Version 4.0

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

[Draft] Opinion

on [an Application for Authorisation] [a Review Report] for

sid_substance_name_internal__1 use: use_title__1

Submitting [applicant] [authorisation holder]

cnt_role_co_submitter__1

ECHA/RAC/SEAC: [Opinion N°]

Consolidated version

Date: [date of adoption/agreement in RAC and/or SEAC]

Format Version	Changes
4.0	Changes in the RAC and SEAC opinions and conclusions and technical adaptations and editorial changes in the justifications. These include: - Update of the conclusions of SEAC based on the request of the European Commission on 30 November 2020 - Restructuring the process-related tables in the beginning of the document - Section for the evaluation of the availability of alternatives in general in the EU identified - Systematically first summarising the applicant's/authorisation holder's analysis and then providing the evaluation by SEAC (section 5 of the justifications) - Update of the summary tables on impacts of authorisation (section 5) - Socio-economic benefits of continued use are referred to as societal costs of non-use for consistency with the updated SEAC conclusions. - The opinion options of RAC have been restructured and edited, mainly to reflect current practice. - The concluding statement regarding exposure and risk estimates for cases based on socio-economic assessment has been simplified. - Tables for comparing exposure and release levels between initial applications and review reports have been added in the justification to the opinions. - The reference to OELs has been moved from the opinion to section 3.4 of the justification to the opinions.
3.1	Update of the SEAC opinion texts, update of the Summary of RAC and SEAC conclusions, update of Table 14 in the justifications section.
3.0	Changes made to the opinion text and the format to increase the clarity of the opinion text and justifications, taking into consideration the conclusions from the General Court's judgments in Cases T-837/16 and T-108/17.
2.0	Major adaptations based on experience and feedback received. The format includes now a summary as well as the conclusions of the opinions to facilitate decision-making. The justifications to the opinions include standardised tables to facilitate reading.

1.0	First version

Consolidated version of the
Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis
on [an Application for Authorisation] [a Review Report]

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to the following [application for authorisation] [review report]:

[Applicant] [Authorisation holder][1]	**cnt_role_co_submitter__2**
Role of the [applicant] [authorisation holder] in the supply chain **{more than one can be selected}**	Upstream ☐[group of] manufacturer[s] ☐[group of] importer[s] ☐[group of] only representative[s] ☐[group of] formulator[s] Downstream ☐[group of] downstream user[s]
Use performed by	☐[Applicant] [Authorisation holder] ☐Downstream user(s) of the [applicant] [authorisation holder]
Substance ID EC No CAS No	**sid_substance_name_internal__2** sid_ec_number sid_cas_number
Intrinsic properties referred to in Annex XIV	☐Carcinogenic (Article 57(a)) ☐Mutagenic (Article 57(b)) ☐Toxic to reproduction (Article 57(c)) ☐Persistent, bioaccumulative and toxic (Article 57(d)) ☐Very persistent and very bioaccumulative (Article 57(e)) ☐Other properties in accordance with Article 57(f) – [endocrine disrupting properties for the environment] [and] [endocrine disrupting properties for human health] [and] [{specify}]

[1] Singular form of 'applicant' or 'authorisation holder' is used in this document also to cover multiple applicants or authorisation holders.

Use title	**use_title__2**
	Other connected uses:
	Similar uses applied for:
[Indicative] number and location of sites covered	
Annual tonnage of the Annex XIV substance used [per site] [total for all sites]	
Function(s) of the Annex XIV substance	
Type of products (e.g. articles or mixtures) made with the Annex XIV substance and their market sectors	
Annex XIV substance present in concentrations above 0.1% in the products (e.g. articles) made	☐Yes ☐No ☐Unclear ☐Not relevant
Review period requested by the [applicant] [authorisation holder] (length)	
Use ID (ECHA website)	prc_consult_no
Reference number	cse_ref_no

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the [application] [review report]	sbm_first_submission
Date of payment, in accordance with Article 8 of Fee Regulation (EC) No 340/2008	dte_payment
[Was the application submitted by the Latest Application Date for the substance and can the applicant [and their downstream users] consequently benefit from the transitional arrangements described in Article 58(1)(c)(ii)?] *{choose this text for an application}* [Was the review report submitted at least 18 months before the expiry of the time-limited review period?] *{choose this text for a review report}*	☐Yes ☐No
Date of consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	dte_public_consult_start – dte_public_consult_deadline
Were comments received in the consultation?	☐Yes ☐No [Link:]
Request for additional information in accordance with Article 64(3)	On [date] [and] [date] [Link:]
Trialogue meeting	[date] / [Not held – reason, e.g. no new information submitted in consultation, no need for additional information/discussion on any technical or scientific issues related to the [application] [review report] from the rapporteurs]
Was the time limit set in Article 64(1) for the sending of the draft opinions to the [applicant] [authorisation holder] extended?	☐Yes, by [date] Reason: [e.g. due to the need to ensure the efficient use of resources, and to synchronise the consultation with the plenary meetings of the Committees] ☐No
Did the [application] [review report] include all the necessary information specified in	☐Yes

Article 62 that is relevant to the Committees' remit?	☐No [Comment:]
Date of agreement of the draft opinion in accordance with Article 64(4)(a) and (b)	RAC: [date], agreed by [consensus] [a simple majority]
	SEAC: [date], agreed by [consensus] [a simple majority]
Date of sending of the draft opinions to the [applicant] [authorisation holder]	[date]
Date of decision of the [applicant] [authorisation holder] [not] to comment on the draft opinions, in accordance with Article 64(5)	[date]
Date of receipt of comments in accordance with Article 64(5)	[date] [Not relevant]
Date of adoption of the opinion in accordance with Article 64(5)	RAC: [date], adopted by [consensus] [a simple majority]
	SEAC: [date], adopted by [consensus] [a simple majority]
Minority positions	RAC: [No minority positions] [Links to the published minority positions]
	SEAC: [No minority positions] [Links to the published minority positions]
RAC Rapporteur RAC Co-rapporteur	cnt_role_rapporteur_rac_lame cnt_role_rapporteur_rac_fname cnt_role_co_rapporteur_rac_lame cnt_role_co_rapporteur_rac_fname
SEAC Rapporteur SEAC Co-rapporteur	cnt_role_rapporteur_seac_lame cnt_role_rapporteur_seac_fname cnt_role_co_rapporteur_seacc_lame cnt_role_co_rapporteur_seac_fname
ECHA Secretariat	act_title_case_responsible act_title_case_backup act_title_case_assistant

LIST OF ACRONYMS

{The most common acronyms are included in this list. Please avoid use of acronyms and consider writing in full. Additional acronyms can be added when necessary.}

