Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

[Draft] Opinion

on an Application for Authorisation for

[substance] use: [use name]

ECHA/RAC/SEAC: [Opinion N°]

Consolidated version

Date: [date]

Version 2.0

December 2018

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Version	Changes
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 justification of opinions includes 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

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 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:

Applicant(s)	**[Legal entity name(s)]** (position in supply chain: [upstream][downstream])
Substance ID EC No CAS No	**[Substance name]** [EC number] [CAS number]
Intrinsic property(ies) 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)
Use title	**[Use name]**
	Other connected uses:
	Same uses applied for:
Use performed by	☐Applicant(s) ☐Downstream User(s) of the applicant(s)
Use ID (ECHA website)	
Reference number	
RAC Rapporteur RAC Co-rapporteur	
SEAC Rapporteur SEAC Co-rapporteur	
ECHA Secretariat	

PROCESS INFORMATION FOR ADOPTION OF THE OPINIONS

Date of submission of the application	[date]
Date of payment, in accordance with Fee Regulation (EC) No 340/2008 on	[date]
Application has been submitted by the Latest Application Date for the substance and applicant(s) [and their DUs] can benefit from the transitional arrangements described in Article 58(1)(c)(ii).	☐Yes ☐No
Public Consultation on use, in accordance with Article 64(2): https://echa.europa.eu/applications-for-authorisation-previous-consultations	[date]
Comments received	☐Yes ☐No Link:
Request for additional information in accordance with Article 64(3)	[date] [date] Link:
The trialogue meeting	[date] / [Not held - justification]
Extension of the time limit set in Article 64(1) for the sending of the draft opinions to the applicant	☐Yes, by [date] Reason: e.g. due to the need to ensure the efficient use of resources, and in order to synchronise the public consultation with the plenary meetings of the Committees. ☐No
The application included all the necessary information specified in Article 62 that is relevant to the Committee's remit.	☐Yes ☐No Comment:
Agreement of draft opinion in accordance with Article 64(4)(a) and (b) on	RAC: [date], agreed by [consensus] [a simple majority].
	SEAC: [date], agreed by [consensus] [a simple majority].
Date of sending of the draft opinion to applicant	[date]

Date of applicant's decision [not] to comment on the draft opinion, according to Article 64(5)	[date]
Date of receipt of applicant's comments, according to Article 64(5), received	[date] [Not relevant]
Adoption of opinion, according to Article 64(5), on	RAC: [date], adopted by [consensus] [a simple majority].
	SEAC: [date], adopted by [consensus] [a simple majority].
Minority positions	RAC: [☐N/A] [Links to the published minority positions]
	SEAC: [☐N/A] [Links to the published minority positions]

{**Case 1t (Threshold substance with 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 risk management measures described,
- the assessment of the risks related to the alternatives as documented in the application, [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[1] for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

RAC concluded that there appears to be [no] alternative that would further reduce the overall risks.

{Option 1.}
[RAC concluded that the risk assessment presented in the application demonstrates adequate control of risks from the use applied for, provided that the risk management measures and operational conditions as described in the application are adhered to. The suggested monitoring arrangements are expected to address RAC's [moderate] concerns.]

{Option 2 – Only for 'future uses' i.e. annex XIV will be used in a plant not yet been built.}
[RAC concluded that the risk assessment presented in the application demonstrates the achievability of adequate control of risks from the use applied for, provided that the risk management measures and operational conditions as described in the application [and the suggested monitoring arrangements [and adjustment of RMMs]] are implemented and adhered to.

The suggested monitoring arrangements [and adjustment of RMMs] are expected to address RAC's [moderate] concerns.]

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 as documented in the application, [taking into account the information submitted by interested third parties,] as well as
- other available information.

SEAC took note of RAC's conclusion that it is possible to determine a DNEL 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/or][the environment] from the use of the substance is [demonstrated to be adequately controlled] [can be adequately controlled in future uses].

SEAC concluded that there appear to be [no] suitable alternatives in terms of their technical

[1] If relevant, references to "DNEL" in this Document may be replaced with "PNEC" or "DNEL and a PNEC".

and economic feasibility that are available [by the Sunset Date] [by the end of the review period of the granted Authorisation].

