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Harmonia axyridis: an environmental risk assessment for Northwest Europe

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Abstract In this paper, we summarize the international situation with respect to environmental risk assessment for biological control agents. Next, we apply a recently designed, comprehensive risk evaluation method consisting of a stepwise procedure to evaluate the environmental risks of *Harmonia axyridis* in Northwest Europe. This resulted in the very clear conclusion that *H. axyridis* is a potentially risky species for Northwest Europe, because it is able to establish, it has a very wide host range including species from other insect orders and even beyond the class of Insecta, it may feed on plant materials, it can cover large distances (>50 km per year), it does move into non-target areas, it may attack many non-target species including beneficial insects and insects of conservation concern, its activities have resulted in the reduction of populations of native predators in North America, it is known as a nuisance in North America and recently also in Northwest Europe, and it may develop as a pest of fruit in North America. Considering the *H. axyridis* case, current knowledge would lead to the conclusion that, although the predator is capable to effectively control several pest species, its risks are manifold and it should, thus, not have been released in Northwest Europe. At the time of the first releases in Nortwest Europe in 1995, the available scientific literature made clear that *H. axyridis* is a large sized polyphagous predator and has a great reproductive capacity in comparison with other ladybird beetles, and that there was a need to study non-target effects because of its

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polyphagous behaviour. In retrospect, this information should have been sufficient to reject import and release of this species, but it was apparently ignored by those who considered release of this predator in Northwest Europe. The case of *Harmonia* releases in Northwest Europe underlines that there is an urgent need for harmonized, world-wide regulation of biological control agents, including an information system on risky natural enemy species.

Keywords *Harmonia axyridis* · Environmental risk assessment · Host range · Dispersal · Establishment · Non-target effects · Quick scan risk evaluation · Comprehensive risk evaluation

Introduction

In the past 100 years many exotic natural enemies have been imported, mass-reared and released as biological control agents for pest control (Albajes et al. 1999; van Lenteren 2000, 2003; Lynch et al. 2000; USDA 2001; Mason and Huber 2002; Copping 2004). Although the majority of these releases have not resulted in unwanted side effects, some serious cases of non-target hazards by exotic biological control agents against insects and weeds have been recently reported (e.g. Boettner et al. 2000; Follett and Duan 2000; Wajnberg et al. 2000; Louda et al. 2003; van Lenteren et al. 2006a). Due to the current popularity of biological control, new Invertebrate Biological Control Agents (IBCAs) will become available. To reduce the chance of releasing exotic natural enemies that might pose a risk for the environment, guidelines are being developed to assist in environmental risk assessment.

Various organizations have developed standards, including guidelines for the export, import, shipment, evaluation and release of biological control agents (e.g. EPPO 2002; IPPC 2005). Environmental effects of biological control agents form a central element of these guidelines and a growing number of countries already apply risk assessment procedures prior to the import and release of a new natural enemy. Earlier, we collected, studied and summarized procedures to assess natural enemies currently used by about 25 countries and codes of conduct or guidelines produced by various organizations (van Lenteren and Loomans 2006). Within an EU funded project (van Lenteren et al. 2003) an OECD working group (Anonymous 2004) and an IOBC Commission (Bigler et al. 2005), guidelines have been developed to harmonize information requirements for import and release of invertebrate biological control agents. Based on all this information, we designed a new comprehensive method. Subsequently, we also developed a quick scan to be used for natural enemies that are already in use (van Lenteren and Loomans 2006). In this way, we hope to provide biological control experts and risk assessors with the tools for a proper and uniform evaluation of the information provided in the application. In this paper, we summarize the development of risk assessment procedures for natural enemies, we then describe a stepwise risk assessment procedure, and we will apply a quick scan and a comprehensive method to evaluate the environmental risks of *Harmonia axyridis* in Northwest Europe.

Environmental risk assessment of natural enemies

Risk assessment procedures for biological control agents are usually characterized by questions on four issues:

1. Characterization and identification of biological control agent
2. Health risks
3. Environmental risks
4. Efficacy

The kind of information needed to evaluate these issues are addressed in Anonymous (2004), van Lenteren et al. (2003) and Bigler et al. (2005), and information on the methods to be used to assess non-target effects are addressed in Babendreier et al. (2005) and Bigler et al. (2006). In this paper we will concentrate on the third issue, but also shortly address the other issues. Assessment of risks related to releases of natural enemies demands integration of many aspects of their biology, as well as information on ecological interactions. A comprehensive risk assessment comprises the following steps:

1. Identification and evaluation of potential risk of releasing a natural enemy,
2. A plan to minimize risk and mitigate unwanted effects of biological control agents (e.g. Moeed et al. 2006), and
3. A risk/benefit analysis of the proposed release of the natural enemy, together with risk/benefit analyses of current and alternative pest management methods (e.g. Bigler and Kölliker-Ott 2006).

The last step is essential, because the risk/benefit posed by the release of an exotic natural enemy might particularly be considered acceptable in comparison with the risks posed by other control methods. For definitions of terms used in this paper, we refer to Anonymous (2003) and Bigler et al. (2006).

