



Deliverable 21

Agreement on criteria for inclusion of species of macrobial BCAs on a 'Positive List'

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Document History

All of the discussions and recommendations concerning macrobial (invertebrate) biological control agents were contained within REBECA Work Package 5 (WP5) and channelled into 5 deliverables (D19 to D23) as set out in the original proposal. These deliverables are in some cases closely interrelated e.g. this deliverable concerning the 'Positive List' of safe biocontrol agents and D22 which reviews the options for implementing a pan-European regulatory system, including the role of an Expert Group.

The development and final agreement on the content of this and other WP5 deliverables relating to insect and mite agents were achieved via a workshop in Wageningen (The Netherlands) in April 2006, a conference in Salgau (Germany) in September 2006, a series of small group meetings on specific topics in the early part of 2007, a second workshop in Frankfurt (Germany) in July 2007, and the final conference in Brussels (Belgium) in September 2007.

Document Abstract

The EPPO 'List of biological control agents widely used in the EPPO region' ('EPPO Positive List') was published in 2002 to facilitate decisions by national regulatory authorities on the import and release of invertebrate biological control agents (IBCA) within EPPO countries. Because the listing of agents is based on expert judgement of available information, other EPPO countries may presume with some confidence that these agents can be introduced and used safely. During the REBECA project, regulators within the macrobiols group stated that they are not currently using this list as a tool because it requires revision, but they expressed keen interest in the possibility of it being

updated. This topic was addressed within workpackage 5 of REBECA and a small workshop was held in Delémont, Switzerland, to discuss the 'Current and future use of the EPPO Positive List for IBCAs'. During this workshop, the process of updating the Positive List was discussed and the criteria and format for inclusion of an IBCA as well as reasons for removal of certain species from the list were agreed upon. Also discussed at this meeting was a method by which the Positive List may be maintained and updated in the future so that it remains a useful and up-to-date tool for industry, regulators and public. Commercial interests of biocontrol manufacturing companies were also taken into consideration. The establishment of an Expert Group to assume responsibility for updating and maintaining the Positive List was proposed. It was later learnt that EPPO wishes to reactivate its interest in the Positive List and that they will collaborate with IOBC to create an Expert Group for this purpose. The macrobials group supports the idea of EPPO-IOBC Expert Group assuming responsibility for updating and maintaining the EPPO Positive List in the future. At the Delémont workshop, an additional role was proposed for the Expert Group of providing advice to national regulatory authorities on the environmental safety of IBCAs proposed for introduction into EPPO countries. This idea of the EPPO-IOBC Expert Group taking on this additional role was strongly endorsed by the REBECA macrobials group and ties in very well with the proposal for implementation of a pan-European regulatory system for IBCAs, which is covered in more detail in deliverable 22.

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Introduction

The idea to create a list of macrobial/invertebrate biological control agents (IBCA) that are currently, or were at one time, widely used without any reports of adverse effects ('EPPO Positive List') was first addressed by the European and Mediterranean Plant Protection Organisation (EPPO). The EPPO Panel on Safe Use of Biological Control compiled a list specifying indigenous, introduced and established biological control agents that they recognised to have been widely used in several EPPO countries (EPPO 2002). The inclusion of IBCAs in this list was based on expert judgement of available information by the EPPO Panel and they were grouped depending on their classification as either: 1) a successful classical biological control agent or, 2) a biological control agent which is (or has been) commercially available, and is indigenous and widespread in the EPPO region, or established and widespread in the EPPO region, or has been used for at least five years in at least five EPPO countries (exceptionally less, if few crops are grown in few countries). The intention of this list was that other EPPO countries would be able to presume with some confidence that these agents could be introduced and used safely. They may, according to their judgement, dispense with, or simplify, the notification procedures proposed in the EPPO Standards PM6/1 and PM6/2 (EPPO 1999, 2001).

However, the current EPPO Positive List has not been updated since its first publication and many national regulatory authorities have stated that they are not currently using the list as an advisory tool, suggesting that a revision is urgently needed. An up-to-date EPPO Positive List would bring several benefits to national regulators:

- It could be used to verify the information given in an application to introduce and/or release an IBCA;
- It would provide additional valuable information on the proposed IBCA, including critical characteristics, such as, its the potential to establish in warmer climates;
- If trustworthy, it would become a criterion for safety in the IBCA risk assessment.

During discussions at the REBECA workshop in Salzau, the macrobials group confirmed that they supported the principle of the EPPO Positive List and its access and use by industry, regulators and public. The group also agreed that maintaining the Positive List under the auspices of EPPO was desirable, as it would convey credibility. As mentioned in Deliverable 22 of the REBECA project, the Director General of EPPO subsequently contacted the REBECA coordinator to confirm that EPPO intended to reactivate its interest in the Positive List.

