Guiding principles on handling information provided by the applicant during UA process

Version 1.1

This document will be reviewed in the light of experience.

Disclaimer

This document aims to assist users in complying with their obligations under Regulation (EU) No 528/2012 in the form of an agreement between Member States' Competent Authorities for biocidal products on a harmonised approach. Please note, however, that this document is agreed by the members of the Biocidal Product Committee and that Member States are not legally obliged to follow the approach set out in this document. Only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Document history

Version	Changes	Date of agreement	Date of applicability
1.0	First edition (original unnumbered version)	24 March 2023	31 March 2023
1.1	Changes in the document: • introduced in relation of the SPC format change from xml to i6z; • Inclusion of the date of applicability in the version history table; • Copying the document in the new BPC document format; • Adding disclaimer.	NA	31 January 2024

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1. Introduction

The purpose of this document is to provide guidance to both applicants as well as authorities on the possibilities to provide information during the Union Authorisation process. This should ensure clarity to the Competent Authorities on the expectations and it should ensure the fair and equal treatment of applicants.

The aim is to harmonise the procedures:

- Clarify during which steps information may be provided;
- Describe who may initiate the submission of new information and who defines what information has to be provided;
- Align between Competent Authorities (CAs) how applications are being validated and evaluated;
- Provide general principles for messages in R4BP, provide templates for voluntary use by the CAs.

2. Timing of submission of information

The BPR defines three points in the process where the applicant can provide information: at the submission of the application, during the validation and during the evaluation. It is important to stress that the application should be complete at the time of submission and it should be adequate to support the evaluation process.

The European Chemicals Agency (ECHA) may request during the acceptance phase missing administrative information. The evaluating Competent Authority (eCA) may request during the validation information to address identified data gaps. During the evaluation the eCA may request additional information necessary to carry out the evaluation. Finally, the BPC Working Groups can exceptionally decide to request information.

The data submitted purely on the initiative of the applicant in any stage of the product authorisation process after the initial application submission, i.e., not requested by the eCA, ECHA or BPC WGs, should not be taken into account. In case the applicant wishes to provide additional information which was not requested by the eCA, the applicant should contact the eCA beforehand. It is within the discretion of the eCA to decide whether or not the applicant will be allowed the opportunity to send the information.

The details of these steps will be discussed in the next chapter, an overview of the process is given in Annex 1.

3. Specifics of information submission opportunities during the authorisation process

3.1. Submission of the application

When submitting the application, the applicant shall submit a dossier fulfilling the requirements as set in Annex III of the BPR. The complete dossier must be compiled in IUCLID and sent via R4BP. In R4BP several additional documents with administrative information on the application should be attached.[1]

[1] Biocides Submission Manual

Note: This is the only step in the process where the applicant is foreseen to submit information on their own initiative. This underlines the importance of compiling a complete and high-quality dossier prior to submitting the application. The quality of the initial dossier has a significant impact on the future authorisation.

3.2. Format check

Upon submission of the application, ECHA checks whether the IUCLID file has the correct format and whether the required additional documents with administrative information have been attached in R4BP. ECHA may request the applicant to resubmit the application if the IUCLID dossier is not in the correct format or if one or more of the administrative documents are missing.

Note: The BPR does not foresee that a resubmission takes place in this phase and therefore also no deadline has been set. Depending on the nature of the request, ECHA grants 7 or 14 days to resubmit the required information.

3.3. Validation

During the validation period, the eCA should ensure that the dossier is complete and may request missing information. The eCA should finalise the validation within 30 days and not make an assessment of the quality or adequacy of the information in the dossier.

- When requesting information, it is preferable that the eCA compiles all comments from the four different expertise areas (APCP, HH, ENV, EFF) in one message to the applicant.

  Since eCAs have different organisation structures and internal procedures, for some eCAs it is not possible to compile all comments in one message. In that case it should be clearly communicated to the applicant that there will be several requests and the deadline for each request should be clearly indicated.