Risk identification and calculation of risk index

Normally, for a risk assessment, one will identify and evaluate the potential negative effects, and determine the probabilities that these will materialize (e.g. Moeed et al. 2006; Bigler et al. 2006). The negative impacts of a biological control agent can be defined as any negative effect, which can be named and measured, such as direct and indirect negative effects on non-target organisms and negative effects on the environment. The risk of negative effects of the release of a biological control agent is the product of the likelihood (L) of impact and the magnitude (M) of impact. The likelihood and magnitude of five groups (ecological determinants) of risks are usually considered: establishment, dispersal, host range, direct effects, and indirect non-target effects. Next, qualitative scales for likelihood and magnitude need to be described (Table 1), after which one may quantify the scales for likelihood and magnitude (Tables 15.2 and 15.3 in van Lenteren and Loomans 2006). In an early version of an environmental risk assessment, a numerical value was added to each descriptor of likelihood and magnitude to be able to quantify risk (see van Lenteren et al. 2003). The overall risk index for each natural enemy was obtained by first multiplying the values obtained for likelihood and magnitude, followed by summing-up the resulting values obtained for establishment, dispersal, host range, direct and indirect effects. Based on an evaluation of 31 cases of natural enemy introductions into Europe, the following risk categories were proposed (van Lenteren et al. 2003):

1. Low risk category: for organisms falling in this category, a proposal of no objection against release of the agent can usually be issued;

Table 1 Qualitative scales for likelihood, magnitude and level of risk of adverse effects (after Hickson et al. 2000; van Lenteren and Loomans 2006)

Likelihood	Description
Very unlikely	Not impossible but only occurring in exceptional circumstances
Unlikely	Could occur but is not expected to occur under normal conditions
Possible	Equally likely or unlikely
Likely	Will probably occur at some time
Very likely	Is expected to occur

Magnitude	Description
Minimal	Insignificant (repairable or reversible) environmental impact
Minor	Reversible environmental impact
Moderate	Slight effect on native species
Major	Irreversible environmental effects but no species loss, remedial action available
Massive	Extensive irreversible environmental effects

Level of risk of adverse effect

Likelihood	Magnitude				
	Minimal	Minor	Moderate	Major	Massive
Very unlikely	Insignificant	Insignificant	Low	Medium	Medium
Unlikely	Insignificant	Low	Low	Medium	High
Possible	Low	Low	Medium	Medium	High
Likely	Low	Low	Medium	High	High
Very likely	Medium	Medium	High	High	High

2. Intermediate risk category: for organisms falling in this category, the advise will be issued to come up with specific additional information before a conclusion concerning release can be drawn;
3. High risk category: for organisms falling in this category, generally a proposal to not to release the agent will be issued.

Low risk indices were found for many parasitoids, several predatory mites, and one predatory insect. Intermediate risk indices were found for all guilds of natural enemies: parasitoids, predatory insects, predatory mites, parasitic nematodes and entomopathogenic fungi. Entomopathogens (*Beauveria, Metarhizium* and *Steinernema*) all score intermediate because of their broad host range, but their very limited dispersal capacities strongly reduce risk. The highest risk indices were found for predatory insects (*Harmonia axyridis* Pallas, *Hippodamia convergens* Guérin-Méneville, *Podisus maculiventris* (Say), *Orius insidiosus* (Say)) and parasitoids (*Encarsia pergandiella* (Howard), *Trichogramma brassicae* Bezdenko and *Cales noacki* Howard). This was not a surprise as they would all be classified by biological control experts in the high-risk category based on what is known of their biology.

Because this was the first quantitative risk assessment developed for natural enemies, it was foreseen that the quantification system might have to be adapted based on growing experience. The main problems encountered with this risk assessment were the following:

1. Information for the likelihood and magnitude of all five areas of assessment needed to be available before an evaluation could be made. This makes the assessment in a number of cases unnecessarily costly.
2. The assessment did not identify candidate natural enemies that appear to be clearly unacceptable for import and release based on data for one group of risks early in the process. This should be improved to prevent unnecessary data collection.
3. The numerical values calculated with this assessment did not allow a very clear separation between risk categories. This may result in interpretation and decision making that can easily be manipulated.
4. The overall risk index was obtained by adding five different categories which are in fact not completely independent from each other and should not be rated equally.
5. The overall score of a certain species for a certain ecoregion might lead to establishing an absolute value and unnecessary strict administrative need for measures.

Therefore, we designed a new environmental risk assessment, which is now a stepwise procedure and includes weight factors to solve the problems mentioned above (van Lenteren et al. 2006a; van Lenteren and Loomans 2006).

Risk management

The next step of a risk assessment process is to discuss risk management, including risk mitigation and risk reduction. If an exotic biological control agent is expected to cause significant adverse effects on non-target organisms a permit for releases will not be issued. In some cases, risks may be minimized by imposing restrictions concerning for example the types of crops on which the use of the organism is or is not allowed (e.g. treatment of flowering plants with a myco-insecticide), by requesting specific application techniques (e.g. soil incorporation only for insect pathogenic nematodes), or by specifying the eco-regions were the organism is allowed for use (e.g. use of tropical natural enemies in greenhouses in temperate climates).

Risk/benefit analysis

The last step in making a justified environmental risk analysis for a new biological control agent is to conduct a risk/benefit analysis which should include a comparative performance of pest management methods. The environmental benefits of use of the proposed biological control agent should be compared to environmental effects of currently used and other alternative control methods. Then, the environmental risk analysis is used in the overall risk/benefit assessment where the data concerning characterization, health risks, environmental risks and efficacy of all the control methods for a specific pest will be compared (for details see van Lenteren et al. 2003, 2006a; Bigler and Kölliker-Ott 2006).

