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RAC/35/2015/08
SEAC/29/2015/06

Guidance Paper on Opinion Trees for Non-Treshold Substances[1] in Applications for Authorisations (AfA)

1. Introduction

The purpose of the opinion tree is to help RAC and SEAC in concluding on authorisation opinions and making recommendations to the Commission in a consistent and efficient manner. The objective of this guidance paper is therefore to explain the reasoning behind the opinion trees:

1) They should help RAC and SEAC in achieving a structured and consistent approach to developing opinions regarding:

a) any recommendation to the Commission advising against granting an authorisation;
b) an appropriate review period;
c) any additional conditions;
d) any monitoring arrangements.

2) They should clarify how SEAC takes up recommendations made by RAC in the opinion-making process.

Some remarks on the current scope of the opinion trees are warranted. They were developed as a priority for AfAs that follow the socio-economic route on a *per use* basis. As such, they are consistent with the common approach paper (RAC/20/2012/06 and SEAC/14/2012/05) and the review period paper (SEAC/20/2013/03). The opinion trees do not address conformity issues, or cases in which RAC and/or SEAC are unable to evaluate the submitted AfA.[2] Lastly, it is stressed that **the Committees may decide to deviate from the opinion tree approach as necessitated by the specific case**.

The paper is structured in the following way. First, the starting point of both the RAC and SEAC opinion trees is outlined. Then, the opinion trees are described in detail. Specific emphasis is given to the sequence of decisions and the terminology used. The third section describes how the two trees are combined into one integrated opinion tree. The integrated opinion-making process and the implied coordination between the committees are then further discussed.

[1] In line with the workload of RAC in dealing with AfA through 2016 and 2017, this paper was developed with non-threshold carcinogens in mind. It is the intention to develop a similar set of opinion trees for threshold substances in the future as the need arises.
[2] RAC and SEAC may conclude that they cannot evaluate an application (e.g. as with HBCDD) because of substantial data gaps, and/or large uncertainties making the applicants assessments unreliable.

2. Starting point and terminology

Both the RAC and SEAC opinion trees start from the assumption that the AfA is in conformity with Art 62 of REACH and can in principle be evaluated by both Committees.[3] The reason for this starting point is purely practical and does not imply that applications cannot later be rejected on grounds of non-compliance with conformity requirements.

The opinion trees rest on two premises:

- Firstly, no review period longer than that requested by the applicant shall be granted;
- Secondly, a review period of 7 years is currently considered "the normal case", implying that a RP longer than 7 years may only be granted, if the criteria outlined in the review period paper (SEAC/20/2013/03) are fulfilled.

It is stressed, however, that the logic of the trees remains intact even if the convention of what constitutes a short (4 yrs), normal (7 yrs), and long review period (12 yrs) would change.

3. RAC opinion tree for evaluating AfAs

The RAC opinion tree starts with the chemical safety assessment (CSA) provided by the applicant. The first question **QR1** asks: Is there substantial uncertainty concerning the exposure assessment and thus, concerning the level of risk? "Substantial uncertainty" here means the actual risk could be substantially different, e.g. orders of magnitude higher than the risk as assessed by the applicant, because there is an important lack of **representativeness** and/or **reliability** of the exposure scenarios related to one or more of the following factors:

- Very poor data quality, i.e., measured data have serious deficiencies in terms of sample size, representativeness, etc.; modelled data is not reproducible, input data is inappropriate, etc.;
- Serious deficiencies in the descriptions of uses/tasks, operating conditions (OCs) and risk management measures (RMMs) (e.g., duration and frequency of exposure, quantities used, temperature, , containment of process, ventilation, organisational measures, PPEs, etc.);
- The CSA is otherwise incomplete, inconclusive or is performed with methodologies, which lead to erroneous numbers that cannot be easily corrected, or data that cannot be readily broken down for analysis.

