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Report on the implementation of the roadmap on authorisation applications under REACH

48th Meeting of the Management Board 14-15 December 2017

Key messages

The Management Board is invited to take note of the final report on the review of the REACH authorisation application process.

The report concludes, that since the discussion in the Management Board in December 2016 on the intermediate report ECHA and its Committees have gained further experience which allowed the implementation of additional process improvements in the areas where the board indicated that further efforts were needed. At the recent "Stock-taking" conference of November 2017 it was concluded that the authorisation process works and delivers on its objectives; REACH authorisation has indeed reduced risks for workers, consumers and the environment by the implementation of suitable alternatives or enhanced risk management measures and operating conditions. Main action areas have been identified and further opportunities for action, like the REACH Review findings and recommendations, will be used to continue to improve the authorisation system.

This report will be submitted to the European Parliament Committee for Environment, Food Safety and Public Health.

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, March and December 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. A final report was scheduled for December 2017.

In December 2016, an intermediate report[1] was submitted to the Management Board which reported on the following major activities:

- A workshop on socio-economic analysis (SEA) in applications for authorisation and restrictions under REACH in Brussels on 29 June 2016;
- The development of a practical guide on how to develop authorisation applications;
- Updated templates used by the Committees to provide their opinions.

According to the conclusions from the meeting, "the Management Board took note of the report and the practical guide to assist applicants in creating their dossier was welcomed whilst acknowledging the need for further development of the guide and of work on other aspects identified in the roadmap that influence the effectivity of the process. The Board appreciated the improvements and recognised authorisations for applications as a maturing process with a high reputational impact. It was at the same time noted that all ECHA opinions so far had not objected to the conclusion of the applicants that the authorisation be granted and, therefore, considered that the process was open to criticism

[1] MB/52/2016
https://echa.europa.eu/documents/10162/2200151/mb_52_2016_afa_intermediate_report_en.pdf/b506edcf-7695-8122-2a7e-7db7bf3c4caa

from some stakeholders. It was mentioned that the practical guide should avoid giving the impression that a negative opinion is not possible or highly unlikely or that a good application ensures a positive opinion.

Board members pointed out a number of areas where further efforts were needed: i) the transparency of the overall process; ii) the conformity check and minimum information requirements; iii) the consistency and standardisation of formulations of opinions especially for applications following the socio-economic route; iv) addressing broad upstream applications and v) clarifying the role and responsibility of ECHA's committees. These aspects will be discussed in the next section.

The Board recognised that further improvements need the optimal technical-scientific cooperation of ECHA, the Commission, Member States and stakeholder representatives, in the Task force for authorisation applications. Moreover, further debate was seen needed at the policy level to weigh the economic advantages of authorisation against the incurred risks."

The Secretariat took these comments into account when continuing the work in 2017. The present final report informs of the further developments, in particular the outcome of a "Stock-taking" conference on 13 and 14 November 2017.

The report will be submitted to the Chair of the European Parliament Committee for Environment, Public Health and Food Safety. The ECHA Secretariat will also offer a technical briefing to interested parliamentary advisors.

Rationale

Transparency of the process

Today, a very small part of the text in applications is "blacked out". In some applications no text is "blacked out" because the application did not contain any commercially sensitive information. This information relates mainly to exact volumes of chemicals used, cost and profit calculations and technical company specific details. ECHA publishes all comments made during public consultation. It will also publish the questions and answers from the committees to the applicant for the applications received in 2017 and thereafter. In summary, the application process is very transparent and the information in the applications received in 2016-17 has very little information that is not disclosed to the public.

The discussions in the Task Force on the Workability of Applications for Authorisation, which supports the Commission and ECHA, take place mainly between regulators. Nonetheless, the Task Force invited stakeholder organisations to participate in several meetings. ECHA is aware of the requests from NGOs to participate in the work of the task force and will continue to seek a close collaboration with all stakeholders while maintaining the necessary space for the authorities to discuss different approaches among themselves.

Conformity and information requirements

Several stakeholders, Member States and Commission services[2] had expressed concerns on how ECHA's committees addressed conformity. The practice had been that the applicants were informed at the beginning of the process whether their applications conformed or not with the requirements of REACH. This was thought not to give enough incentives for the applicant to give additional information after the conformity has been declared. Based on those concerns ECHA consulted the Commission services and implemented a new approach on conformity check in 2017.