AfA	Application for authorisation
AoA	Analysis of alternatives
bw	Body weight
CBA	Cost-benefit analysis
C-E	Cost-effectiveness
CSR	Chemical safety report
DNEL	Derived no-effect level
ES	Exposure scenario
ECS	Environmental contributing scenario
LAD	Latest application date
LEV	Local exhaust ventilation
OC	Operational condition
PBT	Persistent, bioaccumulative and toxic
PNEC	Predicted no-effect concentration
PPE	Personal protective equipment
RAC	Committee for Risk Assessment
REACH	European Union regulation on registration, evaluation, authorisation and restriction of chemicals
RMM	Risk management measure
RP	Review period
RR	Review report
SDS	Safety data sheet
SEA	Socio-economic analysis
SEAC	Committee for Socio-economic Analysis
SP	Substitution plan
SSD	Sunset date
vPvB	Very persistent and very bioaccumulative
WCS	Worker contributing scenario

This document provides the opinions of the Committees for Risk Assessment and for Socio-economic Analysis based on their scientific assessment of the [application for authorisation] [review report]. It thus provides scientific input to the European Commission's broader overall balancing of interests.

{**1. Cases based on adequate control**

Legal relevance: According to Art. 60(2) an authorisation of a threshold substance shall be granted if the risks are adequately controlled}

THE OPINION OF RAC

RAC has formulated its opinion on:

- the risks arising from the use applied for,
- the appropriateness and effectiveness of the operational conditions and risk management measures described,
- [the assessment of the risks related to the alternatives as documented in the [application] [review report], [taking into account the information submitted by interested third parties,]] as well as
- other available information.

RAC concluded that it was possible to determine [a] [DNEL(s)] [and] [PNEC(s)] for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

{Alternatives: Select one section from below. The first section is to be used where technically or economically feasible alternatives do not exist. The second is relevant if SEAC concluded that there are technically and/or economically feasible alternatives for the applicant/authorisation holder.}

{No technical or economic feasibility of alternatives}

SEAC concluded that there are no technically and/or economically feasible alternatives available for the [applicant] [authorisation holder] [or their downstream users] with the same function and similar level of performance by [the Sunset Date[2]] [the expiry date of the authorisation decision[3]] [other date[4]]. Therefore, RAC did not evaluate the potential risk of alternatives.

{Risks of alternatives assessed}

SEAC concluded that there are technically and economically feasible alternatives available for the [applicant] [authorisation holder] [or their downstream users] with the same function and similar level of performance by [the Sunset Date[5]] [the expiry date of the authorisation decision[6]] [other date[7]]. Therefore, RAC evaluated the potential risk of alternatives. RAC concluded that alternative(s) presented by the [applicant] [authorisation holder], [taking into consideration the input of the third parties submitted in the consultation], if implemented, would [not] reduce the overall risks.

{The RAC conclusions can be categorised in three options. Deviating from the typical situation

[2] {For applications for authorisation submitted before the latest application date.}
[3] {For review reports.}
[4] {For 'late' applications for authorisation i.e. submitted after the Sunset Date.}
[5] {For applications for authorisation submitted before the latest application date.}
[6] {For review reports.}
[7] {For 'late' applications for authorisation i.e. submitted after the Sunset Date.}

described in each option is possible, see section 7, 8 and 9 of the justification to the opinion.

Option 1: No concerns, typically no additional conditions, monitoring arrangements, nor recommendations for the review report.

Option 2: Minor concerns, typically no additional conditions, nor monitoring arrangements. Typically, only recommendations are made for the review report to allow RAC to evaluate a possible review report efficiently. In case of a review report, there may be more reason to propose monitoring arrangements for the authorisation compared to initial applications.

Option 3: Moderate concerns but adequate control demonstrated. Typically monitoring arrangements are proposed for the authorisation and recommendations are made for the review report.

Since adequate control has been demonstrated, usually no additional conditions for the authorisation are proposed for the authorisation (however, the option is available for selection).}

{Select the relevant option(s) from below.}

RAC concluded that the risk assessment presented in the [application] [review report] demonstrates [that] adequate control of risks from the use applied for [can be achieved], provided that the operational conditions and risk management measures described in the [application] [review report] are [implemented and] adhered to. {the words 'that', 'can be achieved' and 'implemented and' are selected for future situations}

[The proposed additional authorisation conditions are expected to further reduce [exposure] / [predicted environmental concentration].]

[The proposed monitoring arrangements for the authorisation are expected to provide reliable further information on the effectiveness of operational conditions and risk management measures [implemented as a result of additional conditions] and on the [associated] trends in [exposure] [and] [releases] during the review period. This information should also be included in a possible review report.]

[The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently.]

THE OPINION OF SEAC

SEAC has formulated its opinion on the socio-economic factors and the suitability and availability of alternatives associated with the use of the substance taking into account the information in the [application] [review report], [information submitted by interested third parties,] as well as other available information. SEAC's evaluation is based on relevant guidance, which comprises Commission's Better Regulation guidance, the Guidance documents on applications for authorisation and the socio-economic analysis as well as specific guidance related to how SEAC evaluates the applications (e.g. dose response functions, values of health endpoints).

SEAC took note of RAC's conclusion that it is possible to determine [a] [DNEL(s)] [and] [PNEC(s)] for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC took note of RAC's conclusion that the risk(s) to [human health] [and] [the environment] from the use of the substance [is] [are] demonstrated to be adequately controlled]/[can be adequately controlled]. {the latter would be used if the application/review report concerns a

use in the future}

{SEAC conclusions on the AoA}

SEAC has assessed the availability, and technical and economic feasibility of alternatives for the [applicant] [authorisation holder] [or their downstream users] and in the EU. These are described in section 4. The [applicant] [authorisation holder] short-listed the following alternatives: {include a list}

SEAC concluded on the analysis of alternatives and the substitution plan that:

- The [applicant] [authorisation holder] has [not] demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the [applicant] [authorisation holder] [or their downstream users] by [the Sunset Date[8]] [the expiry date of the authorisation decision[9]] [other date[10]].
- There is [no] information available [in the application for authorisation] [in the review report] [and/or] [in the comments submitted by interested third parties in the consultation] indicating that there are [no] alternatives available that are technically and economically feasible in the EU. {If there is information that alternatives are available} [However, RAC is unable to conclude on whether these alternatives are safer.] {If there is no information no additions needed}
- The [applicant] [authorisation holder] [submitted] [did not submit] a substitution plan. {If substitution plan was submitted} [The substitution plan is [not] credible [for the review period requested] and [not] consistent with the analysis of alternatives and the socio-economic analysis.] {If no substitution plan was submitted} [The [applicant's] [authorisation holder's] justifications for not submitting a substitution plan are reported in section 4.] [No justifications for that were provided].