Stepwise risk assessment procedure

Recently, as a follow up to the first quantitative risk assessment, an environmental risk assessment method was developed consisting of a stepwise procedure which can be used for all types of invertebrate biological control agents in augmentative and classical biological control, for relevant species or biotypes (e.g. in the case of biotypes that diapause or not, or biotypes with and without wings), whether they are native, established exotics or not yet established exotics (Table 2, summarized in Fig. 1; van Lenteren and Loomans 2006). Native species are included in the evaluation procedure as well, because in cases where natural enemies are released in very large numbers for immediate control of the target pest, like innundative biological control, direct dispersal (overflow, drift) from the release area into the surrounding environment is of main concern for direct non-target effects, irrespective whether the natural enemy species is exotic or not. Contrary to the first quantitative risk assessment described in the previous section, here the decision to advise release or not is taken after each relevant step in the process, thus preventing unnecessary research and resulting in early elimination of clearly risky natural enemies. Definitions for specific terms used in the evaluation process are given in Table 3.

At *step 1*, exotic and native natural enemies are distinguished. For native natural enemies only one more step (6) in the procedure needs to be followed. Dispersal (step 5) of native agents may be an important issue to be considered in order to address step 6 accordingly. For example, direct and indirect effects of a polyphagous biological control agent may be limited because of very limited dispersal. However, because experimental procedures to establish the dispersal potential of natural enemies might be quite lengthy, this is not included here as a standard procedure for native natural enemies. For exotic

Table 2 Schedule for an environmental risk assessment of an invertebrate biological control agent

1.	Origin—native	GO TO 6
	Origin—exotic, either absent OR present in target area	GO TO 2
2.	Augmentative Biological Control (ABC) programme—establishment not intended	GO TO 3
	Classical Biological Control (CBC) programme—establishment intended	GO TO 4
3.	Establishment unlikely (likelihood L = 1–2) no weight factor included	GO TO 6
	Establishment possible to very likely (L = 3–5), apply magnitude (M) as a weight factor	
	if risk threshold not crossed (ERI = less than 12)	GO TO 4
	if risk threshold crossed (ERI = 12 or more) (upon request of applicant, GO TO 4)	NO release
4.	If monophagous OR if oligophagous/polyphagous AND only related AND no valued non-targets attacked	Release
	If oligophagous/polyphagous AND related and unrelated non-targets attacked AND/OR valued non-targets attacked (upon request of applicant, GO TO 5)	No release
5.	Dispersal local (L = 1–2)	GO TO 6
	Dispersal outside target area (L = 3 or more) AND extensive (M 2 or more) apply magnitude (M) as a weight factor	
	if risk threshold is not crossed (ERI = 5 or less)	GO TO 6
	if risk threshold is crossed (ERI = 6 or more)	NO release
6.	Direct and indirect effects inside dispersal area of natural enemy unlikely (L = 1–2) AND at most transient and limited (M = 1–2)	Release
	Direct and indirect effects inside 'dispersal area' likely (L = 3–5) OR permanent (M = 3–5)	NO release

The determinants of the Environmental Risk Index (ERI = Likelihood (L) × Magnitude (M)) should be calculated per step as indicated by van Lenteren et al. (2003) and where appropriate with weight factors as given in Fig. 2 (after van Lenteren and Loomans 2006)

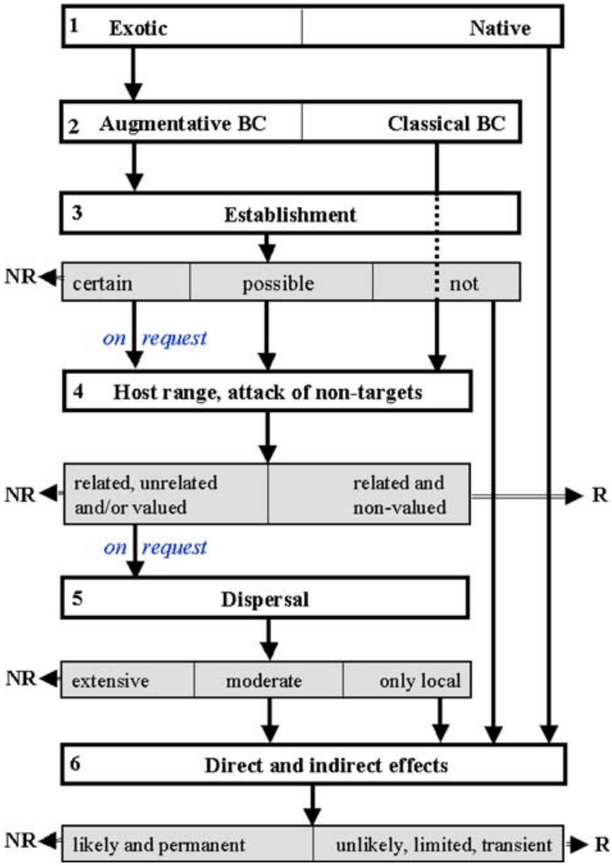

Fig. 1 Simplified scheme of an environmental risk assessment of an invertebrate biological control agent. R, NR: release, no release is recommended respectively (after van Lenteren and Loomans 2006)

Table 3 Definitions of terms used in environmental risk assessment

Term	Definition
Exotic	Non-indigenous to the country of release
Local	Restricted to the vicinity (<100 m) of the target area (establishment, dispersal)
Transient	Restricted to only the season of release (establishment, direct and indirect effects)
Permanent	Effect expected to occur during many seasons/years
Monophagous	No non-target species attacked (likelihood = 1)
Oligophagous	1–10 non-target species attacked (likelihood = 2 or 3)
Polyphagous	>10 species attacked (likelihood = 4 or 5)
Related	Within same genus

natural enemies, whether already present or absent in the target area, more steps need to be followed.