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

[No conditions or monitoring arrangements, [including adjustment of RMMs,] in addition to those described in the application, are proposed.]

Or

[Additional conditions or monitoring arrangements [and adjustment of RMMs], are proposed. These are listed in sections 8 and 9 of this opinion.]

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the applicant and the comments received on the broad information on use, the duration of the review period for the use is recommended to be **x years**.

{**Case 2n (Non-threshold substance, where benefits are higher than the risk and no suitable alternative is available)**

Legal relevance: According to Art. 60(4) an authorisation of a non-threshold substance may be granted 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 risk management measures described,
- the assessment of the [hazards and] [risks] related to the alternatives as documented in the application [taking into account the information submitted by interested third parties], as well as
- other available information.

RAC concluded that it is not possible to determine a DNEL for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

RAC concluded that there appear to be [no] alternatives that would further reduce the overall risks.

{**Option 1:** no concerns, no conditions. But monitoring arrangements to be documented in the review report may be necessary to address moderate uncertainties/concerns (e.g. improved description of the exposure scenarios…).}

[RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk provided that they are adhered to.]

[For the review, RAC concludes that certain information is required. The suggested monitoring arrangements [and adjustment of RMMs] for the review report are expected to address RAC's moderate concerns.]

{**Option 2**: additional conditions are necessary due to serious or moderate concerns regarding risks to exposed populations/compartments identified → immediate action is necessary and the effect of this action is to be documented in the Review Report.}

[RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk.

The suggested additional conditions are expected to address RAC's [moderate concerns/ concerns / serious concerns].

{**Option 3**: very significant concerns that additional conditions may not address.}

[RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. Furthermore, RAC is unable to suggest additional conditions that would address RAC's critical concerns.]

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 as documented in the application, [taking into account the information submitted by interested third parties,] as well as
- other available information.

SEAC took note of RAC's conclusion that it is not possible to determine a DNEL for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC concluded that there appear to be no suitable and available alternatives [by the Sunset Date] [by the end of the review period of the granted Authorisation].

SEAC concluded that the applicant's assessment of: (a) the potential socio-economic benefits of the continued use, (b) the potential adverse effects to [human health][and/or] [the environment] of the continued use and (c) the comparison of the two is based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the continued use outweigh the risk to [human health] [and/or] [the environment], whilst taking account of any uncertainties in the assessment [provided that the recommended conditions are adhered to].

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

[No conditions or monitoring arrangements, [including adjustment of RMMs,] in addition to those described in the application, are proposed.]

Or

[Additional conditions or monitoring arrangements [including adjustment of RMMs], are proposed. These are listed in sections 8 and 9 of this opinion.]

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the applicant and the comments received on the broad information on use, the duration of the review period for the use is recommended to be **x years**.

{**Case 2t (Threshold substance, no adequate control, where benefits are higher than the risk and no suitable alternatives is available)**

Legal relevance: According to Art. 60(4) an authorisation of a threshold substance without adequate control may be granted if the socio-economic benefits outweigh the risk to human health or the environment and no suitable alternative is 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 risk management measures described,
- the assessment of the [hazards and] [risks] related to the alternatives as documented in the application, [taking into account the information submitted by interested third parties], as well as
- other available information.

RAC concluded that it is possible to determine a DNEL for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

RAC concluded that there appear to be [no] alternatives that would further reduce the overall risks.

{**Option 1**: additional conditions are necessary due to serious or moderate concerns regarding risks to exposed populations/compartments identified → immediate action is necessary and the effect of this action is to be documented in the Review Report.}

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

The suggested additional conditions are expected to address RAC's [serious] concerns.

{**Option 2**: very significant concerns that additional conditions may not address.}

[RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. Furthermore, RAC is unable to suggest additional conditions that would address RAC's critical concerns.]

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 as documented in the application, [taking into account the information submitted by interested third parties,] as well as
- other available information.

SEAC took note of RAC's conclusion that it is possible to determine a DNEL 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/or][the environment] from the use of the substance is/are not demonstrated to be adequately controlled.

