# Regulation of invertebrate biological control agents in Europe: review and recommendations in its pursuit of a harmonised regulatory system

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A.J.M. Loomans,
Department of Entomology
Plant Protection Service
P.O.Box 9102
6770 HC Wageningen
The Netherlands
E-mail: a.j.m.Loomans[AT}minlnv.nl

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**A.J.M. Loomans** [a] [1]
[a] *Department of Entomology, Plant Protection Service, POBox 9102, 6770 HC Wageningen, The Netherlands*

## Summary
This report provides an up-to-date review and analysis of the current legislation, regulation and guidance practice in the European Union and in separate European countries. It also includes an overview of the current practice used for risk-assessment for the import and release of invertebrate biological control agents (IBCAs, (macrobials) within the European Community and 20 individual countries in Europe. A defined set of criteria was used to collect corresponding data from each country to allow comparison between the different regulatory systems as existent in Europe. The situation in Europe is compared with similar legislation and regulation practices in other countries where the introduction of new IBCAs has proven to be successful). Recent studies revealed although many European countries have legislation in place, only few have implemented an active regulatory process. In countries with an operational regulatory system this is based on either nature protection, plant protection, and/or pesticide acts. Eight countries (Austria, Czech Republic, Denmark, Hungary, Norway, Sweden, Switzerland, U.K.) have developed a regulatory and administrative procedures to some degree, six countries are still working on the design and implementation of a regulation system (Finland, Germany, Ireland, Netherlands, Slovenia, Spain) and another six, likely more, countries have no regulation implemented yet and would not have a regulatory system in place in the foreseeable future (Belgium, France, Greece, Italy, Poland, Portugal). This report has been compiled as part of the Sixth Framework Programme EU Specific Support Action project entitled 'Regulation of Biological Control Agents' (REBECA[2]). One of the aims is to review current legislation and guidelines at EU and Member State level and create a balanced regulatory environment and a balanced regulatory system that minimizes the costs imposed on industry without compromising risks to human health or the environment.

## Introduction
Invertebrate Biological Control Agents (IBCAs, macrobials) have been used in pest management for over a 100 years and many exotic natural enemies have been imported, mass-reared and released as biological control agents for pest control in areas outside their origin. More than 5000 introductions of about 2000 species of exotic arthropods for control of arthropod pests in 196 countries or islands during the past 120 years have rarely resulted in negative environmental effects, occasionally by weed biological control agents (Louda et al., 2003), but mostly by generalist predators, often vertebrates used in classical biological control programmes (Lynch & Thomas, 2000; van Lenteren et al., 2006). Yet, risks of environmental effects caused by releases of exotics are of growing concern (Howarth, 1991); since Howarth's publication, more attention has been drawn to the risks involved in the import and introduction of exotic species into new natural environments (Simberloff, 1996; Williamson, 1996; Simberloff & Alexander, 1998; Bigler et al., 2006).

During the past decades the interest in biological control has greatly increased. So far, classical biological control programs in Europe have mainly focused on controlling exotic pests in the Mediterranean region, but there is a growing interest in classical biological control of invasive weeds throughout Europe, especially in conservation areas (Waage, 1997). The acreage of protected grown crops - in glasshouses, tunnels, screenhouses - has developed rapidly in many European and Mediterranean countries. As a result many new exotic pests have established, either temporarily or permanently. In addition, there is an increasing social concern about food safety and pesticide residues and food quality regulations are becoming more stringent in countries where most of the products are marketed. This situation favours new means of non-chemical pest control. Biological control by augmentation or inundation is now a major component of (exotic) pest control in protected crops in Europe. The number of exotic IBCA species introduced as well as the numbers released (Van Lenteren, 1997) has greatly increased within a few decades: about 90 species of IBCAs are currently widely used and commercialised across Europe (EPPO, 2002), and many more are under investigation for future release. Europe leads the world in this activity. This current increase in IBCAs shipped

[1] In collaboration with Joop van Lenteren [Wageningen University, Laboratory of Entomology, P.O. Box 8031, 6700 Wageningen, The Netherlands, Joop.vanLenteren[AT]wur.nl] Franz Bigler [Swiss Federal Research Station for Agroecology and Agriculture, 8046 Zürich, Switzerland, franz.bigler [AT]al.admin.ch] and support of the following correspondents: Austria – Sylvia Blümel; Belgium – Patrick De Clercq; Czechia – Miloslava Navrátilová; Denmark – Hans-Erik Svart; Finland - Paula Lilja; France - Jean-Claude Malausa; Germany - Horst Bathon, Martin Hommes; Greece - Katerina Kyriazi; Hungary - Zoltán Ocskó; Ireland - Louise Mark, Robbie MacDonald; Italy - Maria Grazia Tommasini; Netherlands- ; Norway - Marit Skuterud, Eline B. Hågvar; Poland - Marek Tomalak, Danuta Kropczynska, Portugal – Carola Meierose ; Slovenia – Lea Milevoj ; Spain - Josep Jacas Miret; Sweden – Lars Lindqvist, Barbro Nedstam; Switzerland - Andrea Raps, Emma Hunt; UK – Andrew Empson, Sharon Cheek, Jeff Bale.
[2] REBECA, 2006. REBECA: Regulation of Biological Control Agents. URL - http://www.rebeca-net.de/

across the world to control native and exotic pests may result in an increase of risks imposed on the environment: an increasing number of projects will be executed by persons not trained in identification, evaluation and release of biological control agents, an increasing number of agents and products will become available for the control of pest organisms, and the internet increasingly lowers access, sales and demands for public use (Loomans & Van Lenteren, 2005). Regulatory procedures for the import and release of IBCAs are therefore an absolute requirement across Europe, a fact that is accepted by the biological control industry (Blum et al., 2003). National governments, as the responsible authority, have an obligation to regulate and facilitate these regulatory procedures and thereby IBCA application in an efficient and appropriate way (Bigler et al ., 2005b).

A series of international and national frameworks provide legislative controls for the introduction of exotic species, most of these are related to phytosanitary measures to control the introduction of plant pests and to plant protection products. Of a much more recent date the specific aspects of the import and release of IBCAs have been recognized. Twenty countries worldwide already have implemented regulations for release of biological control agents (Sheppard et al., 2003; van Lenteren et al., 2006), in others regulation is currently being implemented, whereas in other countries no regulation yet exists. In Europe, the regulation of import and release of IBCAs is not harmonized yet (Bigler et al., 2005b).

Here we present the review of the regulatory procedures in place for the introduction and release of IBCAs of invertebrates in 20 countries in Europe. In another REBECA-report presented along with this report, Hunt et al., (2007) researched and compared the different systems that New Zealand, Australia, Canada and the USA operate, and determined the best components as recommendation for adoption and incorporation into a workable regulatory framework to suit the needs of Europe.

## Materials and methods

A variety of sources was used to collect the information contained in this report. Our review of international legislation was mainly the result of internet search and international reports and publications (e.g. Fasham & Trumper, 2001; Genovesi & Shine, 2003; Stokes et al., 2004; Riley, 2005). The main source of information of national legislation, provisions and regulations are 2 surveys performed in 2004 and its up-date in 2006. The 2004 survey was conducted into regulatory measures on European countries, more specifically into the information requirements needed by national authorities in Europe. Subsequent direct consultations with employees of those national governments and with scientists directly involved with the regulatory process allowed a fine-tuning of the process. Occasionally websites of the governmental administrative bodies in each country in Europe could be consulted. However, little of the required information was readily available through internet sites or was obtainable from documents accessed. In addition, further information was obtained from already published papers and documents. Some of the results have already been presented by Bigler et al. (2005a). In this report additional information underlying the survey made in 2004 is included as well as information coming from a new up-date made in 2006. The overall state of the art for each country is presented in the separate appendices.

Before this report was compiled, two sets of criteria were devised in order to bring focus to the information retrieved and to allow a comparison of the data requirements and procedures already in place in each of the different countries. The report is therefore structured in a way that presents the information for all countries (and each separate country) under the following set of sub-headings, representing the chosen criteria (*sensu* Hunt et al., 2007), including some additional information on dossier requirements.

- Legislation ( type, year) and administration for regulation (competent / national authority)
- Application procedure (including administrative procedures, application forms used, required dossier; expert judgement included)
- Decision-making process and decision maker (application: advice, decision, permit/licence)
- Data requirements (dossier)
- Administrative fees (first application or renewal)
- Time frame (period necessary for application from submission till decision)
- Availability of information to aid applicants (web, documents, helpdesk)
- Public participation or scrutiny incorporated
- Length of validity of permit
- Conditions included on permit
- 'Safe list' of invertebrate biological control agents that are exempt from regulation

Bigler et al. (2005b) and Loomans & Sütterlin (2005) discussed the history of legislation and regulatory initiatives In Europe, and stressed the need for harmonization of the regulation of invertebrate biological control agents. Below, we first summarize their most important results and then evaluate the information as known for each of the 20 countries.

