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Linking Non-Target Arthropod Testing and Risk Assessment with Protection Goals

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ESCORT 3

Linking Non-Target Arthropod Testing and Risk Assessment with Protection Goals

Hotel Zuiderduin, Egmond aan Zee, The Netherlands
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Editors:

Anne Alix, Frank Bakker, Katie Barrett, Carsten A. Brühl,
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Preface

Anne Alix

The protection of terrestrial non-target arthropods (NTAs) has always been a particular case in the overall environmental risk assessment. This particularity is linked to their status within the cropped area, as well as their belonging to the "invisible crowd" living in the agricultural landscape. This link makes NTAs one of the less familiar groups of organisms in the area of environmental protection and also may be one of the biggest challenges in ecotoxicological risk assessment.

NTAs are not specifically defined in the legislation, but through "species of ecosystems" that could potentially be exposed by the products of concern, although Council Directive 91/414/EEC (EC 1991) establishes as a decision-making criterion that "acceptable effects on beneficial arthropods other than bees" be demonstrated. Regulation 1107/2009 (EC 2009a) evokes the protection of biodiversity. Any classification or categorization based on the NTAs' ecological role, dependence on the crop, effectiveness as a beneficial species, or in providing an ecosystem service that would further lead to categorize levels of protection or priority would need to rely on equally documented inventories and would be contrary to the aim of preserving biodiversity. Thus, NTAs are, for the purposes of this document, all arthropod species that are not intentionally treated as pests. This definition intrinsically suggests why it is important to protect NTAs and to restrict the impact of the plant protection product (PPP) to the pest, as far as possible. On this basis, the level of protection of NTAs in agricultural landscape may be derived for each area defined (in-crop, in-field off–crop, off-field) in relation to that area's status with regard to the pest.

This link of NTAs to cropped areas implies that the regulation on placing PPPs (or pesticides) on the market, of all the environmental regulations, is the only legislation that includes NTAs among the organisms to be specifically protected (EC 2010). Thus, pesticides are the only products for which potential side-effects to terrestrial NTAs are described and assessed in a risk assessment, in contrast to terrestrial vertebrates, aquatic organisms, or soil organisms, for example, which are also addressed in the regulatory frameworks of chemicals and biocides (EC 1998, 2006). As another illustration of this, no dedicated classification criterion has ever been envisaged for labelling purposes (EC 1999).

Despite this singular status, NTAs play an essential role in the agronomic landscape as well as at the coarser level of cropped areas. Besides their essential role in ecosystem functioning, they are essential in food chains as we were reminded in the 1990s when bird populations were depleted by the side-effects of some cropping practices in England (see Aubertot et al. 2005 for a review). For these reasons and because NTAs are essential in pollinating cropped varieties, their function as beneficial organisms in cropped systems is probably the service that leads to their entry into environmental protection policies. The protection of beneficial organism species in cropped areas has been investigated in a regulatory context since 1977, with the development of a quite comprehensive testing toolbox in the laboratory (Hassan et al. 1985), which counted ca. 20 species in the late

1980s (Sterck et al. 1999). More than 100 active substances were tested for their potential toxicity to these species, under controlled and comparable conditions. The testing strategy later involved higher-tier testing, in semi-field and field conditions, and a real classification of the risk based on the level of effects observed (Hassan 1988). This testing strategy first aimed at classifying pesticides on the basis of their intrinsic toxicity to beneficial organisms and thus identified pesticide candidates for Integrated Pest Management (IPM). Subsequently, this strategy led to the optimized testing set proposed in ESCORT 1 that was included in Directive 91/414/EEC data requirements (Barrett et al. 1994; EC 2010). This proposal marked not only the start of a systematic evaluation of the side-effects and related risks of pesticides and their uses to terrestrial arthropods, but also the start of the consideration of NTAs as non-target organisms and not only beneficials.

This entry into regulatory texts on pesticides with a status of non-target organisms favoured the development of dedicated field studies that were constructed as ecotoxicological tools in place of field investigations and that were closer to monitoring which had been implemented for IPM purposes. Measuring effects on arthropod populations, instead of on the level of pest control, after pesticides were applied at the rates recommended for efficient pest control, led to the challenge of isolating side-effects attributable to a pesticide treatment. This challenge involves isolating the ecologically complex interactions that occur in a field. The representivity of standard test species, the recovery of impacted populations, and the role of off-crop populations became progressively central in pesticide evaluations and led to the development of a real ecotoxicological risk assessment scheme for NTAs, further fixed in ESCORT 2 (Candolfi et al. 2001). The approach, built on 25 years of experience in arthropod testing methodology, brought a robust toolbox and rarely failed to provide the expected alert on potential impact, if any, from the use of a product.

Since the implementation of the concepts of ESCORT 2 into the risk assessment for PPPs, diverse events led to the organization of an expert meeting around the issue of risk assessment to NTAs and the current ESCORT guidance documents. Regulatory events, in first instance, introduced the protection of biodiversity in the risk assessment context (EC 2009a) and brought the implementation of use practices for pesticides dedicated to further improve the level of safety for the environment (EC 2009b). Scientific knowledge, generated since ESCORT 2, also naturally calls for a regular update of guidance documents in order that they may always reflect the best scientific basis and allow a real check of the procedure in NTA risk assessment and its performance.

With regard to biodiversity, the risk assessment scheme proposed in ESCORT 2 is designed to evaluate exposure and risks in both in- and off-field areas, thus touching the issue of biodiversity in the areas connected to cropped surfaces. However, having been developed on the basis of in-crop–derived testing protocols and species, the question of the capacity of this scheme to provide a comprehensive characterization of the potential impacts in the off-crop area in the real world needed to be verified. A related question is that of the meaning, in the context of biodiversity, of a risk assessment that concludes to an acceptable impact being based on recovery of impacted populations. This clearly raises the issue of biodiversity as a whole, including communities of other groups of organisms and food chains. Risk assessments seldom address the issue explicitly, and in this respect terrestrial arthropods play a central role.

The task of improving the level of safety through a better implementation of good practices and risk mitigation measures in the context of a sustainable use of pesticides raises two general questions. The first is whether we are able to check the level of protection that is actually achieved for a group of organisms after following a risk assessment procedure. In this respect a missing piece of the picture is probably the lack of real feedback from the field, through the identification of appropriate survey or monitoring data that could, as was done for honey bees, check against the risk calculated in the assessment (Mineau et al. 2008). The second question relates to the capacity of the risk assessment scheme to help identify risk mitigation measures that meet the requirement of both relevance and practicability. Current recommendations at the European Union (EU) level rely on the implementation, as a harmonized mitigation measure, of non-treated buffer zones at the margin of crops (off-crop area), with the aim to provide a refuge area to protect arthropod populations (EC 2010). To date, no harmonised implementation has been recorded among EU Member States, mainly due to difficulties encountered in linking the buffer zones to be implemented in the field areas to the buffer zones being considered for risk assessment purposes. Risk management policies vary among European countries and certainly further drive this difficulty. However, whatever these buffer zones look like, whether they are located in or off the crop, whether they are being managed or not, the question arises of what level of protection they provide compared to the level of effects that is expected from a risk assessment, and that has to be managed. The level of protection of these buffers themselves is a key issue, these concerns currently fail to find a definitive solution in available data from experiments and field surveys, and they therefore call for further research.

Reaching all these goals may be of little help if they are not accompanied by proper communication. Educating farmers on the protective measures to implement in the field, as well as on the reasons why these measures are to be implemented, is a key issue in the success of the process. Proper education of policy makers also is essential, to help them translate the outcome of risk assessment not only into risk management but also into policy making, when the time comes to categorize measures to be dealt with as recommendations or as legal requirements. Educating end users of risk assessment guidance documents may finally be the keystone, because the success of their implementation at a wide scale implies a high level of expertise of risk assessors, which in turns allows a high level of science and expertise to revise their guidance documents. Education may then be the key challenge in developing future guidance documents, and we hope that the attempt that has been made in the preparation of these proceedings makes its contribution to this challenge.

The developments and recommendations proposed in these proceedings also address questions and concerns raised in countries beyond Europe. Although an abundant literature and the development of testing protocols have resulted in a series of impact assessment of pesticides on beneficial species (see, e.g., International Organisation on Biological Control: http://www.iobc-wprs.org), the areas of risk assessment and risk management have been less well developed. The guidance generated in ESCORT 3 is readily transferable into non-European areas, where we hope it can be used as a keystone in the building of their environmental policies.

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Anne Alix

After receiving a PhD in ecotoxicology, conducted on an Integrated Pest Management (IPM) problematic, Anne Alix worked as an environmental risk assessor at Novartis in France, and then was in charge of the scientific evaluation of plant protection products (PPPs) for the Ministry of Agriculture at the French National Institute on Research in Agronomy (INRA). From 2006 to 2010, Alix led the unit in charge of environment and ecotoxicology evaluations of the Plant and Environment Directorate (Direction du Végétal et de l'Environnement) of the French Agency on the Safety of Food (AFSSA). In April 2010 she joined the Ministry of Agriculture and Fisheries, where she was deputy head of the office in charge of regulatory affairs for PPPs.

Frank Bakker

In more than 25 years of contract research for the plant protection industry, Frank Bakker has pioneered the development and scientific evaluation of regulatory testing procedures. He has authored or co-authored numerous guidelines, scientific publications, and study reports related to terrestrial ecotoxicology of arthropods. He has hands-on experience with most study types and participates in various expert panels. His current focus is on the assessment and interpretation of community-level effects, both in-crop and off-field.

Katie Barrett

Katie Barrett worked for 18 years for AgEvo. Working initially in the environmental metabolism department, she was also responsible for setting up the ecotoxicology group. She joined Huntingdon Life Sciences in June 1995 as head of the Ecotoxicology Department, then became program director for agrochemical and veterinary programs. She has been actively involved in liaising on behgalf of clients with regulatory authorities and preparing risk assessments for both veterinary and agrochemical products. Barrett has served on a number of working groups for the Organisation for Economic Co-operation and Development (OECD) and SETAC, developing guidance documents and guidelines for novel test species, including sediment organisms, dung fauna, and beneficial insects.

Carsten A. Brühl

Carsten Brühl has experience in the technical development of terrestrial ecotoxicology studies in field and laboratory, the application of Good Laboratory Practice (GLP) from lab to multi-site field studies, and participation with authorities such as European Food Safety Authority (EFSA), Umweltbundesamt (German Federal Environment Agency, UBA), and Department for Environment, Food and Rural Affairs (UK, DEFRA) and in ring testing with laboratories throughout Europe. He has conducted laboratory studies on beneficial non-target arthropods (NTAs) and managed contracted study projects for the registration of pesticides, as well as organising and directing large-scale field studies on NTA communities in crops (cereals, apples, citrus) in different EU countries.

Mike Coulson

Mike Coulson is a terrestrial invertebrate ecotoxicologist with more than 25 years' experience. He is the Chair of the Beneficial Arthropod Regulatory Testing (BART) Group and CRO group of NTA experts influencing guideline, testing, and risk assessment development, and as such wrote the proposal for ESCORT 3. Coulson also chairs the International Commission for Plant–Bee Relationships (ICPBR) Field and Semi-field Working Group, and subsequently was part of the 7-person European and Mediterranean Plant Protection Organization (EPPO) ad hoc group revising the honeybee chapter of the Environmental Risk Assessment scheme for Plant Protection Products. He is an active member of the 2 European Crop Protection Association (ECPA) groups, Non-target Arthropods and Bees, and Soil Organisms, as well as the ad hoc German IVA groups Seed Treatment Dust-off and Guttation.

Simon Hoy

Simon Hoy is a senior specialist working for the Chemicals Regulation Directorate (CRD) in York, UK. CRD is the UK's national regulatory authority for PPPs, biocides, and other chemicals; its PPPs section was formerly known as PSD. Simon joined PSD in 1990 following his education and interests in the fields of agricultural zoology, conservation biology, and entomology. He is a Fellow of the Royal Entomological Society. Currently Simon's main role is as a regulatory ecotoxicologist and environmental risk assessor for new and existing chemicals and products. He also advises on regulatory and environmental policy and research for chemicals at a national and international level. Simon has worked closely with other European member states and various European Union authorities conducting environmental risk assessments for PPPs and developing related guidance and guidelines. He has a particular interest in invertebrate ecotoxicology and soil risk assessment and has been actively involved in EPPO and other SETAC workgroups and workshops in these areas.

Jean Pierre Jansen

Jean-Pierre Jansen is a Research Scientist in ecotoxicology at the Walloon Agricultural Research Center, Department of Life Science, Plant Protection and Ecotoxicology Unit, a research organization located in Gembloux, Belgium and funded by the Walloon Ministry of Agriculture. He is a specialist in side-effects of pesticides on beneficial arthropods, covering fundamental and applied research, generation of data, and transfer of the relevant information to the final pesticide users. He has been the convenor of the International Organization for Biological Control (IOBC) working group Pesticide and Beneficial Organisms since 2007. Jansen also is involved in the implementation of IPM programs to control several pests in the open field and is responsible for several pest survey and advisory systems. He has been involved as expert in the pesticide registration process for Belgian authorities (part Arthropods and Beneficials Organisms) and is responsible of a GLP testing facility performing several studies on beneficial arthropods for the regulatory process.

Paul Jepson

Professor Paul Jepson is the Director of the Integrated Plant Protection Center at Oregon State University and State IPM Coordinator for Oregon, USA. He has degrees from Imperial College, London and Cambridge University and began his career at the University of Southampton in the UK, where his research focused on invertebrate ecotoxicology and pest management. He was worked internationally on these subjects and elucidated mechanisms for pesticide impacts on natural enemies that span laboratory-based toxicology and long-term, large-scale impacts in the field. Jepson was a consultant to ESCORT workshops 1 and 2 and acted as discussion facilitator and leader at ESCORT 3.

Gavin Lewis

Gavin Lewis initially graduated from Oxford with a degree in zoology, before going on to carry out research into the effects of aphids on tree growth and the mechanisms of host plant resistance for his PhD thesis at University College, Cardiff. He then moved to Jealott's Hill Research Station of ICI (later Zeneca) Agrochemicals, where he was responsible for laboratory and field testing with honey bees and NTAs. His interest in assessing the effects of PPPs on these organisms led him to become involved with groups responsible for developing test methodology and risk assessment schemes at the EU regulatory level. These included the ICPBR Bee Protection Group, for which he is now vice-Chair, and the infamous ESCORT workshop (as Treasurer he has to maintain the ESCORT account and often has difficulty explaining that this is a serious scientific endeavour). After a number of years engaged in practical work, Lewis was recruited to the Regulatory Group at Covance Laboratories, where he was responsible for the whole ecotoxicology area. Lewis found that he preferred working for a smaller, more responsive group and so moved to JSC. He now lives in the "wilds" of the beautiful Yorkshire Dales, where he is surrounded by chickens, sheep, and llamas.

Paul Neumann

Paul Neumann is team leader of the NTA expert group at Bayer CropScience AG in Monheim, Germany. He studied biology with focus on aquatic ecology and entomology and completed his PhD in limnology in 1995 at the Max-Planck-Institute for Limnology, Germany. During a 2-year post doc project at the Great Lakes Laboratory for Fisheries and Aquatic Science in Burlington, Canada, he worked on ecotoxicological aspects of heavy metals and amphipods. In 1998 he joined the department ecotoxicology of the Crop Protection Division of Bayer AG working on side effects on NTAs. Since 1999 Neumann has participated in the development of testing guidelines and testing concepts for regulatory NTA testing (e.g., ESCORT 2 workshop and the workshop on semi-field and field testing in Versailles). Currently he is the chair of the ECPA work group on NTAs and is secretary of the BART group. Since 2008 he has been involved in the development of methods to assess dust drift exposure and the design of ecotoxicological studies to address this exposure pathway for NTAs and bees. He is chair of the German IVA working group on Seed Treatment Dust Exposure and Risk Assessment.

Dirk Süßenbach

Dirk Süßenbach works as scientific officer in the section IV1.3 Plant Protection Products of the UBA in Dessau, Germany. The UBA is responsible for the environmental risk assessment of PPPs within the national authorisation process of PPP and the European active substance programme. Süßenbach studied biology with interests in animal ecology, entomology, and biodiversity. He obtained his PhD in animal ecology at the University of Bayreuth in 2003. His research focused on the diversity of moth communities in the neotropics. From 2003 to 2005, he worked at the Federal Office of Consumer Protection and Food Safety (BVL) in the EPCO-Team, a coordination group that was responsible for the EFSA Peer Review Coordination. In 2005 he joined the UBA as regulatory risk assessor. His area of responsibility includes the environmental risk assessment of PPPs, developing guidance documents, and he is specialised on arthropods.

Peter van Vliet

Peter van Vliet has worked at the Board for the Authorisation of Plant Protection Products and Biocides in The Netherlands as an environmental toxicologist for the past 18 years. His main work consists of evaluating dossiers and performing risk assessments regarding the environment (ecotoxicology). Furthermore he participates in working groups providing guidance on ecotoxicological subjects, in expert meetings in the European Union, and in national and international workshops.

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1 Executive Summary

1.1 Introduction

The third **E**uropean **S**tandard **C**haracteristics **O**f beneficials **R**egulatory **T**esting (ESCORT 3) workshop dealt with questions regarding the protection of non-target arthropods (NTAs) in the context of the use of plant protection products (PPPs) in agriculture.

The first ESCORT workshop was held in March 1994. The purpose of the first meeting was to reach consensus on the regulatory testing requirements for NTAs in the context of European Union (EU) directive 91/414/EEC and the European and Mediterranean Plant Protection Organization (EPPO) risk assessment scheme. The meeting proceedings (Barrett et al. 1994) were published as a guidance document. Recommendations regarding test species and methods are referred to in the Annex II and Annex III data requirements of the European Commission Directive 96/12/EC (8 March 1996).

The second ESCORT workshop was held in the year 2000. The objective of this meeting was not only to review the original recommendations, but also to create recommendations on the use of the data generated into a risk assessment procedure. The published proceedings of the workshop (Candolfi et al. 2001) included a tiered testing and risk assessment approach. The approach also allowed differentiation between the "in-field" and the "off-field" areas. The proceedings were implemented with the Guidance Document on Terrestrial Ecotoxicology (EC 2002).

The ESCORT 3 meeting was held as a review and update of the previous meeting outputs based on current science. Participants also considered new issues and open points that had arisen in the interim period.

1.2 Structure of ESCORT 3

The workshop Organising Committee collated a number of questions arising from the peer review and authorisation processes for plant protection products (PPPs), considering questions raised by risk assessors from regulatory offices and industry performing the evaluation of PPPs, as well as questions raised during the public consultation (EFSA 2009) on the existing Guidance Documents on Aquatic and Terrestrial Ecotoxicology (EC 2001, 2002). Based on these questions, the Organising Committee put together a programme of discussion topics that were addressed at the workshop in plenary sessions alternating with work in subgroups. This allowed for in-depth discussions on each of the four areas identified by the Organising Committee: 1) level of protection and testing scheme, 2) off-crop environment, 3) recovery, and 4) field studies.

Approximately 60 participants registered for the workshop, representing authorities, the private sector, and academia. The participants of the workshop were pre-assigned to the four subgroups on the basis of their knowledge and expertise, and regular plenary sessions gave participants the opportunity to comment on all areas under discussion. An opening plenary session provided background information with presentations from invited speakers (see Appendix 1, Abstracts of the Plenary Presentations).

Text Box 1.1 Terms used throughout the ESCORT 3 proceedings

Non-target arthropod (NTA): as addressed in the risk assessment for plant protection products (PPPs), refers to all arthropod species that are not intentionally treated as pests.

In-crop area: corresponds to the surface covered by the crop plants, including the space between the crop rows (e.g., in the case of orchards).

In-field area: comprises the in-crop area and its boundaries that are managed by the farmer in the context of crop management (e.g., areas needed to turn the tractor at the end of the tree rows in an orchard or a hedge that has been planted as wind break along a field).

Off-crop area: where the product is not intentionally applied (i.e., the NTA risk assessment is based on available spray-drift data, and the exposure assessment starts for arable crops at 1 m from the edge of the directly sprayed crop and for orchard-type applications 3 m from one half-row space beyond the last plant or tree row).

Off-field area: corresponds to the area surrounding the in-field area, excluding neighbouring in-field areas.

Recovery: the return of populations, communities, or functional groups to levels that would be reached without the specific stressor.

Community: an assemblage of species inhabiting an area as defined above. Dedicated functions and biodiversity aspects are associated to these species and thus to a community.

1.3 Level of Protection and Testing Scheme

The European Council Directive 91/414/EEC (EC 2006) and the new regulation (EC 2009a) both require that products and their uses are assessed with regard to their potential effects on NTAs, with the aim to protect these NTAs in the agricultural area. These legislation documents, however, do not provide specific details concerning the NTAs that should be protected. The workshop participants concluded that NTAs as addressed in the risk assessment for PPPs refer to all arthropod species that are not intentionally treated as pests. In evaluating potential approaches for structuring protection goals for these NTAs, we considered several aspects: 1) spatial distribution of NTAs in the agricultural environment, 2) time scale referred to for the risk assessment, 3) ecological function of the NTAs, and 4) life history strategies. On this basis, we developed the following protection goals to differentiate between the in-field and the off-field area:

- In the in-field area, the protection goal was identified as the maintenance of relevant functions.
- In the off-field area, the protection goal was identified as the maintenance of NTA biodiversity.

We identified the following functions as relevant for the in-field area: 1) pollination, 2) control of pest species, 3) food source for wildlife, and 4) soil function (e.g., nutrient cycling by detritivores and coprophagous species.)

Concerning the assessment of soil function, the workshop participants identified a potential overlap with the risk assessment conducted for soil organisms in the regulatory context, although the species considered in the two risk assessment schemes differ in the main functions they represent. We considered two options: 1) to harmonise the risk assessment approaches recommended for NTAs and soil organisms or 2) to perform both assessments in their own context having regard for their specificities. After discussion, we preferred the second option because the two approaches currently allow us, through different and complementary datasets, to address complementary aspects of soil function and exposure modalities.

The protection goal for off-crop areas in the in-field (e.g., unsprayed headlands, uncropped grass strips, hedgerows that were planted as wind breaks) was discussed in detail. The use of such areas might be quite different in different regions. In some regions, they are highly managed as risk mitigation tools or for other agricultural purposes, whereas in other regions they are maintained for conservation purposes. For these areas, an appropriate level of protection should be based on the area's expected role. Thus, the level of protection for such off-crop habitats in the in-field area should be defined at the national level as a function of management measures to be ensured by farmers.

The protection goal for the off-field area should ensure that populations are not affected by PPP use. A higher protection level compared to the in-field area should thus be reached. The off-field environment provides ecological functions for nature and for agriculture. The workshop participants considered the use of a no-observed-effect rate (NOER) for the community and a no-observed-ecological-adverse-effect rate (NOEAER) for the population as the relevant endpoints for the off-field risk assessment, in the context of the evaluation of higher-tier field studies.

With regard to the testing package and process that is needed to ensure these protection goals can be achieved, the information and recommendations contained in current guidance documents were still considered appropriate.

1.4 Off-Crop Environment

Off-crop in the context of arable uses of PPPs was defined at the workshop as "The area where the PPP is not intentionally directly applied, and therefore, the risk assessment for NTAs is based on available arable spray-drift data and the exposure assessment starts at 1 m from the edge of the directly sprayed crop." In the context of orchard-type uses of PPPs, the off-crop was defined similarly as "Based on available spray-drift data, the exposure assessment for the off-crop area for orchard-type applications starts at 3 m from one half-row space beyond the last plant or tree row."

In the context of risk management (and risk mitigation), the off-crop in the in-field area and the off-crop in the off-field area might be considered differently. As an example, some of the off-crop habitats in the in-field were originally planted for mitigation purposes (e.g., hedges for drift reduction). The workshop participants considered it not appropriate to require, for example, buffer zones to protect such areas. In other cases, growers receive compensation for implementing agro-environmental management plans for planting or maintaining such in-field off-crop habitats. This once again highlights the importance of considering such in-field off-crop habitats in the context of risk mitigation on a case-by-case basis in each EU Member State.

We concluded that the off-crop risk assessment for NTAs starts at 1 m distance from the crop because the area in the first metre beside the crop may also be directly over-sprayed. Currently the spray drift data published by Rautmann et al. (2001) are used by most countries in the EU and in the context of EU registrations. Various activities are currently ongoing at the national level to redefine the spray drift values, to address changes in application technology and farming practice. Workshop participants recommended that these activities should finally feed into a harmonization at EU level.

Concern was raised by some participants with regard to the currently recommended Vegetation Distribution Factor (VDF) in estimating exposure of NTA in vegetated area at the edge of crops. The workshop participants recommended that a reevaluation of the VDF could be considered within the context of a reevaluation of the off-crop exposure estimates. Regarding the case of seed treatments and the related potential exposure of off-crop populations to dusts, the workshop participants proposed that risk assessment and risk management approaches should be developed. Concerning the potential exposure of NTAs to vapour drift, further research is required to assess its relevance before it is included within a risk assessment scheme.

In the context of higher-tier testing, it was pointed out that phytophagous NTA species may occur in greater overall abundance or diversity in off-crop habitats compared to in-crop habitats. Therefore, we recommended that, in order to ascertain a balanced consideration for these species, higher-tier studies (e.g., field studies) for the off-crop should also consider effects on such phytophagous species.

The use of in-crop field studies for the purpose of the off-crop risk assessment may not be appropriate due to differences in species diversity, representativeness, ecological traits, and responses. We considered the off-crop field study design developed by Bakker and Miles (see Appendix I in de Jong et al. 2010) as one approach to a more detailed assessment of the effects of PPPs on off-crop communities. Such studies are conducted on pristine meadows in a dose–response design and aim to determine a NOER or a NOEAER for the NTA community and NTA populations[1].

We proposed that in relation to possible different levels of protection, different levels and durations of effects for the off-crop in-field margin area and for the off-field area may be considered. These levels could match the effect classes identified from field studies in order to determine acceptability (de Jong et al. 2010). For example, intermediate effects (Class

1 During the review of these proceedings, the Coordinating Editor of SETAC Books suggested adding a note that there is extensive literature challenging the validity and use of the point estimates NOEC and LOEC (and variations of these terms) in regulatory decision processes (for a recent summary of the arguments, see Landis and Chapman 2011). It should be noted that this discussion is focused mainly on the evaluation of ecotoxicological laboratory studies, and its potential relevance for NTA field testing was not discussed during the ESCORT 3 workshop.

3 proposed in de Jong et al. 2010) may be appropriate for an off-crop in-field margin area immediately adjacent to a crop, whereas no or only slight effects (Class 1 and 2, according to de Jong et al. 2010) might be more appropriate for the off-field area. As mentioned earlier, the assessment of in-field off-crop habitats should be regulated at the EU Member State level with consideration for regional differences.

Currently it is not possible to rule out off-crop exposure; therefore we considered drift reduction to be a priority need, and as such, drift reduction should be promoted among growers, spray machinery operators, and policy makers. Mitigation measures in the context of the off-crop risk assessment might include, for example, cropped or un-cropped buffer zones, or the use of low-drift technology.

1.5 Recovery

When products exert some effects on NTA populations, experiments and risk assessments should evaluate the recovery, or potential for recovery, of these populations.

Recovery was defined at the workshop as "The return of populations, communities, or functional groups to levels that would be reached without the specific stressor."

The question of recovery is of particular importance in the in-crop area, where for some products and particularly insecticides and acaricides, some level of effect cannot be avoided due to either direct or indirect effects on NTAs. The current risk assessment scheme for PPPs considers that effects on populations are acceptable for the in-field area. As explained in ESCORT 2, it is accepted for the in-crop area that the application of these products may result in effects above the threshold value of 50% if "recovery" or at least the "potential for recovery" is demonstrated within one year. For the off-crop situation, the acceptable time period is defined as "within an ecologically acceptable time period."

We defined these endpoints as appropriate for the following scales and areas:

- At the landscape-level, the recovery of populations is the relevant endpoint.
- In off-crop areas, recovery of the communities (e.g., assemblage of arthropod species and their abundance living in a grassy margin) is the relevant endpoint.
- In in-crop areas, the recovery of ecosystem functions (e.g., pollination, pest control) assessed for appropriate functional groups (e.g., pollinators and beneficial arthropods) is the relevant endpoint.

Concerning the recovery of NTAs in field studies, the interpretation of results should consider the mobility of the taxa monitored, as we considered the observed return to the control levels or its absence not to be a robust predictive indicator for the likelihood of recovery under larger-scale use of pesticides. Instead of actual recovery, the possibility for recovery (potential for recovery) can be assessed through, for example, the time needed to reach an acceptable magnitude of effects, by means of aged residue studies, or by combining information on the degradation of a compound with data from effect studies. The concept of the possibility for recovery can be applied to the in-crop area but does not guarantee that actual recovery will occur.

Regarding field studies for off-crop risk assessment, we considered no effect or only transient effects (e.g., de Jong et al. 2010) acceptable, and therefore measuring long-term recovery is not applicable.

In future, recovery may be better predicted by modelling approaches. Models could be used for impact and risk assessment for different agronomic practices (e.g., crop rotation, pesticide use, crop management). Models also could be useful for extrapolation purposes, for example, for extrapolating recovery potential in populations in different climatic regions or, as for the in-crop area, as a support to interpret effects on populations in terms of effect on ecological functions.

1.6 Field Studies

Field studies can be performed if lower-tier studies indicate a risk to NTAs from the use of a PPP. Because effects may have to be assessed at arthropod community level during periods that can be longer than one year, intensive sampling on large-scale plots must be performed, especially for in-crop studies. Thus, because field testing for a PPP cannot be conducted in all possible crops and all geographic areas, there is a need for suitable field study designs and tools that allow us to extrapolate available results to other situations.

Currently winter wheat and apple orchards are used as models for arable crops and orchards, respectively. We considered these surrogate crops still appropriate, but the use of winter wheat for leafy arable crops, for example, may need further investigation and data compilation.

In assessing whether the extrapolation of results to other crops is appropriate, all available information should be considered (e.g., type of fauna, DT50 values concerning the dissipation of residues). From a generic point of view, results of field studies suggest that in Southern Europe the number of species is higher than in Northern Europe, but that the abundance of the species is lower than in Northern Europe. Current data suggest that there are no major differences in the response of communities between North and South but the set of data available is limited (e.g., see Aldershof and Bakker in Appendix 2, Poster Abstracts). Recovery trends also may vary between northern and southern climatic regions. Uncertainties related to these possible differences could also be resolved with the development of dedicated modelling tools.

With regard to the performance of field studies, we recommended that the timing of the application and the application rate in field studies should reflect the realistic worst case of the intended use pattern. For in-crop studies, a rate–response design is impractical and not necessarily needed in every case. Multi-rate designs (e.g., with up to three different application rates) might be suitable to facilitate the interpretation of the results because they enhance the chances to depict dose–effect relationships.

During a field study, the crop must be maintained in good agricultural health with the use of herbicides and fungicides under consideration of minimal crop management. PPPs with the same mode of action as the test product or products known to be harmful to the NTA community should be avoided. When the field sites are selected, the actual surrounding agricultural landscape should be considered.

For the selection of appropriate sampling methods, available guidelines should be followed (e.g., Candolfi et al. 2000). Even though in most cases at least two sampling methods should be used, there are also cases where a field study focusses on a specific arthropod group and the use of only one sampling method may be appropriate (e.g., predatory mite field studies).

If a specific sensitive species has been identified in lower-tier test but is missing in the field study, the expected effects on this species may be further addressed or extrapolation from related taxa is possible.

For the statistical analysis, the statistical power of a field study must be balanced with practical possibilities on a case-by-case basis. We recognised that, regarding recovery, landscape aspects are important for re-colonisation. Thus, they need to be considered in the study design and risk assessment. The duration of a field study can be up to one year, which could be extended if required by the biology of the affected species.

The possibilities of extrapolating the results from in-crop studies for the off-crop risk assessment were extensively discussed. One option identified was to account for the uncertainty when extrapolating from in-crop to off-crop by applying uncertainty factors to in-crop–based endpoints, depending on the relevance and quality of the in-crop field study. An alternative option would be to conduct off-crop field studies. Compared to in-field studies, smaller plots might be appropriate for off-crop studies (see Appendix I in de Jong et al. 2010, and Appendix 2 of these proceedings). Therefore, such off-crop field studies could be conducted within a dose–response design in order to cover different degrees of risk mitigation options and also to derive a NOER and a NOAER.

For the extrapolation of field studies from one formulation to another formulation, the results of extended laboratory studies should be considered.

Species sensitivity distributions (SSDs), which are currently used in other areas such as aquatic risk assessment, can be used for the NTA risk assessment but the actual use may need further evaluation.

Finally, we discussed the question of indirect effects from herbicides that might have no direct toxicity to NTAs but might affect host plants of NTAs in the off-crop. Workshop participants concluded that this question is related to the protection of non-target plants and that these effects would be covered by an appropriate protection of non-target plants.

1.7 Further Topics

For the time being, we recommend using the generic DT50 of 10 days to account for the dissipation of residues in the treated crop, as recommended in the Guidance Document on Risk Assessment for Birds and Mammals (EFSA 2009) for calculating the multiple application factor (MAF; see Neumann in Appendix 1, Abstracts of the Plenary Presentations).

1.8 Conclusions and Recommendations

The proceedings of the ESCORT 3 workshop aim to update the recommendations and guidance for the risk assessment of NTAs, based on the current knowledge on related science and on regulatory evolution. The information and recommendations proposed in this document are to be used along with the recommendation previously published in the ESCORT 1 (Barrett et al. 1994) and ESCORT 2 (Candolfi et al. 2001) guidance documents.

The following four areas were discussed in detail, and the conclusions further developed the positions established in ESCORT 1 and ESCORT 2:

1) level of protection and testing scheme,
2) off-crop environment,
3) recovery, and
4) field studies.

1.8.1 Recommendations for Regulation

1.8.1.1 Protection Goals

- In the in-field area, the protection goal should be the maintenance of relevant functions (e.g., pollination, control of pest species, food source for wildlife and soil function).
- To address the issue of soil function, the risk assessment approaches conducted on one side for soil-dwelling NTAs and on the other side for soil macro-organisms (e.g., collembolans, worms) should be maintained, because they rely on different and complementary data sets and exposure modalities.
- In the off-field area, the protection goal should be the maintenance of NTA biodiversity.
- In the off-crop in-field area, protection goals should be defined at the national level as a function of management measures to be ensured by farmers. They could be different for managed areas implemented for risk mitigation purposes.
- For higher-tier field studies, the NOER for the community and the NOEAER for the population are identified as the relevant endpoints for the off-field risk assessment.

1.8.1.2 Risk Assessment

- The information and recommendations contained in current guidance documents (ESCORT 1 and 2) are considered appropriate for the risk assessment and to achieve the defined protection goals.
- In the first-tier risk estimate calculation, multiple application factors (MAF) should be calculated based on the default DT50 value of 10 days as recommended in the Guidance Document on Risk Assessment for Birds and Mammals (EFSA 2009).
- Higher-tier (field) testing should consider phytophagous species in order to ascertain a balanced consideration of these species.
- In performing field studies, the timing of the application and the application rate should reflect the realistic worst case of the intended use pattern. When necessary

and possible, a multi-rate design (e.g., with up to 3 different application rates) will facilitate the interpretation of the results. The study should involve at least 2 sampling methods except for cases where 1 sampling method is sufficient to monitor the species of concern. The duration of a study can be up to 1 year and can be extended if required by the biology of the study.

- Off-crop in-field areas correspond to the areas that are not over-sprayed. The exposure assessment starts at 1 m from the edge of the directly sprayed crop in arable crops and at 3 m from one half-row space beyond the last plant or tree row in orchards. These recommendations may change in future with the evolution of spraying technologies, and updates in harmonized values that would rely on drift-reducing technologies should be considered in this respect.
- Off-crop field studies address more appropriately the issue of off-crop risk assessment than do in-field studies. Methods for off-crop field studies are available (e.g., Bakker and Miles in de Jong et. al. 2010) that match these objectives and may account for different application rates to reflect different degrees of risk mitigation options.
- Alternatively, extrapolating the effect endpoint measured in an in-crop field study to an off-crop effect endpoint could be accounted for through an uncertainty factor. Appropriate factors for extrapolation from in-crop studies to off-crop should be defined.
- Effect classes, as proposed in de Jong et al. (2010) in considering the extent and temporal scale of effects, may be used to derive effect endpoints that would match with protection goals defined for the different areas. Class 3 effects may be appropriate for the off-crop in-field margin, and Class 1 and 2 are appropriate for off-field area.
- Possibility for recovery can be assessed by aged residue studies or by combining information on the degradation of the product with data from effect studies.
- Extrapolation of the effect data from one formulation to another can be made based on the outcome of extended laboratory studies.
- The risks to NTAs from indirect effects due to impacts of PPPs on non-target plants should be addressed though the evaluation of the risks to non-target plants.
- Concerning the recommendations for the performance of NTA field testing, see Section 6.1.2.