A small workshop was organised in Delémont, Switzerland, to address the 'Current and future use of the EPPO Positive List for IBCAs'. Participants of

this Positive List working group included industry representatives, regulators and biological control researchers, thus representing the main groups that would benefit from such a list. During the workshop, the process of updating the EPPO Positive List was discussed and the criteria and format for inclusion of an IBCA as well as reasons for removal of certain species from the list were agreed upon. Also discussed at this meeting was a method by which the EPPO Positive List may be maintained in the future.

Criteria for inclusion of IBCA species on the EPPO Positive List

The Positive List workshop recommended that IBCAs on the revised EPPO Positive List should be divided into two sections as outlined below. The data requirements for inclusion of IBCAs in the list should also be revised as indicated:

Section 1: Commercially used invertebrate biological control agents with history of safe use, which are either indigenous and widespread in the EPPO region, or established and widespread in the EPPO region, or have been used for at least five years in at least five EPPO countries (exceptionally less, if crops are grown in few countries).

Data requirements:

- Taxonomic classification (alternative names, synonyms, location of voucher specimens);
- Target pest (purpose of use);
- Use (so far limited to indoor or outdoor use in existing list);
- Original distribution (country specific as far as possible);
- EPPO countries where used: approved/rejected, date of first use (some agents used but not necessarily officially approved);
- Distribution in EPPO: whether native or established and range of countries where established following release (draws distinction between area of use and area of establishment as a consequence of use. This is an important consideration for regulators because the potential for establishment in new countries or regions can be inferred from information on whether the species has established widely, or if it has a limited area of establishment);
- Potential for establishment (number of generations/year; development threshold temperature; or Europe versus Mediterranean; diapause characteristics - because they influence establishment);
- Host range;
- Additional remarks (e.g. special characteristics, such as flightlessness, which might affect establishment).

Section 2: Introduced classical invertebrate biological control agents.

Data requirements:

- Taxonomic classification (alternative names, synonyms, location of voucher specimens);
- Target pest and its original distribution
- Host plant of target pest
- EPPO countries where agent introduced
 - Information about establishment
 - Category of results
 - Single/multiple introductions
 - Date of introduction if available
- Distribution of agent within EPPO
 - Current status of spread to other countries after release of agent
 - Host plant of target pest
- Origin of agent (where collected)
 - Information on original distribution
- Host range
- Additional remarks
 - Information of adverse effects if available
 - Environmental risks if applicable
 - Provide key references and sources
 - Additional releases are not favoured based on new knowledge

Creation of an Expert Group to update and maintain the EPPO Positive List

The existing EPPO Positive List needs to be revised on the species level. It was recommended by participants of the Positive List working group that an Expert Group be established for this purpose. During the workshop, the following suggestions were made regarding the areas of expertise required on the Expert Group: (1) regulators; (2) biocontrol industry representatives; (3) classical biocontrol practitioners; (4) taxonomists; and (5) other relevant experts, but no decisions were made regarding which organisation the group should be affiliated to. Later, EPPO informed REBECA that not only does it intend to reactivate its interest in the Positive List but that it would collaborate with the IOBC (WPRS) to create a new Expert Group for this purpose (see Deliverable 22 for more information). At the following REBECA workshop in Frankfurt, it was agreed that this EPPO-IOBC collaboration would be beneficial and that the EPPO-IOBC Expert Group should be supported to take on the role of updating and maintaining the EPPO Positive List. It was recommended that the members of this group should include experts representing several different stakeholders within the field of biological control.

According to the recommendations of the Positive List working group, the EPPO-IOBC Expert Group should therefore initially make revisions of the current EPPO Positive List according to the above-mentioned additional

information requirements and should correct any reported 'errors'. It is recommended that the CABI BIOCAT database (data from 1900 to September 2006) be used to update the information for the introduced classical IBCAs. Some EPPO countries could also provide published information. It should be noted that all introduced IBCAs of arthropods and weeds would be listed, therefore this list would become a comprehensive reference source for regulators. It is highly recommended that the CABI BIOCAT database be maintained since it is a valuable advisory tool for the regulatory process in the EPPO region and elsewhere. The CABI BIOCAT database has not been updated since September 2006 and REBECA should inform CABI about the valuable contribution such a database would make towards achieving future widespread use of the EPPO Positive List as an advisory tool.

In terms of maintaining and updating the EPPO Positive List, this would include assessing the suitability of new IBCAs for inclusion on the list as well as inserting additional information for species already on the list. In addition, decisions would be made about species no longer considered suitable for the list, based on new information as it becomes available. One important suggestion put forward by the regulators at the Positive List workshop was that names of species no longer considered suitable for such a positive list should not simply be removed from the list but instead should remain with details of why they are no longer considered safe to be included. This is essential information for the assessment of subsequent release applications for these particular IBCA species that would be lost if the names were just removed. It is of high priority that the EPPO Positive List be updated regularly by the EPPO-IOBC Expert Group so that it remains a useful tool in future years.

