Helsinki, 24/03/2012

RAC/20/2012/06
SEAC/14/2012/05
agreed RAC-20/SEAC14

TWENTIETH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

06-09 MARCH 2012

FOURTEENTH MEETING OF THE COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS

13-15 MARCH 2012

HELSINKI, FINLAND

Concerns:	**Common approach of RAC and SEAC in opinion development on applications for authorisation**
Agenda Point:	**9.1a (RAC)** **8 a (SEAC)**
Action requested:	**For agreement**

Helsinki, 24/03/2012

PREFACE

The process of opinion development and the content and format of the opinion itself are described in the earlier notes agreed by SEAC and RAC[1]. The approach in this note was presented in the joint RAC and SEAC session "How committees evaluate the Applications for Authorisation" and discussed in breakout groups. The attached note was prepared based on the outcome of this session and the discussion hold in RAC-19 and in SEAC-14 in late 2011.

This note outlines some of the key principles in the development of RAC and SEAC opinions. It has been developed by the ECHA Secretariat in consultation with the relevant Commission services. This note does not cover all aspects of the Committees' work. Rather it concentrates on issues where the line to be taken is not obvious or a common approach is needed for both Committees. Priority is given to general issues that have been raised in the Committees earlier. Once practical experience in evaluating applications is gained, this common approach for both RAC and SEAC is foreseen to be reviewed.

The members and observers in RAC and SEAC are requested to give comments to the main ideas to this note or to identify issues for further consideration. The aim is to develop a finalised version for agreement in the March 2012 meetings of RAC and SEAC.

[1] This note is a follow up of *"The opinions of RAC and SEAC on Applications for Authorisation"* including the format was agreed in June 2011 by SEAC (SEAC/11/2011/05) and by written procedure September by RAC (RAC/15/2011/08 Revised). The note *"The Content of Final Commission Decisions and Their Effect on the Format of the Opinions"* (RAC/11/2010/26 of 12 May 2010 and SEAC/07/2010/12 of 21 May 2010) was discussed in the RAC and SEAC meetings in May and June 2010 as well as the presentations made in RAC 12 and SEAC 8 in September 2010.

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Helsinki, 24/03/2012

Common approach of RAC and SEAC in opinion development on applications for authorisation

1. Purpose

The purpose of this note is to describe the common approach of RAC and SEAC to focus their work so that they can, within the limited time available, develop good quality opinions on applications for authorisation (AfA) that add value to the Commission's decision making.

2. General considerations

Overall the opinions of RAC and SEAC add value by assuring that assessments presented in applications for authorisation are in accordance with appropriate technical and scientific standards. Consistency in the evaluations of RAC and SEAC is pursued by developing common standards on how to carry out the evaluation[2] (guidelines, key principles, shared knowledge base), a capacity building programme, structured feedback and lessons learned on evaluation and organisation of work that supports exchange of information and work practices.

It is the responsibility of the applicant to demonstrate that risks are adequately controlled and/or the benefits (i.e. savings) of continued use of the substance outweigh the remaining risks, taking into account the technical and economic feasibility and risks of alternatives.

RAC and SEAC evaluate and validate the evidence and assessment presented by the applicant in order to develop an independent opinion on the application. This implies that both RAC and SEAC should be reticent and careful in contacting the applicant(s). In principle, contact opportunities foreseen in the Regulation (comment or request for information) should be sufficient to acquire additional information if needed. The draft opinion (or elements thereof) should never be discussed with the applicant. Should the need arise, any contact with the applicant will be coordinated by the ECHA Secretariat.

Furthermore, RAC or SEAC should be reticent to gather additional information or data, other than specified in Article 64(1) and 64(3), and should not redo the applicant's assessments. If members of RAC or SEAC have relevant information, this information should be shared with the Committees and the ECHA Secretariat.