1.8.2 Recommendations for Research

- A more precise identification of representative species for all key functions in the in-crop area would be useful. In addition, it is important to link the level of effects as measured on organisms or population in the current testing protocols with the preservation of ecological functions. Monitoring data and modelling tools may help in this respect.
- There is also a need to characterise patterns of diversity and abundance in off-field habitats.
- Further research is recommend concerning potential differences in sensitivity between in-crop and off-crop communities.
- Research was proposed regarding the interaction between vegetation structure and exposure of the in-crop and off-crop NTA fauna.

- Beyond the available information on drift-reducing nozzles, the efficacy of drift reduction measures should be quantified for use in the risk assessment.
- In the off-crop area, the default value used to account for the dilution of a spray drift in the vegetation (vegetation distribution factor [VDF]) should be reviewed in the context of the review of the spray drift data.
- In the case of seed treatments and a related potential exposure of off-crop populations to dusts, risk assessment and risk management approaches should be developed.
- The potential exposure of NTAs to vapour drift should be assessed in order to evaluate its relevance for the NTA risk assessment.
- The use of winter wheat and orchard as surrogate crops for field studies is satisfying but should be documented further through additional investigation and data compilation.
- Further development of modelling approaches is needed in support of a better prediction of recovery, for extrapolation purposes (time scale, spatial scale, sensitive species not present in a field study, etc.), and also to support predicting the impact of agronomic practices (e.g., crop rotation, crop management) on NTAs.
- The use of data from SSD analysis in the risk assessment is possible in principle but needs further development.
- There is a need to review data on pollinator species (e.g., honey bees, solitary bees, bumble bees, and other pollinators) in comparison to other NTAs, in order to assess whether the data currently generated for EU risk assessment are sufficient to address the pollinator species.
- Even though there is some evidence that the current scheme is protective of the in-field environment, further evidence should be built for active ingredients with special modes of actions such as insect growth regulators (IGRs) as well as for the off-field species. Monitoring data might be useful in this respect.

1.8.3 Recommendations for Education

- Within the context of NTA field testing, guidance in combination with training would be an asset to all involved parties (e.g., those who conduct field studies, those who monitor field studies, and those who evaluate field studies), in order to better understand the general complexity of the subject matter as well as the needs of the other parties involved. The European Food Safety Authority (EFSA) and the Society of Environmental Toxicology and Chemistry (SETAC) were mentioned as organisations that could organise such a training, which preferably should include field visits.
- There is a need to provide useful risk and conservation management advice (e.g., conservation field margins) for farmers. This could be linked to agri-environment direct subsidy payments.
- The use of drift reduction measures by farmers should be promoted.

1.9 References

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2 Introduction

2.0 History of ESCORT

Katie Barrett

The first **E**uropean **S**tandard **C**haracteristics **O**f beneficials **R**egulatory **T**esting (ESCORT 1) meeting was held in March 1994. At the time, the only testing regime for the so called "non-target arthropods" (NTAs) was based on the International Organization for Biological Control (IOBC) testing methodology that had been developed to demonstrate product suitability for Integrated Pest Management (IPM) use. The purpose of the meeting was to reach consensus in the regulatory testing requirements for NTAs in the context of European Union (EU) directive 91/414/EEC and the European and Mediterranean Plant Protection Organization (EPPO) risk assessment scheme. The meeting proceedings were published as a guidance document entitled Regulatory Testing Procedures for Pesticides and Non-target Arthropods (Barrett et al. 1994), and this guidance was written into the Annex II and Annex III data requirements (96/12/EC of 8 March 1996).

The key recommendations arising from the ESCORT 1 workshop were that all plant protection products (PPPs) should be tested against at least 4 species of arthropod, representing the predatory mites, parasitoids, ground-dwelling predators, and foliage-dwelling predators. It was agreed that testing should be required at the recommended application rate, initially conditions of exposure representing a worst case (on glass plates or sand in the case of ground-dwelling species) thus corresponding to Tier 1 worst-case exposure studies. Higher-tier testing would be required where there was >30% effects. This higher-tier testing could take the form of more realistic conditions of exposure either under laboratory or semi-field conditions. The 30% threshold value was then also reflected in the uniform principles for decision-making (Annex VI of EU directive 91/414/EEC).

Six years later the second ESCORT meeting was held. Its objective was not only to review the original recommendations but also to consider how the data could be used in the risk assessment procedure. Again the proceedings were published as a book (Candolfi et al. 2001) and cited in the Guidance Document on Terrestrial Ecotoxicology (EC 2002).

During the ESCORT 2 meeting, some significant revisions to the testing strategy proposed under ESCORT 1 were made. The requirement for testing of 4 species at Tier 1 was optimized and focused on 2 sensitive standard species, the parasitoid *Aphidius rhopalosiphi* and the predatory mite *Typhlodromus pyri*. The rationale for this change was based on a review of data, which demonstrated that either *A. rhopalosiphi* or *T. pyri* had been shown to be the most sensitive in 95% of cases (Candolfi et al. 2000; Vogt 2000). In addition, the ESCORT 2 workshop participants proposed that the test design should now be a dose–response study to determine the LR50, thus allowing the determination of a sensitivity threshold as well as an easier use in the risk assessment for products that are used at different applications rates. It was suggested these data could then be used in evaluating risk by the calculation of a hazard quotient (HQ), as had been used successfully for honeybees (Campbell et al. 2000). The HQ = the application rate / LR50 (Tier 1 on inert substrates).

The original proposal derived from the data was that HQ values of ≥12 for *T. pyri* and of ≥8 for *A. rhopalosiphi* would trigger higher-tier studies. However, in response to concerns raised during discussions, these values were reduced to a more conservative value of 2 for both species. ESCORT 2 participants, as had ESCORT 1 participants, recommended higher-tier testing under more realistic conditions of exposure, and with additional species, where there was a perceived risk. Recommendations on risk assessment for both in-field and off-field were also made. The risk assessment was finally developed for the NTAs in the in-field area as well as in the off-field area, the latter being concerned with exposure to drift from the treated area. It was notable that the ESCORT 1 terminology "in-crop" and "off-crop" was deliberately changed in ESCORT 2 to "in-field" and "off-field", to allow for managed "off-crop" areas within the field such as buffer strips and set-aside.

The ESCORT 3 meeting was held as a review and update of the previous meeting outputs, and to consider new issues that had arisen in the interim period.

In summary, the meeting dates were

- ESCORT 1 (March 1994),
- ESCORT 2 (March 2000), and
- ESCORT 3 (March 2010)

2.1 Structure of ESCORT 3

Katie Barrett and Gavin Lewis

It has now been 10 years since the last ESCORT workshop, and the current Guidance Document on Terrestrial Ecotoxicology (EC 2002) is under review. As part of this review process, the current guidance and risk assessment proposals are also being reevaluated, and it was considered appropriate in this context to have an ESCORT 3 workshop to review the learning on NTA risk assessment for PPPs and to review the literature and knowledge to improve the risk assessment scheme.

The workshop Organising Committee collated a number of questions arising from the peer review and authorisation processes for PPPs at both a European and a national level. The European Food Safety Authority (EFSA 2009) public consultation on the existing Guidance Documents on Aquatic and Terrestrial Ecotoxicology (EC 2001, 2002) was also consulted. The overall tenet of these questions is whether the current tiered risk assessment scheme is sufficiently predictive and protective for NTA communities. The workshop Organising Committee considered all the comments in detail and put together a programme of discussion topics to cover the main areas of concern. The 3-day workshop was organized around plenary sessions alternating with work in subgroups for in-depth discussions on the 4 areas identified by the Organising Committee:

1) level of protection and testing scheme,
2) off-crop environment,
3) recovery, and
4) field studies.

An opening plenary session provided background information on the following:

- The current situation with regard to NTA risk assessment in the EU and the level of protection provided based on a review of active substances that have been assessed since July 2006, both on a national and an EU (peer review) level (see Alix and Heranz, Appendix 1).
- A Europe-wide investigation into the effects of agricultural intensification and its components on the species diversity of wild plants, carabids, and ground-nesting farmland birds. Study areas were located in 8 countries (Sweden, Estonia, Poland, the Netherlands, Germany, France, Spain, and Ireland) with an assessment of factors affecting biodiversity and biological control potential (see Geiger et al., Appendix 1).
- A summary of the findings from a recent UK Chemicals Regulation Directorate (CRD)-funded project on NTA recovery (see Lawrence and Brown, Appendix 1). This project considered the mechanisms that may be involved in recovery, which may be complex and highly scenario specific. Consequently, a number of uncertainties surround the demonstration of recovery, particularly with regard to the interpretation of laboratory and field data. We considered potential sources of uncertainty and included proposals on how they may be reduced.
- A summary of the findings from a recent UK CRD-funded project on NTA representivity (see Lawrence and Brown, Appendix 1). Available regulatory field studies were examined in detail to compare the responses of current test species with the wider NTA fauna. Some taxa are found to follow the overall community response more closely than do others. For those that do not, there is a need to assess the ecology of the taxa and the ability of the study design to describe the effects on them.
- Consideration was given to the conduct of field trials for the assessment of effects on non-target arthropods in the off-field environment (see Bakker, Appendix 1). This considered that the assessment of off-field effects should be performed in off-field habitats due to the limitations of in-field trials, particularly in relation to recovery. A proposal for an off-field study was given with a no-observed-effect rate (NOER)–type endpoint. The results obtained from such a study may be used to assess safe buffer distances and, in combination with product decay data, time to potential recovery.

Summaries of these presentations from the first day of the workshop are provided in Appendix 1.

The proceedings presented here reflect the discussions held during both plenary and subgroup sessions. Where possible the aim has been to achieve consensus, but that was not possible on all issues, and where differing views were held this has been reflected in the proceedings.

Registration for the workshop was open to all interested parties. From all the registrations received, the workshop Organising Committee selected approximately 60 participants, in line with the tripartite representation as recommended by the Society of Environmental Toxicology and Chemistry (SETAC). The workshop participants were preassigned to the 4 subgroups on the basis of their knowledge and expertise, but the plenary sessions gave participants the opportunity to comment on all areas under discussion. In all areas, the aim was to identify recommendations that fell into one of three categories: 1) regulatory, 2) educational, or 3) research.

The recommendations from the workshop are reflected in the following 4 chapters and also in the final concluding plenary chapter.

The proceedings of the ESCORT 3 workshop aim at updating the recommendations and guidance for the risk assessment for NTAs, based on the current knowledge on related science and on regulatory evolution. The information and recommendations proposed in this document are to be used along with the recommendations previously published in the ESCORT 1 (testing) and ESCORT 2 (risk assessment) guidance documents.

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3 Level of Protection and Testing Scheme

Anne Alix, (Chair), Gavin Lewis (Rapporteur), George Broufas, Mike Coulson, Jean-Marie Delpuech, Axel Dinter, Andreas Höllrigl-Rosta, Agnieszka Musŕiska, Guy Smagghe and Gabe Weyman

The general principles for the evaluation of the risks posed by plant protection products (PPPs) used in crop protection for non-target arthropods (NTAs) are provided in Council Directive 91/414/EEC (15 July 1991) and in the new regulation (EC 2009a), which replaces the Council Directive since June 14th 2011. While the Directive defines clearly the conditions under which exposure of NTAs cannot be excluded, thus triggering a risk assessment, the level of protection that is expected from this assessment is stated only in general terms. The level of protection defined in Council Directive 91/414/EEC proposes the term "acceptable effects on beneficial arthropods other than bees" in decision-making criteria without any further clarification. Regulation 1107/2009/EC (EC 2009a) does not provide any detail on the arthropods that should be protected. An indication on the general aims of this regulation with regard to the level of protection of non-target organisms is provided in the list of approval criteria for active substances in article 4, paragraph 3, which states that the PPP

(a) shall be sufficiently effective
…
(e) shall have no unacceptable effects on the environment
  …
  (ii) impact on non-target species, including on the ongoing behaviour of those species;
  (iii) impact on biodiversity and the ecosystem, defining biodiversity as "variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this variability may include diversity within species, between species and of ecosystems.

No clear definition is provided as regards the framework within which this risk assessment should be performed:

- How are NTAs that we aim to protect defined?
- What is the spatial and time scale over which a risk assessment should be performed?

The ESCORT 3 subgroup on level of protection and testing scheme discussed these two questions with the aim of:

- providing more detailed proposals on the framework for NTA risk assessment;
- providing a contribution on the concepts of biodiversity, pest management and ecosystem functions and how to apply these in a risk assessment;
- identifying the implications for testing in terms of nature of the tests and test design, which have been discussed in detail in the other sub-groups.

3.1 Identification of NTAs to Be Protected

With the exception of the general reference to arthropods in the in-field and off-field area, the regulatory guidance in support of the current directive and new regulation does not provide any specific definitions for the communities and populations of arthropods that should be considered in the risk assessment performed in the framework for the use of PPPs. As a first step, there is a need to specify the important aspects that must be considered in defining NTA protection goals, in a regulatory and practical context:

- The implementation of the regulation on PPPs (risk assessment and risk management) is operating within an agricultural environment. This is a managed environment, subject to a number of constraints among which the application of pesticides is only one. In the context of Council Directive 91/414/EEC (EC 1991) and Regulation 1107/2009/EC (EC 2009), the effects of a PPP for which a decision must be made are assessed as effects that come in addition to the those induced by the cropping management operating in agricultural environments.
- We recognise that risk assessments to NTAs for PPPs should be viewed against a background of other agronomic inputs and practices and that these can have an equal or greater impact than PPPs on NTA populations or communities. This regulatory context needs to define the limits in which the risk assessment and risk management are performed. As defined in the Executive Summary, the spatial scale is first the field, comprising the crop where the PPP is applied, and its immediate boundaries, the in-field off-crop area. The time scale over which the risks should be evaluated is related to crop duration, but it also may be extended to the rotation in cases where the product may be used on other crops entering into the rotation.
- There is a need for data that would help to further describe the NTA communities in the different areas defined (in-crop, off-crop, and off-field) in relation to their protection goals (e.g., NTAs involved into pollination in-field). Concerning the level of protection for NTAs, a differentiation is required, focussing for the in-crop on the ecosystem function, for the off-field on the populations (de Jong et al. 2010, Class 1 and 2), and for the off-crop in the in-field on the community level.

In principle in the agricultural environment, ecotoxicological risk assessment is concerned with NTAs, that is, all those arthropod species which are not intentionally treated as pests. However, for practical purposes, it is important to provide structure and identify priorities. We identified a number of possible ways of structuring the protection goals as a basis for identifying NTAs of concern.

3.1.1 Spatial Distribution of NTAs in Agricultural Environment

Spatial distribution may be displayed simply (Figure 3.1). The non-target status of an NTA may depend on its spatial location (e.g., Lepidoptera in the off-crop may be non-target, but the same species in the in-crop may be a target pest).

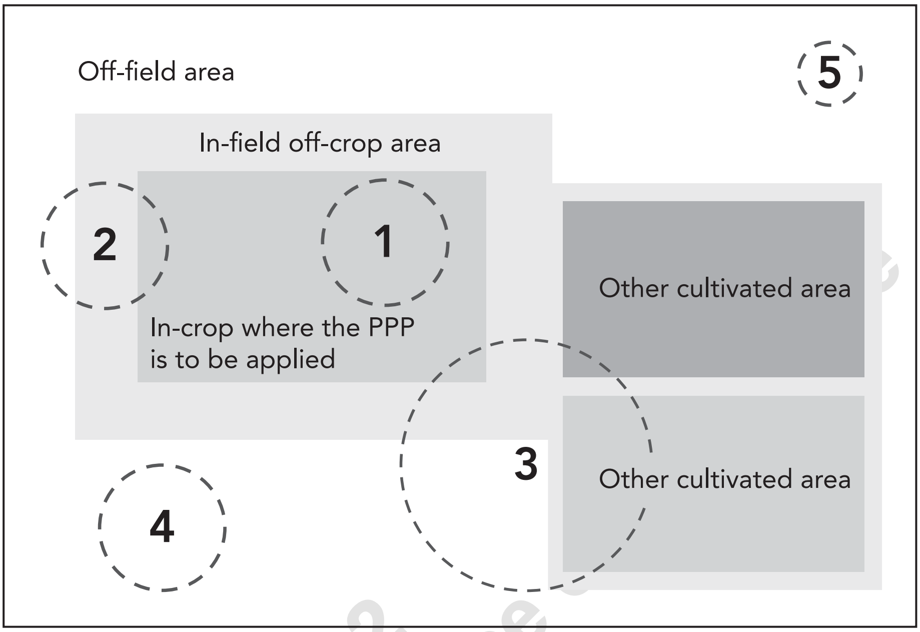

Figure 3.1 Spatial distribution of NTAs in the agricultural environment. The level of exposure decreases from the area 1 to area 5, except of course in the cases where surrounded crops are treated with the same product.

Legend:
1: arthropods primarily living in the in-crop habitat
2: arthropods based primarily in the off-crop habitat but also using the in-crop habitat (e.g., for foraging)
3: arthropods using the agricultural landscape on a larger spatial scale (over several fields, e.g., flying insects)
4: arthropods primarily living in the off-field/off-crop habitat
5: arthropods not living in the immediate agricultural environment.

3.1.2 Time Scale of the Risk Assessment

The time scale over which any risk assessment operates must be considered. Thus, over a period of years, factors such as multiple exposures to different pesticides, crop rotation, and changes in land use become increasingly important to NTA populations and communities.

In principle, exposure of NTAs to PPPs may occur in the following ways:

- By direct exposure at the time of application, when arthropods are present in the crop or in the boundary areas that are exposed to spray droplets or drift or by in-

direct exposure to fresh residues on leaves or flowers. For products applied on bare soils, similar considerations apply.
- After the application, due to the exposure to residues of products that remain on plant surfaces (leaves or flowers) as well as on and in the soil after the application (persistent products). The exposure to residues that move in the plants to flowering parts and may be present in nectar or pollen or are present in aphid honeydew (i.e., show systemic activity) is also to be considered. For such systemic and persistent compounds, exposure may be delayed from the time of application of the product (weeks after sowing in the case of treated seeds or exposure to residues from a previous crop treatment).

Thus, time scale is important when we consider NTA categories of concern for an exposure of a defined nature, because it defines the period over which effects should be monitored and over which recovery should be achieved (see Chapter 5 for additional discussion).

3.1.3 Ecological Function

NTAs may be grouped according to the specific ecological functions they have in the agricultural and wider environment. These functions are important because they reflect the position of a species in the trophic chains, its distribution in the agricultural environment, and the related behaviour and principle routes of exposure in the environment. As an example, a parasitic wasp may be exposed as an adult not only while foraging for hosts in soil or on leaves with the aim of laying eggs but also while foraging for nectar. The presence of hosts in the crop or in a preceding crop (e.g., emergence of overwintering adults in diapause occurs in spring, several months after crop harvest) will determine exposure. In the case of overwintering pupae, the main routes of exposure may be through soil residues if the hosts are developing in the plant roots, or it may be via leaf residues if the hosts are herbivores. The following functional groups were identified:

- parasitoids,
- predators,
- herbivores,
- detritivores.
- coprophages.
- pollinators, and
- food species (e.g., game bird chick food).

The function thus leads the main conditions for exposure; however, for each of these functional groups, several routes of exposure may occur.

It is noteworthy that the first five of these ecological groups represent positions in the food chains, while pollinators and food species reflect specific functions that may already be addressed by species of the 5 previous groups (e.g., butterflies may be categorized as herbivorous when larvae but also contribute to pollination as adults).

This categorization provides a reference point for consideration of the protection goals. Each of these categories is present in the agricultural environment, in proportions that may differ as a result of various factors (e.g., soil, crop, or climatic considerations). They therefore represent groups of organisms that need to be considered in discussing the risks that a product may pose to arthropods. It is not intended that these groups should be specifically included in the risk assessment; rather they provide a reference point for the consideration of the protection goals. The number of representative species needed for a risk assessment is determined on a case-by-case basis, depending on the mode of application or the mode of action of the product.

3.1.4 Life History Strategies

Life history characteristics, as distinguished between r-strategists and K-strategists, were identified as another possible basis for categorising different NTA species. These characteristics tend to reflect extremes of a continuum of life histories, and it may be possible to divide them into more categories. However because representatives of both are found in each of the functional groups, we did not explore this categorization further, but it is addressed with recovery issues.

The degree of association with the crop determines the magnitude of exposure for individual species. For example, species having a strong and specific plant–insect relationship within the crop may be exposed under very different circumstances compared to generalist predatory species. The association of a species with the crop is also linked to the role of the species in the agricultural environment and to the related ecosystem functions. As an example, a species acting as the main pollinator of the crop of concern will have a strong association with this crop. Similarly, a specialist parasitoid species has a stronger relationship with its host and the host crop than would a generalist parasitoid species.

Crop treatments are performed with the aim of controlling pests, weeds, or diseases. The effects exerted on target organisms may also have an influence on the wider agricultural environment, for example, on organisms that depend on the population of the target for food or for habitat. An acknowledged method to take such effects into account (e.g., to distinguish toxic effects from effects related to food shortage or habitat destruction) is not available. Thus, an overall acceptable effect of a product on non-target species is expected, without making a distinction between toxic and indirect effects (e.g., food shortage).

Ecological function was identified as the primary factor for structuring the risk assessment and protection goals. Workshop participants proposed ranking the influence of the other factors by using a matrix grid to assess their influence on the ecological function categories and thus help to identify their implications for risk assessment. Building this grid helped in identifying research needs. For example, the category of pollinators is not explicitly addressed in the current testing package and there is a need to explore, in the current exposure and effect assessment, when and to what extend they are covered. Part of the answer could be provided through a review of toxicity data and their comparison with the general data set for NTAs. The approach allowed us to define protection goals, which could then be related to the specific factors previously identified. The general framework of these protection goals is provided next.

3.2 General Framework and Definition of Protection Goals

The general framework as proposed by the subgroup and agreed on in the plenary session is the definition of "Protection goals for non-target arthropods following the use of pesticides under good agricultural practice (GAP) in the agricultural landscape".

Broad protection goals considered in-field and off-field areas distinctively:

- In the in-field area, we identified the protection goal as the maintenance of relevant functions.
- In the off-field area, we identified the protection goal as the maintenance of NTA biodiversity.

Similar specific protection goals may apply in- and off-crop, depending upon how these areas are themselves defined and used. An illustrated definition of the terms in-field, off-field, in-crop, and off-crop is provided in Section 4.1.

3.2.1 In-Field: Maintain Field Functions

Relevant in-field functions of the NTA community that should be preserved are

- pollination in-field (including off-crop area),
- control of pest arthropods,
- food source for wildlife, and
- soil function as provided by NTAs (e.g., detritivores and coprophagous species).

All these in-field functions are maintained by the NTA functional groups that have been identified previously (e.g., parasitoids, predators, detritivores, herbivores, coprophages, pollinators, and food sources). In principle, this means that as long as the function (e.g., pollination of the crop) is preserved, it ensures that the contribution of representatives of these ecological groups is maintained in the in-field area and a particular species need not be protected per se. The corresponding methodology for an appropriate risk assessment in-field may need further consideration. To what extent the interpretation of current laboratory tests on a parasitoid species such as *Aphidius rhopalosiphi* ensures the preservation of the parasitism by NTAs in-field and, potentially, the preservation of pollination, was not discussed by the subgroup or during the plenary session. Additional data to support or adapt risk assessment methodologies are needed for each of the NTA categories identified above.

The control of pest arthropods was further defined as the account for "the contribution of NTAs to the control of arthropods (insects, mites, etc.)", in order to include natural control and active Integrated Pest Management (IPM) where appropriate. This does not imply that any particular level of control must be maintained.

NTA species also represent a food resource for insectivorous and omnivorous bird and mammal species. Examples of impacts on bird populations resulting from insect depopulation in cropped area are available.

With regard to soil function, there is a need to define a requirement specific to NTAs in comparison with the regulatory requirements that are specific to soil organisms in general. This issue is addressed in a dedicated section of Council Directive 91/414/EEC and of Regulation 1107/2009/EC (EC 2009) and by other groups (e.g., an EFSA Panel on Plant Health, Plant Protection Products and their Residues [PPR] working group). The risk assessment may be conducted differently to NTAs, because it relies on exposure estimates and testing protocols focused on such organisms as soil mites or earthworms. The risk assessment is performed based on the SANCO 10329 (EC 2002) guidance document. Some other species like coleopterans are considered with other NTAs, with study designs and effect endpoints being adapted to ESCORT 2. Taking this into account, we discussed 2 options for their suitability to address the risks for soil function and thus for the NTAs contributing to soil function, being detritivores and coprophages:

1) The risk assessment for all invertebrates living in the soil should be harmonized, or
2) the risk assessment should be conducted under consideration of the current separation evaluating the NTAs according the recommendations of ESCORT 2 and evaluating the soil macro-organism according to SANCO 10329 (EC 2002) for soil organisms.

Participants were in favour of the second option, in order to benefit from the complementary approaches provided by the two risk assessment methodologies and deduce from them the data being relevant for an evaluation of the risks to the organisms in relation to soil function. Also the definite data requirements that will be adopted in the context of Regulation 1107/2009/EC should help in listing the data that should be available in future to conduct both risk assessments based on the corresponding study results.

In defining the level of protection that should be applied to in-field off-crop areas, the nature of the off-crop area has to be taken into consideration. In-field off-crop areas may be unsprayed headlands, un-cropped strips, beetle banks, or even hedgerows having been planted as windbreaks.

These off-crop areas represent different management levels for farmers. Thus, the option of setting a level of protection for off-crop areas similar to the level proposed for the off-field area could in some cases be counterproductive and potentially discourage farmers from using these areas as optional protection measures if they are then obliged to adopt additional protection measures. In addition a level of protection similar to un-cropped areas could be irrelevant if the off-crop margin is highly managed. Thus, as a default approach, similar protection goals as for the in-crop area may be proposed for the off-crop in-field boundaries, and in the cases where these areas require a higher level of protection (e.g., where they are specifically implemented with the aim of preserving biodiversity to support in-field recovery), a similar protection level as for the off-field area may be considered. Directions to take with regard to this issue should be further dealt with at the national level (see also Section 4.8).

3.2.2 Off-Field: Maintain NTA Biodiversity

By addressing biodiversity, we are covering the relevant requirements for environmental risk assessment with respect to NTAs according to EU Regulation 1107/2009/EC (EC

2009), being to reach "No unacceptable effects on the environment", in ensuring 1) no unacceptable impact on non-target species including the ongoing behaviour of those species, and 2) no unacceptable impact on biodiversity and the ecosystem. This may be further improved in taking into account following the points:

- Populations in the off-field environment should not be affected by crop management and should therefore require a higher level of protection compared to the in-field area.
- NTAs in the off-field environment provide ecological functions for both nature and agriculture, and these are specific attributes we are trying to protect (e.g., pollination from non-honeybee species).
- Protecting biodiversity in its various structural and functional manifestations helps to ensure that other goals are being addressed.

3.2.3 Testing Scheme

Practically, the current guidance documents (including recommended test species and calculated hazard quotients or ratios) are still appropriate for the risk assessment to NTAs, but the following issues need to be further addressed:

- There is a need to check whether the current thresholds applied at the lower tiers of the risk assessment are sufficient to provide the required level of protection. If necessary, they might be revised based on a review of the currently available data (including field studies) to ensure that the protection goal that is to be defined is being met.
- In assessing effects in-field, it is important to link the endpoints as generated in laboratory and field studies with the protection goal of preservation of ecological functions. This topic should be further addressed, and monitoring data as well as modelling tools may help in this respect.
- At the higher-tier (field) level of testing, the off-field risk assessment could rely on a no-observed-effect rate (NOER) for the community and on a no-observed-ecologically-adverse-effect rate (NOEAER) for the population (effects of limited magnitude and duration acceptable) as the relevant endpoints for risk assessment. This will better reflect that the structural and functional aspects of biodiversity are protected.

These checks and, if necessary, adaptations may be performed based on the data that have been generated up to now in support of risk assessment in a regulatory context.

The two protection goals for in-field and off-field respectively are not independent of each other. Maintenance of biodiversity in the off-field will contribute to maintenance of in-field function. The level of implementation of the in-field protection goal may therefore depend on the quality or quantity of off-field environment in specific circumstances. These may vary at a national, regional, and even field scale, and so risk management should be determined locally.

3.3 Research Needs and Related Recommendations

We identified the following research needs and recommendations:

- There is a need to review currently available data for NTAs and different pollinator species (e.g., honey bees, solitary bees, bumble bees, and other pollinators), in order to assess whether the data currently generated for EU risk assessment are sufficient to address the pollinator group.[1]
- Further research is needed to identify representative species for all key functions in the in-field area.
- There is also a need to characterise patterns of diversity and abundance of NTAs in off-field habitats.
- There is some evidence that the current scheme is protective of the in-field environment. However, this situation and that for the off-field needs to be supported by data and also monitored as further regulatory data are generated.

3.4 References

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1 A provisional analysis of the issue was presented in a poster by Chaton et al. (see Appendix 2), which reviews data for 5 representative pollinating species.

4 Off-Crop Environment

Peter Campbell (Chair), Simon Hoy (Rapporteur), Frank Bakker, Pierre-François Chaton, Otto Daniel, Bert van der Geest, John Holland, Alan Lawrence, Michael Mead-Briggs, Mark Miles, Paul Miller, Martina Roß-Nickoll and Dirk Süßenbach

The off-crop environment subgroup's goal was to develop risk assessment principles for non-target arthropods (NTAs) exposed to plant protection products (PPPs) in the off-crop area. Our guiding principle was to produce a regulatory scheme, which was simple and practical yet effective, but also realistic and transparent. We sought to develop clear recommendations that would include relevant definitions of "off-crop" and the wider biodiversity issues mentioned in the forthcoming PPPs regulation (EC 2009). Research needs and educational requirements were also identified.

4.1 Definitions of Off-Crop and Off-Field for the Purposes of Risk Assessment

In terms of habitat types and architecture, the off-crop environment is potentially extensive and diverse. It could encompass neighbouring fields (including organic farming systems), managed field margins (including ecological compensation areas), nature reserves, and forests. While the current European and Mediterranean Plant Protection Organization (EPPO) definition of the "off-crop" area as referenced in ESCORT 2 is appropriate from a risk management perspective, it is not helpful when defining the off-crop exposure or risk assessment scenarios to be followed as determined by the available spray-drift data. For risk assessment purposes, in-crop and off-crop are the relevant definitions, where off-crop is largely defined by how the spray-drift data are determined.

The terms "in-crop" and "in-field," as well as "off-crop" and "off-field," are often used ambiguously, but they are distinct. Grassy or managed field margins usually are not considered a "crop" but they are in-field; the in-field finishes at the field boundary where off-field begins. We discussed the situation in which a field margin is intentionally put in by the grower to reduce drift, as a protection or biodiversity measure. Does this "off-crop" area then need protecting in its own right? Such a situation could result in further protection measures (e.g., a buffer zone) being required to protect the original planted protection or conservation zone. In such a case, a grower would then be discouraged from planting such protection or conservation zones, which is not desirable. In the case of conservation headlands, if the grower is compensated for planting such a conservation headland under an agri-environment scheme, then the management plan for that margin might require it to be protected from spray-drift. Therefore, with respect to risk management options and the habitat management required by agri-environmental schemes, local European Union (EU) Member State rules must apply. This is discussed further at Section 4.8.

We identified problems with regard to the practical definitions and protection of off-crop areas in some countries and farming systems (e.g., in particularly intensive areas where there may be very little off-crop field margin and one field is right up against the next). Clear distinctions are needed between definitions of off-crop for risk assessment and for risk and habitat management purposes, although these may need to be tied together for legal and practical reasons in some Member States.

The ESCORT 2 workshop participants preferred to use the term "off-field" as anything in the field that is within a farmer's control to manage as he or she considers appropriate. In this way, the farmer avoids needing to consider additional mitigation measures (e.g., non-sprayed buffer zones) for the protection of parts in the in-field area that were implemented to support NTAs or to reduce exposure of off-crop habitats in the off-field (e.g., a hedge planted for the purpose of drift reduction). However, in some Member States, farmers are now paid to manage edges of fields for wildlife.

We concluded that for NTA risk assessment purposes, it was clearer to refer to off-crop rather than off-field because this reference is based on the use of spray-drift data to define the off-crop area. Therefore, we developed the following definition of off-crop areas in arable and orchard crops as a recommendation for a regulatory perspective.

Recommendation: Regulation

Definition of "off-crop" for risk assessment related to arable uses: The area where the PPP is not intentionally directly applied (i.e., the NTA risk assessment is based on available arable spray-drift data and the exposure assessment is starting at 1 m from the edge of the directly sprayed crop; see Figure 4.1).

For the orchard environment, the understory vegetation and grassed area beneath and between the tree or plant rows are in-crop and should be covered in the in-crop risk assessment. The off-crop boundary in orchards, vines, hops, and similar crops is the outside edge of the track used by the sprayer to move around the orchard. However, this is not a practical definition from an exposure and risk assessment perspective. For NTA risk assessment purposes, the off-crop area should be defined according to how the drift data had originally been determined by Rautmann et al. (2001). In the case of orchard sprayers, the initial spray-drift risk assessment starts at 3 m from one half-row space beyond the last plant or tree row. Therefore, the definition of off-crop for orchard-type applications should also be defined in this way.

Recommendation: Regulation

Definition of off-crop for risk assessment related to orchard-type uses: Based on spray-drift data, the exposure assessment for the off-crop area for orchard-type applications starts at 3 m from one half-row space beyond the last plant or tree row. (This approach is in line with the exposure assessment as applied for water bodies.)

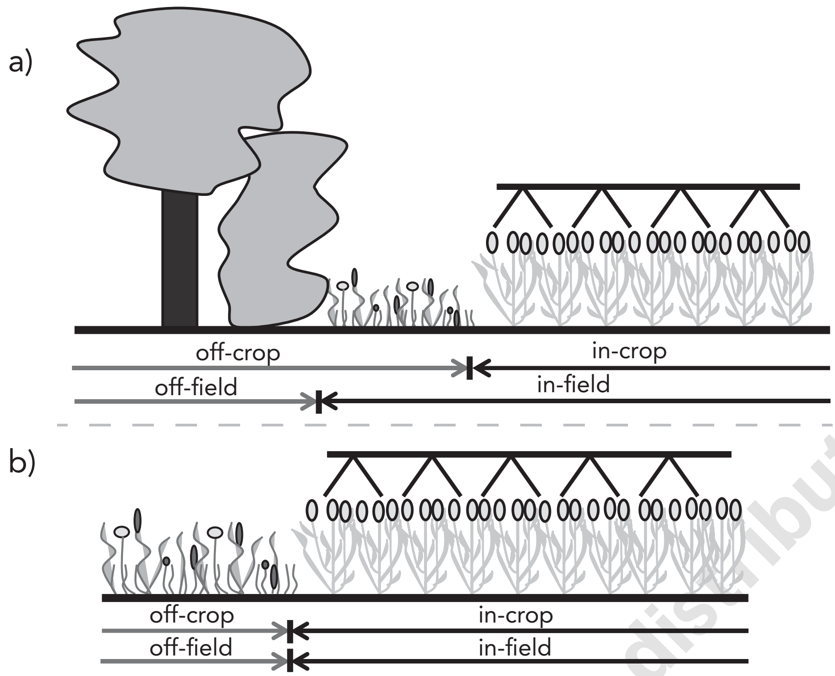

Figure 4.1 Off-crop definition in arable crops with (a) and without (b) a field boundary within the field. The actual situation might differ between different countries and will also be influenced by the legal position concerning property of the land.

4.2 Off-Crop Exposure from Spray-Drift

Due to different application techniques in arable crops and in high crops such as orchards, the off-crop exposure from spray-drift is addressed separately for both crop types.

4.2.1 Arable Crops

At the workshop, figures were presented from the Rautmann et al. (2001) arable spray-drift data set, which show that part of the first metre of off-crop area directly adjacent to the crop is affected by direct overspray. Indeed there may be up to 50% of the applied rate falling within that first metre. The first off-crop spray-drift measurement in the Rautmann data starts at 1 m. Therefore, in case of arable crops, the off-crop risk assessment for all non-target groups (including NTAs) starts at 1 m. Because this first metre directly adjacent to the sprayed crop receives a high spray-drift exposure, growers and spray operators should be encouraged to minimise overspray of this immediately adjacent area (e.g., by use of modified boom-end nozzles).

