ENVIRONMENTAL BENEFITS AND RISKS OF BIOLOGICAL CONTROL: EVALUATION OF NATURAL ENEMIES AS A BASIS FOR RELEASING BCAS IN THE NETHERLANDS

Antoon J.M. LOOMANS[1]

[1]National Plant Protection Organization, Netherlands Food and Consumer Product Safety Authority, Wageningen, The Netherlands

ABSTRACT

The release of biological control agents (BCA) is an important means as to control pest insects worldwide. In Europe, application in greenhouses has reached a high level of implementation and success. Most agents that are released have a positive track record, both in efficacy as in safety. There is, however, growing awareness that potential side effects should be considered prior to that a release is made. In the Netherlands, the release of animal species into the wild is prohibited by the Flora and Fauna Act since 2005. This act forbids the release of animals or their eggs into nature, including biological control agents. Based on the information available until 2005, a short risk-assessment (quick-scan) was made by the Dutch NPPO for each BCA which was already in use. As a result, 135 BCAs were considered to be 'safe' and thereby to continue their release. These species were exempted from being licensed ("vrijstellingenlijst 2005") and thus free to release. BCA species that were not exempted or new, form then on could only be released when licensed ("ontheffing"). This includes species supporting biological control practices such as factitious host or prey. To be eligible for licensing, each stakeholder (e.g. research institute, commercial stakeholder) has to submit an application, including a dossier. In the Netherlands, procedures and criteria for regulation, authorization and preparation of a dossier are used in accordance with international legislation, using harmonized methodologies for regulation and data requirements, adopted as standard PM 6/2(2) by EPPO (2010). Based on the dossier information the NPPO performs an Environmental Risk Analysis. This ERA is based on the information requirements and criteria as described by e.g. Van Lenteren *et al*. (2006) and assesses whether release of a specific BCA or other beneficial is considered 'safe for the native flora and fauna', or not. Taxonomic identity, impact on human and animal health and ecological impact are the main criteria. Efficacy data are optional, but are not required. Establishment and dispersal potential, host specificity and direct / indirect non-target effects of the BCA are assessed to determine ecological impact. Each ERA has a step-wise approach: information requirements needed may vary, based on the type of biological control program (classical, inundative), origin of the organism (native, non-native), ecological factors (known or unknown), 1st or 2nd application, etc. A permit to release can be issued to a single applicant only and is species-based and not product-based: each applicant has to apply for a permit to release a single species. A permit is issued for a maximum period of 5 years and can be mandated by the applicant to end-users to release their organism already under permit. When a release of a BCA is assessed as safe for the native flora and fauna, a licence is issued. From 2004-2013, 55 permits for 27 BCA species have been issued, from native as well as non-native origins. In the presentation the benefits, recent developments, limitations and bottlenecks will be addressed.

Key words: biological control agents, non-native species, regulation, legislation, EPPO/IOBC

[1] PhD., Geertjesweg 15, 6706 EA, Wageningen, The Netherlands; e-mail: a.j.m.loomans@nvwa.nl

IZVLEČEK

OKOLJSKE KORISTI IN TVEGANJA ZARADI BIOTIČNEGA VARSTVA RASTLIN: OCENA NARAVNIH SOVRAŽNIKOV KOT PODLAGA ZA IZPUST BIOTIČNIH AGENSOV NA NIZOZEMSKEM