## Results and Discussion

### I - International and European control of releases of IBCAs

**Legal frameworks, international**

Various international legal frameworks control the introduction of exotic species from their native ranges to new environments, whether intentional or unintentional. The main aim is to prevent the entry and/or release of organisms that are harmful, either to animal or human health, plant health or biodiversity conservation. The International Plant Protection Convention (Rome 1951, revised 1997: IPPC, 1997) and the Convention of Biological Diversity (UNEP, 1992) are the two conventions which are most relevant for biological introductions of economical and environmental concern. IPPC has developed various International Standards for Phytosanitary Measures (ISPM). The main purpose of these ISPMs is to secure common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control (IPPC, 1997[3]). The full range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants, namely through effects on other organisms and thereby causing deleterious effects on plant species, or plant health in habitats or ecosystems (ISPM-11). Legislation and the administration for regulation of IBCAs, when existent, usually fell under the responsibility of the national plant quarantine service and focussed mainly on plant protection and the need to prevent introduced IBCAs from becoming agricultural pests (Wapshere, 1974; Waage, 1997). In 1992 the UN conference on Environment and Development (held in Rio de Janeiro) formulated 15 guiding principles resulted e.g. in Article 8(h) of the Convention on Biological Diversity[4] (CBD), which holds all signing countries to *"....as far as possible and appropriate prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species"*. From there, various national governments or intergovernmental institutions like the European Commission, have incorporated legal frameworks into various legislative provisions and regulative measures. The objectives of these guidelines are e.g. .. to ensure that intentional introductions, including those for biological control purposes, are properly assessed in advance, with full regard to potential impacts on biodiversity…[5]

Whereas for plant pests there is a long history of regulatory provisions, procedures and measures, concerns about the additional risk of introduced IBCAs to biodiversity in non-agricultural ecosystems arose much more recently (IPPC, 2004; Hunt et al., 2007). Since 1992 more and more countries have put legislation in place concerning biological introductions that threaten species habitats and biological diversity. This also increased the international interest in risk assessment as a legislative tool. The FAO Code of Conduct (IPPC, 1996) has brought about important changes in the regulation of IBCAs in western (EPPO, 1999, 2000; NAPPO, 2001) and developing countries (Kairo et al., 2003), but these were still largely non-legislative instruments. The "Code of Conduct for the Import and Release of Exotic Biological Control Agents", became an international standard as ISPM No.3 under IPPC in 1996. ISPM-3, however, was not compulsory so far. Kairo et al. (2002) showed that in particular in countries with little experience in implementing (classical) biological control programmes, it supported decision- making and provided a mechanism for formalizing current good practice and facilitation of regional projects. In contrast, in Europe ISPM No.3 has never been fully implemented. The recently revised ISPM3 (IPPC, 2005) includes assessment of environmental risks and offers contracting parties a minimal standard when putting regulation in place. In addition, although IPPC and CBD have an equivalent status and both put obligations on the contracting parties, through dispute settlement procedure and its recognition by the WTO-SPS agreement (WTO, 1994) IPPC provides ISPM3 becoming an international legally binding instrument (Baker et al., 2005). It provides procedures related to export, shipment, import and release of IBCAs as well as beneficial organisms and provides guidelines for risk management. It also sets out the responsibilities contracting parties such as governmental authorities (National Plant Protection Organizations), exporters and importers of biological control agents, used in research and/or for release. ISPM-3 applies to IBCAs capable of self-replication (parasitoids, predators, parasites, nematodes, phytophagous arthropods and pathogens), i.e. macro-organisms (macrobials), arthropods such as insects and mites, but also nematodes. On the other hand, micro-organisms (microbials) such as fungi, bacteria, viruses, mycoplasmas and protozoa are considered pesticide control provisions. Processes and methods for assessing environmental risks of IBCAs and beneficial organisms are generally, and only indirectly covered by existing standards on Pest Risk Analysis (ISPM-2 and ISPM-11). However, these measures are not yet tailored for the intentional release of an IBCA and novel strategies are needed for assessing and managing risks posed by IBCAs to biodiversity (Baker et al., 2005) .

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[3] https://www.ippc.int/IPP/En/default.htm, Article I

[4] http://www.biodiv.org/convention/articles.asp

[5] Inf. AC.16.10 –IUCN Guideline for the prevention of biodiversity loss caused by alien invasive species. As approved by 51st Meeting of Council, February 2000 (accessed January 31st, 2007 URL - http://www.cites.org/eng/com/AC/16/Inf16-10.pdf

**Legal frameworks, European Union**

Various EC-directives have been adopted that control the introduction of specific, assigned groups of exotic species, such as those that may pose a threat to economically important plants (crops) (Commission Directive 2000/29/EC). Almost all European countries have signed the Convention on Biological Diversity (CBD) and adapted the CBD principles for species of conservation concern (Article 22(b) in the Council Directive 92/43/EEC on the Conservation of Natural Habitats and of the Wild Fauna and Flora (Habitat Directive). Already in the European predecessor to CBD and the subsequent EC Habitat Directive, Article 11(2)(b) of the Convention on the Conservation of European Wildlife and Natural Habitats ("the Bern Convention", 1979), all contracting parties are held to *"…strictly control the introduction of non-native species"*. For import of exotic species, in particular pests to plants of plant products, the Commission Directive 95/44/EC establishes *„...the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections*". Importers may also require licences under European Commission Regulation 3626/82 implementing the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). However, none of these compulsory directives are specifically designed to control IBCAs, and are directed in general to preserve natural habitats and indigenous flora en fauna or prevent pests from entering or spreading in the EU. With respect to invasive plant species, EU and EPPO have taken initiatives to regulate the import and use of non-native aquatic species on a central level (EU, 2006; CEC, 2006[6]). EU, however, has no intention to regulate the import and release of IBCAs on a central level by legislative measures. DG-SANCO will not regulate macrobials, because they are not plant protection products and have no impact of health or consumers. EU, however, but supports initiatives to a balanced, harmonized regulation on IBCA control for member states (MS) and to develop harmonised methodologies for risk assessment, such as the REBECA project.

**Guidelines, guidance documents and standards**

Several international organizations have developed guidelines, standards on the implementation of regulation of IBCAs and guidance documents on data requirements for environmental risk assessment (Bigler et al., 2005b). Since 1996, when EPPO [European and Mediterranean Plant Protection Organization] established its Panel on "Safe use of biological control", it has developed several standards on first import of exotic biological control agents for research under contained conditions (PM 6/1(1)) (EPPO, 1999) , import and release of exotic biological control agents (PM 6/2(1)) (EPPO, 2001), as well as a list of IBCAs widely used in the EPPO region (EPPO, 2002)[7]. Although these standards are not legally binding, they are useful instruments for a National Authority (c.q. National Plant Protection Organisations) to structure the facilitation, implementation and need for information requirements for risk assessment of IBCAs. EPPO also has developed Guidelines on Pest Risk Analysis (standard PM 5/1(1)) with a checklist of information required for making a PRA. It is currently under revision and brought 'in line' with ISPM 11 – IPPC, but yet has to be adopted for IBCAs specifically. Guidelines mentioned above aim to facilitate procedures for a proper risk-assessment, but they do not yet provide working instructions for the risk-assessment itself.

In 2003 the Organization for Economic Co-operation and Development (OECD) developed a Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents[8]. The guidance reviews the type of available information that is required for assessment of risks upon introduction and release of IBCAs: a) characterization and identification of the organism, b) safety and effects on human health, c) environmental risks and d) efficacy, quality control and benefits of use.

Determinants for an environmental risk assessment (ERA) should involve available information on 1) the potential for establishment and dispersal of the biological control agent into non-target habitats, 2) direct and indirect effects on non-target organisms, including information on host range, intra-guild predation, competition and effects on plants, and 3) environmental benefits of a release, compared to current or alternative pest management methods. Although the guidance and standards mentioned above structure the type of information in detail, they do not yet provide working instructions for the facilitation, implementation and risk-assessment itself.

In 2003 the Council of the International Organisation of Biological control – Westpalaearctic Regional Section (IOBC-WPRS)[9] appointed a Commission on Harmonization of Regulation of IBCAs. Based on the FAO Code of Conduct, the EPPO standards and OECD guidance, working groups drafted a detailed Guideline on Information Requirements for Import and Release of Invertebrate Biological Control Agents (IBCAs) in European Countries and was published by Bigler et al. (2005a). Methods for risk assessment were discussed during a scientific workshop in Engelberg, Switzerland in 2004 (Bigler et al., 2006).

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[6] CEC, 2006. Alien species as defined by the proposal for a Council regulation COM(2006) 154 final (Article 3).
[7] http://www.eppo.org/STANDARDS/standards.htm
[8] http://www.oecd.org/dataoecd/6/20/28725175.pdf
[9] http://www.iobc-wprs.org

**II- National legal frameworks for legislation and regulation in Europe**

For the preparation of the workshop organized by the IOBC/WPRS Commission on the harmonization of regulation of invertebrate biological control organisms held in 2004, Bigler et al,. (2005b) sent out questionnaires to regulatory authorities and biological control scientists in 20 European countries, and last year an update was performed. All countries replied, but the quality of information provided differed greatly between countries, but still yielded interesting information and data.

**Legislation and administration for regulation**

Most contributors addressed by the questionnaire had national legislations in place. Legislation with respect to the introduction of exotic species in a country is generally organized in a hierarchical way, top down from the national constitution, to international (European) provisions and national legislative and regulatory provisions. In various countries, basically three types of legislative provisions determine the regulation framework for the protection of plants: plant health acts, pesticide acts and/or environmental acts (figure 1). Depending on a country's national constitution, certain types of legislation and regulative provisions prevail when dealing with IBCAs. There is no specific legislation in any jurisdiction regarding the import and release of non-native IBCAs for the purpose of biological control. In a number of countries where regulation is in place two types of legislation interact, in particular plant protection and nature conservation acts. Often legislation and regulation are approached form a different perspective on the risks of BCAs: the first in managing the risks for agriculture and facilitating pest control, the second in managing the risks for the (native) environment and thus controlling the import and release of an IBCA. In line with CBD, nature conservation acts often include an article stating that is its "forbidden" to release non-native species in the wild (Belgium, Denmark, Germany, Netherlands, Norway, UK).

In some countries (e.g. Germany, Poland (before 2004)), biological methods of plant protection maybe exempted from regulatory measures in line with nature conservation, when authorized by a specific permit based on the plant protection act. A competent or national authority (NA) is hierarchically assigned – depending on the legislative and regulatory ordinances of a country - to different types of institutions, either plant health, pesticide registration or nature conservation authorities (figure 3). The NA is responsible for approval of the import and/or commercial release in a country, regulates the import and/or release under national legislation and evaluate the applications. They, however, do so with different perspectives depending on the legislation.

