Non-target terrestrial arthropods in prospective environmental risk assessment for plant protection products

Specific protection goal options

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In 2015 the PPR Panel of the European Food Safety Authority (EFSA) published a scientific opinion on the state of the science on environmental risk assessment (ERA) for plant protection products and non-target terrestrial arthropods (EFSA PPR, 2015). An EFSA guidance document for prospective ERA of non-target terrestrial arthropods has not yet been developed since specific protection goals (SPGs) have to be defined in concert between risk assessors and risk managers and finally approved by EU risk managers. In this document, the prospective risk assessment procedures for pesticides and non-target terrestrial arthropods as currently used in the EU and in The Netherlands are described. In addition, a short overview of the recommendations in the EFSA scientific opinion on non-target terrestrial arthropods is given. Finally, four specific protection goal options for regulatory ERA for pesticides and non-target terrestrial arthropods are proposed. These options serve to facilitate discussions between risk assessors and risk managers and hopefully are helpful to risk managers in selecting the specific protection goal(s) that could form the basis for developing new EFSA/EU Member State guidance on tiered risk assessment for plant protection products and non-target terrestrial arthropods.

The current report has its focus on the environmental/ecological consequences of the specific protection goal options. Evaluation of the agronomic consequences of the proposed specific protection goal options needs further elaboration and research.

Keywords: non-target terrestrial arthropods, protection goals, pesticides, environmental risk assessment

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Samenvatting

Dit rapport is geschreven ter voorbereiding op de mogelijke herziening van de risicobeoordeling van gewasbeschermingsmiddelen voor niet-doelwit terrestrische arthropoden (anders dan bijen) door de European Food Safety Authority (EFSA). De nadruk van het rapport ligt bij mobiele arthropoden die boven de grond en op planten leven zoals bijvoorbeeld kevers, wespen, vlinders, vliegen, spinnen en mijten.

Het rapport geeft drie bouwstenen voor de milieurisicobeoordeling van niet-doelwit terrestrische arthropoden, i.e.:

i. de biologische/ ecologische context: wat zijn de specifieke biologische en ecologische eigenschappen van niet-doelwit terrestrische arthropoden en wat zijn die van het landelijk gebied welke in beschouwing genomen moeten worden in de beoordeling van milieurisico's van gewasbeschermingsmiddelen?

ii. de huidige ERA regelgeving en richtsnoeren: welke gegevens worden op dit moment gevraagd voor de risicobeoordeling? en wat houdt de huidige 'EFSA guidance' voor niet-doelwit arthropoden (anders dan bijen) in, in Europa en Nederland? en

iii. opties voor de definitie van specifieke beschermdoelen: welke opties zijn er voor het definiëren van specifieke beschermdoelen?

Dit rapport beschrijft vier specifieke opties voor het operationeel maken van het beschermdoel voor niet-doelwit terrestrische arthropoden. Deze opties kunnen als mogelijke bouwstenen gebruikt worden in de verdere ontwikkeling van EFSA richtsnoeren en kunnen handvatten bieden aan (inter)nationale beleidsmakers ten aanzien van welke mogelijkheden er zijn voor het beschermen van niet-doelwit arthopoden binnen de context van de toelating van gewasbeschermingsmiddelen.

De biologische/ ecologische context

Een goede milieurisicobeoordeling van niet-doelwit arthropoden is belangrijk voor het behoud van biodiversiteit in het landelijk gebied. Deze organismen leveren tevens ecosysteem diensten zoals ondersteuning van het voedselweb (zoals voor insect-etende vogels, amfibieën, reptielen en kleine zoogdieren), maar ook culturele ecosysteemdiensten (educatie, inspiratie) die worden geleverd door bijvoorbeeld beschermde niet-doelwit arthropoden zoals bepaalde vlinders. Daarnaast is het van belang dat er voldoende risico-reducerende maatregelen beschikbaar zijn die de vracht op het gewas en het veld verminderen en ook de blootstelling verlagen in gebieden naast het behandelde veld. Ecologische compensatie zones, zoals gewasvrije zones en bloemstroken, zijn verder nodig ter bescherming van niet-doelwit arthropoden.

ERA datavereisten en richtsnoeren

In hoofdstuk 3 van dit rapport worden de huidige data vereisten samengevat for de milieurisicobeoordeling van niet-doelwit arthropoden. Data vereisten van actieve stoffen zijn vastgelegd in EU regulation No 283/2013, die voor de geformuleerde producten in No 284/2013. Testen met twee test-organismen (*Aphidius rhopalosiphi* en *Typhlodromus pyri)* zijn vereist. Wanneer effecten boven een drempelwaarde worden aangetoond kunnen hogere trap studies worden gevraagd.

De huidige risicobeoordelingsprocedures staan beschreven in de SANCO richtsnoer voor terrestrische ecotoxicologie. Er wordt onderscheid gemaakt tussen in-field (in het veld) en off-field (buiten het veld) risico's. De procedures zijn in hoofdstuk 2 van dit rapport samengevat. Wanneer er additionele procedures vanuit de EU lidstaten beschikbaar waren is dit toegelicht. Zowel de datavereisten als het huidige richtsnoer kunnen als referentiekader dienen voor een mogelijk nieuw te ontwikkelen richtsnoer.

Specifieke beschermdoel definitie opties
Duidelijk gedefinieerde specifieke beschermdoelen (SPGs) zijn nodig voor een goede risicobeoordelingsmethodiek. SPGs worden gedefinieerd aan de hand van 5 zogenaamde dimensies, i.e. (1) ecologische entiteit zoals individu, populatie of functionele groep die beschermd moet worden, (2) eigenschappen van de ecologische entiteit die gemeten moeten worden, (3) de grootte van toelaatbare effecten, (4) de temporele schaal van toelaatbare effecten (5) de ruimtelijke schaal van toelaatbare effecten.

Bij elk van de beschreven opties is een link gelegd met de ecosysteemdiensten die van belang worden geacht. Het beschermingsniveau loopt daarbij op van optie 1 (huidige beschermniveau) tot optie 4 (hoog beschermniveau). Omdat de meeste niet-doelwit arthropoden mobiel zijn en een gebied bestrijken dat meerder individuele velden kan beslaan wordt de 'in-field' en 'off-field' risicobeoordeling gezamenlijk bekeken. Beleidsmakers kunnen een van deze opties kiezen op basis van het beschermingsniveau wat zij wenselijk dan wel haalbaar achten.

Deze vier beschermdoel opties zijn:

1. <u>'Status quo-SANCO 2002' SPG optie</u>
   Deze optie poogt het beschermingsniveau te handhaven zoals bedoeld in de huidige SANCO (2002) richtlijn. In deze optie kunnen populaties van niet-doelwit arthropoden in 'in-crop' habitats relatief grote effecten ondervinden van het gebruik van gewasbeschermingsmiddelen onder de conditie dat (i) deze populaties ook weer herstellen binnen hetzelfde groeiseizoen en dat (ii) functionele groepen die van belang zijn van biologische plaagbestrijding in het gewas alleen maar geringe effecten van kortdurende aard ondervinden.

   In de operationele akkerrand (edge-of-field strip; Figuur 4.1) moeten de effecten van lokale 'spray drift' en afspoeling (run-off) gering en kortdurend zijn zodat herstel snel op kan treden, terwijl in de 'off-field strip' (Figuur 4.1) effecten van directe blootstelling aan gewasbeschermingsmiddelen verwaarloosbaar klein moeten zijn. Zogenaamde 'actie op afstand', de impact van een middel op populatie dichtheden buiten het gebied van directe blootstelling, wordt hierin niet expliciet geëvalueerd. Tevens worden in deze optie de mogelijke indirecte effecten van het gebruik van gewasbeschermingsmiddelen op o.a. vogels en zoogdieren niet expliciet meegenomen. Als gevolg van een al dan niet tijdelijke maar kritische afname in voedselbeschikbaarheid in de vorm van arthropoden kan bijvoorbeeld de levensvatbaarheid van akkervogels in het gedrang komen.

2. <u>'Lokale Bescherming van nuttige arthropoden' SPG option</u>
   Deze optie beschouwt de ecosysteemdienst 'gewas productie', alsmede de ecosysteemdiensten 'plaagbestrijding' en 'bestuiving' die door terrestrische niet-doelwit arthropoden verzorgd worden, van het hoogste belang in het 'in-field' gebied. In deze optie is het beschermingsniveau voor 'beneficial arthropods' is strikter dan die van de 'status-quo SANCO 2002' optie. IPM praktijken worden geoptimaliseerd en laag-risicomiddelen (voor niet-doelwit arthropoden) gepromoot. In vergelijking met voorgaande optie worden in deze optie in behandelde velden stringentere drempelwaardes gehanteerd voor de acceptabele grootte en duur van effecten op met name 'beneficial' arthropoden. Voor een afdoende hoog beschermingsniveau in akkerrand (edge-of-field) habitats gaat deze optie ervanuit dat die wordt gerealiseerd als directe toxische effecten van blootstelling aan gewasbeschermingsmiddelen op populaties van niet-doelwit arthropoden hier verwaarloosbaar klein zijn.

   Ook in deze optie wordt 'actie op afstand', de impact van een middel op populatie dichtheden buiten het gebied van directe blootstelling, niet expliciet geëvalueerd. Tevens worden de mogelijke indirecte effecten van het gebruik van gewasbeschermingsmiddelen op andere populaties, bijvoorbeeld vogels, door mogelijke afname van voedselbeschikbaarheid in de vorm van arthropoden, niet meegenomen.

3. 'Lokale bescherming van agrobiodiversiteit (op gebied van niet-doelwit terrestrische arthropoden)' SPG optie
   Deze optie heeft met de voorgaande 'Lokale Bescherming van nuttige arthropoden' gemeen dat de onderliggende procedures gebaseerd zijn op lokale in-field en lokale off-field beoordelingen en dat een landschapsbenadering hier niet expliciet in meegenomen wordt. In deze optie mogen populaties van niet-doelwit arthropoden in 'in-crop' locaties slechts temporele effecten van gemiddelde aard ondervinden van het gebruik van gewasbeschermingsmiddelen als er tevens een duurzame lokale biodiversiteit wordt gefaciliteerd door tenminste 7% van de gronden behorende tot het agrarische bedrijf als ecologische compensatiegebied in te richten (wat in overeenstemming is met het Gemeenschappelijk Landbouw Beleid).

   Tevens tracht de 'Lokale bescherming van agrobiodiversiteit' optie om de agrobiodiversiteit te promoten door alleen verwaarloosbaar kleine directe toxische effecten (door spray-drift en/of run-off) te accepteren in 'off-field' locaties en zelfs in de akkerrand (edge-of-field strip; Figuur 4.1). Ook in deze optie wordt 'actie op afstand', de impact van een middel op populatie dichtheden buiten het gebied van directe blootstelling, niet expliciet geëvalueerd. Ook worden de mogelijke indirecte effecten van het gebruik van gewasbeschermingsmiddelen op andere populaties, bijvoorbeeld vogels, door mogelijke afname van voedselbeschikbaarheid, in de vorm van arthropoden, niet meegenomen. Er wordt echter aangenomen dat dit gecompenseerd wordt door het aanwezig zijn van de ecologische compensatie gebieden en de meer stringentere risicobeoordelingsprocedures waardoor lokale agrobiodiversiteit gepromoot wordt.

4. 'Bescherming van agrobiodiversiteit (op gebied van niet-doelwit terrestrische arthropoden) op lokale en landschapsschaal' SPG optie
   Deze optie is grotendeels gebaseerd op het voorstel in de EFSA opinie (2015) en heeft met de 'Lokale bescherming van agrobiodiversiteit' SPG optie gemeen dat ze niet alleen voorziet in de ecosysteemdiensten 'gewasproductie', 'plaagbestrijding' en 'bestuiving', maar ook voorziet in de ecosysteemdiensten 'ondersteuning voedsel web van insecten-etende vogel en zoogdieren' en 'bescherming van biodiversiteit voor educatieve, esthetische en beschermingsdoeleinden'.

   De 'Bescherming van agrobiodiversiteit op lokale en landschapsschaal' SPG optie wijkt echter van de drie voorgaande opties af omdat de onderliggende ERA procedures gebaseerd zijn op zowel lokale schaal en landschapsschaal. Deze laatste is nodig om het effect van 'actie op afstand', de impact van een middel op populatiedichtheden buiten het gebied van directe blootstelling, te kunnen evalueren op populaties van mobiele arthropoden. Dit om na te gaan dat deze populaties in onbehandelde gebieden door hun hoge mobiliteit in dichtheden afnemen door herkolonisatie van blootgestelde velden. In deze optie mogen individuele populaties van niet-doelwit organismen in 'in-crop' habitats temporele effecten van een gemiddelde grootte ondervinden onder voorwaarde dat de blootstelling in de akkerrand ('edge-of-field' habitat) geen significante directe toxische effecten tot gevolg heeft. Op landschapsschaal moeten de effecten op het voorkomen en de abundantie van populaties kwetsbare niet-doelwit arthropoden ook verwaarloosbaar klein zijn. Deze laatste voorwaarde verzekert ook dat populaties van insectenetende vogels en zoogdieren die afhankelijk zijn van niet-doelwit organismen als voedsel geen indirecte effecten zullen ondervinden ten gevolge van afname in voedselbeschikbaarheid.

Hoofdstuk 5 behandelt de elementen van de zogenaamde 'exposure assessment goals (ExAGs)' en 'effect assessment goals (EfAGs)' die nodig zijn om een geselecteerd SPG te waarborgen. ExAGs en EfAGs zijn de operationele verbinding tussen het SPG en de getrapte blootstelling- en effectbeoordelingsschema's.

Summary

This document anticipates on the possible revision of the risk assessment for non-target terrestrial arthropods other than bees by the European Food Safety Authority (EFSA), particularly on mobile arthropods that are living mostly above the ground and on plants.

This report aims to provide three building blocks for the environmental risk assessment of non-target terrestrial arthropods. These building blocks are:

i. the biological/ecological context: which specific biological and ecological properties of terrestrial non-target arthropods and agricultural landscapes should be considered in prospective ERA for pesticides?
ii. the current ERA regulation/guidance context: what are the current data requirements and which ERA guidance is available for non-target arthropods other than bees in Europe? and
iii. specific protection goal options: what are the possible options for specific protection goals?

This report describes four specific options for consideration to operationalize the protection goals for non-target terrestrial arthropods.

The building blocks feed into the EFSA guidance development process. Also, the presented specific protection goals may guide (Dutch) policy makers in understanding what options can be considered for the protection of non-target terrestrial arthropods within the context of the authorisation process of plant protection products.

Biological/ecological context
An appropriate ERA procedure for non-target arthropods is important for maintaining biodiversity in agricultural landscapes and for the role these organisms play in providing supporting ecosystem services such as food for organisms at higher trophic levels (e.g. insectivorous birds, amphibians, reptiles, small mammals) and in providing cultural ecosystem services (education, inspiration) such as the aesthetic value provided by species like butterflies and non-target arthropods with a conservation status. Beneficial arthropods provide key pollination services to crops and biocontrol of pest species.

In addition, there is a need for (i) sufficient risk mitigation measures to diminish pesticide loads in crops and to reduce exposure in off-crop areas, (ii) ecological compensation areas (e.g. beetle banks, crop-free buffer strips with perennial vegetation or annual flower strips) within agricultural fields.

ERA data requirements and guidance
In Chapter 3 a summary is given of the current data requirements in prospective ERA for terrestrial non-target arthropods. Data requirement for active substances and formulated products are defined in the EU regulation No 283/2013 and 284/2013, respectively. Studies with the Tier-1 indicator species (*Aphidius rhopalosiphi* and *Typhlodromus pyri*) are required. If adverse effects can be clearly predicted from these studies then testing using higher tier studies may be required.

Current risk assessment procedures are described in the SANCO guidance document on terrestrial ecotoxicology. A distinction is made between in-field and off-field ERA for non-target arthropods. In case further guidance is available from EU Member States and organizations concerned with ERA for non-target terrestrial arthropods, these were added as notes to the summary as given in Chapter 2.

Both the data requirements and guidance are summarized to be used as reference for the revision of the environmental risk assessment for non-target terrestrial arthropods.

Specific protection goal options
Well-defined specific protection goals are needed for a proper environmental risk assessment methodology. These specific protection goals are defined along 5 dimensions, i.e (1) Ecological entity to be protected, (2) Attribute to be protected, (3) Magnitude of tolerable effect, (4) Temporal scale of tolerable effect and (5) Spatial scale of tolerable effect.

Four specific protection goal (SPG) options are presented below with increasing protection level. The presented options are linked to ecosystem services that are considered of importance. The options provided should guide the risk managers in their definition of the specific protection goal.

Since most terrestrial non-target arthropods of agricultural landscapes are mobile organisms and their occurrence is not restricted to either in-field or off-field habitats, the defined SPGs are not presented separately but linked for in-field and off-field habitats.

The four SPG options proposed for consideration are as follows:

1. 'Status quo-SANCO 2002' SPG option
   This option is in line with the current SANCO guidance document. It assumes to provide sufficient protection to populations of terrestrial non-target arthropods when fully adopting the current data requirements and protection-level intended by the SANCO 2002 Terrestrial Guidance Document. In in-crop habitats populations of non-target arthropods may suffer relatively large effects of pesticide application under the condition that full recovery takes place within the growing season and functional groups that are essential for biocontrol of crop pests and/or pollination of the crop suffer small transient impacts only. In the operational edge-of-field strip (see Figure 5.1) the ecological effects of local spray drift and/or surface run-off should be relatively moderate and temporal in the sense that potential recovery should be relatively fast, while in the operational nearby off-field strip (see Figure 5.1) effects of direct exposure to pesticides should be negligible. 'Action at a distance' (= the impact of a pesticide on population densities outside the area of direct exposure) of in-crop and off-field impacts due to sink-source population dynamics, and consequently the impact on biodiversity in agricultural landscapes, is not explicitly evaluated. In addition, possible indirect effects of pesticide-use on wildlife populations (e.g. birds), due to the decline in non-target arthropods as food source, are not explicitly taken on board in the risk assessment procedure for non-target arthropods.

