

Agreed at BPC-4
12 February 2014

Framework for dealing with requests for opinions according to Article 75(1)(g) of the BPR

1. Introduction and legal basis

Article 75(1)(g) of Regulation (EU) No 528/2012 states "The Biocidal Products Committee shall be responsible for preparing the opinion of the Agency [...] at the request of the Commission or of Member States' Competent Authorities, [on] any other questions that arise from the operation of this Regulation relating to technical guidance or risks to human health, animal health or the environment". No specific time limit is given in the BPR by which a BPC opinion should be delivered.

Accordingly, this document sets out a framework by which such requests will be dealt by the Biocidal Products Committee (BPC) and where appropriate, its Working Groups (WGs). Since the nature of such requests will vary, a specific working procedure is not considered appropriate for dealing with such requests. Instead this framework sets out *guiding principles* that may assist the BPC in dealing with such requests.

Given the variability of the requests that may arise according to Article 75(1)(g), it is not appropriate to indicate in advance whether the assistance of the BPC WGs will be needed to develop a BPC opinion. However, if time permits and the request requires significant scientific or technical input to draw up a BPC opinion, then one or more of the BPC WGs may be requested to provide their input. The need for BPC WG involvement will be included in the work plan that accompanies a request to the BPC to draw up an opinion.

Requests for opinions under Article 75(1)(g) may or may not be urgent. A work plan will be drawn up for all requests. For non-urgent requests, a work plan will be developed for each request applying similar procedural steps and deadlines to those set out in other BPC working procedures¹, adapted as appropriate. Urgent requests, on the other hand, may require shorter deadlines, omission or merging of certain steps, or other ways of speeding up of the process without compromising the scientific quality of the opinions or the proper involvement of BPC Members. The requester will provide a justification for dealing with certain requests as urgent, which will be considered by the Secretariat.

2. Development of the BPC opinion under Article 75(1)(g)

2.1 Work plan

The Secretariat will draft a work plan for development of the BPC opinion. The work plan will briefly describe the main steps to be undertaken by the (co-)rapporteurs, the BPC, its WGs, if appropriate, the Secretariat and the proposed timelines. The Secretariat will ensure that the timelines are sufficient to allow BPC members to provide their input to the (co-) rapporteurs and that consultation of third parties, if relevant, takes place early enough in the process. Once (co-) rapporteur(s) have been identified, they will be consulted on the work plan.

¹<http://echa.europa.eu/web/guest/about-us/who-we-are/biocidal-products-committee>

Whenever possible, the work plan will be finalised before the Secretariat refers the request to the BPC. The work plan may, if relevant, be revised in the course of the work.

The work plan for development of the opinion may contain the following elements:

- Appointment of (co-)rapporteur(s)
- Adequacy check
- Involvement of BPC WGs
- Referral of the request to the BPC
- Preparation of the first draft opinion
- Commenting round with BPC members
- Revised draft opinion (if necessary)
- A public consultation (if necessary)
- Revised draft opinion (if necessary)
- Opinion adoption at a plenary meeting or by written procedure
- Transmission of the opinion to the Commission or MSCA, as appropriate.

If needed, an ad-hoc working group(s) may be established to support the (co-)rapporteur(s) in their task in accordance with Article 17(6) of the BPC Rules of Procedure (RoPs). The (co-) rapporteur(s) or the Secretariat may flag the need for an ad-hoc working group at any point in time. If such a group is considered necessary, the Secretariat will prepare the mandate of the ad hoc working group to be agreed by the BPC in accordance with Article 18(2) of the BPC RoPs.

The (co-)rapporteurs, where appropriate supported by the Secretariat and if appropriate BPC Working Groups, will draft the opinion and, if needed, any additional documentation. The opinion template will be prepared by the Secretariat on a case-by-case basis.

