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# Revised proposal for the risk assessment of persistence of plant protection products in soil

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# Abstract

**Revised proposal for the risk assessment of persistence of plant protection products in soil**

This report gives revised guidance for the environmental risk assessment of persistency of plant protection products in soil where European legislation is absent.

This report considers three protection goals for soils: 1) protection of soil functions relevant to agricultural production, 2) protection of the structure of agro-ecosystems, and 3) protection of the structure of soil ecosystems in general. Existing guidance at the EU level considers the first protection, so this is not elaborated upon in this report. For the two other protection goals, the report proposes decision schemes in which both exposure and ecotoxicological effects are assessed in a tiered approach. The evaluation is triggered when the half-life of a substance in soil exceeds a value of 90 respectively 180 days.

In line with the European regulations on plant protection products, the guidance considers all relevant scientific information. The revised proposal provides points of departure for further guidance development at the European level.

Key words:
decision tree, ecotoxicological effects, persistence in soil, pesticides, protection goals

# Rapport in het kort

**Aangepast voorstel voor de risicobeoordeling van persistentie van gewasbeschermingsmiddelen in de bodem**

Dit rapport geeft aangepaste richtlijnen voor de beoordeling van milieurisico's van gewasbeschermingsmiddelen die lang in de bodem aanwezig blijven. Deze richtlijnen geven een nadere invulling aan de Europese regelgeving.

Het rapport onderscheidt drie beschermdoelen voor de bodem: 1) behoud van landbouwkundige bodemfuncties, 2) behoud van structuur van levensgemeenschappen van agro-ecosystemen en 3) bescherming van de structuur van bodemlevensgemeenschappen in natuurgebieden. De risicobeoordeling op Europees niveau beschouwt het eerste beschermdoel en blijft daarom buiten beschouwing. De twee overige beschermdoelen zijn vooral toegespitst op de Nederlandse situatie en kunnen later voor Europese regelgeving worden uitgewerkt.

Om tot een nauwkeurigere beoordeling te komen stelt het rapport voor om zowel aan de blootstellingskant als aan de effectenkant met getrapte systemen te werken. Deze beslisbomen worden gehanteerd bij achtereenvolgens halfwaardetijden van de stoffen in de bodem boven 90 en 180 dagen. Stoffen met dergelijke halfwaardetijden werden vroeger in Nederland op een andere manier beoordeeld of niet toegestaan. De nieuwe richtlijnen betrekken alle wetenschappelijke informatie in de beoordeling, zoals de Europese gewasbeschermingsmiddelenrichtlijn vereist.


Trefwoorden:
beschermdoelen, beslisboom, bestrijdingsmiddelen, ecotoxicologische effecten, persistentie in de bodem

# Contents

# Summary

**Why this assessment procedure?**
Persistence of plant protection products in soil is one of the aspects included in the evaluation of plant protection products in the EU as well as in member states. At the EU level there is a general agreement on trigger values that indicate the need for further research, but there are different views on the assessment and the interpretation of this additional information at the national level. As a result, member states adopted different evaluation procedures. For example, the Netherlands included a cut-off value of 180 days for the dissipation half-life ($DT_{50}$) in soil. Most other countries in the EU do not use a cut-off value.

**What was the remit of the workgroup?**
The Netherlands' Ministry of Agriculture, Nature and Food Quality (LNV) and the Netherlands' Ministry of Spatial Planning, Housing and the Environment (VROM) asked the workgroup to evaluate the 2006 proposal for the evaluation of persistency of plant protection products in soil. The workgroup concluded that a revision of the proposal would be appropriate. The most important change is that the functional redundancy principle, which is already assessed at the European level, is taken out of the proposal.

**What are the protection goals?**
The workgroup proposes to consider up to three principles to set protection goals for soil, each having its own timeframe:

| principle to set protection goal | time scale |
|---|---|
| Functional Redundancy Principle (FRP) | in year of cropping |
| Community Recovery Principle (CRP) | two year post last application |
| Ecological Threshold Principle (ETP) | seven years post last application |

The goals are:
1. Protection of life-support functions of the in-crop soil to allow the growth of the crop and protection of key(stone) species (earthworms) of agricultural soils (FRP). This protection goal is assessed at the European level and not further discussed in this report.
2. Protection of life-support functions of the soil to allow crop rotation and sustainable agriculture, with overall protection of the structure and functioning of soil communities characteristic for agro-ecosystems (CRP).
3. Protection of life-support functions of the soil to allow changes in land use, with overall protection of the structure and functioning of soil communities characteristic for nature reserves (ETP).

The approach has been developed for the in-crop area.

**What are the trigger values?**

The half-life for dissipation ($DT_{50}$) of a chemical from soil acts as a trigger value for evaluation according to one or more of the protection goals. Substances having a $DT_{50}$ above 90 days at 10 ºC are evaluated according to the CRP and substances having a $DT_{50}$ above 180 days at 10 ºC are additionally evaluated according to the ETP. The values trigger the assessment, but in general additional tests as well.

**What is the principle of the risk assessment?**

Predicted environmental concentrations ($PEC_s$) are compared to ecotoxicological relevant concentrations, for instance $EC_{50}$ or NOEC values of indicator species. The assessment evaluates whether, in the realistic worst case exposure, i.e. the 90th percentile, critical values of the exposure / toxicity ratio are exceeded. Substances which exceed the critical value can not be authorised. The critical values are derived based on EU Technical Guidance Documents; sometimes with a pronounced preference for one of the given options. The assessment can be based both on the total content of the substance as well as on the pore water concentration.

**What are the main elements of the assessment?**

Both at the exposure side and at the ecotox side, a tiered approach is suggested: ranging from simple and conservative, using higher assessment factors, to more complex and realistic, with lower assessment factors. The first tier of the exposure assessment uses a scenario that is generically vulnerable to persistence. This scenario is run several times, with different input sets in order to ensure conservative results for both total content and on pore water concentration. The second tier of the exposure assessment uses a spatially distributed model so that the realistic worst case condition is determined during the calculations. At the ecotox side, the CRP and ETP protection goals have separate ecotox assessment schemes, existing of three tiers each.

**What else is in this report?**

Usually test reports contain insufficient information to adequately determine exposure concentrations in the test. This report gives suggestions for deriving conservative exposure estimates for the test in case essential information is missing. A mathematical model for the calculation of Tier 1 exposure concentrations was developed. This report gives the concepts of this model and some guidance on the usage. Likewise, based on the same concepts a mathematical model for the calculation of exposure concentrations in test systems was developed.

Toxicological endpoints of metabolites are not always clear from higher tier experiments performed with the parent substance. This report gives some guidance on the derivation of (conservative) endpoints for metabolites.

# Samenvatting

**Waarom dit voorstel?**

Persistentie van gewasbeschermingsmiddelen is een van de aspecten van de toelatingsbeoordeling, in zowel de EU als in de lidstaten. Op EU-niveau is er overeenstemming over signaleringswaarden die aanvullend onderzoek indiceren, maar er is geen overeenstemming over de beoordeling. Als gevolg daarvan lopen beoordelingswijzen voor nationale toelatingen in de EU uiteen. Bijvoorbeeld: Nederland gebruikte een afkapwaarde van 180 dagen voor de halfwaardetijd voor verdwijning ($DT_{50}$) van stoffen uit de bodem; een afkapwaarde wordt in de meeste andere landen niet gebruikt.

**Wat was de opdracht van de werkgroep?**

De ministeries van LNV en VROM hebben de werkgroep gevraagd om het voorstel uit 2006 voor de beoordeling van persistentie van gewasbeschermingsmiddelen in de bodem te evalueren. De werkgroep concludeerde dat een aanpassing van het voorstel zinvol zou zijn om een betere aansluiting bij de Europese beoordeling te krijgen. De Europese beoordeling evalueert risico's voor het functioneren van de bodem. De werkgroep beveelt dan ook aan om dit onderdeel uit het voorstel van 2006 te schrappen.

**Wat zijn de beschermdoelen?**

De werkgroep stelt voor om drie principes te hanteren om beschermdoelen af te leiden, elk met zijn eigen tijdschaal:

| principe | tijdschaal |
|---|---|
| redundantie van functies (FRP) | in het groeiseizoen |
| herstel van levensgemeenschappen (CRP) | twee jaar na de laatste toepassing |
| ecologische drempelwaarde (ETP) | zeven jaar na de laatste toepassing |

De beschermdoelen zijn:

1. Bescherming van de bodem als drager van landbouwgewassen en bescherming van essentiële bodemorganismen zoals de regenworm (FRP). De risicobeoordeling voor dit beschermdoel gebeurt al in de Europese procedure en wordt daarom niet in dit rapport beschreven.
2. Bescherming van die functies van de bodem die essentieel zijn voor duurzame landbouw, met een overall bescherming van de structuur en het functioneren van organismen die kenmerkend zijn voor agro-ecosystemen (CRP).
3. Bescherming van functies van de bodem opdat een terugkeer naar natuurlijke ecosystemen mogelijk is, met een overall bescherming van de structuur en het functioneren van organismen die karakteristiek zijn voor natuurlijke ecosystemen (ETP).

De werkgroep heeft het systeem ontwikkeld voor de evaluatie van gewasbeschermingsmiddelen op behandelde percelen ('in-crop').

**Welke signaleringswaarden worden gebruikt?**

De halfwaardetijd ($DT_{50}$) voor dissipatie (verdwijning) van een stof uit de bodem wordt gebruikt om te achterhalen of een evaluatie van de persistentie moet worden uitgevoerd. Een halfwaardetijd boven 90 dagen bij 10 ºC indiceert een evaluatie volgens CRP en een halfwaardetijd boven 180 dagen bij 10 ºC bovendien een evaluatie volgens ETP. De signaleringswaarden indiceren in het algemeen ook extra onderzoek.

**Wat is het principe van de risico-evaluatie?**

In de evaluatie wordt de voorspelde blootstelling (PEC) gerelateerd aan een ecologisch relevante concentratie, bijvoorbeeld een 50% effect concentratie ($EC_{50}$) of geen waargenomen effect (NOEC) van een indicatororganisme. In de evaluatie wordt nagegaan of, in de realistisch meest kwetsbare (de 90% kwetsbare) situatie, de verhouding tussen blootstelling en toxiciteit een kritische waarde te boven gaat. Zo ja, dan kan een stof niet worden toegelaten. De kritische waarden worden afgeleid op basis van Technical Guidance Documents van de EU, met soms een uitgesproken voorkeur voor gegeven opties. Voor de blootstelling kan zowel het totaalgehalte in de grond als ook de poriewaterconcentratie worden gebruikt.

**Wat zijn de belangrijkste elementen van de beoordeling?**

Voor zowel de blootstelling als voor de ecotoxiciteit is een getrapte benadering opgesteld. Elke benadering loopt van simpel maar conservatief, tot complex maar realistisch. De eerste trap van de blootstellingskant gaat uit van een overall kwetsbare situatie voor persistentie; voor berekeningen worden verschillende invoersets gebruikt voor de berekening van het totaalgehalte en de berekening van de poriewaterconcentratie. De tweede trap van de beoordeling gebruikt een ruimtelijk variabel model; de 90% kwetsbare situatie wordt met dit model expliciet uitgerekend. Voor de ecotoxiciteit worden voor de CRP en ETP beschermdoelen afzonderlijke beslisbomen gebruikt, elk bestaand uit drie trappen.

**Wat biedt het rapport nog meer?**

Experimenten voor de bepaling van ecotoxiciteit in de bodem bevatten vaak onvoldoende informatie om de blootstellingsconcentratie in de test af te leiden. Dit rapport geeft suggesties voor het afleiden van een conservatieve schatting van de blootstellingsconcentratie als niet alle benodigde informatie aanwezig is. Voor de berekening van de blootstelling in de eerste trap van de beoordeling wordt een eenvoudig model gebruikt. Dit rapport geeft de concepten van dit model en enige aanwijzingen voor het gebruik. Evenzo geeft dit rapport de concepten van een model voor de berekening van blootstellingsconcentraties in testsystemen.

Toxicologische eindpunten voor metabolieten zijn niet altijd eenvoudig af te leiden uit een experiment. Dit rapport geeft een procedure om (conservatieve) eindpunten voor metabolieten af te leiden.

# 1 Introduction

In 2006 a methodology for risk assessment of plant protection product was proposed (Van der Linden et al., 2006). It was decided to evaluate this methodology by applying it to a small number of substances before it would be introduced into the authorisation procedure of plant protection products. This evaluation (Van der Linden et al., 2008) led to the conclusion that slight revisions of the methodology would be appropriate. This report describes the revised methodology. For easy reference and the sake of completeness, the chapters on European and national Dutch legislation (see chapter 2), The Functional Redundancy Principle (FRP, Appendix 9), test protocols (see Appendix 3) and relevant appendices are largely reproduced in this report. This report therefore replaces the report of 2006 (Van der Linden et al., 2006); the report is however still relevant for background information.

Appendix 1 gives a recapitulation of the basic concepts of tiered risk assessment approaches.

The validation exercise rendered a number of interpretation questions. Some guidance on questions for metabolites is given in chapter 6. Relatively simple mathematical models for the calculation of exposure concentrations in risk assessment as well as in test systems were developed. The concepts of these models and some guidance on the use are given in Appendix 6 and Appendix 7, respectively. Appendix 8 gives criteria for determining the reliability and the usefulness of ecotoxicological (semi-)field data relevant for persistence risk assessment.

The word conservative is used throughout the text meaning conservative from the regulatory point of view.

# 2 Relevant European and Dutch legislation and policies

## 2.1 Introduction

The significance of pesticide persistence in soil and water has been topic of scientific debate and investigations in the recent past. The fact that persistence is a cause of concern is not so much under dispute, in contrast to the way this concern is identified and dealt with most adequately (Craven, 2000; Craven and Hoy, 2005). With respect to the identification of persistency the criteria applied in the Uniform Principles on Decision Making (annex VI to the plant protection Directive 91/414/EEC) are partly comparable to the approaches taken under the following frameworks:

- the Uniform Principles to the Biocides Directive 98/8/EC;
- the EU REACH program on new and existing substances (see Appendix 5);
- the EU Human Medicines Directive 2004/28/EC (CHMP draft guidance document January 2005);
- the IMO Ballast Water Convention Procedure for approval of active substances (principle agreement 15-10-2004);
- Regulation 850/2004 of the European Parliament and of the Council (EU, 2004), covering both the Stockholm Convention on Persistent Organic Pollutants (see Appendix 4) and the UN ECE LRTAP POP protocol.

Since all EU regulations target the same high level of environmental protection as worded in the Treaty (Treaty on European Union), in principle there should be no difference in the protection level provided by these frameworks (Tarazona et al., 2003). Under all these frameworks persistent compounds are identified and assessed for environmental risks at equally or less strict thresholds as used for plant protection products, but different risk assessment approaches and regulatory decisions are applied.

Besides persistency, several other decision making criteria are operative under the Directive 91/414/EEC. Also, Regulation 850/2004/EC applies to active substances that may be on the market as plant protection products. The following is however not concerned with an analysis of all factors that influence the decision making under 91/414/EC, but only with the scientific strategy towards the 'unless clause' for persistency in soil as defined in the Uniform Principles.

Both the regulatory and the scientific strategy towards the 'unless clause' in the Uniform Principles for persistent plant protection products are not uniform between the member states within the EU. The assessment strategy for substances with $DT_{50} > 90$ days, or with > 70% bound residue and < 5% $CO_2$, differs considerably between EU Member States. A noted difference between EU Member States is the extent to which they are confident with current risk assessment practices at registration. Thus, there seems to be a scale from (on the one hand) the view that reasonably safe decisions can be taken also for persistent substances based on current risk based methodology, to (on the other hand) that there is a need for a 'safety net' (or upper limit, cut-off criterion) for persistent substances since the uncertainty in risk assessment is too large for these substances to allow safe enough decisions to be taken. Next to the Netherlands, the Nordic countries Sweden, Denmark and Norway applied the view on unacceptable uncertainty in the decision-making at certain cut-off values in the registration process. The Netherlands had codified this; the other states not (Montforts, 2006).

In view of the EU precautionary principle (see below), phasing out or disapproving of the authorisation of substances for which the environmental risk cannot be predicted with an acceptable degree of uncertainty, could be a legitimate regulatory decision[1]. In some regulatory frameworks substances that are deemed to be persistent (P), bioaccumulative (B), and toxic (T), are indeed not acceptable for registration or are candidates for phasing out. This approach is written down in the EU Technical Guidance Document on New and Existing Substances and Biocides (TGD) (EC, 2003)[2]. The Technical Committee on Soil Protection of the Netherlands (TCB) advised along these lines of reasoning on criteria for plant protection products. The TCB argued that authorisation of persistent pesticides would lead to extra risks compared to substances that are less persistent, due to the unavoidable uncertainty in the assessment (TCB, 2004). However, the current juridical interpretation of the Directive 91/414/EC leaves no room for the use of a stringent cut-off criterion based on persistency in national legislation[3] for plant protection products.

The purpose of this chapter is to elucidate the regulatory approach in the EU and the Netherlands legislation and policy to the protection of environmental assets, in order to focus on the targeted assessment of *persistent* substances used as plant protection products.

## 2.2 Environment and the EU plant protection product regulation

Environmental protection is one of the cornerstones of the European Union (EU). In Article 174 of the current Treaty a high level of protection of the environment is pursued: 'The Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay' (EC, 2002). Historically, European policy and legislation on environmental protection aim primarily at trans-national environmental assets, such as water and air, and transnational activities, such as disposal of waste.

The emphasis on environmental protection is notably also placed in another policy area, where the Treaty deals with legislation on harmonisation of the market for products. The protection of the environment as a limiting condition at the basis of any product regulation is underlined in article 95. This Article also requires that the assessment of the environmental impact should be based on the most recent scientific developments.

The EU has provided for special regulations on the marketing and assessment of plant protection products based on Article 95 of the Treaty, in which the protection of the environment is warranted. The way the protection of the environment is codified in this Directive provides for clues how to focus the scientific risk assessment of persistent substances. The environmental protection goal is not further

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[1] European Court of Justice Case 53/80 (kaasfabriek Eyssen (Nisin) [1981] ECR 409 at 422 f.) Member States cannot be reproached for discriminating arbitrarily …. when protective measures seem reasonably in view of 'difficulties and uncertainties' of risk assessments equally encountered by other countries or international organisations.

[2] 'For PBT substances a 'safe' concentration in the environment cannot be established with sufficient reliability. The PBT assessment is particularly developed to take into account the unacceptable high uncertainty in predicting reliable exposure and/or effect concentrations hampering quantitative risk assessment.'

[3] LJN: AO4263, College van Beroep voor het Bedrijfsleven, AWB 03/1068

specified in qualitative or quantitative terms in the Treaty. The environment has, as expected, been identified as a protection goal in Article 2 of the Directive 91/414/EEC[4]. The Directive establishes that the physical structures (water, land, air), wild species of flora and fauna, as well as 'ecosystems' (water, air, land, species, organisms and their relations) must be ensured –in general– of a high level of protection. According to Article 4 'Member States shall ensure that a plant protection product is not authorised unless the use has no unacceptable influence on the environment, with regards to fate and distribution in the environment, contamination of drinking water and groundwater, and to impact on non-target species'. The Uniform Principles (Annex VI to this Directive) follow up on this article. In the preambles to Directive 91/414/EEC a distinction is made between unacceptable influences on the environment in general on the one hand and harmful effects on groundwater in particular on the other. The influence on the environment should not be unacceptable; leaving room for interpretation of the degree of influence that is acceptable and of the degree of uncertainty in the proof that is acceptable. The phrasing in Article 95 of the Treaty that environmental conditions constitute reasons to refuse mutual recognition of authorisations is worded both in the preambles and in the Uniform Principles.

## 2.3     The Uniform Principles for Plant Protection Products

The Uniform Principles are the Annex VI to the Directive 91/414/EEC and contain a chapter Evaluation and a chapter Decision-Making. In the chapter Evaluation, the section General Principles specifies the risk-based approach to the assessment: not only should the assessment start with a realistic worst-case approach; this tier should always be followed by some kind of uncertainty analysis. In the chapter Evaluation a listing of evaluation criteria is given:

* soil (section 2.5.1.1);
* groundwater (section 2.5.1.2);
* surface water (section 2.5.1.3);
* air (section 2.5.1.4);
* and for non-target species (section 2.5.2) also a listing is provided (sections 2.5.2.1-6).

In every subsection of 2.5.1 and all subsections of section 2.5.2 it is stipulated[5] that where relevant, other authorised uses of plant protection products in the area of envisaged use containing the same active ingredient or which give rise to the same residues should be observed.

In the Uniform Principles the chapter Decision-Making states that since the evaluation is to be based on data concerning a limited number of representative species, Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species. Here, *preventing repercussions for the abundance and diversity of non-target species* is specified as a liability to the Member States. This liability is justified by the limited number of representative species in the assessment (uncertainty in the damage). Since it concerns a general principle of decision making under 91/414/EEC, it coerces Member States to assess long-term influence on abundance and diversity of non-target species and give the findings due weight in the decision making on registration. It is a liability that is not restricted to persistent substances, but it certainly is appropriate. How this liability should be fulfilled, otherwise than following the Specific Principles of decision making, is not specified.

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[4] 'environment': water, air, land, wild species of fauna and flora, and any interrelationship between them, as well as any relationship with living organisms;
[5] (except for 2.5.1.5 on procedures for destruction and decontamination of the plant protection product and its packaging)

The last chapter, the Specific Principles on Decision-Making quantify the uniform protection goals to a certain extent. The specific principles describe a minimum of legal commitments; they do not limit the liability of Member States. The first Specific Principle on Decision Making (section 2.5.1.1) deals with the quality of persistence[6]. In this section it is codified that persistency, ultimately determined in field soil, triggers an assessment of unacceptable impact on the environment, in accordance with the requirements set out for groundwater, surface water, air, and non-target organisms.

The paradox in the Uniform Principles is that the specified requirements in the unless-clause of section 2.5.1.1, already apply for all substances through the same Specific Principles: sections 2.5.1.2-.4 and sections 2.5.2.1-.6. This leaves us with the question: what should make the difference for persistent compounds? As concluded above, although the Specific Principles on Decision-Making make the protection goal of the environment qualitative and quantified, they do not limit the liability of Member States. Ensuring a high level of protection of the environment and preventing repercussions for the abundance and diversity of non-target species were specified as liabilities for Member States. The assessment procedure must scientifically demonstrate that there are no unacceptable effects for every of the enumerated criteria. A repeat assessment for persistent substances, taking uncertainties and regional differences in parameter values (scenarios), distribution models and effect models into account, is very much in order here. The objective of a procedure for the repeat assessment of persistent substances shall notably be to protect the entire environment, and not just the soil.

## 2.4     Protection goals and assessment strategies

The definition of the level of protection the assessment should aim at is very important in determining the scientific assessment strategy. The statement that the influence on the environment should not be unacceptable leaves room for interpretation of the degree of influence that is acceptable. The EU legislation on plant protection products provides no further criteria to enumerate the level of protection.

In designing a tailor-made scientific assessment strategy for persistent substances used as plant protection products, the definition of the individual protection levels needs to be made in terms of acceptability of risk and of uncertainty. Acceptability of effects and long-term repercussions for abundance and diversity of non-target species have, however, not been elaborated upon in the EU legislation. The definition of protection goals is thus up to the national authority.

