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Intermediate report on the implementation of the roadmap on authorisation applications under REACH

44th meeting of the Management Board 13-14 December 2016

Key messages

The Management Board is invited to take note of the interim report on the progress made by the ECHA Secretariat in reviewing the REACH authorisation application process and give advice to the Executive Director on the submission of the final report that will be made to the Management Board after the "stock taking" conference, scheduled for November 2017.

Background

The authorisation process, and in particular the role of ECHA's Scientific Committees in analysing socio-economic factors, were discussed by the Management Board in December 2015 and March 2016. This discussion was triggered by a resolution of the European Parliament regarding the draft Commission decision on one of the first applications for which ECHA's Committees issued an opinion. On the basis of the discussions, the ECHA Secretariat presented a roadmap (dated 21 April 2016), which foresees an interim progress report to the Management Board in December 2016.

Major activities reported on are the following:

- ECHA organised a fruitful workshop on socio-economic analysis (SEA) in applications for authorisation and restrictions under REACH in Brussels on 29 June 2016;
- Under the lead of the ECHA secretariat, the task force on REACH authorisations developed a practical guide for companies on how to develop authorisation applications;
- Templates used by the Committees to provide their opinions have been updated.

Overall, the application process has further developed and matured during the preparation and adoption of about 150 opinions in ECHA's Scientific Committees during 2015-16.

Matters for consideration

Progress made in the workability of applications for authorisation task force

The task force on the workability of Applications for Authorisation (AfA) has focussed in 2016 on providing a "Practical Guide" on how to prepare an application. Based on experience gained thus far, the about 50-page long guide explains, amongst others, the requirements of necessary information of an application dossier and gives examples of previous applications. The guide attempts to clarify the scope of the "upstream" applications and in particular the description of the uses applied for. It is challenging to give specific advice on how to narrow the description of use because the description cannot be linked to the articles produced. The approach in the Practical Guide is to give progressively detailed advice in the updates of the guide, based on increased knowledge resulting from the actual applications, the comments made and the opinions given.

The conformity check, including minimum information requirements for it, has not been addressed. This is partly due to the fact that the task force has not been able to establish such minimum information requirements in the context of applications for authorisation. ECHA has requested feedback on a draft final version from stakeholders. The aim is to publish Version 1.0 of this guide by the end of 2016, and have updated versions made available in the spring and

autumn of 2017. The first update is planned to add practical guide for low quantity applications (after the Implementing Act has been adopted). The second update is planned to update the practical guide as a result of any changes introduced to the application process and its requirements up to mid 2017.

In 2017, the AfA task force will support the Commission and ECHA in implementing a simplified application process for low quantities and legacy spare parts. The task force may give advice to ECHA on the clarification of minimum information requirements for applications and assist ECHA and the European Commission to organise a "stock taking" conference in November 2017.

Workshop on socio-economic analysis in Applications and Restrictions

On 29 June 2016, ECHA and the European Commission (Directorates-General Internal Market, Industry, Entrepreneurship and SMEs as well as Environment) organised a one-day workshop on socio-economic analysis (SEA) in applications for authorisation and restrictions with the aim to clarify the role of SEA under REACH and to dispel prevailing myths.[1] The workshop brought together around 120 participants from all stakeholder groups, including two representatives of the European Parliament, to discuss i) what is SEA and what is it not; ii) what is possible and meaningful to carry out as part of SEA; iii) how are the opinions of ECHA's Socio-economic Analysis Committee (SEAC) derived in practice; iv) how is SEA used in the decision-making process; and v) how can SEA-related issues be better communicated to stakeholders.

In the discussions different views on the role of and experiences with SEA were expressed, focusing mainly on the authorisation process. ECHA considers the workshop an important step towards a better understanding of SEA and its role within the REACH regulation as some prevailing misconceptions about SEA were clarified. In particular, it was clarified with stakeholders that impacts on human health and the environment can be assessed in a SEA in a qualitative manner (e.g. by stating the direction of an expected impact), quantitatively (e.g. by stating a number or fraction of cases avoided) or in monetary terms (by stating the welfare cost associated with the expected impact).