2. 'Local Protection of Beneficial Arthropods' SPG option
   This option considers the provisioning ecosystem service 'crop production' and the regulatory ecosystem services 'pest control' and 'pollination' provided by non-target arthropods as being of primary importance for in-field areas. The protection level of this option is stricter than that for the 'Status quo-SANCO 2002' option by supporting Integrated Pest Management (IPM) practices and promoting substances characterised by 'low risks' for beneficial arthropods. In treated fields that fall under an IPM regime stricter trigger values for the acceptable magnitude and duration of effects on beneficial non-target arthropods are anticipated. Selecting this SPG option assumes that a sufficient level of protection for non-target arthropods is reached if direct toxic effects on populations of non-target arthropods due to local pesticide exposure in edge-of-field habitats are negligible. Again, 'action at a distance' of in-crop and off-field impacts due to sink-source population dynamics, and, consequently, the impact on biodiversity in agricultural landscapes, is not explicitly evaluated. In addition, possible indirect effects on food-web support for birds and mammals, due to a pesticide-induced decline of non-target arthropods, is not explicitly taken on board in the risk assessment procedure for non-target arthropods.

3. 'Local Protection of Agrobiodiversity' SPG option
   This option has with the 'Local Protection of Beneficial Arthropods' option in common that the underlying ERA procedures are based on local in-field and local-off-field assessments and that landscape-scale ERA procedures are not explicitly taken on board. In this option, in in-crop habitats individual populations of non-target arthropods may maximally suffer pesticide-induced temporal effects of medium magnitude if ecological recovery and a sustainable local biodiversity is facilitated by the presence of at least 7% ecological compensation areas on farmland (in line with

Common Agricultural Policy proposal). In addition, the 'Local Protection of Agrobiodiversity' option aims to promote agrobiodiversity by only accepting negligible direct toxic effects of exposure to pesticides (due to spray drift and/or surface runoff) in off-field areas, even in the operational edge-of-field strip (Figure 5.1). 'Action at a distance' of in-crop impacts due to sink-source population dynamics of non-target arthropods in agricultural landscapes, as well as possible indirect effects of pesticide-use on wildlife populations (e.g. birds) caused by the pesticide-induced decline in non-target arthropods as food source, are not explicitly assessed in the risk assessment procedure. Nevertheless, it is assumed that the implementation of ecological compensation areas on farmland and/or the stricter risk assessment procedures will promote local agro-biodiversity.

4. <u>'Local and Landscape-scale Protection of Agrobiodiversity' SPG option</u>
   This option is largely based on the proposal by EFSA PPR (2015) and has with the 'Local Protection of Agrobiodiversity' option in common that it considers not only the provisioning ecosystem service 'crop production' and the regulatory ecosystem services 'pest control' and 'pollination' as being of importance, but also supporting ecosystem services like 'food-web support for insectivorous birds and mammals' and cultural ecosystem services like 'protection of biodiversity for educational, aesthetic and conservation purposes'. The 'Landscape-level Protection of Agrobiodiversity' option, however, deviates from the three other SPG options that the underlying ERA procedures are based on both local-scale and landscape-scale ERA assessments. A landscape-scale ERA is required to appropriately consider effects of 'action at a distance' of pesticide application due to source-sink phenomena of mobile (meta-)populations of non-target arthropods. In this option, in in-crop habitats individual populations of non-target arthropods may maximally suffer temporal effects of medium magnitude due to the pesticide treatment, as long as direct toxic effects of the exposure in edge-of-field habitats is negligible. At the landscape-scale the effects on the spatial occupancy and overall abundance of vulnerable non-target arthropods should be negligible as well. This latter requirement also secures that wildlife populations (e.g. birds and mammals) that depend on non-target arthropods as a food-source do not suffer indirect effects due to a pesticide-induced decline in abundance and biomass of non-target arthropods.

Exposure Assessment Goals (ExAGs) and Effect Assessment Goals (EfAGs) provide the operational link between the Specific Protection Goals (SPGs) selected and, respectively, the tiered exposure and effect assessment schemes used in environmental risk assessment. These are elaborated in Chapter 5.

1 Introduction

This document anticipates on the expected revision of the risk assessment for non-target terrestrial arthropods other than bees by the European Food Safety Authority (EFSA), particularly on mobile arthropods that are living mostly above the ground and on plants.

1.1 EU developments

(EFSA) is responsible for the development and revision of guidance documents for the assessment of environmental risks of the use of plant protection products at EU level. Because of the possible revision of the Guidance Document on Terrestrial Ecotoxicology (SANCO 2002), the PPR Panel of the European Food Safety Authority (EFSA) published five scientific opinions on the state of the science on risk assessment of plant protection products, i.e. for bees (EFSA PPR, 2012), non-target terrestrial plants (EFSA PPR, 2014a), non-target terrestrial arthropods (EFSA PPR 2015), soil organisms (EFSA PPR, 2017) and amphibians and reptiles (EFSA PPR, 2018). EFSA Scientific Opinions do not have the status of an official guidance document, but the information and recommendations provided can be used as building blocks to update the Guidance Document on Terrestrial Ecotoxicology (SANCO, 2002). Within this context, two EFSA guidance document for the risk assessment of plant protection products were already published, i.e, one guidance document on birds and mammals (2009) and one on bees (*Apis mellifera*, *Bombus* spp.) and solitary bees was published (EFSA, 2013). These document are currently under review. Similarly, possible EFSA guidance documents for non-target terrestrial plants, non-target terrestrial arthropods and soil organisms are anticipated in the near future.

1.2 Role and importance of non-target arthropods

Terrestrial non-target arthropods are taxonomically related to insect pests and consequently may suffer unintended side-effects of the agricultural use of pesticides, insecticides in particular. The naturally occurring non-target arthropods found in agricultural landscapes, however, are typically viewed as worthwhile to protect because of the ecosystem services they provide. Beneficial arthropods provide key pollination services to crops and biocontrol of pest species, with these ecosystem services provided on earth valued by Costanza et al. (1997) at $\$117 \times 10^9$ and $\$417 \times 10^9$ per year, respectively.

Traditionally, the focus of the risk assessment for terrestrial non-target organisms is on beneficial arthropods, determining the current lower-tier test organisms. The challenge for agriculture is to reduce crop losses due to pest species whilst still conserving key beneficial species providing ecosystem services. Protecting beneficial arthropods in in-crop areas and nearby off-crop habitats, and optimising their presence for pollination and biological control of pests, is one of the important tool boxes in agriculture (Birch et al., 2011).

Besides protecting beneficial arthropods, the importance of protecting non-target terrestrial arthropods in general is also stressed by the observation that not only in agricultural landscapes (e.g. Heydemann and Meyer, 1983; EFSA PPR, 2015) but even in protected areas biodiversity and biomass of insects show a decline (Potts et al. 2010; Van Swaay et al. 2013; Ollerton et al. 2014; Hallmann et al. 2017). It is suggested that intensification of agriculture in Europe, including pesticide-use, may have contributed to that. Also the decline of insectivorous birds in agricultural landscapes was associated with pesticide use (Hallmann et al. 2014; Goulson, 2014), indicating that the ecosystem service of food-web support by non-target arthropods is important for the sustainability of wildlife populations in agricultural landscapes.

1.3 Building blocks for ERA

This report provides three building blocks for the environmental risk assessment of non-target terrestrial arthropods, that are relevant for the guidance document which is foreseen by EFSA, i.e.:

i. setting the biological/ecological context: to describe the specific biological and ecological properties of terrestrial non-target arthropods and agricultural landscapes that should be considered in prospective ERA for pesticides,
ii. presenting the current ERA regulation/guidance context: to present an overview of the current data requirements and ERA guidance for non-target arthropods other than bees in Europe and as applied by the Ctgb, and
iii. identifying specific protection goal options for discussion with the EU and national risk managers: to present possible options for specific protection goals. Defined specific protection goals are the basis of the (to be developed) environmental risk assessment methodology.

The building blocks can feed into the EFSA guidance development process. Also, the presented specific protection goals may help (Dutch) risk managers and policy makers in understanding what options can be considered for the protection of non-target terrestrial arthropods.

A similar report was published dealing with protection goals in prospective ERA for plant protection products and arable weeds and non-target plants (Arts et al. 2017).

2 The problem formulation step in ERA for terrestrial non-target arthropods

2.1 Protecting and promoting non-target arthropods in agroecosystems

Environmental risk assessment (ERA) for terrestrial non-target arthropods is important for sustainable agriculture since this organism group contains beneficial arthropods, providing regulating ecosystem services such as pest control (e.g. provided by ground and foliage-dwelling beetles, parasitoid wasps, spiders, predatory mites) and pollination (e.g. besides bees provided by butterflies, flies and beetles) (Crowder and Jabbour, 2014; EFSA PPR, 2015; Huang et al. 2015; Wood et al. 2015; Birch et al. 2011; Landis, 2017; Fijen et al. 2018). In addition, ERA for non-target arthropods is important for maintaining biodiversity in agricultural landscapes and for the role these organisms play in providing supporting ecosystem services such as food for organisms at higher trophic levels (e.g. insectivorous birds, amphibians, reptiles, small mammals) and in providing cultural ecosystem services (education, inspiration) such as the aesthetic value provided by species like butterflies and non-target arthropods with a conservation status (EFSA PPR, 2015 and literature cited).

Populations of terrestrial non-target arthropods that (temporarily) dwell in agricultural fields and nearby off-field habitats may suffer exposure to pesticides. Prospective ERA for pesticides under the umbrella of Regulation 1107/2009/EC concerns the evaluation of the probability of adverse effects of exposure to a pesticide before its marketing, release or use. Consequently, prospective ERA generally is generic. The approach requires the definition of Specific Protection Goals (SPGs) and underlying Exposure Assessment Goals (ExAGs) and Effect Assessment Goals (EfAGs) to inform the exposure and effect assessment procedures, which usually consist of different tiers. So the ExAGs and EfAGs should be consistent with the Specific Protection Goals and provide the operational link between the SPGs, the formalised data requirements in legislation (see section 2) and all other (higher-tier) measurement endpoints and extrapolation tools that underlie the tiered exposure and effect assessment schemes implemented in ERA guidance documents. A tiered decision scheme as a whole needs to be (1) appropriately protective, (2) internally consistent, (3) cost effective and (4) address the problem with a higher degree of realism and complexity when going from lower to higher tiers. The results of the exposure and effect assessment is combined in a risk characterization that is used for decision making (Figure 2.1).

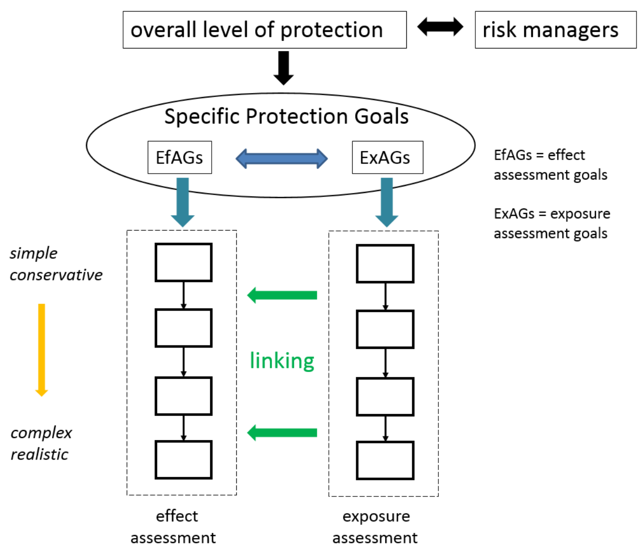

Figure 2.1 *Overview of the risk assessment of organisms based on parallel tiered effect and exposure assessments (after EFSA PPR, 2010, and Boesten, 2017).*

A prospective risk assessment procedure always follows a more or less reductionist approach by making use of scenarios and models to estimate environmental exposure and by adopting an effect assessment procedure based on ecotoxicity tests and extrapolation techniques (that may include computer models). In addition, for regulatory reasons pesticide registration is usually conducted for one chemical or formulated product at a time. Currently, the prospective ERA for non-target arthropods and individual active substances, or a formulated product containing more active ingredients, has its focus on both an in-field and an off-field assessment. Different protection goal options are selected for non-target arthropods in prospective ERA. The 'recovery' option is selected for in-field prospective ERA. The 'recovery' option permits some population-level effect on non-target arthropods in treated fields if ecological recovery occurs before the start of the next growing season. For off-field prospective ERA, however, the 'threshold option' is selected. Currently, after the normal agricultural use of a pesticide this option only permits an exposure level in nearby off-field habitats that will not cause relevant effects on non-target arthropods. This means that the current prospective ERA is restricted to a local in-field and off-field assessment.

Considering the fact that many terrestrial non-target arthropods are mobile and that their home-range is not restricted to single fields, and the fact that cumulative effects of multiple stressors at the landscape-level are not assessed in prospective ERA for pesticides it is well-recognised that prospective ERA in isolation is not sufficient to ensure an appropriate protection of populations of non-target organisms that provide ecosystem services valued by society and to protect the overall biodiversity at the landscape level (see e.g. EFSA SC, 2016a,b,c).

Because the management of total pesticide use in EU Member States does not fall under the scope of Regulation 1107/2009/EC, this regulation does not provide options and tools for this purpose. To address this apparent gap, Directive 2009/128/EC with a focus on the sustainable use of pesticides, was adopted. This Sustainable Use Directive requests the EU Member States to introduce National Action Plans while setting quantitative objectives, measures, and timelines to reduce pesticide risks for human health and the environment. Recently, a toolbox of risk mitigation measures for the agricultural use of pesticides was published as a result of two SETAC MAgPIE workshops (Alix et al. 2017). The latter publication aims to contribute to a better harmonization of the development and use of risk mitigation measures within Europe.

Directive 2009/128/EC forms an important risk management link between the prospective ERA for pesticides under Regulation 1107/2009/EC and the Common Agricultural Policy (CAP) of the European Union. Environmental benefits under the CAP may be achieved using the Cross Compliance mechanism, whereby farmers are encouraged (on voluntary basis) to fulfil certain environmental conditions in return for governmental support payments (Meyer et al. 2014). In the reform of the CAP it is proposed (under Pillar 1) that 3-5% of EU farmland should be managed as ecological focus areas in order to halt biodiversity loss, and that this area should be increased to 7% by 2017 (EC, 2013a). Such ecological focus areas could include land left fallow (land left unsown after being ploughed), buffer strips, hedge rows and off-field natural and semi-natural habitats managed by farmers. These areas should provide sufficient habitats for wild plant and animal species and should facilitate dispersal of species across the landscape (EC, 2010). According to Dollacker et al. (2019) these ecological focus areas could be implemented on less productive subfield areas, thus minimizing yield or farm profitability loss.

In the Netherlands about 66 thousand agricultural holdings manage about 20 thousand square kilometres of land, of which 92% is utilised as agricultural area. The remaining 8% is occupied by (semi-) natural habitats (e.g. hedgerows, banks of surface waters), stables and farmyards (CBS, 2015). Cormont et al. (2016) evaluated the CAP target on natural elements for the Netherlands. They assessed the effects of the density of natural elements in agricultural landscapes on multi-taxon species richness, including vascular plants, breeding birds, butterflies, hoverflies, dragonflies, and grasshoppers. They found that species richness increased either as linear (e.g. for vascular plants) or as a logarithmic function (e.g. for butterflies and birds) of the proportion of natural elements in the landscape. Dutch landscapes with 3-7% of natural elements harboured generally 37-75% of maximum species richness (Cormont et al. 2016).

It has been anticipated that reintroducing habitat diversity and complexity will help to reverse the adverse effects of intensive agriculture. A more diverse habitat mosaic can be introduced into the arable system by the addition of semi-permanent, non-cropped habitat features such as wildflower borders, grassy buffer strips etc. Although maintaining and restoring non-crop habitat in and around farm fields does not always promote biological control of pests (Karp et al. 2018), pollinator studies tend to report more consistently positive effects of the presence non-crop habitats (e.g. Kennedy et al. 2013; Fijen et al. 2018). In addition, Pywall et al. (2015) experimentally demonstrated for a 900 ha commercial arable farm in central England that wildlife-friendly management which supports ecosystem services is compatible with conventional crop yields. Their research suggests that in removing 3 to 8% of land at the field edge from production to create wildlife habitat, there would be no adverse impact of this measure on overall yield in terms of monetary value or nutritional energy over a 5-year crop rotation.

Considering the above, protecting populations of non-target arthropods and promoting their biodiversity in agroecosystems with an acceptable impact on crop yield not only needs (1) an appropriate prospective ERA procedure for pesticides based on clearly defined protection goals, but also requires that (2) sufficient risk mitigation measures are implemented to diminish pesticide loads in crops (e.g. by promoting IPM and precision application techniques) and to reduce exposure in off-crop areas (e.g. drift-reducing nozzles, buffer strips) and (3) that ecological compensation areas (e.g. beetle banks, crop-free buffer strips with perennial vegetation or annual flower strips) within agricultural fields are maintained and/or created, the latter in particular if off-field semi-natural and natural habitats are limited in the agricultural landscape.

2.2 Non-target terrestrial arthropods in agricultural landscapes and responses to pesticide stress

Heterogeneity and variability is a fundamental property of ecological systems and remains so in agro-ecosystems. Annual crops can temporarily provide mobile non-target arthropods suitable circumstances to dwell, in their search for food and shelter. Non-crop habitats can provide non-target arthropods that also dwell in crops (including pollinators and pest enemies) with supplemental food sources, nesting locations, and/or overwintering sites. Consequently, in prospective ERA for pesticides and mobile non-target arthropods it is necessary to consider spatial-temporal dynamics of both pesticide exposure and organisms in realistic agricultural landscapes (EFSA PPR, 2015; EFSA SC 2016b).

No single species of terrestrial non-target arthropod will be the most sensitive to all pesticides and no single population of a non-target arthropod will be the most vulnerable to all environmental stressors. According to EFSA PPR (2015) non-target arthropods display a multitude of traits regarding their life-history, behaviour and food and habitat requirements, influencing their vulnerability to chemical stressors like pesticides.

The vulnerability of populations of non-target arthropods to pesticide stress is determined by (also see De Lange et al. 2010; EFSA SC, 2016a&b):

- The chance to become exposed
  - Occurrence in agricultural fields at times of pesticide application (overspray)
  - Dwelling in habitats where pesticides accumulate (e.g. surfaces of crop plants and on soil beneath crop plants)
  - Consuming plant parts contaminated with pesticides
- The intrinsic sensitivity
  - Non-target arthropods are related to insect pests and consequently toxicologically sensitive to insecticides in particular
  - Some life-stages (e.g. small young individuals; moulting periods) are more sensitive to pesticide exposure than others
- Recovery potential
  - Ability of a perturbed population to return to its normal density/biomass in the undisturbed state
  - Dependent on proportion of survivors, species traits and landscape characteristics

- Susceptibility to indirect effect
  - Reduction of food (e.g. prey organisms affected by pesticides) and shelter (e.g. elimination of weeds by herbicides)
  - Pesticide-related shifts in species interaction within agro-ecosystems

After pesticide exposure has declined to non-toxic levels, the dynamics of impacted populations of non-target arthropods may be governed by internal and external recovery processes. Internal population recovery depends upon surviving individuals in the stressed ecosystem or upon a reservoir of resting propagules not affected by pesticides. External population recovery depends on the immigration of individuals from neighbouring areas to the impacted area by active or passive dispersal, and this redistribution may lead to 'action at a distance', that is, the impact of a pesticide on population densities outside the area of direct exposure (Spromberg et al. 1998; EFSA PPR, 2015; Topping et al. 2015; EFSA SC, 2016b). Population recovery is influenced by species' demographic traits (e.g. life span, number of generations per year, number of offspring) and recolonization traits (e.g. dispersal capacity, distribution patchiness, territorial behaviour) (e.g. Rubach et al. 2011; EFSA SC, 2016b).

