Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods

From the ESCORT 2 workshop
(European Standard Characteristics
Of non-target arthropod Regulatory Testing)

A joint BART[1], EPPO/CoE[2], OECD[3], and IOBC[4] Workshop
organized in conjunction with SETAC-Europe[5] and EC[6]

held at
Wageningen International Conference Centre
Wageningen, The Netherlands

21-23 March 2000

Editors:

M.P. Candolfi, K.L. Barrett, P.J. Campbell, R. Forster, N. Grandy,
M-C. Huet, G. Lewis, P. A. Oomen, R. Schmuck and H. Vogt

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[1] Beneficial Arthropod Regulatory Testing Group
[2] European and Mediterranean Plant Protection Organisation in collaboration with the Council of Europe
[3] Organisation for Economic Co-operation and Development
[4] International Organisation for Biological and Integrated Control of Noxious Animals and Plants
[5] Society of Environmental Toxicology and Chemistry- Europe
[6] Commission of the European Communities

Table of Contents

Executive Summary

The objective of the ESCORT 2 workshop was to develop updated guidance for terrestrial non-target arthropod testing and risk assessment for plant protection products, in accordance with the revised scheme published by EPPO (European and Mediterranean Plant Protection Organisation) (*in prep*.). The revised guidance focuses on providing a simplified tiered testing strategy, which optimises the data requirements and gives realistic decision criteria and trigger values for both in-field and off-field risk assessments.

The workshop participants consisted of 53 invited scientists mainly from Europe representing government, industry and academia experienced in regulatory non-target arthropod issues. The workshop was divided into a series of plenary sessions and syndicate discussion groups. An opening plenary session presented background information on key proposals to be discussed in the syndicate groups. To aid the discussion in the syndicate groups, questions relating to these areas were provided in advance. Syndicate discussion periods were followed by plenary discussions where the workshop participants could review the proposals of all groups. The guidance proposed in this report and summarised below reflects the consensus reached during the plenary discussions at the workshop. The recommendations arising from the workshop can be divided into two main groups: Tier I testing and risk assessment and higher tier testing and risk assessment.

1. Tier I testing and risk assessment

At tier I it was proposed to adopt a Hazard Quotient (HQ) approach to assessing the risk to non-target arthropods. This is calculated by dividing the crop-specific application rates, or drift rates for off-field scenarios by the LR_{50} (Lethal Rate 50) 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 non-target arthropods is concluded. The proposed equations for the calculation of the HQ values with both indicator species for in-field and off-field exposure scenarios are given in Section 4.4.

Where a potential hazard to non-target arthropods is identified it was agreed that the registrant would have the option of recommending appropriate risk mitigation measures or undertaking further testing. It was agreed that these proposals for testing and risk evaluation would not be appropriate for products with special modes of action e.g. IGR's. For these compounds, testing should focus on non-target arthropods with life stages likely to demonstrate effects. The primary toxicity endpoint of the studies should be mortality, with determination of the LR_{50}. However for products where effects on reproduction are expected, assessment of sub-lethal parameters (e.g. oviposition) should also be evaluated. For products with special patterns of use e.g. seed dressings or granular formulations, it is expected that specific methods of evaluation will be proposed by the EPPO soil group but in the interim period the recommendations made at the first ESCORT meeting should be followed.

2. Higher tier testing and risk assessment

Where HQ values are equal or exceed the trigger value of 2 and no appropriate or desired risk mitigation measures can be identified, higher tier testing will be required. Initially the toxicity to the sensitive indicator species affected in the Tier I evaluations should be re-evaluated using a higher tier testing method. In addition, if the HQ(s) are only exceeded or equalled for the in-field risk assessment, one additional species should also be tested. Where both the in-field and off-field HQ(s) are equalled or exceeded, two additional species need to be included in the testing program. The preferred species are *Orius laevigatus, Chrysoperla carnea* and *Coccinella septempunctata*. The staphylinid, *Aleochara bilineata* should preferably be used for early application products and where products are applied to the soil (e.g. granular formulations, seed dressings).

Higher tier testing may incorporate extended laboratory, aged residue studies, semi-field or field studies. At this level the tests should include lethal and if technically feasible and statistically appropriate, sub-lethal end points. It was agreed that the tests need not necessarily be followed sequentially at this level, *i.e.* testing can start directly at the field stage without preceding “higher Tier” steps. The rates which are to be tested in higher tier studies should be calculated according to the formulae given in Section 5.3.

3. Risk mitigation

At the workshop some time was given to the consideration of risk mitigation options. Again these were broken down into in-field and off-field considerations.

In the case of unacceptable effects in-field, modification of the use pattern may be an option for example reducing the application rate, modifying the application frequency and intervals or amending the proposed timing of application.

To protect off-field populations, the exposure of non-target arthropods can be reduced by a number of different agronomic practices including:

- Provision of an unsprayed area of crop at the field margin as a buffer zone
- The presence of wind breaks in the form of hedges or tree rows can reduce the incident of drift to off field areas
- Drift reducing application techniques e.g. specialist application nozzles

Local agronomic practice may also be an influencing factor, which can be taken into consideration.

Concluding remarks

The workshop agreed that:

- It would be acceptable to reduce the number of species tested at Tier I to two sensitive indicator species, *Aphidius rhopalosiphi* and *Typhlodromus pyri* with the provision of LR_{50} data.
- The HQ approach was an acceptable method of first tier risk assessment for both in-field and off-field populations. It was agreed that where the HQ is less than 2, products may be considered to represent a low risk to non-target arthropods.
- Where the HQ trigger value of 2 is equalled or exceeded, and no appropriate risk mitigation can be identified or is to be avoided, further evaluation incorporating additional species would be required.
- Higher tier testing, extended laboratory studies, aged residue studies semi-field or field studies are options available for higher tier testing. At any stage a refined risk assessment can be conducted to demonstrate a plant protection product does not have an unacceptable impact on non-target arthropods.
- Risk mitigation options may be considered as part of the risk assessment to refine the evaluation.

1. Introduction

Side effect testing on terrestrial non-target arthropods (NTA) for the registration of plant protection products (PPP) in the European Union (EU), is currently conducted according to the Council Directive of 15 July 1991 concerning the placing of plant protection products (PPPs) on the market (91/414/EEC) (Council of the European Union, 1991, updated by Commission Directive 96/12/EC, Council of the European Union, 1996). The directive refers to the first SETAC/ESCORT[7] Guidance Document on regulatory testing procedures for pesticides with non-target arthropods (Barrett *et al.*, 1994) and to the EPPO/CoE Arthropod Natural Enemies Risk Assessment Scheme (EPPO, 1994) for non-target arthropod testing methodology and risk assessment, respectively. After several years of experience with these guidance documents, the Commission of the European Communities, the EU Member State Regulatory Authorities and the Agrochemical Industry have identified limitations with the existing guidance (Oomen, 1998; Oomen *et al.*, 1998; Shires, 1998). The main points of concern are:

1. The objective of the testing scheme does not precisely discriminate between in-field, off-field and IPM[8] situations.
2. The trigger value for Tier I data is inappropriate as it produces too many false positives.
3. The current guidance does not clearly define data requirements, testing methodology and evaluation, especially for higher tier studies.
4. The data generated do not allow a satisfactory risk assessment for in-field and off-field habitats (see Appendix IV for definition of in-field and off-field habitats).
5. The current scheme requires excessive testing compared to other 91/414/EEC non-target organism risk assessment schemes.
6. New views on risk management have been developed.

Consequently, the EPPO/CoE Arthropod Natural Enemies sub-group (which includes experts from EU regulatory authorities, industry and IOBC concluded that the existing EPPO/CoE 'Arthropod Natural Enemies Risk Assessment Scheme' needed to be revised to expand it to all non-target arthropods as well as to simplify and harmonize it with risk assessment schemes available for other non-target organisms e.g. honey bees (Oomen *et al.*, 1998). The draft EPPO/CoE "Decision making scheme for non-target terrestrial arthropods" formed the basis of the discussions at the ESCORT 2 workshop.

2. Workshop Objectives

The objective of the workshop was to develop updated guidance for a terrestrial NTA testing and risk assessment scheme for plant protection products to be used for regulatory purposes which is in accordance with the revised EPPO non-target arthropod testing and risk assessment philosophy. The new scheme should overcome the limitations of the

[7] Society of Environmental Toxicology and Chemistry- Europe/European Standard Characteristics Of beneficial Regulatory Testing
[8] Integrated Pest Management

existing scheme listed in the introduction. It should, therefore, provide a simplified and better tuned tiered testing and assessment procedure which optimises the data requirements and gives realistic decision criteria and trigger values for both in-field and off-field risk assessments. It should also indicate options for risk mitigation measures and assess their risk reduction power. At the same time, it should based on the generally accepted recommendations of the first SETAC/ESCORT meeting (Barrett *et al*., 1994). The objective of this guidance document is not the generation of data for IPM.

3. Workshop Structure and Approach

The workshop participants consisted of 53 invited scientists mainly from Europe. They represented 14 EU member state regulatory authorities, the Commission of the European Communities, the OECD, the EPPO, the Agrochemical Industry, contract research organisations and academia. Most participants were experienced in regulatory non-target arthropod issues. A list of participants is presented in Appendix II.

The workshop was organized by a committee consisting of Marco Candolfi (Novartis Crop Protection AG, Chairperson of the organisation committee and Ring-Testing Joint Initiative representative), Katie Barrett (Huntington Life Sciences, Secretary and SETAC-Europe representative), Peter Campbell (Zeneca Agrochemicals and BART representative), Rolf Forster (BBA and EU regulatory authorities representative), Nicola Grandy (Meeting Chairperson and OECD representative), Marie-Chantal Huet (OECD representative), Gavin Lewis (JSC International Ltd. and Treasurer), Pieter Oomen (Plant Protection Service Netherlands, Local Organizer and EPPO/CoE representative), Richard Schmuck (Bayer AG and ECPA representative) and Heidrun Vogt (BBA and IOBC representative).

The three day workshop was divided into four syndicate groups which came together in several plenary sessions. An opening plenary session provided background information on:

1. The shortcomings of the current EU non-target arthropod testing and risk assessment procedures from the perspective of the EC, EU Member State Regulatory Authorities and the Agrochemical Industry.
2. The draft revised EPPO/CoE “Decision making scheme for non-target terrestrial arthropods”.
3. Non-target arthropod species sensitivity to plant protection products.
4. Dose-response testing with non-target arthropods.
5. A Hazard Quotient (HQ) approach with validation for assessing risk to non-target arthropods.
6. Risk mitigation strategies.

Abstracts of these talks are provided in Appendix III.

The following topics were discussed in the syndicate groups:

1. Tier I data: risk assessment via an HQ approach including species selection, testing methodology and trigger values.
2. Higher Tier studies (extended laboratory, semi-field and field studies): risk assessment including species selection, testing methodology and trigger values.
3. Testing of products with special modes of action (e.g. IGRs[9]).
4. Risk mitigation measures.

Participants were asked to discuss the topics in the syndicate groups taking into account that the proposed testing and assessment scheme should deal with both in-field and off-field habitats. Proposals from the syndicate groups were discussed at the plenary sessions. The resulting recommendations were reconsidered in the syndicate groups to develop consensus views.

