Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

TEMPLATE

Opinion

on an Annex XV dossier proposing restrictions

Version 4: February 2016

EXPLANATORY NOTE

This format for an opinion and justification replaces the previous undated version. The revisions are based on the experience from the various restriction reports prepared under the REACH Regulation and the recommendations made by the Restrictions Efficiency Task Force in 2014.

The main changes from the previous version are:

- Adding a plenary plan and a style guide.
- Editorial updates on process information.
- Editorial updates on opinion texts, as well as adding guidance on when to use the various options, plus requirement to include Dossier Submitter proposal as well.
- Additional guidance in the justification on completing the format by rapporteurs to help them in deciding what information goes where.
- Adding a layout to structure the information in each section of the justification and clearly set out what is the Dossier Submitters analysis, what is the conclusion of the evaluation by RAC and SEAC and what is the evidence that underpins this evaluation.
- For certain justifications, giving a joint RAC/SEAC evaluation with one Committee in the lead.
- Adding new sections on uncertaintees in risk characterisation and proportionality as well as a section on overall uncertaintees.

The aim of the format is to enable the Rapporteurs to develop an opinion and justification that clearly sets out and substantiates the evaluation of the Dossier Submitters proposal by the Committees in a consistent manner.

Plenary plan

When drafting the opinion, Rapporteurs should take into account the following plenary plan[1] (i.e. ensure the relevant sections to be discussed are completed for the indicated planary):

	Committee	
Plenary	**RAC**	**SEAC**
0 (Key issues following conformity)	Agree in principle on the scope and key issues to analyse as the core of the evaluation.	
1	Confirm the scope. Finalise hazard and preliminary discussion on exposure/risk.	Confirm the scope. Finalise costs and preliminary discussion on benefits.
2	Finalise exposure/risk and preliminary discussion on proposal/exemptions and	Finalise benefits and preliminary discussion on proportionality and proposal/exemptions and

[1] If the case is simple then the flexible procedure could be used (Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals: Flexible procedure for handling and analysing restriction proposals).

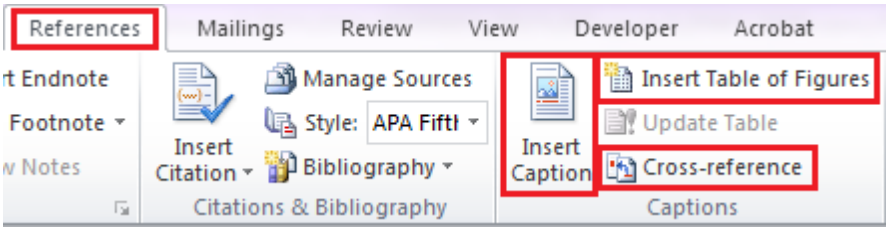
	justifications.	reasoning.
3	Finalise the derogations. Agree the opinion plus justification text and adopt the opinion.	Finalise the proportionality and derogations. Agree the opinion plus justification text and agree the opinion.
4	Not relevant.	Issues raised during the SEAC public consultation. Adopt the opinion.

Style guide (inc. references)

The following style should be used in completing the format.

- Use Verdana 10, 1.15 spacing, space after 6pt for general text. Use Style headings as given in the template.
- All pages should be numbered. Start page numbering on the first page of the actual content, e.g. introduction – not from the table of contents.
- All abbreviations and acronyms should be spelt out in full the first time they appear in a text, followed by their equivalent acronym in brackets. After this, the acronym can be used on its own. However, please use Dossier Submitter, Background Document, Member State, public consultation, Rapporteurs in full in the text, with capitals (or not) as shown.
- Numbers:
    - Generally, one digit numbers (up to nine inclusive) should be written out and two digit numbers (10 and above) should be written as figures.
    - To group thousands, do not use either commas or points but insert thin spaces.
    - Use a decimal point NOT a comma, to mark decimal numbers.
    - Millions and billions should be spelt out.
- Use the auto-generate option for the table of contents so that it can be updated automatically. To that end, make sure you assign the correct headings throughout the dossier (do not create new headings without using a heading selectable from Styles).
- Tables/Figure: Assign a caption to each table and figure by giving it the right label (see Captions in the References tab). Whenever you need to refer to a table or figure throughout the text, you should cross-reference it using the Cross-reference option available from Captions in the References tab. All this will make sure that all the references will stay intact even if new tables and figures are added later on.
- To generate the table of figures, use the Insert Table of Figures option available from Captions in the References tab. This works also for tables, despite its name, and will only work if the previous point has been followed correctly. See picture below[2]:

[2] The diagram is relevant for word 2010 but other versions may have different mechanisms for the same function.



- Provide a copyright source for all pictures and images.
- Avoid using symbols like (&) and (/) in texts but spell out the meaning of the words ('and', 'or').
- Dates in the running text should always be given in full form (1 July 2015). Use cardinal numbers (1, 2, 3) instead of ordinal (1st, 2nd, 3rd).
- Euros presented with the symbol before the figure (€200 000).
- Any confidential information should always be documented in a separate annex.
- Add any references not included in the Background document in the following format:

  Anderson WA, Castle L, Hird S, Jeffery J and Scotter MJ (2011). A twenty-volunteer study using deuterium labelling to determine the kinetics and fractional excretion of primary and secondary urinary metabolites of di-2-ethylhexylphthalate and di-iso-nonylphthalate. Food Chem Toxicol 49(9): 2022-2029.

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

{ADD TITLE OF RESTRICTION}

ECHA/RAC/[Opinion N°(same as opinion number)]

ECHA/SEAC/[Opinion N°(same as opinion number)]

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted [xx Month 20xx]) and SEAC's opinion (adopted [xx Month 20xx])

This document is a working document from the Committees for Risk Assessment and Socio-economic Analysis of the European Chemicals Agency (ECHA) intended for internal use only. It has not been agreed and/or adopted by the Committee. In addition to Committee participants the document may only be disclosed to experts and advisors for the purpose of facilitating the work of the Committees.

Draft date: [xx Month 20xx]

[Date]

[RAC opinion number]

[Date]

[SEAC opinion number]

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

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 the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	***[substance name(s)]***
EC No.:	***[number(s)]***
CAS No.:	***[number(s)]***

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the public consultation and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

[Name of the Member State, or ECHA on a request from the Commission or proposing restriction according to Article 69(2)] has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at ***[http://echa.europa.eu/xxxx]*** on

[date of publication of the dossier]. Interested parties were invited to submit comments and contributions by ***[date of publication + 6 months]***.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: *[Name SURNAME]*

[Co-rapporteur, appointed by RAC: *[Name SURNAME]*][3]

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on ***[date of adoption of the opinion]***.

[The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.**] [**No comments were received from interested parties during the public consultation in accordance with Article 69(6)).**]**[4]

The opinion of RAC was adopted ***by [consensus.][a simple majority]*** of all members having the right to vote. [The minority position(s) including their grounds are made available in a separate document which has been published at the same time as the opinion.**]**[4]

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: *[Name SURNAME]*

[Co-rapporteur, appointed by SEAC: *[Name SURNAME]*][3]

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation on ***[date of adoption of the draft opinion].***

[The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.**] [**No comments were received from interested parties during the public consultation in accordance with Article 69(6)(a).**]**[4].

[The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.**] [**No socio-economic analysis, or the information which can contribute to one, were received from interested parties during the public consultation in accordance with Article 69(6)(b).**]**[4].

The draft opinion was published at ***[http://echa.europa.eu/yyyy]*** on ***[date of publication of the draft opinion]***. Interested parties were invited to submit comments on the draft opinion by ***[date of publication + 60 days]***.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***[date of***

[3] Delete if not relevant
[4] Delete the unnecessary part(s)

adoption of the opinion]. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by ***[number of days]*** by the ECHA decision ***[number and date]*****]**[5].

