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(Agreed at SEAC-62)

SEAC'S RECOMMENDATION ON REVIEW PERIOD

1. Introduction

This note describes how the Committee for Socio-economic Analysis (SEAC) evaluates the review period requested by the applicant(s) in its opinion. The note is based on the previous applications processed by SEAC, and on the discussions held in a SEAC Working Group on the length of the review period, including the views of the European Commission services.

The Commission, after discussion in the REACH Committee, sets the length of the review period for each application for authorisation individually, taking into account the opinion of RAC and SEAC. The REACH Regulation does not request SEAC to recommend a specific review period, but its evaluation of the requested review period is an important aspect for the Commission and the REACH Committee to consider. The duration of the time-limited review of any authorisation shall be determined on a case-by-case basis (Article 60(8)).

For determining the duration, Article 60(8) of REACH provides that the Commission should consider all relevant information as appropriate, including:

a) Risk posed by the use of the substance, including the appropriateness and effectiveness of the risk management measures.
b) Socio-economic impacts (both costs and benefits).
c) The analysis of alternatives or any substitution plan submitted, including possibilities and timelines to substitute based on the information in the application and on any external consultation on alternatives.
d) Available information on risks of alternatives.

The recommendation on the length of the review period by SEAC is based mainly on **technical and scientific aspects** of the application relevant to point (c).

Information on (a) and (d) are in the remit of RAC, and RAC's view on them is available to the Commission in the final RAC and SEAC combined opinion. SEAC does not consider these points in its evaluation or its recommendation on the length of the review period. This is because the conditions recommended by RAC for granting an authorisation aim at ensuring that the risk management measures are appropriate and effective to reduce the risk (point (a)). Point (d) may contribute to SEAC's evaluation e.g. when the applicant is targeting the transition to an alternative that it considers safer even if a longer time is needed for the substitution.

If the application is under the socio-economic route (Art. 60(4) of REACH), the applicant needs to demonstrate that the socio-economic benefits of an authorisation are higher than the risk to human health or to the environment. If this is not demonstrated, an

authorisation cannot be granted.[1] Information on socio-economic impacts (point (b) above) affects the possibilities to substitute (economic feasibility) and contributes in this way to SEAC's evaluation of the length of the review period. SEAC recognises that the review period affects the benefit-cost ratio, but neither the benefit-cost ratio nor the net benefit as such affect SEAC's recommendation for the length of the review period.

SEAC's recommendation is based on how long the substitution process is expected to take. SEAC notes that the end of a review period does not necessarily mean that the substitution process has to be completed by that date. The applicant has the possibility to submit a review report e.g. if the substitution activities are unsuccessful or take longer than expected to complete successfully.

SEAC's evaluation of the overall credibility of the substitution plan should be separate from the evaluation of the review period (focusing on the time needed for the substitution), the latter being only one of the elements considered for the overall credibility.

2. SEAC's approach

The starting point for SEAC's evaluation is the substitution timeline proposed by the applicant (point (c) above) and the corresponding review period requested. SEAC evaluates if the activities are well motivated, and if the time needed for substitution with an alternative substance or technology is justified.

Section 2.1. describes the main elements that SEAC considers when recommending review periods. Section 2.2. describes the default lengths of review periods and how these are used and Section 3. considers special cases (formulation uses and cases following the adequate control route).

2.1. Justification for the substitution timelines

The following elements are considered by SEAC in its scientific evaluation of the proposed substitution timelines. The list is not exhaustive and other aspects may be considered as well. The evaluation does not need to explicitly conclude on each point (fulfilled/not fulfilled), but they should be covered in the opinion when relevant for the overall evaluation of the case and to justify the requested review period. Each applicant needs to properly justify its substitution activities within the requested review period, regardless of whether they have submitted a substitution plan (if there are suitable alternatives available in general) or a research and development plan (in all other cases).

The applicant needs to describe the current state of substitution. It should be clear whether the applicant is planning to substitute the substance in their current products, or if the substitution takes place only after new products are designed and placed on the market.