Under the assumption that the existing EPPO Positive List will be improved according to the recommendations, it is believed that the list will provide important baseline data about the safe use of commercially used IBCAs as well as introduced classical IBCAs in EPPO member countries. It will provide a standard that will facilitate the decision making process for national regulatory authorities within EPPO countries. However, it is important to note that the inclusion of an IBCA in the EPPO Positive List should not lead to the automatic granting of permission to release the agent on a wide scale but should become a criterion for safety in the risk assessment.

Additional advisory role of the EPPO-IOBC Expert Group

Whilst discussing the functions of the EPPO-IOBC Expert Group, it was noted that there is not always sufficient knowledge available to national regulatory authorities to help them make a fair judgement on the environmental safety of IBCAs. It was therefore proposed that the EPPO-IOBC Expert Group could also provide non-binding advice to national regulatory authorities, when

requested, on dossiers for the import and/or release of an IBCA. This would be of particular benefit to regulators in countries where there are no existing regulations for the introduction of new IBCAs. However, countries that already have regulations in place but wish to obtain additional advice could also voluntarily send dossiers to the EPPO-IOBC Expert Group for feedback. This proposal was strongly supported at the REBECA workshop in Brussels where an additional suggestion was made to implement the signing of confidentiality (non-disclosure) forms to ensure that any information received by the EPPO-IOBC Expert Group as well as any advice they give to the national authorities would remain strictly confidential.

There is significant overlap between the outcome of this Deliverable and that of Deliverable 22; 'Evaluation of options for implementing a pan-European regulatory system for microbial BCAs'. In particular, Deliverable 22 provides details of a discussion at the Frankfurt workshop regarding the possibility of implementing regulation on an EU-level. The outcome of this discussion was agreement that the more suitable and 'pragmatic approach' at the current time would be to leave IBCA introduction decisions in the hands of the competent national authorities of each individual country. However, the group also agreed that the creation of an Expert Group to provide advice to national regulatory authorities, especially in countries with no regulation, would help to achieve wide-scale implementation of a harmonised regulatory scheme for IBCAs without the need for EU legislation. Thus, the idea proposed by the Positive List working group was supported.

The additional advisory role of the EPPO-IOBC Expert Group would mean that it would have key two roles; first to maintain the EPPO Positive List and second, to provide advice when requested on the environmental safety of potential IBCA introductions. A schematic description of an EPPO-IOBC Expert Group with this dual function is shown in Figure 1 of Deliverable 22.

Updating the EPPO Positive List and overcoming confidentiality issues

The Positive List working group also went on to develop a potential scheme for maintaining the EPPO Positive List, more specifically, the process by which IBCA species would be added or removed from the list. The scheme was devised in such a way that national regulatory authorities would have permanent access to information about the IBCAs to help them make decisions regarding environmental safety. In developing these recommendations, the group also addressed another matter that arose during the Positive List workshop which was that IBCA manufacturing companies may not be inclined to apply to add a particular agent to the EPPO Positive List since this would create an unfair advantage to other companies that have not invested the time or resources required for assessing the environmental safety of the agent. The group therefore devised a scheme that takes this issue of confidentiality into consideration whilst ensuring that the list will

remain a useful tool for all those involved in biological control. The following recommendations were suggested:

1. Develop a Database on the Regulatory Status (DRS) of new commercially used IBCAs to provide an overview of their regulatory status in EPPO member countries;
2. Develop a procedure for the transfer of commercially used IBCAs from the DRS onto the EPPO Positive List;
3. Develop a procedure for the addition of classical IBCAs on to the EPPO Positive List.

1) Database of the Regulatory Status of new commercially used IBCAs (DRS)

The primary goal of the DRS would be to aid national regulators in their decision making process on IBCA introductions. The database would comprise information on the safety and regulatory status of new commercially used IBCAs before they are approved for inclusion on the EPPO Positive List. The regulators at the Positive List workshop outlined the benefits that such a list would provide:

- A network facility for competent national regulatory authorities;
- An overview of the regulatory status of commercially used IBCAs in Europe (EPPO region);
- Access to existing regulatory decisions (both positive and negative) and their justification;
- A distribution tool for new information, including adverse environmental effects.

In order for a new commercial IBCA and its relevant safety and regulatory information to be included in the DRS, one of the following would be needed:

- A positive recommendation by the EPPO-IOBC Expert Group for its use in at least one EPPO member country;
- An official release permit from at least one EPPO member country.

Justification of positive recommendations and/or granting of release permits would be included in the DRS, as would information and justification of rejected permit applications.

