

Procedure for amendments to the List of biological control agents safely used in the EPPO region (EPPO Standard PM 6/3) ('Positive List')

21-26995 (21-26405 20-26025, 18-23788, 17-23091)

The EPPO Standard PM 6/3 *Biological control agents safely used in the EPPO region* lists in Appendices I and II indigenous, introduced and established biological control agents (BCAs) for plant protection which are recognized to have been safely used in EPPO region. Other EPPO countries may presume with some confidence that in the absence of any reported negative effects on non-target organisms, these agents can be introduced and used safely. Therefore, EPPO countries may, according to their judgement, dispense with, or simplify, the procedures proposed in EPPO Standards PM 6/1 *First import of exotic biological control agents for research under contained conditions* and PM 6/2(3) *Import and release of non-indigenous biological control agents*. The following procedure should be used for additions of BCAs to the EPPO 'Positive List'.

1. Application

The applicant who prepares the application should transfer it to EPPO via:

- The NPPO or,
- Other responsible National authority for BCA applications of any EPPO country or,
- A member of the Joint EPPO/IOBC Panel on Biological Control Agents¹.

The application should contain all required information on the BCA as described in the form for augmentatively used BCAs (form 1) or classical BCAs (form 2). The application should be received by the EPPO Secretariat before 1st July for consideration in the same year. Any application received after 1st July will be considered in the consecutive year.

The applicant is asked to answer the following question:

Do you accept that information from your application is made publicly available in EPPO databases.

2. Procedure within EPPO

Upon receipt of an application, the EPPO Secretariat will conduct an initial check of the format and return it to the applicant if needed along with a deadline for resubmission.

Following the initial check, the EPPO Secretariat will select three members of the Joint EPPO/IOBC Panel on Biological Control Agents to review the application. Each reviewer will be asked if they have a conflict of interest with the application and if they do, a different reviewer will be selected.

Reviewers should check the application for completeness and eligibility (against the information requirements set out in the application) within one month of reception. If information provided in the application is insufficient, the application should be sent back to the EPPO Secretariat with appropriate justification. The EPPO Secretariat will send the application back to the applicant and

¹ If the application is sent by a member of the Joint EPPO/IOBC Panel on Biological control, the responsible national authority should be informed of the submission.

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invite them to provide additional information and resubmit the application. If the resubmitted application is judged sufficient by the reviewers, the application is circulated to the Joint EPPO/IOBC Panel at least one month before the Panel meeting.

At the meeting of the Joint EPPO/IOBC Panel on Biological Control Agents, one of the three reviewers will present the application along with their recommendation. The Panel will then consider the application and will take one of three decisions:

- (1) The BCA fulfils the criteria and will be included on the Positive List,
- (2) The BCA does not fulfil the criteria and will not be added to the Positive List,
- (3) The information in the application is insufficient to make a decision.

If the Joint EPPO/IOBC Panel on Biological Control Agents accepts the proposal to add the BCA to the Positive List, this recommendation is circulated to Member Countries at least two months before the meeting of the Working Party on Phytosanitary Regulations (WPPR). If the WPPR approves the listing, the BCA is added to EPPO Standard PM 6/3 within one month of approval. If the WPPR does not approve the listing, justification for this decision will be provided to the Joint EPPO/IOBC Panel on Biological Control Agents which can take further action accordingly.

If the Joint EPPO/IOBC Panel on Biological Control Agents considers the proposed BCA cannot be added to the Positive List, the justification for this decision is sent to the applicant by the EPPO Secretariat.

If the Joint EPPO/IOBC Panel on Biological Control Agents considers that the information provided is insufficient to take a decision on the application, the request for additional information is sent to the applicant by the EPPO Secretariat. The applicant can resubmit the application with additional information for consideration in the consecutive year.

Deletions

Deletions (transfer of a BCA from Appendices I or II to Appendix III) may be considered by the Joint EPPO/IOBC Panel at the request of any NPPO or responsible national authority of any EPPO member country, or on the initiative of any member of the Joint EPPO/IOBC Panel, or the EPPO Secretariat. Evidence should be provided to the Joint EPPO/IOBC Panel to support this consideration, including any evidence of negative non-target effects.

If the Joint EPPO/IOBC Panel accepts the proposal to delete the BCA from the Positive List, this recommendation is circulated to Member Countries at least two months before the meeting of the WPPR. If the WPPR approves the deletion, the BCA is transferred from Appendices I or II to Appendix III of the EPPO Standard PM 6/3.

