# Post-authorisation conditions for national and simplified product authorisation: harmonising practices

| Date of agreement: 26 April 2023 | Classification: **Public** |
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## 1. Introduction

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 to harmonise the practices. It is expected that such harmonised practices will prevent the submission of referrals to the CG.

This document should not be regarded in any case as guidance for applicants to request a post-authorisation condition. MSs will decide on a case-by-case basis whether the application of a post-authorisation condition is acceptable and can be justified.

Post-authorisation conditions can only be set when an authorisation is granted for the BP/BPF in a national authorisation (NA) or simplified authorisation (SA) 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 an NA or SA procedure, the same post-authorisation conditions will have to be set for all those SBP authorisations.

This document was agreed at the CG-32 meeting and afterwards revised and agreed at the CG-56 meeting.

## 2. Agreed way forward

Post-authorisation conditions should always remain an exception and shall only be applied, where relevant, on a case-by-case basis.

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 the efficacy/risk assessment.

If these criteria are respected, and only as long as the document `CG-53-2022-07 AP 14.1 Shelf-life setting at PA-vf' 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 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[1], but a completed long-term storage test at ambient temperature is not available when authorisation is granted for the BP/BPF in an NA or SA procedure. In such a situation a maximum of 24 months shelf-life

[1] 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 rMS/eCA.

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 NA 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)[2] conditions and/or the efficacy/risk assessment.
- For SA 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 25 conditions and/or the efficacy assessment.
- Complete long-term stability study is missing when authorisation is granted for the BP/BPF in an NA or SA procedure[3] for which the application was submitted after the publication of this CG document, the revised BPC document and the revised APCP TAB entry document concerning shelf-life.

If a receiving Competent Authority/reference Member State (rMS)/evaluating Competent Authority (eCA) is considering setting a post-authorisation condition, it is strongly recommended to bring up the matter for 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.

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

Post-authorisation conditions will be part of the terms and conditions of the authorisation to be recorded in R4BP 3 by the receiving Competent Authority/rMS for the NA-APP and by the eCA for the SA-APP, together with the agreed SPC and the PAR.

The post-authorisation conditions should be included in the PAR in the relevant conclusion section. Post-authorisation conditions are not indicated in the SPC.

# 3. Practical implementation for the follow-up of post-authorisation conditions in national authorisation[4]

The receiving Competent Authority will be responsible for the follow-up of post-authorisation conditions by the authorisation holder (AH). At the time of the authorisation, the receiving Competent Authority 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 are submitted by the AH in due time, the receiving Competent Authority will assess the data. If the data are sufficient to fulfil the requirements of the post-authorisation condition, the receiving Competent Authority will amend the relevant terms and conditions of the BP/BPF authorisation (i.e., removal of the post-authorisation condition) at the time of renewal of the BP/BPF authorisation. If the data are not sufficient to fulfil the requirements of the post-authorisation condition or are not submitted in due time, the receiving Competent Authority will initiate an Article 48(1)(c) procedure.

## 3.1 National authorisation subject to mutual recognition

Post-authorisation conditions should be included in the terms and conditions of the

[2] And where relevant, Article 19(5) conditions.
[3] Making it impossible to set the shelf-life (as it can only be set for the time period that is supported by data).
[4] SBP applications related to the BP/BPF authorisation granted in an NA procedure are addressed under a separate section of this document.

corresponding authorisations granted by the concerned Member States (cMSs). If submission of specific data is requested by a certain deadline as a post-authorisation condition by the rMS, the cMSs should include the same condition that the data should be submitted to the rMS. The rMS should indicate via R4BP 3 to that cMS that the data was submitted for the NA-APP within one day of the deadline as set by the rMS for the AH to submit the data.

In order to facilitate the peer review process, it is proposed to include the post-authorisation conditions in the PAR in the relevant conclusion section. Post-authorisation conditions are not indicated in the SPC.

Both the rMS and cMSs will be responsible to follow up on the fulfilment of the post-authorisation conditions. At the time of the authorisation, the rMS 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. At the time of mutual recognition, the cMSs will send a task driven ad hoc communication via R4BP 3 to the rMS requesting confirmation that the data was submitted to the rMS for the NA-APP (the deadline of this task should be one day after the deadline set by the rMS for the submission of the data).

Where the data are submitted by the AH in due time, the rMS will assess the data. Afterwards, the rMS will send a task driven ad hoc communication via R4BP 3 to all cMSs (including as subject in the communication "Post-authorisation data") with the outcome of the assessment (including clear indication whether the post-authorisation conditions are considered fulfilled) and requesting a response from all cMSs in 30 days[5]. The cMSs will then provide an answer to the rMS with all cMSs in copy indicating their position regarding the assessment of the rMS. The following scenarios are foreseen:

| **Outcome of the rMS's assessment of the data submitted by the AH** | **Outcome of the cMS(s)' review of the assessment of the rMS (within the 30-day period)** | **Actions** |
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| The data are sufficient to fulfil the requirements of the post-authorisation condition. | All cMSs agree with the assessment of the rMS | The relevant terms and conditions of the BP/BPF authorisation (i.e., removal of the post-authorisation condition) will be amended at the time of renewal of the BP/BPF authorisation. |
| | One or more cMS **disagrees** with the assessment of the rMS | Pursuant to the third paragraph of Article 48(3) of the BPR, the cMSs not agreeing can raise a referral to the CG against the decision of the rMS. |
| The data are **not** sufficient to fulfil the requirements of the post-authorisation condition | All cMSs agree with the assessment of the rMS | The rMS initiates an Article 48(1)(c) procedure and notifies the AH, all other MSs and, where relevant, the COM in accordance with the first paragraph of Article 48(3) of the BPR.<br>Within 120 days of the notification of the rMS, the cMSs amend or cancel their authorisations |

[5] In case of need for clarification or a possible disagreement, cMSs are encouraged to inform the rMS as early as possible, so that a bilateral discussion can still take place within the 30-day period.

