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PM 6/2 (4) Import and release of non-indigenous biological control agents

Specific scope: This Standard provides an application form and guidelines to support an application for the import and/or release of a non-indigenous biological control agent (BCA). The Standard does not concern BCAs that are indigenous[1] to the area of release. The Standard applies to invertebrate BCAs used for augmentative and/or classical biological control, and microorganisms used for classical biological control.[2]
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1 | INTRODUCTION

Before non-indigenous biological control agents (BCAs) are introduced into a country, an assessment of their potential risks to agricultural and natural ecosystems should be carried out. This assessment is informed by a period of research on the BCA concerned. In cases where the research is performed in the country where the BCA is intended to be released, the first import of the BCA for research should be carried out following the notification procedure of the EPPO Standard PM 6/1(2) *First import of non-indigenous biological control agents for research under confined conditions* (EPPO, 2023). A BCA may also be released directly following import, in cases where the required research and mass rearing have been carried out in another country, and the conclusion of the research is that BCA constitute no risk to agricultural and natural ecosystems. The present Standard is mainly concerned with the release of BCAs after research and mass rearing have been completed.

If the BCA is released for classical biological control, it is intended to establish and control one or more pests, possibly permanently. If the BCA is used for augmentative biological control, it is not intended to establish but is periodically introduced into a specific environment to suppress pest populations. For both classical and augmentative biological control, there is the potential for the BCA to cause undesirable consequences which may be irreversible, such as long-term negative impacts on non-target species. It is therefore necessary to carry out an assessment of a BCA's risk (focusing on plant health and the environment) prior to release, while taking into consideration the benefits.

ISPM 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*, IPPC, 2005) states that Governments should designate a National Authority responsible for its implementation. For the purpose of import and release of non-indigenous BCAs, the National Authority should establish an appropriate official procedure. Each country should decide what type of administrative system is appropriate (notification, approval or authorization), taking into account official policies in support of biological control and at the same time ensuring safety for agricultural and natural ecosystems.

The current Standard should be used by the applicant when compiling a dossier to support an application to release a non-indigenous BCA. The Standard provides a template of an application form and guidance for answering individual questions (see Appendix 1).

The EPPO Standard *PM 6/4 Decision-support scheme for import and release of biological control agents of plant pests* (EPPO, 2018) should be used by decision makers to assess the dossier.

2 | PREPARATION OF THE DOSSIER

2.1 | Import

If the organism is to be imported for the first time for research or mass rearing before release, the notification procedures of EPPO Standard PM 6/1(2) should be followed (EPPO, 2023).

[1]Native species (also called indigenous) species, meaning that they originate from and have evolved in a local area over a long period of time (see Castella et al., 2022).

[2]Microorganisms used as plant protection products are not considered (since they are often covered by other regulations in EPPO countries, such as EU Regulation 1107/2009). However, microorganisms used for classical biological control may be included.

If the BCA is to be imported with the intention of release, the application form in this Standard (see Appendix 1[3]) should be completed.

2.2 | Release

For an application for release, the applicant should prepare a dossier for submission to the National Authority. The application form in Appendix 1 should be used.

An application for release should include:

Part 1. Application information

(A) Information on the applicant
(B) Purpose of the application and use of the BCA in pest control

Part 2. Information on the BCA

(A) Taxonomy and characteristics of the BCA
(B) Biology and ecology
(C) Origin and distribution of the BCA
(D) Product information
(E) Contaminants

Part 3. Information requirements for intentional release of the BCA

Assessment of risks and benefits

(A) Potential for establishment
(B) Host range assessment
(C) Spread potential
(D) Direct and indirect effects
(E) Potential benefits
(F) Uncertainties
(G) Conclusions

Appendices (for supporting information)