{For uses covering only formulation activity without assessment of alternatives, no list or AoA conclusions are needed but add:} [The assessment of alternatives is not relevant for this use as the substance does not provide any specific function at the formulation stage.]

{SEAC conclusions on the SEA}

SEAC has assessed the information provided by the [applicant] [authorisation holder] and third parties from a scientific perspective, using standard methodology, and following relevant guidance. Based on the elements listed below, SEAC concludes that the [applicant] [authorisation holder] has demonstrated that the societal costs of not granting an authorisation are higher than the risks to [human health] [and] [the environment] resulting from the granting of an authorisation.

The expected societal costs of not granting an authorisation are estimated to be [at least] [approximately] €[x] [per year] [over x years] consisting of {report here the relevant titles from Table 14 of the justifications}. [Additional [important] societal impacts of not granting an authorisation have been assessed [quantitatively or qualitatively] but have not been monetised] and consist of {report here the relevant titles from Table 14 of the justifications}].

RAC concludes that the risks are adequately controlled, so there are no negative [human health] [and] [environmental] impacts from the intrinsic properties for which the substance is listed in Annex XIV of REACH.

[8] {For AfAs submitted before the LAD.}
[9] {For review reports.}
[10] {For 'late' AfAs i.e. submitted after the Sunset Date.}

[Risks to [human health] [and] [the environment] of alternatives have not been assessed.]

{SEAC conclusion on uncertainties covering both AoA and SEA}

{If only negligible uncertainties exist} SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

{If non-negligible uncertainties exist} SEAC acknowledges that there are remaining non-negligible uncertainties in the available information that may affect its conclusions.

PROPOSED CONDITIONS, MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

{Select the relevant option(s) from below:}

[No additional conditions for the authorisation are proposed.]

[No monitoring arrangements for the authorisation are proposed.]

[No recommendations for the review report are made.]

[Additional conditions for the authorisation are proposed. These are listed in section 7 of the justification to this opinion.]

[Monitoring arrangements for the authorisation are proposed. These are listed in section 8 of the justifications to this opinion.]

[Recommendations for the review report are made. These are listed in section 9 of the justifications to this opinion.]

REVIEW PERIOD

Taking into account the information provided in the [application for authorisation] [review report] submitted by the [applicant] [authorisation holder] and any comments received in the consultation, [a [**x**]**-year**] [**no**] review period is recommended for this use[, i.e. until [the end] [month] of [20xx]].

{**2. Cases based on socio-economic assessment:**

1) **Non-threshold substance, where benefits and risks as well as technical and economic feasibility and when relevant safety of alternatives are assessed; a substitution plan may have been provided.**
2) **Threshold substances without adequate control if socio-economic information is included.**

Legal relevance: According to Art. 60(4) an authorisation of a non-threshold substance may only be granted by the Commission if the socio-economic benefits outweigh the risk to human health or the environment and no suitable alternative substances or techniques are available. This is also the case for threshold substances without adequate control if the socio-economic benefits outweigh the risk to human health or the environment and no suitable alternative substances or techniques are available.}

THE OPINION OF RAC

RAC has formulated its opinion on:

- the risks arising from the use applied for,
- the appropriateness and effectiveness of the operational conditions and risk management measures described,
- [the assessment of the [hazards and] [risks] related to the alternatives as documented in the [application] [review report] [taking into account the information submitted by interested third parties], as well as
- other available information.

{Select one section from below. The first section is for non-threshold substances apart from substances with endocrine disrupting properties. The second and third options are for substances with endocrine disrupting properties. The fourth is for PBT/vPvBs. The fifth option is for threshold substances where adequate control has not been demonstrated but where socio-economic analysis has been provided.}

{1. Non-threshold case: "normal"}

[RAC concluded that it was not possible to determine [DNEL(s)] [PNEC(s)] for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.]

{2. Non-threshold case: Endocrine disruptors – applicant has not derived a threshold}

[In this [application] [review report], the [applicant] [authorisation holder] did not derive [DNEL(s)] [PNEC(s)]. Therefore, in accordance with Annex I of the REACH Regulation, RAC concluded that for the purposes of the assessment of this [application] [review report] it was not possible to determine [DNEL(s)] [PNEC(s)] for the endocrine disrupting properties] of the substance [for human health] [and] [for the environment].]

{3. Non-threshold case: Endocrine disruptors – applicant has derived a threshold}

[In this [application] [review report], the [applicant] [authorisation holder] derived [a] [DNEL(s)] [and] [PNEC(s)]. However, RAC concluded that the [applicant] [authorisation holder] has not demonstrated a threshold level for the endocrine disrupting properties of the substance [for human health] [and] [for the environment]. Therefore, in accordance with Annex I of the REACH Regulation, RAC concluded that for the purposes of the assessment of this [application] [review report] it was not possible to determine [DNEL(s)] [PNEC(s)] for the

endocrine disrupting properties of the substance [for the environment] [and] [for human health].]

{4. Non-threshold case: PBT/vPvB}

[In accordance with Annex I of the REACH Regulation, RAC concluded that for the purposes of the assessment of this [application] [review report] it was not possible to determine [DNEL(s)] [PNEC(s)] for the [PBT-] [and] [vPvB-] properties] of the substance.]

{5. Threshold case: no adequate control}

RAC concluded that it was possible to determine [a] [DNEL(s)] [and] [PNEC(s)] for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

RAC concluded that the risk assessment presented in the [application] [review report] does not demonstrate adequate control of risks from the use(s) applied for.

{Alternatives: Select one section from below. The first section is to be used where technically or economically feasible alternatives do not exist. The second is relevant if SEAC concluded that there are technically and/or economically feasible alternatives for the applicant/authorisation holder.}

{No technical or economic feasibility of alternatives}

SEAC concluded that there are no technically and/or economically feasible alternatives available for the [applicant] [authorisation holder] [or their downstream users] with the same function and similar level of performance by [the Sunset Date[11]] [the expiry date of the authorisation decision[12]] [other date[13]]. Therefore, RAC did not evaluate the potential risk of alternatives.]

{Risks of alternatives assessed}

SEAC concluded that there are technically and economically feasible alternatives available for the [applicant] [authorisation holder] [or their downstream users] with the same function and similar level of performance by [the Sunset Date[14]] [the expiry date of the authorisation decision[15]] [other date[16]]. Therefore, RAC evaluated the potential risk of alternatives.

