Post authorisation conditions for biocidal product authorisation: harmonising practices between national and Union authorisation

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Agreed at BPC - 29

1. Introduction

In the Coordination Group (CG) the issue of post authorisation conditions within national authorisation procedures has been discussed resulting in a document agreed at CG-32 entitled "Post authorisation conditions for biocidal products: harmonising practices" (Doc. No. CG-32-2018-16).

Although the main principle is that in general post authorisation conditions should always remain an exception and may only be considered on a case by case basis the document describes on what grounds a post authorisation condition could be justified for biocidal product authorisation applications. The CG document describes in section 2 the following criteria:

"*In order to support the harmonisation of the decision making process by MSs, the following criteria are proposed in order to consider whether a post-authorisation condition may be acceptable:*

- *The data available in the application enabled the MS to conclude the risk assessment and the efficacy assessment (i.e. no data gap preventing them to conclude),*
- *The data to be provided post authorisation would not be expected to affect the conclusions of the risk assessment or of the efficacy assessment but rather to confirm those conclusions.*

In application of these criteria, the situations listed below may be considered for granting a post-authorisation condition for product authorisation:

- *Phys/Chem data to fill gaps in products meeting the conditions in Article 19(1)[1] of the BPR that were not considered as necessary by the refMS/eCA. These data would not change in any way the outcome of efficacy or risk assessment.*
- *Full long term stability studies for the first authorisation of a product provided that acceptable mid-term and accelerated storage stability data has been submitted. A maximum of 24 months shelf life could be granted on a case by case basis.[2]*

In exceptional circumstances such as those described in section 2.2 of document CA-March18-Doc.7.3.b-final[3] (Applications for biocidal products for which the evaluation phase is closed when the ED criteria become applicable but a product authorisation has not been granted yet) or in paragraph 53 in document CA-March17-Doc.7.6.c-final[4] (in case MRLs or migration limits were not possible to establish by product authorisation), it may nonetheless be possible to

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[1] And where relevant, Article 19(5).

[2] Inclusion of this post authorisation condition should be considered on a case by case basis, as long term stability studies are a core data requirement. Data to be submitted should be considered as validation data.

[3] The implementation of scientific criteria for the determination of endocrine-disrupting properties in the context of biocidal product authorisation.

[4] An interim approach for the establishment of maximum residue limits for residues of active substances contained in biocidal products for food and feed and specific migration limits in food contact materials.

derogate to these criteria regarding the risk assessment.

If a refMS is considering whether to derogate to these criteria to address other situations (e.g. absence of guidance on data requirements at the time of the submission of the application), it is strongly recommended to bring up the matter in an electronic consultation and discussion in the CG, in order to seek a common approach among all MSs and agree whether granting a post-authorisation condition is justified and acceptable."

The CG document also states that it should not be regarded as guidance for applicants in order to request a post-authorisation condition. The same applies for the present document.

Section 3 of the CG document entitled "Practical implementation for the follow-up of post-authorisation conditions in mutual recognition procedures" is relevant for Union authorisation but should be adapted. Consequently, the purpose of this document is to describe the practical implementation for Union authorisation[5]. It is proposed that the main principle and the criteria for including post authorisation conditions are taken over directly from the CG document.

2. Practical implementation for the follow-up of post authorisation conditions in Union authorisation procedures

Post-authorisation conditions should be included in the terms and conditions of the corresponding authorisations granted by the Commission[6]. However, ECHA and the evaluating Competent Authority (eCA) will be responsible to follow up on the fulfilment of the post-authorisation conditions by the authorisation holder (AH).

In order to facilitate the peer review process, the post authorisation conditions should be included in the PAR in the relevant conclusion section and in the BPC opinion in section 2.2. Post authorisation conditions are not indicated in the SPC.

At the time of the authorisation, the Commission will send a task driven ad-hoc communication via R4BP 3 to the AH requesting the post authorisation data within a given deadline for the submission of such data.

Where the data is not submitted in due time the Commission will cancel or amend the authorisation in accordance with Article 48 of the BPR.

Where the data is submitted by the AH in due time, the eCA will review the data. Two situations can be distinguished:

- the eCA considers that the data submitted by the AH fulfil the post-authorisation requirements;
- the data is submitted in due time and the eCA considers that the data submitted by the AH do not fulfil the post-authorisation requirements.

In both cases the conclusions of the eCA have to be confirmed in a peer review process organised by ECHA.

[5] The current document describes the process to be followed. If required, a more detailed description of this process will be developed by ECHA.

[6] A same biocidal product (SBP) of any related reference biocidal product having a post-authorisation condition will also have the same post-authorisation condition, irrespectively of whether the SBP is authorised by the Commission (UA) or by MSs (i.e. national SBP of a UA product).

The table below describes the process to be followed:

Step	Outcome	Responsible actor
Monitor submission of data within the time line set in the authorisation	Data not submitted in time: inform COM Data submitted in time: inform eCA	ECHA
Evaluation of data submitted	Report evaluation in amended PAR and if needed SPC Conclusion on if data do fulfil the conditions of the post-authorisation requirement(s)	eCA
Submit evaluation to ECHA Secretariat for peer review in Working Group(s) – where considered relevant - and BPC		eCA
Working Group(s) and BPC discussion	BPC opinion containing conclusion on if data do fulfil the conditions of the post-authorisation requirement(s)	BPC and Working Group(s) SECR
Submission of BPC opinion to COM		BPC SECR
Decision on whether the authorisation needs to be amended or cancelled under Article 48	Where the condition is fulfilled, the terms and conditions of the product authorisation (i.e. removal of the condition) will be amended at the time of renewal of the product authorisation. Where the condition is not fulfilled, the product authorisation is amended or cancelled in accordance with Article 48 of the BPR without undue delay (including notification to MSs under Article 48(3) of the BPR)[7].	COM
Dissemination of revised PAR and if needed SPC		eCA and ECHA

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[7] Member States having granted a national Same Biocidal Product authorisation of a related reference product authorised through the Union Authorisation process will have to cancel or amend the national authorisation accordingly.