

**Sécurité de la lutte biologique**  
**Safe use of biological control****PM 6/04 (1) Decision-support scheme for import and release of biological control agents of plant pests****Specific scope**

This Standard is based on ISPM 11 (FAO, 2013) *Pest risk analysis for quarantine pests*, ISPM 3 (FAO, 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 EPPO Standard PM 6/2 (EPPO, 2014) *Import and release of non-indigenous biological control agents*. It provides detailed instructions for the following elements of environmental impact assessment (EIA) for biological control agents (BCAs) of plant pests (including pathogens): initiation, probability of BCA establishment and spread in the impact assessment area (IAA), and assessment of potential positive and negative environmental consequences. The Standard provides an express scheme which may produce a rapid result. A full scheme follows for use where the express scheme does not lead to a sufficiently clear recommendation. The decision-support scheme (DSS) is based on a sequence of questions to decide whether the introduction of a BCA could cause

unwanted environmental effects and the likelihood and impact of such effects, and also to compare these with the likelihood and impact of potential positive environmental effects in reducing pest populations and the need for other pest control measures. Expert judgement may be required when answering the questions. Assessors may need to call on expertise in the type of BCA under consideration (including the expertise of the applicant), in the regulation of BCAs and experience in the use of this scheme (or related schemes for pest risk analysis).

The DSS does not cover import into confinement facilities for research purposes, for which guidance is provided in EPPO Standard PM 6/1 (EPPO, 1999) *First import of exotic biological control agents for research under contained conditions*.

**Specific approval and amendment**

Approved in 2018-09.

**Introduction**

The EPPO decision-support scheme (DSS) for import and release of biological control agents (BCAs) of plant pests is intended to provide national plant protection organizations (NPPOs) and other relevant authorities within EPPO countries with detailed guidance on impact assessment of BCAs to support decision-making on their introduction and to harmonize the assessment procedure within the EPPO region. The DSS is intended to be used to assess the potential impact of a particular BCA for a clearly defined area (the impact assessment area, IAA). The IAA may range from part of an individual member country to the whole EPPO region.

The scheme provides detailed instructions for the following elements of BCA environmental impact assessment: initiation, probability of BCA establishment in the IAA and

assessment of potential environmental consequences. The DSS consists of two parts: (I) *express assessment* and (II) *full assessment*. The first part (express assessment) leads the assessor either to a fast decision or to the need to conduct a full assessment. The second part (full assessment) supports decision-making in more complicated cases (including that of classical biological control of plants) and, if the decision remains uncertain, identifies what additional information is needed and what research should be conducted to allow a technically justified decision.

Results of the EPPO/IOBC Questionnaire of 2012 on the national use of EPPO Standard PM 6/3 *List of biological control agents widely used in the EPPO region* (EPPO, 2001) showed that regulations for intentional introduction of BCAs in the EPPO region differ significantly from one country to another. To harmonize these regulations within the EPPO region, EPPO Standard PM 6/2 *Import and*

*release of non-indigenous biological control agents* (EPPO, 2014) was developed. One of the main procedures that has to be accomplished prior to the introduction of a BCA is the assessment of potential risks and benefits associated with this introduction. Much of the existing pest risk analysis (PRA) scheme is not appropriate for assessing BCAs for several reasons: BCAs are not usually pests, and they are introduced to control pests (most often non-native pests); additionally, the assessment of probability of entry (a routine part of the assessment under a PRA) is not relevant for BCAs since they are introduced intentionally for plant protection. Pest risk management (a routine part of a PRA) of BCAs is only likely to be relevant during experimental releases when a contingency plan for control could be activated if adverse effects are seen. A PRA is not used to assess benefits from introductions (including benefits for the environment of the introduction of BCAs). 'Environmental risk assessment' for BCAs was developed in many scientific publications but not formalized as an internationally accepted scheme. ISPM 3 *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms* (FAO, 2005) provides only general guidance on the use of BCAs without a detailed assessment scheme.

### Information requirements

Researchers, biocontrol practitioners and relevant regulatory authorities (both risk assessors and risk managers) should establish dialogue at an early stage of any project which might lead to an application for release of a BCA, so that information requirements can be agreed in advance and be satisfied.

Before beginning the assessment, information should be collected on the various characteristics of the BCA that will be evaluated in the procedure, including information gathered from experience of previous releases where available. EPPO Standard PM 6/2 *Import and release of non-indigenous biological control agents* (EPPO, 2014) indicates which information will be of relevance and should be taken into account. Information on the proposed BCA will generally be provided by the applicant, while other information (e.g. on climate and host distribution) may be provided by the applicant or by the assessors according to national arrangements. For BCAs used against plants some parts of EPPO Standard PM 5/1 *Checklist of information required for pest risk analysis (PRA)* should also be taken into account (EPPO, 1993).

In going through the scheme, the assessor will probably find that certain questions cannot be answered. This may be because the question is not relevant in the particular case (N/A), in which case the question can be ignored, and the absence of a reply will not affect the value of the assessment. Alternatively, it may prove impossible to obtain the information, in which case its absence will to a certain degree reduce the value of the assessment depending on the

importance of the question. A meaningful assessment cannot be performed without adequate information, and at the end of this scheme the assessor is asked to indicate whether the quantity and quality of the information was acceptable.

In cases where particular information about a BCA is lacking, useful information may sometimes be obtained by using knowledge about closely related organisms. Where such indirect information is used this should be recorded during the assessment, with a justification and any resulting uncertainties, and this should be taken into account in the final evaluation.

### Documentation

It is important for any possible future re-evaluation of the assessment that all steps of the procedure are fully documented, indicating:

- who performed the evaluation
- how each decision was reached
- on what information each decision was based
- the date on which the information was collected in case subsequent data on the BCA could influence the final decision
- any uncertainties regarding data or the conclusion should be noted.

Templates in a table format have been developed for preparing an assessment. A computerised version of the scheme could be prepared in future. A report of the assessment should be produced.

For definitions of terms used in this scheme see the *Glossary of phytosanitary terms* (FAO, 2017).

### Acknowledgements

This Standard was prepared by the Joint EPPO/IOBC Panel on Biological Control Agents.

## Part I

### Express assessment

#### Step 1: initiation

The aim of the initiation step is to identify the BCA that should be considered for the EIA in relation to the identified IAA, including its indigenous/non-indigenous status for this area.

