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RAC/10/2010/12
SEAC/06/2010/07
(Agreed at RAC-10 and SEAC-6)

FRAMEWORK FOR DEALING WITH REQUESTS FOR OPINIONS ACCORDING TO ARTICLE 77(3)(c) OF THE REACH REGULATION

1. INTRODUCTION AND LEGAL BASIS

The role and tasks of ECHA's Committees are described in Title X of the REACH Regulation. According to Article 77(3), apart from the tasks allotted to the Committees under Titles VI to X (incl. authorisation and restrictions), the Agency Committees may also be asked by the Executive Director of ECHA (ED) to draw up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles (Article 77(3)(c)). This applies also to the cases where the Commission wishes to get an opinion on specific issues related to chemical safety.

Article 77(3)(b) of the REACH Regulation provides that the ED may request the Agency Committees to provide technical and scientific support to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries.

It appears that an opinion may also be requested under the framework of Article 77(3)(b). If that would be the case, such opinions would be prepared in the same way as opinions requested under Article 77(3)(c). At this point in time, however, requests for opinions under Article 77(3)(b) are not seen as very likely.

This document is primarily addressed to RAC and SEAC. The two Committees draw up their opinions according to similar procedures, and it is also likely that, in particular where the requests are related to the restriction or authorisation processes, RAC and SEAC may be asked to prepare an opinion on the same issue, taking the specific qualifications and remits of the respective Committee into account. That would require close cooperation between the Committees in preparation of the opinion. The justification for the involvement of a particular Committee will be stated in the request by the ED.

Requests for opinions under Article 77(3)(c) may or may not be urgent. For non-urgent requests, timetables will be developed applying standard deadlines and best practice as described in the Committee working procedures. Urgent requests, on the other hand, may require shorter deadlines, omission or merging of certain steps of standard procedures, or other ways of speeding up of the process without compromising the scientific quality of the opinions or the proper involvement of Committee Members. The Secretariat will provide a justification for dealing with certain requests as urgent. This document describes the treatment of non-urgent requests as well as offering possible solutions for urgent cases.

2. DEVELOPMENT OF RAC AND/OR SEAC OPINION FALLING UNDER ARTICLE 77(3)(c)

Ensuring preparedness

The timing and the work required from the Committees for requests made under Article 77(3)(c) of the REACH Regulation may be difficult to anticipate beforehand. Prior to the request being issued, the Secretariat will go through the documentation to be submitted to the Committee(s) to make a preliminary evaluation of its adequacy in relation to the tasks to be mandated by the request and the timelines to be proposed. The Secretariat will also assess whether third parties need to be engaged in the process to provide additional information and that this is appropriately taken into account when planning the work to be carried out by the Committee(s). When appropriate, the Secretariat will alert stakeholder observers and other third parties about the potential need for additional information on the issue at stake.

In order for the Committee(s) to be able to react to such requests swiftly, the Secretariat will inform RAC and SEAC as early as possible about the content of potential upcoming requests. If possible, information on which Committees will be asked for an opinion, the likely timing of the request to be issued, and the timetable for drawing up the opinion will also be provided. At this point of time, the Secretariat will also endeavour to identify members familiar with or interested in the subject. For heavy workload requests the Secretariat may propose the use of co-opted members as (co-)rapporteurs.

Appointment of (co-)rapporteurs

To appoint a (co-)rapporteur for an opinion requested under Article 77(3)(c), the Secretariat shall launch a procedure for the appointment of (co-)rapporteurs in line with Article 17 of the Committee Rules of Procedure (RoPs). If time is available, the procedure for the appointment of (co-)rapporteurs will be started only after the official request has been issued. In urgent cases, the Secretariat will launch a procedure for the appointment of (co-)rapporteurs once the Committee(s) have been informed about the (potential) upcoming request for drawing up an opinion. In addition to the appointment procedure presented below, basic principles described in the working procedures for appointment of rapporteurs and co-rapporteurs agreed by RAC and SEAC will be followed to the extent possible. The timelines of the appointment process may be adjusted depending on the expected deadline for the development of the opinion. In urgent cases, the period for responding in the written procedure can be shortened according to the RoPs requirements for urgent procedures.

Upon the Secretariat's call for expression of interest to act as a (co-)rapporteur for the request in question, the Committee members can express their interest to the Secretariat and confirm their availability. The Secretariat will verify whether there are any considerations for excluding any of the candidates, applying the principles described in the above mentioned working procedures.

The Secretariat will contact the candidate(s) in order to clarify any other relevant considerations. If necessary, the Secretariat may request further information from the candidate(s).

When there are no expressions of interest received within a set deadline, the Secretariat will identify suitable candidates on the basis of CVs, the overall competence grid and taking the selection criteria into account.

The Secretariat will draw up a recommendation and seek the agreement of the relevant Committee on its recommendation in a written procedure or at a suitable plenary meeting; if necessary before the request is issued. When preparing its recommendation,

the Secretariat will apply the selection criteria described in the above mentioned working procedures as well as consider the workload of individual members.

In cases where the time available for drawing up an opinion is very limited, the Committee Chair may identify potential (co-)rapporteurs by reviewing their CVs and expertise grids and invite member(s) directly to act as (co-)rapporteur(s).

In all cases, the Secretariat will formalise the appointment of (co-)rapporteurs by a letter of appointment which will be sent to the (co-)rapporteurs as soon as the formal request has been issued and the rapporteurs have been appointed by the Committee.

The remuneration of (co-)rapporteurs will be decided on a case-by-case basis prior to the call for expression of interest according to applicable rules.