The guidance document given in this report presents the consensus reached during the final plenary session of the workshop. This document has been reviewed and all participants have had the opportunity to comment on it. The editorial board carefully considered these comments and included them where judged to be appropriate in the context of the workshop discusssions and the other comments received. The testing and risk assessment recommendations presented below supersede those recommendations of the earlier ESCORT workshop (Barrett *et al.*, 1994).

4. Tier I Testing and Risk Assessment

4.1 General principles

At Tier I, laboratory "worst case" toxicity studies with two indicator species (see Section 4.2) are performed. LR_{50} (Lethal Rate 50, the application rate causing 50% mortality of the test organisms) data are to be generated for the two species which subsequently will be used to calculate Hazard Quotients (HQ) for in-field and off-field exposure scenarios. The HQs are derived from the crop-specific application rates (in-field) or drift rates (off-field), and the LR_{50} values. The Tier I risk assessment is based on semi-field/field validated HQ trigger values which are calculated separately, for in-field and off-field. If the HQ values determined for the two indicator species are below the validated trigger value, no further testing is required and it can be concluded there is low risk to non-target arthropods present in the in-field and/or the off-field habitats. If the HQ value determined for one or both of the indicator species exceeds or equals the trigger value, it has to be demonstrated that the risk to non-target arthropods for in-field and/or off-field habitats, as appropriate, are acceptable by using specific risk mitigation measures or by further testing. A chart illustrating the testing and risk assessment scheme for non-target arthropods is presented in Section 7.

[9] Insect Growth Regulators

4.2 Selection of test species

Two sensitive indicator species, the cereal aphid parasitoid *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) and the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae), are recommended for testing at the Tier I level. The selection of these indicator species was based on a sensitivity analyses of available test species and associated laboratory test methods performed by BART (Candolfi *et al*., 1999) and IOBC (Vogt, 2000).

In the BART analyses, using first-tier GLP[10] non-target arthropod laboratory registration toxicity data covering 7 taxonomic orders, 9 taxonomic families, 12 species and using 95 plant protection products, Candolfi *et al.* (1999) showed that *T. pyri* and/or *Aphidius spp.* were the most sensitive species tested in 93.7% of cases, when only mortality was considered. From laboratory assays with beneficial arthropods performed during the Joint IOBC Pesticide Testing Programs 4-7, covering 8 taxonomic orders, 16 taxonomic families, 23 species and using 75 plant protection products, Vogt (2000) reported that *T. pyri* and/or *Aphidius spp.* belong to the most sensitive species tested. Moreover, Vogt (2000) reported that those pesticides which had effects on species other than *T. pyri* and *Aphidius spp.* under laboratory conditions, turned out to be either harmless (IOBC classification) or had effects < 50% under more realistic exposure conditions. Therefore, the risk of failing to detect significant adverse effects when testing only these two indicator species appears to be very limited. Based on these extensive data it was agreed that *A. rhopalosiphi* and *T. pyri* should be selected as the sensitive indicator species for Tier I testing. It was, however, pointed out that further research is needed on the ecology of off-field non-target arthropods, especially with regard to species distribution between in-field and off-field habitats and their sensitivity to pesticides.

4.3 Testing methodology

Tier I data should be generated by exposing *A. rhopalosiphi* and *T. pyri* to fresh dried product residues applied on glass plates ("worst-case" exposure conditions). For testing, the methods for *A. rhopalosiphi* (Mead-Briggs *et al.*, 2000) and *T. pyri* (Blümel *et al*., 2000) as ring-tested and published by the Joint Initiative should be followed. The aim of the studies should be to determine a rate-response relationship, with the LR_{50} (Lethal Rate 50, application rate causing 50% mortality of the test organisms) as the testing endpoint. Guidance on the adaptation of the proposed single-rate laboratory test methods for rate-response testing and the necessary statistical analyses are proposed and discussed by Grimm *et al.* (2001). It was recognised that in some cases, determination of a statistically sound LR_{50} value is problematic e.g. due to extra binomial variance or a steep dose-response slope. In these cases it may be appropriate to quote a range of rates which includes the LR_{50}. If it can be anticipated that a product has a low toxicity (e.g. from preliminary testing, or analogous chemistry), single-rate limit tests can be performed at a rate

[10] Good Laboratory Practice

equivalent to the maximum application rate multiplied by the Multiple Application Factor, MAF[11].

4.4 Tier I Risk Assessment (Hazard Quotient approach)

The potential hazards of plant protection products to non-target organisms are generally evaluated by comparing estimated environmental exposure values with compound-specific toxicity values. For NTA, it is proposed that hazard evaluation at Tier I is based on a hazard quotient approach. The Hazard Quotient (HQ) is derived from the crop-specific application rates for in-field assessments or drift rates for off-field scenarios, and the LR_{50} value generated with *A. rhopalosiphi* and *T. pyri*. If the resulting quotient is equal to or higher than the threshold value, a potential hazard to NTA is concluded.

The following equations should be used to calculate the HQ values with both indicator species, for in-field and off-field exposure scenarios, respectively:

$$\text{In-field HQ} = \frac{\text{Application rate}^{a} \times \text{MAF}^{\,b}}{\text{LR}_{50}^{\;c}}$$

$$\text{Off-field HQ} = \frac{\text{Application rate} \times \text{MAF} \times \left(\dfrac{\text{drift factor}^{\,d}}{\text{vegetation distribution factor}^{\,e}} \right)}{\text{LR}_{50}} \times \text{correction factor}^{\,f}$$

[11] MAF = Multiple Application Factor = ratio of rate after the maximum recommended multiple applications to initial rate after a single application of a plant protection product (Gonzalez-Valero *et al.*, 2000). See Appendix V.

Legend:

[a] Single application rate in g or ml formulated product/ha (or in g or ml a.i.[12]/ha). Application rate and LR_{50}[c] must not differ in their units, i.e. both must be related to either formulated product or a.i. rates.

[b] MAF = Multiple Application Factor = “ratio between the rate after the maximum recommended number of multiple applications and the initial rate after a single application of a plant protection product”. The multiplication of the 1X application rate by the MAF allows the determination of the maximum residue level after multiple applications of the product. The MAF is derived from the ratio between the half-life of the product and the spray interval together with the number of applications (see Appendix V).

[c] LR_{50} = Lethal Rate 50, application rate causing 50% mortality of the organisms under worst-case laboratory conditions. LR_{50} is expressed in g or ml formulated product/ha (or in g or ml a.i./ha). Application rate [a] and LR_{50} must not differ in their units, i.e. both must be related to either formulated product or a.i. rates.

[d] Spray drift is the most relevant exposure route for NTA in off-field areas. Drift factor = %drift/100. Usually, the overall 90th percentile drift data according to Ganzelmeier *et al.* (1995, recently recalculated by the German BBA and UBA and published by the BBA (2000)) should be used to estimate off-field drift deposition values (%drift). This proposal is based on the recommendations of the FOCUS surface water group which has defined that a reasonable worst case scenario for drift estimation is represented by an overall 90th percentile probability. Default drift values for a distance from the field border of 1 m for arable crops and 3 m for orchards/vineyards should be used to estimate the off-field PEC. Overall 90th percentile drift values are presented in Appendix VI.

[e] The drift values given under note[d] were determined over a non-vegetated area and only under windy conditions. However, the field boundary (crop edge) and the crop-relevant default drift distance is typically vegetated and serves as a filter strip trapping some drifted material. In addition, consistently high wind speeds and the repeated exposure of the same off-field site with maximum drift rates are very much worst-case estimates. Therefore, the overestimated exposure given by the 90th percentile drift values should be corrected by a “vegetation distribution factor” to have a more realistic but still worst-case deposit estimation for off-field habitats. For the time being, a vegetation distribution factor of 10 was considered to be appropriate. At the meeting it was pointed out that research in the area of off-field drift estimation for the terrestrial environment is urgently needed and at the time when such field validated models are available these data should be used for the calculation of off-field drift values. As different countries may develop their own off-field drift models adapted to specific agronomic practices and environmental conditions, some regulators prefer to have the flexibility to incorporate such data into the equation.

[f] Since the species sensitivity analyses (see above) were mainly based on a comparison of in-field species which represent a lower species diversity than expected within off-field habitats, an uncertainty (safety) factor of 10 was included into the off-field HQ calculation to account for uncertainty with the extrapolation from of *T. pyri* and *A. rhopalosiphi* as indicator species, to all off-field non-target arthropods.

Considerable time was spent during the meeting discussing whether the HQ approach was appropriate for Tier I assessments. The main points of discussion concerned

[12] a.i.: active ingredient

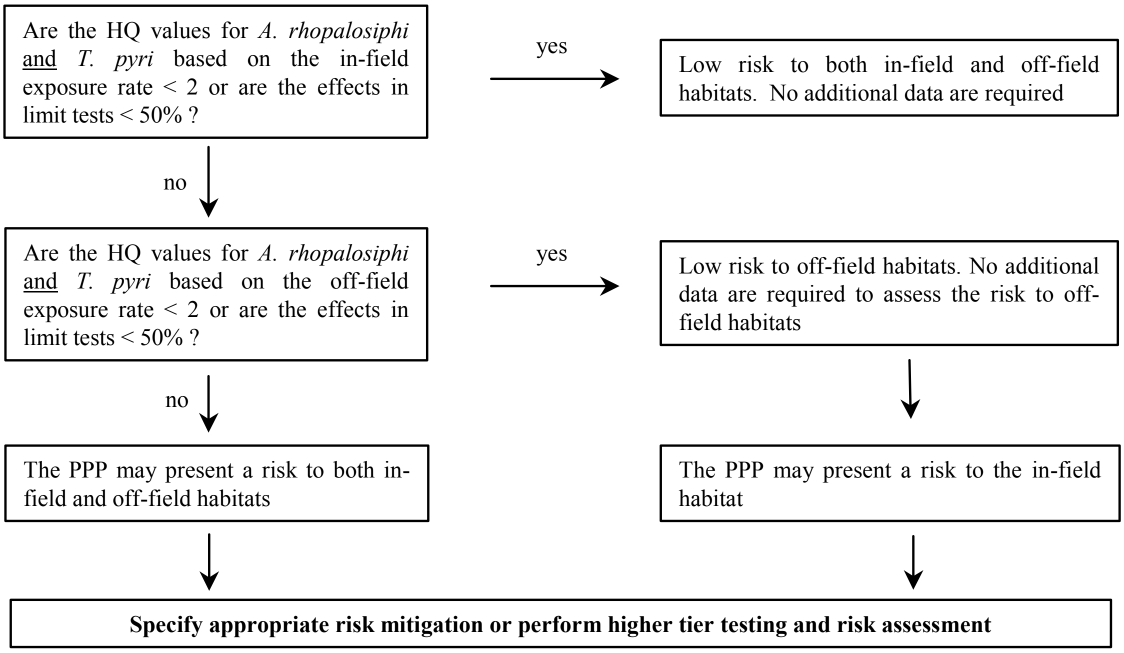
whether or not the HQ is appropriate (1) to estimate risk of multiple application products, (2) to cover both lethal and sub-lethal effects and (3) to assess both in-field and off-field risk. The following aspects were considered in regard to these questions (note that these points were explained in detail during the presentation of the calculations of the HQ):