The possibility of introducing geographical subdivisions of the EPPO region based upon climate was also discussed in depth at the Positive List workshop. Under such a scheme, release of an IBCA in one country would not have to be officially approved if permission for its release had already been granted in another country within the same 'ecoregion' in EPPO. It was decided that at the present time that this was not feasible and thus, to apply for inclusion of an IBCA on the DRS, separate applications would have to be submitted on a per country and per IBCA basis.

In order to address issues of confidentiality and to protect the commercial interests of the biological control industry, IBCAs would remain on the DRS for a period of five years, during which time access to their safety or regulatory information would be restricted to regulators only via a password protected entry. Also during this time period, all other companies or organisations wishing to introduce the same IBCA would be obliged to submit their own dossiers and undergo the same application process to gain approval. After five years, the IBCAs would be critically reviewed for transfer on to the EPPO Positive List, after which there would be free access to information about this agent (see point 2 below).

The DRS would be updated on a regular basis with information on new approvals, and would contain the following fields:

- Scientific name of IBCA;
- Name of applicant;
- Country;
- Regulatory process available in this country? (yes, no);
- Regulatory status (submitted, approved, rejected, used);
- Date of approval;
- Recommendation from the EPPO-IOBC Expert Group;
- Link to the permit document;
- Information on observed adverse environmental effects;
- Contact person.

It was proposed that the Expert Group responsible for maintaining the EPPO Positive List, i.e. the EPPO-IOBC Expert Group, should also assume responsibility for the DRS.

2) Transfer from the DRS to the EPPO Positive List of Commercially Used IBCAs with history of safe use.

After a period of five years of inclusion on the DRS, the EPPO-IOBC Expert Group would automatically critically review the environmental safety of the relevant IBCA. New information on (adverse) environmental effects of the agent would be taken into account. The criteria for transfer to the EPPO Positive List would be as follows:

- At least five years inclusion in the database;
- No new reports on adverse environmental effects;
- A critical review of the environmental safety of the IBCA by the EPPO-IOBC Expert Group.

The withdrawal of an IBCA from the EPPO Positive List would be possible at any time. This may occur, for example, if new information becomes available pertaining to relevant adverse environmental effects of the agent. The EPPO-IOBC Expert Group would decide whether or not to remove the IBCA based on critical evaluation of this information. Companies would be obliged to

report new information about adverse environmental effects of agents on the DRS or the EPPO Positive List to the EPPO-IOBC Expert Group and national regulatory authorities.

3) A procedure for the addition of Classical Biological Control Agents on to the EPPO Positive List

After approval for introduction from one of the EPPO countries or a positive recommendation from the Expert Group is received, the classical IBCA would be added directly on the EPPO Positive List. Additional information on adverse environmental effects would then be included on the EPPO Positive List for Introduced Classical IBCAs if it became available.

The proposal of creating this database was discussed in detail at the Frankfurt workshop where it was suggested that such a scheme might be too costly. Suggestions along the same lines to have the information stored on a simple password protected website were therefore put forward.

Conclusions

The REBECA macrobials group strongly supports the principle of the EPPO Positive List and its access and use by industry, regulators and the public. Maintenance of the list under the auspices of EPPO is also recommended to convey credibility. However, the current EPPO Positive List has not been updated since its first publication in 2002 and a revision is urgently needed. An up-to-date EPPO Positive List would bring several benefits to national regulators and thus its update and maintenance in the future is strongly recommended. The following proposals have been made in order to achieve this task:

Criteria for inclusion of IBCA species on the EPPO Positive List

- IBCAs on the revised EPPO Positive List should be divided into two sections: (1) Commercially used invertebrate biological control agents with history of safe use, which are either indigenous and widespread in the EPPO region, or established and widespread in the EPPO region, or have been used for at least five years in at least five EPPO countries (exceptionally less, if crops are grown in few countries); and (2) Introduced classical invertebrate biological control agents.
- The list of data requirements for inclusion of IBCAs in the list should be revised to include additional criteria, as indicated in this report.

Creation of an Expert Group to update and maintain the EPPO Positive List

- An Expert Group should be established to revise the current EPPO Positive List on a species level, according to the new proposed criteria.

- An EPPO-IOBC collaboration to establish an Expert Group is supported and it is recommended that this EPPO-IOBC Expert Group take on the role of updating and maintaining the EPPO Positive List.
- Members of the Expert Group should represent various relevant stakeholders, including: (1) regulators; (2) biocontrol industry representatives; (3) classical biocontrol practitioners; (4) taxonomists; and (5) other relevant experts.
- The CABI BIOCAT database should be used to update the information for the introduced classical IBCAs.
- REBECA should advise CABI that the BIOCAT database be updated and maintained, as it will be a valuable tool in helping to achieve future widespread use of the EPPO Positive List as an advisory tool.
- Names of species no longer considered suitable for the EPPO Positive List should not simply be removed from the list but instead should remain with details of why they are no longer considered safe to be included.
- The EPPO Positive List must be updated regularly by the EPPO-IOBC Expert Group so it remains a useful tool in future years.