In Switzerland[10], the import and release of beneficial organisms with the intention to be used as biological control agents is subject to different legislation, depending on the nature of the agent, its form and the purpose for which it is used: commercially produced agents fall under different legislation compared to agents intended for use in classical biological control programs. If a biological control agent (of weeds or invertebrate pests) is intended for commercial production on the market, it is considered a plant protection product and falls under the The Ordinance on Plant Protection Products (Pflanzenschutzmittel – Verordnung), within the Federal Law on Agriculture. When For an agents is intended for use in a classical biological control program regulation for the import into containment for research, field tests and full environmental release of classical weed BCAs also falls under the Ordinance on Plant Protection, and is implemented by the Federal Office for Agriculture (FOAG). IBCAs of invertebrates, which are not pests of plants and where establishment is intended, the import and release is regulated under the Federal Law on the Protection of the Environment (LPE). This law is implemented by the Federal Office for the Environment (FOEN) (Bundesamt für Umwelt, BAFU). The LPE has several (revised) ordinances associated with it, two of which deal specifically with the containment and release of non-commercial entomophagous IBCAs: the Ordinance on the Contained Use of Organisms (1999) and the Ordinance on the Release of Organisms into the Environment (1999).

In Germany, however, legislative conditions have caused a conflict of interest and thereby a stand still in the development and implementation of regulatory procedures for IBCAs. According to the federal nature conservation act (Bundesnaturschutgesetz[11]) the release of exotic species is forbidden. The introduction and use of specimens of a native fauna species and a non-native fauna species, however, are exempt to obtain a permit if their introduction and use requires authorization under plant protection legislation for biological methods of plant protection. The "Plant Protection Act" (Pflanzenschutzgesetz ), however, does not adequately foresee in such an authorization and needs to be adapted to allow such an ordinance regulating IBCAs in Germany. At the moment no non-native IBCA can be imported and sold on the market, but the

[10] Hunt, E. et al., 2006. A review of the regulations for the import and release of macrobial biological control agents in Australia, Canada, New Zealand, Switzerland and the United States of America. Unpublished Report WP2 of the REBECA workshop, Salzau, 18-22 September 2006,42pp.

[11] Bundesnaturschutgesetz (BnatSchG), version 25. März 2002 $ 41 – " von dem Erfordernis einer Genehmigung sind auszunehmen… 2. das Einsetzen 1)von Tieren nicht gebietsfremder Arten, 2) gebietsfremder Arten, sofern das Einsetzen einer pflanzenschutzrechtlichen Genehmigung bedarf, bei der die Belange des Artenschutzes berücksichtigt sind, zum Zweck des biologischen Pflanzenschutzes" http://www.buzer.de/gesetz/2122/a30126.htm

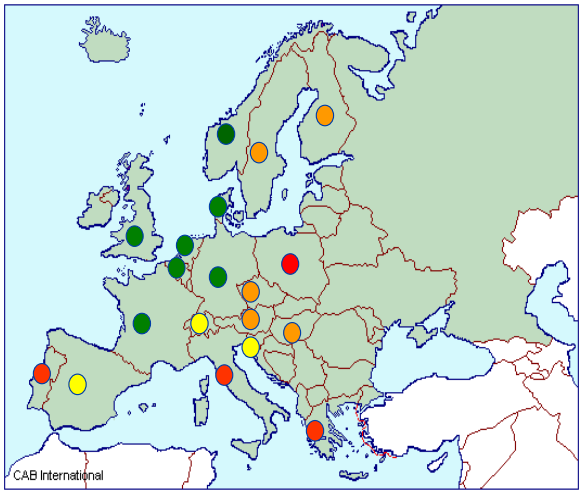



**Figure 1: Legislation -** different types of legislation: Plant Protection Products (pesticides = orange); Plant Health = yellow; Nature Conservation (environment = green); no / other = red ( august 2006)

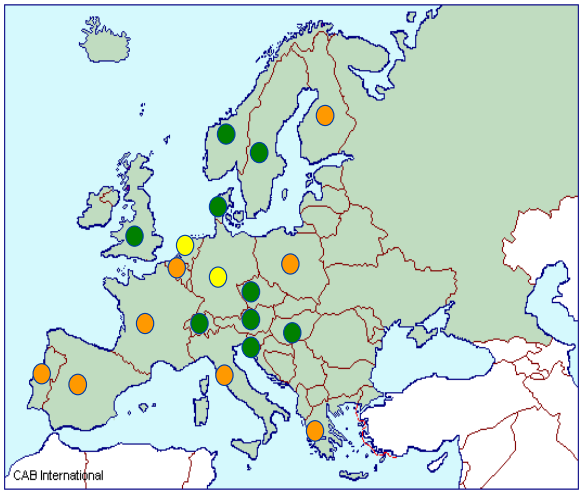



**Figure 2** : **Regulation in place -** Implemented (green), in preparation (yellow), or no regulation (orange) (august 2006)

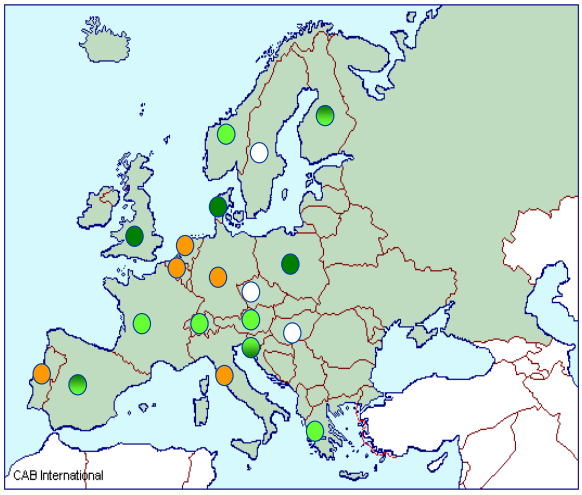



**Figure 3: Competent / National Authority in place -** Assigned (14): environment (dark green), plant health (light green), pesticides (white); Not yet assigned (5 = orange)

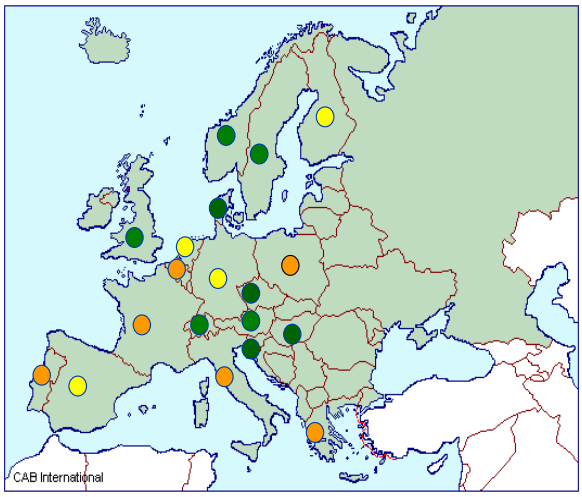



**Figure 4 : Dossier for application required -** Required (green), in preparation (yellow), no forms required (orange)

grower needs - in theory - a permission from a "Bundesland" - agency for releasing a non-native IBCA on his farm. However, there has rarely been applied for this.

In Poland, prior to joining the European Union in 2004, procedures were in accordance with previous acts on plant protection and relevant regulations based on these. Regulations clearly specified all documentation requirements needed for registration and implementation of plant protection products containing living beneficial (macro)organisms. After May 1st 2004, however, when Poland joined the European Union, the registration of macro-organisms has been stopped. The Minister of Agriculture and Rural Development did not issue any regulations to the new Act on Plant Protection, and it is not clear what procedures will be taken, or even if any registration of beneficial (macro)organisms will be required in Poland. In Greece, Italy and Portugal there is knowledge of some general disposition but no legal documents concerning the regulation of IBCAs are in force at present.

In summary, large differences exist in the degree of implementation of regulatory measures of IBCAs in European countries. The present status of regulation can be divided into three different categories:

a) nine countries (Austria, Czech Republic, Denmark, Hungary, Norway, Slovenia, Sweden, Switzerland, UK) have regulation implemented to some degree,
b) five countries are working on the design and implementation of a regulation system (Finland, Germany, Ireland, Netherlands, Spain) and
c) six countries have no regulation developed or implemented yet and will not have a regulatory system in place in the foreseeable future (Belgium, France, Greece, Italy, Poland, Portugal). In other countries no contact had been established were therefore not included in the questionnaire (Cyprus, Estonia, Ireland, Latvia, Lithuania, Luxembourg, Malta, Slovakia).

**Application procedure**

In countries where the regulatory system is in place or in preparation (regulation system - figure 2, national authority - figure 3, dossier - figure 4) the application process for the (import and) release of BCAs is hierarchically structured generally according to the authorisation procedure already in place for plant protection products (91/414/EC: Austria, Czech Republic, Hungary, Sweden), plant health (Norway, Slovenia, Switzerland) or nature conservation acts (UK, Denmark, also The Netherlands). Where regulation is in place or in preparation:

1. application forms for (import and) release and dossier guidelines are available, mostly upon request at the competent or national authority (NA), sometimes online (The Netherlands[12]); the UK does not have a specific form for non-native IBCAs that must be filled in although guidance provides a format that can be used and specifies information that must be supplied in full[13];
2. for an application for release of an IBCA species one (for the organism) or two application forms (for the product, where relevant) are necessary;
3. the applicant usually should reside within the country where the application is submitted; foreign industries / companies / institutions can submit only through a national representative / retailer in that country; in The Netherlands the applicant should be the person that is legally responsible and is

[12] http://www.hetInvloket.nl/ search for 'Aanvraagformulier ontheffing biologische bestrijding'
[13] http://www.defra.gov.uk/environment/gm/nonnav/ (published 09 February 2000)

registered at a chamber of commerce in the EU; the applicant is the one that "owns" the authorisation or licence and mandates responsibility to the grower;

4. application forms (including dossiers on paper) are submitted to the competent authority, where they are checked for completeness, accepted and registered; when the application forms or dossiers are incomplete the applicant must resubmit it once corrections and/or additions have been made, but information given on the application form or in the dossier is often minimal and/or not specific;
5. responses supporting unclear dossier issues are usually resolved directly between the applicant and the co-operator / advisor (e.g. Netherlands).