Izpust biotičnih agensov je podlaga za zatiranje škodljivih organizmov po vsem svetu. V Evropi je uporaba biotičnih agensov v rastlinjakih dosegla visoko stopnjo implementacije in uspeha. Večina izpuščenih agensov ima dokazano učinkovitost in varnost uporabe. Kljub temu pa se ljudje vse bolj zavedajo potrebnosti preučitve morebitnih stranskih učinkov uporabe biotičnih agensov pred njihovim izpustom. Od leta 2005 je na Nizozemskem na podlagi zakona (Fauna and Flora Act) prepovedan vnos živalskih vrst v naravo. Omenjeni zakon prepoveduje vnos živali ali njihovih jajčec v naravo, vključno z biotičnimi agensi. Na podlagi informacij nizozemske nacionalne organizacije za varstvo rastlin (Dutch NPPO), ki so na voljo od leta 2005, je bila narejena kratka ocena tveganja za vsak koristni organizem, ki je bil pred tem že v uporabi. Rezultati so pokazali, da je 135 vrst koristnih organizmov dobilo pozitivno oceno in se je zaradi tega njihova uporaba za namene varstva rastlin pred škodljivimi organizmi nadaljevala. Omenjeni organizmi so bili izvzeti iz licenciranja (t.i. vrijstellingenlijst 2005) in se lahko uporabljajo v biotičnem varstvu rastlin. Koristni organizmi, ki niso bili izvzeti iz licenciranja oz. so novi, morajo biti od takrat naprej pred izpustom obvezno ocenjeni (t.i. ontheffing). Za pridobitev dovoljenja mora vsak uporabnik (raziskovalni inštitut, komercialni ponudnik) priložiti obrazec, ki vključuje tudi dokumentacijo. Na Nizozemskem so postopki in kriteriji za registracijo, avtorizacijo in pripravo dokumentacije v skladu z mednarodno zakonodajo, ki uporablja skladno metodologijo in podatke, privzete po standardih varstva rastlin organizacije EPPO (PM 6/2 [2] EPPO [2010]). Na podlagi dokumentacije NPPO naredi oceno okoljskega tveganja. Ocena okoljskega tveganja temelji na informacijah in kriterijih, ki so opisana v delu Van Lenteren *et al*. (2006) in določa, ali je izpust določenega koristnega organizma 'varna za domorodno živalstvo in rastlinstvo' ali ne. Glavni kriteriji so taksonomska identiteta, vpliv na zdravje ljudi in živali ter vpliv na okolje. Podatki o njihovi učinkovitosti so opcijski, a neobvezni. Lastnosti, kot so zmožnost širjenja biotičnih agensov, njihov posredni in neposredni vpliv na neciljne organizme, so ključnega pomena pri ocenitvi morebitnega vpliva na okolje. Vsaka ocena tveganja ima t.i. fazni pristop: informacije o organizmu lahko variirajo, odvisno od načina njihove rabe v programih biotičnega varstva rastlin (klasično, preplavno), njihovega izvora (domorodni, tujerodni), vplivov na okolje (znanih, neznanih), enkratne ali večkratne aplikacije, itd. Dovoljenje za uporabo lahko pridobi le en prosilec in temelji na vrsti organizma in ne na pripravku: vsak prosilec mora priložiti vlogo za dovoljenje izpusta za vsako vrsto koristnega organizma posebej. Dovoljenje velja za obdobje petih let. Ko je izpust koristnega organizma ocenjen kot varen za naravno okolje, pridobi dovoljenje. V obdobju 2004-2013 je bilo izdanih 55 dovoljenj za 27 vrst koristnih organizmov, tako domorodnih kot tudi tujerodnih. V prispevku bodo predstavljene prednosti in slabosti uporabe koristnih organizmov.

Ključne besede: biotično varstvo rastlin, tujerodne vrste, predpisi, zakonodaja, EPPO/IOBC

1 INTRODUCTION

The release of invertebrate biological control agents (IBCA) is an important means as to control plants and invertebrate pests worldwide. There are several strategies in biological control to achieve this goal: classical biological control, inoculative biological control, inundative biological control and conservation or natural biological control (Eilenberg *et al*., 2001). In Europe, augmentative releases of predators, parasitoids and entomopathogenic nematodes in greenhouses and public green to control various pests have reached a high level of implementation and success. Releases of biological control agents – carnivores or herbivores - into the environment to control invasive species, like invasive plants or pests, is