Additional advisory role of the EPPO-IOBC Expert Group

- The EPPO-IOBC Expert Group should also provide non-binding advice to national regulatory authorities of countries within EPPO, when requested, on dossiers for the import and/or release of an IBCA. This would help to achieve wide-scale implementation of a harmonised regulatory scheme for IBCAs. This is discussed further in Deliverable 22; 'Evaluation of options for implementing a pan-European regulatory system for macrobial BCAs'.
- The EPPO-IOBC Expert Group should therefore have key two roles; (1) to maintain the EPPO Positive List; and (2) to provide advice when requested on the environmental safety of potential IBCA introductions.

Updating the EPPO Positive List

- A Database on the Regulatory Status (DRS) of new commercially used IBCAs should be created to provide an overview of information on the safety and regulatory status of new commercially used IBCAs before they are approved for inclusion on the EPPO Positive List. The primary

aim of this is to help national regulators with the decision making process on IBCA introductions.

- IBCAs should remain on the DRS for a period of five years, during which time access to their safety or regulatory information would be restricted to regulators only via a password protected entry. All other companies or organisations wishing to introduce the same IBCA would be obliged to submit their own dossiers and undergo the same application process to gain approval.
- After five years, the IBCAs would be critically reviewed for transfer on to the EPPO Positive List, after which there would be free access to information about this agent.
- A classical IBCA should be added directly on the EPPO Positive List after approval for its introduction from one of the EPPO countries or a positive recommendation from the Expert Group has been received.
- The withdrawal of an IBCA from the EPPO Positive List by the EPPO-IOBC Expert Group would be possible at any time if, for example, new information becomes available pertaining to relevant adverse environmental effects of the agent. This information should be included on the EPPO Positive List.

Under the assumption that the existing EPPO Positive List will be improved according to the recommendations, it is believed that the list will provide important baseline data about the safe use of commercially used IBCAs as well as introduced classical IBCAs in EPPO member countries. It will provide a standard that will facilitate the decision making process for national regulatory authorities within EPPO countries as well as benefit industry and the public.

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Appendix 1

REBECA Work Package 5 – Macrobiales (Invertebrate) Biocontrol Agents

Report from Small Group Meeting on current and future use of the EPPO List for IBCAs, held at CABI Europe-Switzerland, Delémont, Switzerland, March 11-12, 2007.

This report was subsequently discussed and approved at the REBECA workshop in Frankfurt and final REBECA Conference in Brussels.

In attendance: Ulli Kuhlmann (chair), Andrea Raps, Miloslava Navratilova, Bernd Wührer, Karel Bolckmans, Richard Greatrex, and Emma Hunt.

The idea of listing IBCAs that are currently, or were at one time, widely used without any reports of adverse effects (positive list) was addressed by the European and Mediterranean Plant Protection Organization (EPPO). The first list for the EPPO region was published in 2002. The IBCAs are listed according to expert judgement of available information, and are related to certain criteria, such as: a) IBCAs are native or non-native, but established or widespread in the EPPO region, and successfully used in classical or inundative/inoculative biological control, b) IBCAs have been used for at least five years in at least five EPPO countries.

During the REBECA Meeting – Macrobiales – in Salza in September 2006 the following comments and recommendations were made regarding to the existing EPPO List:

- The group supported the principle of the Positive List – access and use by industry, regulators and public;
- The current criteria require updating with additional information (distribution in EPPO region, countries that have approved/rejected licence, summary of ERA information etc);
- A system needs to be designed so issues of confidentiality do not arise;
- The status of list for use by regulators as an advisory tool needs clarification;
- EPPO 'endorsement' gives credibility.

In order to address the above-mentioned recommendations from Salza, a small expert group was mandated to follow up in a meeting at CABI Delémont and to develop a proposal that will be presented and discussed further during the next meeting in Frankfurt at the beginning of July 2007.

During the meeting at CABI Delémont we discussed in detail the topics listed above as well as the following matters; criteria and format for inclusion of an IBCA on the EPPO List, reasons for removal from an EPPO list and the possibility of introducing some geographical subdivisions of the EPPO region based upon climate. It should be noted that the small expert group took a pragmatic approach in consideration of the current situation that regulation of IBCAs is in place in some EU or EPPO countries, but not in others. As such, it is assumed that the decision-making process lies in the hands of the competent national regulatory authorities in each of the EU or EPPO countries where regulation is currently in place. At this meeting, the small expert group developed recommendations on how to proceed in countries where regulation is not in place and a new commercially or classical IBCA is being considered for release.

At the beginning of this meeting the potential benefits of an EPPO List for the national regulatory authorities were discussed.