Elements that may be relevant for individual applications for authorisation include:

- The **coherence and consistency** of the information provided:

  Information provided in different parts of the application, i.e. Analysis of

[1] This is without prejudice to the possibility to grant authorisations under the adequate control route, based on Art. 60(2).

Alternatives (AoA), Substitution Plan (SP) and Socio-economic Analysis (SEA), should be consistent and the sequence of the different phases and activities needs to be logical.

- The **justification for the actions** proposed:

  The sequence of activities should be complemented with concrete milestones to justify the activities and to be clear what needs to be achieved to move to a next phase of the substitution. The applicant should explain and justify which activities are planned to be conducted in parallel or sequentially. A sufficient level of detail needs to be provided on how exactly each phase will be implemented.

  Cooperation in substitution with e.g. scientific institutes, other operators in the supply chain, competitors (industry/sectoral/sub-sectoral cooperation) or suppliers of substances or technologies should be presented clearly, describing the organisation of the work envisaged and the applicant's role and contribution to the work.

- The **timing and duration of the actions** proposed:

  The time allocated to each phase of the substitution should be plausible and well justified. The applicant needs to provide reasonable time frames for each of the phases and activities. Recognising that all applications are evaluated on a case-by-case basis, the applicant may provide a comparison with development times for similar cases, with justification for the need for a shorter or longer review period.

  Information on past substitution efforts (such as already conducted R&D and testing, and resources already used for substitution) should be provided to describe the current state of substitution. The experience gained through such activities may be relevant to strengthen the justification of additional actions needed and the applicant's estimate of their duration.

  The applicant may justify a need for buffer time to account for unexpected events during the substitution process. In these cases, the applicant should clearly explain in the application why they consider there is a substantive possibility that substitution may not proceed as planned (e.g. based on specific challenges inherent in the substance or based on past experience). The time needed to prepare and submit a review report in time (e.g. 18 months) can also be used by the applicant to justify part of the length of the review period. Longer buffer times than 18 months (based on preparing review reports or other uncertainties in the substitution plan) may be accepted in exceptional cases.

  The manufacturing readiness level (MRL) and technology readiness level (TRL) are quantitative measures to assess the maturity of alternatives that may be available for specific industries.[2] They are not on their own sufficient to justify the review period requested but can be used to underpin the actions and time needed. In these cases, the applicant should explain the time needed to move from one phase to another and justify what these expectations are based on.

- **Availability of technically and economically feasible alternatives** in general

[2] For TRL, see BRIDGE2HE Guiding notes to use the TRL self-assessment tool. H2020-101005071 https://horizoneuropencpportal.eu/sites/default/files/2022-12/trl-assessment-tool-guide-final.pdf For MRL, see Manufacturing Readiness Level Deskbook V2.5, May 2020, OSD Manufacturing Technology Program https://www.dodmrl.com/MRL%20Deskbook%20V2020.pdf

(in the EU):

The current state of feasibility of alternatives in general affects the time needed by the applicant to substitute, and it is relevant information for determining an appropriate review period. The fact that an alternative is technically and economically feasible in general (but is not currently feasible for the applicant) does not automatically mean that substitution can be achieved in a short or even a normal time span. However, it indicates a certain level of development of the alternative that needs to be considered if the applicant is targeting it for substitution.

If the applicant does not target and prioritise one of the alternatives available in general in the EU, they should provide convincing and credible arguments as to why another alternative is a better substitution option.

- **Technical feasibility of alternatives** for the applicant:

  The technical feasibility of the alternatives is often the main element used by applicants to justify the review period. The applicant needs to justify the time needed to achieve specific technical requirements (key functionalities and levels of performance) to make any alternative feasible for them (or for their clients). The guidance document on the preparation of an application for authorisation gives details on assessing the technical feasibility.

