Guiding principles on handling information provided by the applicant during national and simplified authorisation processes

1. Document identifier

CG-56-2023-31 AP 14.2 Guiding principles on providing data_NA-SA processes_v2

Document history

Version	Changes	Date of agreement	Date of applicability
1.0	First edition (original unnumbered version)	27 April 2023 [at CG-56]	3 May 2023 (publication date)
2.0	Main changes in the document: • Replacement of xml format with i6z format due to integration of SPC Editor into IUCLID; • Changes in the structure, including addition of document history; • Correction of typo in the template for Validation – validated and progress to evaluation (Annex II); • Correction of typo in the template for Evaluation – pass and progress to 30 day commenting phase.	29 November 2023 [at CG-59]	9 February 2024 (publication date)

1. Introduction

This document was agreed at the CG-56 meeting and it is an adaptation of a very similar document which was agreed during the BPC-45 meeting for the Union Authorisation process.

The purpose of this document is to provide guidance to both applicants as well as authorities on the possibilities to provide information during the National Authorisation (NA) and mutual recognition (if applicable), as well as Simplified Authorisation (SA) and simplified notification (if applicable) processes. 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 NA process where the applicant can provide information: at the submission of the application, during the validation and during the evaluation. In the SA process it defines two points where the applicant can provide information: at the submission of the application 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.

In the NA process the receiving Competent Authority (recCA) or, in case the NA application is subject of mutual recognition, the reference Member State (refMS) may request during the validation information to address identified data gaps[1]. During the evaluation the recCA/refMS in the NA process, or the evaluating Competent Authority (eCA) in the SA process may request additional information necessary to carry out the evaluation. Finally,in case of a referral, the Coordination Group (CG) can also 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 recCA/refMS/eCA, or ECHA, should not be taken into account. In case the applicant wishes to provide additional information, which was not requested by the recCA/refMS/eCA, the applicant should contact the recCA/refMS/eCA beforehand. It is within the discretion of the recCA/refMS/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, overviews of the process are given in Annex 1.

[1] Not relevant for SA process, as in that case there is no validation.

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 Article 20 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.[2]

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. ECHA may request the applicant to resubmit the application if the IUCLID dossier is not in the correct format.

3.3. Validation[1]

During the validation period, the recCA/refMS should ensure that the dossier is complete and may request missing information. The recCA/refMS 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 recCA/refMS compiles all comments from the four different expertise areas (APCP, HH, ENV, EFF) in one message to the applicant.

  Since MSs have different organisation structures and internal procedures, for some recCAs/refMSs 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 4 a template is given which can be used by the recCA/refMS 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 recCA/refMS on how they complied with the recCA's/refMS's requests.

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

[2] Biocides Submission Manual for NA process, Biocides Submission Manual for SA process

The 90-day deadline shall be respected. The only reason why the deadline may be extended by the recCA/refMS is when a requested study takes more than 90 days to perform[3]. A 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 cannot 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 removing uses or products from the application for which the dataset 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 recCA/refMS without delay, via ad hoc communication in R4BP, when they become aware that they are unable to comply with the request.

3.4. Evaluation

3.4.1 National authorisation process

During the evaluation period of the NA the recCA/refMS 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 recCA/refMS may request additional information:

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

  Since MSs have different organisation structures and internal procedures, for some recCA/refMSss 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[4].

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 recCA/refMS on evaluating the application and the deadlines set to provide additional data shall be such that the 3-year transition period is respected.

[3] The recCA/refMS 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 recCA/refMS a written agreement with the laboratory which also includes timelines.
[4] The recCA/refMS 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 recCA/refMS a written agreement with the laboratory which also includes all timelines.

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 recCA/refMS 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 recCA/refMS on how they complied with the recCA's/refMS's requests.

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

If the requested information cannot 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 removing 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 either result in rejection of the application or have other negative consequences for the outcome of the evaluation. The recCA/refMS may reflect on this in the PAR, possibly leading to non-authorisation of products or uses. The applicant should therefore contact the recCA/refMS without delay, via ad hoc communication in R4BP, when they become aware that they are unable to comply with the request.