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**]** **[**No comments were received from interested parties during the public consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

The opinion of SEAC was adopted ***by*** **[*consensus*.][*a simple majority*]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[6].

5 Delete the unnecessary part(s)

[For substantial opinions, use the following style for table of contents.]

Contents

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

{Add proposed Annex XVII entry proposed in the Annex XV report (section d: conclusion)}
{This will be added by the Secretariat before distribution to the Rapporteurs.}

Substance Identity (or group identity)	Conditions of the restriction
– Substance name, – CAS No xxx, – EC No xxx	

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the restriction proposed by the Dossier Submitter on ***[substance name+ CAS & EC number/s]***[6] is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion.

Opinion to be used when RAC agrees with Dossier Submitter's proposal without adding further conditions.

OR

RAC has formulated its opinion on the proposed restriction based on an evaluation of information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on ***[substance name]*** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the [scope and/or conditions] [is/are][7] modified, as proposed by

Opinion to be used when RAC agrees with Dossier Submitter's proposal but adds further conditions.

[6] Where the name of the substance is too long or complicated, the name can be replaced by 'the substance'.

[7] Delete or keep parts as needed.

RAC.

The conditions of the restriction proposed by RAC are:

Substance Identity (or group identity) – Substance name, – CAS No xxx, – EC No xxx	Conditions of the restriction

OR

RAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on ***[substance name+ CAS & EC number/s]***[8] is not justified, as demonstrated in the justification supporting this opinion, because

Opinion to be used when RAC does not agree with Dossier Submitter's proposal.

– **[**the risks to human health or the environment are considered to be adequately controlled**]**

To be added if, for example, the RCRs are shown to be < 1.

or

– **[**the restriction under REACH is not considered to be the most appropriate Union wide measure to address the identified risks in terms of its effectiveness, in reducing the risks, practicality and monitorability.**]**

To be added if another EU measure would be more effective in reducing the risks.

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers

Opinion to be used when SEAC simply agrees with Dossier Submitter's proposal (either as proposed by the Dossier Submitter or as modified by RAC) and adds no further conditions. If the conditions are the same as for RAC there is no need to repeat the entire set of conditions but simply to refer to RAC's

[8] Where the name of the substance is too long or complicated, the name can be replaced by 'the substance'.

that the restriction proposed by the Dossier Submitter on ***[substance name, CAS & EC numbers]***[9] is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs [provided that the scope or conditions are modified as stated in the RAC opinion][10] as demonstrated in the justification supporting this opinion.

opinion.

OR

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on ***[substance name][6]*** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope or conditions are modified, as proposed by RAC or SEAC, as demonstrated in the justification supporting this opinion.

Opinion to be used when SEAC agrees with Dossier Submitter's proposal and any additional conditions proposed by RAC, and adds further conditions.

The conditions of the restriction proposed by SEAC are:

Substance Identity (or group identity)	Conditions of the restriction
– Substance name, – CAS No xxx, – EC No xxx	

OR

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC has taken into account RACs support for the proposal but considers that the proposed restriction is

Opinion to be used when SEAC does not agree with Dossier Submitter's proposal but RAC does.

[9] Where the name of the substance is too long or complicated, the name can be replaced by 'the substance'.
[10] Delete if not relevant

not an appropriate EU wide measure, as concluded by RAC, when taking into account its socio-economic impacts as demonstrated in the justification supporting this opinion.

OR

The opinion of RAC did not consider that the proposed restriction is appropriate because [the risks to human health or the environment are considered to be adequately controlled]/[the restriction under REACH is not considered to be the most appropriate EU wide measure to address the identified risks]. Therefore there is not a sufficient justification for a restriction and SEAC has no basis to support the proposed restriction as demonstrated in the justification supporting this opinion.

