

Matter for Consideration: Observers' attendance in the authorisation application process

Meeting of the Management Board 16-17 December 2014, Rome

Item	10.3
Action	For information
Status	Final - Public

Key messages

The Management Board is invited to take note of the conclusion of the Secretariat to continue with the policy on stakeholder and case owner participation in the authorisation application process

- ECHA will continue applying its policy on stakeholder and case owner participation in the authorisation application process as presented to the Management Board in 2012¹.
- By way of further development, observers from ECHA's Accredited Stakeholder Organisations are in future allowed specific speaking rights in plenaries of RAC and SEAC with the intent of having contributions with regards to consistency and procedural matters – comments on the cases themselves would be avoided.

Background

Stakeholder and applicant (i.e. case owner) participation in the authorisation process were discussed in the Management Board in June and September 2012. It was agreed that ECHA would report back on the implementation of the policy and make adjustments, if necessary. This note describes how the policy has been implemented, the options for its further development and concludes what ECHA intends to do from 2015 onwards.

Over the past two years all RAC and SEAC plenary meetings have been held so that Accredited Stakeholders (ASO) observers have strictly observed these sessions without speaking rights. For logistical reasons the applicants have not participated in the Committee discussions of their cases. Furthermore ASO's presence in the absence of case owners was thought to lead to claims of unfair hearing, especially if ASO observers were permitted to comment on the cases during plenary sessions.

ASO observers have participated actively in hearings (called 'trialogue') between the two rapporteurs of RAC and SEAC as well as the applicant and the providers for alternatives. In these dialogues ASO observers could discuss the case with the applicant (and with third parties, if appropriate) with full speaking rights. While all dialogues have been held in "observed" mode, in some cases they were ended with a session that was "non-observed" (for Confidential Business Information).

ASO observers have participated in the RAC and SEAC meetings as foreseen in the policy presented in 2012¹. Contrary to what was expected, none of the cases so far was treated as confidential requiring closed, non-observed Committee plenary meeting session. Overall, this arrangement has worked well and ECHA has not received major comments indicating that a change to its current approach is needed. The only question is whether ASO observers could have the possibility to speak in the plenary sessions.

¹ See document MB/46/2012

Rationale

Allowing the ASO observers the foreseen specific speaking rights would ensure that comments on the cases themselves would be avoided. This would still be possible during the 'trialogues' which would be kept. The applicant in any case has the right to comment on the draft opinions of RAC and SEAC. This possibility to comment is a substantial opportunity for the applicant and thus, would mitigate any perceived notion of unfair hearing. This option could help to improve transparency without creating any inefficiency. As increased transparency is an overall aim of ECHA, and as this option does not have drawbacks, it is favoured by ECHA.

Alternative options considered

The application process has strict rules to protect Confidential Business Information, thereby reducing the liability of ECHA. The Secretariat considers that the process is striking the right balance between the core values of ECHA, i.e. transparency and trustworthiness. The Secretariat sees ASO observers' access meaningful in this balance. However, ECHA is still striving to increase transparency to some degree.

The options for ASO speaking rights in plenaries that have been considered are the following:

- i) Carry on with the current system, which works well.
- ii) To have a fully open process and reduce any perceived claims of unfair hearing. In this option ASO would be granted full speaking rights and the applicants would need to be invited to attend the plenary meetings of the Committees and be also allowed to speak. While much more transparent, the drawback of this approach is inefficiency as the logistics of getting as many as 10-15 applicants per day in and out of the two Committees would be burdensome, agendas would become inflexible and it might well be that during the opinion development an applicant could request to take part in several plenaries each of RAC and SEAC. Also in this case the 'trialogue' could not be missed as it provides an opportunity for providers of alternatives to be confronted with applicants. ECHA considers this increase in inefficiency a major concern.

Drawbacks

The proposed option does not have drawbacks.

For questions: jack.de-bruijn@echa.europa.eu with copy to mb-secretariat@echa.europa.eu