External recovery potential of terrestrial arthropods is also affected by landscape characteristics such as fragmentation and complexity (EFSA SC, 2016b). A simulation study with the mobile carabid beetle *Bembidion lampros* (Topping et al. 2015) suggests that the larger the off-crop population is the more efficient is the buffering effect (external recovery) of the landscape. This simulation study also suggests that effects at the landscape-level may increase with multi-year application of a pesticide when recovery is not fully completed within a growing season.

It can be concluded from the information presented above that species traits, community and landscape properties, and exposure patterns together may determine the potential for populations of non-target arthropods to escape or cope with pesticide stress in space and time (see Figure 2.2). This figure also illustrates that the impacts of pesticide exposure on the sustainability of non-target arthropods is context-dependent and multifactorial (EFSA SC, 2016b; Brock et al. 2018).

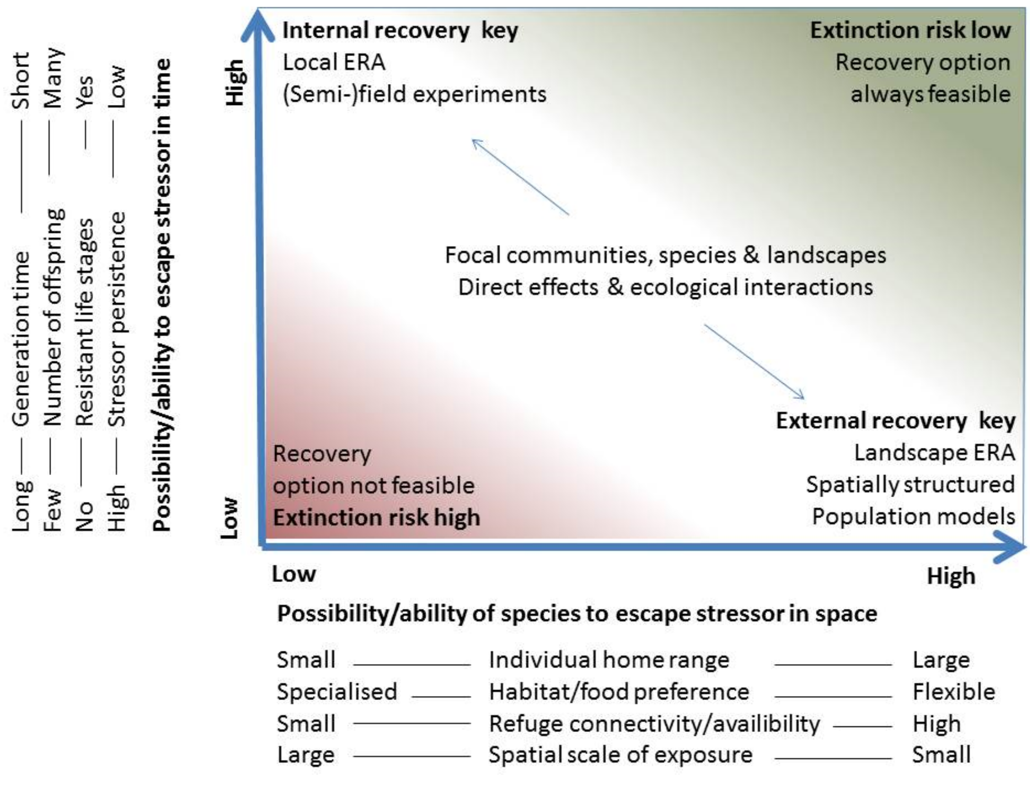

Figure 2.2 *Schematic illustration of the importance of species traits, landscape properties and exposure characteristics on extinction risk and internal and external recovery processes of non-target organisms in agricultural landscapes as well as the role of (semi-)field experiments and spatially structures population models to assess ecological recovery of stressed populations (from EFSA SC, 2016b).*

The complexity for an appropriate ERA of pesticides and the need to consider spatial-temporal phenomena has even resulted in a proposed ERA paradigm by Streissl et al. (2018). This ERA paradigm is based on integrating use patterns and pesticide properties with landscape eco-types and eco-regions, covering the variability of the European agro-environmental conditions by implementing a spatial explicit conceptual model, using the ecosystem services approach and vulnerable key driver species to represent the service providing units. According to Streissl et al. (2018), ideally the impact assessment should allow a proper ERA for each individual pesticide, impact comparison among alternatives, as well as aggregation of the risks for several pesticides used in crops and/or the same area. The proposal is to move from risk to impact assessment (including recovery potential at the landscape scale), aggregating the potential impacts of all intended/authorised uses.

To properly implement the proposed ERA paradigm of Streissl et al. (2018), detailed GIS information of landscape and watershed properties (including dynamics in agricultural land-use) is required. This information is essential to predict exposure concentrations of realistic pesticide applications in space and time as well as the responses of terrestrial and aquatic focal populations, communities and processes by means of spatial-explicit integrative models or model trains. Although data availability and technical capacity for handling ‘Big Data’ are no longer an unaffordable obstacle, linking pesticide marketing authorization with environmental impact assessment in European landscapes, largely is a research activity to date.

3 Current data requirements for prospective pesticide ERA and guidance for non-target arthropods

3.1 Data requirements in EU Commission Regulations

3.1.1 Introduction

In this section a concise overview will be presented of the data requirements mentioned in current EU Commission Regulations published in 2013.

3.1.2 Active substances: Commission Regulation (EU) No 283/2013 (EC, 2013b)

Circumstances in which required
Effects on non-target terrestrial arthropods shall be investigated for all active substances except where plant protection products containing the active substance are for exclusive use in (1) food storage in enclosed spaces that preclude exposure, (2) wound sealing and healing treatments, and (3) enclosed spaces with rodenticidal baits.

Toxicity tests with non-target arthropods
Two indicator species, the cereal aphid parasitoid *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) and the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) shall always be tested (Figure 3.1). Initial testing shall be performed using glass plates and mortality (and reproduction effects if assessed) shall be reported. Testing shall determine a rate-response relationship and LR50 (application rate that kills 50% of the tested individual), ER50 (application rate that causes an effect on 50% of the test individuals) and NOER (No Observed Effect application Rate) endpoints shall be reported for assessment of the risk to these species in accordance with the relevant risk quotient analysis. If adverse effects can be clearly predicted from these studies then testing using higher tier studies may be required (see point 10.3 of Part A of the Annex to the Regulation (EU) No 284/2013 for further details).

With active substances suspected of having a special mode of action (such as insect growth regulators, insect feeding inhibitors) additional tests involving sensitive life stages, special routes of uptake or other modifications, may be required by the national competent authorities. The rationale for the choice of the test species shall be provided.

Figure 3.1 *Tier-1 standard test species for plant protection products and non-target arthropods.*

3.1.3 Formulated plant protection products: Commission Regulation (EU) No 284/2013 (EC, 2013c)

Extended laboratory testing and aged residues studies with non-target arthropods
These tests focus on a realistic test substrate or exposure regime and are conducted with the formulated products.

The Tier-1 indicator species (*Aphidius rhopalosiphi* and *Typhlodromus pyri*) shall always be tested in the context of extended laboratory testing. In addition, where an in-field risk is indicated to one or both standard indicator species, testing of an additional species shall be required within the context of extended laboratory testing. Where an off-field risk to the standard indicator species is indicated, testing of one further additional species shall be required within the context of extended laboratory testing. These extended laboratory studies shall be carried out under controlled environmental conditions, by exposing laboratory-reared test organisms, or field collected specimens, to fresh and dried pesticide deposits applied to natural substrates, for example leaves, plants or natural soil under laboratory or field conditions.

An aged residue study shall be conducted with the most sensitive species to give information on the time scale needed for potential re-colonisation of treated in-field areas. They shall involve ageing of plant protection deposits under field conditions (use of rain protection may be advisable), with exposure of the test organisms on treated leaves or plants either in the laboratory, under semi-field conditions or a combination of both (such as mortality assessment under semi-field conditions and reproduction assessment under laboratory conditions).

> **Note**: The text above shows that aged-residue tests cannot be used for the off-field risk assessment. Further information on the conduct of standard and extended laboratory assays with terrestrial non-target arthropods can be found in Candolfi et al. (2000), DEFRA (2002) and Mead-Briggs et al. (2010).

Semi-field and field studies with non-target arthropods
These tests shall provide sufficient information to evaluate the risk of the formulated plant protection product for arthropods taking field conditions into account and may be required where effects are seen following laboratory testing with the requirements set out for the active ingredient (Commission Regulation (EU) No 283/2013; EC, 2013b) or the formulated plant protection product (Commission Regulation (EU) No 284/2013; EC, 2013c). The semi-field or field tests shall be conducted under representative agricultural conditions and in accordance with the recommendations for use, resulting in a realistic worst case exposure.

In the selection of species for semi-field testing, the results from lower tier testing as well as the specific questions to be addressed shall be taken into account. Testing shall include lethal and sub-lethal endpoints, but such endpoints shall be interpreted with care since they are subject to high variability.

Field trials shall allow the determination of short- and long-term effects on naturally occurring arthropod populations of a plant protection product following application in accordance with the proposed use pattern for the plant protection product under normal agricultural conditions.

Other routes of exposure for non-target arthropods
Where for particular arthropods other than bees (e.g. pollinators such as flies and butterflies and herbivores such as caterpillars) testing conducted in accordance with the methods described above is not appropriate, additional specific testing shall be required, where there are indications that exposure by routes other than by contact occur (e.g. plant protection products containing active substances with systemic activity).

3.2 Guidance Document on Terrestrial Ecotoxicology (SANCO, 2002) and guidance of EU Member States

3.2.1 Introduction

The risk assessment procedures described in the SANCO guidance document on terrestrial ecotoxicology (SANCO, 2002) largely follow the recommendations of the ESCORT 2 workshop (Candolfi et al. 2001). A distinction is made between in-field and off-field ERA for non-target arthropods. The more recent ESCORT 3 workshop (Alix et al. 2012) concluded that overall the guidance provided in ESCORT 2 is considered appropriate for the risk assessment of terrestrial non-target arthropods. They recommend, however, to include phytophagous species (e.g. caterpillars) in the off-field assessment in particular and to consider indirect effects on non-target arthropods by direct effects on non-target plants in the non-target plant evaluation (also see Arts et al. 2017).

In the sections below the guidance provided by SANCO (2002) is supplemented by notes containing information of further guidance provided by EU Member States and organizations concerned with ERA for non-target terrestrial arthropods.

3.2.2 Exposure assessment

Generally, exposure for non-target arthropods is expressed in terms of application rate (g/ha or ml/ha). For the Tier-1 assessment the following scenarios are used to describe the exposure in-field and off-field.

For both, the key input is the nominal field application rate supplemented by various factors:
- In-field exposure = application rate * MAF
- Off-field exposure = application rate * MAF * (drift factor / vegetation distribution factor)

MAF = multiple application factor = the ratio between the initial concentration after the last of several applications and the initial concentration after a single application. Drift factor = spray drift deposits expressed as % of nominal application rate in the field (= nominal application rate/100). For calculation of MAF values, definitions and further details is referred to ESCORT 2. In Tier-1, only single applications are tested. Multiple applications are simulated by applying a MAF to the single application rate. The MAF depends on the ratio between the half-life of the product, the spray interval and the number of applications.

> **Note**: According to EPPO (2003) for multiple application products where no information on residue accumulation or on the half-life of the product and the spray interval is available, a default MAF value of 3 may be used.

With regard to the vegetation distribution factor ESCORT 2 gives a default value of 10 as the 90th percentile drift values overestimate drift in vegetated areas. With regard to the drift factor the tables by Rautmann et al. (2001) or other appropriate (Members State specific) drift tables may be used; the standard assessment should be conducted for 1 m distance (arable crops) or 3 m (orchards and vineyards).
In higher-tier studies relevant exposure issues are considered in the study when establishing the dosing regime. That makes a separate exposure assessment unnecessary; it must, of course, be ensured that the study covers the use scenario under assessment.

> **Note**: According to Ctgb (2018), a NL-specific methodology deviating from the EU evaluation methodology is followed for the aspect arthropods as regards the estimation of off-field exposure. This concerns the use of national drift percentages as well a national system of drift-reducing measures. National drift figures can be applied on the basis of article 8f of the Bgd (Plant protection product and Biocides Decree). Ctgb bases the exposure assessment on average spray drift values determined by Van de Zande et al. (2012; 2017).

A major general change affecting the use of spray drift values in the assessment of plant protection products is the entry into force of the new Activity Decree (Activiteitenbesluit), per January 2018, including the introduction of drift reducing technology (DRT) classes. The standard requirement for field applications is the use of a 75% drift reducing technique (e.g. drift reducing nozzles) on the whole field.
For downward sprayed field crops (including downward sprayed forest trees and hedging plants, and flower bulbs) the amount of drift at 1 m from the centre of the last crop row (evaluation zone is 0.5 – 1,5 m) is assessed. It is possible to apply drift reducing techniques up to 99%. It is also possible to combine DRT classes with an additional crop-free zone. If an additional crop-free zone is chosen as a drift reduction measure, the width of the total crop-free zone must be determined (measured from the middle of the last crop row till the edge of the parcel). The standard crop-free zone is 1.5 m. Hence, in the case of an additional crop-free zone of 0.5 m the total crop-free zone will be 2.0 m.
For large fruit crops (pome- and stone fruit/top fruit) at least a 75% spray drift reduction technique in combination with a crop-free zone of 4.5 m is required, or a 90% spray drift reduction technique and a crop-free zone of 3 m. This means that for the dormant crop stage an off-crop drift% of 10.6% and for the full-leaf stage a value of 3.8% drift will be used as a starting point for the off-crop risk assessment.

Note: According to the '*Guidance document on work-sharing in the Northern zone in the authorisation of plant protection products, version 7.0*' (Anonymous, 2018), on the off-field risk assessment, in-field non-spray buffer zones of 5, 10, 15 and 20 m should be used if required (see Appendix 5 in Anonymous, 2018: List of mitigation options available in the Member States in the zone). If further mitigation (i.e. other than buffer zones) is needed, the risk assessment implementing nationally specific mitigation options (i.e. other than buffer zones) is needed, the risk assessment implementing nationally specific mitigation options should be presented in the national addenda.

Note: According to Ctgb (2016) in cases that only exposure of soil dwelling species is relevant (for example when a reasoned case is made that soil surface spiders are the most sensitive species), interception by the off-crop vegetation may be taken into account in the off-field risk assessment. For the time being the following interception percentages are applied – till better underpinned percentages come available – which are considered realistic worst-case:

- December – February: 20%
- March: 30%
- April: 40%
- May – September: 50%
- October: 40%

It should be noted that when these percentages are taken into account, the vegetation distribution factor cannot be used in the HQ-calculation (off-field).

Note: According to ESCORT 3 (Alix et al. 2012) different exposure routes should be considered during application (direct exposure by drift, indirect exposure to fresh residues on leaves, flowers, soil) and after application (exposure to (aged) residues on surfaces; systemic products in flower parts and pollen). ESCORT 3 also recommends that more research on effects of exposure to vapour drift and exposure to particles (dust) is required.

3.2.3 Standard Tier-1 testing

Standard Tier-1 testing comprises glass plate tests with *Aphidius rhopalosiphi* and *Typhlodromus pyri* (Figure 3.1). Preferably, these tests should be designed as rate-response studies in order to determine the LR50 (i.e. lethal rate that causes 50% mortality) as this allows for applying the data to different use scenarios and also to the risk assessment for off-crop areas. However, if the toxicity is expected to be low then limit tests can be conducted at a rate equivalent to the maximum application rate multiplied by the multiple application factor (MAF). For further explanation of the MAF see the *Exposure assessment section* above. With substances suspected to have a special mode of action (IGRs, insect feeding inhibitors) tests should include sub-lethal endpoints and may need other modifications.

Besides the two sensitive standard test species *Aphidius rhopalosiphi* and *Typhlodromus pyri* that are routinely tested, data may need to be provided for two other crop-relevant species.

> **Note**: According to Ctgb (2016) other crop-relevant species are: *Coccinella septempunctata, Orius laevigatus*, *Chrysoperla carnea* that dwell on plants and *Aleochara bilineata* that dwells on soil (Figure 3.2).
> For insect growth regulators (IGRs) and other plant protection products with a special mode of action the tests should be concentrated on those stages of non-target arthropods that are sensitive to the plant protection product in question (e.g. juvenile stages) while relevant absorption routes should be taken into account. Tests must be carried out with *Typhlodromus pyri* and one other species (e.g. the foliage dwelling predators *Coccinella septempunctata*, *Orius laevigatus* or *Chrysoperla carnea*).
> For products which are applied on (bare) soil, tests with several soil (surface) dwelling species are acceptable (e.g. *Hypoaspis aculeifer*, *Folsomia candida*, *Aleochara bilineata*, *Poecilus cupreus*, *Pardosa* sp.). For products that are applied into the soil (e.g. granules, seed dressings, baits) studies should be carried out with *Hypoaspis aculeifer* or *Folsomia candida,* and when considered suitable also with *Aleochara* (N.B. test compound should be mixed in soil) (Figure 3.3).