RAC concluded that alternative(s) presented by the [applicant] [authorisation holder], [taking into consideration the input of the third parties submitted in the consultation], if implemented, would [not] reduce the overall risks.

{The RAC conclusions can be categorised in five options. Deviating from the typical situation described in each option is possible, see section 7, 8 and 9 of the justification to the opinion.}

Option 1 (non-threshold cases only): No concerns regarding the OCs and RMMs (OCs and RMMs are appropriate and effective in limiting the risk), typically no additional conditions monitoring arrangements, nor recommendations for the review report.

Option 2 (non-threshold cases only): Minor concerns regarding the OCs and RMMs (OCs and RMMs are appropriate and effective in limiting the risk), typically no additional conditions, nor monitoring arrangements. Typically, only recommendations are made for the review report to allow RAC to evaluate a possible review report efficiently. In case of a review report, there may be more reason to propose monitoring arrangements for the authorisation compared to

[11] {For applications for authorisation submitted before the latest application date.}
[12] {For review reports.}
[13] {For 'late' applications for authorisation i.e. submitted after the Sunset Date.}
[14] {For applications for authorisation submitted before the latest application date.}
[15] {For review reports.}
[16] {For 'late' applications for authorisation i.e. submitted after the Sunset Date.}

initial applications.

Option 3 (non-threshold cases only): Moderate concerns regarding the OCs and RMMs (but OCs and RMMs are still considered appropriate and effective in limiting the risk), typically monitoring arrangements are proposed for the authorisation and recommendations are made for the review report. Usually no additional conditions for the authorisation are proposed.

Option 4 (for non-threshold cases and threshold cases without adequate control): High concerns (OCs and RMMs are not appropriate and effective in limiting the risk, no adequate control), typically additional conditions for the authorisation and monitoring arrangements for the authorisation are proposed.

Option 5 (for non-threshold and threshold substances without adequate control): Major concerns, RAC is unable to propose additional conditions: 'negative' opinion. Also, no additional monitoring arrangements, nor recommendations for the review report.}

{Select the relevant option(s) regarding the level of control and additional conditions for the authorisation from below}

[RAC concluded that the operational conditions and risk management measures described in the [application] [review report] **are** [expected to be] appropriate and effective in limiting the risk, provided that they are [implemented and] adhered to.] [The proposed additional conditions for the authorisation are expected to strengthen this conclusion. {this optional text is typically not selected}] {Select for **options 1, 2 and 3**. The optional words 'expected to be' and 'implemented and' are options for future situations.}

[RAC concluded that the operational conditions and risk management measures described in the [application] [review report] are **not** appropriate and effective[17] in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk, provided that they are implemented and adhered to.] {Select for **option 4**, non-threshold substances}

[RAC concluded that the risk assessment presented in the [application] [review report] does **not** demonstrate adequate control of risks from the use applied for. The proposed additional conditions for the authorisation are expected to result in adequate control of risks, provided that they are implemented and adhered to. {Select for **option 4,** threshold cases without adequate control}

[RAC concluded that the operational conditions and risk management measures described in the [application] [review report] are **not** appropriate and effective[18] in limiting the risk. RAC was unable to propose additional authorisation conditions that could make the operational conditions and risk management measures appropriate and effective in limiting the risk for [workers] [the environment] [humans via the environment]]. {Select for **option 5**}

{In addition, select the option(s) for monitoring arrangements and recommendations for the review report from below as relevant}

[The proposed monitoring arrangements for the authorisation are expected to provide reliable

[17] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls and compliance with the relevant legislation: 'Effectiveness' – evaluation of the degree to which the RMM is successful in producing the desired effect – exposure / emissions reduction, taking into account for example proper installation, maintenance, procedures and relevant training provided.

[18] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls and compliance with the relevant legislation: 'Effectiveness' – evaluation of the degree to which the RMM is successful in producing the desired effect – exposure / emissions reduction, taking into account for example proper installation, maintenance, procedures and relevant training provided.

further information on the effectiveness of operational conditions and risk management measures implemented [as a result of additional conditions] and on [associated] trends in [exposure] [and] [releases] during the review period. This information should also be included in a possible review report.]

[The recommendations for the review report are expected to allow RAC to evaluate a possible review report efficiently.]

{Concluding statement}

[The exposure of workers [and the general population] to the substance is estimated to be as described in section 2 of the justification to this opinion.]

[The risk for workers [and the general population] from exposure to the substance is estimated to be as described in section 3 of the justification to this opinion.]

[The use applied for may result in [up to] [approximately] [x] [g] [kg] per year releases of the substance to the environment.]

THE OPINION OF SEAC

SEAC has formulated its opinion on the socio-economic factors and the suitability and availability of alternatives associated with the use of the substance taking into account the information in the [application] [review report], [information submitted by interested third parties,] as well as other available information. SEAC's evaluation is based on relevant guidance, which comprises Commission's Better Regulation guidance, the Guidance documents on applications for authorisation and the socio-economic analysis as well as specific guidance related to how SEAC evaluates the applications (e.g. dose response functions, values of health endpoints).

[SEAC took note of RAC's conclusion that it is not possible to determine [a] [DNEL(s)] [and] [PNEC(s)] for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation. [SEAC also took note that the [applicant] [authorisation holder] did not derive threshold levels for the environmental endpoints.]]

[SEAC took note of RAC's conclusion that it was possible to determine [a] [DNEL(s)] [and] [PNEC(s)] for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation but that the risk assessment presented in the [application] [review report] does not demonstrate adequate control of risks from the use applied for.]

{SEAC conclusions on the AoA}

SEAC has assessed the availability, and technical and economic feasibility of alternatives for the [applicant] [authorisation holder] [or their downstream users] and in the EU. These are described in section 4. The [applicant] [authorisation holder] short-listed the following alternatives: {include a list}

SEAC concluded on the analysis of alternatives and the substitution plan that:

- The [applicant] [authorisation holder] has [not] demonstrated that there are no alternatives available with the same function and similar level of performance that are technically and/or economically feasible for the [applicant] [authorisation holder] [or

their downstream users] by [the Sunset Date[19]] [the expiry date of the authorisation decision[20]] [other date[21]].

- There is [no] information available [in the application for authorisation] [in the review report] [and/or] [in the comments submitted by interested third parties in the consultation] indicating that there are [no] alternatives available that are technically and economically feasible in the EU. {If there is information that alternatives are available} [However, RAC is unable to conclude on whether these alternatives are safer.] {If there is no information no additions needed}
- The [applicant] [authorisation holder] [submitted] [did not submit] a substitution plan. {If substitution plan was submitted} [The substitution plan is [not] credible [for the review period requested] and [not] consistent with the analysis of alternatives and the socio-economic analysis.] {If no substitution plan was submitted} [The [applicant's] [authorisation holder's] justifications for not submitting a substitution plan are reported in section 4.] [No justifications for that were provided].