1. *Estimating risk of multiple application products*: In the HQ validation exercise (Campbell *et al.*, 2000), the HQ was calculated by dividing the single application rate by the LR_{50} value and contrasting the data to semi-field or field results. The semi-field or field studies were conducted with single and multiple application products, the multiple application products being applied at the maximum application rate, the maximum number of applications and the minimum spray interval. Accordingly, the proposed HQ approach was validated also for multiple application products. However, one participant presented a case with a multiple application product where the proposed HQ approach apparently underestimated the hazard potential. Due to this example and the fact that the threshold value validation exercise included a limited number of multiple application products, it was proposed to implement a MAF into the HQ calculation for products with 2 or more applications. This factor covered the presented case and adds additional safety to the proposed HQ approach.
2. *Lethal and sub-lethal effects*: There was specific concern that the HQ approach will not cover sublethal effects. However, the HQ approach has been validated with field or semi-field data, which either measured lethal, sub-lethal and reproduction endpoints directly (*Aphidius spp*. tests) or indirectly by monitoring population responses (*T. pyri* tests). Products with a special mode of action e.g. IGRs will be tested differently (see Section 4.5). This is similar to the way in which the EPPO Honeybee HQ trigger value was validated (Aldridge & Hart, 1993; EPPO, 1993) and adopted under 91/414/EEC. Based on this experience it is considered that the non-target arthropod HQ value (calculation based on laboratory dose-response mortality data) is a reliable predictor of potential field effects at the first tier of risk assessment, covering mortality, sub-lethal and reproductive effects. The way in which the HQ value is derived makes it unnecessary to include sub-lethal or reproductive endpoints at the first tier of risk assessment. This is particularly important as sub-lethal assessments for non-target arthropods to date have been associated with significant technical difficulties e.g. extremely variable fecundity (Schmuck *et al*., 1996).
3. *Assessment of in-field and off-field effects*: The species sensitivity analyses (Candolfi *et al*., 1999 and Vogt, 2000) were based on comparisons of in-field species which may represent a lower species diversity than expected within off-field habitats. It was, therefore, the opinion of the workshop participants that an uncertainty (or safety) factor should be included in the off-field HQ calculation to account for uncertainty associated with the applicability of *T. pyri* and *A. rhopalosiphi* as indicator species for off-field non-target arthropods. An uncertainty factor of 10 was considered to be appropriate at the Tier I testing level.

At the workshop it was concluded that overall the HQ approach is an appropriate tool to estimate risk to in-field and off-field non-target arthropods from both single and multiple application products. Species-specific threshold values were generated and validated by the BART group (Campbell *et al.*, 2000) and formed the basis for the workshop discussions. The threshold values were determined for both sensitive indicator species (*T. pyri* and *Aphidius spp.*) using laboratory and robust (semi-)field data bases for a wide range of products with differing modes of action (29 for *T. pyri* and 18 for *Aphidius spp.*). The products tested included pyrethroids, carbamates, organophosphates and neo-nicotinoid insecticides as well as strobilurin and azole fungicides. The Tier I LR_{50} data of these products were first used to calculate HQ values as described above. Then, based on results from (semi-)field studies, the HQ values were allocated to either a hazardous (any effect > 40%) or to a non-hazardous group to define species-specific threshold values. The proposed Tier I HQ trigger values were HQ = 8 for *A. rhopalosiphi* and HQ = 12 for *T. pyri* (Campbell *et al.*, 2000).

However, it was recognised that the data base available at the moment is limited and that some concern exists on the applicability of the threshold values to off-field habitats. After the workshop, the presented data base was re-evaluated (including further field data) and additional data sets (5 multiple application fungicides) were examined to test whether or not the species-specific HQ threshold values were still sufficient to provide a reasonable margin of safety. The additional data were supplied by regulatory authorities and the Joint Testing Initiative. Based on this analysis the editorial board considered that it was justified to set an HQ value of **2** for both indicator species. It should be stressed here, that once additional data and experience become available, the trigger value may need to be revised for either or both indicator species.

If the HQ values determined for the two indicator species are below this trigger value, no further testing is required and it can be concluded that there is a low risk to non-target arthropods for both in-field and/or off-field habitats. If the HQ value determined for one or both of the two indicator species is above or equal to this trigger value, it has to be demonstrated that the risk to non-target arthropods for in-field and/or off-field habitats are acceptable by using specific risk mitigation measures or by further testing. Where limit tests are conducted, a low risk to NTA can be concluded when the effects at the highest application rate x MAF are below 50% since the resulting HQ value would be < 2. If the effects in the limit test are > 50% a dose-response test has to be performed. The following chart indicates the decision making scheme for Tier I risk assessment (see also Section 7):



4.5 Tier I Data and Risk Assessment for Products with Special Modes of Action

It was recognised by the workshop participants, that the Tier I testing proposed above scheme is not appropriate for special PPP formulations like granular formulations, seed dressings or insect growth regulators. This is due either to: (1) technical reasons (e.g. laboratory glass plate tests with the two indicator species can not reasonably be performed with granular formulations or seed dressings); or (2) due to the fact that effects can not be detected using standard laboratory tests with the indicator species because of a different mode of action of the product (e.g. a laboratory acute toxicity test with an IGR on adult *A. rhopalosiphi* would probably not show any effect). The recommendations made during the workshop to address these issues can be summarised as follows:

1. For granular formulations or seed dressings with no corresponding spray formulation which can be tested with the previously described Tier I scheme, it was recommended that the testing requirements and associated risk assessment scheme should be developed by the EPPO soil organism group. It was recommended that this group should involve non-target arthropod experts to ensure consistency in recommendations. For the time being the recommendations of ESCORT 1 should be followed, i.e. seed coatings, pellets, and baits should be tested on two appropriate species, e.g. spiders and ground dwelling beetles. Ring-tested methods for these species were published by the Joint Testing Initiative (Heimbach *et al.*, 2000a; Heimbach *et al.*, 2000b; *Grimm et al.*, 2000).
2. For IGRs or other PPPs with special modes of action (e.g. insect feeding inhibitors), testing should focus on those stages of non-target arthropods likely to demonstrate effects (e.g. juvenile stages) and taking into account the appropriate

routes of uptake. Testing should be conducted with *T. pyri* and one other species (e.g. *Coccinella septempunctata*, *Orius laevigatus* or *Chrysoperla carnea*). Ring-tested methods for these species were published by the Joint Testing Initiative (Blümel *et al.*, 2000, Schmuck *et al.*, 2000; Bakker *et al.*, 2000; Vogt *et al.*, 2000).

The primary toxicity endpoint of the studies should be mortality (determination of the LR_{50}). However, for products where effects on reproduction are expected (e.g. IGRs) assessment of sub-lethal parameters (e.g. oviposition) should also be evaluated. The Tier I risk assessment for these special products should preferably be carried out by comparing toxicity data with the relevant exposure data for in-field and off-field. The HQ trigger value discussed above cannot be used to evaluate the data for special products, since such products were not included in the validation exercise. In addition, for certain products (e.g. IGRs), sub-lethal parameters have to be included in the data evaluation. For this reason, it was proposed to use a 50% trigger value for both lethal and sub-lethal endpoints and for in-field and off-field exposure scenarios as an indication of hazard potential (to give consistency with the LR_{50} approach). In addition, where Tier I testing for these products does not provide an appropriate way to assess risk, it is recommended to emphasize higher tier risk assessment.

5. Higher Tier Testing and Risk Assessment

5.1 General principles

Higher Tier studies should be conducted if off-field and/or in-field HQ values for *A. rhopalosiphi* or *T. pyri* are above or equal to the trigger value of 2 and no appropriate or desired risk mitigation measures can be identified. Firstly, the indicator species affected in Tier I testing should be tested in higher tiered tests. Where for one or both indicator species the HQ for the in-field risk assessment is ≥ 2, testing of one additional species is required. If the HQ for the off-field hazard assessment is also ≥ 2, one further additional species has to be tested. The Higher Tier level at which testing will be performed (e.g. extended laboratory, aged residues studies, semi-field or field studies) need not necessarily follow a sequential step-wise approach, i.e. testing can start directly at the field stage without conducting tests at the preceding steps. Dose-response studies using natural substrates can be used to identify the most sensitive test species. An aged residue study may then be conducted with the most sensitive species and give information on the time scale needed for re-colonization of treated areas. Higher Tier studies should include lethal and sub-lethal endpoints (e.g. integrated parameters in field studies). However, sub-lethal endpoints have to be interpreted with care since they are subject to high variability. As in Tier I, higher tier risk assessments for in-field and off-field exposure scenarios should be performed separately, taking the differences in exposure into account. 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. If, however, effects in higher tier testing exceed set threshold values and indicates no potential for re-colonisation or recovery within ecologically relevant periods, appropriate risk mitigation measures may be required to protect the habitats of concern and a refined risk assessment should be performed. A chart illustrating the testing and risk assessment scheme for non-target arthropods is presented in section 7.

5.2 Species selection

If one or both indicator species are affected in Tier I testing, the affected species should be tested further in Higher Tier studies. Moreover, as outlined under Section 5.1, one (if only the in-field HQ value is exceeded) or two (if the off-field HQ value is also exceeded) additional species should be included in higher tier tests. For these extended laboratory, aged residue and/or semi-field tests, the following species are proposed:
Orius laevigatus, *Chrysoperla carnea, Coccinella septempunctata* and *Aleochara bilineata*. These species were selected on the basis of the following criteria:

1. Taxonomic and functional diversity is obtained since the species belong to different orders.
2. Test methods for extended laboratory, aged residue and semi-field tests are available (final validation is still required).
3. Mortality and reproduction endpoints can be assessed with published test methods (Bakker *et al.*, 2000; Vogt *et al.*, 2000; Schmuck *et al.*, 2000; Grimm *et al*., 2000).
4. The authors of the published methods claim amenability and robustness of the test system.
5. All four test insects can be easily cultured and are commercially available.
6. All four test insects are regularly tested by agrochemical and contract research facilities and there is a significant amount of data available on these species that has been used to support pesticide registrations.
7. Although a comprehensive test organisms/test system sensitivity analysis of higher tier studies is not yet possible due to the limited data available, it appears that these organisms are relatively sensitive to plant protection products as indicated by risk assessments recently conducted for the re-registration of products according to EU directive 91/414.

Other non-target arthropod orders (e.g. Lepidoptera, Diptera, Araneae) were also considered since they include species which may be more representative for off-crop habitats. These species however, cannot be recommended at present because they do not meet most of the above criteria. Many cases have been reported, where herbivores were less susceptible to pesticides in comparison to entomophagous species (Croft, 1990). Dipteran species contribute to off-crop site diversity but the experience with available test systems (e.g. for *Episyrphus balteatus*) indicates that control mortality is too high and reproduction rates too variable such that practical testing is not feasible. Web-building spiders are one of the most important arthropod predator groups but at present it is not possible to develop an amenable test system. There is currently a test method for ground-dwelling spiders but these species are often less sensitive than the recommended indicator species and the test method does not include reproductive endpoints. Thus, further research is needed on the ecology of off-field non-target arthropods especially with regards to species distribution between in-field and off-field habitats, and their sensitivity to pesticides. When such data become available and appropriate test systems validated, the list of species should be re-considered. In the meantime it is proposed to apply an uncertainty factor to cover potential sensitivity differences between the tested indicator species and other arthropods (see Section 5.3).

For guidance on species selection in field trials, reference is made to the Joint Testing Initiative guidance document on "Principles for regulatory testing and interpretation of semi-field and field studies with non-target arthropods" (Candolfi *et al.*, 2000).