The level of acceptability may be different in space and time (for example in-crop, off-crop, agricultural destination, and nature destination). The Netherlands policy on soil protection (TK, 2003) has

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[6] section 2.5.1.1. No authorisation shall be granted if the active substance and, where they are of significance from the toxicological, ecotoxicological or environmental point of view, metabolites and breakdown or reaction products, after use of the plant protection product under the proposed conditions of use:
- during tests in the field, persist in soil for more than one year (i.e. $DT_{90} > 1$ year and $DT_{50} > 3$ months), or
- during laboratory tests, form not extractable residues in amounts exceeding 70% of the initial dose after 100 days with a mineralization rate of less than 5% in 100 days,
unless it is scientifically demonstrated that under field conditions there is no accumulation in soil at such levels that unacceptable residues in succeeding crops occur and/or that unacceptable phytotoxic effects on succeeding crops occur and/or that there is an unacceptable impact on the environment, according to the relevant requirements provided for in sections 2.5.1.2, 2.5.1.3, 2.5.1.4 and 2.5.2.

exemplified the protection goals and protection levels of land in use for agriculture or for nature conservation with respect to chemicals. The Netherlands Technical Committee on Soil Protection (TCB) recently published a report on sustainable agricultural use of the soil. Aspects of time and space are elaborated in this report and the importance of chemical, physical and biological soil quality is stressed. For the longer term time scale, Netherlands reference values and negligible concentration levels are advised as assessment endpoints for soil protection (TCB, 2005). These quality standards are not the thresholds that require soil remediation. The agricultural requirements in these policy documents are in consonance with the detailed requirements of the 91/414/EEC regarding the protection of plants and plant products, and animals through foodstuff. The minimum quality protection level for water (including sediment) in the Netherlands is defined at the Maximum Permissible Concentration (MPC), and the ultimate policy target is the Negligible Concentration (NC) (NW4, 1998). The MPC also serves as the quality standard required by the Water Quality Act (following the requirements of the Directive 76/464/EEC (Van Rijswick, 2001)). The policy on protection of groundwater follows the requirements of both the Plant Protection Products Directive 91/414/EEC and of the groundwater protection Directive 80/68/EEC (TK, 1989).

Negligible concentrations (NC) for soil are derived from the MPC. The MPC is a concentration above which the impact, or the likelihood of impact, is considered unacceptable. At this level a proper functioning of processes and species is expected (for example translated in a 95% protection level in a log-normal distribution of no-effect-concentrations). The MPC is derived from an assessment of impact on species, functions, and secondary poisoning. At this moment the methodology to be used for soil is in the ECB Technical Guidance Document (EC, 2003). This means that a MPC equals the PNEC as defined in the Uniform Principles for Biocides in the EU Directive 98/8/EC, both in methodology and in protection goal. In principle there should be no difference in the protection level provided by the plant protection products Directive and the Biocides Directive, since many substances are both used as pesticides and as biocides and both Directives follow up on Article 95 of the Treaty (Tarazona et al., 2003). What is important is that deterministic and statistical approaches and even full field studies can be incorporated into the derivation of the MPC (Sijm et al., 2001). The derivation of an MPC is therefore compatible with the unless-clause of the Uniform Principles. The unless-clause provides the opportunity to the applicant to demonstrate the absence of negative effects, which can be used to (re-)establish the MPC.

The use of different chemicals may result in a combined exposure level that, although each chemical is present at its MPC, the combination causes undesirable effects. The NC quality standard accounts for this possible combination of effects of different chemicals. The NC is numerically defined as 1/100 of the MPC. However, in practice it will not be possible to demonstrate that, when the application leads to an exposure level that is higher than the concentration defined by the MPC/100, the effects of that particular residue under field conditions will be acceptable, simply because the effect level of the NC has not been defined. The use of the NC is hence irreconcilable with the system worded in the 91/414/EEC, since the applicant could never demonstrate that there are no unacceptable effects. It is therefore necessary to develop a scientifically underpinned, quantifiable standard for effects resulting from an application, demonstrable under field conditions, and reconcilable with the nature conservation function. This will allow the applicant to demonstrate that under field conditions there are no unacceptable effects.

In the next step, that is the scientific assessment of the environmental risk, the policy principle of the precautionary approach plays a central role. The precautionary principle was introduced in the Treaty

with respect to the environment. The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty (COM, 2000). In view of scientific uncertainties on the possibility of adverse effects or on the extent of damage authorities are justified in making conservative decisions. The precautionary principle, which is essentially to be used by decision makers in the management of risk, should not be confused with the element of (precautionary) caution that scientists apply in their assessment of scientific data. Apart from the (un)certainty of the risk, the uncertainty of the damage is to be observed in a (scientific) precautionary approach (Sanderson and Petersen, 2002; De Sadeleer, 2002). A risk assessment for plant protection products making use of relevant data will provide for a scientific alternative to the cut-off criteria as such. The assessment strategy should focus at reducing or compensating the inherently increasing uncertainty in the results in order to make reasoned decision-making scientifically justified.

## 2.5 The assessment of persistency: towards a consistent approach

From the analysis of the Directive 91/414/EEC it is understood that in addition to the minimum requirements of the uniform Principles, the risk assessment of unacceptable influence of persistent substances on the environment is concerned with:

- every compartment (soil, groundwater, surface water, air) and living organisms, their relations and connections (Articles 2 and 4 of 91/414/EEC);
- taking into account the use of other products containing the same substance or giving rise to the same residues in the envisaged area of use (Annex VI Specific Principles of Evaluation);
- taking regional environmental conditions into account;
- a repeat risk evaluation to determine whether it is possible that the initial evaluation could have been significantly different (Annex VI General Principles Evaluation), taking account of:
- potential uncertainties in the critical data and of;
- a range of use conditions that are likely to occur and;
- resulting in a realistic worst-case approach;
- thus preventing that the use of plant protection products has long-term repercussions for abundance and diversity of non-target species in all compartments (Annex VI General Principles of Decision Making).

In conclusion: persistent substances are to be subjected to a risk assessment in greater detail on the possible consequences of their persistence property, a longer residence time. Persistence results in an increased likelihood for identical residues accumulating (for example due to the use of other products), an increased likelihood for transportation and a longer exposure time at possibly effective concentrations. National environmental policy on soil and water has provided for differentiated and quantifiable quality standards in space and time.

A risk evaluation under worst-case conditions should be performed for soil, water, air, and biota. The influence of leaching, drainage and evaporation on the dissipation kinetics from soil should be taken into account in the assessment, and an evaluation of fate and distribution of residues via these routes should be performed according to the respective decision trees on groundwater, surface water and air.

For persistent substances a thorough evaluation of the ecotoxicity is recommendable, including a wide array of species, processes, bioaccumulation and secondary poisoning. Compared to the initial

evaluation, the selection of data and scenarios must be realistic worst-case, thus further reducing the likelihood that both realistic high exposure levels and unacceptable effects are overlooked (hereby decreasing uncertainty).

Notwithstanding the decision tree and risk assessment strategy that will be proposed in this report, it is taken into consideration that the risk assessment of widespread use of products in the European Union is outside the scope of the proposed risk assessment strategy for national registration. Taking the binding force of the Stockholm Convention (UNEP, 2001) into account, plant protection products that comply with the Stockholm Criteria on Persistent Organic Pollutants should be notified as such. The European Commission and the Netherlands have signed the Final Act of the Conference of Plenipotentiaries on the Stockholm Convention on Persistent Organic Pollutants on 23 May 2001 in Stockholm; the Netherlands accepted the treaty on 28-8-2002. The treaty became legally binding on May 17th, 2004, and is further effected in the Regulation 850/2004 (EU, 2004).

# 3 Ecological Protection goals

## 3.1 Introduction

The aim of this chapter is to discuss the relation between ecological protection goals and endpoints that can be used to evaluate the risks of plant protection products (PPPs), with reference to their persistence in soils of agro-ecosystems and their impact on in soil terrestrial (agro)-ecosystems. The question at stake is whether the normal agricultural use of a PPP with a relatively slow dissipation rate in soils is in conflict with the desire of a sustainable protection of communities of soil organisms in agro-ecosystems.

Most regulatory documents that deal with PPPs are based on policy goals that are ambiguous or difficult to define or measure. In the EU Uniform Principles (EU, 1997) it is for example stated that:

- the influence of PPPs on the environment should <u>not be unacceptable</u> (*comment: leaving room for interpretation of the degree of impact that is acceptable*);
- member states shall ensure that use of PPPs does not have any <u>long-term</u> repercussions for the abundance and diversity of non-target species (*comment: suggesting that shorter-term impacts followed by recovery may be acceptable*);

No authorisation shall be granted if an active substance (and its relevant metabolites) after use under the proposed conditions of use:

- during tests in the field, persist in soil for more than one year (i.e. $DT_{90} > 1$ year and $DT_{50} > 3$ months), or,
- during laboratory tests, form not extractable residues in amounts exceeding 70% of the initial dose after 100 days and have a mineralization rate of less than 5% in 100 days;
  <u>unless it is scientifically demonstrated</u> that under field conditions there is no accumulation in soil at such levels that <u>unacceptable residues in succeeding crops</u> occur and/or that <u>unacceptable phytotoxic effects on succeeding crops</u> occur and / or that there is <u>no unacceptable effect on the environment</u> (including impact on non-target species) *(comment: suggesting a science based risk assessment if certain persistence triggers are exceeded, and that in higher tiers further tests with plants and soil organisms may be conducted to assess the risks of the bioavailable fraction of the persistent substances).*

In the Uniform Principles and the EU Guidance Document on Terrestrial Ecotoxicology (SANCO, 2002) the first tier risk assessment procedure for soil organisms is well described in contrast to the unless procedures, namely:
Member States shall evaluate the possibility of exposure of earthworms and other non-target soil macro-organisms to the plant protection product under the proposed conditions of use; …

- No authorisation shall be granted if the acute toxicity / exposure ratio for earthworms is less than 10 or the long-term toxicity / exposure is less than 5, *unless it is clearly established through an appropriate risk assessment that under field conditions earthworm populations are not at risk after use of the plant protection product according to the proposed conditions of use.*
- No authorisation shall be granted if the nitrogen or carbon mineralization processes in laboratory studies are affected by more than 25% after 100 days, *unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on microbial activity after use of the PPP according to the proposed conditions of use.*

- All compounds having a field $DT_{90} > 365$ days must be assessed for their impact on organic matter breakdown, whereas those with a field $DT_{90} < 100$ days do not have to be tested for this aspect. In agreement with the current Guidance Document on Terrestrial Ecotoxicology, those PPPs with an intermediate persistence (field $DT_{90} \geq 100$ and $\leq 365$ days) should be evaluated with a litter bag test, if significant effects to individual soil organisms or groups of soil organisms have been demonstrated (effect on soil micro-organisms > 25% after 100 d; long-term TER earthworms < 5; long-term TER Collembola < 5; long-term TER soil mites < 5). In case in the litter bag study biologically significant effects are observed the possibility is offered to conduct further higher-tier studies.
- Annexes II and III do not mention specific data requirements for non-target (non-crop) plants. The Guidance Document on Terrestrial Ecotoxicology, however, outlines data requirements and a tiered testing approach (Tier 1, initial screening data; Tier 2, bioassays with 6-10 plant species; Tier 3, field or semi-field studies).

As described above, assessment of persistence in soil is based on $DT_{50}$ or $DT_{90}$ triggers. Both in the Uniform Principles and the EU Guidance Document on Terrestrial Ecotoxicology the $DT_{50}$ or $DT_{90}$ triggers refer to field conditions. To avoid inconsistencies within risk assessment schemes, it is advisable to choose either for $DT_{50}$ or for $DT_{90}$ triggers. We propose to use $DT_{50}$ triggers because $DT_{50}$ triggers are found in (i) the Uniform Principles, (ii) the EU Guidance Document on Terrestrial Ecotoxicology, (iii) REACH (see Appendix 5) and (iv) the Stockholm convention (see Appendix 4) whereas $DT_{90}$ triggers cannot be found in REACH and the Stockholm convention. In addition, a $DT_{50}$ value can be assessed with lower uncertainty and higher accuracy than a $DT_{90}$ value.

## 3.2 Problem formulation

One of the key steps in the problem formulation is the statement of the assessment endpoints or what is to be protected. When assessing the environmental risks of the agricultural use of PPPs it is important to have scientifically sound and broadly accepted ideas of what constitutes an ecologically important effect of these chemicals in agricultural soils, and what constitutes a sustainable soil ecosystem. In intensively used agro-ecosystems it is practically not feasible to keep the communities of soil organisms in a pristine condition comparable to that in nature reserves. Nevertheless, we recognise the multifunctional character of agricultural soils, including their ecological functions.

Within the context of sustainability of communities and ecological functions and services, there are three general categories of undesirable effects of PPPs in the environment. These relate to ecosystem structure, function, and aesthetic value to humans (see for example Calow, 1998; Brock and Ratte, 2002). Structure of an ecosystem is a combination of which organisms are present and how many there are while function relates to what the organisms do in the ecosystem. Changes in structure are generally expressed in terms of overall species richness and densities, and population densities of key and indicator species. Changes in ecosystem functioning are usually expressed as changes in the rate of biogeochemical cycles (for example changes in primary productivity, processing of nutrients and mineralization of organic matter). Changes in perceived aesthetic value usually concern the real and perceived benefits of the ecosystem to humans.

The structure and function of soil communities may be affected by direct toxicity of the PPP, by secondary poisoning, or by indirect effects due to shifts in interactions within the food web. The choice of protection goals (and, by extension, assessment endpoints) may be based on ecological knowledge or

on human value judgements. For example, there is a general tendency to select functional protection goals and assessment endpoints when the populations of the potentially affected organisms may change rapidly for natural reasons, recover from effects rapidly, or are difficult to characterise (for example soil micro-organisms). In populations that have lower recovery potential or are easily characterised, there is a tendency to use structural protection goals such as absolute population numbers (for example earthworms, birds). However, the view of most ecotoxicologists is that in ecosystems structural endpoints are generally more, or at least as sensitive to chemical stressors as functional endpoints. Choices of protection goals may also be determined on the basis of value judgements, for example, if the risky activity brings great benefits, structural changes may be tolerated locally and / or temporarily if functions are unaffected. Societal bodies (including scientists) then have to discuss which protection goal to adopt (in space and time) and whether a certain ecological effect is acceptable or not. In our democratic society the ultimate decision is usually made in the domain of politics and governmental authorities. An important role of scientists in this process is to present options, and the potential environmental and ecological consequences of these options. These options can be used by stakeholders and responsible governmental authorities to underpin their views and decisions.

When considering the risks of PPPs in soils it may be convenient to distinguish four principles (Brock, 2001; Brock et al., 2006) that allow for spatio-temporal differentiated protection goals, namely:
1. *Functional Redundancy Principle;*
2. *Community Recovery Principle;*
3. *Ecological Threshold Principle;*
4. *Pollution Prevention Principle.*

For the in-crop evaluation of the short-, medium- and long-term risks of the agricultural use of persistent PPPs in particular the first three principles may be of use, while the *Pollution Prevention Principle* is more applicable to evaluate risks of PPPs in non-target areas. The *Pollution Prevention Principle* presupposes that all environmental pressure is potentially harmful. Conservative approaches may be necessary, for example to prevent multi-stress impacts due to the presence of low levels of more than one chemical, or unexpected effects of parent compounds and/or their metabolites (for example hormone disruption). Consequently, the 'what if' question is considered more important than the 'so what' question. When adopting the *Pollution Prevention Principle* the use of toxic chemicals and emission of these substances to non-target sites should be prevented as much as technologically and socio-economically feasible. In its most extreme form, implementation of the *Pollution Prevention Principle* restricts the use of PPPs as much as possible (Brock, 2001). In practice, however, on most agricultural fields PPPs are applied, perhaps with the exception of fields in use of biological farming. Evaluations for non-target areas (off-crop) are outside the scope of this report.

The decision to allow the agricultural use of PPPs implies the acceptance of effects on target pest organisms, and, inevitably, the acceptance of certain effects on non-target populations that occur in the agro-ecosystem as well. These non-target organisms are often taxonomically related to the pest organisms of concern. It can be argued that in agro-ecosystems, the ecological risk assessment of PPPs for soil organisms and rooted plants should be based on a dynamic rather than a static view. In the dynamic view populations and communities of soil organisms are considered in their temporal and spatial context within the landscape. In this context the multifunctionality of agricultural soils, crop rotation and future changes in land use of agricultural soils cannot be ignored. For example, in due time agro-ecosystems may be transformed into nature reserves (for example in areas part of the 'Ecological

Infrastructure' in the Netherlands). An overview of the principles and criteria used in the present report to set temporal differentiated 'regulatory acceptable concentrations' of PPPs in in-crop sites of agro-ecosystems is presented in Table 3.1. These principles are described in greater detail in the following paragraphs.

**Table 3.1 Principles and criteria that may be used to set temporal differentiated protection goals for soil organisms in agro-ecosystems and that were agreed upon to use in this report by responsible risk managers of the Ministry of Housing, Spatial Planning and the Environment and the Ministry of Agriculture, Nature and Food Quality in the Netherlands.**

| principle to set protection goal | in-crop (differentiation in time) |
| --- | --- |
| Functional Redundancy Principle (FRP) | in year of cropping |
| Community Recovery Principle (CRP) (see Table 3.2) | two year post last application |
| Ecological Threshold Principle (ETP) (see Table 3.3) | seven years post last application |

After evaluation of the 2006 proposal for persistency risk assessment, it was decided to withdraw assessment according to the FRP from the original proposal and not to include it in the final proposal. The main reason for this withdrawal is the fact that Annex I assessment at the European level covers this principle. For the sake of completeness, the functional redundancy principle is discussed in Appendix 9.

## 3.3    Community Recovery Principle

The *Community Recovery Principle* presupposes that an ecosystem can absorb and endure a certain amount of pollution because of ecological recovery processes. From a scientific point of view, periodically occurring declines in population densities can be considered a normal phenomenon in (agro-)ecosystems. In the course of the evolution organisms developed a large variety of strategies to survive and cope with temporal unfavourable conditions like desiccation, flooding, temperature shocks, shading, oxygen depletion, food limitations, toxins in food, et cetera. In some cases, but certainly not all, the stress caused by a PPP may more or less resemble that of a natural stress factor. Domsch et al. (1983) suggested to use the 'normal operating range' of population densities and functional endpoints in specific ecosystems as a baseline against which to assess pesticide-induced changes. In other words, effects of chemicals of which the bioavailable fraction is restricted in space and time may in certain habitats be regarded as ecologically unimportant when they are of a smaller scale than changes caused by other natural or anthropogenic stresses (Brock et al., 2006).

When defining recovery, a distinction between actual and potential recovery should be made. Actual (or ecological) recovery implies the return of the perturbed measurement endpoint (for example, species composition, population density) to the window of natural variability in the ecosystem of concern, or to

the level that is not significantly different anymore from that in control or reference (test) systems (for example in semi-field experiments). Potential (or ecotoxicological) recovery is defined as the disappearance of the stressor to a concentration at which it no longer has adverse toxic effects on the measurement endpoints of interest (see also Van Straalen and Van Rijn, 1998). In general, risk assessment procedures based on single species toxicity tests and on semi-field experiments allow to derive exposure concentrations indicative for *potential* recovery. In contrast to laboratory single species toxicity tests, (semi-)field experiments also allow the study of *actual* recovery of sensitive populations. Consequently, from properly designed semi-field experiments exposure concentrations may be derived indicative of both *potential* recovery (for example the threshold concentration for effects) and *actual* rate of recovery (for example information that full recovery of stressed populations occurs within a year). (Semi-)field tests that study the response of the soil community to pesticide stress and that last longer than 1 year hardly have been published. In addition, based on experience with aquatic microcosm and mesocosm experiments, the statistical power to demonstrate treatment-related effects will decrease in the course of time due to increased variability between replicate test systems (including controls). Consequently, it is doubtful whether the prediction of *actual* recovery of sensitive populations of soil organisms in the years after the year of application can be done with high certainty by means of long-term field experiments in agro-ecosystems. In combination with metapopulation models, however, results on rate of recovery from shorter-term field experiments might be used in the risk assessment.

When interpreting population responses to PPP-stress in semi-field experiments, it is convenient to make a distinction between *internal* and *external* recovery. Internal recovery depends on surviving individuals in the stressed ecosystem or on a reservoir of resting propagules (for example seeds) not affected by the PPP. In contrast, external recovery depends on the immigration of individuals from neighbouring patches of ecosystem by active or passive dispersal (FOCUS, 2005). In general, recovery of affected populations from chemical stress may be rapid if:

- the exposure regime to the biological available fraction is short-term;
- the physico-chemical environment and ecologically important food-web interactions are not altered by the stressor, or quickly restored;
- the generation time of the populations affected is short;
- there is a ready supply of propagules of eliminated populations through active immigration by mobile organisms or through passive immigration by for example, wind and water transport.

Because of the difficulties in demonstrating *actual* recovery of affected soil populations in experimental field plots several years post last pesticide application, we focus in our report on *potential* recovery. When applying the *Community Recovery Principle* a certain level of a PPP is considered acceptable, if after a certain period post last application the bioavailable concentration of the PPP (and / or its active metabolites) does not impact sensitive structural or functional endpoints of the (agro-)ecosystem anymore (*potential* recovery). In the present report this period for *potential* recovery in in-crop soils is set at two years. This period of two years was adopted after consulting the responsible risk managers of the Netherlands Ministries (VROM, LNV). It is evident that a proper characterisation of the bioavailable concentration at the time interval of interest is crucial. The protection goals in line with the *Community Recovery Principle* focus on the protection of the life-support functions of the soil to allow crop rotation, sustainable agriculture and overall protection of soil organisms characteristic for in-crop soil communities of agro-ecosystems (Table 3.2).

In this report we adopt the trigger 'DT$_{50}$ > 90 days' ($\approx$ DT$_{90}$ > 365 days) - as mentioned in the Uniform Principles (EU, 1997) - to initiate further studies with regard to the overall protection of the structure and functioning of the in-crop soil community. This trigger value was chosen after consulting the responsible risk managers of the Netherlands Ministries (VROM, LNV).

As a first tier approach in line with the *Community Recovery Principle* we propose to base the permissible concentration on the long-term TER (= Toxicity Exposure Ratio) for a basic set of standard soil organisms. We propose to use a long-term TER > 10 (and not > 5 as described in the Guidance Document on Terrestrial Ecotoxicology), since results of the DEFRA funded project 'WEBFRAM 5: A pesticide risk assessment module for below-ground invertebrates' indicate that the current risk assessment practice is not conservative enough (DEFRA, 2002; see also: Frampton et al., 2006; Jänsch et al., 2006). In addition, an AF of 10 is more in line with the risk assessment procedures for other compartments (for example protection of water organisms). A question at stake is whether the test organisms (earthworms; arthropods such as Collembola and gamasid mites; plants) proposed in the EU Guidance Document on Terrestrial Ecotoxicology are representative enough to assess the risks of all PPPs. In the present report it is argued that for a proper evaluation of for example fungicides or nematicides also fungi and nematodes have to be tested. We recognise the necessity of consensus among scientists affiliated with different stakeholders (academia, business, government) how to perform and interpret these single species laboratory tests.

**Table 3.2 Protection goals and criteria in line with the Community Recovery Principle***

| protection goals |
| --- |
| • protection of life-support functions of the soil to allow crop rotation and sustainable agriculture |
| • overall protection of the structure and functioning of soil communities characteristic for agro-ecosystems |

| trigger | type of concentration | effect criteria |
| --- | --- | --- |
| DT$_{50}$ > 90 d (10 ºC) | Maximum of a concentration (total, pore water) two years after the last application in the top 5 cm of soil.<br><br>Note: Pore water concentration is often sufficiently representative for the biologically available fraction. See also Textbox 3.1 | two years after the last application *potential* recovery of sensitive soil populations of agro-ecosystems is assured (TER approach based on chronic lab toxicity tests with a basic set of soil organisms; SSD approach based on chronic tests and the median HC$_5$; field experiment approach)<br><br>Note: The effect assessment endpoint should always be expressed in the same type of concentration (for example total content or pore water concentration) as the fate assessment endpoint. |

* The decision tree for in-crop risk assessment in line with the *Community Recovery Principle* is presented in chapter 5.1.

> **Textbox 3.1 Relevant type of concentration**
>
> In the fate criteria a distinction is made in total and pore water concentration. Pore water concentration is often considered representative for the biologically available fraction for certain organisms such as earthworms and plants (see for example, Van Gestel, 1992; Boesten, 1993; Jager et al., 2003), while this has not been proven for other soil organisms. The evaluation of the proposed risk assessment procedure (Van der Linden et al., 2008) led to the conclusion that it is a priori unknown whether an assessment based on total content or an assessment based on pore water concentrations will be decisive in the decision making. Therefore, both approaches should be followed for the risk evaluation and the most conservative (lowest) TER should be taken for decision making.
>
> It is evident that for a proper comparison of fate and effect criteria the same type of concentration should be used. In other words, when expressing the effect assessment endpoint (for example NOEC of earthworms) in concentrations in pore water this should also be done when calculating the relevant PEC (= Predicted Environmental Concentration).