In some countries – Denmark, Germany, Slovenia, UK - only exotic IBCA species, need an approval for import and release. Native species, or species that are already present, are exempt from regulation by law. In most countries in Europe, however, all IBCA species, both native and exotic, need approval or registration before it can be (imported and/or) released and an application (including a dossier) has to be submitted to the NA. In Switzerland approval of exotic macro-organisms intended for commercial use, follows a two-step procedure: 1) to obtain an import permit (from the Plant Protection and Quarantine (PPQ) Service)) and 2) to register the organism to the registration authority (FOAG), including submission of a dossier. Both services are part of the Ministry of Agriculture.

Import and release of IBCAs are not necessarily confluent. Imports can be made for research and education only by universities, private or governmental institutions as well as the industry, the industry also can import and mass-breed large quantities and subsequently export IBCAs to the country of destiny without a release in the country where it is produced. Production facilities are contained, but are no quarantine facilities and do not ensure prevention of an escape into the wild. In countries, such as Belgium, Denmark, Germany, France, Italy, Spain, The Netherlands, etc. where large or small commercial production facilities occur, import and mass-production of exotic species is not arranged very well.

**Decision-making process**

The administrative part of the process for the approval of (import) and release of an IBCA is similar in most countries. In countries where both native and non-native species need approval, the decision-making process is different, native species are being dealt with in a more flexible way. E.g. in Spain exotics need a permit for import, natives only need registration, e.g. in Norway, Switzerland and The Netherlands both groups need approval and submission of a dossier before release is required, but the evaluation process is different, for native species less data requirements are needed.

Once a complete application has been registered, the process for approval is yet different between most countries. In countries where regulation is in place or in preparation, decisions whether to issue an import permit, a permit for release or to register the proposed IBCA, are based on the quality and quantity of information and data sets provided by the applicant. Information To support such a decision, most countries include consultation by co-operators, reviewers and advisors, who are selected based on their expert knowledge in entomology, biological control, or in other disciplines (Austria: an agronomist, an entomologist and an eco-toxicologist). In the UK and Norway a national advisory committee has been established. The committee evaluates the application and gives an advice to the NA. The advice of the co-operator or committee to accept or reject an application is mostly based on 'expert opinion / knowledge'.

Evaluation of the application is based on the data requirements given in the dossier, including information on the identity and biology, information on effects on human, animal and plant health, on efficacy, and – more and more – on environmental effects. Objective evaluation criteria, however, have not been defined *a priori*. During our survey in 2004 of data information requirements as set by OECD (2004) and used by various countries in Europe, showed (Table 1) that large differences exist between countries. Criteria used to support 'expert knowledge' are very different as a result of the regulation and underpinning legislation that has been put in place in a country. In countries where nature conservation legislation and regulation is in place (e.g. Norway, Netherlands, Switzerland, UK) environmental characteristics are part of the data requirements and support the advice for approval or rejection. In countries where legislation is based on plant protection or plant protection products, regulation is based on common principles of risks posed to animal, human and plant health but these requirements are not tailored to suit an environmental risk analysis. During recent years, guidelines produced by EPPO, OECD and IOBC give strong support to 'expert knowledge', but the expert's advice in this does not always have a legal basis.

The decision of whether to permit (import and) release of an BCA is usually made by the director of the NA or by a public servant assigned by the minister in charge. Examples of licences granted e.g. in the UK[14] or by derogation for The Netherlands[15], can be found on the internet.

[14] http://www.defra.gov.uk/environment/gm/nonnav/10.htm
[15] http://www.hetlnvloket.nl/ search for 'FFW/BB'

**Data requirements**

| Risk category | # | characteristic | Country | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Au | Cz | Dk | Ge | Hu | N | NL | Sl | S | Sw | UK | Fi | F | B | Gr | It | P | Po | Sp |
| ID - Biology | 1 | ID | ± | + | + | + | + | + | + | + | + | + | + | + | + | - | - | - | - | - | - |
| | | Voucher | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| | 2 | Origin | + | + | + | + | + | + | + | + | + | + | + | + | - | - | - | - | - | - | + |
| | | Culture | - | + | - | + | + | ± | + | - | + | + | - | - | - | - | - | - | - | - | - |
| | | Source | + | + | - | + | + | ± | + | + | + | + | + | + | - | - | - | - | - | - | - |
| | 3 | distr-biology | ± | + | + | ± | ± | + | + | ± | ± | ± | - | - | - | - | - | - | - | - | - |
| | | host range | ± | + | + | - | + | + | + | - | ± | + | ± | - | - | - | - | - | - | - | + |
| | 4 | nat en. / contam | - | + | ± | + | + | ± | + | - | + | ± | + | - | - | - | - | - | - | - | - |
| | 5 | strain | ± | - | - | + | + | + | ++ | - | + | + | - | - | - | - | - | - | - | - | - |
| Safety | 1 | health | ++ | ++ | - | ++ | ++ | + | + | - | ++ | ++ | + | - | + | - | - | - | - | - | - |
| Environment | 1 | ecosystem | + | + | + | + | + | ± | ++ | - | + | + | + | - | - | - | - | - | - | - | - |
| | | competitors | + | - | + | + | + | ± | + | - | - | + | + | - | - | - | - | - | - | - | - |
| | | previous use | - | - | - | + | + | + | + | ± | - | + | + | - | - | - | - | - | - | - | - |
| | 2 | host spec test | ± | - | - | ± | - | ± | - | - | - | ± | ± | - | - | - | - | - | - | - | - |
| | | establ-disp | - | + | + | + | + | + | ++ | - | + | + | + | - | - | - | - | - | - | - | - |
| | | indirect | - | - | + | + | ± | ± | + | - | - | - | + | - | - | - | - | - | - | - | - |
| | | diseases | - | + | - | + | + | ± | - | - | - | - | + | - | - | - | - | - | - | - | - |
| | 3 | host range/distr. | ± | ± | - | + | + | + | + | - | - | + | + | - | - | - | - | - | - | - | - |
| | 4 | benefits | a | - | - | + | - | r+ | - | - | a | a | - | - | - | - | - | - | - | - | - |
| | 5 | summary | - | + | - | + | - | - | - | - | + | + | - | - | - | - | - | - | - | - | - |
| Efficacy | 1 | method effic. | + | + | - | - | + | r+ | - | - | + | + | - | - | - | - | - | - | - | - | - |
| | 2 | quality | - | + | - | - | + | r+ | - | + | + | + | - | + | + | - | - | - | - | - | - |
| | 3 | benefits | - | + | - | - | + | r+ | - | + | + | - | - | - | - | - | - | - | - | - | - |
| | 4 | summary | + | + | - | - | - | - | - | - | + | + | - | - | - | - | - | - | - | - | - |

**Table 1 -** Overview of data requirements used by experts and regulators in various European countries fro environmental risk assessment. Criteria and characteristics used as defined in the OECD guidance (2004).

Dossier - Data requirements vary largely between countries and depend largely on the type of regulation underpinning the legislation. In the case of approval as plant protection or plant protection products, most requirements stress human and plant health, but forms do not emphasize specific environmental criteria and characteristics (see also Table 1). In those countries where nature conservation legislation has to be taken into account (Norway, Netherlands, UK, Switzerland), specific environmental criteria, such as information on the establishment in the wild, on host specificity and non-target effects need to be met. Data requirements in Norway are derived from the draft OECD requirements (OECD, 2004), whereas in The Netherlands Bigler et al., (2005a) is used as a basis for compiling the dossier. In the UK[16] an extensive amount of information is given on data requirements to support applications for licences to release non-native animals or plants into the wild. Key requirement is information about the establishment potential in the UK. For a non-native species, DEFRA requires data to be generated, when not already available, in order to properly assess the survival in the environment. Information on efficacy is included as a requirement in most countries where regulation is based on plant protection or products. In Norway and Hungary specific tests are needed before a permit is given. However, we should avoid that in length studies are required, because costly risk assessment studies and long term evaluation of dossiers may keep products off the market and result in few registered BCAs as experienced for microbials (Blum et al., 2003).

Native vs. exotic - When application is required in a country, native species need less data to support the application. Sometimes native species only need registration (Spain). Evaluation usually follows a "short track" risk assessment, whereas exotic species are assessed more thoroughly.

Our survey also showed that there is a need for harmonization on a European level. Initiatives with respect to information requirements for import and release have already been taken (Bigler et al., 2005a).

**Fees**

Fees for administration can vary largely between countries, from 0 € (Denmark), 60-100 € (The Netherlands for a 1-year and 5-year permit respectively) , 500 € (Norway) to 1000 € (Hungary), 1100 € (Sweden) and 1660 € in Austria. For a renewal the same amount is asked, Sweden (400€) and Austria (1250 €) charge less. Some countries require efficacy trials (Hungary, Norway) for which extra costs have to be made. The costs for drawing up a dossier by the applicant, or for generating specific data requirements through experimentation, are hidden costs.

Upon import of live animals, including IBCAs, occasionally veterinary requirements need to be fulfilled at border inspection. When on the basis of the facts presented to the inspection service, it comes to the conclusion that there are no grounds to take action in respect of an agreement or practice, which usually is the case, the Ministry issues a negative clearance either as a formal decision or informally by way of a comfort letter. Nevertheless, fees for shipments, other than commercial products can become very high.

[16] http://www.defra.gov.uk/environment/gm/nonnav/07.htm

**Administrative time frame**
The administrative timeframe for an approval of the release application varies largely between Member States. The National Authorities in the UK and Austria will approve an application within 5 weeks, and in Denmark within 3 months. In Sweden the length of this period varies between 1-2 months and 3-4 months, depending on whether expert opinion is required or not. In The Netherlands, where the regulatory system is not fully operational, the time frame can vary between 2 and 6 months. The NA in Czech Republic decides within a 3 months period from commencement of the proceeding. In Hungary the competent authority decides on the authorization and issues a document to the applicant within 12 months of the full submission of data. In Norway an approval can be expected after 6 months, but sometimes only after 3 years, when efficacy testing is required.

