Helsinki, 10/06/2021

RAC/57/2021
SEAC/51/2021

57TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

31 MAY - 3 JUNE AND 8-10 JUNE 2021

51ST MEETING OF THE COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS

1 MAY - 4 JUNE AND 7-9 JUNE 2021

HELSINKI, FINLAND

Concerns:	**Applications for Authorisation: Approach for evaluating review reports**
Agenda Point:	**10.1.4. (RAC-57)** **6.1b (SEAC-51)**
Action requested:	**For information/discussion**

Helsinki, 10/06/2021

PREFACE

This note outlines some of the issues that may emerge in the development of RAC and SEAC opinions on review reports. It does not cover all aspects of the committees' work. Rather, it concentrates on issues where the line to be taken may not be so clear or obvious. As more practical experience in evaluating review reports is gained, this approach may be updated.

The overall opinion development process is described in earlier notes agreed by RAC and SEAC[1], including

- 'Common approach of RAC and SEAC in opinion development on applications for authorisation'[2],
- 'Guidance paper on opinion trees for non-threshold substances in applications for authorisations',
- 'Working procedure for RAC and SEAC for developing opinions on applications for authorisation'[3]
- 'New approach for the conformity check'[4]
- 'Setting the review period when RAC and SEAC give opinions on an application for authorisation'[5].

The ECHA note 'Review report of an authorisation'[6] outlines 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.

The CARACAL note 'REACH Authorisation - Criteria for longer review periods'[7] has been prepared by the Commission. It outlines indicative criteria for considering review periods longer than 12 years for "exceptional cases".

[1] Documents regarding how the committees evaluate applications for authorisation are available here: https://echa.europa.eu/applying-for-authorisation/evaluating-applications
[2] https://echa.europa.eu/documents/10162/13555/common_approach_rac_seac_en.pdf
[3] https://echa.europa.eu/documents/10162/13579/rac_seac_wp_opinions_auth_app_en.pdf
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[5] https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf
[6] https://echa.europa.eu/documents/10162/13637/authorisation_review_report_en.pdf
[7] https://echa.europa.eu/documents/10162/13580/ca_101_2017_criteria_longer_review_period_afa_en.pdf

Helsinki, 10/06/2021

Approach for evaluating review reports

1. Purpose

The purpose of this note is to describe RAC and SEAC's approaches for assessing review reports, to ensure consistency in the committees' evaluations. It outlines issues that should be considered by both RAC and SEAC, as well as specific considerations related to either committee.

2. General considerations

Authorisation holders must comply with the conditions of the decision. All authorisations have a time-limited review period. During this period, authorisation holders should continue looking for a suitable alternative that would replace the substance of very high concern (SVHC). If the authorisation holders need to continue using the substance, they must submit a review report at least 18 months before the end of the review period.[8]

A review report can only be submitted by the authorisation holder. In the review report, the analysis of alternatives and, where relevant, the substitution plan and the socio-economic analysis, should be updated and any other elements required, e.g. in response to the additional conditions or monitoring arrangements of the authorisation decision, should be submitted. If the update of the analysis of alternatives shows that there is a suitable alternative available in general in the EU, the authorisation holder must have submitted a substitution plan. If the authorisation holder can demonstrate that the risk is adequately controlled, this would be evident in the updated exposure scenario. If other elements of the original application have changed due to technical progress, changes in the market conditions, additional conditions and monitoring arrangements etc. the authorisation holder shall also update these elements.

Furthermore, the authorisation holder is requested to include an explanatory note outlining what has changed since the original application was made and since the authorisation was granted.

In principle, the use in the review report should have the same or a narrower scope (e.g. if, in the meantime, the Annex XIV substance has already been substituted in one part of the authorised use). Otherwise, authorisation holders may also need to submit a new application for authorisation, instead of a review report. This may for example be relevant if they intend to change or broaden the scope of the use (e.g. if they intend to produce new products with the Annex XIV substance) or if they intend to use the substances at another site with different exposure scenarios. If the authorisation holder submits a new application for authorisation instead of a review report, the transitional arrangements of the review report do not apply. If such hypothetical situations arise ECHA will, prior to the submission, strongly recommend the authorisation holder to submit a review report and not an application for authorisation. If a new application for authorisation is submitted for a use that has previously been evaluated by the committees, information from the previous application and opinion

[8] See Art 61(1) of REACH, Q&A 1361 (https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1361) and Q&A 1362 (https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/1362)

may also be reviewed by the committees when evaluating the new application. The process for submitting and handling a review report is the same as for the original application for authorisation.

3. Issues common to RAC and SEAC

Several issues may emerge when the committees start evaluating review reports. Issues relevant for both RAC and SEAC are listed in this section.

i. What to do if the scope of the use in the review report is broader than the scope of the authorised use?

