Helsinki, 14 December 2012
RAC/23/2012/06 (Rev. 1)
SEAC/17/2012/06 (Rev. 1)

23RD MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

27-30 NOVEMBER 2012

17TH MEETING OF THE COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS

03-05 DECEMBER 2012

HELSINKI, FINLAND

Concerns:	**Participation of applicants, third parties and stakeholder observers in the application for authorisation process**
Agenda Point:	**7.1.b (RAC)** **7 b (SEAC)**
Action requested:	**For information**

PREFACE

This note defines ECHA's approach to the participation of applicants, third parties and stakeholder observers in the application for authorisation process. It is consistent with ECHA's key values of transparency, trustworthiness and efficiency. The approach has been discussed with RAC and SEAC and endorsed by the Management Board.

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Participation of applicants, third parties and stakeholder observers in the application for authorisation process

Introduction

The ECHA Secretariat has discussed the participation of applicants and representatives of stakeholder organisations in the authorisation process with the Management Board and the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) on several occasions during 2012. Based on these discussions ECHA has established the following approach to this participation.

The purpose of this note is twofold. First, to clarify the role of applicants, third parties, and stakeholder observers in the opinion-forming process, including their interaction with Rapporteurs and the Committees, so that it is clear for all parties, including RAC and SEAC members, what role these actors play in the different stages of the process. Second, the note describes how the identification and protection of confidential business information are handled in the application for authorisation (AfA) process.

Application case 'trialogue'

The basis for the Committees' opinion development is the documentation provided by the applicant as part of the AfA process. Aside from the application itself, applicants for authorisation may contribute to the authorisation process through their responses to Committees' requests for additional information through the Rapporteurs and through their ability to comment on the draft opinions. However, Committees do not currently have the opportunity to discuss issues raised by an application with applicants in an interactive and discursive way. In addition, the public consultation could generate additional information on possible alternatives, and there will be a need for the Committees to understand the significance of this information within the specific context of the application.

To meet this possible need for additional discussion, an application '***trialogue***' between the applicant and the RAC and SEAC rapporteurs will be established in the opinion-making procedure. This trialogue will allow rapporteurs, to discuss with applicants any information on alternatives generated through public consultation or any other technical or scientific issues with the application. The trialogue should be held after the conclusion of the public consultation so that rapporteurs can explore with applicants (and third parties) the significance of any relevant information received. It should be held sufficiently in advance of the second Committee plenaries as to allow good time for the likely role of confidential business information (CBI) in Committee deliberations to be assessed (see Figure 1).

Rapporteurs will also be able to invite those third parties who submitted information to the public consultation which is of particular interest and relevance to the application. Stakeholder observers of RAC and SEAC will be invited to attend the trialogue to provide scrutiny and transparency, although applicants and third parties will have the opportunity to argue that information to be discussed is confidential and that observers should be excluded from any parts of the meeting when that information might be discussed.

The format of the trialogue should be flexible to the opinion-making needs of the application and the complexities involved, as well as to logistical and financial concerns. It may therefore take place in person, or through video- or teleconference. No trialogue need be held if there are no open questions and no issues have been raised during the public

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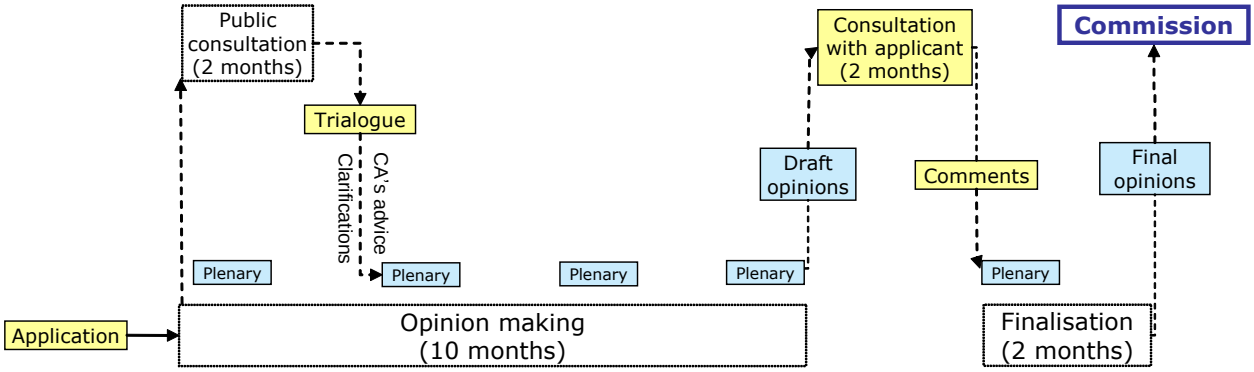
consultation. The ECHA Secretariat will develop general, experience-based criteria for indicating when a trialogue is normally expected, but leave enough flexibility for rapporteurs, in consultation with with the ECHA Secretariat and Committee Chairs, to decide on a case-by–case basis.

