Helsinki, 01/06/2012

RAC/21/2012/12
SEAC/15/2012/06

TWENTY FIRST MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

12-15 JUNE 2012

FIFTEENTH MEETING OF THE COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS

13-15 JUNE 2012

HELSINKI, FINLAND

Concerns:	**Public information in the process of applications for authorisation**
Agenda Point:	**8 b (RAC)** **6 b (SEAC)**
Action requested:	**For discussion**

Helsinki, 1 June 2012

What will be made public by ECHA as "Broad Information on Uses" for the consultation on alternative substances or technologies?

1. Introduction

The REACH Regulation contains the following provisions that stipulate what type of information shall be made publicly available during the authorisation process:

- "*The Agency shall make available on its web-site broad information on uses, taking into account Articles 118 and 119 on access to information, for which applications have been received….*" (Art. 64(2))
- "*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 available on its website*." (Art. 64(6))
- "*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.*" (Art. 64(9))

In the past months, ECHA has worked with its stakeholders to gather different views on how to implement these provisions. In this context, in particular, the scope of the notion "broad information on uses" (BUI) for which authorisation applications have been received has given rise to extensive discussions.

In accordance with Article 64(2) of the REACH Regulation, ECHA shall give third parties the possibility to submit information on alternative substances or technologies to it by making "broad information on uses" for which an authorisation is requested publicly available on its website. In this context, the notion "broad information on uses" is not further defined in the REACH Regulation. Any interpretation of this notion will thus need to take into account the objective pursued by the provision. To the extent that publication of use information is necessary to achieve the objective of Article 64(2), the REACH Regulation also foresees derogation from the general presumption that disclosure of the precise use shall normally undermine the commercial interest.

The aim of the publication of "Broad Information on Uses" (BIU) is to receive from interested third parties meaningful information on alternative substances or technologies for the "uses applied for" in an application for authorisation. In addition to the information contained in the application, the comments received on alternatives from third parties will help ECHA's scientific committees (Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC)) to evaluate the application. This evaluation will be part of their opinions on the authorisation applications or reviews of authorisation.

ECHA has on several occasions organised meetings with stakeholders to receive input on what type of information would be needed to enable third parties to provide meaningful information on alternative substances or technologies to ECHA. At these occasions also the possibility to make other – not strictly use related - information publicly available without infringing legitimate rights or interests of applicants were

considered.

This note presents the results and the key principles used for the development of the Broad Information on Uses, which will be published during the public consultation on alternatives. It has been developed by the ECHA Secretariat in consultation with the relevant Industry, NGOs/Trade Union stakeholders, the Commission services and the Management Board Advisory Group on dissemination. This note has been prepared in conjunction with the note prepared for the June 2012 meetings of RAC and SEAC on what to make public of RAC and SEAC opinions.

2. Summary of discussions with stakeholders

ECHA met with representatives of NGOs and trade unions in July 2011 and industry in November 2011 to discuss activities related to the publication of information from and during the authorisation application process under the REACH Regulation. These meetings were an opportunity for ECHA to understand better the views of NGOs, trade unions and industry on ways to ensure the right balance between the meaningfulness of the BIU and the protection of Confidential Business Information (CBI) and other sensitive information.

ECHA held a consultation meeting with the representatives of NGOs, trade unions and industry in Brussels on 16 April 2012. The purpose of this meeting was two-fold: to update stakeholders on i) how ECHA and the Commission are planning to make public information from the Commission decision and the opinions of the ECHA Committees; and, ii) the content of BIU during public consultation on alternatives. An additional objective was for ECHA and the Commission to consult stakeholders on their views on the approaches for BIU proposed by ECHA. The views of stakeholders present at the seminar on 16 April 2012 were rather convergent and allowed the ECHA Secretariat to prepare draft conclusions on the issue.

ECHA consulted the members of the Management Board Advisory Group on dissemination on 16 May 2012. The advisory group supported the conclusions presented in this note. These conclusions were also presented at the Stakeholders' Day on 23 May 2012.

Based on the input received in the meetings with stakeholders, the current note describes which information ECHA intends to make available during the public consultation aiming at the collection of information on alternatives.

3. Procedural elements

Overall, the public consultation on alternatives for the uses applied for has tight deadlines so that ECHA's Committees can adopt their draft opinions in ten months, as specified in REACH. The following procedural elements need to be taken into account:

- The ECHA Secretariat needs to define the Broad Information on Uses (BIU) from information in the applications in a short period of time (some weeks).
- Third parties have eight weeks to give information on the alternatives during public consultation based on the BIU published by ECHA.

