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

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Agreed at BPC-47

1. Introduction

In the Coordination Group (CG) the issue of post authorisation conditions within national authorisation procedures has been rediscussed resulting in a revised document agreed at CG-56 entitled "Post-authorisation conditions for NA and SA product authorisation: harmonising practices"[1] (Doc. No. CG-56-2023-30)[2]. Thus, the BPC document is revised accordingly to align approach among product authorisation procedures.

The main principle is that in general post-authorisation conditions should always remain **an exception** and may only be considered case by case. The purpose of this document is to define on what grounds a post-authorisation condition could be justified for biocidal product (BP) and biocidal product family (BPF) authorisation applications and practical implementation of the follow-up to harmonise the practices.

Post-authorisation conditions can only be set when an authorisation is granted for the BP/BPF in a Union authorisation (UA) procedure and cannot be set in the course of other procedures, i.e., in the context of changes or renewal applications.

It should be noted that in case there are same biocidal product (SBP) applications related to the BP/BPF authorisation granted in Union authorisation (UA) procedure, the same post-authorisation conditions will have to be set for all those SBP authorisations.

The CG document describes in section 2 the criteria which should be applied also to UAs [3]:

"In order to support 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 on the risk assessment and the efficacy assessment (i.e. no data gap preventing them to conclude),
- The data to be provided post-authorisation is not affecting the classification and labelling of the BP/BPF or of the efficacy/risk assessment.

If these criteria are respected, and only as long as the document `G-53-2022-07 AP 14.1 Shelf-life setting at PA-vf'[4] is not applicable for the BP/BPF authorisation application (i.e., as a transitional measure), granting a post-authorisation condition for a BP/BPF authorisation

[1] NA – national authorisation, SA – simplified authorisation.

[2] CG-56-2023-30 AP 14.1 Post-authorisation conditions for NA and SA final.pdf. Available at: /CircaBC/echa/Biocides CoordinationGroup public/Library/General agreements

[3] The CG document text is updated to address UA authorisations. The changed part of the text is noted *in italics*.

[4] CG-53-2022-07 AP 14.1 Shelf-life setting during PA vf.docx

may be considered in case an acceptable accelerated storage stability test is available and a long-term storage stability test at ambient temperature has been initiated[5], but a completed long-term storage test at ambient temperature is not available when authorisation is granted for the BP/BPF *in a UA procedure*. In such situation a maximum of 24 months shelf life could be granted on a case-by-case basis.

By applying these criteria, a post-authorisation condition for BP/BPF authorisation must never be set in the situations listed below:

- For *UA* of BP/BPF: physical, chemical, physico-chemical data and physical hazards and respective characteristics that affect product classification and labelling, or physical, chemical and technical properties that would affect Article 19(1) conditions and/or the efficacy/risk assessment.
- Complete long-term stability study is missing when authorisation is granted for the BP/BPF in a *UA* procedure[6] for which the application was submitted after the publication of the CG document[7], *this* revised BPC document and the revised APCP TAB entry document concerning shelf-life.

If an *evaluating Competent Authority (eCA) is* considering setting a post-authorisation condition, it is strongly recommended to bring up the matter for discussion in the *BPC*, in order to seek a common approach among all MSs and agree whether granting a post-authorisation condition is justified and acceptable.

Post-authorisation conditions should be linked to timelines that should be carefully and accurately defined case by case."

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

Section 3 of the CG document (Doc. No. CG-56-2023-30) entitled "Practical implementation for the follow-up of post-authorisation conditions in national authorisation" is relevant for Union authorisation but should of course be adapted. Consequently, the purpose of this document is also to describe the practical implementation for Union authorisation. It is proposed that the main principle and the criteria for including post-authorisation conditions are taken over directly from the CG document via this BPC 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. However, (eCA) supported by ECHA will be responsible to follow up on the fulfilment of the post-authorisation conditions by the authorisation holder (AH).

In order to facilitate the opinion forming process, it is proposed to include the post-authorisation conditions in the Product assessment report (PAR) in the relevant conclusion

[5] At least the following information shall be submitted: measurements at least at the beginning of the test (t_0); explanation on why the completed long-term storage study is not available yet; and confirmation from the laboratory of the start of the test and timelines for obtaining the test results and submitting them to *the eCA.*

[6] Making it impossible to set the shelf-life (as it can only be set for the time period that is supported by data).