**Availability of information to aid applicants**
Information to aid applicants with application for an IBCA is very scarce, and with few exceptions (UK[17]) little information is published online or is very limited. Application forms for IBCAs (in the native language) can be downloaded from the websites of the respective National Authorities in Hungary, The Netherlands, Norway, Sweden, Switzerland and the UK.

**Public participation**
Without exception public participation is currently not involved in the decision-making process for biological control agent import and release applications.

**Length of validity of permit**
After an application has been approved, the import and / or release are authorized by the NA. Import permits or permits for release are issued (see figure 5): this can be licenses granted under specific section of national acts (UK), by derogation (a partial revocation of the law; Netherlands), etc.
The length of the issued permits varies between countries (1-5 year in The Netherlands and UK with a maximum of 10 years in Austria, Hungary and Sweden) and from case-to-case within a country from 1 up to 10 years. Within a country, the validity period may be shorter or longer, and conditional according to applications or crops. Length of a renewal of the permit usually is similar to the first authorisation period.

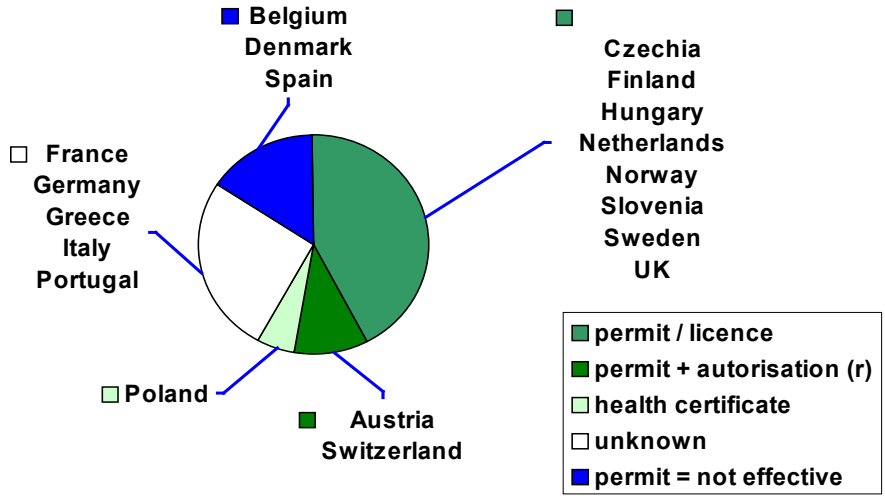



**Figure 5 -** Types of regulation forms issued - by authorisation, permit, license, derogation

**Conditions be included on permit**
In The Netherlands it is mandatory to refer to the derogation on the label of the product containing the licensed organism, and announce this on the company's website. Derogations are published on the website of the Ministry of Agriculture, Nature and Food quality[18]. In Norway there is a statement on the label saying:

[17] Department for Environment, Food & Rural Affairs - The Regulation and Control of the Release of Non-native Animals and Plants into the Wild in Great Britain. A guide to sections 14 and 16 of the Wildlife and Countryside Act 1981. Accessable at URL: http://www.defra.gov.uk/environment/gm/nonnav/01.htm
[18] http://www.hetInvloket.nl/ search for 'FFW/BB'

"it is prohibited to use this product contrary to its approved area of use or to exceed the allowed dosage". In most countries there is an enforcement mechanism for ensuring that licence-holders comply.

Given the nature of the IBCA as a live organism, a release is *per se* authorized for use in the country where the release(s) will be intended, often the greenhouse industry or outdoor crops. Nevertheless, specific conditions can be included on permit or upon authorisation: for experimental use only, for use in certain crops, for use in assigned sites or NOT for use in or near specific areas of nature concern.

Post-approval activities, such as post-release monitoring of escape into the wild respectively establishment and non-target effects can be a statutory condition of a licence, in several countries. In Austria, Norway efficacy testing is part of the application procedure.

**'Safe list' of IBCAs exempt from regulation?**

"Safe lists" of IBCAs already in use are available for some regions (e.g. EPPO, 2002; ANBP, 2004) and countries, but these are seldom the result of a thorough environmental risk-assessment procedure. The agents are listed on the EPPO list on the basis of an expert judgment of available information. These are related to certain broad criteria, which are flexibly applied: the BCA which is (or has been) commercially available and is either indigenous and widespread in the EPPO region, or established and widespread in the EPPO region, or has been used for at least 5 years in at least 5 EPPO countries (exceptionally less, if crops are grown in few countries). EPPO (2002) summarizes data for 90 species of IBCAs (including 6 EntomoPathogenic Nematodes): 54 species are native to the EPPO region, 36 have been introduced. From this database we can see that the number of IBCAs sold is quite variable between countries (Figure 6), and that few species are the core of commercial activity (table 2). In a second appendix, EPPO also publishes a list of 35 classical biological control agents - 25 Hymenoptera, 9 Coleoptera and 1 Diptera - that have been introduced successfully in the Mediterranean Area and/or EPPO region (EPPO, 2002, appendix II). EPPO also gathers lists of existing databases in Europe on registered plant protection products and their uses in Europe[19], some of which include registered IBCAs as well. Most countries that have regulation in place have a register of licensed species (e.g. Austria[20], Sweden[21]) or commercially available species (Germany[22], Denmark[23]). A number of countries use the EPPO list of commercially available species as a basis (EPPO, 2002) [24]. However, these species are not exempt from regulation, as new applications have to be made by other applicants, resp. companies. Czech Republic currently has 32 biological plant protection products/preparations based on 23 macro-organisms in the List of the Registered Plant Protection Products. The Netherlands[25] published a list of 134 BCAs (native as well as exotic species) that are exempt from regulation – by quick scan based on available information *sensu* OECD (2004) (Loomans & van Lenteren, 2005) - and that are permitted for release. In some countries ( e.g. UK), where only exotics need approval, native species are exempt from regulation.

[19] URL http://www.eppo.org/PPPRODUCTS/products.htm

[20] Austria = http://www.ages.at - Verzeichnis der in Österreich zugelassenen Pflanzenschutzmittel ausgenommen Zulassungen gemäß § 12 Abs. 10 PMG 1997 idgF (authorized plant protection products), including Makroorganismen at http://www15.ages.at:7778/pls/psmlfrz/pmgweb2$.Startup?z_user=www

[21] Kemikalieinspektionen, 2006. Försålda kvantiteter av bekämpningsmedel (Sold quantities of pesticides 2005). Sveriges Officiella Statistik, 37 pp. Tabell 3.3 Förteckning över försåld mängd verksamma organismer http://www.kemi.se/templates/Material____3548.aspx

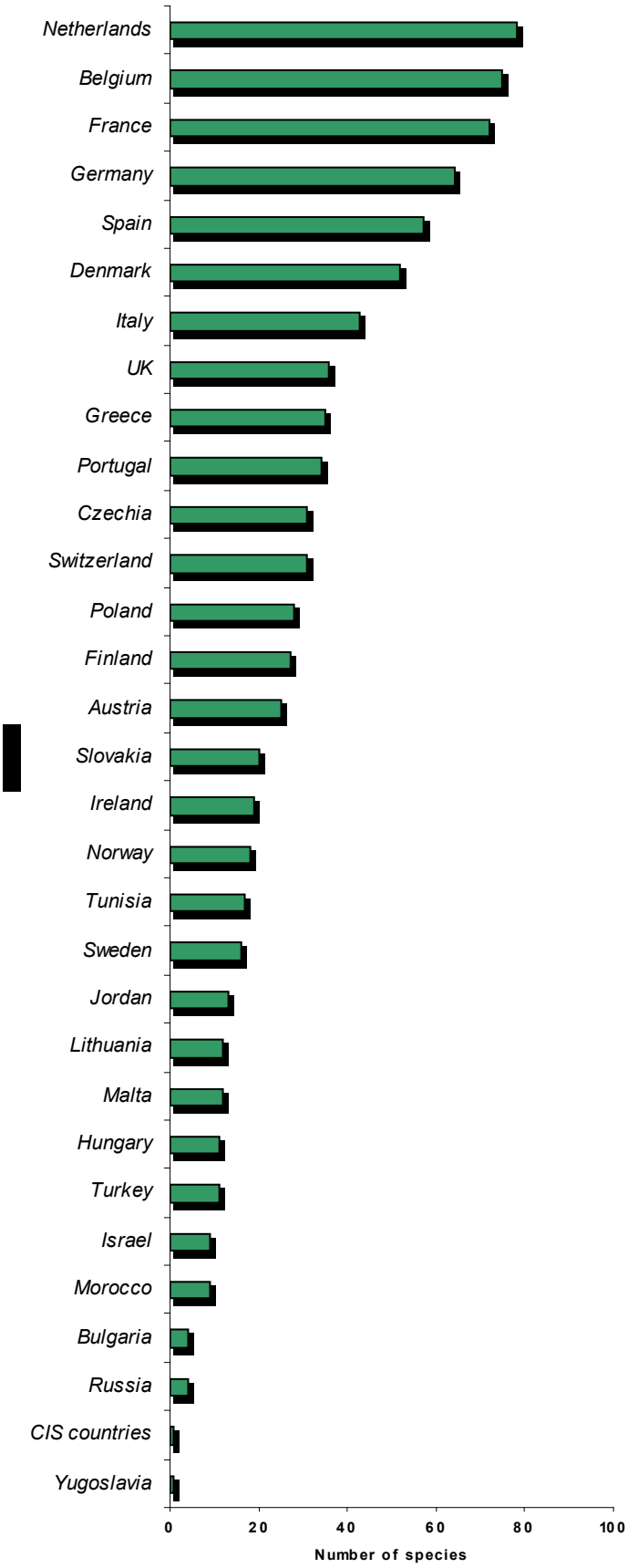
[22] Bathon, H., 2005. http://www.bba.bund.de/nn_912578/SharedDocs/08__BI/Publikationen/nuetzlingsliste.html