yet in its infancy. Most agents that have been released have a positive track record, both in efficacy as well as in safety. There is, however, growing awareness that potential side effects on the non-targetted flora and or fauna should be assessed prior to that a release is made (Van Lenteren *et al*., 2003, 2006).
Several types of international legislations are in place: International Plant Protection Convention (IPPC, 1951) addressing the introduction of exotic phytosanitary (quarantine) pests and biological control, Plant Protection Product acts covering the application of pesticides, biocides and microbial organisms (in some countries also macrobial organisms) and the Convention on Biological Diversity (CBD, 1992) addressing e.g. the environmental (ecological) impact of the introduction of exotic species in nature. In Europe there is no federal EU legislation which covers the regulation of biological control releases; national regulations in the EU member states are based on either one, two or all three types of legislation, and most are implemented in a different way (Hunt *et al*., 2011). Several attempts have been over the past 10 years to harmonize the information requirements, the application and evaluation process of biological control agents in Europe (IPPC, 2005; Bigler *et al*., 2005; EPPO, 2010; Hunt *et al*., 2011). In addition, EPPO has developed a number of standards to harmonize the import and release of exotic biological control agents (EPPO, 1999, 2010) and has drafted a list of widely used biological control agents which are safe for use (also known as the 'positive list') (EPPO, 2014).

2 REGULATION IN THE NETHERLANDS, PROCES AND PROCEDURE

In the Netherlands legislation and regulation on the release of invertebrate biological control agents (BCAs) is in place since 2005 (Loomans & Sütterlin, 2005). The release of animals and / or their eggs into the wild is prohibited by Article 14, paragraph 1 of the Flora and Fauna Act of 1998. This environmental act forbids the intentional release into nature of all animals, including biological control agents, whether native or non-native and whatever their proposed use and including all other organisms (pest species used as factitious host or prey) supporting biological control practices. Releases in crops and produce, whether in greenhouses, agricultural or urban settings are considered as a potential stepping stone to the environment and are thus covered as well. Thereby also all intentional releases of natural enemies as biological control agents, whether or not they are commercially distributed, formally were forbidden and could not be released for biological control purposes from 2004 onwards.
Exemption list - Most macrobial biological control agents (insects, mites, entomopathogenic nematodes) have a long track record as a sustainable, consumer friendly measure for controlling pest species. Therefore the Dutch NPPO chose a two-way approach to regulate their release, one for species already in use, and one for species that were new. For each BCA already in use, a short risk-assessment (quick-scan) was made by the NPPO, using the information available at that time to assess whether it was safe to continue their release. As a result, 150 species were evaluated and considered to be 'safe' and whose release could be continued. As a result 134 species were exempted from being licensed and thus free to release (Anonymous, 2005; Loomans *et al*., 2013). In addition 35 species were listed supporting biological control practices such as factitious host or prey. This list of exemptions is species based, not on the population or product level and complies as much as possible with EPPO standard PM6/3(4) (EPPO, 2014). When considered safe for release for these species and the products thereof no permit is needed and the organism is free for release in any commercial or institutional programme. A number of invertebrate BCAs already in use before 2005 were not exempted, such as *Amblyseius californicus, Cotesia marginiventris, Dicyphus hesperus, Encarsia pergandiella, Harmonia axyridis, Hippodamia convergens, Orius insidiosus,*

Phasmarhabditis hermaphrodita, Podisus maculiventris, etc. Arguments not to include certain organisms on this species list were various: either there was published information available about their broad host or prey range, able to establish in our climatic region, with known or alleged direct or indirect impact on non-target organsims and/or ecosystem effects or their potency to do so, or if there were large differences in ecological features between populations of various sources in for instance establishment potential or host range.