SEAC concluded that there appear to be [no] suitable and available alternatives [by the Sunset Date][by the end of the review period of the granted Authorisation].

SEAC concluded that the applicant's assessment of: (a) the potential socioeconomic benefits of the continued use, (b) the potential adverse effects to [human health] [and/or] [the environment] of the continued use and (c) the comparison of the two is based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the continued use outweigh the risk to [human health][and/or][the environment], whilst taking account of any uncertainties in the assessment [, provided that the suggested conditions are adhered to].

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

[No conditions or monitoring arrangements, [including adjustment of RMMs,] in addition to those described in the application, are proposed.]

Or

[Additional conditions or monitoring arrangements [including adjustment of RMMs], are proposed. These are listed in sections 8 and 9 of this opinion.]

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the applicant and the comments received on the broad information on use, the duration of the review period for the use is recommended to be **x years**.

{**Case 3n: (Non-threshold substance, where benefits are lower than the risks)**

Legal relevance: According to Art. 60(4) an authorisation of a non-threshold substance cannot be granted if the socio-economic benefits do not outweigh the risk to human health or the environment.}

THE OPINION OF RAC

RAC has formulated its opinion on:

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

RAC concluded that it is not possible to determine a DNEL for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

RAC concluded that there appear to be [no] alternatives that would further reduce the overall risks.

RAC concluded that the operational conditions and risk management measures in the application [do not] limit the risk and [no] [additional conditions] [monitoring arrangements [and adjustment of RMMs]] are proposed

[The suggested [additional conditions] [monitoring arrangements [and adjustment of RMMs]] are expected to address RAC's [moderate] concerns.]

THE OPINION OF SEAC

SEAC has formulated its opinion on:

- the socio-economic factors and
- the suitability and the availability of alternatives associated with the use of the substance as documented in the application,
- [taking into account the information submitted by interested third parties,] as well as
- other available information.

SEAC took note of RAC's conclusion that it is not possible to determine a DNEL for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC concluded that there appear to be [no] suitable and available alternatives [by the Sunset Date][by the end of the review period of the granted Authorisation].

SEAC concluded that the applicant's assessment of: (a) the potential socio-economic benefits of the continued use, (b) the potential adverse effects to [human health] [and/or] [the environment] of the continued use and/or (c) the comparison of the two is not based on acceptable methodology for socio-economic analysis. Therefore, SEAC raised reservations that do change the validity of the applicant´s conclusion that overall benefits of the continued use outweigh the risk to [human health] [and/or] [the environment], whilst taking into account of any uncertainties in the assessment, due to the following key deficiencies:

- [list of main failures of the application]

Therefore, the final conclusion of the applicant cannot be supported.

{**Case 3t (Threshold substance, no adequate control, where benefits are lower than the risk)**

Legal relevance: According to Art. 60(4) an authorisation of a threshold substance cannot be granted if the socio-economic benefits do not outweigh the risk to human health or the environment.}

THE OPINION OF RAC

RAC has formulated its opinion on:

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

RAC concluded that it is possible to determine a DNEL for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

RAC concluded that there appear to be [no] alternatives that would further reduce the overall risks.

{**Option 1**: additional conditions are necessary due to serious or moderate concerns regarding risks to exposed populations/compartments identified → immediate action is necessary and the effect of this action is to be documented in the Review Report.}

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

[The suggested [additional conditions] are expected to address RAC's [serious] [moderate] concerns.]

{**Option 2**: very significant concerns that additional conditions may not address.}

[RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. Furthermore, RAC is unable to suggest additional conditions that would address RAC's critical concerns.]

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 as documented in the application, [taking into account the information submitted by interested third parties,] as well as
- other available information.

SEAC took note of RAC's conclusion that it is possible to determine a DNEL 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/or][the environment] from the use of the substance is/are not demonstrated to be adequately controlled.

SEAC concluded that there appear to be [no] suitable and available alternatives [by the Sunset Date][by the end of the review period of the granted Authorisation].