The use(s) being reviewed in the review report would be considered to have a broader scope, for example, if it has a broader function for the Annex XIV substance (e.g. if the original application covered only chrome plating and the review report covers both plating and etching) or covers new sectors (e.g. if the original application was for chrome plating for the aerospace sector while the review report is for chrome plating for the aerospace and automotive sectors). An increased tonnage in the review report would not be considered as a broadening of the scope if the substance function, type of products and market sectors are the same as (or narrower than) in the original application.

Ideally, ECHA should detect any broadening of the scope at the teleconference-based information session or during the initial technical checks. In this case, ECHA will request that the authorisation holder submits a review report with an identical (or narrower) scope to that of the original application and/or a new application for authorisation (e.g. to cover the additional functions/sectors).

Nevertheless, given that the scope of a use consists of multiple components, the comparison of two uses is often not straight-forward. If after initial assessment RAC and SEAC conclude that they are faced with a review report that has a broader scope than the original application, they will be unable to formulate an opinion on the review report. The evaluation would then need to stop (and be documented in the opinion), as the use in its entirety would be out of scope. The authorisation holder would then need to submit a corrected review report. If the authorisation holder wanted to apply for uses outside the authorisation, they would need to submit a new application for authorisation.

ii. Is the level of scrutiny for review reports the same as for the initial application?

REACH Regulation does not indicate whether the level of scrutiny for review reports should be the same as for the initial applications for authorisation. Given that any decision in the context of the review should be taken in accordance with the procedure referred to in Art 64 applied *mutatis mutandis*, the committees and the Commission apply the same level of scrutiny. All the elements of the review report should be assessed. Moreover, some of the issues to be examined in the review report may not have been present at the time of the initial authorisation application, e.g., as adherence by the authorisation holder to any additional conditions, monitoring arrangements for the authorisation and recommendations for the review report). More

information about the specific considerations for RAC and SEAC are outlined in sections 4 and 5 of this note.

Based on their experience from the initial application and from the information and requirements (conditions and monitoring arrangements) contained in the opinion and the decision, authorisation holders should have a very clear idea of the expectations of RAC, SEAC and the Commission for the review reports. If the authorisation holder has adhered well to the conditions, this can facilitate the committees' evaluation. Experience so far with review reports and occasional early reapplications is that they build logically on the original application and on the requirements of the decision; some have radically altered; others are very similar to the original application.

Overall, the committees' assessment should focus on what has changed during the review period. Given that the authorisation holder now has experience of the process and the committees' expectations, each committee should typically not need to send many clarifying questions in one round. The number of questions should be determined on a case-by-case basis and be fit for purpose.

iii. Should RAC and SEAC require and expect a more robust set of information in the review report than in the original application for authorisation?

An overall higher level of robustness in the supporting data would seem to be a natural evolution, as possible uncertainties and unclarities in the original application should have been reduced during the review period. RAC, SEAC and the Commission have already set the level of robustness of the submitted data that is expected from the authorisation holder in the review report, for example in the conditions, monitoring arrangements, recommendations for the review report or the shortcomings identified elsewhere in the opinion. These identified shortcomings are expected to be addressed in the review report.

iv. What to do if the additional conditions or monitoring arrangements as per the authorisation decision are found to be not fulfilled in the review report?

ECHA can check upfront whether the authorisation holder appears to have fulfilled the additional conditions and monitoring arrangements. If these appear clearly not to be fulfilled (i.e. if there is no information and no justification about this in the review report), ECHA can ask the authorisation holder to submit this information.

However, RAC and SEAC may be faced with review reports where the additional conditions and monitoring arrangements are not, or are only partially, fulfilled. In this case, the committees should evaluate:

a) which conditions and monitoring arrangements were not fulfilled or only partially fulfilled, and

b) the authorisation holder's justifications for why they have not been fulfilled.

ECHA will inform the relevant National Enforcement Authorities if the authorisation holder has not implemented or only partially implemented the additional conditions and monitoring arrangements.

RAC and SEAC should complete their evaluation of the review report as per article 64 of REACH. In practice, this means that a failure to fulfil the conditions/monitoring arrangements may not *a priori* and by itself lead to conclude necessarily that the

review report is "not in conformity"[9]. Therefore, the committees should evaluate how the non-fulfilment affects the reliability of the authorisation holder's assessments (e.g. risks, alternatives, socio-economic impacts) and, in consequence, how this affects the Committees' conclusions. This information will also be important for the Commission's decision-making.

If the authorisation holder's assessments have shortcomings due to non-compliance with some of the conditions or monitoring arrangements, RAC and SEAC may further strengthen their proposals and recommendations e.g. in terms of:

a) including conditions or monitoring arrangements with a time limit for their implementation, and/or

b) reducing the recommended review period.

v. What to do if the recommendations for the review report as per the authorisation decision are found to be not fulfilled in the review report?

RAC's and SEAC's recommendations for the review report set out in the Commission decisions are not enforceable by national enforcement authorities, as opposed to conditions and monitoring arrangements.