As a second tier we propose the Species Sensitivity Distribution approach (SSD) and the calculation of the median Hazardous Concentration for 5% of the species (= $HC_5$) (Aldenberg and Jaworska, 2000; Posthuma et al., 2002). Important discussion points are the number of toxicity data to use when constructing SSD's, and whether to focus on a specific taxonomic group in case of a PPP with a specific toxic mode-of-action (Van den Brink et al., 2002; Maltby et al., 2005). In the HARAP guidance document it is recommended to use at least 8 toxicity values of taxonomic groups identified to be sensitive to the PPP of concern when assessing risks in freshwater ecosystems (Campbell et al., 1999). In the Technical Guidance Document in support of Commission Directives 93/67/EC, 94/1488/EC and 98/8/EC (TGD, 2003) it is recommended to test at least 10 species from 8 different taxonomic groups. Concerning sensitive endpoints the TGD states: 'Deviations from these recommendations can be made, on a case by case basis, through consideration of sensitive endpoints, sensitive species, toxic mode-of-action and / or knowledge from structure activity considerations'. With respect to the fit of the toxicity data to a statistical distribution it is stated: 'a lack of fit may indicate that a sensitive group exists and that the focus should be on this group'. However, detailed guidance on this matter (for example selection of species from the sensitive taxonomic group) is not given in the TGD. As for plant protection products a specific mode-of-action is expected, we here propose to focus on the sensitive group indicated by the most sensitive standard test species and knowledge from other compounds with a similar toxic mode-of-action, unless a general biocidal activity is expected (see also notes to Figure 5.1). When using the TER and SSD approaches, in first instance the available toxicity data can be used. In these more or less standardised toxicity tests the bioavailable concentration of the PPP usually is not assessed in the soil matrix. A more advanced approach might be to base the observed effects in the toxicity tests on the bioavailable exposure concentration (for example pore water concentration). The use of laboratory toxicity tests to derive permissible concentrations after two years post last application of the PPP implies that the protection goal concerns *potential* recovery of sensitive endpoints.

As a third tier we propose the performance of semi-field tests in which both the dynamics in bioavailable exposure concentrations and the responses of populations in the soil community are

assessed. In accordance with the expertise on the conduct of aquatic micro / mesocosm tests (for example Giddings et al., 2002), it is recommended to adopt an exposure-response experimental design (preferably 5 or more concentrations) with at least two replicates per treatment. Appropriate assessment endpoints are the absence of differences in population and community structure (and functioning of soil micro-organisms), between treated and control test systems after the time interval of interest. 'Effect Classes' (adapted after Brock et al., 2006 and De Jong et al., 2005) can be used to facilitate the interpretation of concentration-response relationships for relevant measurement endpoints of terrestrial semi-field experiments, namely:

Class I    no treatment-related effects;

Class II   slight treatment-related transient effects, usually on one or a few isolated sampling dates only;

Class III  clear effects on several consecutive sampling dates, lasting less than two months post last application of the PPP in the test system;

Class IV  clear effects on several consecutive sampling dates, lasting longer than two months but full recovery within a year post last application of the PPP in the test system;

Class V   clear long-term effects; full recovery not within one year post last application of the PPP in the test system.

We propose to consider an exposure concentration two years post last application acceptable if this exposure concentration results maximally in class I-II effect responses in an appropriate semi-field test. Consequently, in the highest tier we mainly focus on threshold concentrations for effects derived from (semi-)field tests and we use these values to address the occurrence of potential recovery after two years. An extra assessment factor (AF) may be applied to overcome the remaining uncertainty with respect to spatial extrapolation of the effect assessment based on a single semi-field test. To date, too few terrestrial semi-field experiments with the same PPP have been performed to scientifically underpin the height of such an extra AF. Based on the calculated uncertainty in the geographical extrapolation of threshold levels for effects observed in aquatic micro/mesocosms with PPPs, however, an appropriate AF might be 3. For this purpose, substances (chlorpyrifos, atrazine) were selected for which at least 5 $NOEC_{community}$ values could be derived from adequately performed freshwater model ecosystem experiments and that could be related to a specific exposure regime (short-term or long-term exposure) (see Brock et al., 2006). However, considering the limited number of semi-field experiments that studied the impact of the same pesticide on soil communities, it is prudent to recommend that the proposed AF of 3 to be applied to an Effect class I or II is revisited when more data are available.

## 3.4    Ecological Threshold Principle

The *Ecological Threshold Principle* has in common with the *Community Recovery Principle* that it presupposes that the environment can absorb and tolerate a certain amount of stress before the sustainability of the community structure is affected. The *Ecological Threshold Principle*, however, considers a certain concentration of a substance acceptable if the most sensitive structural or functional endpoints of the communities of concern are not, or only briefly, impacted.

Within the context of the present report, a protection goal in line with the Ecological Threshold Principle has its focus on the protection of the life-support functions of the soil to allow changes in land use and on the protection of soil communities in non-agricultural habitats. For example, in the Netherlands former agricultural fields situated in areas part of the 'Ecological Infrastructure' (for example in river forelands) are currently transformed to nature reserves. The implementation procedure

of governmental decisions to destine land with a former agricultural function for 'nature development' projects at least takes seven years. In the present report the period of seven years was adopted after consulting the responsible risk managers of the Netherlands Ministries (VROM, LNV). Consequently, the adopted approach in line with the Ecological Threshold Principle should guarantee that within seven years post last agricultural use of the PPP, soil communities of sites with a former agricultural function are not negatively impacted by PPP residues anymore. Again it is evident that a proper characterisation of the bioavailable concentration at the time interval of interest is crucial. Since semi-field studies with a duration of seven years are practically not feasible within a cost-effective registration procedure of PPPs, and tests with soil communities of nature reserves are for eco-ethical reasons not desirable, it is difficult to obtain and use information on the actual recovery and succession of the soil communities of concern. However, on the basis of laboratory tests with a larger number of species information might be obtained on concentrations indicative for potential risks on diverse soil communities of nature reserves.

In the present report we use 'soil $DT_{50} > 180$ d' as mentioned in the Stockholm Convention (see Appendix 4 as a trigger to start the risk assessment in line with the *Ecological Threshold Principle* (Table 3.3). This trigger value was chosen after consulting the responsible risk managers of the Netherlands Ministries (VROM, LNV).

An option in line with the *Ecological Threshold Principle* is to always base the maximum permissible concentration on a conservative first-tier approach. A pragmatic approach is to start with the first-tier database in line with the *Community Recovery Principle* (chronic NOEC's for 3 taxa) and to apply a higher assessment factor (for example 50 or 100).

As a second tier the option is to use an additional assessment factor (for example 5) to the median $HC_5$ or to use the lower limit of the $HC_5$ in the SSD based on a sufficient number (for example 8) of appropriate chronic toxicity data from single species lab tests. It seems logical to include some test organisms more representative for nature reserves, besides test organisms more or less typical for agro-ecosystems (Table 3.3). We realise that standard test protocols for additional soil organisms need to be developed when implementing the proposed procedure.

As a third tier a conservative approach is to apply an additional assessment factor (for example 3 or 5) to the acceptable concentration of the PPP as assessed in the (semi-)field tests performed to fulfil the requirements of the medium-term protection goals (*Community Recovery Principle*). This is to account for the possible higher sensitivity of the usually more diverse soil communities in nature reserves. Considering the limited number of semi-field experiments that studied the impact of the same pesticide on soil communities, it is prudent to recommend that the proposed AF to be applied to Effect classes I or II concentrations is revisited when more data are available.

**Table 3.3 Protection goals and criteria in line with the Ecological Threshold Principle***

| protection goals | | |
|---|---|---|
| protection of life-support functions of the soil to allow changes in land use | | |
| overall protection of the structure and functioning of soil communities characteristic for nature reserves | | |
| triggers | type of concentration | effect criteria |
| $DT_{50} > 180$ d (10 ℃) | maximum of a concentration (total, pore water) seven years after the last application in the top 5 cm of soil<br><br>Note: Pore water concentration is often sufficiently representative for the biologically available fraction. See also Textbox 3.1 | seven years after last application exposure to the PPP and its metabolites do not affect sensitive populations of soil organisms (TER approach based on chronic lab toxicity tests with a larger number of species or the application of a larger AF; SSD approach based on chronic lab toxicity tests and the lower limit of the $HC_5$ or the use of the median $HC_5$ value and the application of an AF; model ecosystem approach and extra AF)<br><br>Note: The effect assessment endpoint should always be expressed in the same type of concentration (for example total content or pore water concentration) as the fate assessment endpoint. |

* The decision tree for in-crop risk assessment in line with the *Ecological Threshold Principle* is presented in chapter 5.2.

# 4 Assessment of trigger values and exposure

## 4.1 Introduction

Both estimation of exposure concentrations and estimation of dissipation of substances from soil are important aspects of the assessment of persistency in soil. This chapter describes how both aspects can be dealt with in the evaluation procedure. Section 4.2 describes how $DT_x$ values are derived from experimental results and how these values are used to find out whether trigger values are exceeded. Section 4.3 describes the estimation of exposure concentrations in test systems and section 4.4 presents a tiered approach for estimating Predicted Environmental Concentrations for the risk assessment. Although the text here focuses on single substances, concentrations of several substances can be calculated if required from the ecotoxicological point of view.

In pesticide regulation and in evaluation procedures, both quantities, $DT_{50}$ and $DT_{90}$, are used to indicate the rate of dissipation from / in soil. If the dissipation is only caused by degradation or transformation, then the term $DegT_{50}$ of $DegT_{90}$ is used (FOCUS, 2006). The 50% dissipation or transformation time point is preferred in this report. This chapter therefore focuses on the $DT_{50}$ and the $DegT_{50}$, respectively.

In a pesticide registration dossier usually more than one $DT_{50}$ value will be available. The minimum requirement is four $DT_{50}$ values originating from laboratory studies (EU, 1991). FOCUS (2006) recommends to use the geometric mean $DT_{50}$ value in assessments[7]. This recommendation is generally followed in this report. When used for comparison with trigger values, $DT_{50}$ values obtained with best fit kinetics may be used. When exposure levels or end-points have to be calculated, values obtained via first-order fitting have to be used (FOCUS, 2006). First-order kinetics has to be used in these situations, because all advanced models use first-order kinetics in their calculations. FOCUS (2006) gives extensive guidance on the estimation of $DT_{50}$ values from single experiments. Determination of the geometric mean $DT_{50}$ value is possible only after standardisation of the original experimental values to standard conditions. The standardisation procedures for both laboratory and field experiments are described by FOCUS (2006). The evaluation report of the proposed assessment procedure (Van der Linden et al., 2008) gives a number of examples of these standardisation procedures.

## 4.2 Trigger values

Trigger values are used in legislation and many assessment schemes to classify substances and to identify further research requirements (cf. chapter 2, chapter 3 and Appendix 5). Chapter 3 mentions two $DT_{50}$ values as a trigger for further assessment of persistency of plant protection products in soil. A $DT_{50}$ of 90 days triggers an assessment in line with the community recovery principle and a $DT_{50}$ of 180 days triggers an assessment in line with the ecological threshold principle. This paragraph describes the estimation of $DT_{50}$ values, which are to be compared with the trigger values.

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[7] The recommendation does not refer to the use for comparison with trigger values.

The question arises how the $DT_{50}$ is determined in order to find out whether an additional assessment is triggered or not. The following three options can be considered:

1. the $DT_{50}$ trigger value is related to reference conditions (for example: a temperature of 20 °C and a moisture content equivalent to pF2);
2. the $DT_{50}$ trigger value is related to a scenario, which is relevant for a specific area (for example the Netherlands); standardised $DT_{50}$ values are used as input for scenario calculations;
3. the $DT_{50}$ trigger value is derived directly from relevant field tests.

Option 3, which is the current procedure for Annex I evaluation, has the disadvantage that it is impossible to judge whether conditions during the field test were indeed relevant in view of the assessment. As standardisation procedures for the interpretation of such experiments have become available (FOCUS, 2006), this option is regarded scientifically outdated and not recommended in this report.

In options 1 and 2, the results of degradation / dissipation experiments are standardised to reference conditions, if necessary. The standardised values are then directly (option 1) or indirectly (option 2) used to estimate trigger values. For both options, the procedure consists of two parts (cf. Figure 4.1):

A. estimate the geometric mean $DegT_{50}$ at standard conditions (20 °C, field capacity) from available data (either from laboratory, or from a combination of laboratory and field, or from field only (see also Textbox 4.2);
B. use this geometric mean $DegT_{50}$ to set the trigger using option 1 (standard conditions, for example 10 - 20 °C) or option 2 (calculations with a scenario that is representative for the use of the pesticide).

Part A is identical for both options. This part is in the scientific domain based on considerations such as which data are most reliable for assessment of field conditions. Within this context, all experiments are calculated back to the same standard conditions (20 °C, field capacity) because this is necessary for an appropriate comparison between the different $DegT_{50}$ values. The value may be derived from field experiments studying the dissipation of the substance. All processes contributing to the dissipation of the substance should be addressed in the study. If field $DegT_{50}$-values are not available, $DegT_{50}$-values from laboratory studies may be used as a substitute. Part B actually involves a political choice. Option 2 implies that the trigger for assessment of persistence may vary across the EU, depending on the conditions that are considered relevant in member states.

It is scientifically possible to use either option. In option 1, emphasis is on intrinsic properties of the substance under consideration; the decision is taken mainly on the basis of transformation parameters of the substance. In option 2, emphasis is on the dissipation of the substance under defined (field) conditions. Option 1 is probably more in line with the so-called September letter of the Netherlands Minister of Agriculture, Nature and Food Quality to the Netherlands parliament in which he stated that: persistence is not a national issue in the evaluation of plant protection products. The choice for option 1 implies that also a reference value for the temperature has to be chosen. For example: the long term average Netherlands temperature, approximately 10 °C, may be more relevant to Netherlands field conditions than the standard conditions of 20 °C, whereas in southern France 15 – 20 °C may be more relevant. The $DegT_{50}$ / $DT_{50}$ value for the chosen reference conditions may be obtained from the values under standard conditions using a (default) $Q_{10}$-factor of (the current default value used in (Geo)PEARL calculations is 2.2). The choice for option 2 involves that one or more appropriate scenarios have to be developed, which can be used in the evaluation (cf. section 4.4).
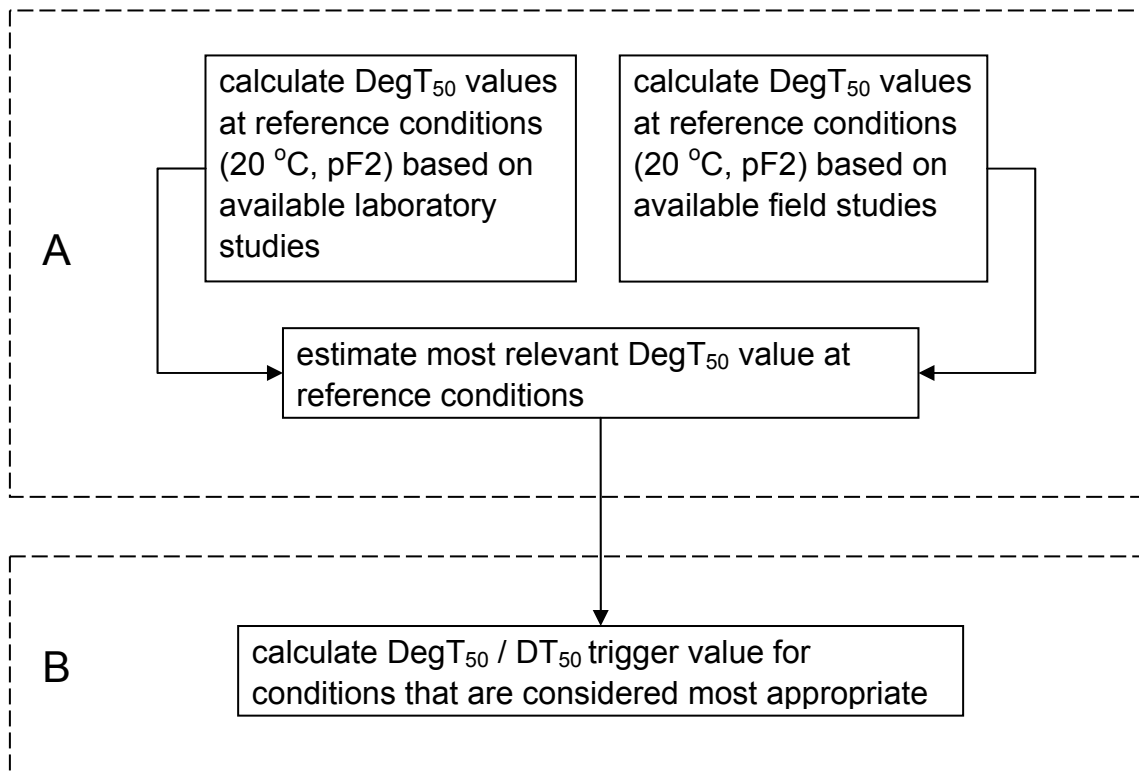
**Figure 4.1 The proposed tiered approach for assessment of $DT_{50}$ trigger values**

If the reference temperature for option 1 is set at approximately 10 °C then option 1 usually will be somewhat more conservative for Netherlands conditions than option 2, because other dissipation processes than transformation are neglected (emphasis is on intrinsic persistence in option 1).

The Ministries of LNV and VROM have chosen to follow option 1 with as reference conditions a temperature of 10 $^{\circ}$C and moisture content equivalent to pF2.

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**Textbox 4.1 Consistency with other assessment procedures**

Current Annex I evaluation uses the maximum $DegT_{50}$ / $DT_{50}$ value obtained in test systems to compare with trigger values and to calculate PECs for soil organisms. For assessing leaching and behaviour in surface water, a more central value (geometric mean) is used. The different approaches are confusing.

For the groundwater and surface water assessments, the choice for using the geometric mean is accompanied by assigning vulnerable conditions to the scenarios for which calculations are carried out. The relatively simple calculation procedures for soil scenarios as given by FOCUS (1997) are quite vulnerable as other dissipation routes than transformation are not considered. The approaches are not consistent. A consistent approach would be to use central values for the $DegT_{50}$ / $DT_{50}$ in combination with a relatively vulnerable scenario in all assessments.

For $PEC_{GW}$ calculation it is recommended to normally use a geometric mean or median $DegT_{50}$ (from laboratory studies or if available from field studies) and an arithmetic mean or median $K_{OM}$ value (or $K_{OC}$ value if appropriate).

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Focus 2006 gives guidance on deriving $DT_{50}$ and $DegT_{50}$ values from laboratory and field experiments. For laboratory experiments, it is recommended to evaluate whether first order kinetics (SFO) can be used to describe the dissipation / degradation pattern. If SFO is not adequate, biphasic models can be used to derive endpoints for dissipation which can be compared with trigger values. Although not stated explicitly, the procedure was not meant for deriving $DT_{50}$ values for field experiments. For calculating exposure levels, $DegT_{50}$ are necessary. Current exposure models need values according to SFO. In specific cases, the Double First Order in Parallel (DFOP) model might be suitable for the interpretation of the field experiment. Then, the parameters of the fast phase may be attributed to the dissipation processes taking place at the soil surface and the parameters of the slow phase may be attributed to the degradation process in the soil (see Van der Linden et al. (2008) for an example). In exceptional cases, the Hockey Stick (HS) model might be suitable, for example when an extreme event happens shortly after the application. Parameters from the slow phase of both DFOP and HS are then used as SFO parameters in the calculation of exposure. The use of DFOP (or HS) for the interpretation of the field experiment should be fully justified. When more field experiments are available, the interpretation needs to be consistent.

**Textbox 4.2 Derivation of $DT_{50}$-values and $K_{OM}$-values in case of additional information**

The applicant may introduce information from additional laboratory experiments, field experiments and / or accumulation experiments in the assessment procedure. The results from the additional studies may lead to new input parameters for the calculation of both trigger values and exposure concentrations. In persistence assessments generally additional transformation parameters may become available, but sorption parameters have also effect on exposure calculations and may be considered in the assessment as well.

The information of additional studies on the transformation rate or the sorption of the substance may reveal that the data in the basic dossier are not representative of the transformation rates or the sorption coefficients in the area of use of the substance. The following situations may occur regularly:

– The average transformation rate obtained in laboratory experiments differs from the average obtained in field experiments or the average transformation rate for soils representative of the area of use of the substance differs from the average transformation rate in the basic dossier. An approach might be to check whether these averages are statistically significant (t-test, 95 % confidence level). In this case the data from the basic dossier (lab data) and / or data not representative of the area of use might be disregarded and the average transformation rate for field data and / or the representative soils could be used as input; that is: the geometric mean $DT_{50}$ respectively the geometric mean $DegT_{50}$ is calculated from the relevant soils only and these values are used to compare with the trigger values respectively used in the calculations of the exposure concentrations.

– The average transformation rate for soils representative of the area of use of the substance is not statistically significant (t-test, 95 % confidence level) different from the average transformation rate in the basic dossier. In this case all data are taken together to calculate the geometric mean transformation rate and this value is used to compare with the trigger values or as input in the exposure calculations.

– The additional information may reveal that the transformation of the substance is dependent on (correlated to) one or several soil parameters. The dependency is tested for statistical significance ($R^2$ of the regression better than 0.8 or F-test with significance level $\alpha = 0.1$). The data from the basic dossier are included in this procedure, unless insufficient information is present in the dossier or it is demonstrated statistically that these data should be considered as outliers (Grubb's test, with significance level $\alpha = 0.05$). Instead of using average transformation parameters in the calculation now specific or soil-dependent properties should be used. For instance, the transformation rate may be dependent on soil organic matter content, clay content and / or pH.

– The additional information may reveal that the sorption of the substance is dependent on (correlated to) one or several soil parameters. The dependency is tested for statistical significance ($R^2$ of the regression better than 0.8 or F-test with significance level $\alpha = 0.1$). The data from the basic dossier are included in this procedure, unless insufficient information is present in the dossier or it is demonstrated statistically that these data should be considered as outliers (Grubb's test, with significance level $\alpha = 0.05$). Instead of using average sorption parameters in the calculation now specific or soil-dependent properties should be used. For instance, the sorption may be dependent on soil texture, soil organic matter content, soil sesqui-oxide content and / or pH.

– Non-equilibrium sorption is expected to occur for most substances and therefore should not be neglected if experimental data are available. The data are used to derive new sorption and transformation parameters and average values are used as input for new calculations.

At the moment there is hardly any experience in deciding on the representativeness of sorption and transformation data. It is recommended to use the suggestions given above in combination with expert judgement.
The reader is referred to FOCUS (2006) for methods deriving adequate $DegT_{50}$ values from laboratory and field studies.

## 4.3 Estimation of exposure levels in test systems

Exposure is important from two points of view: 1) exposure during tests on toxicity to soil organisms, and 2) exposure in assessment schemes. This section describes how to estimate exposure in ecotoxicity tests, while the next section describes how to calculate exposure in assessments schemes. Exposure can be expressed in terms of total content in soil or as pore water concentration. Both types of exposure concentrations will be addressed here. If adequate measurements of the exposure concentration are available, then these measurements are used for deriving the appropriate exposure endpoints. If appropriate measurements of the exposure concentration are lacking, the exposure concentration can be calculated. Results from well-designed and highly characterised ecotoxicity experiments are preferred above results from experiments for which details are missing. The latter results will be disregarded if better data are available. For closed test systems, usually relatively simple calculation procedures can be used to derive exposure concentrations. For open and uncontrolled systems, the calculation of the exposure may require more advanced procedures.

Table 4.1 gives an overview of exposure endpoints for test systems that are frequently used in the authorisation procedure. To make a clear distinction between exposure in test systems and exposure in evaluation procedures, this chapter uses TSC (Test System Concentration) to indicate the exposure in test systems. To indicate exposure in evaluation schemes, the usual term PEC is used. In a number of tests, especially the acute toxicity tests, the initial content or the initial pore water concentration is used to express the ecotoxicological end-point. For other tests a time-weighted average of the total content or pore water concentration is used.