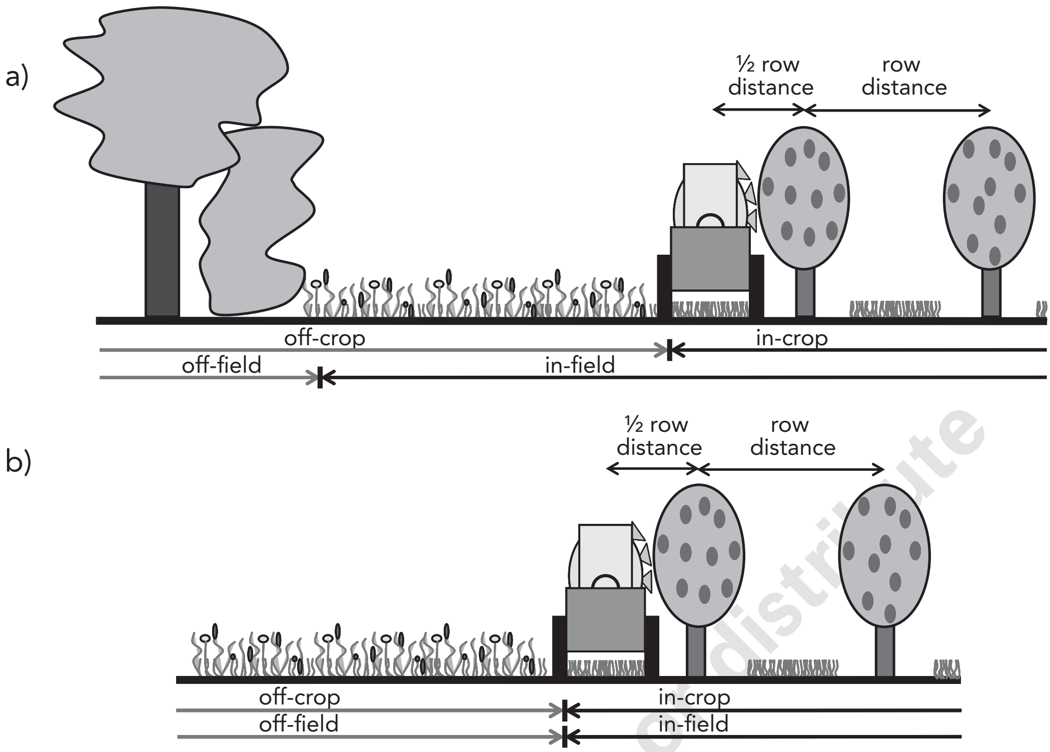

Figure 4.2 Off-crop definition in high crops (orchards, hops, grapevine, and vegetables, ornamentals and small fruits > 50 cm high) with (a) and without (b) a field boundary within the field. The actual situation might differ between different countries and will also be influenced by the legal position concerning property of the land.

Recommendation: Education

Farmer and spray operators should be encouraged to minimise overspray of the area immediately adjacent to sprayed crops (e.g., by use of modified boom-end nozzles).

Member States in vary terms of how pesticides are applied and the standards of machinery used, as well as the methods employed to measure and estimate spray drift. Activities to redefine spray-drift are ongoing at a national level. There should be further harmonization at an EU level, taking into account data from all Member States, although this may take some time. In the meantime the existing data set should continue to be used, at least for EU assessments. However, when harmonised drift data are available, these should be adopted. If data are used from certain Member States with more modern machinery and practices, older practices in other Member States also should be accounted for (e.g., older machinery tends to be operated at a higher boom height).

There is also uncertainty regarding extrapolation of drift estimates between crops (e.g., differences were observed between cereals and oilseed rape due to different boom heights). Further research in this area is needed and should feed into the harmonised data set.

Recommendation: Research

We recommend that there should be further harmonization of spray-drift data at an EU level taking into account data from different Member States and different spraying practices.

Recommendation: Regulation

Until the EU-harmonised spray-drift data are available, the current spray-drift data sets (e.g., Rautmann et al. 2001) should continue to be used for EU risk assessments. However, once a harmonised spray-drift data set is available, this should be adopted.

Data indicate that the levels of airborne drift can be up to 10 times higher than the ground deposition currently estimated by Rautmann et al. (2001). However, it is unknown how this airborne drift translates into actual deposition onto off-crop vegetation and arthropods, although some models have been proposed in Chemicals Regulation Directorate (CRD) projects. There is already activity at an EU level to investigate and revise spray-drift estimates for bystander exposure. Any subsequent revisions of spray-drift deposition data should then also be reconsidered for NTA exposure and risk assessment purposes, which will need the consideration of a number of factors (e.g., deposition onto people will be different than in off-crop habitats).

4.2.2 Orchards

For air-blast sprayers, as used in orchards, the current starting point for off-crop risk assessment is 3 m from one half-row space beyond the last row. These data are based on ground deposition of spray-drift. Unlike sprayers used for the application in arable crops, there has been less change in machinery and farming practices within orchard-type crops, apart from shrouded sprayers in vineyards, for example. Consequently there is less need for reconsideration of ground-based drift deposition data in orchards and similar crops. However, with orchards sprayers, the airborne drift component is also likely to be greater than ground-based deposition, and so research is also required into vegetation deposition from such airborne drift in orchards. In the last few years, there have been improvements concerning the mitigation of spray drift by using nozzles that emit bigger droplets and thus considerably reducing spray drift.

Recommendation: Research

Research is needed to assess off-crop deposition on vegetation from airborne drift in order to better understand NTA exposure in off-crop habitats, both for arable and orchard crops.

As a result of this uncertainty regarding the potential for higher drift deposition than previously predicted on off-crop vegetation, concern was raised regarding the off-crop risk assessment formulae currently used in ESCORT 2. In particular, there is uncertainty regarding the currently recommended vegetation distribution factor (VDF). Therefore, once revised and agreed off-crop vegetation deposition data are available, which take into account airborne drift, then the current ESCORT 2 off-crop exposure estimates (including the VDF) should be re-evaluated. Until then, the current off-crop exposure calculations and associated VDF should continue to be used for EU assessments.

Recommendation: Regulation

A revised and validated off-crop exposure assessment, including re-consideration of the current ESCORT 2 VDF value, is required, in order to predict vegetation deposition from airborne drift. Until such a scheme is available, the ESCORT 2 off-crop exposure calculations and associated VDF should continue to be used for EU assessments.

There are already some Member State differences in application of the ESCORT 2 off-crop equation. For example, the German authorities currently use a toxicity exposure ratio (TER) approach and use a VDF of 5 instead of the ESCORT 2 value of 10. They also separate the off-crop "correction factor" from the exposure part of the equation. This was also proposed by the European Food Safety Authority's Panel on Plant Health, Plant Protection Products and their Residues (EFSA PPR) because the uncertainty is not just related to exposure. The correction factor is also known as an uncertainty or assessment factor, and it is used to account for the greater interspecies variability and sensitivity expected off-crop. There should be further validation of an appropriate off-crop assessment factor, but the ESCORT 2 factor of 10 should remain until this is achieved. The German Federal Environment Agency (Umweltbundesamt [UBA]) stated that they would prefer to harmonise assessment factors applied across and between the different non-target group risk assessments. However, this was a specific desire of that authority and did not gain a consensus.

Recommendation: Regulation and Research

The "correction factor" used in the ESCORT 2 off-crop formula to account for the greater interspecies variability and sensitivity expected off-crop should be validated further. Until then, the current factor of 10 should be retained. In any future revisions of the off-crop formula, this factor ideally should be removed from the exposure part of the equation.

4.3 Off-Crop Exposure from Dust Drift

More data are now becoming available on exposure from dust deposition on to flat surfaces arising from drilling of PPP-treated seeds. Dust exposure has been shown to vary with formulation type, seed types, and drilling methods. There is ongoing industry activity in cooperation with the German authorities to consolidate dust exposure data with the aim of producing a generic dust deposition model. To generate reproducible data suitable for extrapolation, further research is being conducted into the airborne component of dust and how it relates to vegetation deposition in off-crop habitats. The current focus is the risk to honeybees from dust during drilling. However, this risk is also being addressed through risk management restrictions (e.g., compulsory use of deflectors on maize drillers and compulsory introduction of dust quality criteria for treated seed). Honeybee monitoring and data generation is also ongoing in some Member States (e.g., France, Austria), and data thus far show no unacceptable impacts on the honeybee colonies. The wider applicability of the risk assessment approach being developed in Germany is not yet agreed with all other Member States, and some may instead adopt a monitoring or risk management approach.

Currently the focus is on seed treatments, but there may be the need to consider the wider applicability to other solid applied formulations (e.g., granules, pellets). While the current priority is on risks to honeybees, the risk to other non-target groups (e.g., NTAs and aquatic organisms) is also linked and should be considered.

The issue of how to assess exposure and toxicity of solids and dust in NTA lab studies was raised during the discussion, and further method development may be required for NTA studies on seed treatments and also for other products applied as solids. Some work has already been done comparing toxicity of sprays with dust for bees, but exposure from broadcast "drift" of surface-applied granules has not been documented in any detail yet.

Recommendations: Research and Regulation

A new dust risk assessment and risk management approach should be developed and implemented. Eventfully this approach could be adapted to other products applied as solids (e.g., granules, pellets). If considered necessary, further research may be required to develop NTA test methods for dust.

4.4 Off-Crop Exposure from Vapour Drift

Some research work is ongoing regarding bystander exposure estimates from vapour drift. The starting point was to use existing models based on vapour pressure, but measured levels of vapour drift using real formulated products did not match with the expected outcomes (i.e., levels were higher than expected and apparently unrelated to vapour pressure; Paul Miller pers. comm.). The research currently is still focussed on operator and bystander exposure, but it has broader applicability to exposure for a range of environmental compartments and wildlife groups, including NTAs.

The off-crop environment subgroup was unclear what action could or should be taken in the short term. We agreed that further research was needed on vapour drift and how it translates into actual exposure.

Recommendation: Research

Further research iss needed to understand the sources of vapour drift and how it translates into actual exposure for NTAs.

4.5 Are Current Test Species and Methods Relevant and Representative for the Off-Crop Environment?

Species occurring in off-crop habitats will be closely linked to how that habitat is managed (e.g., grassy habitats may be similar to cereals fields at certain growth stages, and a mature orchard fauna may be as diverse as off-crop). As a general principle, the off-crop environment contains a greater diversity of species, life stages, feeding strategies, and ecological guilds than in-crop, particularly for arable systems (Marshall and Moonen 2002).

4.5.1 First-Tier Studies

The Tier 1 glass plate studies with *Aphidius* and *Typhlodromus* are generally worst case due to the high sensitivity of the two indicator species and the way the test species were confined and exposed in the test system. Most evidence so far (e.g., EFSA, AFSSA[1], and CRD reviews; see also Appendix 2) reflects the ESCORT 2 opinion that the Tier 1 test species and methods and the hazard quotient (HQ) trigger of 2 were protective for off-crop NTAs in the majority of cases, but there was uncertainty regarding whether they were predictive and protective in all cases.

Examples of those compounds for which the Tier 1 approach did not appear to be predictive or protective generally involved compounds that were insect growth regulators (IGRs) or had specific modes of uptake and action, which were not reflected in the glass plate or extended lab tests. This included some fungicides and compounds with systemic activity but also some insecticides in which there are novel modes of action.

Also higher-tier data are rarely available for compounds that passed at Tier 1, so there is a data gap for field effects of products that pass the HQ trigger of 2. Consequently, it is not always known whether effects on the broader range of NTAs would have been seen in higher-tier field studies for such compounds. Tier 1 testing also might not have been conducted for all insecticides. The point was made that any insecticide is intended to control insects, so testing at all tiers should be appropriate to the specific mode of action and uptake for a given pesticide. All data, including efficacy data, should be used to justify the appropriate testing methodology. This applies at extended lab and higher tiers, as well as at Tier 1. This point of appropriate testing is already mentioned in ESCORT 1 and ESCORT 2, but some industries do not always recognise the need to do more relevant testing. Therefore, the subgroup recommended that this message be reinforced.

The relationship between the application rate and the exposure of NTAs expressed as internal dose in insects is not fixed, so its toxicological meaning comprises uncertainties. Research is needed to help better understand exposure pathways and toxic mechanisms in relation to existing test methods.

Recommendations: Regulatory

Most evidence so far (e.g., EFSA, AFSSA, and CRD reviews) supports the ESCORT 2 opinion that the Tier 1 test species and methods and the HQ trigger of 2 are protective for off-crop NTAs in the majority of cases. However, in the absence of a more complete validation between effects at Tier 1 and those in the field, some uncertainty remains for IGRs, novel modes of action, and systemic and other orally active compounds.

Testing at all tiers should therefore reflect the mode of action and route of uptake. All data, including efficacy data, should be used to justify the appropriate testing methodology.

1 Since 1 July 2010, AFSSA (Agense Française de Sécurité Sanitaire) has became Anses (Agence Nationale de SEcurité Sanitaire de l'alimentation, de l'environnement et du travail).

Recommendations: Research

A comprehensive validation of the current ESCORT 2 approach and HQ triggers would benefit from further research of a wider range of chemistries and in particular generation of higher-tier field data for products that pass the Tier 1 HQ.

There should be further method development for specific modes of action and exposure and uptake other than direct contact toxicity.

Research is needed to help better understand exposure pathways and internal toxic mechanisms in relation to existing NTA test methods.

4.5.2 Higher-Tier Studies

Due to the greater diversity of plant species occurring off-crop, phytophagous NTA species may also occur in greater overall abundance or diversity off-crop than in-crop. Foliage feeders can feed over long time scales on exposed vegetation and so may be more susceptible to chronic and sublethal effects. They may themselves be highly exposed on leaf surfaces, although some are also well protected or feed outside of the application windows. Foliage and sap feeders also can include important species that are used by birds as a food source (e.g., heteropteran bugs, lepidopteran and sawfly larvae, small beetles and beetle larvae such as Curculionidae and Chrysomelidae), and so an assessment focussed on such species would assist with indirect effect and wider biodiversity assessments. Therefore, when conducting higher-tier (including field) studies, particularly in relation to assessing risk off-crop, we recommend that there should be a consideration of effects on phytophagous species.

4.5.3 Sub-Lethal Effects

Where there is potential concern regarding sublethal or reproductive effects (e.g., from knowledge of the mode of action [MoA]), where possible, sublethal or reproductive effects should be assessed in the NTA test programme. Some in the subgroup considered that at least a reproductive assessment should be carried out in all Tier 1 tests, but there was not full agreement on this. Reproduction or other sublethal effects should, however, be assessed in extended laboratory and higher-tier tests, particularly where these effects are expected because of the MoA.

Recommendations: Regulation

An increased focus on phytophagous species is required for higher-tier studies investigating off-crop risk. These would include species that are used by birds as a food source, which have links in to indirect effects and wider biodiversity assessments.

Where there is potential concern regarding sublethal or reproductive effects (e.g., from knowledge of the MoA), sublethal or reproductive effects should be examined in the NTA test programme, where possible.

4.6 Pollinators Other than Honeybees

If risk assessment for NTAs also needs to consider "pollinators other than honey bees," then oral routes of uptake or exposure and MoAs may also need to be better reflected in the standard suite of NTA tests. However, we recognised that the honey bee acute oral test does provide information on oral toxicity. When the results of this oral honey bee toxicity data are considered alongside the lower-tier NTA data, this should provide an initial understanding of the potential risk to other pollinators.

However, where oral routes of uptake or exposure and MoAs including systemically active products need to be considered further, then higher-tier assessment for "pollinators other than honey bees" should be included. The latest revision of the Annex III (SANCO 2011) data requirements (not agreed at the time of writing) suggests that where the existing tests on honey bees or NTAs do not reflect appropriate routes of uptake, then additional testing may be required. Because pollinators often move freely between in- and off-crop habitats, systemic seed treatments may still need to be assessed for off-crop risk. Also such pollinators may be exposed to dust from the drilling of treated seed (see Section 4.3).

Recommendations: Regulation

The current lower-tier NTA testing scheme, along with the standard honey bee scheme, should provide an adequate screening tool for other pollinators. Where oral routes of uptake or exposure (including systemics) and MoAs need to be considered further, then higher-tier assessment for "other pollinators" should be included.

Recommendation: Research

Further research is required to identify pollinators other than honey bees and to develop exposure and risk assessment models for them.

4.7 Higher-Tier Off-Crop Testing and Risk Assessment

Aspects of higher-tier off-crop testing and risk assessment based on a tiered approach up to the level of field testing are addressed in the following subchapters.

4.7.1 Tiered Approach

Currently under ESCORT 2, when a Tier 1 off-crop HQ assessment indicates a risk, the appropriate indicator species (*Aphidius rhopalosiphi* or *Typhlodromus pyri*) are tested further (e.g., in extended laboratory tests), and an additional two species are also tested. The additional species named in ESCORT 2 are still appropriate; however, this is the subject of ongoing research (e.g., the CRD review of species representivity discussed in Appendix 1).

As discussed in Section 0, there is some uncertainty as to the appropriateness of the available test species and test methods to the diversity of sensitive species, life stages, and associated feeding strategies that may be exposed off-crop. We concluded that for non-insecticides which trigger further evaluation at Tier 1, the current higher-tier approach described in ESCORT 2 should still be appropriate. However, for compounds known to have insecticidal or acaricidal effects, more focussed higher-tier off-crop testing is recommended. An alternative approach highlighted in the plenary session would be simply to risk-manage all such compounds; however, higher-tier testing could still serve to define appropriate risk mitigation.

Recommendation: Regulation

For non-insecticides that trigger concern at Tier 1, the off-crop risk can be refined using the standard ESCORT 2 tiered approach. This is subject to the further research on uncertainty regarding pesticides with novel or unexpected MoAs and those that pass at Tier 1 where higher-tier effects are not examined.

For compounds known to have insecticidal or acaricidal effects, more focussed testing on off-crop species is warranted.

4.7.2 Off-Crop Field Testing

The question was raised as to whether in-crop studies can be used to identify off-crop risks. The subgroup concluded that, for broadly similar systems, some indicative comparisons can be drawn in relation to community composition. While we agreed that in-crop studies can provide valuable information to help assess the risk off-crop, uncertainties would remain regarding the exposure route (drift vs. overspray), species representivity (e.g., phytophagous species) and diversity, ecological traits, response, and complexity of species in the two habitats.

With enough knowledge of the chemistry, MoA, good agricultural practice (GAP), and pest species controlled, it is possible to design a small, targeted, off-crop semi-field or field study to investigate potential effects. Such a study should focus on particular trait groups, niches, or trophic levels expected to be affected. We acknowledged that such a study may not always identify groups that were not expected to be affected (particularly with novel chemistry).

While semi-field study approaches with introduced species can be used, full-fauna field study approaches may also be used or preferred. One approach suggested was to use in-crop field trials at field and drift rates, but also to include off-crop species sampling (sampling species within crop that are common to the off-crop, but such species are often at low densities within-crop, and therefore it is difficult to obtain statistically significant results). This approach might allow comparisons to be drawn between the species and groups found in the in- and off-crop habitats.

Ideally, off-crop field studies also should be designed to help identify any required risk management strategy (i.e., size of buffer zone required) based on, for example, a community no-observed-effect rate (NOER).

One example of a potential off-crop study design, which was developed by Bakker and Miles, is the off-crop field study method summarised in Annex I of de Jong et al. (2010). This approach already has been used for investigating short-term effects on low mobility species (e.g., mites and collembola) in grassy, herbaceous off-crop areas. The general principles followed in this study design are these:

- conducted at different off-crop exposure rates to mimic different drift rates;
- used pristine meadow as a potential representative surrogate off-crop area (de Jong et al. (2010) gives more advice to identify other relevant species associations);
- used a community NOER or no-observed-ecologically-adverse-effect rate (NOEAER) design, which would also cover multiple application products;
- required a broad sampling effort with a strong focus on small, low-mobility species (e.g., soil mites and collembola), which were highlighted in the risk assessment for the particular compound of concern;
- used a chequerboard design; and
- described the initial impact and short-term duration of effects (not designed to look at recovery).

The off-crop field study approach as developed by Bakker and Miles (Appendix I in de Jong et al. 2010 and Appendix 2 of these proceedings) looks promising. It has to be confirmed whether it may also be appropriate for specific cases (e.g., for IGRs, sublethal or chronic MoAs).

Recommendation: Regulation

In-crop arable field studies in isolation may not adequately predict off-crop effects, due to differences in species diversity, representivity, ecological traits, and response.

Recommendation: Research

Further development and validation of off-crop field-testing methodologies is required.

4.8 Off-Crop Risk Management and Protection

A question was raised in the plenary session over whether any exposure of the off-crop environment should be permitted. Currently, however, it is not possible to rule out off-crop exposure, and revised drift data may show this to be even greater than previously envisaged (see Section 4.2). Therefore, where such exposure of off-crop and off-field areas is considered unacceptable, risk management practices should be implemented (e.g., buffer zones, low drift nozzles). Some relevant advice on this may be available the FOCUS landscape and mitigation report (FOCUS 2007, European Commission, SANCO/10422/2005 v2.0. 169 pp.). Drift reduction, in particular, is a priority need, and as such, should be promoted among growers, spray machinery operators, and policy makers. Conservation field margin habitats as practised in some Member States (e.g., the UK) could also be encouraged and promoted more widely, because such habitats provide valuable habitat and species diversity.

We recognised that different levels and durations of effects may have to be accepted for the off-crop in-field margin area, where this exists, compared with the off-field area. For example, a limited magnitude and duration of effects may be acceptable in the field margins, whereas in the "off-field" area, no or limited impact may be more desirable. The

Dutch protection principles for persistent pesticides were raised as an example in which different temporal and spatial protection goals may be identified for different off-crop habitat types. These might then be matched with the effect classes identified from field studies in order to determine acceptability (de Jong et al. 2010). For example, intermediate effects (Class 3 proposed in de Jong et al. 2010) may be appropriate for an off-crop in-field margin area immediately adjacent to a crop, whereas, no or only slight effects (Class 1 and 2, according to de Jong et al. 2010) might be more appropriate for the off-field area.

Habitats within the farmed environment that are primarily there for wildlife protection, where possible, should be protected from anthropogenic inputs, including pesticides. Such wildlife protection areas require a more coordinated approach between pesticide regulatory risk management practices and wider environmental policy activities (e.g., habitat management, agri-environment schemes). We recommended that Member State–specific pesticide risk assessment and risk management practices, and farm habitat management plans, need to be better formulated to complement each other. Each Member State has its own pesticide risk management practices, habitat management schemes, and priorities. Therefore, interpretation of acceptability in off-crop NTA risk assessment is likely to vary among Member States.

Recommendations: Regulation

Different definitions of acceptability in terms of effects and recovery should apply to different off-crop habitats, for example:

- *Off-crop in-field margin area: Intermediate effects may be accepted, but for agri-environment scheme habitats, the meaning of these intermediate effects should be judged according to Member State requirements.*
- *Off-field area: No or only slight and transient effects may be acceptable.*

Off-crop NTA risk management should be according to national Member State conditions and requirements. Options may include cropped or un-cropped buffer zones or the use of low-drift technology (see e.g., FOCUS 2007, European Commission, SANCO/10422/2005 v2.0. 169 pp.).

Recommendation: Education

There is a need to provide useful risk and conservation management advice (e.g., conservation field margins) for farmers, which could be linked to agri-environment direct subsidy payments.

At a national Member State level, pesticide risk assessment and risk management practices and farm habitat management plans need to be better formulated and aligned to complement each other. This may require detailed advice to policy makers and dialogue between Member State bodies involved in pesticide regulation and those responsible for environmental protection and countryside management.

4.9 References

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5 Recovery

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In the current non-target arthropod (NTA) risk assessment scheme for plant protection products (PPPs; EC 2002), it is accepted for the in-crop area, the application of these products may result in effects above the threshold value of 50% if "recovery" or at least the "potential for recovery" is demonstrated. For the in-crop "it has to be demonstrated that there is a potential for re-colonisation / recovery at least within one year but preferably in a shorter period, depending on the biology (seasonal pattern) of the species" (EC 2002). For the off-crop situation, the acceptable time period is less clearly defined ("within an ecological acceptable time period").

The recovery subgroup discussed the concept of "recovery" as currently assessed in field studies that are used in the risk assessment of PPPs (see Section 5.2). Another focus was on the approach of aged residue studies that are used to show that residue levels of the product are no longer affecting test organisms (see Section 5.3).

5.1 Recovery Definition

The subgroup defined recovery as the return of populations, communities or functional groups to levels that would be reached without the specific stressor.

The group defined appropriate endpoints for the following scales and areas:

- At the landscape level, the recovery of populations is the relevant endpoint.
- In off-crop areas, recovery of the communities is the relevant endpoint (e.g., assemblage of arthropod species and their abundance living in a grassy margin).
- In in-crop areas, the recovery of ecosystem functions (e.g., pollination, pest control) assessed for appropriate functional groups (e.g., pollinators and beneficial arthropods) is the relevant endpoint (see also Chapter 3).

5.2 Actual Recovery Under Field Study Conditions

Return of population densities after disturbance (e.g., the application of a PPP) to levels similar to those in undisturbed controls can be observed under field conditions in many situations (e.g., one-hectare field experimental plots).

However, especially for mobile taxa[1], the observed return to the control levels or its absence is not a robust predictive indicator for the likelihood of recovery under larger-scale use of pesticides: it does not consider, for example, applications of different products or different ecological conditions such as the size and distribution of refugia and reservoirs or life cycle parameters of species.

There is a research need for generating knowledge about the influence of these variables under different ecological scenarios.

Field studies can be used to answer specific questions (e.g., magnitude of effects; for further recommendations see Chapter 6).

5.3 Possibility for Recovery

Instead of actual recovery, the possibility for recovery (potential for recovery) can be assessed, being the time needed to reach an acceptable magnitude of effects.

Possibility for recovery can be assessed by

- aged residue studies that give information on the time after which individuals entering a treated area would survive and reproduce normally or
- combining information on the degradation of the product with data from effect studies.

Initial residue levels on the leaves of plants that are treated for the aged residue study might show some variability. Concerns were raised that this variability might lead to false negative results in a bioassay that is conducted within an aged residue study. To reduce this uncertainty, we recommended that in future aged-residue studies, two consecutive bioassays should result in effect values below the trigger to reduce the uncertainty concerning the variability of residue levels. The reliability of available studies could also be evaluated based on the consistency of the decline of effects in the different test runs and the variability seen among replicates. We concluded that the concept of the possibility for recovery can be applied for the in-crop risk assessment but does not guarantee that actual recovery will occur. Considering field studies for off-crop risk assessment, no effect or only transient effects (e.g., de Jong et al. 2010) are considered acceptable, and therefore measuring recovery is not applicable.

Acceptability criteria for the NTA risk assessment need to be re-defined for the in-crop and the off-crop scenarios (see Chapters 3 and 4).

5.4 Future Approaches

In future, recovery could be predicted by modelling approaches (see Topping and Bohan in Appendix 1). Models could be used for impact and risk assessment for different agronomic practices (e.g., crop rotation, pesticide use, crop management). Extrapolation to

1 The subgroup considers species as mobile that are influenced by the spillover effect at the spatial scale of testing. Spillover is defined in this context as the movement of non-target arthropods between adjacent habitats. This may result in an unrepresentative recovery of abundance and function in experimental plots compared to field situations.

other climatic regions might be possible. The subgroup identified the need for a new interdisciplinary working group to design and test suitable models.

The group proposed the following framework to incorporate modelling into risk assessment (Figure 5.1).

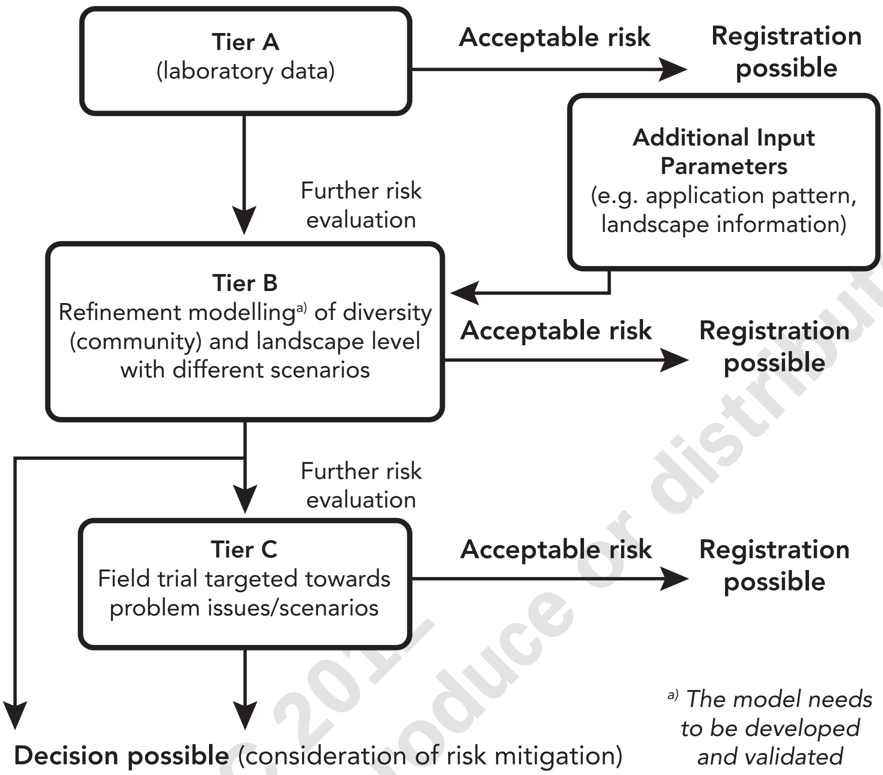

Figure 5.1 Potential framework to incorporate modelling into NTA risk assessment

Further information on modelling approaches is provided by Topping and Bohan in Appendix 1.

5.5 References

de Jong FMW, Bakker FM, Brown K, Jilesen CJTJ, Posthuma-Doodeman CJAM, Smit CE, Van der Steen JJM, van Eekelen GMA. 2010. Guidance for summarising and evaluating field studies with non-target arthropods. RIVM report 601712006/2010. Bilthoven (NL): National Institute for Public Health and the Environment (RIVM). 73 p.

[EC] European Commission. 2002. Guidance document on terrestrial ecotoxicology under Council Directive 91/414/EEC. SANCO/10329/2002 rev 2 final, 17 October 2002. p –162.

6 Field Studies

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In the present regulatory procedure, field studies can be performed if lower-tier studies indicate a potential risk to non-target arthropods (NTAs) of a plant protection product (PPP). Because effects have to be assessed at the arthropod community level during periods that can be longer than one year, intensive sampling on large-scale plots has to be performed, especially for in-crop tests. One consequence is that good quality field tests are time-consuming and expensive. Finding quality field trial sites with suitable populations of arthropods can also be a challenge, particularly in intensively managed crop situations. However, field studies provide the most representative conditions for a proper assessment of effects under the actual use conditions of a product.

The discussion in the field studies subgroup focussed first on field testing performance and extrapolation of results from one particular study to a broader context (e.g., other types of crop or other climatic conditions). Off-field testing, protection goals, and recovery were also included in the discussion following initial input from other subgroups.

6.1 In-Field Testing

The following subchapters address the questions concerning the technical performance of in-field testing as well as the extrapolation of NTA field study results between different geographic areas and between different crops.

6.1.1 Extrapolation

There was a consensus in the subgroup that field testing is time consuming and that assessing effects in all possible situations in all geographic areas is not possible. The implications of zonal registration were also considered. Thus, the needs for suitable field study designs and tools to extrapolate results have been identified.

For products that are used in several crops, there is the need for surrogate crops. For products that are used only in a specific crop, this particular crop should preferably be used to assess effects on NTA. Candolfi et al. (2000) proposed to use model crops for arable crops and for orchards and vines. We discussed the use of winter wheat for arable crops and apple for orchards and considered these crops to be appropriate. The advantages of these surrogate crops are that they have been intensively investigated for several years and that tests can be carried out under more standardised conditions, which allows for a more in-depth judgement and extrapolation to other situations. However, based on the experience of the group, a number of studies have shown differences in NTA communities between certain crops (e.g., wheat and oilseed rape) and similarities between other crops (within cereal crops or within leafy crops) in the same area. Specifically the differences between leafy crops and cereal crops were stressed. However, data showing potential sensitivity differences are not available in an aggregated manner (Croft 1990). As a conclusion, we suggested that a leafy crop should be evaluated as an alternative for a product with an intended use in this crop category.

For extrapolation of results obtained in one study to other in-field situations, both in terms of crop and geographic area, all information should be considered in order to see if extrapolation is appropriate (e.g., types of fauna or DT50 values). Crop-specific field studies should be considered only when it is not considered possible to extrapolate from existing field studies. Possibilities for extrapolation should be substantiated with credible data. Results of field studies suggest that in Southern Europe the number of species is higher but the abundance of the species is lower than in Northern Europe. Current data suggest that there are no major differences in the response of communities between North and South (see Aldershof and Bakker, Appendix 2), but the set of data available is limited. Available information suggests that dissipation of PPP residues may vary between the South and the North; however, dissipation rates are generally faster in the south due to higher temperatures and duration and intensity of light. Recovery trends may also vary between northern and southern climatic regions. These parameters should be considered when results are extrapolated from one region to another, taking into account differences between crops.

The subgroup agreed that additional data are required to determine if we can extrapolate between crops and between different geographic areas. An initial proposal was to review all control data from NTA field trials to compare NTA communities between different crops and different regions. In addition, data from products with similar modes of action, tested under different field conditions, could also be compared. To extrapolate between different formulations of a substance, lower-tier data generated in the laboratory can be used to assess potential differences.

Recommendation: Research

A compilation of field data (control, tested product) could contribute to a better understanding of differences among crops and geographic areas in terms of NTA communities' composition and sensitivity.

6.1.2 Performance of the Test Including Recommendations

One of the main questions addressed in the discussion was "do we have to apply the product when most of the NTA taxa are present, regardless of the intended use of the product (e.g., application of a product during spring time, when NTA population density is higher, although the product is only used in autumn), or do we have to apply the product according to its intended use?" The subgroup recommended that, for products applied at different rates and at different times in the season, a realistic worst-case scenario must be selected, accounting also for aspects of population dynamics. Generally, aspects of the good agricultural practice (GAP) of the product should be accounted for. We do not propose to select a period for application in which sensitive species are present if this period is outside the scope of the intended use of the product.

Concerning the rates to apply, the subgroup concluded that for in-crop studies, a rate–response test design is impractical. However, a multi-rate design (i.e., in addition to the GAP, one or two additional lower rates) is possible for the in-crop situation, which renders the results suitable for evaluation using multivariate analyses (e.g., principal response curve [PRC]).

During the performance of a field test, the plots should be maintained in good agricultural health with use of herbicides and fungicides, when appropriate, so as to avoid crop failure. These products must be applied to all experimental plots (control, test item, and toxic reference) and in the context of minimal crop management, because background spraying might increase uncertainty in the interpretation of the results. The use of substances with the same mode of action as the tested product or which are known to be harmful to the NTA community of interest should be avoided.

Crop rotation in the field study situation should be noted in the report. Field history concerning agricultural management (including PPPs) should be reported for at least the previous two years.

We recommended that when fields are selected for use in a study, the actual surrounding agricultural landscape should be taken into account because this aspect is of primary importance in the context of recovery assessment. Landscape features should be included in the study report in order to facilitate assessment and extrapolation.

Candolfi et al. (2000) recommended using a minimum of two sampling methods. De Jong et al. (2010) recommended using appropriate methods to show a minimum arthropod community for different agro-ecosystems. The subgroup had no time to discuss the sampling methods in detail; however, we suggested following the available guidelines. We also suggested that an overview of the strength and weaknesses of the various sampling methods is desirable as part of guidance for non-experts.

Substances used for knock-down sampling (arthropod inventory sampling from a plant by applying a fast-acting insecticide to the plant and afterwards collecting the affected arthropods from the ground below the plant) should not influence the arthropod community apart from the sampling. Because dichlorvos (DDVP), until now routinely used for knock-down sampling due to its fast-acting and low-residual activity, has been withdrawn within the European Union (EU), alternative products need to be identified that do not adversely affect the conduct of the experiment due to a long-lasting residual activity.

An indication of the differences in sensitivity of different taxa in the field can be derived from laboratory tests. However, apart from showing the possibility of recovery, field studies should reflect effects on a broader NTA community than the taxa already assessed in the laboratory.

For specific compounds (e.g., with a specific mode of action), a field study should not look at the whole community per se. If a specific sensitive species has been identified in a lower-tier test but is missing in the field study, further testing is not required if extrapolation from related taxa is possible.

For the statistical analysis, the subgroup concluded that the statistical power of a field study must be balanced with practical possibilities on a case-by-case basis.