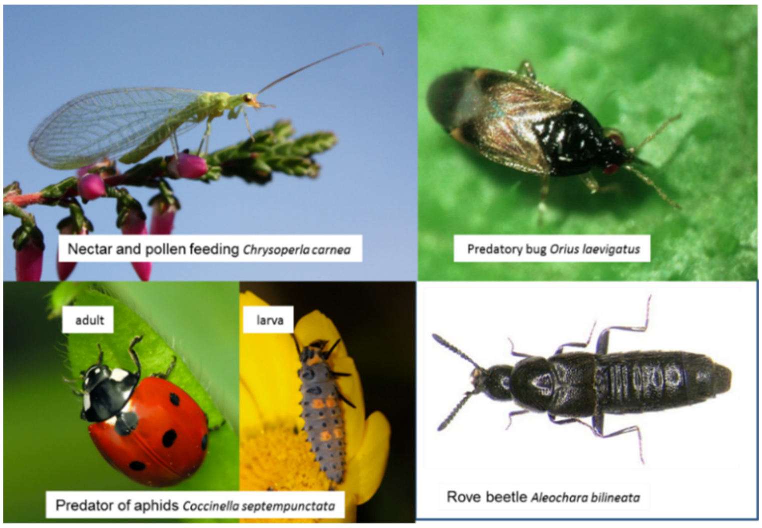

Figure 3.2 *Other crop-relevant additional test species of non-target arthropods.*

Figure 3.3 *Other non-target arthropods than Aleochara bilineata that may be used as test species for products that are applied into the soil or on bare soil.*

Note: A summary of some variable design factors in lower tier toxicity studies with non-target arthropods as provided by DEFRA (2007) is presented below in Table 3.1.

Table 3.1 *Variable design factors in lower tier toxicity studies with terrestrial non-target arthropods (DEFRA, 2007).*

Species	Life stage tested	Duration of mortality phase	Test temp °C	Substrate	Pesticide application
Aleochara bilineata	Adults	28 days (exposure phase)	20	Sand	Overspray organisms & food
Aphidius rhopalosiphi	Adults	48 hours	20	Glass	Dry residue
Chrysoperla carnea	1st instar larvae	Until emergence 4 – 6 weeks	25	Glass	Dry residue
Coccinella septempunctata	Larvae	Until emergence 4 – 6 weeks	25	Glass	Dry residue
Orius laevigatus	2nd instar nymphs	9 days	25	Glass	Dry residue
Pardosa spp.	Adults	14 days	20	Sand	Overspray organisms & food
Poecilus cupreus	Adults	14 days	20	Sand	Overspray organisms & food
Trichogramma cacoeciae	Adults	7 days	25	Glass	Dry residue

3.2.4 Higher-tier tests

Higher-tier tests are required when a risk is indicated in lower assessment tiers. These may include: (1) extended laboratory tests with natural substrate aiming at lethal and sub-lethal effects, (2) aged-residue studies, (3) semi-field tests, and (4) field tests.

Extended laboratory tests concern studies with a refined exposure design in which a natural substrate (i.e. leaf disks or natural soil or a whole plant) is sprayed and the toxicity is assessed on that substrate. Their design may take into account the dilution of exposure by vegetation.

Aged-residue tests concern studies in which spray residues are aged under laboratory or (semi-) field conditions. Subsequently, the time of ageing for the residues to cause effects below an acceptable threshold is determined. Aged residue-studies have the purpose of demonstrating the potential for recovery in-field.

Within the context of non-target arthropod testing, semi-field tests are single-species studies (cage experiments) with exposure under field conditions. For extended laboratory studies and semi-field studies, the 50% effect level is considered in the Hazard Quotient to estimate acceptable risks (both in-field and off-field). Semi-field studies usually involve the release of a single non-target arthropod species into a cage which encloses an area of the crop (arable crop) or part of the plant (fruit tree) grown under conditions as close to commercial practice as possible. In some semi-field methods, survivors may be returned to the laboratory for further studies, such as measuring reproductive rate. Generally, a toxic reference product should be included so that the ability of the trial to detect effects can be confirmed.

Field studies aim to study short- and long-term effects under normal agricultural conditions. In field trials, effects on populations rather than on individuals should be the tested endpoint. The effect on the population of a species including time to recolonization/recovery should be analysed by comparison with control plots. Field size varies, but typically is 25 x 25 m. Movement of species from and into the test plots is not excluded. For the interpretation of the results of field trials there is no fixed threshold (trigger) value for acceptability of effects, since recovery can be markedly different for different organisms and circumstances.

ESCORT 2 (Candolfi et al. 2001) and EPPO (2003) provide advice regarding the choice of studies and the selection and number of species. Usually these studies are conducted with one dose rate matching the field application rate taking into account multiple applications and the use of appropriate risk mitigation measures. In case of extended laboratory studies a dose response design may be more informative than a one-dose design.

> **Note**: According to Ctgb (2016), in in-crop field tests *Aphidius rhopalosiphi* and *Typhlodromus pyri* need not to be present in the crop of concern as long as a representative fauna for this crop is present. In-crop field studies are considered not acceptable to address off-crop risks. In off-crop field studies the non-target arthropod community should be representative for off-crop habitats in the Netherlands (e.g. meadow, hay field or agricultural verge). Studies conducted in e.g. Northern France and Germany are also considered representative for the Netherlands. Preferably a multi-dose rate (NOEC) design is used. Guidance on the evaluation of arthropod field studies can be found in De Jong et al. (2010).

> **Note**: According to ESCORT 3 (Alix et al. 2012) effects observed in field studies may be classified by using effect classes as proposed by De Jong et al. (2010) and these effect classes may be used to determine an acceptable effect.

> **Note**: According to the '*Guidance document on work-sharing in the Northern zone in the authorisation of plant protection products, version 7.0*' (Anonymous, 2018), the evaluation of field studies and the higher tier risk assessment should also be presented in the core assessment according to the guidance document of the Dutch Platform for the Assessment of Higher Tier Studies (De Jong et al. 2010). The interpretation of acceptability/representativeness of the field study for specific agricultural landscape(s) and protection goals should be done for each Member State.

3.2.5 In-field and off-field risk assessment for non-target arthropods

In-field ERA

The assessment of risk for arthropods living in-field and off-field is conducted separately. In the Tier-1 in-field assessment the risk is characterized by the in-field hazard quotient (HQ):

In-field HQ = in-field exposure / LR50

where the LR50 comes from glass-plate tests with the two standard species (see section 2.2.2 for definition of in-field exposure). **The criterion for an acceptable in-field risk is that the HQ value should be lower than 2 (or effects in limit tests <50%).** If the resulting in-field hazard quotient (HQ) is greater or equal to 2 for one or both test species then further data and/or risk management measures are required.

If no appropriate risk mitigation can be identified, then the notifier should carry out higher tier studies on the affected indicator species and **one further species** with different biology. Details of suitable species are provided in ESCORT 2. With regard to **extended laboratory tests and semi-field tests**, lethal and sub-lethal effects of less than 50% are considered acceptable (**so in-field HQ <1**) provided that the tests covered the appropriate field rate. For interpretation of aged residue studies with respect to recolonization, and for interpretation of field studies is referred to ESCORT 2 (Candolfi et al. 2001). Generally, it has to be demonstrated that there is a potential for recolonization / recovery at least within one year but preferably in a shorter period depending on the biology (seasonal pattern) of the species. The assessment may be based on field studies or other evidence (e.g. results of aged-residue studies, environmental fate information). In any case the data and assumptions should be fully justified.

> **Note**: According to Ctgb (2016), where also other species than *Aphidius rhopalosiphi* and *Typhlodromus pyri* have been tested in Tier-1 laboratory tests, these cannot be tested against the HQ trigger of 2 because this trigger has only been validated for the *Aphidius*

and *Typhlodromus*. The results of these tests will be assessed against the criterion of 50% effect (or HQ of 1, if LR50 and ER50 values are available).
When it concerns tests with the soil organisms *Hypoaspis aculeifer* and *Folsomia candida*, the NOEC (mg/kg soil) is the relevant endpoint. For risk assessment a safety factor of 5 is applied. In the case that artificial soil is used in the test, correction for the percentage of organic matter is necessary (if log Koc > 2).
If **in-field field studies** are available, Ctgb considers **Effect Class 6** or lower as described by De Jong et al. (2010) to assess whether recovery within one year can be demonstrated.

Off-field ERA
The Tier-1 risk is characterised by the off-field HQ:

Off-field HQ = (off-field exposure / LR50) * correction factor

where the LR50 comes from glass-plate tests with the two standard species (see section 2.2.2 for definition of off-field exposure); the correction factor is intended to cover remaining uncertainties, **the default value for the correction factor is 10**. If the **off-field HQ is less than 2** for both species, no further assessment is required, if greater than or equal to 2 for one or both species then either risk mitigation measures or higher-tier studies are called for.

If no appropriate risk mitigation can be identified, then higher tier studies on the affected indicator species and **two additional species** should be conducted. Details regarding suitable species are provided in ESCORT 2. With regard to extended laboratory tests and semi-field tests lethal, and sub-lethal effects of less than 50% are considered acceptable provided that the tests covered the appropriate field rate; **the default value for the correction factor is 5 (and off-field HQ <1 for acceptable risks)**. Generally, it has to be demonstrated that there is an acceptable potential for recovery within an ecologically relevant period.

Note: Ctgb (2016) mentions that under the new data requirements aged residue tests can no longer be used for the off-field risk assessment to demonstrate recovery potential. This means that for the off-field risk assessment, off-field field studies demonstrating no effects or actual recovery should be provided. Ctgb is of the opinion that the 'ecologically relevant period' should be very short, because the off-crop area is important for recolonization of species into the in-field area. Hence, a relatively undisturbed off-crop area is necessary to make recolonization possible.
Since clear guidance on the use in ERA of measurement endpoints from field tests is currently lacking, Ctgb follows the recommendations of ESCORT 3 (Alex et al. 2012) for the off-field risk assessment. When evaluating field studies for the off-field risk assessment Ctgb currently uses the no observed effect rate (NOER) for the community and the no observed ecologically adverse effect rate (NOEAER) for populations of non-target arthropods. The NOEAER considers effect of limited magnitude and duration. To further specify 'effects of limited magnitude and duration', Ctgb considers this to be 'slight and transient effects' (= **Effect Class 2** in De Jong et al., 2010 = Quantitatively restricted response of one or a few taxa and only observed on one sampling occasion).
The decision scheme for in-field and off-field ERA for non-target arthropods used by Ctgb (2016) is presented in Figure 3.4.

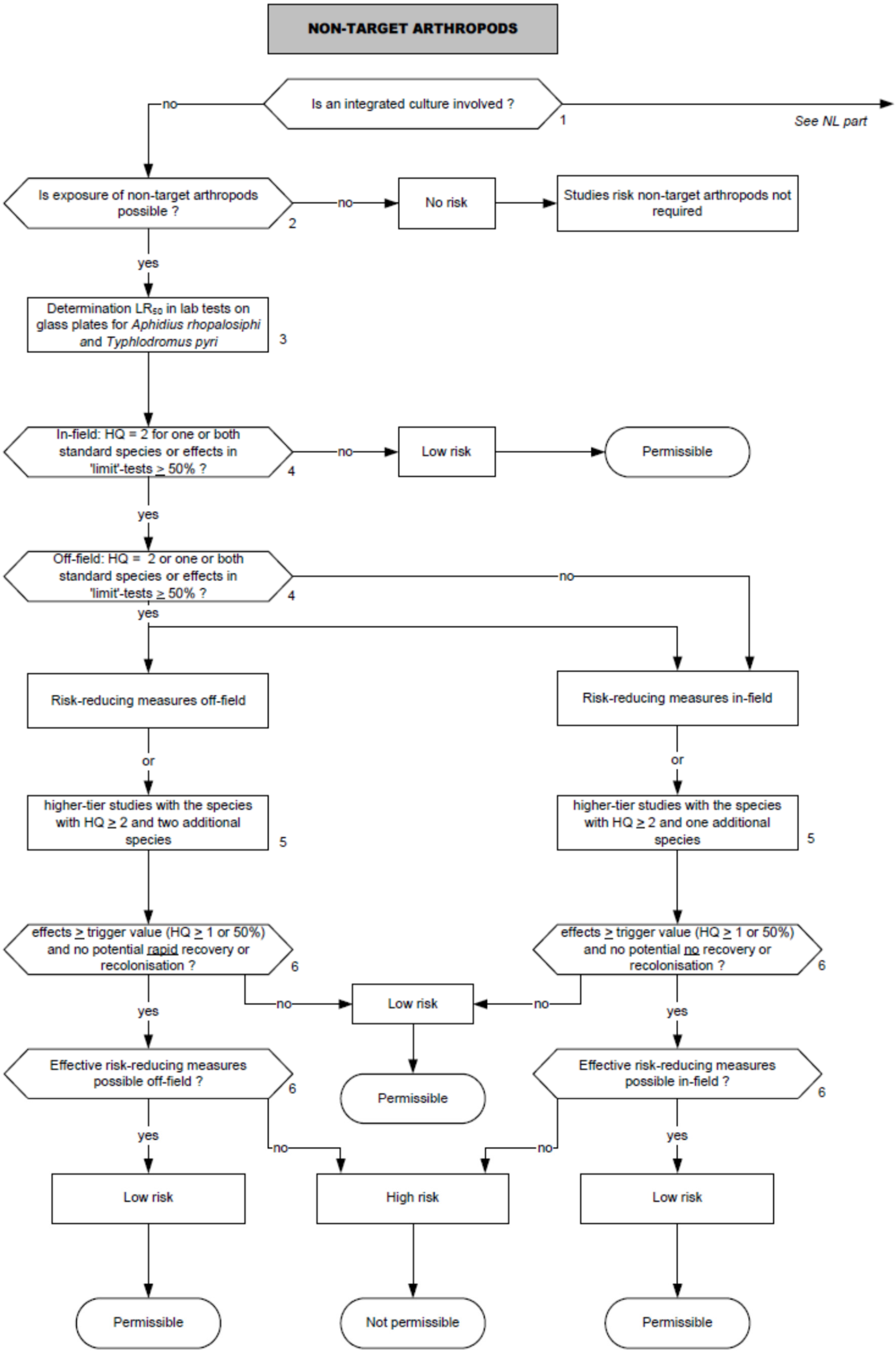

Figure 3.4 *Ctgb decision scheme to assess the in-field and off-field risk for non-target arthropods exposed to plant protection products. The figures next to the boxes refer to explanatory notes given in Ctgb (2016).*

3.2.6 ERA for non-target arthropods in Integrated Pest Management (IPM) systems

For in-field risk assessments, Ctgb (2016; 2018) makes a distinction between integrated (IPM) and non-integrated pest management systems. In the case of IPM systems natural enemies are deliberately brought into the cropping system to control pests and/or naturally occurring beneficial non-target arthropods need extra protection under an IPM regime. In the Netherlands IPM is often implemented in covered crops (greenhouse cultures). The decision scheme for IPM systems (Ctgb, 2018) is presented in Figure 3.5.

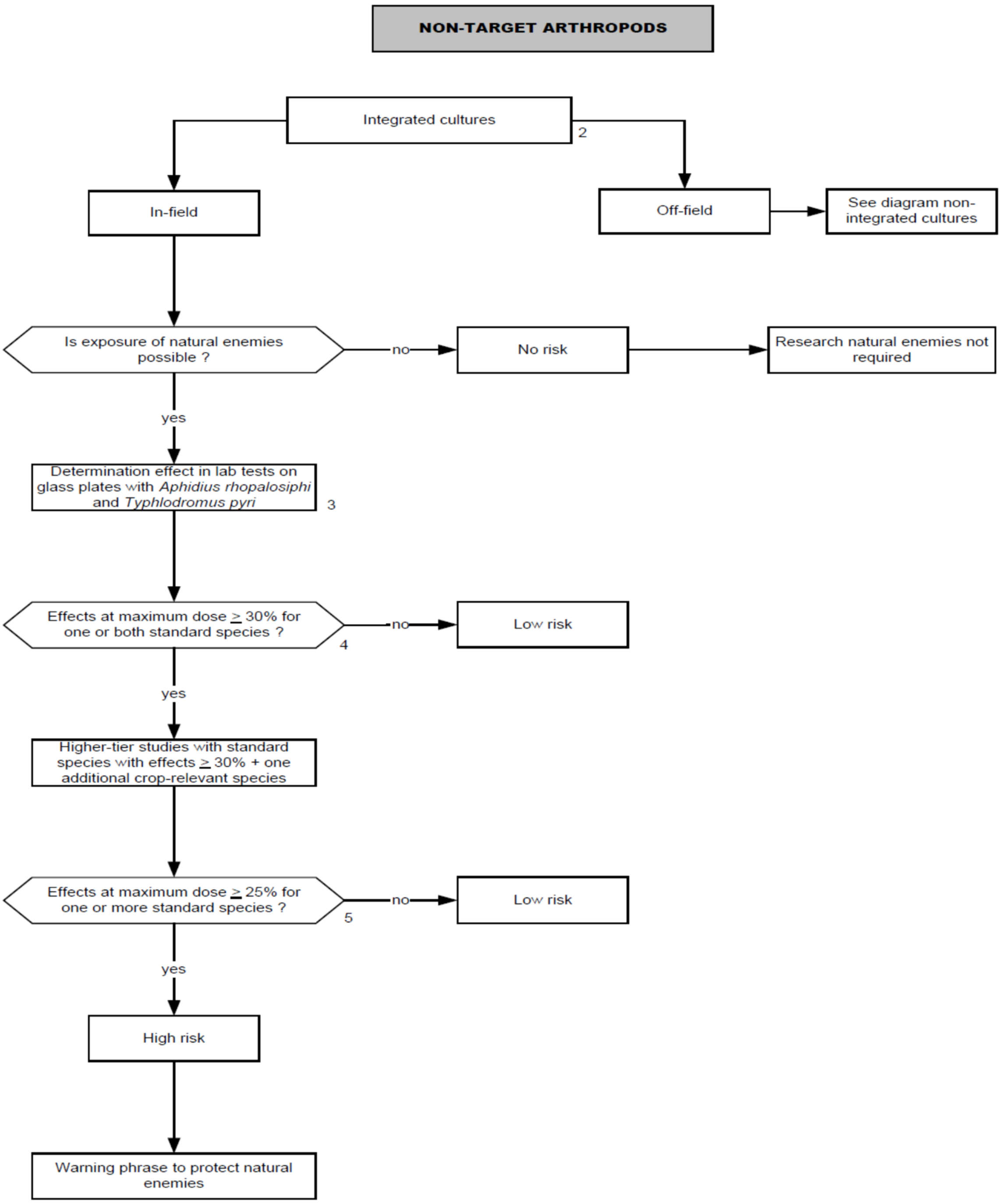

Figure 3.5 *Ctgb decision scheme to assess the in-field risk for non-target arthropods exposed to plant protection products in Integrated Pest Management (IPM) systems. The figures next to the boxes refer to explanatory notes given in Ctgb (2018).*

The main difference between the non-IPM and the IPM decision scheme is that the in-field exposure for the two Tier-1 standard species (*A. rhopalosiphi* and *T. pyri*) may be up to a level of two times the LR50 of these standard test species in the non-IPM scheme, while in the IPM scheme a maximum effect of 30% on one of the two standard test species is allowed. In addition, in semi-field studies with standard species a maximum effect < 50% is allowed on the most sensitive test species in the non-IPM scheme, while that is < 25% in the IPM scheme.