**Table 4.1 Exposure endpoints in test systems and time windows for TWA calculations**

| test | $TSC_{s,I}$ [#] | $TSC_{s,TWA}$ [#,@] |
|------|------|------|
| earthworms, acute | * | |
| earthworms, chronic | * | 56 |
| earthworms, field | * | not defined |
| soil fungi test | * | c. 15 d |
| soil micro-organisms N-test | * | 28 |
| soil micro-organisms C-test | * | 28 |
| Collembola test | * | 28 |
| non-target plant test | * | 14 - 21 |
| litter bag test | * | 180 - 365 |

[#]  Test System Concentration; Initial or Time Weighted Average; either total content in mg kg$^{-1}$ or pore water concentration in mg dm$^{-3}$; relevant layer is the top 5 cm of the soil

[@]  The value indicates the maximum length of the period (d) over which the average is taken. The time period depends on knowledge about the moment at which the effect occurs. A blank indicates that the TWA is not required

When in a test the dose is expressed in kg ha$^{-1}$, it can be converted into mg kg$^{-1}$ soil by a calculation assuming 100% of substance reaching the soil, 5 cm depth and a soil bulk density of $1 - 1.7$ kg dm$^{-3}$. A value of 1 kg dm$^{-3}$ is conservative if a total content has to be established whereas a value of 1.7 kg dm$^{-3}$ is conservative for pore water concentrations. If information on interception is available, this can be taken into account.

TSC$_{s,I}$ in closed test systems

The TSC$_{s,I,tc}$ in the test system can be calculated from the application rate and the dry weight of the soil or the test medium. This will be possible for all tests, although for some test systems it is very questionable whether the derived concentration is representative for the exposure in the test system or in practice. The calculation of the TSC$_{s,I,tc}$ is straightforward if all test conditions were measured. If the moisture content is unknown (not in line with test protocol), the initial TSC$_{s,I,tc}$ can be estimated using the procedure as described in section A7.2 and choosing the conservative value.

The TSC$_{s,I,pw}$ can be calculated when instantaneous sorption equilibrium is assumed and the water content, the Freundlich equilibrium sorption coefficient (K$_{OM}$) and the Freundlich sorption exponent for the soil are known. The pore water concentration can be calculated because of the known relationship between the amount sorbed to the solid phase and solution concentration in combination with the amounts of solid phase and pore water in the test system.

If the Freundlich sorption parameters are not known for the test system, then a conservative approach might be adopted for the calculation of the initial pore water concentration. In this context, a conservative pore water concentration in test systems is a concentration that is lower than the concentration calculated when all parameters would have been known. A conservative concentration is obtained when a Freundlich sorption coefficient, which is above the mean value, is used for the calculation. We recommend to use the maximum observed value. If the sorption of the substance is dependent on the pH of the soil, we recommend to take the upper limit of the 95% confidence interval at the pH of the test system.

TSC$_{s,TWA}$ in closed test systems

If a TSC$_{s,TWA,tc}$ is required, this could be calculated assuming first order degradation kinetics. Prerequisites for the calculation are, at least: the measured decline of the substance for the test system and the temperature at which the test was performed. The Freundlich sorption coefficient and the Freundlich sorption exponent might be necessary for more complex test systems. If these parameters are available and assuming that non-equilibrium sorption does not occur, the content versus time curve can be calculated and the time-weighted average is obtained via integration of this curve and division over the appropriate time period. This time period is dependent on the duration of the experiment. If non-equilibrium sorption cannot be neglected, the time-weighted average of the total content can be obtained using fitting routines or simulation models[8] (see for example FOCUS (2006)).

Frequently, the necessary parameters will not be available. An approximation might then be obtained. A conservative approximation is recommended. Conservative for test systems means that a relatively low TSC is derived; if effects are observed it is assumed that these effects resulted from relatively low estimated exposure levels. A conservative TSC$_{s,TWA,tc}$ for a parent substance is obtained assuming that non-equilibrium sorption does not occur and a relatively low DegT$_{50}$ value. So, for parent substances, we recommend to ignore non-equilibrium sorption in the calculation for total content and to use, if

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[8] Taking non-equilibrium sorption into account is not simply setting parameter values for the ratio between the Freundlich equilibrium constant and the Freundlich non-equilibrium constant and the desorption rate coefficient. As pointed out by Boesten and Van der Linden (2001), taking the non-equilibrium sorption into account requires to re-evaluate the DegT$_{50}$. As the non-equilibrium sorption process renders part of the substances inaccessible to the transformation processes lower DegT$_{50}$ values have to be assumed to describe the behaviour in the soil adequately (see the paper for more information)

unknown for the test soil, the maximum of the $K_{OM}$ values and the minimum of the $DegT_{50}$ values reported in the dossier; these values lead to the lowest exposure in the test system.

Estimation of a conservative $TSC_{s,TWA,tc}$ for a metabolite is not straightforward because more parameters are involved. Probably the lowest concentrations are obtained by using a slow degradation rate for the parent or the precursor (so a slow formation rate of the metabolite considered) in combination with a fast degradation rate for the metabolite considered. Given the current state of knowledge in this field it is recommended to use a best-guess approach for all parameters of the parent and the metabolites (i.e. median/average $DegT_{50}$ and $K_{OM}$ values and the default value of 0.5 for the ratio non-equilibrium to equilibrium sorption and a default value of 0.01 $d^{-1}$ for the desorption rate coefficient).

If a TWA pore water concentration is required then, in addition to the temperature and the $DegT_{50}$ for the test system, the Freundlich sorption coefficient and the Freundlich sorption exponent should be known. The $TSC_{s,TWA,pw}$ is calculated using all parameters in a simulation model, integrating the solution concentration versus time curve and division over the appropriate time period. Non-equilibrium sorption should be accounted for if the necessary parameters for this process are known.

Also here a conservative approach can be taken if one or more parameters are unknown. A conservative approach for test systems must lead to a lower $TSC_{s,TWA,pw}$ as compared to the situation in which all parameters are known. A conservative (i.e. relatively low) $TSC_{s,TWA,pw}$ for a parent substance is obtained with a combination of a relatively high sorption constant and a relatively low $DegT_{50}$. The effect of including non-equilibrium sorption is a priori not clear because this process may slow down the decline of the total amount (so leading to a higher total content) but also decreases the fraction of the substance in the liquid phase. Therefore, assuming default parameters for the non-equilibrium process seems reasonable. So we recommend to assume non-equilibrium sorption and, for the unknown parameters, the maximum of the $K_{OM}$ values and the minimum of the $DegT_{50}$ values from lab studies reported in the dossier; these values lead to the lowest exposure in a closed test system. If the sorption of the substance is dependent on the pH of the soil, we recommend to take the upper limit of the 95% sorption confidence interval at the pH of the test system.

Estimation of a conservative (i.e. relatively low) $TSC_{s,TWA,pw}$ for a metabolite is even more difficult than for a parent substance. Therefore it is recommended to use best-guess values of all parameters (including non-equilibrium sorption) for such estimates.

Appendix 7 gives the concepts of a simple numerical model that can be used for calculation of the different types of $TSC_s$ values in laboratory test systems based on input parameters described above.

Given the above complexity of the estimation of conservative values of total content and pore water concentrations, it is recommended to develop an exposure tool that can handle ranges of values of $K_{OM}$, $DegT_{50}$ and the ratio non-equilibrium to equilibrium sorption and uses Monte-Carlo approaches for estimating for example a $90^{th}$ percentile conservative value of the required type of concentration.

Exposure assessment in open test systems

Exposure concentrations in open test systems can only be estimated when the report contains additional information on the soil (dry) bulk density, organic matter content, water content (in course of time), climatic conditions (temperature, precipitation (both in course of time)), crop and measurements of the substance. Average initial contents can be estimated directly from the measurements, or approximated from the nominal application rate, taking into account interception when plants are growing at the time of application. Estimations of time weighted averages are – in principle – possible via inverse modelling; this however requires high quality datasets. Inverse modelling is used to derive the most appropriate values for sorption and transformation parameters. Thereafter, these parameters are used as input to a usual PEARL calculation (Leistra et al., 2001; Tiktak et al., 2000). This calculation will then result in the necessary exposure concentrations.

## 4.4 Calculation of exposure levels for risk assessment

Table 4.2 gives possible exposure endpoints for use in assessment schemes.

**Table 4.2 Exposure endpoints in assessment schemes**

| endpoint | protection principle | time | possible (approximation of) exposure content / concentration |
|---|---|---|---|
| $PEC_{s,t=2y}$ | CRP | relevant time window two years after last application | $PEC_s$ two years after last application |
| $PEC_{s,t=7y}$ | ETP | relevant time window seven years after last application | $PEC_s$ seven years after last application |

The choice for a calculation of the $PEC_{s,t=2y}$ or $PEC_{s,t=7y}$ expressed as total content or pore water concentration, expressed as a momentary or a TWA concentration, and the choice for a typical soil layer (soil depth) will depend on which type of concentration describes the ecologically relevant response of the species of interest the best. This concept of the Ecologically Relevant Concentration is further explained in Boesten et al. (2007).

For each of the endpoints a tiered approach can be followed. A tiered approach involves the use of conservative scenarios in earlier tiers and the realistic worst case conditions at the highest tier (see also Appendix 1 or Boesten et al., 2007). As shown below, in the highest tier the realistic worst case exposure is calculated for the substance that is being assessed, using information on the area of use of this substance. The realistic worst case is derived from GeoPEARL calculations. A calculation procedure is conservative when, compared to the higher tier calculation procedure, the calculated exposure level in the assessment is relatively high.

In a tiered assessment approach, the first step is the most conservative, i.e. the exposure concentration estimated in following steps will and must be lower. If the toxicity – exposure ratio in a step meets the requirements, a following step needs not to be taken. Following steps should approximate reality better and therefore need to be less conservative. At the highest tier, the 90th percentile can be calculated with

GeoPEARL. GeoPEARL calculates the relevant exposure concentrations for the total area of use; that is the area on which the substance is potentially applied.

The GeoPEARL package can be used irrespective of the target quantity, i.e. the concentration in the pore water or the total (bio)available content in soil. All relevant contents / concentrations are given by the software package. The scenario for which the 90th percentile pore water concentration is calculated will differ substantially from the scenario with the 90th percentile for total content.

Based on the discussion on approaches which occur in practice, we suggest a tiered approach existing of two tiers (see Figure 4.2). The first tier is a combination of a relatively simple model, a worst-case scenario and simplified (conservative) inputs, different for the calculation of pore water concentrations and total contents. The scenario chosen for the first tier is based on realistic worst case conditions as obtained from tier 2 input. It was found that a (constant) temperature of 8 ºC would be appropriate for the first tier. Likewise, an organic matter content of 2% was found appropriate for calculating conservative pore water concentrations. The two tiers are described in some detail below.

*Tier 1*

| scenario | realistic worst case, generically derived from tier 2 assessments |
|---|---|
| application | 26 yearly, biennial or triennial applications of maximum yearly dose each |
| interception | none |
| management | no tillage |
| processes | sorption (equilibrium and non-equilibrium) and transformation |
| $DegT_{50}$ | geometric mean of lab, field and/or field accumulation studies (see also Textbox 4.2) |
| $K_{OM}$ | arithmetic mean of lab studies (see text for specific substances) |
| model | simple numerical model |
| target quantity | total contents and pore water concentrations, initial and /or time weighted averages |

The results of the Tier 1 calculations, i.e. the total available content in soil or the pore water concentration as calculated for the realistic worst case with the simple model, are compared with the results of one of the ecotox tiers. As input to the calculation, the geometric mean $DegT_{50}$ of laboratory or field studies and the mean $K_{OM}$ of laboratory studies, as available from the basic dossier, are used. If the exposure resulting from Tier 1 is too high, the assessor may decide to go to the second tier. The purpose of this tier is to quickly calculate a worst-case maximum of the soil content or the pore water concentration. If this content / concentration is not relevant in terms of potential effects to soil organisms, then no further assessment needs to be undertaken.

Non-equilibrium sorption is included in the Tier 1 calculations for the total contents of the parent substances, because inclusion of this process renders conservative estimates for parent substances. The default ratio between the non-equilibrium sorption and the equilibrium sorption is set at 0.7, which seems to be conservative at the moment. For pore water concentrations of parent compounds it is not clear whether including non-equilibrium sorption leads to higher values. Although the estimation needs further research, for pragmatic reasons we adopt a default ratio between the non-equilibrium sorption and the equilibrium sorption of 0.

For metabolites, it is difficult to foresee which non-equilibrium sorption parameter values give the most conservative (i.e. highest) estimates, both for the total content and the pore water concentration in the Tier 1 calculations. Therefore it is recommended to use best-guess estimates for these parameters for all compounds when metabolites have to be assessed (so a default ratio between the non-equilibrium sorption and the equilibrium sorption of 0.5 and a desorption rate coefficient of 0.01 $d^{-1}$).

Given the above complexity of the Tier 1 estimation of conservative values of total content and pore water concentrations, it is recommended to develop an exposure tool that can handle ranges of non-equilibrium sorption parameters and uses Monte-Carlo approaches for estimating a conservative Tier 1 value of the required type of concentration.

For leaching calculations, Boesten and Van der Linden (2001) recommend to correct the $DegT_{50}$ in order to take account of the non-bioavailable fraction. A corrected $DegT_{50}$ may also be used for calculation of the persistence calculations. The use of a corrected value is only recommended if the correction value can be obtained from adequate experiments in the dossier. The use of the rule of the thumb value (Boesten and Van der Linden, 2001) is not recommended.

*Tier 2*

| scenario | not applicable, total area of use |
|---|---|
| application | 26 annual, biennial or triennial applications of application scheme |
| interception | yes, but conservative |
| management | tillage (included in GeoPEARL when appropriate for a crop) |
| processes | sorption, transformation, volatilisation, leaching, uptake |
| $DegT_{50}$ | geometric mean of lab, field and / or accumulation studies, soil dependent if applicable (see also Figure 4.2 and Textbox 4.2) |
| $K_{om}$ | arithmetic mean of lab and / or field studies (see Figure 4.2 and Textbox 4.2) |
| model | GeoPEARL |
| target quantity | total available content and pore water concentration, initial or time weighted average |

For the calculations with GeoPEARL the option for non-equilibrium sorption is switched on and the relevant parameters are set to the default values unless specific information is available for a substance, for both parent and metabolites. This implies using a default value of 0.5 for the ratio non-equilibrium to equilibrium sorption and a default value of 0.01 $d^{-1}$ for the desorption rate coefficient. A GeoPEARL run with this option switched on will generate higher total content exposure concentrations for a parent compound than a run with the option switched off. Presumably this will not be the case for the pore water concentrations of parent compounds; these might be slightly lower, but insufficient knowledge is available to judge this. The effect of the non-equilibrium sorption parameters on estimated total contents and concentrations in pore water is even more difficult to foresee for metabolites. Therefore it is recommended to use the above default values also for metabolites. $DegT_{50}$ values will not be corrected for non-equilibrium sorption, unless adequate and reliable information is available from the dossier.

The result of the second tier is the realistic worst-case exposure for the area of use of the plant protection product. The realistic worst case exposure here is defined as the spatial 90th percentile of the available soil contents or the available pore water concentrations after 20 periodical application regimes (excluding applications during the so-called warming-up period). An application regime is defined as

the maximum number of applications of a substance within a growing season, with each of the applications at the maximum prescribed rate. Input to the calculations may be obtained from all relevant fate studies with the plant protection product, including both laboratory and field studies (see also Textbox 4.2).

Arable soils are usually tilled prior to or after cropping, depending on the soil type. In the Netherlands, loamy and clayey soils are tilled in autumn, either to prepare the seedbed for a winter crop or as a measure to improve the soil structure through frost action. For sandy soils, tillage usually takes place in spring. Tillage is included in GeoPEARL dependent on both soil type and crop. The user cannot change these settings. Soil tillage is not included in the first tier because this also covers shallow or no tillage (for example grassland).

Interception is accounted for in Tier 2 calculations. Conservative (i.e. low) interception values are taken from FOCUS tables (FOCUS, 2001). If possible, the chosen interception value is underpinned by an evaluation of results of field (accumulation) studies. If the plant protection product is sprayed over the crop, then this application option is chosen. Wash-off from plant leaves may contribute to the total load of the soil. Because relatively little is known about the wash-off process and other processes influencing wash-off (amongst others, sorption onto leaves and photodegradation on leaves) it is recommended to use defaults[9] values for parameters regulating the wash-off process. Also relatively little is known about the amounts of PPPs that reach the soil via crop residues which remain on the field and possibly are incorporated into the soil after harvest. It is recommended to take up research in these fields in order to be able to improve the estimations in future.

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[9] Which default values to use is still under discussion

| Tier | Model | Description scenario |
|------|-------|----------------------|
| 1 | simple | • Realistic worst case, single layer soil<br>• Constant temperature (8 ºC, conservative long term average obtained from GeoPEARL data)<br>• No interception<br>• No soil tillage<br>• $DegT_{50}$ (geometric mean) from lab, field and / or accumulation studies<br>• Non-equilibrium sorption for tc<br>• No other dissipation processes<br>• 26 applications (maximum dose) |
| 2 | GeoPEARL | • 90th percentile area of use<br>• Realistic conservative interception<br>• Wash off from plant leaves, if appropriate<br>• Soil tillage<br>• $DegT_{50}$ (geometric mean) from lab, field and / or accumulation studies or dependent on soil properties<br>• Including other dissipation processes<br>• including non-equilibrium sorption (best guess)<br>• 26 application regimes (maximum dose) |

**Figure 4.2 Exposure assessment scheme for total soil content or concentration in pore water**

Not included in the assessment schemes is the possibility to use monitoring data to determine exposure concentrations. Monitoring would require the determination of concentrations in fields that are treated with the substance for a long time. For these fields management records should be available, which demonstrate amongst others the historical use of the substance and the soil tillage events. We envisage that a monitoring step in the assessment will be rarely used. If a monitoring study is available, exposure experts may be invoked to evaluate the study.

# 5 Risk assessment according to CRP and ETP

In chapter 3 protection goals have been defined for the in-crop soil. Different protection goals are defined at different points in time post last application, i.e. the Functional Redundancy Principle (FRP) for the cropping year, the Community Recovery Principle (CRP) for the situation two years post last application and the Ecological Threshold Principle (ETP) seven years post last application. Assessment in line with the FRP is performed at the EU level as part of the Annex I evaluation. This chapter gives the assessment according to CRP and ETP.

Trigger values for persistence
Table 5.1 presents a scheme that shows the relation between the flowcharts in line with the protection goals as triggered by different $DT_{50}$ values. Since the protection goals are used for different points in time post last application, there is no a-priori hierarchy for the different goals. It is not deemed necessary to test all protection goals for all compounds, since different triggers ($DT_{50}$ values) for the different protection goals are proposed. In this chapter $DT_{xx}$ is used generically, i.e. no distinction is made between laboratory and field values. Mostly, DT-values derived from field experiments are preferred above data from laboratory studies, but laboratory data can be used as well. Chapter 4 addresses methods to derive DT-values and how they are used in decision making.

**Table 5.1 Relation between $DT_{50}$ value of the plant protection product (trigger at 10 degrees) and the testing procedures in line with the protection goals**

| protection goal | time window | trigger | |
|---|---|---|---|
| | | **$DT_{50}$ > 90 days** | **$DT_{50}$ > 180 days** |
| Community Recovery Principle | two years post last application | testing according to CRP (Figure 5.1) | testing according to CRP (Figure 5.1) |
| | | | **AND** |
| Ecological Threshold Principle | seven years post last application | | testing according to ETP (Figure 5.2) |

Risk assessment according to CRP is performed for substances having a $DT_{50}$ > 90 days at 10 ºC (see section 5.1). Substances having a $DT_{50}$ > 180 days at 10 ºC in addition are assessed according to ETP (see section 5.2). In the flowcharts given in this chapter, usually the most sensitive ecotoxicity endpoint is taken for decision making. If more than one ecotoxicity value for a single organism and effect is available, then the geometric mean of these values is taken into account. For the assessments a tiered approach is adopted, c.f. chapter 4 and Appendix 1.

# 5.1 Assessment in line with the Community Recovery Principle

For substances with $DT_{50} > 90$ days it is principally checked whether ecological effects on soil community structures occur two years after the last application. In principle a PEC two years after the last application is used for the assessment. The first step of the flowchart for the Community Recovery Principle (Figure 5.1) tests whether the residues present two years post application exceed the Regulatory Acceptable Concentration (RAC) on basis of No-Observed-Effect-Concentrations (NOECs) for three relevant soil organisms and the application of a safety factor of 10, to take interspecies differences in sensitivity into account (see chapter 3). Relevant soil organisms are organisms that live in the soil; so not organisms dwelling on the soil surface. Ideally these organisms are different for herbicides, insecticides, fungicides or nematicides. For these organisms standard test methods should be available. For some taxonomic groups of soil organisms standard test methods should be developed; for a number of species test methods are under development (see also Appendix 3).

The evaluation of the proposed risk assessment schemes (Van der Linden et al., 2008) revealed that the result of an assessment based on total soil content may differ from the result of an assessment based on pore water concentrations. Therefore, the overall assessment has to be based on both types of concentrations, unless it can be demonstrated that only one type of concentration, total content or pore water, is relevant for the substance under consideration. The minimum TER value is taken for the decision. As a consequence also toxicity data need to be expressed on basis of both pore water concentrations and total content. If not available from the test reports, (conservative) estimations of total content and / or pore water concentrations in test systems can be derived (see chapter 4.3).

In the first tier a limited number of species is tested. The presupposition here is that the species used comprise species that are relatively sensitive to pesticides and that the applied safety factor is appropriate to also protect the non-tested species. In the second tier (Figure 5.1) the assessment factor can be decreased by including more species and applying a Species Sensitivity Distribution. From this sensitivity distribution the value at which 95% of the species are protected can be derived ($HC_5$). In this case the median $HC_5$ for at least 8 chronic NOECs (or chronic $EC_{10}s$) of representative species is tested. When the presupposition described above is right, a good chance exists that the application of a $HC_5$ value without a safety factor (because the uncertainty is reduced) will result in a higher RAC.