If the answer to **QR1** is positive, meaning there is substantial uncertainty about the exposure assessment and thus the actual risk, the next question **QR2** asks whether the risks related to humans and the environment are potentially high.

If the answer to **QR2** is positive, RAC raises **uncertainty concerns** with SEAC which imply a short review period **[→R1]**. RAC may recommend (additional) monitoring/measurement of the exposures (see Section 6 below).

[3] Whether the application can in fact be evaluated, depends on many factors, and may only emerge much later on when key issues such as the representativeness of the exposure scenarios are assessed, i.e. well past the conformity check.

If the answer to **QR2** is negative, meaning that there does not seem to be a potential for high exposure – and in order to reduce uncertainties in the exposure assessment – RAC recommends monitoring arrangements/campaigns and review of RMM's that must be set up during the review period and documented in the review report (monitor, review, imporove) [**→R2]**.

If the answer to **QR1** is negative, meaning the level of risk is fairly well-known (it could still be high), the next question **QR3** asks whether there are concerns relating to the appropriateness and effectiveness of the controls in place; i.e., do the RMMs follow the 'hierarchy of control' and maintain the exposure as low as reasonably possible, and is the exposure monitored frequently and adequately? If the answer to **QR3** is negative, RAC has no recommendations (but may still want to add in the opinion a statement voicing its concern about the 'high' level of risk) **[→R3]**.

If the answer to **QR3** is positive, the next question **QR4** asks whether RAC is able to make recommendations with regard to: i) the OCs, ii) the RMMs, or iii) the monitoring activities in place.[4] If the answer to **QR4** is negative, RAC raises **risk-control concerns** that imply a shortening of the review period (in common cases from 12 to 7 years or from 7 to 4 years) **[→R4]**.[5]

If the answer to question **QR4** is positive, RAC recommends additional conditions and appropriate monitoring arrangements either with immediate effect or for the review report, depending on the degree of concern **[→R5]**.

4. SEAC opinion tree for evaluating AfAs

The SEAC opinion tree starts from the information on alternative(s) provided by the applicant and the comments received during the public consultation. The first question **QS1** asks whether or not there are suitable alternatives. If the applicant fails to demonstrate that: i) no alternatives are available, ii) potential alternatives are either technically or economically infeasible (cf. SEAC/18/2013/03), or iii) potential alternatives are of equal or higher risk than the substance applied for, then **no authorisation shall be granted [→S1]**.

The second question asks whether monetised impacts on human health – arising from direct exposure at the workplace or from using a product that contains the Annex XIV substance and from indirect exposure via the environment – and/or the environment (i.e., the social costs of granting the authorisation, in the following denoted by *C*), are likely to be larger than the assessed benefits to both the applicant and society of granting the authorisation (in the following denoted by *B*). SEAC answers this question based on RACs assessment of the risks pertaining to the use and non-use scenarios.

If the answer to **QS2** is positive, meaning that the social costs are possibly larger than the benefit of granting the authorisation (i.e., $B/C < 1$), the application has failed the benefit-cost test and **no authorisation shall be granted [→S2]**. This can happen if the applicants' assessment of either the social costs or the benefits is exaggerated or based on erroneous assumptions.

If the answer to **QS2** is negative, implying that the *B*/*C* ratio is larger than unity for the benefits and costs of authorised use as provided by the applicant and reviewed by SEAC,

[4] In practice, RAC is not always in a position to recommend workplace-specific RMMs/equipment. Instead, RAC may recommend monitoring campaigns in order for the applicant to review and improve their RMMs.
[5] In situations where the requested review period is 4 years, SEAC will have to set the exact length of the review period on a case-by-case basis.

the next question **QS3** asks whether there is substantial uncertainty pertaining to either the impact assessment or the analysis of alternatives. "Substantial uncertainty" here means the applicant fails to conclusively demonstrate that the benefits of granting the authorisation outweigh the risks of continued use (in term of negative impacts on human health and/or the environment).[6] The following is a non-exhaustive list of factors that may be the cause of substantial uncertainty:

- Deficiencies in the assessment of the cost the applicant and/or their downstream users would have to bear in the non-use scenario (e.g., large overstatement of the cost of relocation/shut down);
- Deficiencies in the assessment of the cost the applicant and/or their downstream users would have to bear in the non-use scenario (e.g., large overstatement of the cost of substitution);[7]
- Deficiencies in the assessment of impacts on the wider economy (e.g., large overstatement of social cost of unemployment or consumer surplus losses).
- Deficiencies in the assessment of impacts on human health and the environment;
- Deficiencies in the assessment ofthe number of people at risk, including workers and the general population (e.g., impacts to man via the environment and via the use of a product);
- Deficiencies in the monetisation of identified health and environmental impacts (e.g., understating the social costs of granting the authorisation).

If the answer to **QS3** is positive, SEAC recommends a short RP **[→S3]**.

If the answer to **QS3** is negative, the next question **QS4** asks whether any of the following criteria for a long review period (cf. SEAC/20/2013/03) are met:

- The investment cycle of the applicant is demonstrably long (meaning >7 yrs);
- Costs of alternatives are very high and unlikely to change over the review period;
- It is unlikely that alternatives become available within a normal review period;
- Possible alternatives require legislative measures that demonstrably need time;
- Remaining risks are demonstrably low and socio-economic benefits are high.

If none of these criteria is convincingly met, SEAC recommends a normal review period **[→S4]**. If these criteria are convincingly met, SEAC may recommend a long review period **[→S5]**.

5. Integrated opinion tree for evaluating AfAs

The integrated opinion tree combines the logic of the RAC and SEAC trees to facilitate a structured and balanced opinion-making process. In particular, it defines how concerns raised by RAC are taken into account by SEAC in the setting of the review period.

[6] SEAC needs to be convinced that the application would in all likelihood pass the B/C test.
[7] This includes a lack of effort to demonstrate: 1) that no suitable alternatives will become available within the normal RP, and 2) why technically feasible alternatives are deemed economically infeasible. This criterion alone can also be used by SEAC to recommend a shortening of the requested RP: either because of the AoA fails to demonstrate that technically/economically feasible alternatives are unlikely to become available within the requested RP, or because of information received in the public consultation, which contradicts the applicant's conclusions.

If RAC does not raise a concern, the logic of the SEAC opinion tree applies. Otherwise, the integrated tree will still start with questions **QS1-QS3** analysing whether there are economic or other analytical reasons not to grant the requested review period **[→S1, S2, S3]**.

Even if the benefits of the Commission granting the application appear to robustly outweigh the risks (and thus the answers to **QS1-QS3** are negative), there might be substantial uncertainty pertaining to the level of risk under evaluation. The integrated opinion tree takes this concern into account by checking whether RAC raised **uncertainty concerns** (i.e., whether the answer to question **QR2** is positive). If so, a short review period is recommended **[→R1]**.

If the answer to **QR2** is negative, the integrated opinion tree moves on to check whether any of the criteria for a long review period are met. If the answer to **QS4** is positive but RAC raises **risk-control concerns** (i.e., the answer to **QR4** is negative), then the review period is shortened from 12 to 7 years **[→R4]**.[8] Else, SEAC recommends a long review period **[→S5]**. In this case, additional conditions and monitoring arrangements may or may not apply **[→R5]**.

If the answer to **QS4** is negative and RAC raises **risk-control concerns** (i.e., the answer to **QR4** is negative), then the review period is shortened from 7 to 4 years **[→R4]**. Else, SEAC recommends a normal review period **[→S4]**. In this case, additional conditions and monitoring arrangements may or may not apply **[→R5]**.