- The ECHA Committees do not have a lot of time to evaluate the suitability of alternatives from assessments made by applicants and third parties.
- The ECHA Committees need to send quickly (and in a structured and efficient manner) any follow-up requests or requirements for additional information to third parties.

The different sets of information (assessments in the application, the BIU, third parties' comments) need to be focussed, well structured and easy to compare.

The difficulty is also to find the right balance between meaningfulness of the BIU and the disclosure of CBI and/or information falling under the scope of competition law. The meaningfulness of the BIU is driven by the type of information to be disclosed and its level of detail.

4. Type of information - provided in the application - that can be published

4.1. Information on uses and functions of the SVHC

In order to provide meaningful information on alternatives during the public consultation, third parties need to have information on:

- Where the SVHC is used and/or ends-up (market sectors, life-cycle stages, service-lives).

- How the SVHC is used: conditions of use i) related to exposure as described in the exposure scenarios, and ii) related to the functional requirements as described in the AoA.

- What function(s) is performed by the SVHC. A brief description of the function (softener, flame retardant, etc) can be provided with the use name and the descriptors. However, more detailed analysis of the SVHC's functional requirements (exact tasks, critical properties, critical process conditions under which these tasks are delivered, quality criteria for end-products, etc) will normally be documented in the AoA.

This information is to be considered as part of the BIU (see section 5).

4.2 Information on alternative substances or technologies

In addition to the analysis of the function of the SVHC, the AoA will also contain a list of possible alternatives, an analysis of their suitability (technical feasibility, economic feasibility, reduction of overall risks) and availability, and a description of the applicant's R&D activities to identify possible alternatives.

While this information is not directly related to the "uses applied for" of the SVHC, information about which alternatives were considered by the applicant may be useful for third parties to focus their comments e.g. on alternatives not evaluated by the applicant. However, the analysis on suitability and availability, and the description of

R&D activities by the applicant are likely to contain very sensitive information (e.g. market analysis, equipment costs, supply chain relationships, precise volumes and prices of substances, etc) which is likely to be CBI and/or raise competition law issues.

4.3 Information from the Substitution Plan and Socio-economic Analysis

The Substitution Plan (SP) and Socio-economic Analysis (SEA) may not always be included in the application. For instance, no SP is necessary if the applicant could not identify suitable alternatives; and a SEA might be of limited value for an application under the "adequate control" route. Furthermore, SP and SEA are unlikely to contain any additional information on how the SVHC is used. Finally, while the AoA may contain business sensitive information, it is clear that SP and SEA will almost certainly contain very commercially sensitive information.

4.4 The name of the applicant

The REACH Regulation states that ECHA is responsible for publishing BIU. However, the REACH Regulation does not explicitly state if the name of the applicant should or should not be made public when it consults on alternatives based on the BIU. Different arguments were considered when ECHA decided whether the names of applicants should be made public at the stage of the public consultation on alternatives. These were:

- Making the name of the applicant public does not *per se* add value to the public consultation on alternatives: the consultation would be meaningful with or without the knowledge of who is applying.
- Making the name of the applicant public may put in question the equal treatment of applicants, although it was not clear why this would be the case.
- Making the name of the applicant public would adhere to ECHA's value on transparency.
- The name of the applicants is public already before the opinion making process in other EU's legislative processes, which are similar to the REACH authorisation. These are EU Regulations on GMOs ((EC) 1829/2003) and medicinal products for human use ((EC)726/2004)).
- Making the name public would make the application for authorisation process more efficient than keeping the name confidential. If the name is public, the ECHA Committees can handle the applications in a more straightforward manner and no coding or masking would need to take place.
- In some exceptional circumstances making the name(s) of the applicant(s) public could be deemed to reveal CBI. However, while theoretically possible, ECHA has not been able to identify such instances in practice.

ECHA has concluded that – also in line with other similar EU wide regulations and supported by the Management Board Advisory Group on dissemination on 16 May 2012 – it will make public the name of the applicant when it launches the public consultation.

This policy adheres to ECHA's core values of transparency and efficiency. ECHA will make this policy very clear to all applicants so that they are fully aware of the manner in which ECHA will carry out the public consultation on alternatives.

Helsinki, 1 June 2012

5. Broad Information on Uses

The following information is submitted in the application:

- Identity of the SVHC (chemical name, CAS/EC numbers);
- Uses of the SVHC (uses names, descriptors) and function(s);
- Chemical Safety Report (CSR) including exposure scenarios (ES) covering the uses;
- Analysis of Alternatives (AoA);
- Substitution Plan (SP);
- Socio Economic Analysis (SEA);
- Name of the applicant(s) (see 4.4).