{For uses covering only formulation activity without assessment of alternatives, no list or AoA conclusions are needed but add:} [The assessment of alternatives is not relevant for this use as the substance does not provide any specific function at the formulation stage.]

{SEAC conclusions on the SEA: select one option from below}

{Option 1: benefits and environmental/health risks are monetised}

SEAC has assessed the information provided by the [applicant] [authorisation holder] and third parties from a scientific perspective, using standard methodology, and following relevant guidance. Based on the elements listed below, SEAC concludes that the [applicant] [authorisation holder] has [not] demonstrated that the societal costs of not granting an authorisation are higher than the monetised risks to [human health] [and] [environment] resulting from the granting of an authorisation.

The expected societal costs of not granting an authorisation are estimated to be [at least] [approximately] €[x] [per year] [over x years] consisting of {report here the relevant titles from Table 14 of the justifications}. [Additional [important] societal impacts of not granting an authorisation have been assessed [quantitatively or qualitatively] but have not been monetised] and consist of {report here the relevant titles from Table 14 of the justifications}].

This conclusion considers:

- the endpoint[s] relevant for listing the substance in Annex XIV of REACH;
- the [x] directly exposed workers [and [x] indirectly exposed workers];
- the general population exposed at local scale ([up to] [approximately] [x] persons) and at regional scale ([up to] [approximately] [x] persons);
- the risk of continued use as assessed by RAC may result in [up to] [approximately] [x] expected additional cases of [endpoint] [per year] [over x years];
- the value of these expected additional cases has been monetised based on the [willingness-to-pay] [{specify other methodology}] methodology and corresponds to an estimate of [up to] [approximately] €[x] [per year] [over x years].

[Risks to [human health] [and] [the environment] of alternatives have not been assessed.]

[19] {For AfAs submitted before the LAD.}
[20] {For review reports.}
[21] {For 'late' AfAs i.e. submitted after the Sunset Date.}

{If only negligible uncertainties exist} SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

{If non-negligible uncertainties exist} SEAC acknowledges that there are remaining non-negligible uncertainties in the available information that may affect its conclusions.

{Option 2: environmental emissions are quantified, but risks are not quantified}

SEAC has assessed the information provided by the [applicant] [authorisation holder] and third parties from a scientific perspective, using standard methodology, and following relevant guidance. Based on the elements listed below, SEAC concludes that the [applicant] [authorisation holder] has demonstrated that the societal costs of not granting an authorisation are [at least] [approximately] €[x]/[t/kg/g] of avoided emissions of [substance] as a result of ceasing the use applied for. If it is considered by the decision-makers that this, together with any non-monetised impacts, are an unacceptably high cost, then the applicant has demonstrated that the societal costs of not granting an authorisation are higher than the risks to the environment from the granting of an authorisation.

The expected societal costs of not granting an authorisation are estimated to be [at least] [approximately] €[x] [per year] [over x years] consisting of {report here the relevant titles from Table 14 of the justifications}. [Additional [important] societal impacts of not granting an authorisation have been assessed [quantitatively or qualitatively] but have not been monetised] and consist of {report here the relevant titles from Table 14 of the justifications}].

RAC has estimated that the use applied for may result in [up to] [approximately] [x t/kg/g] of emissions of [substance] [per year] [over x years] to the environment. Given that the impact of these emissions cannot be quantified, SEAC used the emissions of [substance] as quantified by RAC as a proxy for the risk associated with the continued use.

[Risks to [human health] [and] [the environment] of alternatives have not been assessed.]

{If only negligible uncertainties exist} SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

{If non-negligible uncertainties exist} SEAC acknowledges that there are remaining non-negligible uncertainties in the available information that may affect its conclusions.

{Option 3: break-even outcome}

SEAC has assessed the information provided by the [applicant] [authorisation holder] and third parties from a scientific perspective, using standard methodology, and following relevant guidance. Based on the elements listed below, SEAC concludes that the [applicant] [authorisation holder] has demonstrated that the societal costs of not granting an authorisation are higher than the risks to human health resulting from the granting of an authorisation, if it is considered that the expected number of excess [health endpoint] cases resulting from exposure associated with the continued use of the substance would be lower than [break-even number].

The expected societal costs of not granting an authorisation are estimated to be [at least] [approximately] €[x] [per year] [over x years] consisting of {report here the relevant titles from Table 14 of the justifications}. [Additional [important] societal impacts of not granting an authorisation have been assessed [quantitatively or qualitatively] but have not been monetised] and consist of {report here the relevant titles from Table 14 of the justifications}].

[Risks to [human health] [and] [the environment] of alternatives have not been assessed.]

{If only negligible uncertainties exist} SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

{If non-negligible uncertainties exist} SEAC acknowledges that there are remaining non-negligible uncertainties in the available information that may affect its conclusions.

{Option 4: weight of evidence}

SEAC has assessed the information provided by the [applicant] [authorisation holder] and third parties from a scientific perspective, using standard methodology, and following relevant guidance. Based on the elements listed below, SEAC concludes that the [applicant] [authorisation holder] has [not] demonstrated that the societal costs of not granting an authorisation are higher than the [monetised] risks to [human health] [and] [the environment] resulting from the granting of an authorisation. This conclusion recognises that the [applicant] [authorisation holder] described the societal costs of not obtaining an authorisation only in qualitative terms and it is thus based on a weight-of-evidence approach as described in the relevant guidance.

The expected societal costs of not granting an authorisation are assessed [quantitatively or qualitatively] but have not been monetised and consist of {report here the relevant titles from Table 14 of the justifications}.

[Risks to [human health] [and] [the environment] of alternatives have not been assessed.]

{If only negligible uncertainties exist} SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

{If non-negligible uncertainties exist} SEAC acknowledges that there are remaining non-negligible uncertainties in the available information that may affect its conclusions.

PROPOSED CONDITIONS, MONITORING ARRANGEMENTS, AND RECOMMENDATIONS

{Select the relevant option(s) from below:}

[No additional conditions for the authorisation are proposed.]

[No monitoring arrangements for the authorisation are proposed.]

[No recommendations for the review report are made.]

[Additional conditions for the authorisation are proposed. These are listed in section 7 of the justification to this opinion.]

[Monitoring arrangements for the authorisation are proposed. These are listed in section 8 of the justifications to this opinion.]

[Recommendations for the review report are made. These are listed in section 9 of the justifications to this opinion.]