Application new agents - BCA species that were not exempted or that are new, from 2005 onwards could not be released unless licensed. To be eligible for licensing, each stakeholder (e.g. research institute, commercial stakeholder) has to submit an application, including preparation of a dossier. In the Netherlands, procedures and criteria for regulation, authorization and preparation of a dossier are used in accordance with international legislation, using harmonized methodologies for regulation and data requirements, adopted as standard PM 6/2(3) by EPPO (2010). An application can be submitted online (https://mijn.rvo.nl/biologische-bestrijders), the dossier with additional information has to be sent in by regular post. An application has to be made by an individual legal person (commercial or institutional) and the evaluation made is based on the dossier drafted by each individual applicant. Each application and evaluation of benefits and risks has a step-wise approach (Van Lenteren *et al*., 2006): information requirements may vary, based on the origin of the organism (native, non-native), the type of biological control program (classical, inoculative, inundative), ecological factors (known, generated, unknown), a 1st or 2nd application, etc. In conservation biological control no releases are made and therefore no application is needed.

3 EVALUATION OF AN APPLICATION

In the Netherlands, procedures and criteria for regulation, authorization and preparation of a dossier are used in accordance with international legislation and using harmonized methodologies for regulation and data requirements (EPPO, 1999, 2010, 2014). Based on the dossier information the NPPO evaluates the potential ecological risks of a release of predators and parasitoids of plant pests for the native flora and fauna, in a so called Environmental Risk Analysis (ERA). Such an ERA is based on the information requirements and criteria as described by e.g. Van Lenteren *et al*. (2003, 2006) and Hunt *et al*. (2011) and assesses whether release of a specific BCA or other beneficial is considered 'safe for the native flora and fauna', or not. Taxonomic identity, impact on human and animal health, efficacy and ecological impact are the main criteria. Each permit is licensed to a species and therefore the taxonomic status needs to be verified: a correct species identification is necessary, and needs to be confirmed by an expert; voucher specimens are deposited at the National Reference Centre of the NPPO, and a check for contamination is required. Any known or potential effects on human and animal health are included in a general way, e.g. if and when an agent is known as a vector, when allergy issues might be involved or when it may become a nuisance for animals and humans. Establishment and dispersal potential, host and/or prey range and direct / indirect non-target effects of the BCA are assessed to determine ecological impact. Data can be generated from literature, from new research, e.g. on the diapausing behavior and winter survival or host range. In the Netherlands the method described by Hatherly *et al*. (2008) combining assessments of cold tolerance with availability and use of wild prey is used as an effective screen for establishment potential of non - native BCAs in temperate Europe. In some countries efficacy data are required in an application (Hunt *et al*., 2011), but in the Netherlands these are optional and not required, and not conditional for making an ERA. Because releases are intentional a pathway analysis is not included. The total evaluation procedure is legally limited to a period of 8 weeks once an application is accepted.

4 LICENSES PERMITTED FOR RELEASE

When a release of a BCA is assessed as safe for the native flora and fauna, a licence is issued. A permit to release can be issued to a single applicant only and is species-based and not product-based: each applicant has to apply for a permit to release a single species. A permit is issued for a maximum period of 5 years and can be mandated by the applicant to end-users to release their organism already under permit. In general a permit is licensed for release of the species anywhere in the Netherlands, occasionally release of and agent is conditioned by specific restrictions e.g. to release on certain sites for experimental purposes only, or to use certain populations of the agent with specific biological and ecological features (see below).
Since 2005, 60 permits (10 renewals) have been licensed for 29 species - 22 biological control agents and 7 supporting organisms - from native as well as non-native origins. 2 applications have been rejected. Individual permits have been licensed for 11 parasitoids, 7 predatory mites, 1 predatory bug, 1 coccinellid species, 1 entomopathogenic nematode released as a biocontrol agents and for 7 species (mites, shrimps used as factitious prey) as supporting organisms (Table 1). So far, only one herbivore (*Stenopelmus rufinasus*) has been licensed for the control of an invasive pant, *Azolla*. Some of these agents were already in use before 2005, but had not been placed on the exemption list, have been licensed based on the application procedure for a new agent, performing a full risk assessment, including restrictions to what, where and when to release the agent: e.g. the predatory mite *Amblyseius californicus* is currently licensed for the non-diapausing strains only (see Hatherly *et al*., 2008), *Phasmarhabditis hermaphrodita* is only permited in combination with a specific toxic pathogen, the nearctic mirid bug *Dicyphus hesperus* has been licensed for restricted use only on designated sites, for a period of 5 years, including the requirement to perform a post-release monitoring programme in the vicinity of the release sites.

