference on applications for authorisation held in Helsinki on 10-11 February 2015.

Outcome: The Stock-taking conference on the implementation of REACH authorisation was held on 13-14 November in Helsinki. It was attended by approximately 120 participants from applicants, NGOs, alternative providers and authorities. A key focus of the conference was the results of the European Commission's study on impacts of authorisation, which found that the authorisation system has achieved its objectives in terms of substitution and improvements in the way SVHCs are used (i.e. risk reduction) but it has not been able to quantify the benefits of the authorisation system nor whether those exceed its costs. From the discussions at the conference it was concluded that two key remaining challenges are how to describe uses in applications for authorisation by upstream actors and how to further involve alternative providers in the process. ECHA, the European Commission and the task force will continue their work to meet these challenges and to further improve the authorisation system.

2.2 Guide on how to develop the description of uses in the context of authorisation

Background: A document titled 'How to develop the description of uses in the context of Authorisation' was initially published in 2011. Based on the experiences gained from the evaluation of more than 100 applications for authorisation, it was felt that the initial document should be reviewed and revised to ensure that it reflects the current understanding of best practice.

Outcome: ECHA reviewed and updated the document with input from the task force. The revised document, now with the title 'How to develop use descriptions in applications for authorisation', was published in June 2017. The document has been updated considerably since the previous version and now includes the 'alternatives-driven' approach compatible with the approach outlined in the 'How to apply for authorisation' guide published in December 2016. The document will be updated from time to time in the future as further experience is gained in developing use descriptions in applications for authorisation.

2.3 Update of the application and opinion formats

Background: There is a need to review the formats for applications for authorisation and Committee opinions to ensure that they are fit-for-purpose.

Outcome: The application for authorisation and opinion formats are currently being reviewed and updated by ECHA. The task force has provided suggestions for this exercise, which will continue in 2018. More information is available in the work plan.

B. Work plan for 2018

In addition to regular update of the How to apply for authorisation guide (e.g. as regards to Review Reports), the support of the task force is sought for the below mentioned work items. Items 5 and 6 have been specifically identified during the Stock-taking conference on the implementation of REACH authorisation held on 13-14 November 2017.

1. Revision of the opinion/justification formats

Based on ECHA's experience and feedback received from the Commission, the aim is to:

a) simplify the structure of the opinion format,
b) streamline and harmonise the way the opinions and their justifications are written,
c) improve and standardise the way RAC and SEAC recommend additional conditions and monitoring arrangements. As regards their enforceability, the task force will seek the input of the Forum. The task force may then envisage to consult other Committees e.g. the Senior Labour Inspectorate Committee (SLIC), CARACAL, REACH committee.

Timeline: formats finalised by the task force in **April-May 2018** and agreed in RAC and SEAC in **June 2018**

2. Article 61(2): review of authorisations if the circumstances change

This item is to seek the task force's advice and ideas on how the Commission, in the context of Article 61(2), can deal with changes of circumstances that would trigger a review of the authorisation. This could be administrative changes, such as change of Legal Entity, or changes to the authorisation holder's operations or new information on possible alternatives. The authorisation holder should notify the authorities of such changes.

Timeline: in the course of 2018

3. Simplification for low quantities

The task force has already developed the application for authorisation formats. However the task force may revisit them after the Commission has made progress with the simplification scheme.

Timeline: **Spring 2018**

4. Simplification for legacy spare parts

The task force will review formats developed by ECHA for the use of AXIV substances to manufacture legacy spare parts and for repair activities.

Timeline: **September 2018**

5. Advice on how to involve alternative suppliers

Collect ideas from the task force members on how to i) increase the general awareness of the public consultation and ii) involve alternative suppliers further in the process. This item is also linked to the ECHA's substitution strategy work.

Timeline: in the course of 2018

6. Advice on how to improve the exposure assessment and the analysis of alternative submitted by upstream applicants

Elaborate an approach for upstream applicants on how to approach i) the exposure assessment when covering a large number of sites operating under different sets of OCs/RMMs and ii) the Analysis of Alternatives to make it proportionate to the scope of the use applied for.

Timeline: for the exposure assessment: approach finalised in **April-May 2018** and agreed in RAC in **June 2018**. For the Analysis of Alternatives: no defined timeline.