At *step 2*, natural enemies that are aimed for augmentative biological control (ABC) programmes where establishment of the organism in the area of release is not intended, are separated from natural enemies aimed for classical biological control (CBC) where establishment is the aim. For ABC natural enemies one then needs to demonstrate that they cannot establish in step 3.

If the natural enemy cannot establish (*step 3*, Likelihood = 1–2), one more step of the procedure (6) needs to be followed. However, if it can establish, the Environmental Risk Index (ERI = Likelihood (L) × Magnitude (M)) should be calculated for establishment (Fig. 2a). If a risk threshold is crossed (L = 3–5 AND M = 3–5, Fig. 2a), the natural enemy should not be released, and is thus eliminated early in the evaluation process.

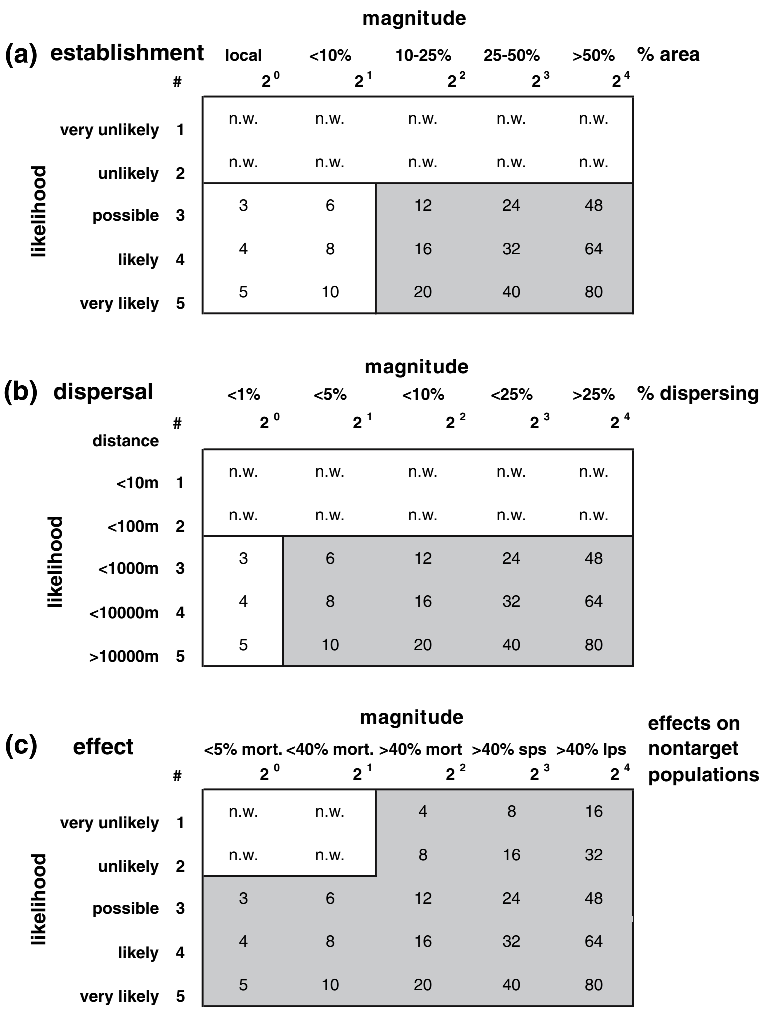

Fig. 2 Ecological Risk Index matrix to determine the level of risk of adverse effects of an IBCA for three ecological determinants: establishment (top), dispersal (middle) and direct and indirect effects (bottom). Ecological Risk Indices calculated as Likelihood (L) (vertical) × Magnitude (M) (horizontal) with their respective calculation factors: 1–5 for likelihood, 2^x as a weight factor for magnitude; n.w. = no weight factor included, mort. = mortality, sps = short term population suppression, lps = long term population suppression (see van Lenteren and Loomans 2006 for descriptions of determinants). White = below threshold, grey = above threshold (after van Lenteren and Loomans 2006)

However, if the applicant desires, he can provide data from studies on host range (step 4), dispersal (step 5) and direct/indirect non-target effects (step 6) and ask for the decision to be reconsidered. If the risk threshold is not crossed, the same procedure needs to be followed as for CBC natural enemies in step 4.

At *step 4*, the host range issue (see van Lenteren et al. 2006b) is addressed. If the ABC or CBC agent is either monophagous, or oligophagous/polyphagous and attacks only related AND no valued non-targets, i.e. species not of conservation concern, it should be considered for release. On the other hand, if the agent is oligophagous/polyphagous and does attack related and unrelated non-targets AND/OR valued non-targets, the agent should not be considered for release. However, if the applicant desires, he can provide data from studies on dispersal (step 5) and direct/indirect non-target effects and ask for the decision to be reconsidered. In that case, continue with step 5. On request, dispersal can be considered relevant for risk assessment of augmentative releases (see Mills et al. 2006).