SEAC considered that the applicant's assessment of: (a) the potential socio-economic benefits of the continued use, (b) the potential adverse effects to [human health][and/or][the environment] of the continued use and (c) the comparison of the two is not based on acceptable methodology for socio-economic analysis. Therefore, SEAC raised reservations that do change the validity of the applicant's conclusion that overall benefits of the continued use outweigh the risk [to human health][and/or][the environment], whilst taking account of any uncertainties of assessment, due to the following key deficiencies:

- [list of main failures of the application]

Therefore, the final conclusion of the applicant cannot be supported.

{**Case 4n: (Non-threshold substance, adequate control not demonstrated) where a suitable alternative is available**

Legal relevance: According to Art. 60(4) an authorisation for a non-threshold substance cannot be granted if 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 risk management measures described,
- the assessment of the [hazards and] [risks] related to the alternatives as documented in the application, [taking into account the information submitted by interested third parties], as well as
- other available information.

RAC concluded that it is not possible to determine a DNEL for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

RAC concluded that technically and economically feasible alternatives [by the Sunset Date] [by the end of the review period of the granted Authorisation] would further reduce the overall risks.

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 as documented in the application, [taking into account the information submitted by interested third parties], as well as
- other available information.

SEAC took note of RAC's conclusion that it is not possible to determine a DNEL for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC concluded that it appears that suitable alternatives are available [by the Sunset Date] [by the end of the review period of the granted Authorisation].

SEAC considered that the applicant's assessment of: (a) the potential socio-economic benefits of the continued use, (b) the potential adverse effects to [human health][and/or][the environment] of the continued use and (c) the comparison of the two is [not] based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise [raised] reservations that [do] change the validity of the applicant's conclusion that overall benefits of the continued use outweigh the risk [to human health][and/or][the environment], whilst taking account of any uncertainties of assessment, [due to the following key deficiencies:

- [list of main failures of the application]

Therefore, the final conclusion of the applicant cannot be supported]

{**Case 4t (Threshold substance, no adequate control, where a suitable alternative is available)**

Legal relevance: According to Art. 60(4) an authorisation cannot be granted for a threshold substance where adequate control has not been demonstrated if 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 risk management measures described,
- the assessment of the [hazards and] [risks] related to the alternatives as documented in the application, [taking into account the information submitted by interested third parties], as well as
- other available information.

RAC concluded that it is possible to determine a DNEL for the [specify] properties of the substance in accordance with Annex I of the REACH Regulation.

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

RAC concluded that technically and economically feasible alternatives [by the Sunset Date] [by the end of the review period of the granted Authorisation] would further reduce the overall risks.

THE OPINION OF SEAC

SEAC has formulated its opinion on:

- the socio-economic factors and the availability,
- suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application, [taking into account the information submitted by interested third parties], as well as
- other available information.

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

SEAC took note that RAC conclusion that the risk(s) to [human health][and/or][the environment] from the use of the substance is/are not demonstrated to be adequately controlled.

SEAC concluded that it appears that suitable alternatives are available [by the Sunset Date] [by the end of the review period of the granted Authorisation].

[SEAC considered that the applicant's assessment of: (a) the potential socio-economic benefits of the continued use, (b) the potential adverse effects to [human health][and/or][the environment] of the continued use and (c) the comparison of the two is [not] based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise [raised] reservations that [do] change the validity of the applicant's conclusion that overall benefits of the continued use outweigh the risk [to human health][and/or][the environment], whilst taking account of any uncertainties of assessment, [due to the following key deficiencies:

- [list of main failures of the application]

Therefore, the final conclusion of the applicant cannot be supported]]