##### 1.1 Provide the reason for performing the EIA

An EIA may be initiated for one or several reasons, the most common being:

- an application is made for the intentional introduction of a BCA for classical biological control of a pest
- a request is made for the intentional introduction of a BCA for augmentative biological control of a pest

- a previous EIA needs to be revised because of the availability of new information
- a previous EIA needs to be revised because of a new phytosanitary policy.

**Go to 1.2, unless any of the following apply:**

- an application is made to release a classical BCA of plants
- a proposal made by another country or by an international organization (RPPO, FAO) is assessed
- a dispute arises on phytosanitary measures concerning a BCA and their environmental impact.

**Go to Part II: full assessment.**

## 1.2 Existence of an earlier EIA

The BCA (e.g. another population of the same species, or an ecotype, or a similar but distinct species) may have been subjected to the EIA process before. This may partly replace the need for a new assessment.

*Note:* in the case that this BCA is either already included in the EPPO 'positive list' in PM 6/3, or a different ecotype of a BCA species has already been released in the IAA, please include this information here.

### 1.2.1 Does a relevant earlier assessment exist?

If yes	Go to 1.2.2
If no	Go to 2.1

1.2.2 *Is the earlier assessment still entirely valid or only partly valid (i.e. the organism has received another scientific name,<sup>1</sup> it is out of date, applied in different circumstances, or is for another area with similar conditions)?*

If entirely valid	End
If partly valid, proceed with the assessment but compare as much as possible with the earlier assessment	Go to 2.1
If not valid	Go to 2.1

## Step 2: BCA categorization

### 2.1 Specify the BCA

2.1.1 *Is the BCA clearly a single taxonomic entity, and can it be adequately distinguished from other entities of the same taxonomic rank?*

<sup>1</sup>Identity is a crucial constituent for validity of the assessment. Thus, the identity of the organism has to be confirmed and preferably supported by a published paper. In the case of a name change only (synonymy, new name), indicate the preferred scientific name and taxonomic position, and provide a reference where the equivalence between new and old names is substantiated.

If yes, indicate the preferred scientific name, taxonomic position, identification method(s) used and name of expert(s) performing the identification	Go to 2.2
If no	Go to 1.2.2

*Note:* the taxonomic unit for a BCA is generally species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale. In the case of levels below species this should include evidence demonstrating that factors such as differences in host<sup>2</sup> range, cold resistance or diapausing capacities are significant enough to affect the potential environmental impact. When the data for risk assessment is from a specific population, the regulatory decision should relate to the same population.

2.1.2 *If the BCA has not yet been fully identified, has it been characterized using classical morphological or molecular methods, or both, and shown to produce consistent results?*

If yes, indicate identification method/s and name of expert(s) performing the identification	Go to 2.2
If no	Stop assessment because of lack of information

### 2.2 Identification of the assessment area

Clearly define the IAA.

*Note:* the IAA can be a whole country, several countries or part(s) of one or several countries. These areas do not need to be contiguous.

**Go to 2.3.**

### 2.3 Distribution of the BCA within the IAA

Specify the current BCA distribution indicating the native area and the area(s) of further establishment (including the result of previous releases, natural spread or accidental introductions).

#### 2.3.1 Is the BCA present in the IAA?

If yes	Go to 2.3.2
If no	Go to 3.1

#### 2.3.2 Is the BCA widely distributed in the IAA?

If yes	Go to 4.3
If no	Go to 2.3.3

<sup>2</sup>Here and after 'host(s)' covers host plants for phytophagous BCAs and host and prey species for other BCAs.

*Note:* a BCA may be ‘present but not widely distributed’. This means that the BCA has not reached the limits of its potential area of distribution either in the field or in protected conditions; it is not limited to its present distribution by climatic conditions or host distributions. There should be evidence that the BCA would be capable of additional spread.

### 2.3.3 Is the BCA indigenous in part of the IAA?

If yes	Go to 3.4
If no	Go to 3.1

## Step 3: Impact assessment

### 3.1 What is the intended use of the BCA?

Indicate the target pest(s) and major host(s) of target pest(s)

3.1.1 Augmentative biological control	Go to 3.2
3.1.2 Classical <sup>3</sup> biological control (establishment is a prerequisite of this type of biological control)	Go to 3.3

### 3.2 Likelihood of BCA establishment (i.e. perpetuation, for the foreseeable future) in the IAA after release

3.2.1 *Is the organism likely to survive, complete its development, and regularly produce viable progeny for more than one year under the climatic conditions of the IAA on the target pest(s) or other host(s)?*

If yes	Go to 3.2.3
If no	Go to 3.2.2

*Note:* if the current area of distribution of the BCA includes ecoclimatic conditions comparable with those of the IAA or sufficiently similar for the BCA to survive, grow, complete its development, and reproduce, establishment is likely.

3.2.2 *Is the organism able to use refuges/protected environments (i.e. indoors/greenhouses) to circumvent unfavourable conditions?*

If yes	Go to 3.2.3
If no	Go to 4.3

<sup>3</sup>BCAs intended for classical biological control are expected to be able to establish. Therefore, the assessor can skip Questions 3.2 on likelihood of establishment.

3.2.3 *Are there elements in the biotic environment (pathogens, predators, competitors etc.) that are likely to prevent establishment?*

If yes	Go to 4.3
If no	Go to 3.3

### 3.3. Likelihood of dispersal of the BCA within the IAA

3.3.1. *Is the BCA likely to disperse outside the area of release? Consider different aspects of dispersal (including the points below) and their probability of occurrence, and make conclusions about the likely dispersal*

- distance (per time unit).
- propensity to leave release site.
- numbers of generations per year/hosts/fecundity.
- human/animal vectoring activity.

If yes or uncertain	Go to 3.4
If no	Go to 4.3

*Note:* dispersal should be tested when BCAs are released in open fields or structures that do not prevent escape (e.g. polytunnels).

### 3.4. Likelihood of occurrence of non-target effects of the BCA within the IAA

Is the BCA likely to cause unacceptable effects on non-target organisms? Describe and weigh up the different aspects of non-intentional effects (including the ones listed below) and conclude

- host range
- competition
- hybridization
- pathogens (vectoring)
- other.