A cost effective method might be to calculate the $HC_5$ on basis of acute toxicity data and to apply a safety factor of 10 in case the acute to chronic ratio for the three standard test organisms each is < 10. This suggestion is based on experiences in the aquatic environment, were the use of acute $EC_{50}$ values to calculate the $HC_5$ data, with a safety factor of 10, appeared to be protective for $HC_5$ values based on chronic NOEC data. Whether this is valid for terrestrial organisms too has to be substantiated with data for the terrestrial environment. The advantage would be a reduction in the data requirements and the use of test organisms.
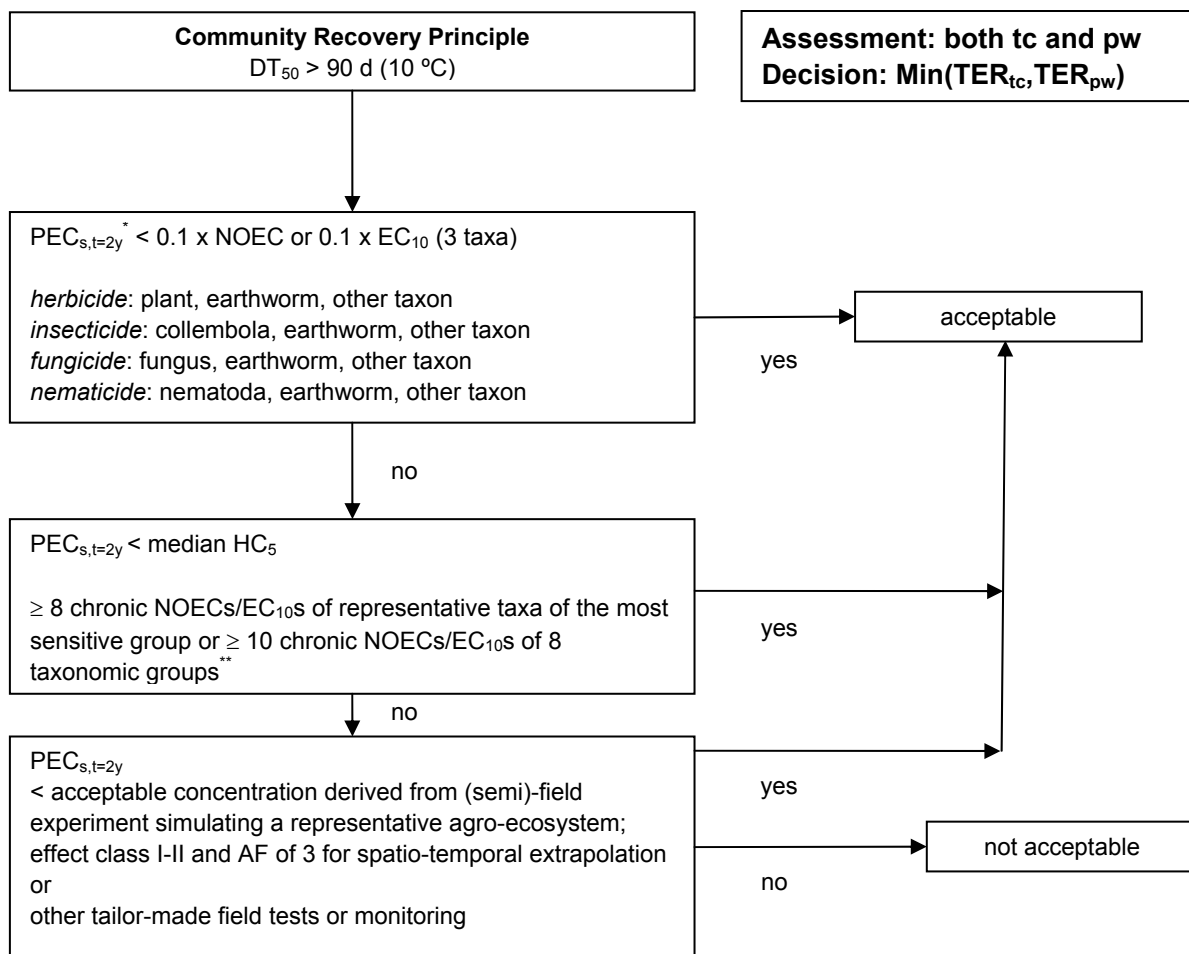
| Community Recovery Principle $DT_{50} > 90$ d (10 ºC) | | Assessment: both tc and pw<br>Decision: Min($TER_{tc}$,$TER_{pw}$) |
|---|---|---|

$PEC_{s,t=2y}^{*} < 0.1$ x NOEC or 0.1 x $EC_{10}$ (3 taxa)

*herbicide*: plant, earthworm, other taxon
*insecticide*: collembola, earthworm, other taxon
*fungicide*: fungus, earthworm, other taxon
*nematicide*: nematoda, earthworm, other taxon

→ yes → acceptable

no

$PEC_{s,t=2y} <$ median $HC_5$

$\geq 8$ chronic $NOECs/EC_{10}s$ of representative taxa of the most sensitive group or $\geq 10$ chronic $NOECs/EC_{10}s$ of 8 taxonomic groups[**]

→ yes →

no

$PEC_{s,t=2y}$
< acceptable concentration derived from (semi)-field experiment simulating a representative agro-ecosystem; effect class I-II and AF of 3 for spatio-temporal extrapolation or
other tailor-made field tests or monitoring

→ yes → acceptable

no → not acceptable

**Figure 5.1 Decision tree for in-crop (in the year post the year of last application) effect assessment in line with the Community Recovery Principle**

[*]    The use of PEC is in conformity with the present approach; when more data are available, such as the time to effect, a $PEC_{TWA}$ can be used as well. Assessment is based on both total content and pore water concentration and the decision is based on the minimum TER value of both assessments (see text).

[**]    Species sensitivity distribution (SSD method, see Aldenberg and Jaworska, 2000). If a clear sensitive group exists, meaning at least an order of magnitude difference in sensitivity compared to other groups, data for 8 taxa from the most sensitive group can be taken, in conformity with the procedure for the aquatic environment (Campbell et al., 1999). Alternatively, in case of general biocidal activity, the TGD approach can be taken (TGD, 2003). A minimum 10 NOECs for at least 8 taxonomic groups should be taken.

The use of more species in a laboratory setting still is inherently conservative: sensitive life-stages are used, without possibilities for population recovery or avoidance. Depending on the working mechanism of the compound and the source of the uncertainty, possibilities for higher tier studies exist, such as population level studies or (semi) field studies. These studies allow interaction, and natural behaviour of organisms and recovery of sensitive endpoints may be assessed. The aim of this type of studies is to show that under more realistic conditions the predicted effects do not occur, or populations do recover.

In the (semi-)field tests in line with the CRP the population- and community-level effects two years after the last application are assessed. For the situation two years after application the situation should have recovered potentially (see chapter 2). This means that in this case the PEC after two years should not exceed the lowest concentration that results in class I-II effects in agro-ecosystems in relevant (semi-)field studies.

One of the remaining questions is whether one field study is enough to 'overrule' the former tiers. The question is if for instance the weather conditions, soil conditions, populations present, et cetera are representative or protective for the conditions of the proposed use, or can be extrapolated using models. Data about the distribution of soil species, the sensitivity of soil species and the vulnerability of soil communities are scarce, however, so standardisation for these aspects is difficult at the moment. In aquatic mesocosm studies performed with chlorpyrifos (seven studies) and atrazine (nine studies) threshold values have a spread of less than approximately a factor of 3 (see for example Maltby et al., 2002; Brock et al., 2006; De Jong et al., 2005). An assessment factor of 3 may also suffice to extrapolate threshold levels of a PPP in soil ecosystems.

## 5.2     Assessment in line with the Ecological Threshold Principle

For the Ecological Threshold Principle a trigger of $DT_{50} > 180$ d is proposed. As a first tier approach (Figure 5.2) it is tested whether a PEC, seven years after the last application, exceeds the Regulatory Acceptable Concentration (RAC) based on the CRP with an extra AF of 10. The extra factor of 10 is deemed necessary because the concern is extended from the agro-ecosystem and the species related to this system to a natural ecosystem and the species related to that system.

Modern research into classification of soils has revealed that the presence of species is a discriminative indicator, although it requires the monitoring of many species. It appeared that biodiversity within functional groups and the related process rates were lower in grasslands with an intensive agricultural regime than in grasslands with a biological regime (Breure et al., 2005; Mulder et al., 2006). Alternative approaches to classifications would be foodweb topology, based on the relations between functional groups, or allometric relations based on the significance of biomass and numbers between functional groups. These indirect classifications have the advantage that the factors that explain structural variation, or that filter out the influence of short-term temperature variations or the day of monitoring are highlighted (Mulder et al., 2006; Mulder, 2006). Mulder et al. (2006) show that the biomass of primary and secundary consumers and decomposers can differ an order of magnitude between land uses; while the total biomass (per surface area) may differ up to six orders of magnitude. Also the within soil connectivity in natural grasslands is much higher that in agricultural grasslands (Mulder et al., 2006).

The studies show that biodiversity and connectivity in natural systems may be much higher than in agricultural systems. It is not necessarily so that species or communities from a natural ecosystem are in general more sensitive to toxicants (i.e. equal thresholds), but it is more likely that the vulnerability of the species is larger (e.g. due to more complex lifecycle characteristics that affect recovery) above the critical threshold level for ecotoxicological effects. This emphasises that for the ETP, in order to maintain or establish this more complex ecosystem, species and functions need to be protected with a larger margin of safety. This approach is not completely equivalent to that taken in the TGD (EC, 2003) for the marine environment, where the presence of more species in the marine environment, including those from several unique phyla not present in freshwater, leads to the introduction of extra uncertainty

factors (in absence of more specific marine data). It is at this point not clear if in a natural terrestrial ecosystem more phyla will be present compared to an agricultural soil. Apart from that lack of knowledge, the level of protection for the marine environment is not different from that of freshwater. While it is straightforward to assume that the terrestrial test species equally well represent both the CRP and the ETP, for the ETP a higher level of protection compared to the CRP, needs to be observed. This may be done by covering a larger part of the distribution of sensitivity ($HC_1$ instead of $HC_5$), or covering a larger part of the uncertainty in the prediction of the desired percentile (lower level instead of median of the confidence interval).

The evaluation of the proposed risk assessment schemes (Van der Linden et al., 2008) revealed that the result of an assessment based on total soil content may differ from the result of an assessment based on pore water concentrations. Therefore, the overall assessment has to be based on both types of concentrations, unless it can be demonstrated that only one type of concentration, total content or pore water, is relevant for the substance under consideration. The minimum TER value is taken for the decision. As a consequence also toxicity data need to be expressed on basis of both pore water concentrations and total content. If not available from the test reports, (conservative) estimations of total content and / or pore water concentrations in test systems can be derived (see chapter 4.3).

In the second tier the *lower limit* of the $HC_5$ of the SSD is tested against a PEC. The use of a higher protection level (for example $HC_1$) has the disadvantage that the uncertainty increases due a lack of data in this exposure range. The use of a safety factor disregards the influence of the spread and the number of toxicity data used to construct the SSD. The number and spread of the data influence both the position as the safety margins of the $HC_5$. Taking the lower limit of the $HC_5$ accounts for both aspects.

Again in case it is hard to obtain a sufficient number of chronic NOECs (chronic $EC_{10}$s) an alternative approach might be to base the $HC_5$ calculation on acute $EC_{50}$ values and to apply an extra assessment factor of 10 to the lower limit of the acute $HC_5$ in case the acute to chronic ratio of the standard test species is on average less than 10 (see section 5.1, at CRP). In the third tier the potential effects are tested seven years after application on basis of results of semi-field tests. The higher tier for the ETP (as for CRP) should focus on structural endpoints. The litter bag study could be part of the third step to get insight in ecological processes, but a functional endpoint, as the litter bag study is, will not be sufficient on itself as a higher tier for the CRP or ETP. In the present scheme (Figure 5.2) the PEC after seven years should be at least lower than the concentration that results in Class I-II effects of a relevant (semi-)field study representative for an agro-ecosystem. Studies conducted in agro-ecosystems will deal with specific ecosystems, adjusted to tillage and various other kinds of agricultural activity. Natural ecosystems will carry other species, for instance species with other life-cycles, in the case of plants for instance perennials, shrubs and trees. To take this difference into account an extra assessment factor of 3 is introduced. So, a total extra assessment factor of 9 (3 x 3) is proposed to translate effects of a single (semi-)field test in an agro-ecosystem to a natural ecosystem. An alternative would be to conduct the (semi-)field study in a natural ecosystem.
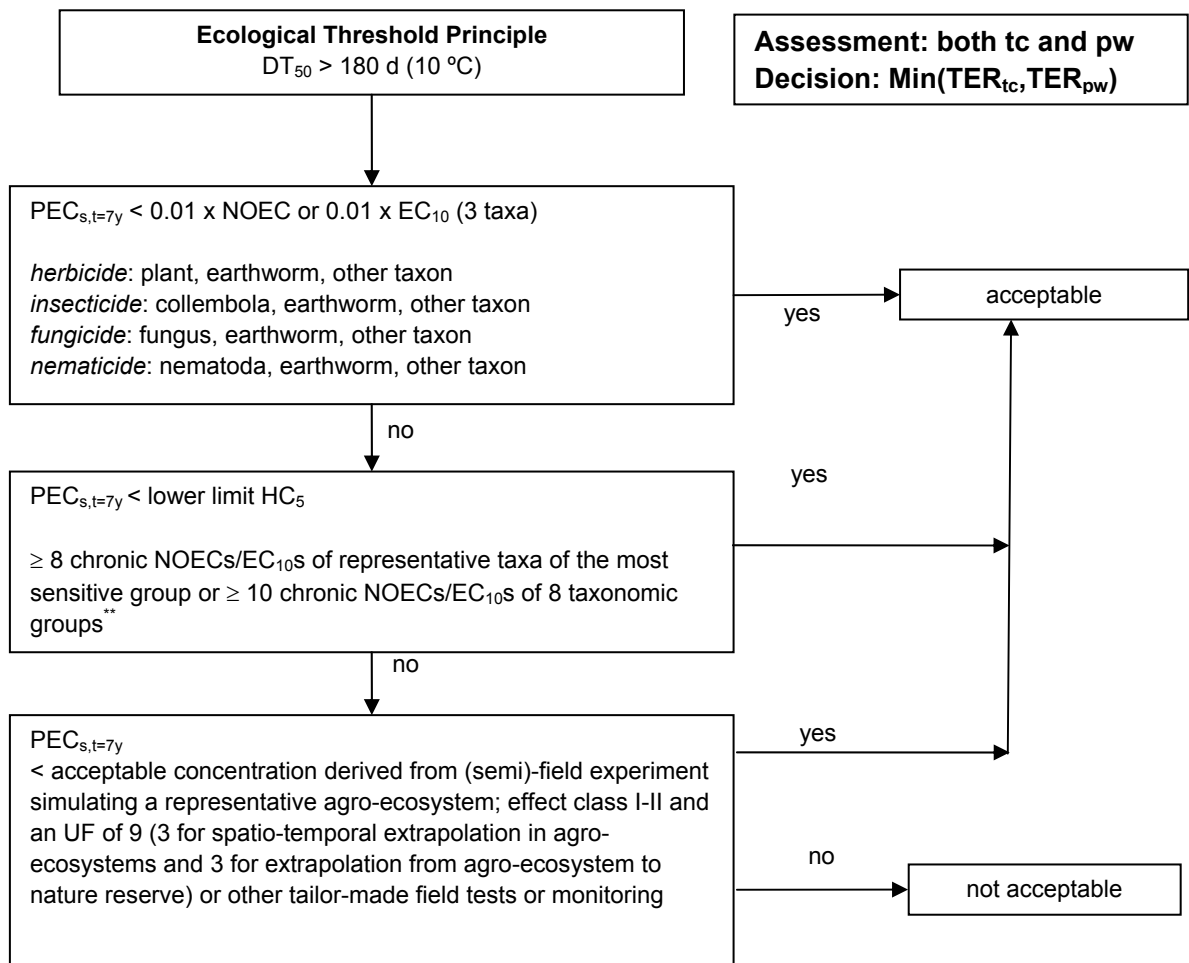
| | |
|---|---|
| **Ecological Threshold Principle** $DT_{50} > 180$ d (10 ºC) | **Assessment: both tc and pw Decision: $Min(TER_{tc}, TER_{pw})$** |

$PEC_{s,t=7y} < 0.01 \times NOEC$ or $0.01 \times EC_{10}$ (3 taxa)

*herbicide*: plant, earthworm, other taxon
*insecticide*: collembola, earthworm, other taxon
*fungicide*: fungus, earthworm, other taxon
*nematicide*: nematoda, earthworm, other taxon

→ yes → acceptable

no

$PEC_{s,t=7y} <$ lower limit $HC_5$

$\geq 8$ chronic $NOECs/EC_{10}s$ of representative taxa of the most sensitive group or $\geq 10$ chronic $NOECs/EC_{10}s$ of 8 taxonomic groups[**]

→ yes

no

$PEC_{s,t=7y}$
< acceptable concentration derived from (semi)-field experiment simulating a representative agro-ecosystem; effect class I-II and an UF of 9 (3 for spatio-temporal extrapolation in agro-ecosystems and 3 for extrapolation from agro-ecosystem to nature reserve) or other tailor-made field tests or monitoring

→ yes → acceptable

→ no → not acceptable

**Figure 5.2 Decision tree for in-crop (seven years post last application) effect assessment in line with the Ecological Threshold Principle**

[*]        The use of PEC is in conformity with the present approach; when more data are available, such as the time to effect, a $PEC_{TWA}$ can be used as well. Assessment is based on both total content and pore water concentration and the decision is based on the minimum TER value of both assessments (see text).
[**]        Species sensitivity distribution (SSD method, see Aldenberg and Jaworska, 2000). If a clear sensitive group exists, meaning at least an order of magnitude difference in sensitivity compared to other groups, data for 8 taxa from the most sensitive group can be taken, in conformity with the procedure for the aquatic environment (Campbell et al., 1999). Alternatively, in case of general biocidal activity, the TGD approach can be taken (TGD, 2003). A minimum 10 NOEC's for at least 8 taxonomic groups should be taken.

## 5.3    Selection of ecotoxicological endpoints in CRP and ETP

In the first tier of the CRP and ETP assessment we propose to apply an AF of 10 (CRP) or 100 (ETP) to a minimum of three species of different trophic levels/taxonomic groups. In our original report (Van der Linden et al., 2006) we proposed to always use the standard earthworm test, but also to take into account knowledge on the toxic mode-of-action of the substance under evaluation by requesting a plant species when evaluating a herbicide, a collembolan when evaluating an insecticide, a fungus when evaluating a fungicide and a nematode when evaluating a nematicide. The need for more data is in line

with the suggestion of the PPR panel for data requirements for soil organisms (EFSA, 2007a), although there are differences.

When more data for the same species and the same endpoint are available, a geometric mean of these data is taken.

In higher tiers, such as the Species Sensitivity Distribution (SSD) approach, also toxicity data from non-standard test protocols may be used if deemed of high enough scientific quality. In the third tier of the CRP and the ETP the option of higher tier studies is presented, possibly in the form of (semi)-field studies. Criteria for the design and evaluation of these studies, however, still have to be developed. A promising possibility is the development of terrestrial model ecosystems (TME) (e.g. Knacker et al., 2004). It is proposed to assess the acceptability of effects based on Class I and II effects. The design of the test however, determines the sensitivity of the test. It should be noted, however, that guidance for the conduct and interpretation of TMEs currently is under development. When this guidance becomes available it is anticipated that also criteria become available to assess whether a proper threshold level can be derived. (Semi-)field experiments should pay attention to or focus on species or processes which turned out to be sensitive in the first tier of the assessment.

# 6 Metabolites

## 6.1 Trigger values and exposure

In general, deriving dissipation and / or degradation half-lives from experimental data is more difficult for metabolites than for parent substances. FOCUS (2006) describes how to derive transformation rate constants for metabolites from metabolism studies. Deriving such endpoints from field studies is even more complicated. It is recommended to follow the guidelines for parents as provided by FOCUS also for metabolites for the time being. Evaluation of the application of this procedure is highly recommended.

The model for estimating exposure concentrations in test systems (see Appendix 7) can also be used to calculate exposure concentrations of metabolites, for rather simple metabolism schemes. The Tier 1 model for calculating exposure for risk assessment is also capable of calculating pore water concentrations and total contents for simple metabolism schemes. The Tier 2 model (GeoPEARL) is capable of handling complex metabolism schemes (up to a total of 20 substances for both parallel and consecutive reactions. It is recommended to skip Tier 1 exposure modelling in case of complex metabolism schemes. For further details see chapter 4 and Appendix 6 and Appendix 7.

## 6.2 Effect endpoints for metabolites in the first tier of the persistence decision tree

The first tier risk assessment in the decision trees for CTP and ETP is based on the lowest NOEC for 3 taxa. Since pesticides are always targeted to a certain group of species, in the first tier always a potential sensitive species should be included (e.g. a plant species for herbicides, an insect for insecticides). In the case of metabolites, several possibilities exist. In some cases, the mode-of-action of a metabolite is known, or the metabolite is the active substance. In that case, the metabolite can be handled in the same way as an active substance of which the mode-of-action is known. In a number of cases, however, it is not clear on beforehand what the potential sensitive groups are. In that case it proposed to base the first tier of the risk assessment on the NOECs for three taxa from three trophic levels. This is in line with the TGD (2003), which aims mainly at substances for which the mode-of-action is not known on beforehand.

## 6.3 Metabolite effect assessment in long-term field studies

This guidance applies to the effect assessment for metabolites in long-term semi-field studies if separate semi-field studies for the metabolites are not provided.

In the past it was assumed that the effects of the metabolite were implicitly covered by the assessment of the parent if this metabolite had been formed 'sufficiently' in the study. However, this approach is only defensible if the ratio between the concentrations of the parent and the metabolite is more or less constant in time. This is difficult to defend for the exposure at two or seven years after the last application (this is also difficult to defend at shorter time scales for parent-metabolite combinations with strongly different sorption properties).

Therefore we propose the following assessment approach:

- estimate on the basis of measured or calculated exposure concentrations in all relevant semi-field experiments the RAC for the metabolite assuming that the effect is completely attributable to this metabolite (e.g. a TWA concentration for a certain time window can be considered as the exposure concentration; if the exposure has not been measured, it has to be calculated using realistic conservative parameters);
- compare these RAC-values with relevant PEC values of the metabolite.

# 7    Discussion, conclusions and recommendations

*Remit*
The ministries of LNV and VROM asked the workgroup to evaluate the 2006 proposal for the assessment of persistence of plant protection products in soil (Van der Linden et al., 2006). The procedure was evaluated using dossier and open literature information on five substances. The evaluation led to the conclusion that changes would be appropriate. It was decided to describe the revised procedure in a new report.

*Assessment schemes*
After evaluation, it was decided to keep the assessment schemes according to the CRP and the ETP, with only one change in the ETP scheme: the required number of ecotoxicological data in the first tier is reduced from five to three, with the corresponding assessment factor set to 100.

In the highest exposure tier of the decision schemes on CRP and FRP the 90th percentile spatial exposure concentration, either the pore water concentration or total content, is calculated. The calculated exposure is compared to the corresponding regulatory acceptable concentration (RAC). Uncertainty in input parameters, for instance in $DegT_{50}$ and $K_{OM}$, contribute to the uncertainty in exposure concentration. It is recommended to investigate the importance of this uncertainty. For the moment, it is assumed that the RACs have no spatial distribution. This also needs further underpinning.

The assessment schemes according to the CRP and the ETP use a SSD approach to evaluate whether critical concentrations are exceeded. The SSD approach is commonly used in aquatic ecotoxicity assessments, but its use in terrestrial ecotoxicity assessment is not. The workgroup recommends to validate the SSD approach for terrestrial organisms. In view of the SSD approach, there is a need to develop and / or standardise test systems for more soil inhabiting organisms (see also Appendix 3), in particular test protocols for soil fungi.

For evaluation of the scientific reliability of test results a systematic approach could be worked out for the specific studies, as is done for e.g. earthworm field studies (De Jong et al., 2006) and mesocosm studies (De Jong et al., 2008). In these cases a detailed checklist for the items necessary to evaluate the scientific reliability of the field study can be constructed. To all items a reliability index is assigned, which should result in an assessment of the scientific reliability of the study. A study that is not reliable should not be used for risk assessment.

In the third tier of the CRP and the ETP the option of higher tier studies is presented, possibly in the form of (semi)-field studies. Criteria for the design and evaluation of these studies, however, still have to be developed. A promising possibility is the development of terrestrial model ecosystems (TMEs) (Knacker et al., 2004).

The assessment of exposure in (eco)toxicity tests has received little attention thus far or has not been reported at all. This is not only true with respect to persistency assessment, but for terrestrial effect assessment in general. Toxicity is expressed in terms of nominal dose instead of measured values or estimates of the ERC. It is recommended that determination of the exposure becomes an integral part of

all toxicity tests. This aspect becomes more important when time weighted averages over prolonged periods are required for the assessment.

The use of field tests is common in most decision trees. In general, these tests are introduced at higher tiers and this implies that they are considered to be more realistic than laboratory studies. In field tests, however, concentrations may vary spatially as well as in time. Because of the position of field tests in the decision trees, the determination of the variability in exposure is tremendously important. Without proper determination of the exposure, the test loses weight and it will be impossible to extrapolate to other situations.

The decision trees for the CRP and ETP principles end with an option for field studies. Depending on the working mechanism of the compound and the source of the uncertainty, possibilities for higher tier studies exist, such as population level studies, terrestrial model ecosystems or (semi-)field studies. These studies allow interaction, and natural behaviour of organisms and recovery of sensitive endpoints may be assessed. In this final step the hazard-based assessment is replaced by an effect-based assessment under field conditions. The aim of this type of studies is to show that under more realistic conditions the predicted effects do not occur, or populations do recover. In order to make this option feasible, further guidance on test performance (how to perform a valid test), on test evaluation and interpretation (what information is to be considered and how should it be treated) and on decision making (what effects are relevant; how much disturbance is acceptable; how much uncertainty is involved when extrapolating this test at this place at this time to other situations?) is needed.

The spatio-temporal extrapolation of ecological responses of semi-field experiments that assess the risks of plant protection products for soil organisms requires that at least for a few selected substances several (semi-)field experiments are conducted which study the same exposure regime but that differ in for example geographical location, soil properties and period of application.