The work plan will lay down how, when and if third parties will be invited to comment on the draft BPC opinion in the form of a public consultation. It will be decided on a case-by-case basis if a wider audience than the BPC and accredited stakeholder organisations should be consulted. Consultation with third parties may involve the publication of a non-confidential version of the document(s) on the ECHA website. If a draft opinion of the Committee is submitted for public consultation, any comments received will be taken into account when revising the draft BPC opinion. Alternatively, other means of consultation of third parties may be carried out, such as a request for information through ASOs or targeted consultation of specific stakeholders and/or applicants.

2.2 Adequacy check

In order to be able to process the requests from the Commission or Member State Competent Authorities (MSCAs) made under Article 75(1)(g) of the BPR and draw up an opinion within a timeframe that is acceptable for the BPC, it is important that the request is made in a clear and concise manner to the BPC Secretariat. If supporting documentation is necessary for the BPC to be able to draw up an opinion in relation to the request, this documentation should be provided with the request.

To ensure that the BPC can deliver an opinion in an efficient manner, an adequacy check will be carried out by the Secretariat on the request and any supporting documentation before the request is referred to the BPC for drawing up an opinion. The adequacy check will look at the following aspects:

- Rationale behind the question;
- The problem to be addressed and the expected output are clearly described;
- The proposed timeframe for delivering the opinion is appropriate;
- If additional input is required from third parties, the rationale and confirmation that this will be made available sufficiently early to the BPC for it to deliver its opinion.

The Secretariat in consultation with potential (co-)rapporteurs will carry out the adequacy check. If the request does not pass the adequacy check, the Secretariat will explore with the Commission or MSCA how to increase the adequacy of the request to an appropriate level.

The Secretariat will assess whether third parties need to be engaged in the process to provide additional information and that this is appropriately taken into account when planning the work to be carried out by the BPC. When appropriate, the Secretariat will alert accredited stakeholder organisations (ASOs), applicants and other third parties about the need for their input.

In order for the BPC to be able to react to such requests quickly, the Secretariat will inform it as early as possible about the content of upcoming requests. If possible, information on which the BPC will be asked for an opinion, the likely timing of the request to be issued and the timetable for drawing up the BPC opinion will also be provided.

2.3 Appointment of (co-)rapporteurs

As early as possible, after the request for an opinion is received, the Secretariat will endeavour to identify a BPC member familiar with or interested in the subject of the request that may wish to become a rapporteur in line with Article 17(3) of the BPC Rules of Procedure (RoPs). For complex requests the Secretariat may propose the use of a co-rapporteur.

Once a request has been received by the Secretariat, the procedure for the appointment of (co-)rapporteurs will be started. In urgent cases, the Secretariat will launch a procedure for the appointment of (co-)rapporteurs once the Secretariat has been informed about a (potential) upcoming request for drawing up a BPC opinion.

Upon the Secretariat's call for expression of interest to act as a (co-)rapporteur for the request in question, BPC members can express their interest to the Secretariat and confirm their availability. The Secretariat will verify whether there are any considerations for excluding any of the candidates, according to Article 9(4) of the BPC RoPs.

The Secretariat will contact the candidate(s) in order to clarify any other relevant considerations. If necessary, the Secretariat may request further information from the candidate(s). When there are no expressions of interest received within a set deadline, the Secretariat will identify suitable candidates on the basis of the CVs and expertise grids provided by the members on their appointment.

The Secretariat will draw up a recommendation for (co-)rapporteurs and seek the agreement of the BPC on its recommendation in a written procedure or at a suitable plenary meeting; if necessary before the request is referred to the BPC.

In urgent cases, the Chair of the BPC may identify potential (co-)rapporteurs by reviewing their CVs and expertise grids and invite member(s) directly to act as (co-)rapporteur(s).

In all cases, the Secretariat will formalise the appointment of (co-)rapporteurs by a letter of appointment which will be sent to the (co-)rapporteurs as soon as the request has been referred to the BPC and the rapporteurs have been appointed by the Committee.

3. Finalisation of the BPC Opinion

Once the BPC has adopted its opinion, it will be transmitted to the Commission or the MSCA, as appropriate, without delay. The opinion will be published on the ECHA website.