The evaluation entails in particular the following: i) whether methods used are appropriate and applied consistently, ii) conclusions are reached logically, iii) evidence is robust and has the right scope, iv) all relevant issues have been included and there are no omissions that would affect the outcome of the evaluation, v) decisions not to include endpoints are justified, and vi) effort in applicant's assessments is proportionate given the importance of the application. Every application in itself should provide the full information on which assessments and conclusions are based. The evaluation of applications should be done for each application independently.[3]

Whereas the legal text describes the specific tasks for the two different committees in evaluating the application it is obvious that there is an important interface in their

[2] In this note document "assessment" is used in reference to the applicant's work (e.g. hazard assessment, risk assessment, assessment of alternatives), whereas "evaluation" is in reference to the process of validating and opinion making on the applicant's assessments.

[3] This would assure that every applicant has full right to use the data that is presented, Standards should be set independently and care should be taken not to take an abnormally high or low quality application set the standard.

work that necessitates close collaboration during the development of their opinions. The interface between RAC and SEAC pertains to the evaluation of (1) scope, level of detail and robustness of the application and justifications for not considering certain risks; (2) opinions of RAC on RMMs and Operational Conditions (OCs) and resulting remaining risk (3) quantification of risks used as an input to health or environmental impact assessments; (4) opinions on alternatives including their technical and economic feasibility; (5) the overall conclusions.

3. Approach to missing or inadequate information

The applicant has an obligation to bring the application into conformity. Furthermore, in the context of opinion development, SEAC can require the applicant to give information related to alternatives[4]. In some cases the Committees may request the applicant to submit additional information[5]. However, they can continue to evaluate without requesting such information from the applicant. Incomplete or missing information and weak evidence could make RAC and SEAC to advice on more stringent conditions or short review periods when granting the authorisation.

If crucial information on possible alternatives becomes available to the Committees during public consultation, the applicant may be given the possibility to comment this information[6]. RAC and SEAC would then evaluate the relevance of this new information for the application also on basis of the applicant's response.

4. Evaluation of the remaining risk related to human health and the environment

In case of a non-threshold substance the adequate control route is not possible[7]. Hence, even in case a DMEL could be established (or is available) for such a substance it cannot be used to demonstrate adequate control, because the adequate control can only be demonstrated in case it is possible to determine a DNEL (or PNEC in case of the environment) for the relevant endpoint.

Therefore, RAC will not give an opinion whether safe (or acceptable) levels are reached in the case where it was not possible to determine a DNEL or PNEC.[8]

However, also in the case of a non-threshold substance RAC should give an opinion[9] on the appropriateness of proposed OCs and RMMs and whether these are effective attaining the exposure levels in the applicant's exposure assessment and ensure that

[4] Naturally, this might also be the outcome even if the committee had enough information to draw its conclusion.

[5] Technically the applicant would submit the updated application file (as a whole) and map the changes compared to the initial application file. The Committees will take into account only the updates that have been requested (i.e. any other information would be ignored).

[6] According to Article 64(3) *"SEAC may if it deems it necessary **require** the applicant to submit additional information on possible alternative substances or technologies".* In the procedure of RAC and SEAC it has been agreed that RAC can use this possibility too (via SEAC). See step c in the "*RAC and SEAC working procedure for RAC and SEAC for developing opinions on the applications for authorisation*".

[7] Article 60(2) and Annex I art 6.4

[8] In the context of REACH (reference to be specified), the concepts of DNEL and PNEC only indicate levels that can be interpreted as safe.

[9] Article 64(4).

the exposure levels are as low as technically and practically possible[10]. When doing so the applicant needs to have included the effects of Community wide or national legislation in the OCs and RMMs.

There will be applications where the remaining risk (after OCs and RMMs) is described quantitatively/semi-quantitatively based on information on dose-response, or qualitatively if dose-response information is not available. RAC should give an opinion of the appropriateness of the manner in which the remaining risk (after implementation of OCs and RMMs) has been estimated. As information on the remaining risk is an input to the socio-economic analysis, SEAC will use this information when developing its view on the health and environmental impacts (see Section 8) and its subsequent opinion.

