Australian Government
Department of Agriculture, Water and the Environment

REVISED GUIDELINES FOR THE INTRODUCTION OF EXOTIC BIOLOGICAL CONTROL AGENTS FOR THE CONTROL OF WEEDS AND PLANT PESTS

Step 1: Approval of the target species as a candidate for biological control

Responsibility: Proponent

Approval: Environment and Invasives Committee or Plant Health Committee

For the biological control of weeds, the weed species must be submitted to the Environment and Invasives Committee (EIC) for approval as a target.

Approval for invertebrate pest species or pathogens as candidate targets for biological control should be sought through the Plant Health Committee (PHC).

This can be done at any time during the process, but the target must be approved before permission to release a biological control agent is sought.

Step 2: Offshore research on possible agents

Responsibility: Proponent

Approval: none

The proponent usually searches for potential biological control agents (BCAs) in the natural range of the target species. Often, some specificity testing is conducted offshore.

Step 3: Host-specificity test list

Responsibility: Proponent

Approval: none

The proponent takes responsibility for the development and finalisation of the host-specificity test list. There is no formal approval process through the Department of Agriculture, Water and the Environment (the department). Applicants are advised to employ the available expertise in Australia's Commonwealth, State and Territory agencies as well as any other relevant expert opinion when preparing host test lists and developing testing methodologies for a biological control agent.

If requested by the proponent, the department can assist this process by publishing proposed host test lists and procedures for a candidate biological control agent on the department's website. Proponents are strongly encouraged to make use of this facility. All host test lists for publishing on the department's website should be emailed (Attention: Plant Import Operations – Research team – Host test list for comment) to the Department of Agriculture, Water and the Environment.

Selection and testing of non-target test species

1. Selection of non-target plant species for testing should be consistent with Wapshere's (1974) "Centrifugal Phylogenetic Method" and modernisations of this method, including Briese 2003, 2005 and/or Sheppard et al. 2005, or other texts that consider species relationships and potential aspects of selection of non-target test species. Non-target test lists should include species in the target species' tribe, genus, subfamily, family and related families. More broadly, testing might also include related orders, as appropriate.

    a. The process of selection of non-target species should include consideration of native species, agriculturally-important species, and amenity species (including horticultural, nursery, landscaping and environmentally significant species).

2. For the selection and testing of non-target species for arthropod biological control agents, there are other requirements that should be addressed. Non-target test lists for arthropod biological control agents should be based on currently accepted methods, such as those outlined in Barratt et al. 2007.

Step 4: Permission to undertake specificity testing under biosecurity containment in Australia

Responsibility: Proponent

Approval: Department of Agriculture, Water and the Environment

Prior to the importation of potential biological control agents for contained experimental work in Australia, a valid import permit issued by the department under the *Biosecurity Act 2015* is required. The permit will specify a containment level and any other conditions required, such as the lodgement of voucher specimens.

Import permit – departmental administrative requirements

- Applications for import permits must be submitted via BICON. Note: in order to be directed to the correct BICON case to apply for a permit, the search term "biological control agents" should be entered into the quick search tab. Please refer to the help tab on BICON for assistance with the import permit application process.
- Approved arrangement site details (approved arrangement site name, number, address, contact details) with appropriate containment level to hold the organism(s) must be supplied.
- Where appropriate, the life stage of the organism(s), the host material or the media used during the importation of the agent should be specified.

Step 5: Testing permit for proposed biological control agents that are animals

Responsibility: Proponent

Approval: Department of Agriculture, Water and the Environment

Where the proposed biological control agent is an animal, an additional permit under the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act) may be required from the department to import specimens for experimental work in contained use into Australia. Conditions on containment and use are specified on the testing permit according to the EPBC Act.

If the BCA is listed on the List of Specimens taken to be Suitable for Live Import (the Live Import List) under the EPBC Act then the species can be imported subject to any conditions given for that species on the list.

- Species listed on Part 1 of the list do not require a permit under the EPBC Act.
- Species listed on Part 2 of the list require a permit under the EPBC Act before they can be imported.

The Live Import List can be found at: http://www.comlaw.gov.au/Series/F2006B01053.

If the BCA is not listed on the Live Import List under the EPBC Act, an application should be made to include the species. Details of the process for amending the list and further information on the assessment of BCAs can be found on the Department of Agriculture, Water and the Environment website.

Testing permit – departmental administrative requirements

A testing permit allows the importation of an unlisted BCA to undertake tests on the species to inform the environmental assessment of the species for inclusion on the Live Import List.

An application including justification of why the testing must be undertaken in Australia must be completed and submitted to the department via the online application form.

An application to add the species to the Live Import List must be made before a permit can be granted.

- Government entities are exempt from testing permit fees.
- If a species is undescribed or there is any doubt about its taxonomy then a voucher specimen(s) of the most recognisable stage must be lodged at a recognised institution (e.g. the Australian National Insect Collection). A permit will not be issued for undescribed specimens without a voucher number.
- Documents proving the source of the specimen/s are required where applicable.
- The BCA must be held in a controlled environment.