[7] CG-56-2023-30 AP 14.1 Post-authorisation conditions for NA and SA_final.pdf

section and in the BPC opinion in section 3.2.2.. Post authorisation conditions are not indicated in the Summary of Product Characteristics (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[8].

Where the data are not submitted in due time the Commission will assess the cancellation or amendment of the authorisation in accordance with Article 48(1)(c) of the BPR.

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

- the eCA considers that the data submitted by the AH are sufficient to fulfil the post-authorisation requirements;
- the eCA considers that the data submitted by the AH are not sufficient to fulfil the post-authorisation requirements, i.e., do not confirm the conclusions of the initial authorisation.

In both cases the conclusions of the eCA have to be confirmed in the opinion forming process organised by ECHA.

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, BPC opinion 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 opinion forming 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 rapporteur, BPC and Working Group(s) SECR
Submission of BPC opinion, amended PAR and SPC (if needed) to COM		BPC SECR
Decision on whether the authorisation needs to be	Where the condition is fulfilled, i.e., the data	COM

[8] The ECHA SECR should be included in cc of this communication.

amended or cancelled under Article 48	provided confirm the conclusions of the initial authorisation, 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, i.e., the data are provided but do not confirm the conclusions of the initial authorisation, 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)[9].	
Dissemination of revised PAR		eCA and ECHA

3. Practical implementation for the follow-up of post-authorisation conditions in Union authorisations of same biocidal product

In case there are UA same biocidal product (SBP) applications related to a BP/BPF authorisation granted in a UA procedure, the same post-authorisation conditions will have to be set for all those SBP authorisations.

3.1 Specific data is requested by a certain deadline as a post-authorisation condition

If submission of specific data is requested by a certain deadline as a post-authorisation condition for the reference UA, the SBP authorisation should include the conditions that within the deadline set by the Commission, the AH of the SBP authorisation should submit[10]:

- proof that the data was submitted for the reference BP/BPF, i.e., including also the communication number in R4BP3 and
- a Letter of Access providing the right to refer to the post-authorisation data submitted for the reference BP/BPF[11].

At the time of the authorisation, the Commission will send a task driven ad-hoc

[9] 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.

[10] The AH of the SBP might decide to submit the data requested for the reference BP/BPF themselves, if this would be in line with the post-authorisation condition set by the Commission. If such case would take place, ECHA will inform the Commission and MSs and will develop procedure to address such case.

[11] This is only relevant when the AH of the reference BP/BPF authorisation and the SBP authorisation is a different legal entity.

communication via R4BP 3 to the AH(s) of the related same product(s), requesting the post authorisation data to be submitted within a given deadline. ECHA will be responsible to monitor the submission of data and assess the fulfilment of the post-authorisation conditions by the AH of the same product[12]. Once the above-described post-authorisation conditions of the SBP authorisation are fulfilled and the process concerning the reference BP/BPF is finalised, the actions taken for the SBP authorisation align with the ones taken for the reference BP/BPF authorisation. In such case, two situations can be distinguished:

- Where the data submitted for the reference BP/BPF authorisation are sufficient to fulfil the requirements of the post-authorisation condition of the reference BP/BPF authorisation, the relevant terms and conditions of the SBP authorisation (i.e., removal of the post-authorisation condition) should be amended at the time of renewal of the SBP authorisation in line with the amendment of the reference BP/BPF authorisation.
- Where the data submitted for the reference BP/BPF authorisation are not sufficient to fulfil the requirements of the post-authorisation condition of the reference BP/BPF authorisation, an Article 48(1)(c) procedure should be initiated by the Commission for the SBP authorisation.

In both cases, ECHA, through its secretariat, will provide an opinion with its conclusions on the fulfilment of the post-authorisation conditions for the SBP and a revised SPC, where relevant.

Where the data submitted for the SBP authorisation are not sufficient to fulfil the requirements of the post-authorisation conditions, ECHA, through its secretariat, will provide an opinion with its conclusions and a revised SPC, where relevant. Subsequently, an Article 48(1)(c) procedure should be initiated by the Commission for the SBP authorisation.

Where the data are not submitted in due time for the reference BP/BPF authorisation and/or the SBP authorisation, ECHA will establish the fact and inform Commission that an Article 48(1)(c) procedure should be initiated by the Commission without undue delay.

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[12] The ECHA SECR should be included in cc of this communication.