5.3 Higher tier testing methodology

5.3.1 Extended laboratory studies

Extended laboratory studies are carried out under controlled environmental conditions by exposing laboratory-reared test organisms to fresh, dried pesticide residues applied to natural substrates, e.g. leaves or plants. With the exception of the test substrate, the protocols developed for acute Tier I studies usually apply also to extended laboratory studies (Bakker *et al.*, 2000; Blümel *et al.*, 2000; Grimm *et al.*, 2000; Mead-Briggs *et al.*, 2000; Schmuck *et al.*, 2000; Vogt *et al.*, 2000). Lethal (mortality) as well as sub-lethal (e.g. oviposition, parasitation) endpoints should be assessed. Study design must include a water-treated control and a toxic standard. The test item should be tested at the maximum application rate and at appropriate drift rates (e.g. for sensitivity analyses), if needed. Rate-response testing should be performed, if appropriate[13]. For multiple application products the application regime should take into consideration the recommended use pattern of the product (maximum number of applications per season and minimum spray interval). It is appropriate to either simulate the use pattern under field conditions and to conduct testing after the final treatment or to directly apply a rate which takes into account the accumulation of residues after multiple application of the product. For the latter approach, the following formulas should be used to calculate the appropriate rates to be tested:

[13] Note that only mortality data can be satisfactorily assessed with rate-response testing aiming to determine an LR_{50}; sub-lethal parameters are usually highly variable and are usually recommended to be only assessed qualitatively and are therefore not appropriate to determine a rate-response relationship. Sub-lethal parameters should therefore, be assessed with a single or multi-rate (e.g. 2 rates) test design which can be included in rate-response test by testing the reproduction effects at the rates where mortality is below 50%.

$$\text{Field rate} = \text{Application rate}^{a} \times \text{MAF}^{b}$$

$$\text{Drift rate} = \text{Application rate}^{a} \times \text{MAF}^{b} \times \left(\frac{\text{drift factor}^{c}}{\text{vegetation distribution factor}^{d}} \right) \times \text{correction factor}^{e}$$

Legend:

[a] Single application rate in g or ml formulated product/ha (or in g or ml a.i.[14]/ha). Application rate and LR_{50} must not differ in their units, i.e. both must be given as either formulated product or a.i. rates. For in-crop situations in 3-dimensional crops e.g. orchards and vineyards, the application rate can be multiplied by a correction factor of 0.5. This factor is derived from ESCORT I and covers both, soil-dwelling and leaf-dwelling arthropods (see also Candolfi *et al.*, 2000).

[b] MAF = Multiple Application Factor = "ratio between the rate after the maximum recommended number of multiple applications and the initial rate after a single application of a plant protection product". The multiplication of the 1X application rate by the MAF allows the determination of the maximum residue level after multiple applications of the product. The MAF is derived from the ratio between the half-life of the product and the spray interval together with the number of applications (see Appendix V).

[c] Spray drift is the most relevant exposure route for NTA in off-field areas. Drift factor = %drift/100. Usually, the overall 90th percentile drift data according to Ganzelmeier *et al.* (1995, recently recalculated by German BBA and UBA and published by BBA, 2000) should be used to estimate off-field drift deposition values (%drift). This proposal is based on the recommendations of the FOCUS surface water group, which has defined that a reasonable worst case scenario for drift estimation is represented by an overall 90th percentile probability. Default drift values for a distance from the field border (crop edge) of 1 m for arable crops and 3 m for orchards/vineyards should be used to estimate the off-field PEC. Overall 90th percentile drift values are presented in Appendix VI.

[d] The drift values referred to under [c] were determined to estimate drift into surface water (2-dimensional structure). These values should therefore, be corrected to take into account the 3-dimensional structure of the off-field vegetation (e.g. leaf area index = LAI). The 90th percentile drift values should be corrected by a vegetation distribution factor to have a more realistic, but still worst-case deposit estimation for off-field habitats. For the time being, a default value of 10 was estimated to be appropriate based on data presented at the workshop (Weisser *et al.*, in press; Koch and Weiser, in press; Gonzalez-Valero *et al.*, 2000). This factor takes into account a number of factors, e.g. the LAI and interception by vegetation. At the meeting it was pointed out that research in the area of off-field drift estimation is urgently needed, and when such field validated models become available (e.g. FOCUS) these data should be used for the calculation of off-field drift values. Note that the vegetation distribution factor can

[14] a.i.: active ingredient

only be included in the calculation if 2-dimensional systems (e.g. leaves or leaf discs) are treated but not when whole plants are treated.

[e] Since a limited number of indicator species are tested when compared to the range of species which could be exposed in off-field habitats, a 5-fold uncertainty (correction) factor was included to the calculation to ensure a higher rate is tested which covers the inter-species variability in sensitivity of off-field non-target arthropod species to plant protection products. However, by testing additional species, uncertainty can be reduced, and a safety factor less than 5 can be applied (the same approach is used in aquatic risk assessment, HARAP, Campbell *et al.*, 1999).

5.3.2 Aged residue studies

Aged residue studies are designed to assess the duration of effects of a PPP to non-target arthropods. These are “hybrid” studies where ageing of pesticide deposits is carried out under field conditions (use of rain protection may be advisable). However, exposure of the test organisms on treated leaves or plants is performed either in the laboratory, under semi-field conditions or a combination of both (e.g. mortality assessment under semi-field conditions and reproduction assessment under laboratory conditions). The endpoints of the study should include mortality and reproduction assessments and determine the duration of either effect (persistence test). The duration of effects is assessed by a series of bioassays, exposing test organisms to treated leaves of plants after different periods of ageing of the residues (e.g. days or weeks) under semi-field/field conditions.

The protocols developed for extended laboratory and/or semi-field studies also apply to aged residues studies. The study design must include a water-treated control and a toxic standard. Test item rates to be tested should include the maximum application rate and appropriate drift rates, if needed. For multiple application products, the application of the product should take into consideration the recommended use pattern of the product. The product should thus be applied at the maximum number of applications per season and minimum spray interval or, alternatively tested at a rate which takes into account the accumulation of residues after multiple application of the product (MAF factor). The same formulae as stated in Section 5.3.1 should be used to calculate the appropriate test item rates to be tested.

5.3.3 Semi-field studies

Semi-field studies are single-species tests where both the test system (treated plants) together with the test organisms are initially maintained in the field. They usually involve use of enclosures or cages and release of laboratory-bred or field-collected test species into these enclosures. The test system can be equipped with UV permeable, transparent rain-covers to avoid premature wash-off of spray deposits and/or extensive control mortality. In semi-field studies, the aim is to examine whether or not a test substance applied under more realistic conditions of exposure may adversely affect survival and viability (e.g. sub-lethal effects such as parasitation or reproduction) of a specific non-target arthropod species. Semi-field studies can provide information on the level of effects and on the duration of the effects, if they are extended into persistence studies (see aged residue studies, Section 5.3.2). The study design must include a water-treated control and a toxic standard. Test item rates to be tested should include the maximum application rate and, if appropriate, drift rates. For multiple application products the application of the product should take into consideration the recommended use pattern of the product. The product should thus be applied at the maximum number of applications per season and minimum spray interval or, alternatively tested at a rate which takes into account the accumulation of residues after multiple application of the product (MAF factor). The same formulas as stated in Section 5.3.1 should be used to calculate the appropriate test item rates to be tested. Guidance for semi-field methodology for registration testing is given by Candolfi *et al.* (2000).

5.3.4 Field studies

Field trials allow the determination of short- and long-term effects of a test substance applied under normal agricultural conditions according to the proposed use pattern on naturally occurring arthropod populations. The potential for re-colonisation/recovery should be one of the key questions to be addressed in field tests. Field tests can be targeted on key species and/or on specific arthropod groups identified from the lower tier testing/risk assessment to be at risk and/or to the whole fauna community. Guidance for field methodology for registration testing is given by Candolfi *et al.* (2000).

5.4 Higher Tier risk assessment and trigger values

During the workshop, a general agreement on trigger values and risk assessment procedures for higher tier testing was reached. These are based on, and elaborate the criteria for acceptability of effects as already given by ESCORT 1 (Barrett *et al.*, 1994).

At each step of a higher tier risk assessment (extended laboratory, semi-field or field testing level), a refined risk assessment (e.g. taking into account the new ecotoxicological data or refined exposure assessments) can be conducted or mitigation measures can be considered in order to demonstrate that the plant protection product does not have an unacceptable impact to non-target arthropods in the habitats of concern.

A chart illustrating the testing and risk assessment scheme for non-target arthropods is presented in section 7.

5.4.1 Extended laboratory and semi-field data

For extended laboratory, aged residue and semi-field studies, lethal (mortality) as well as sub-lethal (reproduction) parameters should be used in evaluating the data. Assessments for in-field and off-field exposure scenarios should be performed separately. A trigger value for lethal or sub-lethal effects of 50%[15] after exposure of the test organisms to fresh or aged residues of plant protection products was judged to be appropriate since the test designs used for semi-field trials usually do not allow the detection of lower statistically significant differences. The same trigger values should be used for both in-field and off-field habitats. Data on lethal and sub-lethal effects from aged residues studies will be used to demonstrate the potential for recolonisation of an affected non-target arthropod population. The potential for recolonisation should be demonstrated within one year for in-field habitats and within an ecologically relevant time for off-field habitats. Further guidance for evaluation, interpretation and acceptability of effects from semi-field data is provided by the Joint Initiative document on "Principles for regulatory testing and interpretation of semi-field and field studies with non-target arthropods" (Candolfi *et al.*, 2000).

5.4.2. Field data

In field trials, population level effects rather than effects on individuals should be the testing endpoint. The population effect on a species including time to re-colonisation/recovery should be analyzed in comparison to control plots. There should be no fixed trigger values for acceptability of effects, because the consequence/impact of treatments can be markedly different for different organisms. Factors such as mobility of a species, reproduction time and developmental stage at risk, can influence the severity of effects of a pesticide on a population. Therefore, acceptability has to be assessed on a case-by-case basis for each arthropod taxon or group under investigation. This is an area where expert judgement is required to interpret field study results. Assessments for in-field and off-field exposure scenarios should be performed separately. As a general acceptability criterion for in-field effects, the potential for re-colonisation after a toxic effect should usually be demonstrated within one year. Where significant off-field effects are detected, the duration of effect and the range of taxa affected should also be taken into consideration. Further guidance for evaluation, and interpretation and acceptability of effects from field data is provided by the Joint Initiative guidance document on "Principles for regulatory testing and interpretation of semi-field and field studies with non-target arthropods" (Candolfi *et al.*, 2000).

[15] The effects observed in the test item treatment(s) should be corrected for control effect levels e.g. Abbott (1925) corrected mortality or effects according to Henderson & Tilton (1955).

6. Risk Mitigation Options

The risk mitigation measures outlined below are options only. These measures will require consideration at a national level and implementation will depend on local factors e.g. climate, agricultural practices, habitat types etc.