4 The EFSA scientific opinion on non-target terrestrial arthropods

4.1 Introduction

The EFSA Scientific Opinion on non-target arthropods (EFSA PPR, 2015) has not the status of an official guidance document, but the information and recommendations provided can be used as building blocks for future possible guidance.

4.2 Specific protection goal options

For the non-target terrestrial arthropods other than bees, specific protection goal (SPG) options were proposed by EFSA PPR (2015) more or less following the procedure described in EFSA PPR (2010) and Nienstedt et al. (2011).

4.2.1 Description of key driver taxa

EFSA PPR (2015) mentions the following non-target terrestrial arthropod taxa as example representatives of key drivers: Coleoptera (including the standard test species *Poecilus cupreus*, *Aleochara bilineata* and *Coccinella septempunctata*), Diptera (e.g. hoverflies), Heteroptera (including the standard test species *Orius laevigatus*), Neuroptera (including the standard test species *Chrysoperla carnea*), Hymenoptera (including the standard test species *Aphidius rhopalosiphi*), Acari (including the standard test species *Typhlodromus pyri* and *Hypoaspis aculeifer*) and Aranea (including the standard test species *Pardosa palustris*). Many key driver taxa can be linked to the ecosystem service pest control that is of particular importance for in-field assessments. For in-field and off-field assessments, however, more ecosystem services may be important (e.g. those related to providing food web support, pollination and cultural services) and these services may be provided not only by the taxonomic groups mentioned above but also by Lepidoptera (butterflies), Orthoptera (grasshoppers), Auchenorrhyncha (plant hoppers), Hemiptera (plant lice, particularly off-crop) and Collembola (including the standard test species *Folsomia candida*).

4.2.2 Specification of the specific protection goal options using 5 dimensions

Following the ecosystem services approach described in EFSA PPR (2010), the EFSA PPR (2015) scientific opinion selected the following SPG dimensions in defining specific protection goal options for terrestrial non-target arthropods, viz., (1) Ecological entity to be protected, (2) Attribute to be protected, (3) Magnitude of tolerable effect, (4) Temporal scale of tolerable effect and (5) Spatial scale of tolerable effect. In addition, in EFSA PPR (2015) a distinction is made between specific protection goal options for in-field (Table 4.1) and off-field habitats (Table 3.2).

It is proposed to accept in in-field habitats small (<35%) to medium size (< 65%) effects on abundance/biomass of populations or functional groups that do not last longer than months (for small effects) to weeks (for medium effects). This makes the proposed in-field effect assessment stricter than that described in the Guidance Document on Terrestrial Ecotoxicology (SANCO, 2002). Furthermore, EFSA PPR (2015) proposes to accept in edge-of-field (off-field) habitats negligible effects (≤ 10%) on abundance/biomass on populations of non-target arthropods due to direct overspray.

It is concluded that the in-field SPG and the off-field SPG cannot be defined independently since individuals of populations of mobile non-target arthropod taxa often have a home-range larger than treated fields so that ‘action at a distance’ can be expected in the sense that the treated in-field area may act as a sink by a redistribution of individuals between treated on non-treated habitats. The scientific opinion proposes to accept negligible population-level effects at the landscape-level considering the attributes abundance and occupancy.

Table 4.1 *Specific protection goal dimensions for critical key driver taxonomic groups in in-field habitats.*

Dimension	Option	Remark
Ecological entity	Populations to functional groups	Populations for cultural services including biodiversity. Functional groups for pest control, food web support and pollination
Attribute(s)	Abundance/ biomass	At the landscape scale spatial occupancy is mentioned as an important attribute as well.
Magnitude of effect	Small (> 10% - < 35%) to medium (>35% - <65%)	Small effects may be acceptable for longer periods than medium effects. According to EFSA PPR (2015) acceptable in-field effects at the landscape scale need to be defined.
Temporal scale	Small effects up to months Medium effects up to weeks	According to EFSA PPR (2015) acceptable in-field effects at the landscape scale need to be defined.
Spatial scale	In-field (local scale)	According to EFSA PPR (2015) acceptable in-field effects at the landscape scale need to be defined.

Table 3.2 *Specific protection goal dimensions for critical key driver taxonomic groups in off-field habitats.*

Dimension	Option	Remark
Ecological entity	Populations	
Attribute(s)	Abundance/ biomass	At the landscape scale spatial occupancy is mentioned as an important attribute as well.
Magnitude of effect	Edge-of-field: negligible (≤ 10%) effects that are directly caused by exposure in off-field habitat. Landscape scale: negligible (≤ 10%) effects on abundance and spatial occupancy.	At landscape scale the negligible effects on abundance and spatial occupancy also takes into account “action at a distance” (redistribution of individuals in the landscape after local reductions).
Temporal scale	Not relevant	Recovery is not an item for negligible effects
Spatial scale	Off-field (local scale and landscape scale)	Local scale effect assessments may concern the traditional experimental effect assessment approaches, while landscape level assessment require effect modelling approaches

4.3 Effect assessment recommendations by EFSA PPR (2015)

EFSA PPR (2015) recommends carrying out Tier-1 toxicity tests on at least four different species, chosen to represent different lifestyles and taxonomic groups. This recommendation includes an oral toxicity study with lepidopteran larvae to represent herbivorous non-target arthropods. Furthermore it is recommended that existing glass-plate protocol tests should be used to test effects on reproduction as well as mortality. As the majority of current test systems with leaf-dwelling non-target arthropods takes only exposure towards dry residues into account, EFSA PPR (2015) considers that the toxicity endpoints derived from tests with bees (fresh residues) could provide a possible surrogate for the overspray exposure route.

For local scale effect assessments, validated/calibrated assessment factors (AF) are required to extrapolate lower tier toxicity tests with non-target arthropods. Validated/calibrated AF may be based on statistical modelling of the relationships between lower tier assessments and higher tier studies.

For local off-field effect assessments, the species sensitivity distribution (SSD) conceptual model may be an appropriate higher tier, particularly when also considering chronic toxicity data if exposure is long-term. SSDs, however, do not incorporate recovery potential of non-target arthropods so that the SSD approach may not be appropriate as a surrogate reference tier for in-field effect assessments. According to EFSA PPR (2015) an appropriate surrogate reference tier may be a field study complemented with spatial-explicit population models for a number of species.

Field studies are important to investigate direct and indirect effects on communities under realistic field exposure situations. It is recommended to develop new field study protocols in order to address uncertainties and the statistical power of the test and to aid the consistent evaluation of field studies. Exposure via the relevant routes (e.g. dermal via overspray or indirectly via soil, or oral via leaves) should be measured in field studies in order to link exposure to effects.

For in-field ERA (recovery option) the effects, especially the time to recovery, observed in field studies using small plots can be misleading for mobile species that move in and out of plots during the course of the study. Since replicated landscape-scale studies are difficult to conduct, a possible compromise suggested is to carry out a field study with a limited number of large plots in combination with a larger number of small plots. In addition, it is suggested that modelling is a useful tool to extrapolate effects observed in small plots to larger landscapes. Modelling and field studies are complementary for assessment of recovery of non-target arthropods. Field studies can provide information on the magnitude of effects at the community level, including indirect effects, while modelling can be used to investigate effects for selected indicator species of non-target arthropods in different landscape scenarios, including source-sink dynamics, effects under different climatic conditions and the impact of standard agricultural management practices.

It is recommended that such modelling follows the EFSA Scientific Opinion on Good Modelling Practice (EFSA PPR, 2014b). EFSA PPR (2015) states that the number of non-target arthropod species for which useful models are currently available is very limited and it is recommended that this be expanded further in order to cover vulnerable representatives of the key drivers identified for the non-target arthropods in the specific protection goal options. In addition these models require the development of environmental scenarios based on the selected focal taxa and focal landscapes. This largely is a regulatory research activity to date.

To ensure that effects in-field do not have unacceptable effects on mobile non-target arthropod populations off-field and biodiversity in the agricultural landscape, it is proposed that always a landscape-level risk assessment is conducted in addition to the local-scale assessment. Such a landscape-level risk assessment could be done with population models and environmental scenarios representative for different agricultural landscapes. The local-scale risk assessment only is considered sufficient to address impacts on species with a very limited mobility. The proposed scheme to assess the risk for non-target arthropods exposed to active substances and their formulated plant protection products is presented below (Figure 4.1).

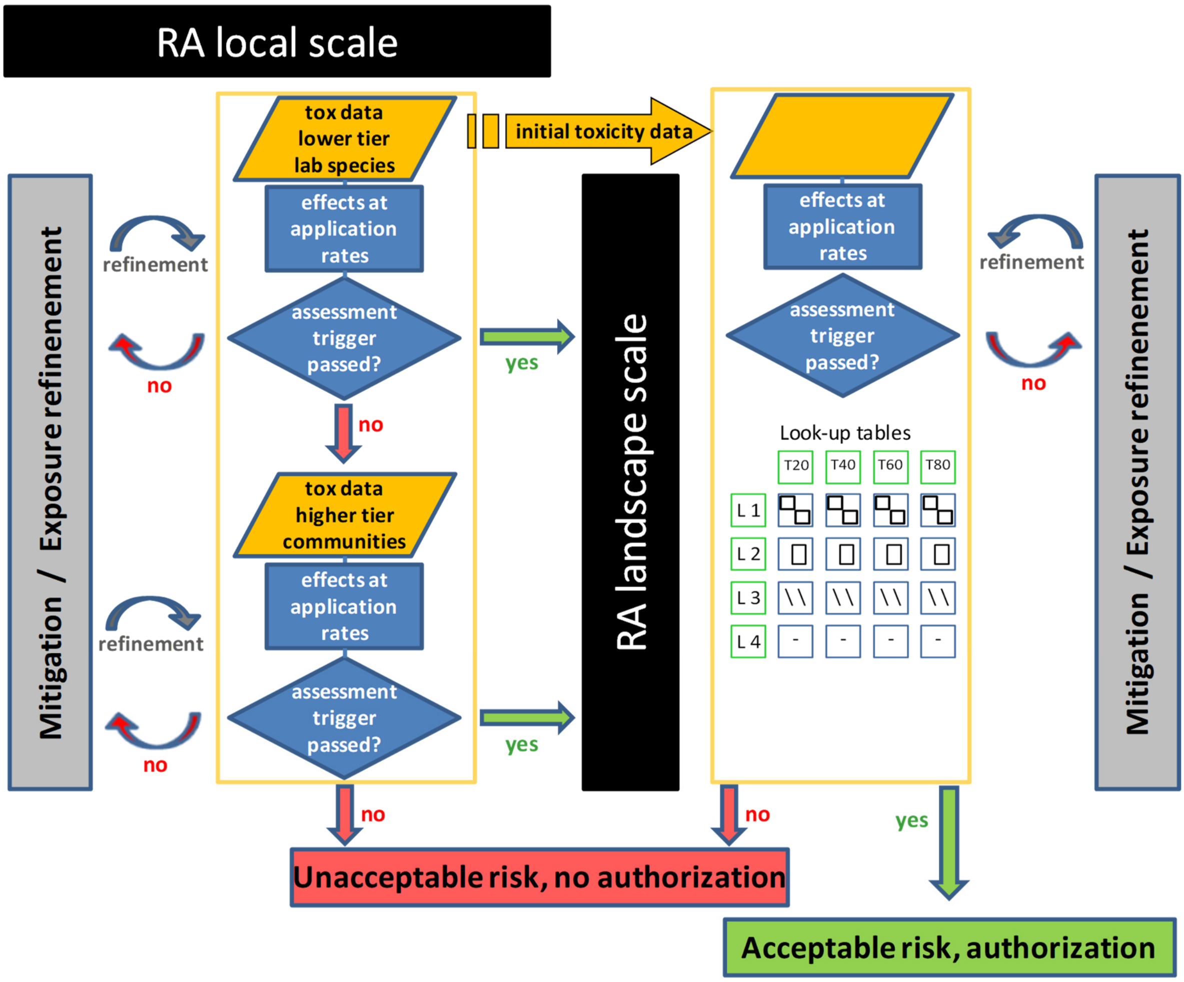

Figure 4.1 *Decision scheme proposed by EFSA PPR (2015) to assess the risk for non-target arthropods exposed to active substances and their formulated plant protection products.*

From the description above it appears that the effect assessment recommendations by EFSA PPR (2015) to appropriately translate the SPGs in regulatory effect assessment schemes are described in general terms and as a research activity only. For example, to appropriately link exposure to effects a clear definition of the Ecotoxicologically Relevant Concentration (ERC) or Ecotoxicologically Relevant Exposure Quantity (EREQ) for both contact and oral exposure is required. Data bases to validate/calibrate the AFs in the different effect assessment tiers are not yet in place. A final choice in focal vulnerable non-target arthropods for different parts of Europe for which population models should be developed, is not yet made. This also is the case for the selection of environmental scenarios required to run the population models for the landscape-scale ERA.

4.4 Exposure assessment recommendations by EFSA PPR (2015)

Assessing the following in-field and off-field exposure routes are recommended by EFSA PPR (2015):
- Contact to dried and fresh residues on plant surfaces and soil
- Contact exposure due to direct overspray
- Oral exposure (ingestion of contaminated food).

Currently, available exposure data in the effect assessment tests hardly distinguish between the various exposure routes and the exposure is then to be seen as lumped over the routes, considered in the tests.

In practise it may be difficult to distinguish between the different exposure routes because of lack of suitable data. As mentioned above a clear definition of the required ERC or EREQ in the ERA for non-target arthropods is missing and currently the application dose-rate is used as a surrogate to link exposure to effects in the risk assessment schemes. In order to improve the risk assessment it needs to be established what the ERCs/EREQs are in both the exposure and effect assessment. This also requires that exposure concentrations/quantities are measures in ecotoxicity studies with non-target arthropods, which currently is not done routinely.

Rather high uncertainties still exist about processes influencing exposure, both in-field and off-field, for example wash-off. Different sets of factors may need to be developed for the risk assessment of soil-dwelling and leaf-dwelling non-target arthropods. The uptake process on leaves need to be understood better for more realistic exposure estimates.

For deposition of drift and dust and exchange of air-borne substances with receptor surfaces, several datasets exist. These datasets should be combined in order to produce harmonised approaches (e.g. drift curves).

Residue Unit Dose (RUD) values could be used to estimate oral exposure of non-target arthropods. RUD data are contents of Plant Protection Product (PPP) residues in food and feed items, harmonised to a PPP treatment with a unit dose. RUD values are usually determined immediately after the application event on food/feed items collected from the treated field, except for food/feed items that need time to establish an incipient concentration. In these latter cases, the highest concentration over time may be taken. The current list of RUD values used in ERA for PPPs for items on which non-target arthropods feed (e.g. plant leaves, nectar, pollen, insects etc.) should be extended.

RUD values for insects could potentially provide a first tier estimate for exposure of non-target arthropods from overspray and contact to fresh residues on plants and soil surfaces.

It should be investigated whether RUD values can be used to verify estimates of exposure modelling. It is recommended to investigate whether the underlying residue data justify the use of RUDs as a conservative estimate of oral, contact and overspray exposure of non-target arthropods.

As neither the implicit dilution of exposure in field studies via vegetation distribution nor the actual ERCs/EREQs of tested non-target arthropods was considered when calibrating current ERAs for non-target arthropods, it is recommended to stop using the Vegetation Distribution Factor (VDF) as a refinement of off-field exposure.

It is recommended that dynamic exposure modelling is used to link effect assessment of mobile non-target arthropods to changing patterns of exposure in space and time at the landscape scale. This should include exposure distribution and more realistically should address temporal issues related to co-occurrence of non-target arthropods and pesticide-stress. Dose-response information should be integrated in such modelling.

5 Options for specific protection goals for non-target arthropods

5.1 Definitions

This section describes specific protection goal (SPG) options for non-target arthropods in prospective ERA. In defining specific protection goals (SPGs) for non-target arthropods it is important to have clear definitions of terms like field margin, edge-of-field, in-field area, off-field area etc. Definitions of these terms are given below, in accordance with the definitions given in the SPG document for arable weeds and non-target plants by Arts et al. (2017). How the different areas relate to each other is visualised in Figure 5.1.

In-field area: The crop area and its boundaries (e.g. minimum agronomic crop-free zone, buffer strip, ecological compensation area such as areas sown with seed mixes to encourage flowering plants, flower visiting insects and food for birds) owned and/or managed by a specific farmer in the context of crop management.

Off-field area: The area outside the managed 'in-field' area. It can encompass neighbouring fields where other crops are grown as well as semi-natural (e.g. drainage ditches, hedge rows) and natural (e.g. patches of woodland) habitats.

Field margin: The border between the in-field and off-field area.

Edge-of-field area: The off-field area between the in-field area and the nearby off-field area. The *field margin* is its inner border while the boundary between the *edge-of-field* area and the *nearby off-field* area is its outer border (see Figure 5.1).

Operational edge-of-field strip: The off-field strip that starts at the *field margin* and where the protection levels apply for non-target terrestrial arthropods in edge-of-field habitats.

Nearby off-field area: The off-field area further away from the treated field and that borders the *edge-of-field area*.

Operational nearby off-field strip: A strip of nearby off-field area that starts at the outer border of the edge-of-field area and where the protection level applies for non-target terrestrial arthropods in the *nearby off-field area*.

In-crop area: In-field area used by the farmer to grow a specific crop. It concerns both the surface covered by the crop plants including the space between the crop rows.

Off-crop area: Off-field area as well as in-field area not used by the farmer to grow a specific crop.

Crop-free buffer strip: Non-cropped in-field area between field margin and minimum agronomic crop-free zone. A non-cropped buffer strip may consist of bare soil or vegetation other than the crop. In the Netherlands a buffer strip should always be crop-free.

Cropped buffer strip: In-field area where the crop is present but that is not sprayed and is located between the sprayed crop and the minimum agronomic crop-free strip.

Conservation headlands and wildlife strips: In-field ecological compensation area along the edge or at the corners of an agricultural field that aim to promote biodiversity (e.g. flowering weeds, insects, birds). These in-field ecological compensation areas usually are part of environmental stewardship schemes. These areas usually are not directly sprayed and this may serve as buffer strip to minimise exposure of off-field habitats. The farmer may be financially compensated for creating these ecological compensation areas.

Minimum agronomic crop-free strip: Because of the use of machinery (e.g. ploughs, tractors, spraying machines) there will always be a certain distance between the field margin and the area of the field that is directly accessible by the machinery. This distance is called the minimum agronomic crop-free strip. According to Van de Zande et al. (2012) the width of the minimum agronomic crop-free strip is 0.25 m for grass and cereals, 0.75 m for crops grown on ridges, 3 m for orchards, 2 m for avenue trees and 0.5 m for all other arable crops.