Information on use of the SVHC (= use applied for) consists of the following:

- Name of the use applied for as provided in the application;
- Conditions of use:
  - related to exposure, as provided in the ES;
  - related to functional requirements, as provided in the AoA;
- List of descriptors (codes, brief description of the function).

In order to ensure a meaningful public consultation on alternatives, ECHA will publish **"Broad Information on Uses"** and additional supporting information. It will publish the following:

- Brief wording[1] (see Table 1) based on:
  - Use name;
  - Key elements of conditions of use (exposure and functional requirements);
  - List of descriptors (codes, brief description of the function);
- Public version of the ES (as provided in the application);
- Public version of the AoA (as provided in the application);
- Public version of the SP (if provided);
- Public version of the SEA (if provided);
- The name of the applicant.

Table 1 illustrates the possible differences between the information to be made publicly available (i.e. brief wording for the BIU) and possibly confidential information. For instance, the operating conditions in the process (exact temperature or concentration of substance) can be considered confidential, and would be illustrated e.g. by ranges in the public version.

[1] ECHA has established a procedure to define the brief wording for BIU. This technical/procedural issue is not addressed in this note.

Table 1: Example of a brief wording for BIU vs possibly confidential information

	Public	Possibly confidential
Use name	*"Industrial use as a pigment in paints to be applied by spraying techniques onto wood and plastic articles"*	*"Industrial use as a pigment in water-based paints to be applied by HPLV spraying techniques onto wood and plastic furniture"*
Key elements of the conditions of uses (exposure and functional requirements)	Concentration of SVHC in paints is 20-30%. Paints can be applied at low temperatures with an average drying time of less than 8 hours	Concentration of SVHC in water-based paints is 25%. Water-based paints can be applied at temperatures ≤ 15 ºC (limit = 5 ºC) with an average drying time at 15 ºC of less than 8 hours
List of descriptors codes Function	**SU3**: industrial uses **PROC7**: industrial spraying **ERC5**: industrial use resulting in inclusion into or into a matrix **AC11; 13**: wood, plastic articles Pigment with high resistance to UV	Identical

6. Conclusions

This note describes what information ECHA will make public. Such information would thus, contain details on the use and conditions of use of the SVHC, the analysis of its function and the suitability of possible alternatives assessed by applicants. The public summaries of the SP and SEA, if provided, would supplement the other information made available for the purpose of a public consultation. The name of the applicant will also be published.

With this approach, the information to be made publicly available for the purpose of the public consultation on alternatives would be relatively easy and quick for ECHA to prepare, and ECHA should be in a good position to publish a focussed information package, which does not contain any confidential information.

This information will help third parties to focus their comments and analysis better, which in turn will help the Committees to save time in evaluating the information and requesting additional information (either from the third party or from the applicant).

It is also in the interest of the applicant to provide meaningful public information in his application so that third parties submit only relevant information. Unrelated information/comments might also generate work for the applicant in clarifying issues raised or addressing any resulting confusion or misunderstanding on the part of the Committees. Limiting the number of such comments will help to reduce the administrative burden on the Committees of evaluating comments and on the applicant of making his case.

Once the public consultation has started, ECHA also foresees to relay to the web all non-confidential and valid comments received from third parties so that the applicant and other parties can transparently see what the information was and give, thus, an opportunity for the applicant to react/comment them as he feels fit. The potential voluntary follow-up information from the applicant could also contribute to help the Committees in developing their targeted requests for additional information. When making public the opinions, it needs to be demonstrated how the comments had been taken into account.

7. Follow-up actions

- ECHA will make clear to all applicants in advance that it will make public the exposure scenario so that the applicant can provide a public and up-to-date version of it as part of its application.
- ECHA will update the format of the existing template[2] for the AoA on ECHA's website to reflect the approach on Broad Information on Uses.
- ECHA will make clear to third parties that the non-confidential comments received during the public consultation will be posted on ECHA's website.
- ECHA is currently developing a template for third parties to submit their comments on alternatives. ECHA intends to consult stakeholders with whom it collaborated up to now on the usability of these templates. They need to be practical, i.e. easy to fill, and set out in such a manner that it is absolutely clear what information is public and what is confidential.
- ECHA will update the related web pages and web forms.

[2] ECHA's existing templates for CSR, AoA, SP and SEA are available in the section "Preparing an application" at http://echa.europa.eu/web/guest/applying-for-authorisation.