6.1 In-field Areas

If unacceptable effects (e.g. severe and persistent impacts) to non-target arthropods within the cropped area are predicted, the following aspects of the use pattern may be considered for modification in order to mitigate the predicted risk:

- application rate
- application frequency and intervals
- timing of application (early and late crop stages, presence of NTA populations under consideration)
- unsprayed headlands

6.2 Off-field Areas

If unacceptable effects (e.g. severe and persistent impacts) to non-target arthropods within off-field areas are predicted, the exposure of NTA species can be reduced by different measures. The following options for risk management have been investigated and proposed:

(1) Buffer Zones

The exposure of non-target arthropods can be reduced by leaving untreated a part of the cropped area adjacent to the field margin. Depending on their size, such buffer zones between treated and vulnerable non-target areas can lead to a decrease of spray drift deposition of more than 90%. The drift values tabulated in Ganzelmeier *et al.* (1995), recently revised by the German BBA (2000), describe the magnitude of drift reduction relative to the distance between the treated area and the point of deposition. However, for the estimation of drift rates from areas with buffer zones, it has to be taken into account that the cropped area which remains untreated serves as a filter for drifted aerosols and causes a considerable reduction of spray drift deposition in the off-field area (De Snoo and De Wit, 1996). Furthermore, these drift aerosols deposit on a three-dimensional plant surface which results in lower surface concentrations compared to those on water surfaces (Koch and Schietinger, 1999; Campbell *et al.*, 2000). Further details for assessing cost/benefits in the implementation of buffer zones are given e.g. by Boatmann (1998), Orson (1998) and Campbell (1998).

(2) Wind Breaks

Hedgerows or tree rows planted to serve as windbreaks may also serve to reduce drift into vulnerable off-field areas and so may be required specifically for this purpose. During pesticide application in an orchard with trees present as a windbreak, Van

Vliet & Tas (1996) reported drift depositions down to 0.7 % of the applied rate over a 3 metre distance to the orchard margin compared to 6.8 % drift from orchards without windbreaks (trees with leaves; application directed into the orchard).

(3) Drift-Reducing Application Techniques

Air injected spray nozzles produce significantly larger spray droplets which are less easily displaced in the air and thus reduce drift considerably. For the application of agrochemicals in field crops, drift-reducing application devices are already widely used. For example, in Lower Saxony (which is one of the largest districts in Germany with respect to agricultural production) 95% of the recently sold application equipment were already equipped with drift-reducing nozzles (Ripcke and Warnecke-Busch, 1999). Several authors measured or estimated drift reductions of 75% - 98%, when field crop sprayers were equipped with such injector nozzles (Ganzelmeier and Rautmann, 2000; Ripcke and Warnecke-Busch, 1999; Schmidt, 1999).

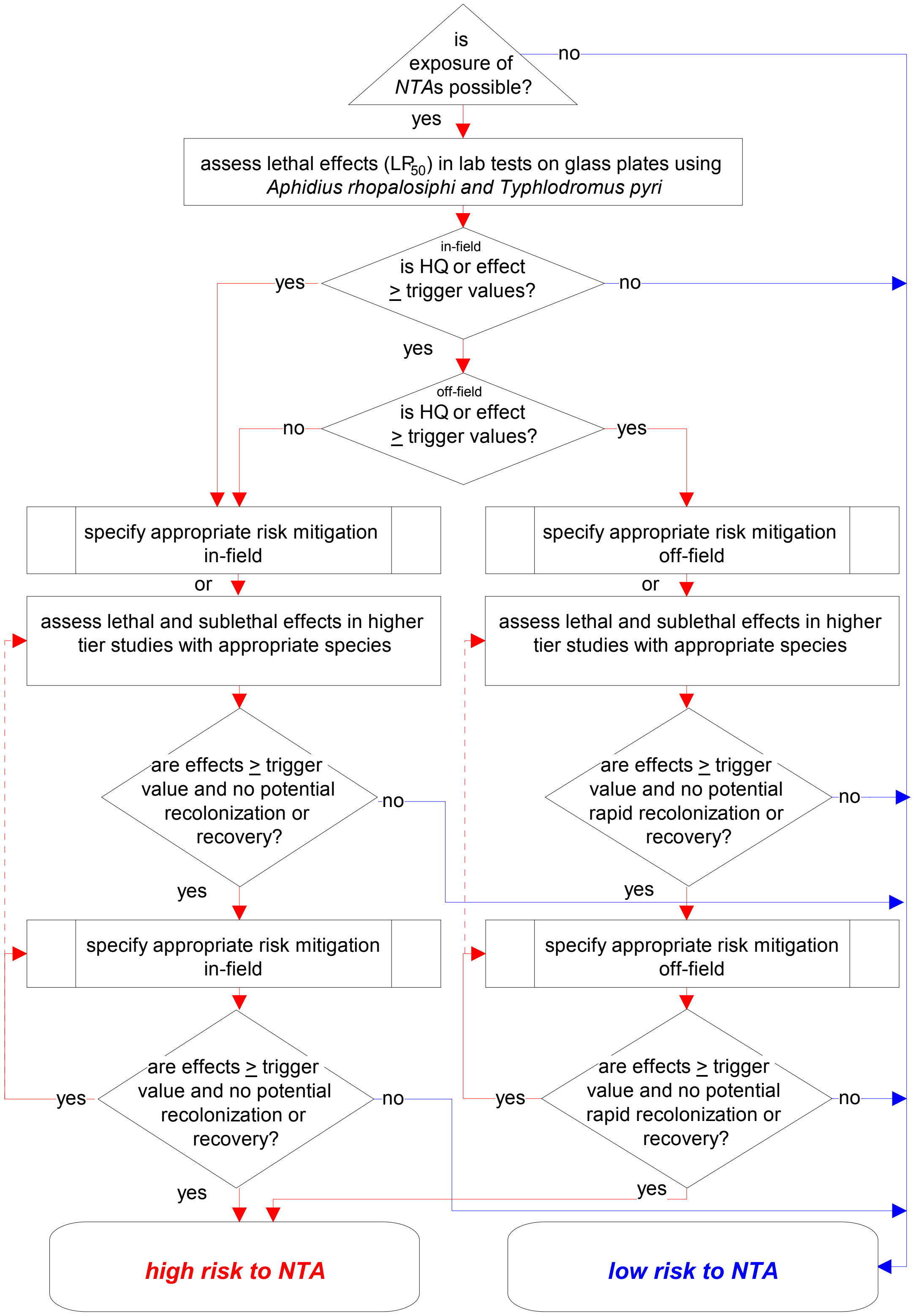
Similar spray drift reductions for 3-dimensional crops, e.g. orchards and vineyards can also be achieved by similar techniques (e.g. Wicke *et al.*, 1999; Schmidt 1999). During experiments in hops, a 90 % reduction of basic drift values by use of air injection nozzles was achieved (Landesanstalt für Pflanzenschutz Stuttgart, 1998). Also, for application in orchards, Ganzelmeier and Rautmann (2000) estimate a possible drift reduction of 75 %, if conventional sprayers are modified. According to these authors, tunnel sprayers with a drift reduction of more than 90 % are already available for the application of agrochemicals in grapevine.

6.3 Local Modifications of Risk Management

Different regulatory authorities in the EU are considering whether or not risk management systems can be adapted to reflect local agronomic practice and conditions. For example, Forster and Rothert (1999) in Germany propose to take into account parameters such as the size of treated areas, the size of adjacent off-field sites, the proportion of off-field sites at the landscape level and the interception by field edges. For some compounds labelled with a buffer-zone requirement in order to protect aquatic life, the UK Pesticide Safety Directorate (1999) requires farmers to evaluate and document the local risk posed by pesticides and to modify the use restriction on the label if local conditions justify this modification (LERAP[16]).

[16] Local Environmental Risk Assessment for Pesticides

7. Testing and Risk Assessment Diagram



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Appendix I

Workshop Sponsors

The following organisations and companies have sponsored the workshop:

- American Cyanamid
- Aventis
- BASF
- Bayer
- Dow
- Du Pont
- European Commission (support of Member State representatives)
- FMC
- IOBC (support of IOBC members)
- Monsanto
- Novartis Crop Protection AG
- OECD
- Uniroyal
- Zeneca Agrochemicals

Appendix II

Workshop Participants

Name	Institute	Country
Albuquerque Bártolo M.	Direcção Geral de Protecção das Culturas	Portugal
Arnó, J.	IRTA	Spain
Bakker, F.	Mitox Consultants	The Netherlands
Barrett, K.	Huntingdon Life Sciences	United Kingdom
Bigler, F.	Fedaral Res. Station for Agroecology and Agriculture	Switzerland
Blümel, S.	BFL, Institut für Phytomedizin	Austria
Brown, K.	Ecotox Limited	United Kingdom
Bylemans, D.	Opzoekingsstation van Gorsem	Belgium
Campbell, P.	Zeneca Agrochemicals	United Kingdom
Candolfi, M.P.	Novartis Crop Protection AG	Switzerland
Cañez, V.	American Cyanamid Company	United States
Clook, M.	Pesticides Safety Directorate MAFF	United Kingdom
Dinter, A.	DuPont Agricultural Products	Germany
Drukker, B.	European Commission	Belgium
Forster, R.	BBA	Germany
Goetzl, M.	Federal Environment Agency (Umweltbundesamt)	Austria
Gonzalez-Valero, J.	Novartis Crop Protection AG	Switzerland
Grandy, N.	OECD	France
Grasso, P.	Mario Negri Institute	Italy
Harrison, E.	Zeneca Agrochemicals,	United Kingdom
Heimbach, U.	BBA	Germany
Hucorne, P.	Ministère des Classes moyennes et de l'Agriculture	Belgium
Jepson, P.	Oregon State University	United States
Koch, H.	Landesanstalt für Pflanzenbau und Pflanzenschutz	Germany
Künast, Ch.	BASF AG	Germany
Lawlor, P.	Pesticide Control Service	Ireland
Lenteren van, J.	Wageningen University	The Netherlands
Lewis, G.	JSC International	United Kingdom
Løkke, H.	National Environment Research Institute	Denmark
Loutseti, S.	Ministry of Agriculture	Greece
Martin, S.	UBA	Germany
Mead-Briggs, M.	MamboTox Agrochemical Evaluation Unit	United Kingdom
Miles, M.	Dow AgroSciences	United Kingdom
Moyle, J.	Uniroyal Chemical Ltd.	United Kingdom
Mulye, H.	Health Canada Pest Management Regulatory Agency	Canada
Neumann, P.	Bayer AG	Germany
Oomen, P. A.	EPPO / Plant Protection Service	The Netherlands
Orson, J.	Morley Research Centre	United Kingdom
Powell, W.	IACR-Rothamsted	United Kingdom
Romijn, K.	Aventis CropScience GmbH	Germany
Schmuck, R.	Bayer AG	Germany
Sherratt, T.	University of Durham	United Kingdom

Name	Institute	Country
Silvo, R.	Finish Environment Institute	Finland
Stallknecht, H.	Deutscher Bauernverband	Germany
Stokke, R.	Norwegian Agricultural Inspection Service	Norway
Tencalla, F.	Monsanto Europe SA	Belgium
Tornier, I.	GAB Biotechnologie GmbH	Germany
Ufer, A.	BASF AG	Germany
Vergnet, Ch.	SSM, INRA/DGAL	France
Viñuela, E.	Universidad Politecnica de Madrid	Spain
Vliet van, P.	Board for the Authorization of Pesticides	The Netherlands
Vogt, H.	IOBC / BBA	Germany
Waltersdorfer, A.	Aventis CropScience GmbH	Germany

Appendix III

Plenary Presentations (Abstracts)

Does not necessarily represent the views of the Commission

Revision of the EU testing approach on non-target arthropods: An EU Perspective

Bas Drukker
European Commission Health and Consumer Protection - Unit E.1 "Plant health"

Since the adoption of Council Directive 91/414/EEC, dossiers on c. 80 new active substances have been submitted for review. Most of these have been granted provisional authorisations at Member State level, but so far only five have been officially included in Annex I of the Directive. In addition, existing active substances - on the EU market before 1993 - are being reviewed: a first list of 90 actives has been published in Commission Regulation 3600/92, nine of which have been withdrawn, three have been included in Annex I, the other 78 are in some stage of evaluation. The remaining existing active substances, comprising about 800 compounds, are addressed under Commission Regulation 451/2000. There are two phases running concurrently. The 2nd list comprises 148 actives divided into four groups with a clear timetable for the review process (e.g. notification within six months from the date of the Regulation, then one year for submission of a dossier, six months for a completeness check and one year for evaluation). The 3rd list comprises the remaining active ingredients, with an initial requirement for notification within three months, while the complete data package is required three years later, after which a comparable evaluation process will start.The original aim was to have full evaluation and a decision on Annex I inclusion in a period not exceeding 3 years from the time a dossier was first submitted. In practice the evaluation procedure has proved to take longer. A number of factors have been identified to contribute to this delay, e.g. submission of incomplete dossiers, dependence on higher-tier testing for decision making, etc. The latter also applies to risk assessment for non-target arthropods, as the recommendations from ESCORT 1 have resulted in the generation of extensive data sets on effects both under laboratory and field conditions, but the workshop failed to provide detailed guidance on how to evaluate and interpret this information.