Finally, we concluded that guidance is needed for interpreting and evaluating field studies. The question at stake was whether the same criteria for interpretation are used in different Member States. We concluded that there are principal differences due to a difference in focus (e.g., on NTAs vs. only beneficial organisms involved in Integrated Pest Management [IPM]). We also concluded that harmonisation of the criteria is potentially desirable. We proposed to initiate an inventory of criteria to gain insight into the differences between Member States.

Recommendation: Research, guidance documents

Overview of the strength and weaknesses of the various sampling methods is desirable as part of guidance for non-experts.

An inventory of criteria used in the different EU Member States to interpret field test results is needed.

6.2 Recovery Versus Re-Colonisation

The question of recovery vs. re-colonisation is an important aspect when PPPs are evaluated under field conditions. In this context, the subgroup raised several questions:

- How can recovery be extrapolated from the one study to another?
- Is the replacement of NTA taxa by other NTA taxa acceptable? According to the definition of protection goals by the subgroup on level of protection and trust (Chapter 3), the answer is probably "yes" for the in-crop situation if functional endpoints are unaffected. For other protection, goals this replacement probably will not be acceptable.
- What are the practical options in the case of crop rotation when recovery is not demonstrated within the cropping season? The identified options were either to leave it fallow (no crop) or to put in a crop by also considering crop rotation aspects.

The subgroup concluded that landscape aspects are of importance for re-colonisation and should be considered both in the study design and in the actual situation of the crop, because agricultural practices also influence re-colonisation. We concluded further that the duration of a field study can be up to one year, which could be extended if required by the biology of the affected species.

6.3 Off-Crop Field Testing

The following subchapters address the questions of the extrapolations for the off-crop based on in-crop field studies, technical aspects of off-crop field studies, and the question of secondary effects on NTAs.

6.3.1 Extrapolation from In-Crop to Off-Crop[1]

In the context of extrapolating from in-crop to off-crop situations, the subgroup concluded that NTA communities in the in-crop are different from the off-crop. Moreover, there were differences of opinion as to whether an in-crop study can also be used for the off-crop risk assessment. Because currently no overview exists of potential sensitivity differences between in-crop and off-crop communities, we felt that it is difficult to extrapolate directly from in-crop to off-crop, as well as when considering the potential differences in the vegetation structure and the distribution of PPP residues between in-crop and off-crop (off-crop habitats are not sprayed directly like in-crop areas and receive PPP via drift, which is different from direct overspray).

One option identified by the subgroup to account for uncertainty when extrapolating from in-crop to off-crop was the application of an uncertainty factor on in-crop–based endpoints; the size of the actually applied assessment factor should account for the relevance and the quality of the in-crop study. Research is needed to define appropriate assessment factors.

Another option identified by the subgroup was to conduct off-crop field studies. We discussed that it might be difficult to conduct off-crop field trials in naturally occurring off-crop field habitats due to their high structure variability and technical difficulty in treatment application and sampling, which would generate highly variable data. On the other hand, an example of such a study was presented during the workshop, showing that it is possible to conduct such a study.

6.3.2 Off-Crop Field Testing Performance

One of the difficulties in off-crop field testing is how to mimic drift in a representative way. Moreover, because there is also no uniform off-crop habitat, the subgroup identified the need to develop guidance on when and how to conduct off-crop field studies (in accordance with Candolfi et al. 2000). For the off-crop situation, field trials with a dose–response design are preferred in order to account for mitigation options (because different risk mitigation options can lead to different drift rates). Moreover, we suggested that for off-crop studies, smaller plots than for the in-crop situation might be more appropriate. At present, only a few off-crop studies on NTA have been conducted, using plots of about 24 x 24 m (see Miles and Bakker, Appendix 2). The careful interpretation of an in-crop study could give valuable information for designing a potential off-crop study.

1 In this chapter, we use "in-crop" because almost all available regulatory field studies are in-crop studies. We use "off-crop" to indicate that we are discussing extrapolation to all that is adjacent to the in-crop area, that is, off-crop and off-field, but off-crop always includes off-field.

Recommendation: Research

We recommend further research concerning potential differences in sensitivity between in-crop and off-crop communities.

We propose research regarding the interaction between vegetation structure and exposure of the in-crop and off-crop NTA fauna.

We recommend defining appropriate factors for extrapolation from in-crop studies to off-crop.

6.3.3 Secondary Effects

The subgroup further discussed the assessment of off-crop indirect effects of herbicides (e.g., direct effects on host plants). Because these products are in general harmless to NTAs in the first-tier assessment, they normally are not tested for off-crop effects on NTAs. However, they could have important indirect effects on NTA off-crop communities, simply by the destruction of off-crop host plants (e.g., drift of herbicides). However, we felt that this should be covered by the non-target plant risk assessment.

6.4 Education

During the subgroup's discussion, several important points regarding education were raised, resulting in the following recommendations:

Recommendation: Education

We considered that within the context of NTA field testing, guidance in combination with training would be an asset to all involved parties (i.e., those who conduct field studies, those who monitor field studies, and those who evaluate field studies), to better understand the general complexity of the subject matter as well as the needs of the other parties involved. EFSA and SETAC were mentioned as organisations that could organise such training, which preferably should include field visits.

We identified the promotion of drift-reducing measures, from farmers to decision makers, as a means to effectively minimise environmental impacts.

6.5 References

Croft BA, editor. 1990. Arthropod biological control agents and pesticides. New York: J Wiley.

Candolfi M, Bigler F, Campbell P, Heimbach U, Schmuck R, Angeli G, Bakker F, Brown K, Carli G, Dinter A, et al. 2000. Principles for regulatory testing and interpretation of semi-field and field studies with non-target arthropods. Pest Sci. 73(6):141–147.de Jong FMW, Bakker FM, Brown K, Jilesen CJTJ, Posthuma-Doodeman CJAM, Smit CE, Van der Steen JJM, van Eekelen GMA. 2010. Guidance for summarising and evaluating field studies with non-target arthropods. RIVM report 601712006. RIVM, Bilthoven, The Netherlands. 73p.

7 Report of the Plenary Sessions

Plenary sessions took place daily throughout the workshop as subgroups presented their collective output and members of the workshop raised questions and sought clarification. To make it easier to follow, this chapter has been arranged in the order of the subgroups with a final heading for general discussions. The feedback that was received during the plenary sessions was considered in the previous chapters.

7.1 Level of Protection and Testing Scheme

- The subgroup had defined (in the presentation to the plenary) criteria to delimit the stages on which it was operating. These criteria restricted the remit to the agricultural environment, assessing the effects of individual pesticides. There was disagreement over the restriction to consider only the agricultural environment. The subgroup based their reasoning to scale the agricultural environment on the spatial scale of non-target arthropods (NTAs) (Figure 3.1).
- Concern was expressed that although the subgroup wanted to assign functional endpoints, there was not enough ecological knowledge available to do so. The group rapporteur responded that functional groups were seen as a way to structure the protection goals but not necessarily a rigid framework.
- The proposed use of the terms *r*- and *K*-strategists (see Section 3.1.4) was questioned. Referring to features such as the number of generations per year, mobility and possibly body size would be better.
- The use of the terms in-crop and off-crop in the context of protection goals needed clarification. Was this terminology being used to refer to the locations or to the species, bearing in mind that species may move between the two? The subgroup rapporteur responded that the terms were being used to define habitat associations of the species.
- Some noted that the terms off-crop and off-field were introduced, but were not interchangeable and had specific but different meanings. The "field" term was used in the definition because of the existence of in-field buffers and beetle banks. If they were off-crop, then there was the possibility of having to protect the protection measures. An off-crop and an off-field definition are provided in Section 4.1.
- There was further discussion of the status of the in-field un-cropped strips, which would be off-crop and so may have to be protected. There may be off-crop-structures in the in-field that deserve higher levels of protection than the in-field. However, since such off-crop structures in-field are put there by the farmer, he or she will be likely to want to protect them anyway.
- It was clear that in different parts of Europe the crop margin and field boundary may have many different forms. Concern was raised over the status of a hedge or tree row that separates cropped areas from off-field areas. It was mentioned that in some countries this hedge belongs to the farmer, whereas in others it belongs to

other owners (and is off-field). Field separation might not be as strict as in a typical British hedge scenario.

- Following the presentation, there was a proposal to go from two areas to three areas for use in the NTA risk assessment: 1) crop, 2) off-crop in-field, 3) off-field. (see Figures 4.1 and 4.2).
  However, a separate risk assessment would not be required for the field margin (off-crop in-field), and only two would be required: one for "crop" and one for "off-field". Protection levels for the third area (off-crop in-field) should be decided at local level because the nature of crop margins differs markedly between European Union (EU) Member States. The off-field area required the highest level of protection; therefore the in-crop area, receiving the treatment, can be afforded lower levels of protection. It is also important to consider that if the system discourages farmers to take in-field measures that will encourage NTA, then they will remove potentially valuable habitats within the field.
- The extent and proportion of off-crop in-field habitat in the wider landscape was questioned. Good GIS data was said to be available in Germany for off-crop in-field areas, but this is not the case in all Member States. With regard to hedgerows, a natural hedgerow may be considered off-field, but a planted windbreak would be in-field. From a regulatory risk management perspective, a judgement would need to be made about the consideration of hedges in the risk management depending to their location. There was concern raised in the meeting about over-regulation. If a farmer planted a hedgerow specifically to reduce drift, then it seemed unreasonable to expect him or her to have to protect it.
- We concluded that the primary goal is to protect biodiversity off-field but to protect functions in-field.
- We discussed the nature and function of off-field arthropod populations. Off-field populations are not directly affected by crop management (except by the exposure to drift from plant protection products [PPPs]), provide ecological functions for both nature and agriculture, and protect structural and functional aspects of biodiversity.
- The subgroup considered that it would be possible to use the current indicator species and safety factors, but it would be necessary to check the safety factors.
- At the level of field studies, the no observed effect rate (NOER) community and the no observed ecologically adverse effect rate (NOEAER) population (effects of limited magnitude and duration) should be used for the off-field risk assessment.
- The subgroup was specifically asked to take into account the contribution of NTAs to the control of phytophagous arthropods.
- There was discussion about the importance of the various research needs with a suggestion that priority should be given to biodiversity (also taking into account function). The functional research need was to ensure that appropriate representatives of the relevant groups were addressed in the in-crop assessment. Because there were many different soil functions, it would be better to refer to specific ones (e.g., nutrient cycling).
- With regard to research needs, the plenary session considered them as being described in Section 3.3.

7.2 Off-Crop Environment

There was a call for consistency in terminology among the subgroups, specifically over the terms off-crop and off-field. In writing the record of the plenary sessions, this consistency has been applied and was considered during the writing of the previous chapters.

- There was a request for clarification of applying a buffer to a buffer for in-field risk management (see also Section 7.1). Participants felt that if un-cropped land was managed for biodiversity, then you would probably have to protect it, but if it was just an un-cropped margin, then a lower level of protection should be applied.
- The area under and between the trees in orchards should be treated from a regulatory point of view as in-crop and should be considered in the in-crop risk assessment.
- We recognised that the requirements and expertise of the farmer should be taken into account in the process, particularly when considering buffer zones because the farmer directly implements any management programmes for these areas.
- There was discussion over the use of model off-field studies, such as the chequerboard design proposed by Miles and Bakker (see Miles and Bakker, Appendix 2), to investigate potential off-field effects. It was asked whether the inclusion of abundant taxa unrepresentative of the experimental plots due to their high mobility would dilute the principal response curve (PRC) analysis and present an unrealistically favourable picture. Furthermore, are open-plan small plot studies not designed to address recovery or duration of effects? There was some concern that the animals found in such "meadow" studies would not be representative of those that could occur off-field. However, because there is no single off-field fauna, such studies are useful in off-field risk assessment.
- There was a request for clarification on the tiered test system for evaluation of herbicides and fungicides compared to that for insecticides. It was felt that for herbicides and fungicides, the current procedure was acceptable and there was potential to extrapolate from in-field to off-field. For insecticides, indirect or more complex effects would be expected, which cannot be extrapolated easily from in-field to off-field.

There was also considered to be a need for better investigation of sublethal and indirect effects.

- Because NTAs are part of an overall risk assessment, there should be efforts to emphasise areas of cross-fertilisation between different sections of the dossier.
- One person in the plenary noted that the effects classes that are given as acceptable (de Jong et al. 1999) for off-crop in-field (e.g., field margins) appeared to be harsh (class 3) which was different from the output of the recovery sub-group.
- There was some misunderstanding that, because three physical zones had been identified (in crop, off-crop in-field, and off-crop off-field), it might be necessary to conduct three risk assessments. The rapporteur confirmed the subgroup's intention that there would be two areas for risk assessment but potentially three for risk management.
- There was discussion and explanation about how to handle the area described as off-crop and in-field. Following questions as to how to deal with wind-breaks and

tree margins, it was concluded that the off-crop in-field may be very diverse in terms of legal status and morphology, so the plenary session did not consider it possible to produce a generic approach for this. For this reason, the off-crop in-field area was to be subject to national-level assignment of labelling for national risk management plans.

- Given that some of the off-crop in-field structures were themselves management tools (e.g., beetle banks), there was concern over the possibility of enforcing mitigation measures on them. Given the number of potential off-crop in-field structures that could be also management tools, the plenary session felt that there needed to be an assessment of their variety.
- Whilst the output of the subgroups Level of Protection and Testing Scheme and Off-Crop Environment had presented the view that the use of the hazard quotient (HQ) indicated overall protectiveness of the NTA fauna, some participants argued that there could be a flaw in the argumentation. There has been very little evaluation of the level of protection provided when an HQ is less than 2. Research was needed to address this point.
- The question of vegetation distribution factor (VDF) was raised because some regulators are already applying different VDF values at a national level. While there was a suggestion to form a smaller focus group to produce a position paper on this, the rapporteur stated that consideration of the VDF in isolation would be inappropriate and there is a need to look at deposition profile for drift as a whole.
- The off-crop in-field area for orchards was discussed. For example, in orchards with a 3 m distance between the rows, the off-crop area starts half a row distant (typically 1.5 m) plus 3 m (in total 4.5 m) from the centre of the last row.
- An example was given of a scenario for risk assessment with and without an off-crop in-field area directly adjacent to the cropped area. In the example, it was assumed that the off-crop risk assessment concludes that a 6 m non-sprayed buffer zone will be required to protect the off-field. If the farmer has an un-cropped in-field strip that is 6 m wide, this un-cropped strip would be sufficient as risk mitigation. However, if the farmer planted right up to the edge of the field, he or she will be required to not spray the last 6 m of the cropped area.
- There was concern that the scenario described reflected the British situation only. In Germany, no farmer plants a 6 m floral boundary strip. However, this was not perceived to be a problem because under the German situation, the grower would default to the option where he would use the crop as the buffer zone. Where scenarios resulted in huge buffer zones that were impractical, there would be a need to use a combination of mitigation measures, such as low-drift nozzles, buffer zones, and planting barriers. It was pointed out that FOCUS landscape mitigation group describes all kinds of drift-reducing measures (FOCUS 2007, European Commission, SANCO/10422/2005 v2.0. 169 pp.).
- If large buffer zones are required, there will be a need to encourage the use of a range of mitigation measures. Regulators will need to determine the effectiveness of such measures alone and in combination to be able to conduct the risk assessment. Reference was made to the UK Local Environment Risk Assessment for Pesticides

(LERAP) scheme, which includes a combination of features such as nozzles, distance, wind-breaks, and how each affects mitigation measures.

- It was pointed out that areas of land included in agri-environment schemes will have to be included in an off-field area because the farmer is being paid to leave these un-cropped. This is fully compatible with the approach of allowing decisions at a national level for the off-crop in-field area.

7.3 Recovery

- Clarification was sought about whether organisms with high mobility could receive higher levels of exposure. From a modelling perspective, bees, for example, could receive multiple exposure from different fields because they can move between fields. Counter to this argument, it was mentioned that mobility could also provide organisms with an escape option, resulting in lower exposure.
- It was mentioned that there are a number of problems with the assessment of true recovery (e.g., scale). Potential recovery (as shown by aged residue studies) is a key point to be addressed and is also a key input for models.
- The subgroup considered populations at the landscape level. There was a question as to whether it would be helpful to use the term “meta-population” and take into account connectivity between subpopulations. A modeller in the subgroup explained that the term “population” was taken to include connectivity.
- There was a request for clarification of the definition of mobile and non-mobile species with respect to recovery. After discussion, mobile species were defined as those that are influenced by the spill-over effect at the spatial scale of testing (for further details see Section 5.2).
- In response to a comment that the subgroup appeared to be saying that recovery could not be measured, it was explained that for mobile species, while you can observe and measure it within experiments, it cannot be used as a predictive tool for recovery elsewhere. There is a research need to evaluate for different taxa the relevance of mobility with respect to plot size.
- Clarification was requested over the requirement for aged residue studies to have two assessments below the threshold in order to confirm the acceptable decline in residual toxicity. This was seen as potentially a significant burden, particularly given the fact that results from one bioassay may not be available before initiation of the next. When a second result is generated with effects below the threshold, the meeting participants agreed to recommend using the first result for the purposes of risk assessment.
- From a regulator’s perspective, the possibility that absence of residual toxicity cannot be taken to guarantee recovery presented difficulties. How does the risk assessor make the link to the functions they want to maintain in-field?
- There was reservation about the use of landscape and population levels in risk assessment that is focussed on one substance. The meeting participants agreed that such an approach could compromise the protection goal of biodiversity.
- It was suggested by one participant that the potential for recovery in the in-crop area could be evaluated using a community NOER study conducted in a model

off-crop system. Such studies could be used to set the residue level below which populations could begin to recover.

7.4 Field Studies

- There was a discussion about the use of surrogate crops, in particular the addition of testing a representative leafy crop such as alfalfa if a PPP were to be used in a leafy crop situation. The plenary session felt that any changes concerning introduction of testing crops should be backed up by evidence (i.e., in relation to the NTA communities present).
- A research need was identified to validate whether a combination of studies in wheat and apples would be appropriate as model crops. From an industry perspective, because more and more field studies are being performed, if the burden increases to include more crops then some compounds would not be commercially viable. While it is possible to get access to sites to do studies on lower-value crops or where a product is registered, it is very difficult to perform studies in higher-value crops.
- There was a question concerning replication in the optimal study design and whether it was better to have more control replicates and fewer treatment replicates. Feedback was given by a participant that it is preferable to use the same number of replicates for all treatment groups and then relate back to the control with appropriate statistical techniques.
- The usefulness of species sensitivity distributions (SSDs) for terrestrial risk assessment was discussed. It was pointed out that a laboratory-derived SSD for individuals might not reflect a field response for populations. Any NTA SSD would need to include efficacy data. The applicability of the SSD approach for NTAs might need further evaluation.
- It was pointed out that for aquatic studies a safety factor is used to account for spatial and temporal variation. Could such a factor also be applied to terrestrial NTA field studies?
- The subgroup presentation mentioned that at least two sampling methods should be used in a field study. However, if a study is focussing on a specific arthropod group, then only one may be appropriate. Separate predatory mite studies are a specific example where one method would normally be used, and for such a situation this should be sufficient.
- The field subgroup was asked if there was any plan to get the methods adopted by OECD or ISO accredited. This was recognised as being desirable. ISO (2011) recently designed a Collembola avoidance test that would be applicable for use with granules and seed dressings.
- Where taxa were absent or insufficiently abundant in a field study, it may be possible to extrapolate results from related species that were sufficiently abundant in the study (such an extrapolation should be appropriately justified).
- Concerning the extrapolation of field study results for one formulation to a different formulation based on lower-tier data, any extrapolation between different formulations should not be based on Tier 1 (glass plate) tests because there often

are false positives due to the formulation (e.g., oil-based formulation). It is better to use extended laboratory results to justify the extrapolation (if appropriate).
- There was concern over the general statement concerning arthropod abundance North vs. South (see Section 7.1.1), but this reflected the difference of opinion within the subgroup.

7.5 Further Points from the Plenary Discussion

- The plenary session recommended for the time being to use the generic DT50 of 10 days from the Guidance Document on Risk Assessment for Birds & Mammals (EFSA 2009) for the calculation of the multiple application factor (MAF) (see Neumann, Appendix 1). Nevertheless, it was recommended as a topic for further research to revisit the validity of the generic value of 10 days.
- The workshop participants proposed that the group of scientists present at ESCORT 3 might continue to meet, potentially as a SETAC Non-Target Arthropod working group.
- Given that modelling had been proposed as a potential tool for predicting recovery, there was a request for a summary of what the models could achieve in this area (see Appendix 1, Section A1.6). This summary was intended to improve understanding of some of the outputs from the workshop.

7.6 References

[EFSA] European Food Safety Authority. 2009. Risk assessment for birds and mammals. EFSA Journal. 7(12):1438.

[ISO] International Organization for Standardization. 2011. Soil quality. Avoidance test for determining the quality of soils and effects of chemicals on behaviour. Part 2: Test with collembolans (*Folsomia candida*). Geneva: ISO. Available from: http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=50779.

Appendix 1: Abstracts of the Plenary Presentations

The content of the abstracts in Appendixes 1 and 2 reflect the opinions of the authors, which may deviate from the opinion of other workshop participants. (The content of these abstracts was not peer reviewed during the workshop or the preparation of the workshop proceedings. Therefore, only minor editorial changes have been made.)

Abstracts for the following plenary presentations are provided in this chapter:

A1.1 *Alix and Herranz:* Level of Protection: Review of Four Years of Risk Assessment for Non-Target Arthropods in Europe and France

A1.2 *Geiger et al.:* Persistent Negative Effects of Pesticides on Biodiversity and Biological Control Potential on European Farmland

A1.3 *Lawrence and Brown:* Non-Target Arthropod Recovery: Summary of the Findings from a UK CRD/Defra, Funded Project

A1.4 *Lawrence and Brown:* Non-Target Arthropod Representivity: Summary of the Findings from a UK CRD/Defra, Funded Project

A1.5 *Bakker:* (Off)-Field Studies

A1.6 *Neumann:* Rational for Harmonization of the Multiple Application Factor (MAF) Approach in Ecotoxicological Risk Assessment

A1.7 *Topping and Bohan:* Potential for Use of Modelling in Regulation and Risk Assessment

A1.1 Level of Protection: Review of Four Years of Risk Assessment for Non-Target Arthropods in Europe and France

Anne Alix and Francisco Javier Herranz

The evaluation of the risks posed by plant protection products (PPPs) used in crop protection to the environment, and more particularly to non-target arthropods (NTAs), is mandatory prior to the placing of these products on the market (EC 2006). Data requirements aiming at characterizing their potential effects on arthropod species and the corresponding general risk assessment principles are provided in Annexes II and III of Directive 91/414/EEC respectively, while decision-making criteria related to NTAs are provided in Annex VI (EC 2006). In addition to the regulatory text, guidance documents have been developed with the aim to provide harmonized test guidelines (ESCORT 1) and risk assessment principles (Candolfi et al. 2001; EC 2002).

About 15 years have passed since the implementation of Directive 91/414/EEC. The regulatory framework is currently being updated through a new regulation (EC 2009a) aiming at updating requirements and assessment rules according to past experience and the regulatory texts being related to (e.g., EC 2009b). In addition to the level of protection defined in Directive 91/414/EEC as “acceptable effects” on “beneficial arthropods other than bees”, the new Regulation 1107/2009/EC (EC 2009a) mentions in the approval criteria that a product 1) shall have no unacceptable effects on the environment, with regard to 2) its impact on non-target species, including on the ongoing behaviour of those species, and 3) its impact on biodiversity and the ecosystem” (EC 2009b). Revision of the current data requirement Annexes (II and III) is ongoing, and this currently gives a wider perspective of the conditions under which exposure cannot be excluded, including systemic compounds and plant exudates, and dusts generated at sowing, among others. It is also proposed that other pollinators be considered in addition to honey bees and thus, in future, these may be considered together with NTAs.

A revision of the risk assessment principles has thus been undertaken under the auspices of ESCORT 3, with the aim of providing information to support this evolution of regulatory guidance. In order to also consider the experience gained from years of implementation of the current regulatory system, a review of the risk assessments having been performed during the last years has been undertaken. This review addresses the evaluation of active substances in the context of the peer review as well as the evaluation of PPPs in one European Union (EU) Member State and aims to help in identifying the issues that may need to be considered in revising risk assessment principles.

A1.1.1 Evaluation of Active Substances: an EFSA Review

The analysis focused on active substances having been reviewed since July 2006, thus being the third list of re-evaluation. Data were collected in the draft assessment reports and additional peer reviewed information. For each substance, the mode of action (MoA) and chemical family were addressed and the data package having been used for the risk assessment was described. Each use was considered separately. All MoAs were considered without exclusion. The analysis, despite being focused on active substances of the third list, is not exhaustive but reflects risk assessments performed with up-to-date methods and in most cases according to ESCORT 2 recommendations.

The analysis concerned 85 active substances and 125 uses. Substances were 26 herbicides, 25 fungicides, 22 insecticides, seven plant growth regulators, four acaricides, and two rodenticides. Tier 1 hazard quotient (HQ) calculation, based on laboratory tests on *Aphidius rhopalosiphi* and *Typhlodromus pyri* (ESCORT 2), indicated a need for a refined risk assessment for 44 uses (35% of cases). Results per group of substance are detailed in Table A1.1.

Higher-tier studies consisted of extended laboratory studies (29 use cases), aged residues studies (14 uses), semi-field studies (5 uses), and field studies (11 uses). Based on refined risk assessment, an acceptable in-field risk was identified for 16 uses, an acceptable risk dependent on recovery potential was identified for 2 uses, and an unacceptable risk was identified in-field for 17 uses. For the off-field area, a need for risk mitigation measures was identified for 15 uses (mainly as non-spray buffer zone).

Table A1.1 Number of uses for which a refined risk assessment was triggered by HQ values, according to ESCORT 2 recommendations

HQ indicating the need for a higher-tier risk assessment in-field	Number of uses	%
Total	44	35
Fungicides	15	12
Herbicides	3	2.4
Plant Growth Regulators	0	0
Insecticides	20	16
Acaricides	6	4.8
Rodenticides	0	0

An attempt to analyse whether the need for higher-tier risk assessment was related to the chemical family of an active substance was performed for herbicides, insecticides, and fungicides. No clear trend was observed due to a low representation of each chemical family, except maybe for the triazole fungicides where 5 of 7 substances triggered a refined risk assessment.

A1.1.2 Evaluation of Plant Protection Products: a French review

The analysis focused on PPPs having been reviewed since July 2006. Data were collected from evaluation and registration reports. The analysis focused on products containing only one active substance. One product per substance was considered, except for cases where two products containing the same active substance are proposed for spray and soil or seed treatment, respectively, in which case the two products were considered. Finally, the products representing the highest number of uses were selected. Products were grouped per target (i.e., insecticide) and mode of application (spray on foliage or soil or seed treatment). For each of them, the data package having been used for the risk assessment was described. As for substances, the analysis is not exhaustive but reflects the risk assessments performed with up-to-date methods and in most cases according to ESCORT 2 recommendations.

The analysis concerned 137 products and 132 active substances. Substances were 57 herbicides, 31 fungicides, 30 insecticides, 5 plant growth regulators, 4 acaricides, 2 insect growth regulators, 2 molluscicides and 1 plant strengthener. Products were 43 re-examination (post annex I inclusion of the active substance) and 94 new preparations, proposed for spray (120 cases), soil treatment (8 cases), or seed treatment (9 cases).

For sprayed treatments, Tier 1 HQs were calculated for 106 cases. HQ indicated a need for a refined risk assessment for 44.3% of cases, as detailed in Table A1.2 below:

Table A1.2 Number of sprayed treatments for which a refined risk assessment was triggered by HQ values, according to ESCORT 2 recommendations

HQ value in-field	N	%	H + PGR + PS	F	A + I + IGR
< 2 for both	59	55.6	42	11	6
> 2 for both	31	29.2	8	5	18
> 2 for *A. rhopalosiphi*	7	6.6	4	1	2
> 2 for *T. pyri*	9	8.5	5	3	1
Insecticides	20	16			

H=Herbicide, PGR= Plant growth regulator, PS= Plant safener, F=Fungicide, A=Acaricide, I=Insecticide, IGR=Insect Growth Regulator

There were five cases where despite not being triggered by HQ values (HQ both <2) higher-tier data were available. These data indicated effects at the intended application rate for four cases, which led to the conclusion that risks were acceptable after a period of recovery, and risk mitigation measures in-field in one case. These products included three fungicides and one insecticide, of three different chemical families. Semi-field and field data were available in original dossiers. The data packages were further completed with new Tier 1 data aiming at addressing potential changes in toxicity being related to changes in formulation. In these cases, differences in toxicity due to formulation changes were not noticed, and as a consequence the effects observed on the population monitored during these studies could not be linked to a higher toxicity of the formulation that had been tested.

Higher-tier studies consisted of extended laboratory studies (27 products), aged residues studies (15 products), semi-field studies (8 products), and field studies (12 products). From 1 to 3 semi-field studies were used to refine the risk assessment for 1 to 60 uses. Similarly, 1 to 4 field studies were used to refine the risk assessment for 1 to 340 uses. After a refined risk assessment, it was concluded to accept the risks in-field for 28 products, based on recovery or a potential for recovery for 20 products (71.4%). A need for mitigation measures was identified for 16 products. Risks in-field were concluded as unacceptable in 3 cases, mainly due to a lack of data.

Off-field, Tier 1 HQ values indicated a need for a refined risk assessment for 12 products, 11 of which were insecticides, acaricides, or insect growth regulators (IGRs), and 1 fungicide. After a refined risk assessment, acceptable risk was concluded for 11 products, with risk mitigation measures in 10 cases.

For soil and seed treatments (17 products), the need for a refined risk assessment was identified in 83.3% of cases. After a refined risk assessment, acceptable risk was concluded in-field for 4 products, based on recovery or a potential for recovery for 6 products. The need for mitigation measures was identified for 1 product.

A1.1.3 Learning

The current scheme has generated about 1130 studies, which have allowed a reasonably comprehensive view of the ecotoxicological profile of PPPs. For the ecotoxicological profiles of low concern, the current screening may generally be considered as reliable. The effects (populations depressed at the field application rate followed by medium-term recovery) observed in the higher-tier studies not triggered by HQ values, however, indicate that there is a need to further explore the validation of the screening (i.e., HQ calculation) step, through the comparison of HQ values with field monitoring. Additionally, screening steps for some MoAs, as for example IGRs, are needed. A higher proportion of refined risk assessment is required at the French national level (29%) compared to the European level (17%), which may be explained by higher application rates required in Member States.

The two analyses confirmed the frequency of higher-tier studies as follows: extended laboratory study > aged residue study > field study > semi-field study. Thus, recommendations of the guidance document are followed in general, with a preference toward realism when the higher-tier studies are required. The small number of semi-field and field studies used to refine a high number of uses suggests that extrapolation between regions and crops is being applied between crops without being supported with detailed description on the elements in favour of such extrapolations.

Recovery concerns a high proportion of products (71.4%), and acceptable risks rely on a potential for recovery (i.e., not demonstrated) for 25.8% of the cases. Recovery and the conditions for its occurrence in the field thus need to be clearly addressed in the risk assessments performed, in the context of land use and crop management.

Off-field refined risk assessments mainly included insecticides (91.7% of cases). Studies performed at drift rate appeared to be of low reliability in the cases where effects were observed, mainly because of the uncertainties for exposure conditions and communities of concern. There is, therefore, a need to define how to assess effects off-field with greater certainty.

A refined risk assessment was needed in 83% of cases for soil and seed treatments, mainly for insecticides and fungicides. As for sprayed treatments, recovery was critical, because the conclusions relied on recovery or a potential for recovery in 35.3% of cases. Similar questions as for sprayed treatments therefore arose, considering in addition that the recovery of soil populations may be quite different compared to that of foliar arthropod species.

The authors would like to thank Domenica Auteri, Christine Fuell, Alf Aagaard and Franz Streissl for their important contribution to the database, and more particularly Alf Aagaard for his review of the document.

A1.1.4 References

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A1.2 Persistent Negative Effects of Pesticides on Biodiversity and Biological Control Potential on European Farmland

Flavia Geiger, Jan Bengtsson, Frank Berendse, Wolfgang W. Weisser, Mark Emmerson, Manuel B. Morales, Piotr Ceryngier, Jaan Liira, Teja Tscharntke, Camilla Winqvist, Sönke Eggers, Riccardo Bommarco, Tomas Pärt, Vincent Bretagnolle, Manuel Plantegenest, Lars W. Clement, Christopher Dennis, Catherine Palmer, Juan J. Oñate, Irene Guerrero, Violetta Hawro, Tsipe Aavik, Carsten Thies, Andreas Flohre, Sebastian Hänke, Christina Fischer, Paul W. Goedhart, Pablo Inchausti

In her presentation, Flavia Geiger presented parts of results published by Geiger et al. (2010) in *Basic and Applied Ecology*. For further details, please refer to the original publication.

A1.2.1 Reference

Geiger F, Bengtsson J, Berendse F, Weisser WW, Emmerson M, Morales MB, Ceryngier P, Jaan Liira, Tscharntke T, Winqvist C, et al. 2010. Persistent negative effects of pesticides on biodiversity and biological control potential on European farmland. Basic Appl Ecol. 11(2):97–105.

A1.3 Non-Target Arthropod Recovery: Summary of the Findings from a UK CRD/Defra, Funded Project

Alan Lawrence and Kevin Brown

A1.3.1 Abstract

The potential for non-target arthropods (NTAs) to recover following application of a plant protection product (PPP) may indicate acceptable risk under current guidance. A number of uncertainties surround the demonstration of recovery, particularly with regard to interpretation of laboratory and field data.

For laboratory aged residue data, key sources of uncertainty include exposure levels, routes of exposure, and relevance to a field scenario where recovery would depend upon the presence of recolonising individuals. A second assessment period demonstrating acceptable effects may serve to address uncertainty with regard to heterogeneous exposure. Consideration of the life history of arthropods under field conditions would aid contextualisation of the results.

For field data, effects of background heterogeneity, plot scale, and taxonomic resolution are discussed. Arthropods exhibit dynamic distributions at the landscape, farm, and field scale. Populations may be highly localised, which may affect the power of a study to detect both effects and recovery. The influence of plot scale in relation to the mobility of arthropod populations is discussed. Taxonomic resolution may also influence the detection of effect and demonstration of recovery where life histories vary markedly within groups, for instance at the family level.

Typical recovery responses that may be observed in field studies are presented with examples from field data where available. The underlying mechanisms are discussed with reference to the factors discussed above, where applicable.

While the concept of recovery is simple, the mechanisms involved may be complex and highly scenario specific. Overall, uncertainty may be reduced with careful study design and interpretation. Suggestions are made that may reduce uncertainty surrounding recovery. This work was funded by UK Chemicals Regulation Directorate (CRD; DEFRA project reference PS 2355).

A1.3.2 Introduction

A1.3.2.1 Recovery Background

Application of PPPs may result in depletion of arthropod populations, both in-field and off-field. Where Tier 1 (glass plate) and extended laboratory (natural substrate – leaf or soil) studies indicate unacceptable effects with fresh residues at the anticipated application rate, aged residue, semi-field, or field studies may be conducted in order to investigate the potential for recovery following application. At the field scale, recovery may occur where two pre-requisites are satisfied:

1) residues have declined to harmless levels, and
2) recolonising individuals are present.

The requirements must be met in sequence; residues must decline to harmless levels before individuals may repopulate the depleted area successfully without adverse effects.

Where adverse effects on NTAs are observed in lower-tier laboratory studies, acceptable risk may nonetheless be concluded where recovery is anticipated under field conditions. According to ESCORT 2 (Candolfi et al. 2001):

> If higher tier testing demonstrates effect values below a set threshold value or indicates an acceptable potential for re-colonisation/recovery, no additional testing is required and low risk to the habitat of concern can be concluded.

The concept of recovery is simple, yet in reality, complex factors interact to affect the detection and demonstration of recovery. The focus of this study was to determine the factors that may influence the detection and demonstration of recovery.

A1.3.3 Project Methods

The uncertainties associated with laboratory (aged residue), semi-field, and field data (background heterogeneity and arthropod distributions, experimental scale, taxonomic resolution) were investigated using both the open literature and regulatory field study data. Because the in-field area is better studied with regard to NTA dynamics, many of the examples from the open literature related to this area; however, certain principles may also apply to the off-field area.