At *step 5*, questions about dispersal of ABC and CBC (where appropriate and on request) agents are addressed. If dispersal is local and mainly in the area of release (L = 1 or 2, see Fig. 15.2b in van Lenteren and Loomans 2006), the procedure can be continued at step 6. But if dispersal is outside the target area (L = 3 or more) AND is extensive (M 2 or more) and thus the environmental risk index (ERI) crosses the value of 6 (Fig. 2b), the agent should not be released. If the ERI is 5 or less, the procedure can be continued at step 6.

At *step 6*, issues related to direct and indirect non-target effects are addressed as releases of exotic agents may negatively affect the abundance of native non-target species or other natural enemies that exploit the same resource (see Messing et al. 2006). If direct and indirect effects inside the 'dispersal area' are unlikely (L = 1–2) AND at most transient and limited (M = 1–2), the agent can be released. However, if direct and indirect effects inside the 'dispersal area' are likely (L = 3–5) OR permanent (M = 3–5), the agent should not be released (Fig. 2c).

To calculate risk levels for establishment, dispersal and direct/indirect non-target effects, the criteria are applied as given in van Lenteren et al. (2003), but weight factors are added, and the resulting values can be obtained from Fig. 2. If the ERI is below the risk threshold, the value will be in a white box (=continue procedure/release recommended). When the ERI is above the threshold, the value will be in a grey box (=discontinue procedure/no release recommended). Although threshold values as indicated in Fig. 2 are currently still largely based on expert judgement, these values need justification and fine-tuning. Here, accuracy and stringency are likely to increase as more data become available through experimental research. The final part of this new risk assessment, i.e. the risk management and the risk/benefit analysis, is the same as described in the previous section.

The stepwise risk assessment procedure has successfully been applied to the 150 species of natural enemies that are currently commercially available in Northwest Europe (producers information on the web; producers price lists; Loomans 2004). This includes the 92 natural enemies in the EPPO list of commercially available agents (EPPO 2002). The following conclusions could be drawn after this exercise (van Lenteren and Loomans 2006):

1. All native species that were evaluated are considered safe for release.
2. Exotic species intended for use in augmentative biological control that are likely to establish and cross the risk threshold are detected very early in the evaluation process, and will be excluded from release without the need to study host range, dispersal and direct/indirect non-target effects.

3. Exotic species that are monophagous, or oligophagous/polyphagous with attack of only related and no attack of valued non-targets are also detected early in the evaluation without the need to study dispersal and direct/indirect non-target effects; they can be released
4. Exotic species that are oligophagous/polyphagous and attack related and unrelated non-targets and/or valued non-targets will be excluded from release without the need to study dispersal and direct/indirect non-target effects.

Some exotic IBCAs that are not on the EPPO list, but are actually released commercially in Europe (e.g. *H. axyridis*, *H. convergens* and *O. insidiosus*), had a high ecological risk index in our previous assessment (see van Lenteren et al. 2003), indicating a high potential risk. When we evaluate these exotic IBCAs for release using the stepwise assessment procedure, they are considered unsuitable for release at step 3 or 4. On the other hand a species such as *T. brassicae*, also with a high risk index in our previous assessment (see van Lenteren et al. 2003) is not eliminated early in the stepwise procedure and can be released (establishment possible, polyphagous, but dispersal is local and direct and indirect effects within dispersal area unlikely) (see Babendreier et al. 2003; Kuske et al. 2003; Mills et al. 2006). The early elimination of obviously risky species, and the acceptance of other species, that scored – erroneously – a high index in the previous assessment by van Lenteren et al. (2003), clearly show improvements of the stepwise assessment proposed in van Lenteren and Loomans (2006).

Risk identification and risk indices for *Harmonia axyridis*

In this section, we present risk identification and the calculation of risk indices for *H. axyridis* prepared by two quantitative assessment procedures summarized above, and we will also attempt to prepare a risk assessment based on data available by the mid 1990s when *Harmonia* was not yet considered a problem.

Risk identification and risk index for *H. axyridis* based on the van Lenteren et al. (2003) approach

We will use the qualitative scales for likelihood and magnitude presented in Table 1 as a basis. This table was used by van Lenteren et al. (2003) to develop lists of descriptors as a first step towards quantification of risk; these lists are summarized in Table 4. The next step was to give a numerical value to each criterion. For likelihood, very unlikely was given a 1, unlikely a 2, etc.; for magnitude, minimal received a 1, minor a 2, etc. The overall risk index for each natural enemy is obtained by multiplying the figures for likelihood and magnitude, and then by adding the resulting figures obtained for dispersal, establishment, host specificity, direct and indirect effects. The data for *H. axyridis* are summarized in Table 5. van Lenteren et al. (2003) estimated the risks for Italy, but these estimates are also valid for Northwest Europe. Of a possible maximum of 125, the risk index for *H. axyridis* scored 101, and was the second highest value determined for 31 cases presented in the van Lenteren et al. (2003) paper.