- The applicant should only be granted one possibility to submit additional information per request and the deadline for providing the information should normally not exceed 90 days.

In Annex 2 a suggested template can be found for the message to the applicant which should be sent through R4BP. In Annex 3 a template is given which can be used by the eCA to provide comments to the applicant on how the dossier should be updated. The template should subsequently be used by the applicant to respond and communicate to the eCA on how they complied with the eCA's requests.

The applicant should not submit any other information than what has been requested by the eCA without prior agreement by the eCA. The applicant can contact the eCA via ad hoc communication in R4BP to discuss submission of other information than previously requested by the eCA.

The 90-day deadline shall be respected. The only reason why the deadline may be extended by the eCA is when a requested study takes more than 90 days to perform[2]. A

[2] The eCA might also decide to prolong the deadline by considering the laboratory availability. However, in order to grant a longer deadline, the applicant should – if possible - provide for the eCA a written agreement with the laboratory which also includes timelines.

large amount of missing studies is likely caused by a poorly prepared dossier and is not a valid reason to extend this deadline.

If the requested information can not be provided before the deadline, the applicant should consider to either withdraw the application or amend the application (PAR and SPC) to fit them with the available information. In the latter situation, the applicant should consider to remove uses or products from the application for which the data-set is incomplete. These uses or products can be added by applying for a change after the first application has been authorised.

Failure to provide the requested information or failure to reply within the deadline will result in rejection of the application. The applicant should therefore contact the eCA without delay, via ad hoc communication in R4BP, when they become aware that they are unable to comply with the request.

3.4. Evaluation

During the evaluation period the eCA should finalise the evaluation within 365 days, during this period the applicant should also be granted the opportunity to provide their comments (within a 30 day timeframe). The eCA may request additional information:

- When requesting information, it is preferable that the eCA compiles all comments from the four different expertise areas (APCP, HH, ENV, EFF) in one message to the applicant.

  Since eCAs have different organisation structures and internal procedures, for some eCAs it is not possible to compile all comments in one message. In that case it should be clearly communicated to the applicant that there will be several requests and the deadline for each request should be indicated.

- The applicant should in principle only be granted one possibility to submit additional information per request and the deadline for providing the information should not exceed 180 days. Deviations from these principles can be granted in exceptional cases, where it is justified by the nature of the information requested.

- A solid justification for exceeding the 180 days deadline should be provided by the applicant. The main reason why the deadline may be extended is when a requested study takes more than 180 days to perform[3].

Note: For products subject to the transitional provisions set in Article 89 of the BPR, the general 3-year transition period set in Article 89(3) should be respected. The time spent by the eCA on evaluating the application and the deadlines set to provide additional data shall be such that the 3-year transition period is respected.

In Annex 2 a suggested template can be found for the message to the applicant which should be sent through R4BP. In Annex 3 a template is given which can be used by the eCA to provide comments to the applicant on how the dossier should be updated. The template should subsequently be used by the applicant to communicate to the eCA on how they complied with the eCA's requests.

[3] The eCA might also decide to prolong a deadline by considering the laboratory availability. However, in order to grant a longer deadline, the applicant should provide for the eCA a written agreement with the laboratory which also includes all timelines.

The applicant should not submit any other information than what has been requested by the eCA without prior agreement by the eCA. The applicant can contact the eCA via ad hoc communication in R4BP to discuss submission of other information than previously requested by the eCA.

If the requested information can not be provided before the deadline, the applicant should consider to either withdraw the application or amend the application (PAR and SPC) to fit them with the available information. In the latter situation, the applicant should consider to remove uses or products from the application for which the data-set is incomplete. These uses or products can be added by applying for a change after the first application has been authorised.

Failure to provide the requested information or failure to reply within the deadline will have negative consequences for the outcome of the evaluation. The eCA may reflect on this in the PAR, possibly leading to non authorisation of products or uses. The applicant should therefore contact the eCA without delay, via ad hoc communication in R4BP, when they become aware that they are unable to comply with the request.