3.4.1.2 Mutual recognition procedure

During the MR phase the refMS may request additional information from the applicant in order to resolve issues raised by concerned Member States. The deadline for the applicant/authorisation holder to provide the requested information is set by the refMS and for this the steps and timelines established in the Standard operating procedures for the MR process in parallel and sequence[5] and of minor changes applications[6] shall be respected. Since not providing the requested data can lead to the cMS initiating a referral, the applicant is encouraged to indicate when the requested additional information will be provided and provide the requested data as soon as possible.

The applicant/authorisation holder shall not submit additional information on their own initiative.

3.4.2 Simplified authorisation process

During the evaluation period of the SA process the eCA should finalise the evaluation within 90 days. 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.

[5] The Standard operating procedure for the MR process in parallel and sequence applications is available here: /CircaBC/echa/Biocides_CoordinationGroup_public/Library/Procedures/Procedures_and_templates_for_Mutual_Recognition_process

[6] The Standard operating procedure for the MR process of minor changes applications is available here: /CircaBC/echa/Biocides_CoordinationGroup_public/Library/Procedures/Procedures_and_templates_for_Mutual_Recognition_of_Minor_Change_process

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 90 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 90 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 90 days to perform[7].

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 3 a suggested template can be found for the message to the applicant which should be sent through R4BP. In Annex 5 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.

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 cannot 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 removing uses or products from the application for which the dataset 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 either result in the rejection of the application or have other 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.

[7] 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.

3.4.2.1 Simplified notification procedure

During the bilateral discussions of the simplified notification process the eCA may request additional information from the applicant in order to resolve issues raised by notified Member States. The deadline for the authorisation holder to provide the requested information is set by the eCA and for this the steps and timelines are established in the Working Procedure for resolving of disagreements[8] shall be respected. Since not providing the requested data can lead to the notified Member State initiating a referral, the authorisation holder is encouraged to indicate when the requested additional information will be provided and provide the requested data as soon as possible.

The authorisation holder shall not submit additional information on their own initiative.

3.5. Referral

For a referral agreement needs to be reached within the Coordination Group (CG) between the refMS and cMSs/eCA and nMSs within 60 days. During the referral the applicant shall be allowed the opportunity to make its point known. The applicant/authorisation holder is granted one possibility to submit comments, including additional information per the request of the Secretariat of the CG within 2 weeks of the launching of the referral. After this the applicant/authorisation holder shall not submit additional information on their own initiative, but the CG may request additional information from them in order to resolve the disagreement:

- When requesting information the request covers all expertise areas (APCP, HH, ENV, EFF) of the disagreement points involved and it is recorded in the conclusions of an additional or regular CG meeting and shared with the applicant and/or authorisation holder in one message.

- 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 be exceeded. Deviations from the principle of one such possibility could only occur in case the refMS and cMSs/eCA and nMSs consider the additional information submitted by the applicant and/or authorisation holder not acceptable and consider that if further information is requested it can still be considered within the 60 days of the referral.

  The deadline for providing the information should not be exceeded and the applicant and/or authorisation should be aware that in such a case the refMS and cMSs/eCA and nMSs will not take the information submitted late into consideration for their agreement. Thus, exceeding the deadline for submitting the requested information might lead to the non-authorisation of the product, as the 60 days for the referral process cannot be extended or suspended.