Table 4 Descriptions of likelihood and magnitude for establishment, dispersal, host range, direct and indirect effects (after van Lenteren et al. 2003)

Likelihood	Establishment[a] in non-target habitat	Dispersal[b] potential	Host range[c]	Direct and Indirect effects
Very unlikely	Very unlikely	<10 m	0 species	Very unlikely
Unlikely	Unlikely	<100 m	1–3 species	Unlikely
Possible	Possible	<1,000 m	4–10 species	Possible
Likely	Likely	<10,000 m	11–30 species	Likely
Very likely	Very likely	>10,000 m	>30 species	Very likely
Magnitude	**Establishment[d] in non-target habitat**	**Dispersal[e] potential**	**Host range[f]**	**Direct[g] and Indirect[h] effects**
Minimal	Local (transient in time and space)	<1%	Species	<5% mortality
Minor	<10%	<5%	Genus	<40% mortality
Moderate	10–25%	<10%	Family	>40% mortality and/or > 10% short term population suppression
Major	25–50%	<25%	Order	>40% short term population suppression, or > 10% permanent population suppression
Massive	>50%	>25%	Phylum	>40% long term population suppression or local extinction

[a] The propensity to overcome adverse conditions and availability of refuges

[b] Distance moved per release

[c] The propensity to realise its ecological host range in the release area

[d] Percentage of potential non-target habitat where biological control agent may establish

[e] Percentage of released biological control agent dispersing from target release area

[f] Taxon range that biological control agent attacks

[g] Direct effect: mortality, population suppression or local extinction of directly affected non-target organisms

[h] Indirect effect: mortality, population suppression or local extinction of one or more species of non-target species that are indirectly influenced by the released biological control agent

Risk identification, risk index and risk assessment for *H. axyridis* based on the stepwise approach

We will follow the schedule for an environmental risk assessment of an invertebrate biological control agent presented in Table 2 and summarized in Fig. 1. *Harmonia axyridis* is an exotic natural enemy (question at step 1), thus we go to step 2. In Northwest Europe, the use of *H. axyridis* was proposed for augmentative releases without the goal to have the biological control agent established, so we go to step 3. The species can establish, which

Table 5 Calculation of risk index for *Harmonia axyridis* made in 2003 with the van Lenteren et al. (2003) approach

	Establishment	Dispersal	Host range	Direct effects	Indirect effects	Risk indix (sum L × M's)	References
Likelihood (L)	5	4	5	5	5		Burgio et al. 2002
Magnitude (M)	4	4	5	4	4		Tedders and Schaefer 1994
L × M	20	16	25	20	20	101	

means that we have to estimate the Environmental Risk Index (ERI = likelihood × magnitude) for establishment. Based on literature data summarized in Koch et al. (2006) and our own field experience we estimate the likelihood of establishment as "very likely" (the best proof is, of course, that *H. axyridis* has already established in a dozen Northwest European countries (Brown et al. 2007a)). The estimate for magnitude of establishment is that *H. axyridis* will establish in 25–50% of the potential non-target habitats. This estimate is based on our own field experience since 2003 indicating that *H. axyridis* might have spread to and established since in up to 50% of potential non-target habitats. When applying these two estimates to the section on establishment in Fig. 2 we come to an ERI of 40, which would mean that the risk threshold is crossed (the value is in the grey marked section of the figure) and that it should be advised not to release this natural enemy. However, if the producer of natural enemies desires, he can provide data from studies on the host range of the organism (step 4). Let us suppose that he did provide these data. We collected host range data from the literature (e.g. Koch et al. 2006; Loomans, unpublished) and found that *H. axyridis* may feed on many aphid species, as well as on numerous other insect prey (e.g. Hemiptera, Psyllidae, Coccoidea, Chrysomelidae, Curculionidae, Coccinellidae and Lepidoptera), spider mites (Tetranychidae), dead insects and also on plant material (e.g. damaged fruit, pollen and nectar). It seems safe to conclude that the organism is highly polyphagous, attacks related and unrelated non-target species and attacks valued non-target species. Thus, the conclusion would once more be that the species should not be released. However, the producer of the biological control agent might be willing to provide data on dispersal (step 5) and direct/indirect non-target effects (step 6), and ask that the decision to not release be reconsidered . At step 5 questions about dispersal of the species are addressed. Direct and indirect non-target effects might be limited if the species does not leave the area of release. Dispersal data for *H. axyridis* show, however, that the species may cover large distances (up to 442 km per year in North America, McCorquodale 1998; 50–100 km in Northwest Europe, Loomans 2007; Brown et al. 2007b) and does move into non-target areas, including nature reserves. This results in an estimate for likelihood of dispersal of more than 10 km per release and for magnitude of dispersal of more than 25% of the released biological control agent from target release area. The ERI of 80 for dispersal of this species crosses the threshold (Fig. 2) and for the third time the conclusion would be that the species should not be released. But let us continue with the procedure and also try to answer the questions at step 6. The literature provides a number of cases of negative direct and indirect effects in the dispersal area of the species for *H. axyridis*. The species attacks many non-target organisms including beneficial insects and insects of conservation concern (Ware and Majerus 2007), has resulted in the reduction of populations of native predators in North America, is known as a nuisance in North America and recently also in Northwest Europe, and is a pest of fruit production in North America (e.g. Koch et al. 2006 and references therein). The estimate for likelihood of effects on non-target populations is "very likely". The most difficult aspect of this whole procedure is to make an estimate for magnitude of non-target effects. Based on all current knowledge, we estimate that the magnitude is between less than 40% mortality of one or more non-target organisms and more than 40% long term population suppression of one or more non-target organisms. Even the lowest estimate results in an ERI of 10 and, thus, the risk threshold is crossed for the fourth time. It is obvious from the information that we have now, that application of this stepwise approach would have led to the very clear conclusion that *H. axyridis* is a potentially risky species for Northwest Europe.