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| | | issued under the mutual recognition procedure in accordance with the first paragraph of Article 48(3) of the BPR. |
| | One or more cMS **disagrees** with the assessment of the rMS | Pursuant to the third paragraph of Article 48(3) of the BPR, the cMSs not agreeing can raise a referral to the CG against the decision of the rMS. |

Where the data are not submitted in due time to the rMS, the rMS will inform the cMSs about this and directly initiate an Article 48(1)(c) procedure, without prior consultation with the cMSs, in order to cancel or amend the authorisation. Then the rMS informs the cMSs, AH and, where relevant, the COM in accordance with the first paragraph of Article 48(3) of the BPR. The cMSs will also cancel or amend the authorisation within 120 days of the communication via R4BP 3.

# 4. Practical implementation for the follow-up of post-authorisation conditions in simplified authorisation[6]

The eCA will be responsible to follow up on the fulfilment of the post-authorisation conditions by the AH.

The post-authorisation conditions should be included in the PAR in the relevant conclusion section and will not be indicated in the SPC.

The eCA will be responsible for the follow-up of post-authorisation conditions. At the time of the authorisation, the eCA 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.

After the deadline for the submission of the data by the AH expires, the eCA will assess the data and, if necessary, initiate an Article 48(1)(c) procedure.

## 4.1 Simplified authorisation that was notified in another Member State

Where the data are submitted by the AH in due time, the eCA will assess the data. Afterwards, the eCA will send a task driven ad hoc communication via R4BP 3 to all notified Member States (nMSs) (including as subject in the communication "Post-authorisation data") with the outcome of the assessment (including clear indication whether the post-authorisation conditions are considered fulfilled) and requesting a response from all nMSs in 60 days. The following scenarios are foreseen:

[6] SBP applications related to the BP/BPF authorisation granted in an SA procedure are addressed under a separate section of this document.

| **Outcome of the eCA's assessment of the data submitted by the AH** | **Outcome of the nMS(s)' review of the assessment of the eCA (within the 60-day period)** | **Actions** |
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| The data are sufficient to fulfil the requirements of the post-authorisation condition. | All nMSs agree with the assessment of the eCA | The relevant terms and conditions of the BP/BPF authorisation (i.e., removal of the post-authorisation condition) are amended by the eCA. |
| | One or more nMS **disagrees** with the assessment of the eCA | The nMS(s) disagreeing with the assessment of the eCA pursuant to the second paragraph of Article 27(2) of the BPR raises a referral to the CG against the decision of the eCA. |
| The data are **not** sufficient to fulfil the requirements of the post-authorisation condition | All nMSs agree with the assessment of the eCA | The eCA initiates an Article 48(1)(c) procedure and notifies the AH and all other MSs in accordance with the first paragraph of Article 48(3) of the BPR.<br>All nMSs cancel the notification.<br>In case the AH wishes to make the product available in another Member State, it needs to submit a new notification application in accordance with Article 27(1) of the BPR. |
| | One or more nMS **disagrees** with the assessment of the eCA | The nMS(s) disagreeing with the assessment of the eCA does not cancel the notification and pursuant to the second paragraph of Article 27(2) of the BPR raises a referral to the CG against the decision of the eCA. |

Where the data are not submitted in due time, the eCA will inform the nMSs about this and the eCA will directly initiate an Article 48(1)(c) procedure, without prior consultation with the nMSs, in order to cancel or amend the authorisation. Then the eCA informs the nMSs and AH in accordance with Article 48(3) of the BPR.

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

In case there are SBP applications related to a BP/BPF authorisation granted in an NA or SA procedure (hereby called `reference BP/BPF'), the same post-authorisation conditions will have to be set for all those SBP authorisations.

### 5.1 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 BP/BPF, the SBP authorisation should include the conditions that within two weeks of the deadline set in the authorisation of the reference BP/BPF for submission of the data the AH of the SBP authorisation should submit:

- proof that the data was submitted for the reference BP/BPF, and
- a Letter of Access providing the right to refer to the post-authorisation data submitted for the reference BP/BPF[7].

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 should align with the ones taken for the reference BP/BPF authorisation.

If 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.

If 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, and/or the data are not submitted for the reference BP/BPF authorisation in due time, and/or the post-authorisation conditions of the SBP authorisation are not fulfilled, an Article 48(1)(c) procedure should be initiated for the SBP authorisation.

## 6. Further actions

The same approach will be presented for the BPC for the UA process.

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