[23] Wang et al., 2003 - URL http://www2.mst.dk/udgiv/publikationer/2003/87-7972-898-7/pdf/87-7972-899-5.pdf

[24] URL http://archives.eppo.org/EPPOStandards/biocontrol_web/bio_list.htm

[25] http://www.hetlnvloket.nl/ search for 'Wijziging Regeling vrijstelling Flora- en faunawet'

| Species | # C |
|---|---|
| *Aphidius colemani* | 26 |
| *Encarsia formosa* | 26 |
| *Phytoseiulus persimilis* | 26 |
| *Aphidoletes aphidimyza* | 25 |
| *Macrolophus melanotoma* | 25 |
| *Neoseiulus cucumeris* | 25 |
| *Orius laevigatus* | 24 |
| *Diglyphus isaea* | 23 |
| *Cryptolaemus montrouzieri* | 21 |
| *Dacnusa sibirica* | 21 |
| *Eretmocerus eremicus* | 21 |
| *Aphidius ervi* | 20 |
| *Aphelinus abdominalis* | 19 |
| ***Heterorhabditis megidis*** | 19 |
| *Orius majusculus* | 18 |
| ***Steinernema feltiae*** | 18 |
| *Amblyseius degenerans* | 17 |
| *Neoseiulus californicus* | 17 |
| *Stratiolaelaps miles* | 17 |
| *Chrysoperla carnea* | 16 |
| *Feltiella acarisuga* | 16 |
| *Hypoaspis aculeifer* | 16 |
| *Leptomastix dactylopii* | 16 |
| *Trichogramma evanescens* | 16 |
| *Trichogramma brassicae* | 15 |
| *Delphastus catalinae* | 14 |
| *Metaphycus helvolus* | 12 |
| *Leptomastidea abnormis* | 11 |
| *Opius pallipes* | 11 |
| *Podisus maculiventris* | 11 |
| *Rhyzobius lophanthae* | 10 |
| *Amblyseius barkeri* | 9 |
| *Cales noacki* | 9 |
| *Franklinothrips vespiformis* | 9 |
| *Microterys flavus* | 9 |
| ***Steinernema carpocapsae*** | 9 |
| *Typhlodromus pyri* | 9 |
| *Aphytis melinus* | 8 |
| *Coccophagus lycimnia* | 8 |
| *Metaseiulus occidentalis* | 8 |
| *Anagyrus pseudococci* | 7 |
| *Anthocoris nemorum* | 7 |
| *Aphidius matricariae* | 7 |
| *Chilocorus bipustulatus* | 7 |
| ***Heterorhabditis bacteriophora*** | 7 |
| ***Phasmarhabditis hermaphrodita*** | 7 |
| *Stethorus punctillum* | 7 |
| *Anagrus atomus* | 6 |
| *Anagyrus fusciventris* | 6 |
| *Aphytis holoxanthus* | 6 |
| *Chilocorus nigrita* | 6 |
| *Coccophagus scutellaris* | 6 |
| *Encyrtus infelix* | 6 |
| *Episyrphus balteatus* | 6 |
| *Leptomastix epona* | 6 |
| *Orius albidipennis* | 6 |
| *Adalia bipunctata* | 5 |
| *Aprostocetus hagenowii* | 5 |
| *Cheyletus eruditus* | 5 |
| *Cotesia marginiventris* | 5 |
| *Encarsia citrina* | 5 |
| *Encyrtus lecaniorum* | 5 |
| *Eretmocerus mundus* | 5 |
| *Hungariella peregrina* | 5 |
| *Karnyothrips melaleucus* | 5 |
| *Metaphycus swirskii* | 5 |
| *Pseudaphycus maculipennis* | 5 |
| *Scutellista cyanea* | 5 |
| *Thripobius semiluteus* | 5 |
| *Chilocorus baileyii* | 4 |
| *Chilocorus circumdatus* | 4 |
| *Coccophagus rusti* | 4 |
| *Franklinothrips megalops* | 4 |
| *Gyranusoidea litura* | 4 |
| *Hungariella pretiosa* | 4 |
| *Metaphycus lounsburyi* | 4 |
| *Picromerus bidens* | 4 |
| *Praon volucre* | 4 |
| *Scymnus rubromaculatus* | 4 |
| *Trichogramma cacoeciae* | 4 |
| *Anthocoris nemoralis* | 3 |
| *Aphytis lingnanensis* | 3 |
| *Coccinella septempunctata* | 3 |
| *Compariella bifasciata* | 3 |
| *Lysiphlebus testaceipes* | 3 |
| *Metaphycus flavus* | 3 |
| *Bracon hebetor* | 2 |
| *Rodolia cardinalis* | 2 |
| *Trichogramma dendrolimi* | 2 |
| *Aphytis diaspidis* | 1 |




Overview of the number of species listed on the widely available list of IBCAs in the EPPO region (EPPO, 2002). **Table 2** (left) - distribution number of countries per species: 48 Hymenoptera, 12 Coleoptera, 10 Acari, 8 Heteroptera, 5 Nematoda, 3 Diptera, 3 Thysanoptera, 1 Neuroptera, **Figure 6** (right) - number of species per country.

## Summary & Conclusions

### General

Here we summarize the legislation and regulatory system as is now in place (or not) in Europe (for an overview of most relevant issues for 8 countries, see Table 3). Since the publication of the FAO Code of Conduct in 1996, attempts to harmonize regulation of invertebrate biological control agents in Europe have been undertaken. Regulatory guidelines - developed by international organizations, such as the EPPO and OECD during the last ten years - have been adopted and implemented by national authorities in a few European countries only. At the present time there is no coordinated system of regulation for IBCAs across Europe. In Europe biological control agents are regulated according to the nature of the agent, the mode of action (microbial, macrobial), its way of application and the purpose for which it is used. Laws are not yet in place in some countries, and where they are in place, responsibilities are often not yet clearly assigned to ministries or government agencies on national levels. In those countries with regulation, the 'legal' basis may be related to legislation on pesticides, plant health or the environment. The format of applications for licences (permits) is also very variable. This situation has both advantages and disadvantages. On the one hand, it is easier for companies to release control agents in countries that have no regulation. On the other hand, those countries with regulation differed in their information requirements, and hence companies have to prepare separate dossiers for each country. Overall, if regulation is likely to increase (i.e. introduced into countries that have no current system), it would be desirable for a consistent Europe-wide agreement to be developed. Given the heterogeneous backdrop to the current regulatory position in Europe, it was recognised that those countries with regulation would not accept a 'no regulation' recommendation (...). Some form of environmental risk assessment (ERA) will be important, not least to reassure those countries that would be encouraged to devolve the 'decision making' powers on non-native species to an EU 'Expert Group'[26].

| Criteria | Norway | Sweden | Denmark | Czech Republic |
|---|---|---|---|---|
| Data requirements | species, product, efficacy | A (species) B (product) | yes | Annex 13 to Decree 329/2004 |
| Administrative procedures | Norwegian FSA | KEMI | Danish Forest & Nature Agency | State Phytosanitary Administration |
| Adm . fees / costs (in €) | 489 € | 1100 (first), 400 (renewal) € | 0 € | ? |
| Adm. time frame | 0.5 – 3 years (efficacy) | 1-2 m > 3-4 m expert | 3 month | 3 month |
| Length permit | 5 years | max 10 years | > 1 yr - - unltd | unlimited |
| Dossier: organism/product | organism / producer | product / producer | organism / producer | organism / producer |
| Opinion science / industry | scientist expert committee | scientists (ent., tox., agron.) | scientist experts | scientist experts |
| Conditions? | yes, label | yes, label | yes | yes |
| Information available | http://www.mattilsynet.no/ | http://www.kemi.se | http://www.skovognatur.dk | http://www.pan-germany.org/ |
| Public scrutiny | no | no | no | no |
| Safe List? | products: 31 species | 58 products: 19 species | no | 37 products: 23 species |
| **Criteria** | **Netherlands** | **UK** | **Austria** | **Hungary** |
| Data requirements | dossier native / exotic | yes (establishment, etc.) | yes, dossier | Annexes 9-10 to Decree 89/2004 |
| Administrative procedures | Ministry Agriculture NF | DEFRA | AGES | Central Service PPSC |
| Adm . fees / costs (in €) | 60 € (1yr) – 100 € (5yr) | 0 € | 1660 € (first), 1234 € (renewal) | 1000 € (applic.), > 2000 (efficacy) |
| Adm. time frame | 2 - 6 months | 5 weeks | 5 weeks | 12 months |
| Length permit | 1-5 years | case-to-case: new < renewals | case-to-case: new < renewals | 10 years |
| Dossier: organism/product | organism / producer | organism / producer | product / producer | organism / producer |
| Opinion science / industry | PPS | expertpanel ACRE | tox, ecotox, agronomist | authority |
| Conditions? | National, application, expt. | always: disease free, nondiap | yes: pest/crop | yes |
| Information available | http://www.lnvloket.nl | http://www.defra.co.uk | http://www.ages.at | http://www.fvm.hu, www.ontsz.hu |
| Public scrutiny | no | no | no | no |
| Safe List? | yes, 134 species exempt | no (licensed species) | 44 products: 25 species | no BCAs exempt, 17 species |

**Table 3 –** Overview of regulation requirements in 8 European countries (situation August 2006)

In contrast to Europe, many other countries in the world have implemented the FAO Code of Conduct (Kairo, et al., 2002). Historically, Europe's position in trade and in pest control and subsequent developed set of legislations is different from many other countries in the world. Other countries traditionally were the recipient of invading (European) pests and diseases. These countries perceived another perspective of (phytosanitary) risk and developed (e.g. Anglo – Saxon based or oriented) legislative and regulatory instruments accordingly. Whereas in continental Europe the balance between protection of trade and protection of food production from a phytosanitary perspective is tipped towards the first ("yes, if"), in many other countries it is the reverse ("no, unless"). It is not a coincidence that many other countries have a rich history in classical biological control (production), whereas Europe is leading in commercially biological control agents (trade). With the changing routes in trade and the introduction of invasive species, pests and IBCAs into Europe becoming increasingly important, national legislations and regulations need adaptation. Lessons can be learned from regulatory measures implemented and guidelines published by national

[26] Minutes of the Macrobial WG meetings in Wageningen – The Netherlands, April 2006 and Salzau – Germany, September 2006 (see http://www.rebeca-net.de/); Bigler et al. (2005b).

governments elsewhere in the world. Sheppard et al. (2003) and Hunt et al., (2007) provide a good summary of the do's and don'ts for European regulators.