[2] For instance, a letter from the Commission services to ECHA of 25 July 2016 raised this issue among their suggestions for further improvement of the application process.

Today the committees express their views on the conformity at the end of the opinion making process with the idea that the applicants would be more prone to answer questions throughout the opinion making. This amended way of working addressed the concerns while being also within the legal framework of the REACH Regulation.

In terms of minimum information requirements ECHA has made publicly available check lists of what RAC and SEAC will focus on during their evaluation. This has increased the transparency on what minimum information requirements exist and should further improve the consistency of the process towards all parties, and in particular towards the applicants.

Scope of opinions: revised standard wording and formats

ECHA already 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, as encountered in the case of DEHP in recycled plastics, were no longer applied. ECHA has further discussed with the Commission services how the wording and formats of opinions could be improved. ECHA has also checked the standard wording used in relevant opinions on applications for authorisation with the Commission services who consider that these do meet the requirements of 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 to ascertain that the role of the ECHA Committees vs the Commission's decision making role is clear in the opinions and 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 and feedback received by stakeholders, ECHA will continue to work on improving the current formats and to 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, so that the system would generate all background information for the opinion. ECHA has identified in 2017 what needs to be updated in the application and opinion formats. Due to the high workload until October 2017 ECHA will complete this work in early 2018[3].

Addressing broad upstream applications

The main challenge in the application for authorisation system has been to improve the broad, upstream applications (covering multiple downstream users). ECHA has addressed these through various means. Firstly, the "Practical Guide" on how to prepare an application gives advice on the provision of pertinent information in the application. It also gives examples of previous applications to concretely illustrate the guidance. The guide helps the applicants how to properly explain their scope and in particular how to best describe the uses applied for.

Secondly, in June 2017 ECHA published an updated Use Description guide. The guide is based on the lessons learnt from the first applications and strongly recommends applicants to follow an "alternatives driven" approach rather than an exposure scenario driven approach. This new approach is meant to improve the use descriptions of the upstream applications so that they are narrowed down to be as clear and meaningful as possible. The initial reactions to the Practical Guide and updated Use Description Guide have been positive.

[3] i.e. before the submission of the new applications for authorisation.

Thirdly, ECHA has addressed upstream applications in its main events in 2016-17 (see Annex). In particular, in the "Stock-taking" conference of 13-14 November 2017 much of the discussion was around how to further improve the upstream applications. Several ideas were proposed, including improvements in the communication in the supply chain and improvements in the way the uses are described (so that the analysis of alternatives is increasingly clearer). It was recognised that ECHA should work with the Commission, the AfA Task Force and stakeholders to address this challenge.

Clarifying the role and responsibility of ECHA's committees

In consultation with the Commission ECHA's committees changed the conclusion on the conformity to concur with the adoption of draft opinions, and have prepared and published check-lists that RAC and SEAC use when evaluating the applications. The role and responsibility were also discussed and further clarified in the workshop on Socio-economic analysis (in June 2016) and the "Stock-taking" conference of November 2017. Therefore, it was concluded that the roles and responsibilities concerning the decision-making process are clear.

Conclusion

By the end of 2017, ECHA's Scientific Committees have provided 176 opinions in total. As the application and opinion processes have gradually matured the difficulties that existed in the first opinions did not exist in the opinions adopted on authorisation applications in 2016-17. In particular, the wave of applications for chromium VI compounds, which was handled efficiently, has significantly increased the experience of ECHA and its Committees and allowed the implementation of further process improvements.

ECHA has addressed the five areas where the Management Board concluded in 2016 that further efforts are needed. Consequently, this report, in conjunction with the interim report of December 2016, provides a comprehensive response to the European Parliament resolution of November 2015. Nevertheless, the work to further improve the authorisation system of the REACH Regulation will continue.

In the concluding session of the "Stock-taking" conference of November 2017, which was introduced by the Commission and ECHA, it was noted that progress has been made and that the authorisation system works and delivers on its objectives: substitution has taken place and risks have been reduced. ECHA, the Commission and the AfA task force will continue to improve the authorisation system in the years to come. The main action areas identified are i) better matching the use description and analysis of alternatives, in particular for broad upstream applications, and involving alternative providers ii) improving the cost-effectiveness of applications and iii) enhancing supply-chain communication. Further action areas may also come from the Commission REACH Review.