Table 1: Overview of biological control agents (parasitoids, predators) and supporting organisms (factitious host or prey) licensed in the Netherlands from 2005-2014 by species name.

Biocontrol agents			Prey
Allotropa convexifrons	*Leptopilina heterotoma*	*Androlaelaps casalis*	*Carpoglyphus lactis*
Allotropa musae	*Muscidifurax raptorellus*	*Euseius gallicus*	*Lepidoglyphus destructor*
Anagyrus sinope	*Spalangia cameroni*	*Euseius ovalis*	*Suidasia medanensis*
Aphidius gifuensis	*Trichogramma achaeae*	*Macrocheles robustulus*	*Thyreophagus entomophagus*
Aphytis lepidosaphes	*Dicyphus hesperus*	*Neoseiulus californicus*	*Tyrolichus casei*
Ephedrus cerasicola	*Nephus quadrimaculatus*	*Phytoseiulus macropilis*	*Artemia parthenogenetica*
Ephedrus plagiator	*Amblydromalus limonicus*	*Phasmarhabd.hermaphrodita*	*Artemia fransiscana*

5 TRENDS AND CONSIDERATIONS

During the past decades in many countries the number of natural enemy has increased for releases in inundative, commercial biological control programmes in orchards, crops and greenhouses, and biological control has become a serious sustainable management tool. Development of regulation of biological control takes increases as well, making import and release of exotic agents more complex. It is of great priority to find a balance between reasonable regulation of importation and release of new candidates for biological control and the possibility to develop sustainable, environmentally safe pest control. Taking into account the benefits and risks of a release, the current risk assessment procedure for greenhouse BCAs

in the Netherlands is a 'light' form of assessment: 'yes, unless' instead of 'no, provided that'. The drafting of white (positive/exemption) lists, such as PM6/3(4) (EPPO, 2014), assessed prior to application, helps to facilitate further implementation of biological control as a pest management tool.

There are a few questions and challenges which still need to be addressed. First, legislation and regulation is in most countries focused on species from an exotic origin. It questions to consider what is exotic and what is native: to a country, to a climatic region, to a biogeographical or political (EU) area? Are population differences of species, native to Europe but occurring over a wider geographical area relevant for an ecological risk-assessment and release? And if so, how to define and characterize exotic / native?! Second, legislation is currently addressing risks upon release, not upon import, transport or export. Agents that are imported for biological control purposes partly can be used for research only, for release after a period of research in the laboratory or released directly from product facilities across the world. Every year billions of specimens, of BCA species widely used in biological control are imported from production facilities outside the EU. Current veterinary checks on the product and phytosanitary permits are in place to cover the identity, the purity product (potential contamination with other species, with parasites or diseases), the presence of quarantine pests in some countries, but not everywhere. In the Netherlands a quality check is performed on commercially produced and released BCA: checks on identity and purity are in place by a yearly audit of the production system, the mass-rearing process, personnel qualifications, checks on identity en purity, before issuing of phytosanitary and veterinary certificates.

Finally, the release of natural enemies in the classical biological sense, where the pest and the agent both need to establish and disperse, has thus far mainly been restricted to releases in orchards in the Mediterranean area. The planned release of herbivores, such as *Aphalara itidori* in the UK and *Trichilogaster acaciaelongifoliae* in Portugal, for the biological control of invasive plants is relatively new for Europe. It challenges researchers, politicians and regulators to find a right balance between safety and efficacy and we have to come up with tailor-made solutions. A narrow host range and high specificity for the target plant has a key role in the process. International organizations such as EFSA, EPPO and IOBC could play a role in drafting standards for introduction, research and release of such exotic biological control agents and evaluation of risks.

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