The next step in the risk assessment procedure is to discuss risk management, including risk mitigation and risk reduction. Based on the biology of *H. axyridis*, it can be concluded that there are no easy ways to mitigate or reduce risk (Kenis et al. 2007). It has been suggested to release flightless strains of this predator in order to reduce risk of dispersal into non-target ecosystems (Ferran et al. 1998). Although the flightless strain could result in a significant reduction in dispersal and spread, it does not necessarily reduce its non-target impact. However, the potential consequences of such releases are not yet fully evaluated. Moreover, there are other, native coccinellid species that have a similar capacity for control of aphids.

The last step in making a justified environmental risk analysis for a new biological control agent is to conduct a risk/benefit analysis which should include a comparative performance of pest management methods. In the *H. axyridis* case, current knowledge would lead to the conclusion that, although the predator is capable to effectively control several pest species (a strong benefit; e.g. Landis et al. 2004), its risks are manifold (reduction in population size of native ladybird beetles, attack of many of non-target species, frugivorous behaviour, large aggregations are nuisance to humans, allergic reactions in and biting of humans; e.g. Koch et al. 2006), and it should, thus, not have been released in Nortwest Europe.

Environmental risk assessment for *H. axyridis* based on pre-1995 data

Harmonia axyridis is of Asian origin, is a predator of aphids and other soft-bodied arthropods, is frequently associated with trees in natural and agricultural settings when prey is available, but also occurs in herbaceous habitats (Koch et al. 2006). The predator has been used in biological control programmes since 1916 in the USA, when the first intentional releases were made in California, with later and more frequent releases in the USA and Canada during the 1970s and 1980s (Gordon 1985). The ladybird beetle has also been introduced intentionally in Europe, Africa, Central and South America (see Koch et al. 2006 and references therein). Established populations were first detected in North America in 1988 (Chapin and Brou 1991).

INRA (France) imported *H. axyridis* in 1982 and kept the species in quarantine until 1992. The first intentional, experimental releases were made from 1990–1997 in Southeast France followed by commercial releases in France in 1994, and in 1995 in Northwest Europe. Mass production of *H. axyridis* was started in 1992 by the French company Biotop (Kabiri 2006). The Belgian company Biobest and the Dutch company Koppert Biosystems started to sell *H. axyridis* (produced by Biotop) in 1995 and 1996, respectively (Kabiri 2006). Interestingly, this predator, while released in Italy and southern France, does not seem to have established and created problems there in spite of predictions on its establishment potential in that region in a later period (Iperti and Bertrand 2001; Bazzocchi et al. 2004). In Greece (Katsoyannos et al. 1997) the establishment potential was considered low in citrus orchards, but no observations where made at that time outside the release area. The first European record of a feral *Harmonia* population originates from 1999, in the town Frankfurt-Niederrad (Germany), where *H. axyridis* releases were made nearby in previous years for aphid control in roses (H. Bathon, personal communication, July 2007), and subsequently many records were made across West European countries (Brown et al. 2007a).

The earliest paper on potential negative side effects of *H. axyridis* dates from 1995 and is from North America (Coderre et al. 1995). Were the biological data about this predator at that time such that one could have concluded it was a highly risky species? To answer this question, we have searched the literature for information about the biology of *H. axyridis* and negative side effects. In the most recent review of the predator by Koch et al. (2006) we found quite a number of papers on *H. axyridis* published before 1995, but most of these concerned taxonomy, distribution patterns and use in biological control. An internet search using Google Scholar with the keywords *Harmonia axyridis* in the title of the paper and for the period before 1995 revealed more than 120 papers. When we combined the species name with risk(s), or nontarget we did not find any paper. As a control, we used risk(s) or nontarget in combination with biological control, and we always found several papers. A check of the more than 120 papers found with *H. axyridis* in the title and published before 1995 showed six papers that might contain information about potential risks. This literature search, together with the pre-1995 papers listed in Koch et al. (2006) and contact with some of the authors of papers resulted in the following information.

1. In a number of papers it is mentioned that *H. axyridis* is a large sized polyphagous predator and has a great reproductive capacity in comparison with other ladybird beetles
2. In some papers, not only the polyphagous habit is mentioned, but also prey species are listed indicating a wide prey range (Vasil'ev 1963; Hodek 1973; Iablokoff-Khnzorian 1982; Schanderl et al. 1985; McClure 1987)
3. In one paper, the need to explicitly study non-target effects because of the polyphagous habit of *H. axyridis* is mentioned (Coderre et al. 1995).

Based on this, we may conclude that the potential risk (climate matching and polyphagy, including attack of benficial insects) of *H. axyridis* was clear before the first releases were made in Northwest Europe. In retrospect, this information should have been sufficient to reject import and release of this species, but it was apparently ignored by those who considered release of this predator in Northwest Europe.