Work plan

The Secretariat will draft a short work plan for development of the opinion for the cases when existing Committee procedures cannot be applied due to different nature of the case or due to its timelines. The Secretariat will draft the work plan as soon as it is fairly certain that a request by the ED will be issued. The work plan will briefly describe the main steps to be undertaken by the (co-)rapporteurs, the Committee(s) and the Secretariat and the timelines in order to produce the opinion within the deadline set in the request by the ED. If needed, the timelines for urgent cases specified in the respective Committee Rules of Procedures may be applied. The Secretariat will ensure that the timelines are sufficient to allow Committee members to provide their input to the (co-)rapporteurs and that the consultation of the third parties, if relevant, takes place early enough in the process. When the (co-)rapporteur(s) have been identified, they will be consulted on the work plan.

Whenever possible, the work plan will be finalised at the latest by the time when the formal request is issued and will be made available to the relevant Committee(s). The work plan may, if relevant, be revised in the course of the work.

Possible elements to include in the work plan for development of the opinion

The work plan for development of the opinion may contain the elements described below.

Appointment of (co-)rapporteur(s)

The appointment process described above may be included in part or in full in the work plan, depending on if it started before or after the formal request had been referred to the respective Committee, in particular where it differs from the procedures laid down in previously agreed working procedures.

Referral of the request and the documentation to the Committee

The request by the ED and the documentation to be evaluated by the Committee in question will be made available to the Committee without delay.

Adequacy evaluation

As soon as the official request has been issued, the (co-)rapporteur(s) have been appointed by the Committee and the request with relevant documentation has been referred to the Committee(s), the (co-)rapporteur(s) will check whether the documentation provided with the request and the information intended to be generated from third parties during the process as stipulated by the work plan is adequate to carry out the task specified in the request.

The (co-)rapporteur(s) should document the outcome of the evaluation by listing observed shortcomings in the documentation or the information assumed to be provided

in the process. Where the required information assumed to be obtained from third parties is considered insufficient, the (co-)rapporteur(s) shall propose changes to the work plan to address the information gaps.

If time is available, the (co-)rapporteur(s) will provide the outcome of the adequacy evaluation to the Committee for comments. The (co-)rapporteur(s) will consider the comments when finalising the outcome of the adequacy evaluation. The Secretariat will communicate the outcome of the adequacy evaluation to the submitter of the documentation to complete the documentation if needed and/or take steps to accommodate the proposed changes in the work plan.

When the adequacy evaluation is completed, the Committee(s) will proceed with the opinion development.

Establishment of ad-hoc working group(s) to support the (co-)rapporteur(s)

If needed, ad-hoc working group(s) may be established to support the (co-)rapporteur(s) in their task. The (potential) (co-)rapporteur(s) or the Secretariat may flag the need for an ad-hoc working group at any point in time. If such group is considered necessary, the Secretariat will prepare the mandate of the working group. The Secretariat will consult the mandate and the composition of the working group with the (potential) (co-)rapporteurs whenever possible. The Secretariat will normally organise a call for expression of interest to act as a member in the working group, at the earliest after the Committee(s) have been informed about the potential upcoming request, but ideally after the recommendation for the (co-)rapporteur has been agreed by the Committee. If the request is urgent, the Chair may select working group members on the basis of the CVs and expertise grids. The Secretariat will invite the Committee members to express their interest in the working group and to agree on the establishment of the working group either by written procedure or at a suitable plenary meeting.

Drafting the opinion

The (co-)rapporteurs, where appropriate supported by the Secretariat, will draft the opinion and, if needed, the supporting documentation. The opinion template will be prepared by the Secretariat on a case-by-case basis at the latest by the time when the formal request is issued and will be made available to the relevant Committee(s). The work plan will specify internal and public consultations and the delivery of the draft and final versions of the opinion.

Inter-Committee coordination and rapporteur dialogues

When more than one Committee is requested to prepare an opinion on the same issue (each based on a specific request), relevant documents will be exchanged between the Committees. (Co-)rapporteurs may communicate with each other in the form of teleconference, videoconference or face-to-face meeting as decided by the (co-)rapporteurs on a case-by-case basis. The (co-)rapporteurs will reflect relevant aspects arising from the opinion of the other Committee in their opinions as necessary.

Mechanism for adoption of the opinion

The work plan may clarify whether the Committee(s) will be requested to adopt the opinion in a written procedure or at a plenary meeting as appropriate.

(Public) Consultation

The work plan will lay down how, when and if in the process third parties will be invited to comment on a document referred to the Committee with the request for an opinion, or on a Committee draft opinion (public consultation). Consultation with third parties may involve the publication of a non-confidential version of the document(s) on the ECHA website and comments received will be compiled by the Secretariat in an RCOM¹ table. If a draft opinion of the Committee is submitted for public consultation, the responses will

¹ Response to comments table

be prepared by the (co-)rapporteurs, if appropriate supported by the Secretariat. The (co-)rapporteurs will take the comments into account when drafting or revising the opinion.

Alternatively, other means of consultation of third parties may be carried out, such as a request for information through the stakeholder organisations admitted by the Committee as regular or sector specific stakeholder observers, hearings, meetings, scientific colloquia, surveys, or consultation platforms, etc. Such activities may be targeted to specific stakeholders.

Circulation of documentation

The work plan will describe how relevant documentation will be circulated. Unless specified otherwise, all documentation to the members will be made available on the respective Committee CIRCA Interest group, organised in specific folders.

Communication from Committee members to ECHA

If appropriate, the work plan will specify any specific issues regarding the communication by the Committee members to ECHA. Normally, Committee members will use the CIRCA Newsgroup function when commenting. Other communication with the Secretariat can be via e-mail using the functional mailboxes rac@echa.europa.eu or seac@echa.europa.eu unless confidential data is dealt with.

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