Annex 1

Background

EPPO Standard PM6/3 lists **indigenous, introduced and established biological control agents (BCAs)** for plant protection which are recognized by the Joint EPPO/IOBC Panel on Biological Control Agents to have been used in several EPPO countries. Other EPPO countries may therefore presume with some confidence that in the absence of unacceptable adverse effects on non-target organisms, these agents can be introduced and used safely. Appendices I and II of this Standard are sometimes therefore known as the 'Positive List'. Countries may, according to their judgement, dispense with, or simplify, the notification procedures proposed in EPPO Standards PM 6/1 and PM 6/2(3).

Form 1 should be used for a BCA used augmentatively and form 2 should be used for classical BCAs.

Form 1: Application for an augmentative applied BCA

Application to support the addition of [insert species name here] to the List of biological control agents safely used in the EPPO region EPPO Standard PM 6/3) for augmentative use

Date of submission of application:

1. Criteria used for addition to the List*

A biological control agent which has been used for at least 5 years in at least 5 EPPO countries (exceptionally fewer, if relevant crops, target pests or plants are present in <5 countries), or	<input type="checkbox"/>
Is indigenous and widespread in part of, or the whole of EPPO region, or	<input type="checkbox"/>
Is established and widespread in part of, or the whole of the EPPO region	<input type="checkbox"/>
AND	
There are no previous reports of adverse effects	<input type="checkbox"/>

* Mark the check box for the criteria that applies to the BCA

All used criteria should be supported by evidence. For no previous reports of adverse effects, lack of evidence should be supported by specifying the methods of literature searches including search terms used.

2. Name and contact details of the applicant (organization/company name, address, phone number, email address and name of contact person)

3. Name and contact details of the NPPO, National authority for BCA applications or Joint EPPO/IOBC member of the Panel on Biological Control Agents² who sends the application to the EPPO Secretariat.

4. Identity and classification of the organism

Names of genus and species, and if relevant, subspecies:

Order:

Family:

Common name(s):

Synonyms:

[Short description, (2-3 lines) with photograph or drawing if possible, and a reference for taxonomic identity]

5. Identification and location of voucher specimens

The locations (institutes, contact details) where voucher specimens of the organism were deposited and are available. Also provide the names of experts who have confirmed the identity of the material for which information is provided, and the methods by which this was done.

² If the application is sent by a member of the Joint EPPO/IOBC Panel on Biological control, the responsible national authority should be informed of the submission.

6. Geographical distribution

Describe the natural and (if different) the current geographical distribution of the organism and provide supporting references.

7. Releases of the organism within and outside of the EPPO region

7.1 Provide details of releases in countries within the EPPO region, specifying for each country the year of first known release, and if known, whether the release was based on a regulatory decision and the basis for that decision.

7.2 Provide details of releases in countries outside of the EPPO region, if any.

7.3 List any countries where application for release was rejected and if known, the reason for the rejection.

7.4 List any restrictions about the use of the BCA (e.g. indoor or outdoor)

8. Establishment and spread potential

If available, provide information on the establishment and spread potential of the organism (e.g. as related to availability of hosts/prey in the environment, dispersal ability, climatic adaptation).

9. Main target pests and crops

9.1 List the main pest(s) against which the release of the organism is suggested or practiced.

9.2 List the crops/habitats in which the organism has previously been used. Specify whether releases were done in open field or in protected cultivation.

10. Host or prey specificity and feeding habits

10.1 List the known hosts or prey of the organism and provide supporting references. This may include information on observed host ranges in the field or the laboratory.

10.2 If relevant, include information on plant feeding by the organism.

11. Non-target effects

11.1 If relevant specify any characteristics of the population/strain of the organism used for release that may be relevant for its potential to establish or cause non-target effects (e.g. non-diapausing strains, strains with limited dispersal ability).

11.2 If available, provide information on observed or potential effects of releases of the organism on non-target organisms in the environment.

12. Other relevant information

12.1. Provide any other relevant information here that may influence the decision on inclusion of the organism in EPPO Standard PM 6/3, (e.g. the formulation of the products containing the organism, the presence of host or prey organisms or symbiotic bacteria in the release formulation).

13. References

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List references cited in the above sections. Any references that are not publicly available should be provided in full at the time of application submission.