To date terrestrial semi-field experiments with persistent plant protection products to study treatment-related responses in a regression design are relatively scarce and predominantly have been performed using soils of agro-ecosystems. Therefore it is not clear whether the results can be extrapolated in space and time, and which AF should be applied if only one valid semi-field experiment is available, or how many semi-field experiments are needed to lower the AF. Therefore, the AF of three as proposed in the decision trees therefore needs further research. A nice example of a research comparing the effects in semi-fields studies on different agro-ecosystems are the semi-field tests performed with carbendazim which are described in Van der Linden et al. (2008, chapter 2). The variation of the response of the most sensitive endpoints between different systems is relatively large, underpinning the need for further research. For this reason at present no guidance can be given for the number of field studies needed to lower the safety factor. We recommend this to be a case by case decision.

The methods to study effects on soil fungi, which are now used in the authorisation procedures, suffer from uncertain exposure of the test organisms and therefore are difficult to interpret. The development of better soil fungi test methods, including in situ tests, is highly recommended.

Another research need is to investigate for soil organisms of different trophic/taxonomic groups what constitutes the ecotoxicologically relevant concentration (ERC).

*Increasing work load for risk assessment agencies*
It is necessary to define the exposure in the ecotoxicological studies in a consistent and transparent way, for both laboratory studies and field studies. A problem is that in most laboratory and field studies the concentration in soil or pore water is not measured or estimated. In the risk assessment procedure, exposure in ecotoxicological studies has to be evaluated along with the toxicological aspects. Existing studies may need to be reinterpreted and re-evaluated for both aspects. This requires additional skills of the assessors and may bring additional work for the risk assessment agencies.

Given the complexity of estimating of conservative values of total content and pore water concentrations for ecotoxicological tests in the laboratory, it is recommended to develop a user friendly exposure tool that can handle ranges of values of $K_{OM}$, $DegT_{50}$ and non-equilibrium sorption parameters and that uses Monte-Carlo approaches for estimating a conservative value of the required type of concentration.

Given the complexity of the estimation of conservative values of total content and pore water concentrations for Tier-1 assessment of exposure in agricultural field soils, it is recommended to develop a user friendly exposure tool that can handle ranges of non-equilibrium sorption parameters and that uses Monte-Carlo approaches for estimating a conservative Tier 1 value of the required type of concentration.

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# Appendix 1 Glossary

**Aerobic degradation** Degradation occurring in the presence of molecular oxygen.

**AF** Assessment factor; usually a factor that accounts for uncertainty.

**Anaerobic degradation** Degradation occurring under exclusion of molecular oxygen.

**BBA** Biologische BundesAnstalt, the German Federal Biological Research Centre for Agriculture and Forestry.

**Breakdown products** see degradation products.

**CBb** College van Beroep voor het Bedrijfsleven (the Court of Appeal for Trade and Industry).

**CHMP** Committee for Medicinal Products for Human Use.

**Conservative** In this report the word conservative is used in the context of (regulatory) ecotoxicological risk assessment. In general this would mean that realistic worst case conditions are considered.

**CRP** Community Recovery Principle.

**Ctgb** College voor de toelating van gewasbeschermingsmiddelen en biociden. Board for the Authorisation of Plant Protection Products and Biocides.

**Degradation** Degradation processes, such as microbial degradation, hydrolysis and photolysis, break down substances in different environmental compartments by transforming them into degradation products. Degradation also includes the transformation into microbial biosynthetates or polymerisation products, which may be larger molecules than the parent substance.

**Degradation products** All substances resulting from biotic or abiotic transformation reactions of the test substance including $CO_2$, microbial biosynthetates, and products that are in bound residues.

**DegT$_{50/90}$** Term with no association to any particular type of kinetics to describe the time taken for a 50/90% decline in mass or concentration of a substance to occur by degradation from the environment or an environmental compartment after it has been applied to, formed in, or transferred to, an environmental compartment. The first half-life of a substance may be identical to the DegT$_{50}$. But for the purposes of this document, the term half-life has been restricted to mean the half-life from fitting single first-order (SFO) kinetics to data, due to its familiar association with the 'half-life concept' of SFO kinetics, and to avoid confusion in the use of terminology. The models referred to in chapter 4 need DegT$_{50}$ values of single first-order kinetics. When non-equilibrium is included in the calculations, the DegT$_{50}$ value refers to the transformation in the equilibrium phase of the soil.

**Disappearance** see dissipation.

**Disappearance/Dissipation time (DT$_x$)** Term with no association to any particular type of kinetics to describe the time taken for a 50/90% decline in mass or concentration of a substance to occur by dissipation from the environment or an environmental compartment after it has been applied to, formed in, or transferred to, an environmental compartment. DT$_x$ does not differentiate between transfer processes and degradation processes. The first half-life of a substance may be identical to the DT$_{50}$. But for the purposes of this document, the term half-life has been restricted to mean the half-life from fitting single first-order (SFO) kinetics to data, due to its familiar association with the 'half-life concept' of SFO kinetics, and to avoid confusion in the use of terminology.

**Dissipation** Overall process leading to the eventual disappearance of substances from the environment, or an environmental compartment. Dissipation comprises two main types of processes: transfer processes, such as volatilisation, leaching, plant uptake, run-off or erosion that transfer substances to different environmental compartments; and degradation processes such as microbial degradation, hydrolysis and/or photolysis transforming substances into degradation products.

**Dissipation/degradation kinetics** Equation or set of equations used to describe the eventual disappearance of substances from the environment, or an environmental compartment by various dissipation processes.

**Dissipation/degradation rate** The first time derivative for the dissipation/degradation for a substance, namely the amount per unit time by which the amount ($N\,T^{-1}$) or mass ($M\,T^{-1}$) of the substance decreases.[10]

**dw** dry weight.

**EC** European Community.

**EC$_{xx}$** Effect concentration xx%. Concentration at which xx% of the test organisms is effected or a process is changed by xx%. Cf. LC$_{xx}$.

**ECB** European Chemicals Bureau.

**ECPA** European Crop Protection Association.

**EFSA** European Food Safety Authority.

**EPA** US Environmental Protection Agency.

**EPFES** Effects of Plant Protection Products on Functional Endpoints in Soil.

**EPPO** European and Mediterranean Plant Protection Organisation.

**ER$_{xx}$** Effect rate xx%. Application rate at which xx% of the test organisms is effected or a process is changed by xx%.

**ERC** ecotoxicologically relevant concentration.

**ETP** Ecological Threshold Principle.

**EU** European Union.

**FOCUS** FOrum for the Coordination of pesticide fate models and their USe.

**FRP** Functional Redundancy Principle.

**GAP** Good Agricultural Practice.

**GeoPEARL** The PEARL model coupled to a geographical information system.

**Geometric mean**

$$\overline{x}_G = \left( x_1 * x_2 * \ldots * x_n \right)^{\frac{1}{n}}$$

with $\quad \overline{x}_G$ = geometric mean

$x_i$ = observation

n = total number of observations

**GLP** Good Laboratory Practice.

**Half-life** Is the time taken for 50% degradation of a test substance described by single first-order kinetics following the concept of radiodecay, where the decay rate constant for each radionuclide is independent of concentration and time.

**HARAP** Guidance document on Higher-tier Aquatic Risk assessment for Pesticides.

**HC$_x$** Hazardous Concentration x%; x% denotes the percentage of organisms potentially affected.

**HQ** Hazard Quotient, exposure toxicity ratio.

**IMO** International Maritime Organisation.

**IUPAC** International Union for Pure and Applied Chemistry.

**Kinetic model** Set of assumptions and mathematical expressions that describe the variation of the concentration of the different compounds that participate in a transformation process.

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[10] M: mass;  N: amount of substance (i.e. number of moles); T: time

**K$_{om}$** Freundlich sorption constant; constant for sorption of a substance onto organic matter.

**K$_{ow}$** Octanol – water partitioning coefficient.

**LC$_{xx}$** Lethal Concentration xx%. Concentration at which xx% of the test organisms die.

**LNV** Ministerie van Landbouw, Natuur en Voedselkwaliteit. Netherlands Ministry of Agriculture, Nature and Food Quality.

**LR$_{50}$** Lethal Residue 50%. Residue at which 50% of the beneficial arthropods die.

**LUFA** Deutscher Landwirtschaftlicher Untersuchungs- und ForschungsAnstalten.

**Metabolite** see degradation product.

**MPC** Maximum Permissible Concentration. See MTR.

**MTR** Maximaal Toelaatbaar Risiconiveau. Dutch for MPC.

**MWHC** Maximum Water Holding Capacity.

**NC** Negligible Concentration. See VR.

**NOEC** No Observed Effect Concentration. Highest concentration in a test system with no observed effects on organisms or processes.

**OECD** Organisation for Economic Cooperation and Development.

**OM** Organic matter in soil.

**P-value** The probability that a variate would assume a value greater than or equal to the observed value strictly by chance.

**PAH** Polycyclic Aromatic Hydrocarbons.

**PBT** Persistent, Bioaccumulative and Toxic substances.

**PCB** Poly Chlorinated Biphenyl substances.

**PEARL** Pesticide Emission Assessment at Regional and Local scales.

**PEC** Predicted Environmental Concentration. Subscripts are used to specify the concentration in detail: I initial, pw pore water, s soil, tc total content, TWA time weighted average.

**pF** Negative logarithm of the soil moisture pressure head in cm water column.

**PIEC** Predicted Initial Environmental Concentration. Subscripts are used to specify the concentration in detail.

**PNEC** Predicted No Effect Concentration.

**POP** Persistent Organic Pollutants.

**PPR** scientific Panel on Plant protection products and their Residues.

**PPP** Plant Protection Product.

**pw** pore water.

**Q$_{10}$** Quotient 10. Quotient of reaction rate coefficients at temperatures T + 10 °C and T.

**RAC** Regulatory Acceptable Concentration.

**Rate coefficient** A kinetic parameter describing an aspect of the rate at which a substance dissipates from the environment or an environmental compartment. Such parameters may be non-specific, simply describing net dissipation due to degradation and transfer processes, or they may be specific, describing dissipation due to degradation, formation, or transfer. The unit of the rate coefficient depends on the equation with which it is defined.

**REACH** Registration, Evaluation and Authorisation of CHemicals (EC, 2006).

**RI** Reliability Index.

**RIVM** RijksInstituut voor Volksgezondheid en Milieu. Netherlands National Institute for Public Health and the Environment.

**RUMB** Regeling Uitvoering Milieutoelatingseisen Bestrijdingsmiddelen. Regulation under the Pesticide Act concerning environmental criteria for pesticides.

**SCP** Scientific Committee on Plants.

**SMO** soil micro-organism.

**SSD** species sensitivity distribution.

**State variable** Dependent variable of a dynamic system, for example concentration or mass of parent or metabolite.

**tc** total content.

**TCB** Technische Commissie Bodembescherming. Netherlands Soil Protection Technical Committee.

**TER** Toxicity Exposure Ratio.

**TGD** Technical Guidance Document.

**Transformation** see degradation.

**Transformation product** see degradation product.

**TSC** Test System Concentration.

**TWA** Time Weighted Average.

**UN-ECE-LRTAP** United Nations Economic Commission for Europe, Long Range Transport of Air Pollutants.

**vPvB** Very persistent, very Bioaccumulating substances.

**VR** Verwaarloosbaar Risiconiveau. Dutch for Negligible Concentration.

**VROM** Ministerie van Volkshuisvesting, Ruimtelijk Ordening en Milieu. Netherlands Ministry of Housing, Spatial Planning and the Environment.

# Appendix 2 Considerations for ecotoxicologically based risk assessments

A risk assessment for the soil ecosystem consists of two domains with different expertises: exposure / fate and effects / ecotoxicology. The general procedure within the EU is to develop tiered approaches for both domains (see for example FOCUS surface water scenarios with four steps (FOCUS, 2001), the report of the FOCUS Soil Modelling Workgroup (FOCUS, 1997) and CLASSIC (Giddings et al., 2002) and HARAP (Campbell et al., 1999) documents which use tiered approaches for ecotoxicological aquatic risk assessment). The justification to use tiered approaches is that they are usually cheaper than other approaches.

The following terminology is adopted within this section: we call the tiered approaches within each domain 'flow charts' and we call the overall system 'the decision tree'. The following general principles apply to tiered flow charts:
1. *earlier steps are more conservative than later steps and later steps more realistic than earlier steps* (background: lower / higher tiers imply a hierarchical / sequential approach; alternative would be a parallel approach without such a restriction);
2. *jumping to later steps is usually acceptable* (background: this is a consequence of the first principle);
3. *earlier steps require usually less efforts than later steps* (background: if this is not the case, industry will jump to later cheaper steps thus changing the flow chart in practice);
4. *each tier acts as a sieve and has sufficient discriminatory power;*
5. *willingness to accept any relevant information* (background: on a scientific basis, there are no reasons to reject relevant information);
6. *(restricted to fate flow charts) the same target quantity (i.e. type of concentration) applies to all steps, so for different target quantities in principle different flow charts are needed* (background: this may be of academic relevance only if the different target quantities are very similar; for example initial concentration in top 5 cm in soil versus 28-d time weighted average concentration in top 5 cm of soil).

The above principles are used in the Netherlands decision tree for leaching to groundwater and have shown to be non-controversial there (Van der Linden et al., 2004). A consequence of these general principles is that the highest well-established tier within a flow chart serves as a yard-stick for the lower tiers because the lower tiers have to be more conservative than this highest tier. 'Well-established' in this context means that it is clear what has to be done and how results should be interpreted (excluding for example the highest tier that may refer mostly to expert judgement). The consequence of this yard-stick principle is that it is advisable to concentrate first on the highest well-established tier: once this tier has been clearly defined, the job will be relatively easy.

The aim of the risk assessment procedure is to assess whether there is no unacceptable risk to soil organisms. 'Unacceptable risk' has to be specified in terms of an ecologically-based protection goal. Next, the ecotoxicological domain has to define what this means in operational terms and how it can be assessed via a tiered approach. Within all steps, exposure estimates are needed. As a consequence, the ecotoxicological experts have to define the type of concentration that is relevant to assess the ecotoxicological risk: for example highest concentration in top millimetre of soil, highest concentration in top 5 cm of soil, 28-d time weighted average concentration of top 5 cm in soil, average concentration

in plough layer 2 years after the last application, concentration based on total extractable amount or pore water concentration etcetera. This type of concentration is called the Ecotoxicologically Relevant Concentration ('ERC', Boesten et al., 2007).

Both ecotoxicological and fate experts have to ensure consistency of the types of concentration produced in the fate domain with the procedure to estimate the exposure in ecotoxicological experiments. For example if the ecotoxicologist bases the concentration calculation for his/her NOEC in an ecotoxicological experiment on for example the 28-d time weighted average, also a 28-d time weighted average has to be used for the estimation of exposure in the fate domain. Keeping this principle in mind, pragmatic approaches can be followed in practice. For example the EU aquatic Guidance Document recommends to use concentrations in surface water immediately after the spray drift event for assessing chronic effects in a first tier. If this tier gives a problem, then the document recommends to use time weighted average concentrations for assessing chronic effects. This is defensible because the initial peak concentrations are always higher than the time weighted averages. Thus the conservativeness is ensured without using exactly the same type of concentration.

Different types of concentrations will in general lead to different fate flow charts. For example a soil concentration based on the total extractable amount will lead to scenarios with soils that have high organic matter contents because sorption is high and thus leaching losses are low. However, such soils are no vulnerable cases if one is interested in the pore water concentration.

Figure A2.1 shows how the interaction between the ecotoxicological and fate flow charts may work. In a rationally designed and transparent decision tree, economical considerations determine the flow. For example if it is very cheap to perform the steps F1 to F4 (for example because sophisticated exposure scenarios are available and model runs take only 3 minutes), then this will happen first before going from E1 to E2. If steps F2 to F4 are more expensive than moving from E1 to E2, then of course E2 will be done first. Boesten et al. (2007) call this the criss-cross model (see their Figure 3).

As described in chapter 3, this report proposes to consider three protection goals: one in line with the functional redundancy principle (assessed at the European level), one in line with the community recovery principle and one in line with the ecological threshold principle. The CRP and ETP protection goals are triggered by their own value for the half-life for dissipation in soil and have their own decision scheme. Each of the decision schemes follows a tiered approach and follows the general principles of tiered decision schemes. The general principles of decision schemes do not apply in between the three schemes. For example it is not allowed to jump from one scheme to the other.
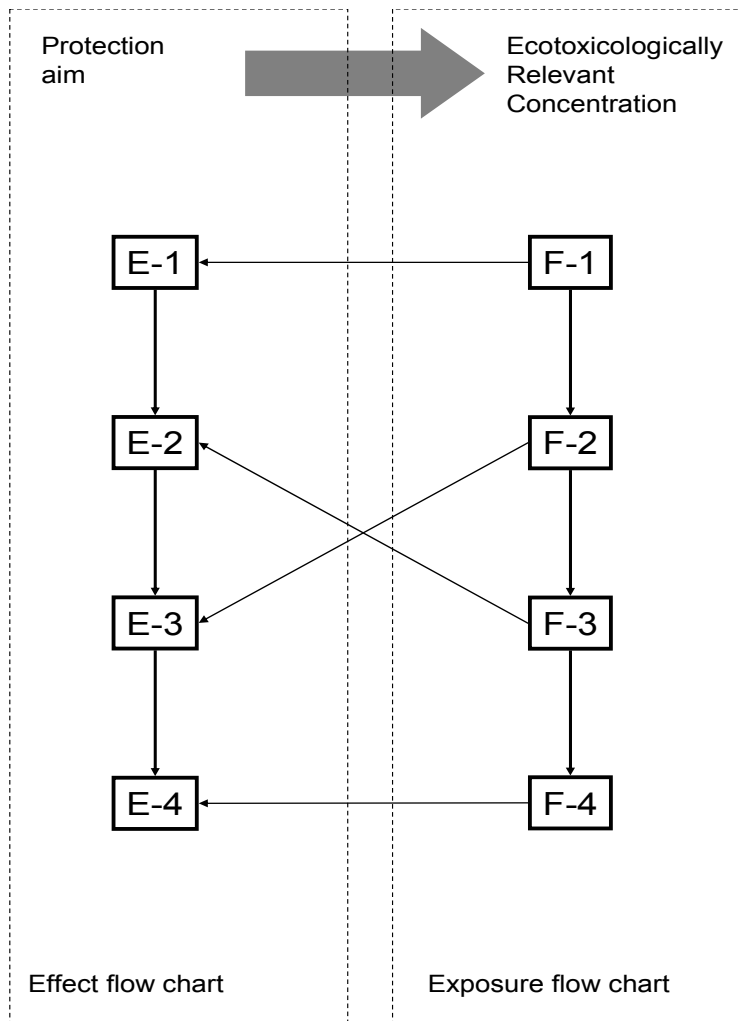
**Figure A2.1 Relationship between fate and effects in tiered environmental risk assessment approaches. The boxes F1 to F4 are tiers in the exposure flow chart. The boxes E1 to E4 are tiers in the effect flow chart. The arrows from the fate domain to the effects domain are examples of exposure estimates that are needed within the effect flow chart. In principle, there will be arrows from all boxes in the fate domain to boxes in the effects domain but only a few arrows are shown for simplicity.**

# Appendix 3 Current tests and data requirements at the EU level

## A3.1 Fate requirements

Reference: Directive 91/414, Annexes II, III and VI. Rev.7

| | Data requirement | Decision making | PEC$_s$ calculation |
|---|---|---|---|
| Laboratory studies | The rate of aerobic degradation of the active substance in four soils must be reported. If testing of metabolites, degradation and reaction products is necessary, studies must be reported for three soils. | If worst case lab DegT$_{50}$ < 60 days (best fit) decision making will normally be based on lab data. Authorisation possible because lab DT$_{50}$ < 90 days and DT$_{90}$ < 1 year. | Based on worst case DT$_{50,lab}$ |
| Soil dissipation studies | The tests have to be conducted for the active substance, metabolites, degradation and reaction products in those conditions where:<br>- DegT$_{50,lab}$ (20 °C, pF2) for active substance, metabolites, degradation and reaction products, in one or more soils, is greater than 60 days or<br>- DegT$_{90,lab}$ (20 °C, pF2) for active substance, metabolites, degradation and reaction products, in one or more soils, is greater than 200 days. Individual studies on a range of representative soils (normally four different types) must be continued until > 90 % of the amount applied has dissipated. The maximum duration of the studies is normally 24 months. | If worst case lab DT$_{50}$ > 60 days and worst case lab DegT$_{90}$ < 200 days decision making will be based on field data. Authorisation possible because DT$_{50}$ < 90 days and DT$_{90}$ < 1 year. | Based on worst case DT$_{50/90,field}$ |
| Soil accumulation studies | Where on the basis of soil dissipation studies it is established that DT$_{90}$, in one or more soils, is greater than one year and where repeated application is envisaged, whether in the same growing season or in succeeding years, the possibility of accumulation of residues in soil and the level at which a plateau concentration is achieved must be investigated except where reliable information can be provided by a model calculation or another appropriate assessment. Long term field studies must be done on two relevant soils and involve multiple applications. | If worst case field DT$_{90}$ > 200 days decision making will be based on accumulation studies.<br>A plateau concentration is compared with ecotoxicological data (litter bag*). | Plateau concentration based on worst case DT$_{50/90,field}$ or realistic worst case measured accumulated concentration. |

* Litter bag testing is required where:
- contamination of soil is possible and the DT$_{90,field}$ value is > 365 days, or
- mineralisation is < 5% in conjunction with bound residue formation of > 70%, or
- contamination of soil is possible and the DT$_{90,field}$ value is between 100 and 365 days and
    - effects on soil micro-organisms > 25 % after 100 d,
    - the long-term TER for earthworms < 5, or the TER for Collembola or soil mites < 5.

**Soil dissipation studies**
*Aim of the test*
The soil dissipation studies should provide estimates of the time taken for dissipation of 50 % and 90 % ($DT_{50}$ and $DT_{90}$) and if possible the time taken for degradation of 50 % and 90 % ($DegT_{50}$ and $DegT_{90}$), of the active substance under field conditions. Where relevant, information on metabolites, degradation and reaction products must be reported.

*Circumstances in which required*
The tests have to be conducted in those conditions where $DegT_{50,lab}$, in one or more soils, determined at 20 °C and at a moisture content of the soil related to pF2 (suction pressure) is greater than 60 days.

Where plant protection products containing the active substance are intended to be used in cold climatic conditions, the tests have to be conducted where $DegT_{50,lab}$, determined at 10 °C and at a moisture content of the soil related to pF2 (suction pressure) is greater than 90 days. If in adequate field studies metabolites, degradation and reaction products which are present in laboratory studies are not present on the lowest feasible LOQ basis, no additional information on persistence is necessary.

Guidance on the degradation and transformation parameters of the active substance and / or metabolites is provided in the current or later revisions of the FOCUS Groundwater and the FOCUS Degradation Kinetics documents.

*Test conditions*
Individual studies on a range of representative soils (normally four different types) must be continued until > 90 % of the amount applied has dissipated. The maximum duration of the studies is normally 24 months.

*Test guideline*
SETAC - Procedures for assessing the environmental fate and ecotoxicity of pesticides.

# A3.2    Available soil ecotoxicity tests

The following sections give an overview of soil ecotoxicity tests, which are currently being used to evaluate possible effects of plant protection products on the soil ecosystem. Furthermore, some references are given for soil ecotoxicity tests, which are not yet being used as standard tests for the evaluation of plant protection products.

General remarks with respect to the tests given in this appendix are:
on the test substance:
Some guidelines, but certainly not all, give information on or specify how the test substance (preferably) should be applied. Sometimes it is prescribed to use a formulation and sometimes the use of the active substance is recommended. Possibilities vary too much to give adequate advice here. Evaluating authorities should judge whether the form in which the substance is applied is adequate for the (proposed) use of the pesticide.

on the application:
In some tests, the test substance can be either mixed with or sprayed on the test medium. Spraying in the field is usually carried out according to GAP (Good Agricultural Practice). After spraying no water is added and the test substance is not further mixed with the soil. This seems not a suitable procedure for organisms that live predominantly in the soil (e.g. earthworms). Therefore it is recommended to ignore results of tests where the substance is sprayed on the soil without any mixing for such organisms.