SUMMARY OF THE APPLICATION FOR AUTHORISATION / USE

Type of application (applicant)	☐Upstream (M/I/OR or group of) ☐Upstream (Formulator or group of) ☐Downstream (group of users) ☐Downstream (single user) ☐Other [specify, e.g. Group of M/I/OR/DU]?
Indicative number and location of sites covered	
Annual tonnage of Annex XIV substance used per site (or total for all sites)	
Function(s) of the Annex XIV substance. Type of products (e.g. articles) made with Annex XIV substance and their market sectors	
Shortlisted alternatives discussed in the application	Alternative substances considered: [list] Alternative technologies considered: [list] Others: [list]
Annex XIV substance present in the products (e.g. articles) made by the downstream users	☐Yes ☐No ☐Unclear ☐Not relevant
Number of workers exposed per site (or total for all sites):	Directly: Indirectly:
Number of humans exposed via the environment	Local scale: Regional scale:
Environmental compartments affected:	☐Air ☐Water ☐Soil ☐None
Applicant has used the [DNEL] [Dose response relationship] recommended by RAC	☐Yes – [link to the relevant document] ☐No – [alternative values used]

All endpoints listed in Annex XIV were addressed in the assessment	☐Yes ☐No if 'No' – which endpoints are not addressed
All relevant routes of exposure were considered	☐Yes ☐No if 'No' – which routes are missing
Adequate control concluded by applicant for the relevant endpoint(s)	☐Yes ☐No ☐Not Applicable – non-threshold substance
Level of (combined, daily) exposure/release used by applicant for risk characterisation	Workers: Inhalation: Dermal: Consumer: Inhalation: Dermal: Oral: Humans via environment: Inhalation: Dermal: Oral: Environment: Air: Water: Soil:
[RCR] [combined risk level]	Workers: Consumer: Humans via environment: Environmental compartments:
Applicant is seeking authorisation for the period of time needed to finalise substitution ('*bridging application*')	☐Yes ☐No ☐Unclear

Review period argued for by the applicant (length)	
Most likely Non-Use scenario	
Applicant concludes that benefits of continued use outweigh the risks of continued use	☐Yes ☐No [Annualised][For the review period argued]: - Applicant's benefits of continued use: - Society's benefits of continued use: - Monetised health impact on workers: - Monetised health impact on the general population ☐Not Applicable – threshold substance with adequate control

SUMMARY OF RAC AND SEAC CONCLUSIONS[2]

2. Operational Conditions and Risk Management Measures are appropriate and effective in limiting the risk?

2.1. Conclusions of RAC:

Conclusion for workers:

[Add text]

OCs / RMMs implemented are:

Appropriate: ☐Yes ☐No

Effective: ☐Yes ☐No

[Add text]

Conclusion for consumers:

[Add text]

OCs / RMMs implemented are:

Appropriate: ☐Yes ☐No

Effective: ☐Yes ☐No

Conclusion for environment and / or Humans via environment (HvE):

[Add text]

OCs / RMMs implemented are:

Appropriate: ☐Yes ☐No

Effective: ☐Yes ☐No

Additional [conditions] [monitoring arrangements and adjustment of RMMs] related to the operational conditions and risk management measures are recommended for the authorisation:

☐Yes ☐No

[2] The numbering of the sections below corresponds to the numbers of the relevant sections in the Justifications.

Recommendations to the [applicant/s] related to the content of the potential Review Report are made:

☐Yes ☐No

3. Exposure Assessment

Combined exposure level used by RAC for risk characterisation:

Workers: Direct exposure

- Inhalation:
- Dermal:

Consumers' exposure

- Inhalation:
- Dermal:
- Oral:

Humans via environment

- Inhalation:
- Dermal:
- Oral:

Releases to the environmental compartments:

- Air:
- Water:
- Soil:

Conclusions of RAC:

[Add text]

Additional [conditions] [monitoring arrangements] related to exposure assessment are recommended for the authorisation

☐Yes ☐No

Recommendations to the [applicant] related to the content of the potential Review Report are made

☐Yes ☐No

4. Risk Characterisation

[RCR] or [Risk level used for health impact assessment] calculated by RAC:

Workers:

Direct exposure

Indirect exposure:

Consumers:

Humans via environment:

Environmental compartments:

Conclusions of RAC:

[Add text]

5. Analysis of alternatives. Are suitable alternatives available [before the Sunset Date]?

Conclusions of SEAC and RAC:

☐Yes ☐No

[Add text]

Additional [conditions] [monitoring arrangements] related to the assessment of alternatives are recommended for the authorisation

☐Yes ☐No

Recommendations to the [applicant/s] related to the content of the potential Review Report