In a nutshell, the workshop underlined the importance of SEA for the public acceptance of REACH decisions as it makes the comparison between different impacts explicit. It was also clearly concluded that SEA is a tool for supporting, not replacing, the decision-making. The presentations given at and the conclusions drawn from the workshop are available on ECHA's website.[2]

Workshop on acceptable risk level to workers and consumers on carcinogens

ECHA senior scientific officers participated in a workshop on *"Acceptable level of risk to workers and consumers exposed to carcinogenic substances"* organised by the European Commission (Directorate-General Internal Market, Industry, Entrepreneurship and SMEs) in Brussels on 22 November 2016. The issue of acceptable levels of risk has been discussed on many occasions in the past. However, in the context of REACH Authorisations and Restrictions but also the interaction with Occupational Health and Safety and other legislation, this issue has recently gained in importance. The workshop discussed the Netherlands and German systems for deriving and assigning various risk levels (e.g. 4:1 000 or 4:10 000 over working life) for non-threshold carcinogens in the workplace. Industry speakers contributed with an overview of typical 'closed' risk management measures for dealing with carcinogens and the mechanisms and problems of communicating risk management measures to workers in particular in the metals industry.

[1] ECHA also hosted a workshop for OECD Socio-economic Impact Assessment of Chemicals in July, see echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/socio-economic-impact-assessment-of-chemicals-management

[2] echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/workshop-on-socio-economic-analysis-in-applications-for-authorisation-and-restrictions-under-reach

The workshop tentatively concluded that such threshold levels are useful in comparing the potency of carcinogenic substances, in motivating further risk management measures and in better ensuring minimisation. It was clear from this first discussion that there are many issues to consider and that it is early days yet. There was a call from several participants for methodologies in this field to be harmonised; reference was also made by the Commission to Task 2 of the ECHA/RAC-SCOEL joint task force[3], which deals with non-threshold carcinogens and is due to start this part of its work in 2017.

Scope of opinions: revised standard wording and formats

ECHA, including its Scientific Committees, have revised the standard wording and formats of the opinions in 2016 based on the experience gained in earlier years. For instance, the inconsistent wordings used in the first opinions, for instance in the case of DEHP in recycled plastics, have no longer been applied. In response to suggestions made by the Commission on 25 July 2016, ECHA's staff have further discussed with Commission staff on how the practice, wording and formats of opinions could be improved. These thoughts were documented in ECHA's response to the Commission of 6 October 2016[4]. ECHA has also checked the standard wording used in opinions on applications for authorisation with the Commission services, who have indicated that they do not see a reason for additional revisions beyond those already adopted. ECHA has a continuous dialogue with the Commission services on how to further develop the opinions to be increasingly helpful for decision making.

Moreover, additional ECHA staff resources have been allocated to scrutinise the draft opinions written by the Rapporteurs. The purpose of this has been

i) to ascertain that role of the ECHA Committees vs the Commission's decision making role is clear in the opinions and

ii) to ensure consistency amongst the opinions and clarity of the conditions, monitoring arrangements and the justifications for the suggested review periods.

Based on the experience gained of the current opinion-making phase, ECHA will further work on improving the current formats and make them more user and reader friendly, consistent and based on as much standard texts as possible. The aim is also to have the formats linked to ECHA's IT systems, in particular to the application used for storing all details of opinion making, so that the system would generate all background information for the opinion. The plan is to take the new formats to use in the latter part of 2017.

Other activities related to the authorisation process

The Commission is in the process of adopting an implementing act to have a "special case" for giving the opinions and decisions related to low quantities (<100 kg/year) of substances of very high concern. The fees for such applications would be adjusted downward by 50%, too. The implementing act is likely to be adopted in the spring of 2017 and ECHA will publish the application formats and opinion templates immediately after the publication. This activity is one milestone in the simplification of the AfA process. It is planned to be followed by another simplification process for legacy spare parts, after the Commission has decided to postpone the latest application dates for the substances that are used in legacy spares. It is not known for how many cases this is a relevant issue for but it is politically important to address this.

Conclusions

The AfA process works efficiently and delivers quality output. By the end of 2016, ECHA's Scientific Committees have provided 63 opinions in total. At least another 62 will be provided to the Commission in 2017. The difficulties that were identified in some of the opinions stemmed

[3] The document is available upon request from the Secretariat
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to a large extent from the fact that these were the earlier opinions provided by the Committees. Since 2014, the application process has gradually become more mature.

In 2016, in collaboration with the Commission and the AfA task force, ECHA has made good effort to further develop the process. By the end of 2016 ECHA will publish the first version of the Practical Guide to provide information to the applicants. In addition, ECHA has given and received feedback from stakeholders, has built the capacity of the Scientific Committees, updated the formats and standard wordings, identified the additional development needs for 2017 and held topical workshops on socio-economic analysis.