Figure 1: Timing of the Application case 'trialogue' in the opinion making procedure



Committee management of cases according to the expected role of confidential business information

The authorisation process is a novel procedure which could attract controversy because it will determine whether or not businesses can continue to use substances of very high concern. For this and more general reasons of good governance, it is important to establish an open and transparent opinion-making process which can be subject to outside scrutiny by relevant stakeholders on the part of their constituencies and the general public. However, applications for authorisation might contain significant amounts of CBI[1], and there is a need to strike the right balance between transparency and the need to protect confidentiality.

The existing rules governing the participation of stakeholder observers in RAC and SEAC (e.g. Code of Conduct for Observers at ECHA Meetings (Art 12/13), RAC/SEAC Rules of Procedure, Article 6(12)) require that the regular disclosure of CBI to stakeholder observers should be avoided. To this end, Committee Chairs can close plenary discussions to stakeholder observers at any time if they consider that there is a chance that CBI might otherwise be disclosed (RAC/SEAC RoPs Article 6(11).

In case discussions where CBI does not play a key or frequent role, it should be practically and logistically feasible to close sessions on an *ad hoc* basis when CBI might feature. However, if CBI does play a key or frequent role, it will be difficult for the Committee Chairs to manage cases in such a way that stakeholder observers are always excluded from those parts of discussions featuring CBI whilst allowing them to observe other parts. In such cases it will also be more difficult to ensure that CBI is not disclosed accidentally in the course of proceedings.

Definition of cases as 'observed' or 'non-observed'

To facilitate appropriate management, each authorisation case will be given a definition of ***'observed'*** or ***'non-observed'*** on the basis of an assessment of the likelihood that Committee deliberations of the case will employ reference to CBI. The exact criteria for

[1] See Annex 1 for a discussion of the definition of CBI.

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defining a case as 'observed' or 'non-observed' are to be determined. However, as a general principle, if there is a high probability that CBI will play a key or frequent part in Committees' discussions, it is more likely that the case will be defined as 'non-observed'. If the probability is low that CBI will play a key or frequent role in Committees' discussions, it will be more likely that the case will be defined as 'observed'. The Committee Chairs will manage Committee plenary discussions of individual cases on the basis of whether the case has been defined as 'observed' or 'non-observed' (see below).

ECHA will nominate a member of staff to assume the new role of ***Confidentiality Advisor***, who will make an assessment on the definition of each case. Applicants will be allowed to make a representation in respect of the definition of their case. The Confidentiality Advisor's advice will be based on an assessment of the information contained in the application and of that submitted through public consultation, on discussions with rapporteurs, on experience of the discussions at the trialogue and on any representation made by the applicant.[2] To permit as much open discussion as possible, the Confidentiality Advisor will encourage rapporteurs to reply on CBI for their deliberations only where necessary, and will scrutinise applicants' (and third parties') claims as to the confidential status of their information.

This assessment should occur after the conclusion of the public consultation, and sufficiently in advance of the second Committee plenaries as to be able to facilitate the appropriate management of the case in those plenaries. The format of the assessment will be flexible. It will be expected to occur as part of the trialogue, if one is held. This might be in person or by video- or teleconference.[3]

The Confidentiality Advisor's assessment will be given in the form of written advice to the Committee Chairs. On the basis of this advice, the Chairs will decide whether they will manage the case in question as 'observed' or 'non-observed', and disseminate this decision to the Committees via the agendas for the second Committee plenary meetings. The Secretariat will inform the applicant of the Chairs' decision at this point.[4]

Stakeholder observers' participation in Committee meetings

The Chairs of RAC and SEAC will invite accredited stakeholder representatives to the plenary sessions for 'observed' cases. Stakeholders' presence in the absence of applicants could lead to claims of unfair hearing, especially if they were permitted to comment on the cases. Therefore, stakeholders will be allowed access strictly as observers only with no speaking rights and no right to be accompanied by expert advisers.

To ensure consistency with the existing ECHA Code of Conduct, the Committees Rules of Procedure and current practice in the Committees, they will not have access to documents which contain CBI, and will be excluded from any part of the meeting where CBI will be discussed.[5] The possibility remains that CBI might be disclosed accidentally in the course of Committee discussions, in which case existing provisions in the Committees Rules of Procedure governing confidentiality will apply.