Testing permit – renewals

A testing permit allows multiple consignments of an organism to be imported for testing over a six month period. If more imports are required after this period, the permit must be renewed, requiring a new application and a report updating the progress of testing.

Step 6: Specificity testing

Responsibility: Proponent

Approval: none

After importing the potential biological control agents, the proponent can undertake host specificity testing under approved biosecurity containment conditions in Australia.

Step 7: Application to release a biological control agent– Information requirements (Release Package)

Responsibility: Proponent

Approval: none

If release of a biological control agent is sought, the proponent must submit an application for release to the Department of Agriculture, Water and the Environment – Plant Import Operations Branch.

The application should comprise of an information package about the proposed biological control agent. This package should contain details of:

1. Agent name and phylogeny (order, family, genus, species, author, date and common name if available)
2. A brief description of the biology of the agent
3. The native range of the agent
4. Species related to the agent and a summary of their host range(s)
5. The proposed source(s) of the agent
6. The current status of the target species in Australia, including a summary of the economic and environmental losses caused by the target
7. Whether and when the target species was approved for biological control, and the proposing organisation
8. The agent's potential for control of the target
9. Information on non-target organisms at risk from the agent
10. Copies of any references referred to in the application
11. Information and results on any other similar assessments, including environmental risk assessments, undertaken on the species both in Australia and overseas
12. Information on all other relevant Commonwealth, State and Territory legislative controls of the target species
13. Report of host-specificity testing, including:
    a. Quantified laboratory evaluation of life cycle characteristics, as appropriate, on tested species. Submitted data should include raw data and details of analyses of test results
    b. Testing methods used
    c. Overseas host records, including literature and details of any discussions with experts
    d. Evaluation of risks to non-target species
    e. Any evidence to reveal laboratory artefacts in behaviour or development of the agent
14. Possible interactions, including conflicts with existing biological control programs
15. Information on where, when and how initial releases would be made
16. Information on whether the agent has established populations in other countries outside its native range, and if so, details of introduction, spread and any non-target impacts recorded.

The above list is provided as a guide, and it is noted that in some cases more information will be required. It is also noted that for some targets and agents, not all points will need to be covered. The notes below (see 'Notes on data package requirements') provide guidance on materials that should be supplied in relation to the numbered items above.

Step 8: Assessment of release package

Responsibility: Department of Agriculture, Water and the Environment

Approval: Department of Agriculture, Water and the Environment

After the application and the information package are received, the department will conduct a risk analysis in accordance with the BIRA guidelines.

A preliminary draft risk analysis report will be distributed to state and territory departments of primary industry and the Commonwealth Scientific and Industrial Research Organisation (CSIRO) through the Plant Health Committee (PHC). Comments received via this consultation process will be incorporated into the draft risk analysis report.

A draft report will be published on the Department of Agriculture, Water and the Environment website for public comment and will be distributed to registered stakeholders for comment. Comments must be submitted within 30 days. The department will consider comments and will produce a final report.

The department also has an approval process for the import and release of biological control agents that are animals under the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act). Under Section 303EE (4) of the EPBC Act, a Department of Agriculture, Water and the Environment final risk analysis report may be used by the responsible Minister in making a determination to include the species on the List of Specimens taken to be Suitable for Live Import (the Live Import List).

Step 9: Release conditions/requirements

Responsibility: Department of Agriculture, Water and the Environment

Approval: Department of Agriculture, Water and the Environment

Following the risk analysis process, if the department recommends approval for release, a letter will be sent to the applicant providing conditions of release.

Additional voucher specimens must be lodged with the Australian National Insect Collection or an Australian State/Territory agricultural collection or herbarium, labelled with the following information:

- Reference numbers for undescribed species
- Country of origin
- Host
- Date collected
- Collection location
- Target species
- Source of identification
- Contact officer for biological control program

Step 10: Amending the live import list for biological control agents that are animals

Responsibility: Department of Agriculture, Water and the Environment

Approval: Department of Agriculture, Water and the Environment

If release of the biological control agent is recommended as an outcome of the risk analysis process, a recommendation will be made to the Minister for the Environment to amend the Live Import List to include the biological control agent species.

The department is responsible under the EPBC Act for assessing the environmental impact associated with proposals to import live species. Should the department require more extensive information to meet the requirements of the EPBC Act, the applicant must provide this.

If the Minister for the Environment approves the proposal then the species will be added to Part 1 of the Live Import List. This authorises the release of the specimens imported into biosecurity containment under a testing permit subject to the conditions of release from the department (Step 9).

Notes on data package requirements (Step 7)

Recognising that each application for release of a biological control agent will be of unique character, prescriptive directives are not and cannot be provided in regard to the content of data packages provided with applications. The following notes are intended to provide some additional insight into processes for development of suitable data packages, and of considerations that reviewers will seek and potentially take into consideration in decision-making.