In order to speed up the review process it is proposed that in future Annex I inclusion will be based on one or a few major uses, which can be extended at a later stage at the Member State level. In addressing the question of how to avoid unnecessary higher tier testing, there is a need for more reliable Tier 1 data, with a limited set of standard species for all active substances, allowing the establishing of a comparative database. Particular importance should be given to dose response data, which can make a more general comparison possible among active ingredients in terms of risk assessment and risk management. It should e.g. be possible to predict effects when a use pattern of a product is changed without the need for additional experimental data. In addition, the identification of clear-cut trigger values for the higher tier tests based on toxicity and exposure would be an important improvement. In reviewing the data, clearer guidance is also required about the acceptability level of the effects eg. recovery of the ecosystem, and what opportunities are available for risk mitigation. The recommendations from

ESCORT 1 were readily integrated into the Uniform Principles and the ECCO review process. Hopefully the same will happen to the recommendations from this workshop.

Limitations and need for review of the current EU non-target arthropod testing procedure: A regulatory perspective

Rolf Forster, BBA, DE
Mark Clook, PSD, UK
Martin Götzl, UBA, AU
Pieter A. Oomen, PD, NL

Side effect testing on terrestrial non-target arthropods (NTA) for registration of plant protection products in the European Union (EU) is currently conducted according to the Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC). Directive 91/414/EEC references the SETAC/ESCORT Guidance Document on regulatory testing procedures for pesticides with non-target arthropods (Barrett *et al.*, 1994) as a source of guidance on non-target arthropod testing and data interpretation. However, after 5 years of use several limitations have been identified (Oomen, 1998; Oomen *et al.*, 1998). The main points of concern are:

(1) The objectives of the testing scheme are not clear, e.g. it does not precisely discriminate between non-target arthropods in an ecological context and beneficial arthropods in an agricultural or IPM context.
(2) The trigger value for 1st tier data (30 % effects as laid down in Annex VI C point 2.5.2.4) has been mistaken for the threshold of an acceptable impact and in practice it produces too many false positives and consequently requires excessive higher tier testing.
(3) The single-dose laboratory data generated are inflexible, e.g. they do not allow a satisfactory risk assessment for in-field and off-field habitats.
(4) Uncertainty about data requirements, testing methodology and evaluation, especially for
a) multiple application products, where currently population dynamics, spraying interval and persistence are ignored and b) for off-field habitats, where exposure scenarios and mitigation measures are not yet agreed.
(5) There are conflicting objectives with respect to the denial of authorizations, e.g. Directive 91/414/EEC calling for a denial, if unacceptable effects on non-target arthropods cannot be ruled out, whereas the SETAC/ESCORT Guidance Document suggests, not to deny authorizations.

These main points of concern stress the need for a reviewed guidance on asking the right questions, generating the appropriate data and interpreting these data in relation to the agreed principles for evaluation and authorization of plant protection products as laid down in Directive 91/414/EEC.

Limitations and need for review of the current EU non-target arthropod testing procedure: An Industry Perspective

Richard Schmuck
Bayer AG, ECPA representative

The current EU testing requirements focus primarily on the need to evaluate effects with in the crop. Since the crop management practices such as cultivation, pruning, harvesting etc are already having a substantial effect on field populations of non-target arthropods, the emphasis for protection should focus on the off-field area, as this forms a more stable habitat and a natural reservoir for recolonisation of disturbed crop areas. Regarding the number of test species, an analysis of the currently available data base has shown that there is a clear ranking in sensitivity in the species commonly tested. Based on this analysis it should therefore be acceptable to restrict testing to the most sensitive of these species. The current testing regime also requires mainly an evaluation of maximum field application rates, with the application of an arbitrary 30% threshold value for acceptable effects. A more valuable data set could be generated which looks at a range of application rates, which would allow exposure under different temporal and spatial conditions to be evaluated in the subsequent risk assessment. Higher tier testing using natural substrates provides more realistic effect data, however there is a clear need for detailed guidance on data generation, and evaluation of this type of data. For a refined risk assessment it is also important to incorporate information of the physical/chemical properties of the compound and its fate in soil/plant surfaces when deciding what represents realistic worst case exposure conditions. Finally, there is a need for clearer guidance on the risk assessment procedure including options of risk management and the identification of what constitutes an unacceptable level of effect in the environment. In this respect, the current EU scheme does not sufficiently differentiate between in-field and off-field areas or between the criteria applied to Tier I data or higher tier data, or what constitutes an acceptable risk mitigation procedure.

The EPPO scheme for environmental risk assessment of terrestrial non-target arthropods

Pieter A. Oomen
EPPO/CoE representative

The experiences with the existing NTA-scheme made the EPPO/CoE Panel on Environmental Risk Assessment decide to revise the scheme. Accordingly, a new draft scheme has been developed by the EPPO working group on NTA. This draft "Decision making scheme for non-target terrestrial arthropods" provided the basis framework for the deliberations of the ESCORT2 workshop.

The scheme is concerned with assessing the potential risks of plant protection products to non-target terrestrial arthropods that are living on or above the ground, i.e. to species dwelling on plants and the ground surface . The objective of the scheme is to ensure that any impacts on non-target arthropods, in and off-field, are highlighted. Non-target arthropods play a vital role in the ecosystem, and therefore, plant protection products that are used as prescribed should not cause significant and persistent effects on the populations of non-target arthropods both in and off-field. The objective of the scheme is therefore to ensure that any risk to non-target arthropod populations, both within and off the cropping field, are highlighted and to assess the nature of the risk so that adequate risk mitigation measures can be taken.

Based on toxicity data and on estimates of the environmental exposure in off-field and within-field areas, applications of plant protection products are classified by this scheme for risk to non-target arthropods. The effects of single applications of a plant protection product on non-target arthropods are assessed at each stage of a tiered testing scheme. After each assessment, single applications of a product can be categorised as of low or high risk. Risks of multiple applications are evaluated by increasing dose rates in the first tier or repeating applications in higher tier tests. No further testing need to be done for negligible (where exposure is unlikely) or low-risk categories. Products of medium or high risk to the arthropod may be tested in higher tiers to show harmlessness in more realistic conditions. The final assessment is made on a crop-by-crop basis but as many non-target arthropods are common to more than one crop and exposure is similar for various crop groupings this sub-scheme takes into account, during the testing stages, all intended uses.

The main changes of the new scheme compared to the old one are simplification, optimisation of data requirements and realistic decison criteria:

Risk assessment to non-target arthropods as natural enemies is abandoned as an objective of the scheme. The new NTA-scheme separates two areas of risk to the non-target arthropods: in the within-field area and in the off-field area.

The new scheme will use as first tier indicator species only the Hymenopteran parasitoid *Aphidius* spp. (Hymenoptera: Braconidae) and the predatory mite *Typhlodromus pyri* (Acarina: Phytoseiidae). The scheme will require dose-response (LD_{50}) studies in stead of laboratory tests at recommended dose rates, as with most other non-target groups. Annex II will be linked to the first tier evaluations, Annex III will be linked to higher tier testing i.e. to address significant risks identified in the first tier. This will result in a considerable reduction in data required and in a more standardised dataset.

The new scheme will use in the first tier a *hazard ratio*: *exposure* divided by *toxicity* (LD_{50}). A realistic and relevant trigger value for first tier evaluation of the hazard ratio will be based on a comparison of field and laboratory data, all comparable to the honey bee risk assessment.
The expected exposure will be the highest recommended dose rate within-field, or the drift values corrected for standing vegetation off-field. For multiple applications, as a realistic worst-case, a multiplied single rate residue accumulation will be used unless real data on residue accumulation on vegetation are available.

References:

OEPP / EPPO, 1994: Decision making scheme for the environmental risk assessment of plant protection products, Chapter 9: Arthropod natural enemies. Bulletin OEPP/EPPO Bulletin 24: 17-35.

Could *Typhlodromus* and *Aphidius* be used as indicator species in Tier I regulatory testing ?

Marco P. Candolfi
Novartis Crop Protection AG, Joint Initiative representative

Data on the sensitivity of nine non-target arthropod families to 95 plant protection products (PPP), including herbicides, fungicides, insecticides and plant growth regulators, tested using currently established laboratory Tier I methods were analyzed (Candolfi *et al.*, 1999). The data presented were supplied by 11 agro-chemical companies and were generated for regulatory purposes. All the studies were performed in compliance with Good Laboratory Practice (GLP) standards. Differences in sensitivity among arthropod species to the same PPP, the relative sensitivity of arthropod species among PPP tested, and the potential use of the more sensitive species as indicator species for regulatory testing purposes was discussed. *Typhlodromus pyri* and *Aphidius* spp., showed the greatest sensitivity to PPP. Ranking of the arthropod species tested, in order of decreasing sensitivity follows: *T. pyri, Aphidius* spp*., Coccinella septempunctata, Orius* spp*., Pardosa* spp*., Episyrphus balteatus, Chrysoperla carnea, P. cupreus* and *A. bilineata*. With lethal parameter as assessment endpoint, if a PPP elicited an adverse effect ≥ 30% on any of the arthropod species tested, an adverse effect also was observed in either *T. pyri* and *Aphidius* spp. in 93.7% of the cases. These results indicate that the potential of an arthropod species to be adversely affected following exposure to a PPP under worst-case exposure conditions can be effectively predicted by determining the lethal and sub-lethal effects of the PPP on the two sensitive species, *T. pyri* and *Aphidius* spp.

References:

Candolfi M., Bakker F., Cañez V., Miles M., Neumann C., Pilling E., Priminani M., Romijn K., Schmuck R., Storck-Weyhermüller S., Ufer A. and Waltersdorfer A., 1999: Sensitivity of non-target arthropods to plant protection products: could *Typhlodromus pyri* and *Aphidius* spp. be used as indicator species? Chemosphere 39: 1357-1370.