☐Yes ☐No

6. Has the applicant adequately demonstrated that the benefits of continued use exceed the risks of continued use?

Conclusions of SEAC:

☐Yes ☐No

[Add text]

Recommendations to the [applicant] related to the content of the potential Review Report

☐Yes ☐No

7. Proposed review period for the use

☐ 4 years

☐ 7 years

☐ 12 years

☐ Other – … years

8. Proposed additional conditions and monitoring arrangements [and adjustment of RMMs] for the authorisation

RAC:

Additional conditions:

For workers	☐Yes	☐No
For consumers	☐Yes	☐No
For the environment / HvE	☐Yes	☐No

Monitoring arrangements [and adjustment of RMMs]:

For workers	☐Yes	☐No
For consumers	☐Yes	☐No
For the environment / HvE	☐Yes	☐No

SEAC:

Additional conditions:

Monitoring arrangements:

9. Proposed recommendations for the review report

RAC:

For workers	☐Yes	☐No
For consumers	☐Yes	☐No
For the environment / HvE	☐Yes	☐No

SEAC:

AoA	☐Yes	☐No
SEA	☐Yes	☐No

10. Applicant(s) commented on the draft opinion

☐Yes ☐No

Action(s) taken resulting from the analysis of the applicant's comments?

☐Yes ☐No

JUSTIFICATIONS: FULL VERSION:

1. Short description of use

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

Table 1: Contributing Scenarios presented in the Use

Contributing scenario	ERC / PROC	Name of the contributing scenario	Size of the exposed population
ECS1			Regional: Local:
WCS 1			
WCS 2			
...			

[Add text]

1.2. Key functions and properties provided by the Annex XIV substance

[Add text]

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

[Add text]

1.4. For upstream applications: Downstream User survey

[Add text]

2. Operational Conditions and Risk Management Measures are appropriate[3] and effective[4] in limiting the risk?

Workers ☐Yes ☐No

Environment/Humans via Environment ☐Yes ☐No

2.1. Workers

[Add text]

[3] 'Appropriateness' – relates to the following of the principles of the hierarchy of controls and compliance with the relevant legislation

[4] '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.

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**	**PPE** (RPE and Skin protection used) **+ effectiveness as stated by the applicant**	**Organisational controls** (access control, procedures, training)
WCS 1 PROC:					
WCS 2 PROC:					

*If changing through the process

[Add text]

2.2. Environment / Humans via Environment

Technical measures in place for control of emissions to:

Air:

[Add text]

Water:

[Add text]

Soil:

[Add text]

Waste:

[Add text]

Table 3: Environmental RMMs

Compartment	**RMM**	**Stated Effectiveness**
Air		
Water		
Soil		

[Add text]

2.3. Discussion on OCs and RMMs in place and relevant uncertainties

[Add text]

2.4. Conclusions on OCs and RMMs

[Add text]

Overall conclusion: RMMs implemented are [not] appropriate and [not] effective in limiting the risk.

[Add text]

[Concerns/uncertainties about RMMs lead to
- additional conditions and monitoring arrangements [and adjustment of RMMs] for authorisation presented in S. 8]

[Shortcomings in the RMMs assessment lead to
- recommendations for the review report presented in S. 9]

3. Exposure assessment

3.1. Inhalation exposure

Monitoring:

[Add text]

Modelling:

[Add text]

3.2. Dermal exposure

Modelling:

[Add text]

Monitoring:

[Add text]

3.3. Biomonitoring

[Add text]

Table 4: Exposure – 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				
	Biomonitoring				

[Add text]

3.4. Environmental emissions

Water:

[Add text]

Air:

[Add text]

Soil:

[Add text]

Table 5: Summary of environmental emissions

Release route	Release factor	Release per year	Release estimation method and details
Water			
Air			
Soil			
Waste			

Table 6: Summary of indirect exposure to humans via the environment

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

3.5. Discussion of the information provided and uncertainties related to exposure assessment

Workers exposure

[Add text]

Humans via the environment

[Add text]

3.6. Conclusions on exposure assessment

[Add text]