REVIEW PERIOD

Taking into account the information provided in the [application for authorisation] [review report] submitted by the [applicant] [authorisation holder] and any comments received in the consultation, [a [**x**]**-year**] [**no**] review period is recommended for this use[, i.e. until [the end]

[month] of [20xx]].

JUSTIFICATIONS

0. Short description of use

[Add text]

0.1. Description of the process in which the Annex XIV substance is used

[Add text]

Table 1: Contributing scenarios presented in the use

Contributing scenario	ERC[/PROC]	Name of the contributing scenario	Size of the exposed population
ECS 1			Regional: Local:
[WCS 1]			
[WCS 2]			
…			

0.2. Key functions provided by the Annex XIV substance and technical properties/requirements that must be achieved by the products made with the Annex XIV substance

[Add text]

0.3. Type(s) of product(s) made with the Annex XIV substance and market sector(s) likely to be affected by the authorisation

[Add text]

0.4. [For upstream [application] [review report]: Downstream user survey]

[Add text]

1. Operational Conditions and Risk Management Measures

1.1. Workers

[Add text]

Table 2: Operational Conditions and Risk Management Measures (sub-set of Succinct Summary of RMMs and OCs)

Contributing scenario	**Concentration of the substance {**}**	**Duration and frequency of exposure**	**Engineering controls** (e.g. containment, segregation, automation, LEV) **+ effectiveness as stated by the [applicant] [authorisation holder]**	**PPE** (RPE and Skin protection used) **+ effectiveness as stated by the [applicant] [authorisation holder]**	**Organisational controls** (access control, procedures, training)
WCS 1 {add WCS name} PROC:					
WCS 2 {add WCS name} PROC:					

[Add text]

1.2. Consumers

[Add text]

1.3. Environment/Humans via the environment

Air

[Add text]

Water

[Add text]

Soil

[Add text]

Waste (other than wastewater)

[Add text]

Table 3: Environmental RMMs – summary

Compartment	RMM	Stated effectiveness
Air		
Water		
Soil		

[Add text]

1.4. RAC's evaluation on the OCs and RMMs

[Add text]

1.5. RAC's conclusions on the OCs and RMMs

Overall conclusion

Are the operational conditions and risk management measures appropriate[22] and effective[23] in limiting the risks?

[22] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls as well as prevention or minimisation of releases in application of OCs and RMMs and compliance with the relevant legislation.
[23] 'Effectiveness' – evaluation of the degree to which the OCs and RMM are successful in producing the

Workers	☐Yes	☐No	☐Not relevant
Consumers	☐Yes	☐No	☐Not relevant
Humans via the environment	☐Yes	☐No	☐Not relevant
Environment	☐Yes	☐No	☐Not relevant

[Add text]

2. Exposure assessment

2.1. Inhalation exposure

Monitoring

[Add text]

Modelling

[Add text]

2.2. Dermal exposure

Modelling

[Add text]

Monitoring

[Add text]

2.3. Biomonitoring

[Add text]

Table 4: Summary of exposure information – dermal and inhalation

Contributing scenario	Route of exposure	Method of assessment	Exposure value (8h TWA)	Exposure value corrected for PPE	Exposure value corrected for PPE and frequency
WCS 1	Inhalation				
	Dermal				
	Biomonitoring				
WCS 2	Inhalation				
	Dermal				

desired effect – exposure / emissions reduction, taking into account for example proper installation, maintenance, procedures and relevant training provided.

	Biomonitoring				

[Add text]

[Comparison of current exposure data with the exposure values from the [initial application] [previous review report]

[**Table 5: Comparison of exposure data**

WCS	Route of exposure	[Initial application] [Previous review report]		Current review report	
		Days per year	Exposure value (8-h TWA)corrected for PPE and frequency	Days per year	Exposure value (8-h TWA) corrected for PPE and frequency
WCS 1	Inhalation				
	Dermal				
	Biomonitoring				
WCS 2	Inhalation				
	Dermal				
	Biomonitoring				

[Add text]]

2.4. Environmental [exposure] [releases]

Air

[Add text]

Water

[Add text]

Soil

[Add text]

Table 6: Summary of releases to the environment

Release route	**Release factor**	**Release per year** [tonnes] [kilograms] [grams]	**Release estimation method and details**
Air			
Water			
Soil			

Table 7: Summary of exposure to the environment and humans via the environment

Parameter	**Local**	**Regional**
PEC in air (mg/m^3)		
Daily dose via oral route (mg/kg bw/d)		

[Comparison of current release, exposure to the environment and humans via the environment data with those from the [initial application] [previous review report]]

[**Table 8: Comparison of release data**

Release route	**[Initial application] [Previous review report]**		**Current review report**	
	Release factor	**Release per year** [tonnes] [kilograms] [grams]	**Release factor**	**Release per year** [tonnes] [kilograms] [grams]
Air				
Water				
Soil				

[Add text]]

[**Table 9: Comparison of exposure to the environment and humans via the environment data**

Parameter	**[Initial application] [Previous review report]**		**Current review report**	
	Local	**Regional**	**Local**	**Regional**
PEC in air (mg/m^3)				
Daily dose via oral route (mg/kg bw/d)				

[Add text]]

2.5. RAC's evaluation of the exposure assessment

[Workers exposure]

[Add text]

[Environment] [and] [Humans via the environment]

[Add text]

2.6. RAC's conclusions on the exposure assessment

[Add text]

3. Risk characterisation

3.1. Workers

[The [applicant] [authorisation holder] has [not] used the [DNELs] [Dose response relationship] recommended by RAC.]

[Add text]

Table 10: Combined exposure and risk characterisation

Contributing scenario	Exposed population	Route	Exposure value corrected for PPE and frequency	RCR or excess risk*	
					Combined
WCS 1	{number of workers exposed}	Inhalation			
		Dermal			
WCS 2		Inhalation			
		Dermal			
		Inhalation			
		Dermal			
WCS 3 + WCS 4		Inhalation			
		Dermal			
Total exposure for 8 hours		**Inhalation**			
		Dermal			

* Estimated individual risk resulting from exposure

[Add text]

3.2. Humans via the environment

[Add text]

Table 11: Exposure and risk to humans via the environment – local and regional scale

Parameter	Local		Regional	
	Exposed population: {number at local scale}		Exposed population: {number at regional scale}	
	Exposure	RCR or excess risk*	Exposure	RCR or excess risk*
Humans via the environment – Inhalation				
Humans via the environment – Oral				
Humans via the environment - Combined	Not applicable		Not applicable	

* Estimated individual risk resulting from exposure.