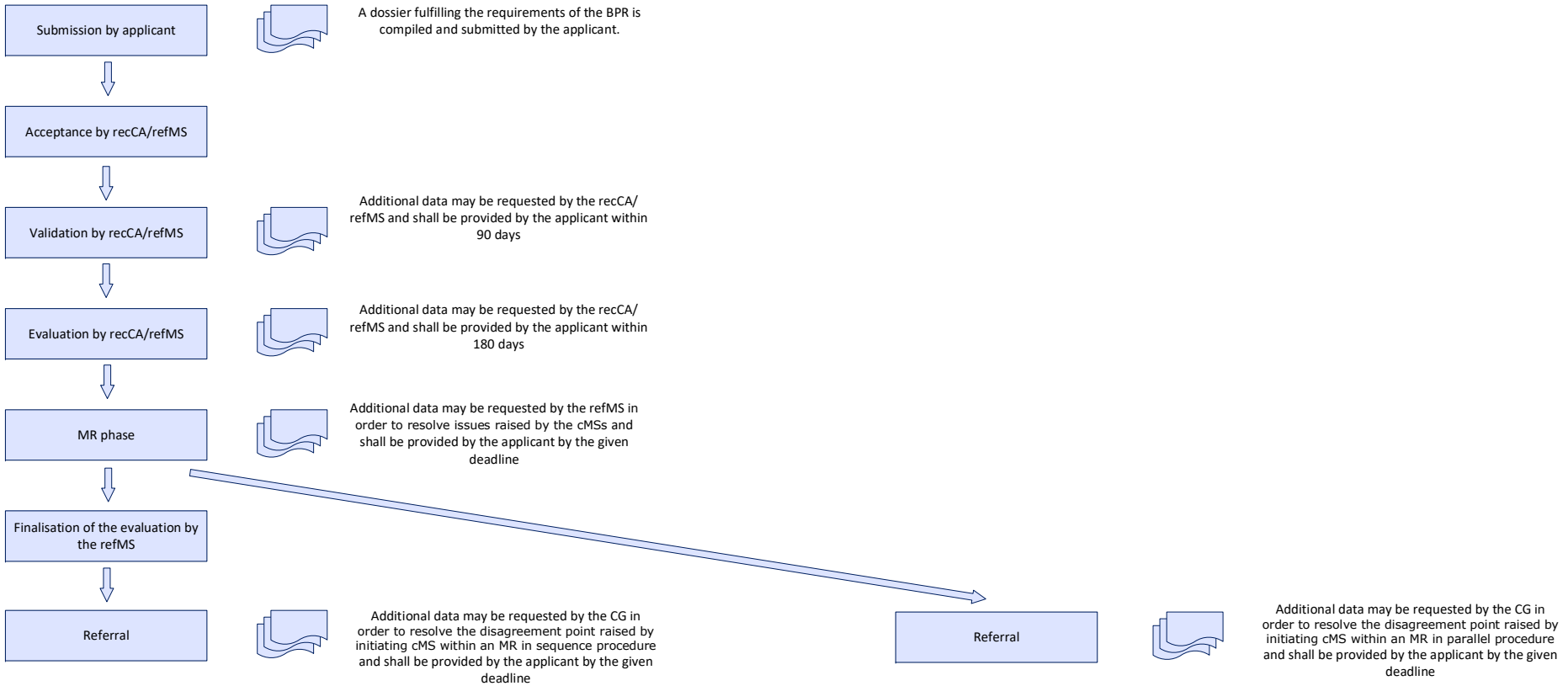
Additional information where the study would take longer to perform than the deadline of the referral or would not allow enough time for the refMS and cMSs/eCA and nMSs reasonable time to take into consideration should not be requested.

[8] The Working Procedure for resolving disagreements is available here: /CircaBC/echa/Biocides Coordination Group (CG)/Library/Non Confidential Folder/01. General & Procedural documents

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

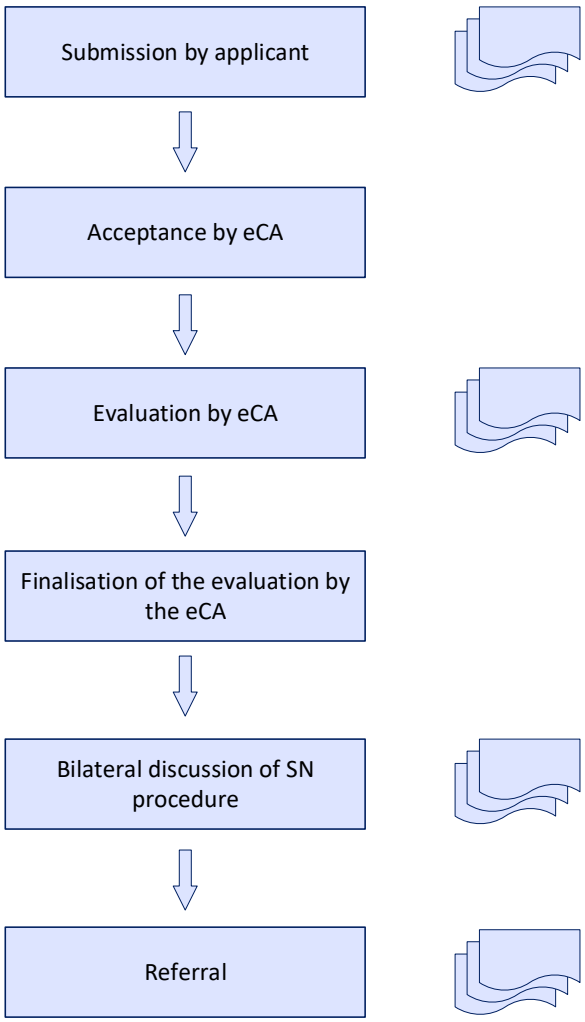
National authorisation and mutual recognition process

It should be noted that mutual recognition of an NA is not mandatory. A referral is not necessarily part of the mutual recognition process.