The logic of the integrated opinion tree can be summarised as follows. There are positive criteria that may qualify an application for a long review period and negative criteria that may limit the review period to a maximum of 4 years or shorter. If none of these criteria applies, a normal review period of 7 years is recommended. In the spirit of the AfA process, the applicant has the obligation to provide solid evidence in support of the requested review period. All scenarios are summarised in Table 1.

6. Types of recommendations

Both committees may incorporate recommendations and conditions into their opinions. RAC may make recommendations to the Commission including the following:

- Not granting the application due to specific and overriding concerns regarding the safety of workers (e.g. high risk and large uncertainty);
- Operational conditions (OC) and/or risk management measures (RMM);
- Monitoring arrangements.

With regard to operational conditions and risk management measures, such recommendations will nearly always be phrased as binding conditions, which the Commission can directly apply in granting the authorisation. On the other hand, and depending on the degree of urgency, monitoring arrangements (usually in the form of '*monitor, review, improve*' statements) can be phrased as binding conditions for the Commission to apply in granting the authorisation. However, in cases of less urgency (i.e. when risks and uncertainties are limited, but monitoring data has been sparse),

[8] There could be cases where the applicant asks for 7 years, but would actually meet the long-review period criteria. RAC might still have concerns related to the risk control measures in place. In order to respect the applicant's intention to substitute within 7 years, SEAC would consider that the long-RP criteria are met in that case. In concrete terms this means that the RP would not be shortened in such a case.

monitoring arrangements can also be recommended by RAC. These are not intended as binding conditions, but to provide advice as to what RAC expects to see in any review application in the future. This stems from ECHA's and RAC's concern to improve the quality of the data submitted by applicants and the overall quality and ease of evaluation of the applications in order to increase the overall efficiency of the process.

SEAC may also make specific recommendations to the Commission including the following:

- Not granting the application due to the availability of suitable alternatives;
- Outphasing of specific substance uses;
- Reporting of substitution-related efforts.

Again, such recommendations will nearly always be phrased as binding conditions, which the Commission can directly apply in granting the authorisation.

Table 1: Summary of all possible scenarios.