For Item 6: Target pest species identification should include order, family, genus, species, author, date, synonyms and changes in nomenclatural combinations, and common name(s) if available.

For Item 7: If the target species is a weed – declaration of weed status and legislation under which this was made or body by which it was made (including whether approved as a target for biological control);

If the target species is an invertebrate pest – declaration of invertebrate pest status and legislation under which this was made or body by which it was made (including whether approved as a target for biological control).

Note that applications will not be considered unless target approval has been agreed.

For Item 13. Data and information on host specificity testing should include:

1. Overview of the scope of testing, including

    a) a list of the non-target plant/arthropod species that were tested (with scientific names, including author, year and changes in combination and synonyms);
    b) a description of the phylogenetic relationship of those species to the target species, aligned with the most recent appropriately peer-reviewed published phylogeny. The basis on which the non-target species were selected for testing, could, in addition to phylogenetic relatedness, include biogeographic overlap and ecological similarity (Briese 2005).

Selection of non-target species for testing should consider relevant agricultural, amenity and environmentally significant species (see also below).

2. Details and description of testing methodology and results for target and non-target species. This should include:

    a) Description of the methodology/ies that was/were used, including the rationale behind methods selection see, for example, Sheppard et al. (2005).

        i. Indicate whether the target species was present during tests (i.e. whether these were 'choice', 'choice minus target', or 'no-choice' experiments);
        ii. For plant trials, indicate whether whole plants or parts of a plant were used in the experiments. General preference is for tests using whole plants.
        iii. Stipulate the control treatment in each test, and include this in the results.
        iv. Stipulate how long the biological control agent was left with the off-target test material (for arthropods was it until death?);
        v. Stipulate the life stage that was used to infect/infest the off-target material;
        vi. Identify any handling issues with the BCA that may mask a true result (for example, for very small insects are they likely to be damaged during transfer?);
        vii. Describe and where possible quantify any infection/infestation that occurred, and levels of damage and effect observed.

    b) Details of the number of replicates for each species and each methodology used.

        i. For plant trials each replicate test should use a different mother plant (ie, tests should provide true experimental replication); multiple replicate subjects should not be derived from the same mother stock (ie, not represent pseudo-replication). Pseudo-replication should always be avoided – for a more general discussion see B3.NZ/testing.
        ii. For native species, state the geographic origin of test subjects where possible; this should adequately reflect the genetic diversity within the species. For ornamental species, state the sources and geographical origin as available. For agricultural species, state the sources and origin of varieties or cultivars.

    Adequate levels of replication with appropriate control treatments should always be used; this is a key element that reviewers of any application will consider. It is not possible to stipulate precise numbers for any element of any application; self-evidently, tests on larger numbers of subjects will be more highly regarded than those on very small numbers. It is also to be expected that species of critical importance (for example, closely related to the target species, or non-target native species, or species of high economic importance) to the application will be more extensively tested than those of a less critical nature.

    c) Indication of whether BCA replication/reproduction was observed.

i. Stipulate the progeny life stage observed, how long they survived, whether they reproduced and number of offspring produced.
ii. Indicate whether any damage to the test plants was observed from progeny, if appropriate.

3. Data for each experiment.

    a) Provide electronic records of collated data and observations for each test.

        i. Include a summary of all data, including any statistical analysis.

4. Other supporting data

    a) State whether the methodology used in the application is similar or equivalent to that previously used in Australia or described in published literature, with consideration of any recognised weaknesses in the methodology used.

    b) If the BCA has been used overseas, identify results of any active surveys to examine non-target effects, and/or any other available information. Evidence may include references such as publication, 'grey literature', agency reports, etc.

    Note: if there is reliance on overseas data, details of tests will need to be provided as per Australian data requirements.

References

Barratt, BIP, Berndt, LA, Dodd, SL, Ferguson, CM, Hill, RL, Kean, JM, Teulon, DAJ & Withers, TM 2007, 'BIREA - Biocontrol Information Resource for EPA applicants', http://www.b3nz.org/birea/ (accessed May 2020).

Briese, DT 2003, 'The centrifugal phylogenetic method used to select plants for host-specificity testing of weed biological control agents: Can and should it be modernised?' in HS Jacob & DT Briese (Eds), *Improving the selection, testing and evaluation of weed biocontrol agents*, CRC for Australian Weed Management Technical Series no. 7, Adelaide, Australia.

Briese, DT 2005, 'Translating host-specificity test results into the real world: the need to harmonize the yin and yang of current testing procedures', *Biological Control* vol. 35(3), pp. 208-214.

Sheppard, AW, Van Klinken, RD & Heard, TA 2005, 'Scientific advances in the analysis of direct risks of weed biological control agents to nontarget plants', *Biological Control,* vol. 35, pp. 215–226.

Wapshere, AJ 1974, 'A strategy for evaluating the safety of organisms for biological weed control', *Annals of Applied Biology,* vol. 77, pp. 201–211.