

## **Opinions on technical and scientific matters concerning mutual recognition: working procedure for the Biocidal Products Committee (BPC)**

The purpose of this document is to establish principles to be applied by participants in the work of the BPC and its Working Groups (WGs) for preparing opinions on technical and scientific matters concerning mutual recognition. Participants include WG and BPC members, alternates, rapporteurs, the secretariat, applicants and authorisation holders and accredited stakeholder organisations.

This working procedure will be reviewed in the light of experience.

## 1. Purpose

This document forms the basis for the process of opinions on technical and scientific matters concerning mutual recognition in the Biocidal Products Committee (BPC). According to the Biocidal Products Regulation (BPR) the opinion has to be submitted by ECHA to the Commission within 120 days of the date on which the matter in question was referred to ECHA by the Commission. The process documented until the finalisation of the opinion by the BPC.

## 2. Scope

This document details the steps to be taken during the opinion-forming process for technical and scientific matters concerning mutual recognition under Article 38 of the BPR. The steps covered are those starting from the request by the Commission until the finalisation of the opinion of the BPC. The steps are described for all the actors in the process including the ECHA Secretariat (SECR), MSCAs, the applicants that are involved for product authorisation or authorisation holders, ASOs (ECHA accredited stakeholder organisations), BPC Working Group members and BPC members.

## 3. Description

The Agency may be requested by the Commission to prepare an opinion on technical and scientific matters concerning mutual recognition in relation to:

- A disagreement between MSCAs in the Coordination Group as described in Article 36;
- A scientific or technical question raised by the applicant or the Member State concerned in relation to a request for a derogation from the mutual recognition process as described in Article 37.

An important first step in this process is the consultation between COM and SECR on the scope and timelines of the foreseen request. This consultation will start well in advance of the formal request submitted by COM to SECR.

The individual steps and indicative timelines for the process are described in Table 1 and the actual calendar dates for each step are given in [5.1 Timelines](#) in Table 2 for 2014 and 2015 starting from the meeting schedule for the BPC for these years. Submission windows are included in which requests can be submitted by the Commission. Urgent action may be required, with the consequence that the process has to be started earlier than the end of the submission window in the scheme and specific measures may be taken: ad hoc meetings of the BPC, either virtual or physical, may be considered for these cases.

The contact point between the Agency, the MSCAs and the applicant for national authorisations or the authorisation holder, is the dossier manager (DM) appointed by the SECR for each request.

The CIRCA BC site for document distribution will be restricted to members, including their alternates, of the BPC and core and flexible members of the WGs. In addition, a dedicated mailbox will be provided by SECR for the process of technical and scientific matters concerning mutual recognition. This mailbox will be used for communication with the applicant for national authorisation, the authorisation holder and the ASOs. If an MSCA has not yet appointed a member of the BPC and is involved in the case, specific measures will be taken.

**Table 1.** Description of the steps in the opinion forming process

| Process step   | Responsible actor<br>(Approximate time limit)       |
|--|---|
| 1) Request from COM received by SECR <sup>1</sup> . Before the SECR receives the request, a consultation phase will take place between COM and SECR. In this consultation phase the SECR will assign the dossier manager (DM).   |   |
| 2) <b>Distribution of draft opinion.</b> SECR prepares and distributes the draft opinion to the BPC (and, where considered relevant by the SECR, (ad hoc) WGs) and the involved applicant for national authorisation or the authorisation holder via CIRCA BC. The SECR will inform the BPC about the contact details of the DM.   | SECR<br>(21 days)                                   |
| 3) <b>Commenting phase.</b> BPC and the involved applicant for national authorisation or the authorisation holder provide comments via CIRCA BC via the dedicated RCOM provided by SECR.   | BPC, applicant or authorisation holder<br>(21 days) |
| 4) <b>Distribution of draft opinion.</b> The SECR takes the comments provided by the BPC, the involved applicant for national authorisation or the authorisation holder into account and revises, if considered appropriate, the draft opinion. The SECR distributes the draft opinion to the BPC and the involved applicant for national authorisation or the authorisation holder via CIRCA BC. The involved applicant for national authorisation or the authorisation holder is requested by SECR to provide written comments within 30 days. | SECR<br>(14 days)                                   |
| 5) <b>The applicant for national authorisation or the authorisation holder informs the SECR if more time is required to provide written comments on the draft opinion.</b> Article 38 provides for this possibility. The request shall be submitted in writing via the functional BPC mailbox for technical and scientific matters concerning mutual recognition and include a justification.  | applicant or authorisation holder<br>(21 days)      |
| 6) <b>SECR suspends the 120 day time limit and sets a new dead line for the applicant for national authorisation or the authorisation holder.</b> If the SECR accepts the request it will suspend the time limit and inform the BPC, the applicant for national authorisation or the authorisation holder of the new dead-line.  | SECR<br>(7 days)                                    |
| 7) <b>Applicant for national authorisation or the authorisation holder submits written comments to SECR on the draft opinion within the dead line set.</b>   | applicant or authorisation holder                   |

<sup>1</sup> The BPR does not set a time limit for COM to adopt its decision under Article 37(2), nor for referring the matter to ECHA. COM may informally inform the requesting MSCA if COM has a concern on the derogation. In any case, the requesting MSCA can contact COM if it is considering to grant the authorisation after the 90 days period in line with Article 37(3).

