

Helsinki, 30 November 2018

Agreed at RAC-47

Procedure for agreement seeking: Introduction of a differentiated approach to agreement and adoption of opinions on applications for authorisation of the Committee for Risk Assessment (RAC)

I. Introduction

Evaluation of the first Applications for Authorisation started in 2013/2014 and since then, ECHA, through its Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) has produced about 200 opinions. With annual additions of Substances of Very High Concern to Annex XIV expected, resulting in sometimes unpredictable numbers of applications, peaks of authorisation work can be expected to continue for the medium term. Such peaks need to be dealt with efficiently both through planning to even out the distribution to Committee agendas and in plenary, by ensuring adequate scrutiny with less debating time when appropriate.

As the Application for Authorisation is the most recent process, it is still evolving and more amenable to efficiency gains. Debating time in the Committee is one of the key bottlenecks; an increase in meetings days from 15 in 2013 to 30 in 2016 has been noted. Hence, the authorisation and review report opinions for agreement (or adoption) or parts of the opinions need to be handled as efficiently as possible in RAC under set criteria, and should be fully scrutinised and agreed where possible prior to the Committee's plenary meetings. This paper concerns **A-listing with scrutiny**.

Experience with A-listing has been gained in the CLH fast-tracking process since its agreement at RAC 29 in June 2014¹ and was subsequently implemented in full. This forms the basis for the current paper, although it is accepted that there are significant differences in the two processes to be aware of such as the origin of the dossiers.

A pilot phase of 18 months is proposed, following which, experience gained would be analysed and a further decision taken on continuation.

¹ RAC Working procedure. Classification, labelling and packaging: Procedure for agreement seeking
https://echa.europa.eu/documents/10162/13579/rac_cl_fasttrack_agreements_en.pdf/dee7ad41-cde6-499a-94a3-4f47329598e5

II. A-listing with scrutiny agreement

Agreement by A-listing means that following adequate scrutiny by the appointed Committee Rapporteur(s) and by members that commented in writing, selected opinions on applications for authorisation would be proposed for agreement through an A-list without further debate during plenary meetings. By introducing A-listing, it is not the intention to make any changes to the opinion development process for Applications for Authorisation as such. A-listing is seen as an alternative form of agreement seeking in Committee on the basis of an opinion.

The procedure is proposed as follows:

- 1) At the key issues identification stage in the AfA process, the Rapporteur identifies with the Secretariat the potential draft authorisation opinions or their components, which could go to A-list with scrutiny agreement and would not then be tabled for discussion in plenary prior to adoption; this is called the **draft A-list**.
- 2) The following aspects could be taken into account in deciding if an opinion or parts of it are suitable for agreement through A-listing:
 - Is it a small scale or specific downstream application.
 - The type of application and configuration of OCs and RMMs: are they very similar to other applications (e.g. cooling systems, chemical synthesis or manufacturing of active pharmaceutical ingredients in closed systems) already evaluated by RAC?
 - The degree of RAC's initial concerns and the quality and clarity of the applicants' replies.
 - If conditions/monitoring arrangements typical to the type of application are anticipated?
- 3) Should circumstances evolve between the key issues discussion and submission of the draft opinion for plenary consideration, contrary to what was anticipated when A-listing was proposed (e.g. the applicant failed to provide key information), then the discussion will be brought back to the plenary, at the request of the Chairman, the RAC rapporteurs, or members of RAC.
- 4) The Committee will be informed of those authorisation/review report opinions or parts thereof proposed for A-listing through cover message accompanying the launch of the first draft opinion for RAC consultation. The decision-making criteria for A-listing are:
 - a. The rapporteurs agree in principle with the applicant's conclusions.
 - b. The commenting members agree with the rapporteurs' conclusions and explicitly with A-listing.
 - c. Active participation of RAC members in the written commenting round(s) is necessary.
 - d. The ORCOM table will be distributed to stakeholder observers; to this end, Member's comments should be in a format which will allow them to be anonymised

as per Article 11(4) of the Rules of Procedure for the Committee for Risk Assessment².

- 5) Following normal evaluation of the opinion during the RAC consultation, the A-list would be updated and prepared for agreement by the Committee. It will be presented by the Secretariat, and agreed by the Committee, unless there are objections by the members, in which case that opinion would be tabled for plenary debate. Stakeholder observers will have the opportunity to make oral observations on the listing during the RAC plenary meeting, as per the Rules of Procedure for RAC³. Transparency of opinion making will be maintained.
- 6) All opinions or their parts of that clearly need to be discussed in the plenary would remain on the agenda for discussion. However, the parts which are agreed beforehand, e.g. exposure of workers or humans via the environment would not be tabled.