If yes (likely and/or permanent) or uncertain	Go to 4.1
If no (unlikely, limited and transient)	Go to 4.3

## Step 4: Decision taking

4.1 **Is the BCA likely to make a positive environmental impact in the IAA by reducing target pest populations and/or by preventing/reducing plant protection product treatments/procedures?**

If yes	Go to 4.2
If no	Go to 4.4

**4.2 Is the BCA's positive environmental impact in the IAA likely to significantly exceed the negative environmental impact identified in Question 3.4?**

If yes	Go to 4.3
If no	Go to 4.4
If uncertain	Go to Part II: full assessment

**4.3 The BCA is not likely to present a risk for the IAA or the risk is likely to be compensated by a positive environmental impact from the introduction of the BCA. The assessment can stop, and import and releases can be recommended (summarize the main reasons for stopping the assessment).**

**4.4 The BCA is likely to present a risk for the IAA and this risk is not likely to be compensated by a positive environmental impact from the introduction of the BCA. The assessment can stop, and import and releases should not be recommended (summarize the main reasons for stopping the assessment).**

## Part II

### Full assessment

The aim of the initiation stage is to identify the BCA which should be considered for EIA in relation to the identified IAA.

#### Step 1: Pre-assessment

**1.01 Give the reason for performing the full assessment**

The full assessment may be initiated for one or several reasons, the most common being:

- the express scheme indicates that a full assessment is required
- an application is made to release a classical BCA of plants
- a proposal made by another country or by an international organization (RPPO, FAO) is assessed.
- a dispute arises on phytosanitary measures linked to BCAs and their environmental impact.

**Go to 1.02**

**1.02 Specify the BCA<sup>4</sup>**

Indicate the preferred scientific name, taxonomic position, identification method(s) used and name of expert(s) performing the identification.

**Go to 1.03**

<sup>4</sup>The taxonomic level at which BCAs are considered should normally be the species level. The use of higher or lower taxonomic levels should be scientifically justified.

**1.03 Clearly define the IAA**

*Note:* the IAA can be a complete country, several countries or part(s) of one or several countries. These areas do not need to be contiguous.

**Go to 1.04**

**Earlier assessments**

The BCA, or a very similar organism (e.g. another population of the same species), may have been subjected to the EIA process before, nationally or internationally. This may partly or entirely replace the need for a new assessment.

**1.04 Does a relevant earlier EIA exist?**

If yes	Go to 1.05
If no	Go to 1.06

**1.05 Is the existing EIA still entirely valid or only partly valid (out of date, applied in different circumstances, for a similar but different organism, for another area with similar conditions)?**

If entirely valid	End
If partly valid, proceed with the EIA but compare as much as possible with the earlier assessment	Go to 1.06
If not valid	Go to 1.06

**1.06 Specify all known hosts<sup>2</sup> of the BCA under assessment, including host range studies which have been carried out in support of the application for release. Indicate those which are present in the IAA.<sup>5</sup>**

**Go to 1.07**

**1.07 Specify the BCA distribution, indicating the native area and the area(s) of further establishment (including the result of previous releases, natural spread or accidental introductions).**

**Go to 1.08**

<sup>5</sup>The taxonomic level at which hosts are considered should normally be the species level. The use of higher or lower taxonomic levels should be scientifically justified. It may be appropriate to distinguish between major and minor hosts when answering this question. If the EIA is conducted for a BCA which could have an environmental impact through effects on other organisms, the presence in the IAA of these organisms should also be considered.

**1.08 Is the BCA clearly a single taxonomic entity, and can it be adequately distinguished from other entities of the same taxonomic rank?**

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If yes indicate the preferred scientific name and taxonomic position	Go to 1.10
If no	Go to 1.09

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*The identity of the BCA should be clearly defined to ensure that the assessment is being performed on a distinct organism, and that biological and other information used in the assessment is relevant to the organism in question.*

*Note:* the taxonomic unit for the BCA is generally the species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale. In the case of levels below the species, this should include evidence demonstrating that factors such as differences in host range, cold resistance or diapausing capacities are significant enough to affect the potential environmental impact. When the data for assessment is from a specific population, the regulatory decision should relate to the same population.

**1.09 Can the BCA be unambiguously identified even if it has not been formally described (including naming)?**

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If yes	Go to 1.10
If no	Go to 1.18

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**1.10 Is the BCA indigenous in the IAA?**

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If yes	Go to 1.12
If no	Go to 1.11

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**1.11 Is the BCA present in the IAA (e.g. in case of repeated introduction)?**

*Note:* presence includes organisms which have been introduced intentionally. Organisms present for scientific purposes under adequate confinement are not included.

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If yes	Go to 1.12
If no	Go to 1.13

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**1.12 Will releases of the BCA widen its distribution in the IAA?**

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If yes	Go to 1.13
If not	Go to 1.17

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**1.13 Is at least one non-target host present in the IAA (outdoors/in fields/in polytunnels and/or in protected conditions indoors/greenhouses)?**

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If yes or uncertain?	Go to 1.14
If no	Go to Step 2

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For a BCA to cause non-target effects, it should find hosts other than the target pest in the IAA. Records of natural hosts (i.e. hosts scientifically found to be infested or predated by the BCA under natural conditions and able to sustain its development to viable adults) should be of primary concern, but if such information is lacking, records of hosts under experimental conditions or records on accidental or very occasional hosts may also be considered.

**1.14 Does the known area of current distribution of the BCA include biotic or abiotic conditions (consider also protected conditions) comparable with those of the IAA or sufficiently similar for the BCA to survive, reproduce and spread or to cause transient effects?**

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If yes or uncertain	Go to 1.15
If no	Go to 1.17

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The BCA should find environmental conditions suitable for its survival, growth, completion of individual development, reproduction and spread under either natural or protected conditions.

**1.15 With specific reference to the environmental impact caused by the BCA in its area(s) of current distribution (especially in area(s) of its introduction if such exist), could the BCA cause unwanted environmental impacts in the IAA?**

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If yes or uncertain	Go to 1.16
If no	Go to 1.17

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**1.16 This BCA could present an environmental risk to the IAA (summarize the main elements leading to this conclusion)**

**Go to Step 2**

**1.17 The BCA does not present an environmental risk for the IAA. The assessment can stop and import and releases can be allowed (summarize the main reason for stopping the assessment).**

**1.18 If the environmental impact of the BCA cannot be assessed or it is not appropriate for use for plant or environmental protection, import and releases should not be allowed and the assessment should stop (summarize the main reason for stopping the assessment).**

## **Step 2: Assessment of probability of establishment**

**2.0 Is establishment intended (specify whether the BCA is intended for classical biological control)?**

*Selecting the ecological factors that influence the potential for establishment*

Seven factors may influence the limits to the area of potential establishment and the suitability for establishment within this area:

- 1) hosts necessary to complete development and reproduction, and their distribution in the IAA
- 2) alternative hosts and other essential species
- 3) climatic suitability
- 4) other abiotic factors
- 5) competition and natural enemies
- 6) the managed environment
- 7) protected cultivation.