  Relevant regulatory requirements (e.g. type approvals or recycling levels), certificates and technical standards may affect the technical (and economic) feasibility of alternatives and the time needed to substitute. When regulatory frameworks affect the substitutability, SEAC expects the applicant to provide details of the process to obtain approvals, certify the use or possibilities to amend the standards, including supportive evidence. This could be complemented e.g. by describing past projects affected by the same or a similar regulatory context and clear information demonstrating that the need for approvals is supported by the regulatory authorities.

- **Economic feasibility of alternatives** for the applicant:

  The cost of substitution affects both the feasibility and the time needed by the applicant to substitute with a technically and economically feasible alternative. The guidance document on the preparation of socio-economic analysis as part of an application for authorisation including its Appendix I (calculation of compliance costs) gives details on assessing costs. The concept of economic feasibility is also described in ECHA's questions and answers (see entry 753 in ECHA's Q&As).

  The resources allocated by the applicant to substitute can be used to describe the economic feasibility for the applicant and to justify the review period requested. The financial means of the applicant (e.g. the possibilities to allocate working time and financial resources, including the ability to raise capital to fund substitution investments) may affect whether and when an alternative is economically feasible for them.

  In specific cases, the applicant may need to develop more than one alternative to cover its total portfolio, and this affects the overall economic feasibility of the alternatives. It is possible that, e.g. due to limited financial means or available space in the facility, the applicant can only develop a single alternative to cover all products. In these cases, SEAC expects the applicant to justify the infeasibility of

adopting several alternatives and why it is appropriate to cover the different products under one use and review period.

Even if SEAC takes into account the practical and economic limitations of the applicant (e.g. due to the number of products that are to be covered or the availability of the alternative), they may conclude that the shortest applicable review period is justified for the whole use if the justification is not sufficient for the requested review period. The key principles in defining use descriptions for applications for authorisation are provided in a separate document.

The need for the applicant to take account of their customers' requirements and to obtain their approval of the affected products may indicate economic infeasibility (or technical infeasibility) for the applicant. In these cases, SEAC expects the applicant to provide evidence on the technical requirements requested by its customers (see entry 2013 in ECHA's Q&As). The same applies to contractual requirements and justification that they cannot be amended. The substitution efforts and timelines of the applicant's customer(s) with existing authorisation(s) may also be relevant for the review period; however, this needs to be justified by the applicant.

- **Availability of alternatives**:

  The alternative substances need to be available to the applicant in sufficient quantity. This could be affected e.g. by limitations in the supply of critical raw materials or by legal limitations. In these cases, the applicant should provide supporting evidence for why they consider the alternative is not currently available and how this is expected to evolve during the requested review period.

For applications up the supply chain (upstream applications) and applications covering different products or markets, SEAC will also consider the quality, completeness and representativeness of the assessment and to what extent differences between downstream users, product groups or customer groups are considered.

2.2. Standard lengths for the review periods

SEAC's recommendation on the length of the review period is based on the technical and scientific arguments given in the AoA, SP and SEA of the application for authorisation. However, for practical reasons, it has been useful for SEAC to define defaults for short, normal and long lengths for the review periods (4, 7 and 12 years).

The applicant should request and justify the number of years they consider necessary, regardless of the defaults. However, if the activities and/or timelines presented by the applicant do not justify the review period requested, SEAC will typically[3] use the established default lengths. SEAC will automatically consider if the activities and/or timelines justify the next shortest default review period and if so, that will be its recommendation. It is recognised that the applicant may need to submit a review report to justify the additional time if the substitution cannot be achieved during the shorter default period. A review period longer than 12 years is justified only in exceptional cases.

[3] SEAC reserves the possibility to deviate from this approach if there are specific reasons to do so, but it is expected that in the vast majority of cases, the approach applied will be as described in this document.

The criteria are set out in this CARACAL note.

A **normal review period of 7 years** has often been considered appropriate for the authorisation holders to take benefit from technical progress and to carry out scientific research and development activities in order to find and deploy a technically and economically feasible alternative.[4] The length of a normal review period takes into account that the applicant needs to submit the review report at least 18 months before the end of the review period. Overall, 7 years is considered long enough to allow authorisation holders to continue looking for alternatives but not too long that it might provide a disincentive to finding substitutes.