|   |  |
|---|--|
| <b>8) Distribution of the draft agenda for the BPC including the written comments provided by the applicant for national authorisation or the authorisation holder.</b> Note: the draft opinion is already distributed by SECR to the BPC under step 4. | SECR<br>(no later than 10 days before the BPC meeting) |
| <b>9) BPC meeting.</b> The ASO will be present but do not have access to the meeting documents.   |  |
| <b>10) BPC opinion finalisation.</b> The BPC opinion is finalised and forwarded to COM.   | SECR<br>(21 days)                                      |

## 4. Definitions and acronyms

| Abbreviation | Definition   |
|--------------|--|
| ASO          | ECHA Accredited Stakeholder Organisation   |
| BPC          | Biocidal Products Committee  |
| BPR          | Biocidal Products Regulation   |
| CIRCA BC     | Communication and Information Resource Centre for Administrations, Businesses and Citizens |
| COM          | European Commission  |
| DM           | (ECHA) Dossier Manager   |
| ECHA         | European Chemicals Agency  |
| MSCA         | Member State Competent Authority   |
| RCOM         | Response to Comments table   |
| SECR         | ECHA Secretariat   |
| WG           | Working Group  |

## 5. Annexes

### 5.1 Timelines

The timelines in the table below indicate the pre-defined time limits for the various steps of the peer review process for 2014 and 2015. The first submission window after the application date of BPR of 1 September 2013 is given in the third column and the timeline following from this submission window is named "process flow 1". Similarly, the subsequent "process flow 2" follows from the second submission window etc. Starting and end dates (deadlines) are given for each step including the time limits for each step as described above. These start and end dates have always been set on a working day. Each process flow lasts 120 days.

Table 2. Timelines for the steps in the opinion forming process of technical and scientific matters concerning mutual recognition for 2014 and 2015.

| Task  |       | Process flow 1 | Process flow 2 | Process flow 3 | Process flow 4 | Process flow 5 | Process flow 6 | Process flow 7 | Process flow 8 |
|---|-------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| Submission window   | Start | 1 Sep 2013     | 01 Jan 2014    | 12 Mar 2013    | 24 Jun 2014    | 26 Aug 2014    | 29 Oct 2014    | 06 Jan 2014    | 10 Mar 2015    |
|   | End   | 31 Dec 2013    | 11 Mar 2013    | 23 Jun 2014    | 25 Aug 2014    | 28 Oct 2014    | 05 Jan 2014    | 09 Mar 2014    | 22 Jun 2015    |
| SECR prepares and distributes draft opinion (21 days)   | Start | 31 Dec 2013    | 11 Mar 2013    | 23 Jun 2014    | 25 Aug 2014    | 28 Oct 2014    | 05 Jan 2014    | 09 Mar 2014    | 22 Jun 2015    |
|   | End   | 21 Jan 2013    | 01 Apr 2013    | 14 Jul 2014    | 15 Sep 2014    | 18 Nov 2014    | 26 Jan 2014    | 30 Mar 2014    | 13 Jul 2015    |
| Commenting period (21 days)   | Start | 21 Jan 2014    | 01 Apr 2013    | 14 Jul 2014    | 15 Sep 2014    | 18 Nov 2014    | 26 Jan 2014    | 30 Mar 2014    | 13 Jul 2015    |
|   | End   | 10 Feb 2014    | 21 Apr 2013    | 04 Aug 2014    | 06 Oct 2014    | 09 Dec 2014    | 16 Feb 2014    | 20 Apr 2014    | 03 Aug 2015    |
| SECR prepares and distributes draft opinion (14 days)   | Start | 10 Feb 2014    | 21 Apr 2013    | 04 Aug 2014    | 06 Oct 2014    | 09 Dec 2015    | 16 Feb 2014    | 20 Apr 2014    | 03 Aug 2015    |
|   | End   | 24 Feb 2014    | 05 May 2014    | 18 Aug 2014    | 20 Oct 2014    | 23 Dec 2015    | 02 Mar 2014    | 04 May 2015    | 17 Aug 2015    |
| Applicant or authorisation holder provides written comments to SECR (30 days after SECR distributed draft opinion)      |       | 26 Mar 2013    | 04 Jun 2013    | 17 Sep 2014    | 19 Nov 2014    | 22 Jan 2015    | 01 Apr 2014    | 03 Jun 2015    | 16 Sep 2015    |
| Distribution draft agenda BPC including written comments applicant or authorisation holder by SECR (10 days before BPC) |       | 28 Mar 2013    | 06 Jun 2013    | 19 Sep 2014    | 21 Nov 2014    | 24 Jan 2015    | 03 Apr 2014    | 05 Jun 2015    | 18 Sep 2015    |
| BPC   | Start | 8 Apr 2014     | 17 Jun 2014    | 30 Sep 2014    | 2 Dec 2014     | 3 Feb 2015     | 14 Apr 2015    | 16 Jun 2015    | 29 Sep 2015    |
|   | End   | 10 Apr 2014    | 19 Jun 2014    | 2 Oct 2014     | 4 Dec 2014     | 5 Feb 2015     | 16 Apr 2015    | 18 Jun 2015    | 01 Oct 2015    |
| BPC opinion finalisation (21 days after BPC)  | Start | 10 Apr 2014    | 19 Jun 2014    | 2 Oct 2014     | 4 Dec 2014     | 5 Feb 2015     | 16 Apr 2015    | 18 Jun 2015    | 01 Oct 2015    |
|   | End   | 29 Apr 2014    | 08 Jul 2014    | 20 Oct 2014    | 22 Dec 2014    | 24 Feb 2015    | 04 May 2015    | 07 Jul 2015    | 19 Oct 2015    |