3.3. Environment

[Add text]

3.4. RAC's evaluation of the risk characterisation

[Add text]

[For reference, the current indicative (IOEL) or binding Occupational Exposure Limit (BOEL) for this substance is: [x] [mg] [µg]/m^3.]

3.5. RAC's conclusions on the risk characterisation

[Add text]

4. Analysis of alternatives and substitution plan

4.1. Summary of the analysis of alternatives and substitution plan and of the comments received during the consultation and other information available

[Add text]

SEAC's evaluation of the [applicant's] [authorisation holder's] approach to the analysis of alternatives and the substitution plan

[Add text]

4.2. Availability and technical and economic feasibility of alternatives for the [applicant] [authorisation holder] and in the EU in general

Has the [applicant] [authorisation holder] demonstrated that there are no alternatives with the same function and similar level of performance that are technically and/or economically feasible for the [applicant] [authorisation holder] [or their downstream users] [before the Sunset Date] [before the expiry date of the authorisation decision] [other date]?

☐Yes ☐No

Is there information available in the [application for authorisation] [review report] or the comments submitted by interested third parties in the consultation indicating that there are alternatives available that are technically and economically feasible in the EU?

☐Yes ☐No

[Add text]

SEAC's evaluation of the availability and technical and economic feasibility of alternatives for the [applicant] [authorisation holder] and in the EU in general

[Add text]

4.3. Risk reduction capacity of the alternatives

Would the implementation of the short-listed alternative(s) lead to an overall reduction of risks?

☐Yes ☐No ☐Not applicable

[Add text]

4.4. Substitution plan/activities

Did the [applicant] [authorisation holder] submit a substitution plan?

☐Yes ☐No

[Is the substitution plan credible [for the review period requested] and consistent with the analysis of alternatives and the socio-economic analysis?

☐Yes ☐No]

[Add text]

SEAC's evaluation of the substitution plan/activities

[Add text]

4.5. SEAC's conclusions on the analysis of alternatives and the substitution plan

{Present the standard conclusions on analysis of alternatives and substitution plan:}

SEAC concluded on the analysis of alternatives and the substitution plan that:

- The [applicant] [authorisation holder] has [not] demonstrated that there are no alternatives available with the same function and similar level of performance that are

technically and/or economically feasible for the [applicant] [authorisation holder] [or their downstream users] by [the Sunset Date[24]] [the expiry date of the authorisation decision[25]] [other date[26]].

- There is [no] information available [in the application for authorisation] [in the review report] [and/or] [in the comments submitted by interested third parties in the consultation] indicating that there are [no] alternatives available that are technically and economically feasible in the EU. {If there is information that alternatives are available} [However, RAC is unable to conclude on whether these alternatives are safer.] {If there is no information no additions needed}
- The [applicant] [authorisation holder] [submitted] [did not submit] a substitution plan. {If substitution plan was submitted} [The substitution plan is [not] credible [for the review period requested] and [not] consistent with the analysis of alternatives and the socio-economic analysis.] {If no substitution plan was submitted} [The [applicant's] [authorisation holder's] justifications for not submitting a substitution plan are reported in section 4.4.] [No justifications for that were provided].

{For uses covering only formulation activity without assessment of alternatives, no list or AoA conclusions are needed but add:} [The assessment of alternatives is not relevant for this use as the substance does not provide any specific function at the formulation stage.]}

{If only negligible uncertainties exist} SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

{If non-negligible uncertainties exist} SEAC acknowledges that there are remaining non-negligible uncertainties in the available information that may affect its conclusions.

5. Socio-economic analysis

Did the [applicant] [authorisation holder] demonstrate that the societal costs of not granting an authorisation are higher than the risks to [human health] [and] [the environment]?

☐Yes ☐No ☐Not relevant (the risk cannot be compared with the costs of non-use)

5.1. Human health and environmental impacts of continued use

[Add text]

SEAC's evaluation of the impacts on human health and the environment

[Add text]

Table 12: Summary of additional statistical <endpoint> cases

	Excess lifetime	Number of	Estimated statistical	Value per statistical	Monetised excess risk

[24] {For AfAs submitted before the LAD.}
[25] {For review reports.}
[26] {For 'late' AfAs i.e. submitted after the Sunset Date.}

	<endpoint> risk[1]	exposed people	<endpoint> cases ([per year[4]][over x years])[5]	<endpoint> case	([per year[4]][over x years])[5]
Workers					
Directly exposed workers[2]					
Indirectly exposed workers[3]					
Sub-total					
General population					
Local					
Regional					
Sub-total					
Total					
Latency (years)					

Notes:

1. Excess risk is estimated over a typical lifetime working exposure (40 years) and via the environment over a typical lifetime exposure (70 years). As excess risks are likely to be different depending on the task, overall minimum and maximum excess risk among of all the tasks carried out by the workers are reported.
2. Directly exposed workers perform tasks described in the worker contributing scenarios, typically characterised by an 8-hour Time Weighted Average (TWA) exposure of a representative worker.
3. Indirectly exposed workers (bystanders) do not use the substance.
4. [Per average year during the time horizon used in the analysis.]
5. Derived from the lifetime risk of 40/70 years.

5.2. Societal costs of not granting an authorisation

Non-use scenario

[Add text]

Economic impacts of non-use

[Add text]

[<specify type of impact> of non-use]

[Add text]

SEAC's evaluation of the societal costs of non-use

[Add text]

Table 13: Societal costs of non-use

Description of major impacts	Monetised/quantitatively assessed/qualitatively assessed impacts
1. Monetised impacts	**€ [per year[1]] [over x years]**
Producer surplus loss due to ceasing the use applied for OR Investment and/or additional production costs related to the adoption of an alternative	
Relocation or closure costs	
Loss of residual value of capital	
Social cost of unemployment	
Spill-over impact on surplus of alternative producers	
[Please specify]	
Sum of monetised impacts	
2. Additional quantitatively assessed impacts	**[Per year] [Over x years]**
[Please specify]	
3. Additional qualitatively assessed impacts	
[Please specify]	

Notes:

1. [Per average year during the time horizon used in the analysis.]

