

Committee for Risk Assessment (RAC):

Procedure for agreement seeking:

A-listing for agreement and adoption of opinions on REACH applications for authorisation

I. Introduction

At RAC-47 in the November 2018 the Committee agreed a procedure for A-listing opinions on applications for Authorisation following adequate scrutiny, which included a pilot phase of 18 months, following which, experience gained should be analysed and a further decision taken on continuation.

At its 48th plenary meeting, RAC established the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC AFA WG).

Experience with A-listing, i.e. the procedure whereby opinions are reviewed by the working group or on the basis of written comments from members to the extent that they can be agreed/adopted by RAC without plenary debate, has been gained through 11 RAC plenary meetings (including RAC-59) and 9 meetings of the RAC AFA WG. In that period 158 draft opinions have been agreed by RAC. Among those RAC has agreed 57 (or 32%) draft opinions via A-listing.

This paper concerns a revision of the **A-listing procedure** bearing in mind that the opinions on authorisations and review reports for agreement (or adoption) or parts of the opinions need to be handled as efficiently as possible.

II. A-listing with scrutiny agreement

Agreement by the A-listing means that following adequate scrutiny by the appointed Committee rapporteurs and by members that commented in writing or during the RAC AFA WG, selected opinions on applications for authorisation or review reports would be proposed for agreement through an A-list without further debate during plenary meetings. The 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 rapporteurs identify with the Secretariat the potential draft authorisation opinions or their components, which could go to the A-list with a scrutiny agreement and would not then be tabled for discussion in a plenary prior to adoption. This is called the **draft A-list**. The list will be always tabled for discussion at the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC AfA WG). Based on its discussion and if supported by the rapporteurs the RAC AfA WG can propose to add draft opinions to the A-list.
- 2) All draft opinions proposed for the A-listing will be always tabled for discussion at the RAC AfA WG.
- 3) The following aspects could be taken into account in deciding if an opinion or parts of it are suitable for agreement through A-listing:
 - The type of application or review report and the configuration of OCs and RMMs: are they very similar to other applications or review reports (e.g. cooling systems, chemical synthesis or manufacturing of active pharmaceutical ingredients in closed systems, fully automated or semi-automated chrome plating) already evaluated by RAC.
 - The degree of RAC's initial concerns and the quality and clarity of the applicants or authorisation holders' replies.
 - Anticipated conditions/monitoring arrangements are typical to the type of application or review report.
- 4) Should circumstances evolve between the key issues discussion and the submission of the draft opinion for plenary consideration, contrary to what was anticipated when the A-listing was proposed by the rapporteurs or recommended by the RAC AfA WG (e.g. the applicant or authorisation holder failed to provide key information), then the discussion will be brought back to the plenary, at the request of the Chair, the RAC rapporteurs, or members of RAC.
- 5) The Committee will be informed of those authorisation/review report opinions or parts thereof proposed for the A-listing through a cover message accompanying the launch of the draft opinion for the RAC consultation or it can be proposed during discussion at a relevant meeting of the RAC AfA WG. The decision-making criteria for the A-listing are:
 - a. The rapporteurs agree in principle with the applicant or authorisation holder's conclusions.
 - b. The commenting members and/or the RAC AfA WG agrees with the rapporteurs' conclusions and explicitly with the A-listing.
 - c. Active participation of RAC members in the written commenting round(s) and/or during discussion at a relevant meeting of the RAC AfA WG is necessary.
 - d. The ORCOM table will be distributed to stakeholder observers; to this end, Members' 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 Assessment¹.

- 6) Following normal evaluation of the draft opinion during the RAC consultation and/or a relevant meeting of the RAC AFA WG, the A-list would be updated and presented at a meeting of the RAC AFA WG and then 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 a 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 RAC². Transparency of opinion making will be maintained.
- 7) 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.

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.

Conclusion

The Committee agreed upon the usefulness and effectiveness of the revised Committee A-listing procedure and approved its implementation until further notice from RAC-59 in November 2021, so ended the pilot phase.

¹ https://echa.europa.eu/documents/10162/13579/rac_rops_en.pdf/a9f6376e-318f-41de-be0a-1631be9f34c4

² *Ibid.*