Dose-response toxicity tests with *Typhlodromus pyri* and *Aphidius rhopalosiphi*

Marco P. Candolfi
Novartis Crop Protection AG, Joint Initiative representative

The existing standardised ring-tested test systems for assessing the toxicity of crop protection products to the non-target arthropods *Typhlodromus pyri* (Acari: Phytoseiidae) and *Aphidius rhopalosiphi* (Hymenoptera: Aphidiidae) (Blümel *et al.*, 2000 and Mead-Briggs *et al.*, 2000, respectively) are limit tests designed to compare a single use rate of the product with a water control. The suitability of these test systems for generating dose-response data as required for refined ecotoxicological risk assessment was evaluated. Data on dose-response toxicity of plant protection products (17 fungicides, 20 insecticides and 3 herbicides) to *T. pyri* and *A. rhopalosiphi* were generated under worst case laboratory and to *T. pyri* under extended laboratory conditions, and analysed using the standard Probit method, a logistic regression, a generalised Probit analysis and the moving average-angle method in order to calculate the LR_{50}-values (application rate killing 50 % of the exposed organisms). The fit of the models, the precision of the resulting LR_{50} values and the required minimum number of replicates were compared. In 85 % of the studies, at least one of the statistical methods led to satisfactory results. The results show that the existing guidelines can be used to perform dose-response tests. For a detailed descriptions of testing methods, statistical evaluation of the data and discussion of the results we refer to Grimm *et al.* (2001).

References:

Grimm C., Schmidli H., Bakker F., Brown K., Campbell P., Candolfi M.P, Chapman P., Harrison E.G., Mead-Briggs M., Schmuck R. and Ufer A., 2001: Use of standard toxicity tests with *Typhlodromus pyri* and *Aphidius rhopalosiphi* to establish a dose-response relationship. J. Pest Science (in press).

The Hazard Quotient Approach and Validation for Tier I Non-Target Arthropods Risk Assessment

Peter Campbell
Zeneca Agrochemicals, BART representative

The EU Plant Protection Product Directive 91/414/EEC recommends the EPPO/CoE Arthropod Natural Enemies Risk Assessment Scheme for guidance on how to conduct risk assessments for terrestrial non-target arthropods. This scheme is currently in the process of being revised by EPPO/CoE. A major change will be the recommendation for the generation and use of 'Dose Response' toxicity data instead of limit test data. In addition, the revised EPPO/CoE Non-target Arthropods Risk Assessment Scheme will replace the current arbitrary 30% threshold trigger value applied to limit test data, with a Hazard Quotient (HQ; = Ratio Application Rate / LC50 on Glass)), comparable to the successful approach adopted in the EPPO/CoE 'Honeybee Risk Assessment Scheme'. However, in order for this new approach to be implemented under 91/414/EEC, an appropriate regulatory HQ trigger value needs to be derived. Such an HQ trigger value has been established by calculating HQ values for the 2 recommended sensitive indicator species (*T. pyri* and *Aphidius*) for a wide range of products and validating opposite robust semi-field/field data. This validation indicated that an HQ trigger value of ≥12 for *T. pyri* and ≥8 for *Aphidius spp*., should be used to trigger higher-tier risk assessment and/or higher-tier testing for non-target arthropods. As these trigger values were validated with realistic semi-field/field data they apply for both lethal and sub-lethal effects as well as single and multiple application scenarios. Due to the worst case assumptions used in this HQ validation analysis, no further uncertainty factors need to be applied for in-field risk assessment. Whilst a small amount of uncertainty exists regarding the comparative sensitivity of *T. pyri* and *Aphidius spp*. for off-field non-target arthropod guilds of arthropods, this is balanced by the fact that the off-crop exposure assessment used in the HQ derivation, is at least an order of magnitude higher than that realistically likely in the field. This HQ approach and trigger value is an appropriate and conservative tool for tier 1 risk assessment, which should reduce the number of false positive results leading to unnecessary higher-tier testing.

References:

Campbell P.J., Brown K.C., Harrison E.G., Bakker F., Barrett K.L., Candolfi M.P., Cañez V., Dinter A., Lewis G., Mead-Briggs M., Miles M., Neumann P., Romijn K., Schmuck R., Shires S., Ufer A. and Waltersdorfer A., 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. J. Pest Science 73 (5): 117-124.

Risk Mitigation

Jim Orson
Morley Research Centre, UK

There is increased pressure on European arable farming both to compete on world markets while at the same time to increase the biodiversity of the countryside. These can be competing objectives and so specific measures may be necessary. Minimising the impact of pesticides on non-target organisms or non-target areas of the landscape can be significantly influenced by registration procedures including limiting where pesticides that pose a risk can be used. This paper discusses some of the issues.

The major trends in arable farming in Northern Europe are:

- Prices of commodity crops now reflect world prices.
- World prices are low and are likely to be low in the medium term.
- Arable farms are responding by getting larger and by minimising labour costs.
- Large fields are proving to be a big advantage in labour efficiency and minimising yield losses due to field boundaries.

Field size:

- Optimum size for labour efficiency and minimising the impact on yield of field boundaries is above 30 ha.
- The area of uncropped land between 30 ha fields can be as low as 1% of the total area.
- Uncropped land is a vital habitat for biodiversity although there is also the requirement to improve within crop biodiversity.

Role of cropped or uncropped buffer strips around field edges:

- Reduce pollution caused by pesticides and fertilisers.
- Provide habitats to encourage biodiversity.

Problems with zones around field edges, where some but not all pesticides are restricted:

- Farmer acceptance - what are these areas for and what is in it for them?
- Inconvenience where a pesticide used in the field may not be able to be used close to the field edge and an inferior pesticide has to be used in this area. The additional time for application is very significant and crop losses may occur due to having to use an inferior pesticide, particularly where they are applied with a 24 metre sprayer.

Solution:

- Keep farmers informed about what restricted pesticide zones around fields are trying to achieve.
- Provide a decision making structure which involves farmers and which gives them incentives to improve practice. A good example is LERAPs (Local Environmental Risk Assessment for Pesticides) introduced in the UK to protect watercourses. Farmers using approved low drift spray equipment can reduce the width of the no-spray zone next to water from 5m to 1m for all pesticides except organo-phosphates and pyrethroids.
- Targeting risk mitigation measures at large fields in particular.

Appendix IV

Definitions of the 'within and off-field areas' as used by the EPPO/Council of Europe Panel on Environmental Risk Assessment

W.W.M. Brouwer, P. Jellema, P.A. Oomen and A.J.W. Rotteveel
(on request of the EPPO Panel on Environmental Risk Assessment)
Plant Protection Service, Wageningen NL, April 2000

Background

The Panel on Environmental Risk Assessment has discussed several times the topic of risk assessment within and off-crop areas. Discerning and defining these areas is relevant for assessing risks arising from drift deposition and run-off during application of agricultural pesticides. Risk assessment and risk management are usually different within the crop and outside the crop. Therefore, clear definitions to separate these areas are needed. These definitions are relevant for assessment and management of each of the environmental risks of plant protection products. On request of the Panel, the Netherlands Plant Protection Service has prepared these definitions which were discussed and accepted by the Panel in March 2000.

Considerations

The definitions are intended to be consistent in different risk assessment schemes and be applicable to both aquatic and terrestrial elements of ecological interest adjacent to fields.
Good agricultural practice is used as a base for the definition. For this reason, the cropped area is defined as extending half a crop row distance beyond the centre of the last crop row.
The definitions must be applicable both to cropped fields as well as temporarily uncropped fields, i.e. including pre-emergence, cropping periods and after-harvest periods.
All physical landscape elements intended for reducing drift outside the field and mitigating adverse ecological impacts are considered to be located *within* the field.
Landscape elements of ecological interest, either aquatic or terrestrial, are situated *outside* the field.
Plant protection products are not necessarily used in crops, nor are these necessarily used during cropping periods. Therefore it is better to speak of and to define off-*field* risk assessment in stead of off-*crop* risk assessment.

Definitions

A *field* (or *within-field area*) is the land intended for agricultural production activities (including horticulture and forestry). The *field* includes *a cropped area* and *field margins*.

A *cropped area* is that part of the *field* intended to grow the crop. It does extend half a row distance beyond the centre of the last crop row.

A *field margin* is the outer part of the *field*, between the *cropped area* and the *off-field area*.
The *field margin* includes the parts of land used for agricultural purposes such as roads and fences, wind breaks, and vegetation planted for reduction of drift (catch crop) and run-off.

The *off-field area* is all area surrounding the *field.* The *off-field area* includes natural and semi-natural habitats, in particular ditches, watercourses, lakes, hedgerows and woodland.

The *edge of the field* is the boundary line between the *field margin* and the *off-field area*.

Possible confusion may arise from the word *buffer zones.* A definition of buffer zones is not included in the above set of definitions, because this is not relevant for the purpose of EPPO. Nevertheless, a description is given below to set this commonly used word in the perspective of the above set of definitions. A *buffer* zone is the strip of land adjoining the cropped area where it is not allowed to use the pesticide of concern. *Buffer zones* and *field margins* may overlap but are not identical. *Buffer zone* restrictions may vary for different plant protection products and application methods. They can be set to mitigate risks arising from emission (drift, run-off, etc) towards the off-field area. Buffer zones can either be non-spraying zones, or non-cropped (with the crop of concern) zones.

Appendix V

Multiple Application Factor

Multiple Application Factor (MAF) for various half-life ($T_{1/2}$) : spray interval ratios and up to 8 (n) applications. Table extracted from: Gonzalez-Valero J.F., Campbell P.J., Fritsch H.J., Grau R. and Romijn K., 2000: Exposure assessment for terrestrial non-target arthropods. J. Pest Science 73 (6): 163-168.

$T_{1/2}$: Spray Interval	**MAF after n applications, where n =**							
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
1 : 16	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
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

Note: When dissipation data ($T_{1/2}$) are not available, default values which represent the 90th percentile of a data base of 32 products (for details see Gonzalez-Valero *et al.*, 2000) can be used for allocating a half-life ($T_{1/2}$) : spray interval ratio to this compound. The default values (highlighted by shadowed rows) differ between soil (= 6:1) and leaf substrates (= 2.3:1) since the half-life in soil is usually substantially higher than on leaves. Accordingly, for a product where dissipation times are not available, use a default ratio of 2.3:1 which applies to all arthropods in off-crop habitats (these habitats are usually vegetated) and to leaf-dwelling arthropods within the cropped area. For soil-dwelling arthropods within the crop a default ratio of 6:1 should be applied if the ground is not yet vegetated (e.g. pre-emergence herbicides, early stages of crop plants).

Where neither dissipation rates ($T_{1/2}$) nor the number of treatments is specified, it is recommended to use a default MAF value of 3.

Appendix VI

Drift values

Drift values tables according to BBA (Federal Biological Agency of Agriculture and Forestry, Germany), 2000: Bekanntmachung des Verzeichnisses risikomindernder Anwendungsbedingungen für Nichtzielorganismen. Bundesanzeiger 100: 9878-9880.