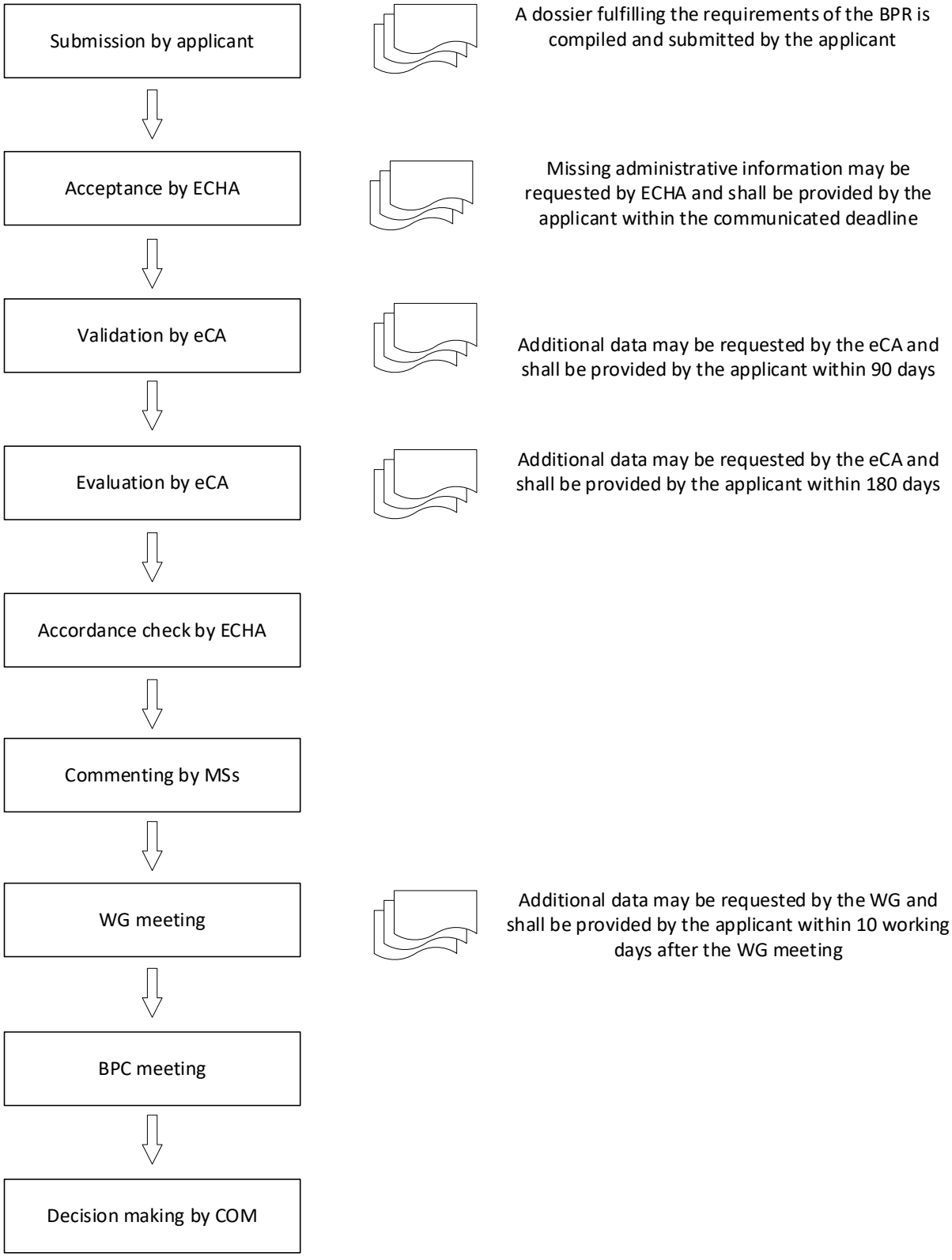
3.5. Working Group

The BPC Working Group members may request additional information which shall be provided within 10 working days after the after the day of the conclusion of the WG to invite provision of further information. This should therefore be limited to issues that are raised in the WGs for the first time and to information which can be provided within 10 working days, as the 180-day deadline of the opinion forming phase must be respected. Further details can be found in the relevant guidance document.[4]

Since 10 working days is a rather short deadline for providing information, the eCA and applicant are encouraged to consider the initiation of early Working Group discussions in case of doubts on data requirements and the outcome of the evaluation.