Opinion to be used when RAC does not support the proposal

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope)

Guidance[11]
Give under the subheadings below RAC's evaluation of the justification for targeting the restriction and of any grouping of substances (if the Dossier Submitter has done so) - are reasons given for targeting the assessment, or grouping, relevant (eg targeting a certain sector or a certain type of risk). Any general scoping issues can also be covered here. This section can be deleted if not relevant.

Summary of proposal:

Add summary of Dossier Submitter proposal from the Problem identified section (hazard, exposure/emissions and risk) of the Annex XV restriction report to introduce the issues. {To be added by Secretariat before distribution to Rapporteurs.}

RAC conclusion(s):

Give conclusion(s) of RAC.

Key elements underpinning the RAC conclusion:

Add analysis that justifies the conclusion given above[12]*.*

Description of the risk(s) addressed by the proposed restriction

Guidance[11]
Give under the following sub-headings (Information on hazard, Information on emissions and exposures and Characterisation of risk(s)), RAC's evaluation of the hazard/exposure/risk assessment described by the Dossier Submitter, or information submitted in the public consultation, to include, amongst other issues, if RAC agrees with the Dossier Submitter's consideration of:

(a) the relevant CSR submitted by the registrants and justification if the Dossier Submitter's conclusions on hazard(s) or risk(s) deviate from the conclusions in the registration dossiers?

(b) other recognised risk assessment reports (e.g. RARs under the existing substance regulation) or EU scientific opinions (e.g. EFSA, SCOEL) refered to in the Dossier Submitter's assessment?

[11] Such instructions to the Rapporteurs should be deleted when the relevant section has been completed.

[12] The evaluation should be based on the information in the relevant sections of the report and any relevant information submitted in the public consultation.

Information on hazard(s)

Guidance[11]
Considering the guidance above, give RAC's evaluation of the hazard(s) (health, environment, physicochemical) of the substance(s) covered[13] *by the restriction proposal, for example:*

(a) Are there descriptions of the identified hazard(s) and the studies supporting them adequate?

(b) For threshold substances, is RAC of the opinion that the hazards described are relevant and of sufficient adversity to derive a suitable point of departure? Are the DNELs or PNECs chosen relevant and, where relevant, have suitable assessment factors been used? Are the DNELs/PNEC values used by the Dossier Submitter the same as (or different from) in the registration dossier(s)?

This does not require RAC to look for different or lower DNELs or PNECs if the values in the dossier are sufficient to demonstrate a risk.

(c) *For non-threshold substances, has a relevant qualitative assessment been included and any dose response relationship described?*

It may be useful to list the registrations and other risk assessment assessed by the Dossier Submitter and if the relevant parts have been taken into account or not due to relevant information.

Summary of proposal:

Add summary of Dossier Submitter's proposal from the Problem identified section (hazard exposure/emissions, risk) of the Annex XV restriction report.

RAC conclusion(s):

Add conclusion(s) of RAC

Key elements underpinning the RAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

Information on emissions and exposures

Guidance[11]
Considering the guidance above, give RAC's evaluation of emissions and exposures described by the Dossier Submitter or information submitted in the public consultation, for example:

(a) Are the manufacture (import) and uses clearly identified, described and listed in the Annex XV restriction report and do they give a good basis for the exposure/emmissions assessment?

(b) Is RAC of the opinion that the relevant exposure estimates derived for relevant uses and manufacture identified are reasonable?

(c) Are the relevant exposure estimates explained and the models used to calculate them

[13] RAC should not formulate an opnion regarding the elements of the recognised risk assessments or parts of the Chemical Safety Assessment referred to.

described sufficiently (is it clear which risk management measures and operational conditions are assumed in the models)?

(d) Are monitoring data available and described sufficiently to allow evaluation of their representativeness and reliability, or has suitable monitoring been undertaken? Is it clear which risk management measures and operational conditions were applied when monitoring emissions or environmental concentrations?