Introduction of this approach would enable the Committee to:

- 1) Save time at plenary meetings so that the difficult/contentious points can be discussed appropriately in plenary.
- 2) Maintain the required transparency of the authorisation and review report opinion development: stakeholder observers would have the opportunity to take note of the proposed A-listing with scrutiny before the relevant plenary session in RAC.
- 3) Improve the quality of the discussion of complex dossiers by optimising the available debating time for critical issues.

III. Actions requested

The Committee is invited to agree upon the proposed Committee procedure for implementation from RAC-47 in November 2018.

The Secretariat, based on the experiences gained from this pilot phase, is requested to summarise the findings and present it to the Committee for the discussion not later than at the March 2020 plenary meeting.

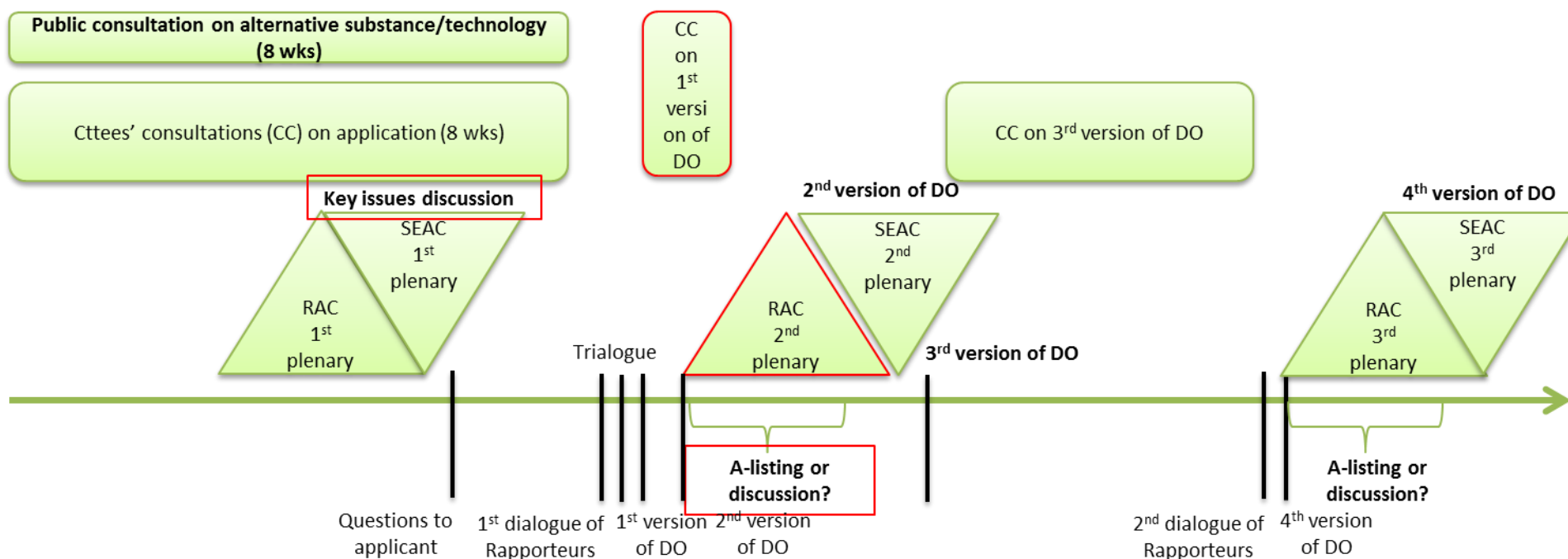
This document revokes for RAC the document "Introduction of a differentiated approach to agreement on the Committees' draft opinions on the applications for authorisation" (RAC/32/2015/08 and SEAC/26/2015/06 agreed at RAC 32 and SEAC 26).

Annex: Figure. Opinion making on Applications for Authorisation

² https://echa.europa.eu/documents/10162/13579/rac_rops_en.pdf/a9f6376e-318f-41de-be0a-1631be9f34c4

³ *Ibid.*

Opinion making on Applications for Authorisation



Stages of the AFA opinion development process, which relate to the potential A-listing of the draft opinion are outlined in red. The indication whether the draft opinion might be suitable for A-listing shall be done as early as the key issues discussion at the first RAC plenary. The proposal to A-list the draft opinion should be mentioned specifically in the Secretariat's message to the RAC members by which the Committee's Consultation on the 1st version of the draft opinion is launched.

If the Secretariat receives supportive feedback from the RAC members who comment on the draft opinion, it is included to the A-list for the next RAC plenary meeting.

The A-listed draft opinions on applications for authorisation are agreed in the beginning of the authorisation-related plenary meeting segment.