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Functioning of the authorisation applications process

68th Meeting of the Management Board, 15-16 December 2022

Key messages

A potentially high number of REACH authorisation applications in 2023 risks exceeding the capacity of ECHA committees. As a mitigation measure, the secretariat developed an approach which would allow to stagger the handling of the incoming applications over time based on pre-defined principles, issuing fee invoices when work on an application is started.

This risk for the achievement of ECHA's objectives and the wider developments outlined in this note exemplify the lack of efficiency of the authorisation process that was also identified in ECHA's assessment described in the ten years' report on the operation of REACH and CLP[1].

Introduction

In the 2023 Risk Register, the secretariat described the expected number of authorisation applications and review reports significantly exceeding the committees' capacity and the risks this may entail for the Agency (see risk No 4, agenda item B.4, annex 3).

Indeed, a high number of REACH applications for authorisation and review reports has been received in 2022, and it is expected that a high volume, mainly applications for hexavalent chromium substances, will continue in 2023-2024.

The consequence would be that applications and review reports can only be processed gradually, considering the capacity constraint. It will therefore take significantly longer before opinions will be available and the Commission can take decisions. This may lead to uncertainty and potential market impacts for companies. Years of work at maximum capacity on authorisation applications and review reports may also put a strain on RAC, SEAC and the ECHA Secretariat and reduce ECHA's capacity for other work, including restrictions. This combination of factors may lead to legal or reputational risk for ECHA.

It is noted that the issues above relate in particular to the failure of the concept of so-called "upstream" applications, which were, together with questions around the opinion format of RAC and SEAC, key issues considered in the context of the review of the process for authorisation applications conducted in 2019-2020 (see reports provided to the March[2] and June 2021[3] Management Board plenary meetings). The review work was initiated in response to the findings of the Commission's REACH Refit Evaluation[4], as well as Court cases and European parliamentary resolutions. ECHA has been monitoring the developments in this regard together with the Commission services, including a pending Court case initiated by the European Parliament following a resolution adopted in 2019[5].

[1] Report on the operation of REACH and CLP, 2021 (REACH Article 117.2).
[2] MB/M/02/2021.
[3] MB/M/03/2021.
[4] COM(2018) 116 final.
[5] P8_TA(2019)0317.

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Volumes of authorisation applications

In 2014-21, ECHA has adopted – on average – 44 opinions per year on applications for authorisation[6]. The capacity of the ECHA scientific committees, RAC and SEAC, is to issue a maximum of 60 opinions per year, i.e., about 15 opinions per quarter. This capacity is the basis for planning of this work. It takes into account efficiencies gained in the process over time and the limitations set by the membership of the committees (which has been declining over time).

According to Article 64(1) of the REACH Regulation, ECHA's *"Committees for Risk Assessment and Socio-economic Analysis [RAC and SEAC] shall give their draft opinions within ten months of the date of receipt of the application".* Article 62(7) states that *"An application for an authorisation shall be accompanied by the fee required in accordance with Title IX"*. This means that an application is considered "received" once the applicant or authorisation holder has made the payment to ECHA's account. It is at this moment in time that the 10-month period for the committees to give their draft opinions starts to run.

In 2022 ECHA has again received applications and review reports for more than 15 uses per quarter. In line with the approach taken for the OPE/NPE (nonylphenol ethoxylates and octylphenol ethoxylates) peak[7], it has managed the pipeline by only sending the invoices to those applicants whose applications it has started to process in RAC and SEAC.

For 2023-2024, consultations with industry show that the inflow of applications, mainly stemming from chromium plating, may significantly increase. ECHA therefore approached the Commission in August 2022 with the latest forecasts and suggesting options to manage the situation in order to come to an agreed approach. In parallel, the secretariat considered, as part of the ongoing corporate risk management, what mitigation measure can be taken at Agency level to manage the inflow of chrome plating related applications.