(e) For PBT and vPvB substances, have relevant emissions been given and are they plausible.

Summary of proposal:

Add summary of Dossier Submitter's proposal from the Problem identified section (hazard, exposure/emissions, risk) of the Annex XV restriction report.

RAC conclusion(s):

Add conclusion of RAC.

Key elements underpinning the RAC conclusion(s):

Add analysis that justifies the conclusion given above[12.]

Characterisation of risk(s)

Guidance[11]
Give an overall evaluation of the risk(s) as described by the Dossier Submitter or information submitted in the public consultation. Risks do not necessarily need to be described on a quantitative basis. Qualitative or semi-quantitative descriptions may be sufficient.

In case the risk assessment shows that the Risk Characterisation Ratio for a threshold substance on its own or in combination with other related substances is above 1 for human health or for environment, the risk is not adequately controlled. However, this is not applicable to non-threshold substances, PBT, vPvB and possible further categories of substances fulfilling the criteria for SVHC. Any uncertainties related to this should be covered in a separate section.

Summary of proposal:

Add summary of Dossier Submitter proposal from the Problem identified section (hazard, exposure/emissions, risk) of the Annex XV restriction report[12]

RAC conclusion(s):

Add conclusion of RAC, to include:

- *Which activities (manufacture and/or use(s) of a substance(s) as such, in mixtures or in articles or waste stage resulting from these) result in emissions or exposures causing the risk?*
- *Which human populations or environmental compartments are at risk?*

Key elements underpinning the RAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

Uncertaintees in the risk characterisation

Guidance[11] *Give the relevant uncertainties here and summarise in the separate section at the end of the justification.*

Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

Add summary of Dossier Submitter proposal from the Problem identified section (hazard, exposure/emissions, risk) of the Annex XV restriction report.

RAC conclusion(s):

Add conclusion of RAC.

Key elements underpinning the RAC conclusion(s):

Add analysis that justifies the conclusion given above.[12]

Evidence if the existing regulatory risk management instruments are not sufficient

Guidance[11] *Give an evaluation if the Dossier Submitter provides evidence that implemented risk management measures are not sufficient.*

Summary of proposal:

Add summary of Dossier Submitter proposal from the Problem identified section (hazard, exposure/emissions, risk) of the Annex XV restriction report.

RAC conclusion(s):

Add conclusion of RAC

Key elements underpinning the RAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Guidance[11] *Give an evaluation if the suggested restriction option is justified on a Union-wide basis. SEAC should be in the lead with input from RAC (from the perspective of risk and risk reduction) if necessary.*

Summary of proposal:

Add summary of Dossier Submitter proposal from the Problem identified (justification for an EU-wide restriction measure) section of the report.

SEAC and RAC conclusion(s):

Add conclusion of SEAC and RAC

{Standard text that can be used if appropriate: Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with {add restriction title} should be implemented in all MS.}

Key elements underpinning the SESEAC and AC conclusion(s):

Add analysis that justifies the conclusion given above[12]

JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

Guidance[11]
Give an evaluation if the suggested restriction option is the most appropriate measure (if the Committees are of the opinion other EU legislation may also be appropriate to reduce the risk, this should be covered in the Background Document).Both Committees should give their opinion here.

Scope including derogations

Guidance[11]
Give here an evaluation of:

(i) the scope of the proposal, according to the Annex 1 of the Framework document, and

(ii) the derogations proposed by both the Dossier Submitter and those that are proposed in the public consultation. Typical derogations that should be discussed for each opinion incude: stocks, 2nd hand articles and recycling. This evaluation should consider:

(a) the risk of introducing a derogation in terms of the human heath or environmental risks and the effect if known on the risk reduction capacity of the restriction (by RAC), and

(b) socio-economic factors given to justify each derogation (by SEAC),

A clear conclusion should be given if the overall scope and if each derogation are supported or not. If the information supplied in the dossier or in the public consultation is not sufficient to make an evaluation, this should be stated in the key elements underpinning the decision.