Simplified authorisation and notification process

It should be noted that SN of an SA is not mandatory. A referral is not necessarily part of the SN process.



A dossier fulfilling the requirements of the BPR is compiled and submitted by the applicant.

Additional data may be requested by the eCA and shall be provided by the applicant within 90 days

Additional data may be requested by the eCA in order to resolve issues raised by the nMS and shall be provided by the authorisation holder by the given deadline

Additional data may be requested by the CG in order to resolve the disagreement point raised by initiating nMS and shall be provided by the authorisation holder by the given deadline

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

These templates are provided as a courtesy, the recCA/refMS 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 recCA/refMS 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 National authorisation in accordance with Article 29(2) 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 29(3) 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 National Authorisation in accordance with Article 29(3)/29(5)[9] of Regulation (EU) No 528/2012 (BPR). We will now proceed with the evaluation of your application in accordance with Article 30 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 National authorisation, following our request for additional information in accordance with Article 29(3) of Regulation (EU) No 528/2012 (BPR).

Decision
The additional information is insufficient / You failed to provide the requested information within the deadline 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 29(3) 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.

Legal redress [if applicable for the Member State]
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 30(1) 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

[9] Delete as appropriate

- 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 30(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 deadline or failure to address all comments properly in the attached documents will either result in rejection of the application or have another 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 (e.g. 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 30(3)(b) of the BPR. After taking due account of your comments we will then proceed to authorise your application/peer review by concerned Member.

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 30(3)(b) 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[10]. This commenting table will be supplemented with our response and will be made available to the other member states at the start of the peer-review 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:

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

- The commenting table with your comments
- Draft PAR
- Draft PAR confidential Annex
- SPC in i6zin English language, the i6zSPC has to be made by copying the text of 'authorised uses' in the PAR into the i6zfile using IUCLID.

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 finalised.

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

Evaluation – rejection

Dear applicant,

We have continued to assess your application for National authorisation, following our request for additional information in accordance with Article 30(2) of Regulation (EU) No 528/2012 (BPR).

Decision
The additional information is insufficient / You failed to provide the requested information within the deadline and therefore the evaluation step of your application cannot be completed. 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 can result in the rejection of the application. Accordingly, your application is rejected in accordance with Article 30(2) 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.

Legal redress [if applicable for the Member State]
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

Annex 3: Template messages to applicants in evaluation phase of SA process

These templates are provided as a courtesy, the eCA 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.).

Evaluation – request for additional information

Dear applicant,

We have performed an evaluation of your dossier in accordance with Article 26(3) 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 90 days. In accordance with Article 26(4) 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 90 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 (e.g. request to add new uses to be assessed, or substitute uses applied for).

Upon finalising the evaluation we will then proceed to take a decision on your application.

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

Evaluation – rejection

Dear applicant,

We have continued to assess your application for Simplified authorisation, following our request for additional information in accordance with Article 26(4) of Regulation (EU) No 528/2012 (BPR).

Decision
The additional information is insufficient / You failed to provide the requested information within the deadline and therefore the evaluation step of your application cannot be completed. 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 can result in the rejection of the application. Accordingly, your application is rejected in accordance with Article 26(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.

Legal redress [if applicable for the Member State]
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

Annex 4: Template commenting table to be used when requesting information during validation and evaluation phase of NA process

This template is provided as a courtesy, the recCA/refMS 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 recCA/refMS First validation/evaluation	Response applicant	Conclusion recCA/refMS Second validation/evaluation

APCP

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

Efficacy

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

Human health

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

Environment

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

Annex 5: Template commenting table to be used when requesting information during evaluation phase of SA process

This template is provided as a courtesy, the eCA is not obliged to use it.

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

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

General

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

APCP

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

Efficacy

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

Human health

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

Environment

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