3 | EVALUATION OF THE DOSSIER

Following receipt of the dossier, the National Authority will assess the information provided. EPPO Standard PM 6/4 *Decision-support scheme for import and release of biological control agents of plant pests* (EPPO, 2018) provides a framework for doing this. PM 6/4 is based on ISPM 11 (IPPC, 2013) *Pest risk analysis for quarantine pests*, ISPM 3 (IPPC, 2005) *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*, EPPO Standard PM 5/3 (EPPO, 2011) *Decision-support scheme for quarantine pests* and a previous version of EPPO Standard PM 6/2 (EPPO, 2014) *Import and release of non-indigenous biological control agents*. It covers the following elements of environmental impact assessment (EIA) for BCAs of plant pests: initiation, probability of BCA establishment and spread in the impact assessment area (IAA), and assessment of potential positive and negative consequences on agricultural and natural ecosystems.

The National Authority should determine whether all relevant national and international regulations have been respected. For example, whether natural resources are safeguarded (access and benefit sharing or the movement of rare or endangered organisms). The National Authority may consider organizing a stakeholder consultation as part of the evaluation process, especially in the case of classical biological control. Stakeholders may include industry bodies, conservation organizations, the public, and regulators from neighbouring countries.

The National Authority should determine if a release programme along with a post-release monitoring protocol should be submitted alongside an application for release.

After the dossier has been reviewed and consulted on, the National Authority will decide whether to grant approval for the import and/or release of the BCA. In cases where a permit is granted, the National Authority may give conditions for the import and/or release of the BCA. The authorisation can be issued for a specific duration, after which a renewal may be sought.

4 | CONDITIONS OF THE RELEASE

After being granted a permit for release, the applicant or organization undertaking the release proceeds under the appropriate supervision of the National Authority, taking account of the following:

(1) All appropriate safety procedures should be put in place. In particular, the BCA should be free from any contaminants, hyperparasitoids, parasites and pathogens;
(2) Authoritatively identified reference (voucher) specimens of the BCA involved in the release should be deposited in appropriate collections, where they should be available for reference and study;
(3) Where cultures are refreshed through new additions, confirmation of identity should be sought at regular intervals and additional reference (voucher) specimens should be deposited accordingly;
(4) For a classical BCA, the release programme should be planned in advance and fully documented

[3]The application form was originally developed in the EU-funded REBECA project. This project aimed to review possible risks of biocontrol agents and propose efficient regulation procedures.

concerning approximate numbers/quantity released, dates, localities and any other data relevant to assessing and controlling the outcome;

(5) Post-release monitoring is encouraged. Information from post-release monitoring (if required) should be reported (for example information on establishment, spread, or impact on the target pest and non-target organisms) to the National Authority on a regular basis.

The procedure described in this Standard is intended to be used for the first release of a BCA in a particular country. Under certain circumstances (e.g. different strains or populations), it may be necessary to repeat the process for further releases.

5 | GENERAL SAFEGUARDS

5.1 | For import (see EPPO Standard PM 6/1(2), EPPO, 2023)

a. Shipments should be properly packaged to ensure that the organisms cannot escape or be contaminated (infected) during transport,
b. The shipment should be properly labelled to ensure identification by customs and other relevant authorities. Suitable information should be prominently displayed on the outside of the package to inform those handling the package of the contents,
c. Advance notice of the content of the package (with full details of routing) should be provided to those handling it and to the receiver to minimize delays and alert those concerned,
d. Risks to plant, animal and human health should be considered, and all appropriate regulations should be respected,
e. Biodiversity conventions (e.g. Nagoya Protocol and other legislative acts) should be respected.

5.2 | For release

a. Any adverse effects caused by the BCA in the country in which it has been released should be reported to the relevant National Authority,
b. Biodiversity conventions and intellectual property rights (e.g. access and benefit sharing) should be respected.

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APPENDIX 1 - APPLICATION FORM AND GUIDANCE FOR THE IMPORT AND RELEASE OF A NON-INDIGENOUS BIOLOGICAL CONTROL AGENT IN EPPO COUNTRIES

The application form and guidance is provided as a Word document.

A link to the application form can be found at https://upload.eppo.int/download/2045o1b140ca16.