A1.3.4 Results and Discussion

A1.3.4.1 Aged Residue Data

Aged residue studies are, in practice, toxicity bioassays of the rate of decline of residues on leaves or in soil. Whole plants or units of soil are treated with the appropriate application rate and weathered out of doors for a set time period before arthropods are exposed to leaves or soil sub-samples in the laboratory. This process is repeated to determine the time to harmlessness. The toxic response is a function of the rate of decline of residues. In theory, knowledge of the rate of decline and the toxicity to arthropods would be sufficient to characterise the anticipated time to harmlessness. Various uncertainties with regard to aged residue studies were identified:

- Heterogeneity of exposure: Where whole plants are over-sprayed, deposition on leaves will vary. This nonhomogeneous deposition may result in variability in exposure, and thus toxic response during the assay. For instance, use of leaves carrying a lower residue on day x may result in a clear result, whereas other leaves may still carry a hazardous residue.
- Effect of local climate on ageing of residues: Residues may age more rapidly in warmer climates.

- Exposure route: Only contact exposure is considered in the study design; in the field, exposure may also occur via oral and topical uptake.
- Presence and mobility of re-colonisers: The studies do not provide information on the actual process of recovery under field conditions.

Aged residue studies are, therefore, a demonstration of the potential for recovery, rather than a confirmation that recovery would occur. Use of aged residue data may be improved by:

1) incorporation of additional information to further inform the potential for recovery of arthropods in the field, including duration of residue persistence relative to NTA life history and mobility.
2) inclusion of two assessment occasions demonstrating acceptable effects before the study is halted; this would capture heterogeneity of residues on test substrates.

A1.3.4.2 Field Data – Background Heterogeneity in Arthropod Distributions

The agricultural landscape is heterogeneous. Highly disturbed monocultures may occur next to relatively undisturbed, florally diverse, off-field areas. The nature and extent of each will vary from region to region.

The in-field area may be characterised by low plant diversity and high disturbance, including cultivation, removal of (crop) cover (arable crops), and applications of PPPs (Croft 1990). Here, target and non-target species co-occur. Successful (abundant) NTAs are typically opportunistic; characteristics of in-field NTAs which enable exploitation of this habitat may include short generation times, relatively high fecundity, polyphagy, or high mobility. The off-field area may be characterised by a higher diversity of plant species and a lower level of disturbance. This area may range from recent, naturally regenerated strips at the edge of fields to semi-permanent features such as hedgerows and wooded areas. The arthropod fauna may be characterised by a greater diversity and the presence of specialists.

Heterogeneity in arthropod distribution may occur at the landscape, farm, and field scale. Factors driving distribution in both types of organism may include survival cues and microclimate preferences (Holland 2002). The scale at which such factors exert influence is dictated by dispersal ability.

In Austrian oilseed rape (OSR) crops, pollen beetle (*Meligethes* spp.) numbers were shown to be associated with percentage woody area, isolation of OSR crop in the landscape, landscape heterogeneity, and proportion of non-crop areas (Zaller et al. 2008). Other pest species of OSR responded similarly. Stem weevil (*Ceutorhyncus* spp.) was negatively associated with OSR area but positively associated with OSR isolation and proportion of woody areas; pod midge (*Dasineura brassicae*) larvae were associated with landscape diversity at a radius of 1000 to 1250 m only and the proportion of woody areas within a radius up to 500 m, but no further. These results indicate both the influence of landscape factors in arthropod abundance and the effects of scale; certain landscape features exerted influence only at defined spatial scales, indicating the effective range of these species.

At the farm scale, the spatial distributions of four predatory beetles were investigated for three years across fields totalling 64 ha, in the UK (Holland et al. 2005). A grid of 973 pitfall traps was established across the study area. Results were reported for 3 carabids (*Pterostichus madidus*, *Pterostichus melanarius*, and *Poecilus cupreus*) and 1 staphylinid (*Philonthus cognatus*). All species showed aggregation, but the size and location of patches differed. In some species, patches were stable between years; in others, patches were more dynamic and spread across field boundaries. Patch extent was species specific, as were responses to crop management practices.

Heterogeneity may also occur at the field scale. The distribution of carabid beetles, linyphiid spiders, and Collembola in UK winter wheat fields was investigated (Holland et al. 1999). The results showed that some carabids were associated with the field edge and some were found in patches. Linyphiidae were largely homogeneously distributed, possibly as a result of the process of ballooning. Spermophagous beetle species were found to be associated with weed cover.

The effects of different types of off-field vegetation on abundance and distribution of natural enemies in a vineyard was studied, including both epigeal and foliar-dwelling groups (Thomson and Hoffman 2009). The authors reported positive relationships between numbers of various beneficial groups and the presence of woody vegetation (remnant) in off-field areas. Adjacent pasture, however, had little effect on abundance of beneficial arthropods.

Arthropods do not respect plot boundaries and may move freely across the landscape. An understanding of the role of heterogeneity in abundance data would reduce uncertainty during interpretation of field data.

A1.3.5 Field Data: Experimental Scale

Plot scale can directly affect the detection of effect and recovery. Where recovery occurs via invasion of a depleted area by surface-active arthropods (such as ground beetles), the rate of recovery will be directly related to plot size. Therefore, rate of recovery may be artificially elevated where plot scale is small and very mobile arthropods (such as large carabids) are sampled. Even 1 ha plots may be too small for the very mobile species. Conversely, for groups such as Collembola, small plots (such as 20 m x 20 m) may be adequate, because recovery is more likely to occur by regeneration of survivors than by reinvasion from the plot edges.

Brown (1989) compared treatment effects of an IGR and subsequent recovery in adjacent orchards, comparing small plots of 30 trees (and a replicated design) and larger plots of 130 trees, but without replication. In the small plots, the effects of the reference item were apparent only for larvae of a coccinellid beetle (*Stethorus punctillum*) and lasted only for a single sampling occasion (approximately 1 week) before recovery appeared to occur. In the larger plots, many more taxa appeared to be affected, and numbers in the reference item plots remained at low levels for 3 weeks. While orchard plots of 30 trees are too small for use in regulatory studies, the investigation demonstrated the effect of scale on rate of recovery and potential issues from extrapolation of plot-scale studies to field-scale scenarios.

The effects of plot scale on time to recovery of arable arthropods was investigated (Duffield and Aebischer 1994). Plots ranged in size from 4 x 4 m to 288 x 288 m. The results indicated that for carabids, fewer individuals were trapped far into the plots than at the edge; this effect also lessened with time, indicating progressive re-invasion from the field edge. There was a positive relationship between time taken to recover and distance into the plot. During the study, the larvae of some species were replaced by adults, indicating the need to understand the phenology of focal species.

Duffield et al. (1996) reported the effects of scale on recovery following application of dimethoate in UK cereals. Plots of 7.65 and 8.29 ha were established within fields. Predator abundance was equally distributed across plots prior to application; however, following treatment, abundance was reduced in-field. Effects of treatment were most prolonged at greater distance from the field edge. Presence of prey was also highest in the centre of plots post application, indicating that predation pressure was reduced and that recovery was mediated through re-invasion from the field edge.

Experimental scale may have a major influence on certain types of recovery. Reinvasion of depleted areas by surface-active arthropods would be directly affected by the size of the plot. Conversely, recovery by regeneration of resident survivors with low mobility (such as Collembola) may be less affected by scale and may be successfully demonstrated in smaller plots. An understanding of the interaction between plot scale and mobility of the sampled taxa would aid in effective study design.

A1.3.6 Taxonomic Resolution

The taxonomic resolution applied to arthropod groups varies due to difficulty, perceived relevance of the group, availability of expertise, and financial constraints. Identification of all samples to species level would be prohibitively expensive. A decision must be made, therefore, regarding the level of effort to invest in each group.

Responses to pesticides may vary significantly within groups (e.g., family), driven by inherent sensitivity or life history, for example. Therefore, identification to the family level only may miss certain structural effects. An example is provided in Tables A1.3 and A1.4 (Brown and Miles 2006).

Table A1.3 Family-level effects data (reprinted with permission from Brown and Miles 2006, IOBC/wprs Bulletin).

Family	Insecticide 1 Drift rate	Insecticide 1 Field rate	Insecticide 2 Field rate
Carabidae Coleoptera	Reduction 3% Recovery 1 week	Reduction 20% Recovery 8 weeks	Reduction 33% Recovery 8 weeks
Staphylinidae Coleoptera	Reduction 1% Recovery 1 week	Reduction 77% Recovery 8 weeks	Reduction 82% Recovery 8 weeks
Linyphiidae Araneae	Reduction 18% Recovery 6 weeks	Reduction 90% Recovery 1 year	Reduction 90% Recovery 1 year

Table A1.4 Example species-level effects data (reprinted with permission from Brown and Miles 2006, IOBC/wprs Bulletin).

Example species	Insecticide 1 Drift rate	Insecticide 1 Field rate	Insecticide 2 Field rate
Asaphidion curtum Col: Carabidae	No reduction	No reduction	Reduction 90% Recovery not seen
Bembidion lampros Col: Carabidae	No reduction	Reduction 96% Recovery 6 weeks	Reduction 99% Recovery 6 weeks
Nebria brevicollis Col: Carabidae	No reduction	No reduction	No reduction
Stenus clavicornis Col: Staphylinidae	No reduction	Reduction 100% Recovery 8 weeks	Reduction100% Recovery 8 weeks
Erigone dentipalpis. Male Araneae: Linyphiidae	No reduction	Reduction 100% Recovery 1 year	Reduction 100% Recovery 1 year

For the Family Carabidae (ground beetles), a 20% reduction following application of insecticide 1 was recorded with recovery in 8 weeks (Table A1.3). When examined at the species level, however, the data show that *Bembidion lampros* was reduced by 96%, whereas *Nebria brevicollis* was apparently unaffected (Table A1.4).

Taxonomic resolution should be closely linked to the aim of the study. A suite of focal taxa could be identified to allow resources to be used in a more efficient manner. It may be desirable to include representatives of different arthropod life histories, rather than a broad range of taxonomic groups.

Grouping of taxa may mask effects at the species level, so while overall numbers within a family, for instance, may return to pre-treatment levels, this may be at the expense of sensitive species. Clarification of protection goals for in-field and off-field compartments, with regard to preservation of structure vs. function, would therefore aid in appropriate selection of taxonomic resolution.

A1.3.7 Types of Recovery

Recovery may occur via different mechanisms. These mechanisms may be broadly identified as regeneration of survivors (through reproduction or emergence) and reinvasion of the depleted area. In addition to plot scale and taxonomic resolution, , other crucial interacting factors relevant to both types of recovery are persistence of harmful residues and timing of reproduction in relation to residue decay.

Examples of recovery types are shown below. These are schematic diagrams (not real data). Redistribution recovery (Figure A1.1) may occur after residues have declined to harmless levels and animals migrate from surrounding areas (off-field, control, and drift rate plots). Arthropods invading from control or drift rate plots and untreated areas will survive and numbers will build. Numbers in donor areas will reduce until equilibrium with treatment plots is reached. Time to reach this equilibrium, when observed, is scale dependent; larger treatment plots would lead to longer recovery times for certain taxa (e.g., surface active).

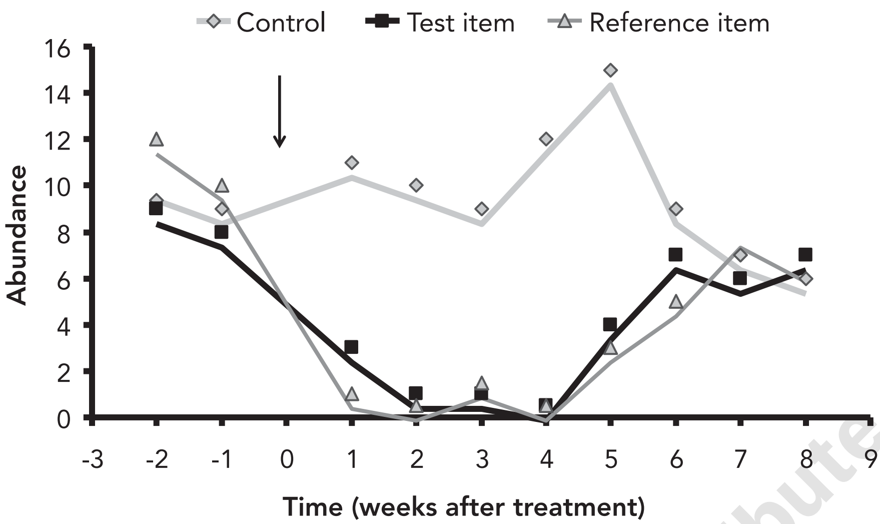

Figure A1.1 Redistribution recovery. Application at time 0 (arrow); residues in treatment plots then decline to harmless levels and arthropods may colonise from surrounding areas (off-field, control and drift rate plots). Numbers in donor areas reduce until equilibrium with treatment plots is reached. This process is scale dependent.

Life history–mediated recovery (Figure A1.2) occurs when animals undergo reproduction after application, but the depleted test item plots remain behind the control plots as density is much lower when breeding commences. This type of recovery may occur for less mobile taxa which regenerate from survivors, such as Collembola, or for those with an in-field protected life stage (emergence from egg or pupa).

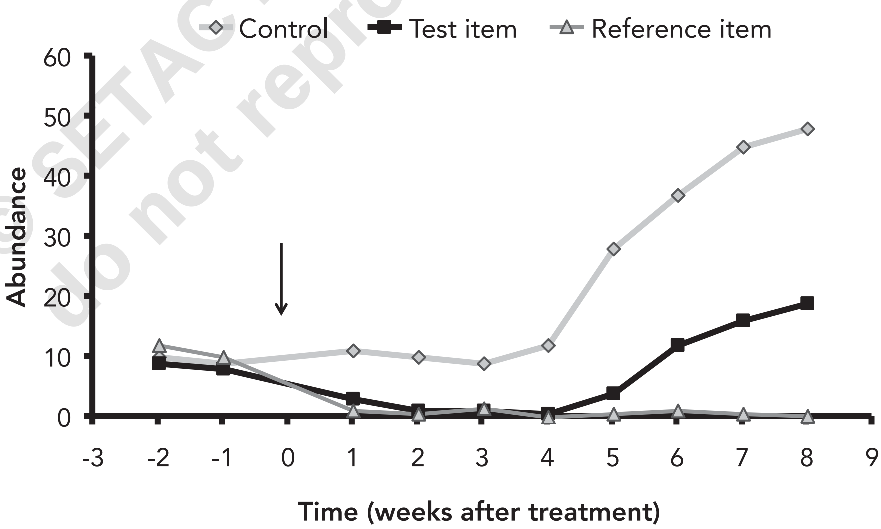

Figure A1.2 Regeneration recovery. Application at time 0 (arrow); life history event then leads to increasing abundance, but levels in previously depleted treatment plots may not equal those in control plots at the end of the study.

The timing of reproduction in relation to application and decline of harmful residues is crucial for this type of recovery. If reproduction occurs before and not after application, there may be little potential for recovery until the following year.

The signs of recovery observed in field studies must be interpreted in the light of the factors discussed above: background heterogeneity, plot scale vs. mobility, taxonomic resolution, life history in relation to persistence of residues, and timing of reproduction in relation to application time.

A1.3.8 Conclusion

Recovery is a valid concept for NTA risk assessments. It is important, however, to consider the points discussed here when we interpret recovery data for risk assessment purposes. All data types represent only an approximation of processes that may occur at the whole field scale, even "field" plot studies.

Aged residue data could be enhanced by inclusion of an additional assessment occasion and ecological information.

In field studies, care must be taken to match the plot scale to the taxa sampled; sampling very mobile taxa in small plots will artificially elevate the apparent rate of recovery. Grouping of taxa, for example at the family level, may lead to masking of effects at the genus or species level where life history varies within family. The fact that some effects are masked may be acceptable, depending upon protection goals for the compartment studied.

Overall, uncertainty may be reduced when recovery mechanisms are understood. Knowledge of the origins of observed recovery (e.g., reproduction vs. redistribution) allows relevance in NTA risk assessments to be better understood.

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A1.4 Non-Target Arthropod Representivity: Summary of the Findings from a UK CRD/Defra, Funded Project

Alan Lawrence and Kevin Brown

A1.4.1 Abstract

The current suite of test species used in the NTA risk assessment process consists of "beneficial" taxa selected largely for ease of use. The test species are predators and parasitoids of pest species and were not chosen to represent the wider arthropod fauna that may occur in off-field areas.

A life history analysis indicated the characteristics of the test species do not include certain modes of feeding or food types. Herbivorous and detritivorous species are underrepresented by the test species. Current laboratory test methods expose arthropods via contact only; topical (overspray) and oral routes are not considered but may be important in the field.

Five regulatory field studies were provided. The studies were examined in detail to compare the responses of current test species to the wider NTA fauna. Where soil exposure occurred, such as in a field crop scenario, Collembola were found to respond strongly. Where exposure to foliage of tree and bush crops occurred, the current Tier 2 test species were considered to broadly represent the response of the community.

Within the studies, some taxa were found to follow the overall community response closer than others. Those that did may be considered to be represented by the study. Other taxa did not follow the response as closely; however, the numerical responses of these taxa were varied. Some showed a tendency to recover more strongly than the more impacted taxa, whereas others did not recover or were not adversely impacted. The assessment indicated that the taxa which most closely follow the community response would be represented by a risk assessment based on the field study, and those taxa which responded differently may or may not be represented, depending upon the individual response of that taxa. Apparent responses may be strongly affected by field study design. Therefore it was concluded that, for taxa not following the overall community response, there is a need to assess both the ecology of the taxa and the ability of the study design to describe effects on such taxa. This work was funded by the UK Chemicals Regulation Directorate (CRD; DEFRA project code PS2356).

A1.4.2 Introduction

Candolfi et al. (1999) reviewed the available toxicity data for the (then) tested beneficial arthropod species, including both lethal and sublethal endpoints. If both mortality and sublethal effects were taken into account, testing of both *Typhlodromus pyri* and *Aphidius rhopalosiphi* would detect 95.8% of effects that occurred in any of the other species. On this basis, *T. pyri* and *A. rhopalosiphi* were selected as sentinel species for NTAs as a whole.

All of the candidate taxa are predators or parasites. There remains no consideration (in laboratory studies) of the potential impact on arthropods with different feeding habits or with relatively long life cycles. The arthropod fauna is extremely diverse; in contrast, the suite of test species used for Tier 1 and Tier 2 laboratory studies is necessarily limited due to practical considerations.

Responses to pesticides vary widely among taxa. Individual sensitivity may be driven by biochemical factors. Collembola are known to be less sensitive to pyrethroids than to organophosphates, for instance (Frampton et al. 2001). Timing of exposure in relation to developmental stage may affect the response. Mobility may allow arthropods to escape the treated area and then recolonise; immobile species or life stages, in contrast, may experience prolonged exposure (in regulatory field studies and the "real world" scenario). Plot scale and mobility may also interact. Small plots may not detect effects on mobile species as surviving animals move freely between plots. Various studies have demonstrated the interaction between plot scale and time to recovery (e.g., Duffield et al. 1996). At the population level, arthropods with infrequent breeding or long generation times may be particularly vulnerable. The interaction of these factors may lead some taxa to be more susceptible to PPP applications; in terms of risk assessment, both inherent (biochemical) sensitivity and life history may interact, therefore, to give widely differing responses to exposure among arthropod taxa.

The in-field and off-field areas may be very different. Key aspects that define the in-field area are high disturbance and a crop monoculture (Croft 1990). The resident in-field fauna and those typically found in regulatory field studies are able to exploit this type of habitat, being characterised by high mobility and fecundity or an opportunist or generalist approach. In contrast, the off-field area is typically less disturbed. A lesser disturbance allows for a comparatively diversified botanical component; off-field vegetation may be naturally occurring and, while also subject to management, may persist between years. The resident arthropod fauna may include those taxa with longer life histories, association with certain perennial plants, or other specialist strategies. A higher diversity of arthropods is typically found in the off-field area, which may include species that rarely or never occur in-field.

Overall, therefore, the extrapolation of the laboratory and in-field sensitivity data to the wider (untested) arthropod fauna involves considerable uncertainty (see e.g., Chaton et al. 2008 for further discussion). The aim of the current study was to determine the extent to which the current testing approach is representative of the wider NTA fauna.

A1.4.3 Methods

A1.4.3.1 Life History Assessment

As an initial qualitative step, the life history characteristics that may drive sensitivity of the current test species were directly compared to those of the wider NTA fauna.

A previous Department for Environment, Food and Rural Affairs (DEFRA)-funded project (Tones et al. 2001) assessed the potential for exposure of non-target organisms to pesticide drift, including NTAs. For a number of arthropods, including the current sentinel species (or close relatives) and other taxa, life history characteristics that may drive exposure to drift were tabulated. The assessment included both juvenile and mature stages. This work was considered a sound basis for the current assessment.

A1.4.3.2 Regulatory Studies

Five regulatory field studies conducted in sorghum, orchards, cereals, and a model off-crop habitat (grassland) from both northern and southern Europe were made available (Table A1.5). Principal response curve (PRC) analysis (Van den Brink and Ter Braak 1999) had previously been conducted for all studies.

Table A1.5 Summary of regulatory arthropod field studies used to compare the responses of current test species (and relatives) to the wider NTA fauna

Study	Crop	Location	EU Zone	Study type
1	Cereals	Southwest UK	Central	Full fauna
2	Orchard	Northwest France	South	Full fauna
3	Sorghum	Southwest France	South	Full fauna
4	Off-field (meadow)	Northwest France	South	Full fauna
5	Off-field (meadow)	Southwest France	South	Full fauna

The aim of using this data was to compare the responses of the current test species (and their relatives) to those of the wider NTA fauna found in the studies. For each study, the species scores from PRC 1 were tabulated. The taxa with high species scores were identified and compared to responses of current indicator species (or closely related species) and those taxa that represent currently untested groups.

The presence of drift rates in the studies allowed for the comparison of responses of taxa to both high and low levels of exposure.

A1.4.4 Results and Discussion

A1.4.4.1 Arthropod Life History Characteristics

The suite of test species consists largely of foliar-dwelling predators with a chewing or piercing and sucking feeding mode. Each of the 6 main test species, apart from *Typhlodromus*, has a winged adult stage that facilitates high mobility. This lends the arthropods to an opportunistic life strategy such as that required to exploit the in-field area.

The arthropods considered not to be represented by the current test species are dominated by herbivores and detritivores from a range of taxa. Many may represent pest species in field and orchard crops, but the wider NTA fauna of off-field areas would also consist of such taxa.

The exercise highlighted numerous characteristics that are not covered by the current NTA test species. Arthropods that feed on foliage, nectar, and mould or fungus are under-represented by the current sentinel species. Collembola feed on fungal hyphae and soil moulds, but these species are not routinely tested under the NTA risk assessment scheme. Leaf-chewing herbivores, foliar- or bark-dwelling mould scrapers, and nectar-sucking arthropods are currently not represented.

The life history assessment identified various combinations of feeding mode and taxonomy that are not represented. Areas of particular concern were the leaf-chewing herbivores (such as Orthoptera and Lepidoptera), detritivores (such as Psocoptera), and small sap-sucking herbivores (such as Cicadellidae, Delphacidae, and Cercopidae).

A1.4.4.2 Regulatory Studies

The highest species scores from all taxa and those for currently tested (or closely related) species were tabulated (Table A1.6). Taxa present in low numbers were not included. Species scores shown in bold type represent the strongest response and species of note. Because data were combined from 5 studies into 1 table, there is a degree of overlap between groups as taxonomic resolution varied between study designs. Absence from the table means these taxa were not recorded from the study. All test or related species and herbivores were included, regardless of species score. Others were included where species score was equal to or greater than 1.

Table A1.6 Tabulated species scores from PRC analyses for the selected regulatory studies used to compare responses of arthropod taxa

Study type		**Off-field meadow**	**Off-field meadow**	**Cereals summer**	**Sorghum All**	**Orchard DR**	**Orchard TI**	**Orchard TR**
Region		N France	S France	UK	S France	NW France	NW France	NW France
Plot size		24 m × 24 m	24 m × 24 m	1 ha	1 ha	44 m × 44 m	44 m × 44 m	44 m × 44 m
				Test or related species				
Parasitic wasps								
Aphelinus mali	Ad.					**3.13**	1.62	
Braconidae	Ad.					0.12		
Hymenoptera	Ad.			**2.6**				
Aphidiinae	All	1.52						
Diapriidae	Ad.			**2.3**				
Scelionidae	All			**2.9**				
Megaspilidae	Ad.						2.25	
Mites								
Phytoseiidae	All		**2.16**					
Oribatidae	Ad.				–0.80	**3.47**		1.97
Ladybirds								
Coccinellidae	Ad.				0.71	**2.42**		
	Juv.	1.54			0.59	**2.42**	**2.87**	**2.37**

Table A1.6 continued

Study type		Off-field meadow	Off-field meadow	Cereals summer	Sorghum All	Orchard DR	Orchard TI	Orchard TR
Spiders								
Pardosa spp.	Ad.				**2.44**			
	Juv.				0.97			
Alopecosa (Lycosidae)	All		1.12					
Bugs								
Anthocoridae	Ad.					–0.60	**2.20**	0.63
	Juv.					–0.93	**2.89**	1.55
Miridae	Ad.					0.49		
	Juv.					–0.71		
Lacewings								
Chrysopidae	Juv.					1.39	1.25	0.63
Rove beetles								
Aleocharinae	Ad.		1.42		0.92	0.36	0.76	
	Juv.			**2.3**				
Hoverflies								
Syrphidae	Juv.					1.56		
Ground beetles								
Carabidae	Ad.	1.31				0.06		0.32
	Juv.			**2.9**				
H. tardus	Ad.		1.00					
B. lampros	Ad.			**3.0**				
Carabus	Ad.				**2.44**			
Harpalus	Ad.				**2.24**			
Collembola								
Collembola	Ad.				**3.9**			
Lepidocyrtus cyaneus	Ad.			**4.9**				
Sminthurus viridis	Ad.			**4.2**				
Isotoma spp.	Ad.			**2.6**				
Arthropleona	All	**3.01**	**4.94**			–1.55		
Symphypleona	All	1.20	**2.98**					

Table A1.6 continued

Study type		**Off-field meadow**	**Off-field meadow**	**Cereals summer**	**Sorghum All**	**Orchard DR**	**Orchard TI**	**Orchard TR**
				Non-test or related species				
Herbivores								
Orthoptera (grasshoppers)	Ad.				1.20	–0.20		0.10
	Juv.				1.64			
Cicadellidae (leafhoppers)	Ad.	**2.73**	**2.06**		1.40	–0.20	1.05	1.81
	Juv.	**3.84**	**2.89**		0.76	**2.95**	**3.48**	**5.21**
Lepidoptera (butterflies)	Ad.					0.89	0.16	–0.65
	Juv.		1.18		-0.01	–0.59	1.04	–0.70
Delphacidae (planthoppers)	Ad.	**2.33**			-0.12			
	Juv.				0.40			
Aphidoidea (aphids)	Ad.		2.02			**2.95**	**3.61**	
Detritivores								
Psocoptera (bark lice)	Ad.					**2.43**	**2.02**	2.55
	Juv.					**2.00**	1.90	1.67
Others								
Achaeranea (spider)	Ad.							**2.28**
Philodromus (crab spider)	Ad.							**2.23**
Isopoda (woodlouse)	Ad.		1.60		**2.79**			
Formicidae (ants)	Ad.						2.30	
Megaspilidae (parasitoid wasp)	Ad.						2.25	
Phrurolithus (Araneae) (spider)	All	**2.89**						

Ad. Adult; Juv. Juvenile

The results from each study are briefly summarised below.

- In the off-field studies (northern and southern France), Collembola and predatory mites represented the response of the wider community. However, small plot size may limit conclusions on other, more mobile taxa. The studies included overspray, and hence soil exposure was assumed.
- Following summer application to the cereal study in the UK, Collembola, small and relatively less mobile carabid and staphylinid beetles, and parasitoid wasps (wingless) represented the wider community response. Soil exposure occurred.
- The sorghum study conducted in southern France included both full field and drift rates. In the full field rates Collembola and *Pardosa* were representative of the wider

community response. The current Tier 1 species (mites and wasps) were not representative of the response. In the drift rates, soil-surface dwellers were less impacted and may not be representative of this compartment, probably because soil exposure was lower.
- The orchard system was dominated by aphids and associated predators or parasitoids. Coccinellids, oribatids, anthocorids, and braconids appeared to represent the community response in this system. The drift rates were more discriminatory, and only the more sensitive taxa had species scores greater than 1 in this treatment.

The use of regulatory study data provided an insight not possible from the open literature alone. The analysis of the regulatory studies divided crop and off-crop systems into two main types: 2-dimensional and 3 dimensional. The 2 dimensional systems include arable crops and grassed off-field areas, and community responses here were dominated by soil surface–dwelling organisms (such as Collembola). The 3 dimensional systems include orchard and other structurally complex crop and off-field areas; community responses in orchards typically were dominated by aphids and associated predator and parasitoid assemblages.

A1.4.4.3 Further Investigation of Species Score

The above assessment was based on species scores from PRC analyses. The species score may be considered a measure of affinity to the overall community response. In the above studies, Abbott values (Abbott 1925) also were provided for each taxa and each treatment at each sampling occasion. Therefore, it was possible to compare species score (one value representing the response of a taxon over a series of sampling occasions) to a measure of reduction or effect (available over all sampling occasions) for each taxon.

For the NW France off-field study (chosen for the wide variety of NTA fauna present), the highest Abbott value from all sampling occasions for taxa collected by pitfall trap was compared to the species score for that taxa. Species scores were taken from the PRC analysis of all treatment rates (Figure A1.3).

The plot revealed a broad trend between positive species scores and higher Abbott values. Very high species scores would indicate a response similar to the overall community but of higher magnitude (e.g., those taxa circled to the upper right, in this case, small-bodied Cicadellidae, spiders, and Collembola).

There were a number of taxa with a species score <1 but with an Abbott value of >50%. At very high Abbott values, there is a range of species scores, from <1 to >3. This indicated that, while all these taxa were impacted, not all were closely following the response of the overall community. This result may be due to the timing of effect and recovery relative to the overall community response, or variability in numbers resulting in a strong reduction at one time point (i.e., high Abbott value) but no overall pattern in the data (low species score). A low species score and high Abbott value may also indicate nonrecovery, if the overall trend of the data is for depletion followed by recovery.

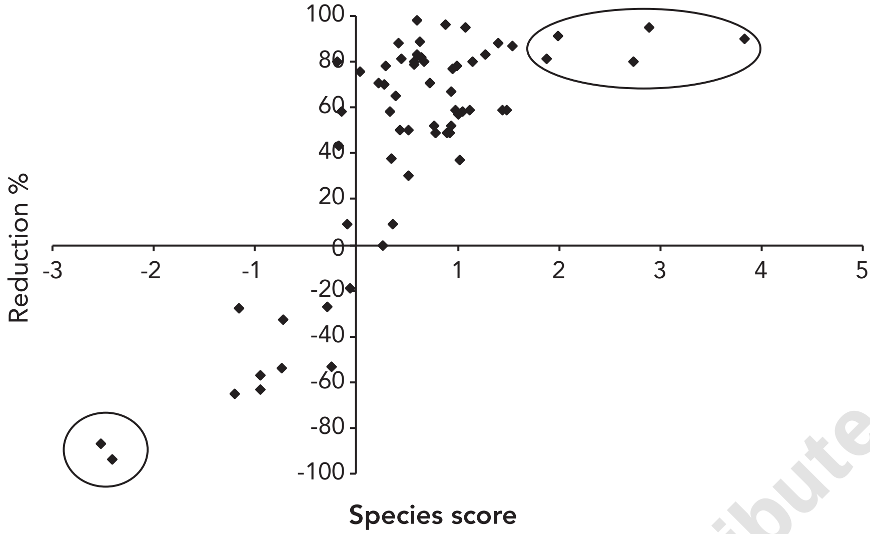

Figure A1.3 Comparison of species score and highest Abbott value (from 5 sampling occasions) for NW France pitfall data (all taxa; all treatment rates).

There was an apparent trend for negative species score and negative Abbott value, indicating that those arthropods that are increasing in numbers (negative Abbott value) are responding in the opposite fashion to the overall community. This may be an indirect effect, due, for instance, to a reduction in predation rate caused by depletion of predatory taxa. Two example taxa (carabids) are circled to the lower left; each would be more mobile than the species with high positive species scores and Abbott values. As such, plot scale in this instance may be driving this interaction for these taxa. Affinity to the study plot would be lower, and because the plots were unbarriered, the arthropods would be able to move freely between the plots. Therefore, the results for these mobile arthropods must be considered in the context of the study design.

A second assessment compared species score to abundance. This comparison indicated that for taxa with a high species score, there was a weak tendency for abundance to be higher. All taxa with a species score of >1.5 were present in total numbers >1000 individuals in pitfall trap samples. Similarly, for taxa with a species score <–1.5, abundance was >1000 individuals. Abundance may therefore affect species score and should be considered in study interpretation.

A1.4.4.4 Summary of Species Score and Representivity

In general, taxa with a high species score and Abbott value may be considered represented by the study design; a risk assessment based on the overall community response would therefore represent these taxa. Strongly positive or negative species scores were never associated with a low (positive or negative) Abbott value.

A variety of factors may cause a combination of high Abbott value and low species scores (taxa impacted but not following the community response). Timing of impact may affect the extent to which a taxon follows the community response. A high maximum Abbott value and low species score, therefore, may not necessarily indicate adverse effects at the population level, but may be indicative of a different response profile (impact and recovery but at different times to the overall community). Conversely, high Abbott value and low species score may indicate nonrecovery within the duration of the study. Therefore, a risk assessment based on a study where the community recovered may not represent such taxa. Clearly this is open to some interpretation because there is a continuum of responses.

The extent to which such effects may be caused by life history is unknown; lesser-studied taxa represent greater uncertainty in this regard. The effects of sampling timing in relation to life history events, plot scale vs. mobility, and potential indirect effects must be considered during study interpretation.

Overall, this assessment highlighted the importance of a detailed interpretation of the study data, especially where certain taxa appear not to follow the overall trend of the data. For taxa with a high species score and correspondingly high Abbott values, interpretation may be relatively straightforward. For impacted taxa that do not appear to follow the wider community response, ecological information and an understanding of the effects of study design may aid interpretation.

A1.4.5 Conclusion

The regulatory field data indicated that habitats could be divided into two categories, 2-d and 3-d, based on the responses of the arthropods. Where soil exposure may occur, Collembola appeared to be most sensitive. When woody habitats (in this case, orchards) were exposed, aphids and related predators and parasitoids appeared most sensitive.

A comparison of percent reduction (as indicated by Abbott values) to species scores from the available PRC analyses suggested that high species scores might be considered reliable estimates of response relative to the community. Taxa with lower species scores may not follow the community response as closely, yet may still be impacted and may or may not demonstrate recovery. The community response will vary between each study and the species score is a measure of affinity to this response, rather than the sensitivity of each taxa. The studies used here included broad spectrum insecticides and therefore provided information on the responses of a broad range of taxa. The range of response among taxa with lower species scores highlighted the need for ecological knowledge when we interpret such results.

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A1.5 (Off)-Field Studies

Frank Bakker

A1.5.1 Background

In the context of this workshop, aspects of design, performance, and interpretation of NTA field studies in-crop and off-field that were of potential relevance for discussions in the 4 subgroups were highlighted. The in-crop studies concerned the 2 model agro-ecosystems proposed under current guidance (Candolfi et al. 2000, 2001), viz. arable and orchard systems, whereas the off-field studies were based on the design presented by Bakker and Miles (2007).

A1.5.2 Test System

Obviously, the choice of model agro-ecosystem (arable, orchard) will be determined by the proposed use pattern for the test product. Whereas potential effects of spray drift usually have been assessed in in-field situations, the question has arisen whether in-field and off-field fauna are sufficiently similar to render such an approach valid. In terms of community descriptors, Bakker and Miles (2007) and Bakker et al. (2008) have shown relevant differences between arable and orchard systems on the one hand and off-field systems on the other. Using standard biodiversity indices, they showed for different levels of taxonomic precision arable systems to be the least diverse (Fisher's alpha) and the least even (Simpson). These systems are generally characterized by a high degree of dominance (Berger-Parker). Off-field meadows have more even fauna than orchards, but in term of diversity (Fisher's alpha), these systems apparently are similar. However, in terms of estimated species richness, off-field habitats were clearly the most diverse as shown by the spider example in Figure A1.4. Bakker and Faraji (2008) reported similar findings for the mite fauna of orchards and surrounding habitats.

The ecotoxicological relevance of these findings is not a priori clear, but the results presented by Aldershof and Bakker (Appendix 2) also show different effect profiles for the different NTA communities. For example, the distribution of taxa over acute effects was skewed toward high effect values in arable systems and more balanced in orchards and off-field habitats. There may be multiple explanations for these findings, but these analyses suggest that where in-field effects are of interest, studies should be performed in a relevant crop type. Off-field effects, on the other hand, should be performed in off-field habitats.

