

Participation of applicants / stakeholders in the Biocidal Product Committee (BPC)

Meeting of the Management Board 19-20 June 2013

Item	8.3
Action	For information
Status	Final - internal

Action requested

The members of the ECHA Management Board are invited to take note of this document which describes the participation of observers (applicants and stakeholders) in the Biocidal Products Committee (BPC), and to provide comments as appropriate.

Background

The participation of observers is one of the elements of the working approach of the BPC which needs to be in place by the application date of the Biocidal Products Regulation (BPR) when the BPC has to be operational. As defined in the draft Rules of Procedure (RoP) observers are considered other participants of the BPC or its working groups (WGs) who are not members, advisers or invited experts. Observers include among others applicants and accredited stakeholders organisations (ASOs) from industry or NGOs. For the first meeting of the BPC¹ the ECHA Secretariat prepared a proposal on the participation of applicants² and stakeholders in the BPC and its WGs taking into account the need for an efficient and effective approach to running the BPC and its WGs, the practice under the Biocidal Products Directive, potential confidential business information (CBI) content of the discussions, the ECHA policy for ASOs and the approach that has been established for the other ECHA Committees. A number of elements were further clarified in a revised draft prepared by the ECHA Secretariat for the second BPC³. Before BPC a document was received from 3 ASOs expressing their concerns over the proposal, in particular regarding a too limited access of applicants to BPC plenary meetings.

No comments were provided by BPC members regarding the approach proposed for the participation of ASO's. However, six members intervening on this agenda item expressed their disagreement over the proposal by the ECHA Secretariat (the other members remaining silent), in particular on the proposal to not allow the participation of applicants in the BPC meetings for Type I (approval of active substances and Union authorisation) and type II processes (scientific and technical matters concerning mutual recognition)⁴. Arguments brought forward were related mainly to efficiency through the clarifications that the applicant can provide, the "right to be heard" and transparency of the process. The ECHA Secretariat remained concerned about the arguments related to efficiency, especially as during the earlier discussion there was a clear agreement that additional critical information should not be provided by the applicant at this last stage of the evaluation process. The ECHA Secretariat also noted that the "right to be heard" is to a certain extent addressed by the participation of the applicant to WGs. In addition, the Secretariat was concerned about the administrative

¹ The Committee held its inauguration meeting on 28-29 March 2013.

² The main processes in the BPR where the BPC is requested to deliver an opinion are schematically presented in Annex II of the ECHA Secretariat proposal. In REACH sometimes the term "case owner" is used instead of applicant.

³ 29-30 May 2013

⁴ Opinions for Type I and II processes will be the majority of cases for which the BPC has to deliver an opinion.

workload in managing the participation of applicants in plenary meetings.

It was concluded that the ECHA Secretariat will revise the proposal taking into account the opinions expressed and inform the ECHA Management Board accordingly. In revising the proposal several options mentioned in BPC were to be considered:

- Participation of applicants in BPC meetings and of ASOs also in the Type II process⁵ either via physical or virtual participation;
- Development of a code of conduct for the participation of applicants in the BPC. There was general support for the opinion of the ECHA Secretariat that critical information should be provided well in advance of the BPC meetings;
- It was agreed that consultation between the evaluating Competent Authority and the applicant between the WG and BPC is of high importance. Such consultation will be included in the relevant working procedures.

Matters for consideration

The ECHA Secretariat plans to implement the following approach to the attendance of ASOs and applicants in the BPC and its working groups:

1) ASOs will be invited

- regularly to the plenary and working group meetings of the BPC to all sessions of general nature, unless there are specific circumstances justifying a closed session (e.g. CBI);
- also to plenary meetings of the BPC as well as for working groups meetings concerning opinion forming on type I and type II processes, unless the applicant has submitted a justified objection (based on protection of CBI) that has been assessed to be valid by ECHA.

2) Applicants will

- have the opportunity to provide their input for Type I cases in the one year evaluation period preceding the peer review by the BPC and its WGs; ECHA will promote a harmonised approach through relevant working procedures;
- be invited to BPC working groups both for Type I and Type II processes to observe the discussion on their cases and to provide technical and scientific input as requested by the WG's, coordinated through the Secretariat;
- be invited to observe their cases in the BPC plenary meeting, and to provide clarifications (but no new data) when specifically requested by the Committee.
- For type III processes a case-by-case decision is taken by the Committee Chair on the participation of ASOs and, where relevant, applicants;
- The above approach is reviewed, and if necessary revised in two years from the BPR application date (i.e. by 1 Sep 2015)

⁵ In the proposal of the ECHA Secretariat ASOs were not allowed to participate in Type II processes for reasons of proportionality in contrast to the other processes.