[4] Introducing new information during the peer review process of an application for Union authorisation

Annex 1: Schematic overview of the UA process, indicated are the steps where information can be provided by the applicant



Annex 2: Template messages to applicants in validation and evaluation phase

These templates are provided as a courtesy, the evaluating Competent Authority is not obliged to use them. However, any messages sent to the applicant should at least contain the following items:

- The reason why the applicant is being contacted and the legal basis
- Description of the findings.
- Description of expected actions by the applicant.
- A deadline by which an answer is expected.
- Consequences for not complying with the request, or not complying with the request within the legal deadline.
- Means of legal redress in the case of rejection (which is member state specific and should be included in every decision letter).

The eCA should amend the text of the messages in order to comply with national specific procedures and application specific details (type of information, deadline etc.).

Validation – request for additional information

Dear applicant,

We have assessed your application for Union authorisation in accordance with Article 43(3) of Regulation (EU) No 528/2012 (BPR). Please find the results of the validation step in the commenting table attached to this message.

Your application could not be validated for the reasons set out in the commenting table. You should therefore update your IUCLID dossier, PAR and SPC according to the instructions in the commenting table. You should ensure that the information contained in all documents is consistent with each other.

You are not allowed to make any other alterations to the dossier for any other element than what has been requested in the commenting table. In case you are unable to provide the requested information by the timeline set, you are required to remove (part of) the claims in PAR and SPC in order to pass the validation phase. The remaining claims should be consistent in the IUCLID dossier, PAR and SPC documents.

Upon resubmitting your IUCLID dossier, PAR and SPC you should return the commenting table via R4BP as well. The commenting table should be filled with an explanation in the column marked ‘Response applicant’ on how you answered every single point.

In accordance with Article 43(4) of the BPR the deadline to respond to our request for additional information is 90 days from receipt of this letter. Failure to submit the requested information within the deadline will result in the rejection of your application.

Kind regards,
On behalf of the <<name member state>> Competent Authority

Validation – validated and progress to evaluation

Dear applicant,

We have validated your application for Union Authorisation in accordance with Article 43 of Regulation (EU) No 528/2012 (BPR). We will now proceed with the evaluation of your application in accordance with Article 44 of Regulation (EU) No 528/2012 (BPR).

Kind regards,
On behalf of the <<name member state>> Competent Authority

Validation – rejection

Dear applicant,

We have continued to assess your application for Union authorisation, following our request for additional information in accordance with Article 43(4) of Regulation (EU) No 528/2012 (BPR).

Decision

The additional information is insufficient / You failed to provide the requested information within the deadline [delete as appropriate] and therefore your application cannot be validated and cannot proceed to the evaluation step. The reasoning for this conclusion is set out in the attached commenting table.

As mentioned at the resubmission request, failure to submit the requested information within the deadline results in the rejection of the application. Accordingly, your application is rejected in accordance with Article 43(4) of the BPR.

Consequences

Biocidal products cannot be made available on the market or used if they are not authorised, as per Article 17 (1) of the BPR. Transitional provisions may apply under Article 89(4) of the BPR.

Note that you are entitled to partial reimbursement of the fee paid as per Article 80(3) BPR, including the fee paid to ECHA (Article 13(1) of Commission Regulation (EU) No 564/2013).