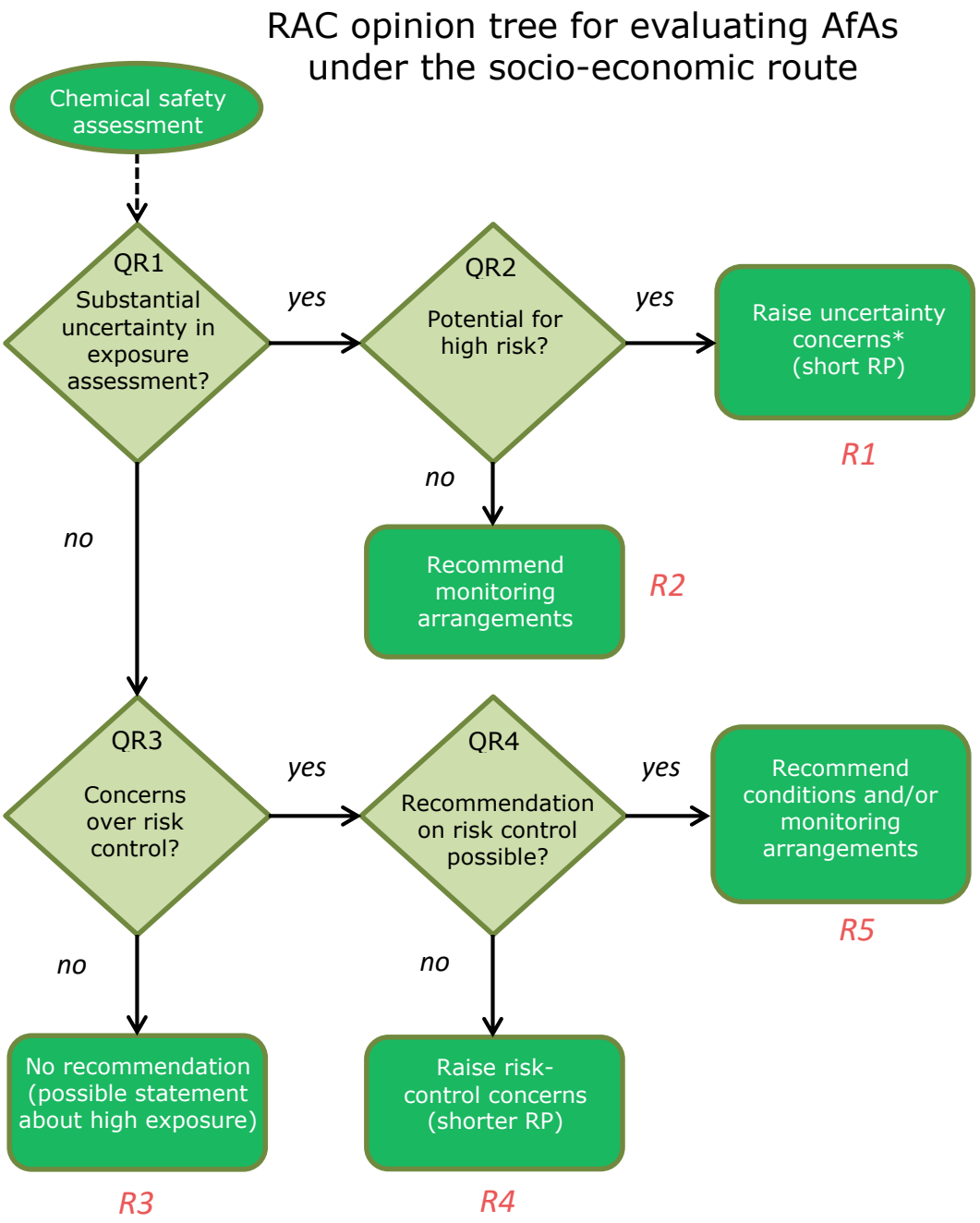
	R1	**R2**	**R3**	**R4**	**R5**
S1	No authorisation	No authorisation	No authorisation	No authorisation	No authorisation
S2	No authorisation	No authorisation	No authorisation	No authorisation	No authorisation
S3	Short RP*	Short RP*	Short RP	Short RP	Short RP*
S4	Short RP*	Normal RP*	Normal RP	Short RP	Normal RP*
S5	Short RP*	Long RP*	Long RP	Normal RP	Long RP*