Mitigation measures and alternatives

Different mitigation measures have been considered, including further efficiency gains in the authorisation process. On this basis operating at a maximum capacity of 60 AfA opinions of the committees per year is expected to be realistic. As a mitigation measure, ECHA foresees to systematically apply the approach outlined above, which was also applied in the past: sending the invoices to those applicants or authorisation holders for which the opinion making would start and delay the sending of other invoices accordingly. This is in line with the principle that fees should be linked to the delivery of the respective services. Information about the delay and the reasoning are sent in such cases to the concerned companies. This is considered a transparent and legally sound way to allow the applications to be treated equally. Thus far this system has worked well. RAC and SEAC have been able to appoint rapporteurs and provide opinions in a timely manner. Applicants have so far not complained about this as they have understood the impact of the capacity constraint.

Alternatively, ECHA could directly dispatch invoices for all applications and review reports. This would create a stockpile of pending applications and risks exceeding the 10-month period for adopting a draft opinion for a significant number of cases. Exceeding the deadline would not impact the legality of an authorisation decision, as long as there is a justification for consistently

[6] Thus far 93% of the opinions have been given within the deadline stipulated in Article 64(1). When there were delays, they have been mainly 2-3 months when RAC or SEAC needed to take extra time to finalise the draft opinion. In three opinions the delay was considerable (about a year) due to the need to translate the application and all correspondence with the applicant.
[7] MB/43/2019 final.

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exceeding the 10 months opinion making deadline[8].

However, the secretariat considers that it should avoid exceeding the deadline consistently if there are other options available, especially also with a view to the annuality principle of the Financial Regulation and the risk that fee income not used for delivering actual work in the same financial year may not be used for the intended purposes.

ECHA, in consultation with the Commission, has defined the principles of the approach for prioritising the handling of applications and review reports. The key principle is to ensure the good functioning of the EU market[9]. The second principle is equal treatment, i.e., applicants and authorisation holders in similar situations need to be treated in a similar manner. The third principle is efficiency, i.e., that committees can adopt opinions (and the Commission take its decisions) efficiently and in an orderly manner. Throughout the process, transparency, i.e., informing the applicants, authorisation holders and stakeholders why ECHA postpones the opinion making of certain applications needs to be ensured. The adherence to these principles reduces the risk of legal action of applicants and authorisation holders against ECHA or the Commission.

As regards the specific situation of chrome plating related applications, it is furthermore considered less disruptive to the EU market to start the opinion making of the downstream users' chrome plating applications and to carry over the applications that have been made before the latest application or review date, because the use of the substances can continue. If this is not sufficient, the applications and review reports will be then treated on a "first-come-first-served" basis.

The length of the delay will depend on the number of applications and review reports, considering the above-described capacity of the secretariat and committees (60 opinions per year overall). Based on previous experience the delay could range from 2 month to up to a year.

Possible implications

Reputational implications include on the one hand complaints from industry or public health and environment NGOs about the prioritisation method applied or the possible lack of compliance with legal deadlines. Delayed authorization decisions may increase uncertainty for applicants. If delays would cause market disruptions, this might even lead to legal challenge to ECHA and the Commission. It may also be that the Court of Auditors or the Commission's Internal Audit service remark on the approach for delaying the dispatching of invoices, or in the alternative scenario that fees are collected whilst the corresponding services are only provided with significant delay. The approach chosen aims to balance these reputational risks, but it cannot be excluded that ECHA will have to handle complaints or address audit findings in 2023-2024.

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[8] The Commission faced long delays in adopting decisions relating to requests for the extended one generation reproductive toxicity study due to an unprecedented amount of draft decisions being referred to it. The European Ombudsman stated that "In view of what the Commission rightly refers to as the complexity of the issue and the unusually high number of cases it had to handle with limited resources, the Ombudsman is reassured that the Commission made particular efforts to ensure legally sound decision-making, administrative efficiency and buy-in from all stakeholders, who range from Member States' Competent Authorities, ECHA, the chemical industry, NGOs and registrants themselves." and closed the case.

[9] The two other objectives of authorisation, risk management and substitution, are addressed under the current decision concerning CTAC use 2 and are under consideration in the decision making of use 3.