4. Risk characterisation

4.1. Workers

[Add text]

Table 7: Combined exposure and risk characterisation

Contributing scenario	Route	Exposure value corrected for PPE and frequency	RCR or Excess risk[5]	
				Combined
WCS 1	Inhalation			
	Dermal			
WCS 2	Inhalation			
	Dermal			
	Inhalation			
	Dermal			
WCS 3+ WCS 4	Inhalation			
	Dermal			
Total exposure for 8 hours	**Inhalation**			
	Dermal			

[Add text]

4.2. Environment and/or Humans via Environment

[Add text]

[5] Estimated individual risk resulting from exposure

Table 8: Exposure and risk to humans via the environment – local and regional scale

Parameter	Local		Regional	
	Exposure	RCR or Excess risk	Exposure	RCR or Excess risk
Human via Environment – Inhalation				
Human via Environment – Oral				
Human via Environment - Combined				

4.3. Uncertainties

[Add text]

4.4. Conclusions on risk characterisation

[Add text]

5. Evaluation of the suitability and availability of alternatives

[Add text]

5.1. Summary of the Analysis of Alternatives by the applicant/s and of the comments received during the public consultation

[Add text]

5.2. Short-listed alternatives and past substitution R&D efforts

[Add text]

5.3. Would the implementation of short-listed alternative/s lead to an overall reduction of overall risks?

☐Yes

☐No

☐Not applicable

[Add text]

5.4. Are the short-listed alternatives technically and economically feasible and available before the Sunset Date?

☐Yes

☐No

[Add text]

SEAC's evaluation / view on the suitability and availability of alternatives:

[Add text]

5.5. Is the applicant [and its downstream users] already engaged in a substitution programme and / or R&D and is it seeking a defined transitional period to phase out the use the Annex XIV substance?

[Add text]

5.6 Conclusions on the analysis of alternatives

[Add text]

6. Has the applicant adequately demonstrated that the benefits of continued use exceed the risks of continued use?

☐ Yes

☐ No

☐ Not relevant (adequate control demonstrated for threshold substance)

6.1. Additional statistical [endpoint] cases and monetised risks of continued use

[Add text]

Table 9: Summary of additional statistical <endpoint> cases:

	Excess <endpoint> risk[2]	**Number of exposed people**	**Estimated statistical <endpoint> cases**	**Value per statistical <endpoint> case**	**Monetised excess risk per year[1]**
Workers					
Directly exposed workers[3]					
Indirectly exposed workers[4]					
Sub-total					
General population					
Local					
Regional					
Sub-total					
Total					
Latency (years)					

Notes:

1. Annualised to a typical year based on the time horizon used in the SEA;
2. Excess risk is estimated over a lifetime working exposure (typically 40 years) and via the environment over a typical lifetime exposure (typically 70 years);
3. Directly exposed workers perform tasks described in the worker contributing scenarios, typically based on 8 hour Time Weighted Average (TWA) of a representative worker;
4. Indirectly exposed workers (bystanders) do not use the substance;

6.2. Benefits of continued use

Non-use scenario

[Add text]

Economic impacts of continued use

[Add text]

Table 10: Socio-economic benefits of continued use

Description of major impacts	Quantification of impacts [annualised to € million per year]
1. Benefits to the applicant(s) and/or their supply chain	
1.1 Avoided profit loss due to investment and/or production costs related to the adoption of an alternative	
1.2 Avoided profit loss due to ceasing the use applied for[6]	
1.3 Avoided relocation or closure cost	
1.4 Avoided residual value of capital	
1.5 Avoided additional cost for transportation, quality testing, etc.	
Sum of benefits to the applicant(s) and / or their supply chain	
2. Quantified impacts of the continuation of the SVHC use applied for on other actors	
2.1 Avoided net job loss in the affected industry[7]	
2.2 Foregone spill-over impact on surplus of alternative producers	
2.3 Avoided consumer surplus loss (e.g. because of inferior quality, higher price, reduced quantity, etc.)	
2.4 Avoided other societal impacts (e.g. avoided CO_2 emissions or securing the production of drugs)	
Sum of impacts of continuation of the use applied for	
3. Aggregated socio-economic benefits (1+2)	

[6] Profit losses to be counted in only for the first [x] years, see SEAC note on economic surplus changes (not yet available).