*Additional Conditions/monitoring arrangements may be set up

Figure 1

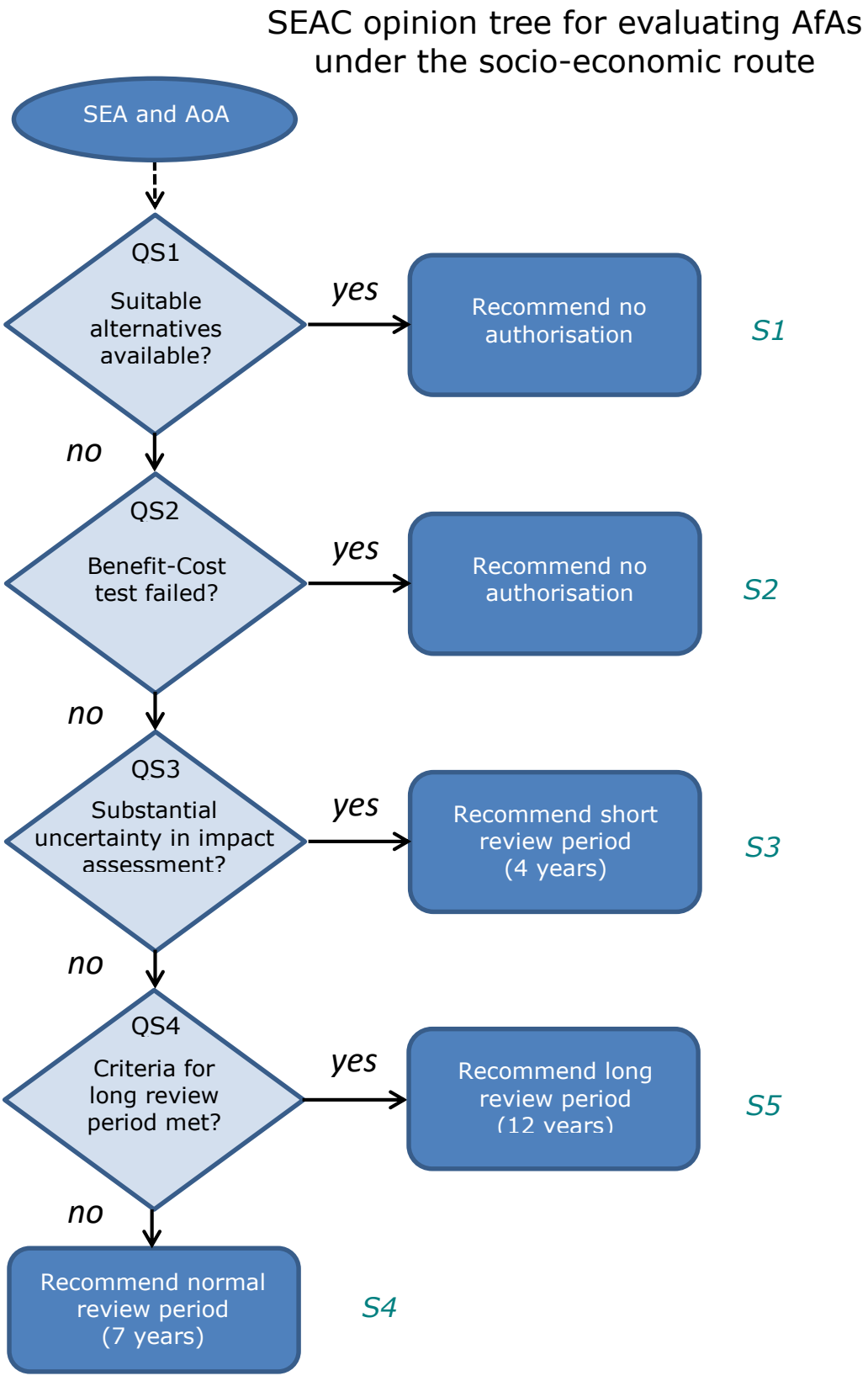

Integrated opinion tree for evaluating AfAs under the socio-economic route
SEA and AoA
Suitable alternatives available?
yes
Recommend no authorisation
S1
no
Benefit-Cost test failed?
yes
Recommend no authorisation
S2
no
Substantial uncertainty in impact assessment?
yes
Recommend short review period (4 years)
S3
no
Uncertainty concerns raised?
yes
Recommend short review period (4 years)
R1
no
Criteria for long review period met?
yes
Risk-control concerns raised?
yes
Recommend normal review period (7 years)
R4
no
Recommend long review period (12 years)
S5/R5
no
Risk-control concerns raised?
yes
Recommend short review period (4 years)
R4
no
Recommend normal review period (7 years)
S4/R5

Figure 2



* In special cases RAC may also recommend (additional) monitoring/measurement of the exposures, with or without immediate effect, which are to be documented in the review report.

Figure 3


SEAC opinion tree for evaluating AfAs under the socio-economic route
SEA and AoA
QS1
Suitable alternatives available?
yes
Recommend no authorisation
S1
no
QS2
Benefit-Cost test failed?
yes
Recommend no authorisation
S2
no
QS3
Substantial uncertainty in impact assessment?
yes
Recommend short review period (4 years)
S3
no
QS4
Criteria for long review period met?
yes
Recommend long review period (12 years)
S5
no
Recommend normal review period (7 years)
S4