In 2002, the European Commission presented a detailed risk assessment procedure for soil organisms including a test for earthworms (EU, 2002). The guidance given for earthworms implies that the pore water concentration in soil is considered as the yardstick for assessing effects (also recommended by Van Gestel, 1992). However, nowhere any guidance is given on how to estimate reliable realistic worst-case exposure concentrations for soil pore water. Instead it is recommended to divide the $LC_{50}$ by a factor of 2 for compounds whose sorption is correlated to organic matter. The justification for this is that the standard soil used in earthworm tests has an organic matter content of about 10%, whereas the EU guidance document considers 5% organic matter more representative for agricultural soils. However, this 5% is nowhere justified and is certainly not justifiable as a realistic worst-case assumption for the EU (see organic carbon map of the EU; Jones et al., 2004). It is also not defensible as a realistic-worst case for Dutch soils (see Figure A3.1). It seems thus not acceptable to use this 5% in the first (and also final) exposure tier.

A correct procedure for assessment of effects in such a case is:
1. base a RAC for earthworms on pore water concentrations estimated for the ecotoxicological experiment;
2. estimate a PEC (pore water concentration) for field exposure on the basis of the exposure flow chart (including GeoPEARL as Tier 2 if necessary);
3. compare RAC and PEC.

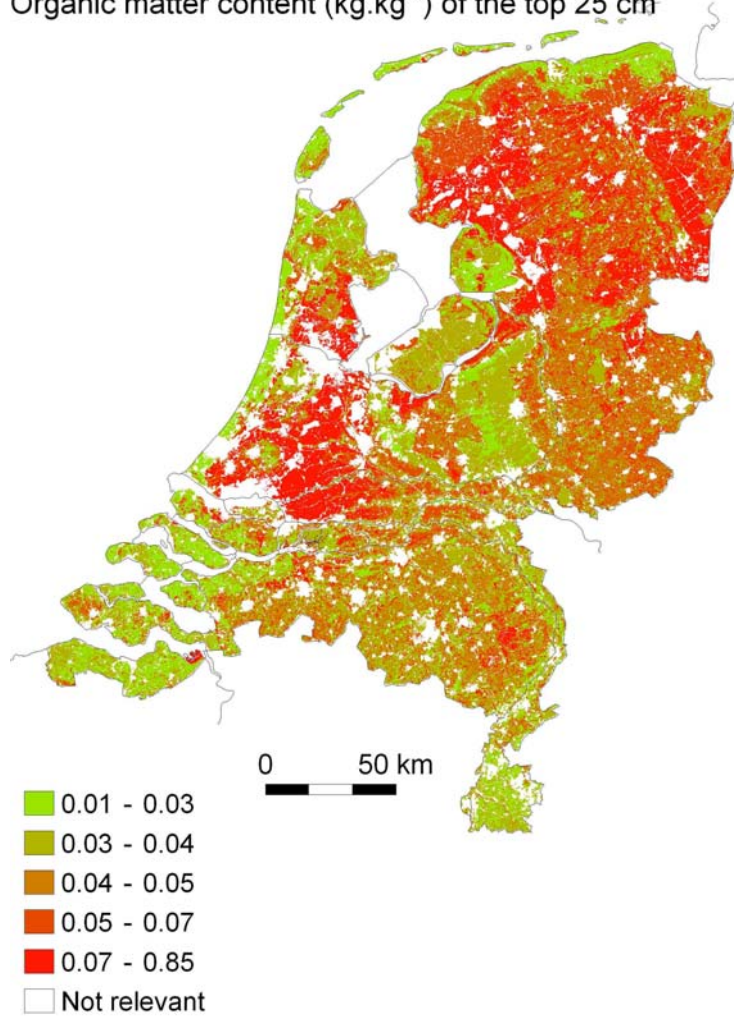Organic matter content (kg.kg$^{-1}$) of the top 25 cm



Legend:
- 0.01 - 0.03
- 0.03 - 0.04
- 0.04 - 0.05
- 0.05 - 0.07
- 0.07 - 0.85
- Not relevant

**Figure A3.1 Soil organic matter map of the Netherlands**

## A3.2.1 Earthworms

| Test | earthworm acute toxicity test (standard test) |
|---|---|
| Guideline | OECD 207 (1984) |
| Test species | earthworm (*Eisenia foetida foetida / andrei*) |
| Exposure duration | 14 d |
| Test medium | artificial soil[#]; 750 g wet mass in glass containers of about 1 dm$^3$ |
| Dose | range of 5 concentrations in a geometric series, single application |
| Dosing method | a) test substance in deionised water mixed with artificial soil or sprayed (after introduction of worms) over it,<br>b) if insoluble in water as a) but test substance dissolved in a volatile organic solvent,<br>c) if test substance not soluble, dispersible or emulsifiable, mixed with quartz sand, then mixed with artificial soil. |
| Physico-chemical measurements | moisture content of test medium at start and end, pH value at start of test |
| Biological observations | average live mass and number of live worms at start and end of test, mortality assessment at day 7 (after day 7 assessment worms and medium are replaced in test container) and at day 14, reporting of behavioural or pathological symptoms |
| Endpoint | $LC_{50}$[$] |
| Units and characterisation endpoint | mg kg$^{-1}$ active substance per dry weight soil (total content, nominal) |
| Endpoint is compared to[11] | $PIEC_s$ after last application in growing season |

[#] (10% OM (Sphagnum peat), pH 6.0 ± 0.5, 20% kaolin clay, 70% industrial sand, moisture content ± 35% of dw; see guideline for more details)

[$] If $\log(K_{ow}) > 2$, endpoint is corrected for the high organic carbon content of the artificial soil by dividing it by a factor 2 (based on 10% OM in artificial soil and ± 5% OM in a reference soil). *Note: not longer defensible, see introductory remarks at the beginning of this section.*

---

[11] Current practice in the Netherlands

| Test | earthworm reproductive toxicity test |
|------|--------------------------------------|
| | (standard test when certain criteria are fulfilled) |
| Guideline | ISO 11268-2:1997 / OECD 222 |
| Test species | earthworm (*Eisenia foetida foetida / andrei*) |
| Exposure duration | 56 d |
| Test medium | artificial soil[#] mixed with food source (for example dried, finely ground cow manure); test containers of about 2 $dm^3$, cross-sectional area 200 $cm^2$, such that a moist substrate depth of 5-6 cm contains 500-600 g dry mass |
| Concentrations (range/limit) | range of at least 5 concentrations in a geometric series, single application |
| Dosing method | a): test substance in deionised water mixed with artificial soil or sprayed[$] (after introduction of worms) over it, |
| | or, if insoluble in water b): test substance dissolved in a volatile organic solvent, mixed with a portion of the quartz sand and after evaporating the solvent mix with artificial soil, |
| | or, if test substance not soluble, dispersible or emulsifiable c): mixed with quartz sand, then mixed with artificial soil |
| Physico-chemical measurements | moisture content and pH of test medium at start and end of test |
| | verifying amount of test substance applied by a suitable calibration technique (for example by weighing)[%] |
| Biological observations | total number and mass of living adult worms at start of test and after 4 weeks (adults are then removed), number of offspring at end of test (8 w), reporting of behavioural or pathological symptoms |
| Endpoint | NOEC (reproduction)[&] |
| Units and characterisation endpoint | mg $kg^{-1}$ active substance per dry weight soil (total content, nominal) |
| Endpoint is compared to[11] | $PIEC_s$ after last application in 1 growing season |

[#] (10% OM (Sphagnum peat), pH 6.0 ±0.5, 20% kaolin clay, 70% industrial sand, moisture content 40 - 60 mass% of $WHC_{max}$; see guideline for more details)

[$] Spraying is only an option in OECD 207. A water application rate of 600-800 $dm^3$ $ha^{-1}$ is recommended.

[%] Says the guideline, but often not carried out in the tests. There is also a note included in the ISO-guideline which says: 'No provision is made in the test method for monitoring the persistence of the substance under test.'

[&] If $log(K_{ow}) > 2$, the endpoint is corrected for the high organic carbon content of the artificial soil by dividing it by a factor of 2 (based on 10% OM in artificial soil and ± 5% OM in a reference soil)

| Test | earthworm field toxicity test |
|---|---|
| | (higher tier test) |
| Guideline | ISO 11268-3:1997 |
| Test species | earthworm (natural occurring species) |
| Exposure duration | depends on characteristics of test substance, usually 1 year |
| Test medium | field sites |
| Concentrations (range/limit) | application according to GAP, expressed in kg ha$^{-1}$ (active substance), no dose-response |
| Dosing method | according to GAP |
| Physico-chemical measurements | characteristics of study site (for example soil parameters), weather conditions during test |
| Biological observations | abundance and biomass of earthworms (overall and species level, adults and juveniles) 1, 4 - 6 and 12 months after application |
| Endpoint | differences in species and numbers and biomass of earthworms between control and treated plots |
| Units and characterisation endpoint | statistically analysed differences, sometimes expressed as reduction percentages, test dose in kg ha$^{-1}$ (active substance), nominal |
| Endpoint is compared to[11] | effects are evaluated based on expert judgement, test dose should be relevant for field dose rate according to GAP |

## A3.2.2  Soil micro-organisms

| Test | soil micro-organisms nitrogen transformation test (standard test) |
|---|---|
| Guideline | OECD 216 |
| Test species | soil micro-organisms |
| Exposure duration | 28 or 100 d[#] |
| Test medium | field soil[$] amended with organic substrate (usually powdered Lucerne-grass-green meal with C/N ratio between 12/1 and 16/1), no specification of dimensions of test container / depth of test medium layer is made in the guideline |
| Concentrations (range/limit) | minimum of 2 concentrations, lower concentration at least max $PEC_s$ according to GAP and higher concentration at least five times the lower concentration, single application; test concentrations are calculated assuming uniform incorporation to 5 cm depth, soil bulk density 1.5 g cm$^{-3}$ |
| Dosing method | mixing of test substance with the soil, test substance either dissolved in water or by using fine quartz sand as a carrier |
| Physico-chemical measurements | soil parameters (incl. moisture content at start and end of test) nitrate formation per mass of dry soil per day (mg kg$^{-1}$ d$^{-1}$) on days 0, 7, 14 and 28 |
| Biological observations | |
| Endpoint | differences in nitrate formation rate between treatment and control |
| Units and characterisation endpoint | % deviation, at a certain nominal dose rate (dose rate in mg kg$^{-1}$)[&] |
| Endpoint is compared to[11] | trigger value (%), and test concentration should be relevant for field dose rate according to GAP |

[#] Usually duration is 28 days. If on day 28 differences are $\geq$ 25%, measurements are continued in 14 day intervals to a max of 100 days.

[$] Field soil with the following recommended characteristics: sand content between 50 and 75%, pH 5.5 - 7.5, organic carbon 0.5 - 1.5%, microbial biomass should be at least 1% of total soil organic carbon. See guideline for further details.

[&] Usually in the test reports test concentrations are converted to doses active substance in kg ha$^{-1}$; in the Terrestrial Guidance Document however it is recommended to compare test concentrations to $PEC_s$ in mg kg$^{-1}$ because different modes of calculations could cause a bias in risk interpretation.

| Test | soil micro-organisms carbon transformation test (standard test) |
|---|---|
| Guideline | OECD 217 |
| Test species | soil micro-organisms |
| Exposure duration | 28 or 100 d[#] |
| Test medium | field soil[$] amended with organic substrate (usually powdered Lucerne-grass-green meal with C/N ratio between 12/1 and 16/1)<br>no specification of dimensions of test container / depth of test medium layer is made in the guideline |
| Concentrations (range/limit) | minimum of 2 concentrations, lower concentration at least max $PEC_s$ according to GAP and higher concentration at least five times the lower concentration, single application; test concentrations are calculated assuming uniform incorporation to 5 cm depth, soil density 1.5 g $cm^{-3}$ |
| Dosing method | mixing of test substance with the soil, test substance either dissolved in water or by using fine quartz sand as a carrier |
| Physico-chemical measurements | soil parameters (incl. moisture content at start and end of test)<br>at days 0, 7, 14 and 28 samples are mixed with glucose and glucose-induced respiration rates ($CO_2$ released per kg dry soil per h or $O_2$ consumed per kg dry soil per h (mg $kg^{-1}$ $h^{-1}$)) are measured for 12 consecutive hours |
| Biological observations | - |
| Endpoint | differences in respiration rate between treatment and control |
| Units and characterisation endpoint | % deviation, at a certain nominal dose rate (mg $kg^{-1}$)[&] |
| Endpoint is compared to[11] | trigger value (%), and test concentration should be relevant for field dose rate according to GAP |

[#] If on day 28 differences are $\geq$ 25%, measurements are continued in 14 day intervals to a max of 100 days.

[$] Field soil with the following recommended characteristics: sand content between 50 and 75%, pH 5.5 - 7.5, organic carbon 0.5-1.5%, microbial biomass should be at least 1% of total soil organic carbon. See guideline for further details.

[&] Usually in the test reports test concentrations are converted to doses active substance (kg $ha^{-1}$) and compared to the field dose; in the Terrestrial Guidance Document however it is recommended to compare test concentrations to $PEC_s$ in mg $kg^{-1}$ soil because different modes of calculations could cause a bias in risk interpretation.

| Test | Soil fungi test (higher tier test) |
|---|---|
| Guideline | no guideline, general guidance by Ctgb |
| Test species | soil fungi, preferably one of the following species:<br>• *Mucor circinelloides*<br>• *Paecelomyces marquandii*<br>• *Marasmius oreades*<br>• *Phytophtora nicotianae*<br>• *Suillus granulatus* |
| Exposure duration | depends on growth rate fungus, but should be sufficiently long to obtain lowest possible NOEC or $EC_{10}$ (for example 15 d) |
| Test medium | common agricultural field soil[#] and nutrient agar[$] (see dosing method) in a mixture of 10 g soil (dw) and 20 ml agar; soil should be sieved to particle size ≤ 2 mm and sterilised before adding test substance. |
| Concentrations (range/limit) | geometrical series, factor ≤ 3.3, highest concentration ≤ 1000 mg $kg^{-1}$ soil |
| Dosing method | Mixing of test substance with the soil (see earthworms) and subsequent incubation for 2 days at 20 - 25 °C. Then soil/agar plates are prepared by adding 10 g soil dw to Petri-dishes followed by pouring twice 10 $cm^3$ autoclaved, molten nutrient agar on top of the soil. During pouring the dishes are swirled in order to evenly distribute soil and agar.<br>After solidifying of the agar, a piece of mycelium inoculum is placed in the centre of each plate, or alternatively, fungal spores may be mixed through the still liquid soil / agar. |
| Physico-chemical measurements | |
| Biological observations | radial growth of the fungus, or in the case of fungal spores, germination and growth |
| Endpoint | NOEC and / or $EC_{50}$ |
| Units and characterisation endpoint | mg $kg^{-1}$ as active substance per dry soil (nominal, total content) |
| Endpoint is compared to[11] | endpoint is processed into $MPC_s$ and compared to $PEC_s$ 2 years after 10 yearly applications calculated according to RUMB (2000) |

[#] pH 6.5 - 7.5, OM 2.5 - 6 %
[$] composition of the agar depends on fungus to be used, for example malt agar or mineral salts / glucose agar

In case of the soil fungi test 10 g of soil is mixed with 20 ml agar. However, little is known about the interaction (adsorption, degradation) between the pesticide and the agar. As the soil is sterilised before the test substance is added, it may be assumed that transformation of the substance is negligible. Agar contains approximately 25 g solids per litre medium and it may be regarded as organic matter. A $TSC_{s,I,tc}$ can be derived assuming 10.5 g of solids in one Petri-dish; the $TSC_{s,I,tc}$ is then 0.95 times the nominal value of the tested soil. As the transformation is assumed to be absent, the $TSC_{s,TWA,tc}$ is equal to the $TSC_{s,I,tc}$. An approximation of the $TSC_{s,I,pw}$ can be derived if it is assumed that the agar is acting as soil organic matter. The soil is 'enriched' with additional organic matter; in the test system the organic matter content is 5% higher than in the soil. So, if the organic matter content of the soil is 2%, the organic matter content in the enriched soil is 7%.

## A3.2.3 Other soil non-target organisms

| | |
|---|---|
| Test | <u>Soil quality – Inhibition of reproduction of Collembola (*Folsomia candida*) by soil pollutants</u> (higher tier test) |
| Guideline | ISO 11267: 1999 |
| Test species | springtail (<u>*Folsomia candida*</u>) |
| Exposure duration | 28 days |
| Test medium | artificial soil[#] in glass containers of $\pm$ 100 cm$^3$, diameter $\pm$ 5 cm, 30 g soil (ww) per container, at day 0 and day 14, 2 mg of granulated dry yeast is added to each test container |
| Dose | at least five concentrations in a geometric series spaced by a factor $\leq$ 2, single application |
| Dosing method | a) test substance in deionised water mixed with artificial soil<br>b) if insoluble in water as a) but test substance dissolved in a volatile organic solvent and mixed with a portion of the medium<br>c) if test substance not soluble, dispersible or emulsifiable, mixed with quartz sand, then mixed with artificial soil |
| Physico-chemical measurements | pH and water content at beginning and end of test, water content also after 2 weeks and adjusting when necessary. |
| Biological observations | number of surviving springtails (adults and juveniles) |
| Endpoint | NOEC (reproduction) |
| Units and characterisation endpoint | mg kg$^{-1}$ as active substance per dry soil (nominal, total content) |
| Endpoint is compared to[11] | PIEC$_s$ after last application in 1 growing season |

[1] (10 % Sphagnum peat, pH 6.0 $\pm$ 0.5, 20 % kaolin clay, 70 % industrial sand, moisture content 40 - 60 % of MWHC; see guideline for more details)

A note is included in the guideline which says: the stability of the test substance cannot be assured over the test period; no allowance is made in the test method described for possible degradation of the test substance over the course of the experiment.

| Test | Litter bag test (higher tier test) |
|---|---|
| Guideline | EPFES Guidance Document (Römbke et al., 2003) |
| Test species | soil organisms involved in organic matter breakdown |
| Exposure duration | at least 6 months, continued up to 12 months if 60 % mass loss in control is not reached after 6 months. |
| Test medium | litter bags containing dried OM (wheat straw) buried in field soil |
| Dose | plateau concentration + annual cumulative application rate (see dosing method) |
| Dosing method | Plateau concentration ($mg\ kg^{-1}$) which has been calculated for the top 20 cm of soil according to FOCUS guidance is incorporated into top 10 cm of soil. Two weeks after this, litter bags are buried into the soil at a depth of 5 cm. Within 1 week after burying the bags, total annual application rate (sum of all applications of the Plant Protection Product (PPP) within a year)[#] is sprayed[$] in 1 dose on the bare soil / soil with only little plant cover. |
| Physico-chemical measurements | characterisation of study site (soil properties, vegetation type and cover, etc) weather data test concentrations in soil immediately after incorporation of plateau concentration and immediately after application of the cumulative annual dose[&] |
| Biological observations: | determination of ash-free dry weight of straw in litter bags after 1, 3 and 6 months after burying bags (or further sampling if 60% mass loss in control is not reached) |
| Endpoint | mass loss of litter bags in treatment compared to mass loss of litter bags in control |
| Units and characterisation endpoint | % effect (mass loss) |
| Endpoint is compared to[11] | trigger value (%) |

[#] No degradation of test substance is taken into account, crop interception levels for the applications at different growth stages however, should be taken into account.
Units of the annual cumulative dose rate are not mentioned in guideline.

[$] Special use patterns as seed treatment or granule application should be applied according to GAP.

[&] In light of the wide variability in field studies, EPFES recommends a range of 50 – 150 % of nominal should be reached.

| Test | A laboratory test protocol to evaluate effects of PPP on mortality and reproduction of the predatory mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) in standard soil<br>*(non-validated test protocol)* |
|---|---|
| Guideline | Bakker et al. (2003) |
| Test species | the predatory mite *Hypoaspis aculeifer* Canestrini |
| Exposure duration | 21 days (14 + 7) |
| Test medium | LUFA 2.1 soil  in<br>• 6 x 10 cm glass units with a circular space of 4 cm in diameter and 2 circular holes in top plate (mortality)<br>• small plastic units approx. 24 mm in diameter and 37 mm high, with a layer of humidified plaster, closed with a plastic cap with a gauze (reproduction).<br>As a food source the mite *Tyrophagus putrescentiae* (Schrank) (Acari: Acaridae) is used. |
| Dose | Limit or dose-response (5 rates); dimethoate as toxic reference. |
| Dosing method | mixing the test item through the soil (1) and applying the test item as a spray before introduction of the test organisms (2)<br><br>(1) Mix for each treatment 5.00 ml solution thoroughly in 33.33 g LUFA 2.1 soil (WHC 50%, equivalent to 15% w/w). Fill the test units with 4.30 – 4.70 g dry soil each. Compress slightly to smoothen the surface.<br>(2) Fill the bottom part of each unit with 4.5 g dry LUFA 2.1 soil (layer of approx. 3 mm) and smoothen the surface. Subsequently add 675 μl deionised water to each unit (WHC 50%). Subsequently use standard laboratory application techniques to apply the test item. |
| Physico-chemical measurements | not mentioned in protocol |
| Biological observations | surviving mites, occurrence of offspring, number of juveniles and non hatched eggs |
| Endpoints | mortality<br>reproductive capacity<br>relative to control |
| Units and characterisation endpoint | Both endpoints as % reduction, at a certain nominal dose rate (mg kg$^{-1}$). Mortality also as $LR_{50}$ in dose-response test. |
| Endpoint is compared to[11] | Effect percentage is compared to trigger value (%), and test concentration should be relevant for field dose rate according to GAP. $LR_{50}$ compared to initial $PEC_s$ after last application in 1 growing season. |

## A3.2.4 Non-target plants

(NB: Non-target plants are non-crop plants located outside the treatment area)

| Test | Seedling emergence and seedling growth test (standard for herbicides, higher tier test for non-herbicides) |
|---|---|
| Guideline | draft OECD 208 (2003) |
| Test species | higher plants |
| Exposure duration | 14 to 21 days after 50 % of the control plants have emerged |
| Test medium | artificial or natural / field soil (sandy loam, loamy sand, sandy clay loam) in pots |
| Dose | at least five concentrations in a geometric series spaced by a factor $\leq 3$, single application |
| Dosing method | incorporation into soil (see earthworm tests) before planting of seeds or surface application according to GAP after planting of seeds |
| Physico-chemical measurements | analytical verification of soil concentration, at least at the lowest and highest concentration<br>for surface application, calibration of spraying equipment should be done environmental conditions |
| Biological observations | visual phytotoxicity and mortality during test, % emergence and biomass (shoot weight or height, dw) at end of test |
| Endpoint | $ER_{50}$ values (lowest used for risk assessment) |
| Units and characterisation endpoint | g ha$^{-1}$ (nominal / measured) |
| Endpoint is compared to[11] | off-crop exposure (g ha$^{-1}$), based on drift values |

The initial soil content (or the initial pore water concentration) is relevant for the interpretation of the test. See acute earthworm test for estimation of the PIEC$_s$.

Other available tests with terrestrial plants can be screening tests, which are carried out for efficacy assessment. In these studies endpoints as phytotoxicity, chlorosis, (crop) yield, etcetera are measured by visual inspection. No NOEC value is derived, but an effect percentage at application rate can be derived. These data are used for a preliminary assessment for terrestrial plants in order to decide whether further testing is necessary.

Generally, screening data are tests carried out with the formulation to assess the efficacy against the target-organisms and to assess unwanted side effects on the crops. The tests are usually carried out at maximum dose. Therefore, it is questionable whether these data are useful for the risk assessment for persistence.