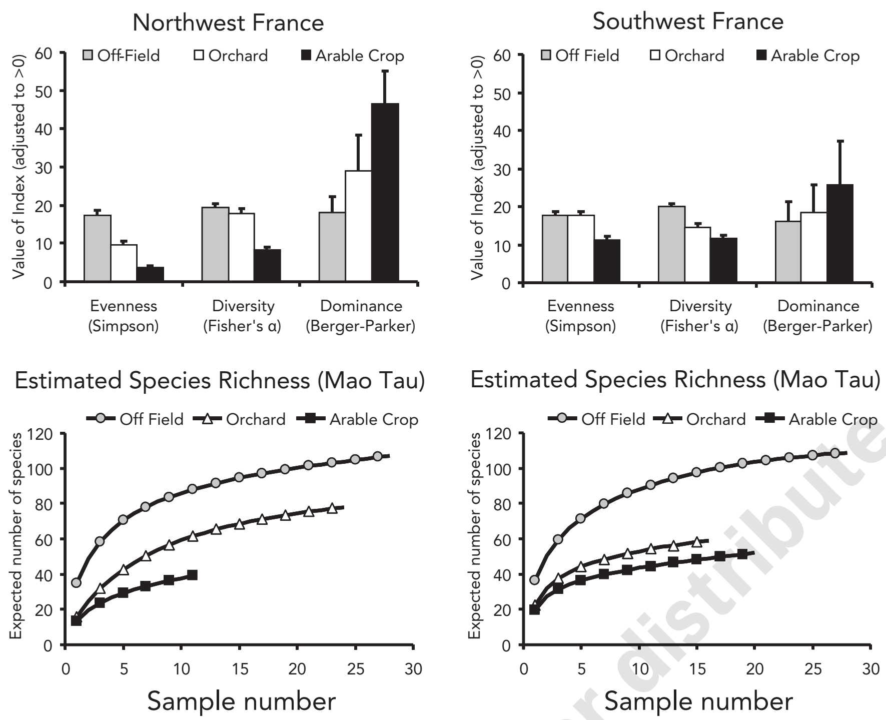

Figure A1.4 Standard biodiversity indices for ground dwelling spiders captured in various habitats. Left-hand graphs shows results for North-West France, right hand graphs for South West France. EstimateS (Colwell 2009) was used for all calculations (Error bars show the standard deviation).

A1.5.3 Study Location

Likewise the choice of study site location will in principle depend on the proposed use for the test product. However, the macro range over which field study results can in principle be extrapolated will be determined by prevailing climate and geography. Several proposals for agro-ecological zonal divisions of the pan-European landmass exist. For example, the European and Mediterranean Plant Protection Organization (EPPO; Bouma et al. 2005) proposed a system with 4 zones (maritime, Mediterranean, north-east, and south-east) and the European Commission proposed 3 zones (SANCO/6896/2009), whereas current procedures for NTA testing imply a simple North–South division. Comparison of NTA faunas in orchards, arable crops, and off-field meadows using similarity indices showed faunal composition to be more different between than within regions (Bakker et al. 2008). Although based on a limited dataset, these results suggest regional differences in faunal composition may have to be taken into account in the risk assessment. NTA field study results in North and South Europe were contrasted by Aldershof and Bakker (Appendix 2). The first findings of this analysis, based on a single product, indicate that overall treatment effects of this product were similar between Northern and Southern European regions, but there was a trend toward longer recovery times and a broader spectrum of taxa affected in the Northern region.

The observed similarities in ecological effects, despite differences in faunal composition, seem to suggest that community-level effects probably may be extrapolated over a broad range of agro-ecological zones.

A1.5.4 Sampling Targets and Sampling Methods

NTA field studies should be designed to enable a comprehensive evaluation of effects of treatment on a broad range of arthropod taxa. There is ongoing discussion as to whether herbivorous (i.e., pest) species should be included for in-field studies (see, e.g., Lawrence and Brown, Sections A1.3 and A1.4), but for the evaluation of off-field effects there seems to be consensus that they should. De Jong et al. (2010) have included in their guidance for evaluators a table with taxa that should be addressed by the sampling in different study situations, together with the taxonomic detail required for an ecologically robust interpretation of the sample data.

The NTA habitat is, in the context of this and earlier SETAC workshops, restricted to litter or top soil and vegetation. For arable crops, there has traditionally been a bias toward assessing effects on ground-dwelling species, whereas for perennial crops the focus has been on canopy-dwelling species, including predatory mites. For the off-field environment, both soil dwellers and plant inhabiting species are addressed. The suite of taxa populating these ecological compartments can be censused with a relatively limited number of sampling methods. Table A1.7 provides an example of how different sampling techniques may be combined to provide for a comprehensive community sample in different agro-ecosystems.

Table A1.7 Example of how different sampling methods may be combined in several (agro)ecosystems

Method	Target	Grapevine	Tree crop	Cereals	Cotton	Grassland	Hedgerow
Leaf sampling	Mites	√	√	-	-	-	√
Pan traps	Flying insects	-	-	(√)	(√)	-	-
Sweep netting	Flying insects	-	-	√	-	√	-
Beating Inventory	Canopy	√	√	-	√	-	√
Chemical Inventory	Canopy	-	√	-	-	-	√
Pitfall traps	Soil dwellers	-	-	√	√	√	-
Aspirator	Plant or litter	-	-	√	-	√	-
Photo-eclector	Plant litter or soil	-	-	√	-	√	-
Soil cores	Top soil and litter	-	-	(√)	(√)	√	-

- Predatory mites are best sampled by first collecting the matrix of interest (e.g., leaves from the target crop, a representative sample of weeds or soil cores from the top soil) and subsequently extracting the mites from these samples by washing or heat extraction techniques.
- For tree crops in particular, chemical inventory or beating techniques will provide a comprehensive sample of the NTA community in the canopy. For chemical inventory sampling, we should keep in mind that the product used must be broad spectrum and short lived to avoid interference with effects of the test application. Dichlorvos (DDVP) remains the best available choice to date.
- Canopy dwellers in low crops, such as many arable crops or weeds in the off-field environment, can be sampled effectively by aspiration (e.g., with the D-vac apparatus).
- The standard for assessing soil-dwelling arthropods is of course pitfall trapping. The criticism that these traps measure activity rather than density is in practice rarely relevant to NTA field tests, and pitfalls generally produce robust sampling data.
- NTA species inhabiting top soil and litter can be sampled effectively by taking soil cores (followed by extraction) and by placing photoeclectors.
- Finally, more mobile and flying species such as grasshoppers and flies may be sampled by a combination of sweep net sampling and pan or water traps. Obviously the value of the species trapped with these techniques for an NTA risk assessment is limited, because usually their migratory capacity is not matched by plot size. Nonetheless, these techniques may provide useful information, in particular for assessing acute effects.

Clearly, more than one sampling technique will be needed to assess effects at the NTA community level, both in-field and off-field. Often the taxonomic range captured with the different techniques will overlap. It may not always be necessary to count the same taxon for different sample types, but in certain cases different sample types may represent different ecological compartments, even if the same taxa are involved. For the statistical evaluation, it probably is wise to analyse different sample types separately.

A1.5.5 Field Design and Size In-Field Studies

The design of in-crop studies is currently driven by the recovery endpoint for a limited number of test rates, whereas off-field studies are tailored to no observed effect concentration (NOEC)-type endpoints. The actual physical design of an in-field study will be a compromise between desirable attributes such as sufficient replication, plot size tailored to study duration and ecological characteristics of species of concern, and agronomical or practical constraints such as homogeneity of plantation, cropping cycle, and field size.

It is generally agreed that 4 replicates per treatment provide sufficient experimental power to assess ecological effects at currently prevailing threshold levels. It is important to keep in mind that this is in part due to the fact that most studies are designed to test more than one rate and generally include a reference product. Studies with more simple design may require a higher level of replication.

In-crop studies with a recovery endpoint generally run for periods of 1 year or more. As outlined by Lawrence and Brown (Section A1.3), plot size must match ecological traits, in particular mobility, in combination with the experimental period to enable a meaningful assessment of actual recovery. Current practice has it that, for in-field NTA studies in arable crops, minimum plot size should be 1 ha and in orchard crops 0.2 ha (cf. Candolfi et al. 2000). However, as argued by Lawrence and Brown (Section A1.3), even plots of this size may not be ecologically relevant for a suite of taxa both in arable and in orchard crops. Notwithstanding this constraint, NTA field studies with these standard plot sizes may be adequate to demonstrate the potential for community recovery at the farm scale.

The organization of plots is not a straightforward matter. A very common design is the randomized complete blocks design. However, there are several important pitfalls with this design. It is mostly a priori unclear how the blocking should be set up. The myriad of species involved respond to many different gradients, and it is not likely to find a singular blocking solution. Usually fields are organized as 4 adjacent groups of replicate plots, using landscape or geometric characteristics to set these up. In this case, randomization often leads to a spatial arrangement that intuitively is not appropriate. An example can be the case where randomization causes all control plots to be adjacent on the same side of the field. Most experimenters acknowledge that in such cases they reshuffle the cards until deemed appropriate, which procedure is then referred to as "quasi-random". A desirable alternative would be a non-random approach such as a Latin squares design, but this is usually not feasible because there are more or fewer treatments than replicates or, most of the time, because actual field geometry prevents a symmetrical design. This is a clear area for expert statistical advice.

Within plots, there are also several issues to bear in mind. To reduce the effects of spatial heterogeneity, it is good practice to combine several subsamples for each plot. For example, in orchard studies with inventory sampling, the faunistic content of 3 or 4 trees may be combined to provide a representative sample for one plot. Likewise for ground-dwelling species, usually more than one pitfall trap is set up for each plot. In addition to this demand plots need to be buffered against each other and against edge effects at the field boundary. The necessity for buffered plots implies that, unless there are specific research questions (e.g., concerning mobility patterns), plot edges normally should not be sampled. For orchards, within-plot buffers could be the outermost 2 tree rows and within each row the last 5 m. For arable fields, a non-sampled buffer could be 40 m wide, thus leaving a sampling area of 20 x 20 m in the centre of the plots. When chemical inventory sampling is performed, the sampled trees and their direct neighbours should not be sampled again. These practical requirements already lead to a minimum plot size. For example, for a pome fruit orchard with a typical planting density of 4 x 1.3 m and 0.18 ha plots (9 rows of 50 m length), each plot effectively has a sampling area of 3 rows of 40 m length or 100 trees. Because neighbouring trees should not be sampled, this leaves 3 x 10 sample positions. With 3 subsamples per plot, a plot size of 0.18 ha thus permits for a study with 9 sampling dates (one position being reserved for predatory mite sampling).

For these practical reasons alone, a typical pome fruit orchard NTA study with 4 to 5 treatments requires a plantation of about 3 to 4 ha, a citrus grove about 6 ha, and an arable study 20 ha. A single low-mobility species short-term study, such as predatory mites, by contrast would require no more than 0.15 ha.

A1.5.6 Field Design and Size Off-Field Studies

Off-crop studies with a NOEC-type endpoint (cf. Bakker and Miles 2007) have more relaxed plot size requirements. Because the endpoints are fully based on (the absence of) acute effects, species mobility is less of an issue. Mobility is not completely irrelevant, however, because in these studies sampling is performed over a period of several weeks. Such a sampling schedule, spread over time, is justified because on the one hand, certain effects need time to become manifest (effects on cryptic life stages, slow death, but also recovery from initial knock down, etc.), whereas on the other hand the no observed ecologically adverse effect level (NOEAEL) may imply that an effect is not considered adverse when seen only transiently or shortly after treatment. Plot sizes of around 24 x 24 m have been proven adequate for this purpose.

For the plot arrangement, the same random-nonrandom discussion as for the in-field studies applies, but with an additional constraint. Due to the NOEC-type endpoint, off-field studies not only tend to have more, but also tend to have a broader range of test rates. With large differences in test rates, there is a serious risk of drift contamination within the study. For this reason, Bakker and Miles (2007) have proposed to lay out the plots as the coloured squares on a checkerboard. In this way, each plot is surrounded by similar (untreated) plots and the risk of drift contamination is much reduced.

A typical off-field study with a running time of 6 to 8 weeks would require a meadow of 2 to 4 ha, depending on the number of test rates chosen.

A1.5.7 Quantifying Community-Level Effects

Whereas analysis of effects on abundance at the population level is a relatively straightforward exercise, effects at the community level are more complex to quantify. In principle, community-level effects could be described using biodiversity tools such as the Morisita-Horn or Bray-Curtis similarity indices to describe changes in diversity (cf. Magurran 2004). Bakker et al. (2008) found that these indices do pick up differences in diversity when taxonomic precision is at the species level, but not at higher levels of identification. In NTA field studies, it normally is not feasible to identify all specimens to the species level. Together with the biases inherent to these indices and the additional computation required to identify the species underlying changes in the index, these drawbacks make these methods not favoured by many.

Community-level effects in ecotoxicological studies are usually shifts in the relative abundance of species. Effects on species richness per se rarely, if ever, occur. NTA field studies are generally performed over extended periods, usually longer than a season. During the study period, populations exhibit their site-specific phenology and they interact with each other. Reductions in one species may allow for increases in another. Experimentally induced shifts in abundance thus take place in a dynamic and interactive context. As outlined by van den Brink and Ter Braak (1998), an appropriate multivariate technique that involves scaling the data to the control is PRC analysis. This technique has the advantage that different response patterns may be captured and that species weights may be calculated to identify the degree of similarity between the response of individual taxa and the overall response pattern. Often species weights are taken as a measure for sensitivity or representivity, but without the appropriate context of overall PRC and individual taxon responses, this is incorrect (cf. Lawrence and Brown, Section A1.4). A disadvantage of PRC analysis may be that it is computationally involved and requires skilled interpretation.

A less sophisticated, but straightforward method of looking at community data is to calculate for each sample date and treatment the proportion of taxa showing statistically significant responses in univariate analyses such as ANOVA. This method will produce a significant response curve (SRC). As shown by Bakker and Miles (2007) and Bakker et al. (2008), the SRC is usually congruent with the (first) PRC (see e.g., Figure A1.5) and a ranking of taxa according to the magnitude of effect (e.g., according to Abbott) consequently shows a high degree of similarity with the species weights table from a PRC analysis (using the same data, Lawrence and Brown report a similar finding, in Section A1.4).

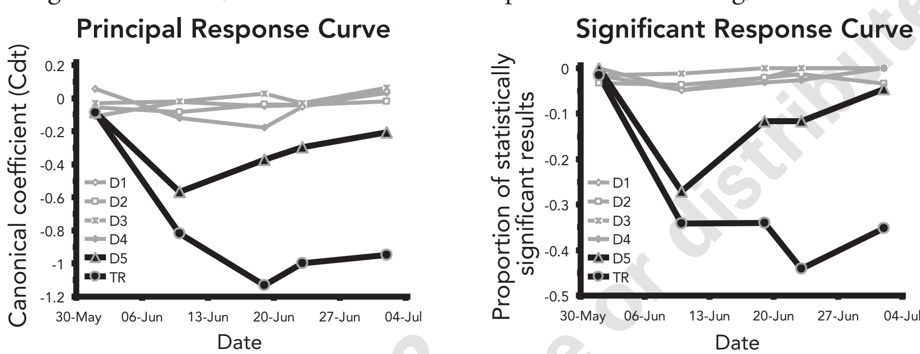

Figure A1.5 Complex dataset analysed with principal response curve and significant response curve.

A1.5.8 Discussion

When acute effects on NTA may be anticipated, either based on lower-tier studies or on insecticidal MoA, in-field studies may be set up to investigate whether recovery can occur under normal use conditions. Because the time span for acceptability is currently set at 1 year, this is the typical running time for in-field studies. Lawrence and Brown (Section A1.4) point to several methodological shortcomings that may hamper correct interpretation of recovery data. Among other things, they point to the importance of scale, taxonomic resolution, and an understanding of the mechanism underlying recovery. In addition to these factors, we should keep in mind that in NTA field studies products are usually tested in isolation (i.e., in the absence of other PPPs with insecticidal MoA). Although this is experimentally the most valid approach, it also means that recovery is regarded only in the context of a single PPP with an insecticidal MoA. As shown by de Roos and Bakker (see de Roos and Bakker, Appendix 2), the degree to which populations may be affected depends not only on the toxicity and on the half-life of the chemical, but also on the application interval relative to the life history of the affected species. The same compound may theoretically either lead to extinction or be relatively harmless, when only the application interval differs. Consequently, recovery patterns may vary with agricultural regime.

Given these restrictions, the question is whether there are experimental alternatives to these expensive long-running field studies aimed at assessing recovery. A widely used alternative is the aged-residue study. As outlined by Lawrence and Brown (Section A1.4), there are several uncertainties with these studies, but they generally provide a valid demonstration of the potential for recovery at the population level for a given species and a single exposure event. At the community level, an alternative could be to use a community NOEC-type endpoint (e.g., NOEAER) in combination with residue decline data. If the off-field community may represent the in-field community in terms of sensitivity, the off-field study could thus serve two purposes: 1) to assess the distance from the treated area at which no ecologically adverse effects are expected to occur and 2) to assess the time period after which in-field recovery could potentially occur (see also Miles and Bakker, Appendix 2).

A1.5.9 Summary of Conclusions

Field studies are highly complex but powerful tools in NTA risk assessment. Where in-field effects are of interest, studies should be performed in a representative and relevant crop type. Off-field effects on the other hand should be performed in off-field habitats. The observed similarity in ecological effects, despite differences in faunal composition, seems to suggest that community-level effects may probably be extrapolated over a range of agro-ecological zones.

Sampling effort should be broad, ranging from top soil to canopy, but we should keep in mind that highly mobile species are not informative to assess recovery. Clearly, more than one sampling technique will be needed to assess effects at the NTA community level, both in-field and off-field. Often the taxonomic range captured with the different techniques will overlap. For the statistical evaluation, it probably is wise to analyse different sample types separately.

There are methodological problems associated with both random and nonrandom study designs such as Latin squares. This is a clear area for expert statistical advice. Biodiversity indices are less appropriate to analyse NTA field studies than are PRC or SRC analyses. PRC has the advantage that different response patterns may be identified, but care should be taken to correctly interpret species weights.

For practical reasons alone, a typical pome fruit orchard NTA study requires a plantation of about 3 to 4 ha, a citrus grove of about 6 ha, and an arable study of about 20 ha. During the study period, background treatments with insecticidal products should be avoided, often resulting in important crop loss and enhanced study costs. Consequently, observed recovery patterns will pertain to the tested PPP in isolation of agricultural context. This implies that a field study may only, but robustly, demonstrate the potential for recovery for a wide range of taxa and for complexly structured communities. A typical NOEC-type off-field study would require a meadow of 2 to 4 ha and will have no crop loss. The results obtained may be used to assess safe distances and, in combination with product decay data, also time to potential recovery.

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Acknowledgements

Special thanks to Saskia Aldershof for computation of biodiversity indices, PRCs, SRCs and comments on the manuscript and to Mark Miles for useful comments and inspiring discussions.

A1.6 Rational for Harmonization of the Multiple Application Factor (MAF) Approach in Ecotoxicological Risk Assessment

Paul Neumann

A1.6.1 The Concept of the Multiple Application Factor

Multiple applications of PPPs may cause the accumulation of residue on the treated plants. Therefore, a potential increase in the level of residues after multiple applications must be taken into account in the NTA risk assessment for PPPs. Within the interval between the individual applications and after the last application, the residues decline. For the risk assessment, it is generally assumed that this decline follows an exponential first-order kinetic (see Figure A1.6). Although this might not be in all cases the best possible model for the description of the residue dissipation process on plants, it can be considered an acceptable approach that results in conservative worst-case exposure estimates (EFSA 2009).

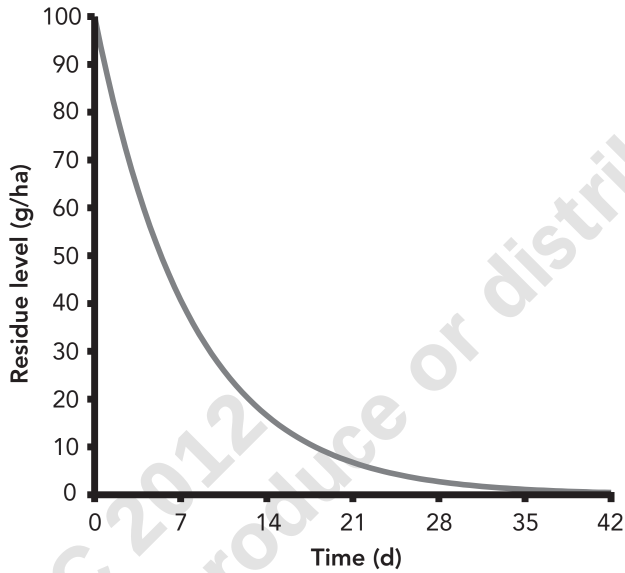

Figure A1.6 Exponential first order dissipation of residues (example: 1 × 100 g/ha). $C_t = C_0 \text{ x } e^{-kt}$; with C_t: actual concentration at time *t*, C_0: initial concentration, *k*: rate constant were $k = \ln (2/DT50)$.

When estimating residue accumulation after repeated applications, it is an established practice to include a multiple application factor (MAF) in the exposure calculation. The MAF describes the ratio between the peak residue level after multiple applications and the initial residue level after a single application (see Figure A1.7).

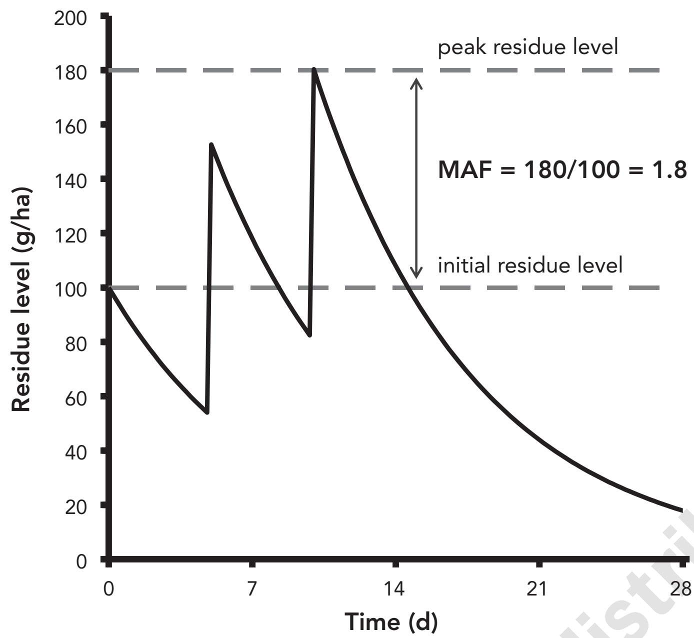

Figure A1.7 Sum-up of PPP residues after repeated applications (example: 3 × 100 g/ha, 5-day interval, DT50 = 5.4 days). Multiple application factor (MAF) is the ratio of the peak residue level divided by the initial residue level.

The magnitude of the MAF depends on the number of applications, the duration of the application intervals, and the half-life (DT50) of the applied compound.

A1.6.2 Deriving MAF Values

Gonzalez-Valero et al. (2000) evaluated residue and DT50 values for a set of PPPs and generated a look-up table to select the relevant MAF value for a given number of applications relative to the ratio between the DT50 value and the application interval. This look-up table (see Table A1.8) is also based on the assumption of a first-order exponential decay of residues, has been included in the proceedings of the ESCORT 2 workshop (Candolfi et al. 2000), and has been used routinely for the exposure assessment in the NTA risk assessment.

If no specific data on the DT50 value are available for a compound, a default ratio of DT50-to-spray interval of 2.3:1 is recommended in the ESCORT 2 proceedings.

The Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (2009) also recommends using MAF values for the exposure estimation in the context of repeated PPP applications. The MAF values also are calculated assuming a first-order exponential decay function.

Table A1.8 Multiple application factor for various half-lifes (DT50) : spray interval ratios. Table taken from the ESCORT 2 proceedings (modified, Candolfi et al. 2000). The shading indicates the line with a DT50 : spray interval ratio of 1:2.3, that is recommended by ESCORT 2 if no specific data on the DT50 value and the application interval are available.

DT50 : spray interval ratio	**MAF after n applications, where *n* =**							
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
1:8	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
1:4	1.0	1.1	1.1	1.1	1.1	1.1	1.1	1.1
1:2	1.0	1.3	1.3	1.3	1.3	1.3	1.3	1.3
1:1	1.0	1.5	1.8	1.9	1.9	2.0	2.0	2.0
2:1	1.0	1.7	2.2	2.6	2.8	3.0	3.1	3.2
2.3:1	1.0	1.7	2.3	2.7	3.0	3.2	3.4	3.5
4:1	1.0	1.8	2.5	3.1	3.6	4.1	4.4	4.7
6:1	1.0	1.9	2.7	3.4	4.0	4.6	5.1	5.5
8:1	1.0	1.9	2.8	3.5	4.2	4.9	5.5	6.0
16:1	1.0	2.0	2.9	3.8	4.6	5.4	6.2	6.9

The MAF_m value that is used for the long-term risk assessment of birds and mammals is calculated according to the following equation.

$$MAF_m \quad \frac{1 \quad e^{nki}}{1 \quad e^{ki}}$$

Where:

k = ln(2)/DT50 (rate constant)

n = number of applications

i = application interval (d)

Clearly, this equation will give the same results for the MAF value as obtained from the ESCORT 2 look-up table because it is based on the same first-order exponential decay function.

Example:

A compound with a DT50 of 10 days and 3 applications with an application interval of 5 days:

ESCORT 2 look up table:

(DT50 : application interval) = (10:5) = (2:1) for 3 applications à MAF = 2.2 (see Table A1.8)

Birds and Mammals Guidance Document:

$$MAF_m \quad \frac{1 \quad e^{3 \quad \frac{\ln(2)}{10} \quad 5}}{1 \quad e^{\frac{\ln(2)}{10} \quad 5}} \quad 2.2$$

In addition to the MAF_m values, a further MAF90 value is recommended in the birds and mammal guidance document for use in the acute risk assessment. This MAF90 values gives lower MAF values compared to the MAF_m because its definition accounts for a repeated use of 90th percentile residue values from the crop to achieve an overall 90th percentile for the acute dietary exposure estimate for the birds and mammals risk assessment.

For the NTA risk assessment, the in-crop exposure estimate is based on the in-field application rate (g/ha) that is derived from the use pattern of the product (and does not rely on 90th percentile values). Hence, the more conservative equation of the MAF_m can be considered appropriate for the estimation of the in-crop exposure calculation for NTAs.

For the assessment of the off-field exposure of NTAs after repeated applications, the corresponding drift rates are already adjusted to achieve an overall 90th percentile exposure value (Rautmann et al. 2001). Therefore, the equation for the MAFm also is considered appropriate for use in off-field exposure calculations.

A1.6.3 Generic DT50 Value

The explicit equation for the MAF_m calculation is given in the Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA 2009). This guidance document also recommends the use of a generic DT50 value of 10 days to describe the dissipation of a compound from plant material in case no specific data are available. This value was derived from a data evaluation by Willis and McDowell (1987). Moreover, a generic DT50 value of 10 days for the dissipation of residues plants also is used in the FOCUS models (SANCO/4802/2001-rev.2 final, May 2003) in the context of calculating predicted environmental concentrations for surface water (PEC_{sw}).

The generic DT50 value of 10 days that is used as a default value to calculate MAF values in the bird and mammal risk assessment corresponds well to the generic ratio DT50-to-application interval of 2.3:1 that is used to derive generic MAF values for the NTA risk assessment because it reflects a DT50-to-application interval of 10:4.3 (= 2.3:1). The corresponding application interval of 4 to 5 days reflects a worst-case assumption for the application interval of most PPPs.

A1.6.4 Conclusion

- The MAF values as tabulated in the proceedings of the ESCORT 2 workshop are in line with the MAF values as calculated based on the equation for the MAFm from the bird and mammal guidance document (EFSA 2009).

- Refinements of the MAF values can be based either on the look-up table from ESCORT 2 or on the equation given for the MAFm in the bird and mammal guidance document (EFSA 2009).
- The generic DT50 of 10 days for the dissipation of residues from leaves also can be used in the NTA risk assessment.

A1.6.5 References

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A1.7 Potential for Use of Modelling in Regulation and Risk Assessment

Chris Topping and Dave Bohan

NOTE: This paper was not presented during the ESCORT 3 workshop. During the workshop plenary discussion, it was considered to be useful to include into the workshop proceedings a summary of what models could achieve concerning the prediction of NTA recovery. Chris Topping and Dave Bohan volunteered to provide such a summary.

Questions of the effects of PPPs on non-target organisms can be posed using computer models that would otherwise be logistically and economically impractical in experiments. For regulation and risk assessment, the use of modelling has manifold benefits, including these:

- the logistic and economic costs of what effectively would be a range of tiered and experimental assessments could be reduced,
- the number of potential tiered and field scenarios investigated could be much higher,
- uncertainties could be quantified,
- unexpected outcomes could be identified, and
- the detection of unacceptable risks could be made at an early stage.

A variety of modelling approaches might be used for regulation and risk assessment. However, from discussions within the ESCORT 3 subgroups, two classes of models are likely to be needed. These are landscape-level models and community or ecosystem-level models.

Landscape-scale population-level models for risk or impact assessment of PPPs have been developed over the last decade, and although primarily used in avian and mammalian risk assessments, arthropod versions are also developed and ready for use (see Topping et al. 2009). These models take the structure of a geographic area together with the agricultural utilization of the landscape into account and can thus estimate exposure spatially. Spatial estimates of exposure, combined with the ability to predict distributions of non-target organisms in time and space, allow for an integration of distributions with exposure and toxicity, and thus the ability to predict population-level impacts as well as local impacts. Models of this type simultaneously predict dispersal and reproductive potential; hence modelling of recovery is also possible. In fact, taking account of these dynamics is the only way to overcome the problems of estimating meaningful recovery that was identified in the ESCORT 3 subgroups. From a realism perspective, this kind of integration is also a positive step forward allowing issues such as scale of use, climatic zones, and the background agronomic realities to be included in determining impact and recovery. These issues have been shown to be critical to obtaining accurate assessments of risk (Topping et al. 2009).

Recent modelling approaches have shown that it is possible to model the interactions within an agricultural ecosystem by simplifying from the large number of species present in the system to a much smaller number of community or functional groups to predict changes in community structure and ecosystem function due to PPPs (Caron-Lormier et al. 2009; Hawes et al. 2009). Such dynamic food-web models could be used at the interface of regulation and risk assessment to evaluate the likely impacts of a particular product on non-target communities and ecosystem functions in or off the field or crop. Such models might help answer in or off, field or crop questions, including which community groups change, in which direction the change occurs, what is the duration of change, is this change ecologically important, what is the (or is there an) NOER/NOEAER for particular groups or the ecosystem as a whole, might particular timings of application be used to achieve minimum community change, which community groups should be mitigated, and how many individuals would be required to "disperse" or "reproduce" for recovery and change mitigation? It would also be possible to estimate the power required of field trials to appropriately test the predictions of these models.

Ultimately, models are dependent upon data input and need to be tested and shown fit for their purpose. This constraint limits the range of potential models that could be used in regulatory risk assessment because testing needs to be feasible, and likely to be supported by data collected in association with the risk assessments or by subsequent monitoring programmes (e.g., on the model of the monitoring that is ongoing in France in maize crops, under the auspices of the Ministry of Agriculture and of the Office National de la Chasse et de la Faune Sauvage (ONCFS; http://www.oncfs.gouv.fr). However, this does not mean that testing need be a stumbling block. During the last decade, the science of developing, and testing, even complex models has progressed considerably (e.g., Grimm et al. 2007), and with increasing use of open-source programs and new documentation methods, models are no longer black boxes (Topping et al. 2010). It is now feasible to develop realistic models for use in regulation and risk assessment that are both open and tested within a relatively short time frame.

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Appendix 2: Poster Abstracts

Abstracts for the following posters are provided in this appendix:

A2.1 *Aldershof and Bakker:* Comparison of Arthropod Community Responses to an Insecticidal Active in Different Geographic Regions

A2.2 *Chaton et al.: Pollinating Insects in Agroecosystems: Are They Covered by the Current Risk Assessment?*

A2.3 *Kimmel and Brühl:* Risk Assessment in Terrestrial Ecotoxicology: the Sensitivity of *Drosophila* spp. Towards Pesticides

A2.4 *Miles and Bakker:* Use of Higher Tier and Field Data to Assess the Risk of Insecticide Applications to Non-Target Arthropods: Assessing the Off-Field Risk Using a Novel Terrestrial Mesocosm Test Design

A2.5 *Miles et al.:* An Evaluation of the Non-Target Arthropod Hazard Quotient since ESCORT 2

A2.6 *Miles et al.:* In-Field Recovery of Non-Target Arthropod Communities in the Context of Regulatory Risk Assessment in the EU

A2.7 *de Roos and Bakker:* Effects of Stage-Specific Mortality and Multiple Insecticide Exposure on Predatory Mites: Implications for Optimal Application Schedules

A2.8 *Swarowsky et al.:* Comparison of Standard Laboratory Tests and Extended Laboratory Tests for the Non-Target Arthropod Species A*phidius rhopalosiphi* and *Typhlodromus pyri*

A2.9 *Weyman et al.:* Proposal for an NTA Scheme for Non-Spray Products Applied to Soil

A2.1 Comparison of Arthropod Community Responses to an Insecticidal Active in Different Geographic Regions

Aldershof S and Bakker F

On behalf of Beneficial Arthropod Regulatory Testing (BART) Group: M Coulson, P Neumann, F Bakker, K Barrett, M Mead-Briggs, K Brown, M Candolfi, A Dinter, A Drexler, G Lewis, M Miles, G Weyman

A2.1.1 Introduction

At present the hypothesis that arthropod communities in different geographical c.q. climatological regions respond differently to exposure to plant protection products has not been tested empirically. We use the results of ten large scale field studies performed with the same active substance but in different cropping systems and different regions to provide a first insight into the importance of geographical gradient for the response of non-target arthropod communities to insecticide exposure.

We examine the effect of latitude on

1) community structure,
2) initial impact of the insecticidal active substance (OP1),
3) temporal response patterns of arthropod communities, and
4) integrated population effect levels.

A2.1.2 Materials and Methods

In total, 10 good laboratory practice (GLP) field studies at 9 different locations were used to test hypotheses on effects of geographical gradient on ecotoxicological response at the population and community levels. All trials had a randomized block design with 4 replicate plots ($n = 4$) per treatment (active substance and a water-treated control). See Figure A2.1 and Table A2.1 and Table A2.2 for study locations and features.

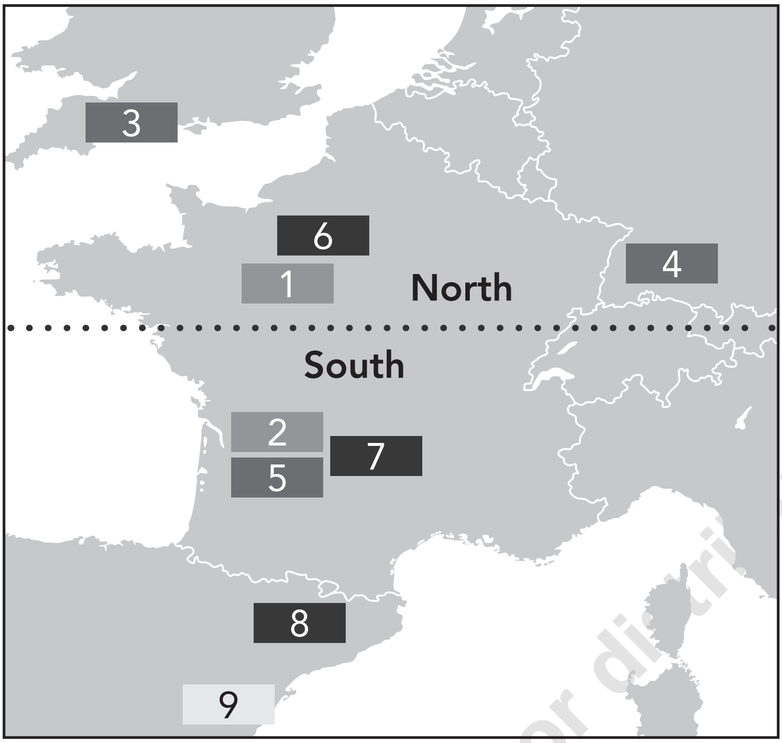


Figure A2.1 Trial locations

Table A2.1 Background information concerning the field studies: crop, location, and year of conduct. OP1 = test compound, OP1b = closely related test compound from the same chemical class as OP1. Crop type: G = grassland, A = arable crop, O = orchard crop. Location: N = North, S =South

Trial	Compound	Crop (crop type)	Location		Year
1	OP1	Grassland (G)	N	NW France (Dame Marie-le Bois)	2006
2	OP1	Grassland (G)	S	Lot et Garonne, SW France (St Pé St Simon)	2006
3	OP1	Cereals (A)	N	Cornwall, SW England	2005
4	OP1b	Maize (A)	N	Tübingen, W Germany	2006
5	OP1	Sorghum (A)	S	Lot et Garonne, SW France (St Pé St Simon)	2007
6	OP1	Apple (O)	N	Indre-et Loire, NW France (St Paterne-Racan)	2006
7	OP1	Apple (O)	S	Monheurt, SW France	2007
6	OP1	Apple (O)	N	Indre-et Loire, NW France (St Paterne-Racan)	2006
8	OP1	Apple (O)	S	Lleida province, NE Spain (Tornabous)	2008
9	OP1	Citrus (O)	S	near Traiguera, Castellón, NE Spain	2007

Table A2.2 Background information concerning the field studies: sampling methods, treatment specifications, and crop development stage during treatments. Sampling methods: D-vac = suction sampling, PF = pitfall, PE = photo-eclector, I = inventory sampling

Trial	Sampling Method	Application Rate (g.a.i./ha)	Spray Volume (L/ha)	Application Timing and Frequency	BBCH
1	D-vac, PF	1 × 100	100	2-June	-
2	D-vac, PF	1 × 100	100	30-May	-
3	PF	1 × 480	200	Summer (1)	
4	PF, PE	1 × 342	200	25-April	0
5	PF	1 × 960	200	28-June	12–16
6	I	1 × 960	1000	24-May	71–73
7	I	2 × 500	1000	13-May, 27-May	73–74
6	I	2 × 960	1000	24-May, 03-June	71–73
8	I	3 × 750	1250	15-April, 29-April, 13-May	68–72
9	I	1 × 2400	2000	04-June, 18-June	69–72

All datasets were analysed using an identical protocol, to enhance comparison. At the population level, direct impact was calculated as the ratio of population densities in treatment groups to population densities in control groups according to Abbott at the first sampling moment after treatment. Duration of effects was categorized using the following classification:

1) short-term effects (less than 1 month),
2) intermediate effects (1 to 2 months),
3) long-term effects (during a large part or the season), and
4) no recovery at the end of the season.