Bigler et al., (2005b), taking into account and reshaping parts of previous guidelines published by EPPO, NAPPO and OECD, wrote a set of unique guidelines on information requirements for import and release of invertebrate biological control agents in European countries. This can be a solid basis from where REBECA can proceed in preparing instruction for preparation and evaluation of an IBCA dossier by National Authorities in Europe.

**Legislation & Administration**

- There is no legislation in any jurisdiction in European countries regarding specifically the import and release of exotic species for the purpose of biological control. For macro-organisms, there is no specific EU directive available and EU does not intend to develop such directive.
- Provisions for IBCAs have been arranged in countries under either nature protection, plant protection, and/or pesticide acts, depending of the historical and nature of the act;
- The results of the surveys showed that the competent or national authority is assigned accordingly to different types of institutes: either plant health, pesticide registration or nature conservation authorities;
- Regulatory system is necessary and unavoidable; it should be harmonised, but not governed by EU legislation; it also improves the reputation of the biocontrol industry;
- Few countries have a regulatory system in place that suits the requirements of a proper IBCA risk-assessment;
- Weed biocontrol agents, are arranged accordingly, either as micro-organisms, or as macro-organisms. Switzerland has specific ordinances for different types of IBCAs: weed BCAs and invertebrate BCAs that are sold commercially are considered plant protection products, and thus fall under the Plant Protection Act, whereas invertebrate BCAs that are imported and released for classical biocontrol (of weeds and invertebrates) approval is regulated under the Federal Law on the Protection of the Environment (LPE).
- Past experience has shown that over-regulation, i.e. rigid legislation with stringent data requirements may keep such products off the market for a long time or even prevent industry to submit applications in some countries. This situation is experienced in the EU since 1992 with the registration of microbial biocontrol agents that are regulated under the Directive 91/414/EEC which largely follows requirements developed for synthetic pesticides.
- Uncoordinated regulation of biological control organisms bear the risk that approval for release in one country may have impacts for others if the organism crosses borders and establishes in other countries.

**Application procedures**

- In most countries a system of authorization, registration, regulation and/or evaluation applies per species and per product (per distributor). In The Netherlands every distributor or retailer has to apply for a permit to release a specific organism. In Switzerland also every distributor of a specific product needs to apply for a permit.
- Different regulations among European countries may cause serious problems to the industry as dossiers must respect national requirements and criteria in those countries where regulation is in place. This makes applications more time consuming and costly, and can be a factor for a company not to develop the organism to a product if the market potential is estimated low in comparison to the development costs (Bigler et al, 2005b).

**Decision-making process and decision maker**

- Except for phytosanitary, veterinary, pesticide measures and requirements, the decision making process in Europe on IBCAs (and other invasive species) has not been centralised, but has been drawn up according to historical lines of national legislation. National Authorities – where applications are submitted and permits are issued - are assigned for plant protection plant protection products (pesticides), and occasionally for nature conservation or the environment. Evaluation of an application (and dossier) is based on the data requirements given in the dossier, including information on the identity and biology, information on effects on human, animal and plant health, on efficacy, and on environmental effects by "expert knowledge". Objective criteria, however, have not been defined (in contrast to e.g. the PRA standards and procedures for risk-evaluation of phytosanitary pests) and need to be harmonised. Different application procedures should be designed for native resp. exotic species.

**Data requirements**

- Although several countries require an application with a dossier included (Austria, Netherlands, Norway, Switzerland, UK) for authorisation of IBCA species, data requirements upon which the evaluation is based are very different. Data requirements are already different for native resp. exotic species, this should be

fine-tuned. There definitely is a need for harmonisation of information requirements to allow more uniform, science based decisions.

**Costs – Fees**

- Costs for administration vary from 0€ -1660 €. but costs are relatively low compared to those charged for compilation and evaluation of a pesticide or microbial dossier. Additional costs, e.g. for efficacy testing (Norway, Hungary) and risk-assessment (UK – winter survival) may significantly increase both the costs and time to acquire an application. Host range testing has not been required in Europe yet. Switzerland, however, recommends doing so when compiling the data set.

**Time frame**

- The time frame for administration and evaluation varies largely (2-6 months up to 2-3 years when efficacy tests are required; long

**Availability of information to aid applicants**

- Little or no information is available online to aid applicants and this strongly needs improvement. Information, based along with the criteria we included in our questionnaires, about the application procedure, the decision-making process, who and how decisions are taken, what data requirements have to be fulfilled, how dossiers have to be prepared, the costs and time frame for administrative handling, the length of the validity of a permit and the presence of what species an application is needed or what species are exempted form regulation…. was difficult to obtain from outside the national organisations. Even for those that know the system it took quite some effort to gather the information we used in the report!

**Public participation**

- In Europe there is no public participation included in the regulatory process. In most cases licensed species are published as a species register. In few cases (Austria) an online database can be consulted

**Length of validity of permit**

- The length of the licence or permit varies upon conditions, crops and application of the BCA and varies between 1 –10 years.

**'Safe list' of IBCAs exempt from regulation?**

- With the exception of The Netherlands there are no 'safe lists' available in Europe, where a proper environmental risk analysis. In a number of countries native natural enemies are excluded from regulation by law (UK, Germany, Norway, Sweden, Czech Republic, Hungary?), whereas in others native BCAs are subject to regulation (Switzerland, Netherlands).
- To exempt release of native natural enemies as BCAs from regulation would make changes necessary in various national laws and decisions and would evokes a discussion on definitions, the area (geographical, political) of origin.

## Recommendations[27]

**Legislation and Administration**

- Do not reinvent the wheel: adjust existing instruments to make legislation and regulation already in place work and design or develop only new instruments when not yet available.
- Implement IPSM #3 a.s.a.p., including a regulatory system for import, production, release and export of IBCAs ;
- Assign one competent or national authority;
- Adjust instruments for evaluation of risks, already available for other purposes, to the specific group subject to approval. e.g. adjust PRA schemes developed for unintentional introductions for intentional introductions – such as plants, IBCAs - as well;
- Retain the potential use of non-native species as biological control agents; licensing arrangements should remain in place whereby desirable non-native species can be introduced, for commercial or for classical biological control;
- Promote grounds for co-regulation and self-regulation.

**Application procedures**

- Make application procedures transparent to the applicant and to the public;
- Start the application with a consultation (helpdesk) : based on a quick scan analysis of the organism, product, or application it can be decided about how and what type of procedure has to be followed, what data requirements are necessary and how the dossier has to be prepared; it also gives the NA a face.
- If the application has not been complied with within the given time frame, or when the approval has been negative, the applicant should have the right to appeal;
- Producers (industry) should apply individually for a licence to release a certain species or organism in a country, thus avoiding that making an investment.

**Decision-making process and decision maker**

- Make also the decision-making process transparent to the applicant and to the public;
- Develop or adjust decision-making schemes, such as PRAs, to analyse risks posed by the functional group, i.c biological control agents for the control of invertebrates and plants;
- Adjust existing risk-assessment schemes (PRA) to the specific group , i.c. IBCAs, that will be subject to an environmental risk analysis (ERA);
- Create short lines: solve issues about the content of the dossier directly between the applicant and the cooperating advisor(s) until the co-operator is satisfied;
- Set-up a science-based peer-review of applications through a PRA (EPPO) or expert panel (EFSA) including different stakeholders;
- Evaluate options for implementing a pan-European regulatory system for macrobial BCAs, including creation and terms of reference for an 'expert group' and its relationship to national competent authorities;
- Let National Authorities build confidence in the regulatory guidelines and protocols supporting an Environmental Risk Analysis (ERA): they will otherwise not delegate decision-making responsibilities to a pan-European 'expert group';
- Applications for import, production and release of IBCAs should require legally enforceable risk assessments, including cost-benefit analyses that consider the potential loss of ecosystem goods and services.

**Data requirements**

- Harmonise data requirements between countries, *sensu* Bigler et al. (2005a); these guidelines give comprehensive details of information to be included in a full dossier, but that information should be used in conjunction with an hierarchical scheme – all information requirements are described in paper, but not all will be necessary for most species;
- Use a uniform format of dossier common to all EU MSs;
- For evaluation of applications for commercial releases, order of assessments are establishment, host range, dispersal if appropriate, but there may be alternative routes through scheme case-by-case;
- Refer to 'assessments' based on information available in literature, or when necessary, on data generated by specific tests;

[27] Including part of the outcome of the presentations at the Macrobial WG meetings in Wageningen – The Netherlands, April 2006 and Salzau – Germany, September 2006 (see http://www.rebeca-net.de/)

- Some information is very important: original papers from which data obtained (plus narrative summaries), including a source of taxonomic identification should be included;
- Countries within the same ecoregion ( similar climate) should share / accept evaluations from neighbouring MSs – provided that assessments have been conducted by biocontrol 'experts'.

**Costs – Fees and Research**

- Minimize costs for application, for drawing up a dossier by the applicant through helpdesks, online available forms of a uniform format, publishing safe lists, etc.;
- Minimize costs for research where possible by using an hierarchical information evaluation (and risk-assessment) scheme *sensu* Van Lenteren et al. (2006) ; information required will then differ per type of organism, going all the way will then be most costly;
- Play fare play: every applicant should apply with an own dossier (to protect its investment) and adopt the 'level playing field' axiom: create an environment in which all companies in a country must follow the same rules and are given an equal ability to compete.