Justification for the opinion of RAC

Summary of proposal:

Add summary of Dossier Submitter proposal and suggested derogations from the Impact Assessment section of the Annex XV restriction report.

RAC conclusion(s):

Add conclusion of RAC.

Key elements underpinning the RAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

Justification for the opinion of SEAC

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

SEAC conclusion(s):

Add conclusion of SEAC

Key elements underpinning the SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

Effectiveness in reducing the identified risks

Guidance[11] *Give an evaluation of the proposed restriction and other identified restriction options against effectiveness in terms of whether they are targeted to the effects and exposures causing a risk and whether they are capable in reducing the identified risks in reasonable time.*

Justification for the opinion of RAC

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

RAC conclusion(s):

Add conclusion of RAC.

Key elements underpinning the RAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

Socio-economic impact

Guidance[11] *Give an evaluation of the socio-economic impacts of the proposed restriction and of the other restriction options. This evaluation takes into account the available information on availability and technical and economic feasibility of alternatives and available socio-economic assessment of the proposed restriction documented under the Impact Assessment section of the Annex XV restriction report.*

Justification for the opinion of SEAC

Costs

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

SEAC conclusion(s):

Add conclusion of SEAC

Key elements underpinning the SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

Benefits

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

SEAC conclusion(s):

Add conclusion of SEAC.

Key elements underpinning the SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

Other impacts

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

SEAC conclusion(s):

Add conclusion of SEAC.

Key elements underpinning the SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

Overall proportionality

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section of the Annex XV restriction report.

RAC and SEAC conclusion(s):

Add conclusion of RAC and SEAC.

Key elements underpinning the RAC and SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

Uncertainties in the proportionality section

Give the relevant uncertainties here and summarise in the separate section at the end of the justification.

Practicality, incl. enforceability

Guidance[11]
Give an evaluation of such issues as the practicality of any concentration limits and any sampling/test methods/strategy that are necessary to comply with the concentration limits. RAC should be in the lead with input from SEAC if necessary. The Forum advice should be reflected here.

Justification for the opinion of RAC and SEAC

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section (Other impacts, practicality and monitorability) of the Annex XV restriction report.

RAC and SEAC conclusion(s):

Add conclusion of RAC and SEAC

Key elements underpinning the RAC and SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]*, including relevant elements from the Forum's advice.*

Monitorability

Justification for the opinion of RAC and SEAC

Guidance[11]
Give an evaluation of the proposed restriction and other identified risk management options against their monitorability. RAC should be in the lead with input from SEAC if necessary. The Forum advice should be reflected here.

Summary of proposal:

Add summary of Dossier Submitter proposal from the Impact Assessment section (Other impacts, practicality and monitorability) of the Annex XV restriction report.

RAC and SEAC conclusion(s):

Add conclusion of RAC and SEAC.

Key elements underpinning the RAC and SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]*, including relevant elements from the Forum's advice.*

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

Guidance[11]
Give a summary of the uncertainties already raised in the evaluations carried out by RAC and SEAC (RCR and Proportionality section) including any views on the uncertainties raised by the Dossier Submitter.

RAC

Summary of proposal:

Add summary of Dossier Submitter proposal from the Uncertainties section of the Annex XV restriction report.

RAC conclusion(s):

Add conclusion of RAC.

Key elements underpinning the RAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

SEAC

Summary of proposal:

Add summary of Dossier Submitter proposal from the uncertainties section of the Annex XV restriction report.

SEAC conclusion(s):

Add conclusion of SEAC.

Key elements underpinning the SEAC conclusion(s):

Add analysis that justifies the conclusion given above[12]

REFERENCES

Guidance[11] *Include here new references that were not in the Background Document.*