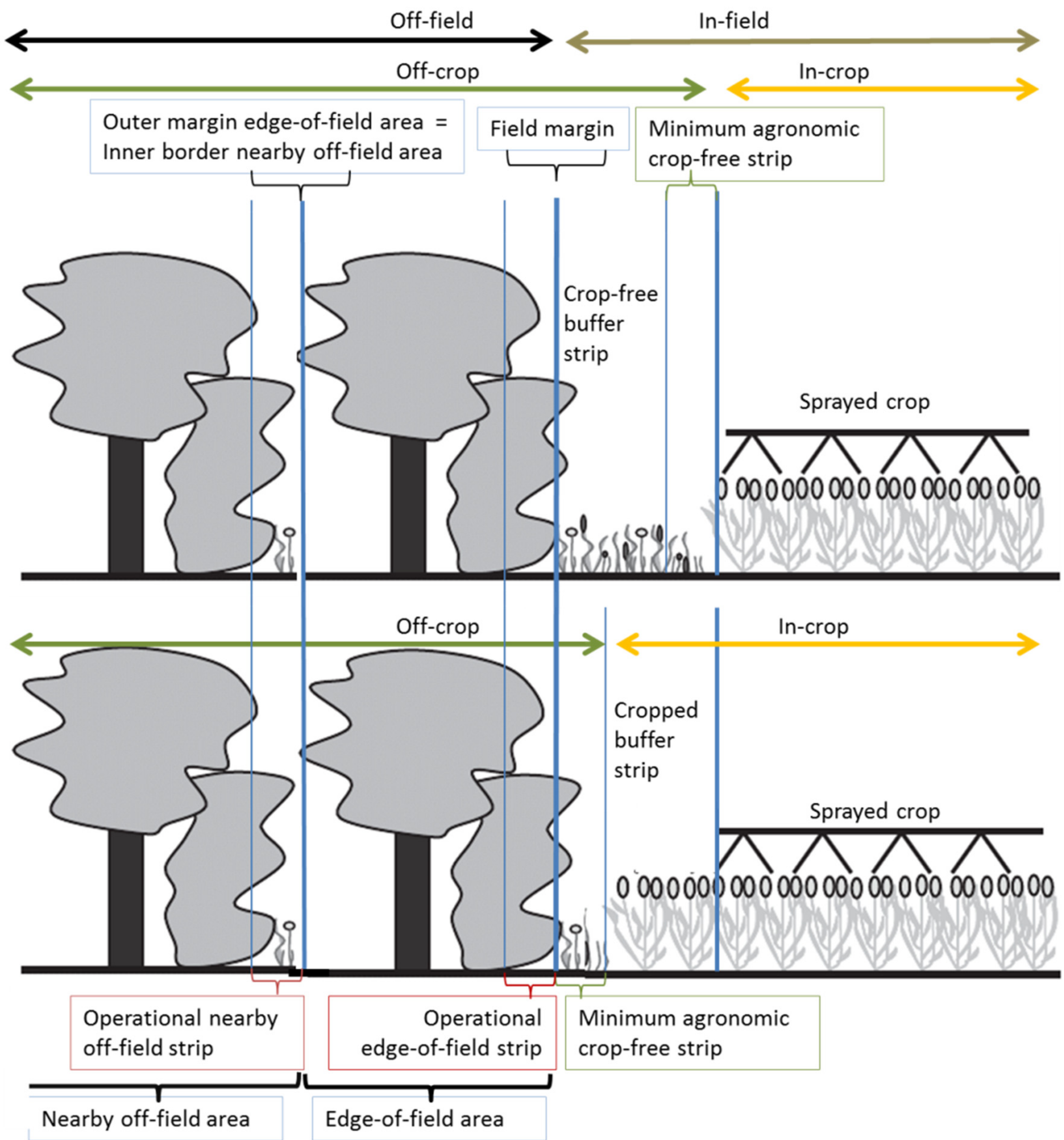

Figure 5.1 *Schematic representation of a crop (in-crop area) bordered by at least an in-field minimum agronomic crop-free strip and an off-field woodland habitat (lower part of Figure 5.1) or an in-field minimum agronomic crop-free strip, a crop-free buffer strip and an off-field woodland habitat (upper part of Figure 5.1). Note that in the Netherlands a crop-free buffer strip is mandatory. Figure adapted after Alix et al. (2012) and Van de Zande et al. (2012).*

In the upper part of Figure 5.1 the off-crop but in-field area comprises a crop-free buffer strip (management option selected by the farmer to minimise spray drift exposure in off-field habitats) and a minimum agronomic crop-free zone that is obligatory. The sum of the widths of the crop-free buffer strip and the minimum agronomic crop-free zone is the total in-field zone not directly sprayed. In some EU Member States, but not in the Netherlands, it is possible to use an unsprayed cropped buffer strip to minimise spray drift exposure in off-field habitats (lower part of Figure 5.1). Although in Figure 5.1 the off-field area comprises trees and shrubs, the off-field area may be diverse comprising fields with other crops, drainage ditches, herbaceous vegetation etc.

Important definitions of abbreviations used in this report to describe specific protection goals and related exposure and effect assessment goals for non-target arthropods are presented below:

AF:	Assessment Factor
EfAG:	Effect Assessment Goal
ExAG:	Exposure Assessment Goal
ERA:	Environmental Risk Assessment
ERC:	Ecotoxicologically Relevant Concentration
EREQ:	Ecotoxicologically Relevant Exposure Quantity
ER50:	(Sub-lethal) Effect Rate for 50% of the test organisms
ES:	Ecosystem Services
HQ:	Hazard Quotient
IPM:	Integrated Pest Management
LR50:	Lethal Rate for 50% of test organisms
MDD:	Minimum Detectable Difference
NOEC:	No Observed Effect Concentration
NOER:	No Observed Effect Rate
PEC:	Predicted Environmental Concentration
PEQ:	Predicted Environmental exposure Quantity
PPP:	Plant Protection Product
RAC:	Regulatory Acceptable Concentration
RAQ:	Regulatory Acceptable exposure Quantity
SPG:	Specific Protection Goal
SPU:	Service Providing Unit
SU:	Spatial Unit

5.2 Introduction to SPGs

Before developing regulatory guidance for assessing the environmental risks of pesticide exposure on non-target terrestrial arthropods, options for SPGs have to be defined. Ideally, the definition of SPGs, requires a dialogue between risk assessor and risk managers (e.g. those of SCoPAFF, the Standing Committee on Plants, Animals, Food and Feed, in which risk managers of EU Member States are represented).

In the problem formulation phase of the ERA for non-target arthropods, the responsibility of risk assessors is (i) to acknowledge existing general protection goals and regulatory data requirements, (ii) to propose possible SPG options, and (iii) to describe the possible environmental consequences of each option. The risk assessors should present the SPG options in a concise and transparent manner, understandable for all stakeholders involved. What is a tolerable level of risk to non-target arthropods, and whether a plant protection product can be placed on the market for a specific use, is decided by risk managers (EFSA PPR, 2010; EFSA SC, 2016c). A transparent dialogue not only will assist risk managers to make more informed decisions on (agronomic and economic) trade-offs, but will also help risk assessors to focus their efforts on the development of environmental risk assessment schemes that address the level of protection required by risk managers. According to Selck et al. (2017) policy decisions should be made by risk managers with the democratic mandate to make such decisions and decision makers must be held responsible for their policy decisions should they differ from consensus opinion. The scientific reliability of the decision schemes that underlie the selected SPGs, however, is the responsibility of the risk assessors that develop ERA guidance.

In the definition of SPG options EFSA has adopted the Ecosystem Services (ES) approach (see EFSA PPR, 2010; EFSA SC, 2016c). ES provide an integrative approach to environmental and social impact assessment and can help resolve three key problems with risk assessment: transparency, objectivity and communication. Consequently, in explaining the consequences of selecting different SPG options this will also be done in terms of main ecosystem services that are potentially impacted.

Since most terrestrial non-target arthropods of agricultural landscapes are mobile organisms and their occurrence is not restricted to either in-field or off-field habitats, the defined SPGs are not presented separately but linked for in-field and off-field habitats in the three main options given below.

For in-field buffer strips implemented to mitigate exposure of the off-field area (drift and run-off reduction) the same protection level as for in-crop areas applies. This is also applicable for the minimum agronomic crop-free strip. Since buffer strips and the minimum agronomic crop-free strips are not directly sprayed and receive lower pesticide loads they may also serve as a refuge area for certain non-target arthropods. Like buffer strips, in-field compensation areas should not be sprayed. For pragmatic reasons, we adopt in our proposal the same protection level for ecological compensation areas as for buffer strips. The protection level for in-field ecological compensation areas (e.g. conservation headlands and wildlife strips) for which the farmer receives financial compensation, however, may be more strict than that for the in-crop area.

All SPG options presented below are based on the principle of ecological recovery of non-target arthropods in in-crop habitats, recognising the fact that here negligible effects on population densities of sensitive non-target arthropods most likely cannot be achieved at application rates of pesticides required to combat insect pests. In all SPG options, however, effects of direct exposure of the pesticide on sensitive and vulnerable non-target arthropods should be negligible to moderate and transient in the operational edge-of-field strip and negligible in the operationally nearby off-field strip (Figure 5.1). In addition, in one of the SPG proposed also the consequences of possible indirect effects of pesticide-induced declines in populations of non-target arthropods on other organisms (e.g. birds and mammals that feed on arthropods) and biodiversity at the landscape-level are taken on board.

If the goal is to protect populations of certain red-list non-target arthropods this can best be achieved locally by implementing specific conservation measures that may require the status of nature conservation area or financial compensation of the owner of these areas to achieve this goal.

5.3 Integrated in-field and off-field SPG options

5.3.1 'Status quo-SANCO 2002' option

This option assumes to provide sufficient protection when fully adopting the current data requirements (EC, 2013 b&c) and the protection-level intended by SANCO (2002). This option considers the provisioning ecosystem service 'crop production' and the regulatory ecosystem services 'pest control' and 'pollination' provided by non-target arthropods as being of primary importance for in-field areas. This means that the monetary value of the crop, and the basic conditions to optimise this (e.g. biocontrol of pests and pollination of the crop), are prioritised over other ecosystem services offered by non-target arthropods in in-field habitats. In these habitats, populations of non-target arthropods may suffer relatively large effects of pesticide application under the condition that full recovery will occur within the growing season, as long as it is guaranteed that in in-crop habitats biocontrol of crop pests and/or pollination of the crop suffer short-term treatment-related impacts only. This is assumed to be achieved in in-crop habitats by protecting here functional groups of non-target arthropods that play important roles in the provision of the ecosystem services 'biocontrol of crop-pests' and 'pollinators of the crop'.

For off-field areas and non-target arthropods, the 'Status Quo-SANCO 2002' option considers that the required level of protection is sufficiently reached if actual pesticide exposures (e.g. due to drift or run-off exposure) maximally cause (i) small to medium transient direct toxic effects in the operational edge-of-field strip that last no longer than a few weeks and (ii) negligible direct toxic effects in the operational nearby off-field strip (see section 4.1 and Figure 5.1 for the definition of operational edge-of-field strip and nearby off-field area). Although currently not done, an ERA for the operational nearby off-field strip is introduced here, since allowing some population-level effects in edge-of-field habitats requires that the spatial dimension of this tolerable effect has to be defined more precisely. This, for example, is also done in the current Aquatic Guidance Document of EFSA (EFSA PPR, 2013), where the selected Ecological Recovery Option may allow some transient population-level effects in edge-of-field surface waters as long as no effects will occur in larger surface waters that fall under the mandate of the Water Framework Directive.

A schematic representation of the 'Status Quo-SANCO 2002' option in terms of SPG dimensions (see section 3.2.2) for key driver taxa (ecosystem service providing units) is presented in Figure 5.2.

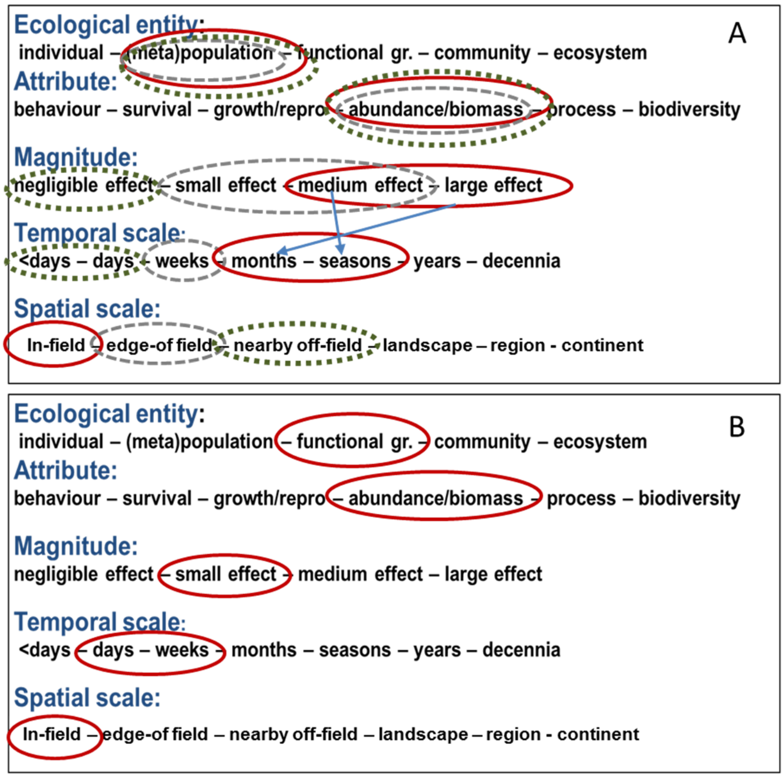

Figure 5.2 *Schematic representation of the 'Status Quo-SANCO 2002' option in terms of SPG dimensions for key driver taxa of non-target arthropods caused by direct toxicity of on-site exposure to the PPP under evaluation (indirect effects and action at a distance in off-field areas not considered). Panel A represents the choices for SPG dimensions of non-target arthropod populations in in-field (red solid ellipse), edge-of-field (grey dashed ellipse) and nearby off-field (green dotted ellipse) habitats and panel B that for the additional requirement in in-field habitats to protect functional groups of non-target arthropods that play important roles in the ecosystem services biocontrol of pests and pollination of the crop. This implies that individual populations of beneficial arthropods may suffer pronounced effects in in-crop habitats as long as the protection of the functional group of arthropods that provide the ecosystem services 'biological pest control' and 'pollination of the crop' is secured.*

The 'Status Quo-SANCO 2002' option does not consider 'action at a distance' of in-crop and off-field impacts due to sink-source population dynamics, and, consequently, the impact on biodiversity in agricultural landscapes is not explicitly evaluated. In addition, possible indirect effects of pesticide-use on wildlife populations (e.g. birds), due to the decline in abundance and biomass of non-target arthropods in in-crop habitats as food source, are not explicitly taken on board in the risk assessment procedure. Furthermore, this SPG option does not take into account the influence of the proportion of (semi-)natural elements (including in-field ecological compensation areas) in the agricultural landscape on potential treatment-related effects of pesticides, although buffer strips may be required as mitigation measure to reduce off-field exposure.

5.3.2 'Local Protection of Beneficial Arthropods' option

This option assumes to provide sufficient protection on basis of the current data requirements and protection-level intended by SANCO (2002), if additionally the ERA is made stricter compared to the 'Status Quo-SANCO 2002' option to facilitate Integrative Pest Management (IPM) practises. Again, for in-field areas, this option considers the provisioning ecosystem service 'crop production' and the regulatory ecosystem services 'pest control' and 'pollination' provided by non-target arthropods as being of primary importance. To facilitate IPM practises stricter trigger values in in-crop areas are selected for the acceptable magnitude and duration of effects on, for the crop, beneficial non-target arthropods. Similar to the 'Status Quo-SANCO 2002' option, the monetary value of the crop, and the basic conditions to optimise this (e.g. biocontrol of pests and pollination of the crop), are prioritised over other ecosystem services offered by non-target arthropods in in-field habitats (e.g. supporting services like food web support for insectivorous birds and mammals and cultural services like protection of agrobiodiversity for educational, aesthetic and conservation purposes).

For off-field areas a high level of protection of non-target organisms is warranted, amongst others to optimise viable refuge areas for beneficial non-target arthropods. The 'Local Protection of Beneficial Arthropods' option considers that this high level of protection is sufficiently reached if local pesticide exposure in the operational edge-of-field strip (e.g. due to drift or run-off exposure) causes negligible direct toxic effects on populations of non-target arthropods dwelling there. It is assumed that by achieving this, local exposure in nearby off-field areas always will be lower than the threshold level for population-level effects of sensitive non-target arthropods and that also negative indirect effects (e.g. decline in food for insectivorous birds) will be reduced.

The ecological consequence of this option is that in in-crop habitats those non-target arthropod populations that do not play an important role in pest control and/or pollination of the crop may suffer relatively large effects of pesticide application under the condition that full recovery is guaranteed within the growing season. In in-crop habitats, populations of non-target arthropods that are essential for biocontrol of crop pests and/or pollination of the crop maximally may suffer medium-size effects for maximally several weeks. In addition, reducing toxic levels of the pesticide in off-field habitats below the threshold-level of ecological effects for vulnerable non-target arthropods may secure a fast recovery of beneficial arthropods in in-crop habitats and/or a sufficient protection of the ecosystem services 'biocontrol of crop pests' and 'pollination of the crop'. 'Action at a distance' of in-crop and off-field impacts due to sink-source population dynamics, and consequently the impact on biodiversity in agricultural landscapes, however, are not explicitly considered. Furthermore, this SPG option does not consider the influence of the proportion of (semi-)natural elements (including in-field ecological compensation areas) in the agricultural landscape on treatment-related pesticide effects, although buffer strips may be required as mitigation measure to reduce off-field exposure.

A schematic representation of the 'Local Protection of Beneficial Arthropods' option in terms of SPG dimensions (see section 3.2.2) for key driver taxa (ecosystem service providing units) is presented in Figure 5.3.