## A3.2.5 Other test methods

Apart from the test methods summarized above, methods are available from other sources or under development. Some examples are:

- Effects of pollutants on insect larvae (*Oxythyrea funesta*) - Determination of acute toxicity (ISO 20963:2005).
- Test on the Enchytraeid *Cognettia sphagnetorum* See: Rundgren and Augustsson, chapter 6 in Handbook of Soil Invertebrate Toxicity Tests, edited by Lokke H and Van Gestel CAM, 1998, John Wiley & Sons Ltd, Chichester.
- Enchytraeid reproduction test (OECD 220).
- Tests on the oribatid mite *Platynothrus peltifer*, see: Van Gestel and Doornekamp, chapter 8 in Handbook of Soil Invertebrate Toxicity Tests.
- Test on the Centipede *Lithobius mutabilis*, see: Laskowski, Pyza, Maryanski and Niklinska, chapter 11 in Handbook of Soil Invertebrate Toxicity Tests.
- Test on the Millipede *Brachydesmus superus*, see: Tajovsky, chapter 12 in Handbook of Soil Invertebrate Toxicity Tests.
- Test on the Isopod *Porcellio scaber*, see: Hornung, Farkas and Fischer in Handbook of Soil Invertebrate Toxicity Tests.
- E2172-01 Standard Guide for Conducting Laboratory Soil Toxicity Tests with the Nematode *Caenorhabditis elegans* (ASTM).
- ISO 16387. 2004. Soil quality -- Effects of pollutants on Enchytraeidae (Enchytraeus sp.) -- Determination of effects on reproduction and survival.

# Appendix 4 Relevant items Stockholm Convention

Annex D

INFORMATION REQUIREMENTS AND SCREENING CRITERIA

1) A party submitting a proposal to list a chemical in Annexes A, B and/or C shall identify the chemical in the manner described in subsection (a) and provide the information on the chemical, and its transformation products where relevant, relating to the screening criteria set out in subsections (b) to (e):
   a) Chemical identity:
      i) Names, including trade name or names, commercial name or names and synonyms, Chemical Abstracts Service (CAS) Registry number, International Union of Pure and Applied Chemistry (IUPAC) name; and
      ii) Structure, including specification of isomers, where applicable, and the structure of the chemical class;
   b) Persistence:
      i) Evidence that the half-life of the chemical in water is greater than two months, or that its half-life in soil is greater than six months, or that its half-life in sediment is greater than six months; or
      ii) Evidence that the chemical is otherwise sufficiently persistent to justify its consideration within the scope of this Convention;
   c) Bio-accumulation:
      i) Evidence that the bio-concentration factor or bio-accumulation factor in aquatic species for the chemical is greater than 5,000 or, in the absence of such data, that the log $K_{ow}$ is greater than 5;
      ii) Evidence that a chemical presents other reasons for concern, such as high bio-accumulation in other species, high toxicity or ecotoxicity; or
      iii) Monitoring data in biota indicating that the bio-accumulation potential of the chemical is sufficient to justify its consideration within the scope of this Convention;
   d) Potential for long-range environmental transport:
      i) Measured levels of the chemical in locations distant from the sources of its release that are of potential concern;
      ii) Monitoring data showing that long-range environmental transport of the chemical, with the potential for transfer to a receiving environment, may have occurred via air, water or migratory species; or
      iii) Environmental fate properties and/or model results that demonstrate that the chemical has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For a chemical that migrates significantly through the air, its half-life in air should be greater than two days; and
   e) Adverse effects:
      i) Evidence of adverse effects to human health or to the environment that justifies consideration of the chemical within the scope of this Convention; or
      ii) Toxicity or ecotoxicity data that indicate the potential for damage to human health or to the environment.

2) The proposing Party shall provide a statement of the reasons for concern including, where possible, a comparison of toxicity or ecotoxicity data with detected or predicted levels of a chemical resulting or anticipated from its long-range environmental transport, and a short statement indicating the need for global control.

3) The proposing Party shall, to the extent possible and taking into account its capabilities, provide additional information to support the review of the proposal referred to in section 6 of Article 8. In developing such a proposal, a Party may draw on technical expertise from any source.

# Appendix 5 Relevant items of REACH

## REACH ANNEX XII

### CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES

This Annex lays down the criteria for the identification of:

i)   persistent, bioaccumulative and toxic substances (PBT-substances), and
ii)  very persistent and very bioaccumulative substances (vPvB-substances).

A substance is identified as a PBT substance if it fulfils the criteria in Sections 1.1, 1.2 and 1.3. A substance is identified as a vPvB substance if it fulfils the criteria in Sections 2.1 and 2.2. This annex shall not apply to inorganic substances, but shall apply to organo-metals.

## 1    PBT-SUBSTANCES
A substance that fulfils all three of the criteria of the sections below is a PBT substance.

### 1.1   Persistence
A substance *fulfils* the persistence criterion (P-) when:
- the half-life in marine water is higher than 60 days, or
- the half-life in fresh- or estuarine water is higher than 40 days, or
- the half-life in marine sediment is higher than 180 days, or
- the half-life in fresh- or estuarine water sediment is higher than 120 days, or
- the half-life in soil is higher than 120 days.

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.

### 1.2   Bioaccumulation
A substance *fulfils* the bioaccumulation criterion (B-) when:
- the bioconcentration factor (BCF) is higher than 2000.

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

### 1.3   Toxicity
A substance *fulfils* the toxicity criterion (T-) when:
- the long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01 mg/l, or
- the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or
- there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

## 2    vPvB – SUBSTANCES

A substance that fulfils the criteria of the sections below is a vPvB substance.

### *2.1    Persistence*

A substance *fulfils* the very persistence criterion (vP-) when:
- the half-life in marine, fresh- or estuarine water is higher than 60 days, or
- the half-life in marine, fresh- or estuarine water sediment is higher than 180 days, or
- the half-life in soil is higher than 180.

### *2.1    Bioaccumulation*

A substance *fulfils* the very bioaccumulative criterion (vB-) when:
- the bioconcentration factor is greater than 5000.

# Appendix 6 TIER 1 calculation procedure

## A6.1 Description of the Tier 1 model

The aim of the model is to obtain conservative estimates of exposure of pesticide and transformation products in the top 5 cm of soil in the field (in line with the philosophy of the tiered exposure approach).

The model considers only the top layer of soil (i.e. up to the ploughing depth). It assumes that transformation in soil at a fixed temperature is the only loss process from this top layer both for parent and metabolites. It considers one parent and two sequential transformation products. Long-term sorption kinetics is described as in the PEARL model but assuming a linear sorption isotherm.
Pesticide sorbed at the non-equilibrium site is assumed not to transform and the pesticide in the liquid phase and that sorbed to the equilibrium site is transformed considering first-order kinetics.

The model is based on the following set of equations for the parent compound and the two transformation products:

$$m = W\,c + X_{EQ} + X_{NE} \tag{A6.1}$$

$$X_{EQ} = K_{EQ}\,c \tag{A6.2}$$

$$K_{EQ} = K_{OM}\,m_{OM} \tag{A6.3}$$

$$\frac{dX_{NE}}{dt} = k_D(K_{NE}\,c - X_{NE}) \tag{A6.4}$$

$$K_{NE} = f_{NE}\,K_{EQ} \tag{A6.5}$$

where:

| | |
|---|---|
| $m$ | content of substance in soil (i.e., mass of substance per mass of dry soil, (mg kg$^{-1}$)) |
| $c$ | concentration in the liquid phase, (mg dm$^{-3}$) |
| $W$ | water content defined as volume of water per mass of dry soil, (dm$^3$ kg$^{-1}$) |
| $X_{EQ}$ | content sorbed at equilibrium sites, (mg kg$^{-1}$) |
| $X_{NE}$ | content sorbed at non-equilibrium sites, (mg kg$^{-1}$) |
| $K_{EQ}$ | equilibrium sorption coefficient, (dm$^3$ kg$^{-1}$) |
| $K_{OM}$ | organic-matter/water distribution coefficient, (dm$^3$ kg$^{-1}$) |
| $m_{OM}$ | mass fraction of organic matter, (-) |
| $K_{NE}$ | non-equilibrium sorption coefficient, (dm$^3$ kg$^{-1}$) |
| $t$ | time, (d) |
| $k_D$ | desorption rate coefficient, (d$^{-1}$) |
| $f_{NE}$ | the ratio between the equilibrium and non-equilibrium sorption coefficients, (-) |

The equation for the transformation of the parent is as follows:

$$\frac{dm_P}{dt} = -k_{t,P}(W\,c_P + X_{EQ,P})$$

(A6.6)

where:
the subscript P refers to the parent compound and
$k_t$    degradation rate coefficient for equilibrium phase, $(d^{-1})$

The equation for formation and transformation of the first metabolite M1 reads:

$$\frac{dm_{M1}}{dt} = +F_1\left(\frac{M_{M1}}{M_P}\right)\frac{dm_P}{dt} - k_{t,M1}(W\,c_{M1} + X_{EQ,M1})$$

(A6.7)

where:
the subscript M1 refers to the metabolite M1
$F_1$    molar fraction of parent transformed into metabolite M1, (-)
$M_{M1}$    molar mass of metabolite M1, $(g\,mol^{-1})$
$M_P$    molar mass of parent, $(g\,mol^{-1})$

Similarly, the rate equation for formation and transformation of the second metabolite M2 reads:

$$\frac{dm_{M2}}{dt} = +F_2\left(\frac{M_{M2}}{M_{M1}}\right)\frac{dm_{M1}}{dt} - k_{t,M2}(W\,c_{M2} + X_{EQ,M2})$$

(A6.8)

where:
the subscript M2 refers to the metabolite M2
$F_2$    molar fraction of M1 transformed into M2, (-)
$M_{M2}$    molar mass of metabolite M2, $(g\,mol^{-1})$

The half-lives of the parent and the metabolites in soil ($DegT_{50}$) are defined by

$$DegT_{50} = \ln 2 / k_t$$

(A6.9)

Note that this $DegT_{50}$ refers only to the equilibrium phase of the soil and thus not to the decline resulting from degradation as observed in a laboratory incubation study. For instance, if there is a strong effect of long-term sorption kinetics (i.e. non-equilibrium sorption in the PEARL submodel), then even a comparatively short $DegT_{50}$ may result in a slow decline of the total amount in soil in a laboratory study.

The effect of soil temperature on the transformation rate coefficient in soil is described by the Arrhenius equation:

$$f_T = \exp\left(\frac{E\,(T-T_{REF})}{R\,T_{REF}\,T}\right) = \exp\left(\frac{-E}{R}\left[\frac{1}{T}-\frac{1}{T_{REF}}\right]\right) \qquad (A6.10)$$

where:
$f_T$     the multiplication factor for the rate coefficient, (-)
$E$     Arrhenius activation energy, (kJ mol$^{-1}$)
$T$     temperature of the soil, (K)
$T_{REF}$     the reference temperature for the specified $DegT_{50}$, (K)
$R$     the gas constant, (kJ mol$^{-1}$ K$^{-1}$).

The model has been programmed in FORTRAN. The rate equations are integrated with Euler's rectilinear method and the time step $\Delta t$ is calculated by:

$$\Delta t = \frac{a}{\max(k_t, k_D)} \qquad (A6.11)$$

where: $a = 0.001$ (-) and the maximum applies to the $k_t$ and $k_D$ values of all substances. This value of $a$ ensures enough numerical accuracy in the calculation procedure (see p. 84 of Leistra et al., 2001). The FORTRAN programme will be combined with a user-friendly interface for easy use in the risk assessment procedure.

## A6.2    Parameterisation

Values given in this section are default values for the Tier-1 exposure calculations.

The reference temperature is 20 $^o$C because $DegT_{50}$ values in dossiers are given for this temperature. The default Arrhenius activation energy is 65.4 kJ mol$^{-1}$ (EFSA, 2007b).

The soil temperature is 8 $^o$C because this is considered conservative enough for a first-tier approach under Dutch conditions. The value of 8 was based on an analysis of climate data stored in the GeoPEARL database. This database contains 20-y weather data of 15 Dutch meteorological stations. The 20-y average temperature of these stations ranged from 9.3 to 10.2 $^o$C and the minimum of the annual averages ranged from 7.6 to 8.8 $^o$C.

The model simulates the contents of the three substances for two layers: the target layer (to be specified by the user but usually from 0 to 5 cm deep, default 5 cm) and the remainder of the plough layer (usually from 5 to 20 cm deep). Pesticide application is always to the target layer. At ploughing times, the two layers are mixed to give a uniform content in both layers. The ploughing option is switched off for the tier-1 calculation.

Pesticides are applied either every year, every second year or every third year. If a pesticide is applied every year, it is applied during 26 years. If a pesticide is applied every second year, it is applied every second year starting in year 1 and finishing in year 45. If a pesticide is applied every third year, it is

applied every third year starting in year 1 and finishing in year 64. This is the same procedure as used in GeoPEARL.

The pore water concentration increases with decreasing values of (i) the water content $W$, (ii) the mass fraction of organic matter and (iii) the dry bulk density. So conservative values in the low range are needed for these parameters. It is proposed to use a water content of 0.1 kg kg$^{-1}$, an organic matter content of 2% and a soil dry bulk density of 1000 kg m$^{-3}$. The value of 2% for soil organic matter was based on the cumulative probability density function of organic matter for Dutch agricultural land: it corresponds with about the 3$^{rd}$ percentile of this distribution. Soil dry bulk densities for mineral soils range from approximately 1000 kg m$^{-3}$ to 1700 kg m$^{-3}$, depending on the compaction of the soils. The minimum value was chosen because it is expected to be conservative. *Note that the assumption for calculating exposure is different from the assumption for estimating the pore water concentration in test systems.*

If the sorption of a parent substance is dependent on the pH of the soil, a conservative estimate of the exposure pore water concentration is obtained by taking an apparent $K_{OM}$ value corresponding to a relatively high pH value. The $K_{OM}$ values corresponding to a pH$_{CaCl2}$ of 8.0 should be taken; in most cases, the $K_{OM,base}$ will be appropriate. In case of metabolites, it is recommended to jump to a GeoPEARL calculation.

# Appendix 7 Model for estimating exposure concentrations in laboratory test systems

## A7.1 Description of the model

The aim of the model is to obtain conservative estimates of total content and pore water concentrations of a pesticide and at most two sequential transformation products in ecotoxicological laboratory studies if these have not been measured. The model assumes that the pesticide has been mixed through the soil before the ecotoxicological experiment started and that the only loss process is transformation of pesticide or its transformation products.

The model is based on equations A6-1 to A6-11 as described in Appendix 6. It simulates the behaviour of a pesticide and two sequential transformation products in a perfectly mixed layer of soil. The model runs for one year and includes calculation of TWA values for a time window with a length that can be specified by the user.

## A7.2 Estimation of model input

Section 4.3 describes how values of $K_{OM}$, $DegT_{50}$ and the non-equilibrium sorption parameters should be selected. Here follows a list of model input and procedures for estimating the remaining model input:

1) Initial content of parent (mg kg$^{-1}$):
Usually available from the report.

2) Temperature at which the experiment was performed ($^o$C):
Usually available from the report.

3) Arrhenius activation energy (kJ mol$^{-1}$):
It is recommended to use the default value of 65.4 kJ mol$^{-1}$ (EFSA, 2007b) if no specific values for the substances under investigation are given in the dossier.

4) Half-life (d) of parent and the two metabolites at 20 $^o$C and field capacity:
See section 4.3.

5) $K_{OM}$ (dm$^3$ kg$^{-1}$) of parent and metabolites:
See section 4.3.

6) Molar mass (g mol$^{-1}$) of parent and metabolites:
These are available from the dossier.

7) Substance formation fractions for (i) parent to metabolite-1 and (ii) metabolite-1 to metabolite-2 (mol mol$^{-1}$):
These parameters are only relevant for the metabolites. If available, values specific for the soil under investigation should be used. Otherwise, average values derived from soil metabolism studies are recommended.

8) Organic matter (%):
This is usually available from the report. If this is not the case, it is recommended to make two calculations: one with a lower limit of 2% and one with an upper limit of 20%. Subsequently the most conservative result should be selected.

9) Water content (dm$^3$ kg$^{-1}$) of the soil during the ecotoxicological experiment:
This is usually available from the report. If this is not the case, it is recommended to make two calculations: one with a lower limit of 0.1 dm$^3$ kg$^{-1}$ and one with an upper limit of 0.4 dm$^3$ kg$^{-1}$. Subsequently the most conservative results should be selected.

10) Desorption rate coefficients of parent and metabolites, $k_D$ (d$^{-1}$):
See section 4.3.

11) The ratio between the equilibrium and non-equilibrium sorption coefficients, $f_{NE}$ (-):
See section 4.3.

# Appendix 8 Criteria for acceptability of effect studies for persistence risk assessment

In general, for the evaluation of specific studies for risk assessment of persistent pesticides in soil, it is needed to distinguish the following phases in the evaluation process:
1. evaluation of the scientific reliability of the study (including evaluation of the results);
2. evaluation of the usefulness for risk assessment;
3. assessment of the acceptability of the effects.

In the first tier of the proposed decision trees for persistence risk assessment, partly results are required from tests that are available in a standard dossier, and partly results are required for tests that are not required yet for the assessment of pesticides.

Data from the EU-monograph are not re-assessed for their scientific reliability, and when no reliability index is present in the monograph, a Reliability Index (RI) value of 2 is assigned. This does not mean that all studies in the EU monograph can be used for persistence risk assessment. For instance in the case where plants are directly oversprayed with a herbicide, the results of such a study cannot be used for assessing the effects of a substance in the soil. Apart from the studies available in the monograph, data from the open literature can be used. These data, however, must also be assessed for their scientific reliability. For this the following criteria can be used (*cf.* Klimisch et al., 1997):

1. *Reliable without restriction*
   *This includes studies or data from the literature or reports which were carried out or generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters are based on a specific (national) testing guideline (preferably performed according to GLP) or in which all parameters are closely related/comparable to a guideline method.*
2. *Reliable with restrictions*
   *This includes studies or data from the literature, reports (mostly not performed according to GLP) in which the test parameters do not entirely comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.*
3. *Not reliable*
   *This includes studies or data from the literature/reports in which there are interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g., unphysiologic pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for an assessment and which is not convincing for an expert judgment.*
4. *Not assignable*
   *This includes studies or data from the literature, which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etcetera).'*

As a starting point, the scientific reliability of lab studies that are assessed acceptable in a EU-DAR are not re-assessed for their scientific reliability for the purpose of persistence risk assessment.

A study that is not reliable should not be used for risk assessment. Whether a reliable study is used for risk assessment depends on the usefulness of the study. A RI score of 1 or 2 does not automatically mean that a study is useful for risk assessment of persistent pesticides. The relevance of the study for derivation is not included in the RI; a study that is not relevant will not be used, even when its reliability is very high.

Studies in which the compound is sprayed on the soil surface and not distributed in the soil can have a RI value of 1, since they can be performed according to internationally accepted guidance and GLP. For the aim of performing persistence risk assessment in soil, however, these studies are only useful, when a reliable estimate of the concentration *in soil* can be made.

The effects that are considered as relevant for persistence risk assessment are those that affect the population dynamics, such as survival, immobilisation, growth, and reproduction. Other effects such as reburial or photosynthesis might be considered relevant as well, if they are strongly related to one of the above mentioned effects. Toxicity studies with endpoints such as biochemistry or animal behaviour are not taken into account, as they do not have a clear relationship with population dynamics.

For evaluation of the scientific reliability a systematic approach could be worked out for the specific studies, as is done for e.g. earthworm field studies (De Jong et al., 2006) and mesocosm studies (De Jong et al., 2008). In these cases a detailed checklist for the items necessary to evaluate the scientific reliability of the field study can be constructed. To all items a reliability index is assigned, which should result in an assessment of the scientific reliability of the study.

Whether a reliable study is useful, depends among others on the question whether the study addresses the lower tier concern. When for instance a certain group of species is the most sensitive group in the lower tier, this group should be part of the higher tier study as well. Further, the results of the particular field study need to be extrapolated to the situation of concern, for instance concerning exposure, soil type, type of ecosystem, etcetera.

A further point is that the results of a field study should be evaluated. For this evaluation a classification of effects could be used:

| | |
|---|---|
| Class I | no treatment-related effects; |
| Class II | slight treatment-related transient effects, usually on one or a few isolated sampling dates only; |
| Class III | clear effects on several consecutive sampling dates, lasting less than 2 months post last application of the PPP in the test system; |
| Class IV | clear effects on several consecutive sampling dates, lasting longer than 2 months but full recovery within a year post last application of the PPP in the test system; |
| Class V | clear long-term effects; full recovery not within 1 year post last application of the PPP in the test system. |

This classification needs further elaboration and refinement, especially concerning the duration of the recovery period. Since, however, for persistence risk assessment, only class I and class II effects are deemed acceptable, this further elaboration is not needed in the framework of this guidance document.

For the evaluation of a semi-field study the following questions can be used as a guideline to obtain a transparent description of a study:

1. Does the test system represent a relevant soil community?
2. Is the experimental set-up of the experiments adequately and unambiguous described?
3. Is the exposure regime in the test systems adequately characterized?
4. Are the investigated endpoints sensitive and in accordance with the working mechanisms of the compound, and with the results of first tier studies?
5. Is it possible to evaluate the observed effects statistically and ecologically (univariate and multivariate techniques).

For the usefulness of the field studies more knowledge is needed about the variation in effects between different soil ecosystems for different groups of compounds. At the moment, based on experiences from the aquatic risk assessment, an extrapolation factor of 3 is proposed for the extrapolation between different soil agro-ecosystems. Further experience, however, is needed to adjust this extrapolation factor.

Some experience on giving a reliability index to ecotoxicity test results and on determining the usefulness of test results has been gained when evaluating carbendazim. The criteria possibly need an update after having gained more experience, with a number of substances with different functionality and different modes-of-action.

# Appendix 9 FRP

Assessment according to the FRP (see chapter 3) is performed at the European level, for all substances and independent of whether a persistency assessment is triggered. This Appendix describes the FRP and therewith gives more background to the CRP and ETP assessment.

The *Functional Redundancy Principle* presupposes that, for a sustainable functioning of the agro-ecosystem, a temporal decrease in biodiversity can be tolerated, as long as key(stone) species (for example earthworms) and their functions (for example mineralization of organic matter) are not impacted above an unacceptable level. This because of the redundancy in roles and functions provided by the surviving species in the community. This principle is in line with the Functional Redundancy hypothesis (Lawton, 1994).

When adopting the *Functional Redundancy Principle* the emphasis is on ecosystem processes; impacts are considered acceptable when functional attributes are not changed, despite possible effects on community structure. At the community and ecosystem level functional endpoints are rarely more sensitive than structural ones (for example Kersting, 1994). Effects on functional endpoints indicate the limit of functional redundancy within the stressed community. Once ecosystem processes have changed due to contamination, this usually is an indication of really severe effects on structural endpoints.

The text in the Uniform Principles with respect to the environmental risk assessment of PPPs in soils of agro-ecosystems is in line with the *Functional Redundancy Principle.* The EU Guidance Document on Terrestrial Ecotoxicology (SANCO, 2002) gives insight in the current view on the (tiered) approach to assess unacceptable risks of PPPs.

Table A9.1gives an overview of protection goals and criteria in line with the *Functional Redundancy Principle*.

**Table A9.1 Protection goals and criteria in line with the Functional Redundancy Principle**

| Protection goals | | |
|---|---|---|
| Protection of life-support functions of the in-crop soil to allow the growth of the crop | | |
| Protection of key(stone) species (earthworms) of agricultural soils | | |
| Trigger | Type of concentration | Effect criteria |
| Not relevant | Initial peak concentration during the cropping period (total, pore water) in top 5 cm of soil. Alternatively, if time-to-effect information can be derived from toxicity tests, a Time Weighted Average (TWA) concentration in the top 5 cm of soil might be used. The averaging period of this TWA concentration should correspond to the time-to-effect-period as derived from the toxicity test. | NOEC earthworm and AF of 5 (AF = Assessment Factor) Lab tests after 100 d: effects on soil micro-organisms < 25% Secondary poisoning of vertebrates via earthworms is not expected No significant effect on mineralization of organic matter in field litter bag study |

Allowing temporal effects on ecosystem structure and functioning presupposes that the environment can absorb and endure a certain amount of pollution. When adopting the *Functional Redundancy Principle* an important evaluation criterion should be the length of time required for reversibility of the effect, since complete irreversible change in land use should be guarded against. In the case of persistent Pops it may be argued that the pollution should be limited to a level below which medium- to long-term adverse impacts on agro-ecosystem structure and functioning occur.