A **short review period of 4 years** is considered appropriate for cases where the applicant (and when relevant its customers) is already advanced in the process of substitution. It is also considered appropriate when the information in the application is not thorough enough in demonstrating the need of a normal review period, but fully justifies a short review period.

A **long review period of 12 years** has been considered appropriate for cases where finding and implementing an alternative is more challenging, and clearly needs a more substantial effort and time. Uncertainties in substitution timelines do not alone justify a long review period, but the request needs to be substantiated with concrete actions.

SEAC reports in its opinion the recommended end date of the review period, based on the activities in the substitution or research and development plan. If a date is not explicitly mentioned by the applicant, the end date will be calculated as the date of the submission by the application or review report, plus the recommended default review period. This approach is considered appropriate also for review reports (for uses currently authorised) and for uses that are currently covered by other applications (e.g. upstream applications), as the state of the substitution process is only known in the application until the submission of an application or of a review report and the time needed for activities during the requested review period is uncertain. If SEAC does not consider the requested review period justified, the submission date will be used to calculate the end-date based on a lower default review period that is justified by the application.

3. Considerations on formulation and adequate control cases

Formulation cases

The Annex XIV substance has typically no function at the stage of the formulation use, because the function is delivered during the subsequent use of the mixtures (i.e. at the stage of the end-use of the substance). This is applicable also to other ancillary uses, such as purification and repackaging.

The following describes two scenarios and how SEAC approaches them:

[4] See Socio-economic impacts of REACH authorisations - a meta-analysis of the state of play of applications for authorisation (ECHA, 2021).

- **Scenario 1**: the application for authorisation contains the formulation use (Use 1) and the end-use (Use 2).

  Use 1 aims at producing mixtures and Use 2 is the use of these mixtures. Applicants often request the same review periods for both uses. SEAC evaluates Use 2 in terms of the review period needed and typically the same period as for Use 1 is justified.

- **Scenario 2**: the application for authorisation contains only the formulation use (and does not perform any function in this use) and the end-uses are performed outside the EU or applied in other applications.

  According to the use description guidance, no AoA (and consequently no SP) is required for these uses. Applicants have often requested long review periods for formulation uses. SEAC has typically recommended the requested period for such uses without detailed assessment of the end-use from the applicants (if the requirements for granting an authorisation are met), as the actual end-use requires an authorisation of its own with a justification for the requested review period.

Additional scenarios (including a hybrid scenario) may exist, and those will be assessed case-by-case. SEAC opinion should transparently describe all relevant information available and justify its recommendation for the review period. Available information may include e.g. lengths of the review periods recommended for similar uses covered by other applications that may fall under a different scenario.

Adequate control cases (for threshold substances)

SEAC evaluates the requested review period for threshold substances in the same way (described in this document) as for any non-threshold substance, regardless of the outcome of the RAC assessment. This is applicable also for cases that fail to demonstrate adequate control.

If RAC concludes that adequate control is not demonstrated, they recommend conditions that should result in adequate control when implemented. The rationale here is that unlike for non-threshold substances for which there is no safe exposure level, the exposure limit value is known and should be achieved without undue delay. As RAC conditions should ensure adequate control (where these are possible to set), the risk level at the time of submission does not affect the evaluation of the review period by SEAC.

4. Review periods recommended for review reports

The SEAC and RAC note on review reports describes how the Committees evaluate such applications. It outlines issues common to RAC and SEAC, as well as specific considerations related to either Committee. The submitters of review reports are expected to consider this document also when justifying their requests for a new review period.

According to the SEAC and RAC note, authorisation holders may in many cases 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 substitution may have been reduced during the first review period. Nevertheless, it is recognised that 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 the initial application did not justify the review period initially requested.

Therefore, SEAC's recommendation for the review period will be given on a case-by-case basis, considering the justifications provided and the substitution efforts made based on the approach described in this document, as well as expectations set in the review report note.