**Time frame**

- Set a fixed time frame for acceptance of the application form and for evaluation of the dossier, depending on the type of evaluation that needs to be made;
- When there is no response from co-operator(s) / experts (s) within a fixed time frame it may be assumed there is no objection and the NA can proceed with the application

**Availability of information to aid applicants –**

- Put information online to aid applicants (helpdesk, forms, procedures)

**Public participation**

- Publish licences that have been granted, permits that have been issued for specific IBCAs or derogations on the website of the National Authority

**Length of validity of permit**

- Allow a period substantial enough for the industry to cover expenses made for the approval (5year).

**'Safe list'** - a list of species / organisms that, following a quick scan or full scan risk –assessment procedure, that are considered as being safe for release and that are exempted from further regulation; preferably insight should be given into the criteria and evaluation of information used.

- Every country should make a 'safe list' available; it can aid applicants and regulators, and helps to avoid lengthy administrative procedures;
- Support the principle of a Safe List on an EU or EPPO level, and make it readily accessible for the industry, regulators and public; it can facilitate applications for the industry or other applicants in different countries and thus stimulate biological control applications; EU or EPPO 'endorsement' gives credibility;
- Update the current criteria – 5 years, 5 countries, no significant impact – used in the EPPO list with additional information (such as distribution in EPPO region, countries that approved/rejected licence, summary of ERA information);
- Design a system so issues of confidentiality do not arise;
- Promote the use of the vast reservoir of native European IBCA species.

**General -** To adapt or change legislation and regulatory measures already in place in a country is very difficult and lengthy. Each country has its own constitution and sovereign rights. In any case countries have an obligation to make policy decisions and application procedures transparent and facilitate application procedures. Use the internet for communication with applicants and the public. European countries should be willing to learn lessons from regulatory biological experiences elsewhere in the world (See Hunt et la, 2007). A major gain can be achieved by developing uniform (or harmonised) tools, scientific methods and legal instruments (uniform dossier requirements, tools for risk-assessment evaluation) to support expert judgement in their evaluation of an application.

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1. **Austria** – Dr. Sylvia Blümel, Austrian Agency for Health and Food Safety (AGES), Institute of Plant Health (PGH), Spargelfeldstrasse 191, P.O. Box 400, A-1226 Wien, Austria, E-mail: sylvia.bluemel[AT]ages.at. Web: http://www.ages.at
2. **Belgium** – Patrick De Clercq, Laboratory of Agrozoology, Department of Crop Protection, Faculty of Bioscience Engineering, Ghent University, Coupure Links 653, B-9000 Ghent, Belgium. Email: patrick.declercq[AT]ugent.be. Web: www.agrozoology.ugent.be
3. **Czech Republic** – Miloslava Navrátilová, State Phytosanitary Administration, Section of Plant Protection Products, Brno, Czech Republic, Email: miloslava.navratilova[AT]srs.cz Web:
4. **Denmark** - Hans Erik Svart, Miljøministeriet, Skov- og Naturstyrelsen , Haraldsgade 53 , 2100 København, email: hes[AT]sns.dk, sns[AT]sns.dk Web: http://www.skovognatur.dk
5. **Finland** - Marina Niemi, Verdera Oy, Forest marketing and Registration, Finland Email:MarinaN[AT]verdera.fi; Paula Lilja, Ylitarkastaja / Senior Inspector, Kasvintuotannon Tarkastuskeskus / Plant Production Inspection Centre, Kasvintarkastus / Plant Protection Service, Vilhonvuorenkatu 11C, PL 42 / P.O. Box 42, FI-00501 Helsinki. Sähköposti / e-mail: paula.lilja[AT]kttk.fi; Web: www.kttk.fi
6. **France** – Yves Monnet (chair L'AFPP = Association Francaise de Protection de Plantes), Ministère de l'agriculture, de l'alimentation, de la pêche et des affaires rurales, DGAL (Direction générale de l'alimentation), SDQPV (Sous-direction Qualité et protection des végétaux), 251 rue de Vaugirard, 75015 Paris Cedex 15, France. Email: yves.monnet[AT]agriculture.gouv.fr. Jean-Claude Malausa, INRA, Unité de Lutte biologique, 1382 route de Biot, F-06560 Valbonne, France. Email: malausa[AT]antibes.inra.fr
7. **Germany** - Horst Bathon, Biologische Bundesanstalt – Insitut für Land- und Forstwirtschaft, Institut für biologischen Pflanzenschutz, Heinrichstr. 243, 64287 Darmstadt, Germany. E-mail: h.bathon[AT]bba.de. Martin Hommes, Biologische Bundesanstalt, Institut für Pflanzenschutz im Gartenbau. Messeweg 11/12, 38104 Brunswick. Email: m.hommes[AT]bba.de Web: http://www.bba.bund.de/
8. **Greece** - Katerina Kyriazi, Ecotoxicology, Evaluation of Plant Protection Products, Department of Pesticides, Ministry of Rural Development and Food, 150, Syngrou Ave., 176 71 Athens, Greece. E-mail: syg037[AT]minagric.gr
9. **Hungary** - Zoltán Ocszkó, Central Service for Plant Protection and Soil Conservation, H-1118 Budapest, Budaörsi út 141-145., Hungary. E-mail: Ocsko.Zoltán[AT]ntksz.ontsz.hu. Web: Http://www.fvm.hu, http://wwww.ontsz.hu
10. **Ireland** - Robbie McDonald, Quercus, Queen's University Belfast, School of Biological Sciences, 97 Lisburn Road, Belfast BT9 7BL, Northern Ireland. Email: quercus[AT]qub.ac.uk/r.a.mcdonald[AT]qub.ac.uk. Website: http://www.quercus.ac.uk/; Louise Mark-Byrne, The BIOMERIT Research Centre, Biosciences Institute, National University of Ireland, University College Cork Ireland. Email: l.mark[AT]ucc.ie;
11. **Italy** - Maria Grazia Tommasini, CRPV - Crop Production Research Centre, Fruit Crop Protection Service, Via Vicinale Monticino, 1969, 47020 - Diegaro di Cesena (FC) Italy. Email: tommasini[AT]crpv.it
12. **Netherlands** - Loomans, A.J.M. Department of Entomology, Division Diagnostics, Plant Protection Service, P.O. Box 9102, 6700 HC Wageningen, The Netherlands. E-mail: a.j.m.loomans[AT]minlnv.nl. Web: http://www.hetlnvloket.nl/
13. **Norway** - Marit Skuterud, Mattilsynet, RK Oslo, Akershus og Østfold, Nasjonalt senter for planter og vegetabilsk mat, Seksjon plantevernmidler, Felles postmottak, Postboks 383, 2381 Brumunddal. Email = masku[AT]mattilsynet.no; Eline B. Hågvar, Dep. of Biology and Nature Conservation, Agricultural University of Norway, P.O. box 5014, N-1432 Ås, Norway. E-mail: eline.hagvar[AT]ibn.nlh.no.
14. **Poland** - Danuta Kropczynska – Linkiewicz, Department of Applied Entomology, Warsaw Agricultural University, Nowoursynowska 166, 02-787 Warszawa, Poland, kropczynska[AT]alpha.sggw.waw.pl; Marek Tomalak, Department of Biological Pest Control and Quarantine, Institute of Plant Protection, Ul. Miczurina 20, 60-318 Poznan, Poland. Email = m.tomalak[AT]ior.poznan.pl
15. **Portugal** - Carola Meierrose, Biology Department, University of Évora, P7002-554 Évora, Portugal. Email = cmrose[AT]uevora.pt; Miguel Serrão, Ministério da Agricultura do Desenvolvimento Rural e Pescas, Praça do Comércio, 1149-010 Lisboa, Portugal. Email: mserrao[AT]madrp.gov.pt
16. **Slovenia** – Lea Milevoj, Biotechnical Faculty, Agronomy Department, University of Ljubljana, Jamnikarjeva 101, SI-1111, Ljubljana. Email: lea.milevoj[AT]bf.uni-lj.si
17. **Spain** - Josep Jacas Miret, Universitat Jaume I, Depratament de Ciències Experimentalis, Campus del Riu Sec, E-12071-Castelló de la Plana, Email : jacas{AT}exp.uji.es

18. **Sweden**- Lars Lindqvist, KEMI [Swedish Chemicals Inspectorate], Box 2, SE-172 13 Sundbyberg, Sweden. Email = Lars.Lindqvist[AT]kemi.se Web: http://www.kemi.se; Barbro Nedstam, Swedish Board of Agriculture, Plant Protection Centre, Box 12, 230 53 Alnarp (Sweden), E-mail: barbro.nedstam[AT]sjv.se
19. **Switzerland** – Andrea Raps, UVEK Bundesamt für Umwelt BAFU, Federal Office for the Environment, Switzerland Email: andrea.raps[AT]bafu.admin.ch; Franz Bigler, Swiss Federal Research Station for Agroecology, 8046 Zurich Switzerland, E-mail: franz.bigler[AT]fal.admin.ch; Emma Hunt, CABI Bioscience, Délémont, Switzerland.
20. **UK** - Sharon Cheek, Plant Health Consultant/Entomologist, Central Science Laboratory, Sand Hutton, York YO41 1LZ UK. Email: s.cheek[AT]csl.gov.uk Web: http://www.csl.gov.uk; Andrew Empson, Non-native licensing team, Defra 3/E7 Ashdown House, 123 Victoria Street London SW1E 6DE, Andrew.Empson[AT]defra.gsi.gov.uk. Web = http://www.defra.gov.uk/environment/gm/nonnav/
21. No contacts established yet: Cyprus, Estonia, Ireland, Latvia, Lithuania, Luxembourg, Malta, Slovakia

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## Appendices

An overview of the separate countries included in the surveys will be issued on a later date of the project.

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A.J.M. Loomans
Plant Protection Service
Department of Entomology
P.O. Box 9102
6700 HC Wageningen
The Netherlands
E-mail: a.j.m.Loomans[AT]minlnv.nl