Analysis at the community level was performed using principal response curves (PRC) analyses.

A2.1.3 Results

A2.1.3.1 Community Structure

Arable communities were least similar (23% to 27% species overlap), and orchard communities were most similar (54% to 69% species overlap: Table A2.3). This difference between arable crops and orchards may in part be due to the level of identification (most taxa were identified to species level in arable studies, and to genus or family level in orchard studies).

Species overlap in the different cropping systems between and within geographical regions was similar (Table A2.3). Species abundance (evenness) differed considerably in arable studies, but less so in orchard studies.

Table A2.3 Taxonomic similarity of the test sites. The number of taxa occurring in each of two locations was taken as the proportion of the total number of taxa found in both sites. The resulting figure was interpreted as a similarity index (excluding rare taxa).

	Inter-Region Comparisons					
Location 1:	Grass N 1 × 100 (1)	Arable N 1 × 480 (3)	Arable NE 1 × 324 (4)	Apple N 1 × 960 (6)	Apple N 2 × 960 (6)	Apple N 2 × 960 (6)
Location 2:	Grass S 1 × 100 (2)	Arable S 1 × 960 (5)	Arable S 1 × 960 (5)	Apple S 2 × 500 (7)	Apple S 3 × 750 (2)	Citrus S 1 × 2400 (9)
No. of taxa evaluated Location 1:	80	47	57	74	73	73
No. of taxa evaluated Location 2:	65	45	45	64	65	74
Total taxa evaluated Locations 1 and 2:	103	73	84	83	78	96
No. taxa occurring at both locations:	42	20	19	54	56	53
% taxa occurring at both locations:	**41%**	**27%**	**23%**	**65%**	**72%**	**55%**

	Intra-Region Comparisons			
Location 1:	Arable N 1 × 480 (3)	Apple S 2 × 500 (7)	Apple S 2 × 500 (7)	Apple S 3 × 750 (2)
Location 2:	Arable NE 1 × 324 (4)	Apple S 3 × 750 (2)	Citrus S 1 × 2400 (9)	Citrus S 1 × 2400 (9)
No. of taxa evaluated Location 1:	47	74	74	65
No. of taxa evaluated Location 2:	57	65	74	74
Total taxa evaluated Locations 1 and 2:	80	77	91	92
No. taxa occurring at both locations:	24	52	52	52
% taxa occurring at both locations:	**30%**	**68%**	**57%**	**57%**

A2.1.3.2 Initial Population Effects

The two grassland studies had a similar distribution of initial effect classes at the 2 test sites, but the proportion of unaffected taxa was higher in the South (Figure A2.2).

The arable studies, which tested higher application rates, had effect size distributions that were more skewed to the larger effect classes. In general, all sites had a qualitatively similar distribution pattern (Figure A2.2). In particular, the site in South France had a striking distribution in that the lowest two effect classes did not occur, indicating that the entire community was affected. At the German site (with lower application rate), the 80% to 100% effect classes occurred less than at the other arable sites.

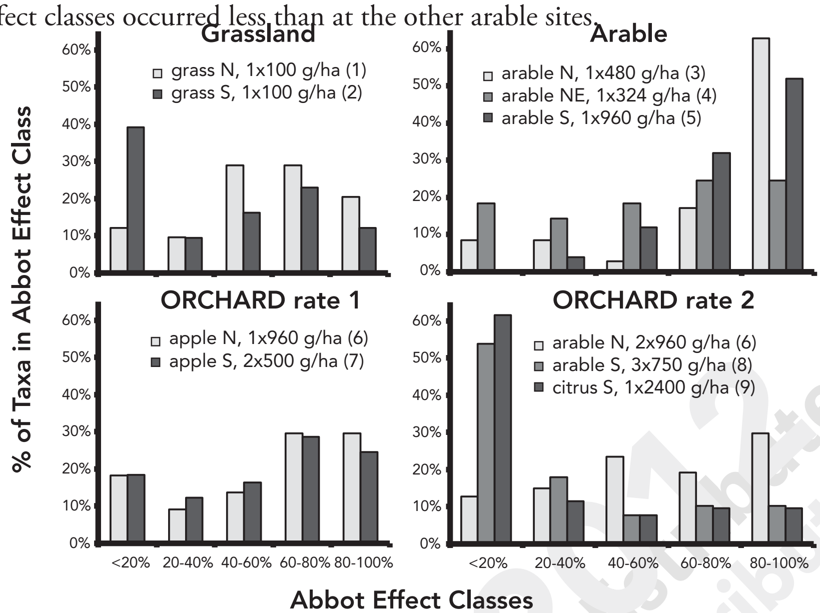


Figure A2.2 Initial effects (Abbott) for different cropping systems and rates in North and South

Note: Effects measured on first sample after treatment. Effect class <20% includes density increases. 1 × 100 = 1 application at 100 g a.i./ha; numbers in brackets refer to study locations (Figure A2.1).

For the two apple studies involving relatively low application rates in North and South France, effect-class distributions were very similar, with most taxa occurring in the 60% to 100% effect classes. Whereas the trend for the apple study in the North was an increasing frequency with increasing effect, the reverse is seen for the two Spanish studies. More than 50% of the taxa was not affected after treatment in these studies (Figure A2.2).

A2.1.3.3 Community Effects

For OP1, PRC responses of North and South studies expressed by the first ordination axis were similar in all crop types (Figure A2.3). Both magnitude and duration of responses were similar, except the magnitude of the two orchard studies performed in Spain were lower (locations 8 and 9; Figure A2.1).

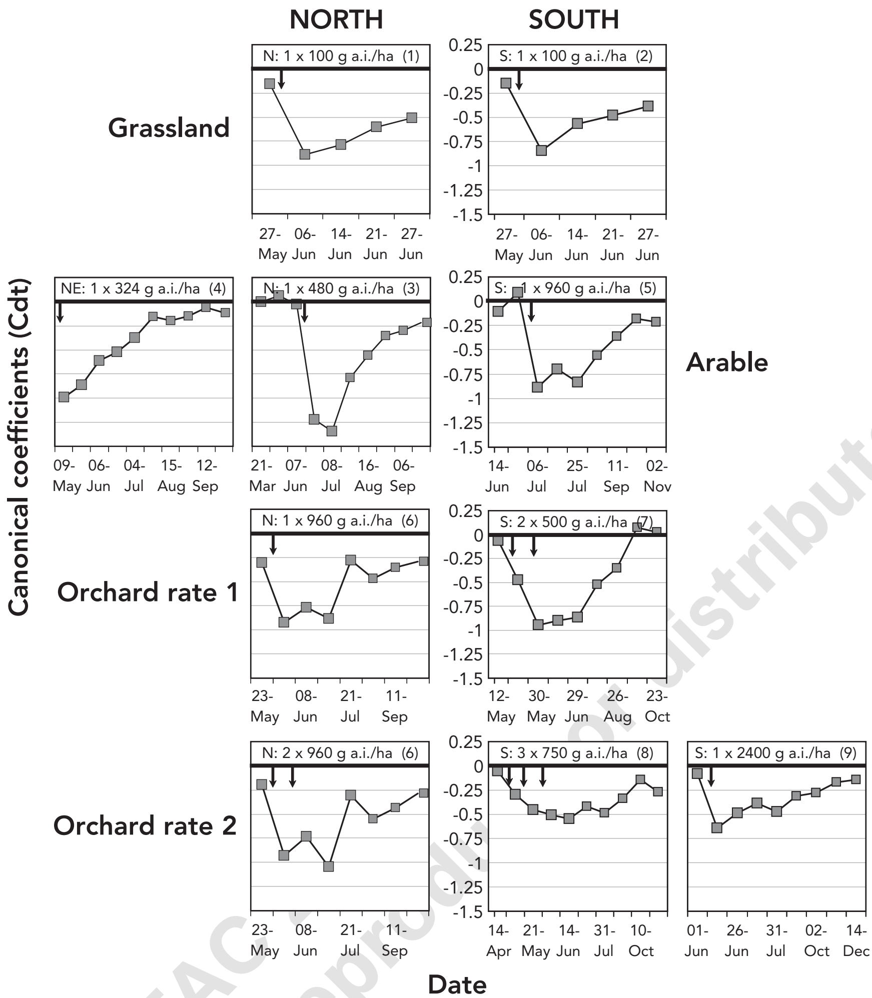


Figure A2.3 Results of PRC analysis (axis 1)

Statistics of PRC analyses (e.g., % of variance explained by treatment, % of variance captured by the first and second ordination axis, Table A2.4) were similar, except for the two orchard studies performed in Spain.

Table A2.4 Summary PRC statistics. Percentages of the total variance that can be attributed to time and treatment regime for the analysed data sets. The treatment component includes the interaction between treatment and time. The remaining fraction of the variance is residual variance. The table also indicates which fraction of the variance explained by the treatment regime is captured by the first and second Principal Response Curves (axis 1 and axis 2). In addition, P-values (Monte Carlo Permutation tests) are given for overall PRCs (axis 1 and axis 2), and for individual time points (all axes together).

		NORTH					SOUTH				
	Total arthropods per sample (control):	8226	8008	5276	58839	58839	11274	2791	240830	152643	262563
	Total arthropods all samples (control):	41130	80078	52757	470714	470714	56368	25120	2167467	1526425	1312816
	Compound	OP1	OP1	OP1b	OP1	OP1	OP1	OP1	OP1	OP1	OP1
	Crop	Grass	Cereal	Cereal	Apple	Apple	Grass	Cereal	Apple	Apple	Citrus
	Region	N	N	NE	N	N	S	S	S	S	S
	Application (no. × g/ha)	1 × 100	1 × 480	1 × 324	1 × 960	2 × 960	1 × 100	1 × 960	2 × 500	3 × 750	1 × 2400
	Trial no.	(1)	(3)	(4)	(6)	(6)	(2)	(5)	(7)	(8)	(9)
% Variance time explained by	**time**	26.8	48	70.8	63.8	63.3	36.9	44.6	65.4	69.9	61.7
	treatment	11.4	12.9	7.5	9.4	10.4	12.3	12.3	10.5	4.8	6.4
% Variance captured by	**axis 1**	60.4	59.7	53.9	51.2	52.3	50.4	52.5	54.6	45.6	23
	axis 2	16.2	14.9	10.9	13.1	13.9	17	11.4	12.2	11.7	13.1
	axes 1+2	76.6	74.6	64.8	64.3	66.2	67.4	63.9	66.8	57.3	41.4
	***P*-value ax1**	0.212	0.051	0.033	0.037	0.030	0.056	0.034	0.031	0.076	0.161
	***P*-value ax2**	0.876	0.433	0.32	0.242	0.052	0.667	0.562	0.033	0.652	0.616

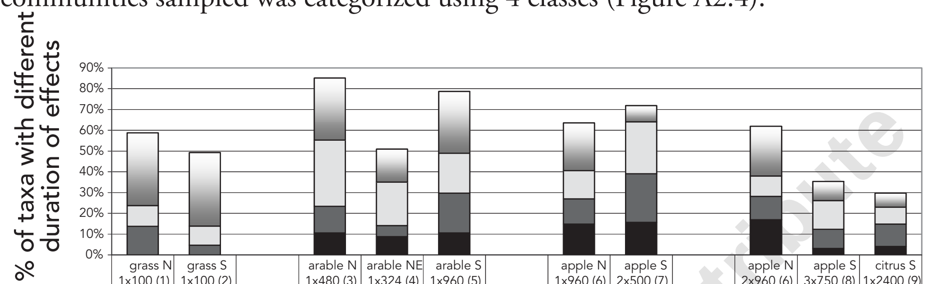
Table A2.4 continued

	P-values at individual sampling moments (Monte Carlo Permutation Test)									
		0.891								
		0.800					0.361			
Pre-application	0.858	0.836		0.572	0.637	0.683	0.340	0.208	0.867	0.632
Post-application	0.035	0.032	0.036	0.031	0.023	0.017	0.031	0.061	0.129	0.146
	0.217	0.027	0.036	0.026	0.028	0.030	0.091	0.039	0.094	0.167
	0.316	0.035	0.030	0.030	0.021	0.090	0.039	0.026	0.048	0.051
	0.418	0.152	0.028	0.114	0.089	0.228	0.065	0.034	0.137	0.036
		0.206	0.140	0.028	0.028		0.086	0.087	0.230	0.193
		0.720	0.059	0.456	0.027		0.790	0.293	0.639	0.090
		0.810	0.625	0.138	0.036		0.059	0.023	0.711	0.376
			0.244					0.022	0.664	0.814
***P* < 0.05** (dark shading)			0.409						0.673	0.561
***P* < 0.1** (light shading)			0.744							0.595
										0.799

Principal response curves show the response pattern (relative magnitude and duration) of arthropod communities in treated plots in relation to the control community (set at 0). Only the fist PRC (ax 1) is shown here. As can be seen in Table A2.4, in most studies approximately 50% to 60% of the variance in captured by this PRC. 1 × 100 = 1 application at 100 g a.i./ha; numbers in brackets refer to study locations (Figure A2.1).

A2.1.3.4 Integrated Population Effects

The overall effect of the insecticidal active substance on arthropod populations in the various communities sampled was categorized using 4 classes (Figure A2.4).



	grass N 1x100 (1)	grass S 1x100 (2)		arable N 1x480 (3)	arable NE 1x324 (4)	arable S 1x960 (5)		apple N 1x960 (6)	apple S 2x500 (7)		apple N 2x960 (6)	apple S 3x750 (8)	citrus S 1x2400 (9)
1: <1 month	35.0%	35.4%		29.8%	15.8%	29.8%		23.0	7.8%		23.9%	9.2%	6.8%
2: <2 months	10.0%	9.2%		31.9%	21.1%	19.1%		13.5%	25.0%		9.9%	13.8%	8.1%
3: entire season	13.8%	4.6%		12.8%	5.3%	19.1%		12.2%	23.4%		11.3%	9.2%	10.8%
4: > season	0.0%	0.0%		10.6%	8.8%	10.6%		14.9%	15.6%		16.9%	3.1%	4.1%

Figure A2.4 Summary effects at taxon level

There are differences between cropping systems, but a high degree of similarity within study pairs with comparable application rates is observed. This was again with the exception of the two studies in Spain where, in general, effects were less pronounced. See also the large proportion of taxa that were initially unaffected in these studies (Figure A2.4).

A2.1.3.5 Conclusions

OP1 treatment effects were similar in studies performed in North and South Europe. Only a slight trend was observed that more (statistically significant) adverse effects were detected in studies performed in the North, and that recovery of some taxa was slower in the North.

In exception to the conclusion above, adverse OP1 treatment effects were clearly lower in orchard studies performed in Spain. Analysis of more Mediterranean studies is needed to examine whether this result was related to geographical location or to other factors.

These preliminary conclusions are based on 10 studies concerning 1 test product only. Examination of additional datasets is needed.

A2.2 Pollinating Insects in Agroecosystems: Are They Covered by the Current Risk Assessment?

Chaton PF, Duchard S, Foldrin J, Lambin S and Alix A

Pollinating insects are widely present in agroecosystems (Kevan 1999). Being essential or occasional pollinating species, they may be exposed to PPPs in frequenting treated crops during pollen or nectar collection and consumption. While the vast majority of efforts in research and risk assessment has focused on the honey bee over the last years (EC 2002, 2006, 2009), little is known about side-effects of PPPs on other domestic pollinators and even less is known about wild species (Kevan 1999). This work proposes, through 5 examples of pollinating species widely encountered in France and Europe, to discuss the level of protection of such species, which is provided by the current risk assessment for NTAs (Candolfi et al. 1999). For this purpose, an overview of their biological and ecological traits, along with the existing information about their sensitivity to PPPs are provided.

A2.2.1 *Episyrphus balteatus* (Diptera, Syrphidae, De Geer)

Episyrphus balteatus is a commonly recorded hoverfly in Europe (e.g., 60 plant species visited in the Netherlands [Hoffman 2005]). Adults feed on the pollen and nectar from herbaceous flowers, many of which can be found in field margins and hedgerows. This species has one (occasionally two) generation. Oviposition takes place in midsummer when year-to-year variation in aphid phenologies is much lower. *E. balteatus* lays their eggs on the primary hosts of aphids, that is, in hedges, forest boundaries, house gardens (Tenhumberg and Poehling 1995), or agricultural land where larvae are obligatory aphidophagous (MacLeod 1999). Adult females may overwinter occasionally, but the bulk of the population migrates to southern Europe where, presumably, it breeds or overwinters (Sadeghi and Gilbert 2000).

Information on effects of insecticides, herbicides, and fungicides on *E. balteatus* are available (Candolfi et al. 1999) based on Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA) test guideline showing that this species is sensitive but can be covered by standard species in cases where tests were performed.

A2.2.2 *Gonepteryx rhammi* (Lepidoptera pieridae L.)

The Brimstone butterfly (*Gonepteryx rhammi*) is encountered in Europe and in France and is typical of woodland biotopes. It can be observed on field and wood margins. The larvae of this species are not described to be a potential pest for crops. This is an univoltine species (Aviron et al. 2007), which overwinters as an adult and lay eggs in April on host plants. The larval development takes about 3 and one-half months. The sensitivity of this species to pesticide is currently unknown, and it is not possible to conclude whether the current risk assessment is protective of this butterfly except if the butterfly is present in some monitoring.

A2.2.3 *Megachile rotundata* (Hymenoptera, Megachilidae, Fabricius)

Megachile rotundata is a solitary bee species present in Europe and in France. The foraging range can be within 100 to 500 m (Zurbuchen et al. 2010), but the foraging behaviour indicates a trend to collect pollen and nectar from the nearest suitable source regardless of the population density that may exist. The *Megachile* species can have more than one generation per year (*M. rotundata* seems to have 2 generations per year) and generally overwinters as prepupae (Stephen et al. 1969). The nest could be in narrow crevices in almost any material.

Some acute contact toxicity data on this species are available in the United States Environmental Protection Agency (USEPA) ecotox database (http://www.epa.gov/ecotox). Because these data are expressed in µg a.i./bee, they had been compared to the corresponding toxicity data available for the honey bee *Apis mellifera* in the European dossier and in the French database (http://www.dive.afssa.fr/agritox/index.php). This comparison indicates that *M. rotundata* may be more sensitive than honey bees to pesticides.

A2.2.4 *Osmia cornuta* (Hymenoptera, Megachilidae, Latreille)

Osmia cornuta is a solitary bee species common in all Europe except in northern countries. Its maximum foraging distance is estimated to be about 600 meters (Gathmann and Tscharntke 2002), but most of the females tend to forage at short distances around their nests. This polylectic species, collecting pollen from 8 plant families, shows a tendency to be oligolectic especially on *Prunus* (Tasei 1973). *O. cornuta* is one of the first pollinators foraging beginning in March in central Europe (females). *O. cornuta* has no more than one generation per year, according to literature. It builds its nests in holes of old timber and walls.

Few data on contact and oral toxicities are available. Acute and delayed effects of five formulated fungicides were reported in Ladurner et al. (2005) for *Osmia lignaria* and *A. mellifera*. For one fungicide, *O. lignaria* was more sensitive than *A. mellifera*.

A2.2.5 *Bombus terrestris* (Hymenoptera: Apoidae L.)

The *Bombus terrestris* species of bumble bees is commonly recorded in Europe and is commercially produced for pollination in greenhouses. *B. terrestris* is associated with withered grass and prefers field boundaries and other open ground (Svensson et al. 2000). *B. terrestris* has one (occasionally two) generation per year. Queens emerge from hibernation in spring to found colonies. The sexual leave the parental nest to mate in summer, after which the entire colony including the males dies. Young inseminated queens will survive by hibernation and start a next colony generation the following spring (Baer and Schmid-Hempel 2003). The nest is normally maintained by the queen for the duration of its life. However, a decline in the food supply often causes the nesting population to move (Stephen et al. 1969).

For toxic substances, the LD50 for bumblebees cannot be derived from known *A. mellifera* LD50 values (van der Steen et al. 2008).

A2.2.6 Conclusions

These five examples illustrate the diversity of biological and ecological traits that pollinating species may display in agroecosystems. Feeding and reproduction habits may in some cases generate very specific plant-insect relationship, which may need particular attention particularly in cases where side-effects of PPP on Non-Target Species may not be excluded based on current risk assessment methodologies. Test guidelines for laboratory investigations are available for some of these species, which may easily be included into risk assessment schemes. Where laboratory test guidelines are not available, risk assessments should address the issue through for example a reasoning on whether these species may or not be considered as covered by the data and approach retained. Alternatively, a dedicated monitoring should be undertaken in implementing field trials for higher tier risk assessment purposes.

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A2.3 Risk Assessment in Terrestrial Ecotoxicology: the Sensitivity of *Drosophila* spp. Towards Pesticides

Kimmel S and Brühl C

A2.3.1 Introduction

The risk assessment of pesticides concerning the effects on NTAs currently considers only a selection of a few beneficial species, which are exclusively predators or parasitoids and therefore do not represent the whole range of life histories and related sensitivities that exist among the arthropods. Concerning the actual standards, basic ecotoxicological studies for PPPs are reduced to two species: *Aphidius rhopalosiphi* and *Typhlodromus pyri*. This aspect of the tier-testing approach is set due to the risk assessment requirements of ESCORT 2 (Candolfi et al. 2001).

This study introduces a new arthropod genus to ecotoxicological testing: *Drosophila* spp., one of the most studied insect organisms in modern biology and the standard organism for genetic and developmental research.

Compared to predatory species and parasitoids, *Drosophila* spp. shows a completely different lifestyle, feeding on rotten fruit and microorganisms. It is also an important group within the Diptera, containing about 3000 species with a worldwide distribution. For scientific research, specific strains are established for easy handling. The extensive knowledge of *Drosophila* spp. also allows a data transfer to other areas of research, which should enhance the understanding of the effects of PPPs on functional pathways.

A2.3.2 Material and Methods

This study aimed to establish acute LR50 values for *Drosophila funebris* and *Drosophila melanogaster* for a range of PPPs. Overall, 12 active substances were tested, including fungicides, herbicides, and insecticides as existing formulations of currently registered PPPs. Substances of different chemical classes were selected preferably on their high frequency of actual usage or production. All chemicals were tested at a rate of 200 L/ha. Each test was carried out with 5 concentrations and 4 replicates with 10 flies each (5 males, 5 females) to possibly obtain an LR50 value using the test design available for *Aphidius rhopalosiphi* (Mead-Briggs et al. 2000). For the acute toxicity tests, effects were regarded at 2 h, 24 h, and 48 h after exposure. Application rates never exceeded 200 L/ha in order to avoid runoff from the glass plates (Candolfi et al. 2001). All acute and extended toxicity tests were carried out with freshly emerged flies, i.e., wasps not older than 24 h. All tests were stored at 22 °C ± 2 °C and a relative humidity of 70% ± 15%. A day–dark rhythm was installed with 16 h of light and 8 h of darkness at an average light intensity of 4000 lux. All tested *Drosophila* flies or wasps were introduced into the test system within 1 h after application because of eventually volatile compounds depending on the tested substance in each case. Every pesticide was tested several times in order to validate the test system and to provide more reliable results. Besides self-testing, all assessed endpoints for both *Drosophila* spp. were also compared to existing data for *A. rhopalosiphi* and *T. pyri*.

A2.3.4 Results and Discussion

The obtained LR50 values for *Drosophila* spp. mortality were compared with both literature data as well as *A. rhopalosiphi* tests that were carried out in parallel. As an example, the average Dimethoate LR50 of *D. melanogaster* was located at 0.01 g a.i./ha, whereas the *A. rhopalosiphi* LR50 concerning Dimethoate averaged 0.05 g a.i./ha. All results for the dose–response tests are displayed in Table A2.5. In cases no LR50 value could be calculated, the mortality at the highest test rate is given. All insecticides led to definite values, whereas the testing of fungicides and herbicides led to more heterogenic results.

Table A2.5 Comparison of LR50 concerning all tested substances

Product	**Active ingredient**	**LR50[1]** ***D. funebris*** **[g a.i./ha]**	**LR50[1]** ***D. melanogaster*** **[g a.i./ha]**	**LR50[1]** ***A. rhopalosiphi*** **[g a.i./ha]**	**LR50[1]** ***T. pyri*** **[g a.i./ha]**
Rogor 40 LC	Dimethoate	0.04	0.01	0.05	2.24
Pirimor	Pirimicarb	1.95	1.05	3.68	835
Decis liquid	Deltamethrin	0.83	0.54	0.55	0.0081
Karate Zeon	λ - cyhalothrin	0.18	0.15	0.5	0.2
Confidor WG 70	Imidacloprid	2.86	2.19	0.02	4.23
Flint	Trifloxystrobin	1176.4	336.42	<30% at 500	<30% at 500
Dithane NeoTec	Mancozeb	32.5% at 10000	55% at 10000	>75% at 3600	0.4% at 2600
Discus	Kresoxim - Methyl	20% at 4000	3810	1071	45% at 900
U 46 D - Fluid	2,4 - D	10% at 3000	32.5% at 3000	5.3% at 3000	7.5% at 3000
Stomp SC	Pendimethalin	2292.62	1083.96	38% at 3200	18% at 2400 100% at 3200
Arelon Top	Isoproturon	12.5% at 5000	27.5 % at 5000	16% at 2500 3% at 120	7% at 2500 21% at 1800
Glypho Unkraut Ex	Glyphosat	27.5% at 5000	35% at 5000	100% at 3600	100% at 5760 25% at 3720

[1] Average values of multiple test results and/or available literature data; if no LR50 calculation was possible, the mortality at the highest testing rate is shown.

A2.3.5 Conclusion and Outlook

Referring to the above presented results, both tested *Drosophila* spp. are at least equally sensitive or more sensitive compared to *A. rhopalosiphi* and *T. pyri* for most of the tested substances. This particular sensitivity can be of great interest for future investigations and risk assessments concerning the effects of pesticides on NTAs, because it shows that other organisms apart from beneficial arthropods can be used as indicator species, either with focus on acute (lethal) or sublethal (reproductive) effects. A modified test system with a focus on the *Drosophila* approach would be useful for further pesticide risk assessment studies, especially because these modified test systems represent a fast, cheap, and easy alternative to existing test systems.

Our research on reproduction effects showed reliable and reproducible results, especially concerning the reproduction rate in the untreated controls. Another possible option is the adaptation of an extended test into a multigeneration test, for example, for potential endocrine-disrupting chemicals. The short life cycle (7 to 14 d) enables chronic studies and detection of multigeneration effects within a short period of time. This short generation time can also lead to helpful research results concerning the possible development of resistance in the tested species toward chemical substances, an aspect already under research with the help of the *Drosophila* genus (Peyronnet et al. 1994). The high reproduction rate as well as a short life cycle qualifies *Drosophila* spp. as an ideal testing organism for the research on long-term substance effects over multiple generations, an aspect of great research interest (Newman et al. 2006).

A2.3.6 References

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Acknowledgements

The authors would like to thank Dr. Thomas Schmidt and Lukas Jeker from Harlan Laboratories Ltd. for their support and stimulating discussions.

A2.4 Use of Higher-Tier and Field Data to Assess the Risk of Insecticide Applications to Non-Target Arthropods: Assessing the Off-Field Risk Using a Novel Terrestrial Mesocosm Test Design

Miles M and Bakker F

A2.4.1 Introduction

NTA risk assessment is required under 91/414EEC when exposure can occur and follows the guidance of ESCORT 2 and the EU guidance document on terrestrial ecotoxicology (EC 2002). This paper summarizes the conduct, results, and analysis of a higher-tier study and demonstrates how the data can be used to conduct a risk assessment for off-field communities of NTAs. Insecticide A is a broad-spectrum insecticide effective on a range of sucking and chewing pests. It has a short environmental persistence (DT50 2 to 3 days on foliage). It is used in arable crops at rates of 480, 720, and 960 g a.i./ha.

A2.4.2 Experimental Methods: Off-Field Terrestrial Mesocosm Study (TMC)

This study was designed to assess the potential adverse effects of Insecticide A in off-crop habitats by performing the study in a true off-crop habitat, that is, a grassland habitat with little agricultural input in northwest France. The trial had a randomized block design with 4 replicates per treatment. Each block had 7 treatment plots of 24 × 24 m. The soil-surface- and plant-dwelling arthropod communities were monitored on a weekly basis for approximately 1 month following application. To sample the broadest possible spectrum of arthropods, a variety of sampling methods was employed (pitfall trapping, photo-eclector sampling, tractor mounted aspirator sampling, and Berlese extraction of collected weeds). Insecticide A was applied at 5 application rates 1, 5, 10, 25, and 100 g a.i./ha. Figure A2.5 shows the PRC for the arthropod community sampled by all sample types.

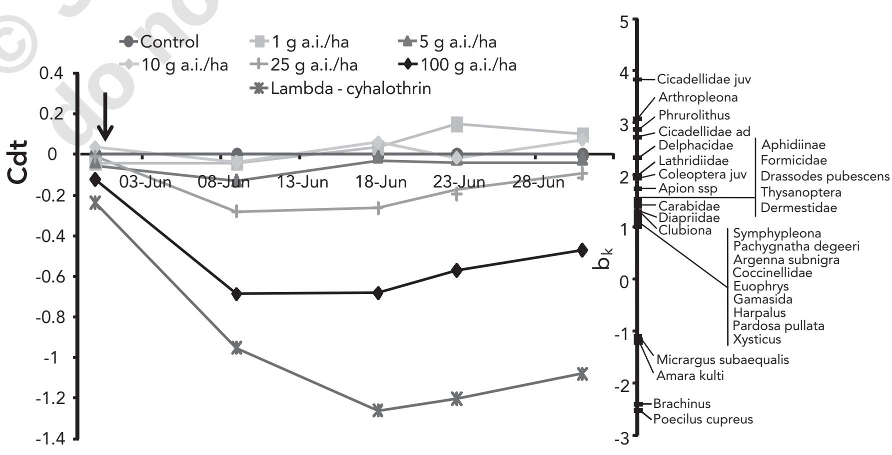

Figure A2.5 PRC for the off-field arthropod community, all sample types

A water control treatment and a toxic reference treatment were run in parallel. No recovery was seen in the positive reference treatment, indicating that test design parameters such as plot size were adequate to demonstrate persistent adverse treatment-related effects.

A2.4.3 Risk Assessment

Effects were classified according to the scheme of de Jong et al. (2010). At the community level, the 1, 5, and 10 g a.i./ha rate were placed into Class 1 (NOER). The rate of 25 g a.i./ha caused only minor short-term effects on the arthropod community, which were classified as Class 2 effects. This rate was considered to be the ecologically acceptable rate (EAR). At 100 g a.i./ha, Insecticide A caused persistent adverse effects with no recovery observed within the 4-week study period. According to ESCORT 2 and EC 2002 for off-field risk assessment, the duration of effect and the range of taxa affected should also be taken into consideration. Consequently the EAR of 25 g a.i./ha was used for risk assessment. This value can be used as the critical endpoint for off-field risk assessment and compared to the predicted off-field environment exposure rates under conditions of use in arable crops where a TER of 1.0 or greater indicates low risk (Table A2.6).Consequently, applications of Insecticide A were low risk to off-field communities of NTAs at 1 to 5 m distance. This type of assessment can be repeated for a range of other uses to assess off-field risk.

Table A2.6 Off-field risk assessment for NTAs, arable uses

Application	Application rate (g a.i./ha)	Drift distance (m)	Exposure g a.i./ha	Endpoint g a.i./ha	TER
Oilseed rape	480	1	13	25	1.9
		5	3.0		8.3
Cereals Fruiting vegetable	720	1	20	25	1.3
		5	4.2		6.1
Sugar beet Leafy vegetable	960	1	27	25	0.93
		5	5.5		4.6

A2.4.4 Conclusions

The terrestrial mesocosm method was a suitable method to obtain a refined higher-tier estimate of the off-field communities of NTAs. It allowed for the evaluation of the test item to a community of arthropods that represented the off-field fauna. The endpoint from this study was shown to be useful for higher-tier risk assessment using a TER approach and can be used in a variety of risk assessments for off-field situations.

A2.4.5 Reference

[EC] European Commission. 2002. Guidance document on terrestrial ecotoxicology under Council Directive 91/414/EEC. SANCO/10329/2002 rev 2 final, 17 October 2002. p –162.

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A2.5 An Evaluation of the Non-Target Arthropod Hazard Quotient since ESCORT 2

Beneficial Arthropod Regulatory Testing (BART) Group

Miles M, Coulson M (Chair), Drexler A, Bakker F, Barrett K, Brown K, Candolfi M , Dinter A, Lewis G, Mead-Briggs M, Neumann P , Weyman G

A2.5.1 Introduction

One of the significant outcomes of ESCORT 2 was the recommendation to adopt an HQ approach to assessing the risk to NTAs at Tier I. This HQ is calculated by dividing the crop-specific application rates or drift rates for off-field scenarios by the LR50 derived from worst-case laboratory studies generated using two sensitive indicator species, *Aphidius rhopalosiphi* and *Typhlodromus pyri*. If the resulting quotient is greater than or equal to 2, a potential hazard to NTAs is concluded. Where a potential hazard to NTAs is identified, the registrant would have the option of recommending appropriate risk mitigation measures or undertaking further testing.

Since the publication of ESCORT 2, many compounds and uses have been evaluated through European Union review processes, and consequently far more data are available. In addition, much of these data are now publicly available in the form of Draft Assessment Reports (DARs) and EFSA peer-reviewed conclusions on PPPs. This paper draws on and reviews the publicly available data on terrestrial NTAs and makes conclusions on the effectiveness of the HQ of 2 as a Tier I risk assessment tool.

A2.5.2 Materials and Methods

DAR and ESFA conclusion reports (http://www.efsa.europa.eu/en/scdocs.htm) were examined and LR50 values for both indicator species were collected into a Microsoft Excel spread sheet. HQ for the GAP disclosed in the documents was used to calculate the exposure rate using the methods of ESCORT 2. For products with more than a single application per season, the MAF technique was applied. Unless otherwise stated in the DAR or conclusion report, the default MAF value for foliar applications in ESCORT 2 was used. If a calculated HQ value for a given product use was below the trigger value, it was concluded that the use was of low risk. For all product uses, the information given by any higher-tier data was evaluated and the outcome classified as

- low risk (i.e., effects below the higher-tier trigger of 50%),
- acceptable risk (i.e., effects above the trigger of 50% but potential for recovery or actual recovery demonstrated), or
- further refinement required (i.e., insufficient data in the review to draw a conclusion).

In this way, the ability of the HQ to accurately indicate product uses of low risk could be confirmed and the impact on the Tier I risk assessment of applying different HQ triggers such as 1.0 or the values of 8 and 12 proposed by Campbell et al. (2000) evaluated. In the figures below, the categories of "low", "acceptable," and "further refinement" sum to 100%.