5. Relevance of endpoints

For the applicants aiming at authorisation based on Article 60(2) (adequate control route), in order to conclude whether the adequate control is demonstrated, only endpoints (i.e properties of concern) for which the substance is in Annex XIV need to be addressed in the hazard assessment[11]. Furthermore Article 62(4)(d) states that the applicant shall include a CSR covering the intrinsic properties specified in Annex XIV. As a consequence, only these endpoints need to be taken into account in drawing conclusions on whether the adequate control is demonstrated.

The exposure assessment need only to include the uses for which authorisation is applied for. Of course an applicant may have included information relating to other endpoints. While RAC would not need to evaluate these to establish adequate control, this information may be relevant in the context of the assessment of alternatives and comparing them with the Annex XIV substance with regard to the overall risks reduction (see more below).

For the applicants aiming at authorisation based on Article 60(4) (SEA route) Article 62(4)(d) also applies and the SEA route will as a consequence focus on the risks that are related to the intrinsic properties specified in Annex XIV. The SEA should in turn consider the impacts related to such risks. In practice the applicant is expected to provide this information in its (possibly updated) CSR. However, for an authorisation to be granted, the applicant should also demonstrate that there are no suitable alternatives.

In the assessment of alternatives the applicant needs to consider all endpoints[12]. RAC needs to evaluate if alternatives are suitable from risk point of view. In case the authorisation application is based on Article 60(2) and a Substitution plan has to be available, the risks of alternatives may an impact on the review period.

For applicants aiming at authorisation based on Article 60(4), RAC also needs to take into account all endpoints of the alternatives in its opinion as the alternative should reduce the overall risks to be considered suitable. However, the amount of work for RAC's evaluation is expected to be limited. The assessment of risks of alternatives will have a lighter form as the applicant is not expected to go into the same level of detail compared to the Annex XIV substance. RAC should adopt a tiered approach, for

[10] Article 60(10)

[11] Article 60(2) states "…an authorisation shall be granted if the risk to human health or the environment from the use of the substance arising from the **intrinsic properties specified in Annex XIV** is adequately controlled".

[12] Article 62(4)(e) states that "Analysis of alternatives **considering their risks**…" (risks are used in a generic manner).

instance a brief comparison of hazard information can be sufficient to conclude that the overall risk will be reduced in many cases, whilst in some situations more detail may be appropriate.

Some relevant parts of the ECHA Authorisation guidance[13] related to the analysis of alternatives may be considered useful by RAC and SEAC when developing their opinions.

6. Focus of the evaluation of the "Analysis of alternatives"

The evaluation of alternatives in an AfA is prone to many shortcomings for several reasons: (1) it is hard to decide on scope and level of detail; (2) applicants may experience difficulties in gathering and presenting information on alternatives; (3) risk assessment requires judgement of acceptability of risks of different nature. For RAC and SEAC this implies that their evaluation will occasionally have to be made on judgements on incomplete and qualitative information or information that is difficult to evaluate, presented by the applicant. It is recognised that the Committees' possibility to request third parties for information may alleviate the situation.

An analysis of alternatives needs always to be included in an application. Applicants may choose to analyse potential alternatives in different levels of detail. This would be influenced by their preliminary assessment of either technical and economic feasibility or the risk and the approach taken by the applicant.

In practice, the applicant may adopt different lines of reasoning. Depending on this reasoning the focus and level of detail of the evaluation carried out by RAC and SEAC should be adapted in a consistent manner. The main cases are given below:

i) The applicant may have concentrated his analysis on demonstrating whether or not the alternative is technically and/or economically feasible. If SEAC concluded that the alternative is not technically or economically feasible, RAC's evaluation could concentrate rather on the remaining risk (i.e. if appropriate OCs and RMMs are implemented to minimise the risk) if an authorisation for use of the substance was granted. In other words, it would not be necessary for RAC to focus on the assessment of the risks of the alternatives, if SEAC concluded that these alternatives were not technically or economically feasible.

ii) The economic feasibility of the alternatives would be relevant also in the context of the applicant demonstrating that the additional costs of using an alternative (i.e. the benefits of the granted authorisation) would outweigh