Benefits of the EPPO List for Regulators:

- EPPO List can be used to verify the information given in the dossier;
- EPPO List provides additional valuable information, e.g on critical characteristics such as potential for establishment in warmer climates;
- EPPO list - if trustworthy – becomes a criterion for safety in the risk assessment.

Based on the discussions it became clear that not all national regulatory authorities are using the current EPPO List as an advisory tool because a revision is urgently needed.

At this point, the existing EPPO list accordingly specifies indigenous, introduced and established biological control agents which are recognized by the EPPO Panel on Safe Use of Biological Control to have been widely used in several EPPO countries. Based on this knowledge, other EPPO countries may therefore presume with some confidence that these agents can be introduced and used safely. They may, according to their judgement, dispense with, or simplify, the notification procedures proposed in the EPPO Standards PM6/1 and PM6/2. The agents are listed on the basis of expert judgement of available information.

In order to ensure that national regulatory authorities use the EPPO List as advisory tool the following recommendations to improve the existing EPPO List are suggested:

In the future, the revised EPPO List should divide IBCAs into the two following sections:

1. *Commercially used invertebrate biological control agents with history of safe use*, which are either indigenous and widespread in the EPPO region, or established and widespread in the EPPO region, or have

been used for at least 5 years in at least 5 EPPO countries (exceptionally less, if crops are grown in few countries).

2. *Introduced classical invertebrate biological control agents.*

Data requirements for both sections of the EPPO List need to be revised as follows:

EPPO List, section 1; Commercially used IBCAs with history of safe use:

- Taxonomic classification (alternative names, synonyms, location of voucher specimens);
- Target pest (purpose of use);
- Use and extent of use (so far limited to indoor or outdoor use in existing list);
- Original distribution (country specific as far as possible);
- EPPO countries where used: approved/rejected, date of first use (some agents used but not necessarily officially approved);
- Distribution in EPPO: whether native or established and range of countries where established following release (draws distinction between area of use and area of establishment as a consequence of use. This is an important consideration for regulators because the potential for establishment in new countries or regions can be inferred from information on whether the species has established widely, or if it has a limited area of establishment);
- Potential for establishment (number of generations/year; development threshold temperature; or Europe versus Mediterranean; diapause characteristics - because they influence establishment);
- Host range;
- Additional remarks (e.g. special characteristics, such as flightlessness, which might affect establishment).

Consideration provided by regulators: Names of species no longer considered suitable for such a list remain on the list with details of why they have been withdrawn – this is essential information for any subsequent application for use of these particular species. Simple removal of a species from the list results in a loss of available information.

Obviously the existing EPPO List for commercially used IBCAs needs to be revised on the species level according to the requested additional information requirements (identity and taxonomic considerations/changes) by an expert group. The objective will be to identify and correct reported 'errors' on the list. Experts will include individuals considered to have relevant competence, such as (1) regulators; (2) biocontrol industry representatives; (3) taxonomists; and (4) other relevant experts.

EPPO List, section 2; Introduced classical IBCAs:

- Taxonomic classification (alternative names, synonyms, location of voucher specimens);
- Target pest and its original distribution
- Host plant of target pest
- EPPO countries where agent introduced
 - Information about establishment
 - Category of results
 - Single/multiple introductions
 - Date of introduction if available
- Distribution of agent within EPPO
 - Current status of spread to other countries after release of agent
 - Host plant of target pest
- Origin of agent (where collected)
 - Information on original distribution
- Host range
- Additional remarks
 - Information of adverse effects if available
 - Environmental risks if applicable
 - Provide key references and sources
 - Additional releases are not favoured based on new knowledge

A revision of the list by an expert group is needed, according to additional information requirements specified above. Information on countries and results of introduction will be updated based on information in the CABI BIOCAT database (data from 1900 to September 2006). Some EPPO countries will also provide published information. It should be noted that all introduced IBCAs of arthropods and weeds will be listed, therefore this list will become a comprehensive reference source for regulators. It is highly recommended that the CABI BIOCAT database be maintained since it is a valuable advisory tool for the regulatory process in the EPPO region and elsewhere. The CABI BIOCAT database has not been updated since September 2006 and REBECA needs to inform CABI about the valuable contribution such a database would make towards achieving future widespread use of the EPPO List as an advisory tool. The list of introduced classical IBCAs will be updated annually to include newly introduced species as well as any additional information for species already on the list. The expert group will consist of members who can offer the relevant expertise in classical biological control, such regulators with relevant competence, classical biological control practitioners and taxonomists.

Under the assumption that the existing EPPO List will be improved according to the recommendations, it is believed that the list will provide important baseline data about the safe use of commercially used IBCAs in EPPO

member countries. The list will provide a standard that will facilitate the decision making process for national regulatory authorities within EPPO countries. The inclusion of a commercially used IBCA in the EPPO List should not lead to the automatic granting of permission to release the IBCA on a wide scale but should become a criterion for safety in the risk assessment.