Basic drift values for one application Ground sediment in % of the application rate (90th percentiles)								
Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruits	
[m]		early	late	early	late		Height < 50 cm	Height > 50 cm
1	2.77						2.77	
3		29.20	15.73	2.70	8.02	19.33		8.02
5	0.57	19.89	8.41	1.18	3.62	11.57	0.57	3.62
10	0.29	11.81	3.60	0.39	1.23	5.77	0.29	1.23
15	0.20	5.55	1.81	0.20	0.65	3.84	0.20	0.65
20	0.15	2.77	1.09	0.13	0.42	1.79	0.15	0.42
30	0.10	1.04	0.54	0.07	0.22	0.56	0.10	0.22
40	0.07	0.52	0.32	0.04	0.14	0.25	0.07	0.14
50	0.06	0.30	0.22	0.03	0.10	0.13	0.06	0.10
75	0.04	0.11	0.11	0.015	0.05	0.04	0.04	0.05
100	0.03	0.06	0.06	0.009	0.03	0.02	0.03	0.03
125	0.025	0.03	0.04	0.007	0.024	0.01	0.025	0.024
150	0.021	0.021	0.03	0.005	0.018	0.006	0.021	0.018
175	0.018	0.015	0.024	0.004	0.014	0.004	0.018	0.014
200	0.016	0.011	0.019	0.003	0.011	0.003	0.016	0.011
225	0.014	0.008	0.016	0.003	0.010	0.002	0.014	0.010
250	0.012	0.006	0.013	0.002	0.008	0.001	0.012	0.008

Basic drift values for two applications Ground sediment in % of the application rate (82nd percentiles)								
Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruits	
[m]		early	late	early	late		Height < 50 cm	Height > 50 cm
1	2.38						2.38	
3		25.53	12.13	2.53	7.23	17.73		7.23
5	0.47	16.87	6.81	1.09	3.22	9.60	0.47	3.22
10	0.24	9.61	3.11	0.35	1.07	4.18	0.24	1.07
15	0.16	5.61	1.58	0.18	0.56	2.57	0.16	0.56
20	0.12	2.59	0.90	0.11	0.36	1.21	0.12	0.36
30	0.08	0.87	0.40	0.06	0.19	0.38	0.08	0.19
40	0.06	0.40	0.23	0.03	0.12	0.17	0.06	0.12
50	0.05	0.22	0.15	0.02	0.08	0.09	0.05	0.08
75	0.03	0.07	0.07	0.01	0.04	0.03	0.03	0.04
100	0.023	0.03	0.04	0.008	0.03	0.01	0.023	0.03
125	0.019	0.02	0.024	0.005	0.02	0.007	0.019	0.02
150	0.015	0.011	0.017	0.004	0.015	0.004	0.015	0.015
175	0.013	0.008	0.013	0.003	0.012	0.003	0.013	0.012
200	0.012	0.005	0.010	0.002	0.009	0.002	0.012	0.009
225	0.010	0.004	0.008	0.002	0.008	0.001	0.010	0.008
250	0.009	0.003	0.006	0.002	0.007	0.001	0.009	0.007

Basic drift values for three applications Ground sediment in % of the application rate (77th percentiles)								
Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruits	
[m]		early	late	early	late		Height < 50 cm	Height > 50 cm
1	2.01						2.01	
3		23.96	11.01	2.49	6.90	15.93		6.90
5	0.41	15.79	6.04	1.04	3.07	8.57	0.41	3.07
10	0.20	8.96	2.67	0.32	1.02	3.70	0.20	1.02
15	0.14	5.23	1.39	0.16	0.54	2.26	0.14	0.54
20	0.10	2.36	0.80	0.10	0.34	1.05	0.10	0.34
30	0.07	0.77	0.36	0.05	0.18	0.34	0.07	0.18
40	0.05	0.35	0.21	0.03	0.11	0.15	0.05	0.11
50	0.04	0.19	0.13	0.02	0.08	0.08	0.04	0.08
75	0.03	0.06	0.06	0.01	0.04	0.03	0.03	0.04
100	0.021	0.03	0.03	0.006	0.03	0.01	0.021	0.03
125	0.017	0.015	0.022	0.004	0.02	0.007	0.017	0.02
150	0.014	0.009	0.016	0.003	0.014	0.004	0.014	0.014
175	0.012	0.006	0.012	0.002	0.011	0.003	0.012	0.011
200	0.010	0.004	0.009	0.002	0.009	0.002	0.010	0.009
225	0.009	0.003	0.007	0.002	0.007	0.001	0.009	0.007
250	0.008	0.002	0.006	0.001	0.006	0.001	0.008	0.006

Basic drift values for four applications Ground sediment in % of the application rate (74th percentiles)								
Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruits	
[m]		early	late	early	late		Height < 50 cm	Height > 50 cm
1	1.85						1.85	
3		23.61	10.12	2.44	6.71	15.38		6.71
5	0.38	15.42	5.60	1.02	2.99	8.26	0.38	2.99
10	0.19	8.66	2.50	0.31	0.99	3.55	0.19	0.99
15	0.13	4.91	1.28	0.16	0.52	2.17	0.13	0.52
20	0.10	2.21	0.75	0.10	0.33	0.93	0.10	0.33
30	0.06	0.72	0.35	0.05	0.17	0.31	0.06	0.17
40	0.05	0.32	0.20	0.03	0.11	0.14	0.05	0.11
50	0.04	0.17	0.13	0.02	0.08	0.08	0.04	0.08
75	0.03	0.06	0.06	0.01	0.04	0.02	0.03	0.04
100	0.019	0.03	0.04	0.006	0.03	0.01	0.019	0.03
125	0.016	0.014	0.023	0.004	0.02	0.006	0.016	0.02
150	0.013	0.008	0.016	0.003	0.014	0.004	0.013	0.014
175	0.011	0.005	0.012	0.002	0.011	0.002	0.011	0.011
200	0.010	0.004	0.010	0.002	0.009	0.002	0.010	0.009
225	0.009	0.003	0.008	0.002	0.007	0.001	0.009	0.007
250	0.008	0.002	0.006	0.001	0.006	0.001	0.008	0.006

Basic drift values for five applications Ground sediment in % of the application rate (72nd percentiles)								
Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruits	
[m]		early	late	early	late		Height < 50 cm	Height > 50 cm
1	1.75						1.75	
3		23.12	9.74	2.37	6.59	15.12		6.59
5	0.36	15.06	5.41	1.00	2.93	7.99	0.36	2.93
10	0.18	8.42	2.43	0.31	0.98	3.36	0.18	0.98
15	0.12	4.61	1.24	0.15	0.51	2.03	0.12	0.51
20	0.09	2.09	0.72	0.09	0.33	0.88	0.09	0.33
30	0.06	0.69	0.34	0.05	0.17	0.29	0.06	0.17
40	0.05	0.31	0.20	0.03	0.11	0.14	0.05	0.11
50	0.04	0.17	0.13	0.02	0.08	0.07	0.04	0.08
75	0.025	0.06	0.06	0.01	0.04	0.02	0.025	0.04
100	0.018	0.03	0.03	0.006	0.03	0.01	0.018	0.03
125	0.015	0.014	0.023	0.004	0.02	0.006	0.015	0.02
150	0.012	0.008	0.016	0.003	0.013	0.004	0.012	0.013
175	0.011	0.005	0.012	0.002	0.010	0.003	0.011	0.010
200	0.009	0.004	0.009	0.002	0.008	0.002	0.009	0.008
225	0.008	0.003	0.008	0.002	0.007	0.001	0.008	0.007
250	0.007	0.002	0.006	0.001	0.006	0.001	0.007	0.006

Basic drift values for six applications Ground sediment in % of the application rate (70th percentiles)								
Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruits	
[m]		early	late	early	late		Height < 50 cm	Height > 50 cm
1	1.64						1.64	
3		22.76	9.21	2.29	6.41	14.90		6.41
5	0.34	14.64	5.18	0.97	2.85	7.79	0.34	2.85
10	0.17	8.04	2.38	0.30	0.95	3.23	0.17	0.95
15	0.11	4.51	1.20	0.15	0.50	1.93	0.11	0.50
20	0.09	2.04	0.68	0.09	0.32	0.83	0.09	0.32
30	0.06	0.66	0.31	0.05	0.17	0.28	0.06	0.17
40	0.04	0.30	0.17	0.03	0.11	0.13	0.04	0.11
50	0.03	0.16	0.11	0.02	0.07	0.07	0.03	0.07
75	0.023	0.05	0.05	0.01	0.04	0.02	0.023	0.04
100	0.018	0.02	0.03	0.006	0.02	0.01	0.018	0.02
125	0.014	0.013	0.018	0.004	0.017	0.006	0.014	0.017
150	0.012	0.008	0.013	0.003	0.013	0.003	0.012	0.013
175	0.010	0.005	0.009	0.002	0.010	0.002	0.010	0.010
200	0.009	0.004	0.007	0.002	0.008	0.002	0.009	0.008
225	0.008	0.003	0.006	0.002	0.007	0.001	0.008	0.007
250	0.007	0.002	0.005	0.001	0.006	0.001	0.007	0.006

Basic drift values for seven applications Ground sediment in % of the application rate (69th percentiles)								
Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruits	
[m]		early	late	early	late		Height < 50 cm	Height > 50 cm
1	1.61						1.61	
3		22.69	9.10	2.24	6.33	14.63		6.33
5	0.33	14.45	5.11	0.94	2.81	7.60	0.33	2.81
10	0.17	7.83	2.33	0.29	0.94	3.13	0.17	0.94
15	0.11	4.40	1.20	0.15	0.49	1.86	0.11	0.49
20	0.08	1.99	0.67	0.09	0.31	0.81	0.08	0.31
30	0.06	0.65	0.30	0.05	0.16	0.26	0.06	0.16
40	0.04	0.29	0.17	0.03	0.10	0.12	0.04	0.10
50	0.03	0.16	0.11	0.02	0.07	0.06	0.03	0.07
75	0.023	0.05	0.05	0.01	0.04	0.02	0.023	0.04
100	0.017	0.02	0.03	0.006	0.02	0.01	0.017	0.02
125	0.014	0.013	0.017	0.004	0.017	0.005	0.014	0.017
150	0.012	0.008	0.012	0.003	0.013	0.003	0.012	0.013
175	0.010	0.005	0.009	0.002	0.010	0.002	0.010	0.010
200	0.009	0.003	0.007	0.002	0.008	0.001	0.009	0.008
225	0.008	0.003	0.005	0.002	0.007	0.001	0.008	0.007
250	0.007	0.002	0.004	0.001	0.006	0.001	0.007	0.006

Basic drift values for more than seven applications Ground sediment in % of the application rate (67th percentiles)								
Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruits	
[m]		early	late	early	late		Height < 50 cm	Height > 50 cm
1	1.52						1.52	
3		22.24	8.66	2.16	6.26	13.53		6.26
5	0.31	14.09	4.92	0.91	2.78	7.15	0.31	2.78
10	0.16	7.58	2.29	0.28	0.93	3.01	0.16	0.93
15	0.11	4.21	1.14	0.14	0.49	1.82	0.11	0.49
20	0.08	1.91	0.65	0.09	0.31	0.78	0.08	0.31
30	0.05	0.62	0.29	0.04	0.16	0.25	0.05	0.16
40	0.04	0.28	0.16	0.03	0.10	0.12	0.04	0.10
50	0.03	0.15	0.11	0.02	0.07	0.06	0.03	0.07
75	0.022	0.05	0.05	0.009	0.04	0.02	0.022	0.04
100	0.017	0.02	0.03	0.006	0.02	0.01	0.017	0.02
125	0.013	0.012	0.017	0.004	0.017	0.005	0.013	0.017
150	0.011	0.007	0.012	0.003	0.013	0.003	0.011	0.013
175	0.010	0.005	0.009	0.002	0.010	0.002	0.010	0.010
200	0.008	0.003	0.007	0.002	0.008	0.001	0.008	0.008
225	0.007	0.002	0.005	0.001	0.007	0.001	0.007	0.007
250	0.007	0.002	0.004	0.001	0.006	0.001	0.007	0.006