Interestingly, in 1996, a first application for commercial release of *H. axyridis* in Switzerland was submitted to the Swiss Pesticide Regulatory Authority, which is responsible for licensing pesticides and biological control agents. Based on information in the literature on origin, potential for establishment, host range and potential of spread, a license for commercial use was refused in January 1997. Other applications for commercial release in Switzerland submitted in later years were not approved for the same reasons. Despite the fact that the licence for commercialising *H. axyridis* was rejected by the Swiss authority, the insect had been commercialised and released in Switzerland before and during the submission process (e.g. Anonymous 1996). Thus, rejecting an application for release is not always sufficient to prevent release. In addition, *H. axyridis* has crossed the Swiss border and was first found there in 2006 (Eschen et al. 2007). *H. axyridis* has now spread over many regions in Switzerland and has established. When the EU funded project to develop the quantitative risk assessment method (see Section Environmental risk assessment of natural enemies) was initiated, we discussed risks of releasing exotic natural enemies with two specialists (Dr. B. Aukema and Ir. H. Stigter) of the Dutch Plant Protection Service. These specialists warned us for releases of *H. axyridis* and *H. convergens* based on their wide host range (Loomans, personal communication). These two cases show (1) the importance and urgent need of harmonized regulation of biological control agents in Europe, (2) the need of a generally accessible system which provides information on natural enemies that are considered safe or not safe for release in certain ecoregions of Europe, and (3) the requirement of a group of experts which can advise European bodies (e.g. EC, EPPO, EFSA) and national authorities about the risks of import and release of exotic natural enemies.

Discussion

In this paper environmental risk evaluation methods were summarized and applied to *H. axyridis*. Proposed methods of risk assessment gradually have shifted, coming from a descriptive, more qualitative framework, largely based on expert judgment in general (e.g. Hickson et al. 2000), via an overall qualitative and quantitative method (van Lenteren et al. 2003) to a stepwise evaluation procedure, using quantitative information when needed and where possible (Bigler et al. 2006; van Lenteren and Loomans 2006). This not only allows better insight into relevant ecological factors, but also constitutes a more objective approach for evaluating the risks of biological control agents. Methods to determine establishment, dispersal, host range, direct and indirect effects on non-target organisms are discussed in Babendreier et al. (2005) and Bigler et al. (2006). When we apply the most recent, stepwise risk assessment procedure to *H. axyridis*, we have to conclude that, based on current knowledge, (1) this predator is a potentially high risk species for Northwest Europe, (2) there are no easy and reliable ways to mitigate or reduce risk of releases of this predator, and (3) a risk/benefit analysis which includes a comparative performance of pest management methods would result in the advice not to release this predator. However, the predator has already been released, is established and is spreading rapidly (Brown et al. 2007a, b). The simple fact that regulation concerning import and release of exotic natural enemies does not exist in some countries and is not well organized in other countries has resulted in this problematic situation (Bigler et al. 2005). As a result, the topic of implementation of a registration procedure for natural enemies is currently hotly debated by the biological control industry, scientists and regulators (Blum et al. 2003; GreatRex 2003; Hokkanen 2003; van Lenteren et al. 2003, 2006a; Anonymous 2004; Bigler et al. 2005, 2006).

The biological control industry foresees lengthy, cumbersome procedures leading to high costs, and, thus, in some cases, the impossibility to marketing a potentially useful natural enemy because of too high costs. Such costs will strongly depend on the biological and ecological characteristics of a natural enemy. When dealing with a natural enemy that has a very narrow host range, testing and the preparation of a dossier can be limited to about six person months. However, preparation of a dossier for an exotic polyphagous natural enemy that is able to establish, such as *H. axyridis*, could take up to several years, particularly if experiments on dispersal and direct/indirect ecological effects are needed. We estimate that a comprehensive dossier can be appraised in up to six person weeks by governmental agencies. Based on the experience with classical biological control agents reviewed by peers, evaluations, however, take at least 6 months to complete (Sheppard et al. 2003).

Regulators within ministries of environment and agriculture want to prevent unnecessary and risky releases of exotic organisms, and their concerns have been triggered by the *Harmonia* case. Current activities in the field of regulation will hopefully result in a light and harmonized registration procedure that is not prohibitive for the biological control industry and will result in the pre-selection of safe natural enemies (see e.g. Bigler et al. 2005). A proposed quick scan method for organisms already in use (van Lenteren and Loomans 2006) should be considered as a kick-start from a situation with no regulations for the use of biological control agents, to one where import and release are regulated to ensure safe use. This quick scan method applied for Northwest Europe resulted in continuation of release of a large number of exotic species. Use of such a quick scan method results in the continuation of ongoing successful and safe biological control programmes, without the risk of returning to chemical control programmes. We estimate that preparation of a dossier for a quick scan will take two person weeks, and appraisal one to six person days per biological control agent. The end result of such a quick scan method applied in various countries may result in lists of species that can be used in certain, specified regions (ecoregions) of the world. These species will be exempted from a comprehensive environmental risk analysis. The availability of regularly updated 'white lists' might stimulate the application of biological control worldwide.

The case of *Harmonia* releases in Northwest Europe underlines once more that there is an urgent need for harmonized, Europe-wide (indeed global) regulation of biological control agents, including an information system on risky natural enemy species.

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