[7] Job losses to be accounted for only for the arithmetic mean period of unemployment in the concerned region/country as outlined in the SEAC paper on the valuation of job losses (See The social cost of unemployment and Valuing the social costs of job losses in applications for authorisation).

6.3. Combined assessment of impacts

[Add text]

Table 11: Comparison of socio-economic benefits and risks of continued use

Socio-economic benefits of continued use		**Monetised excess risks associated with continued use**	
Benefits to the applicant(s) and/or their supply chain [annualised to € million per year]		Monetised excess risks to workers directly exposed in the use applied for [annualised to € million per year]	
Quantified impacts of the continuation of the SVHC use applied for on other actors		Monetised excess risks to the general population and indirectly exposed workers [annualised to € million per year]	
Additional qualitatively assessed impacts		Additional qualitatively assessed risks	
Aggregated socio-economic benefits [annualised to € million per year]		Aggregated monetised excess risk [annualised to € million per year]	

Table 12: Benefit / risk summary

Net benefits (€) [annualised to € million per year]	
Benefit/monetised risk ratio	

Table 13: Cost of non-use per kg and year (for PBT/vPvB substances and endocrine disruptors)

	Per year
Total cost (€) [annualised to € million per year]	
Total emissions (kg)	
Ratio (€/kg)	

Notes:

1. "Total cost" (of non-authorisation) = Benefit of authorisation
2. "Total emissions" (if authorisation is granted) = Estimated emissions to the environment, kg per year, based on Table 5
3. "Ratio" = Total cost/Total emissions
4. Annualised to a typical year based on the time horizon that you used in the analysis

Table 14: Distributional impacts of continued use

Affected group[1]	**Economic impact**	**Health and environmental impact**
Economic operator		
Applicant		
Suppliers of alternatives in the EU		
Suppliers of alternatives outside the EU		
Competitors in the EU		
Competitors outside the EU		
Customer group 1 (identify[2])		
Customer group 2 (identify)		
Public at large in the EU (identify)		
Geographical scope		
Region or Member State x		
Region or Member State y		
Within the applicant's business		
Employers/Owners		
Exposed workers		
Non-exposed employees		

Notes:
[1] Adapt the groups as relevant for your application.
[2] Identify group or groups as relevant. These may comprise the downstream or end users of the substance or the final customers of the products.
Severity of impacts: either monetary [annualised to € million per year] or using scale high (+++ or ---), medium (++ or --), low (+ or -) or not applicable (n/a).
Adapted from Table 12 (Chapter 4.2.3.) of SEA Guidance on the preparation of SEA in the Applications for Authorisation.

6.4. SEAC's view on Socio-economic analysis

[Add text]

6.5. Conclusion on the socio-economic analysis

[Add text]

7. Proposed review period

☐ Normal (7 years)

☐ Long (12 years)

☐ Short (…. years)

☐ Other:

When recommending the review period SEAC took note of the following considerations:

7.1. RAC's advice:

[Add text]

7.2. Substitution and socio-economic considerations

[Add text]

Taking into account these points, SEAC recommends a [...]-year review period.

8. Additional conditions and/or monitoring arrangements [and adjustment of RMMs] for the authorisation proposed

☐ Yes

☐ No

8.1. Description:

RAC

Additional conditions

[Add text]

Monitoring arrangements [and adjustment of RMMs]

[Add text]

SEAC

Additional conditions

[Add text]

Monitoring arrangements

[Add text]

8.2. Justification:

[Add text]

9. Recommendations for the review report proposed

☐ Yes

☐ No

9.1. Description:

[Add text]

9.2. Justification:

[Add text]

10. Did the applicant provide comments on the draft final opinion?

☐ Yes

☐ No

10.1. Action/s taken resulting from the analysis of the applicant's comments:

☐ Yes

☐ No

☐ Not applicable – the applicant did not comment

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

[Add text]

10.1.2. Reasons for not amending the opinion

[Add text]