A2.5.3 Results and Discussion

In total, 92 product uses (for 74 active substances) were employed in the analysis using publicly available data, conclusions, and independent expert opinions. These represented the range of active substances evaluated over the past 5 years. Of the total of 92 product uses, 38 (43.1%) were observed to pass at Tier I using a trigger of 2.0 indicating that nearly 60% of all product uses required further evaluation, testing, and risk assessment. Based on the evaluated data, 64 (69.6%) of the product uses were confirmed at higher tier to be of low risk, 18 (20.7%) were of acceptable risk, with only 9 (9.8%) indicating that further evaluation was needed. Analysis of the data revealed that the same or similar level of protection could be provided the implementation of an HQ value of 5.0, as these uses were confirmed at low risk in extended laboratory, semi-field, or predatory mite field tests (without the consideration of aged residue study results). When these uses were summarised by product type (herbicide, fungicide, and insecticide), it can be seen that 21 of 35 (60%), 16 of 34 (47.1%) and 1 of 23 (4.4%) uses passed at Tier I using an HQ trigger of 2.0. For insecticides, 4.4% of uses pass at Tier I (HQ = 2) and only 8.7% of uses were shown to be of low risk. Raising the HQ trigger to 8 and 12 did not change the number or type of insecticide uses passing at Tier I and had little or no impact on herbicide and fungicide uses.

Table A2.7 An evaluation of the non-target arthropod hazard quotient since ESCORT 2

% of compound uses	Product uses			
	All	Herbicide	Fungicide	Insecticide
Pass HQ = 1	23.2%	34.3%	26.5%	4.4%
Pass HQ = 2	41.3%	60.0%	47.1%	4.4%
Pass HQ = 8 and 12	56.5%	71.4%	76.5%	4.4%
Low risk at higher tier	69.6%	97.1%	82.4%	8.7%
Acceptable risk at higher tier	20.7%	2.9%	14.7%	56.5%
Further refinement required	9.8%	0.0%	2.9%	43.8%

A2.5.4 Conclusion

Based on a sample of 92 product uses evaluated as part of the EU directive 91/414/EEC, it can be concluded the following:

- Using the current Tier I trigger of 2.0, nearly 60% of all compounds fail the Tier 1 risk assessment for NTAs, requiring higher-tier risk assessment.
- Based on the analysed data, the HQ could be increased to 5.0 without loss of the current level of protection with this dataset.

- These results indicate that the current HQ of 2.0 is sufficiently conservative and discriminatory because 40.0% of herbicides, 53.0% of fungicides, and 95.7% of insecticides require higher-tier testing and risk assessment.
- The new analysis confirmed the need to assess both indicator species (*T. pyri* and *A. rhopalosiphi*) in the Tier 1 assessment.

A2.5.5 Reference

Campbell PJ, Brown KC, Harrison EG, Bakker F, Barrett KL, Candolfi MP, Cañez V, Dinter A, Lewis G, Mead-Briggs M, et al. 2000. A hazard quotient approach for assessing the risk to non-target arthropods from plant protection products under 91/414/EEC: Hazard quotient trigger value proposal and validation. Pest Sci. 73(5):117–124.

A2.6 In-Field Recovery of Non-Target Arthropod Communities in the Context of Regulatory Risk Assessment in the EU

Beneficial Arthropod Regulatory Testing (BART) Group

Miles M, Coulson M (Chair), Drexler A, Bakker F, Barrett K, Brown K, Candolfi M, Dinter A, Lewis G, Mead-Briggs M, Neumann P, Weyman G

A2.6.1 Introduction

Under the provisions of EU directive 91/414/EEC, the potential side-effects of PPPs on terrestrial NTAs must be evaluated where exposure can occur. The ESCORT 2 guidance document specifies species and test designs required to meet the minimum data for this area of risk. Where risk cannot be excluded by the conduct of Tier I, extended laboratory tests, or semi-field tests, it is necessary to conduct higher-tier and refined risk assessments. The EU guidance document on terrestrial ecotoxicology (EC 2002) states:

> Generally it has to be demonstrated that there is a potential for re-colonisation/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-residues studies, environmental fate information).

Based on these requirements, three possible approaches for higher-tier risk assessment are demonstrated, including estimation and measurement of potential for recovery of affected populations, and understanding and interpreting the impact and recovery in regulatory field studies.

A2.6.1.1 Estimation of Recovery Time From Extended Laboratory and Semi-Field Tests and Environmental Fate Data Only

An estimation of the time needed for re-colonisation or recovery of affected NTA taxa to occur after application can be made by using a theoretical approach, taking into account the DT50 of the active ingredient and the lowest endpoint generated in laboratory or semi-field tests. The example below is for a fungicide X applied 4 times at 1.6 kg a.i./ha with a foliar DT50 = 7.4 d, assuming a 50% interception factor on leaves. This application regime gave a peak residue of 1543 g a.i./ha. Critical endpoints for *T. pyri* under extended laboratory conditions of LR50 = 681.6 g a.i./ha and effect rate ER50 = 128 g a.i./ha. From the decline curve in Figure A2.6, it can be concluded that direct toxic effects of the test item would decline by 9 d after the last application and sublethal effects by 27 d. Consequently, the time for when recovery can potentially take place is 27 d after the final spray.

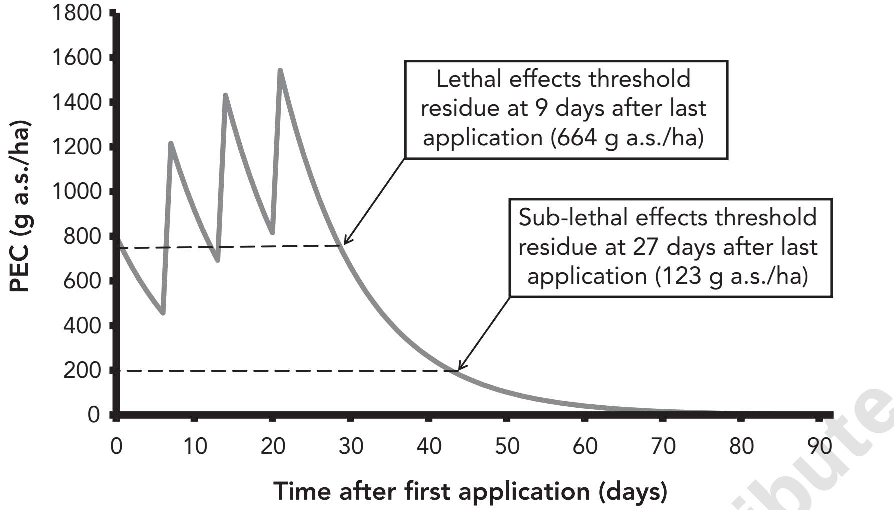

Figure A2.6 Environmental fate data

A2.6.1.2 Measurement of Recovery Time from Extended Laboratory and Semi-Field Experiments with Naturally Aged Product Residues and Multiple Bioassays

A measurement of the time needed for re-colonisation or recovery of affected NTA taxa can be made by showing the decline of residual toxicity by means of a bio-indicator, that is, the most sensitive species tested. The example in Figure A2.7, shows the findings of a study in which one application of insecticide A was made at a rate of 1.0 L/ha to barley plants.

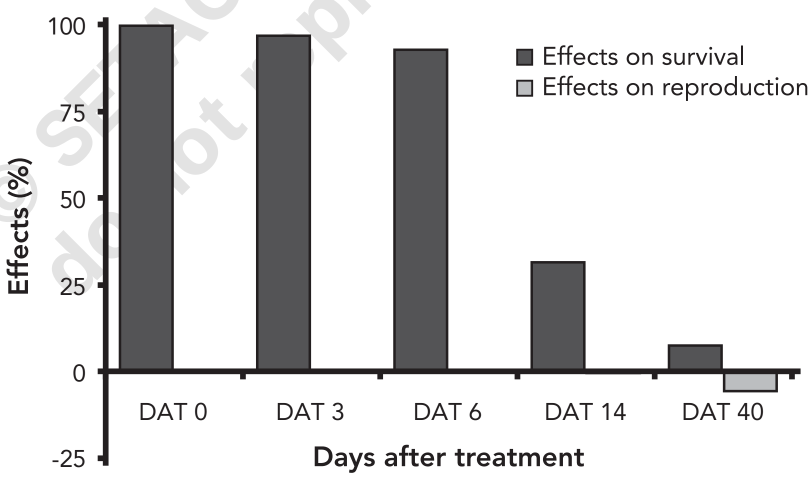

Figure A2.7 Aged residue bioassay data

Directly after application and after certain time intervals, *A. rhopalosiphi* was exposed to fresh and aged residues on the plants. Bioassays under extended laboratory conditions were set up day 0 (DAT 0) and after 3, 6, 14, and 40 d of aging. A clear time-dependent effect can be observed. As effects on survival and reproduction were below the trigger of 50% for the bioassay started 14 d after application, it was concluded that the potential for recovery time is not greater than 2 weeks.

A2.6.1.3 Effects and Recovery Under Field Conditions

Large-scale field trails can be used to demonstrate re-colonisation or recovery in the field. Modern studies are validated for analysis by PRC. Figure A2.8 shows PRC for a large-scale study in cereals using data from pitfall catches. PRC analysis 1) identifies responding and sensitive species or taxa for further investigation, 2) identifies relationships between different treatments, 3) provides community-level potential for recovery time, and 4) uses all data for a more powerful analysis.

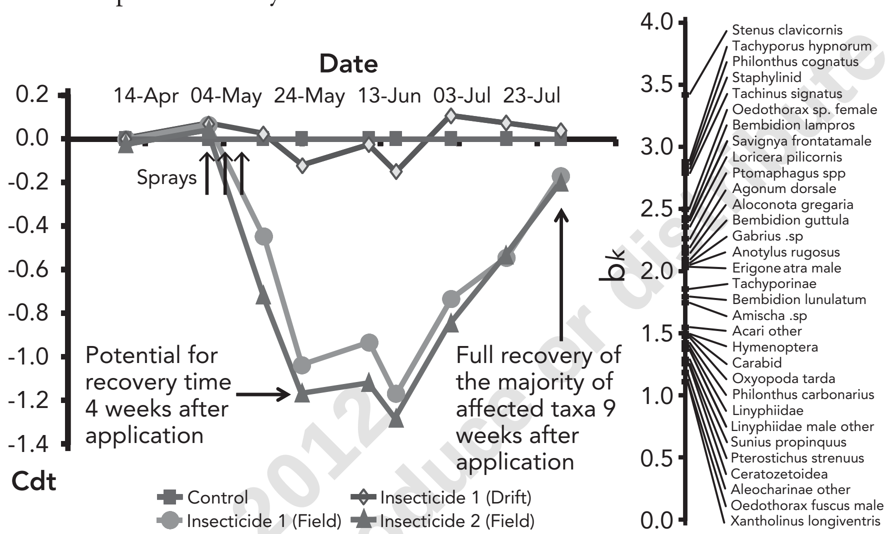

Figure A2.8 Ecological effects and recovery under field conditions

A2.6.2 General Recovery Mechanisms of Non-Target Arthropods Under Field Conditions

Non-target arthropods occur in agricultural landscapes because of the habitat they provide (plant structure, humidity, moisture) and the presence of abundant prey items. Agro-ecosystems that undergo regular perturbations are rich in arthropod fauna adapted to highly disturbed systems. These taxa have been shown to have a high intrinsic capacity to recover following the application of a PPP; mechanisms for recovery are these:

- reproduction of survivors,
- emergence of individuals from a protected life stage, and
- immigration from neighbouring habitats.

Many published references document the recovery of affected taxa as a natural ecological function, for example, Thomas et al. 1990, Duffield and Baker 1990, Duffield et al. 1996, and Wick and Freier 2000.

A2.6.3 Conclusions

All approaches presented are suitable for higher-tier or refined in-field risk assessment. It has to be considered that recovery is a natural ecological process and generally independent from acute pesticide effects. The rate at which communities recover depends on the size of the residual populations and their reproductive capacities, proximity of suitable invading populations, availability of prey and food and of environmental conditions.

A2.6.4 References

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Duffield SJ, Jepson EC, Wratten SD, Sotherton NW. 1996. Spatial changes in invertebrate predation rate in winter wheat following treatment with dimethoate. Entomologia Experimentalis et Applicata. 78:9–17.

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Thomas CFG, Hol EHA, Everts JW. 1990. Modelling the diffusion component of dispersal during recovery of a population of linyphiid spiders from exposure to an insecticide. Funct Ecol. 4:357–368.

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A2.7 Effects of Stage-Specific Mortality and Multiple Insecticide Exposure on Predatory Mites: Implications for Optimal Application Schedules

de Roos AM and Bakker F

A2.7.1 Introduction

Current procedures to assess the risk of PPPs to NTA populations do not account for the stage-structure of arthropod life histories. Using recently developed techniques to compute population growth rates for populations with complex life histories in both constant and periodic environments (de Roos 2008), we address this problem by examining the effect of stage-specific mortality on populations of *Typhlodromus pyri*, induced by periodic applications of PPPs.

A2.7.2 Methods

Four distinct life stages are recognised in the life cycle of our model test species, a predatory mite: eggs and larvae, nymphs, pre-ovipositing, and oviposting females (males are ignored). Life stages differ in duration and background mortality. Ovipositing females show decreasing fecundity with age.

We contrast PPP-induced mortality affecting all non-reproductive (juveniles) and reproductive individuals (adults). Population growth rates are calculated using computational techniques to evaluate Lotka's integral equation for age/stage/size-structured population models depending on ambient PPP concentrations. Population growth rate depends on adult fecundity and background mortality, as well as on PPP-induced mortality (see Figure A2.9).

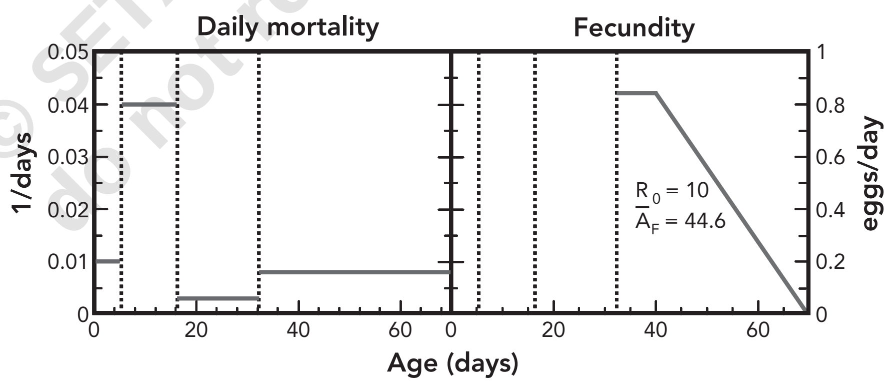

Figure A2.9 Life history parameters used to model population growth of the predatory mite.

The PPP is assumed to be applied periodically and decay exponentially. Mortality follows the normal cumulative distribution function in relation to the logarithm of the ambient PPP concentration. PPP concentrations ([P]) are measured relative to the concentration, at which the probability of death after a 1-d exposure is 50% ([P50]). We contrast high-dose PPP applications with fast decay with low-dose applications with slow decay.

A2.7.3 Results

- High-dose, fast-decaying PPP applications cause the strongest reduction in population growth rate.
- The strongest negative effects are found when juveniles are vulnerable.
- Population growth rate is least affected if the period between successive PPP applications equals the egg-to-egg period. In these cases indeed, PPP "knocks a hole" in the NTA age-distribution, which is hit again if the re-application period equals the average lifespan (egg-to-egg period).
- Both longer and shorter re-application periods can result in stronger reduction of population growth.

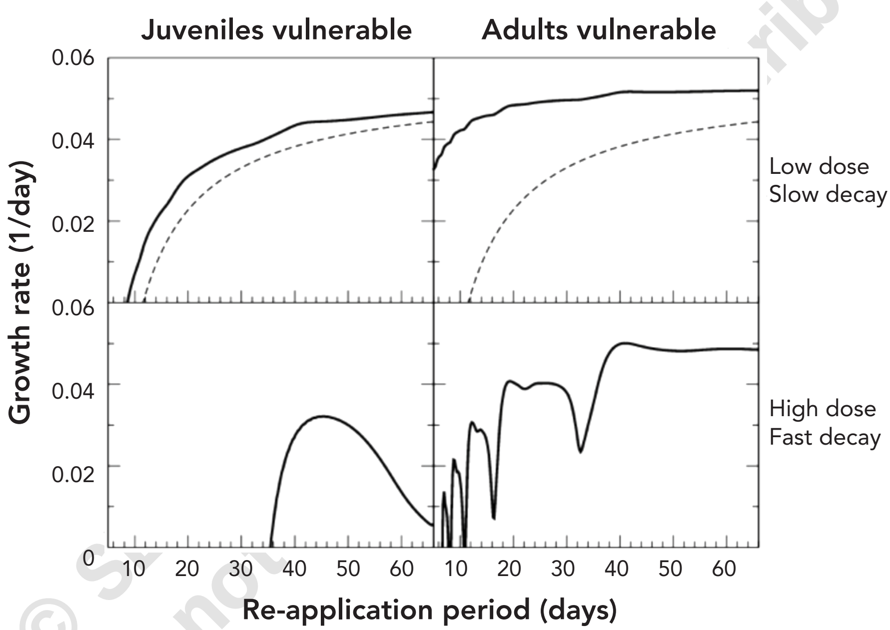

Figure A2.10 Population growth rate as a function of the period between consecutive applications for a low-dose, slowly decaying PPP application (top row) and a high-dose, rapidly decaying PPP application (bottom row). Either juvenile mortality is increased by the PPP (left column) or adult mortality (right column). Dashed lines in top row denote the population growth rate if all individuals experience a higher mortality through the PPP application. In case of a high-dose, rapidly decaying PPP, the population always goes extinct if all individuals experience a higher mortality.

A2.7.4 Conclusions

- NTA recovery strongly depends on the life stage affected by PPP application. Current test methods are conservative because they emphasize the juvenile stage.
- If the PPP is applied more than once during growth season, interplay between the period of PPP applications and NTA life cycle determines the level of effect, at the same dose ranging from extinction to hardly affected.

- Methods provide insight about the recovery potential of NTA after PPP application; full population models are required to assess the extent of recovery within a season.
- Methods only require data on NTA life history (fecundity schedule, background mortality, life stage durations) and PPP toxicity (affected life stage, decay rate, induced mortality).

A2.7.5 Reference

de Roos AM. 2008. Demographic analysis of continuous-time life-history models. Ecol Lett. 11(1):1–15.

A2.8 Comparison of Standard Laboratory Tests and Extended Laboratory Tests for the Non-Target Arthropod Species *Aphidius rhopalosiphi* and *Typhlodromus pyri*

Swarowsky K, Brühl C, Süßenbach D, Wogram J

A2.8.1 Introduction

The main intention of the current analysis was to verify the current pesticide risk assessment concept for NTAs in the EU with "real" test data for the 2 standard test species *Aphidius rhopalosiphi* and *Typhlodromus pyri* in 2-dimensional (2D) glass tests on inert material and "extended laboratory tests" on excised leaves ("2D ext") and whole plants ("3D plant").

We compared the acute toxicity endpoints deriving from tests with different substrates and different species, and calculated ratios between the acute toxicity in different tests (e.g., two LR50s) from valid test data gathered from an internal database of the German UBA. Ratios were calculated in different ways depending on the availability of test data. Because some of the estimated toxicity ratios represent minimum differences in toxicity, the presented results should be read as "equal to or greater than" values.

In the current analysis, we wanted to figure out

1) whether testing both standard species is necessary or can be substituted by a safety factor applied on one species (by analyzing the variability in the sensitivity of the two standard test species) and
2) whether 2D ext tests or 3D plant tests could be substituted by a numerical safety factor applied on tests with a more conservative exposure situation (2D ext/2D glass tests, 3D plant/2D ext tests were compared).

The comparison of 3D and 2D tests should be interpreted with a view to the VDF that is applied to correct the estimated exposure in 2D tests for dispersion of spraydrift droplets caused by the vegetation structure in the off-field risk-assessment and has been recently recalculated by the German UBA (2006).

A2.8.2 Results and Conclusions

A2.8.2.1 Comparison of T. pyri *and A. rhopalosiphi*

As expected, the results for the 2D glass tests showed a high level of between-substances variability in the ratios of the LR50 values of the two species *A. rhopalosiphi* and *T. pyri*. The 95th and the 5th percentiles of the LR50 ratios were 262.9 and 0.014, respectively (Figure A2.11). These results support the current ESCORT 2 approach to test both species at this tier because the differences detected by this analysis were too large to be covered by a practicable safety factor.

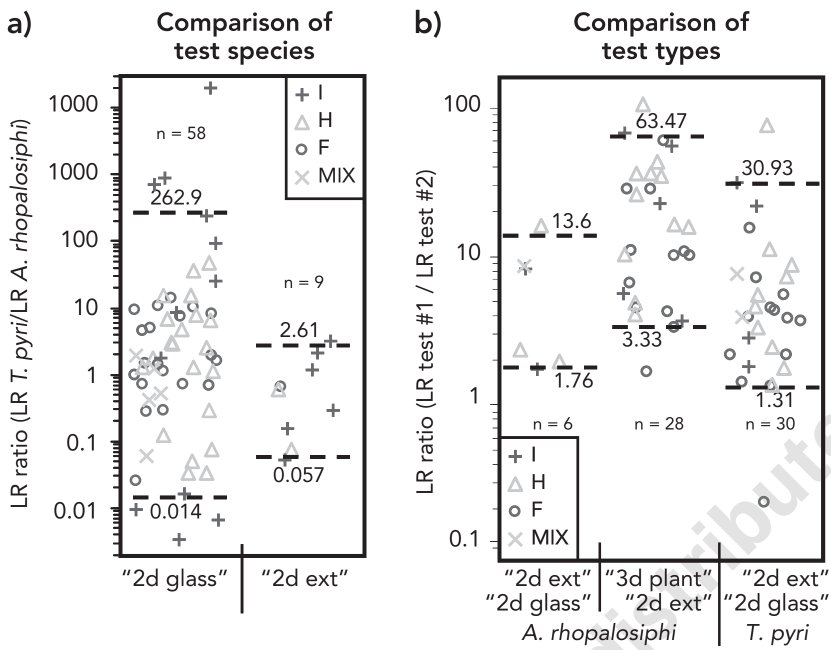

Figure A2.11 Scatter plots of the ratios between the toxicity (a.) to the different test species and (b.) in different test types. "F", "H", "I" and "MIX" represent fungicide, herbicide, insecticide, and mixture products. Dashed lines indicate the 5th and 95th percentiles of the distributions. The x-axis has no scale; data points fluctuate in the horizontal.

A2.8.2.2 Comparison of Tests with Inert and Natural Substrate

Ninety percent of the ratios between LR50 values from 2D ext tests and 2D glass tests were in a range of 1.76 to 13.6 (*A. rhopalosiphi*) and 1.31 to 30.93 (*T. pyri*). Hence, it has to be concluded that the results of Tier 1 tests on inert substrate (2D glass) to the results of 2D tests on natural substrate (2D ext) with suitable certainty. In other words, we do not recommend substituting Tier 2 tests on natural substrate with an additional assessment factor applied to LR50 values from Tier 1 tests on inert substrate.

A2.8.2.3 Comparison of 2D and 3D Tests

The median ratio between LR50 values from 2D ext and 3D plant tests was 12.9, that is, slightly higher than the established EU VDF of 10. In this context, it should be noted that current data (UBA 2006) indicate that the mean distribution factor under field conditions is 5 rather than 10 (that led to the convention of using a VDF of 5 in the national authorization procedures in Germany). Hence, 3D tests probably overestimate the reduction in exposure caused by dispersion of spray drift droplets in the vegetation under field conditions. Because this can lead to underprotective risk management decisions, we strongly recommend reassessing the VDF on the basis of all available data and accordingly revising the risk assessment concept based on 3D and 2D tests.

A2.8.3 References

[UBA] Federal Environment Agency [Germany]. 2006. Exposure calculation for arthropods in field border structures: selection of an appropriate 'vegetation distribution factor'. Position paper for the PRAPeR Expert Meeting 03 on Ecotoxicology (Round 01); Parma, Italy; 2006 Sep 12–15.

A2.9 Proposal for an NTA Scheme for Non-Spray Products Applied to Soil

Beneficial Arthropod Regulatory Testing (BART) Group

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A2.9.1 Summary

This proposed scheme applies to PPPs applied directly into the soil (e.g., seed treatments) and non-spray products applied directly onto the soil surface (e.g., granules). Products sprayed onto the soil surface should be assessed according to the established scheme for spray products.

In-field assessment is conducted using *Aleochara* data from a test system related to the use pattern.

Where off-field assessments are required, a standard off-field exposure or risk assessment, as for spray products, should be conducted, using the same test species and with appropriate drift values and carriers for the test substance.

A2.9.2 Application Methods and Scenario Covered by this Scheme (at Dossier Point IIIA 10.5)

This scheme applies to PPPs applied directly into the soil and non-spray products applied directly onto the soil surface, for example, granule (broadcast and in furrow), seed treatment, shank chisel, drip irrigation, pellet.

This scheme does not apply to spray products applied onto soil, which should be treated as for other spray products (with *Aleochara* included for one of the higher-tier test species, linking to this scheme).

A2.9.3 Study design

A2.9.3.1 In-Field

For soil-applied products, the following species is required at the first tier: *Aleochara bilineata*.

This species is chosen to represent a combination of 2 different exposure modes. *A. bilineata* is an arthropod (Staphylinid beetle) living on or near the soil surface as adults but with a parasitic larval stage in the soil; this species is therefore exposed to both surface residues and soil residues during its life cycle. A ring-tested IOBC test method is available (Grimm et al. 2001); it was recommended under ESCORT 1 and it is a current test species under ESCORT 2. Further species are considered unnecessary because testing soil macro-invertebrates species (*Folsomia candida* and *Hypoaspis aculeifer*) will be a compulsory requirement for soil-applied products in future under Directive 91/414/EC, Annex III, point 10.6 (Effects on earthworms and other soil macro-organisms).

The *Aleochara* tests should be conducted in standardised sandy soil (e.g., LUFA 2.1 or a soil with similar characteristics).

The potential for enhancement or reduction of effects through having a localised treatment application (e.g., spot treatments or in-furrow applications) rather than an even treatment distribution (e.g., broadcast applications) is not currently quantified. The exact spacing of the treatment and its physical or chemical properties and its inherent toxicity would influence the level of effect in a complex way. Therefore, it is not possible to say which is worst-case in a first Tier test: an even distribution throughout the test vessel or a realistic distribution with treated and untreated areas. In this scheme, it is considered best to go immediately to a realistic distribution, as far as possible within the test vessels. The treatment variants should either be selected for a dose–response approach or be equivalent to the maximum field rate (i.e., a worst-case scenario). In general, treatment within a confined test vessel is considered more severe than exposure in the open-field.

Seed treatments should be applied on the seed (i.e., not as an aqueous form), granules should be applied intact and in such a way as to mimic the normal application method as closely as possible (i.e., broadcast on the surface or incorporated in a defined area), shank chisel applications should be made at an appropriate depth, drip irrigation treatments should be applied to the soil surface in an appropriate spacing and water volume. Note that it can be difficult to mimic the normal application mode in standard laboratory test vessels recommended in existing guidelines. It may, therefore, be necessary to use a larger vessel, or a vessel with different dimensions, in order to best mimic the field application mode. Validity criteria of the test method (e.g., reproduction in the control and effects in the toxic standard group) may need to be checked in non-standard vessels and adjusted if appropriate. Care should be taken in the positioning of the test substance within the vessel in order to best mimic the field. The endpoint should be determination of an ER50 or effect concentration EC50, or effect level at a target rate (if not done as a dose–response design).

<u>Higher Tier:</u> There are many potential approaches, including tests in relevant field-collected soils, laboratory aged residues tests, field aged residues (field treated as per GAP and sampled at intervals for laboratory bioassays), semi-field tests (e.g., enclosures), field tests, repellence tests (relevant for treatments with “hot” and “cold” spots).

A2.9.3.2 Off-field

Tier 1: The standard indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* should be tested. The data for *A. rhopalosiphi* and *T. pyri* may be taken from tests already available with spray products containing the same active ingredient, or if they are not available, new ER50 tests with the soil-applied product may be conducted. Tests with the soil-applied product may require the use of a modified carrier to enable spraying of the test substance.

If recommendations for off-field risk assessment of spray products change under ESCORT 3, the recommendations before the publication of ESCORT 3 should also be considered here.

Tier 2: As for spray products, affected Tier 1 species + additional 2 species in higher-tier test design (e.g., foliage instead of glass plate; 3D test design; aged residues).

If recommendations for off-field risk assessment of spray products change under ESCORT 3, these should also be considered here.

It is acceptable to bypass lower tiers and go directly to higher-tier testing, for both in-field and off-field.

A2.9.4 Exposure

A2.9.4.1 In-Field

The in-field GAP should be used.

A2.9.4.2 Off-Field

For most non-spray formulations with applications made directly to the soil, no off-field exposure is to be expected and no risk assessment is required. Where drift of the treatment cannot be excluded, a standard off-field exposure assessment is required using appropriate drift values for the application method.

A2.9.5 Risk Assessment

A2.9.5.1 In-Field

Compare the in-field GAP directly to the study endpoint (50% effect level), analogous to the standard spray application higher-tier risk assessment.

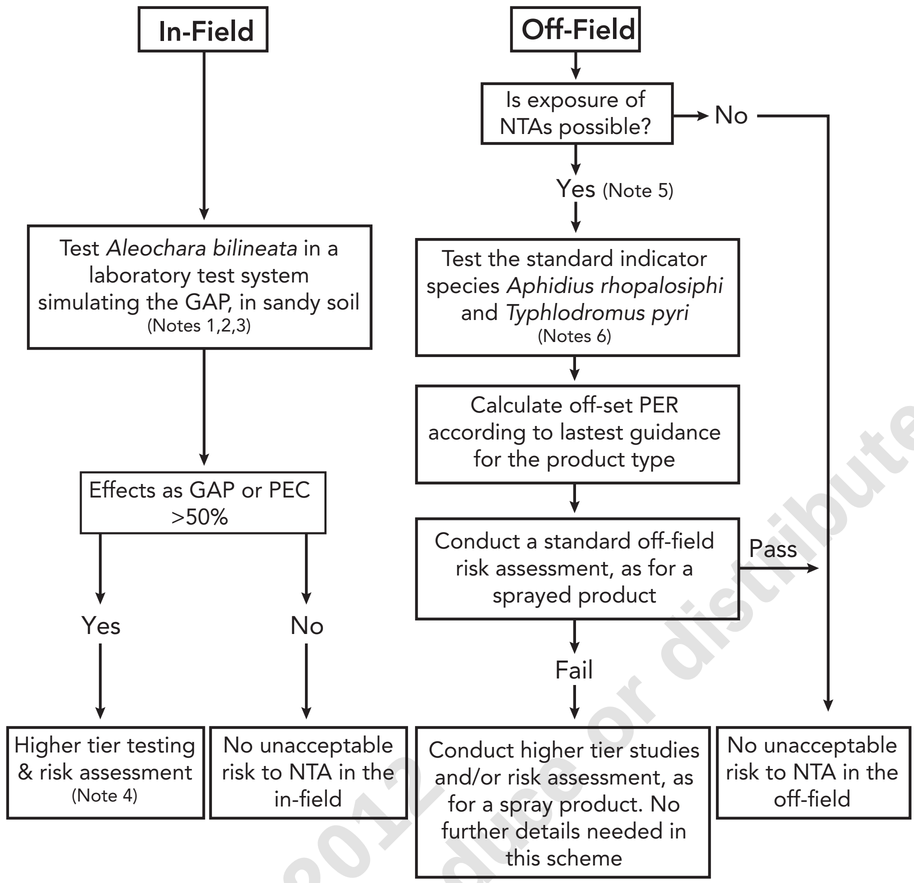
A2.9.5.2 Off-Field

For most non-spray formulations with applications made directly to the soil, no off-field exposure is to be expected and no risk assessment is required. Where drift of dust generated during application (or sowing of treated seeds) cannot be excluded, a standard off-field risk assessment is required. For the off-field risk assessment, the standard indicator species *A. rhopalosiphi* and *T. pyri* should be used at the first tier, and the standard off-field risk assessment scheme as for a spray-applied product should be used.

If effects are seen at Tier 1, additional species are required as for standard spray products, and may be drawn from data for other products with the same active ingredient, in order to indicate relative sensitivity.

At higher tiers, appropriate mitigation measures or higher-tier studies may be considered.

If recommendations for off-field risk assessment of spray products change under ESCORT 3, these should also be considered here.



Note 1: Further species are considered unnecessary because soil macro-invertebrates species (*Folsomia candida* and *Hypoaspis aculeifer*) will be a compulsory requirement for soil-applied products in future under dossier Point 10.6 (Effects on earthworms and other soil macro-organisms).

Note 2: *A. bilineata* is chosen to represent a combination of 2 different exposure modes: it is an arthropod (Staphylinid beetle) living on or near the soil surface as adults but with a parasitic larval stage in the soil; this species is therefore exposed to both surface residues and soil residues during its life cycle. A ring-tested IOBC test method is available; it was recommended under ESCORT 1 and it is a current test species under ESCORT 2.

Note 3: Tests should be conducted in standardised sandy soil (e.g., LUFA 2.1 or a soil with similar characteristics). Seed treatments should be applied on the seed (i.e., not as an aqueous form); granules should be applied intact and in such a way as to mimic the normal application method as closely as possible (i.e., broadcast on the surface or incorporated in a defined area); shank chisel applications should be made at an appropriate depth; drip irrigation treatments should be applied to the soil surface in an appropriate spacing and water volume; etc. Note that it can be difficult to mimic the normal application mode in standard laboratory test vessels recommended in existing guidelines. It may, therefore, be necessary to use a larger vessel, or a vessel with different dimensions, in order to best mimic the field application mode.

Note 4: For example: tests in relevant field-collected soils; laboratory aged residues tests; field aged residues (field treated as per GAP and sampled at intervals for laboratory bioassays); semi-field tests (e.g., enclosures); field tests; repellence tests (relevant for treatments with "hot" and "cold" spots). Triggers as for higher tier sprayed product scheme.

Note 5: For most non-spray formulations with applications made directly to the soil, no off-field exposure is to be expected and no risk assessment is required. Where drift of the treatment cannot be excluded, a standard off-field exposure assessment is required using appropriate drift values for the application method.

Note 6: A carrier may be required to enable spraying of the product, or it may be possible to use available data from a spray formulation containing the same active ingredient.

Abbreviations

AFSSA	French Agency on the Safety of Food
a.i.	active ingredient
ANOVA	analysis of variance
BART	Beneficial Arthropod Regulatory Testing Group
BBCH	Tbl A2.2
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (German Federal Office of Consumer Protection and Food Safety)
CRD	Chemicals Regulation Directorate (Directorate of the Health and Safety Executive responsible for ensuring the safe use of biocides, industrial chemicals, pesticides and detergents in the UK)
DAR	Draft Assessment Report
DDVP	dichlorvos
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DT50	period required for 50% dissipation of residues
EAR	ecologically acceptable rate
EC	European Commission or European Council
ECPA	European Crop Protection Association
EC50	
EFSA	European Food Safety Authority
EPPO	European and Mediterranean Plant Protection Organization
ER50	
ESCORT	European Standard Characteristics Of beneficials Regulatory Testing
EU	European Union
GAP	good agricultural practice
GLP	good laboratory practice
HQ	hazard quotient
ICPBR	International Commission for Plant–Bee Relationships
IGR	insect growth regulator
INRA	French National Institute on Research in Agronomy
IOBC	International Organization for Biological Control
IPM	Integrated Pest Management
IVA	
LERAP	Local Environment Risk Assessment for Pesticides (in the UK)
LR50	The application rate which when applied in a toxicity test results in 50% mortality of the exposed NTA species

MAF	multiple application factor
MoA	mode of action
NOAEL	no observed adverse ecological effect level
NOEAER	no observed ecologically adverse effect rate
NOEC	no observed effect concentration
NOER	no observed effect rate
NTA	non-target arthropod
ONCFS	Office National de la Chasse et de la Faune Sauvage (France)
OSR	oil seed rape
PECsw	predicted environmental concentration for surface water
PPP	plant protection product
PPR	Panel on Plant Health, Plant Protection Products and their Residues (a scientific panel of the European Food Safety Authority)
PRC	principal response curve
SANCO	Health and Consumer Protection Directorate-General, European Commission
SETAC	Society of Environmental Toxicology and Chemistry
SRC	significant response curve
SSD	species sensitivity distribution
TER	
UBA	Umweltbundesamt (German Federal Environment Agency)
VDF	vegetation distribution factor