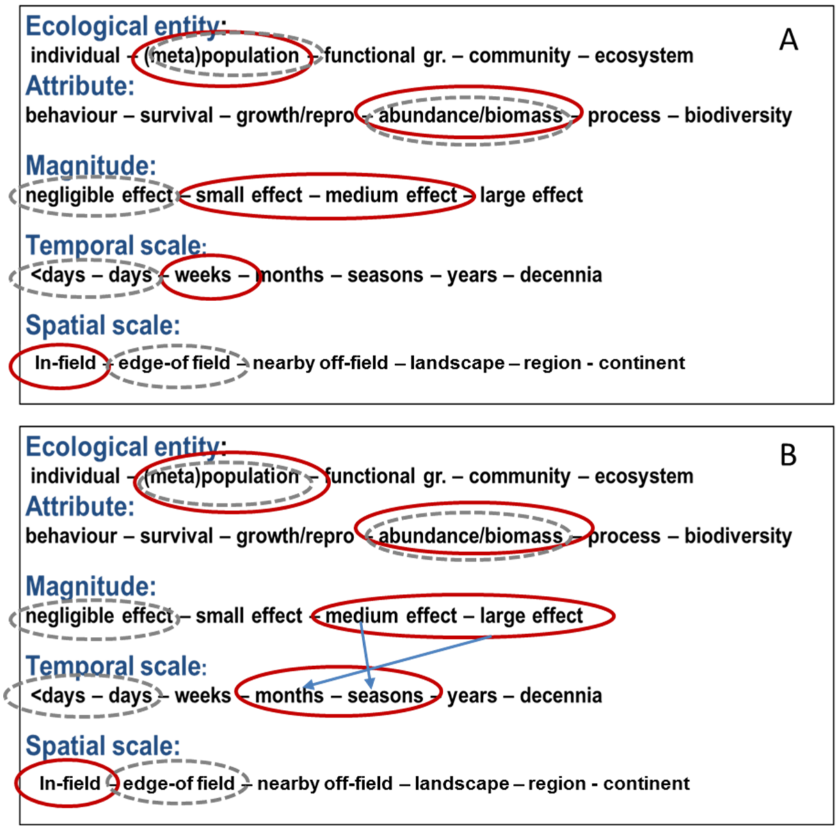

Figure 5.3 *Schematic representation of the 'Local Protection of Beneficial Arthropods' option in terms of SPG dimensions for key driver taxa of non-target arthropods caused by on-site exposure to the PPP under evaluation (action at a distance not considered). Panel A represents the choices for populations of beneficial non-target arthropods that support the ecosystem services 'biological pest control' and 'pollination of the crop'. Panel B represents the choices for all other non-target arthropods.*

= SPG dimensions for in-field habitats

= SPG dimensions for edge-of-field habitats

5.3.3 'Local Protection of Agrobiodiversity' option

This SPG option has with the 'Local Protection of Beneficial Arthropods' option in common that the underlying ERA procedures are based on local in-field and local off-field assessments. This option, however, considers not only the provisioning ecosystem service 'crop production' and the regulatory ecosystem services 'pest control' and 'pollination' as important in the prospective ERA procedure for pesticides, but also supporting ecosystem services (e.g. food web support for insectivorous birds and mammals) and cultural ecosystem services (e.g. protection of agrobiodiversity for educational, aesthetic and conservation purposes). To support the delivery of all these ecosystem services a sufficient protection of the biodiversity of non-target arthropods in agricultural landscapes is required. It is assumed that this is achieved if the same SPG dimensions for in-field and off-field habitats are selected as for the 'Local Protection of Beneficial Arthropods' option, under the additional condition that sufficient ecological compensation areas are available on farmland.

This SPG option aims to promote agrobiodiversity by the additional requirement that on farmland at least 7% ecological compensation areas should be present. For the ecological compensation areas the farmer may select less productive subfield areas, thus minimizing yield and farm profitability loss. For off-field areas a sufficiently high level of protection is assumed if local pesticide exposures in edge-of-field areas are lower than the threshold level for population-level effects of sensitive non-target arthropods. This option is in line with the Common Agricultural Policy of the EU by managing 7% of the farmland as ecological focus area (see e.g. EC, 2013a).

In this option, in in-crop habitats individual populations of non-target arthropods may suffer temporal effects (maximally a few months) of medium magnitude caused by pesticide application, comparable to the protection level of 'Local Protection of Beneficial Arthropods' option, if the sustainability of populations of non-target arthropods is facilitated by the presence of at least 7% refuge areas on farmland. Nevertheless, in this option 'action at a distance' due to sink-source population dynamics is not explicitly considered. The in-field ecological compensation areas of this SPG option should always be crop-free and for a large part consist of perennial habitats to facilitate overwintering of non-target arthropods; flower strips to promote pollinators is also an option. If farmers receive financial compensation for managing these ecological compensation areas on farmland (e.g. by Cross Compliance under CAP), in may be requested by the financing party that a more stricter protection level is required for these ecological compensation areas than for in-crop habitats and buffer strips implemented as mitigation measure.

A schematic representation of the 'Local Protection of Beneficial Arthropods' option in terms of SPG dimensions (see section 3.2.2) for key driver taxa (ecosystem service providing units) is presented in Figure 5.4.

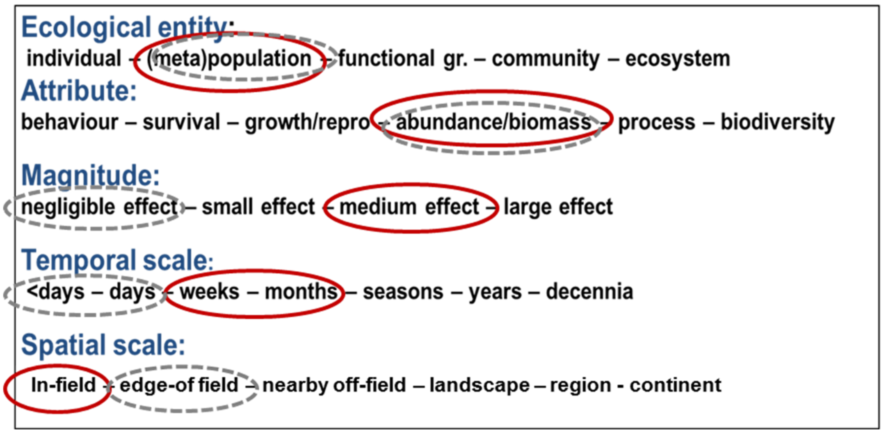

Figure 5.4 *Schematic representation of the 'Local Protection of Agrobiodiversity' option in terms of SPG dimensions for key driver taxa of non-target arthropods caused by on-site exposure to the PPP under evaluation. 'Action at a distance' and food-web support provided by non-target arthropods for birds and mammals is not explicitly considered, but assumed to be secured by the implementation of 7% ecological compensation area on farmland.*

= SPG dimensions for in-field habitats

= SPG dimensions for edge-of-field habitats

5.3.4 'Local and Landscape-level Protection of Agrobiodiversity' option

This SPG option is largely based on the proposal by EFSA PPR (2015) (see section 3) and has with the 'Local Protection of Agrobiodiversity' option in common that it considers not only the provisioning ecosystem service 'crop production' and the regulatory ecosystem services 'pest control' and 'pollination' as being of importance in the prospective ERA procedure for PPPs, but also supporting ecosystem services (e.g. food web support for insectivorous birds and mammals) and cultural ecosystem services (e.g. protection of agrobiodiversity for educational, aesthetic and conservation purposes). The 'Local and Landscape-level Protection of Agrobiodiversity' option, however, deviates from the three other SPG options that the underlying ERA procedures are based on both local-scale and landscape-scale ERA assessments. A landscape-level ERA is required to appropriately consider effects of 'action at a distance' of PPP application due to source-sink phenomena of mobile (meta-)populations of non-target arthropods and to secure the food-web support provided by non-target arthropods for birds and mammals.

In this option, in in-crop habitats individual populations of non-target arthropods may maximally suffer temporal (weeks to months) effects of medium magnitude on their abundance/biomass, as long as direct effects of local exposure to the pesticide in edge-of-field habitats is negligible. At the landscape-level the pesticide effects on spatial occupancy and overall abundance of vulnerable non-target arthropods should be negligible as well. The option requires detailed information on the normal operating range (NOR) or baseline condition of abundance and spatial occupancy of focal (sentinel) non-target arthropods in agro-ecosystems for the definition of the negligible effects at the landscape-level. This information may be landscape/region specific. Information on both abundance to and spatial occupancy at the landscape-level may provide a clear picture of the changes in the range and density of animals relative to a baseline condition in the landscape under evaluation. Since experimental approaches are difficult to implement at the landscape scale, modelling approaches to assess landscape-level effects of pesticide application on abundance and spatial occupancy of focal (sentinel) non-target arthropods are a prerequisite.

A schematic representation of the 'Local and Landscape-level Protection of Agrobiodiversity' option in terms of SPG dimensions (see section 3.2.2) for key driver taxa (ecosystem service providing units) is presented in Figure 5.5.

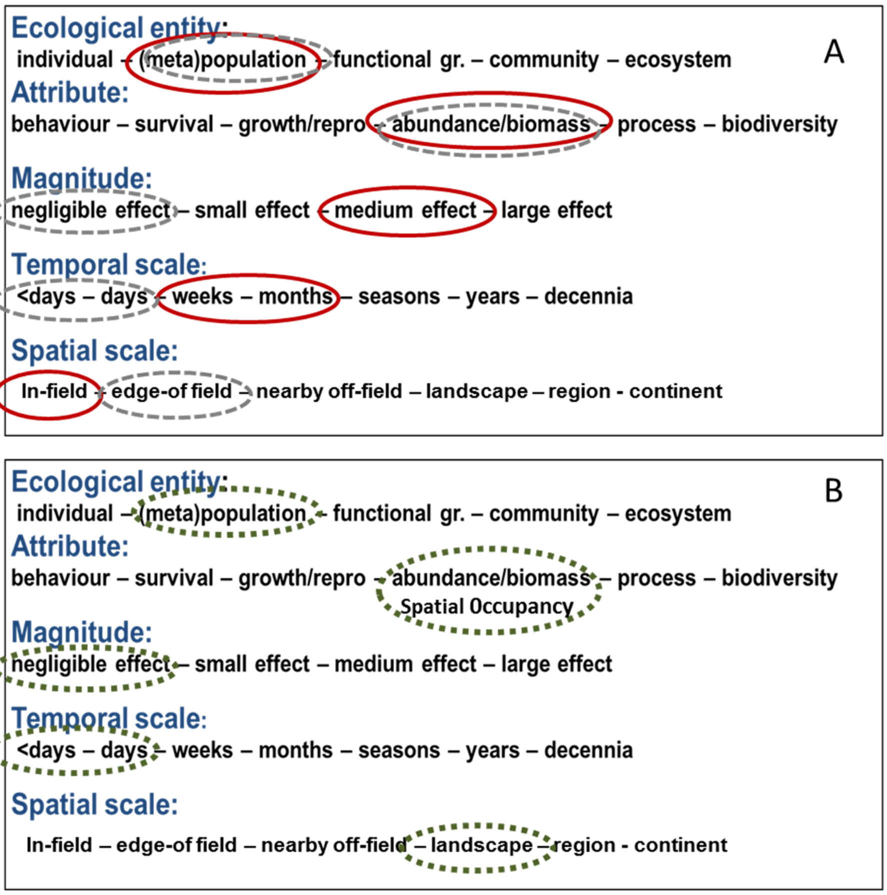

Figure 5.5 *Schematic representation of the 'Local and Landscape-level Protection of Agrobiodiversity' option in terms of SPG dimensions for key driver taxa of non-target arthropods caused by on-site exposure to the PPP under evaluation. Panel A represents the choices for local in-crop and edge of field areas ('action at a distance' not considered). = SPG dimensions for in-field habitats. = SPG dimensions for edge-of-field habitat. Panel B represents the choices for the landscape-level (takes 'action at a distance' on board).*

For communication purposes, the four SPG options presented above are operationalised in general terms only. As explained in section 1.1, the Exposure Assessment Goals (ExAGs) and Effect Assessment Goals (EfAGs) form the operational link between the selected SPG, the formalised data requirements in legislation (see section 2) and all other (higher-tier) measurement endpoints and extrapolation tools that underlie the tiered exposure and effect assessment schemes implemented in ERA guidance documents. Although not worked out in great detail, the next chapter provides some food-for-thought for important elements of ExAGs and EfAGs.

6 Exposure and Effect Assessment Goals

6.1 General introduction

Exposure Assessment Goals (ExAGs) and Effect Assessment Goals (EfAGs) provide the operational link between the Specific Protection Goals (SPGs) selected and, respectively, the tiered exposure and effect assessment schemes used in environmental risk assessment (Figure 6.1).

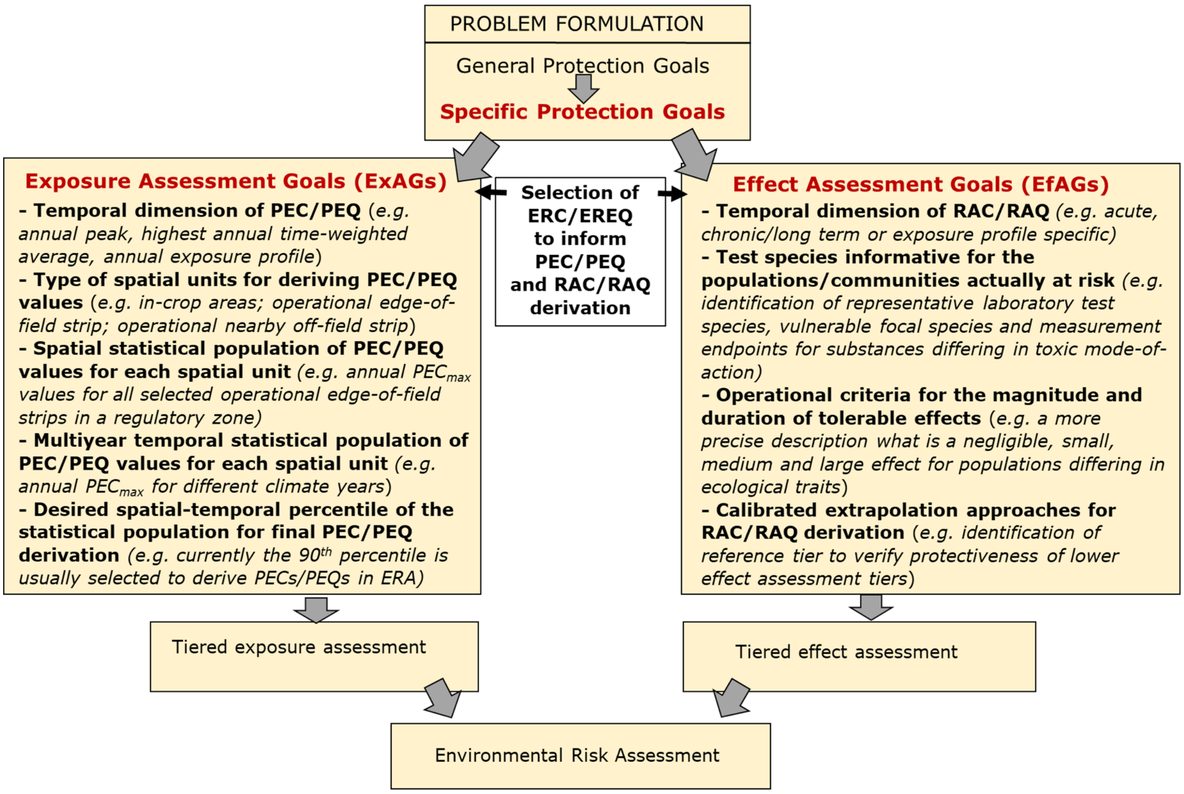

Figure 6.1 *Important elements in the definition of the Exposure Assessment Goals (ExAGs) and Effect Assessment Goals (EfAGs) that form the operational link between Specific Protection Goals and tiered exposure and effect assessment schemes. ERC = Ecotoxicologically Relevant Concentration; EREQ = Ecotoxicologically Relevant Exposure Quantity; PEC = Predicted Environmental Concentration; PEQ = Predicted Environmental exposure Quantity; RAC = Regulatory Acceptable Concentration; RAQ = Regulatory Relevant exposure Quantity.*

An important element for both the ExAGs and EfAGs is the definition of the Ecotoxicologically Relevant Concentration (ERC) or Ecotoxicologically Relevant Exposure Quantity (EREQ) (Boesten et al, 2006). The ERC/EREQ represents the type of exposure concentration or quantity (e.g. mg a.s./kg dry soil, or mg a.s./m^2 leaves surface area) that gives the best correlation to the observed ecotoxicological effects in the effect assessment tests. So the ERC/EREQ that forms the basis for Predicted Environmental Concentration (PEC) or Predicted Environmental exposure Quantity (PEQ) values should not be in conflict with the ERC/EREQ values underlying the toxicity estimates (e.g., LR50; ER50; NOER) used for Regulatory Acceptable Concentration (RAC) or Regulatory Acceptable exposure Quantity (RAQ) derivation. In first instance it is the responsibility of ecotoxicologist to define, in communication with exposure experts, the ERC/EREQ relevant for the risk assessment scheme.

The exposure estimate in laboratory toxicity tests with non-target arthropods usually concern the dry residues on e.g. glass plates, direct overspray or the residues in/on food due to overspray (see Table 3.1). In (semi-)field tests the treatment-related responses usually are expressed in terms of application rates, although organisms may be exposed via contact exposure and oral exposure. Contact exposure may be different in different layers of the vegetation and at the sediment surface (e.g. dependent on interception of the spray drift droplets by the vegetation) and, consequently, vary with the habitat preference of non-target arthropods. Oral exposure may be affected by the food (e.g. pollen, nectar, leaves, invertebrates) and water sources (guttation water, water puddles, edge-of-field surface waters) used in in-field and off-field habitats, and, consequently vary between life-stages and species of non-target arthropods. In theory, the best ERC/EREQ is the internal concentration (body burden) of the pesticide in non-target organisms. This internal concentration may be the result of several exposure routes. In practise, however, the EREQ in terms of application rates is used in the majority of cases.

In the sections below, a concise description will be presented of the various element of ExAGs (also see Boesten, 2018) and EfAGs that are mentioned in Figure 6.1. Before developing tiered exposure and effect assessment schemes, these elements of ExAGs and EfAGs need to be worked out in greater detail, partly in consultation with risk managers, and dependent on the final SPG option selected by risk managers.