The main challenge that has been identified in the process is still the same: how to narrow the scope of so-called "upstream" applications in order to obtain an optimal amount of representative information so that ECHA's scientific committees are able to better evaluate them than today. Further discussion and work is needed in order to ensure that the uses applied for are described in a meaningful manner and allow for an appropriate analysis of alternatives, since these applications are vital for the application system. While some progress has been made and the Practical Guide will give direction on this, it is evident that ECHA, the Commission and the AfA Task Force need to further work in 2017 to make the "upstream" broad scope applications pertinent. ECHA will report to the Management Board about this development at the end of 2017.

Attachment:

- Annex: Roadmap submitted to the Management Board on 21 April 2016

Note to the members of the Management Board

Overview of the next steps in Applications for Authorisation

1. 1. Introduction

This overview summarises the next steps that are to be taken in the application for authorisation (AfA) process following the discussion in the March 2016 meeting of the Management Board.

2. 2. Next Steps

2.1. AfA Task Force

The 2014-15 report and the objectives for 2016-17 of the AfA Task Force were endorsed in the March 2016 Caracal meeting and are made available separately to the Management Board. Among the objectives, the Task Force will provide advice and propose solutions to the issues identified as of most relevance i.e. to clarify and streamline the application process for all applicants in the "upstream" and "low impact" applications[5]. The Task Force will also aim to establish more clarity on what would be considered as minimum requirements relating to the conformity of the applications. These tasks are aimed to be finalised before the end of 2016 in the form of a Practical Guide.
The Task Force has already invited stakeholder experts to its meetings to discuss specific issues. It will hold a Webex meeting in May to discuss the progress made and how stakeholders could be more closely associated in the work.

2.2. Workshop on Socio-economic Analysis on 29 June 2016

ECHA and the Commission will organise the workshop on how socio-economic analysis (SEA) is used in restrictions and AfA on 29 June. This one day workshop aims at increasing the understanding of Member States, European institutions, applicants and other stakeholders of the role of SEA under REACH, in particular what SEA does and does not do, why it is needed, and how it adds value to the decision making processes under REACH. The workshop will give an opportunity to exchange views and to learn from different examples on how SEA has been used in restrictions and AfA, how SEA and SEAC opinions have contributed to the decision making.

2.3. Risk limits

Concerning the discussion on risk limits raised by some board members, ECHA has started to reflect the topic with the Commission.

2.4. Scope of the opinions

ECHA has initiated discussions with the Commission services on the scope and the form in which the opinions of RAC and SEAC are documented and forwarded to the Commission for decision making. This will take into account the results of the SEA workshop, and aims

[5] "Upstream" applications refer to those made by manufacturers, importers or only representatives covering the whole supply chain. "Low impact" applications refer to cases where the applicant considers that the use of the substance has a low human health or environmental impact, for instance, because the substances is used in a closed system were fugitive emissions are small. The Task Force will need to specify what such cases might be.

to ensure that the wording used will properly reflect the scientific and technical advice provided by the Agency. Any changes that would go beyond just improving the clarity of the opinions would also be consulted with the Member States. The aim is to have identified any need for changes in the standard wording and possibly the structure of the analysis and the tiered conclusions by July in order to discuss the results in the RAC and SEAC September 2016 meetings and adopt them in the December meetings. The timelines depend on the scope of the envisaged changes. Further discussions will take place with the Commission on where and how to inform Member States and the stakeholders.

2.5. Other activities

The Commission is in the process of finalising the two first outputs of the Task Force by means of implementing acts, namely related to AFAs for uses in low quantities (i.e. applications concerning less than 100 kg of use of a substance) and for the production of legacy spare parts. Concurrently, the Fee Regulation will be amended and ECHA will implement these as soon as the Regulation enters into force. At the time of writing ECHA understands that the implementing acts and the Fee Regulation are planned to be voted in the REACH Committee meeting in July 2016 and subsequently adopted by the Commission and published in the Official Journal. After this ECHA will make available on its website the formats for the application of low quantities.

In mid-autumn 2017, ECHA is planning to hold with the Commission a third[6] "lessons learnt" conference/workshop on applications for authorisation. This will take stock of progress relating to the about 150 opinions that will have been adopted by RAC and SEAC at that time.

3. 3. Reporting

ECHA will prepare an interim report on the progress made thus far for the December 2016 Management Board meeting. A final report will be written after the third "lessons learnt" conference and discussed in the September 2017 Management Board meeting.

[6] AfA "conference" was held in Helsinki in February 2015, AfA "workshop" in Brussels in November 2015.