Hosts and climate always influence the potential for establishment, and will therefore always be taken into account. For the other factors listed, there is often little or no information available for use by assessors.

In the first subsection 'Identification of the area of potential establishment', the questions act cumulatively to delimit the area of potential establishment.

In the second subsection, 'Suitability of the area of potential establishment', the suitability of this area is assessed.

*Identification of the area of potential establishment*

### Factor 1: host

*2.01 Identify and describe the area where the hosts are present in the IAA outside protected cultivation*

### Factor 2: alternative hosts and other essential species

*2.02 Does all the area identified in 2.01 have alternative hosts and any other species required to complete the BCA's life cycle?*

*Note:* the BCA may need more than one host or another essential species to complete its life cycle or to allow for transmission (e.g. vectors).

If not required: record this information.

If yes: record this information and provide justification.

If no: based on the area assessed as being suitable for establishment in Question 2.01, identify and describe the area where alternative hosts or other essential species are present. Describe how this affects the area of potential establishment.

**Go to the next question.**

### Factor 3: climatic suitability

*2.03 Does all the area identified as having suitable host presence also have a suitable climate for establishment?*

*Note:* when comparing climates in the BCA's current distribution with those in the IAA, it is important to consider factors necessary for survival (including how to survive periods unsuitable for activity, e.g. winters, drought periods), growth, completion of individual development and reproduction. It may be helpful to compare the global distribution of the BCA and that of its hosts. If they have similar climatic responses, all the hosts in the IAA might be considered to be helpful to the establishment of the BCA and a 'Yes' response may be appropriate.

If yes: record this information and provide justification.

If no: based on the area assessed as being suitable for establishment in previous questions, identify and describe the area where the climate is similar to that in the BCA's current area of distribution. Describe how this affects the area of potential establishment.

**Go to the next question**

### Factor 4: other abiotic factors

*2.04 Does all the area identified as being suitable for establishment in previous questions have other suitable abiotic factors if these are required for establishment?*

*Note:* the major abiotic factors to be considered are the physical and chemical characteristics of the soil; others include, for example, environmental pollution and topography. For organisms having an aquatic stage, the pH, salinity, current and temperature of water bodies are important factors to consider.

If yes: record this information and provide justification.

If no: based on the area assessed as being suitable for establishment in previous questions, identify and describe the area that is not under protected cultivation where additional abiotic factors that can affect establishment are favourable. Describe how this affects the area identified where hosts, suitable habitats and other essential species are present.

**Go to the next question**

### Factor 5: competition and natural enemies

*2.05 Is all the area identified as being suitable for establishment in previous questions likely to remain unchanged despite the presence of competitors and natural enemies?*

*Note:* competitors are organisms already present in the IAA occupying the same niche as the BCA. Natural enemies may include micro-organisms, predators and parasitoids.

If yes: record this information and provide justification,

If no: identify and describe any locations where the area suitable for establishment based on previous questions is likely to be altered due to competition and natural enemies. Provide justification.

#### Go to the next question

#### Factor 6: the managed environment

2.06 *Is all the area identified as being suitable for establishment in previous questions likely to remain unchanged despite the management of the environment?*

*Note:* factors that should be considered include cultivation practices such as the time of year that the crop is grown, soil preparation, method of planting, irrigation, surrounding crops, time of harvest, method of harvest, soil water balance, fire regimes, disturbance, etc. Existing pest management practices should also be considered.

If yes: record this information and provide justification,

If no: identify and describe any locations where the area suitable for establishment based on previous questions is likely to be altered due to the management of the environment. Provide justification.

#### Go to the next question

#### Factor 7: protected cultivation

2.07 *Are suitable conditions for establishment present in protected cultivation in the IAA?*

*Note:* 'protected cultivation' in the context of this scheme means synthetic or glass structures (e.g. glasshouses) which provide suitable conditions for crop growth and thus the presence of the BCA's host(s), protecting them from adverse environmental extremes.

The BCA may already have been recorded in protected cultivation elsewhere, but it may also happen that the BCA's hosts are present outside and the possibility that they can be both outside and in protected cultivation has to be considered.

If no: record this information and provide justification.

If yes: identify and describe the areas where the conditions are present in protected cultivation or where similar protected cultivation occurs in the IAA.

#### Go to the next question

#### Area of potential establishment

2.08 *By combining the cumulative responses to Questions 2.01–2.07, identify the part of the IAA where the presence of hosts and other factors favour the establishment of the BCA*

*Note:* the area of potential establishment may be the whole of the IAA, or part or parts of the area (e.g. the whole EPPO region or whole or part of several countries in the EPPO region). It can be defined ecoclimatically,

geographically, by crop or by production system (e.g. protected cultivation such as glasshouses) or by types of ecosystem.

#### *Suitability of the area of potential establishment*

#### Availability of suitable hosts or suitable habitats, alternative hosts and vectors in the IAA.

2.09 *How likely is the distribution of hosts in the area of potential establishment to favour establishment?*

*Note:* in Question 2.01 the area where hosts are present in the IAA was identified, but this question is assessing the abundance and patchiness of the distribution of hosts in the area of potential establishment defined in Question 2.08.

**Very unlikely, unlikely, moderately likely, likely, very likely**

Level of uncertainty	Low	Medium	High
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2.10 *How likely is the distribution of alternative hosts or other species critical to the BCA's life cycle in the area of potential establishment to favour establishment?*

*Note:* although this is based on the response to Question 2.02, in this question the abundance and patchiness of the distribution of alternative hosts and other species critical for the life cycle in the area of potential establishment (defined in Question 2.08) is evaluated. For examples, see the note for Question 2.02.