Recommendations concerning maintenance and use of the EPPO List:

The small expert group feels that there is not always sufficient knowledge available to national regulatory authorities for them to make a fair judgement on the environmental safety of IBCAs. In order to help national regulatory authorities with the evaluation of permit applications for new IBCAs, the small expert group strongly recommend the following:

- 1) Creation of an Expert Group on Environmental Safety of IBCAs (EGES), which can give non-binding advice on the environmental safety of new IBCAs;
- 2) Development of a Database on the Regulatory Status (DRS) of IBCAs to provide an overview of the regulatory status of new commercially used IBCAs in EPPO member states;
- 3) Development of a procedure for the transfer of commercially used IBCAs from the DRS onto the EPPO List after a critical review by the EGES.
- 4) Development of a procedure for the transfer of classical IBCAs onto EPPO List

1. Expert Group on Environmental Safety (EGES) of IBCAs

- A country that has no existing regulations for the introduction of new IBCAs may choose to seek advice from EGES on dossiers they receive. Countries that already have regulations in place but wish to have additional advice may also voluntarily send dossiers to EGES for feedback. Any recommendations given by EGES would be non-binding.
- The members and the necessary competence of EGES are yet to be defined, as are its terms of reference and affiliation to an international or EU organisation.

2. Database on the Regulatory Status of IBCAs (DRS)

- *Goal:* the goal of the DRS is to provide regulators with a database of information on the safety and regulatory status of new commercially used IBCAs that they could use in their decision making process.
- In order for an IBCA to be included in the DRS, one of the following is needed:
 - Positive recommendation by EGES for its use in at least one EPPO member country, or
 - An official release permit from at least one EPPO member country.
- The recommendation by EGES and the release permit by the national regulatory authority should always be based on critical evaluation of a

permit application dossier and sufficient justification should be provided and included in the DRS.

- Information on rejected permit applications, including detailed justification for rejection, will also be placed in the DRS.
- The DRS will also include information on the use of IBCAs in countries that do not have a regulatory process in place yet. The advice of EGES can be requested for those countries.
- It was decided that at the present time it is not feasible to subdivide the EPPO region into different ecoregions. Therefore, to apply for inclusion of an IBCA on the DRS, separate applications will have to be submitted on a per country per IBCA basis.
- The DRS should be updated on a regular basis with information on new approvals.
- The DRS should contain the following fields:
 - Scientific name of IBCA
 - Name of applicant
 - Country
 - Regulatory process available in this country? (yes, no)
 - Regulatory status (submitted, approved, rejected, used)
 - Date of approval
 - Recommendation from the EGES
 - Link to the permit document
 - Information on observed adverse environmental effects
 - Contact person
- It is recommended that access to the DRS be restricted to regulators only (password protected) in order to protect the commercial interests of the biocontrol industry.
- It is recommended that IBCAs will be placed in the DRS per company. That is to say, when one company is successful in its application to include an IBCA in the database, this information will remain confidential for a period of five years (see below) such that all other companies or organisations will still have to submit their own dossiers and undergo the same application process to gain approval for the same IBCA.
- The DRS will be maintained by a host still to be defined, under the auspices of an independent international organisation such as EPPO, IOBC or another European organisation that is able to provide the necessary financial support.
- Benefits of the DRS for Regulators:
 - Network facility for competent national regulatory authorities;
 - Overview of regulatory status of IBCAs in Europe (EPPO, EU?);
 - Access to existing regulatory decisions and their justification;
 - Distribution tool for new information, e.g. on adverse environmental effects.

NOTE: until the database is available, a compendium of the national regulatory authorities including the internet addresses would be helpful to enable the collaboration of regulators.

3. Transfer from the DRS to the EPPO List of Commercially Used IBCAs with history of safe use.

- After a period of five years of inclusion on the database, the EGES will automatically critically review the environmental safety of an IBCA. New information on (adverse) environmental effects of the IBCA will be taken into account.
- Criteria for transfer to the EPPO List
 - At least 5 years inclusion in the database;
 - No new reports on adverse environmental effects;
 - A critical review of the environmental safety of the IBCA by EGES.
- An IBCA can be withdrawn from the EPPO List at any time. This may occur, for example, if new information becomes available pertaining to relevant adverse environmental effects of the IBCA. EGES would decide whether or not to remove the IBCA from the EPPO List based on critical evaluation of this information.
- Companies have the obligation to report new information about adverse environmental effects to EGES and national regulatory authorities.