[13] See e.g. Section 3.7.1.General considerations on assessing and comparing the risks" which states i.a.
- "The use of a suitable alternative must lead to a reduction in overall risks to human health and the environment compared to the Annex XIV substance. Therefore, in the analysis of alternatives it is essential to compare the potential risks of possible alternatives to the Annex XIV substance for the uses that are being applied for. This should also include the consideration of the appropriateness and effectiveness of risk management measures that control risks."
- "It is therefore important not only to consider the risks that resulted in the requirement for authorisation (based on the substance properties listed in art. 57), but also all other possible risks resulting from the Annex XIV substance and the alternative. The aim is to assess the effects of the transferral to the alternative in reducing the identified risk of the Annex XIV substance while not causing other risks that cannot be controlled."
- "The applicant is not required to generate new hazard data or provide a chemical safety assessment for each of the alternatives. Nor is it required that the risks associated with alternative substances or technologies are assessed in the same detail as the risks associated with the Annex XIV substance."

the (health and environmental) benefits of substitution (i.e. environmental or health impact of the remaining risk).

iii) For RAC the evaluation of the risks of alternatives would also be necessary, if the applicant claimed that the use of technically and economically feasible alternatives would lead to higher overall risks than use of the Annex XIV substance. It is possible – albeit unlikely – that the applicants would base their consideration on such cases.

iv) It might also happen that information on technically and economically feasible alternatives is submitted during the public consultation. The applicant would be expected to comment on this information, in particular if required to do so by SEAC[14]. If the third party had claimed that the alternative is indeed technically and economically feasible SEAC would need to evaluate and balance this against the Applicant's claim. If an alternative would be available, RAC would be expected to evaluate the risks associated to the use of this alternative.

As stated above in their opinion making RAC and SEAC should evaluate whether the approach taken by the applicant is valid and the evidence support the conclusions.
RAC or SEAC should be reticent in gathering additional information or data, other than specified in Article 64(2) and 64(3), and not make their own assessment.

7. Appropriateness and effectiveness of RMMs and OCs

For applicants aiming at authorisation based on Article 60(2) (adequate control route) RAC should evaluate whether, given the use and described OCs and RMMs, adequate control is demonstrated.

For applicants aiming at authorisation based on Article 60(4) (SEA route) the applicant should describe all the OCs and RMMs that lead to the remaining exposure and related (minimised) risk if the authorisation is granted. RAC should evaluate whether these OCs and RMMs are effective to attain this risk level.

Substances for which authorisation is applied for, may be subject to other community wide or national legislation.. Clearly an authorisation under the REACH regulation cannot change the legal requirements. The effects of all such legislation need to be correctly reflected in the OCs and RMMs specified in the application. (see Section 4).

8. From risk assessment to impact assessment and socio-economic analysis

Making a comprehensive socio-economic analysis is a methodologically difficult process which generally suffers from lack of data, in particular on health and environmental impacts, uncertainties in projections of future behaviour of economic actors (produces and consumers) and difficulties in modelling/quantification. Like in risk assessment expert judgement is also needed at various steps. As applicants may use different methods for their appraisal of costs and benefits, RAC and SEAC will occasionally have to evaluate the methodology as well.

In its evaluation of an application RAC should advise SEAC on the accuracy with which a remaining risk and risk of alternatives has been described by the applicant in quantitative and/or qualitative terms. RAC may also evaluate and advise SEAC

[14] Article 64(3).

whether information and methodology used to derive the impacts on human health or the environment from the remaining risk seem appropriate[15]. SEAC can then use this information when giving its opinion whether the overall assessment of cost and benefits is valid. This would enable SEAC to conclude whether the benefits outweigh the risks if the authorisation was granted.

9. Taking into account all discharges, emissions and losses

It is RAC's and SEAC's task to provide opinions on authorisation applications based on their own merits. This will ensure not only consistency among different opinions but also equal treatment of all applications. Thus, in their evaluation RAC and SEAC do not have to consider other discharges, emissions and losses for the same substance.

[15] The applicant may have even used monetary values to aggregate these impacts so that they can be compared with the benefits of the granted authorisation (see section 6).