**Very unlikely, unlikely, moderately likely, likely, very likely**

Level of uncertainty:	Low	Medium	High
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#### Suitability of the environment

2.11 *Based on the area of potential establishment already identified, how similar are the climatic conditions that would affect establishment of the BCA to those in the current area of distribution?*

*Note:* in Question 2.03 the area where climate is suitable for establishment in the IAA was determined, but here the extent to which the climate is suitable in the area for potential establishment (defined in Question 2.08) is assessed. Using BCA distribution maps and maps of world climate zones (e.g. the Köppen–Geiger zones), identify the climates where the BCA is currently present. Then compare these with the climates in the area for potential establishment (defined in Question 2.08). The relative distributions of the hosts and the BCA in areas where the BCA has a stable distribution (i.e. is not still spreading) may help indicate whether both the hosts and the BCA have similar climatic responses. It is important to take into account the fact that the relationship between the current BCA distribution and climate may not be clear because: (a) the current BCA distribution is poorly known, (b) the species is still spreading, (c) the limits to its distribution depend on factors such as



the presence of hosts or geographical barriers, for example the sea or mountains, rather than climate and (d) climate, as measured at weather stations, may be unrelated to the microclimate inhabited by the species because it may complete much of its life cycle in protected or irrigated cultivation, submerged aquatic habitats, the soil, thick woody plant tissue or in vectors.

**Not similar, slightly similar, moderately similar, largely similar, completely similar**

Level of uncertainty:	Low	Medium	High
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*2.12 Is the BCA likely to establish in protected cultivation in the IAA?*

*Note:* for crops in Northern/Central Europe and BCAs from warmer climates the question is ‘Could the relevant conditions be present under protected cultivation?’. This sub-question is only relevant for BCAs that cannot establish outdoors in the IAA.

**Yes, no, N/A**

Level of uncertainty:	Low	Medium	High
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*2.13 Based on the area of potential establishment, how similar are other abiotic factors that would affect the establishment of a BCA to those in the current area of distribution?*

*Note:* this question evaluates the extent to which the abiotic factors are suitable in the area of potential establishment (see Question 2.04).

The major abiotic factors to be considered are the physical and chemical characteristics of the soil; others include, for example, environmental pollution and topography or orography. For organisms having an aquatic stage, the pH, salinity, current and temperature are important factors to consider.

**Not similar, slightly similar, moderately similar, largely similar, completely similar**

Level of uncertainty:	Low	Medium	High
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*2.14 Based on the area of potential establishment, how likely is it that establishment will occur despite competition from existing species and/or despite natural enemies that are already present?*

*Note:* see Question 2.05

**Very unlikely, unlikely, moderately likely, likely, very likely**

Level of uncertainty:	Low	Medium	High
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## Cultural practices and control measures

*2.15 How favourable for establishment is the managed environment (including pest management practices) in the area of potential establishment?*

*Note:* see Question 2.06. This question refers to the situation outdoors, i.e. not in protected crops.

**Not at all favourable, slightly favourable, moderately favourable, highly favourable, very highly favourable**

Level of uncertainty:	Low	Medium	High
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## Other characteristics of the BCA affecting the probability of establishment

*2.17 How likely is the reproductive strategy of the BCA and the duration of its life cycle to aid establishment?*

*Note:* consider characteristics which would enable the BCA to reproduce effectively in a new environment and answer the following questions either yes or no (some may not be appropriate for the BCA taxon studied, these should be identified and do not need to be answered)

**Very unlikely, unlikely, moderately likely, likely, very likely**

Level of uncertainty:	Low	Medium	High
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*2.18 Is the BCA highly adaptable?*

*Note:* evidence of variability may indicate that the BCA has a great capacity to withstand environmental fluctuations, to adapt to a wider range of habitats or hosts, to develop resistance to plant protection products and to overcome host resistance, to have cryptic or refuge-seeking behaviour. If the response to this question is ‘yes’, this is an important indication that this species is likely to have a greater potential for establishment. In addition, the magnitude of future impacts may increase. High adaptability also indicates that data from the native range, for example on climatic responses and host range, may not continue to be representative of the population in the IAA so that the assessment itself may need revision at a shorter interval. Examples of high adaptability include *Harmonia axyridis*, which seems to be able to evolve quickly to produce new biotypes, develop resistance to pesticides and expand its host range.

*If the BCA is highly or very highly adaptable, this should be mentioned in the section degree of uncertainty.*

**Yes (highly or very highly adaptable), no (moderately adaptable or less adaptable)**

Level of uncertainty:	Low	Medium	High
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2.19 How widely has the BCA established in new areas outside its original area of distribution (specify the instances, if possible; note that if the original area is not known, answer the question only based on the countries/continents where it is known to be present)?

**Not established in new areas, not widely established, moderately widely established, widely established, very widely established**

Level of uncertainty:	Low	Medium	High
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#### Conclusion about the probability of establishment

2.20 The overall probability of establishment should be described

**Very low, low, medium, high, very high**

Level of uncertainty:	Low	Medium	High
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### Step 3: Assessment of probability of spread

Spread is defined as the expansion of the geographical distribution of a BCA within an area. Spread potential is an important element in determining how quickly impact is expressed. In the case of an intentionally imported BCA, the assessment of spread concerns spread from the intended habitat (or the intended use) to other habitats where the BCA may establish. Further spread may then occur to other unintended habitats. The nature and extent of the intended habitat should be specified in the application and will also influence the probability of spread. Some BCAs may not have effects on non-target hosts immediately after they establish, and in particular may only spread after a certain time. In assessing the probability of spread, this should be considered, based on evidence of such behaviour.

#### **3.0 To what extent is spread expected (specify whether the BCA is intended for classical biological control across a larger area than the initial release)?**

3.01 What is the most likely rate of spread by natural means (in the IAA)?

*Note:* natural population spread, increasing the area of distribution, can result from the movement of the BCA by flight (of an insect), wind or water dispersal and transport by vectors such as insects, birds or other animals.

Consider potential vectors of the BCA in the IAA, the presence of natural barriers and the suitability of the environment. In this question, the mean rate of spread should be taken into account to decide on the rating. The maximum spread capacity should be described in the justification text, and the corresponding rating may also be given when the assessor(s) considers it important to describe different scenarios.

Spread can be described as distance covered per unit time (e.g. 50 m year<sup>-1</sup>) or in increasing area occupied over time (e.g. km<sup>2</sup> year<sup>-1</sup>).

**Very low rate of spread, low rate of spread, moderate rate of spread, high rate of spread, very high rate of spread**

Level of uncertainty:	Low	Medium	High
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3.02 What is the most likely rate of spread by human-assisted means (in the IAA)?