Attachment:

- Annex: Main events in 2016-17 to improve the application for authorisation process

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Annex

Main events in 2016-17 to improve the application for authorisation process

Stock-taking conference on the implementation of REACH authorisation

On 13-14 November 2017 the European Commission and ECHA organised a "stock-taking" conference on the implementation of the authorisation system[4][5]. 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.

The conference which was attended by more than 100 participants from various parts of industry, NGO's, Member states, and RAC and SEAC members helped to further increase confidence and understanding of the application for authorisation process over the years to come.

Overall, it was noted that since the first conference in 2015, a lot of experience has been gained. In the concluding session which was introduced by the European Commission and ECHA it was concluded that the authorisation system works and delivers on its objectives in terms of promoting substitution and achieving improvements in the risk reduction of substances of very high concern. Concerning the future, the improvement would be sought in i) matching use description and analysis of alternatives including the involvement of alternative providers ii) improving the cost-effectiveness of applications and enhancing supply-chain communication.

Accordingly, the main conclusions of the conference were:

- While REACH authorisation still is a learning-by-doing exercise clear evidence exists that the system has and will stimulate substitution.
- Human health and environmental risks have reduced both due to substitution and to the risk management measures applied as part of the decision making process.
- Specific downstream applications generally have worked well.
- Applications from actors higher up covering multiple downstream users is not a default but a possibility. The conference devoted a lot of attention on how to improve this part of the process and identified that action is needed, including improvements in the communication in the supply chain and improvements in the way the uses are described (so that the analysis of alternatives is increasingly clearer).
- It was also concluded that the so called "Downstream user notifications" have already brought pertinent information.
- ECHA has received the first re-applications, called review reports in autumn 2017. The evaluation of the information in these new review reports and the comparison of these with the original applications made in 2013 is likely to bring new insights and thus help in the further development of the authorisation system.
- Several recommendations were made to improve the making of the authorisation system more cost-effective. These comprised i.a. adding standardised formats/tables, providing examples of good applications, building further on the

[4] See http://echa.europa.eu/-/stock-taking-conference-on-applications-for-authorisation
[5] The conference was 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.

experiences with the practical guide and continue providing reference DNELs and dose-response curves early in the process.
- Improve the communication in the supply chain, for instance by having a stronger role for the national and EU wide associations to increase awareness and by using article oriented sectors, chambers of commerce, distributors and trade-unions. It was noted that communicating in national languages is key.

Workshop on environmental endocrine disrupters

On 22 August, ECHA hosted a workshop in Brussels on 'Applications for Authorisation for Environmental Endocrine Disrupters'. The purpose of the workshop was to have an open exchange of views on the available scientific evidence relating to the hazard and risk assessment of Nonyl- and octylphenols (ethoxylated). The workshop focussed on the potential to derive thresholds or dose-response relationships for these specific substances and raising awareness of other relevant key issues when applying for authorisation (i.e. minimisation of emissions).

Workshop on acceptable risk level to workers and consumers on carcinogens

ECHA staff participated in a workshop on *"Acceptable level of risk to workers and consumers exposed to carcinogenic substances"* organised by the European Commission 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 tentatively concluded that 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, which deals with non-threshold carcinogens.

Workshop on socio-economic analysis in applications and restrictions

On 29 June 2016, ECHA and the European Commission organised a workshop[6] 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.[7] The workshop discussed 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.

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.

[6] 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

[7] ECHA also hosted a workshop for OECD Socio-economic Impact Assessment of Chemicals in July, 2016. See echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/socio-economic-impact-assessment-of-chemicals-management

Furthermore 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).

Other activities related to the authorisation process

In 2016-17, the Task Force on the Workability of Applications for Authorisation supported the Commission and ECHA. This comprises, for instance, the amended working method on conformity and the update of the guide on use description[8] (both published in mid-2017) as well as helping in the organisation of the "Stock-taking" conference organised in Helsinki on 13-14 November 2017.

The Commission was unable to take further in 2017 an implementing act to have a "special case" related to low quantities of substances of very high concern. The Commission is planning to advance this activity further, alongside another simplification process for legacy spare parts. ECHA plans to publish the application formats and opinion templates subject to these developments.

[8] This new version strongly recommends applicants to take an 'alternative driven approach' when scoping the use applied word. In other words applicants are guided to apply for uses for which they can clearly demonstrate that no suitable alternatives are implementable before the Sunset Date and for uses and for which the substitution potential is clear in terms of the time needed to phase out the Annex XIV substance.