Helsinki, 17/09/2012

RAC/21/2012/11
SEAC/15/2012/05

TWENTY FIRST MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

12-15 JUNE2012

FIFTEENTH MEETING OF THE COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS

13-15 JUNE2012

HELSINKI, FINLAND

Concerns:	**What to make public of opinions on applications for authorisation**
Agenda Point:	**8 b (RAC)** **6 b (SEAC)**
Action requested:	**For discussion**

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Elements of RAC and SEAC opinions and of the Commission's decision on applications for authorisation that would be made public

1. Introduction

Article 69(6) of REACH provides that: *"The Agency shall determine in accordance with Articles 118 and 119 which parts of its opinions and parts of any attachments thereto should be made publicly available on its website."* According to Article 64(9): "*Summaries of the Commission decisions, including the authorisation number and the reasons for the decision, in particular where suitable alternatives exist, […] shall be made publicly available in a database established and kept up to date by the Agency."*

As the Commission decision and the opinions of Committees are interlinked ECHA and relevant Commission services worked together to coordinate the approaches to determine the dissemination policy of ECHA opinions on applications for authorisation (AfA) and the Commission's authorisation decisions. The purpose of this note is to inform what information from ECHA Committees' opinions should be made public on ECHA's website and how this relates to the Commission's decisions.

This note has been prepared in conjunction with the note on what will be made public by ECHA as "Broad Information on Uses" for the consultation on alternative substances or technologies.

ECHA has also consulted the Management Board Advisory Group on dissemination on 16 May 2012. The outcome of that consultation is reflected in this note and in the short presentation made on the issue at the Stakeholders' Day on 23 May 2012.

2. Parts of the Commission's decision to be made public

Article 64(9) of REACH provides that a summary of the Commission decision shall be published in the Official Journal. The Commission may publish more detailed information (i.e. the decision itself) on its website, too, in which case the summary could be very short. What is of importance in this note is what information is public in nature.

In next section, the details of what to make public of the RAC and SEAC opinions are described.

3. Parts of RAC and SEAC opinions to be made public

This section discusses which parts of the RAC and SEAC opinions[1] would be made publicly available after adoption.

[1] As the RAC and SEAC opinions serve the same (single) decision by the Commission they should also be given in one document, as is the case in the restrictions procedure. Thus, while there are two opinions the applicant is likely to get one document containing them. Whether one or two documents, the issues relating to confidentiality are the same.

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Annex 1 lists the elements of the RAC and SEAC opinions that could be made public or kept confidential. The basic idea is to clearly indicate which information will always be made public, keeping in mind that any annexes to the opinion will not be made publicly available as these are not essential for the understanding of the opinions and they are very likely to contain confidential business information. Annexes are to be subject to Access to Documents (ATD) requests, though.

Given that the name of the applicant is made public during the consultation on the alternatives[2] they will be made public as part of the opinion.

RAC and SEAC opinions themselves are based on the standard phrases that have been agreed upon in the opinion template agreed by RAC and SEAC[3]. The opinions themselves should contain very limited amount of confidential information. Furthermore, the opinions need to include *various dates* reflecting when different milestones in the opinion making process were reached. They are public to demonstrate that the legally binding deadlines have been respected during the opinion making process.

It has been decided in other REACH processes that *the names of the rapporteurs* will not be disclosed during the opinion making process. However, the names will be made public when the opinion is made public.

The *justifications of the opinion* will be based on the non-confidential summaries of different elements in the application forms, prepared by the applicant. These will also be made public as part of the opinions of RAC and SEAC. A summary of justifications would facilitate the drafting of the reasons for the Commission decision and their translations to all EU languages. Therefore this will be added to the template.

The *substance name, CAS and EC numbers and the brief wording of the uses applied for* (part of the Broad Information on Uses) will be made public. These have been disclosed during the public consultation on alternatives.

The Committees may specify in their opinions *additional risk management measures* or *monitoring arrangements.* These are to be written in such a manner that that they do not contain business confidential information.

Moreover, the following elements of the AfA opinion will be made public:

- *Reference number,* on which the authorisation number will be based if authorisation is granted.
- *The recommended duration of the review period* for the authorised use to be [e.g. 4, 8 or 12] years.
- *Wording of opinion's adoption* (by consensus or majority).

The detailed description of the uses applied for, for which authorisation is granted, should be confidential. Information on the precise use is normally to be considered to undermine the protection of the commercial interests of the applicant as per Article 118(2) of the REACH Regulation. If the applicant considers that *uses applied for* is not a confidential element, he should include it in the proposed Broad Information on Uses.

[2] See RAC/21/2012/06 and SEAC/15/2012/06.

[3] See RAC/15/2011/08 Revised and SEAC/11/2011/05.

The publication of the RAC and SEAC opinions is planned to take place immediately after adoption[4].

4. Conclusion

The approach taken in this note as well as in the note on what will be made public by ECHA as "Broad Information on Uses" for the consultation on possible alternatives, is in line with ECHA's core values of transparency and efficiency. Before ECHA will publish the opinions as indicated in Annex 1, the opinion template (RAC/15/2011/08, SEAC/11/2011/05) will have to be updated to include the summary of justifications.

[4] This is also the way that the opinions in GMOs (developed by European Food Safety Authority-EFSA) and medicinal authorisations (developed by European Medicines Agency-EMA) are processed.

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Annex 1: Elements of the opinions (public or confidential)

Elements	Public or confidential	Source
(1) The identity of the substance(s)		
Chemicals name	Public	Application
EC No	Public	Application
CAS No	Public	Application
(2) Brief wording of the uses applied for	Public	Application
(3) Name(s) of applicant(s)	Public	Application
(4) Reference number *(Commission's authorisation number will be based on this, if authorisation is granted)*	Public	ECHA
(5) Names of RAC/SEAC rapporteurs	Public	Opinion making
(6) Important dates		
6.1 Date of receipt of the application (i.e. fee)	Public	Opinion making
6.2 Date of publication of the information for consultation on alternatives	Public	Opinion making
6.3 Deadline for submission of comments by interested parties	Public	Opinion making
6.4 Date of sending the draft opinion to the applicant	Public	Opinion making
6.5 Date of comments received from the applicant	Public	Opinion making
6.6 Date of adoption of RAC & SEAC opinions	Public	Opinion making
(7) The RAC & SEAC justifications for the opinion concerning:		*(Non confidential summary)*
7.0 Summary	Public	Opinion making
7.1 The substance being a threshold or non-threshold	Public	Application
7.2 The demonstration of adequate control of risks	Public	Application
7.3 The availability and suitability of alternatives	Public	Application
7.3.1 The risks of alternatives	Public	Application
7.3.2 Technical and economic feasibility of alternatives	Public	Application
7.4 Conclusions on the remaining risk	Public	Application
7.5 Conclusions on the socio-economic benefits and potential adverse effects of the use	Public	Application
7.6 Justification for conditions and monitoring arrangements	Public	Opinion making
7.7 Justification for the suggested review period	Public	Opinion making
(8) "Detailed description of the uses applied for" for which authorisation is considered *(more detailed than (2)) If no concern of confidentiality identical to (2).*	Normally confidential	Application
(9) Suggested conditions and monitoring arrangements		
9.1 Additional conditions or conditions that modify some of the Risk Management Measures and Operating Conditions	Public	Opinion making
9.2. Monitoring arrangements	Public	Opinion making
(10) The recommended duration of the review period for the use to be [e.g. 4, 8 or 12] years	Public	Opinion making
(11) Wording of adoption ("consensus" or "majority")	Public	Opinion making