The approach related to the recommendations for the review report should be the same as the approach related to the additional conditions and monitoring arrangements outlined in point iv. above. This means a case-by-case evaluation based on the extent of the (non-)fulfilment and the authorisation holder's justifications. The evaluation may lead RAC and SEAC to strengthen their recommendations (e.g. by including conditions or monitoring arrangements with a time limit) and/or reducing the recommended review period. With a by now knowledgeable authorisation holder applying for an extension of their authorisation, there should be no need for RAC and SEAC's advice on the (next) review report in section 9 of the opinion. In principle, any further recommendations should be placed in Sections 7 and/or 8 so that they are made enforceable.

vi. Are "early review reports" submitted well in advance of the legal deadline treated differently?

RAC and SEAC do not treat "early review reports" differently from review reports submitted closer to the legal deadline. Review reports submitted early are not a justification for non-fulfilment e.g. of the authorisation conditions, the monitoring arrangements or the committees' recommendations for the review report. The committees should approach early review reports with the same approach as described in points iv. and v. above.

If the authorisation holder submits a review report before a condition enters into effect, it should report this in an unambiguous manner.

[9] The new approach for the conformity check applies also to review reports. The approach is outlined in this note:
https://echa.europa.eu/documents/10162/13579/afa_process_new_approach_for_conformity_check_en.pdf

4. RAC's evaluation

RAC should analyse the risk (Chemical Safety Report) as it does for applications for authorisation from the point of view of the hierarchy of control. For review reports, RAC should also evaluate:

- any changes in operational conditions and risk management measures,
- any reduction or increase of direct and indirect exposure of workers or humans via the environment respectively (e.g. from changes to tonnage, operational conditions or risk management measures) and
- the provision and quality of monitoring data as requested in the RAC opinion or Commission decision.

To a lesser extent, RAC should also analyse any changes to the risks (comparative hazards) of alternative substances/.

5. SEAC's evaluation

SEAC should analyse the situation concerning alternatives and socio-economic elements (Analysis of Alternatives, Socio-economic Analysis, Substitution Plan) as it does for applications for authorisation. For review reports, SEAC should also evaluate:

- any changes in the suitability of alternatives for the authorisation holder and in the EU in general,
- any progress made by the authorisation holder and their downstream users (where applicable) with the identification and implementation of alternatives (different or identical to those identified in the initial application),
- in case substitution has not gone as planned, the authorisation holder's justifications of the reasons,
- any changes in the risks that affect the conclusions of the Socio-economic Analysis,
- any changes in the benefits that affect the conclusions of the Socio-economic Analysis (e.g. due to a change of the non-use scenario, tonnage or other socio-economic aspects).

Specific issues for SEAC's evaluation are outlined in the headings below.

i. Are the review period note (SEAC/20/2013/03) and the CARACAL note for exceptional cases also valid for review reports (CA/101/2017)?

The note 'Setting the review period when RAC and SEAC give opinions on an application for authorisation'[10] was prepared by ECHA in collaboration with the Commission. The CARACAL note 'REACH Authorisation - Criteria for longer review periods'[11] was prepared by the Commission. Both notes are considered valid also for review reports.

[10] https://echa.europa.eu/documents/10162/13580/seac_rac_review_period_authorisation_en.pdf
[11] https://echa.europa.eu/documents/10162/13580/ca_101_2017_criteria_longer_review_period_afa_en.pdf

Authorisation holders may in many cases be expected to need a shorter review period at the review report stage as compared with the initial application (as progress should have been made and obstacles to substitute may have been reduced during the first review period). Nevertheless, there may also be reasons that a similar or longer review period is justified, e.g. if problems have emerged with the alternative or if uncertainties in the initial application that led e.g. to a shorter review period than the one initially requested, have been reduced. Therefore, the recommendation regarding the review period will be given on a **case-by-case basis**, considering the justifications provided and the substitution efforts made.

The second review period is no longer counted from the sunset date, but either from the end of the first review period, from the date of the Commission's decision or from another date specified by the Commission. When the review report is submitted 'at' 18 months before the end of the review period, the situation is similar to an application for authorisation submitted 'at' the latest application date. In this case, the second review period would typically be counted from the end of the first review period.

ii. What should SEAC do if the authorisation holder robustly justifies why substitution activities were delayed during the first review period?

SEAC evaluates the justification and draws a conclusion on whether it is considered robust. The justification constitutes one of the elements for recommending the length of the second review period. The other elements are the criteria outlined in SEAC's review period note and the CARACAL note for exceptional cases.

iii. What should SEAC do if the authorisation holder fails to robustly justify why substitution activities were delayed during the first review period?

When the authorisation holder fails to robustly justify why substitution activities were delayed, its credibility and its commitment to substitution are undermined. The credibility of the substitution activities provided in the review report is also undermined. SEAC could then consider one of the following outcomes:

- Shortening of the requested review period.
- Recommending "no review period", which in effect would mean not granting the authorisation.