5.3. Combined assessment of impacts

[Add text]

SEAC's evaluation of the combined assessment of impacts

[Add text]

Table 14: Societal costs of non-use and risks of continued use

Societal costs of non-use		Risks of continued use	
Monetised impacts (€ [per year[1]] [over x years])	{report the monetised net impacts of granting an authorisation; should be consistent with the total reported in Table 13; fill with 'not available' if there are none}	Monetised excess risks to directly and indirectly exposed workers (€ [per year[2]] [over x years])	{report the monetised risks to workers in case of granting an authorisation; should be consistent with Table 12; fill with 'not available' if there are none}
Additional quantitatively assessed impacts	{report additional quantitatively assessed impacts that	Monetised excess risks to the general population	{report the monetised risks to indirectly exposed

([per year] [over x years])	were not monetised, e.g. number of patients treated; should be consistent with the information reported in Table 13;fill with 'not available' if there are none}	(€ [per year[2]] [over x years])	workers/general population in case of granting an authorisation; should be consistent with Table 12; fill with 'not available' if there are none}
Additional qualitatively assessed impacts ([per year] [over x years])	{report additional qualitatively assessed impacts, e.g. availability of treatment for patients with disease A; should be consistent with the information reported in Table 13; fill with 'not available' if there are none}	Additional qualitatively assessed risks ([per year] [over x years])	{report additional qualitatively assessed risks, e.g. risks associated with releases of the Annex XIV substance to the environment of x kg; should be consistent with Table 6; fill with 'not available' if there are none}
Summary of societal costs of non-use	{list the most important elements from the above rows in a bullet point manner}	**Summary of risks of continued use**	{list the most important elements from the above rows in a bullet point manner}

Notes:

1. [Annualised to a typical year based on the time horizon used in the analysis.]
2. [Per average year during the time horizon used in the analysis.]

{Table 15 below should be completed for PBT/vPvB substances and other non-threshold substances (e.g. endocrine disruptors for environment) where excess risk cannot be calculated (option 2 in the SEAC conclusions).}

Table 15: Costs of non-use per [t/kg/g] of release

	[Per year[4]] [Over x years]
Total costs[1] (€)	{should be consistent with the total reported in Table 13 and Table 14}
Total releases[2] (kg)	{should be consistent with the releases reported in Table 14}
Ratio[3] (€/kg)	

Notes:

1. "Total costs" (in case of non-authorisation) = Societal costs of non-use
2. "Total releases" (in case of continued use) = Estimated releases to the environment.
3. "Ratio" = Total costs/Total releases. [This ratio needs to be interpreted with care as any release amount significantly smaller than 1 kg gives the impression that large costs would occur in the non-use scenario. However, this impression is an outcome of reporting the ratio in € per kg.]
4. [Annualised to a typical year based on the time horizon used in the analysis.]

5.4. SEAC's conclusion on the socio-economic analysis

{Choose the applicable standard conclusion}

{Option 1: benefits and health risks are monetised}

[SEAC concludes that the [applicant] [authorisation holder] has [not] demonstrated that the societal costs of not granting an authorisation are higher than the monetised risks to [human health] [and] [environment] resulting from the granting of an authorisation.]

{Option 2: environmental emissions are quantified, but risks are not quantified}

[SEAC concludes that the [applicant] [authorisation holder] has demonstrated that the societal costs of not granting an authorisation are [at least] [approximately] €[x]/[t/kg/g] of avoided emissions of [substance] as a result of ceasing the use applied for. If it is considered by the decision-makers that this, together with any non-monetised impacts, are an unacceptably high cost, then the applicant has demonstrated that the societal costs of not granting an authorisation are higher than the risks to the environment from the granting of an authorisation.]

RAC has estimated that the use applied for may result in [up to] [approximately] [x t/kg/g] of emissions of [substance] per year of the substance to the environment. Given that the impact of these emissions cannot be quantified, SEAC used the emissions of [substance] as quantified by RAC as a proxy for the risk associated with the continued use.]

{Option 3: break-even outcome}

[SEAC concludes that the [applicant] [authorisation holder] has demonstrated that the societal costs of not granting an authorisation are higher than the risks to human health resulting from the granting of an authorisation, if it is considered that the expected number of excess [health endpoint] cases resulting from exposure associated with the continued use of the substance would be lower than [break-even number].]

{Option 4: weight of evidence}

[SEAC concludes that the [applicant] [authorisation holder] has [not] demonstrated that the societal costs of not granting an authorisation are higher than the [monetised] risks to [human health] [and] [the environment] resulting from the granting of an authorisation. This conclusion recognises that the [applicant] [authorisation holder] described the societal costs of not obtaining an authorisation only in qualitative terms and it is thus based on a weight-of-evidence approach as described in the relevant guidance.]

{The following conclusions are relevant for all options 1 to 4}

This conclusion of SEAC is made on the basis of:

- the [application for authorisation] [review report],
- SEAC's assessment of the societal costs of non-use,
- SEAC's assessment of the availability, technical and economic feasibility of alternatives,
- [SEAC's assessment of the information submitted by interested third parties,]
- [any additional information provided by the [applicant] [authorisation holder] [or their downstream users]], and
- RAC's assessment of the risks to [human health] [and] [the environment].

{If only negligible uncertainties exist} SEAC has not identified any remaining uncertainties of such magnitude that they may affect its conclusions. Therefore, any remaining uncertainties are considered negligible.

{If non-negligible uncertainties exist} SEAC acknowledges that there are remaining non-negligible uncertainties in the available information that may affect its conclusions.

6. Proposed review period

☐Normal (7 years)

☐Long (12 years)

☐Short (4 years)

☐Other: … years

☐No review period recommended

When recommending the review period SEAC took note of the following substitution and socio-economic considerations:

[Add text]

Taking into account all of the above points, [a [**x**]**-year**] [**no**] review period is recommended for this use[, i.e. until [the end] [month] of [20xx]].

7. Proposed additional conditions for the authorisation

Were additional conditions proposed for the authorisation?

☐Yes ☐No

7.1. Description

RAC

[Add text]

[SEAC]

[Add text]

7.2. Justification

RAC

[Add text]

[SEAC]

[Add text]

8. Proposed monitoring arrangements for the authorisation

Were monitoring arrangements proposed for the authorisation?

☐Yes ☐No

8.1. Description

RAC

[Add text]

8.2. Justification

RAC

[Add text]

9. Recommendations for the review report

Were recommendations for the review report made?

☐Yes ☐No

9.1. Description

RAC

[Add text]

[SEAC]

[Add text]

9.2. Justification

RAC

[Add text]

[SEAC]

[Add text]

10. [Applicant's] [Authorisation holder's] comments on the draft opinion

Did the [applicant] [authorisation holder] comment the draft opinion?

☐Yes ☐No

10.1. Comments of the [applicant] [authorisation holder]

Was the opinion or the justifications to the opinion amended as a result of the analysis of the [applicant's] [authorisation holder's] comments?

☐Yes ☐No ☐Not applicable – the [applicant] [authorisation holder] did not comment

10.2. Reasons for introducing changes and changes made to the opinion

[Add text]

10.3. Reasons for not introducing changes

[Add text]