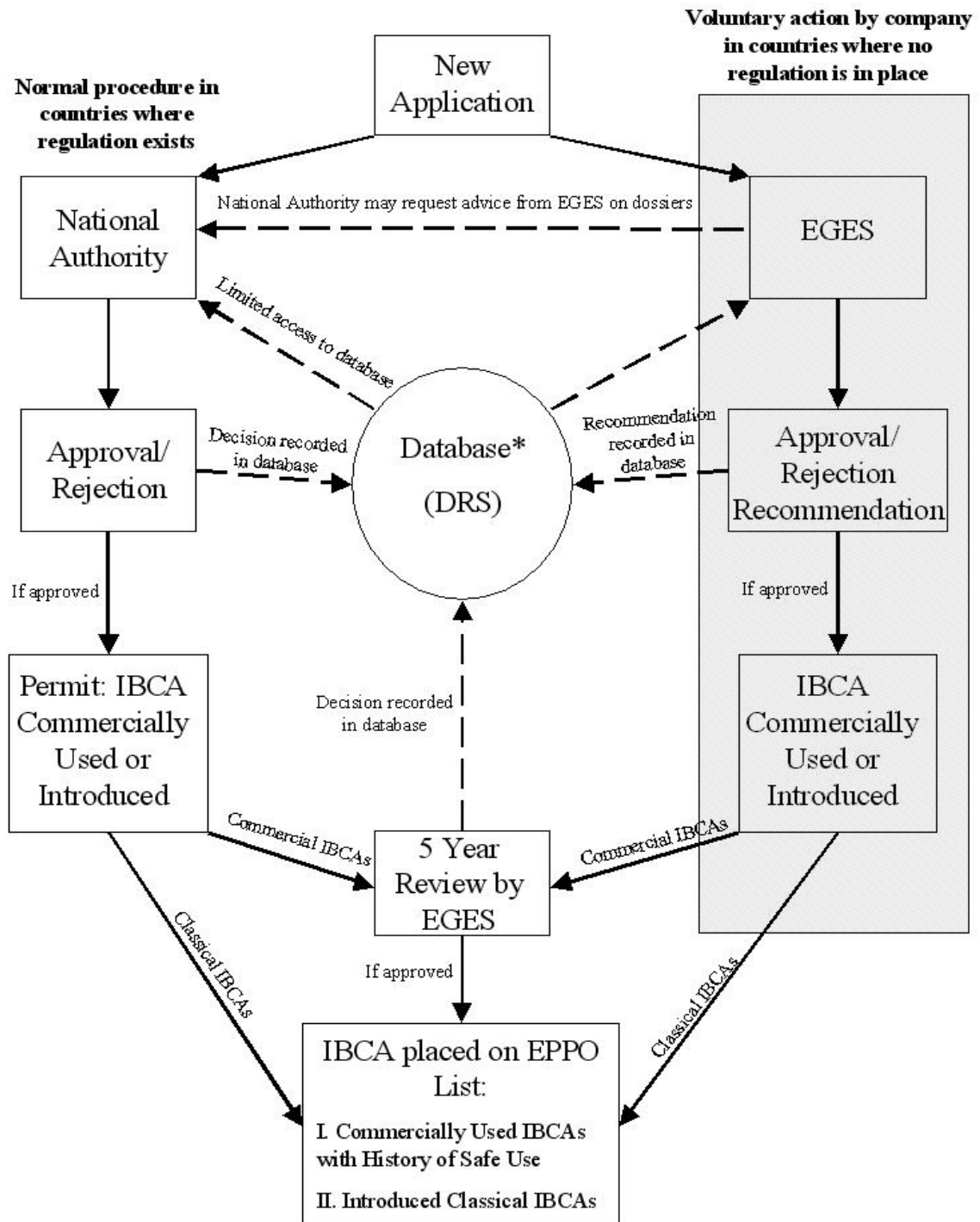
4. Transfer from the DRS to the EPPO List of Classical Biological Control Agents

- After approval for introduction from one of the EPPO countries or a positive recommendation from EGES is received, the classical IBCA will be transferred directly from the DRS to the EPPO List
- Additional information on adverse environmental effects will be included on the EPPO List for Introduced Classical IBCAs if it becomes available.

NOTE: The EPPO List as it stands acts as only a database for introduction of classical IBCAs and even if there are indications of their environmental safety this does not have the same impact as the commercial IBCAs which are labelled with a history of safe use. There is no current mechanism to assess the safety of previously introduced classical IBCAs and this should be addressed in the future. It could be considered that section II of the list could be labelled “ Introduced Classical IBCAs with History of Safe Use”. This needs to be followed up in Frankfurt.

Please refer to flow-chart below.

Procedure for placing a new IBCA on the EPPO List



* Assessment documentation and reasons for acceptance or rejection included on database. Dossier not displayed.

DRS: Database on the Regulatory Status of IBCAs
 EGES: Expert Group on Environmental Safety of IBCAs
 IBCA: Invertebrate Biological Control Agent