6.1.1 Elements of ExAGs

Temporal dimension of PEC/PEQ
In acute risk assessments it is common practise to select the annual peak PEC/PEQ for each relevant spatial unit (e.g. in-crop area of treated field or operational edge-of-field strip) as exposure estimate. In chronic/long term risk assessment, in first instance the annual peak PEC/PEQ is selected as a worst-case exposure assessment as well, but if scientific data indicate linear reciprocity of effects, also a time-weighted-average (TWA) PEC/PEQ may be an option to use. Linear reciprocity of pesticide-induced effects can be assumed if different exposure patterns with the same area-under-the-curve have more or less the same treatment-related effect. In the linking of exposure estimates to effects estimates, and to achieve a realistic worst-case risk assessment, the time-window of the highest annual TWA-PEC/PEQ should always be smaller than the duration the toxicity test that drives the lower tier risk assessment (see e.g. Brock et al. 2010; EFSA PPR, 2013). Alternatively, the annual exposure regime may be directly used in the risk assessment as input for toxicokinetic/toxicodynamic (TK/TD) models to address the risks of time-variable exposures (see e.g. EFSA PPR et al., 2018). In turn, for landscape-level risk assessment these TK/TD models can be linked to spatial-explicit population models for focal species of non-target arthropods.

Type of spatial units for deriving PEC/PEQ values
Another key element of ExAGs is the Spatial Unit (SU) for which the PEC/PEQ will be assessed. In the four SPG options, different habitats are considered where the risks of pesticide-exposure to non-target arthropods need to be evaluated: the in-field habitat, the edge-of-field habitat, the nearby off-field habitat and the landscape (for explanation, see Figure 5.1). The association between the four formulated SPG options and the spatial units considered in the risk assessment is presented in Table 6.1.

Table 6.1 *Association between SPG option and spatial units for exposure assessment.[1] For local-level risk assessment; [2] Considered sufficiently protective if tolerable effects in operational edge-of-field strip are set at negligible; [3] All quantitatively important habitats in the landscape that serve as refuge and recolonization area for focal (vulnerable) non-target arthropods considered representative for populations of non-target arthropods at risk.*

SPG assessed for	Exposure assessed in	Status Quo-SANCO 2002 Option	Local Protection of Beneficial Arthropods Option	Local Protection of Agro-biodiversity Option	Local and Landscape-level Protection of Agro-biodiversity Option
In-field area	Crop-specific in-crop area	Yes	Yes	Yes	Yes
Edge-of-field area	Operational edge-of-field strip related to specific crop	Yes	Yes	Yes	Yes[1]
Nearby off-field area	Operational nearby off-field strip related to specific crop	Yes	No[2]	No[2]	No[2]
Landscape	To be defined[3]	No	No	No	Yes[3]

Note that for reasons of simplicity the exposure assessment in off-field habitats for local-level risk assessment has been restricted to the ‘operational edge-of-field strip’ and ‘operational nearby off-field strip’ (for explanation see Figure 5.1). The exposures (e.g. due to spray drift and/or surface run-off) will be averaged over the width of these strips. For reasons of required conservativeness, the width of these strips, as well as the distance between both types of strips, have to be selected in consultation between risk assessors and risk managers. The exposure assessment in in-crop habitats concerns the in-field crop area directly treated with the pesticide, so excluding the cropped buffer strip and the minimum agronomic crop-free strip (see Figure 5.1).

For the landscape-level, the type and dimensions of Spatial Units selected for exposure assessment will depend on the vulnerable focal non-target arthropod species selected (representative for a wider array of non-target arthropods) as well as the related environmental scenarios to conduct the integrated exposure and effect modelling using spatial-explicit population models (also see EFSA PPR, 2014b; 2015). To cover different European landscapes in the assessment, either realistic Member State specific landscapes should be considered as scenario (see e.g. Topping et al. 2015) or realistic worst-case landscape scenarios that cover certain regions in Europe need to be developed. An environmental scenario is a combination of an exposure and ecological scenario (see Figure 6.2). For more information on environmental scenarios in landscape-level risk assessment see EFSA PPR (2014b), EFSA SC (2016b) and Rico et al. (2016).

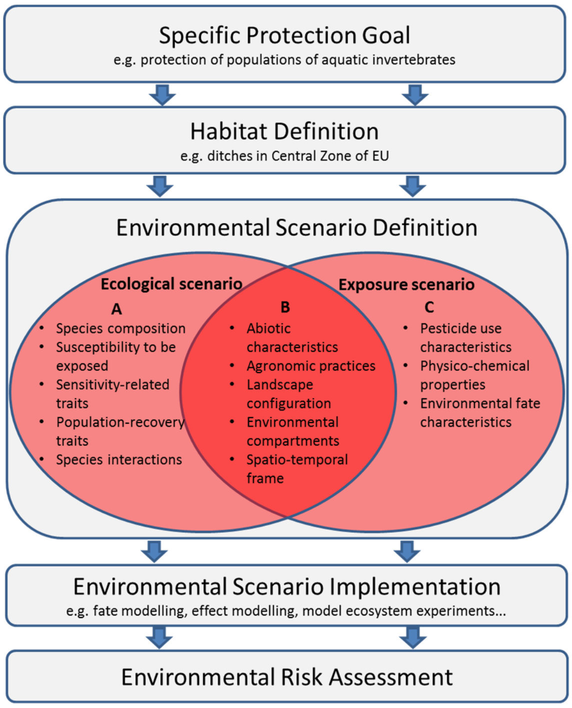

Figure 6.2 *Conceptual framework of the role of an environmental scenario in prospective ERA to assess landscape-level impacts of pesticides (adapted after Rico et al. 2016).*

Spatial statistical population of PEC/PEQ values for each type of Spatial Unit selected
For the local-level risk assessment also the statistical population of each Spatial Unit selected should be defined. This is relevant since environmental conditions of fields where the crop grows and the pesticide is applied, as well as the properties of the off-field habitats surrounding these fields, may differ within and between farmlands, regions, EU Member States and geographical zones. For that reason the conservativeness of the exposure assessment will depend on the statistical population of the Spatial Unit considered. For example, the overall exposure in the Spatial Units 'operational edge-of-field strip' and 'operational nearby edge-of-field strip' (for explanation see Figure 5.1) due to spray drift will be higher when selecting strips located in the main wind direction only than when selecting them surrounding the treated fields in all directions. In addition, the overall wind speed may be higher in polder landscapes near the sea than in inland landscapes. Consequently, selecting 'operational edge-of-field strips' or 'operational nearby edge-of-field strips' that are located in the main wind direction of treated fields of polder landscapes as statistical population of this Spatial Unit, will result in a more conservative exposure estimate than when selecting these strips independent of wind direction and coastal or inland position as statistical population. For reasons of required conservativeness, the selection of the statistical population of each Spatial Unit to be used in the exposure assessment may require consultation between risk assessors and risk managers.

For the landscape-level risk assessment, the statistical population of the PEC/PEQ estimates is not required, since in the modelling exercise the exposure and effect assessment is integrated, resulting in a spatial distribution of risks in the landscape represented by the environmental scenario.

Temporal statistical population of PEC/PEQ values for each type of Spatial Unit selected
Climatic conditions (e.g. frequency and intensity of rain events, wind speed, irradiation) show variation from year to year. This also results in variation in estimated annual highest PEC_{max}/PEQ_{max} or TWA-PEC/PEQ for each Spatial Unit selected for the local-level risk assessment (e.g. due to year to year variation in spray drift and surface run-off deposition of pesticides in off-field areas). To capture this variation, time series for exposure estimates must be long enough. For example, the EFSA exposure scenarios for soil organisms consider a time series of 20-60 years (see EFSA, 2015). Note that this variation may differ between permanent crops and crops in rotation (also see Boesten, 2018). Again, for reasons of required robustness, the selection of the number of years to be considered in the exposure assessment requires consultation between risk assessors and risk managers.

To capture the influence of year to year variation in climatological conditions, the integrated exposure and effect assessment modelling at the landscape-level by means of spatial-explicit population models, can also be conducted for a selected number of climate years.

Desired spatial-temporal percentile of the statistical population for final PEC/PEQ derivation
For local-level risk assessment, the ultimate task in the definition of the ExAG is to combine the element 'Spatial statistical population of PEC/PEQ values for each type of spatial unit selected' and 'Multiyear statistical population of PEC/PEQ values for each type of spatial unit selected'. This to select a percentile from the spatial-temporal population of exposure estimates. In exposure assessments usually the overall 90th percentile is selected for the final PEC/PEQ to be used in the risk assessment (for further discussions on this item see Boesten, 2018). Selecting an overall 90th percentile for the final PEC/PEQ for a specific Spatial Unit means that 90% of the exposure values calculated in space and time are lower than the final PEC/PEQ, and 10% higher. For reasons of required conservativeness, the selection of the spatial-temporal percentile of exposure values to be considered in the risk assessment requires consultation between risk assessors and risk managers.

A landscape-level risk assessment on basis of spatial-explicit population models and associated environmental scenarios, directly results in a spatial-temporal distribution of risks at the landscape-level if the models are run for a representative number of years differing in climatological conditions (number of years to be selected in consultation with risk managers).

6.1.2 Elements of EfAGs

Temporal dimension of RAC/RAQ
In ERA it is common practise to make a distinction in an acute and chronic effect assessment. The acute effect assessment aims to derive a RAC/RAQ for adverse effects of pesticide-exposure to (non-target) organisms (individuals, populations, communities) occurring within a short period after exposure (hours to weeks; dependent on the life span of the organisms of concern). Note that this is not synonymous with 'assessment of effects due to short-term exposure' since short-term exposure may result in delayed short-term or delayed long-term effects. Both these short-term and delayed long-term effects may be observed in higher-tier (semi-)field tests. In the current practice of lower-tier effect assessments for pesticides and non-target arthropods, however, the assessment scheme seems to be based on acute to semi-chronic laboratory toxicity data and the endpoint mortality (see e.g. Table 3.1).

EFSA PPR (2015) already recommended that also a chronic effect assessment procedure for pesticides and non-target arthropods should be developed with a focus on sub-lethal and reproduction effects. The chronic effect assessment aims to derive a RAC/RAQ for adverse effects of pesticide exposure to vulnerable (non-target) organisms (individuals, populations, communities) caused by short-term exposure (latent effects) or long-term exposure. Consequently, a chronic effect assessment is not synonymous with 'assessment of effects due to long-term exposure', but does not exclude it. Ideally, chronic toxicity tests should cover the complete life-cycle of the non-target arthropod under evaluation, or at least the most sensitive life-stage.

Since in the current lower-tier effect assessment for pesticides and non-target arthropods a clear distinction between acute and chronic effect assessment is not made, it needs to be critically evaluated whether the assessment factors to extrapolate the toxicity data for standard test species cover the potential chronic effects on relevant sub-lethal endpoints as well (see below section 'Calibrated extrapolation approaches for RAC/RAQ derivation').

Test species informative for the populations actually at risk
It is practically not feasible to test all species of non-target arthropods potentially at risk in in-field and off-field habitats. For that reason internationally accepted protocol tests for a limited number of non-target-arthropod species have been developed and implemented as tier-1 effect assessment procedure This tier-1 procedure is adopted by risk managers in the form of data requirements in EU Regulations (see chapter 2). In combination with an appropriate assessment factor it is assumed that the toxicity estimates for these standard test species sufficiently cover the sensitivities of, and protection-levels

required, for a wider array of non-target arthropods not tested. This assumption, however, is up till now hardly verified (see section on 'calibrated extrapolation approaches for RAC/RAQ derivation'). Furthermore, due to differences in protection level required between in-crop and off-crop areas, different types of RAC/RAQ values need to be derived in the local-level risk assessment, such as an ERO-RAC/RAQ (Ecological Recovery Option) for in-crop habitats and an ETO-RAC/RAQ (Ecological Threshold Option) for edge-of-field habitats. In the ERO-RAC/RAQ derivation recovery of impacted populations of non-target arthropods is considered, while ETO-RAC/RAQs aim to avoid population-level effects, even for a short period.

The lower-tier tests for standard test species of non-target arthropods predominantly provide information on the sensitivity of the individuals tested and not on population-level recovery. Information on both population sensitivity and recoverability, however, can be obtained in field tests, certainly when supplemented with population models.

Compared to tier-1 protocol tests with standard test species, less detailed regulatory guidance exists for the conduct and interpretation of field tests (see Candolfi et al. 2000 & 2001; Alix et al. 2012; De Jong et al. 2010). In analogy to the regulatory requirements of aquatic semi-field tests (see EFSA PPR, 2013), it seems reasonable that in non-target arthropod field tests a minimum number of populations (e.g., 8) belonging to a minimum number of different families/genera (e.g., 6) should be present, all characterised by a low enough minimum detectable difference (MDD) to demonstrate potential treatment-related effects (including recovery) on their population abundance/biomass. For more details on the use of MDD information in the interpretation of (semi-)field test is referred to Brock et al (2015) and Andrade et al. (2017).

In the landscape-level assessment exposure and effect assessment is integrated. Focal (sentinel) non-target arthropods representative for European agro-ecosystems need to be selected for which spatial-explicit population models need to be developed. It seems logical, to select representative beneficial arthropods, that play an important role in IPM programmes, as focal species. In addition, to also project biodiversity in agro-ecosystems the biological traits determining the vulnerability of non-target arthropods potentially at risk have to be considered in the selection of focal species (see section 1.2 for more details).

As already explained above in section 5.1.1., spatial-explicit population models for selected focal non-target arthropods and landscape-level ERA require the development of environmental scenarios representative for the region/agricultural landscape of concern. Overly simple models and environmental scenarios do not represent important aspects of the system's dynamics and have large model bias. According to Collie et al. (2016) and Van de Brink et al. (2018), overly complex models and environmental scenarios require detailed knowledge of species and environmental interactions and need a large number of parameters to specify detailed dynamics; they have large parameter uncertainty.

Ideally, the combination of model predictions based on realistic uses of pesticides and targeted monitoring of the abundance and occupancy of non-target arthropods in agricultural landscapes would be the best alternative for larger spatial scale assessments (Streissl et al. 2018).

Operational criteria for the magnitude and duration of tolerable effects
Since for non-target arthropods the ecological identity to protect will be the population or functional group, tests and tools that allow to assess treatment-related effects on populations and functional groups form the basis to define operational criteria for the magnitude and duration of tolerable effects. These test and tools concern field studies (e.g. replicated field plot experiments) and/or spatial explicit population models. To facilitate the derivation of RAC/RAQ values from treatment-related effects on non-target arthropods in experimental field studies, De Jong et al. (2010) developed Effect classes that integrate the duration and magnitude of effects (Table 6.2).

Table 6.2 *Effect classes for the evaluation of treatment-related responses in non-target arthropod field studies (from De Jong et al. 2010).*

Effect class	Description	Criteria
1	Effects could not be demonstrated (NOER)	• No (statistically significant) effects observed as a result of the treatment • Observed differences between treatment and controls show no clear causal relationship
2	Slight and transient effects	• Quantitatively restricted response of one or a few taxa and only observed on one sampling occasion
3	Pronounced short term effects; recovery within two months after first application	• Clear response of taxa, but full recovery within two months after the first application • Effects observed at two or more sampling instances
4	Pronounced effects; recovery within four months after first application	• Clear response of taxa, effects last longer than two months but full recovery within four months after the first application • Effects observed at two or more sampling instances
5	Pronounced effects; recovery within eight months after first application	• Clear response of taxa, effects last longer than four months but full recovery within eight months after the first application • Effects observed at two or more sampling instances
6	Pronounced effects; full recovery one year after first application	• Clear response of taxa, effects last longer than eight months but full recovery within one year after first application • Effects observed at two or more sampling instances
7	Pronounced effects; full recovery more than one year after first application	• Clear response of taxa, effects last longer than twelve months after the first application but full recovery found within the study period • Effects observed at two or more sampling instances
8	Pronounced effects; no recovery within the study period	• Clear response of taxa, no recovery within the duration of the study • Effects observed at two or more sampling instances

Using the effect classes presented in Table 6.2, and by also taking on board criteria for minimum detectable differences (MDDs) to demonstrate potential treatment-related effects (including recovery), effect class 1 and 2 values might e.g. be used to derive ETO-RAQs (Ecological Threshold option for population-level effects), while effect class 3 to 5 values might be used to derive ERO-RAQs (Ecological Recovery Option for population-level effects). To address remaining uncertainties, an additional assessment factor may be requires in ETO-RAQ and ERO-RAQ derivation based on these effect classes, e.g. by following the procedure described in the EFSA Aquatic Guidance Document (EFSA PPR, 2013).
The final choice requires a dialogue between risk assessors and risk managers.

A possible operational criterion for a tolerable magnitude of effect in landscape-level assessments based on predictions of spatial-explicit population models for vulnerable focal species may be ≤ 10% effects on overall abundance and spatial occupancy in the landscape (scenario) of concern (see e.g. the proposals by EFSA PPR, 2015). Again, the final choice requires a dialogue between risk assessors and risk managers.

Calibrated extrapolation approaches for RAC/RAQ derivation
As already explained in section 1.1, a tiered effect assessment scheme as a whole needs to be (1) appropriately protective, (2) internally consistent, (3) cost effective and (4) address the problem with a higher degree of realism and complexity when going from lower to higher tiers. This also means that higher tiers need to be used to calibrate the lower tiers. EFSA PPR (2010) proposed to identify a so-called ‘reference tier’ that can be used to calibrate the protectiveness of the lower tier assessments (see Figure 6.3).

In the effect assessment scheme for non-target arthropods an appropriately conducted field test (e.g. a controlled and replicated plot experiment that meets the quality criteria) or sufficiently ‘validated’ spatial-explicit population models for vulnerable focal non-target arthropod species can be selected as reference tier. However, the calibration of lower tier effect assessment procedures for pesticides and non-target arthropods with results of a reference tier hardly has been done and remains an important research activity to date.

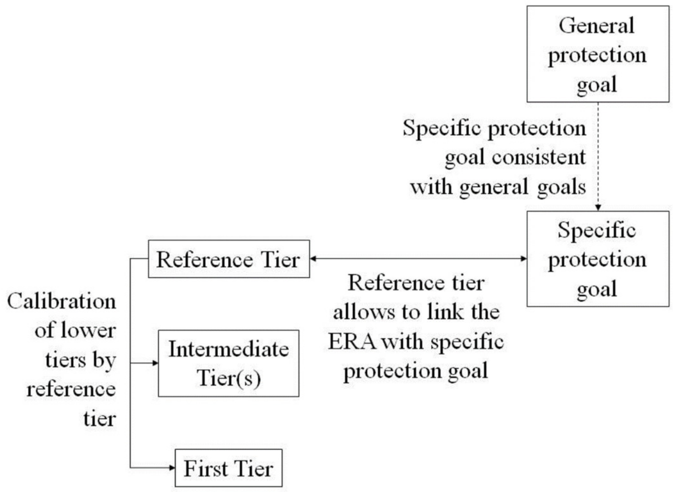

Figure 6.3 *Procedure to verify the consistency of the tiered approach by means of a reference tier (after EFSA PPR, 2010).*

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