*Note:* consider the potential for movement with commodities, packing materials, baggage, mail or conveyances, the fact that the species may be intentionally dispersed by people and the ability of the BCA to be unintentionally dispersed along major transport routes. Consider spread to unintended habitats.

Mechanical transmission through human activities commonly occurs over short distances within the place of production. However, since employees often travel long distances to work and contract workers (who visit many production sites) are commonly employed, it is considered that evidence of mechanical transmission indicates the potential for at least moderate spread.

**Very low rate of spread, moderate rate of spread, high rate of spread, very high rate of spread**

Level of uncertainty:	Low	Medium	High
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#### Conclusion on the probability of spread

3.03 What is the overall rate of spread?

*Note:* the overall rate of spread should combine assessments of the rate of natural spread and human-assisted spread. In most situations, the overall rate of spread is equal to the highest rate of spread given as responses to either Question 3.01 or Question 3.02.

**Very low rate of spread, low rate of spread, moderate rate of spread, high rate of spread, very high rate of spread**

Level of uncertainty:	Low	Medium	High
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### Step 4: Assessment of potential environmental consequences

The main purpose of this section is to determine whether the introduction of the BCA will have unacceptable or, conversely, positive environmental consequences. It may be possible to do this very simply if sufficient evidence is already available and the risks and benefits presented by the BCA are widely agreed. In cases where the organism has already entered and is established in part of the IAA,

responses to Questions 4.02 and 4.04, which refer to positive and negative impacts in its area of current distribution, should be based on an assessment of current impacts in the IAA in addition to impacts elsewhere.

Expert judgement is used to provide an evaluation of the likelihood and scale of impact. If precise environmental evaluations are available for certain BCA/host combinations, it will be useful to provide details.

The responses should take account both short-term and long-term positive and negative effects of all aspects of environmental impact. One option is to evaluate the impact for different scenarios where different proportions of the area of potential establishment are considered to be invaded (e.g. 10%, 25%).

In any case, providing replies for all situations may be laborious, and it is desirable to focus the assessment as much as possible. The study of a single case may be sufficient, for example if the effect on one non-target host exceeds the effect on all other non-target hosts together. It may be appropriate to consider all hosts together in answering the questions once, if effects on these hosts are comparable. If a selection is made, it should be justified. Only in certain circumstances will it be necessary to answer the questions separately for specific hosts. This is the case if the majority of the affected areas suffer minor or moderate impacts but a small area suffers major or massive impacts. Positive effects due to the decrease of target pest populations should be considered separately from positive effects due to the replacement of other plant protection actions. Positive effects due to the decrease of target pest populations mainly depend on the level of negative environmental effects caused by the target pest. Positive effects due to the replacement of other plant protection actions mainly depend on negative environmental effects caused by these plant protection actions.

### Possible negative environmental impact

#### 4.01 What are the known negative environmental impacts of the BCA in the current area of distribution?

- list any negative impacts known on ecosystem services (see EFSA, 2016)
- list any negative impacts on protected species or biodiversity
- list any known negative impacts on other protected objects, such as landscapes, habitats, individual objects.

#### How important are negative environmental impacts caused by the BCA within its current area of distribution?

**N/A, minimal, minor, moderate, major, massive**

*Note:* this question rates the current negative environmental impact in other regions that can be used as an indicator for determining the potential negative environmental impact in the IAA (Question 4.02). If the

species has not spread in any other area, or if the spread is too recent and too little is known about its ecology in these areas, this question cannot be answered properly (assuming that no additional investigations can be undertaken during the time available for producing the assessment). The assessor may choose to answer these questions based on well-studied closely related species or data for the target species from the region of origin. Although the concept of ‘negative environmental impact’ of an indigenous species on native biodiversity and ecosystem is debatable, in some cases native species clearly have a negative environmental impact, usually resulting either from climate change or ecological mismanagement (e.g. *Harmonia axyridis* currently causing outbreaks and extending its range in China). Nevertheless, the assessor should take into account the fact that the negative environmental impact of a BCA in its region of origin is often a very poor predictor of potential negative impact in regions where it has been introduced. In particular, the absence of any obvious negative environmental impact in a region of origin should not be considered as a predictor for a low negative impact in a new area.

Data on negative impact may be available in several regions where the BCA has been introduced or even from the region of origin, for example resulting from climate change or ecological mismanagement. Priority should be given to the negative impact observed in regions that are most closely related, geographically and ecoclimatologically, to the IAA and especially those that are not the area of origin of the BCA. However, data from other regions should not be excluded. For example, when performing an assessment on a BCA for the whole of Europe, data on negative impact already observed in Europe should be given priority but information from other regions should also be provided. In any case, the assessor should specify the region where the information on negative impact has been gathered.

#### 4.02. How important is the negative environmental impact likely to be in the IAA?

##### **Minimal, minor, moderate, major, massive**

Verify whether, based on Question 4.01, a negative environmental impact is likely to occur in the IAA, and, if yes, at a comparable level, using the following sub-questions. For this, responses in the ‘Likelihood of establishment’ section should be taken into account.

*Note:* to answer this question, take into account the responses to the relevant questions (on hosts, climatic conditions and abiotic factors) in the establishment section. Are the conditions in the IAA sufficiently similar to those in the area of its current distribution to expect a similar level of negative impact? Does the same native species or community, or the same threatened ecosystem, occur in the IAA and, if not, is it known whether the equivalent native species, community or ecosystem in the IAA are similarly susceptible?

The BCA has to be assessed for four categories of impact using several indicators that need to be rated. The precise region (and whether introduced or native) and the species (target species or closely related species) for which the question is answered should be clearly described.

**Before answering Question 4.02, answer the following sub-questions:**

(a) Impacts on pest control and monitoring

4.02.01 *To what extent is the BCA likely to disrupt existing biological or integrated systems for pest control?*

**Minimal extent, minor extent, moderate extent, major extent, massive extent**

Level of uncertainty:	Low	Medium	High
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4.02.02 *If options are available to monitor, eliminate or reduce identified negative impacts, how great an increase in other costs resulting from introduction is likely to occur?*

*Note:* other costs include costs to the government, such as project management and administration, enforcement, research, extension/education, advice, publicity, costs to the crop protection industry.