[2] There might also be a case for allowing representation by third parties as to the appropriate classification of the case, if they contribute information through the public consultation which they consider to be CBI. The Confidentiality Advisor could then assess whether the inclusion of this CBI in the Committees' discussions merits any subsequent need to define the case as 'non-observed'. The views of the rapporteurs on the potential significance of this information to their opinion-making will be taken into account in the discussions, as relevant. This issue will be given further consideration.
[3] If no trialogue takes place, the assessment might be undertaken in correspondence.
[4] As with other aspects of ECHA's operations, interested parties have the possibility of raising this issue with the Executive Director.
[5] It remains to be decided what access stakeholder observers should have to documents which do not contain CBI but which might still be regarded as confidential.

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The Chairs of RAC and SEAC will not invite the stakeholder observers to the plenary sessions for 'non-observed' cases. For these cases, stakeholder observers will receive a non-confidential ***briefing*** in open sessions on the progress of the Committees' discussions and any significant issues which have been raised. ECHA will consult with stakeholder representatives to ensure that the briefing meets their needs as far as possible whilst maintaining standards regarding the management of CBI.

Stakeholder observers will continue to be invited to non-case-specific Committee meetings related to applications for authorisation as currently.

Applicants' observation of plenary discussions of their cases

The 'trialogue' has been established as part of the opinion-making procedure to give a possibility for the RAC and SEAC rapporteurs to discuss with the applicant if such need arises either through the identification of issues by the Committees or due to issues raised during the public consultation.

Member States Committee experience demonstrates that applicants' attendance at plenary meetings of the Committees at which their case is discussed would add to the administrative burden associated with running the meetings. When the application for authorisation system is up to speed, it is possible that, in any given RAC or SEAC meeting, in the order of 50 or 100 applications could be on the agenda. Applicants would add a potentially very large number of attendees to each Committee meeting, and proceedings would need to be halted after each case to allow applicants to leave and enter the session. This alone could add hours to the time required to complete Committee business, on top of any other tasks they must complete. Even if applicants could be accommodated in the shorter term when the numbers of applications might be more manageable, this would not be sustainable in the longer term due to the considerable inefficiency that this would entail.

As the 'trialogue' has been designed to address significant issues in a transparent, trustworthy and efficient manner, and as having the applicants participate in the plenary meetings would entail significant inefficiency, Committee plenary sessions where individual applications for authorisation are to be discussed will be closed to applicants.

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ANNEX 1: What is confidential business information

The definition of confidential business information (CBI) is important since its scope will directly affect the probability that a case will be classified as 'observed' or 'non-observed'. ECHA will guide RAC and SEAC on what constitutes CBI in the context of applications for authorisation. The purpose of this annex is to provide a general understanding of what could constitute CBI. It is not meant to provide a legally binding definition of this concept. [6]

Article 118(2) of the REACH Regulation describes what normally shall be considered CBI within the context of the Regulation. In general, CBI is information which provides an enterprise with an economic benefit that translates into competitive advantage. This advantage directly derives from the fact that the information is generally unknown to competitors for whatever reasons, including the efforts of its owner to keep it secret.

CBI typically has the following characteristics: (1) the information is only known to a limited number of persons (i.e. not in the public domain or general knowledge in the industry); (2) the information has commercial value or represents legitimate commercial interests at stake; and (3) disclosure may cause harm to the applicant's or another entity's interest.

Examples of information that could potentially constitute CBI include:

- trade secrets and intellectual property, e.g., information relating to formulas, patterns, devices or other compilation of information that is used for a considerable period of time in a business (e.g. an exact formula or a composition of a mixture);

- technical information used in the manufacturing process for production of goods, including software used for various business purposes (e.g. a company's IT software system to reduce the production time);

- business secrets, e.g. technical and/or financial information relating to a company's know-how; methods of assessing costs; production secrets and processes; supply sources; quantities produced and sold; market shares; customer and distributor lists; cost and price structure; marketing, export or sales strategies; or a method of bookkeeping or other business management routines;

- Other information may include financial information (e.g. business plans), purchase prices of key raw materials, product specifications, test data, technical drawings or sketches, engineering specifications, contents of workbooks, the salary structure of a company, any kind of agreement, promotional or marketing material under development, and the like.

Applicants are required to identify in their applications which information they consider confidential. This can be used as the starting point for any confidentiality assessment, but there is a need to be able to challenge applicants on the definitions they use to ensure they do not use it routinely to avoid any disclosure, as this would reduce transparency and make it more difficult to run a meaningful public consultation. In addition, new information might be input into the case via further requests or the public consultation, and there will be a need to classify this information also as confidential or non-confidential.

[6] Sources for this section include case-law of the European Court of Justice, the WTO agreement on TRIPS and the document "How to manage confidential business information " of the Helpdesk of the Executive Agency of Competitiveness and Innovation (EACI) (July 2012) available at http://www.iprhelpdesk.eu/sites/default/files/newsdocuments/How_to_manage_confidential_business_information.pdf

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