14. Summary table

Complete the following table with references (if available) supporting the criteria of the ‘Positive List’ (EPPO Standard PM 6/3) regarding the BCA proposed: This table will be published in EPPO Global Database

Criteria	Summary information (for EPPO region*)	References
BCA has been used for at least 5 years in at least 5 EPPO countries (exceptionally fewer, if relevant crops, target pests or plants are present in less than 5 countries)		
Is indigenous and widespread in part of, or the whole of EPPO region		
Is established and widespread in part of, or the whole of the EPPO region		

* e.g. date of release, country of release, country where BCA is indigenous

15. Do you accept that information from your application is made publicly available in EPPO databases

(Yes/No*)

* Delete as appropriate

Form 2: Application for a classical BCA

Application to Support the Addition of a classical BCA [insert species name here] to the List of biological control agents safely used in the EPPO region (EPPO Standard PM 6/3)

Date of submission of application:

1. Criteria used for addition to the List*

Classical BCA that is found at least five years after release to be successfully established in part of or the whole of the EPPO region	<input type="checkbox"/>
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AND

There are no previous reports of adverse effects	<input type="checkbox"/>
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* Mark the check box for the criteria that applies to the BCA

All used criteria should be supported by evidence. For no previous reports of unacceptable adverse effects, lack of evidence should be supported by specifying the methods of literature searches including search terms used.

2. Name and contact details of the applicant (organization/company name, address, phone number, email address and name of contact person)

3. Name and contact details of the NPPO, National authority for BCA applications or Joint EPPO/IOBC member of the Panel on Biological Control Agents³ who sent the application to the EPPO Secretariate.

4. Identity and classification of the organism

Names of genus and species, and if relevant, subspecies:

Order:

Family:

Common name(s):

Synonyms:

[Short description, (2-3 lines) with photograph or drawing if possible, and a reference for taxonomic identity]

5. Identification and location of voucher specimens

the locations (institutes, contact details) where voucher specimens of the organism were deposited and are available. Also provide the names of experts who have confirmed the identity of the material for which information is provided, and the methods by which this was done.

³ If the application is sent by a member of the Joint EPPO/IOBC Panel on Biological control, the responsible national authority should be informed of the submission.

6. Geographical distribution

Describe the natural and (if different) the current geographical distribution of the organism and provide supporting references.

7. Releases of the organism within and outside of the EPPO region

7.1 Provide details of releases in countries within the EPPO region, specifying for each country the year of first known release, and if known, whether the release was based on a regulatory decision and the basis for that decision. Summarise the release parameters (e.g. number of individuals, life stage) and the outcome of the release.

7.2 Provide details of releases in countries outside of the EPPO region, if any.

7.3 List any countries where application for release was rejected and if known, the reason for the rejection.

7.4 List any restrictions about the use of the BCA (e.g. indoor or outdoor)

8. Establishment and spread potential

If available, provide information on the establishment and spread potential of the organism (e.g. as related to availability of hosts/prey in the environment, dispersal ability, climatic adaptation). Indicate any environmental parameters that may limit establishment and spread and provide information on their strength in limiting the organism in question, and in what life stage.

9. Main target pests and their host plants

9.1 List the main pest(s) against which the release of the organism is suggested or practiced.

9.2 List the habitats in which the organism has previously been released.

10. Host or prey specificity and feeding habits

10.1 List the known hosts or prey of the organism and provide supporting references. This may include information on observed host ranges in the environment or the laboratory.

10.2 If relevant, include information on plant feeding by the organism.

11. Non-target effects

11.1 If relevant specify any characteristics of the population/strain of the organism used for release that may be relevant for its potential to establish or cause non-target effects (e.g. non-diapausing strains, strains with limited dispersal ability).

11.2 If available, provide information on realised or potential effects of releases of the organism on non-target organisms in the environment.

12. Other relevant information

2.10. Provide any other relevant information here that may influence the decision on inclusion of the organism in EPPO Standard PM 6/3, (e.g. the mode of release of the organism, the presence of host or prey organisms or symbiotic bacteria, or other contamination).

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13. References

List references cited in the above sections. Any references that are not publicly available should be provided in full at the time of application submission.

14. Summary table

Complete the following table with references (if available) supporting the criteria of the ‘Positive List’ (EPPO Standard PM 6/3) regarding the BCA proposed: This table will be published in the EPPO Global Database

Criteria	Summary information (for EPPO region*)	References
Classical BCA that is found at least five years after release to be successfully established in part of, or the whole of the EPPO region		

* e.g. date of release, country of release

15. Do you accept that information from your application is made publicly available in EPPO databases?

(Yes/No*)

* Delete as appropriate