**Minimal, minor, moderate, major, massive**

Level of uncertainty:	Low	Medium	High
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(b) Negative impact on native biodiversity

*Note:* the word ‘native’ in ‘native species’ or ‘native biodiversity’ throughout Questions 4.01–4.04 should be understood in a broad sense, that is it should also include species that have been naturalized for centuries and play an important role in the ecosystems or local cultural heritage. The assessor may also include other more recently introduced beneficial organisms such as BCAs or non-indigenous plants that play a role in ecosystem services (EFSA, 2016), for example plants used against erosion.

*Phytophagous BCAs:* most impacts by introduced BCAs occur through direct feeding on native and managed plants in the wild, in agriculture and forestry.

*Hybridization:* hybridization between an introduced and a native species or subspecies may affect the genetic identity of native species or subspecies, although well-documented examples are rare for BCAs.

*Competition for resources:* BCAs may affect native biodiversity by competing for food (hosts) or by affecting the quality and availability of food.

*Predation and parasitism:* the use of non-specific BCAs over wide areas may affect native biodiversity, in particular when used in natural or semi-natural areas (e.g. forests, swamps, etc.).

*Apparent competition:* apparent competition occurs when the presence of one species indirectly decreases the fitness

of another species (e.g. a native species) through the increased presence of a shared enemy.

4.02.03 *To what extent could the BCA cause a decline in native species?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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4.02.04 *To what extent could the BCA cause negative changes in the composition and structure of native species communities?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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4.02.05 *To what extent could the BCA hybridize with native species?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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(c) Alteration of ecosystem processes and patterns

*Note:* only the impact on natural or semi-natural areas should be considered when assessing the impact on ecosystem processes and patterns. However, natural and semi-natural areas have to be considered in a broad sense, that is every area that is not under constant human management.

4.02.06 *To what extent could the BCA cause physical modifications of areas (e.g. changes to the hydrology, significant increase of water turbidity, light interception, alteration of river banks, changes in fire regime)?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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4.02.07 *To what extent could the BCA cause negative changes in nutrient cycling and availability?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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4.02.08 *To what extent could the BCA cause negative modifications of natural successions (e.g. acceleration or temporary freezing of successions)?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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4.02.09 *To what extent could the BCA disrupt trophic and mutualistic interactions (e.g. disruption of food web, pollination or plant–mycorrhiza webs) leading to ecosystem imbalance?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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(d) Negative conservation impacts

4.02.10 *To what extent is the BCA likely to spread to areas of high conservation value (includes all officially protected nature conservation areas)?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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4.02.11 *To what extent could the BCA cause harm to rare or vulnerable species (includes all species classified as rare, vulnerable or endangered in official national or regional lists within the IAA)?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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(e) Negative impact on ecosystem services (see EFSA, 2016)

4.02.12 *To what extent could the BCA cause disruption to provisioning ecosystem services (e.g. providing food, raw materials, fresh water and medicinal resources)?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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4.02.13 *To what extent could the BCA cause disruption to supporting ecosystem services (e.g. providing habitats for species and maintaining genetic diversity)?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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4.02.14 *To what extent could the BCA cause disruption to regulating ecosystem services (e.g. regulating local climate, air quality, carbon sequestration and storage, buffer for extreme weather events or natural hazards, biological breakdown of waste in soil and water, erosion prevention and maintenance of soil fertility, regulating pollination and biological control)?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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4.02.15 *To what extent could the BCA cause disruption to cultural ecosystem services (e.g. natural features or places maintaining recreation and mental and physical health, tourism, aesthetic appreciation and inspiration for culture, art and design, creating spiritual or religious experiences)?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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Additional questions (only for phytophagous BCAs)

*Note:* some of this information may already have been provided in responses to previous questions, but more detail, more closely based on PRA, may be required by risk managers in the case of phytophagous BCAs because the potential risks to plants are inherently higher in this case.

(f) Negative impact on native and managed plants:

4.02.16 *What is the probability that the host range of the BCA includes native or managed plants in the IAA?*

**Low probability, medium probability, high probability**

Level of uncertainty:	Low	Medium	High
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4.02.17 *What is the level of damage likely to be caused by the organism on its major native or managed host plants in the IAA? (If possible, this question should be answered by taking account of the impacts on its major target and non-target host plants in the IAA. If the effects on the host plants in the IAA are not well known, then the answer should be based on damage levels in other areas, but with a higher level of uncertainty)*

**Low level, medium level, high level**

Level of uncertainty:	Low	Medium	High
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(g) Negative impact on ecosystem patterns and processes

4.02.18 *What is the ecological importance of the hosts in the IAA?*

**Low importance, medium importance, high importance**

Level of uncertainty:	Low	Medium	High
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(h) Negative conservation impacts

4.02.19 *To what extent do the host plants occur in ecologically sensitive habitats (includes all officially protected nature conservation habitats)?*

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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4.02.20 What is the probability that the BCA would harm rare or vulnerable species (includes all species classified as rare, vulnerable or endangered in official national or regional lists within the IAA)?

**Low probability, medium probability, high probability**

Level of uncertainty:	Low	Medium	High
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#### Taking into account the responses to Questions

**4.02.01–4.02.20 return to answer Question 4.02 before going to Question 4.03**

#### Possible positive environmental impact

*Note:* if possible, all mechanisms of positive impact on native biodiversity should be considered, but only the mechanism providing the highest score and lowest uncertainty is kept for the scoring of the indicators. Mechanisms of positive impact may include, among others:

*Phytophagous BCAs:* most positive impacts by introduced BCAs occur through direct feeding on plants having a negative impact on biodiversity (e.g. the introduction of *Cactoblastis cactorum* to Australia).

*Competition for resources:* BCAs may positively affect native biodiversity by competing for food (hosts) or by affecting the quality and availability of food with species having a negative impact on biodiversity.

*Predation and parasitism:* the use of BCAs over wide areas may positively affect native biodiversity, in particular when used in natural or semi-natural areas (e.g. forests, swamps, etc.) by decreasing populations of species having a negative impact on biodiversity (e.g. the introduction of *Rodolia cardinalis* to the Galapagos and many other areas).

*Apparent competition:* apparent competition occurs when the presence of one species indirectly decreases the fitness of another species (e.g. a species that has a negative impact) through, for example, the increased presence of a shared enemy.

Only the impact on natural or semi-natural areas should be considered when assessing the positive impact on ecosystem processes and patterns. However, natural and semi-natural areas have to be considered in a broad sense, that is every area that is not under constant human management.