Legal redress

You may bring a challenge against this decision [include explanation appropriate for the Member State]

Kind regards,
On behalf of the <<name member state>> Competent Authority

Evaluation – request for additional information

Dear applicant,

We have performed an evaluation of your dossier in accordance with Article 44(2) of Regulation (EU) No 528/2012 (BPR).

Please find the results of the evaluation in the documents attached to this message:
- Commenting table with the comments and specific requests from our Competent Authority (CA) on your application
- Product Assessment Report (PAR) including comments by our CA
- Confidential annex to the PAR including comments by our CA
- Summary of Product Characteristics including comments by our CA
- Document containing annotations by our CA, extracted from IUCLID.

You are requested to take note of our comments and specific requests in the commenting table and to provide answers in the relevant column.

You are also requested to update the attached documents and the IUCLID file in accordance with the provided comments. In addition you should make sure that the information contained in all documents of your dossier is consistent.

Please submit the updated dossier within 180 days. In accordance with Article 44(2) of the BPR this deadline may only be extended if justified due to the nature of the data requested, or due to exceptional circumstances.

Failure to comply with the 180 days deadline or failure to address all comments properly in the attached documents will result in a negative outcome of the evaluation.

Please note that this is your only opportunity to generate and submit additional information. No additional opportunities will be granted. You are only allowed to submit the information as requested in the attached documents, and you cannot extend the scope of your initial application (eg: request to add new uses to be assessed, or substitute uses applied for).

Upon finalising the evaluation you will be given the opportunity to provide written comments on the conclusions of the evaluation in accordance with Article 44(1) of the BPR. After taking due account of your comments we will then proceed to forward the PAR and the conclusions of the evaluation to ECHA.

Kind regards,
On behalf of the <<name member state>> Competent Authority

Evaluation – pass and progress to 30 day commenting phase

Dear applicant,

We have finalised the evaluation of your application. Attached to this message you will find the resulting PAR and the confidential annex.

In accordance with Article 44(1) of Regulation (EU) No 528/2012 (BPR) you are hereby given the opportunity to provide written comments on our conclusions within 30 days from receipt of this letter. Please be advised that you are only allowed to provide written comments, there is no possibility to submit additional information.

The comments should be inserted in attached commenting table[5]. This commenting table will be supplemented with our response and will be made available to the other member states at the start of the opinion forming phase.

If you would like to make us aware of minor, textual changes you should do so in the PAR and/or confidential annex with 'track changes'.

We kindly ask you to provide in the answer to this message:
- The commenting table with your comments
- Draft PAR
- Draft PAR confidential Annex
- SPC in i6z in English language, the i6z SPC has to be made by copying the text of 'authorised uses' in the PAR into the i6z file using the SPC in IUCLID tool.

The comments need to be provided within the 30-day deadline and any comments made will be taken into account before the assessment report and conclusions are submitted to ECHA.

Kind regards,
On behalf of the <<name member state>> Competent Authority

[5] Information for the eCA: the template used for 30 day commenting period is available on ECHA website: Formats and templates - ECHA (europa.eu)

Annex 3: Template commenting table to be used when requesting information during validation and evaluation phase

This template is provided as a courtesy, the evaluating Competent Authority is not obliged to use it.

When preparing the file, either replace or delete the text with grey background

Outcome validation / evaluation of the biocidal product family <<name product (family)>>

General

Document/IUCLID Paragraph	Remark eCA First validation/evaluation	Response applicant	Conclusion eCA Second validation/evaluation

APCP

Document/IUCLID Paragraph	Remark eCA First validation/evaluation	Response applicant	Conclusion eCA Second validation/evaluation

Efficacy

Document/IUCLID	Remark eCA	Response applicant	Conclusion eCA

Paragraph	First validation/evaluation		Second validation/evaluation

Human health

Document/IUCLID Paragraph	Remark eCA First validation/evaluation	Response applicant	Conclusion eCA Second validation/evaluation

Environment

Document/IUCLID Paragraph	Remark eCA First validation/evaluation	Response applicant	Conclusion eCA Second validation/evaluation

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