#### 4.03 How important are known positive environmental impacts caused by the BCA within its current area of distribution?

*Note:* the answer should include evidence of positive impacts from use of the BCA in other regions, with references.

**N/A, minimal, minor, moderate, major, massive**

Level of uncertainty:	Low	Medium	High
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#### 4.04 How important is the positive environmental impact likely to be in the IAA?

**Minimal, minor, moderate, major, massive**

Level of uncertainty:	Low	Medium	High
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Verify that, based on Question 4.03, a positive environmental impact is also likely to occur in the IAA, and, if yes, at a comparable level, using the following questions.

*Note:* to answer this question, take into account the responses to the relevant questions (on hosts, climatic conditions and abiotic factors) in the establishment section. Are the conditions in the IAA sufficiently similar to those in the area of its current distribution to expect a similar level of positive impact? Does the same native species or community, or the same threatened ecosystem(s), occur in the IAA and, if not, is it known whether the equivalent native species, communities, ecosystems in the IAA are similarly susceptible?

#### Before answering Question 4.04, answer the following sub-questions:

4.04.01 How important are the negative environmental impacts caused by the target pest(s) in the IAA?

*Note:* consider impacts such as the decline of native species caused by the target pest, changes in composition and structure of native species communities, physical modification of areas caused by the target pest (e.g. changes to the hydrology, significant increase in water turbidity, light interception, alteration of river banks, changes in fire regime, etc.), changes in nutrient cycling and availability, modifications of natural successions, disruption of trophic and mutualistic interactions, impacts on ecosystem services including provisioning, supporting, regulating and cultural services (EFSA, 2016).

**N/A, minimal, minor, moderate, major, massive**

Level of uncertainty:	Low	Medium	High
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4.04.02 How likely are the negative environmental impacts caused by the target pest(s) to be prevented or reduced or reversed by the BCA in the IAA?

**N/A, very unlikely, unlikely, moderately likely, likely, very likely**

Level of uncertainty:	Low	Medium	High
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4.04.03 How important are the negative environmental impacts caused by control procedures against the target pest(s) in the IAA?

**N/A, minimal, minor, moderate, major, massive**

Level of uncertainty:	Low	Medium	High
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*4.04.04 How likely are the negative environmental impacts caused by control procedures against the target pest(s) to be prevented or reduced by the BCA in the IAA?*

**N/A, very unlikely, unlikely, moderately likely, likely, very likely**

Level of uncertainty:	Low	Medium	High
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*4.04.05 To what extent is the BCA likely to improve existing biological or integrated systems for pest control?*

*Note:* for example, it is necessary to take into account that the replacement of existing plant protection actions (e.g. pesticide treatments) against the target pest by the use of the BCA may facilitate biological or integrated control of other pests.

**N/A, minimal extent, minor extent, moderate extent, major extent, massive extent**

Level of uncertainty:	Low	Medium	High
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*4.04.06 To what extent is the BCA likely to spread to areas of high conservation value (includes all officially protected nature conservation areas)?*

*Note:* establishment of the BCA in such areas could be a solution to protect biodiversity when the use of pesticides is prohibited.

**N/A, low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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*4.04.07 To what extent could the BCA protect rare or vulnerable species from impact by the target pest(s) (includes all species classified as rare, vulnerable or endangered in official national or regional lists within the IAA)?*

**N/A, low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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*Additional questions (only for phytophagous BCAs)*

*4.04.08 What is the ecological importance and role of the target host plants in the IAA?*

**N/A, low importance, medium importance, high importance**

Level of uncertainty:	Low	Medium	High
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*4.04.09 To what extent do the target host species cause damage in ecologically sensitive habitats (includes all officially protected nature conservation habitats)?*

*Note:* establishment of the BCA in such areas could be a solution to protect biodiversity when the use of herbicides is prohibited.

**Low extent, medium extent, high extent**

Level of uncertainty:	Low	Medium	High
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*4.04.10 What is the probability that the BCA would protect rare or vulnerable species? (includes all species classified as rare, vulnerable or endangered in official national or regional lists within the IAA)*

*Note:* establishment of the BCA could protect rare, vulnerable or endangered plant species by suppressing plants, which compete with them.

**Low probability, medium probability, high probability**

Level of uncertainty:	Low	Medium	High
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**Taking into account the answers to Questions 4.04.01–4.04.10 return to answer Question 4.04 before going to Question 4.05**

**Conclusion of the assessment of environmental consequences**

**4.05 With reference to the area of potential establishment identified in Question 2.01, identify the areas which have the highest probability of positive and negative environmental impacts. Summarize the impacts (and also indicate how these may change in future)**

**Minimal impact, minor impact, moderate impact, major impact, massive impact**

Level of uncertainty:	Low	Medium	High
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**4.06 With reference to the likelihood of negative and positive environmental impacts identified in Questions 4.01–4.04, conclude how these should be summarized (also indicate how the balance between them may change in future)**

**Very positive impact, positive impact, neutral or no impact, negative impact, very negative impact**

Level of uncertainty:	Low	Medium	High
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## Step 5: Recording the degree and types of uncertainty

Estimation of the probability of establishment of a BCA and of its environmental consequences involves many uncertainties. In particular, this estimation is an extrapolation from the situation where the BCA occurs to the hypothetical situation in the IAA. It is important to document the areas of uncertainty (including identifying and prioritizing of additional data to be collected and research to be conducted) and the degree of uncertainty in the assessment, and to indicate where expert judgement has been used. This is necessary for transparency and may also be useful for identifying and prioritizing research needs.

Characterize the nature of the uncertainty (genuine lack of knowledge, conflicting data, unreliable data, lack of precision or sensitivity, data from limited circumstances, etc.)

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Go to 'Conclusion of the EIA'

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## Step 6: Conclusion of the EIA

### Establishment

Evaluate the probability of establishment, and indicate the elements which make establishment most likely or those that make it least likely. Specify which part of the IAA presents the greatest probability of establishment.

### Spread

Evaluate the probability of spread, and indicate the elements which make spread most likely or those that make it least likely.

### Environmental impact

List the most important potential positive and negative environmental impacts, and estimate how likely they are to arise in the IAA. Specify which part of the IAA is most likely to experience the impacts.

### Overall conclusion

The assessor should give an overall conclusion on the assessment and if it would be of overall benefit to introduce the BCA in the IAA, and an estimation of the associated environmental consequences.

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